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FUNCTIONAL ELECTROSTIMULATION

BASICS, TECHNOLOGY, CLINICAL APPLICATION

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POSTER PRESENTATIONS

IMPROVEMENTS IN SACRAL ANTERIOR ROOT STIMULATION

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Implantation of a sacral anterior root stimulator (1,2), usually with simultaneous sacral posterior rhizotomy, has long been a useful way of achieving voluntary micturition and urinary continence, and of protecting the kidneys from back-pressure damage, in patients with spinal cord lesions. Two recently developed accessories to the sacral anterior root stimulator will be described. One provides a simple way of generating a mode of stimulation that diminishes sphincter spasm. The other allows simultaneous recording of pressure in the rectum and the upper and lower parts of the anal canal, for the purpose of setting up better defaecation programs.

A means of diminishing urethral sphincter spasm

In neurologically intact people, the pelvic floor and intrinsic urethral rhabdosphincter are active except during micturition, when they relax. In all people with complete transections of the spinal cord, and in many with incomplete spinal cord lesions, the relaxation during micturition is absent. It is often replaced by an increase in activity, called detrusor-sphincter dyssynergia (DSD). Sacral posterior rhizotomy usually abolishes DSD, but leaves the resting rhabdosphincter tone and its persistence during micturition unchanged.

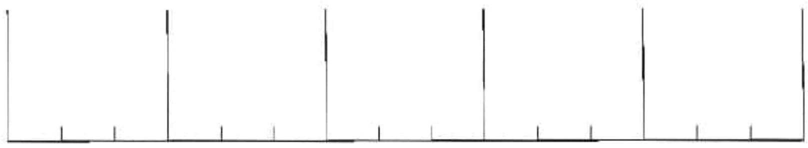
Because the resting rhabdosphincter activity is not inhibited, the outflow resistance in micturition driven by a sacral anterior root stimulator is higher than it is in the voluntary micturition of neurologically intact people. This increased resistance seems usually to be harmless, but in a few patients it prevents the bladder from emptying completely.

The parasympathetic fibres of the sacral anterior roots cannot be stimulated without also stimulating the somatic fibres that innervate the rhabdosphincter and pelvic floor. It is, however, easy by using weak stimuli to do the reverse. Such stimulation of the somatic but not the parasympathetic fibres has for a long time been used by a small minority of patients with sacral anterior root stimulators, either at low frequency to treat stress incontinence of urine, or at high frequency to fatigue the rhabdosphincters before applying the micturition program. It does more than merely cause local muscular and motor end-plate fatigue in the sphincters; it can also be shown electromyographically to inhibit their motor neurons. The inhibition is likely to be due to activation of Renshaw cells by impulses passing antidromically along the relevant somatic fibres and spreading into recurrent collateral branches.

Fatigue and inhibition of the sphincters would be expected to be more effective if their nerve fibres could be stimulated at high frequency not only before the beginning of the micturition program, but also during it. One cannot usefully increase the frequency of the strong pulses that make up the bursts of this program, because this would cause excessively high bladder pressure during the first and second bursts, and fatigue the bladder so that later bursts of the sequence might be ineffective. What can usefully be done is to interpose weak pulses that stimulate only the somatic fibres between the strong ones that stimulate the parasympathetic fibres as well. There is a simple electrical trick for doing this. The drive box of a sacral anterior root stimulator does not send pulses to its three transmitters simultaneously, but in regular rotation: ABCABC.... By interposing fans of diodes (3 diodes in each fan) in the lead from drive box to the transmitter block, the pulses intended for transmitters A, B and C can all be sent into transmitter A, and these same pulses also into transmitter B. If now the "A" output from the drive box is set to a high voltage and the "B" and "C" outputs to a low voltage, the parasympathetic fibres accessible to the A and B channels of the implant are stimulated at the same frequency as if the diode fans were not in use, and the somatic fibres are stimulated at three times this frequency (see Fig.1). Use of this device in two patients with high outflow resistance has greatly improved the completeness with they empty their bladders.

<-------------------------------- 150 msec --------------------------->

Part of a burst from a standard micturition programme.



<------------------------------------150 msec -------------------------->

Part of a burst from the modified micturition program generated by the Diode Fan for SARS.

Fig.1. How to modify the pattern of stimulation so that the somatic motor nerve fibres are stimulated at 3 times the frequency at which parasympathetic fibres are stimulated.

Simultaneous recording from the lower and upper parts of the anal sphincter and the ampulla of the rectum

Fig.2 shows the device. It is made of silicone rubber, and contains three cavities, which in use are filled with water and connected by tubes to external pressure transducers. Such a system cannot respond at high frequencies, but for its practical purpose only frequencies between 0.02 and 2 Hz are needed, and in this frequency range it can record changes faithfully.

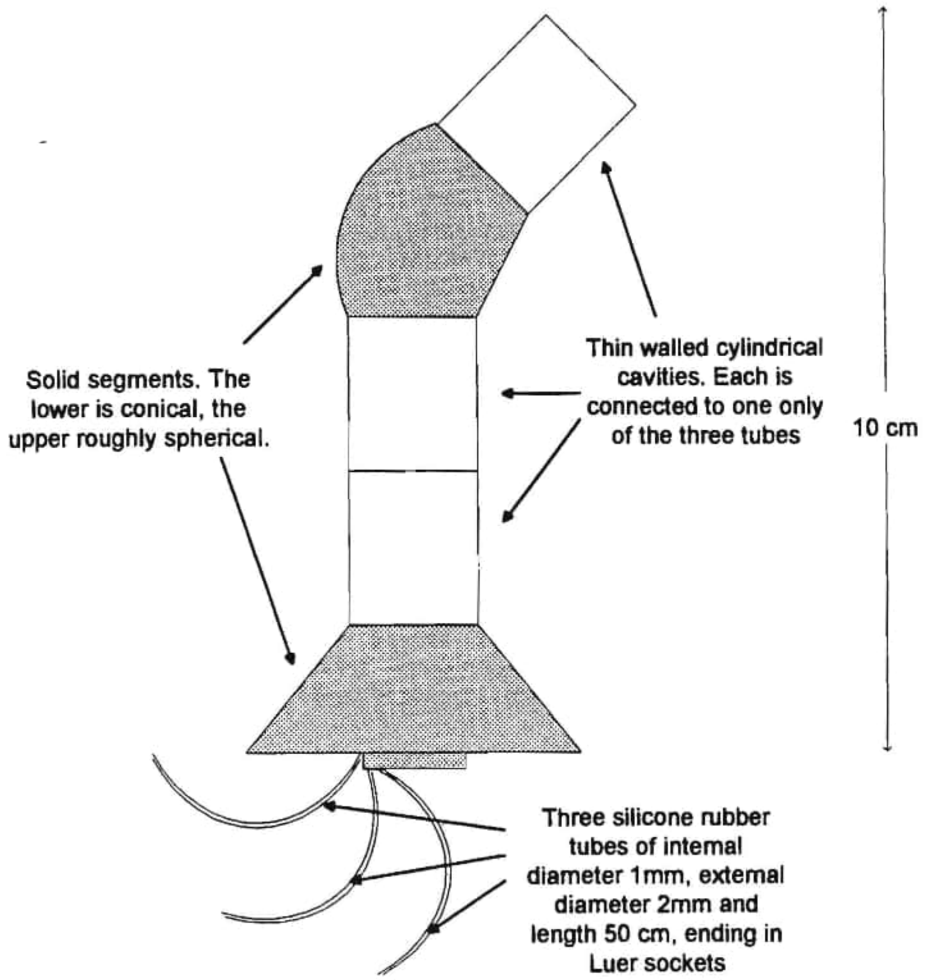


Fig.2. Triple recording balloon for anal and rectal pressure.

Implant-driven defaecation, like implant-driven micturition, uses a program of bursts and gaps adjusted so that the sphincter pressure is low when the expulsive pressure (in this case rectal) is high. A sufficiently good program can often be set up by a fixed rule, the same for all patients: bursts of 10 seconds separated by gaps of 20 seconds. However, if this fixed rule is used, about half the patients fail to achieve implant-driven defaecation, though many of those who fail nevertheless find the stimulator useful as an aid to digital evacuation. A technique for adjusting the program to the needs of each patient is needed.

The sphincter that surrounds the lower part of the anal canal consists entirely of striated muscle innervated by somatic motor nerve fibres of S2, S3 and S4 origin. In the upper part of the anal canal the sphincter consists mainly of smooth muscle. This muscle has an excitatory sympathetic and an inhibitory parasympathetic innervation. The 3-cavity device distinguishes between the two parts of the sphincter. Records from its lowest cavity show exclusively the rapid excitatory responses to stimulation that are characteristic of striated muscle. Records from its middle cavity show predominantly slow delayed inhibitory responses to stimulation, with small rapid excitatory ones superimposed. The highest cavity lies in the ampulla of the rectum, and records from it show mainly the slow excitatory responses to sacral root stimulation that one would expect of rectal smooth muscle. Sometimes faster responses can be seen superimposed on the slow ones. Inspection of the abdominal wall will usually show whether these are reflex abdominal contractions or direct responses of the levator ani muscle.

A good defaecation program must achieve high rectal pressure during periods (which must be at least 10 seconds in duration) when the pressure is low in both the deep and the superficial parts of the anal canal. It will be easier to search for a pattern of stimulating pulses that will achieve this if a device is available that allows simultaneous independent measurement of the three variables (rectal pressure, smooth muscle sphincteric pressure and striated muscle sphincteric pressure) whose time-course needs to be adjusted.

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Technology and speech coding strategies for third generation cochlear implants

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Cochlear implants employ electrical stimulation of the auditory nerve to elicit hearing sensations in deaf subjects. They consist of an implantable part comprising of a receiver/stimulator driving the stimulating electrodes and an external part consisting of the speech processor, containing batteries, and a transmitter for transmission of the transcutaneous signal and power. Candidates for cochlear implants are deaf adults and children who derive little or no benefit from conventional hearing aids.The lower age limit for children has come down to around 2 years, and even younger children are accepted in special cases, especially if signs of cochlear ossification are detected.

Third generation cochlear implants have the following characteristics:
Back telemetry, multichannel stimulation (8 or more channels) and high stimulation rate (at least 800 p.p.s per channel). Therefore these devices can implement strategies which make use of both spectral as well as temporal features. The "CIS" (continuous interleaved sampling) strategy, according to B. Wilson of RTI (USA), exhibits these features, and generates non-simultaneous pulses at a constant rate. The amplitude of each pulse depends on the output of an envelope detector (low pass filtering and rectification stages) for each of a number of frequency bands, which together cover the speech frequency range, and corresponding to the number of contacts in the intracochlear electrode. Since the envelopes of the individual filter outputs contain frequencies of up to at least 400 Hz., sampling frequencies higher than 800 Hz. are necessary.

Non simultaneous stimulation is instrumental in achieving good communication capabilities since it greatly reduces field interaction problems leading to channel cross talk which has hampered multichannel analog stimulation strategies.

Telemetry is a valuable feature, especially with young children, because by checking electrode impedences it allows objective tests of correct implant function. A Euro-pean multicentre clinical study is being conducted at 16 ENT departments.

The use of the highrate CIS-strategy at 12 000 p.p.s. overall sampling rate (that is 1500 p.p.s. per channel) and monopolar stimulation, as implemented in the COMBI 40 cochlear implant system, has resulted in a fast learning process and open speech understanding without lip reading within days of the speechprocessor switch-on with the majority of the postlingually deafened adult study patients.
At the 6 months test the mean single syllable understanding score is 48%.

A comparable value has not been reported with first or second generation cochlear implants.

FUNCTIONAL ELECTRICAL STIMULATION ON PARAPLEGIC PATIENTS

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ABSTRACT

We report on clinical and physiological effects of 8 months Functional Electrical Stimulation (FES) of quadriceps femoris muscle on 16 paraplegic patients.
Each patient had muscle biopsies, CT-muscle diameter measurements, knee extension strength testing carried out before and after 8 months FES training. Skin perfusion was documented through infrared telethermography and xenon clearance, muscle perfusion was recorded through thallium scintigraphy.

After 8 months FES training baseline skin perfusion showed 86 % increase, muscle perfusion was augmented by 87 %.
Musclefiberdiameters showed an average increase of 59 % after 8 months FES training. Muscles in patients with spastic paresis as well as in patients with denervation showed an increase in aerob and anaerob muscle enzymes up to the normal range. Even without axonal neurotropic substances FES was able to demonstrate fiberhypertrophy, enzyme adaptation and intracellular structural benefits in denervated muscles.
The increment in muscle area as visible on CT-scans of quadriceps femoris was 30 % in spastic paraplegia and 10 % in denervated patients respectively. FES induced changes were less in areas not directly underneath the surface electrodes.

We strongly recommend the use of Kern`s current for FES in denervated muscles to induce tetanic muscle contractions as we formed a very critical opinion of conventional exponential current. In patients with conus-cauda-lesions FES must be integrated into modern rehabilitation to prevent extreme muscle degeneration and decubital ulcers. Using FES we are able to improve metabolism and induce positive trophic changes in our patients lower extremities.

In spastic paraplegics the functions „rising and walking" achieved through FES are much better training than FES ergometers. Larger muscle masses are activated and a increased heart rate is measured, therefore the impact on cardiovascular fitness and metabolism is much greater. This effectively addresses and prevents all problems which result from inactivity in paraplegic patients.

Keywords: Paraplegia, Functional Electrostimulation (FES), musclebiopsy, fibre size, histochemical changes, enzyme-activity, force-measurement, Xenon 133, Thallium 201, IR-Thermography.

INTRODUCTION

Functional Electrical Stimulation (FES) and its role in metabolism, trophic changes, function and movement with respect to cardiovascular fitness, spasm control and musclestimulation and training in paraplegic patients are reviewed.
Our knowledge of morphology, biochemics and training of spastic and denervated muscle still seems to be incomplete.

Is it possible to stimulate spastic and denervated muscles?
Can effects of training be measured by computed tomography(CT), muscle histology or biochemical enzyme diagnostics?
Does FES induce perfusion and trophic changes in skin and underlying musculature and are these changes relevant to decubital ulcer prophylaxis?
How can we increase effectiveness of FES by modifying stimulation parameters?
Which recommendations can we deduce from our experiments for FES in paraplegic patients?

MATERIALS AND METHODS

We investigated 14 male and 2 female paraplegics, 6 of which had denervated muscles because of conus-cauda lesions. Informed consent was obtained for muscle biopsies before and after 8 months FES. The biopsies served for histologic and biochemical workup. Furtheron we investigated CT-Scans of quadriceps femoris muscle, isometric force tests and xenon clearance, thallium szintigraphy as well as infrared telethermography for perfusion measurement. Because of noncompliance with the second biopsy the data of 2 Patients were eliminated.

FES was applied through a 2 channel constant voltage stimulator developed by our technicians according to our specifications and clinical experience in mobilisation of paraplegic patients. We conducted several series of studies to optimize stimulation parameters, electrodes and stimulators.
Stimulation frequency was 27 Hz which induced forcefull tetanic contractions while minimizing neural and muscle fatigue. We used biphasic rectangular pulses of 1,2 ms duration. Total number of stimuli exceeded 48.000 stimuli per day. The patients stimulated for 30 min. twice a day through eight months.
Patients were told to stimulate until complete extension in the knee was achieved and to increase weight load at the ankle accordig to maximal force gain.

Patients with denervated muscles stimulated while seated or supine. At the beginning forceful single contractions were intended, only with progresssion of training and normalisation of contraction character as well as muscle membrane excitability was the reduction of pulse duration and therefore tetanic stimulation possible.
We used Kern´s current for denervated muscles which is characterised by 30ms duration biphasic pulses, 20 ms silent period and bursts of 2-3 sec. and 5 sec. off.

Patients used rubber electrodes on both thighs(impendance of 20 Ohm/ cm^2 and $200cm^2$ surface area) for autonom daily stimulation at home, they adhered to a strict and precise stimulation protocol.

Stimulation of quadriceps femoris muscle was used because this muscle is not only easily accessible but also of critical importance for the rise-to-stand from the wheelchair as are glutaeus muscles in paraplegic patients.
The vastus lateralis portion of quadriceps femoris is also the best investigated human skeletal muscle with respect to exercise changes, histology, biochemical changes etc and we can therefore compare our results to those of normal adults.

In the paraplegic we are confronted with different extent of atrophy. In denervated muscles we can expect about 25% fibre thickness and in spastic muscles around 50% fibrediameter of normal controls.

Four biopsies of each patient, one of each leg, before and after 8months stimulation were obtained of vastus lateralis muscle. Histologic, electronemicroscopic and enzymatic investigations were conducted. We adhered to international criteria as known in sports medicine(Bergström, Hoppeler).

A few days before the biopsies CT-scans, xenon-clearence, thalliumszintigraphy and telethermographies as well as force measurements were performed.

RESULTS

After 8 months FES an increase in maximal isometric force from x=35 Nm to x=51Nm while equally intense stimulation was observed. This represents a 45,7% force increase. The small absolute amount of measurable force during FES could be due to electrical co-stimulation or spastic co-contraction of antagonist muscles, the hamstrings in our case.

Histologic changes were prominent with respect to fibre diameter increase in type I and type II fibres in denervated muscles of a median 58 and 74% respectively. In spastic patients we found a 65% increase in diameter type I fibres and a 37% increase in diameter type II fibres ($p<0,05$).

Our stimulation regimen, comprising 48.000 Stimuli per day, induced a rise in aerobe and anaerobe muscle enzyme concentrations of 60% in denervated and 53% in spastic muscles which reaches into the levels of normal healthy muscles.
CT-scans showed a cross-sectional increase of muscle tissue of 27% in spastic patients. Denervated patients achieved a rise of 12% in proximal and 8% in distal quadriceps femoris muscle. Between the two stimulation electrodes cross sectional muscle tissue surface increased by only 1,8%. This surprising result shows that neuronal degeneration forces electrical conduction to follow muscle fibres which in turn implies that stimulation of denervated muscles is best when large surface areas, ideally the whole muscle, are covered by electrodes. Current flow is higher and therefore stimulation and training adaptations of muscle tissue are more pronounced directly underneath electrodes where contractions are most intense.

We underline that increases of cross sectional area in CT scan are accompanied by 5 to 10 bigger improvements of intramuscular structure as shown only through muscle biopsies.

Xenon clearance of the skin showed perfusion increments of 76% after 15 min. FES at the beginning of the training period. After 8months FES results showed an increase from resting perfusion to 4,78ml/100g/min. which corresponds to a 86% rise.
Resting perfusion was augmented by 43% in the stimulated leg after 8months FES, a concommitant rise was shown in the non-stimulated leg of spastic patients.

Muscle perfusion of the skin cannot be measured in absolute values. Therefore we determined skin perfusion in comparison to brain perfusion which is known to remain fairly costant during one year.
8months FES produced a highly significant 5fold increase of quadriceps femoris muscle perfusion in denervated muscle and an even 9,5fold rise in spastic muscle. Small increases in lower leg perfusion remained insignificant.

Skin hyperemia of 1,57°C in infrared telethermography expanded slowly from the stimulated thigh to the contralateral side and to both feet and reached statistical significance after 25 min. This increase lasted for up to one hour after stimulation ceased both on the stimulated and non stimulated leg.
Denervated patients showed a comparable reaction in the thigh region, but expansion until the lower leg and foot was not observed.

DISCUSSION

We deduce that FES should be used in prophylaxis of decubital ulcers because it produces immediate and longterm perfusion increases in muscle and skin.

Adaptation of muscle fibres seems to follow number of stimuli per day in respect of type I or type II fibre characteristics and actual workload in respect of fibrehypertrophy.
Modern FES parameters must be adapted to these principles of fibre type characteristics and fibre hypertrophy.

It is now clear that denervated muscle can be trained through FES, as we demonstrated through muscle biopsies(fibre diameter increase of median 66% and cross sectinal area increase of 8% underneath the electrodes) and through the rise of anaerobe and aerobe muscle enzymes into the normal range.
The large increase in CT-cross sectional areas and in perfusion as shown in the thallium szintigraphies are further arguments for the training of denervated muscles through specialized FES. To our kowledge these results can only be achieved when using Kem´s current for denervated muscles, because only these stimulation parameters assure forceful tetanic contractions which induce the hypertrophy in paralysed muscle.

From our research we deduce that patients with conus-cauda leasions should begin as early as possible with FES to prevent muscle degeneration and decubital ulcers in this population at extremely high risk for such leasions. We hope that this kowledge will spread quickly to all rehabilitation facilities and soon be implemented in day to day patient care.

For spastic paraplegics FES rise-to-stand and walking represents an appropriate means of enhancing local perfusion and trophic changes, muscle fibre hypertrophy and increasing muscle cross sectional areas and intracellular structural gains.
Active FES rise-to-stand and walking training seems preferable to FES-ergometry because it is cheaper, easier to handle and nearly everwhere applicable.
FES walking training is an additional sportive activity and cardiovascular training for paraplegic patients.

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FES FOR MOBILITY: THE LESSON LEARNED IN 30 YEARS

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SUMMARY

This paper is attempting to discuss the developments in the FES field for mobility restoration occuring in the last 30 years. This developments are discussed in view of the evolution of the simple one channel foot drop correcting peroneal FES brace and with time emerging other FES devices as they were proposed in Ljubljana during this period. Only the progress steps and problems with perspectives for future developments in the FES field are highlighted. It is shown that technological insufficiencies and advances were limiting the FES field progress more than expected. Interesting is also the conclusion that clinically developed knowledge associated to the FES utilisation is with time little advancing or changing. This discussion of FES developmental events is showing that the FES field is still in its infancy and that major technological improvements enabling progress are still waiting to be introduced.

INTRODUCTION

Since the foot drop correction or peroneal functional electrical stimulation (FES) brace was proposed more than 30 years have passed. During this period different FES orthotic devices for mobility enhancement in hemiplegic, paraparetic, paraplegic and cerebral palsy children were developed and clinically used but many of them were later abandoned. This presentation is an attempt to highlight some of the developmental events with the aim of learning how did the entire FES field perform and what influenced the evolution of devices and clinical utilisation. The said is an ambitious, difficult and not very rewarding task. Nevertheless it can provide interesting findings, guidelines for understanding and decision making in the present and future.

The main questions one would like to have answered are what was in FES accomplished, did we proceed and learn efficiently and which essential lessons have been or should have been learned in 30 years. In Ljubljana FES research was conducted in more or less a steady pace and the authors were privileged to be part of this development nearly for the entire period considered . There were many other vital and important focal points of FES research in the field considering such long period. To mention some of distinguished research centres in FES: in USA the VA Hospital Hines in Chicago where Dr. W.T. Liberson was contributing much of his pioneering work, the Cleveland Case Western Reserve group started by Dr. J. B. Reswick. Dr. L. Vodovnik and Dr. C. Long and continued by Dr. T. Mortimer, Dr. H. Peckham, Dr.

P. Crago, Dr. B. Marsolais and others and the Rancho Los Amigos Hospital group with Dr. H. Wilemon, Dr. W. Money, Dr. R. Watters and Dr. D. Mc. Neal, and partly Dr. J.B. Reswick. In England Dr. G. S. Brindeley's group was active and many others contributed to the FES developments. In Europe the Ljubljana group was active since 1965, the Vienna group by Dr. Thoma started around 1970 and in the last years the group of CALIES is very active, headed by Prof. P. Rabischong. Looking back and considering the state of the art in FES for locomotion restoration there are many questions. Some are of great interest like why some FES devices have clinically succeeded and are accepted as a common approach and methodology, while others have more or less been forgotten and have never made it to a commercialisation state or marketable product. Could we learn some lessons from such development and could we perhaps foresee where the next FES developments and clinical successful applications might be? The period of 30 years is probably a good time to highlight the expected future events and to avoid less promising approaches. It is evident that the authors are able to make only a limited review of the events in FES for the last 30 years from their own and Ljubljana perspective. We are going to limit this discussion only to the development of FES systems for locomotion restoration in hemiplegic (stroke and head injured or brain tumor operated patients), spinal cord injured patients (complete and incomplete lesion) and partly cerebral palsy children. Most of the developed FES systems were inspired and started from the idea of the simple peroneal brace. The FES peroneal brace developmental story was therefore selected in this paper as the case for discussing advances. All the other FES developments of locomotion systems were created, started and influenced by the developmental events and aspects of the peroneal system functional enhancement. We believe that such a display of developments is correct, advantageous and can provide answers with realistic judgements for the many new designs undertaken in the last 30 years for FES enabled locomotion improvements in different aetiologies of patients.

THE PERONEAL BRACE EVOLUTION

The original idea for the FES based drop foot correction system which with the time was commonly named the FES peroneal brace, was proposed by Dr. Wt. Liberson /1/ in 1961. The original design was patented in October 1967 and even commercialisation started but was soon stopped. In Ljubljana 1965 Dr. L. Vodovnik /2/ started his own design of FES peroneal brace inspired by the idea published by Dr. Liberson. Probably at that time similar projects were undertaken by other researchers and some of them have even considered FES as a modality for foot drop correction before of Liberson as it is documented in /4/. Around the seventieth there were already producing the peroneal brace and in the FES business were some larger companies. To mention some. The Phillips company in Holland, was manufacturing and marketing a device, and in USA the Medtronic Co. was producing and marketing an implanted system co-designed by the Rancho Los Amigos Hospital FES researchers /5/. At that time also in Ljubljana surface stimulation units were already in clinical use and an independent design for an implantable system was in progress by Jeglič et al /6/, at the beginning with a circumferential RF transmitting coil and later with a surface coil. Regardless where the evolution steps in the design of peroneal brace were made, it is interesting to observe the main steps of this progress. The steps of progress as they occurred in the

Ljubljana, and the developmental stages of the peroneal brace are displayed in Figure 1. and are quite instructional.

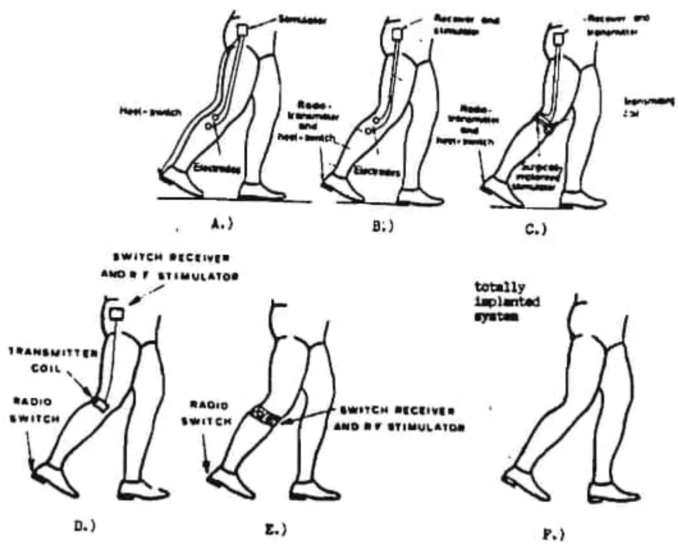

Figure 1

The designs in Figure 1 are indicating thc desire for minimising patients involvement, maximising cosmetic appearance and practicality by means of miniaturisation and improved technology. Many units of the first design in Figure 1 were applied in Ljubljana and the follow up version of this design is still marketed today. From 1980 to 1990 out of 2500 hemiplegic patients 1575 were FES treated and 60 % utilised one channel FES, 30% two channel FES systems and only 10% more channels /16/. From 1979 in Ljubljana more than 4000 hemiplegic patients were treated. Today in Ljubljana 8 - 10 different FES systems are clinically utilised on a daily basis /16/. The current and the last Ljubljana version is attached to the leg like shown in Figure F.). The radio link from heel switch was already foreseen in the Medtronic's Co. version designed around 1973 and in different versions built in Ljubljana at that time. The design with radio link did never get enough practical, reliable and price attractive to be a widely marketable solution. The design C.) in Figure 1 was discarded soon due to large energy losses, and the version d.) utilised, which was redesigned to the current marketed and used design presented in E.). The version in F.) is the extrapolated and expected next developmental state for achieving a totally implanted FES brace for foot drop. In this version the sensory nerve picked up information will provide the control for the FES system containing an implanted power source. Such a design should also foresee two stimulation channels for the adjustment of a balanced dorsiflexion and eversion, thus overcoming the main problem of all one channel FES peroneal braces so far marketed and utilised. The energy demanding but adjustment tolerant coil design C.) in Figure 1 was changed to the one in D.). This design is requiring more detailed antenna adjustment but is energy more efficient. The design of E.) is today probably a feasible one with the newly designed class E transmitters proposed for powering the implantable micro-stimulators. This is again an example that technological advances influence the FES developments more than it was recognised in the past. It is expected that the described application of FES devices will be considerably improved after implantable event detectors for FES system triggering will be developed and totally implanted system utilised as shown in Figure 1 F.). Here, the patient is free of carying the system and maximal cosmesis is achieved. No external devices are present, accordingly no donning and doffing is required for the daily use. According to the said it seems that the broad utilisation of FES systems for locomotion enhancement and restoration has potential to be started in the coming years. It is interesting to note that the existing and developed knowledge in the numerous applications like the multichanel systems for stroke patients, complex gait rehabilitation in CP children and incomplete spinal cord injured patients gait enhancement with gait enabling and restoration in paraplegic patients is at present a difficult marketable knowledge from the point of view of chronic application. However this knowledge is clinically utilised already today. It represents the basis upon which the next generation of the devices will be built. It is interesting to note that the clinical advances of FES systems utilisation, if compared to the many proposed technological solutions in the past, display a more solid and permanent value and do not change rapidly with time. The clinical knowledge is emerging slowly in FES and dissemination of it is costly and time demanding. Probably, owing to the said rehabilitation engineering studies are more frequently addressed to technological solutions and are in less cases focused on a clinical problem solution.

MANY IDEAS WITH FEW CLINICAL APPLICATIONS

In general clinical applications and the number of patients benefiting from FES as judged today is rather low considering the 30 years of extensive investigations, developments and investments made. This general view applies to nearly all categories and areas of FES applications for movement restoration. For the time being the simple FES one or two channel devices which are potentially applicable to the very large population of stroke, head injured, and tumor operated patients are not broadly accepted as vital and practical devices. Therefore, FES is quite limited in utilisation if viewed internationally and consequently not of interest to producers. All the other multichannel FES devices for motion restoration or mobility enhancement are in this aspect even less attractive for the clinicians and producers due to their complexity and costly utilisation. In comparison the FES field for bladder functions restoration and enhancement started at least 10 - 20 years later than FES research for mobility restoration and yet more than 500 sacral anterior root stimulators are internationally applied, demonstrating in several years over 1900 patient years of follow up with rather small drop outs and failures /8/. The sacral anterior roots FES system is by far technologically more demanding compared to a two - channel peroneal system and yet much simpler if compared to an implanted system for restoring gait functions in paraplegic patients. For the latter case and for the last two decades, there does not exist a successful FES implanted case. It is known that in this regard many attempts were made for the last 20 years starting with the Rancho Los Amigos implant for paraplegic patient FES ambulation /7/. This was also the first hybrid system. The Rancho implant was followed by Dr. Brindley's, Dr. Thoma's multichannel implant /9/, up to the recent implant used by Dr. R. Davis /10/. It is questionable whether the existing technology is sufficient for the application of such devices? It seems that the restored functioning, involvement, complexity, the art of current technology and price play an important role in the introduction of such devices but also the quality of the management, and the methodology applied are crucial for a positive outcome as learned from the cited last years accomplished bladder stimulation application. Owing to the very small application numbers of FES systems for mobility restoration it is justified to ask what, when and why did the FES field fail in the past? Or perhaps is the field of movement restoration different and hence more difficult from a technological application and management point of view. In movement restoration there were known different approaches which were promising in past and today not much of them remains. Just for reasons of reminding, let us mention some of this approaches. From the EMG control approach did not remain much in clinical use until today. The biofeedback principle and optimistic promises made in the past did not prove effective in a long run. FES for CP children was not commercialised, while in some areas research did not start on a larger scale in spite of obvious importance. Similarly to the development of a two channel peroneal brace and also in view of sensory restoration for movement enhancement, there was not done much. In Figure 2 this principle is displayed. It is well known that sensation plays in movement control an essential role and yet only motoric FES approaches were in the past mostly considered. What was the reason for such attitude? Was this a consequence of unavailable and missing suitable technology? Would perhaps sensory nerve selective recording and selective nerve fibers activation advances with FES enabled blocking of nerve conduction change this course of approaches and open for sensory restoration a new era? Is the complexity of systems for movement restoration out of reach for the present technological level for providing successful clinical applications particular if combined with sensory restoration?

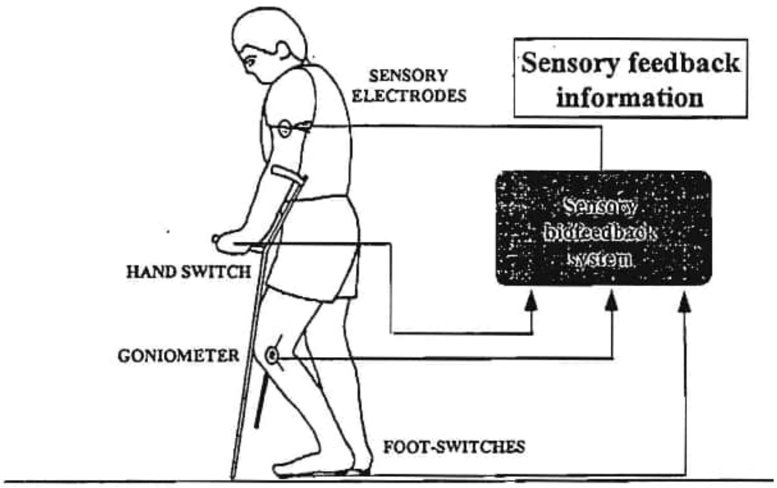

Figure 2

Are the control problems associated with hand and locomotion functions restoration misjudged or is the current FES activation too crude and time varying? Would it be better to start instead of providing complex gait systems to promote again simple few channels FES systems utilising the today superior technology compared to the one 20 years ago? Is a breakthrough expected in mobility restoration in the near future owing to the international sponsored research in selective nerve fibers activation, spinal cord structures stimulation, spinal roots stimulation and sensory nerve fibers recording? The selective nerve fibbers activation research was started and was attractive already in 1970, Caldwell /11/, as can be redrawn from his idea displayed in Figure 3. How closer to an usable solution are we today? How realistic is the very promising research for spinal roots stimulation /8/, selective nerve fibers information recording /12, 7/ and selective nerve fibers stimulation /13, 14/, with rather sophisticated implant developments /15/ enabling and challenging new and improved clinical applications for mobility restoration? We are concluding from this discussion that the FES field is according to the said still in its infancy. But it should be noted that the complexity of the applications is rapidly increasing with the new technological

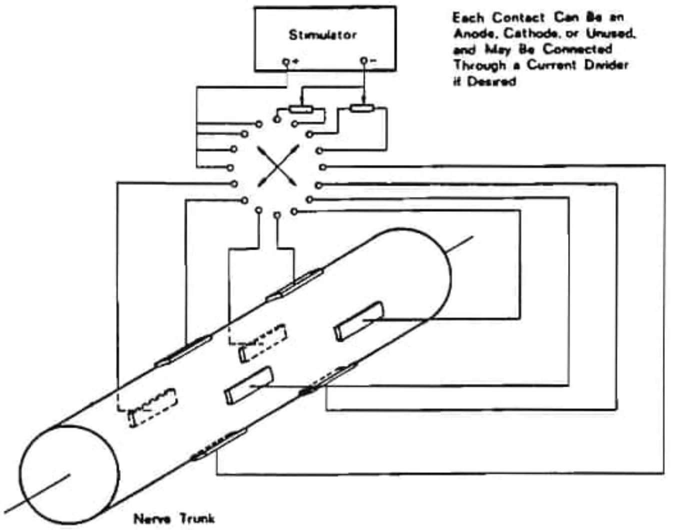

Figure 4.3.1 Schematic diagram of stimulating electrode array placed around nerve trunk.

Figure 3.

improvements and the consequences are hard to foresee. We should be also aware that somewhere along the development challenging technologies like nerve regeneration, and nerve grafts may enter the field. Therefore, it is wise and justified to discuss the trends of the FES field at large.

TRENDS IN FES

The developmental states as displayed in Figure 1 are showing the evolution of the simple one channel FES orthotic system. It displays the trend toward the development of totally implanted FES systems which are patient care free, cosmetic and non disturbing. Therefore, the FES applications technology will probably continue its development in the direction of complex totally implanted systems. From a functional point of view new aspect are introduced if the selective nerve fibers recording and activation will be clinically accomplished. The main trends as foreseen in FES system development are shown in Figure 4. The utilisation of pathological neural organisation

Figure 4.

and natural sensors information is feasible already today. Essential improvement of FES systems will be accomplished with better artificial sensory restoration and the incorporation to a larger extent of the feedback control. It is evident that most of severely injured patients are suffering from multifunctional deficits. Therefore, integrative rehabilitation systems will be the logical further step in the development of complex FES systems.

For the expected technological advances it is very important that new improved electrodes are designed and new implant biocompatible materials are successfully developed. This may promote the FES advances in all aspects. Here, let us mention the biocompatibility problem, techniques for easy implants servicing and changing, surgical techniques for placing of complex multichannel nerve electrodes, problems which all seek solutions. In the coming years, the technical knowledge considering efficient detection of nerve signals, amplification and information extraction will play an important role not mentioning the functional application software for the totally implanted complex systems. We may conclude this presentation by stating which lessons were learned in the last 30 years. It is evident from our discussion that insufficient technology is the main limiting factor for broader clinical FES utilisation and that knowledge advances for clinical FES application are slow in progress. We have also learned the hard way that the entire FES field is in regard of the developmental possibilities still in its infancy and the future is showing nearly unlimited possibilities for progress.

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PROGRESS TOWARDS PERMANENT CARDIAC ASSISTANCE FROM CONDITIONED SKELETAL MUSCLE

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SUMMARY

The goal of the British Heart Foundation Skeletal Muscle Assist Research Group is to work towards alternative surgical approaches to the treatment of end-stage heart failure that depend on harnessing the power of skeletal muscle for cardiac assistance. This calls for a detailed understanding of the structure and function of skeletal muscle deployed as an active surgical biomaterial. We have to be sure that the nerve supply is intact and that the blood supply is equal to the metabolic challenge. The muscle must be stimulated in such a way that all parts of it are used. It must operate under appropriate conditions of stretch and load. It must not fatigue progressively under the working conditions it encounters in the new application. Its contractile properties must be appropriate not only to the energy demanded but to timing restraints imposed by the cardiac cycle. This paper reviews some of the recent progress we have made in these areas.

STATE OF THE ART

There is growing recognition of the potential of skeletal muscle assist as a surgical alternative to transplantation in selected cases of end-stage heart failure. The main steps—transferring a pedicled graft of latissimus dorsi muscle into the chest, and 'conditioning' the muscle to perform cardiac-type work—are now standard features of the operation known as cardiomyoplasty. At the time of writing, over 600 of these operations have been performed world-wide. The feasibility of this type of surgery is not therefore in doubt. Currently, however, this form of skeletal muscle assist has several major drawbacks:

- The conditioning protocol postpones for about 2 months the full benefit that could be derived from an active muscle wrap. During this time, the patient is seriously at risk, so the operation has to be restricted to patients who have an adequate cardiac reserve.
- The conditioning protocol results in full transformation of the muscle to the slow-contracting phenotype, with a resultant loss of power and problems of synchronization with the cardiac cycle.
- Approximately 20% of patients are not helped by the procedure, and it is suspected that in these cases—and possibly in others too—there is serious fibro-fatty degeneration of the graft.
- Muscle that is wrapped around the heart, particularly an enlarged heart, is too heavily loaded to develop anything like its optimum power.

IMPROVING THE CONDITIONING PROTOCOL

Relationship of the pattern of chronic stimulation to transformation

Long-term stimulation induces the synthesis of slow muscle forms of myosin, which confer a slow contractile speed. The muscle is actually better suited for cardiac assistance at an intermediate stage of transformation, when changes in the blood supply and metabolism have already occurred but the myosin heavy chains are still of the fast type. We have conducted experiments at lower stimulation frequencies to see if these properties could be maintained stably. We showed that skeletal muscle could become sufficiently fatigue-resistant to perform cardiac work—without concomitant induction of slow myosin heavy chain isoforms—by continuous stimulation at 2.5 Hz /1/. We have also analyzed the metabolic changes taking place in these muscles. Earlier we had observed that the rise in oxidative enzyme activity during the first few weeks of stimulation at 10 Hz was consistently followed by a smaller secondary decline, despite continuing stimulation /2, 3/. We have now established that muscles stimulated at 2.5 Hz, in which slow myosin isoforms were not induced, also fail to show this secondary decline in oxidative enzyme activity. This suggests that the bioenergetic consequences of myosin isoform transitions might modify the influences that drive metabolic change /4/.

Some properties of the muscles stimulated at 2.5 Hz appeared not to have stabilized fully at 12 weeks. We therefore conducted a more extended study in which rabbits were stimulated for 10 months at 2.5, 5 or 10 Hz. The experiment confirmed that the stable intermediate character of the 2.5 Hz-stimulated muscles could be maintained essentially indefinitely (H. Sutherland, J.C. Jarvis, S.J. Gilroy, S. Salmons, manuscript in preparation).

Optimized patterns

Continuous stimulation at a low frequency is a scientific stratagem: it enables us to examine the effects of changing the aggregate impulse activity with a single variable: frequency. Practical, force-generating patterns for therapeutic use will, of course, demand more complex partitioning of the impulse trains. Conventional, constant-frequency burst stimulation is unphysiological and wasteful of energy. We are therefore developing new approaches based on changing interpulse intervals, of the type found in motoneurone firing patterns /5/.

We have conducted a comprehensive study of the relationship of force and force-time integral to the interpulse intervals contained in the stimulating pattern /6/. Three approaches were used: (1) an incremental method in which the response to each pulse in a train was successively optimized (2) ranking of the responses to a series of quasi-random computer-generated bursts (3) construction of 3-D contour maps in which the response was plotted against frequency and the number of pulses in the train. The study has generated methods for determining the optimum pulse train for muscles of given contractile speed.

The general form of an optimized pulse train can be described as an initial burst of impulses with short interpulse intervals, followed by a series of impulses at a lower frequency. The initial burst elicits a rapid development of tension (the 'doublet effect'); the low-frequency train then maintains the tension optimally for the required duration /7/. An important aim of the recent work was to extend these findings to muscles that had been conditioned by chronic stimulation. The results show that the doublet effect is abolished by régimes of stimulation that produce slowing of contractile speed; in such muscles optimized protocols of stimulation confer no advantages /6/. We have now begun to investigate the energy costs and long-term effects of optimized burst stimulation by means of a new generation of implantable stimulators based on semi-custom CMOS technology.

THE VIABILITY OF THE GRAFT

Damage studies

Some published studies have seriously overestimated the role of damage in the adaptive transformation of skeletal muscle. We have carried out a systematic, quantitative study of damage in rabbit muscles that were stimulated *in situ*. Because our previous experience indicated that there could be large variations in the extent of damage, we combined point-counting morphometric techniques with multivariate statistics in order to evaluate the sources of variation: position within the cross-section, position along the length of the muscle, the anatomical muscle, frequency of stimulation, left vs. right limbs, sex, and individual animals /8-10/. The study established that damage was not a necessary concomitant of type transformation (a finding that is reassuring from a clinical viewpoint). For example, in tibialis anterior muscles stimulated continuously at 10 Hz the mean percentage volume of damaged muscle was a mere 3%. Foci of damage were randomly distributed within a muscle, and their extent depended systematically on the muscle studied and the frequency of stimulation.

The mechanisms responsible for the damage induced by stimulation have never been established. We have examined the role of permeabilization of the muscle membrane by measuring increases in the uptake of $^{99}Tc^{m}$-pyrophosphate /11/. By using radioisotopic markers of blood volume and extracellular space we could show that Tc uptake involved a hierarchy of mechanisms not all of which were associated with membrane permeabilization. We also showed that permeabilization did not necessarily lead to necrosis of the muscle fibre, confirming earlier suggestions that some types of damage are reversible.

Blood flow studies

Fibro-fatty degeneration has been shown to be present in cardiomyoplasty flaps formed in dogs, goats and man, affecting more than 50% of the muscle in some cases, yet stimulation *in situ* does not produce damage on this scale. With our surgical colleagues in Manchester we have studied in a systematic way the effect of different stages of the surgical procedure on damage produced in the latissimus dorsi muscle (LD) of sheep /12/. The study showed that mobilization, particularly when the muscle was reattached at reduced tension, produced significant damage, and that the effect was compounded if stimulation at 2 Hz were introduced 2 weeks later. Damage was worst in the distal part of the muscle, whose normal supply from the perforating branches of intercostal arteries is interrupted during mobilization of the flap.

We therefore suspected that stimulation-induced damage was dependent on changes in the blood supply to the muscle, and that the rest period of 2 weeks that forms part of the normal clinical protocol may not be sufficient to re-establish normal perfusion in all cases. This has prompted an extensive study of factors influencing the distribution of regional blood flow, measured by means of coloured or fluorescent microspheres. We are also investigating the relationship between intramuscular pressure, tension (measured under both isometric and isotonic conditions) and blood flow. These studies are in progress.

THE EVALUATION OF SMV PERFORMANCE

The external work performed during a single contraction of skeletal muscle depends on the force developed, the velocity of shortening, and time available for contraction, the last two determining the distance through which the force acts. The velocity of shortening is not independent of the force: it is related to it by the familiar hyperbolic relationship first described by Hill /13/. Thus when the force is low, the velocity of shortening is high, and conversely when the force is high, the velocity of shortening is low. In these two extreme situations the rate of doing work (the power) is very low. Between the two there is an optimum loading that produces the best combination of force and shortening velocity for doing external work.

In cardiomyoplasty the power available for assisting the heart cannot be optimized because the loading on the muscle wrap is determined by the pre-existing geometry. If, however, the graft is configured as a skeletal muscle ventricle (SMV), then the size, shape, wall thickness and fibre orientation can all be manipulated to achieve the best result. In principle, it should therefore be possible to optimize the geometry so that the muscle graft operates at or around maximum power. There may well be a need for compromise—for example, to deal with anatomical constraints or to improve the flow characteristics of the ventricle. Moreover, since the work done by the muscle is non-linearly dependent on wall stress, and since wall stress is a non-linear function of the shape and size of the SMV, which itself varies throughout a pumping cycle, the problem of determining the optimum geometry is far from trivial.

We set out to use the contractile performance of a muscle working under well-controlled, linear conditions to predict the hydraulic performance when the same muscle was configured as an SMV. The strategy was to load the muscle with a fast, computer-controlled servomotor that simulated the complex, time-varying loading conditions that would be encountered in the wall of an SMV. Initially the experiments were conducted on rabbit hind limb muscles, and provided some useful general predictions concerning SMV behaviour. However, we needed to test the predictions against real SMVs, and to this end we conducted a series of experiments with sheep LD muscles, first characterising the performance under linear conditions and then constructing SMVs of different size from the same muscle and measuring their hydraulic performance. Using a mathematical model we could predict the passive behaviour of the ventricles well, but we found that active linear contractions of the muscle could not be used as a basis for predicting the performance of an SMV during single ejections. We now recognize the limitations of this approach: contraction is less efficient when the muscle is wrapped concentrically in an SMV configuration, and there is a loss of power that we could not take into account. We are currently using a modified apparatus to characterize the hydraulic performance of SMVs constructed and tested acutely in sheep.

THE FLOW WITHIN SKELETAL MUSCLE VENTRICLES

Physical simulation

Any SMV poses a risk of thromboembolic complications arising from events at the interface with the blood. To minimize the risk it is necessary to establish suitable flow characteristics inside the ventricle, avoiding both high shear stresses, which can lead to haemolysis and platelet activation, and areas of stagnation, in which thrombus can form. In our physical simulation, the inner surface of the SMV is represented by a translucent elastomeric ventricle, which is enclosed within a sealed, fluid-filled chamber. The pressure in the chamber is varied by a computer-driven displacement pump, causing the ventricle to interact with the flow in a separate circulation, which can be static, constant or cyclically varying with any desired waveform. The fluid in this circulation contains suspended polystyrene particles. Particles that enter the ventricle are illuminated by a laser and flow is visualized by a video system that has been specially designed to capture the movement of particles over an adjustable time interval /14/.

With this apparatus we have been able to show that flow is dominated by the formation of coherent vortices /15/. We have studied the dependence of these structures on pulse shape, amplitude and frequency, and we have begun to explore the influence of inlet configuration and flow in the pumped circuit. We have also established that extended quiescent periods at the end of the filling phase generate travelling vortices (A. Shortland, R.A. Black, J.C. Jarvis, S. Salmons, manuscript in preparation). Since these are mixing structures they are highly relevant to SMV design.

Numerical simulation

The numerical analysis of flow in SMVs is a very challenging problem, even with the latest in Computational Fluid Dynamics codes. To simplify the problem, data has been assembled that describes the wall movements of the elastomeric ventricle in the physical model. This has been used as the input to a corresponding moving-wall model and predictions generated that could be compared to the empirical data obtained by flow visualization. Initially, the numerical analysis failed to predict the observed flow with any accuracy. With improved temporal and spatial resolution, and refinement of the analysis, a much better agreement has been obtained (F.S. Henry, A. Shortland, F. Iudicello, R.A. Black, J.C. Jarvis, M.W. Collins, S. Salmons, manuscript in preparation). This is one of the few cases in which a thorough validation of the codes has been performed, and illustrates the value of the combined approach. Developments are in hand to refine further the predictive value of the computer model.

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INFLUENCE OF ELECTRICALLY STIMULATED ANKLE PLANTARFLEXORS ON THE SWINGING LEG

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SUMMARY

The influence of functionally electrically stimulated ankle plantarflexors on the swinging lower extremity was studied in incomplete spinal cord injured persons. Stimulation sequences with different time and frequency parameters were delivered to ankle plantarflexors, knee extensors, and peroneal nerve. The results of kinematic assessment showed that stimulated calf muscles provide noticeable forward and upward propulsion to the swinging leg.

STATE OF THE ART

The ankle plantarflexors provide significant energy during the push-off phase of human walking. As they are easily accessible by both surface or implanted functional electrical stimulation (FES), it is sensible to include this important muscle group into the FES assisted gait pattern of incomplete spinal cord injured (SCI) subjects. In our preliminary experiments /1/, performed in stationary conditions, it was shown that up to 14.5cm of horizontal displacement of the center of body (COB) can be obtained by the stimulation of ankle plantarflexors. In FES assisted walking of incomplete SCI patients /2/, this effect of ankle plantarflexors stimulation was less pronounced. However, a noticeable difference was observed in instantaneous horizontal velocity of the COB which was found more continuous and fluid and approached more near normal appearance.

In the studies performed in normal persons a noticeable increase of the COB energy, resulting from the ankle plantarflexors activity, was not found /3,4/. Only some of the energy generated by the calf muscles continues upwards through the knee joint and small energy continues across the hip joint to the trunk. It, therefore, appears more probable that the work of ankle plantarflexors provides the kinetic energy for the initiation of the swing phase. In the present investigation, it was our aim to study the influence of electrically stimulated calf muscles on the effectiveness of the swinging leg movement. In surface electrical stimulation rather large electrodes are usually placed over both m. soleus and m. gastrocnemius. M. gastrocnemius which extends from the heel to the thigh is a biarticular muscle. Immediately after the start of the push-off phase, when the knee is in slightly flexed position, m. gastrocnemius not only maintains the ankle in plantarflexion but can also further flex the knee. It was hypothesized that FES of ankle plantarflexors may provide three important gait functions:

- rising of the heel and preparation of the leg for the swing phase,
- providing upward and forward propulsion to the swinging leg,
- enabling knee flexion and thus shortening of the swinging leg.

METHODS

The FES assisted push-off was realized by controlling three stimulation channels delivered to the ankle plantarflexors, knee extensors and peroneal nerve. FES of the knee extensors, being active during the entire midstance phase, was discontinued. Electrical stimulation was delivered to the ankle plantarflexors. Adequate swing phase was accomplished by triggering of flexion response. Proper timing of the three stimulation sequences was based on the experiences from the previous work. An important gait parameter is the delay between the start of the train of stimuli delivered to the peroneal nerve and maximal knee and hip flexion obtained during the elicited withdrawal response. This latency was found to be in the range from 0.5s and 0.75s /5,6/. Similarly, a delay of 0.3s was observed between the start of the train of stimuli delivered to the ankle plantarflexors and maximal vertical reaction force /1/. Based on this data the duration of flexion reflex stimulation was selected to be 0.5s, while the stimulation of ankle plantarflexors lasted for 0.3s.

Six combinations of stimulation sequences, characterized with different time and frequency parameters, were investigated in the present study. They are displayed in Fig. 1. The first set belongs to our present simple FES gait pattern where only knee extensors and flexion reflex are stimulated /5/. Hand pushbutton is used to discontinue the stimulation of knee extensors and to start the flexion reflex. The stimulation frequency in both channels was 20Hz. In the second set of stimulation sequences the afferent stimulation frequency was increased to 50Hz in order to reduce the latency of the withdrawal response /6/. In the next four combinations of stimulation sequences, the FES of ankle plantarflexors was added. In order to obtain strong and fast propulsion, 50Hz stimulation frequency was used also with the efferent stimulation of the calf muscles. The four stimulation sequences are characterized by different delays with regard to hand triggering and different types of stimulated muscle groups coactivation. The positioning of the surface electrodes over the knee extensors, ankle plantarflexors, and peroneal nerve was the same as described in our previous work /1/. The amplitudes for all three stimulation channels were selected before the test when the subject was in the seating position. In all six combinations of the stimulation sequences the same amplitudes were used for each subject. The amplitude for flexion reflex triggering was adjusted at 50Hz stimulation frequency.

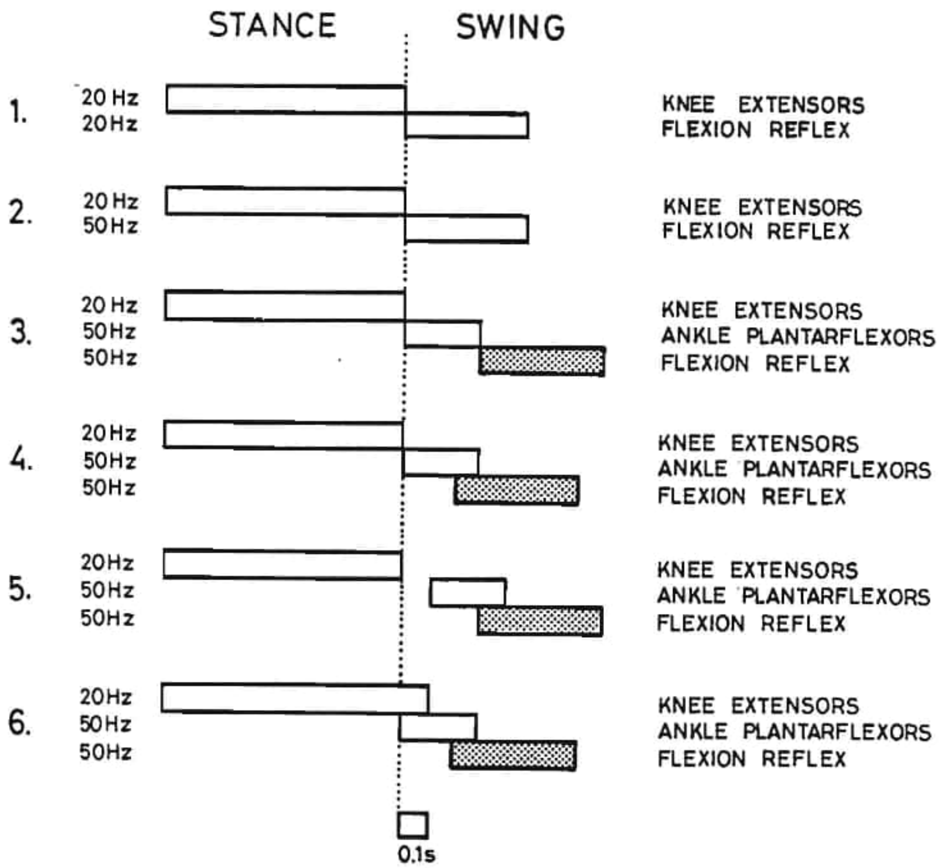

Fig. 1. Electrical stimulation sequences delivered to the knee extensors, ankle plantarflexors, and peroneal nerve.

Repeated measurements were performed in four incomplete SCI patients. The incompletely paralyzed patients had the following spinal cord lesions: T-11,12 (subject IM, 34 years old), C-7 (subject TP, 24 years), C-7 (subject BS, 18 years) and C-6 (subject LG, 18 years). All incomplete patients were selected from the group of SCI subjects having one leg almost completely paralyzed, while the other leg was under voluntary control and sufficiently strong to provide safe standing. The three channel FES was therefore applied to them only unilaterally. During the measurement the incomplete SCI subjects stood supported by the help of parallel bars. The subjects entered first the push-off phase and then the swing phase by voluntarily activating the hand pushbutton. The experiment was repeated three times in each incomplete SCI subject tested.

The described stimulation sequences were generated by eight-channel MC68HC16 microcontroller based stimulator. The stimulation parameters such as pulse amplitude (0-150V), pulse duration (50-800μs) and frequency (5-100Hz) were selected independently for each channel. The amplitude of the stimuli was adjusted manually by means of potentiometers. Stimulator functions were selected through hierarchical menu oriented control system, accessible through LCD screen and three pushbuttons. The movements of the swinging leg were assessed by contactless OPTOTRAK measuring system (Nothern Digital Inc., OPTOTRAK/3010, Waterloo, Ontario N2L 3V2, Canada) including two precalibrated position camera systems which permit measurement of 3-D marker coordinates at 50Hz sampling rate and accuracy of 0.35mm. Four OPTOTRAK markers were placed in the estimated anatomical positions of the hip, knee, ankle and metatarsal joints in the sagittal plane. The OPTOTRAK data were collected and checked with a PC computer and further processed on Unix based HP 9000/700 workstation with commercial Matlab software and custom written subroutines.

RESULTS

The aim of the present investigation was to evaluate experimentally the effectiveness of the FES delivered to the ankle plantarflexors in order to obtain improved swing phase of walking. It was hypothesized that ankle plantarflexors provide necessary propulsion to the swinging lower extremity. Two parameters were found particularly interesting to estimate the swinging leg movement: maximal horizontal swing of the metatarsal joint and maximal vertical swing of the knee joint. The first parameter indicates the effectiveness of propulsion in forward direction and it corresponds to the step length. The second parameter demonstrates the propulsion of the swinging limb in upward direction and is therefore interesting when planning tasks such as overcoming sidewalks or climbing stairs.

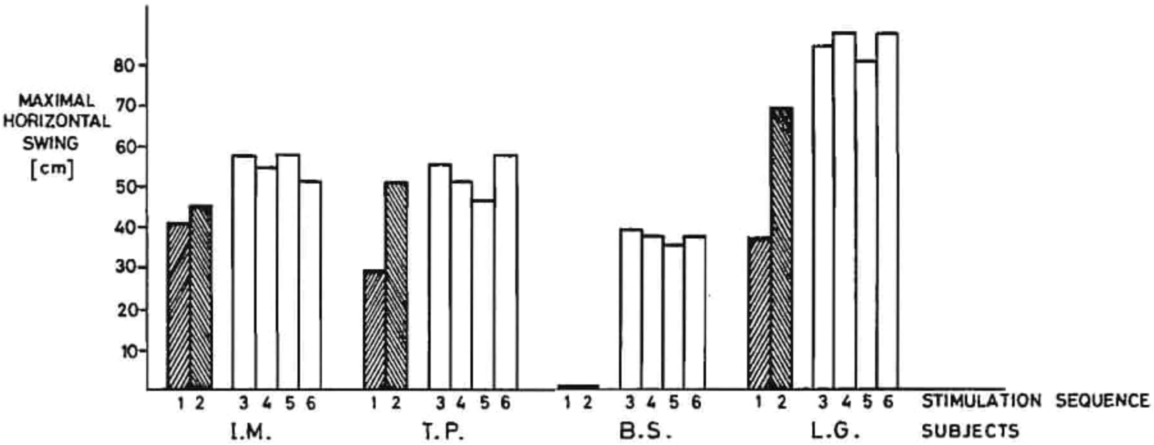

Fig. 2. Maximal horizontal swing of the metatarsal joint resulting from application of six stimulation sequences.

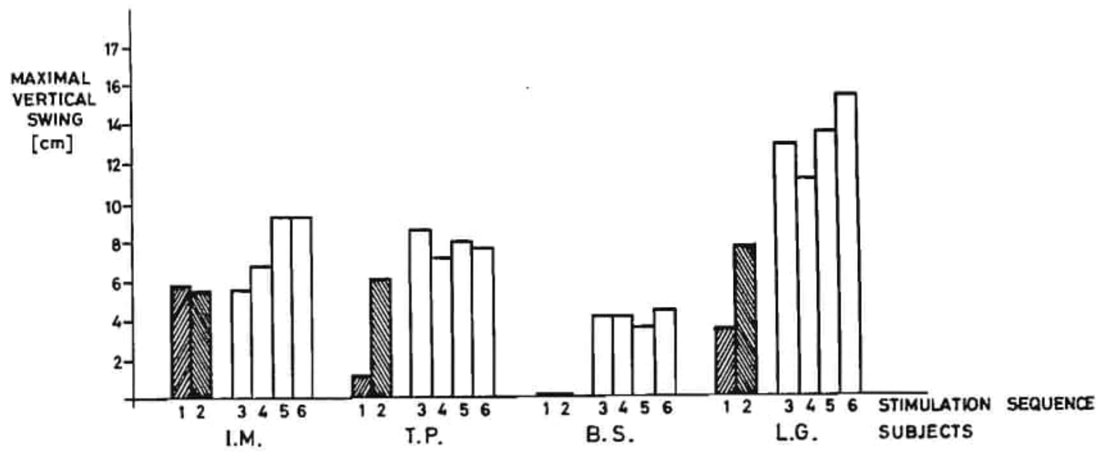

Fig. 3. Maximal vertical swing of the knee joint resulting from the application of six stimulation sequences.

The results of the assessment of the maximal horizontal swing of the metatarsal joint in the sagittal plane are displayed in Fig. 2. The first two columns belong to the stimulation sequences 1 and 2 where only flexion reflex was elicited, first with 20Hz stimulation and second with 50Hz stimulation. The next four columns represent the stimulation sequences 3 - 6 where also the stimulation of ankle plantarflexors was added. It can be first noticed that stimulation of ankle plantarflexors resulted in improved responses in all four incomplete SCI patients. The influence of stimulated calf muscles is specially evident in subject B.S. where flexion reflex alone was unable to move the limb forward. Next, it can be noticed that the differences among the four stimulation sequences including the ankle plantarflexors stimulation are small and cannot be considered significant. In two patients (T.P. and L.G.) increasing of the stimulation frequency of the flexion response (stimulation sequence 2) resulted in noticeable improvement of the forward swing. From the results obtained in patient L.G. it can be seen that steps lengths over 80cm can be obtained with the three-channel stimulation of the paralyzed limb what exceeds the step length of normal walking. Similar results were obtained when measuring the maximal vertical swing of the knee joint (Fig. 3). The highest amplitudes were again assessed in patient L.G. indicating that the stimulated extremity can be lifted sufficiently to be placed on a sidewalk or a stair. The effectiveness of the ankle plantarflexors on the swinging leg is somewhat more pronounced when observing vertical lift of the lower extremity.

DISCUSSION

When comparing the results of our previous work, when the energy of the stimulated ankle plantarflexors was delivered to the trunk /1/, with the results of the present investigation, when this same energy is transferred to the swinging leg, we can conclude that the latter approach is more advantageous for FES walking of incomplete SCI patients. It was further demonstrated that small differences in the timing of the stimulation sequences of the knee extensors, flexion reflex, and ankle plantarflexors have insignificant effect on the movement of the swinging extremity.

Electromyographic recordings show that the muscles of the swinging leg are predominantly silent during the swing phase. Assumption was, therefore, made that no muscular moments are provided to any of the joints of the extremity after the initial positions and velocities of the joints have been established at the beginning of the swing phase /7/. Swing phase of the human gait was described as a ballistic motion. According to our observations in incomplete SCI subjects, it appears that the stimulation of calf muscles alone can provoke the swing phase of walking.

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CONTROL STRATEGIES FOR FES-SUPPORTED STANDING UP

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SUMMARY

Real-time closed loop control of standing up using electrical stimulation of quadriceps and hamstrings was investigated in a biomechanical simulation study. The model was based on literature and experimental identification of relevant parameters in two paraplegic subjects. The simulations indicated that hamstrings stimulation can be effectively controlled based on observations of knee and hip angular velocities if the stimulated muscles are well trained and the body weight of the subject is limited.

STATE OF THE ART

Restoration of mobility in paraplegics can be supported by Functional Electrical Stimulation (FES). From a functional point of view, the support of standing up is especially important, since it enables the paraplegic subject to reach objects, make transfers and communicate with other people face to face.

A well-coordinated standing up movement requires a balanced activity of electrically stimulated muscles acting at the knee and hip, taking account of the upper body activity voluntary exerted by the subject. This upper body effort is required since joint moments generated with current electrical stimulation systems are insufficient to lift the body weight. In this way, the subject can also voluntary assist in balancing the body during standing up.

Previous research on FES supported standing up /1-2/ mainly focused on the control of knee extension via quadriceps stimulation. Mulder et al. /1/ proposed an on-off control scheme based on switching curves in the knee angle - angular velocity state space.

However, activation of hip extensors in good coordination with knee extensor activation may be required for optimizing standing up /3/: it may reduce the required upper body effort and improve the balance. The biarticular hamstrings muscles are especially suited for this purpose, because they simultaneously influence knee and hip joint moments and are well accessible for surface stimulation.

CONTROL OF STANDING UP

The current study focuses on strategies for the control of standing up. These control strategies should generate a well coordinated standing up movement, with simultaneous extension of knee and hip joints, requiring minimal arm force for lifting and balancing the body and minimizing muscle stimulation to reduce muscle fatigue.

Several alternative control strategies may be conceived. The first is real-time feedback control, adjusting stimulation on the basis of on-line acquired sensory information, such as joint angles, orientations of the leg segments and/or interaction forces with the environment (ground reaction force and arm force). Several questions arise with respect to this approach:

- can real-time adjustment of stimulation effectively influence standing-up, considering the relatively high inertia's and weights of the body segments and the relatively low joint moments that can be generated?
- what sensory information is required for adequate feedback control?
- what control algorithm should be used to adapt the stimulation on the basis of the sensory feedback information?

If real-time control would not be sufficiently effective alternative control strategies may be considered, like the application of preprogrammed stimulation patterns or model based predictive control. However, the effect of preprogrammed patterns may be variable and the model prediction inaccurate in the presence of relatively large voluntary upper body activity, which may not be very reproducible.

As a first phase in investigating the possibilities of real-time feedback control, we performed a biomechanical model study. Two alternative control strategies for coordination of knee and hip extension were considered: the first strategy stimulates hamstrings if hip extension angle is behind knee extension angle, according to a preset linear relation; the second strategy stimulates hamstrings if hip extension velocity is behind knee extension velocity. In both strategies quadriceps, assumed to be mainly monoarticular knee extensors, were continuously stimulated.

MATERIALS AND METHODS

The biomechanical model

A 2D three link biomechanical model was implemented in the simulation package SIMULINK, with arm force, hip and knee moments as kinetic input. The equations of motion were derived using the method of Lagrange /4/. Hip and knee elasticity were modeled using two exponential functions /5/. Hip and knee damping were assumed linear. Elasticity and damping parameters were taken according to Yamaguchi et al. /5/. Anthropometric data were obtained from Winter /4/, and scaled to total body length and mass. Muscle dynamics were modeled with first order dynamics (time constant 30 ms) and maximal joint moments depending on knee and hip angles. These angle dependencies were identified for one paraplegic subject. Voluntary upper body activity was simulated by an arm force controller, which continuously adjusted arm force according to a proportional control law, with a vertical velocity setpoint of 0.2 m/s for the center of mass and with a horizontal position setpoint.

Preliminary open loop stand-up tests

Standing up was tested in three patients, two of which are reported in this paper (TN and JO). Open loop stimulation of only quadriceps was compared to simultaneous stimulation of quadriceps and hamstrings. The muscles were stimulated using surface electrodes. Movements were measured with a VICON system, ground reaction forces with AMTI force plates, arm forces with instrumented arm supports.

Model identification

Model parameters of TN and JO were identified: body mass and length were determined for both subjects. Knee moments at several combinations of hip and knee angles were determined under isometric conditions using a KINCOM dynamometer system. For TN these relations were only determined at a single hip angle of approximately 90 deg. For JO knee moments were measured at varying hip and knee angle combinations for quadriceps and hamstrings stimulation. Only the angle - moment relations of JO were used for identification. For TN, these relations were scaled for the difference in maximal quadriceps knee moments. Hip and knee angle dependence of hamstrings hip and knee moments were identified from the measurements of JO, assuming a constant position of hamstrings attachment and center of rotation at the hip according to Brand et al. /6/, a Gaussian length - force characteristic of hamstrings /5,7/ and a straight muscle connection between origin and insertion.

RESULTS

Identification

Body mass of JO and TN were 100 kg and 60 kg respectively. Their lengths were approximately the same (1.90 m). Maximal quadriceps knee moment was 20 Nm for JO and 75 Nm for TN, both at a knee angle of approximately 40 deg. The quadriceps knee angle - moment relation did not show a large dependence on hip angle (figure 1a). As expected, the hip angle dependence of the hamstrings knee angle - moment relation was much larger (figure 1b).

Open loop stimulation of mono and biarticular muscles: preliminary experiments

Open-loop standing up in TN (figure 2) showed knee extension before hip extension when using only quadriceps stimulation, whereafter the subject had to extend the hip joints by using his arm force. Adding hamstrings stimulation resulted in a simultaneous extension of knee and hip joints. However, too large activation of hamstrings resulted in insufficient knee extension moment and the body tended to fall backwards. Required arm forces were between 30 and 60% of body weight. It was concluded that the monoarticular parts of quadriceps should be stimulated at a maximal level throughout most of the standing up and that hamstrings should be adjusted via feedback control.

Open-loop standing-up in JO showed a large required arm force of approximately 80% of body weight. Quadriceps and/or hamstrings stimulation did not show a marked influence on standing up. Furthermore, JO had hip flexion spasms, which influenced standing up in a negative way.

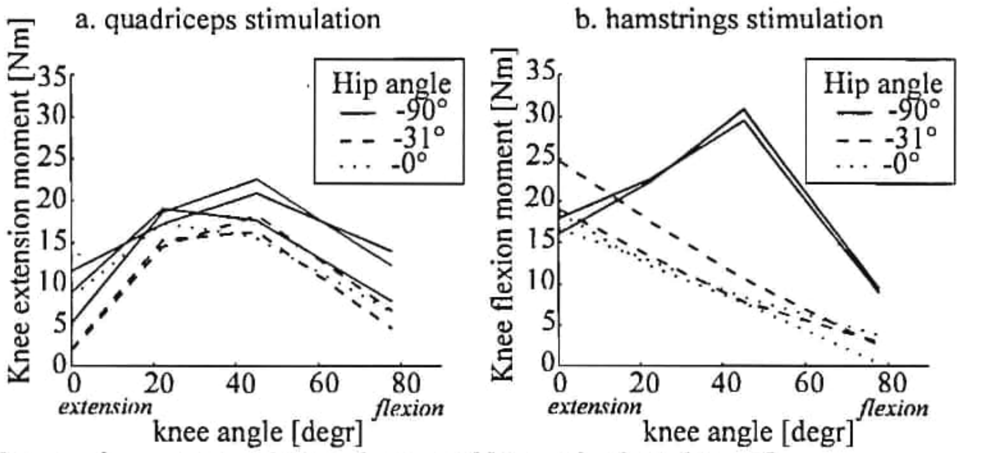

Figure 1. Knee angle - moment relations for several hip angles for subject JO.

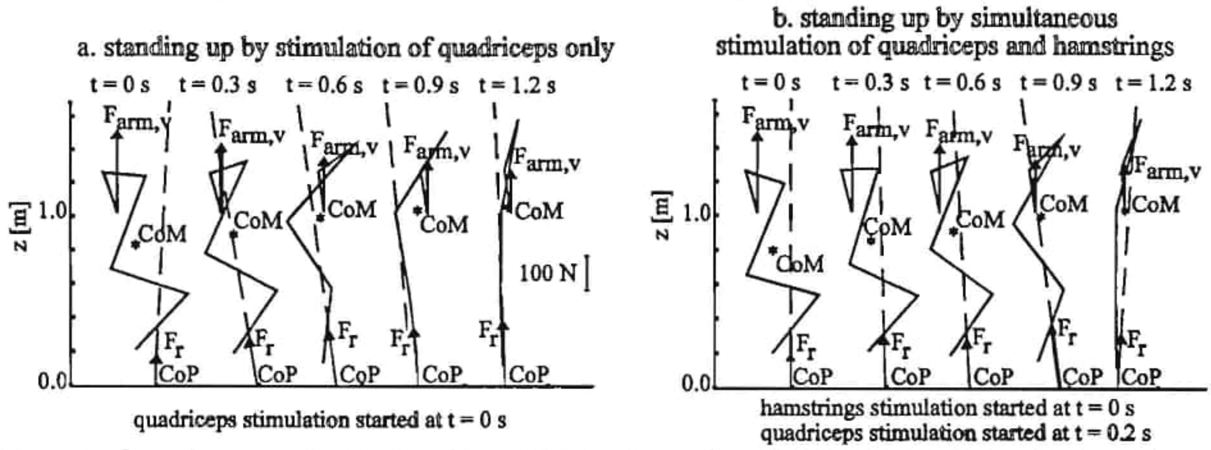

Figure 2. Open-loop standing up in subject TN (experimental result /3/).

Closed-loop control of standing up: simulations

Simulation of JO standing up predicted a large required arm force of between 60 and 80% of body weight throughout standing up, and thus a low contribution of quadriceps, which is in agreement with open loop experimental tests. Hamstrings were not activation, since the large arm force already resulted in sufficient hip extension. For TN, however, simulations predicted an improved coordination of knee and hip extension with hamstrings stimulation, again in agreement with the experimental results.

The two alternative hamstrings control strategies (based on the comparison of knee and hip angle or knee and hip angular velocity) were simulated for TN's body weigth and length for 3 strengths of hamstrings muscles: 1, 2 and 3.5 times the hamstrings strength of JO. Figure 3a shows that hamstrings are activated too late, when controlled on the basis of knee and hip angle assessment. However, hamstrings control on the basis of knee and hip angular velocities yields an improved result in tracking the linear relation between knee and hip extension angles during standing up (figure 3b).

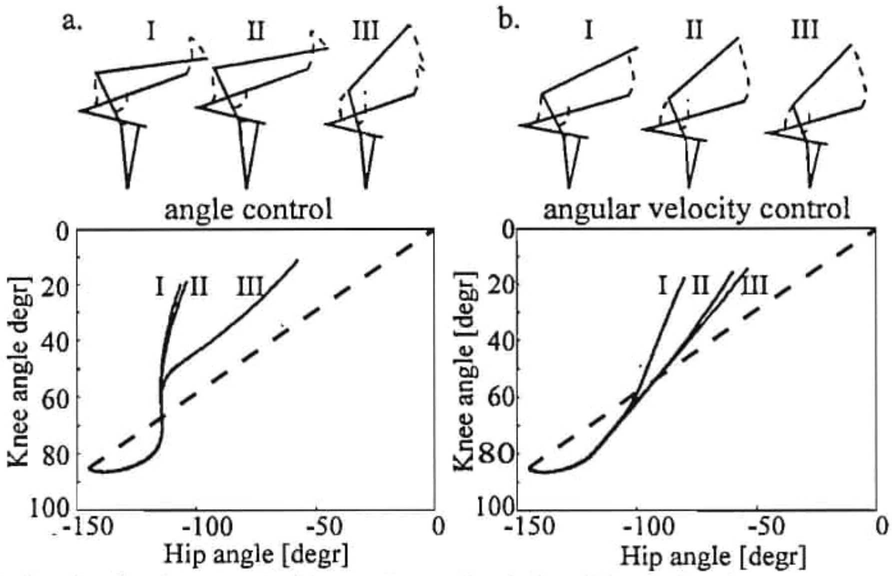

Figure 3. Real-time feedback control of hamstrings stimulation (simulations).

DISCUSSION

The current simulation results indicate that real time control of hamstrings stimulation can be effective despite large inertia's and low joint moments generated by the muscles. However this can only be achieved if it is based on angular velocities rather than angles. It is evident that deviations from a simultaneous knee and hip extension can be earlier observed from angular velocities than from angles. More general, a proportional differential (PD) controller may be used for hamstrings control.

It has not yet been evaluated whether such a control also results in reduced vertical and horizontal arm forces (balance) and reduced stimulation.

Experiments and simulations indicate that real-time feedback control can only be effective in relatively well-trained subjects (high joint moments generated by stimulated muscles), who are not too heavy.

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COMPUTERIZED ELECTROMYOGRAPHICAL ANALYSIS OF THE BIOMECHANICAL FUNCTION OF SELECTED MUSCLES IN LEVEL GAIT: A CONTRIBUTION TO THE DESIGN OF THE FES WALK

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SUMMARY

A knowledge of the exact activity pattern exhibited by the lower extremity muscles during the gait cycle is the basis for FES applications to human walk. We have developed a computer - assisted electromyographic gait analysis system which is suitable for investigations of this kind. This paper describes the basic features of this system presenting exemplarily some selected findings of typical muscle activity patterns measured in the lower leg of test subjects during continuous level walk. In particular, the electromyographic status found in a young athlete suffering from a temporary paresis of the peroneus communis nerve is presented and the possible application of FES in cases of this type is discussed.

MATERIAL AND METHODS

In the biomechanics laboratory of our department the following computer - assisted gait analysis system is used: During an uninterrupted test gait of a subject on a level walk way of about 12 meters length the following measurements can be carried out:

- Electromyographic surface activity of up to 14 muscles by electronically active skin electrode arrangements
- Angular motion of the upper and lower leg in the sagittal plane by an optoelectronic goniometer system

The measuring signals are transmitted from the walking subject via a trailing cable running in a track on the laboratory ceiling to a stationary signal conditioning unit. The suitably amplified and filtered signals are fed to a computerized data acquisition and processing system. In the subsequent digital data analysis the angular measurement data are used to identify the motion cycles of the recorded gait sequence. The electromyographic signal data are subjected to a digital high pass filtering for motion artefact suppression, a digital full wave rectification, and a digital low pass filtering, in that order. The signals of all recorded gait cycles (i.e. full strides) are then linearly superimposed (signal ensemble averaging). This procedure is carried out for a sufficiently large number of test gaits of the same type (n = 10) in order to obtain a sufficiently high number of gait motion cycles for a final signal averaging. It was found that by averaging over about 50 full strides electromyographic activity and angular motion patterns are obtained that are highly characteristic for the subject examined and the experimental conditions given. They are reproducible within narrow limits for most muscles of the leg in different experimental sessions if the experimental conditions are the same. The averaged angular motion curves of the upper and lower leg are used to calculate the angular motion curve of the knee and to obtain by numerical differentiation the respective angular velocity and acceleration curves.

These investigations are carried out within an experimental study endeavouring to develop a diagnostic tool for the clinical evaluation of selected gait characteristics of patients before and after orthopaedic and/or physiotherapeutic treatment. Healthy test subjects are examined to establish a normal gait data base for the assessment of pathological findings in patients or, as in the present instance, for the planning of selected FES measures in the treatment of gait disorders.

RESULTS

We exemplarily present in the following the electromyographic activity curves of some muscles during the gait cycle of a young athlete suffering from a temporary impairment of the dorsal extension biomechanics of the right foot due to a lesion of the peroneus communis nerve. Fig. 1 shows, top to bottom, the activities of the rectus femoris, biceps femoris, tibialis anterior, peroneus longus, and soleus muscles of the left healthy leg (left column) and of the right leg while affected by the paresis (middle column), and of the right leg 4 months later after partial rehabilitation (right column). The curves of 10 test gaits obtained by averaging over 6 full strides each have been superimposed in these graphs to demonstrate the fluctuations remaining when averaging over too small a number of motion cycles. A further averaging over these 10 curves comprising a total of 60 gait cycles in this case would yield the highly reproducible curves described above. Nevertheless, the missing activity of the peroneus muscle of the affected leg is clearly evident from these graphs as well as the heavily reduced activities of the tibialis anterior and the soleus muscle (middle column). This is a consequence of the disturbed foot motion during both the stance and the swing phase of the gait cycle. 4 months later the walking motion of the patient's left leg had approached the normal pattern again with a partially recovered peroneus longus muscle activity and nearly normal activities in the tibialis anterior and soleus muscle. The patient was treated by a special shoe that kept the left foot permanently at right angles to the tibia thus facilitating level walk but leaving the concerned muscles inactive. In this particular case an appropriate FES could have been used to try to effect a close to normal walking motion. Moreover, by such a procedure a continuous training effect in the muscles inactivated by the disorder could have been achieved during the rehabilitation period. The findings obtained in the investigation of the walk of healthy test subjects could be used in the development of an optimum electrical stimulation pulse pattern. In all subjects, for instance, widely symmetric activity patterns in the right and left leg muscles during uniform level walk have been observed. In context with the particular case study presented here we show in fig 2 as typical examples the electromyographic activity curves of the left (top) and the right (bottom) tibialis anterior (1), peroneus longus (2), and gastrocnemius (3) muscles. The phase shift of half a motion cycle has been omitted in these diagrams. Curves A, B, and C show the respective angular motion, angular velocity and angular acceleration of the lower leg. It is evident that the EMG signal of normally activated contralateral muscles could be used as FES triggers for their handicapped counterparts in periods of uniform level gait at constant speed, for instance.

DISCUSSION

We conclude from the results elaborated in our gait analysis program so far that although there is a basic similarity comparing different healthy subjects the individual electromyographic muscle activation patterns are, nevertheless, very characteristic in detail. They are highly reproducible at unchanged experimental conditions. Although not completely identical, the electromyographic activation patterns of the left and the right leg are very similar in a healthy individual. These basic facts have to be considered in the planning of FES assisted walk.

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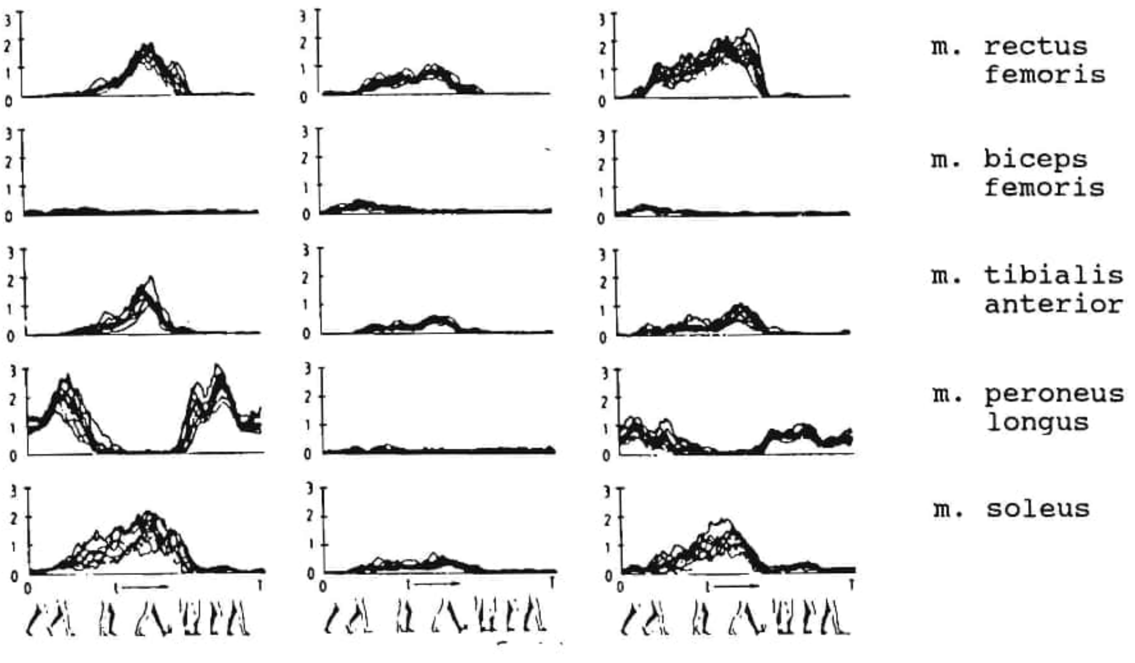

Fig. 1 EMG activity pattern of patient suffering from a temporary paresis of the peroneus communis nerve (described in text)

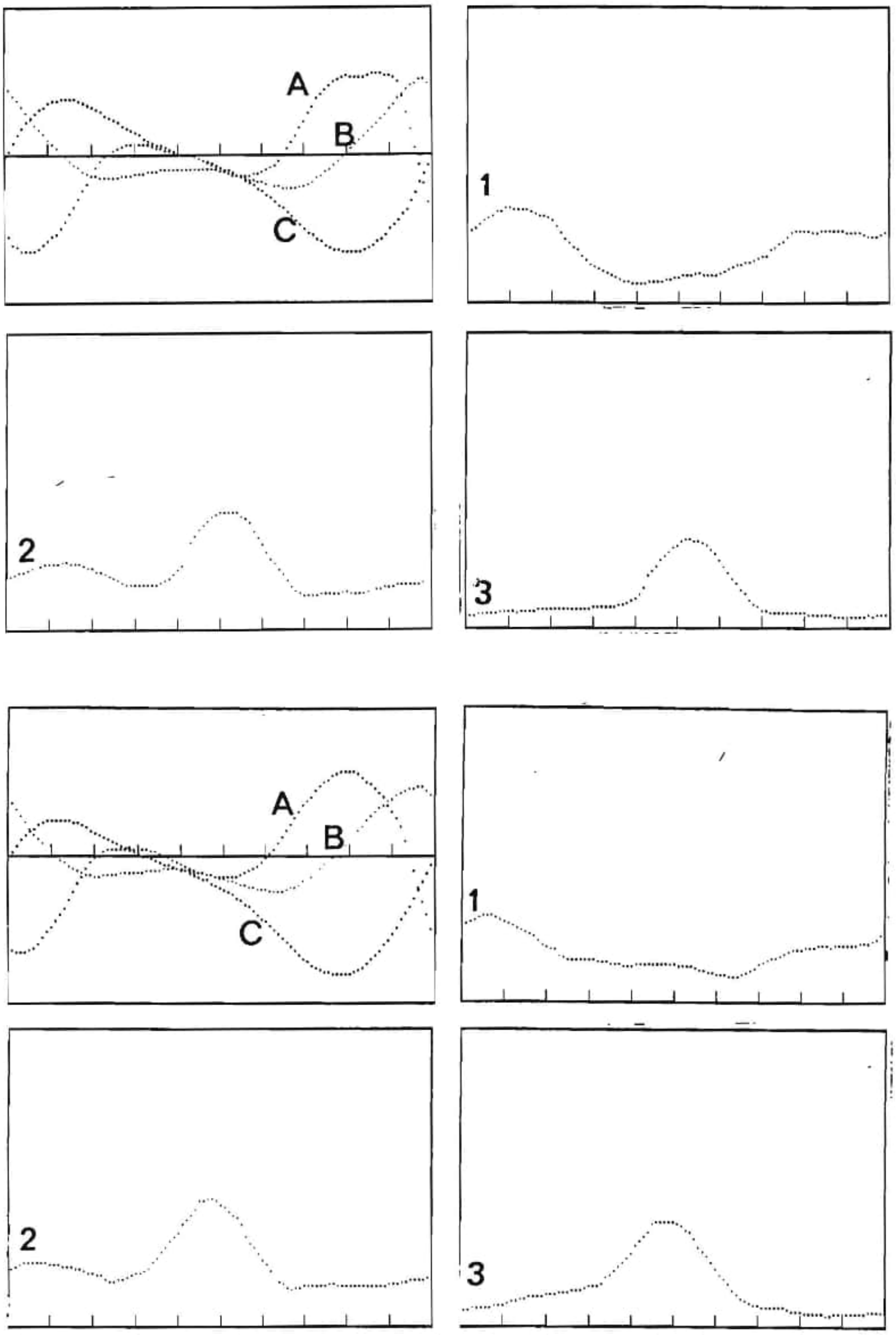

Fig. 2 Comparison of EMG activity patterns of 3 muscles of the left (top) and the right leg (bottom) of a healthy test subject (1 m. per. long., 2 m. tib. ant., 3 m. gastrocn.)

LUMBAR ROOT STIMULATION FOR RESTORING LEG FUNCTION: RESULTS IN PARAPLEGIA

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SUMMARY

In December 1994 we implanted an intradural array of 12 tripolar electrode systems on the anterior roots L2-S2, left and right, at cauda equina level, in a 33 year old woman with a complete T9 cord lesion of 3 years duration. They are driven by the stimulator system described in an accompanying communication. All channels give movements, in patterns that might be predicted from the known anatomy of the cauda equina. In particular, L2,3 give hip adduction; L3,4,and 5 give knee extension; all the above give hip flexion in addition; L5, S1,2 give hip extension and abduction; and S1,2 give plantarflexion. L5 gives mixed movements at the ankle. Responses have been stable. Some thresholds have varied, probably as a result of tissue encapsulation.

The moment generated within each degree of freedom of the legs has been measured for each root, using the multi-moment measurement apparatus described in an accompanying communication. For some roots (L5 in particular), a movement of lower threshold may be accompanied by a second movement of higher electrical threshold, suggesting that different muscles may have fibre populations that differ in their diameter or their location in the root. The use of stimulus forms which enable selective anodal block may in the future perhaps enable separation of two distinct movements from a single motor root.

STATE OF THE ART

As yet, there is no system for lower limb functional neurostimulation (FNS) in widespread community (as opposed to laboratory) use for restoring standing or walking in paraplegia. One of the reasons for this is that each of the stimulator systems tried has proved to have significant disadvantages in practice. The first and simplest type uses surface electrodes, and was first demonstrated in the laboratory over thirty years ago /1/. This device stimulated quadriceps femoris only. For simple standing, this method works well. The problem is that if the system is elaborated by providing stimulation to further muscle groups, applying the electrodes soon becomes too time-consuming to be practicable. Also, surface stimulation is wasteful of current, good skin-care is essential, and stimulation varies with movements of the limbs. For these reasons, many workers /2,3,4/ have concluded that the scope of surface stimulation methods is essentially limited to experimental work, and that to obtain selective and consistent results, the electrode system must be implanted. At present, implanted electrodes fall into three main groups. The first type is percutaneous wires, which are inserted through the skin, and located to the motor point using trial stimulation /3/. These are easy for a practised operator to insert, and do not require formal surgery. It is possible to add as many wires as are needed; but they break eventually, and require skin-care at the entry-point. The second type is the nerve-cuff electrode, which is inserted around peripheral motor nerves in a formal surgical procedure /2/. Self-wrapping helical electrodes are a variant on this type /5/. The problem with these types is that a multichannel system for paraplegic standing and walking calls for increasingly extensive surgery, in order to access all the required nerves. The third group is the epimysial type of electrode, which is an implanted disc electrode, which in the case of large muscles is usually placed near the motor point. These require less dissection than the cuff type, but multichannel lower-limb systems still require extensive surgery. Cuff and epimysial electrode types both require a system of implanted cabling in the limb. Up to now, cabling in the lower limb has not been very satisfactory; cable conductor fractures are common.

MATERIALS AND METHODS

This paper describes a new approach to lower limb FNS, which employs 12-channel stimulation of the lumbosacral anterior roots, between L2-S2 inclusive. The electrode design, cable type, surgical approach and implantation technique are based on the successful and long-proven sacral anterior root stimulator implant ('SARSI'), which is widely used in Europe to restore bladder control in paraplegia /6/. The stimulator design, the controller hardware and software, the patient selection procedure, and the 'multi-moment chair' used to measure the responses to root stimulation, are described elsewhere at this meeting. The patient is a woman aged 33 years, with a complete T9 traumatic cord lesion of 3 years duration. She is the first patient to be implanted with this design of system, although an earlier version with a different multiplexer was implanted in 1990, in a man aged 50 years with a complete T6 traumatic cord lesion of 15 years duration /7/.

RESULTS

Effects of stimulating single roots

Each motor root when stimulated gives rise to a set of moments in the appropriate limb. One set of moment measurements obtained in this way is shown in Table 1. All roots except for L2R give substantial responses. In each cell of Table 1, the upper figure relates to the 'sitting' posture (hips and knees at 90°), and the lower figure relates to the 'standing' posture (hips and knees extended). Ankles are at 90° in both cases. For many cells, the moment is independent of posture. For some, such as hip extension using S1, the moment is posture-related, probably because of the change of mechanical advantage of the muscle actions involved. In some, such as ankle inversion from L4 or L5, the movement was also highly posture-related, without any change in the joint angle concerned. This was probably reflex.

	L2	L3	L4	L5	S1	S2
Hip Ext	-30 -25	-25 -30	-10 -15	-8 -10	24 0	5 0
Hip Abd	-28 -20	-30 -30	-8 -9	12 12	12 5	2 -2
Hip Ext Rot	0 -5	0 -4	-2 0	2 8	15 10	2 4
Knee Ext	10 15	20 20	15 12	0 5	-8 -10	-3 -3
Ankle Pl Flex	0 -8	-5 -8	8 0	10 -9	20 20	5 7
Ankle Invert	0 0	0 0	15 1	10 0	15 10	1 4

Table 1. Joint moments (Nm) for each degree of freedom in the left leg, for stimulation of single roots. Data collected 3 months after implantation.

Standing

The patient stands using her implant, during her regular visits to the laboratory. Two months after surgery she stood well, but during the following two months there was an increase in reflex hip flexion (which had to be countered with large upper body forces) and ankle inversion, (which occasionally overturned one ankle). We then altered the daily training so as not to stengthen inversion; this has been successful. Meanwhile the hip extension moments available from S1 and S2 have increased, so that standing has improved. Six months after surgery the patient was able to stand with only one hand for support. Standing is improving as the reflex pattern settles, and the extensors strengthen.

Finding an inverse map

The moments resulting from stimulation of different roots should not inhibit, occlude or facilitate each other, so that in theory the results of stimulating two or more roots should be predictable by adding the sets of moments algebraically. However, in practice the shape of the relationship between stimulation strength and moment may differ for each root, each moment, and each joint angle. It is likely that the most useful stimulation patterns will involve more than one root. The Multi-Moment chair simplifies the problem by making isometric measurements. If, after any initial transient, the response settles to a set of steady values, then that response can be located to a coordinate position in 6-dimensional moment space (there are 6 important degrees of freedom in the leg), while the corresponding excitation is located to a coordinate position in 6-dimensional stimulation space (there are 6 roots available for stimulation, for each leg). To produce particular desired combinations of moments, we need an inverse mapping between these two spaces, so that for each desired moment combination we can calculate a corresponding stimulus pattern. We have used Radial Basis Functions for the inverse mapping /8/.

The practical difficulty is the number of moment combinations required in order to produce a useful model. The automated stimulation and data collection methods used allowed us to collect the responses to 90 such patterns of stimulus intensity in 30 minutes of testing. This is the longest practicable uninterrupted testing period, because of the patient's need for pressure relief. In one experiment we applied 360 patterns which gave all combinations, with 2 or 3 intensities at each root. This was tiring for the subject and causes significant muscle fatigue. The variations induced by moment changes from one testing session to another were attributable to changes in the pattern of reflex responses, and continuing changes in the strength and state of training of important muscle groups. The model generated, however, had a mean error of only 8% in intensity for each electrode, when tested using unseen data. Another model generated more recently, using only 135 data samples, had a mean 14% error. We hope that when the muscles are fully trained and less fatiguable, so that the responses are more constant, the model will be accurate enough to use in a controller.

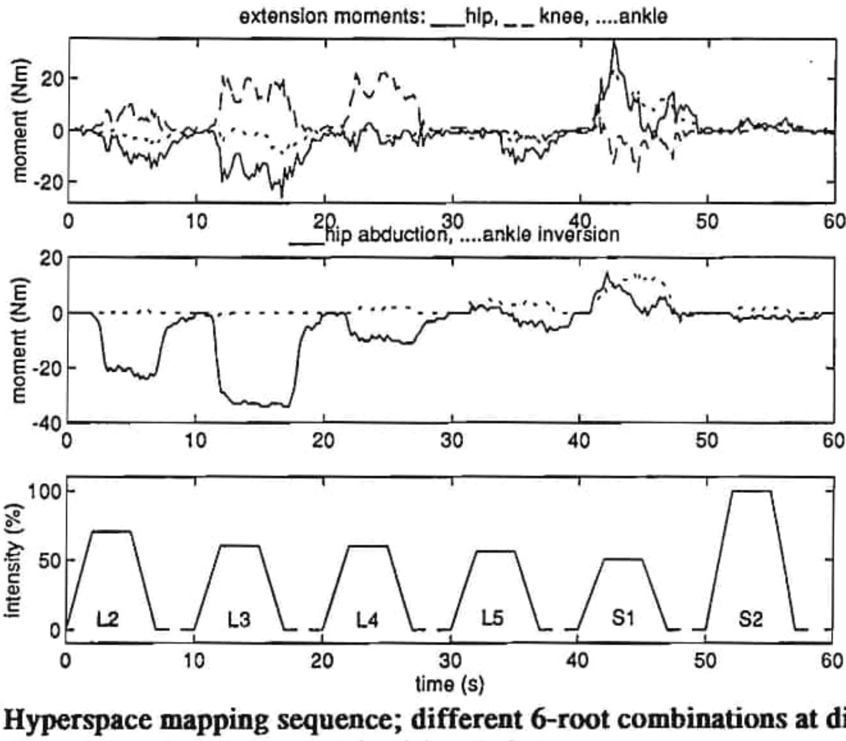

Figure 1. Hyperspace mapping sequence; different 6-root combinations at different strengths
Hip rotation moments are omitted for clarity

DISCUSSION

The strength and fatigue-resistance of all muscle groups in this patient have continued to improve during the first six postoperative months, in spite of the fact that she trained every day, using surface stimulation, during the selection procedure (see accompanying communication) and for six months prior to surgery. This is likely to be because root stimulation gives access to the *whole* motor output, while surface stimulation reaches only part of it. One root (L2R) has given small moments throughout (except on the day of surgery), and it is likely that this is attributable to surgical damage. Regeneration may yet occur. It is known from experience with the SARSI that spinal roots are sometimes damaged, in spite of taking every surgical precaution /6/. Besides training, and the moment mapping experiments reported here, standing tests have been performed regularly, in which the intensities have been adjusted empirically, and satisfactory standing has recently been achieved. Good intensity patterns for extension, found by expert trial and error during standing, agree well with data found by rapid automated searching in the Multi Moment Chair. The flexion reflexes noted on the moment measurements have also been clinically present on standing, particularly hip flexion. In this patient, the combinations of lower limb moments that are accessible to root stimulation include those that are essential for standing and stepping. The stimulator control programmes, the multi-moment chair apparatus, and the data collection programmes together enable the rapid collection of large quantities of data. This enables us to make the testing sessions relatively 'friendly' for the patient.

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DESIGN OF AN INTENTION DETECTION SYSTEM FOR FES ASSISTED MOBILITY IN PARAPLEGICS

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SUMMARY

A FES control system for support of the mobility tasks standing up, making a right or left step and sitting down has been designed and tested. The control system features the detection of the intentions of the user by artificial sensor inputs and an intention detection finite state model of the tasks. No voluntary command input is required from the user during the use of the system. The control system is realised and tested as part of a hybrid system, consisting of a STEEPER Advanced Reciprocating Gait Orthosis (ARGO) and external stimulation of quadriceps, hip flexors and hamstrings using electrodes on the surface of the skin. The sensor system consists of spring preloaded switches in the crutches, accelerometers, used as inclinometers, at the upper legs, hip and knee lock switches and (optionally) hip goniometers. The sensors are integrated in the crutches or attached to the orthosis. Preliminary testing has been performed.

STATE OF THE ART

Stimulation systems have been developed for the restoration of mobility of paraplegic patients /4, 5, 7/. All of these systems need explicit control by the user during the performance of the mobility tasks. In most cases the control input is generated by the patient using manually operated switches.

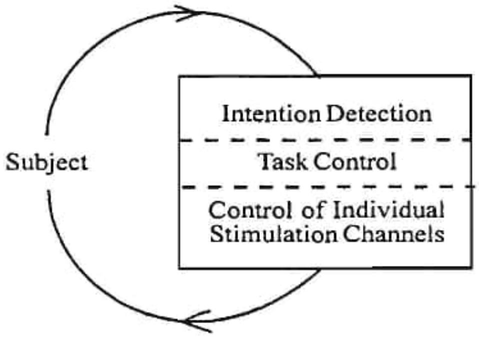
Andrews et al. /1/ introduced implicit intention detection using artificial sensors on the body used for the control of standing and gait. In this study we extend this principle of implicit intention detection also for the tasks standing up and sitting down and the automatic identification of the task to be performed.

MATERIALS AND METHODS

Control System Design

The control system architecture has a multi-level architecture (see also Chizeck et al. /2/) (figure 1): the *high level intention detection*, the *intermediate task control level* and the *low level stimulation control*.

The structure of the *high level intention detection system* is shown in figure 2. The mobility tasks standing up, sitting down, making a right or left step are modeled as transfers between stable states. The initiation of these state transfers is controlled by the intention of the user, which is implicitely detected by sensors on the orthosis and in the crutches: The intention to *stand up* is detected by crutch loading in a sitting posture; *sit down* by the unlocking of the hip and knee locks of the orthosis during a standing posture. The intention for a *left step* is detected by crutch loading with the right leg in front; a *right step* by crutch loading with the left leg in front.



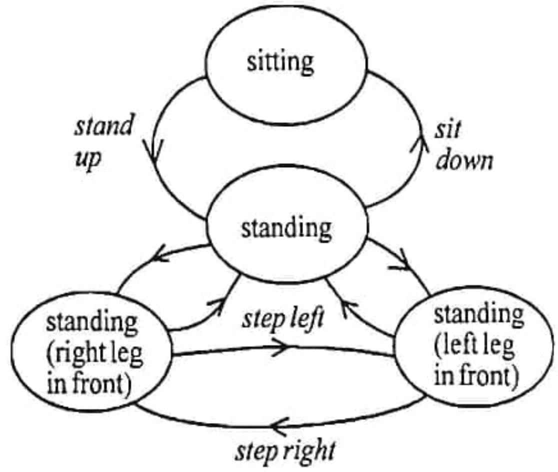


Figure 1

Figure 2

Figure 1. Hierarchical structure of the FES mobility control system.
Figure 2. Finite state model of mobility tasks. The mobility tasks standing up, sitting down, left step and right step are modeled as transfers between postures. The conditions for these transers are detected using artificial sensors on the orthosis and in the crutches.

In the current control system stimulation supported stepping is initiated after the patient has made the first step with only upper body effort. Stimulation support of the first step would require an extension of the current intention detection system.

Identification of the postures sitting and standing is performed using tangentially directed accelerometers at the upper leg /9/, statically measuring the inclinations of these body segments. The detection of the relative position of the legs during stance is also performed by accelerometers on the upper leg used as inclinometers. Previously /3,11/, a goniometer at the hip was used.

At the *task control level* the coordination of a task is performed. Stimulation timing and activation levels of the stimulated muscles groups are determined by this level. Stimulation is only required during the dynamic transfer tasks standing up, sitting down, stepping left or right. The postures sitting and standing (both feet together, or one in front of the other) do not require stimulation, because the required stabilisation is realised by the orthosis. In the current control system preset stimulation patterns are mainly applied open loop, after the detection of the intention of a transfer task. During standing up quadriceps is first stimulated and hamstrings beyond a preset inclination angle of the upper legs. During sitting down quadriceps and hamstrings stimulation is gradually reduced. Left hip flexors and right hamstrings are stimulated at the start of a left step, right hip flexors and left hamstrings at the start of a right step.

The *low level stimulation control* is currently limited to stimulation of the muscles with fixed frequency, pulse width and pulse amplitude. Only the timing of the stimulation bursts are applied according to the commands from the intermediate layer.

Control System Realisation

The hybrid system consists of a combination of surface stimulation and a STEEPER Advanced Reciprocating Gait Orthosis (ARGO). The control system requires the following sensor set: Spring preloaded switches in the crutches (the switches detect crutch loading above a preset force threshold), hip and knee lock switches and upper leg accelerometers (tangentially mounted), used as inclinometers. A hip goniometer is optional. The accelerometers, hip and knee lock switches and the optional hip goniometer are attached to or integrated in the orthosis. Stimulation electrodes are mounted directly on the skin using self adhesive electrodes (Pals Axelgaard, 5x9 cm).

The control system has first been implemented on a portable controller/datalogger system (Infotronic Ultraflex) for initial testing, and is now implemented in dedicated hardware. In the initial phase an 8 channel programmable, and with the dedicated system a 4 channel non-programmable stimulator (SMS4) was used, designed by Roessingh Research and Development.

The gait control part of the system using a hip goniometer and spring preloaded switches in the crutches has been tested previously in 5 paraplegic subjects /3, 11/. The first implementation of the total control strategy was tested in two sessions with one patient.

RESULTS

Testing of the gait control part in five subjects indicated good functioning. Some erroneous state detection occured especially during turning.

Preliminary testing of the total control strategy, indicated the principle well functioning of the system. The subject needed some assistance during standing up and sitting down, because his quadriceps and hamstrings were insufficiently trained and he had some flexion spasms during standing up. This indicated that only well selected and trained paraplegic subjects may benefit from the standing up and sitting down parts of the system. Walking was satisfactory with the system, comparable to the first tests of gait control. Detection of relative leg positions using upper leg accelerometers showed comparable performance as a hip goniometer (figure 3).

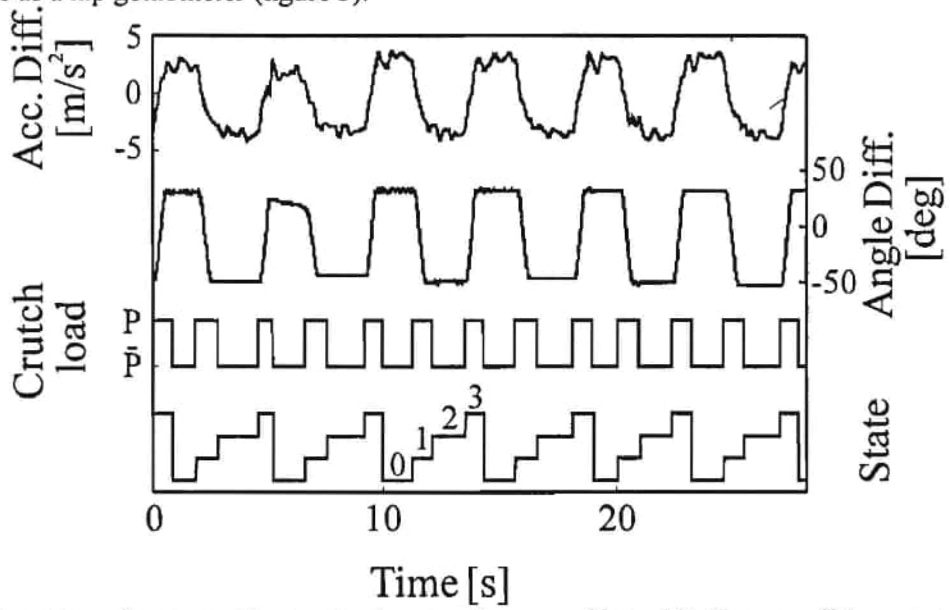


Figure 3. Detection of states in the gait cycle using low pass filtered (2 Hz cutt-off frequency) upper leg accelerometer signals in a paraplegic subject walking with FES and orthosis. For comparison hip angles are given.

DISCUSSION

In this paper, we presented a hierarchical control strategy, which requires minimal explicit attention from the user. The intentions of the user with respect to the task to be performed and the moment of execution are automatically detected using a finite state model of the tasks and artificial sensors on the orthosis and on the crutches.

The sensor set, consisting of upper leg accelerometers, hip and knee lock switches and spring preloaded switches in the crutches, could be well integrated with the orthosis. Upper leg accelerometers performed reliably in detecting the relative leg positions during gait, when their signals were low pass filtered at 2 Hz. The stance phase appeared to be sufficiently static to use the accelerometers as inclinometers. Accelerometers on the upper legs have the advantage that they can more easily be integrated with the orthosis than hip goniometers and that they additionally can distinguish sitting from standing by the inclination of the upper legs.

The control system has been designed in combination with an existing orthosis system and surface stimulation. Part of the principles may however also be applicable in the control of implanted stimulation systems, combined or not combined with orthosis. In the current control system preset stimulation patterns are applied open loop, after the detection of the intention of a transfer task. In future the stimulation patterns can be adjusted from step to step for gait, e.g. to control step length /3/.

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FURTHER DEVELOPMENT OF HYBRID FES ORTHOSES

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SUMMARY

In this study two aspects of hybrid FES orthoses were investigated: joint motion constraints and the FES control strategies. The effects of joint motion constraints on the gait of normal subjects were firstly investigated using modern motion analysis systems including EMG and heart rate measurements. An orthosis was developed to impose joint motion constraints, the knee and ankle could be fixed or free and the hip joint could rotate independently or coupled according to a pre-set flexion-extension coupling ratio (FECR). Compared with 1:1 hip FECR, the 2:1 ratio was associated with a reduced energy cost, increased speed and step length. The knee flexion during swing significantly reduced energy cost and increased walking speed. Ankle plantar flexion reduced knee flexing moment during early stance phase. Secondly, trials on three paraplegic subjects were conducted to implement some of these findings. It appeared that the 2:1 FECR encouraged hip flexion and made leg swing easier. A simple FES strategy increased walking speed and step length, and reduced crutch force impulse using fixed orthotic joints.

STATE OF THE ART

A reciprocal walking pattern can be restored in complete paraplegic persons using purely mechanical orthoses, for example, the ParaWalker [1] and the Reciprocating Gait Orthosis (RGO) [2]. Although the energy cost of reciprocal gait is lower than that of swing-through gait, it is still up to 6 times the energy cost for using a wheelchair, even at very slow walking speed, so that the users gain only limited functional benefits [3]. Functional electrical stimulation (FES) in conjunction with mechanical orthoses (the hybrid FES orthosis systems) has been used to increase the efficiency of paraplegic gait [4-6], and moderate reductions in energy cost have been achieved, suggesting that further improvement in hybrid orthoses may be possible.

Many hybrid FES systems are based on existing mechanical orthoses which were originally designed without considering the potential incorporation of electrical stimulation. Inadequate hip flexion and fixed knee ambulation are major shortcomings of the exiting systems. To address these problems, this study investigated the effects of joint motion constraints on the gait of three normal subjects with the aim to derive guidelines for further development of hybrid systems. Paraplegic gait was then evaluated in the optimal configurations and FES strategies were implemented.

MATERIAL AND METHODS

Normal Subject Study

To impose joint motion constraints to the subjects, an assessment brace was developed. It had uniaxial knee joints with drop locks, uniaxial modular ankle joints with double action, and specially designed hip joints which could rotate either independently or coupled to each other according to a pre-set extension-flexion coupling ratio (FECR). A total of 12 configurations was tested in the study: free hip or coupled hip with 1:1 or 2:1 FECR, free or locked knee (FK or LK), locked or plantar flexion free ankle (LA or PA). Figure 1 shows the theoretical angle-angle diagram of the coupled hip joint demonstrating the definition of FECR at the ends of the curves.
The VICON movement analysis system, two Kistler forceplates, two foot switches and an eight-channel

EMG system were used to collect all data necessary for gait analysis. To obtain some estimate of energy cost, heart rate was recorded and the Physiological Cost Index (PCI) was calculated [7]. Three healthy subjects participated in the study. Prior to the test programme, they underwent a training programme. During the actual tests, sufficient time was allocated for the subject to adjust to the new joint constraints before any data was collected.

Patient Study

Three paraplegic volunteers participated in the study, two of them used elbow crutches to assist walking and the other walked in parallel bars. Two sessions were undertaken for each of the comparisons: 1:1 and 2:1 FECR without FES, and with and without FES assisted hip flexion. The peroneal nerve or rectus femoris was stimulated to produce hip flexion. Goniometers and strain gauge transducers were used to measure the hip angles and crutch axial forces, respectively. Again, PCI was used as an estimate of energy cost.

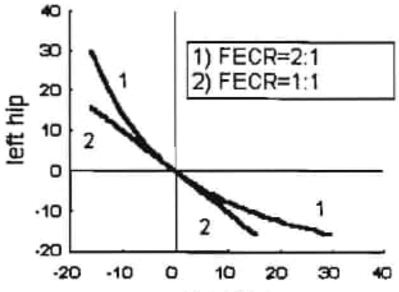


Figure1. Theoretical angle-angle diagram of the new orthotic hip.

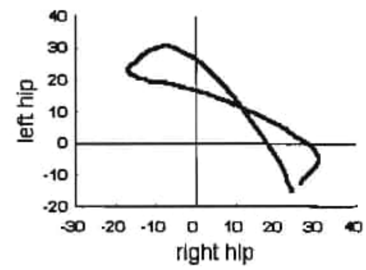


Figure 2. Hip angle-angle diagram of normal walking.

RESULTS AND DISCUSSION

Normal Subject Study

The three subjects had significantly ($p<0.01$) different PCIs and walking speeds, so that the data were normalised as percentage of the individual subject's overall mean to eliminate the inter-subject variability. As shown in Table 1 the 2:1 hip ratio was associated with lower PCI, higher speed and longer stride length compared with the 1:1 hip ratio, demonstrating superior performance of the 2:1 hip in normals. In normal walking the hip FECR is approximately 2:1 at heel strike (Figure 2). The hip coupling mechanism in the RGO imposed a hip FECR of 1:1. By imposing a ratio higher than 1:1 on paraplegic walking, an increase of the step length is expected. The objective is to increase the step length and speed without significantly increasing the energy requirement. Compared with the free hip, the 2:1 hip produced similar PCI, lower speed but longer stride length, having no obvious advantages over the free hip configuration.

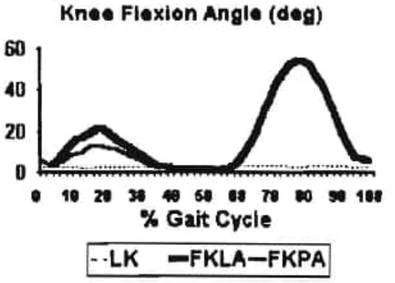
Table 1. Mean(±SD) normalised PCI and speed, and stride length in different brace configurations

	PCI (%)	speed (%)	stride length (m)
free hip	92(±16)	106(±11)	1.031(±0.155)
1:1 hip	115(±34)	95(±15)	1.101(±0.072)
2:1 hip	92(±24)	100(±11)	1.170(±0.075)
LKLA	123(±28)	88(±12)	1.036(±0.142)
FKLA	99(±24)	99(±10)	1.093(±0.099)
LKPA	89(±22)	102(±7)	1.118(±0.126)
FKPA	85(±16)	112(±9)	1.157(±0.080)

LKLA - Locked Knee, Locked Ankle
FKLA - Free Knee, Locked Ankle
LKPA - Locked Knee, Plantar free Ankle
FKPA - Free Knee, Plantar free Ankle

The LKLA configuration produced the highest PCI in all knee and ankle configurations. Therefore, FK or/and PA are desirable in reducing energy cost. During swing phase, knee flexion ensures foot ground clearance and keeps excursions of the centre of gravity of the body small, resulting in an energy efficient gait. Ralston [8] reported an 45% increase in energy cost in normal walking when the knee movement was restricted. Bataweel and Edwards [9] demonstrated that a 56% reduction in energy cost could be achieved in paraplegic walking if the knee joint was allowed to flex during swing phase. Existing hybrid systems using RGO or ParaWalker usually have a fixed knee joint which results in a high energy cost.

Compared with the LA (Figure 3), the knee flexion angles and flexing moments at early stance phase were significantly lower when the ankle was allowed to plantar flex. It is a potential advantage in FES walking that less knee extension stimulation is required when the knee is self-locked by the extending moment. Ankle plantar flexion occurs in early stance to achieve a controlled foot flat and in late stance to facilitate push-off. Bajd [10] tested FES assisted ankle plantarflexing at the terminal stance phase in paraplegic walking, and found that for the incomplete subjects FES ankle plantar flexion brought about significant improvement.



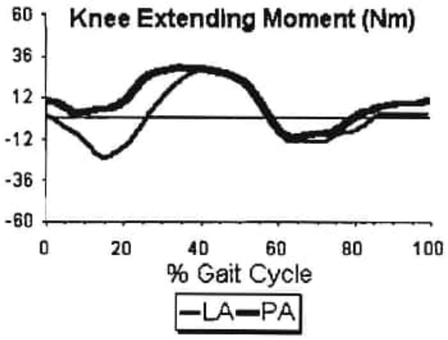


Figure 3. Average knee joint angles and moments showing differences among orthosis configurations.

Patient Study

The hip coupling mechanism worked well with the FECR approaching the designed values. All subjects felt that the leg was easier to swing through with 2:1 FECR. Compared with the 1:1 FECR, the 2:1 FECR was consistently associated with lower PCI and longer stride lengths although this was not always statistically significant. The effects of hip configuration on the walking speed were variable between different days. Increases in walking speed did not always coincide with the increases in stride length, suggesting that the cadences were decreased. From the limited crutch force data, it appeared that 2:1 FECR was related to higher crutch impulse compared with the 1:1 FECR. This may related to the fact that with an increased step length, the centre of mass (CM) of the torso would be lower at heel strike and more power was required to move the CM upwards and forwards from the upper limb muscles.

Table 2. Results from patient tests

	Subject G				Subject A				Subject W			
	Trial 1		Trial 2		Trial 1		Trial 2		Trial 1		Trial 2	
			Fixed knee and ankle				No FES					
FECR	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1	1:1	2:1
PCI(beat/m)	2.7	*2.2	1.8	1.6	3.4	3.6	9.4	8.3	5.6	*3.2	3.6	3.2
Speed (m/s)	0.29	*0.32	0.42	0.40	0.24	0.23	0.14	0.11	0.10	*0.14	0.17	0.18
Stride Length (m)	1.04	1.08	1.14	1.12	0.91	0.94	0.66	0.68	0.48	*0.52	0.65	0.71
Actual FECR	1.05	2.10	n/a	n/a	1.0	1.9	0.9	1.8	0.9	1.9	1.1	2.1
Crutch impulse (Ns)	n/a	n/a	361	364	n/a	n/a	559	634	n/a	n/a	n/a	n/a
			FECR=2:1		Fixed knee and ankle							
FES	No	HFS	No	HFS	No	HFS	No	HFS				
PCI(beat/m)	4.2	*2.8	3.7	3.3	5.2	*2.8	5.3	*1.1				
Speed (m/s)	0.31	0.34	0.31	0.36	0.18	0.20	0.19	0.22				
Stride Length (m)	0.98	0.96	0.94	1.12	0.74	0.78	0.76	*0.82				
Crutch impulse (Ns)	420	*327	431	*367	617	*445	454	*434				

HFS: Hip flexor stimulation.

*: $p < 0.05$

The FES assisted hip flexion, compared with no FES, was associated with significantly reduced PCIs and crutch force impulses and with increased walking speeds and stride lengths. To achieve a step in RGO walking, a paraplegic person transfers his weight onto the stance leg by pushing down the ipsilateral crutch and then extend the contralateral hip and pull the body towards the anteriorly positioned contralateral crutch thus flexing the ipsilateral hip via the coupling cable. With FES assisted hip flexion, the effort to extend the contralateral hip and to pull the body would be reduced. Solomonow [5] found that RGO+FES walking was related to the lowest energy cost compared with RGO, long leg brace, and pure FES gait. The ORLAU [6,11] reported that compared with pure ParaWalker walking the stimulation of gluteal muscles resulted in 6-9% reduction of energy cost and 10-50% reduction in crutch force impulses.

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- the input for the control algorithm is the information of pressure sensors under the feet, strain gauges and hand switches on the crutches, switches and electrogoniometers on the knee.
- the controller should increase the number of stimulation channels from 2 to 2x2 by multiplexing the output of the stimulator, so that i.e. the Hamstrings and Quadriceps can be activated alternately.

Clearly a lot of input and output channels, digital as well as analogue, are required. This is why we have chosen the Motorola MC68HC11: it has a large number of input and output channels, an 8-channel A/D converter and a built-in programmable timer.

Input: the input data to the controller is acquired from 5 different sources.
- 6 pressure sensors (Interlink FSR 151) under the feet and 2 strain gauge bridges on the crutches provide information on the gait phase as an input to an automatic step intention detection algorithm. The analogue signals are amplified and conditioned before they are converted to a digital value.
- 2 hand switches may override the automatic intention detection in case of malfunctioning
- 2 switches inside the knees detect if they lock at the end of the swing phase
- 2 electrogoniometers (Hewlett Packard HEDS 5500) follow the trajectories of the knees during the swing phase

Processing: the programmable timer generates a 100 Hz timer interrupt. The interrupt routine polls the input channels. An automatic gait detection algorithm updates the step phase (finite state) and the controller activates the necessary output lines for the stimulation pattern.
Figure 1 is an example of the control scheme during normal gait. When a timer interrupt is generated, the program checks if the stimulation is going on yet, which means that the person is in the process of taking a step forward. If that is the case, the counter is incremented and the program looks up in a table which action the new counter value corresponds with. If the person is not taking a step, the program checks consecutively if a hand switch is pressed or if the automatic step intention algorithm has detected a step intention. If so, the counter is reset and the appropriate stimulation pattern is started. If flexion of the knee during swing phase is allowed, the control scheme is adapted taking into account the additional information of the switch in the knee and the electrogoniometer.
The main program is stored in external EPROM. To change the parameter settings, the microcontroller has to be serially linked to a PC. The settings are then stored in EEPROM. To increase the memory capacity of the MC68HC11, 8K external RAM and 8K external EPROM are added to the built-in memory (256 byte RAM and 512 byte EEPROM)

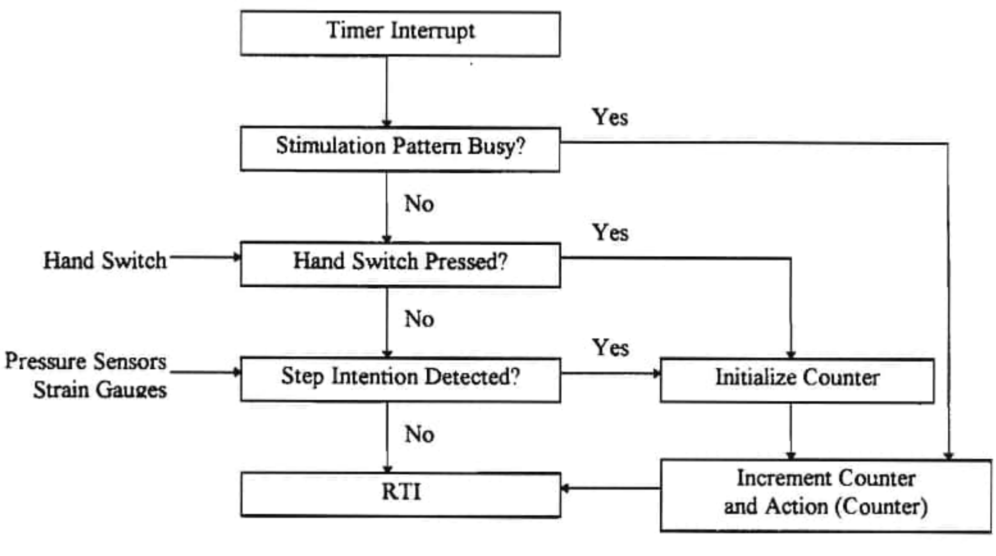

FIG. 1 OPEN LOOP CONTROL SCHEME

DESIGN AND IMPLEMENTATION OF A PORTABLE CONTROL SYSTEM FOR A HYBRID GAIT ORTHOSIS

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SUMMARY

A portable control system has been developed to be used with a commercially available 2-channel stimulator and an Advanced Reciprocating Gait Orthosis (ARGO) with a flexible knee mechanism. Because of the great number of input and output signals the Motorola MC68HC11 has been selected. The input to the system consists of signals from pressure sensors, switches, electrogoniometers and strain gauges. Based on this information, the control unit can activate the stimulator and unlock the knee at the appropriate moment.
The controller works with a commercially available 2 channel EMPI stimulator. The output of the stimulator is multiplexed to get a 2x2 channel system.
The micro controller is programmed in Assembler. To change the settings of the parameters, the controller has to be linked with a PC. The necessary changes can then be made using a software platform written in C++.
First test results of the different parts of the control system are positive.

STATE OF THE ART

For the restoration of walking of paraplegics, several techniques are applied: Functional Electrical Stimulation (FES), a gait orthosis or a combination of both [1]-[4]. The later option benefits from the advantages of both other techniques: the orthosis provides safety and low energy consumption during standing and FES assists the propulsion. The current paper describes the control unit of such a combined ARGO-FES system. The knee mechanism of the ARGO, used for this hybrid system, is adapted so that flexion of the knee is allowed during the swing phase [5].
The control unit is built around a Motorola MC68HC11. This microcomputer is becoming a standard building block for the control and analysis of gait [6]-[7].
Most of the controllers described in literature are designed to work with a self-developed stimulator. The control unit in this paper is intended to increase the functionality of a commercially available stimulator.

MATERIAL AND METHODS

The idea of this study was not to build a complete stimulation system, but to take a commercially available stimulator, in this case the EMPI Respond Select Neuromuscular Stimulator, and to overcome its programming and control limitations by developing a control unit.
The EMPI Respond Select Neuromuscular Stimulator is a 2-channel stimulator that can be controlled by hand switches. The stimulation channels function as long as their respective hand switches are pressed. The frequency and the stimulation amplitude can be set manually.
The general design considerations for the control unit were the following:
- the controller must generate the appropriate stimulation pattern by switching the two available stimulation channels on and off and it also has to control the knee mechanism.

Output: the controller has to switch the stimulation channels on and off and select which of the 2 muscles that are attached to that channel, is going to be stimulated. This is achieved by the circuit on figure 2 with mechanical relay switches (only the control of 1 channel is shown schematically). The signal generated by the microprocessor is amplified by a transistor in order not to drain too much current. Two Clark PRMA 1B05C relays switch the channels on and off. Two Zettler AZ830 2C relays select the muscle groups. The Zettler is a double relay so that the 2 internal switches are controlled by the same signal. This is important in order to ensure the synchronicity of the switching. Otherwise, if the toggling of one switch is delayed, an electrode on the Hamstrings could become connected with an electrode on the Quadriceps during that delay.
The controller also gives the triggering signal to the knee unlocking circuitry.

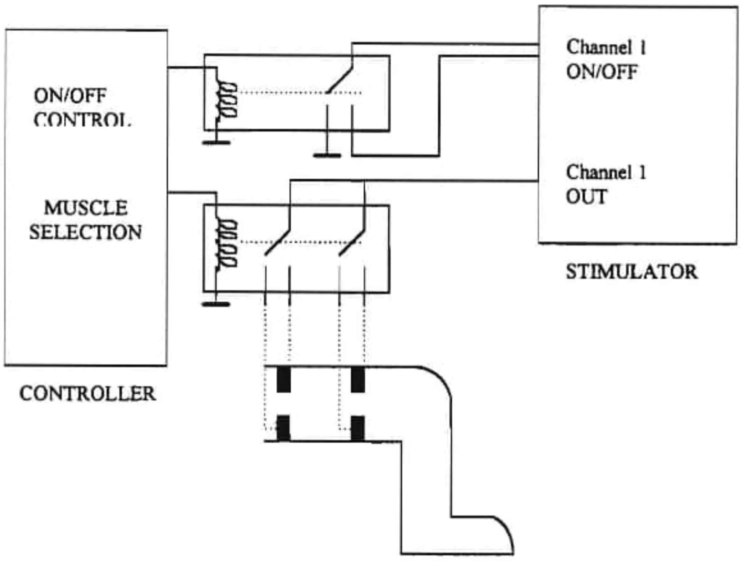

FIG. 2 CONTROL AND MULTIPLEXING

RESULTS

The different control elements (pressure sensors, switches, strain gauges and electrogoniometers) have been tested with a positive result.. The automatic gait detection system based on pressure sensors alone works well during normal walking, but it has some difficulties to detect turns. The effect of combining the information of the pressure sensors with that of strain gauges in the crutches is still under investigation. The entire system is not yet tested in the ARGO-FES combination. It is not yet clear if the 100 Hz sampling rate can be retained if all the different parts of the control program are combined.
However, the control of the stimulator and the multiplexing of the output channels have been tested in a FES-bicycling environment.
Considering the information of an electrogoniometer mounted on the crank of an ergometer, the Hamstrings and Quadriceps were stimulated. The control system worked properly.

DISCUSSION

A portable control system developed for an ARGO-FES hybrid gait orthosis is presented. By multiplexing the output of a commercially available stimulator, a 2-channel system can be turned into a 2x2-channel system. The major advantage of this is of course that it is a cheap way of enhancing the possibilities of your system. It is clear however that you do not get a real 4-channel system so that it is only interesting when you have muscle groups that are never activated at the same moment (e.g. the Hamstrings and the

Quadriceps of the same leg). Another drawback is the fact that the parameter settings of the 2 muscles stimulated by the same channel cannot be set independently.
Future research will be concentrated on the further development and testing of the entire control system.

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HYBRID STANDING WITH THE COCHLEAR FES-22 STIMULATOR AND ANDREWS FRO BRACE

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SUMMARY

The re-designed Cochlear FES-22 implantable stimulator has received considerable development in both hardware and software over the past three years; specifically for muscle conditioning, muscle testing and stimulation artifact recordings, muscle force output measurement, and state controller for open loop stimulation during standing with built in capability for closed loop. The implanted subject, a T-10 paraplegic male (CS), is able to exercise his knee and hip extensors for 20 minutes before onset of muscle fatigue. Subject CS is also able to stand using the Cochlear FES-22 stimulator and the Andrews FRO braces for 5 minutes before general tiredness.

INTRODUCTION

For the thoracic level Spinal Cord Injured (SCI) person, there has not yet been developed a safe and independent, energy efficient standing system using an implantable FES device with below the knee bracing for home and work use. Advances in the control of the neuromuscular system with Functional Electrical Stimulation (FES) alone or in combination with orthotic support have been made by several researchers [1]. Our aim is to continue to develop and demonstrate the use of the Cochlear FES-22 channel implantable stimulator [2-4], together with the Andrews' hybrid system [5], composed of a Floor Reaction Orthosis (FRO) and a sensor feedback controller. The system will be used daily both in the home and work place for the restoration of prolonged standing (30 minutes) and reaching (shelf, counter) in paraplegic persons.

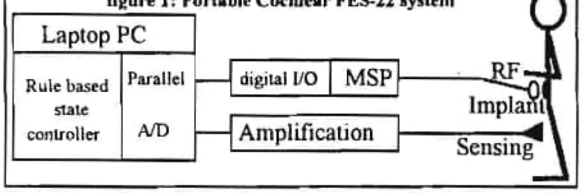
DEVELOPMENT

The Cochlear FES-22 stimulator is a modified Cochlear Mini-22 (Cochlear Pty. Ltd., Australia) cochlear implant which was re-designed to provide limb movement in paraplegic individuals. A 23 year-old T-10 paraplegic male (CS) was implanted in November 1991 [3]. Extensive modification of the external hardware and software has been done to convert the Cochlear FES-22 system to FES use with the possibility of multiple electrode stimulation for lower limb movement.

Basic FES-22 System

The receiver/implant delivers a balanced biphasic, constant current pulse to any of the 22 channels with independently adjustable amplitude up to 4.3 mA and pulse width 400 μs. Each channel is connected through a lead wire to a 2.5 mm platinum epineural disk electrode, which is sutured over the branches of the femoral, gluteal or sciatic nerves [3]. The implant requires a command word for each channel to be stimulated (anode, cathode, amplitude, pulse width). An external device (MSP) provides this control and power to the implant through a 2.5Mz radio-frequency link (Fig 1). It generates the code to stimulate a group of elec-

figure 1: Portable Cochlear FES-22 system



trodes once (burst). The MSP stores up to 7 groups of 10 electrodes maximum. Global control of stimulation patterns is done on a 486 desktop (Gateway 2000) through the parallel port and a custom design I/O interface build around the MSP. Sensor signals for test or closed loop control are acquired through a acquisition board (Data Translation): 12 bit, 16 channel A/D with a sampling rate of 100 Hz and 8 digital I/O. Programming is done in C for DOS (Visual C++). A ruled base state controller is driving the stimulation and sampling with a base cycle of 10ms (100Hz). Since at least one controller cycle is reserved for the implant power charge, this allows a stimulation burst to be triggered by the controller every 20, 30, 40 or 50 ms, which yields a stimulation frequency of 50, 33, 25 or 20 Hz. To start a stimulation burst, the controller select the correct group in the MSP memory, load any variable parameters and trigger the stimulation. The stimulation code for each group and any static stimulation parameters are loaded before the controller is started. A user interface allows the management of the stimulation parameters.

Home Muscle Conditioning

A streamlined system (PC-386, MSP) was devised for muscle restrengthening at home. The program allows the continuous stimulation of up to 5 groups of 10 electrodes for a duration of 1 to 59 sec per group. Once the last group is terminated, the 1st group is started again. Each channel is individually programmable and each group has its own stimulation frequency. The stimulation parameters cannot be modified by the subject (password protection).

Manual Muscle Test & Stimulation Artifact Recording

The state of each implant channel, implanted electrode and stimulated muscle/nerve has to be periodically controlled. A Manual Muscle Test program controls the stimulation of each channel individually, the amplitude or pulse width can be continuously changed using a hand held control box. The expected muscle contraction can be graded from 0 for no contraction to 10 for a normal contraction. The stimulation artifacts are recorded by surface electrodes (Ag/AgCl Dynatrace, Medtronic) connected to a P-15 differential AC amplifier (Grass Inst.), visualized on a digital oscilloscope (HP model 54601A). The artifact can be downloaded to a PC for storage and off-line analysis (HP ScopleLink with RS-232 interface).

Muscle Force Output Measurement

To quantify the muscle contraction during isometric exercise for different stimulation parameters, the subject can be tested on a Cybex 350 dynamometer (Cybex). The Test program controls the stimulation of each channel individually for a fixed set of parameters, while storing the Cybex output signal. The Cybex is fully calibrated before each test. The test data is stored in a binary, and can be reconstructed off-line using the calibration matrix to determine the muscle torque output. A variation of the test is to stimulate a group of up to 3 electrodes for an extended period of time (30 to 60 minutes) with variable on/off cycles. This will quantify the fatiguability of muscles involved in a specific limb movement (i.e., knee extension).

Open Loop Standing

A simple standing open loop program provides the three following patterns: sit to stand , stand to sit and standing. In sit-to-stand pattern, the stimulation is applied 1] bilaterally to the hip extensors at the preset maximum level of stimulation; 2] bilaterally to the knee extensors, first for 1 second at the preset minimum level of stimulation, then for 1 second at a level half between minimum and maximum preset level of stimulation, then for 2 to 10 seconds at the preset maximum level of stimulation. The controller then switches to the standing pattern. In standing pattern, the stimulation is applied 1] bilaterally to the hip extensors at the preset maximum level of stimulation; 2] bilaterally to the knee extensors, at a submaximum level of stimulation. This level can be changed in real time while the patient is standing. The knee extensors can be manually turned on/off and the FRO is able to maintain the knees in extension, if correct posture is maintained [5]. The knee extensors stimulation can also be toggles between the preset maximum and the submaximum level . In stand-to-sit pattern, the stimulation ramps down from the preset maximum to the preset minimum level of stimulation bilaterally on the knee and hip extensors, in 2 to 10 seconds.

Safety Standing Frame

A standing frame is used to support the subject if the stimulation fails to prevent any injury. It is a prototype design and manufactured by the Maine Anti-Gravity System (MAGS), Inc., Portland, Maine. The system is composed of the MAGS suspension vest and a ten foot overhead track with a winch motor and safety hanging line. The vest wraps around the subject from the iliac crest up to the chest. The vest is self tightening around the abdomen as soon as the patient pulls down the suspension system. The winch motor is powerful to assist the patient to regain an upright position in case of knee collapse. This system does not in any way impeach the subject movement and posture, but will prevent any falling.

RESULTS

During the 40 months of implantation, there has been no medical complication, especially infection. The original receiver/stimulator implant was thought to have been partially damage by electrostatic discharges (ESD). With changes in the software and hardware, the receiver was energized to a level of partial function. Artifact measurements reveal that 14 of the 20 channels have appropriate output waveforms and elicit muscle contraction, including the knee extensors and half of the hip extensors and ankle electrodes. The two spare channels are still producing a stimulation artifact (Table 1).

Table 1
implanted electrodes for subject CS

artifact	16	7	Good to Normal	14	functional
		7	Poor		
		2	Zero grade		
no artifact	4	4	Zero grade	6	non functional
spare	2			2	spare
total	22			22	total

Conditioning of the knee and hip extensors and the ankles is done at home by subject CS lying supine with hips in 30° of flexion. Each knee extends alternately with a duty cycle of 4 sec on, 4 sec off. Stimulation is set at 20 Hz, 200μs pulse width, with an amplitude set at supramaximal contraction at the start of the exercise. CS conditioned muscles are graded to good contraction (8 to 10/10). They are able to contract for 20 minutes before onset of muscle fatigue.

Subject CS is now training in the use of the hybrid FES-22 stimulator for continuous standing (open loop). CS is able to stand safely in the 'C' posture for up to 5 minutes before general tiredness. During the stance, the stimulation is set to a submaximal level to avoid hip flexion by the contraction of the rectus femoris, while maintaining the knees locked in extension. After four months of training, subject CS is able to stand with minimal use of his arms. CS is aware of the position his body in space and mirrors provide visual feedback for him to make posture adjustments. Also, the hip joints have improved their ability to stretch in extension. This is due in part to the stance in the 'C' posture which ask for the stretch of the hips in extension. Furthermore, CS does hip stretch exercises as part of his conditioning. CS is now adopting a position just before standing up where his hips are just above his ankles. This allows him to lift himself while the stimulation propels his body up. Several adjustments to the standing frame have been made. The suspension system is capable of supporting our subject when the knees buckle and the winch motor is capable to lift our subject back to a standing posture.

Because of his muscle conditioning and standing achievements, our subject is now requesting a replacement of the partially damage implanted stimulator. This is now being planned.

DISCUSSION

We have demonstrated the possibility of long term implantation of a Cochlear FES-22 stimulator (40 months) and the control of complex stimulation patterns for limb movement including knee and hip extension and ankle dorsi/plantar flexion. Future plans are to increase the standing time by closing the loop with knee sensors. It is also planned to replace the receiver/implant in the near future.

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INDUCTIVE MACHINE LEARNING IN CONTROL OF FES-ASSISTED GAIT AFTER SPINAL CORD INJURY

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Abstract: **An obstacle to wide acceptance of FES-systems for walking after spinal cord injury is the lack of safe and reliable control of the stimulation. Most clinically used systems that assist the locomotion in complete paraplegia are manually controlled by the subject or therapist. Such a control may elicit slow and unnatural gait and impose a cognitive load on the subject. The use of sensory feedback offers automatic control. However, generation of the control rules requires customization for each subject that is time consuming with limited improvement in performance. An inductive learning (IL) algorithm was evaluated for automatic generation of control rules and the systematic selection of sensors, which is an implementation of supervised learning in mapping the relationship between sensory input signals and output control signals. The skill of the subject in manually switching the stimulation is cloned from this relationship and stored in a decision tree. The sensory requirements for detection of the gait transitions and states were investigated in a paraplegic subject walking with long-leg braces and assisted in the swing phase by the surface functional electrical stimulation (FES) at the common peroneal nerves. Gait phases were identified using six force sensing resistors, mounted under the braces, and four tilt sensors mounted on the lateral sides of the braces. The IL is used to select the most significant four of ten sensors, and to produce an optimized rule-base using the reduced sensory set. The performance of this rule-base was better than performance of the initial rule-base, which suggests that the technique may be useful for designing of the optimal rule-based control systems for FES-assisted locomotion.**

STATE OF THE ART

The external control of limb trajectories achieved through the use of impaired natural mechanisms is a complex problem, particularly if multichannel functional electrical stimulation (FES) is used. Sensory feedback, which provides necessary information to the intact natural control system, also plays a major role in the external control. The difference between the two is that in the natural system the evolutionary development optimized the choice and the use of the feedback information so that there is not only always enough information to make a particular decision, but in most situations there is a high redundancy. In contrast, in control system design for FES-aided locomotion, the design engineer has to decide which sensors to use for feedback information and how to use them. The decision could be based on the amount and quality of information that particular sensors provide for particular functions targetted for control. The choices are: a) to use preserved afferent, efferent or brain neural signals or electromyograms, originating above or below the lesion; b) to use artificial transducers for measurement of physical variables related to the gait functions; or c) to combine both of the above. Advantages and disadvantages are described for both natural /1, 2, 3/ and artificial sensors /4, 5/ for use in control of FES-aided movements. Following the decision on which sensors to use, the next problem to resolve is the control itself. Analysis of the dynamics of human limb motion was used in numerous research studies. However, this approach is not efficient for the rehabilitation of paralyzed humans. In relation to biomechanical studies of complex mechanisms, we emphasize that basic research results in neurophysiology suggest the hierarchical structure of natural control in vertebrates /6/. The external control of FES-aided locomotion usually consists of two parts: the coordination level controller, taking care of the movements, and the actuator level controller, taking care of the actions required to perform a particular movement /7/.

Most natural control processes are nonlinear and probably non-numerical. Non-numerical control of movements in the form of a finite state controller was proposed by Tomovic and McGhee /8/. This type of control later evolved to the artificial reflex control (ARC) method /9/, and adaptive reflex control comprising gait mode selection and intention recognition /10/. Since the ARC method is of the ON-OFF type, which is similar to control of synchronous activity of multi-cells system, such as muscle, it is appropriate for use as an upper level controller. Based on the similar approach of transferring the knowledge from a skilled person to the machine learning program, the coordination level controller for FES-assisted walking of subjects with spinal cord injury (SCI) was proposed by Kirkwood and Andrews /11/ and Kostov et al. /12, 13/. Kostov /14/ demonstrated a real-time control of the FES-assisted walking by machine learning technique and traditional sensors. Control rules are automatically generated by transferring the stimulation switching skill of the subject with incomplete SCI to the controller. Kostov et al. /15/ and Heller et al. /16/ suggested that even actuator level control actions requiring control signals in the form of a continuous function, can be learned and predicted using biological signals as the source of feedback information. Performance of most machine learning systems used in control applications depends on the sensors selected and on the preprocessing techniques applied to the sensory signals. Sensors and preprocessing techniques are usually intuitively selected by the researcher making the final results dependent on the researcher's expertise. In this study we also use our knowledge and intuition in designing the initial sensory set for a control system. However, to reduce the sensory set without significant loss in the performance we exploit some of the features of the IL technique. Firstly we reduce the sensory set from the initial ten to just four sensors, and then we use the same technique to optimize the learning and generalization results.

MATERIAL AND METHODS

A) Inductive learning algorithm: Inductive learning uses a supervised learning method resulting in decision trees based on examples presented during the training. The algorithm is based on the hierarchical mutual information classifier of Sethi and Sarvarayudu /17/. The program Empiric developed for the IBM PC by Heller /18/ was used to implement this algorithm. This program operates on up to 16 sensory inputs and one control output. While generating the decision tree, the IL algorithm performs hierarchical partitioning of the domain multidimensional space. Each new node of the decision tree contains a rule using a threshold on one of the inputs classifying the example set. The training finishes when the number of incorrectly classified training samples becomes smaller than that corresponding to the preset training error for a given size of the decision tree. The number of classes in the output signal equals the number of events to recognize. The features that make this learning algorithm attractive are: relatively small decision trees; fast learning; the rules have comprehensible *IF (...) THEN (...) ELSE (...)* form; decision trees inform on the importance of sensors used during training.

B) Patient & FES System: This study was focused on a T2, ASIA A, female subject, aged 11 years, who sustained spinal cord injury 7 years ago and is using FES and long-leg braces (fixed knee) for walking on level ground. FES to the common peroneal nerves is used to elicit a flexion reflex (flexion at the hip) assisting in the swing phase. Switching the stimulation for both legs is controlled manually by the subject pressing on the corresponding switches installed on the wheeled four-point walker. This operation requires the use of both hands and constant attention. Quadstim stimulator by Biomech Design Inc. is used to apply the stimulation through reusable self-adhesive surface electrodes by Chattanooga Co.

C) Recording setup: Signals were recorded during four walking sessions from six circular force sensors (FSRs) by Interlink Electronics Co. installed in the subject's shoes to measure the pressure under her braces and four UV-1B inclinometers by Midori America Co. installed on her braces to measure inclination of her hips in two orthogonal planes, i.e.. hip flexion-extension (FE) and adduction-abduction (AA). Each of the walking sessions consists of 20 to 24 steps. A/D conversion was done using 12-bit data acquisition system by Axon Instruments Inc. The digital signals obtained were low-pass filtered (0.5 Hz) by a phase canceled, fourth order Butterworth digital filter.

D) Data processing: The critical characteristic of an inductive learning technique is the size of the decision tree. As the tree grows, most of the IL advantages disappear due to the overtraining which also increases the training time. The training for IL is usually very fast (within 10 seconds on an IBM PC 486DX/50MHz machine for 1000 samples) and it was optimized with regard to the preset training error /7/. In the first step of automatic generation of the control rules, IL was used to reduce the number of sensors and, consequently, the complexity of control system. After the set of sensors was reduced by excluding those of least importance, derivatives and past data samples were used together with original signals to heuristically improve rule induction. The quality of the rule induction was quantified by its ability to generalize and this was estimated by counting wrongly predicted samples in data sets not used for training. The number of such samples represents the test error and it is expressed as a percentage of the total number of samples in a given data set.

RESULTS

A) Reduction of the number of sensors: Each training on one of four basic data sets resulted in the IL decision tree. Depending on the position of the first occurrence of a particular signal in the decision tree, the corresponding sensor's significance was estimated on the scale from one (the least significant sensor) to the total number of sensors M (the most significant sensor). This resulted in an array of coefficients representing relative importance of sensors used in that particular decision tree. The coefficients are then averaged over all four data sets for prediction of right and left hand switches separately (see Fig. 1). Using these coefficients the number of sensors was reduced from ten to four in three steps. In each step the two least significant sensors were excluded from further analysis introducing significant increase in the average decision tree size. Generalization error remained in the same range (see Fig. 2).

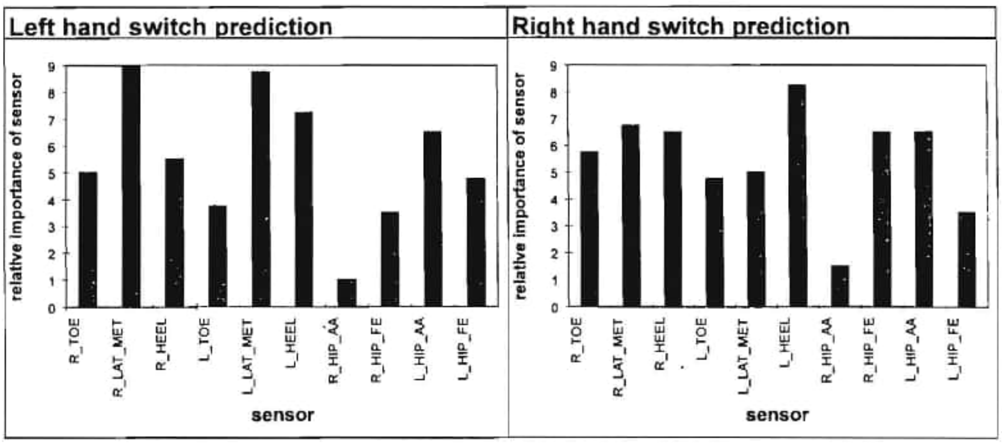

Fig. 1. Estimate of the relative importance of all ten sensors used in prediction of left and right hand switches operations

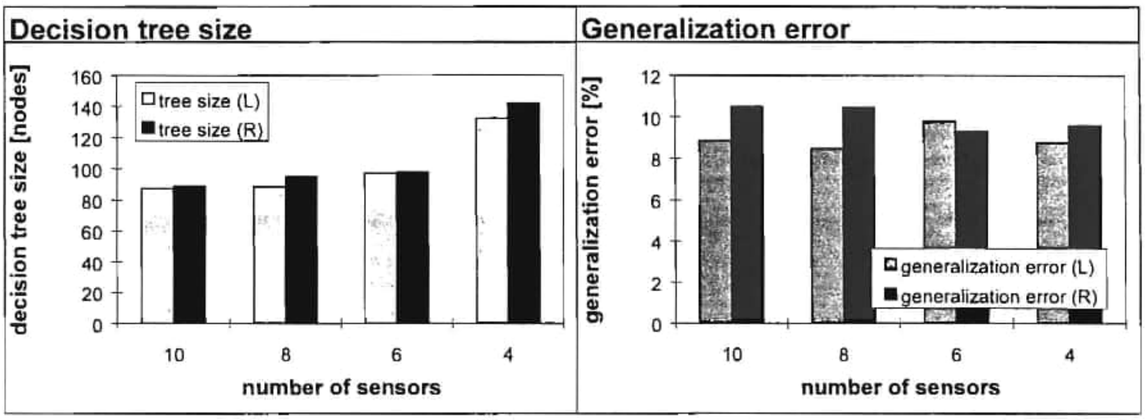

Fig. 2. Effects of the reduction in number of sensors on the size of decision trees and generalization error.

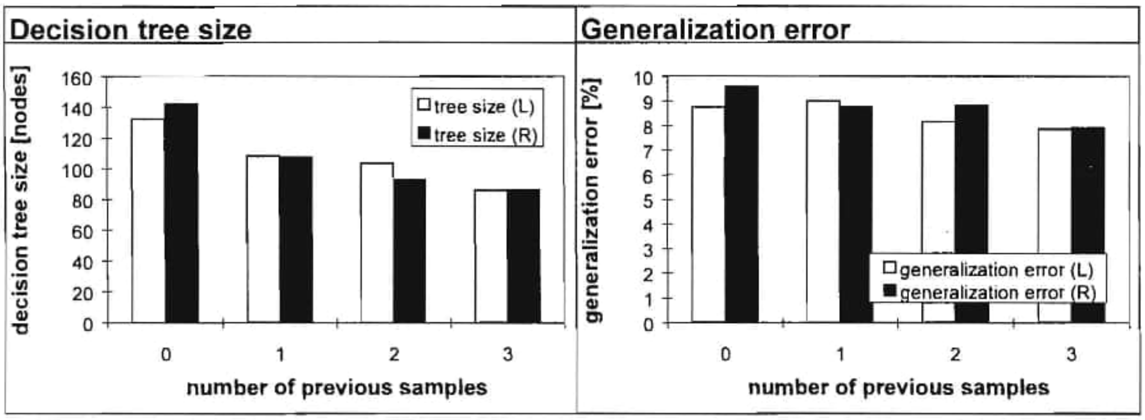

Fig. 3. The use of previous samples adds a temporal dimension to the learning algorithm. Effects of up to three previous samples on the decision tree size and generalization error are shown.

B) Optimization of the training using a reduced set of sensors: Generalization of the learning on the reduced set of sensors can be improved using signals derived from originals and samples from the past /12/. The IL performs only spatial mapping of the input/output relationship in multidimensional space. To add temporal dimension to the algorithm, samples from the past can be used in predicting the outputs for the current sample. The use of up to three samples from the past together with the original four signals recorded from the reduced set of sensors decreased the average decision tree size and the test error below the corresponding size obtained using ten sensors (see Fig. 3). Further improvement of the rule induction was achieved using derivatives together with original signals and, in the most successful of all training trials, with one sample from the past. The use of more than one sample from the past would be even more productive, but it was restricted by the program which could not deal with more than 16 input signals. Both, the size of the decision tree and the generalization error achieved were below those resulting from the experiments with all ten sensors.

DISCUSSION AND CONCLUSION

Estimating the sensory input significance by IL was used in this experiment to reduce the number of sensory inputs from the initial ten to only four. Reduction of number of sensors increased slightly the size of the decision trees but it did not change IL test error, demonstrating a high redundancy in the system. The size of decision trees was brought down to the initial level by optimizing the learning setup with reduced set of sensors. Previous samples and derivatives were used together with the original signals to obtain smaller decision trees and even smaller test errors than with all ten sensors. Precision of timing in control signals obtained during the test shows that IL is qualified to be used as an advising tool in FES-control systems. We have found the above procedure to be a new way forward for the design of finite state controllers based on reliable and unobtrusive sensors.

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ELECTRICAL STIMULATION IN THE MANAGEMENT OF MUSCLE DISUSE OR TEMPORARY MUSCLE DENERVATION CAN BE EFFECTIVE AND COMFORTABLE

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SUMMARY

The use of electrical stimulation [ES] in rehabilitation of both innervated and denervated muscle has been discarded by some therapists because of patient discomfort and non- compliance. The purpose of this paper is to review commonly overlooked principles of therapeutic stimulation for denervated as well as innervated muscle and to present the results of a study in which minimal, comfortable ES improved quadriceps muscle performance (work performed [W] and fatigue resistance [FR]) significantly more than the use of EMG feedback ($p<.0001$) in 39 healthy individuals. The characteristics of the first recruited quadriceps motor units were related to volitional performance and the improvement in W and FR when ES was added to knee extension exercise. Individuals who recruited larger motor units early demonstrated the greatest improvements in W and FR during ES.

STATE OF THE ART

Although patients with muscle weakness secondary to disuse and patients with temporary but complete loss of motor innervation have different short-term goals, they have a mutual interest in remaining comfortable during therapeutic ES. Selection of an appropriate stimulus is critical to the success of any clinical or home ES program. This is often overlooked by engineers, manufacturers and clinicians.

The changes in muscle after loss of peripheral nerve supply are profound and axonal regrowth may continue for months to years before it can reinnervate all of the key muscles for function [1]. In the absence of volitional control, ES is the only tool available to keep the intramuscular connective tissue mobile so that the muscle will be able to become useful once nerve supply has been restored [2]. Simple joint range of motion will not generate the three dimensional movement within denervated muscles. For decades, clinicians have prescribed ES to help maintain denervated muscles. Galvanic current has been the most popular, and the most painful current [3]. Galvanic is unidirectional, painful, and likely to burn the skin. The majority of patients with muscle denervation have skin sensation overlying the paralyzed muscle and they cannot tolerate enough ES to activate the denervated muscle. A classic example is the patient with facial nerve damage whose trigeminal nerve still innervates the skin over the face. It is possible to move the denervated muscles with a much shorter, more tolerable waveform. A standard electrodiagnostic test, the Strength-Duration Curve, permits visualization of a pulse duration that will effectively activate the denervated muscle with minimal or no discomfort [4]. Selection of a pulse duration just above Chronaxie (ie 2-20mS) assures a muscle response with minimal discomfort.

Selection of the most comfortable stimulus characteristics and ES protocol are equally critical to the management of muscle weakness secondary to immobilization, trauma, residual weakness after peripheral nerve reinnervation, traumatic brain injury or stroke. Comfortable stimuli (ie balanced 300 uS pulses) [5] have been used to provide sensory cues, elicit functional reflexes and manage spasticity in patients with central nervous system pathology. The majority of ES applications for the patient with disuse weakness, however, have focused on maximal tolerable ES and the measurement of muscle force production as the criterion for success. Most patients will not tolerate enough ES to generate forceful movement against gravity and prefer not to use high stimulus levels during exercise. Assessment of the work performed and the fatigue resistance during an exercise protocol have been largely ignored despite the clinical relevance of these measures. Maximal tolerable ES superimposed upon volitional effort did not prove to be more effective in changing muscle performance than minimal, comfortable ES [6]. In a study of healthy subjects, we proposed to detect differences in knee extension [KE] muscle performance (peak moment [PM], work performed [W] and fatigue resistance [FR]) between maximal volitional exercise [VOL] (60 deg/S), and the same exercise with superimposed ES [VOL+ES] or visual electromyographic feedback [VOL+EMGFB]. Characteristics of the first recruited motor units [MU] were compared with exercise performance.

MATERIALS AND METHODS

Subjects: 39 normal subjects (28.0 $\pm$4.8 years) participated. **Instrumentation:** Cutaneous electrodes (3x4 inch, PALSFLEX, Axelgaard Mfg, Fallbrook, CA) were used for open loop ES exercise (asymmetrical biphasic, 300 uS, 33 pps). ES was provided by a modular stimulator, plug-in board in an IBM PC/AT. KE exercise was controlled by a LidoActive dynamometer (Loredan Biomedical, Davis, CA). Analog signals from the LidoActive system were sampled by the IBM for angular position, velocity and moment. A second IBM system sampled the integrated EMG signal (skin electrodes) and displayed a dynamic vertical bar with a target level based upon the subject's maximum IEMG. Calibration, gravity compensation and all data acquisition were performed by the IBM system. An auditory beep (headphones) cued the subject to perform the next KE in voluntary trials, and the onset of ES cued the subject in VOL+ES KE. Disposable monopolar needle electrodes were used for MU assessment (Cadwell 5200A, Cadwell Laboratories, Kennewick, WA). **Procedure:** During each exercise session, a 40 repetition, maximal KE protocol was performed. A recruitment curve was performed immediately prior to the VOL+ES trial. The current intensity at which the subject first noted stimulation was recorded as their threshold, and the minimal level of ES used was the intensity (mA) required to produce 1-2 Nm of KE moment [PKEM] (ie 1-2 Nm compared to a range of 100-300 Nm VOL KE). PKEM and W were documented for each KE repetition. Maximum effort was accepted as MVC based upon previous documentation of the repeatability of isokinetic fatigue curves [7]. A high intensity burst of ES was not employed because of the discomfort involved and the potential influence on subject compliance and performance [8]. The amplitude, firing rate and recruitment strategy of the first motor units in the quadriceps were recorded.

RESULTS

VOL+ES resulted in larger PKEM in some subjects, but only VOL+EMGFB resulted in statistically greater PKEM (Table). ES improved KE W and FR over the 40 repetition test (p<.0001, p<.01). None of the subjects were uncomfortable during VOL+ES exercise. W and FR were not altered by the addition of EMG feedback. A statistical trend indicated that subjects with larger early MU demonstrated the greatest improvements in FR and in W during VOL+ES when they were compared to subjects with smaller initial motor units.

Table. KE muscle performance during 40 repetition exercise test (60 deg/S). The addition of 1-2 Nm of ES muscle contraction improved W and FR over voluntary and EMG feedback trials. (Repeated measures ANOVA, Bonferonni.)

	VOL	VOL+ES	VOL+EMG FB	SUMMARY * p<.01, ** p<.0001
Peak KE Moment (Nm)	181.6 ±54.5	180.1 ±50.1	191.1 * ±52.7	VOL+EMGFB > VOL & VOL+ES
% Decrease in KE Moment (40 reps)	43.8 ±11.2	39.3 * ±11.4	46.3 ±9.6	VOL+ES < VOL & VOL+EMGFB
Work (Nm-deg) 40 reps	3907 ±1222	4921 ** ±1327	4058 ±1162	VOL+ES > VOL & VOL+EMGFB
Work (Nm-deg) on Peak KE rep	133.8 ±44.1	159.1 ** ±45.7	138.9 ±39.2	VOL+ES > VOL & VOL+EMGFB
% Decrease in Work (40 reps)	41.8 ±12.9	38.1 * ±12.2	43.5 ±12.3	VOL+ES < VOL & VOL+EMGFB

DISCUSSION

The addition of a minimal ES muscle contraction (1-2% of MVC) to KE exercise significantly improved W and FR. The addition of EMG feedback improved PKEM, but FR and W were not significantly altered. The relationship between early recruited motor units and the shift in performance during VOL+ES may point to an underlying neurological mechanism. Contrary to previous suggestions [9], subjects with larger initial MU improved the most in W and FR with minimal ES, while their PKEM remained the same or decreased slightly. If ES of superficial, large motor axons differentially inhibited volitional MU firing, it could result in a greater reliance upon smaller, more fatigue resistant MU in the quadriceps [10]. Muscle performance and function can be significantly improved by ES in both disuse and denervation, but it is not necessary to torture patients with excessive amounts of ES. Comfort is the "bottom-line" to patient compliance and successful outcomes.

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MODIFICATED TRANSCUTANEOUS ELECTRICAL STIMULATION FOR THE MAINTAINING DENERVATED SCELETAL MUSCLES AFTER REPLANTATION OF LARGE SEGMENTS OF UPPER LIMB

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Rehabilitation nerve muscle apparatus after replantation large segments of upper limb

Transcutaneous electrical stimulation (TES) nerve-muscle apparatus has been in practice during the last two centures for the treatment of paralysed patients. Many scientists have used TES for maintaining and for the restoration of sceletal muscles function after their denervation (Apfet - L.M., et al., 1987, Heinhant K., Duchateau I., 1992, Hooker-S.P., et al., 1992). Many experimental works have shown that TES alter many of biochemical properties of muscle. The long term stimulation with low frequency (<10Hz) increases the fatique resistance of animal muscles and without excestion on muscle strength what may actually induce muscle atrophy. Recently TES has been used as a modality of strengthening in healthy subjects for highly trained athletes, for training voluntary exercises with injured muscles or group of muscles. After hard traumatic injury nerve-muscle apparatus owns oscillating frequency, labile and irritation level will be changing in a big range (Grigorovits K.A., 1981). Many examinators have noted that the TES has positive alteration on the energetic potential of muscles as production of energetic substances of oxide processes in muscles and the compositation of protein becomes smaller (Rosca D., et al., 1992, Lange A., 1992), and it also has positive alteration on the opposite side on the same symmetrical muscles of healthy limb, which has stimulated on the injured limb (Bredikis J.J., et al., 19883, Korletjanu M.A., et al., 19883).

TES parametres which have been used for the denervated muscles stimulation were not suitable for the maintaining and restoration of nerve-muscle apparatus function replanted brachium, antebrachium and manus, so we have used a new modificated transcutaneous electrical stimulation method (MTES). Last time many researches had mentioned (Kolesnikov G.F., Antropova M.I., 1984) that more effective was to use irritating impulses by right angle. The balancing range of the parametres which have usually been used for the TES procedures, is very high, electrical impulses power runs to 100 mA, duration from 0,5 to 300 ms, frequency to 10 kH by Jasnogorodskii V.G., and 1987, Antropova M.I., 1982,1984.

In this research we have studied more closely the action of two different stimulation methods of the nerve-muscle apparatus. In total we have examined 77 patients who had the replantation of upper limb large segments. Patients age was from 18 to 47 years and five of them were women. 24 of them were stimulated by TES (first group), 23 by MTES where five patients had on replantated hand external fixation device, four patients had nerve-muscle flap transposition, two patients had replantatio both antebrachiums (second group) and 30 of them belonged to control group (third group).

In the first group we used "Amplipulss-3" for the stimulation and in the second group stimulator "Koz". This apparatus gives for us a change to modify for every patient (with replantation of large segments of upper limb) and individually suitable stimulating program, because the patient`s sensor threshold has been changed very much after replantation (being many times bigger than normally). According to this apparatus we have a chance to change stimulating parametres (every time if necessary) as power, frquency and irritating impulse duration. Duration the one procedures was 15 minutes, for the patients from the first and also for the patients from second group. One procedure was divided into five equal periods of three minutes, where the irritationg period and pause between irritating periods were also three minutes. For the procedures of TES we have used electrodes of (5x6 cm) one pole position. We used plate electrodes in one pole position and two pole position. Active electrode position was on muscle abdomin or on the proximal end of muscle and passive elestrode position was on opposite side or on the distal end of muscle. We used one pole position and two pole position of electrodes for the patients who have external fixation device , transplantation muscle-nerve flap or transposition muscle or part of the muscle. The patients were stimulated by TES one time per day and by MTES from one to four times per day during the whole hospital period. The stimulating parametres of the two different methods are described in the table 1.

The parametres of MTES and TES   Table 1

Stimulating method	Power (mA)	Irritating impulse duration (ms)	Irritating impulse frequency (Hz)
1. TES	10-15	50-150	30-150
2. MTES	sensor threshold	T(i)=100(10-J)/3J	J=1/T

The MTES parametres were the following: the power of irritating impulses was equal to sensor threshold on healthy hand, duration of the irritating impulses 15 ms, and frequence was inversely proportional to the oscillating period of the stimulating muscles oscillating period.We got suitable parametres for the MTES by the use of original method electromyotonometre (EMT), 11-T 7725 worked out by Vain A. and Humal L., 1979 in Tartu University. By the EMT we registrated oscillating period (T) and common logarithm (Θ).These parametres can be registrated in different muscles regimes as relaxation, volitional effort, peripheral and central paralyse, and also different neuro-muscle diseases. The readings of the EMT directly characterize sceletal muscles biomechanical status and therefore give picture about physiological condition of muscles (Table 2).

Functional results by 100 grading system   Table 2

Replantation level and examination results	Stimulation method MTES Examination		TES Examination		Control group Examination	
	First	Last	First	Last	First	Last
1. Brachium						
a)grades	34	59	-	-	40	41
b)oscillating period (ms)	82	79	-	-	83	93
c)common logarithm	1,71	1,83	-	-	1,83	1,60
2. Antebrachium						
a)grades	34	65	40	55	40	41
b)0scillating period(ms)	86	92	92	88	93	93
c)common logarithm	1,90	1,70	1,68	1,68	1,71	1,72
3. Manus						
a)grades	46	70	35	51	36	37
b)oscillating period(ms)	97	87	93	88	88	80
c)common logarithm	1,87	1,62	1,74	1,78	1,81	1,84

For estimating the sceletal muscles and injured hand function we have the following examination program: electromyotonometry, electrothermometry, dynamomety, electrical resistance of the skin, measuring movement range, orthopaedical-traumatological status, neurological and vasological status. We examined patients before and after stimulation (table 2.), and also at the end of the stimulation course and also before they left the hospital. After the certain treatment period we carefully examined the patients according to a 100 grading system scale (where 100 the best and more closely to 0 bad functional results) and found out that the patients who had been treated by TES had 52 grades, by MTES - 61 grades and control group - 39 grades. In our research according to the statistical analyse the patients who were treated by MTES method had the best functional results and better muscle tone and whos replantation level was antebrachium and manus. It`s also of importance how many times per day, and after what kind of period of time to do the stimulation procedures. Patients who were treated by MTES four and twice per day have the best functional results, and pateients who were treated by MTES three time per day had the worst functional results whatever in order to.

According to our experience we concluded, that MTES was effective and individually very suitable for the patients maintaining the nerve-muscle apparatus until the reinnervation becomes.

LIB-Stimulation -

Long Term Clinical Experiences With Electrotherapy of Denervated Muscle

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Abstract

This clinical study proves the efficacy of electrotherapy in permanent denervation atrophy. Being successful in animal experiments, a recently developed technique (LIB-stimulation, e.g. long impulse bidirectional stimulation) is herewith successfully introduced in human therapy. 16 patients were investigated (traumatic or inflammatory destruction of the cauda equina, n=3; lesions of the brachial plexus or cervical root avulsions, n=13). Paralysis was complete and without reinnervation. Treatment started 1 - 21 months after the trauma or the onset of the disease. Therapy was successful in all of the patients. During a subsequent observation period of up to 38 months, the electrically inducible contraction force increased in all muscles (16-400%) up to one third that of normal controls. Magnetic resonance imaging (MRI) investigations of several muscles showed an increase of muscle volume by 9-29% (calf), and 33-84% (thigh).

State of the art

Permanent, e.g. chronic and complete forms of denervation mostly occur following major trauma of either the brachial or the lumbosacral plexus, or avulsion of nerve roots (3, 7). The clinical feature is a flaccid paralysis. Loss of force and loss of muscle bulk might be delayed by various forms of electrical stimulation (4, for rev. see 17), until reinnervation becomes manifest either spontaneously or following a surgical manoeuvre (19). In the permanent absence of reinnervation, however, electrotherapy has always failed to prove its long-term effectiveness in stopping or reversing the atrophic process.

In previous denervation experiments, we were able to maintain the fibre diameter of completely and permanently denervated rabbit fast tibialis anterior muscle at a useful level of 75-95% of normal (10). Twitch and tetanic tension was maintained at levels between 40 and 100 percent of the normal values, depending on the individual stimulation parameters (11). Following this success, the most interesting question was whether these positive results could be repeated in human therapy. Thus, the aim of the present study was to determine the clinical value of this new method.

Material and Methods

16 patients suffering from permanent denervation without any signs of reinnervation were investigated. 3 patients had a flaccid paraplegia of both legs due to irreversible lesions of the cauda equina, 13 patients had a flaccid paralysis of one arm due to plexus ruptures and/or multiple root avulsions. The patients showed no voluntary movement in any of the denervated muscles, and tendon reflexes were missing. All the muscles were flaccid and showed no signs of reinnervation or spasticity during the subsequent observation period of 4-38 months. There was a complete sensory loss during the period of therapy and extended electrophysiological investigations also proved a complete peripheral denervation.

LIB (long impulse, bidirectional) impulses of rectangular shape and balanced in polarity, were delivered repeatedly for 10 sec to each muscle group via surface electrodes up to an effective stimulation time of 2-6 minutes per day. Impulse duration variied from 50 to 70 msec, intensity was about 50-60 mA (10). Measurements of maximum tetanic tension and endurance were performed with a portable dynamometer (Myometer, Penny & Giles, Christchurch, GB). MRI was repeatedly performed on a 1.5 T SIEMENS Magnetom before and several times during therapy.

Results

A few general beneficial effects were obvious in all patients: previous foot edema showed a distinct reduction, the repeated occurrence of panaritia stopped and a general improvement of trophism was observed. All patients showed an increase of contraction force and an improvement of endurance, as well as an increase of muscle volume. The greatest increase was seen within the first three months, especially during the first week when an intensive training was performed. A further continuous increase took place over the whole observation time. In each case, increase of force was statistically significant with $p \leq 0.05$ in a paired t-test.

In 3 patients with lesions of the cauda equina, electrotherapy started 2-15 months after trauma, observation time variied from 3 to 38 months. Contraction force of all muscles increased (foot flexors: 5.6->10.4 kp, 2.8->7.8 kp, 5.7->9.8 kp. Fatigue resistance: 39%->65%, 54%->63%, 44%->73%. Increase of muscle volume was 23-29% (calf), and 33-84% (thigh).

The patients with lesions of brachial plexus or cervical nerve roots showed an increase of the contraction force of hand flexors by 16-400%, fatigue resistance improved in all cases. Cessation of therapy always led to an immediate loss of contraction force which was reversible with re-onset of therapy.

Discussion

Usually, the aim of electrical stimulation in denervation atrophy is defined as: 1) retarding the rate of atrophy and shortening the time interval between injury and recovery, and 2) reducing the period to restore muscles after reinnervation (17). For this purpose, since 1841 a great number of animal studies have been done, with different designs and a great variety of results (15, 17). Several clinical reports also describe contrary findings. In most cases, the current state of denervation was not described very clearly, and in none of these reports, reinnervation was excluded (2, 6, 8, 9, 12, 13, 14, 16).

A powerful electrotherapy has now become possible in cases of permanent (complete and irreversible) peripheral denervation. This, however, might be only the beginning of a new development. In those cases, where no reinnervation can be expected spontaneously or by a surgical manoeuvre, one should try to restore the mass of the denervated muscle and above all to maintain its contraction force (therapeutic electrical stimulation, TES). I feel that the present result of an electrically inducible tetanic contraction force of one third of normal can still be improved, and I hope that this will be possible to such an extent, that strong and vigorous movements might become inducible for all muscle groups. In addition to all the advantages of an improved trophism, it would be helpful for a patient if his own muscles supported the performance of simple movements with the paralyzed arm, or allowed them to walk on crutches (functional electrical stimulation, FES). They could gain a little more independency of wheel-chairs, of personal assistance, and of technical aids in their environment (1, 5, 18).

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HYPERTROPHY AND TRANSFORMATION OF MUSCLE FIBERS IN PARAPLEGIC PATIENTS

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SUMMARY

Transcutaneous electrical stimulation of the quadriceps femoris muscle was applied in 14 paraplegic patients (10 spastic patients with spinal cord lesions and 4 patients with conus-cauda lesions with denervation atrophy). In both the spastic and the denervated group, the vastus lateralis muscle was biopsied and CT-images of the entire upper leg were taken both at the onset and termination of the 8 month training period. The stimulation was carried out twice a day for 20 minutes. The increase in muscle tissue was significant in the CT-images. The biopsies showed that the fiber diameter of both fiber types increased during the training period in the spastic group from 47 to 67 µm and in the denervated group from 22 up to 38 µm. In both groups the differences were significant between the first and second biopsy. Both groups showed a marked type II fiber predominance. The histological and CT findings correlated with the clinical improvement of muscle function.

STATE OF THE ART

Stimulation devices with implantable or transcutaneous electrodes have been used world-wide for functional electrical stimulation of skeletal muscles. Up till now there are few authors /1,2,3/ who have described the effects of transcutaneous electrical stimulation of human limb muscles in paraplegic patients. No data have been published on the stimulation of denervated muscles.

MATERIAL AND METHODS

For the rehabilitation of 14 complete paraplegic patients the quadriceps femoris muscle of both legs was stimulated transcutaneously with surface electrodes. 10 patients showed central spastic paresis after spinal cord lesion (Th 4 - Th 11). The other 4 patients suffered from conus-cauda lesions with peripheral denervation and advanced muscular atrophy. The experiment commenced after an average interim of 3,4 years after the spinal cord injury.

Stimulation parameters: Two conductive rubber electrodes were used, 250 cm^2 in size, and fixed to both upper legs. Stimulation in the spastic group could be immediately started by biphasic pulses using a frequency of 27 Hz, a pulse width of 1.3 msec, a 36 msec pause and a peak to peak voltage up to 70 V. In the denervated group the muscles initially had to be trained with a primary longer pulse width up to 200 msec, with a frequency of 1.25 Hz, a 600 msec pause and a peak to peak voltage up to 60 - 100 V until contractions could be observed. The parameters of the denervated group improved during further training and almost reached those of the spastic group. Finally biphasic single pulses were used with 25 - 30 msec duration, 20 - 30 msec pause at a frequency of 15 - 20 Hz.

<u>Training period</u>: The spastic patients were trained for 2 months until complete extension in the knee joint was achieved. Afterwards the legs were laden with weights of 3 to 5 kg for a further 6 months training period.
The denervated patients were trained with the above described initial parameters for two months to achieve marked contraction of the quadriceps femoris muscle. Afterwards the legs were stimulated until complete extension in the knee joint was achieved. The entire training period lasted for 6 months. The transcutaneous stimulation was applied in both groups twice a day initially with a period of 15 min which was prolonged during the experiment up to 30 minutes.

<u>CT-recordings</u>: CT-recordings were taken by a Siemens Somatom DR 3 at the onset and termination of the experiment. The cross-sectional area of the upper leg muscles (quadriceps, adductor and flexor muscles) was measured at three different levels of the CT-images.

<u>Muscle biopsies</u>: The muscle biopsies were taken with a Bergström needle from the vastus lateralis muscle. The samples were frozen in 2-methylbutane (Uvasol) cooled by dry ice and 10 µm thick sections were cut on a cryostat. The sections were stained for HE, actomyosin ATPase after preincubation at pH 10.4 and 4.3 /3/, NADH-TR and for PAS. Fibre size and fibre type composition was evaluated by computer assisted image analysis at a final magnification of 100x from ATPase stained sections. At each tissue section about 600-1100 muscle fibres were evaluated, the type I and type II muscle fibers were differentiated and the cross-sectional area of the fibres was determined.

<u>Statistics</u>: Statistical parameters (mean, median, standard deviation, standard error of mean), histograms and the ratio between the counts of type I and type II fibres were evaluated. Statistical differences were examined by the Student's T-test between the morphological results of the first and second biopsy and the CT-recordings.

RESULTS

All patients were able to stretch their legs in the knee joint and the girth of the upper leg increased. The patients of the spastic group were able to lift more than 5 kg with the aid of stimulation at the end of the 6 months training period. The patients with the conus-cauda lesions were able to lift their lower legs against gravity at the end of the 6 months training period. This means that transcutaneous stimulation enabled muscle contraction of the denervated muscles thereby accomplishing complete stretching in both knee joints.

CT-recordings: The cross sectional area of the quadriceps femoris muscle in the spastic group increased by 27.5%. The cross sectional area of the adductor and flexor muscles increased by 22%. The cross sectional area of the quadriceps femoris muscle in the denervated group increased by 10%. The cross sectional area of the adductor and flexor muscles by 7%.

Histological Results: The diameter of the muscle fibres increased during 8 months of stimulation, twice daily, in both groups.
Spastic patients: The median diameter of the Type I fibers increased from 34 to 56 µm. The median diameter of the type II fibers increased from 52 to 70 µm. The fiber diameter was significantly different ($p<0.05$) for both fiber types. The fiber type ratio for type I fibres was 1 : 5.2 in the initial biopsies which means 16.2 % type I fibers. No significant changes of the fiber type ratio could be found in the final biopsies.
Denervated patients: The median diameter of the type I fibers increased from 24 to 37 µm. The median diameter of the type II fibers increased from 24 to 42 µm. The fibre type ratio was 1 : 2.6 in the initial biopsies which means 27% type I fibers. The fibre type ratio was 1 : 4.4 in the final biopsies which means 19% type I fibers at the end of the training period. Therefore the ratio changed into a more pronounced type II predominance.
The fiber size of all type I fibers (denervated and spastic patients) increased from 28.8 µm to 46,6 µm ($p<0.02$), and the fiber size of all type II fibers increased from 35.8 µm to 56,3 µm ($p<0.001$). On average, the fiber diameter for all types in both groups increased from 32.3 to 51.5 which means hypertrophy of approximately 59% ($p<0.02$).

DISCUSSION

Both the denervated and spastic groups /4/ showed significantly smaller diameters in the initial biopsies for both fiber types compared with the data of healthy humans /5/. The fiber type ratio /6/ also showed a significant difference due to the type II predominance in the paraplegic patients. This fact can be explained by the lack of muscular activity in these patients. Transcutaneous electrical stimulation enables the hypertrophy of innervated muscle fibres as well as the hypertrophy and reactivation of muscular function of denervated muscle fibres in contrast to the data published by Greve /3/.
The total amount of hypertrophy of the muscle fibers was similar for both fiber types and about 20% in the spastic group and about 15% in the denervated group. The difference of the fiber size between the type I and type II fibers was not significant at the beginning nor at the end of the training period. This means, that the transcutaneous stimulation affected both fiber types in both groups to the same extent and no preference for one fiber type was observed. Therefore we can conclude that the improvement of muscular activity by transcutaneous stimulation is

not dependent on the type of paraplegic lesions but on the co-operation of the patients and the correct stimulation pattern. The histological data were reinforced by the CT-recordings which showed an improvement in size of all the stimulated muscles of the upper leg as described by Pacy /8/.
The data proved that transcutaneous electrical stimulation can improve paralysed muscle function, especially in the group of conus-cauda lesions where the denervated muscles regained muscle contractions and movements. This allows for a better rehabilitation with an increased blood flow, prevention of decubital ulcer and osteoporosis. Finally, this stimulation technique will enable active walking even in patients with denervated muscles with the improvement of technology.

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FES-ASSISTED LOCOMOTION IN A PATIENT WITH INCOMPLETE TETRAPLEGIA

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SUMMARY

We tried FES to a 53-year-old male tetraparetic due to radiation myelopathy to improve walking ability. Percutaneous wire electrodes were implanted for electrical stimulation. Before FES application, therapeutic electrical stimulation (TES) was applied to his upper and lower extremities for 14 months. But he could hardly walk in the parallel bar by his own effort. FES was applied to his paretic lower limbs in order to boost the incomplete locomotive activities. Stimulated muscles or nerves were slected according to his own muscle power and spasticity, and these were the peroneal nerve, quadriceps muscle, gluteus medius muscle and gluteus maximus muscle. The on and off of the stimulation was controlled by heel switches. He could be able to walk easily in the parallel bar by using this FES system.

STATE OF THE ART

30 years have passed since Liberson introduced the conception of FES as "Functional Electrotherapy" for the first time[1]. After that FES has been making steady progress in the world. But it has been paid little attention to the FES-assisted walk for the paretic lower limb except for hemiplegia. Recently we tried FES to paretic lower limbs of a tetraparetic and got a good result. Here we present a case report.

MATERIAL AND METHODS

FES was applied to a 53-year-old male tetraparetic due to radiation myelopathy. He has been suffering from malignant tumor of pharynx for about 2 years. At first he visited our clinic for the purpose of therapeutic electrical stimulation (TES), and percutaneous wire electrodes were implanted in his upper and lower limbs on Oct. 22 1993[2]. After that, TES had been continued for about 14 months, but he coud hardly walk in the parallel bar by his own effort. FES has been applied to his lower limbs to improve his walking ability from Jan. 1995. The manual muscle testing of his lower limbs ranged from 0 to 3 on the right side and from 0 to 2 on the left side at the beginning of FES application. The muscles or nerves to be stimulated were the peroneal nerve, quadriceps muscle, gluteus medius muscle and gluteus maximus muscle. These were stimulated simultaneously or respectively in accordance with his own stance phase and swing phase.

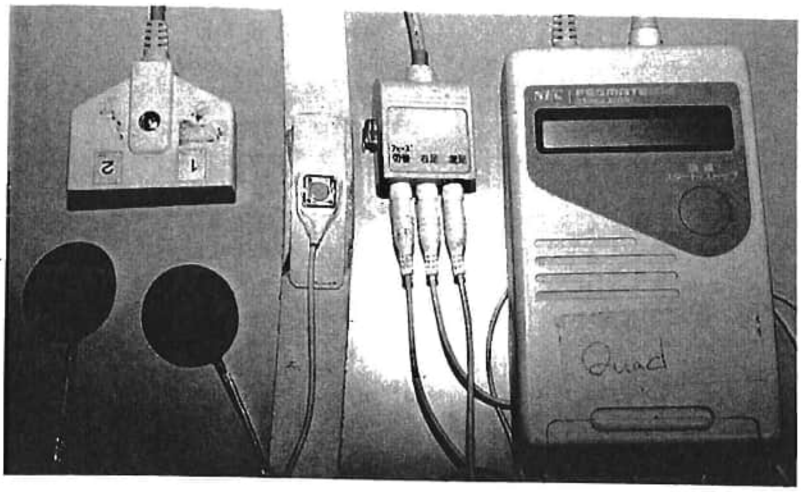

Fig. 1 FES system

FESMATE 1230 was used as a FES system[3]. Main stwitch was bound about his wrist and he controlled on and off of the power sourse by his opposite hand. The on and off of the stimulation was controlled by two switches attached to the left and right heels of the shoes (Fig1, 2).

The state of gait was analysed two dimentionally by using Quick Motion Analyser G-series (Quick MAG). The marked points were the acromion, trochanter major, fibular head, heel (lateal aspect) and 5th toe (lateal aspect).


Fig. 2 FES walking

By using this analyzer, stick picture was described and the changes of the angle of the hip joint, knee joint and ankle joint were analyzed between Non-FES and FES walk.

RESULTS

The state of walking became better by the application of FES.

Subjectively, the patient said that he could step longer and faster and felt less fatigued in FES walk compared with non-FES walk.

Actually he could go and return seven or eight times in the parallel bar by using FES system in comparison with only once in the non-FES walk.

Fig. 3 shows the stick picture described by Quick MAG. The measuring time was 12 seconds. Fig. 3-(a) and (b) shows the stick picture of the mark attached to the right side of the body during non-FES (a) and FES(b) walk. Fig. 3-(c) and (d) shows that of the left side of the body during non-FES(c) and FES(d) walk. Without FES, the stride length was short and he couldn't walk through in the parallel bar within 12 seconds, and because the muscle power was weaker on the left lower limb than on the right, the stepping was more difficult on the left lower limb (Fig. 3-(a) and (c)).

With the application of FES, the stride length became longer bilaterally and the walking speed became faster (Fig-3 (b) and (d)).

As to the changes of the angle of the joint, the decrease of flexion angle of the knee joint during swing phase in the FES walk was observed. The change of the angle of the hip and ankle joint between non-FES and FES walk was little.

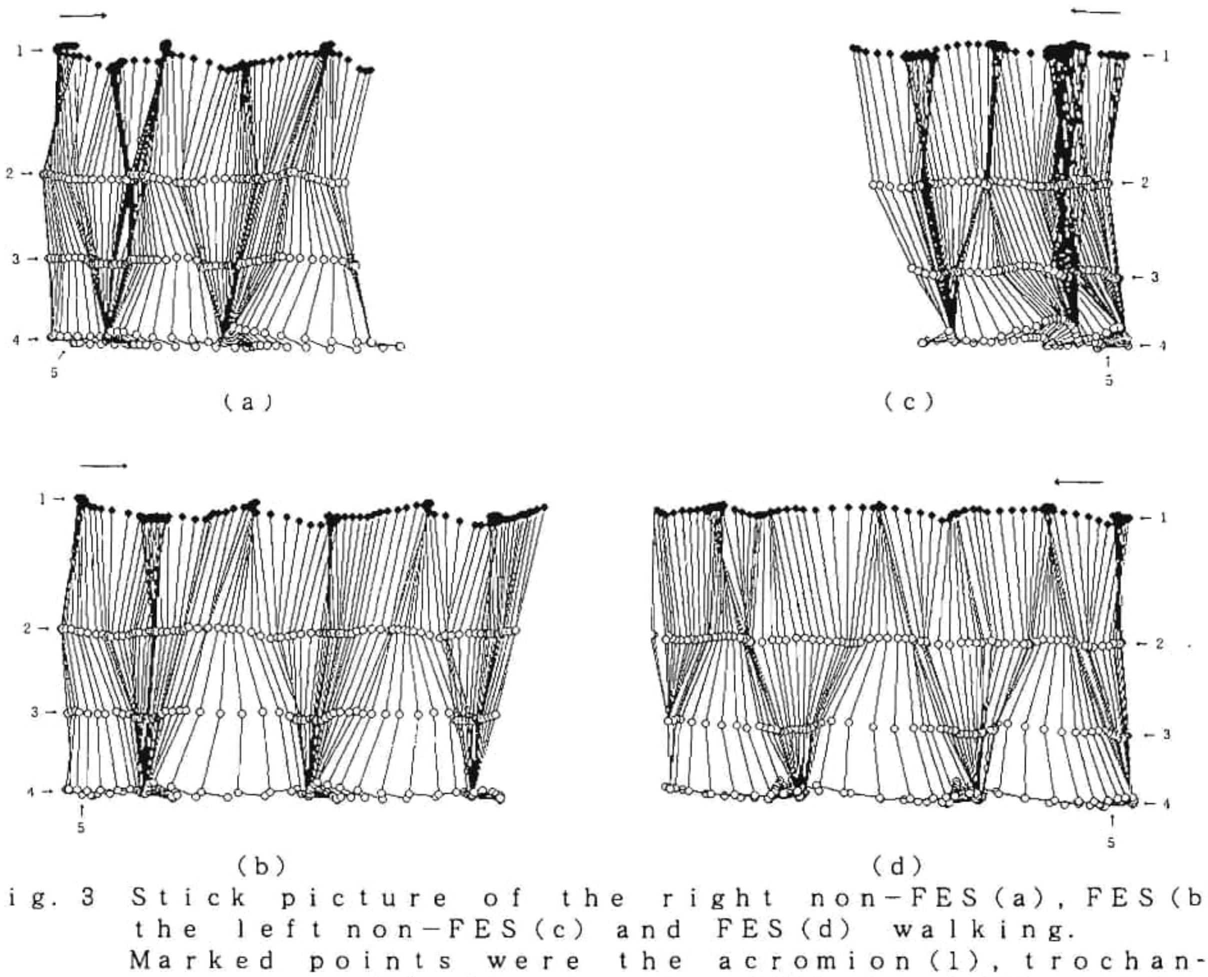

Fig. 3 Stick picture of the right non-FES(a), FES(b), the left non-FES(c) and FES(d) walking.
Marked points were the acromion(1), trochanter major(2), fibular head(3), heel(4) and 5th toe(5).

DISCUSSION

It is difficult to reconstruct the walking ability in complete paraplegia by FES alone, although many reserchers have been trying to do so in the world. On the other hand, there are many patients of tetraparesis or paraparesis who can hardly walk. These patients usually have moderate or severe spasticity that disturb volitional movements. It is well known that electrical stimulation sometimes decrease this spasticity. Here we thought that if FES is applied to these paretic patients, it is easier to control the movements compared to complete paralysis because of some alived motor and sensory function. Actually in the case we presented here, the restoration of walking ability in a tetraparetic by FES was achieved to some degree without difficulty. And this type of FES is a good motivation for the patient, if the percutaneous wire electrodes had already been implanted for the purpose of TES.

We are going to develop this type of FES not only for paraparetics and tetraparetics but also for hemiplegics and other kinds of paretics.

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STANDING-UP AND SITTING-DOWN IN COMPLETE PARAPLEGIA USING MULTI-CHANNEL FES

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SUMMARY

Standing-up from and sitting-down on a wheelchair in T6 complete paraplegia were restored by functional electrical stimulation using electromyogram and knee joint torque data taken on 12 normal subjects. In the normal subjects, the sitting-down motion was similar to the reverse pattern of the standing-up motion; hands-assists reduced many muscle activities and the vertical floor reaction force. The maximum mean knee joint torque during standing-up and sitting-down were 1.6 Nm/kg and 1.8 Nm/kg for both knees, respectively. The standing-up motion in paraplegia was characterized by knee flexion preceding extension; the sitting-down motion was performed by sustaining the body weight with the arms, followed by leaning backward.

STATE OF THE ART

Functional electrical stimulation (FES) has been used to restore the motor function of paralyzed limbs /1-6/. Handa and associates /1/ have restored smooth motor functions using a multi-channel stimulation pattern based on a trapezoidal approximation of averaged electromyogram (EMG) data obtained from normal subjects. However, the strength of stimulation cannot be determined from EMG data. On the other hand, Bajd and associates /2/ have restored standing-up motion utilizing the maximum knee joint torque in a normal subject, but they do not mention a stimulation pattern. Here we describe the restoration of standing-up and sitting-down in complete paraplegia; we used multi-channel FES utilizing EMG and knee joint torque data from normal subjects.

EMG ANALYSIS DURING STANDING-UP AND SITTING-DOWN

Materials and methods

Twelve normal men participated in the study. The average age was 26 years (range, 21-33), average height 1.71 m (range, 1.62-1.77), and average body weight 66.0 kg (range, 56.6-78.1). Informed consent was obtained from all subjects.

Subjects sat on a chair with the height of 0.45 m. Since complete paraplegics need hands-assists during the standing-up and the sitting-down motion, we initially asked the subjects to stand up and sit down under the following conditions: 1) standing-up with arms crossed in front of the chest (standing-up without hands-assists), 2) hands-assisted standing-up using parallel bars, 3) sitting-down with arms crossed in front of the chest (sitting-down without hands-assists), and 4) hands-assisted sitting-down using parallel bars. However, we found that hands-assisted sitting-down was very difficult, because some would depend more on leg muscle power as in sitting-down without hands-assists and others would use mostly their arms so that the sole would leave the floor. We therefore asked them to perform only conditions 1, 2, and 3. In addition, we asked them to adopt the "C" posture (leaning slightly forward, with the hips and knees fully extended) at the end of the hands-assisted standing-up motion, since this posture was mechanically stable in paraplegia /3/. The speed of movement was not controlled. We investigated the synchronized EMG, the joint angle, and the floor reaction force. The EMG data from 10 muscles were recorded using silver-silver chloride bipolar surface electrodes; the iliopsoas muscles of 4 subjects were recorded using fine wire intramuscular electrodes. The EMG data were A/D converted, sampled at 1,000 Hz, full-wave rectified, band-pass filtered at from 20 Hz to 500 Hz, smoothed by a 101 point moving averaging filter, normalized as to the percentage of amplitude at the time of maximum voluntary contraction of the muscle, and averaged. Hip, knee, and ankle angles were calcu-

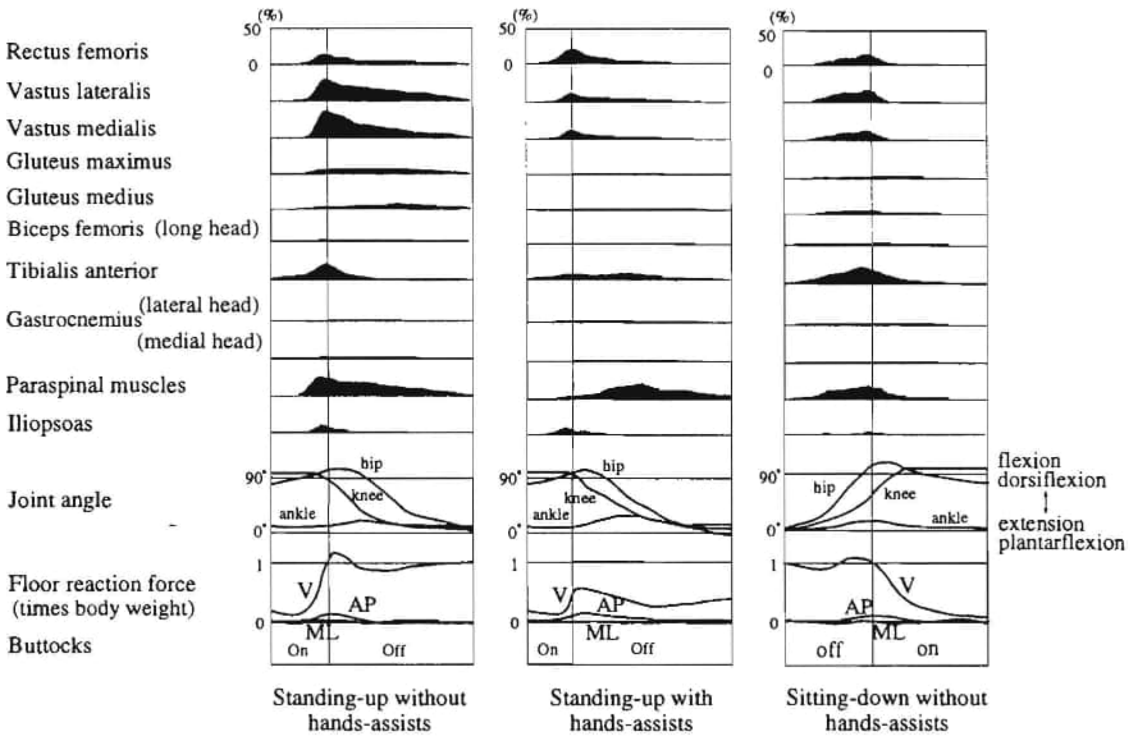

Fig. 1. Synchronized EMG and kinematic data. EMG activity was normalized as a percentage of amplitude at the time of maximum voluntary contraction. (V: vertical, AP: anterior and posterior, ML: medial and lateral)

lated at 60 Hz by a motion analysis device (Quick-MAG, OKK, Japan), and floor reaction force was measured at 200 Hz by a force plate (9281B, Kistler, Switzerland). Buttocks-off or buttocks-on time were determined only when the seat weight was observed.

Results

The motion times for conditions 1, 2, and 3 were 2.0±0.6 sec (Mean±SD), 2.6±0.5 sec, and 2.6±0.5 sec, respectively; the time during standing-up without hands-assists was significantly short (Student's t-test, $p<0.05$). The main muscles used for the 3 motions were the quadriceps femoris, tibialis anterior, and paraspinal muscles. The peak muscle activity for the quadriceps femoris occurred at the buttocks-off or buttocks-on time. Hands-assists reduced many muscle activities. The peak vertical floor reaction force during the 3 motions was 1.18±0.05, 0.61±0.13, and 1.13±0.04 times the body weight, respectively; the force during hands-assisted standing-up was significantly small (Student's t-test, $p<0.001$). The sitting-down motion was similar to the reverse pattern of the standing-up motion (Fig. 1).

MAXIMUM KNEE TORQUE DURING STANDING-UP AND SITTING-DOWN

Materials and methods

Data from all 12 subjects were used. Body segment parameters were measured on each subject. A three-segment link model, as described by Yukawa /7/, was used for the analysis. We calculated the knee joint torque during standing-up and sitting-down when hands did not assist, then normalized it by dividing by the body weight. Details of the equations are described elsewhere /7/.

Results

The maximum knee torque during standing-up and sitting-down was 1.6±0.2 Nm/kg (Mean±SD) and 1.8±0.3 Nm/kg for both knees, respectively (not significant difference); the knee joint angle when buttocks-off and buttocks-on occurred was 93±9° and 104±8°, respectively (Student's t-test, $p<0.05$).

Materials and methods

A 19-year-old man with T6 complete paraplegia participated in the study. His height was 1.69 m and body weight 42.0 kg. We obtained informed consent from him.

We assumed that one knee joint torque was half the value of both knees. Bajd and associates /2/ have described how the knee joint torque decreases by half when hands-assists are used. The maximum knee joint torque for this patient can therefore be shown as follows:

standing-up with hands-assists

$$1.6 \text{ Nm/kg} \cdot 1/2 \cdot 1/2 \cdot 42.0 \text{ kg} = 16.8 \text{ Nm}$$

sitting-down with hands-assists

$$1.8 \text{ Nm/kg} \cdot 1/2 \cdot 1/2 \cdot 42.0 \text{ kg} = 18.9 \text{ Nm}$$

Fifteen percutaneous electrodes (SES115, Nippon Seisen, Japan) for each leg were inserted through the skin, and placed at the nerves and motor points of muscles. The muscle strengthening program was performed for 6 months before the treatment for the restoration of the motion. We measured the knee joint torque in isometric measurements using the Cybex 6000 (Lumex, USA) during the time that the knee extensors were stimulated. The amplitude was modulated from 0 to -15 V. The pulse trains used consisted of a pulse width of 0.2 ms and a pulse interval of 50 ms. For standing-up, the output voltage necessary to get 16.8 Nm at 93° knee flexion was -2.0 V on the right side and -5.5 V on the left side. For sitting-down, voltage requirements to get 18.9 Nm at 104° knee flexion was -2.1 V on the right side and -6.0 V on the left side.

We made a graph of stimulation data based on maximum output voltage for the knee extensors using a trapezoidal approximation of EMG data during hands-assisted standing-up and during sitting-down without hands-assists. We gave stimulation during standing to prevent knee buckling (Fig. 2). In addition, stimulation patterns for other than knee extensors were obtained by a trapezoidal approximation of EMG data (Fig. 3).

The obtained data were entered into a computer (FES MATE CE1100, NEC San-ei, Japan), and the patient stood up from and sat down on a wheelchair using parallel bars. Records were taken on three trials. The floor reaction force, and the hip, knee, and ankle angles were measured.

Results

The patient could stand up from and sit down on a wheelchair smoothly with the help of parallel bars. The standing-up and sitting-down times were 3.0±0.3 sec (Mean±SD) and 3.3±0.1 sec, respectively (not significant). The characteristics of the standing-up motion was knee flexion preceding extension. The maximum knee flexion angle from the initial knee angle was 12±2°. On the other hand, during the sitting-down motion, the vertical floor reaction force decreased, followed by changes in the joint angles; the beginning of knee flexion was delayed, and the ankle plantarflexed (Fig. 4).

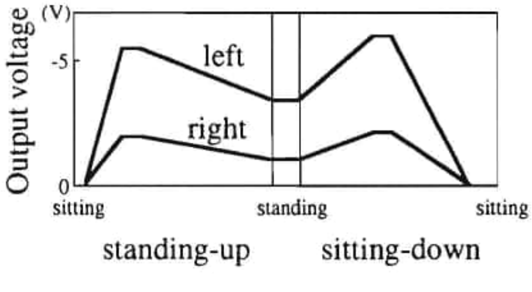

Fig. 2. Stimulation data for the knee extensors. Note that stimulation was also given during standing.

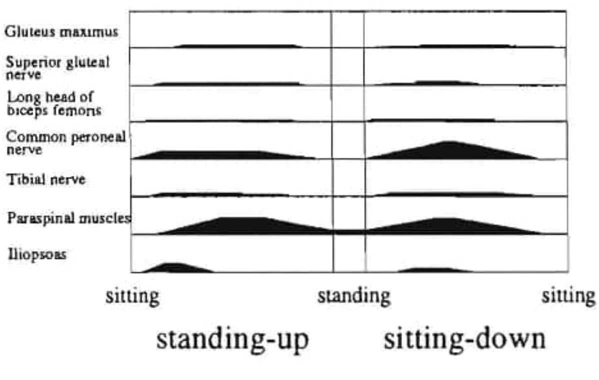

Fig. 3. Stimulation patterns for other than knee extensors. Data were obtained by a trapezoidal approximation of EMG.

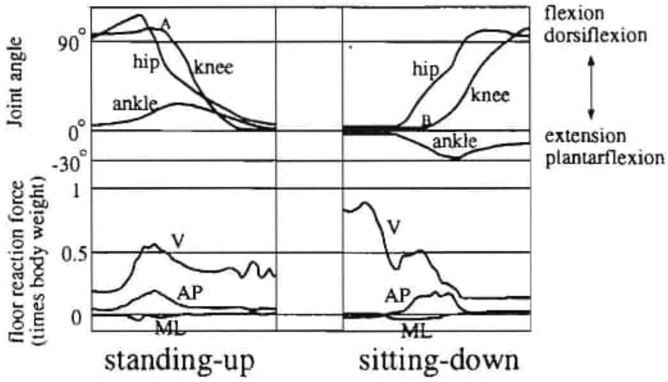

Fig. 4. Representative kinematic data in paraplegia. Note that knee flexion during standing-up (A); the delay of the changes in the joint angles, especially in the knee (B) and the plantarflexion of the ankle during sitting-down. (V: vertical, AP: anterior and posterior, ML: medial and lateral)

DISCUSSION

We could not obtain a stimulation pattern for the sitting-down motion from the hands-assisted EMG data. However, we suppose that this is similar to the reverse pattern of the hands-assisted standing-up motion.

Different patterns were observed between normal subjects and a paraplegic patient in the restoration of motion. Regarding the knee flexion preceding extension during the standing-up motion, the timing between the patient's actions and the electrical stimulation may be a problem, because the amount of knee flexion decreased following exercise /6/. During the sitting-down motion, the decrease of the vertical floor reaction force, the delay of the knee flexion, and the plantarflexion of the ankle indicate an increase of body weight sustained by the arms, followed by a leaning backward motion. We believe that this pattern is derived from the timing and/or the stimulation of the knee extensors administered at the beginning of the motion.

We have effectively restored the standing-up and sitting-down motion of a paraplegic patient utilizing EMG data and knee joint torque data from normal subjects. We have not, however, determined the strength of electrical stimulation necessary for any muscles except the knee extensors. We recognize that the patient must learn the timing of the motion, and we realize that further research is necessary for a more complete restoration of the motion .

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STABILITY AND ENERGY CRITERIA IN HEALTHY AND PARAPLEGIC SUBJECTS GAIT

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SUMMARY

FES assisted gait of paraplegic patients is inferior compared to a healthy subject. The difference can be observed in terms of speed, up-right balance, biomechanical energy consumption and generation of propulsion forces in the direction of walking. The biomechanical structure is the same as in normal, however the mode of walking differs significantly because of reduced number of activated muscles and primitive control. The healthy subject is utilizing two-point dynamically stable gait. The paraplegic patient is employing 4-channels of FES and utilizing a four-point statically stable gait. We believe that FES gait can be improved if converted into a semi-dynamically or dynamically stable gait.

The gait is considered statically stable if the center of gravity (COG) projection on the ground (PCOG) is inside the supporting area. In quadruped this is only possible if it is utilizing creeping crawl gait. In this paper the relationship between PCOG and the supporting area are discussed as a criterion for dynamic stability assessment. Results are shown for three different modes of two-point and four-point gaits.

STATE OF THE ART

In selected spinal cord injured patients the restoration of biped gait can be realized by means of functional electrical stimulation FES /1/. The patients are using 4-channel surface FES. Swing phase is realized through afferent FES provoking flexion reflex resulting in simultaneous flexion of hip and knee and ankle dorsiflexion and thus providing clearance of the foot from the ground. Stance phase is achieved by stimulating bilaterally knee extensors enabling sufficient support to the patient utilizing crutches for balance and partial support. Such FES assisted gait of paraplegic patients is in terms of biomechanics significantly inferior to a healthy subject gait. The main drawbacks are:

- Velocity is considerably lower. Average speed achieved by a paraplegic is about 0.15 m/s while a healthy person walks at about 1.5 m/s /1/.
- Energy inefficiency is resulting in high energy consumption, which is about 14 J/kg m for paraplegic walking at 0.15 m/s. A healthy subject gait at 1.5 m/s requires only 3.3 J/kg m /1/.
- Insufficient horizontal propulsion impulse in the direction of walking is clearly demonstrated from the amplitude ratios of propulsion forces in paraplegic (40 N) and healthy subject (200N) /2/.
- Up-right balance is adjusted mainly by hands provided forces.

In addition, there are also other factors. It is evidently that all of the factors are interrelated in a complex manner.

Owing to it the gait cannot be improved on a subjective way or by simply copying a normal biped gait. In both gaits we are dealing with the same biomechanical structure consisting of segments and rotational joints but with FES performing a different gait mode. The FES gait is a quadrupedal gait because the subject is utilizing the crutches for balance, partial propulsion and support. As it is unlikely for the balance problem to be solved in the near future, the FES enabled gait will remain quadrupedal and therefore we are dealing with the problem of how to improve the existing four-point FES gait /3/.

The basic theoretical approach of multilegged gait analysis is derived from robotics, where several walking and running machines have already been constructed. The whole analysis is performed for walking on the flat, hard, level surface. Here, several new terms are introduced into the analysis.

MATERIALS AND METHODS

The supporting area in a certain phase of gait is defined as the minimum convex point set in the ground plane such that all the leg contact points are contained. All quantities are using a fixed global coordinate system shown in Figure 1. The center of gravity location (COG) is defined as the first normalized moment along the given axis, with eq. (1) presenting the exact formula for COG x component x_{COG}:

$$x_{COG} = \frac{\sum_M x_i m_i}{\sum_M m_i} \tag{1}$$

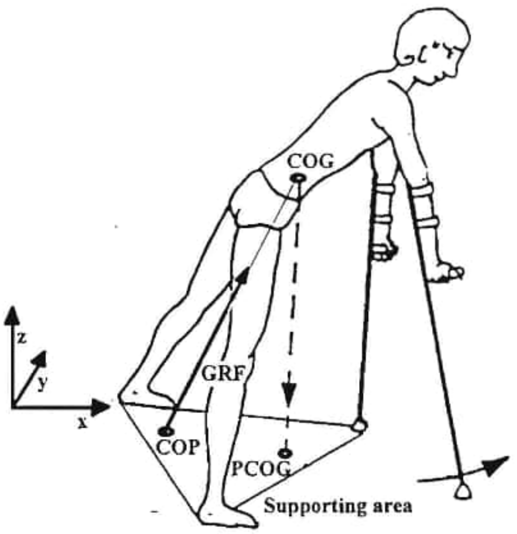

Figure 1: Definition of biomechanical parameters

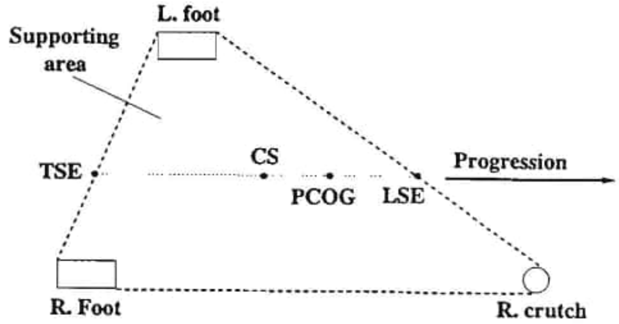

Figure 2: Parametrs for the definition of *SSI*

M is the total body mass, m is mass of segment i and x_i is the x component of the segment i. In human walking the COG is, because of its difficult assessment, often replaced with the center of body (COB), which is defined as a fixed anatomical quantity. Though such replacement could introduce significant errors - mainly in non gait activities, it is often used because of its simple application. Another important parameter is the vertical projection of COG on the ground level (PCOG). Similary vertical projection of COB on the ground plane is marked as PCOB. The parameters are graphically explained in Figure 1. The sum of the ground reaction forces (GRF) is calculated as a vector sum of forces under each supporting leg/crutch. GRF is a vector quantity and has three orthogonal components as described in eq.(2):

$$G\vec{R}F = \vec{F}_x + \vec{F}_y + \vec{F}_z \tag{2}$$

GRF is always pointing from the point on the ground level, called center of pressure (COP), to the COG. Therefore COP can be defined as the point projected on the ground along the direction of the resultant reaction force acting to the COG. Ground reaction forces are related by Newton's 2nd law to the acceleration of COG as shown in eq. (3):

$$\begin{aligned} F_x &= \ddot{x}_{COG} \cdot M \\ F_y &= \ddot{y}_{COG} \cdot M \\ F_z &= \ddot{z}_{COG} \cdot M + F_g \end{aligned} \tag{3}$$

M is the total body mass, $\ddot{x}$, $\ddot{y}$, $\ddot{z}$ are accelerations of COG in the respected directions, F_g is gravitational force and F_x, F_y, F_z are forces acting on COG. An important conclusion is that the COP is always inside the supporting area, while this is not true for PCOG.

A statically stable gait is a gait pattern /4/, when the PCOG is during the whole gait cycle inside the supporting area. There are 5040 nonsingular gait patterns out of which only three can be statically stable. Out of these three creeping patterns the crawl gait offers superior static stability properties. This type of gait is adopted by four-legged animals for a slow walking and intuitively also by FES assisted paraplegic subjects. The main characteristic of statically stable gait is that a system, in our case the paraplegic subject, can maintain its posture in any gait phase for an arbitrary amount of time. Such a gait must and can be as slow as desired, but is consequently at the higher velocities not feasable.

Quite opposite a healthy person is utilizing semidynamically stable gait. This is a gait mode with both statically stable and statically unstable phases. The statically unstable states in the gait cycle occur, when PCOG is outside the supporting area. When the gait cycle consists of only statically unstable states the gait is truly dynamically stable, e.g running. The movement assures the stability of the system in statically unstable phases. If the system stops, it falls. In statically unstable gait phases the dynamics of the mechanism together with the propulsion forces determines the gait velocity. As the statically unstable phases are mandatory gravity and inertia driven, the gait cannot be arbitrary slow. Thus developing a FES assisted (semi)dynamically stable gait would doubtlessly lead into faster and more efficient gait.

So far no quantity or index has been proposed to enable a quantitative analysis or describtion to be universally valid for both static and dynamic gait stability. Therefore numerous approximations have been introduced. When measuring system (in)stability, the first approximation is to use the simple relationship between PCOG and the supporting area as a stability measure. This approach neglects all inertial and propulsive forces. Therefore, it is suitable only for a very slow statically stable gait. It is a reliable indicator whether the gait is statically unstable or not. In statically unstable phases of the gait, a system is definitely gravity/inertia driven what reduces the energy consumption.

For assessment of system (in)stability in faster but still statically stable gait the COP compared to the supporting area can be used instead of PCOG vs. supporting area relationship /5/. COP position depends not only on system posture but also on system inertial or ground reaction forces. In faster statically stable gait the static stability margin is smaller as compared to a slower gait modes. This means that the control system needs to react faster, specially when static stability margin is small. The COP can come close to the supporting area edge not only because the mechanism is actually close to the static stability edge or transition to an unstable phase, but also because of the high propulsion/breaking forces. The COP to supporting area relationship cannot be used in (semi)dynamically stable gait, because there is no information, whether a system is statically stable or not.

For (semi)dynamically stable gait is the only useful parameter PCOG compared to the supporting area, while the COP is always inside the supporting area and is therefore useless. PCOG determines whether the mechanism is in certain moment statically stable or not.

To understand these basic stability criteria we have measured the static stability index in heathy subject biped gait, healthy subject four-point gait and in a below knee amputee. Dimensionless relative static stability index (SSI) is defined in eq.(4):

$$SSI = 1 - \frac{distance(PCOG,CS)}{\frac{distance(LSE,TSE)}{2}} \qquad \textbf{(4)}$$

Leading stability edge point (*LSE*) is the intersection point of the supporting area leading edge and the line from PCOG in the direction of COG velocity. Trailing stability edge point (*TSE*) is the equivalent point in the trailing supporting area edge. Center of stability area (*CS*) is the midpoint between *LSE* and *TSE*. Figure 2 graphically explains the parameters used in the definition of *SSI*.

When *SSI* is positive, a mechanism is statically stable. With increasing negativity of *SSI*, increases the static unstability of the mechanism. Theoretically there is no lower bound on *SSI* as the denominator in eq. (3) can be arbitrary small. To assess *SSI* index only the knowledge of COG position and motion and supporting area geometry is required.

RESULTS

For measuring purposes, we used the OPTOTRAK contactless motion analysis system. Due to easy assessment, we measured the motion of COB instead of COG. Foot contact model has been characterized by three different types: heel contact only, toe contact only and foot flat. The first two contacts were modeled as irregular triangles, while the latter one included a rectangular support area in between the triangles. The actual dimesions were assessed individually. The crutch-floor contact was modeled as point contact. MATLAB@ was used for data processing and visualization.

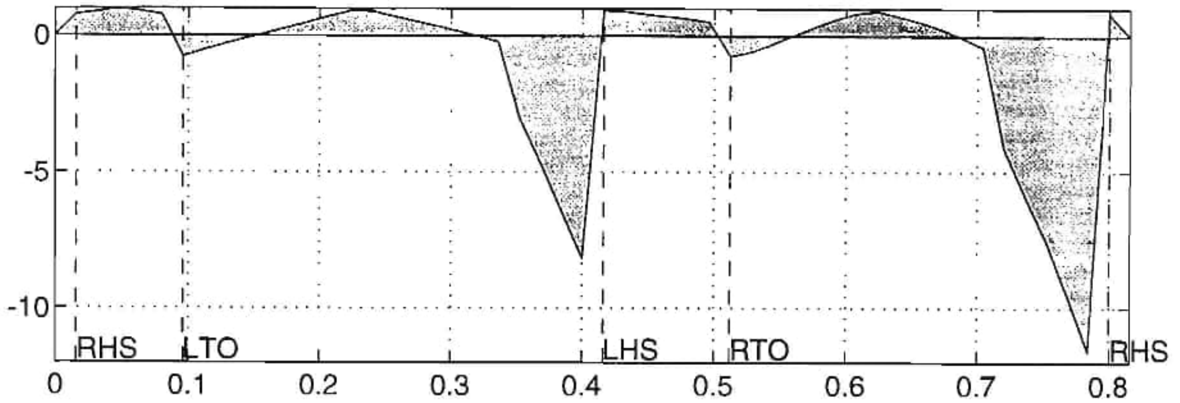

Figure 3: *SSI* assessed in a healthy person biped gait. RHS: right heel strike, LHS: left heel strike, LTO: left toe off, RTO: right toe off

Figure 3 shows the *SSI* for a healthy subject biped free gait. As expected there are two statically unstable gait phases: initial and final part of the single support phase. The variance of *SSI* in the final part of the single support phase

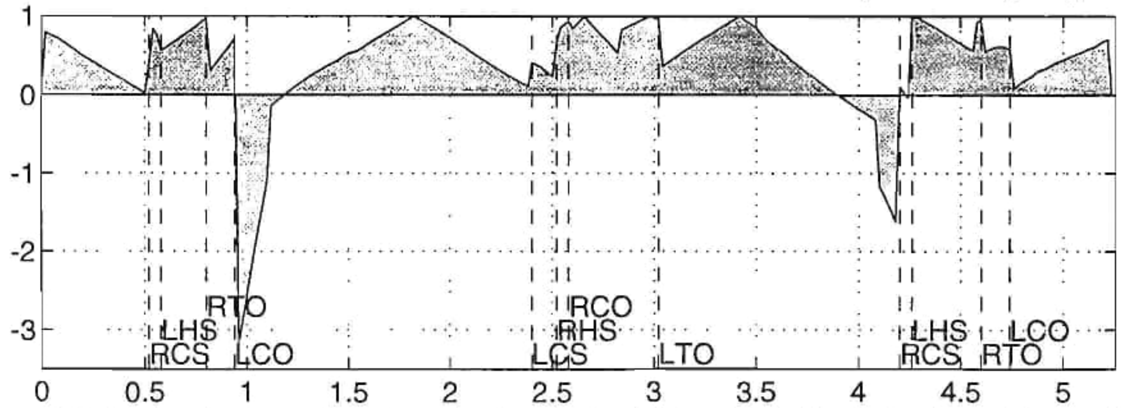

Figure 4: SSI in a healthy subject four point gait. RHS: right heel strike, LHS: left heel strike, LTO: left toe off, RTO: right toe off, LCO: left crutch off, RCO left crutch off, LCS: left crutch strike, RCS: left crutch strike

before the heel strike is due to small foot-floor contact area. So even a small variation from step to step causes significant changes in *SSI*. The distance between PCOG and CS rarely exceeds 10 cm, which is only about 12% if compared to the vertical distance from COG to the floor. So even a small swing of COG around its vertical position enables semi-dynamically stable gait.

Figure 4 shows the *SSI* for a healthy subject four-point gait in slow pace. As expected the minimum value of

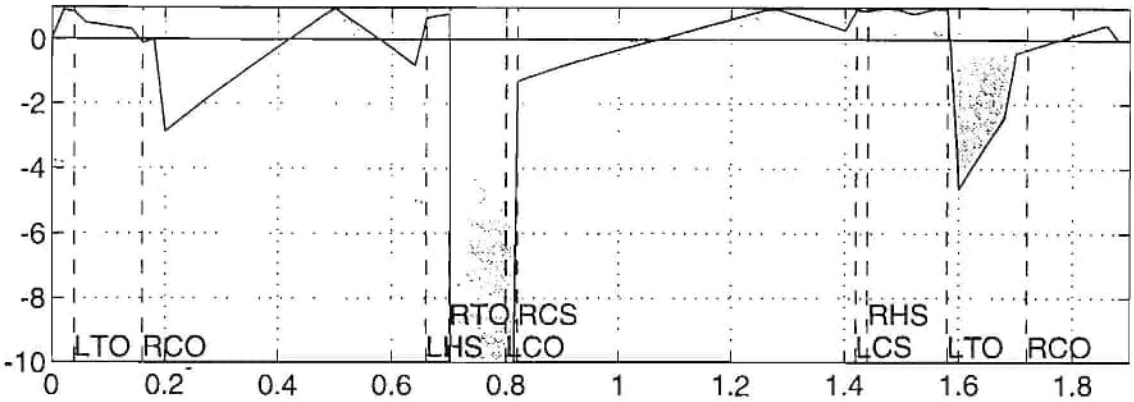

Figure 5: *SSI* in a below knee amputee four point gait. RHS: right heel strike, LHS: left heel strike, LTO: left toe off, RTO: right toe off, LCO: left crutch off, RCO left crutch off, LCS: left crutch strike, RCS: left crutch strike:

SSI is higher than in biped gait. However, the gait is still semidynamically stable. The variance of *SSI* is higher.

Figure 5 shows the *SSI* for a right leg below knee amputee four-point gait in normal pace. As expected the negative peak of *SSI* ocurs due to the rigid prosthetic foot. During this interval the *SSI* is less than -50, so was the Figure 5 clipped at -10 for better visibility. The gait is still semi-dynamically stable.

DISCUSSION

We hypothesize that the introduction of the unstable states into the paraplegic gait can improve its efficiency and increase the average speed. Because it is impossible for an FES walker to utilize a normal-like gait, we are forced to copy other four-point gaits, which already incorporate unstable states. Above/below knee amputees walking by crutches are good four-point walkers as shown in our results. They serve as a model for paraplegic FES gait. Still an important difference exist. Amputees heavily utilize hip flexors and extensors, which are difficult to stimulate by surface electrodes and are not used in here described FES gait. In our future work we will try to find out, if semidynamically or dynamically stable FES gait is possible at all and if it is possible, we will try to synthesize it.

To quantitatively assess the dynamic stability a new criterion needs to be established which will include the mechanism kinetic energy as well. *SSI* doesn't suffice for assessing the dynamic stability. Namely, even if the mechanism is statically unstable, e.g. biped walking at the beginning of the single support phase, it can recover into a statically stable posture, e.g. mid single support phase, without any propulsion forces. The reverse is also true: a mechanism can slip out of statically stable state just because of its kinetic energy, e.g. transfer from mid to end of single support phase. This kind of phenomena occur in faster multilegged gaits as well. Therefore, the understanding of dynamic stability control is essential particular for the synthesis of semidynamically stable FES and crutch assisted gait.

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MEASUREMENT OF HEART RATE DURING EXERCISE INDUCED BY CYCLIC FUNCTIONAL ELECTRICAL STIMULATION IN SPINAL CORD INJURED INDIVIDUALS. METHODOLOGICAL PROBLEMS.

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SUMMARY

Studies investigating cardiovascular responses to functional electrically induced (FES) exercise in spinal cord injured (SCI) individuals include measurements of heart rate using mainly electrically recordings of signals derived from precordial electrodes /1-7/. To test the reliability of different methods to determine heart rate, a computerized electrically derived signal recording was tested against measurement of peripheral pulse by light absorption. Nine SCI subjects performed FES cycling for 30 min and six able-bodied men performed voluntary cycling as controls. During exercise, heart rate rose in the spinal cord injured from 64 +/- 4 (mean +/- SE) to 129 +/- 10 when determined with equipment based on light absorption. In contrast, when using electrically heart rate determination, in all SCI subjects heart rate only rose to 80-100, being precisely matched to the cycling cadence indicating a match to the stimulation pattern rather than to true heart beat frequency. In control subjects heart rate rose from 59 +/- 3 to 130 +/- 9, and measurements with both methods were identical.

In conclusion, during exercise induced by electrostimulation measurements of heart rate using computerized recordings of electrical signals, may reflect the stimulation pattern rather than the actual change in heart rate. Caution has to be taken when recording heart rate during FES and the interpretation of some previously presented published data might be reconsidered in the view of the present findings.

STATE OF THE

Most research groups investigating use of FES in different exercise models in spinal cord injured persons use heart rate as a measurement of intensity of the exercise. The most used technique is measurement of the precordial ECG, done with different instrumentation, ranging from sports testers with the receiver in a wrist watch to highly advanced hospital equipment with a possibility of manipulating and filtering the signals.

MATERIALS AND METHODS

Nine SCI subjects gave their informed consent to participate in the study, which was approved by the Municipal Ethical Committee of Copenhagen. The group consisted of five tetraplegics (injury level C5 to C7, postinjury time 5-13 years) and four paraplegics (injury level Th 4 to Th 7, postinjury time 13-24 years). All were neurologically stable with clinically complete lesions (Frankel class A). The SCI individuals had full passive hip and knee range of motion and participated in an ongoing training program including functional electrical stimulation of their legs for bicycling for 30 min three times a week /8,9/.

In addition to SCI subjects, 6 healthy males were used as controls performing voluntary cycling on the same equipment as the SCI subjects.

FES exercise

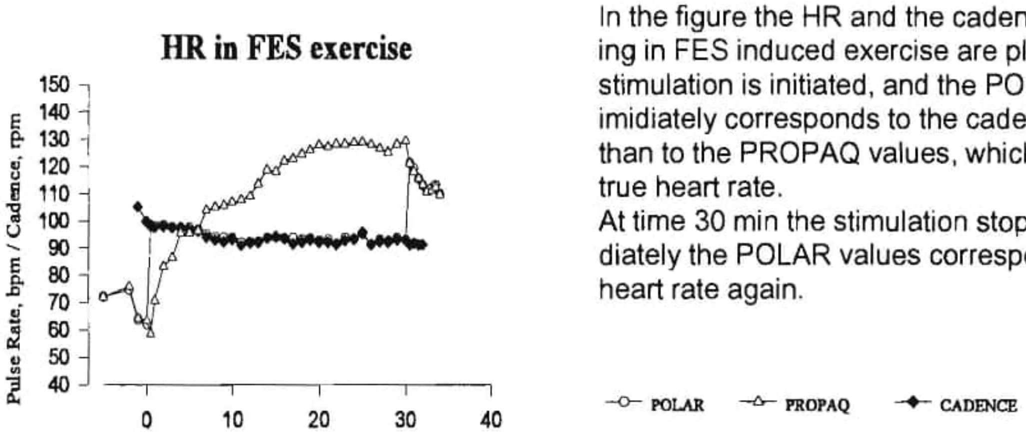
The SCI subjects were placed in the sitting position on a computer-controlled FES exercise ergometer (REGYS I Clinical Rehabilitation System, Terapeutic Technology Inc., Tampa, USA). This system was comprised of three primary subsystems: a lower extremity ergometer (Monark ergometer), a stimulus control unit and a reclinable patient chair. The stimulus control unit was a computer which controls and monitors the electrical stimulation according to prescribed parameters (see below) entered into a microprocessor by a remote control keyboard. Before exercise, surface electrodes were placed over motor neuron end plates (motor points) of the quadriceps, hamstrings and gluteal muscle groups of both legs. Three electrodes (two active and one reference) were applied over each muscle group. Each electrode was coated with a buffered electrode gel that provides a conductive interface between the electrode and the skin. Six separate channels for sequential surface muscle stimulation were used during ergometry with a computer-controlled closed loop system. Each channel supplies monophasic rectangular pulses lasting 350 microseconds and delivered at 30 Hz to each of the two active electrodes over a given muscle. Stimulation intensities ranged from preset threshold levels determined for each individual muscle group to elicit a palpable contraction (18-40 mA (range)) up to a maximum of 130 Ma. An ergometer power output, based upon prior studies, was chosen to enable subjects to work 30 min. A pedal position sensor, allowing continuous calculation of velocity, was used by the computer to control the instantaneous stimulus amplitude required for each of the six muscle groups to result in a smooth motion and a constant cranking frequency of 50 revolutions per min (cadence = 100). Fatigue was said to occur when revolutions per minute decreased below 35 in the face of maximal stimulation intensity (130 Ma). Stimulation was automatically stopped at fatigue.

Control exercise

The control subjects with intact nervous system carried out voluntary bicycle exercise with a cadence of app. 100 per minute (50 rpm) and body position were the same as in SCI individuals. The work load was set to result in a rise in heart rate during the first 5 min up to approximately 80 bpm, during the next 5 min up to app. 100 bpm, and during the last 5 min up to app. 140 bpm.

RESULTS

During FES exercise in SCI patients, the POLAR Sports tester was used to determine HR on the basis of the R-R interval in the precordial ECG and the PROPAQ equipment was used to determine HR on the basis of light absorbtion in the pulp of the finger tips.



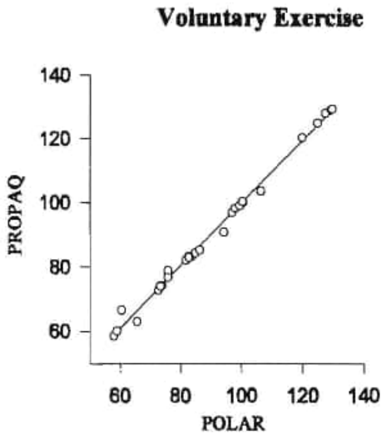
In the figure the HR and the cadence of the biking in FES induced exercise are plottet. At time 0 stimulation is initiated, and the POLAR values imidiately corresponds to the cadence, rather than to the PROPAQ values, which here is the true heart rate.

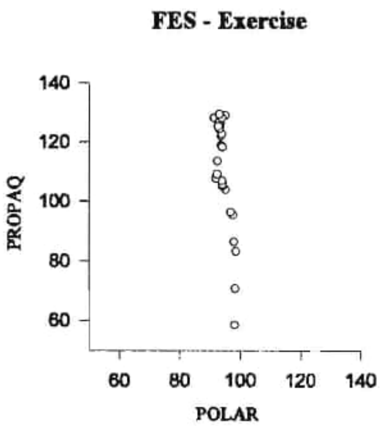
At time 30 min the stimulation stops, and imidiately the POLAR values correspond to the heart rate again.

In contrast to the FES induced exercise, the POLAR and the PROPAQ values are identical throughout the biking session in voluntary controls, as shown in this figure.

—o— POLAR —△— PROPAQ —◆— CADENCE

The correlations between HR measured with POLAR and PROPAQ in voluntary exercise was found to be very near to one whereas there was no correlation between the two values in the FES induced exercise. The correlations are shown in the two following figures.





DISCUSSION

The present study shows, that heart rate recording using either electrical signals derived from precordial electrodes or pulse registration on the basis of light absorption as expected correspond with one another during voluntary exercise. However, the important finding is the notion that computerized electrical determination of heart rate was markedly altered if exercise was induced by cyclic electrical stimulation via surface electrodes. This was true for both paraplegic and tetraplegic subjects when they carried out functionally electrical induced cycling with their paralyzed leg muscles at the highest possible work load for 30 min. In fact the heart rate determined during exercise was markedly lower than the true heart rate, and was exactly matched to the frequency of electrical induced muscle contraction (cadence) pattern. This was the case both during exercise where the aimed 50 rpm was kept up as well as during exercise in which only 40-45 rpm could be maintained, and it indicates an interference of muscle stimulation signals on the heart rate recordings.

In the present study a electrical heart rate recording was used that was set to register QRS complexes, but also other equipments based on R-R interval registration have been shown to present inconsistent heart rate results during electrical induced exercise (unpublished results).

From the present study it is not possible to rule out that similar methods used by other research groups give more correct values, but in the present state one has to be cautious regarding the correctness of heart rate determinations based on electrically derived signals during cyclic FES exercise.

In contrast to electrically derived signals, when heart rate was determined on the basis of light absorption in peripheral vessels, true heart rate values were obtained in spinal man during FES exercise.

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SCREENING & ASSESSMENT FOR A LUMBOSACRAL ANTERIOR ROOT STIMULATOR IMPLANT PROGRAM

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SUMMARY

The Multichannel Lumbosacral Anterior Root Stimulator Implant (LARSI) was developed to restore lower limb functions in individuals with paraplegia following spinal cord injury.

Criteria related to classification of injury, medical status, spasticity, joint mobility, psychological status & presence of spinal instrumentation were implemented to ensure appropriate subject selection for a sequential assessment & surface stimulation training programme. The effects of the programme on the impairment, disability & handicap of the subjects were evaluated.

51 paraplegics were identified from a total population of 224 for further investigation. Of the 11 consenting subjects fulfilling all criteria, 9 completed the programme. No change in neurological status, joint range & locus of control & a decrease in anxiety & depression was observed in all subjects. An increase in muscle power & bulk & spasticity was seen in 9 subjects. 6 subjects achieved closed-loop standing and 1 subject has so far progressed to implantation.

STATE OF THE ART

Surface stimulation systems to restore lower limb functions in spinal cord injured subjects present practical problems and safety issues. Percutaneous wire electrodes, whilst enabling specific placement and reduced set-up time for the patient user, lack cosmetic acceptability and have a high rate of electrode failure and incidence of infection. Progression to a fully implanted system provides a solution to practical problems of application but the extensive sites for surgical implantation of the peripheral nerve cuff or epimyseal electrodes do not overcome the cosmetic difficulties for the patient. The aim of the Lumbar Anterior Root Stimulator Implant (L.A.R.S.I) is to maintain the benefits of an implanted stimulator whilst minimising the site of surgery to the lumbar spine.

The World Health Organisation International Classification of Impairment, Disability & Handicap (1980) **[1]** provides a construct within which health care professionals may examine the concept and consequence of disease and evaluate the rehabilitation programmes devised to minimise the impact of the disease process. Studies investigating the effects of programmes of electrical stimulation to restore lower limb function in patients with complete paraplegia have primarily considered the evaluation of impairment - muscular changes, peripheral blood flow, and bone metabolism and at the level of disability - achievement of standing and walking **[2]**. Anecdotal evidence has also been put forward that participation in a programme of FES may bring about social and psychological change **[2]**, but formal evaluation at the level of handicap was not addressed in these studies. The need for holistic evaluation of stimulation programmes, by a multidisciplinary research team was recognised and a collaborative project incorporating the Spinal Units at the Royal National Orthopaedic Hospital Trust and Salisbury District Hospital, each with experience with surface stimulation to restore standing in paraplegics **[3,4]**, and the Medical Implanted Devices Group, University College London was devised to evaluate the Multichannel Lumbosacral Anterior Root Stimulator Implant.

MATERIALS & METHODS

A sequential selection and assessment process was developed from the criteria & assessment protocols already established at the two centres in previous programmes of surface stimulation **[3,4]**. Initial selection criteria related to age, level and classification of injury, medical status, level of spasticity, joint mobility, skin condition and psychological condition. Additional criteria were introduced to ensure suitability for implantation, relating to presence of spinal fixation instrumentation and history of autonomic dysreflexia.

Measurement techniques for each of the assessment areas shown in Table 1 were standardised for use at both centres and high inter-therapist reliability was demonstrated in patient positioning and measurement of joint range of movement using goniometry, rating of spasticity and the measurement of muscle bulk.

Table 1: ***Sequential Selection & Assessment Programme***

Stage	Assessment	Level of measurement
I Subject selection	Paper screening of medical notes using selection criteria	Impairment, Disability & Handicap
II Introduction to project	Joint range of movement Response to stimulation Standing posture Psychological tests	Impairment Impairment Disability Handicap
III Training	Bone density & muscle biopsy Motor & sensory neurology Spasticity Muscle strength & bulk Psychological tests	Impairment Impairment Impairment Impairment Handicap
IV Standing - in laboratory	Standing - open & closed-loop Psychological tests	Disability Handicap
V Standing - at Home	Standing - closed loop	Disability
VI Implantation	Spinal canal diameter Autonomic dysfunction Root mapping & muscle strength Psychological tests	Impairment Impairment Impairment Handicap
VII Standing	Root mapping & muscle strength Standing Psychological testing	Impairment Disability Handicap

Stage III comprised a twelve week exercise programme, using surface stimulation to the quadriceps femoris, anterior tibial muscles and glutei directly and the hamstrings and hip flexors via the flexor withdrawal response. Stimulation frequency was 20Hz, pulse width 300 microseconds, contraction time 8 seconds and a relaxation time of 10 seconds. Stimulation produced alternating knee extension in one leg with knee flexion in the contralateral leg. The exercise period increased from 30 minutes to a maximum of two and a half hours. On completion of Stages III, IV & V, fulfilment of further criteria relating to muscle strength and stance times were a prerequisite for the subjects to progress to the next stage.

RESULTS

Medical records of 224 complete paraplegics from the two Spinal Units were examined. 128 patients were excluded by the selection criteria and 45 patients were untraceable. The 51 remaining potential candidates were sent information regarding the study of which 19 attended the centres for further discussion of the project. 11 patients (4.9% of the initial population) started the exercise programme. Two of these subjects did not complete the training regime; one due to personal commitments preventing adequate time for stimulation and the second attributed a decrease in his sexual function to the stimulation. Results from the remaining nine subjects are presented.

Motor & Sensory Neurology

No change in voluntary muscle power, joint proprioception or sensation to light touch and deep pressure was observed in any of the subjects.

Joint Range of Movement

No change in joint range of movement in the hips, knees or ankle joints was observed in any of the subjects.

Spasticity

Therapist rating of resistance to passive movement of the lower limbs showed an increase in spasticity in 7 subjects. Four of these 7 subjects also showed an objective increase in spasticity using the Wartenburg Pendulum test.

Muscle Strength

Eight subjects demonstrated an increase in peak torque during isometric contractions of the quadriceps mechanism with the knee held at 90 degrees flexion in the left leg and six in the right leg. Endurance, examined by repeated stimulation at a predetermined level with the knees at 15 degrees of flexion, increased bilaterally in 5 subjects and unilaterally in 2 of the other subjects.

Muscle bulk

Thigh and calf circumference and gluteal bulk measured with a tape measure at 10 fixed points increased in six subjects. Linear ray ultrasound scan demonstrated increased quadriceps bulk in 5 of these subjects.

Psychological Assessments

The Hospital Anxiety & Depression scores were within normal limits for all nine subjects. Six subjects showed a reduction in their anxiety score and 4 a decrease in their depression score.

The Multi-dimensional Health Locus of Control Scales showed that there was no significant change in Internal, Powerful Others or Chance Loci of control for any of the subjects.

Ability to Stand

Of the nine subjects who completed the exercise programme, 1 failed to increase muscle strength sufficiently to progress to standing (despite an extended period of stimulation - 23 weeks). A further subject experienced a substantial increase in spasticity which interfered with his functional ability and forced him to withdraw from the programme. A third subject stood using open loop stimulation with poor posture and fatigued after 2 minutes due to the excessive upper limb work required to keep himself erect. Despite further training and additional means of support, posture correction was not achieved and tolerance to standing did not increase and the subject discontinued the programme. The remaining six subjects progressed to standing with a closed loop stimulation system and one subject has undergone implantation.

DISCUSSION

The proportion of spinal cord injured patients who would be considered suitable for FES standing using clinical criteria has been estimated as between 5 - 12% **[5]**. From the total patient population of the two participating units in this study, 19% were found to be suitable, but 14% showed disinterest. 11 subjects (5%) agreed to participate and 6 subjects (2.7%) achieved closed loop standing in the community. The impracticalities of using a surface system on a long term basis are recognised but the importance of surface stimulation as a non-invasive means of assessment and training support its continued use prior to progression to an implanted system.

The predicted number of subjects to complete Stage 5 of the programme from those accepted for the programme was 50%. At the final stage of the LARSI programme, 45% of the subjects selected have failed to reach Stage V, indicating that the selection process had fulfilled its objective. A review of the subjects failing to complete Stages III - V may indicate predictive indicators of failure and enable further refinement of the selection and assessment protocol in order to improve the subject outcomes.

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SPINAL LOCOMOTION IN PARAPLEGIC PATIENTS

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SUMMARY

We investigated whether a spinal gait pattern can be induced in patients following spinal cord injury through stepping movements on a treadmill. During 5-13 weeks, patients performed stepping movements on a motor-driven treadmill with a weekly frequency of 2-3 training sessions of 30-45 minutes each. Patients were supported by a harness suspended from the ceiling by a set of pulleys allowing a defined body weight support (BWS), as well as by therapists providing manual help whenever necessary. In the course of the therapy, 6 patients showed at least a doubling of walking distance and time. The average speed in these patients could be increased by approximately 0.4 m/s. 2 patients mainly experienced functional improvements, such as taking a few steps at the parallel bars and a walker, respectively.

The question of the most promising point of time to start locomotion therapy after spinal cord injury as well as the optimal course of therapy will have to be clarified in subsequent investigations.

STATE OF THE ART

On the basis of the results of numerous experimental studies in spinal cord transected animals /1,2,3,4,5/, in which spinal gait automatisms could be reactivated by means of coordinated stepping movements on the treadmill, subsequent studies revealed that both quantity and quality of the spinal gait can be improved through prolonged training on a *Laufband* (treadmill) /3,5/. Furthermore a spinal gait pattern could be induced in paraplegic patients with more or less missing voluntary movements through activation of locomotor centres after walking on the treadmill /6/.

Patients with incomplete spinal cord lesions turned out to show significantly better functional results as regards the triggering off of stepping movements while in patients with complete lesions the full stepping pattern, i.e. flexion and extension, could not be entrained /6/. In accordance with these findings other authors detected only a marginal increase in EMG-activity in the m.gastrocnemius in complete paraplegics during stepping on the treadmill. Stepping movements could only be elicited with significant body weight support; decreasing support resulted in inability to step at all /8/. Similarly, data collected in experimental studies in primates with complete transection of spinal cord showed that no spinal gait could be induced on the treadmill /2,8/. By contrast, in some incomplete paralysed patients it was possible to reduce body weight support entirely during therapy - some were even able to step on a static surface, while their voluntary muscle activity in rest was still absent to varying degrees. Also in many chronic paretic patients at least the flexion pattern could be reactivated by using the *Laufband*, which seems to justify to start with locomotion training even years after an incomplete spinal cord lesion /6/. A recently published study showed a significant advantage of the treadmill therapy in 89 patients as compared to 64 patients treated with conventional therapy /9/.

The aim of the present investigation is to find out whether the above-mentioned findings about the locomotion training can be applied to 7 of our paraplegic patients.

MATERIALS AND METHODS

Up to now we have recruited 5 male and 2 female patients with a spinal cord lesion showing an age between 18-55 years. The cause of the s.c. injury in all patients was trauma, which in 5 patients occurred 28-37 months ago, in 1 patient (R.B.) 9 years and in 1 patient (E.M.) 29 years ago. 5 of these patients had an incomplete spastic paraparesis (Th9, Th11, Th6, Th1, L1), 1 had a complete spastic paraparesis (Th11), and 1 had a spastic tetraparesis (C5/6). Muscle activity, sensibility, and proprioception were present in varying degrees. Concomitant with the treadmill training all patients took part in our standard rehabilitation program, including stretching and passive joint movements. 4 patients were also subjected to an electrotherapy. After several weeks of treadmill training, the attempt was made to perform stance and gait exercises at the parallel bars, with a walker and a cane, respectively. Training should be executed at least 2-3 times weekly with a duration of 30-45 minutes each. Patients were supported by a harness suspended from the ceiling by a set of pulleys allowing a defined body weight support (BWS). Whenever necessary, 2 therapists supported the gait pattern, especially the dorsal extension in the ankle at the beginning of the swing phase as well as the manual knee extension and stabilisation during the stance phase. In the first therapy sessions an initial speed of the treadmill of 0.6-1.4 m/s was chosen. At the beginning of therapy and in fixed intervals during therapy a manual muscle function test and a functional testing in defined positions were carried out. Furthermore we documented various treadmill parameters, the degree of body weight support, the frequency and intensity of spasticity as well as the elicitability of flexor and extensor reflexes.

RESULTS

The patients performed *Laufband* training over 5-13 weeks with an average of 2.1 training sessions per week with a duration of 30-45 minutes each. In the course of the therapy, 6 patients showed at least a doubling of walking distance and time, although, in some cases, the duration of therapy was relatively short. The average speed in these patients could be increased by approximately 0.4 m/s. On the one hand, patient no.6 showed no significant alterations of these parameters, on the other hand, after only 4 weeks, he was able to take a few steps with a cane without major support, while, prior to therapy, he was not even able to get up. Regarding the reduction of body weight support, after 5 and 13 weeks of treadmill training, respectively, 2 patients needed the same weight as before. In the case of 4 other patients, BWS could be reduced by 15-35% of the initial value. In particular in patient no.4 an improvement of his pronounced spasticity could be noticed in the course of therapy. In patients no.3 and 4 considerable flexor and extensor reflexes were registered already during the first therapy units. As of the 7th therapy unit, patient no.2 (tetraplegic) was able to walk more than 200 meters with more or less support from the therapists, while he continued to show no voluntary muscle activity during rest. In patient no.5, who has been performing a functional electrostimulation for more than 5 years, an electrical stimulation of the peroneal nerve was needed to elicit the dorsal extension on the left side even after 20 therapy sessions.

DISCUSSION

Our preliminary results regarding locomotion therapy in spinal cord lesions confirm the findings of other investigators that spinal gait automatisms can be evoked by regular walking on the treadmill combined with BWS in the form of coordinated flexion and extension movements. Even with less frequent weekly training sessions we could make considerable functional progress. In agreement with other recently published studies /8/, we were able to show that also chronic paraplegic patients can benefit from this kind of therapy. The decrease in the frequency and intensity of spasticity in patient no.4 in particular, contrasts with the increase in spasticity in other patients during therapy. At present, this prevents us from predicting the influence of the treadmill therapy on the frequency of spasticity.

Our preliminary results not only demonstrate the therapeutic potential of spinal locomotion in incomplete spinal cord lesions as an adjunct to conventional rehabilitation programs, but also highlights the necessity of further investigations.

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INJECTABLE MICROSTIMULATORS AND MICROSENSORS

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SUMMARY

Hermetic sealing of miniature, cylinder-shaped electronic devices into glass capillaries has proven to be adequate for long term in-vivo implantation, as demonstrated by implantable transponders and Microstimulators. The success in encapsulation techniques and the complexity of the control required in Functional Electrical Stimulation (FES) has prompted the development of Microtelemeters: externally powered, controlled, and monitored implantable sensors/transducers that would allow closing of the stimulation control loop. Examples of transducers and sensors include implantable joint angle goniometers, accelerometers and temperature sensors. The oblong cylindrical shape of the glass capsule with electrodes on each end is also well suited for detection of biological signals, originating from afferent or efferent neural signals or from natural or stimulated muscular activity. The extremely small size and shape of the Micromodules (Microstimulators and Microtelemeters) make them suitable for implantation with minimal traumatic intervention, i.e. by insertion into the site through the lumen of a hypodermic needle. A single external coil can be used for both powering of Microstimulators and Microtelemeters and for receiving of telemetered data.

STATE OF THE ART

Implantable electrical stimulators have become an integral part of several Functional Electrical Stimulation (FES) clinical applications. Initially used in the late seventies /1,2/ and improved in the late eighties /3/ as single channel stimulators to correct foot-drop, they have developed into multichannel stimulators to facilitate hand control in tetraplegic, and enable simple locomotion of paraplegic patients /4,5/.

Multichannel implants in most applications appear as "centralized" implants in the form of a hermetically sealed electronic circuit with lead wires and electrodes reaching to the stimulation sites. "Distributed" multichannel implants were first introduced in 1975 /6/. They consist of multiple addressable single channel stimulators powered and controlled from the same external controller and antenna. Their properties, advantages and disadvantages are discussed elsewhere /7/.

Among the transducers used in FES for ambulation, goniometers placed over joints and ground reaction force transducers are most commonly used. However, they have only been used in laboratory settings and are highly impractical for everyday use because of their bulk, dangling wires and time consuming application. As is the case with stimulators, the best way to minimize the detrimental impact of external sensors is to miniaturize and hide them under the skin. In 1984 Troyk et al /8/ described an implantable goniometer which could sense the differential field produced by two implanted magnets. Recently, a new technique has been developed that allows recording of electroneurographic activity generated by skin receptors /9/. The combination of implanted goniometers and the measurement of afferent nerve signals may open new possibilities for closing the control loop in FES applications.

MATERIALS AND METHODS

The Microstimulator and its power and control systems have been developed over the last six years under a contract with the National Institutes of Health. During the first three-year contract period, a first generation Microstimulator was successfully built that met or exceeded most of the required specifications. It is characterized by small size (14mm x 2mm dia), 256 addresses, ability to deliver current pulses with amplitudes from 0.1 mA to 30 mA and pulsewidths from 3 μs to 256 μs. Over the last two years, these devices have been tested chronically in five cats, demonstrating their safety and effectiveness.

Microtelemeters, with the same shape and dimensions as Microstimulators, are being developed to complement the microstimulators and to make possible closing of the FES control loop. Again, as with Microstimulators, a custom chip is required to identify individual telemeters, define their function (sensor, transducer), operation mode (idling, sensing, signal processing, or transmitting), and other features. One self resonant coil is required for powering, controlling and reception of processed data with a small off-chip capacitor to maintain operating power. Biocompatibility is achieved by hermetic glass encapsulation.

Microstimulators and Microtelemeters may reside and operate in very close proximity. The Microstimulators deal with relatively large signals and are not sensitive to minor EM field variations caused by nearby devices. The Microsensors, on the other hand, manage signals with amplitudes as low as a few microvolts. Therefore both stimulation pulses from Microstimulators and the EM field from the external powering antenna can critically compromise the effectiveness of the Microsensors. It is obvious that for the cooperative operation of Micromodules, a protocol different from the one used in Microstimulators alone has to be utilized. First, we must turn off the transmitter carrier while the transducer/telemetry modules collect and process transducer or biological signals and also when they telemeter the processed data out to the external controller. Second we must disable all unwanted Microstimulator outputs at least during the signal acquisition.

The required conditions are provided by a half-duplex protocol. In this scheme, the external transmitter is turned on for a period of time sufficient to charge an energy storage power supply capacitor contained within the Micromodule. During this time the Micromodule only decodes incoming information. Following this charge-up period, the transmitter is turned off, the Microtelemeter senses the loss of carrier and, according to the information received either collects and processes data or begins to telemeter these data. Further advantages of this system are that the extracorporeal controller does not have to filter out the large transmitter carrier when trying to detect the extremely small telemetry signal and that the same frequency can be used for power transfer to the Microtelemeter and for telemetry from the Microtelemeter back to the external controller. The disadvantage of this scheme is that a large, off chip, energy storage capacitor has to be used. The Micromodules must contain sufficient energy storage so as to permit transmitter interruptions of up to 3 msec. Calculations which use typical values of power consumption indicate that at least a 10,000 pF capacitor is required to maintain the power supply of the Microtelemeters.

A novel modulation method has additionally been developed, called "Suspended Carrier Transmission Scheme" using a Class E oscillator in which the oscillation can be instantaneously stopped and restarted with almost no power loss. The period of time during which the oscillation is suspended can be varied to encode incoming data. The Suspended

Carrier scheme allows a very high data transmission rate and sophisticated data encoding strategies.

Joint angle measurement

Several different schemes for measurement of joint angles using bidirectional Micromodules have been proposed and evaluated. One uses RF triangulation . A reverse telemetry signal from an "emitter" Micromodule on one side of a joint is sensed by a transducer/telemeter Micromodule on the other side of the same joint. The strength of the signal is proportional to the angle between two long coils used as receiver/transmitter antennas. Preliminary experiments show that a signal strength change measured on a receive Micromodule from such an emitter module is 5 mV for every 5 degrees of angle change. The measurement was made at a distance of approximately 1inch, with the transmitter module excited with 5 volts at 470 kHz. These data readily demonstrate that the RF triangulation approach is viable and that magnetic field measurements can be avoided. The method, of course, requires on chip amplifiers with sufficient bandwidth and gain to measure the microcoil voltage. This measurement must be made during the external controller transmitter off times.

Bioelectric signal measurement and processing

The ability to store operating power during suspended-carrier conditions also enables the storage of infrequently changed parameters in static RAM on the CMOS IC chip. Key features include:

Logarithmic series for variable amplifier gains (powers of 2) and stimulus currents (steps of 3.5%) to facilitate use over very wide dynamic ranges (1X - 64000X gain, 10μA - 40mA, respectively)

Bin-integration for extraction of area-under-the-curve measurements of wide bandwidth bioelectric signals such as EMG, with digitally defined sampling bins

Dynamic reprogramming of sensor gain and integration time to fine-tune a relatively low-resolution digitizer (8 bits) for optimal performance with wide dynamic range signals

Pipelined sampling, in which a device is commanded to telemeter out a previous digitized and stored value while receiving the trigger conditions and parameters for the next sampling period

Low-power signal filtering using dedicated IC circuits

DISCUSSION

The Micromodules approach to control and monitor FES movements represents a considerable improvement when compared to conventionally used FES based rehabilitation technology. The possibility of closing the control loop with implantable sensors along with the implantable stimulators will usher in an entirely new level of FES system integration, bringing many clinical applications from research curiosity to accepted practice, particularly for disabilities where FES has proven its functionality but has been rejected because of poor patient acceptance.

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ENERGY TRANSFER PERFORMANCE FOR SENSOR POWER WITH AN IMPLANTED FES SYSTEM

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SUMMARY

The transfer of power to a sensor circuit is described for use with a multichannel stimulation system based upon a cochlear implant. One of the unique features of this system is its capability to measure voltages on any of its 16 leads and to telemeter this information to the extracorporeal controller of the system. Sensors could be employed to provide closed loop control of electrical stimulation using this system. The issues of power generation for use by such a sensor and the implementation of these features are the subjects of this discussion.

INTRODUCTION

The Clarion™ cochlear stimulator was developed as an orthotic device for the deaf. Its function is to stimulate the auditory nerve via an array of sixteen miniature electrodes distributed along the end of a single multiconductor electrode lead. The Pulsar™ implantable FES stimulator consists of the modified electronic circuitry of the Clarion™ cochlear implant, hermetically sealed into a ceramic case brazed to a metal band with a header that contains four quadruple feedthroughs. Seventeen four-inch long wires exit the cast epoxy header protecting the feedthroughs. Sixteen leadwires connected to the feedthroughs provide sixteen stimulation and/or sensing channels. The seventeenth lead is connected to the metal header and is used for an indifferent electrode. In-line connectors are used to extend the lead wires from the stimulator to the stimulating electrodes.

The implant package receives data and energy required for its operation from an external antenna via inductive coupling. A 49 MHz amplitude-modulated carrier is used to transfer data into the implant with an information transfer rate of 1.1 Mbit/sec. The same 49 MHz signal also supplies the power for the implant circuitry as well as for the stimulation current.

Backtelemetry

The implant communicates with the external device using a separate telemetry channel. It operates at 10.7 MHz and employs frequency modulation. It operates in two modes. In the first mode, the carrier is turned on as soon the implant receives both enough power for operation and a unique data string from the external control unit. The presence of this carrier signals the external device that the implant is operating correctly. If the implant detects an error in the forward transmission it turns off the backtelemetry carrier, forcing the external device to restart the initialization procedure.

The second mode is the data transmission mode. The implant circuitry contains an analog to digital converter circuit (A/D) that is connected, via a multiplexer, to a number of internal nodes of the circuitry. This mode is activated by specific ninth-word commands. Signals which may be monitored under control of these commands include the stimulus output voltages and currents as well as power supply levels. This feature also allows monitoring of electrode/leadwire impedance thus providing a means of system fault identification. Sensors attached to the Pulsar™ could also provide voltages related to the state of the sensor. Other ninth-word commands are used to turn the A/D converter on and off to conserve power, and to set the gain of the A/D preamplifier stages. Five different gains from x1 to x100 can be programmed. The A/D subsystem has 6 bits of resolution and at maximum gain, the resolution is 2 mV. Transmission of backtelemetry data is synchronized with the incoming frame pulses, with one bit of information sent per word time.

Output stages

There are eight identical output stages. Each one is a current source, or sink, that can provide currents between 2.4 μA and 6 mA. Under control of the ninth-word commands, each output stage can be configured as an isolated bipolar source/sink or as a dual monopolar source/sink against the indifferent electrode. Furthermore, any two electrodes of the 16 may be configured as an electrode pair. In addition, an internal discharge resistor can be connected across the outputs on each of the channels and each channel can be individually disconnected from the external electrodes. The coupling between the output stages and the electrodes is made via 1 μF coupling capacitors. These capacitors are absolute necessary to prevent any DC leakage currents from damaging either electrodes or tissue.

Sensor and Implant Integration

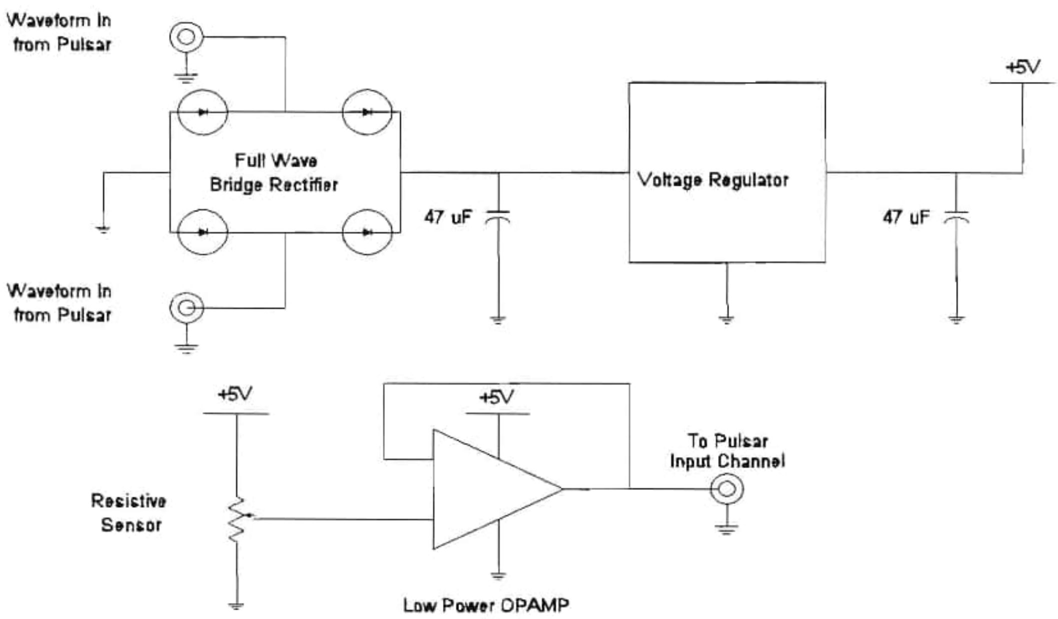
In order for a sensor to utilized by the implanted Pulsar™ FES system it must be electrically connected to one of the stimulus output leads and have a reference connection to the indifferent lead. If the sensor has its own power source then this is the only connection necessary. If however the sensor requires external power, this may be supplied by a stimulus output lead.

If the outputs of the Pulsar™ did not have series capacitors then 6 mA DC could be supplied to external sensor circuitry for short periods of time, limited only by the implant power supply capacitors. This would be inherently a dangerous condition as any leakage in the system could allow DC currents to be passed to exposed metallic components potentially causing corrosion and tissue damage. The only other option is to use the AC coupled stimulus pulses to generate power for the sensor. This has been achieved experimentally by using the symmetrical biphasic pulse generation capability of the Pulsar™ to drive a full-wave rectifier bridge and storage capacitor.

The maximum pulse output from a single lead of the stimulator is 6 mA with a maximum voltage of about 10 volts using a 14 volt refresh voltage. In an FES application where pulses are being generated at a maximum frequency of 100 Hz with a combined phase duration of 1 mS, this means that this power supply could be refreshed with a 10% duty cycle. This means that significantly less than 0.6 mA continuous current is available to power a sensor and its conditioning circuitry.

RESULTS

In an actual test of the system, a single bipolar channel was used to generate a biphasic rectangular pulse to a full wave rectifier. This was filtered with a 47 uF 16VDC tantalum capacitor and was fed to a MAX883 5 Volt voltage regulator. The typical quiescent current consumption of this device is only on the order of 15 to 20 uA. The output of the voltage regulator was filtered with another 47 uF 16V capacitor. The output of the regulator was fed to a variable resistive load and the output of the regulator was observed on an oscilloscope. As the load was decreased to 9 Kohm the output voltage was stable with no discernable ripple. This demonstrates that at least **500 uA** of steady state current is available to power an external device from the capacitively coupled outputs of the Pulsar system.



Test Circuit used to evaluate Pulsar for powering and measuring Implanted Sensors

In a separate experiment voltages from an external stimulus load were read and fed back to the external controller using the on-board a/d system of the Pulsar™ and the back-telemetry channel. This was used to determine the impedance of the load to verify electrode integrity.

The output of the opamp in the figure above would have to be gated under control of the power generating channel since the input to the Pulsar™ channel which would measure the sensor voltage is capacitively coupled as well.

From the above description it is clear that a closed loop FES system is achievable with the Pulsar™ system with the addition of a sensor device and its support circuitry. Separate hermetically sealed packages containing their own power source or receiving power and then sending back information pulses to the Pulsar™ could be realized

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VOLUNTARY WIRELESS CONTROL OF FES SYSTEMS

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SUMMARY

The SMT based wireless system making use of radio-frequency medium at 40 MHz was developed. Signals from crutch pushbuttons are coded and transferred from transmitters on both crutches to the receiver. The receiver is firmly attached to the patient's waist and is connected to the stimulator. The wireless control system was designed to suit the requirements of various FES rehabilitative systems from simple one channel peroneal brace to complex multichannel stimulators. An evaluation of the wireless system reliability was carried out.

INTRODUCTION

Considerable efforts have been directed towards investigations in FES assisted gait of complete and incomplete spinal cord injured (SCI) subjects /1/. The Ljubljana FES assisted gait patterns are based on control events triggered voluntarily by the paralysed person. In simple four-channel pattern the gait cycle is divided into a stance and swing phase by pushbuttons built into the handles of the crutches. These pushbuttons are in present systems hard wired to the stimulator. Interconnecting wires between the switches and the stimulator are inconvenient in daily activities and represent frequent source of malfunction. Further, they represent an obstacle during walking and they hinder the patient when standing up or sitting down. Finally, these wires are anaesthetic what can be considered as an important factor for patient's acceptance.

In the future we expect the development of more complex gait patterns which will include also other muscle groups apart from ones that are used in minimal reciprocal gait pattern. Additional control events will be introduced during the gait cycle. It seems that contact force of the crutch may be valuable information and should be therefore included into FES control synthesis. However, transferring the force signals from the crutch to the stimulator would require additional wires. Such solution is not acceptable because of the above mentioned reasons. Therefore, a reliable telemetry system for transferring the control signals from the crutches to the stimulator is of great importance for a SCI subject.

There were only few attempts in the past which were directed towards telemetry system development for the purpose of FES control. Jennings /2/ has developed a system, that uses infrared transmission of pushbutton signals on the crutch handles and provides on/off switching of electrostimulation. The system was specially designed for controlling an FES system which was used in conjunction with mechanical orthosis. The receiver was attached to the side of the mechanical orthosis while the transmitter was clipped onto the shank of the crutch. A reliable communication link was achieved due to the described position of the transmitter and receiver.

Graupe /3/ patented a stimulation system which employs ultrasound wireless link. The telemetry link provides transmission of the switch signals to the stimulator. Switches and the transmitter are mounted on the walker which is used to provide support to the patient during walking. The receiver is mounted in the stimulator which is attached to the patient waist.

Visibility between the transmitter and receiver is required for errorfree communication in both telemetry systems due to the narrow emitting and receiving angle of infrared diodes or ultrasound sensors. In case when the visibility is not assured the infrared or ultrasound communication is not possible. As a consequence the receiver cannot be hidden under the patient's clothing and the transmitter cannot be build into the crutch what is another inconvenience related to the infrared or ultrasound medium. Therefore, the radiofrequency medium was selected for our telemetry system.

METHODS

At the beginning of telemetry system development, certain requirements and limitations were imposed:

1. time delay between pressing the pushbutton and stimulator response should not exceed 100 ms
2. transmitting system should not consume power while not active
3. telemetry system should be designed in such a way that several patients would be able to use it in the same room at the same time
4. transmitter should be installed into a crutch together with the rechargeable power supply, therefore its dimensions should be as small as possible
5. energy consumption of the telemetry system should be minimal
6. the system should provide reliable communication in condition of radiofrequency disturbances

It can be noticed that some of the requirements are contradictory. The use of the rehabilitative system by several patients in the same room at the same time requires frequency separation among the communication channels. In such case it is difficult to accomplish minimal dimensions of the system. One possibility to achieve the first requirement is by introducting the phase locked loop (PLL) principle. However, PLL requires a precise frequency oscillator for reference frequency, a voltage controlled oscillator (VCO), a presetable frequency prescaller (to enable generation of different frequency channels), a phase comparator and finally a low pass filter, all these only for generation of suitable carrier frequency. By the application of the mentioned principle and with electronic components that are available on the market, we can design, for example, frequency synthesiser from 143.82MHz to 148.92MHz with channel separation of 20kHz. This enables 256 different communication channels. But this solution would comply with only the third while disregard the fourth and the fifth requirement. The power consumption of system would be 40mA at 5V, what is rather high. The system would consist of large number of components what increases the volume of the system. Therefore, this solution is not acceptable.

Another possibility to achieve several communication channels is by use of crystal oscillator in frequency range where a wide pallete of crystals is accessible on the market. In this way we could separate channels by simply replacing crystal resonator in both transmitter and receiver. Manufacturers offer more than sixty frequency channels in 27, 40 and 49MHz band.

An important issue in radiofrequency transmission is also the question of transmitting and receiving antennas. Since the patient uses a crutch, it is natural to employ crutch as a transmitting antenna. Generally, the antenna length is reciprocal to the used carrier frequency. Frequency of 150 MHz is optimal for average crutch length.

Another important issue is the type of modulation used. In today's commercially available telemetry systems there are employed only two mudulation techniques. Frequency modulation (FM) offers better quality of transmission than amplitude modulation (AM), while the latter requires substantial reduction of complexity of modulating and demodulating circuits. In case when only the state of signal is relevant (low or high state, i.e. digital signal) AM is adequate choice, since the quality of transmission is not of the main importance.

According to the findings from the previous paragraphs, we developed telemetry system employing ASK (amplitude shift keying) modulating principle and operating in 27 MHz band. Our intention was to use different crystals in order to obtain different communication channels what would fulfil also the fourth requirement. The system was built around two integrated circuits dedicated for control of plane models. The crutch was cut in half, thus providing dipole antenna for transmission. The receiver antenna was 15 cm long wire. The receiver used single superheterodyne principle. The transmitter was placed into the crutch together with the power supply and the receiver was placed into separate plastic case which was tied to the patient's waist.

For the purpose of comparison we also tested a commercial telemetric system operating at 433.92 MHz and also using ASK modulating principle. The output power of both telemetric systems was 10 mW. The bandwidth of our receiver could be set either to 10 kHz or 100 kHz, while the commercial system had 400 kHz bandwidth.

RESULTS

The evaluation which is described in details elsewhere /4/, revealed that system operating at 27 MHz behaved reliably in all environments evaluated (room with no RF disturbances, presence of microwave device and presence of running car engine) while that was not the case with wider bandwidth configuration. The commercial system operated reliably only in case of no RF disturbances. The range of commercial system was at least 100 m due to optimal antenna size which was realisable within this wavelength. The evaluation also revealed that our developed system operated reliably only when patient held the crutch and wore receiver firmly attached to the waist what shows very limited range of system operation.

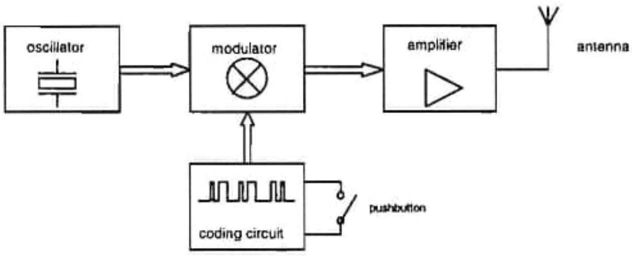

Figure 1 Block scheme of transmitter

This gave us an idea to use patient's body as part of transmitting antenna which is closely coupled to the receiving antenna. In this way we would obtain a reliable transmission of control signals from the crutch pushbuttons. On the other hand poor sensitivity of receiver by using very small antenna in comparison to the wavelength is highly desirable in our application. In this case we would not need channel separation since the operating range of the system is practically only across patient's body.

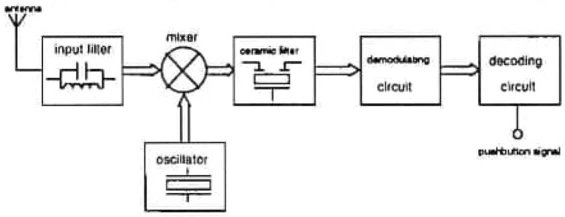

Figure 2 Block scheme of receiver

According to the findings of the evaluation we developed the final version of the telemetric system. We retained the principle of the previous system and we used SMT (surface mount technology) parts in order to reduce the size of the system. The "hot" part of the antenna is patient when pressing the pushbutton whose metal case is connected to the transmitter and the "cold" part is represented by the crutch. The receiver antenna is the clip which is also used for attaching the receiver to the patient's waist. In the Figure 1 and Figure 2 we see block schemes of transmitter and receiver.

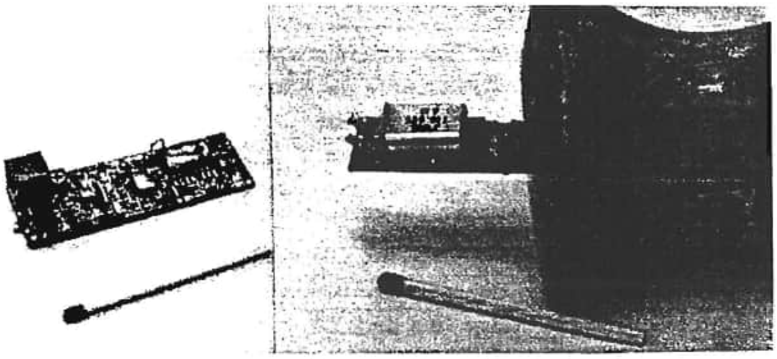

Figure 3 The receiver and transmitter printed board circuits

Figure 3 shows the printed circuit boards of the receiver and transmitter. The following table summarises technical properties of the telemetric system.

	TRANSMITTER
OUTPUT POWER	5 mW
MAX. MOD. FREQ.	2 KHz
VOLTAGE SUPPLY	6 V
CURRENT DRAW	5 mA

	RECEIVER
INTER. FREQ.	455 kHz
BAND WIDTH	10 kHz
VOLTAGE SUPPLY	4.8 V
CURRENT DRAW	5 mA

DISCUSSION

We developed small size, interference resistant telemetry system for wireless control of FES assisted walking. System in present state employs a coding and decoding circuit for pushbutton signals transmission. In future the system should transmit also the information of force on the tips of the crutches while the pushbutton signals will be incorporated into the digital force signal.

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A USER-FRIENDLY FES SYSTEM FOR THE REHABILITATION OF HEMIPLEGIC PATIENTS

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INTRODUCTION

Since the work of Liberson [1], several surface FES systems have been implemented for the rehabilitation of hemiplegic gait [2, 3]. Generally they have all benefited from advances in electronic technology, making them cosmetically acceptable and more reliable. As part of the FES research project at the University of Surrey we are investigating two of the major remaining problems with hemiplegic gait re-education using electrical stimulation. These are the application of closed-loop techniques to account automatically for any internal or external perturbations, e.g. fatigue and spasms, and environmental obstacles [4], and the development of software and hardware tools to maximise the ease with which the electrical orthoses can be set up by the bioengineer and therapist. This paper reports on the development of a two channel FES system which enables user-friendly, on-line control and subsequent programming of the stimulating parameters with a personal computer (PC). The friendly human-machine interface and the stimulator's flexibility is expected to encourage the system's application in the exercise and gait re-education of hemiplegic patients.

METHOD

The proposed system can be divided into three distinct areas: stimulator, stimulator-PC communication protocol and PC control/programming software. Each of these will be discussed in the following sections.

Development of the stimulator. A portable, dual-channel, dual microcontroller-based stimulator has been developed and evaluated on a population of hemiplegic patients. A block diagram of the stimulator system is shown in fig 1.

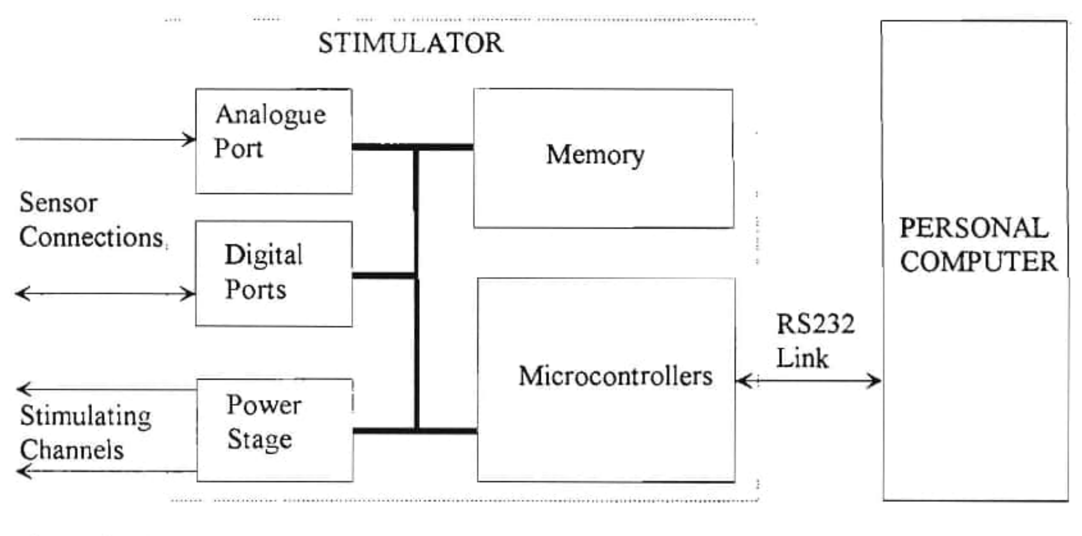

Fig 1. Block diagram of stimulator system

It incorporates; 32Kbytes of EEPROM, 8Kbytes of RAM, digital/analogue inputs, an 8 bit digital output port, a 5V reference output and an RS232 link for direct communication with a PC. The maximum output from each channel is a pulse train of amplitude 120 Volts, frequency 100 Hz and pulsewidth 300 µs (using a 1k//100nF simulated load). It is powered by a standard PP3, 8V4 battery. The stimulation parameters can be controlled by the microcontrollers, which in turn can be controlled by the PC via the RS232 link. The latter makes the stimulator a strong experimental tool since control algorithms currently being developed in a High Level Language (C++) on the PC, can, after minor modification, be compiled and the resulting code ported to the stimulator.

Development of the stimulator-PC communication protocol. A simple three wire (transmit data, receive data and ground) RS232 serial interface is used for communication between the stimulator and the PC. The communication parameters are:

- 19,200 baud
- 1 start bit
- 1 stop bit
- 8 data bits
- Even parity

The transfer of data is initiated by the PC upon reception of an Initialisation Byte sent by the stimulator. This byte is transmitted once every 50 ms. Once this has been received successfully by the PC, the transfer of information conforms to the protocol illustrated in fig 2, if the PC wishes to send data to the stimulator, or fig 3, if the PC wishes to receive data from the stimulator. In both cases the data block may be up to 7 bytes in width (only 2 shown in figs 2 and 3).

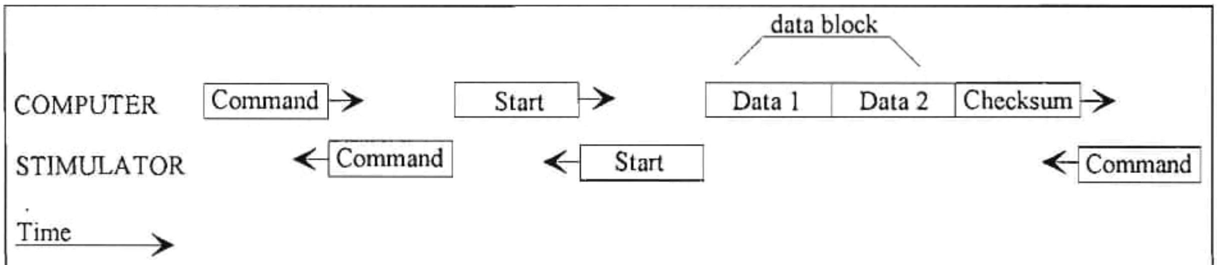

Fig 2. Communication protocol for data transfer to the stimulator

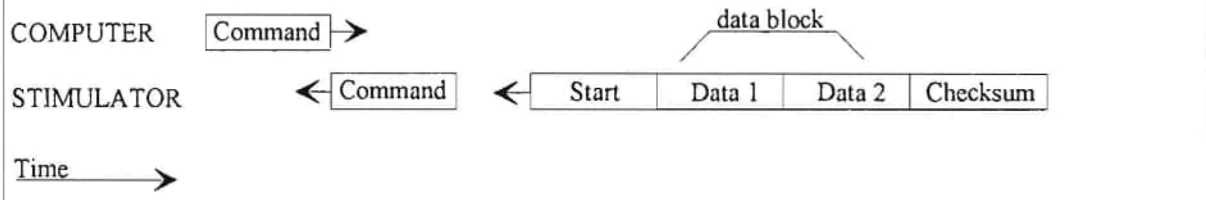

Fig 3 Communication protocol for data transfer to the PC

Two forms of error checking are built into these protocols - parity and checksum. Parity only is used for the single Initialisation, Command, Start and Checksum bytes. Parity and checksum are used for the data block information, where the Checksum is the number of '1's in the data making up the data block. Errors determined by the stimulator are transmitted to the PC in the form of a zero return byte, or a delay in transmission which can be timed by the PC. Should errors occur, then with the present

LabVIEW software unless a maximum number of retries have been made or the PC times out, the PC waits for the next Initilisation Byte and then starts the process again. In our experience to date, once problems in the software had been resolved, this protocol has worked well.

Presently, the communication protocol supports two main modes of operation: STANDARD and SPECIAL. In the STANDARD mode, the stimulator acts as a terminal. It will update the pulsewidth, amplitude and frequency of both stimulating channels upon request by the PC, and will transfer collected digital and analogue information from its input/output ports again when requested by the PC. In the SPECIAL mode it will support the download or upload of parameters between the PC and the on-board open-loop dropped foot program in the stimulator. The details of these parameters will be discussed in the next section.

Development of the PC control/programming software. The LabVIEW virtual instrumentation software package developed by National Instruments was used for the development of the PC software. This was chosen because it allows the construction of user friendly and interactive virtual instrument panels, with a programme execution speed which approaches that of conventional compiled languages. A 486DX40 PC with 8MB RAM was used for software development.

Before developing the LabVIEW software the form of the stimulator based program was agreed. A dual channel open-loop program was decided on. The stimulation amplitude envelopes are shown in fig 4 and are typical of that used in many dropped-foot stimulators currently available. In fig 4, a stimulation sequence is initiated by heel rise (HR) on the affected limb or by heel strike (HS) on the contralateral limb.

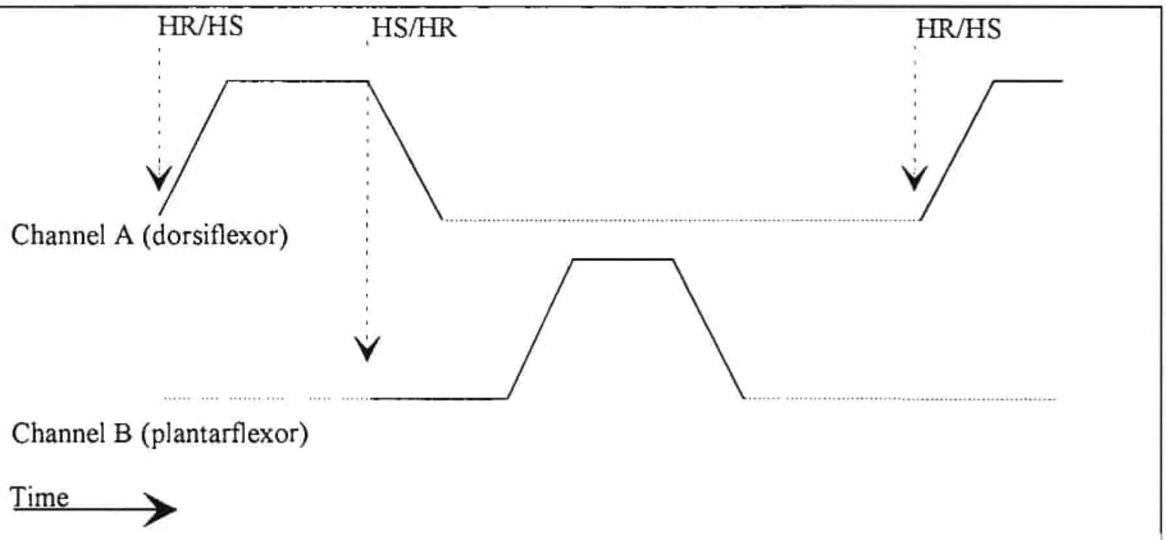

Fig 4. Stimulation amplitude envelopes for the dual channel dropped-foot stimulator

As well as allowing on-line control of the envelope section times, it was felt that stimulation pulsewidth, amplitude and frequency, together with selection of heel strike or heel rise for sequence intialisation, should also be under the control of the operator.

The LabVIEW front panel is divided into 5 sections. The Communication Controls and Indicators section enables selection of the PC COM port to be used, the time out limit to be set and provides an indication of the state of transmission and reception on the serial port. The Heel Switch section allows the operator to select heel rise or heel strike action as the initiator for the start of the stimulation sequence. It also allows the sensitivity of the heel switch to be adjusted. The Channel A and Channel B Control sections allow the operator to alter the stimulation and timing parameters for these channels, or to see the values currently being used in the stimulator. The final section, Mode Control, allows three modes of use:

- READ DATA. Update front panel with values currently held in the stimulator.
- WRITE DATA (temp). Update stimulator with front panel values but do not save.
- WRITE DATA (perm). Update stimulator with front panel values and save.

The difference between the last two modes is that only in the last one will data be saved when the stimulator is turned off. In all cases data transfer takes place when the START switch is pressed. It takes a maximum of 200 ms (4, 50 ms cycles) to read or write all of the data.

CONCLUSIONS

The LabVIEW based interface is currently being evaluated with normals. The next stage is to begin its clinical evaluation to determine what changes, if any, should be made to the layout and form of the operator panel and the core stimulator software.

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AN IMPLANTABLE MULTIPURPOSE 8-CHANNEL TELEMETRY SYSTEM

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SUMMARY

The realization of an implantable µP-controlled 8-channel telemetry system for the measurement of active biosignals like ECG or EMG and passive signals such as impedance, temperature or pressure is described. Additionally mechanical parameters such as force, acceleration and displacement by means of a magnetic field sensor or a differential transformer can be measured. In general all types of sensors which can be configured as a Wheatstone-bridge are suitable for adaptation. The use of a micro-controller (MC68HC705C8), a fast RF-data-telemetry and a slow bi-directional communication link for parameter setting via a magnetic coupling makes the device suitable for a wide field of applications. The scheme of channel selection and signal priority can be configured and re-configured after implantation as well as gain, offset and current source for the Wheatstone bridges for each channel. Maximum sampling-rate is 8kHz (10kHz EMG only) at 8 Bit. Data transmission is realized by digital FM-modulation of a 433MHz carrier. The fully implantable device is battery powered by a lithium thionyl chloride-battery and has a consumption between 300 µA and 4.4 mA depending on the sampling rate. By reducing the µP´s clock frequency for slow-signal-recordings below a sample rate of 100 Hz, the consumption can be droped down to 60 µA. In this case the telemeter prospectively will work for more then 4 years. Full-speed-EMG can be recorded for 27 days - 24 hours per day. The implant is enclosed in a titanium package and has no galvanic path to the environment. As sensors and electrodes are exposed to aging or can break they can be exchanged individually.

STATE OF THE ART

A lot of new electronic components especially analog-digital-converters, micro controllers and amplifiers are characterized in their power saving operation and the feature of power down modus. Therefore an extended field of applications in biomedical engineering problems is offered. Especially battery powered implantable devices use the new technology in order to prolong the time of its operation.

In most applications of implantable measurement devices the recording of parameters from the internal of the body is limited to slow signals in order to limit the power consumption. Typical low-frequency signals are blood-gas variables such as pH, Glucose and SaO2, intracranial pressure, inner body temperature for e.g. hyperthermy-studies and strain gages in bone remodeling. For rate adaptive cardiac-pacing information about the heart rate or sequences of the ECG acts as an input for closed loop systems as well as pressure, SaO2, transthoracic impedance and accelerometric signals. So there is an increasing interest in implantable transducers. Most of the presented devices are constructed for specific questions described above. Previous general-purpose implantable multichannel telemetry systems are not battery powered or are designed for low-frequency signals. Our aim was to develop a configurable battery-powered system which is also able to telemeter higher frequency signals like the EMG.

MATERIAL AND METHODS

The multichannel telemetry system was designed to meet the following specifications: free choice of any combination of channels and parameters up to eight signals, different sampling rates with a maximum of 8 kHz, galvanic isolation, µP-read or control-only modus and last but not least a minimum of power consumption. The principle design of the implant is shown in

Fig.1. The whole system can be divided into the analog-multiplexer unit, programmable amplifier, switchable current source, microcontroller, ADC and control unit, magnetic link and RF-transmitter. All of this units are activated by the control unit in order to save power consumption. Without the µP, consumption is proportional to the sampling rate. (105µA/kHz + 400µA/kHz (RF-transmitter)). The processor consumption depends on the complexity of the software resulting in different crystal frequencies. For example at a simple task converting 4 channels with a sampling rate of 1kHz each, the µP will draw a current of 80 µA. In sleep mode, consumption is reduced to 30µW. Energizing of the short-range magnetic-field-coupling will be realized from an external device and is necessary only during program and parameter setting. The current of the Wheatstone bridges is reduced with a factor of 0.04ms x sampling rate.[kHz].

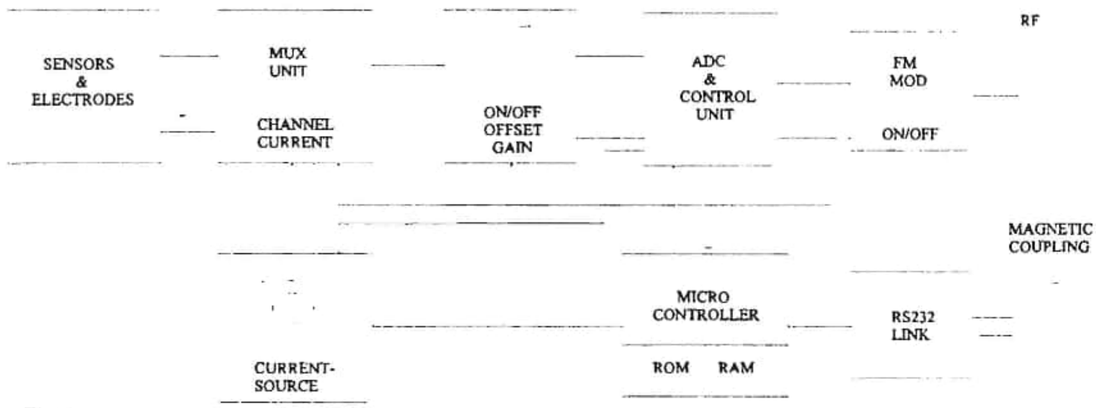

Fig.1

The designe of the packaging provides the possibity to exchange the analog input unit by separeting the circuit in two parts in a pick-a-back way. In the future moduls for problems requiring special electronic design e.g. pulsoximetry or komplex impedancemetry will be built in instead of the 8-channel featur.

Galvanic isolation: The problems and risks arising form DC-current flowing from the electrodes surface into tissue is well investigated. To realize a galvanic isolation by an AC-coupling in order to reject the amplifiers bias current is state of the art. But also the supply of an Weatstone bridge is referenced to this problem, because there is no flexible isolation material that will not open a DC-path after a certain time of implantation. Ion transport will cause tissue damage and corrosion of the leads and electrodes. So we prevent any path of DC-current by choosing a pulsed operation principles and attaching each sensor lead to a capacitor.

RESULTS & DISCUSSION

Function and reliability was tested with surface EMG and EKG, impedance and temperature from the authors body. Telemetry was tested with a dummy in order to simulate the damping coefficient of the body. The implementation of the electronic circuit, battery, glass-feed-throughs and connectors in a laser welded titan housing is realized and we are ready now for implantation in an animal. The advantages of this telemetric device is its flexibility and powersafing operation and therefore the system is suitable not only for implantation but also for all battery powered applications in scientific and clinical tasks, whereas weight and size are limited.

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THERAPEUTIC ELECTRICAL STIMULATION FOR THE PATIENT WITH AMYOTROPHIC LATERAL SCLEROSIS

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SUMMARY

This paper describes the effects of therapeutic electrical stimulation (TES) on the wasting muscles in patients with amyotrophic lateral sclerosis. Percutaneously indwelling intramuscular electrodes were implanted to the affected muscles of the upper and/or lower extremities. Cyclic stimulation with duration of 10 minutes was applied 6 times per day. Within a month of TES therapy, a rapid improvement of motion often appeared in the TES treated extremities. Long-term application of TES more than 3 months showed the maintenance or an increase in muscle strength.

CT findings of TES treated muscles showed an increase in the density and a reduction in the moth-eaten image. An increase in the thickness of the muscles was also observed.

STATE OF THE ART

Amyotrophic lateral sclerosis (ALS) is a rapidly progressive untreatable disease affecting both the upper (the lateral column) and the lower (the anterior horn cells) motor neurons. Recently, therapeutic trials for treating motor neuron diseases including ALS have been reported[1]. However, we have failed to find an article describing the therapeutic effect of electrical stimulation on ALS affected muscles of ALS.

Electrical stimulation to the paretic muscles involved in upper and lower motor neuron disorders, such as cerebrovascular accident, spinal cord injury and brachial plexus injury, induces some therapeutic effects, i.e., an improvement of atrophy and an increase in muscle strength, a reduction of spasticity and so on. It is likely that electrical stimulation has therapeutic effects on the wasting muscles in both upper and lower motor neuron disorders.

This paper describes therapeutic electrical stimulation(TES) on the affected muscles of ALS patients.

MATERIALS AND METHODS

Ten ALS patients (8 males and two females) were selected as TES candidates. Most of the patients except one (patient #1) showed no bulbar palsy and respiratory dysfunction and their motor function of either the upper or lower extremities was still survived for activities of daily living (ADL). The patients and their families knew their illness and its prognosis.

An FES system with percutaneously indwelling intramuscular electrodes (NEC Co. Ltd., Tokyo, Japan)[2] was used for TES application to the paretic muscles of the extremities by ALS. This FES system contains an automatic training mode where the duty ratio and duration of cyclic stimulation can be adjusted.

Electrode implantation was achieved under general anesthesia. Although the electrode was implanted to bilateral upper and/or lower extremities in most patients, the patient #1 agreed to receive electrode implantation to unilateral (right) upper and lower extremities for comparison.

Joint torque were caluculated from the the data which were obtained by electrical tension meter (MICROFET, Hoggan Health Ind. USA) Joint movements of the upper lower extremities were analyzed using a three dimensional motion analyzer(APAS Ariel, USA). Computed tomography(CT) was used to detect the changes in volume and quality of the muscle.

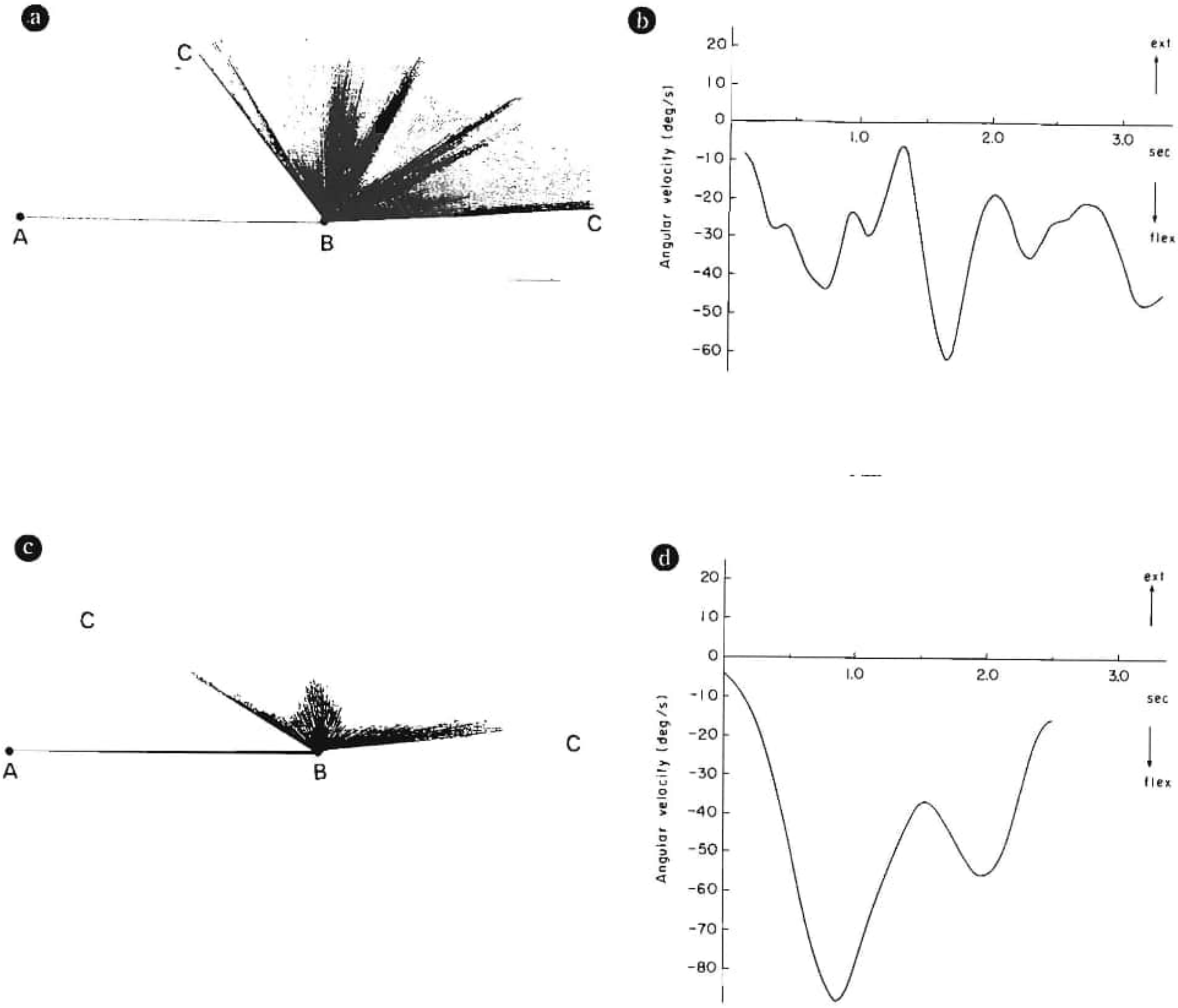

Fig. 1, Motion analysis of elbow flexion
stick picture and angular velocity of flexion of the right elbow before (a, b) and 3 months of TES therapy (c, d), respectively. A - B; upper arm, B - C; forearm

RESULTS

During the first month from the start of TES therapy, rapid improvements in the motion of the TES treated extremities were observed in some ALS patients (short term effects).

The patient #2 who showed difficulty of standing up from a chair of 38cm height could easily stand up from the chair without the aid of the upper extremities after 2 days TES application.

Within 2 weeks of TES therapy, the patient #1 could tie strings with both hands which was very hard to perform before the TES application. The patient #3 also showed an improvement of chop stick operation.

However, six out of ten patients did not show any apparent functional improvement by the short term TES.

Long-term TES application more than 3 months provided further and gradual functional improvement of the extremities in the patient #1.

Fig. 1 shows the motion analysis of voluntary elbow flexion, where the patient #1 was requested to flex the elbow with a constant speed. A stick picture of the elbow flexion showed apparent instability of the movement before TES treatment, with more stability after 3 months of TES therapy. The fluctuation of angular velocity was much smaller in the movement of the elbow after TES therapy than before.

Fig. 2 shows CT findings for the bilateral quadriceps femoris in the patient #1. Before TES treatment, both quadriceps femoris show typical findings of muscle degeneration (Fig 2-a). TES therapy for 3 months caused an apparent change in the CT image as shown in Fig. 2-b. Although the density of the mus-

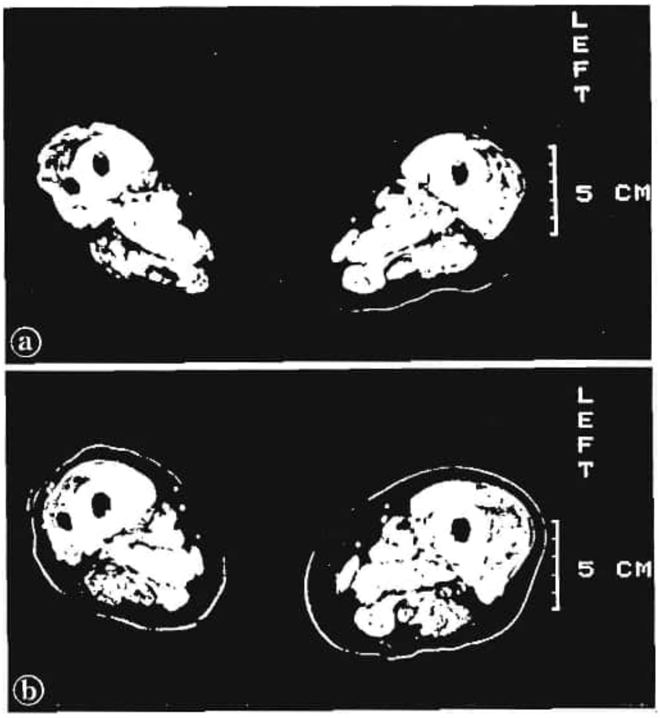

Fig. 2 CT image before and after 3 months of TES therapy
Cross section of the bilateral thighs before (a) and after (b) TES therapy

cle increased in both quadriceps femoris muscles, it was rather dominant in the TES treated muscle. The moth-eaten image observed in the stimulated muscles markedly decreased. The shape of the cross section of the right thigh became round from oval through long-term TES and its circumference decreased. The contralateral thigh showed no change in its oval shape and only a slight increase in the circumference.

DISCUSSION

TES application on ALS patients for more than 4 months brought therapeutic effects to function and morphology of the affected muscle. Neurologically, an ALS process can be characterized by signs of upper motor neuron deficit and/or lower motor neuron loss. The former are the pyramidal tract signs, i.e., spasticity, pathological reflex and hyperreflexia. The latter are the denervation signs such as weakness, atrophy and fascicular contraction of the muscle.

In the process of functional improvement by TES, two phases may exist. One is an relatively acute phase and the other is chronic. The former was observed within one or two weeks from the onset of TES therapy. The latter appeared afterwards and its process was very slow.

Since spasticity in ALS is not usually dominant as compared with muscle waste, it seems that spasticity constitutes only a small portion of motor disturbance[3]. However, joint movements induced by a certain muscle group may be prevented by even a slight increase in spasticity of its antagonists. One of the possible explanations for rapidly appearing therapeutic effects is a reduction of spasticity which is caused by stimulation of afferent nerve fibers within muscle branches of the nerve to be stimulated by intramuscular electrodes.

On the other hand, chronic effects such as increases in volume and force on the muscles stimulated may be obtained by stimulation of alpha-motoneurons. It is likely from the fact that the long-term comparison of the movement and muscle strength between TES treated and non-treated extremities of the ALS patient #1 showed a decrease in laterality in the upper extremity and a reversal of laterality in the lower extremities.

In order to discuss the effects of TES on the wasted muscles of ALS more precisely, further follow-up study with more patients is required.

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EXTERNAL ELECTROSTIMULATIONAL THERAPY FOR CURING SPINAL COLUMN DISEASES

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Private practitioner

SUMMARY

We have worked out an original method and a complex structure for the prevention and cure of spinal diseases, spinal deformations and spinal injuries. The method was tested experimentally and clinically on 200 patients. My original therapy has been combined with electrostimulational therapy. The use of microelectronic technique allows us to reduce the weight and size of the applied electric stimulators and to increase their working period for 5-10 years, thus unlimited number of muscles can be stimulated and the impulse magnitude can be changed. Long term (5-10 hours a day or longer) and multicanal (4-6 muscle groups) electric stimulation was carried out with external stimulation and an original costume for the procedure. This makes it possible to effect the deformed vertebral column during child's growth. Preliminary results of external stimulation suggest the stabilisation of the pathological process and further 40-60% correction of the deformation.

STATE OF THE ART

The basis of the method was laid down at the Department of Traumatology and Orthopaedics of the Novosibirsk Research Institute in 1979, when the permanent implanted electrostimulation method was worked out both experimentally and clinically. The biomechanical interpretation of the cure of the deformed spinal column was provided and the efficiency of the constant and lasting electrostimulation of the deformed spinal column was demonstrated.(1) However, the deficiencies and the potentials of the method made it possible to elaborate a new, original system in order to make a better technological use of the constant, lasting external electrostimulation, which will result in more efficient treatment and its range of application is much wider.

MATERIAL AND METHODS

In the paper the results of the treatment of more than 200 patients with the pathological deformation of the spinal column are shown from 1991. The group consisted mainly of patients with column deformation. Most of the patients i.e. 130 persons suffered from scoliosis and their age ranged from six to forty years. The size of deformation ranged from 10 to 60 degrees. This group can be divided into two subgroups. Patients of six to sixteen years whose deformation ranged from 10 to 30 degrees belong to the first subgroup. The number of patients amounts to 85 patients. The rest of the patients, i.e. 45 persons with scoliosis of 30 to 60 degrees belong to the age group of 16 to 30 years.

Patients suffering from the kyphosis of the spinal column belonged to another group (the Scheuermann-Mauch disease: 33 persons, juvenile osteochondrosis: 12 persons, Lindenmann's round back: five persons and others). Patients of six to sixteen years belong to the first group of 32 persons, whereas patients of 16-30 fall into the other group. The kyphosis deformation ranged from 10 to 30 degrees.

The age of the group of patients suffering from the spondylolisthesis of the L5 vertebra ranges from to 12 to 18 years, the number of patients is 13. The degree of the shift of the vertebra ranged from 15 to 30 %.

The number of patients with the traumatic injury of the spinal column is six, in four cases the injury of the spinal column of the chest was not serious, the patient complained about functional deficiency and pain, the neck part of the spinal column of two patients was seriously injured, one of them had been in total tetraplegia for four years after the injury and two years after the operation of the frontal spondylodes of vertebras C3-C5.

The duration of stimulation, the amount of the muscles stimulated and the position of the electrodes and the amount of manual therapy varied according to the age and the pathology of the patients.

Thus, in case of the kyphoscoliosis (the chest and the waist part of the spinal column) the electrodes were placed in an asymmetrical projection.

In cases of pure kyphosis deformation eight electrodes were placed in the projection and symmetrically with the spinal column.

In case of spondylosthesis the electrodes were placed symmetrically in the projection.
The pattern of treatment varied according to the age group. In the first age group the duration of stimulation was enhanced, whereas the amount of manual therapy was reduced to minimal. In the other age group we increased the amount of manual therapy on account of the smaller plasticity of the spinal column and the tissues that cover the spinal column whose mobilisation requires larger effort.

In case of the serious injuries of the spinal column, the paralysed muscles and the place of the injury were exposed to electrostimulation for 8-16 hours a day.

In the experiments the external and lasting multicanal electrostimulation of the muscles was applied by an original equipment, which did not hinder the patients in their movement and their normal activity.

The electrostimulator consists of a four canal stimulator and the costumes required for the stimulation. The electrostimulator is a small equipment consisting of four stimulation canals with the display of signals, like the rectangular bipolar symmetric impulses consisting of the alternation of the consecutive high and low frequencies. The amplitude of the current is regulated from 0-50 mA. The transfer of electric signals to the tissues to be stimulated is carried out through a skin-tight costume, to which electrodes of any size and shape can be attached. The inside surface of the costume is made of material conducting electric current, whereas on the outside the fasteners of the wires leading to the electrostimulator are fixed.

RESULTS

The results are shown in this table:

	Disease and its phase	patients' number	patients' age	number of electrodes	number of manual therapy	duration of treatment	degree of correction	spinal column pain, functional deficiency before and after the treatment	
1	scoliosis 10-30 degrees	85	6-16 years	8-10	20-60	1-4 years	60%-85%	42	--
	scoliosis 30-60 degrees	45	16-30 years	8-10	40-100	1-4 years	20%-50%	38	1
2	kyphosis 10-40 degrees	32	6-16 years	8	20-40	1-4 years	30%-70%	25	--
	kyphosis 10-40 degrees	25	16-40 years	8	40-100	1-4 years	20%-50%	22	1
3	spondylolisthesis	13	12-16 years	8	20-60	1-4 years	10%-30%	11	--

The degree of correction of scoliosis was measured by Koba's scoliosis protractor. Ninety percent of the patients with scoliosis and their parents complained about the cosmetic faults of the posture (scoliosis, the asymmetric position of the shoulders, the shoulder blade and the chest etc.) After the treatments these complaints came to an end. In case of five patients the stabilisation of the scoliosis was observed, in case of two patients the curvature increased to 10 degrees. In case of three patients the skin looked reddish under the electrodes , which disappeared after putting cream on the skin. In case of seven patients the stimulation triggered pain due to hypersensitivity.

The degree of correction in case of patients with spondylolisthesis was established by the reduction of the shift of the L5 vertebra and the decrease of the angle of inclination of the sacrum. A patient, whose C4 vertebra was seriously injured and had been in total tetraplegia for four years, is able to walk 30 metres a day on his own one year after the treatment.

DISCUSSION

This brief preliminary report has attempted to demonstrate that the spinal column can be corrected by the method, the functional deficiency of the spinal column and the pains can be cured and the function of the injured muscles can be recovered. All these can be achieved by the many-sided, lasting biomechanical stimulation. However, further clinical analysis, and the technological improvement of the equipment and the method of stimulation and biomechanical analysis are required , because the external stimulation effects all muscle layers and every point of the spinal column, its spatial structure and mechanical stability.

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IMPROVEMENT OF MICROCIRCULATORY BLOOD FLOW UNDER EPIDURAL SPINAL CORD STIMULATION (ESCS) IN PATIENTS WITH NON-RECONSTRUCTIBLE PERIPHERAL ARTERIAL OCCLUSIVE DISEASE (PAOD).

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SUMMARY

Epidural spinal cord stimulation (ESCS) has been suggested to improve microcirculatory blood flow and to reduce amputation rate in vascular patients. We studied the effects of ESCS on microcirculatory blood flow in 237 patients with non-reconstructible peripheral arterial occlusive disease. Clinical status was classified as Fontaine stage III (ischemic rest pain) in 169 patients and as Fontaine stage IV (ulcers/gangrene) in 68 patients. After a mean follow-up period of 31,2 months, major pain relief (>75%) was noticed in patients who retained their limbs. Sixty-four patients underwent major amputation despite ESCS. Clinical improvement was confirmed by the increase in TcPO2.

STATE OF THE ART

SCS is a medically accepted therapeutic modality for the control of chronic pain. In patients with ischemic rest pain, not only pain relief could be achieved but also healing of ischemic ulcers (1-5).

MATERIAL AND METHODS

From January 1986 to August 1992, 237 patients with ischemic pain due to non-reconstructible PAOD were treated by ESCS. Diabetic vascular disease was present in 42 patients. The sample group consisting of 83 women and 154 men, ranged in age from 45 to 83 years with a mean of 68.2 years. Clinical status was classified as stage III in 169 and as stage IV in 68 patients. The severity of the pain was rated by the patient as disabling. The duration of the vascular symptoms, ranged from 2.1 months to more than 10 years. Only patients with a systolic ankle pressure of < 40 mmHg (or systolic toe pressure < 35 mmHg) were considered for stimulation. Arteriography was performed and if the crural/pedal vessels were found to be unsuitable for bypass procedure, the patient was considered non-reconstructible. Prior to implantation all patients had received conservative therapy, which was no longer effective. Two-hundred-and-eight patients presented with the typical history of failed peripheral bypass, with a mean of 2.8 procedures on the involved leg. Twenty-three patients had undergone lumbar sympathectomy. Patients with significant cardiac, pulmonary or renal insufficiency, unstable angina or hypertension were excluded.

Visual analogue scale was used to help quantify the pain. Several noninvasive vascular tests were performed, these included systolic ankle/brachial index (ABI), systolic toe pressure, transcutaneous oxygen measurements and capillaroscopy. The TcPO2-electrodes were attached to the skin, the heating element was warmed to 45° C. The measurements were performed at rest in the supine position. One electrode was attached on the dorsum of the foot and one on the chest. The ratio between foot and chest TcPO2 was referred to as the regional perfusion index (RPI) and can be interpreted similarly to the ABI. (6)

Capillary density and red blood cell velocity were studied with the patient in the sitting position. The nailfold capillaries were visualized with a drop of paraffin oil. The following parameters were determined: capillary density (number of capillaries/mm2) and capillary red blood cell velocity (RBCV). RBCV was measured with the flying spot technique, whereby spots move over the videoscreen and can be synchronized with the moving red blood cells. Velocities can be measured in different ranges, equivalent to 0.01 to 1.05 mm/s. The flying spot values correlate well and do not deviate systematically from the reference in practical use. These tests were performed at 3 months interval during follow-up.
We considered three types of outcome: 1° success: defined as significant pain relief (>75%) and limb survival, 2° partial success: limb survival with pain relief between 50 and 70% or limb loss after a period of temporary success (minimum 6 months) and 3° failure: no or little pain relief under stimulation with limb loss during the first 6 months of stimulation.
The technique involves placing a quadripolar lead into the epidural space at the level of Th 11-12. Connecting a portable stimulator to the lead allows intraoperative test stimulation producing comfortable paresthesias in the painful foot or limb. During a trial period of one week the clinical effects are monitored. When the patient has experienced adequate pain relief an externally implantable pulse generator is placed in a subcutaneous pocket of the abdomen. The usual initial settings are a pulse amplitude varying between 1.0 - 2.5 V, a frequency between 70-120 Hz, and a pulse of 180-450 microseconds.
The data are presented as mean values and standard deviations. For comparison of group means, analysis of variance was used, with a two-tailed t-test. $P < 0.05$ was chosen as the level for statistical significance.

RESULTS

All patients experienced pain relief during the first weeks after implantation, varying between significant pain relief (>75%) or lesser degrees of pain relief. In 158 patients (66.6%) the obtained ischemic pain relief documented by VAS was maintainted throughout follow-up. Initial positive results on ischemic pain dropped during the ensuing months (mean of 8.7 months) in the remaining 34 patients. Severe ischemic pain developed once again, leading to above-knee amputation in 3 stage III and 5 stage IV patients and to below-knee amputation in 6 stage III and 5 stage IV patients. ESCS was ineffective in controlling ischemic pain from the start in 45 patients. All these patients underwent major amputation within the first 6 months (mean of 3.6 months) after implantation. The cumulative limb survival rate showed a 64 % 4-year-survival. Twenty-eight patients died during follow-up; 22 due to heart failure, 1 due to septic shock following a stump infection post-amputation and 1 from a cerebrovascular accident. The cause of death remained uncertain in 4 patients. There was no method-related perioperative mortality.
Data of two-hundred-two patients were included into further analysis. No significant changes were noticed in the ABI or toe pressure values before implantation and during follow-up in patients with limb survival. TcPO2 foot values in the stage III patients with limb survival increased from 21.7 +/-4.3 mmHg to 44.5 +/- 6.1 mmHg ($p<0.025$) and the RPI from 0.47 to 0.85. In the stage IV patients with limb survival, TcPO2 foot values showed an average improvement from a mean of 14.3 +/-5.8 mmHg to 33.2 +/-

5.3 mmHg ($p<0.031$), RPI increased from 0.29 to 0.68. Videocapillaroscopy was performed in 66 patients. Problems like bad visualisation, no blood filled capillaries or restless legs during the examination led to the exclusion of 19 patients. The study of capillary density in 47 patients revealed an increase in the number of perfused capillaries under stimulation from 12 +/- 8 to 20 +/- 7 ($p<0.01$). Mean capillary RBCV increased from 0.11 mm/sec. before stimulation to 0.29 mm/sec. during the follow-up ($p<0.021$). Technical complications interfered with the procedure in 23.5 %. Breaking of the probe and dislodgement were recognized by a change or loss of the stimulation-produced paresthesias. Lead break occurred in 12, dislocation in 30 patients, usually within the first 2 months following implantation. In 22 of these 30 patients replacement was necessary and posed no special difficulties. In the other 7 patients comfortable paresthesia could be restored after reprogramming the system. Seven patients developed an infection around the device that required its removal. In 3 other patients skin necrosis occurred over the generator; in two of these cases an immediate reimplantation was possible, the other patient developed an infection of the generator pocket. Liquor fistula also complicated the procedure for 2 patients, and resolved on its own.

DISCUSSION

The precise mechanisms to explain the effect of ESCS on pain and peripheral blood flow still remain uncertain. A neurophysiological explanation is based on the Gate Control Theory of Pain postulated by Melzack and Wall in 1965. (7) This theory of segmental pain inhibition postulates that the stimulation of large afferent nerve fibers in the dorsal columns of the spinal cord prevents the transmission of pain information from smaller diameter pain fibers. Relief of ischemic foot pain might be assisted by improvement of the microcirculatory blood flow resulting from a release of sympathetically mediated vasoconstriction, the inhibition of normal sympathetic activity and the release of vasoactive peptides or prostaglandines. There is also the possibility that ESCS may act by releasing neurotransmitters involved in pain modulation. (8,9) Pain relief is definitely assisted by improvement of the microcirculation as shown in different experimental and clinical studies. (8,10,11) The results of experimental work done by Linderoth, indicates that spinal mechanisms are essential and that antidromic activation of primary afferents is unlikely to account for peripheral vasodilation. (12) We have studied the effects of ESCS in 237 patients with clinical and angiographic evidence of non-reconstructible PAOD. The majority of the patients (81%) noticed immediate pain relief; this relief appeared to be most effective in stage III. In 66.6% of the patients the improvements were maintained for as long as stimulation was continued. TcPO2 and capillary RBCV were chosen as objective parameters of the microcirculation. These values showed a significant overall increase in the patients with limb survival following the stimulation. This increase in cutaneous blood circulation and explains the clinical improvement. It is unlikely that the increase in skin perfusion is caused by an improved arterial inflow since the ABI or systolic toe pressure did not show significant alteration. In the 64 patients who went on to major amputation, TcPO2 did not rise under stimulation. An increase of the TcPO2 with +/- 20 mmHg can be applied predicatively to divide the patients into responders and non-

responders. However, it takes 3-4 months on average before the net changes are evident. The best clinical results were achieved in patients with a significant TcPO2 increase and in patients with previous rest pain.
In effect ESCS is an effective treatment modality in controlling ischemic pain in non-reconstructible patients and is therefore a technical advance in the field of ischemic pain management. Prospective randomized studies are necessary to evaluate the effect on ulcer healing and limb salvage.

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CONTROL OF HYPOTENSION IN SCI USING ELECTRICAL STIMULATION

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BACKGROUND

Orthostatic hypotension occurs following spinal cord injury: blood pressure drops when the individual moves to an upright position. Symptoms include loss of vision, dizziness, ringing in the ears and fainting. These symptoms are common in the early phases and although a tolerance develops it can impede progress in rehabilitation and for some patients these symptoms persist and are problematic for upright activities of daily living.

This also imposes a severe limitation on attempts to stand (using stand-up wheelchairs, standing frames, orthoses or FES) spinal cord people with high thoracic or low cervical levels. The motivation for the present studies arose out of attempts to stand high level paraplegics using the hybrid FES system described in /1/. This hybrid system incorporates ankle foot orthoses of the floor reaction type and a knee control system that reduces quadriceps stimulation to a minimum (typically 5% of standing time). The first individual with a high lesion complained of the symptoms described above when using the hybrid system but not when using open loop FES control in which bilateral stimulation was applied continuously. In the hybrid standing time was limited to a few minutes by orthostatic hypotension and in the open loop case FES induced quadriceps fatigue limiting the standing time to less than seven minutes. We are now seeking a solution to prolonging standing for high level lesions who suffer from these symptoms and possibly the problem more generally in spinal injury.

Here we present some preliminary results.

METHODS

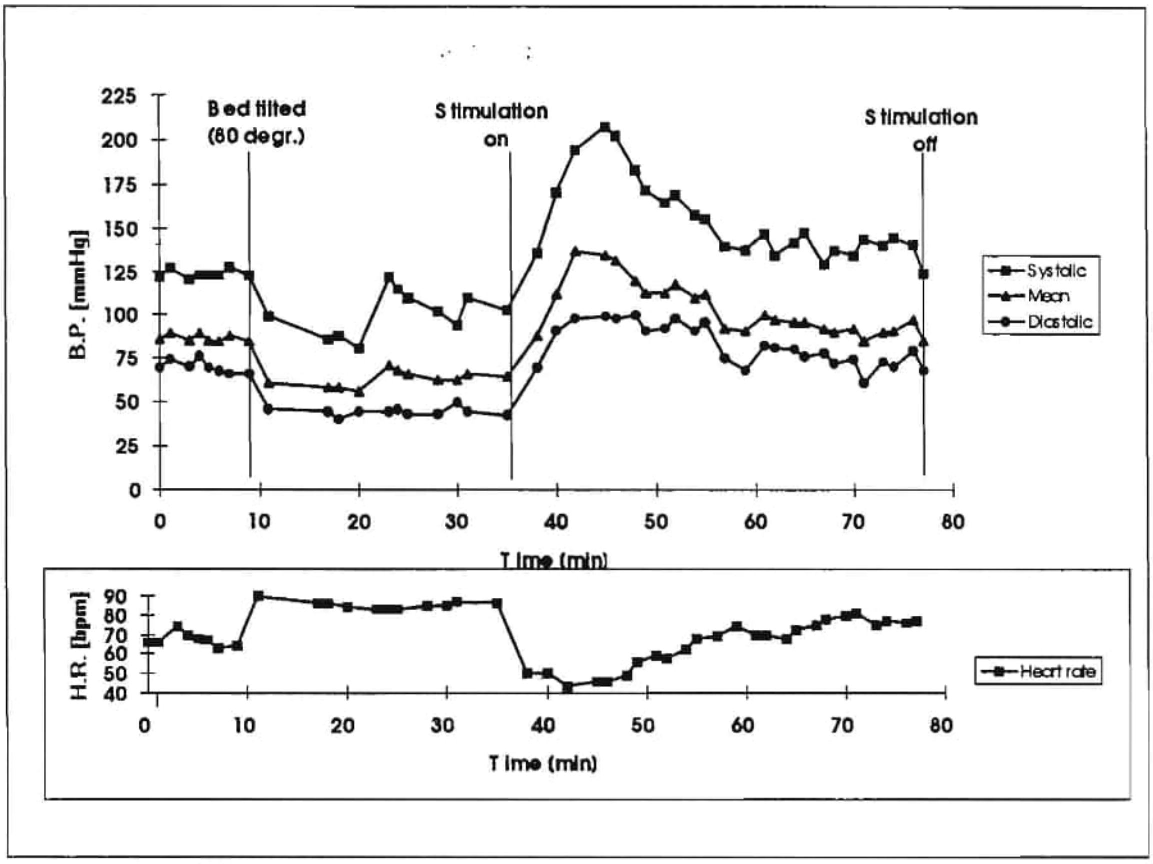
Recently we have conducted preliminary tests involving two spinal cord injured volunteers with high spinal lesions.

The test protocol:

1. Resting period in the horizontal position for at least 8 minutes during which heart rate and blood pressures (systolic, diastolic and mean) were recorded at one minute intervals using a computer controlled system.
2. Tilt table raised to 80 degrees. BP & HR recordings continued at one minute intervals for 25 minutes.
3. Bilateral electrical stimulation (35Hz, 300μs pulse width, 90mA) applied to quadriceps using Pals+ surface electrodes. BP & HR continue to be recorded every minute for at least 20 minutes.
4. Stimulation switched off, tilt table returned to horizontal position, test terminated.

The blood pressure and heart rate was measured with computer controlled system using an inflatable forearm cuff (supplied by Dynapulse Inc., Ca, USA). The recording took approximately 45 seconds. Occasionally a reading was incorrect due to motion artifact and was eliminated from the record. Stimulation was applied using a custom designed programmable unit controllable from a IBM PC. Pals+ surface electrodes were used. An IBM compatible PC was used to control the stimulation and log the BP & HR measurements.

The figure below shows a typical record from one subject (male, Age 30, 5yrs post injury, T2 complete, height 1.8 m, weight 190lbs).



DISCUSSION

Figure 1 demonstrates an immediate fall in BP and rise in HR when the table is tilted. This is consistent with previous reports, see for example /2/.

Application of stimulation caused a reversal i.e. an immediate fall in HR and rise in BP. The HR can be observed to progressively rise with time of stimulation. BP's were higher than normal with this level of stimulation.

Previous studies by our group, involving quadriceps stimulation in a group of eleven patients with high spinal cord injuries (seven quadriplegics and four paraplegics, lesion levels C3/4 - T4/5) demonstrated heart rate and blood pressure responses suggestive of autonomic dysreflexia /3/.

Other test indicate that the elevation of BP is dependent on the intensity of the electrical stimulation. The two subjects do not complain of symptoms during tests in which their blood pressures were elevated by FES. Our protocol dictates termination of the test if there is any evidence of significant autonomic dysreflexia. This has not yet occurred.

The feasibility of a simple closed-loop regulator is being investigated based on the above apparatus in which desired reference blood pressure is compared with the observed BP and the error controlling the electrical stimulator.

CONCLUSION

Low blood pressures as a result of orthostatic hypotension can be elevated to normal ranges by electrical stimulation applied to the quadriceps during tilt table standing tests. Symptoms of orthostatic hypotension were not present during the periods of FES elevated blood pressure.

Further work is required to demonstrate the feasibility of closed loop control of blood pressure.

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THE CONSEQUENCES OF THE CONTROL STRUCTURE OF VOLUNTARY MOVEMENT ON THE PROCEDURE OF THERAPEUTICAL STIMULATION

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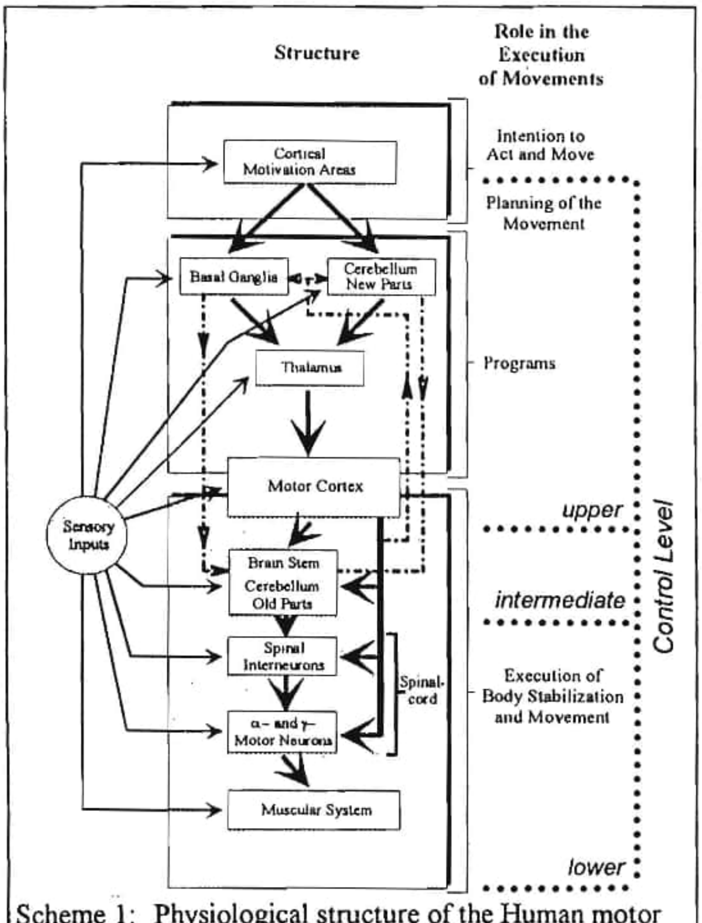
SUMMARY

In the course of applying Electrical Stimulation, ES, to more than 70 patients with different secondary motor deficiencies due to more or less extended paralysis specific therapeutic procedures are evolved. Combining the physio-pathological phenomenology with the control structure of the Human Motor-System leads to a further inside into the functional aspects of the motoric disorders. From these specific therapeutic procedures may be derived of Therapeutical / Functional Stimulation for paralyses stemming from different causes and its secondary effects.

INTRODUCTION

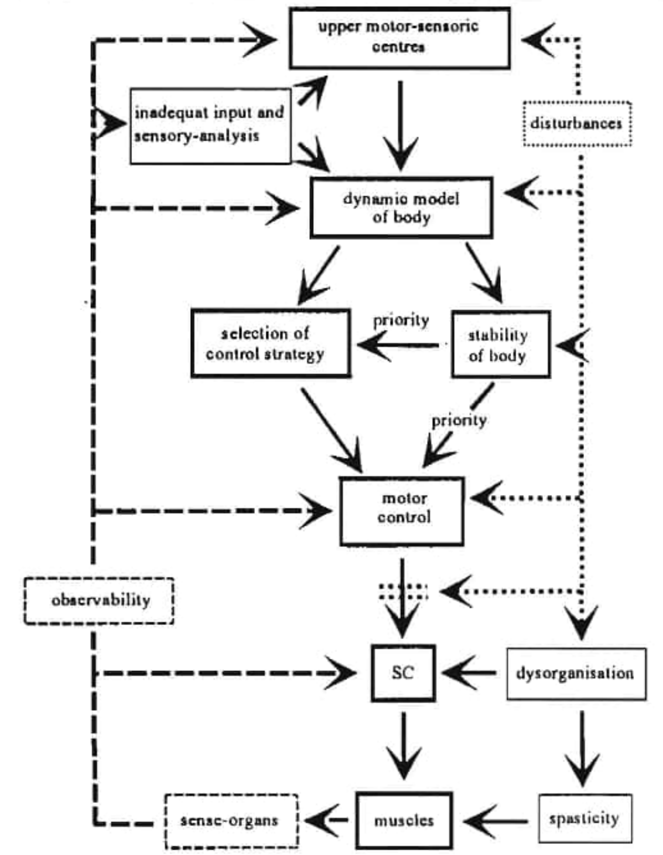
Physiologically the structure of the Human Motor Control System may be represented by the following scheme 1 (after /1/):



Scheme 1: Physiological structure of the Human motor control system

This scheme represents the motoric nervous centers with the functions attributed to them and its connections in a gross way. It allows no insight in the control structure and strategies incorporated in these centers, which are used to fulfil these control tasks. From a control point of view the Human Motor System has to incorporate the following basic functions, scheme 2.

In an upright position the body as a whole is in an instable state. In addition the human skeletton is to a large extend a flexible structure and achieves only in cooperation with the muscles the stabilisation of the body. Because of this its stabilisation in itself and in respect to the surrounding is of utmost importance. Therefore one can identify within the nervous motor center parts, which are especially concerned with the task of stabilisation and others, which execute movements, whereas in technical systems the aspect of stability is commonly incorporated into the control strategy.



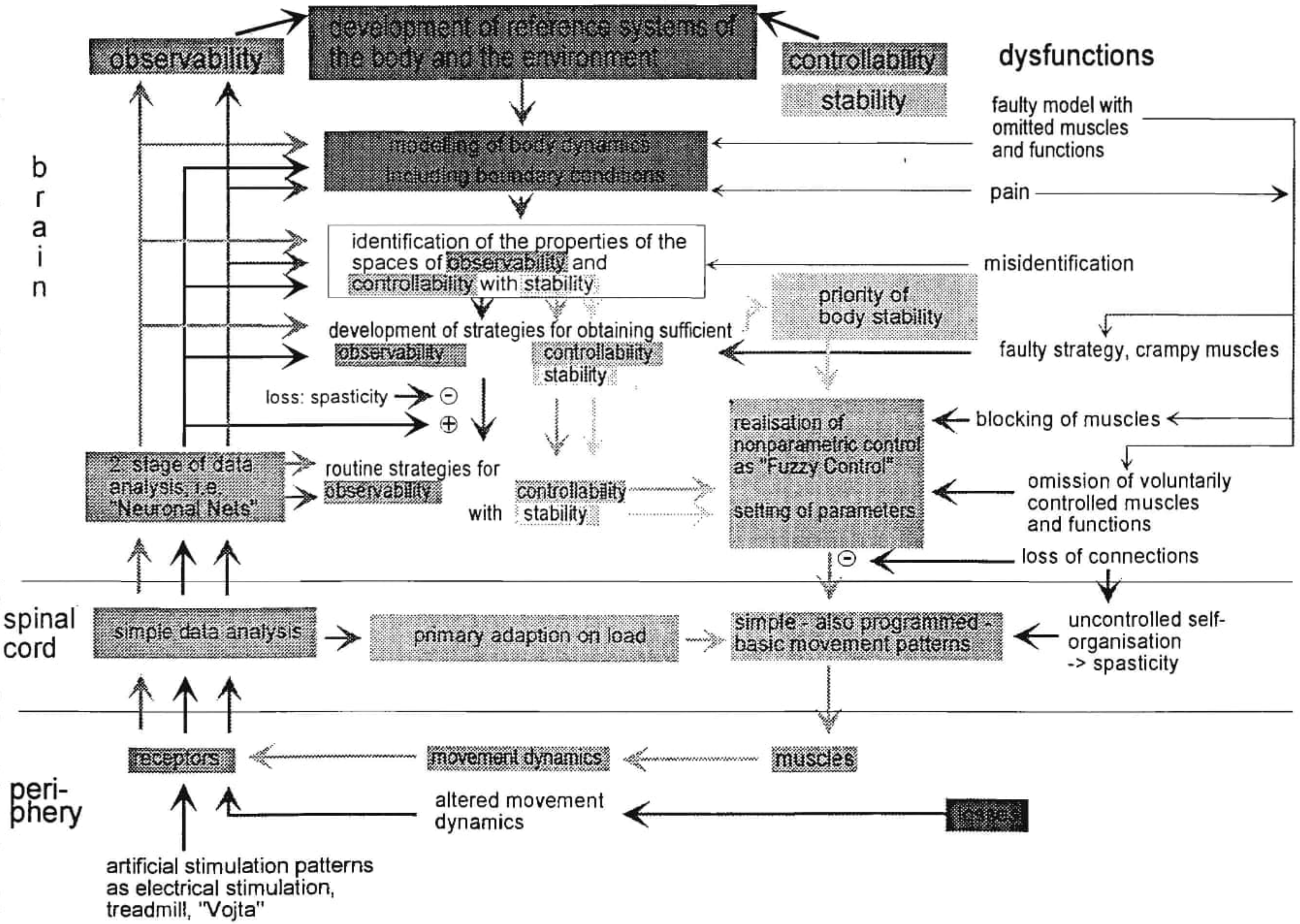
Scheme 2: Control structure of the Human motor control system

BASIC CONTROL ASPECTS

In motor control of man the requirements of keeping stability has absolute priority, because otherwise he would be unable to execute any skillful movement. If his motoric actions are not coordinated well enough his movements are of a crampy nature, this way impeding his actions. In case of a more or less extended paralysis the muscles struck by it are missing for sustaining stability. Therefore the nervous centers responsible for modelling the body dynamics and for planing the movement executions have to exclude these paretic muscles; otherwise these would act as severe disturbances. They will no longer be represented in this domain. This exclusion may continue, even if the possibility to use these muscles is returning again in case of a temporary paralysis. In this case a skillful measure taken by the control system turns later into the opposite by preventing the use of all muscles available. In addition the muscles still in use for voluntary control might be overstrained. Consecutively they might be weakend and further on develope a crampy contraction mode, which depicts itself similar to spacticity.
On the other side lesions of the Central Nervous System are often accompanied by spasticity. The spasticity omits more or less controlled movements in case of incomplete paralysis. The reduction of spasticity by means of electrical stimulation does not only improve the voluntary control of the parts of the body struck directly by it. In case of lesions of the motor centers of the brain its reduction seems to be able to reopen also larger parts of the domain of motor control, which have been apparently functionally blocked so far by the spastic action. (The treatment of spasticity itself was extensively covered elsewhere , i.e. at the 3rd and 4th Vienna International Workshop on FES; /2/, /5/)
Combining these very shortly reported phenomenology and its underlying physio-pathology with the equally important control aspects lead to scheme 3, which connects the functional deficiencies with the control structure.

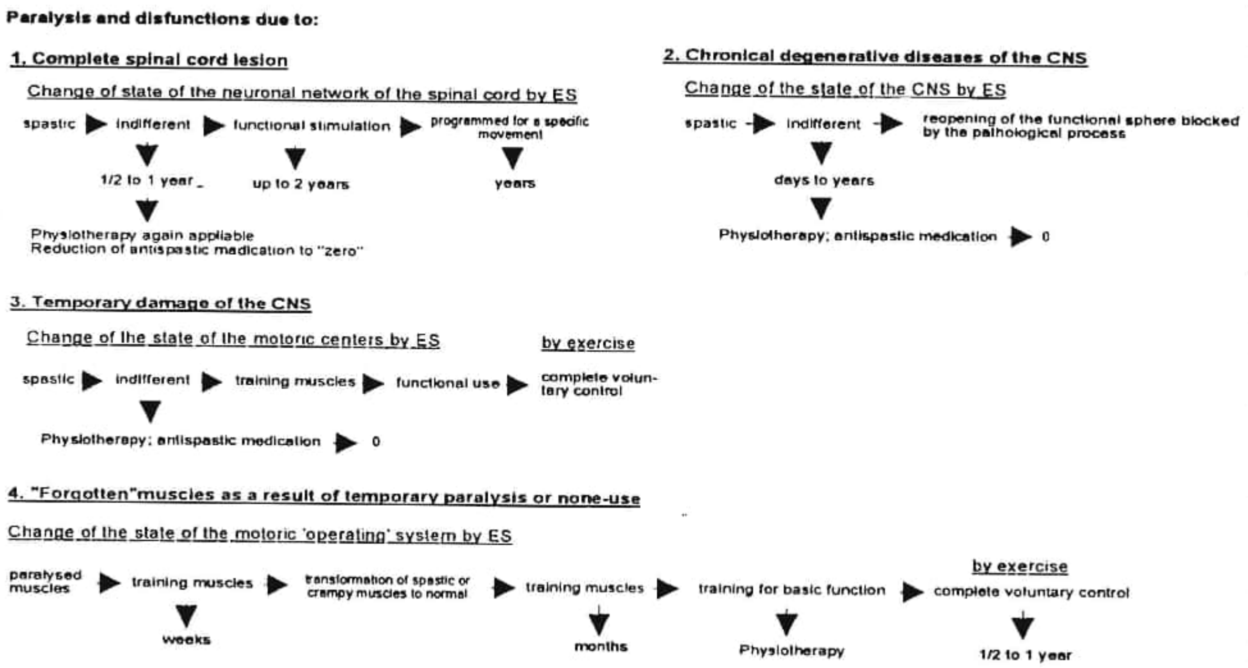
CONSEQUENCES ON THERAPEUTICAL STIMULATION

From scheme 3 one is able to derive clinical procedures for applying ES adapted to the individual background and extent of the paralysis. The first mayor goal is the restoration of stability of the body. I.e. in a quadroplegic this might be the stabilisation of the trunc to allow him to sit selfsupported and make use of his arms and hands as far as possible - and not at least to enhance his breathing capability - Similarly, but in an inverse manner, the walking training of incomplete paraplegic in a treadmill is acting. In this case the patient has not enough force to support himself in an upright position. Therefore he is suspended by a parachute belt, which takes the weight from his legs - and by doing so, stabilises him - allowing this way to train the walking movement and the strength of his legs till he may support himself -
In order to achieve this goal of stability one has, as mentioned in /2/ to /5/, to act carefully and slowly in the beginning in order to train the weakend muscles, remove the spasticity or the crampiness and to reopen - if possible - forgotten pathways for the execution of voluntary movements. In the latter case one may differentiate again between the reinstallation of the voluntary control of specific muscles, seemingly being



Scheme 3: The control structures of the Human Motor Control System and the origins and working points of motoric deficiencies.

paralysed, and of wrongly patterned functions, if some muscles might not be used voluntarily for the execution of a specific movement. I.e. in one case a patient was able to flex the right foot when lying down, but was unable to lift it during walking. After three month of ES the function had returned to normal in everydays use.
In the proportion the voluntary function is returning, at first physio- and occupational therapy are included into the treatment, finally ending up with the normal mobility training.
We conducted this therapeutic procedure successfully with patients suffering from a broad range diseases leading to paralysis. The range of success is of course limited by the remaining basic capability of the neuro-muscular system.



Scheme 4: structure of the therapeutic procedures for different causes of paralysis and a rough estimation of the time spans the treatment requires.

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EFFECT OF CHRONICALLY IMPLANTED NERVE CUFF ELECTRODES ON THE ELECTROPHYSIOLOGICAL PROPERTIES OF HUMAN SENSORY NERVES

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SUMMARY

During a long term implantation (307 days) of a tripolar split cuff electrode around the radial interdigital nerve of the left index finger in a medullary leasioned C6 patient, the physiological state of the nerve was intensively monitored. The resulting Sensory Nerve Action Potential (SNAP) amplitude was recorded using both near nerve electrodes and the implanted cuff electrode. The SNAP amplitude declined within 10 days to around 50% of the first SNAP cuff amplitude measured on day 2 after implant and recovered to the initial amplitude within three months. The SNAP amplitude measurements made with near nerve electrodes were consistent with the cuff results; the SNAP Conduction Velocity (CV) recorded by the near nerve electrodes and the cuff electrode was constant during the whole implantation period. This is in agreement with the results from two other patients with a cuff implanted around the sural, respectively a branch of the tibial nerve, and animal studies showing that the cuff electrode is an electrically stable neural-electrical transducer.

STATE OF THE ART

In spinal cord and brain injured persons many sensory pathways in the affected part of the body remain intact. If the sensory nerve activity can be recorded reliably it can be used for supplying feedback signals to control paralyzed muscles /1/. At the Center for Sensory-Motor Interaction, a Functional Electrical Stimulation (FES) system is under development to re-establish lateral hand grasp in C5/C6 tetraplegic patients. As part of such a system a medullary leasioned C6 patient had a recording cuff electrode implanted around the radial interdigital nerve (branch of the median nerve) of the left index finger. Feedback information to an FES system was provided through the tripolar split cuff type electrode /2/ with a length of 23 mm, and an inner diameter of 2 mm giving min. 30% free space within the cuff after implant. For details about the site of the cuff implant and its use in FES, see Haugland et. al. /3/.

The patient's Sensory Nerve Action Potential (SNAP) amplitude and Conduction Velocity (CV) were measured prior to surgery and monitored on a regular basis during the implantation period of 307 days. The main goal of this study was to investigate to which extent the cuff electrode affected the electrophysiological properties of the nerve. This was achieved by monitoring/comparing the SNAPs obtained from the cuff electrode and measurements made with near nerve needle electrodes.

MATERIAL AND METHODS

Sensory nerve stimulation

The distal surface of the three radial fingers was stimulated using ring electrodes. The cathode was placed around the distal joint of each finger, and the anode was placed around the most distal part of each distal phalanx. Current pulses up to 40 mA (0.2 msec in duration) were used to stimulate the fibres maximally. Increasing the stimulus intensity further did not increase the amplitude of the recorded potentials.

Figure 1 gives an anatomical overview of the relevant area and shows the experimental set-up. A thermostatically controlled heater was placed 20-30 cm above the arm, and the surface temperature of the hand was maintained at approx. 38 degrees Celsius.

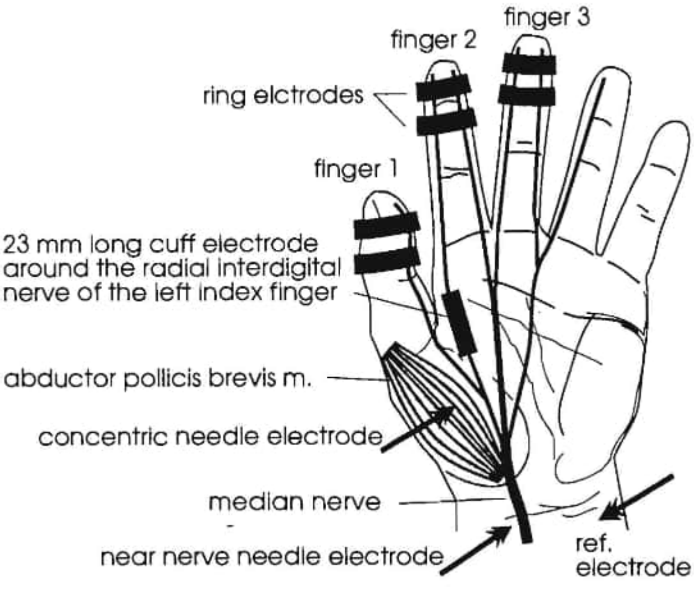

Figure 1. The anatomical location of the surface stimulation electrodes, the implanted nerve cuff and the needle electrodes.

Recording of the sensory potentials

The SNAPs from each of the 3 radial fingers were recorded from a near-nerve needle electrode /4/, placed close to the median nerve at the wrist. The placement of the near-nerve electrode was guided by the motor action potential from the abd. pol. br. muscle, until a threshold for motor stimulation of less than 1.0 mA was secured. As reference, we used another needle electrode placed subcutaneously at the ulnar side of the wrist with a transverse distance of approximately 4 cm.
The low and high frequency cut offs of the amplifier were 20 Hz and 10 kHz respectively, and 20-100 SNAPs were averaged to reduce the noise level.
When the index finger was stimulated, the SNAP was also recorded from the cuff-electrode placed in the hand around the radial interdigital nerve of the left index finger, a branch of the median nerve.

Recording of the motor potentials

The Motor Action Potential (MAP) was recorded from the abd. poll. br. muscle after stimulation of the median nerve at the wrist. The stimulation was delivered via the near-nerve needle electrode, and the MAP was recorded using a concentric needle electrode placed at the end-plate zone of the muscle. The threshold for motor stimulation was less than 1.0 mA when the near-nerve electrode was guided into position. The supramaximal motor response was evoked using a stimulus intensity of 10 mA.

Measurements

The latency of the sensory potentials was measured to the initial positive peak of the potential. The motor latency was measured to the initial deflection from the base line of the motor action potential. The amplitude of the sensory and motor potentials was measured peak-to-peak. The SNAP CV was calculated from the SNAP latency and the actual length of the segment measured from the stimulation electrodes to the needle electrode. The SNAP CV measured with the nerve cuff was calculated from a estimated nerve length of 80 mm.

RESULTS

Post-surgical measurements were started at day two after implantation of the cuff electrode. The SNAP amplitude and velocity measured at day two were taken as an initial reference in the cuff SNAP data. An initial decline of the amplitude from the index finger was measured as shown in *figure 2A*. The SNAP amplitude reached a minimum of approximately 50% of the initial amplitude after about 10 days and recovered to the initial amplitude in approximately three months. At day 244 we experienced a broken lead to the cuff electrode which necessitated that the cuff could be used as a bipolar electrode after this date.

The SNAP amplitude measurements made with the near nerve needle were all within the normal range during the observation period. The range varied for digit 2 from 9.6 to 30.0 μV, with a mean of 18.5 μV and a standard deviation of 7.3 μV (digit 1: 56.3 μV ±15.5μV; digit 3: 21.4μV ±10.4μV). *Figure 2B*

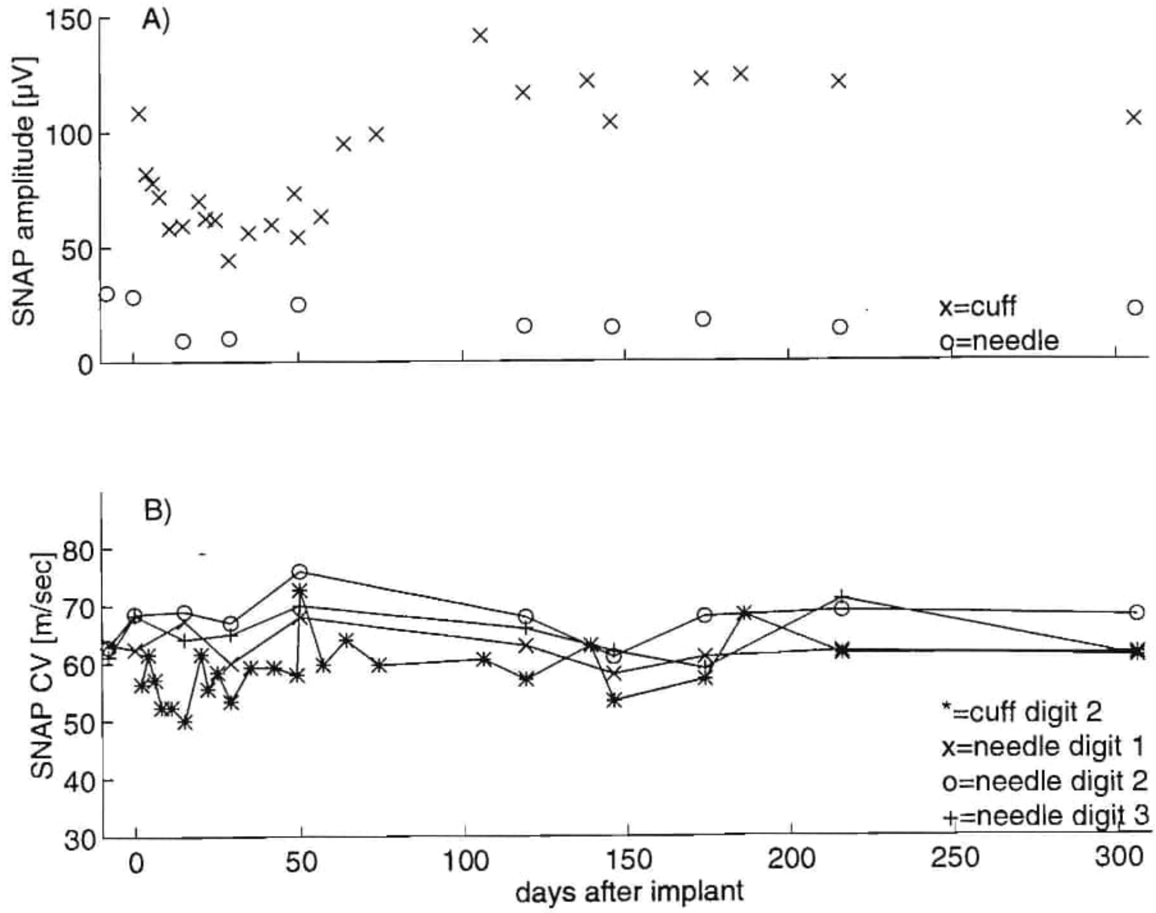

Figure 2. A) Amplitude of the electrically evoked SNAPs from the index finger. The near nerve needle amplitude from the median nerve at the wrist (o) and the nerve cuff amplitude from the radial interdigital nerve (x) are plotted in relation to time after implantation (days).
B) Sensory conduction velocity from the digits 1,2 and 3 recorded at the wrist with near nerve needle electrodes and with the cuff èlectrode recorded from digit 2.

shows the SNAP CV from all three digits innervated by the median nerve and measured with a near nerve electrode as shown in *figure 1*. *Figure 2B* also shows the SNAP CV as measured in the nerve cuff when stimulating digit 2. No significant change in SNAP CV has occurred in any of these measurements during the observation period. The mean SNAP CV and standard deviation for digit 1 to 3 are 62.6 m/sec ± 3.1 m/sec, 67.7 m/sec ± 4.0 m/sec, 64.8 m/sec ± 4.1 m/sec, respectively.

Another patient with multiple sclerosis had a split cuff implanted on the calcaneal nerve (a branch of the tibial nerve). No change in SNAP amplitude and CV has been observed during the 270 days in which the cuff has been implanted so far /5/. The SNAP amplitude and CV were also found to be within the normal range in a third patient (hemiplegic) with a sural nerve cuff implant /6/. The latter has had the cuff implanted for 3 years and 1 month at the time of writing.

DISCUSSION

The conditions for monitoring the physiological state of the interdigital nerve of the index finger equipped with a cuff electrode are excellent. The nerve branch is relatively easy to access with stimulation electrodes and the interdigital nerve is a purely sensory nerve which reduces motor artifacts in the recorded signal.

The monitoring results of the interdigital nerve reflect a temporary reduction of 50% in SNAP amplitude measured with the cuff electrode and a simultaneous change in the amplitude measured with a near nerve needle electrode. The conduction velocity seems to be stable and without initial changes both when measured with cuff and needle electrodes. The drop in amplitude measured with the nerve cuff is less obvious in the near nerve needle recordings. This might be due to small variations in positioning the near nerve electrode and fewer recordings using this technique compared to the cuff electrode.
The temporary reduction of the SNAP nerve amplitude of the interdigital nerve patient and the fast recovery as indicated by the cuff SNAP measurements, may reflect a nerve trauma resulting in a reversible partial block of nerve-fibers. The reason for this drop of SNAP amplitude is unclear.
The stability of the SNAP CV suggests that the fibers are affected independent of fiber diameter. Compression (e.g. caused by edema) is therefore less likely to be the cause since it affects mainly the large fibers selectively /7/, which would have resulted in a lowering of the CV. Another explanation of the drop of SNAP amplitude seen in the patient with an interdigital nerve cuff might be a surgical trauma. However, the minimum amplitude of the SNAP occured after 10 days which is later than one would expect if the nerve was traumatized at the time of operation.
The interdigital nerve implant in the hand is subject to a considerable mchanical stress where nerve damage may occur when the cuff is not yet fixed by connective tissue. This mechanical interaction between the cuff and the nerve can effect the fibers in the periphery of the nerve first and will be independent of fiber diameter.
After three months all three patients show stable SNAP amplitudes and CVs. This supports the hypothesis that nerve cuff electrodes are suitable in chronic FES implants. We have now monitored stable functioning implants for more than three years.

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CHARACTERIZATION OF FLEXIBLE ELECTRODES WITH INTEGRATED CABLES FOR RECORDING AND STIMULATION OF PERIPHERAL NERVES

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SUMMARY

A new design of flexible nerve electrodes with integrated cables for recording and stimulation of peripheral nerves has been developed using micromachining techniques. We have used spin casted and cured polyimide resin as insulation layers on which platinum thin-film electrodes and multi-strand ribbon cables were deposited and structured by a lift-off process in the same step. Alternating insulation and electrode layers, we have fabricated a multilayer, multielectrode device which overcomes the "classical" separation of substrate and insulation. The electrode sites were opened by reactive ion etching (RIE). The same RIE technology has been utilized to separate arbitrary shapes of the device. Electrode *in vitro* characterization was performed for two different designs, a patch electrode (flexible nerve plate) and a sieve electrode for contacting regenerating peripheral nerves. Measurements were performed to test the electrode-electrolyte impedance and insulation leakage currents. Bending tests have been conducted to evaluate the mechanical stability of the thin film interconnects in saline solution. In first acute *in vivo* tests we have recorded electroneurograms (ENG) from the stomatogastric nervous system of the crab (*Cancer pagurus*). It is concluded that our new light-weight electrode design exhibits promising mechanical and electrical properties and a good signal to noise ratio during ENG recording. On-going work will be directed to evaluate mechanical biocompatibility and material stability in chronical test systems.

STATE OF THE ART

Different approaches like cuff /1/ and book electrodes /2/ have been reported to contact peripheral nerves for recording and stimulation. However, limitations exist in reducing the electrode geometries and increasing the number of electrodes per unit size. This is mainly due to the manual lamination procedure for fabricating the different layers of the device. Penetrating microelectrodes on silicon shafts /3/ are usually used to contact the central nervous system or to stimulate the peripheral nervous system /4/. Regenerating peripheral nerves can be contacted by silicon microelectrode arrays with via holes /5,6/. In silicon technology the fabrication of integrated cables and round shaped devices needs a complex technology /7/. Little information is given on the procedure of connecting wires to the electrodes and housing of the interconnects. Electrode failure mostly results from broken interconnects. Thick polyimide foils with electrodes for recording cardiomyograms /8/ show limited design possibilities of outer shape geometries due to manual separation with surgical scissors. Nerve traumatization often occurs because of the rigid material and the relatively high weight of the devices. Because of its low weight and its flexibility polyimide is a promising material for developing a new light-weight electrode design. Histological examinations of polyimide PI 2556 as a coating for cochlear prostheses reveal no pathological effects /9/. Though the stability of some polyimide species in saline solutions is not finally clarified /10/, improvements in the chemical composition of a new generation of polyimides promise excellent life times.

MATERIALS AND METHODS

Electrode Fabrication

Micromachining techniques are used to develop a new design of flexible nerve electrodes with integrated cables for recording and stimulating peripheral nerves. Using polyimide we receive a light-weight design, which overcomes the "classical" separation of substrate and insulation layers in most electrode designs and allows to integrate interconnects and to generate arbitrary shapes of the device. We use DuPont polyimide resin PI 2556 because of its low curing temperature to develop the process technology. Figure 1 shows the process of fabricating a flexural nerve plate (FNP) with integrated electrodes:

In a first step a silicon wafer, which is used as a carrier during fabrication, is spin coated with polyimide resin PI 2556 (Fig. 1a). Multiple coating of thin layers leads to a bottom layer thickness of 6.5 μm. In a curing step at 300 °C for 2 h the polyimide is fully imidized. We use thin film technology to create electrodes, multi-strand ribbon cables and connection pads in a single process step. After roughening the polyimide surface, we deposit platinum (HF-sputtering, 300 nm) on a titanium adhesion layer (DC-Sputtering, 30 nm) and use lift-off technique for structuring (Fig. 1b). A polyimide top layer of 6.5 μm thickness gives additional mechanical support and insulates the metallization (Fig. 1c). Reactive Ion Etching (RIE) is used to open the areas of the electrodes and connection pads (Fig. 1d). A structured aluminum layer (DC Sputtering, 300 nm) serves as an etching mask. RIE is performed at 13,56 MHz and 300 W in a STS 320 reactor with O_2 or CF_4 plasma. After removing the aluminum, a resist layer, which protects the electrode and pad areas, is spun on and an aluminum etching mask is deposited (Fig. 1e). RIE is used to etch the polyimide down to the support wafer and to separate all devices in one etching step. After removing the aluminum and the resist, the single devices can be separated from the support wafer. Resulting components have a total thickness of 13 μm (Fig. 1f). In order to obtain cuff-like forms, the device can be modified by bending and a final temper step at 300° C for 2 hours.

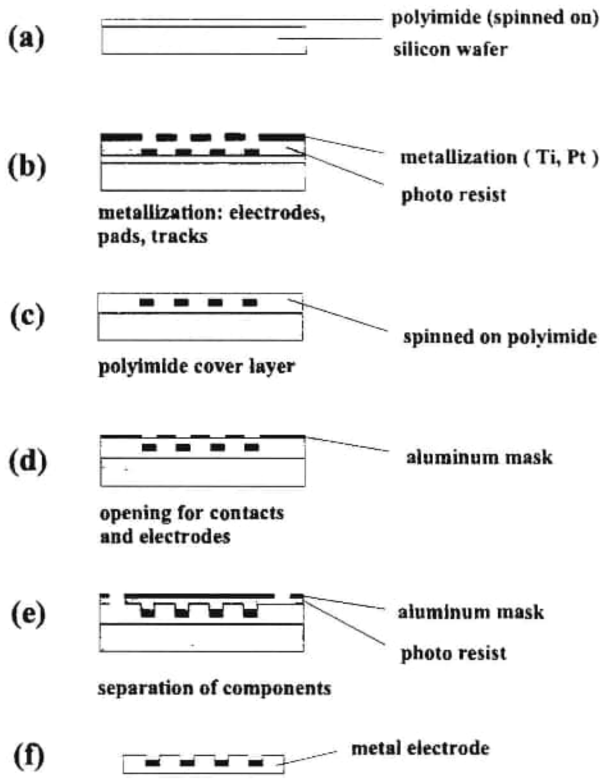

Fig. 1: Fabrication process of a FNP with integrated electrodes

<u>*In Vitro* Characterization of Electrode Properties</u>

Mechanical and electrical tests have been performed in physiologic saline solution to evaluate the stability of the multilayer devices and the thin film electrodes and the elecrode-electrolyte impedance:

* <u>Bending tests:</u> Electrodes (n= 3) have been fixed at the ends and bend for 100,000 times at an angle of 160° with a repetition frequency of 0.5 Hz.
* <u>Pulse Trains:</u> Adjacent electrodes have been exposed to 10,000 pulses (biphasic rectangular, i = 1 mA, pulse width t_{PW} = 200 μs, repetition rate f= 20 Hz).
* <u>Impedance measurement:</u> Mesurements have been performed between two adjacent electrodes on the same device (sine wave: 20 Hz to 100 kHz, constant voltage amplitude of 100 mV).
* <u>Leakage currents:</u> Completely insulated devices have been biased at U = 0.5 V against a platinum wire electrode. Leakage current through the polyimide have been measured in intervalls of 1 minute. Reference measurements have been done in dry air at room temperature.

<u>Acute *In Vivo* Measurements</u>

First acute *in vivo* tests have been performed on the *dorsal ventricular nerve* (dvn) of the stomatogastric nervous system of the crab (*Cancer pagurus*), which consists of only few neurons and delivers well known patterns of excitation. A FNP has been bend and tempered in the form of a gutter. After cutting a hole in the carapace of the crab, the epidermis is incised and retracted and the dvn is freed from the adhering tissue. The nerve is placed in the gutter electrode and bipolar, extraneural ENG is recorded via a electrophysiologic measurement setup.

RESULTS

Electrodes

We have performed two designs of electrodes in one and the same process: Fig 2. shows a sieve electrode for contacting regenerating nerves and Fig 3. a patch electrode (FNP).

Fig 4. presents a cuff electrode with a diameter 700 μm which is a FNP modified by rolling and tempering. SEM micrographs show holes in the sieve electrode that have been achieved by O_2 (Fig. 5) and CF_4 (Fig. 6) RIE. We receive an extremly light-weight design, resulting in 4 mg per electrode, which is minimizing the mechanical load on the nerve.

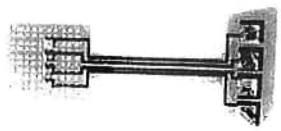
1 mm

Fig. 2: First laboratory version of sieve electrode


1 mm

Fig. 3: First laboratory version of a FNP

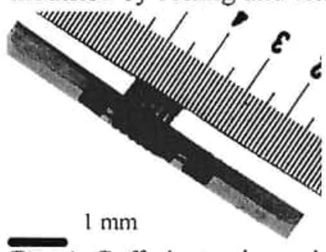
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Fig. 4: Cuff-electrode made of a FNP

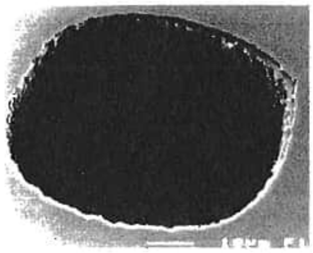

Fig. 5: Via etched by O_2 RIE

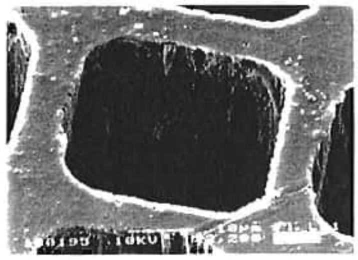

Fig. 6: Via etched by CF_4 RIE

In Vitro Measurements

Bending tests delivered very good results for the life time of electrodes. No cracking or delamination was observed of the deposited metal. The resistance of the cables remained stable after the bending cycles. Pulse trains of 10,000 showed no cracking in any of the electrodes. An impedance spectrum is presented in Fig. 7

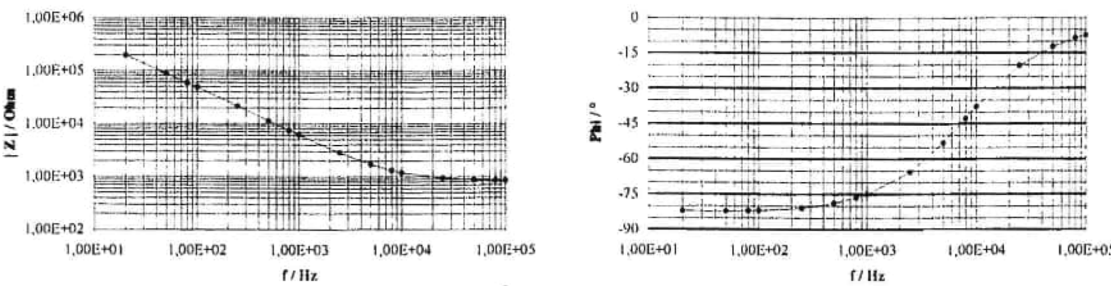

Fig. 7: Impedance measurement at an 1 mm^2 electrode area

Leakage currents were measured in the range of 4 pA and 8 pA in dry air at room temperature for 3 days. In saline solution we observed an initial leakage current of 5 pA and a current of 9 pA to 11 pA after 60 hours.

Acute *In Vivo* Measurements

The signal to noise ratio (S/N) of an ENG recorded from the dvn is in the range of 4:1 (Fig. 8).
The S/N was good enough to discriminate single neuron activity in the recording.

DISCUSSION

Fig. 8: ENG recorded from the dvn of the stomatogastric nervous system of the crab

A microfabrication technique for flexible electrodes with integrateded cables made of a polyimide resin has been established. Bending tests showed a good mechanical stability of the platinum ribbon cables, insulated and supported by polyimide layers. The platinum electrodes exhibited a good stability in the stimulation mode and a fairly low electrode-electrolyte impedance. In dry air, the insulation resistance revealed high values. On-going work is directed to examine the long term behaviour of the device in physiologic saline solutions without and with different values of bias voltage. ENG recordings delivered a good signal to noise ratio. Further investigations will optimize electrode shape and distance to obtain high spatial and temporal signal resolution for recording and stimulation purposes.

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IMPLANTABLE STIMULATOR FOR SELECTIVE STIMULATION OF THE COMMON PERONEAL NERVE

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SUMMARY

We present the modelling and design of an implantable system with a monopolar half-cuff for selective stimulation of fibres within the superficial region of the human common peroneal nerve. A half-cuff electrode is capable of making a long term selective activation, mainly of those muscles that contribute to strong dorsal flexion and moderate eversion of the hemiplegic foot. One of the modelling objectives was to determine the three dimensional spread of the electric field that would be generated by the half-cuff within the deep peroneal branch of the nerve by the half-cuff. Moreover, the extent of initial excitation of the nerve fibres within the superficial region was predicted. For this purpose a total equivalent driving function at six positions within the half-cuff was calculated. The modelling objective was also to introduce a time delay between the cathodic and anodic parts of the stimulating pulse pair, mainly to predict eliciting more gradual recruitment of motor units.

STATE OF THE ART

Contractons of paralyzed skeletal muscles can be induced by electrical stimulation of peripheral nerves to obtain functional limb movements in patients having upper motoneuron lesion (5, 9, 12, 14). Among various applications, Functional Electrical Stimulation (FES) of the common peroneal nerve to correct the gait has been shown to be a potentially useful means for the restoration of functional movement in the lower extremities of hemiplegic individuals (9, 14). The stimulation is applied during the swing phase of the affected leg dorsiflexing the foot and preventing its equinovarus position. By raising the affected leg, the patient releases the heel which in turn activates the external unit, thus transmitting information and energy to the implanted assembly via the antenna. Closing of the switch at the beginning of the stance phase turns off the transmission/stimulation. Stimuli are therefore synchronized with the swing phase by a heel switch which is worn inside the shoe. The goal in the work presented was to develop an implantable system with a half-cuff for selective stimulation of the superficial region of the common peroneal nerve innervating mostly the tibialis anterior muscle, partly one of the peroneus muscles and to a lesser degree the triceps surae muscle. Recently it was demonstrated that peripheral nerves are organized into individual fascicles near their terminal branching points (11). It was also demonstrated that electrodes placed proximal to the branching point enable stimulation a single fascicle and thus selective activation of an individual muscle (9, 12). In a recent study, (9) the efficacy of a monopolar half-cuff in activating an individual fascicle in a human common peroneal nerve just above its bifurcation in superficialial and deep peroneal branches in two hemiplegic patients was tested. However, the main goal in this study was to change the stimulating scheme using capacitively coupled biphasic pulses where thick nerve fibres are recruited before thin ones by the scheme where the time delay between the cathodic and anodic phase of the biphasic stimulating pulse pair was introduced. It was expected that a more gradual recruitment of motor units can be obtained (6, 12).

MATERIAL AND METHODS

Modelling of the human common peroneal nerve and half-cuff geometry was based on histological examinations and the data obtained in literature (4, 5, 7, 8). The longitudunal dimensions of the half-cuff were determined mainly according to the request that the surface of the nerve covered by the half-cuff should be as small as possible to prevent damage associated with the blood supply system. It was concluded that in further modelling the optimal length of the half-cuff would be 18mm. For the purpose of histological examination, part of the common peroneal nerve at the level behind lateral head of the fibula was removed from the cadaver (75-years, male). In the model, based on histological examination of aforementioned samples population of fibres consist of four distinct nerve fibre diameter groups: (1) 0.9 to 4.67μm, (2) 4.68 to 8.45μm, (3) 8.46 to 12.22μm, and (4) above 12.23μm. We focused only on the recruitment of α-motoneurons and thus considered groups 2, 3, and 4. It was previously shown that fibres in peripheral motor nerves are recruited according to their axonal conductivity rather than by their type. Thus, α_1-motoneurons are recruited first, followed by α_2 and then α_3-motoneurons. The mean adopted conduction velocity of four distinct groups are as follows: (1) up to 17m/s, (2) 31m/s, (3) 50m/s, and (4) 58m/s and above (3, 10). By introducing the time delay between cathodic and anodic part of the stimulating pulse pair we attempt to influence a positive regenerative process to proceed more reliably in fibres for which the stimulus is suprathreshold until maximum depolarization is achieved, and, especially on fibres for which is only slightly suprathreshold or very close (5). Thus the main goal in introducing the delay between cathodic and anodic part of stimulating pair was to prolong the period of time following the increase of the memebrane potential induced by the cathodic part of the stimulating pair before clear signs of the regenerative process take hold to give rise to the action potential. Namely, it may not be possible to predict initiation of an action potential by cathodic stimulating part if immediately after its application an anodic hyperpolarizating part occured. It was shown that the activating function for myelinated axons is given by the second differential quotient of the external potential at the Ranvier nodes (RN), which is the component of an electric field that lies parallel to the myelinated axons (2, 7). It was also shown that the activating function is incomplete in distinguishing between target fibres of different diameters. Recently, Warman et al. (1992) (13) developed a method to predict excitation of axons based on the response of passive models. They found that two terms drive the polarization of each RN. The first was a source term described by the activating function at the node, and the other was an ohmic term resulting from redistribution of current from sources at other nodes which is independent of fibre diameter. Accordingly, a total equivalent driving function includes both terms. Adopting the aforementioned model, a total equivalent function driving the polarization of RN of fibres at six locations within the half-cuff was defined. The nerve model used in this study consists of a number of compartments with different conductivities (1, 2, 8, 9). For evaluating the electric field, (1, 2) the virtual neutral electrode was supposed to be situated at the edge of the half-cuff proximal to the electrode and perpendicular to the longitudinal axis of the half-cuff. The electrical potential distribution due to a nerve monopolar half-cuff was obtained by solving the Laplace equation within a three-dimensional domain using the finite element method.

RESULTS

The electric field in the nerve trunk caused by the monopolar stimulating electrode was calculated according to a proposed geometrical model. We sought to determine the region within the deep peroneal fascicle where activation of nerve fibres could be expected. This was done by calculating the driving function for nerve fibres situated in six levels within the deep peroneal fascicle. Activating and driving functions for nerve fibres situated at a distance of 0.95mm from the stimulating electrode is presented in Fig. 1. The half-cuff system was constructed taking into consideration the results of modelling selective stimulation of superficial regions and fibres with different diameters in the human peroneal nerve and the evaluated electric field generated in the nerve by the monopolar stimulating electrode. The completed half-cuff is presented in Fig.2.

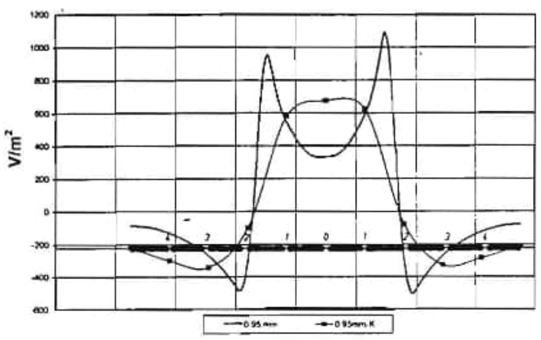

Fig. 1. Evaluated activating and driving functions for nerve fibre located at 0.95mm from stimulating electrode.

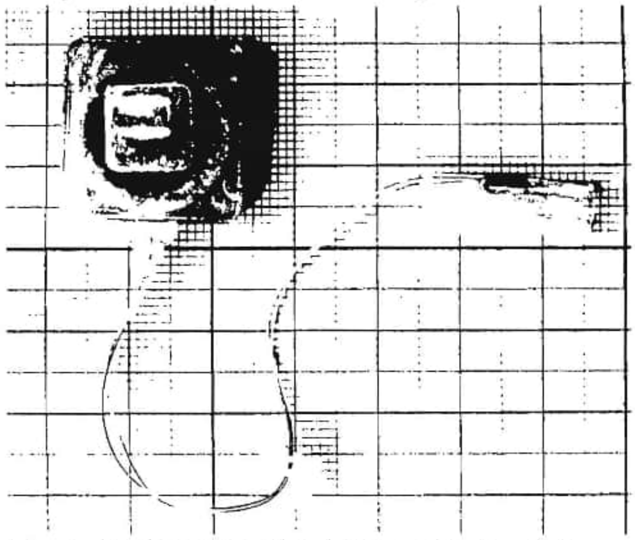

Fig. 2. Implantable stimulator and half-cuff for monopolar, selective stimulation of superficial region in peripheral nerve.

In conventional stimulating schemes thick nerve fibres are recruited before thin ones as they have lower excitation threshold. A more gradual recruitment of nerve fibres during selective stimulation of a certain superficial region can be obtained if it is possible to increase the difference in threshold between different diameter nerve fibres. A possibility used in this work is introducing the time delay between the cathodic and the anodic phase of the biphasic stimulating pulse (5). Namely, it was found that the presence of the secondary anodic phase of the biphasic pulse could be used to abolish excitation initiated by the primary cathodic pulse. According to results of a recently published preliminary report (9) concerning stimulation using a half-cuff, we proposed relatively a short cathodic phase with higher amplitudes, mainly to decrease the slope of the recruitment curve. Thus, the stimuli proposed in this work were current, charge balanced, and biphasic pulses with a rectangular cathodic component, and exponential decay anodic component. The Implantable Gait Corrector (IGC) system consists of three units: an external stimulator with antenna that generates and transmits radio-frequency signals through the skin to the implant assembly; a heel switch which triggers the stimulator synchronously with the swing phase; and a surgically implanted unit consisting of a passive receiver which receives the signal from the external stimulator and converts it into a train of electrical pulses delivered to the electrode within the half-cuff.

DISCUSSION

An implantable system with a monopolar half-cuff for selective stimulation of fibres with different diameters within a certain superficial region of the human common peroneal nerve was designed, fabricated, and implanted. A system is capable of making a selective activation of muscles that contribute to strong dorsal flexion and moderate eversion of the hemiplegic foot, thus preventing drop foot in hemiplegics. Accordingly, the modelling objectives were threefold: (1) to predict the possibility of selective stimulation of the superficial region within the common peroneal nerve innervating mostly the tibialis anterior muscle and one of the peroneus muscles, (2) to predict the extent of initial excitation of the 12μm motor fibres within aforementioned superficial region, and (3) to control propagating action potentials of fibres with different diameters out of the half-cuff. We expect the presented model to have some limitations in cases of older subjects (3, 6). Specifically, in a reduced number of thick, fast, and low threshold motor fibres the introduced time delay would not be necessary to stimulate naturally slowed muscle in more physiological manner (10). We also believe that activation of strong skeletal muscles in as natural a manner as possible is required mainly to reduce changing the pattern of dynamic load on joints that can arise when motor units are activated in reversed order of recruitment as in the conventional stimulating scheme.

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CAN ULTRASOUND IMPROVE MAGNETIC STIMULATION

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SUMMARY

Magnetic stimulation represents an attractive method for stimulating intact nervous systems because of its noninvasiveness. Unfortunately, the ability of conventional magnetic stimulation to excite a spatially defined tissue volume in a precise way is rather limited; therefore it cannot be used for a number of clinical applications. This report describes preliminary experimental results in vitro with a new method which can improve the spatial resolution significantly by using the synergy of ultrasound and magnetic fields for neural stimulation. Tests on sciatic nerves of the frog xenopus laevis also verify the previously predicted lower magnetic field requirement which represents another advantage of this new method.

INTRODUCTION

There have been numerous reports about modeling the induced electric fields in neural structures produced by magnetic stimulation /1-3/. They show that for both unbounded and semi-infinite, as well as bounded media the focality of magnetic stimulation is determined by coil configurations. It can be improved somewhat for certain applications by using so-called figure-of-eight coil /4/; however, its spatial resolution is still rather marginal, thus severely limiting the use in many important clinical applications. A new method overcoming these disadvantages by combining focused ultrasound and magnetic stimulation was previously introduced based primarily on theoretical analysis and some phantom results /5, 6/. This report presents preliminary in vitro results with animal nerves in an attempt to verify the synergy between focused ultrasound and magnetics for stimulation with high spatial resolution and low magnetic field requirements.

MATERIALS AND METHODS

Stimulation is tested using a frog's sciatic nerve in vitro. Fig. 1 shows a schematic of the experimental setup of our new approach using the synergy of pulsed magnetic and focused ultrasound fields in order to a) produce spatially precise stimulation, and b) to lower the magnetic field requirements as compared to conventional stimulation using magnetic fields only.

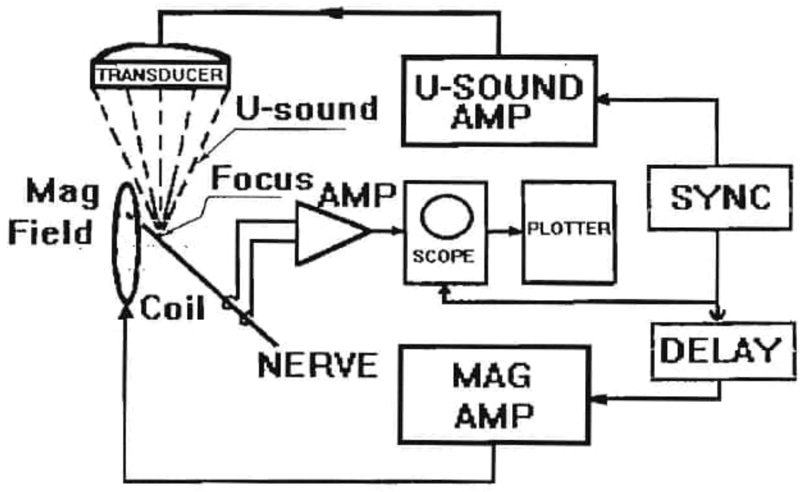

Fig. 1: Block diagram of the experimental setup for combined ultrasound and magnetic nerve stimulation

The stimulating magnetic field is produced by a circular coil. The focused ultrasound transducer is driven by a 1.6 MHz amplifier The entire system is synchronized by the SYNC unit. The magnetic stimulator is activated after the ultrasound by means of the Delay unit, in order to achieve simultaneous interaction of magnetic and ultrasound fields in the focal region. The delay time is adjusted according to:

$$\tau_d = l/\upsilon \qquad (1)$$

where l is the focus length and υ the ultrasound propagation velocity in the solution within the tank. This tank is omitted in fig. 1 for simplicity. It contains the transducer, the coil and the nerve as shown in the photograph of fig. 2. In this case the delay is about 40 µs.

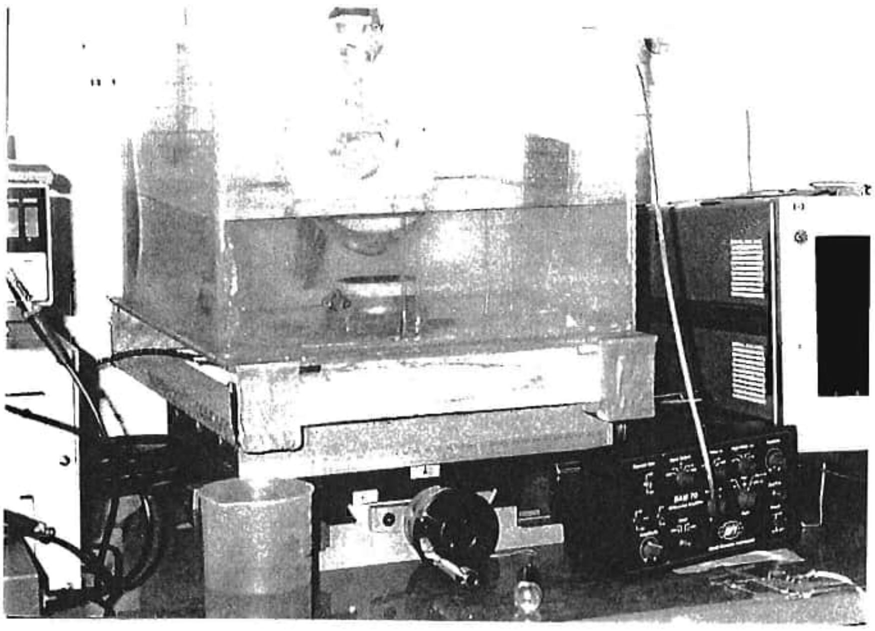

Fig. 2: Photograph of the experimental setup, showing the tank filled with Ringer's solution. It contains a partially submerged circular coil with the sciatic nerve directly underneath of it. On the bottom of the tank the focusing ultrasound transducer is visible. Silver chloride electrodes pick up the nerve's response. It is amplified by the differential amplifier seen on the right bottom side.

RESULTS

The Strength-Duration Curve

The strength duration curve is a traditional expression for describing excitability of neural tissues. The excitation of neural tissue is intrinsically random in nature. We therefore define the excitation threshold in our setup as the magnetic field V_{th} when we can just barely observe the response (i.e., the compound action potential) on an oscilloscope, and the response would disappear if we reduce the field by 5%.

Initially, the effect of ultrasound on the strength-duration curve was tested experimentally. Fig. 3 shows a group of typical curves with varying ultrasound power, for which the duration is kept constant at 490 µs. For convenience we show the normalized expressions for both the ultrasound P and magnetic field V_{th}

Fig. 3 shows that the strength-duration curves are obviously affected by the ultrasound in a complex, nonlinear way. Changing the pulse width or the ultrasound power produces entirely different curves. The narrower the pulse width is, the more rapidly changes the threshold.

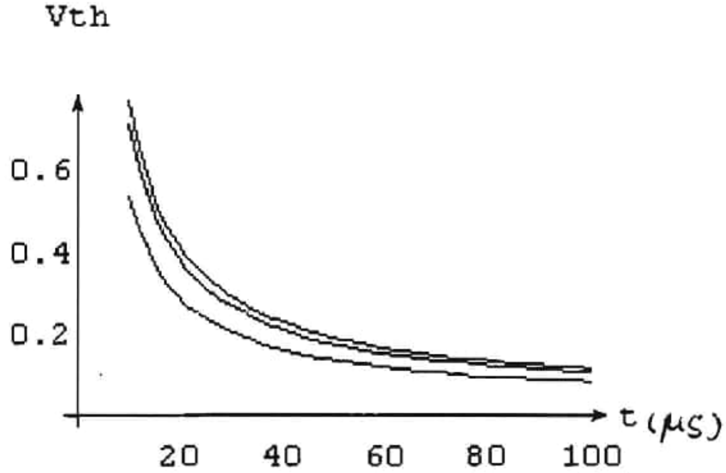

Fig. 3: Strength-Duration curves for different ultrasound power levels.
- upper curve: $P/P_{max} = 5\%$, middle one: $P/P_{max} = 10\%$,
and lower one: $P/P_{max} = 15\%$

Experimental Relationship between Ultrasound and Magnetic Stimulation

The threshold was investigated by changing both the ultrasound and magnetic field in order to study the interaction of ultrasound and magnetics in regard to excitation. As shown in Fig. 4, the magnetic field required to stimulate the nerve decreases gradually with increasing ultrasound power. Due to the random effects of neural excitability some uncertainty is produced resulting in the bars of the curve in Fig. 4.

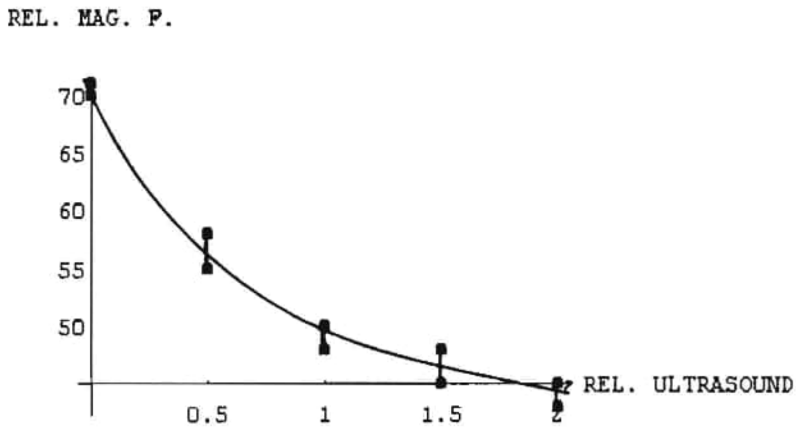

Fig. 4: Experimental relationship between ultrasound and magnetic field regarding the excitation threshold

DISCUSSION

Our preliminary results show that the neural excitation threshold depends on both the magnetic field and ultrasound power; however, not all of the parameters influencing the new stimulation method have been determined yet. The interdependence of magnetics and ultrasound implies that the focal behavior of the stimulation is determined by the focusing ability of the ultrasound which can, of course, be easily focused to the order of a few mm. A second important advantage of the new method is that it requires a much lower magnetic field level.

Despite of extensive analytical and experimental studies there are still many questions open regarding the main mechanism of the new stimulation. More experiments and more analysis is needed in order to more fully explain the phenomena; however, it is clear that the influence of ultrasound on the excitation is not simply an ultrasonic heating effect, which can also by inspection be concluded from the Fig. 3, where the same dose of ultrasound affects the threshold differently at different pulse widths.

One possible caveat regarding this new stimulation might be the well-known ultrasound cavitation in biological tissues. We have considered this problem before /5/, and have found the ultrasound power level used in these experiments to be far below the threshold for cavitation.

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USEFUL APPLICATIONS AND LIMITS OF BATTERY POWERED IMPLANTS IN FES

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SUMMARY

Battery powered stimulation implants are well known for a long time as heart pacemakers. In the last few years fully implantable stimulators are more used in the field of FES like dynamic cardiomyoplasty and electrostimulated graciloplasty for fecal incontinence.
The error rate of battery powered implants is significant smaller than in conventional stimulator systems, the quality of live for the patient is increased because the need of an external power and control unit is eliminated. The use of battery powered implants is limited by the complexity of the stimulation control strategies and the battery capacity. Therefore applications like the stimulation of lower extremities for walking, cochlea stimulator or direct muscle stimulation cannot be supported.
The improvement of implantable batteries, microcontrollers and ultra low power products is still going on. Battery powered implants will meet in the future also the needs of complex application.
Systems for restoration of hand and breathing function after spinal cord injury can be the next field of use for battery powered implants. For this purposes we developed a battery powered multichannel implant with a sufficient lifespan for phrenic pacing. The problems during development and the limits of this system is described in this paper.

STATE OF THE ART

Battery powered implants are used clinically in a representative number for the dynamic cardiomyoplasty [4] and the electrostimulated graciloplasty [2,13] for fecal incontinence. Basically, these muscular stimulation devices consist of a single channel programmable pulse generator, a programmer, pacing leads and sensing leads if necessary. Programming of stimulation frequency, amplitude, pulse duration a.s.o. is achieved by radio frequency telemetry. The implant can be activated or deactivated by a magnet. A programmed and activated implant works as an independent system in the human body without the need of any external devices.
Conventional systems for restoration of hand [9], leg [1,12] and breathing [6,10,12] function after spinal cord injury, as well as cochlea implants [3,7] are still powered and controlled via an external transmitter. Signalprocessing by cochlea implants and the complexity of control strategies for walking inhibits the use of battery powered implants, but in the next step they will be adapted for restoration of hand function and phrenic pacing.

MATERIAL AND METHODS

To extend the application of battery powered implants we developed an 8 channel stimulator and the related external programming unit. The implant consists of five functional blocks (Fig. 1). The stimulation can be started by an internal time interrupt or a hardware interrupt. The trigger unit analyses the activity of the sensor inputs and responds to predefined event with a microcontroller interrupt. The stimulator offers 8 output channels with free programmable electrodes configuration with constant - current stimulation pulses of up to 4 mA. The implant is supplied from a Lithium-Thionyl-Chloride battery (Wilson Greatbatch WG8602); a lifespan of about 2-8 years depended on stimulation energy is expected. The microcontroller coordinates the overall timing, supervises the bidirectional link for data exchange and stores the received stimulation parameters.
The external programming device and a transmitter provide the possibility to adjust freely and change on a large scale the timing, the measurement and the stimulation parameters of the implant.

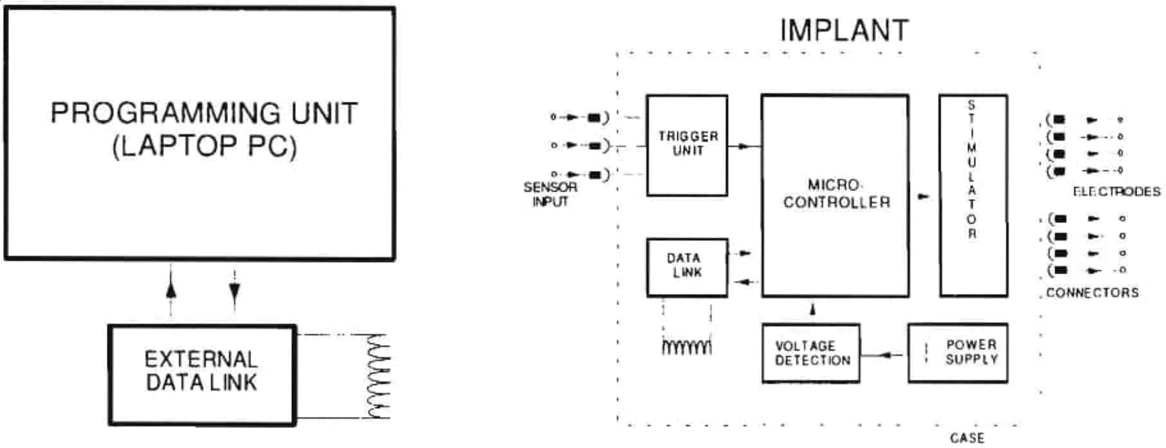

Fig.1 Block diagram of the stimulation device

The major design problem is to reach a sufficient operating time based on the embedded battery. The energy you need for one muscle contraction is:

$$W = \eta \cdot f \cdot t \cdot I^2 \cdot T \cdot R$$

η....efficiency of the output stage
f.....stimulation frequency
t.....contraction time
I.....stimulation current
T....pulse duration
R...tissue and electrode impedance

The impedance of the tissue and the epineural electrodes we use varies between 200 and 2000 ohms, the stimulation amplitude for a submaximal contraction varies between 1 and 4 mA. Using the equation above by neglecting the efficiency, the energy of one muscle contraction amounts to W=480μWs (η=1, f=25Hz, t=1s, I=4mA, T=0.6ms, R=2000Ω).

Two terms are important to increase the durability of the battery, the efficiency of the output stage and the power consumption of the control unit. Therefore we implemented the following features:
The microcontroller controls all functions of the stimulator to optimise power saving. The oscillation frequency of the microcontroller is kept as low as possible, and it is switched to waitmode in stimulation pauses.
The voltage of the battery during the whole livespan is 3.5V, so step up conversion is required to drive the load. To reduce losses, the stimulator multiplies the battery voltage only at the moment of activity by a high efficiency charge pump. The multiplication of the voltage is controlled by the microcontroller as a function of the stimulation current and the impedance of the electrodes.

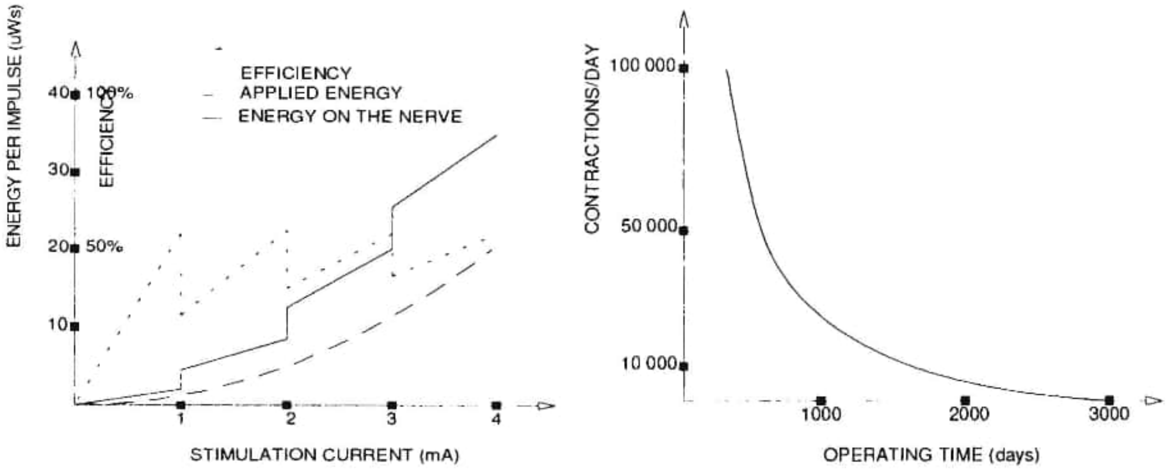

Fig. 2 Power efficiency vs. stimulation current and operating time vs. contractions/day (η=0.57, f=25Hz, t=1s, I=4mA, T=0.6ms, R=2000Ω).

RESULTS

The new developed battery powered implant enables the stimulation of two muscles following to the principle of the "carrousel" stimulation. Stimulation can be triggered by an internal timer interrupt or a hardware interrupt. At present a trigger unit for ECG to use for cardiomyoplasty is available, a EMG unit is being designed.
Without further improvement the implant can be used as a diaphragm pacemaker with an expected lifetime of 5 years applying the stimulation data after Glenn, Fodstad [6,5] or 3 years using the "carrousel" stimulation [11].

DISCUSSION

Systems for restoration of hand and breathing function after spinal cord injury can be the next field of use for battery powered implants. For this purposes we developed a battery powered multichannel implant with a sufficient lifespan for phrenic pacing.
This make possible to decrease the error rate and increase the quality of live for the patient by eliminating the external components for power and control.

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A PROGRAMMABLE FLEXIBLE FUNCTIONAL ELECTRICAL STIMULATION SYSTEM

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SUMMARY

A flexible, miniaturized, multiprogrammable stimulation channel has been designed using standard devices (FPGA, RAM and DAC) which is able to generate a great number of stimulation patterns and stimulation strategies. In a modular architecture similar and totally independent stimulation channels can be selected and programmed by a personal computer (PC) or a portable programmer. Once a stimulation channel is down-loaded by the desired stimulation parameters, it generates the programmed stimulation pattern. The FPGA was developed under *Wiew Logic* environment using the ACT1 library. FPGA devices allow the fast, low cost and miniaturized realization of the digital circuits at VLSI level.

STATE OF THE ART

Several stimulators have been designed for transcutaneous or direct nerve or muscle electrostimulation during neuromuscular investigations /1-9/. It is well known that each of commercially available system is dedicated to a specific application and they do not completely satisfy the requirement of other applications. They are also designed to deliver a limited stimulation pattern and are not able to support the new algorithms for selective stimulation of nerves and muscles.

The goals for this work are: the design and test of a new generation of multiprogrammable flexible stimulators for FES supporting a wide range of neuromuscular applications and stimulation algorithms. This stimulator was designed for the following and many other applications: 1) investigation of new selective stimulation algorithms; 2) studying the stimulation strategies dedicated to bladder control and other neuromuscular applications in acute animal test; 3) restoration of walking in subjects with a complete spinal cord injury or an incomplete CNS injury and restoration of reaching and grasping /5/; 4) application of atrioversion which is a method of converting atrial, or ventricular tachyarrhythmias to normal sinus rhythm /9/; 5) muscle strengthening.

MATERIALS AND METHODS

A. System Description

Fig. 1 shows the general block diagram of the stimulation system. It includes a microcontroller-based programmer and stimulation channels. The programmer, which can be replaced by a personal computer, comprises a microcontroller unit (68HC11), a keyboard and a liquid crystal display (LCD). In the down-load mode (DLM), the programmer down-loads the memory of the stimulation channels with the desired stimulation parameters. In the stimulation mode (SM), channels are totally independent and the active ones produce the programmed stimulation pattern. In the SM mode the programmer can be separated from stimulation channels and therefore the stimulator dissipates a lower power.

The stimulator is powered by a rechargeable battery with a 1-Ah capacity. A switch-mode DC/DC converter is used to obtain high voltage power supply (150 V) of stimulation channels output stages.

B. Stimulation Channels

The stimulation channels are completely similar. Each one is composed of a RAM, an FPGA, a digital-to-analog converter (DAC), and the output stage (Fig. 2).

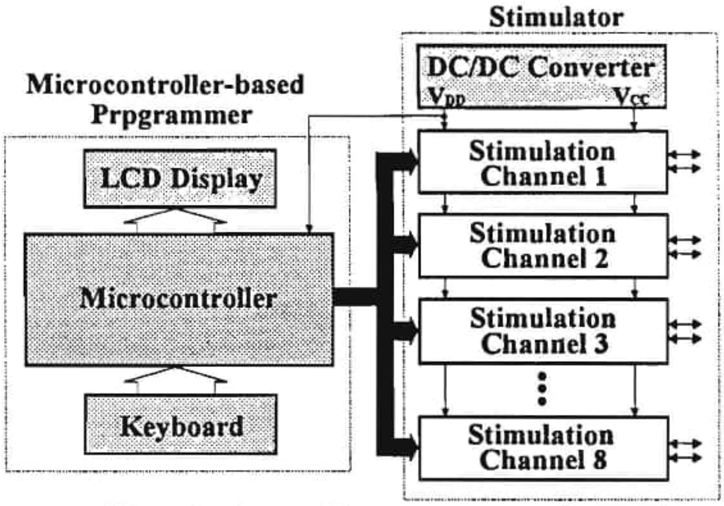


Fig. 1: The block diagram of the stimulator. The programmer selects and programs the stimulation channels (V_{DD}: battery voltage, V_{CC}: high voltage generated by the DC/DC converter).

A simple way to generate flexible stimulation patterns is to save all its digital samples in a memory and then read successively the content of the memory and convert them to their analog equivalent values using a DAC. In this case, the most significant bit (MSB) of each digital sample represents its sign. Therefore, each sample is represented by a number of 7-bits for its absolute amplitude and one bit (MSB) for its sign. In this way, any type of stimulation waveform can be programmed in a memory and to be reproduced when it is necessary. The problem associated with this technique for the generation of flexible waveforms is the requirement of a high volume of memory which renders the technique non practical in the majority of cases. To overcome this problem, we have developed a simple data compression language which allows to eliminate the redundant data. The desired stimulation pattern is therefore compressed and saved in the memory and then during the regeneration of the stimulation pattern the saved data is decompressed. This technique allows to minimize the required memory space and made it possible to save various stimulation patterns and then select them when the stimulation pattern must be reproduced. The main principles of our data compression technique are as follow:

1. When a stimulation waveform must be repeated many times (wave train), we define a macro containing the samples of the basic waveform and the repetition times. Each macro is composed of the following elements: 1) the first byte which represents the beginning of the macro (FD), 2) the second byte which indicates the number of basic waveforms in the wave train, 3) the following bytes represent the basic waveform, and 4) the last byte mentions the end of the macro (FE).
2. When the amplitude of the stimulation pattern is constant or zero for a long period of time, the similar bytes must be consequently saved in the memory. In order to avoid this redundancy of information, we use a byte, which indicates the existence of a delay (FC) followed by a byte which represents the value of the delay. The previous value of the signal will be conserved when introducing the delay.

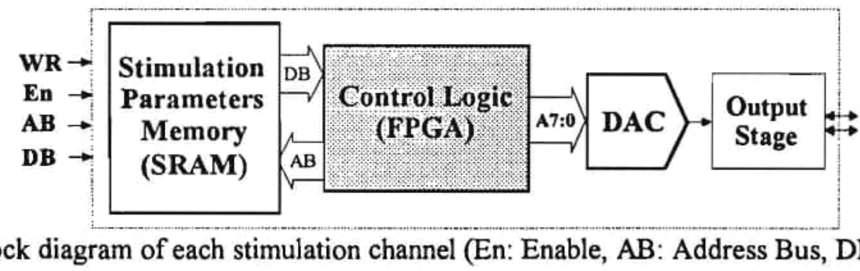


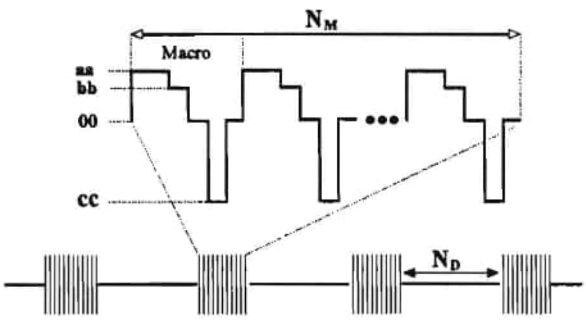
Fig. 2: Block diagram of each stimulation channel (En: Enable, AB: Address Bus, DB: Data Bus)

Table 1: Definition of the data compression language.

Code	Definition
FC	The following byte is the delay value (N_D). The delay is equal to the period of the clock multiplied by the delay value and a constant which depends on the employed finite state machine.
FD	The beginning of a macro. The following byte (N_M) represents the number of stimulation waveform in the wave train, and the succeeding byte is the first sample of the basic stimulation waveform.
FE	The end of the macro. The macro must be repeated N_M times.
FF	The end of the stimulation pattern. The whole stimulation pattern must be repeated.

FD	00
N_M	01
aa + 80	02
aa + 80	03
bb + 80	04
00	05
cc	06
00	07
FE	08
FC	09
N_D	0A
FF	0B

(a)



(b)

Fig. 3: Example of generation of a simple stimulation pattern: stimulation pattern (a), and its related program based on the data compression technique (b).

Table I represents the summary of the data compression technique and Fig. 3. depicts an example of stimulation waveform generation. Fig. 4 shows the schematic of the output stage which interfaces the DAC and the muscle or nerve. It has been designed to generate constant current stimulation pulses of 0-145 mA. The least significant bit (LSB) of the output stage is programmable and can be selected by the user to adapt the range of current stimuli to the desired application.

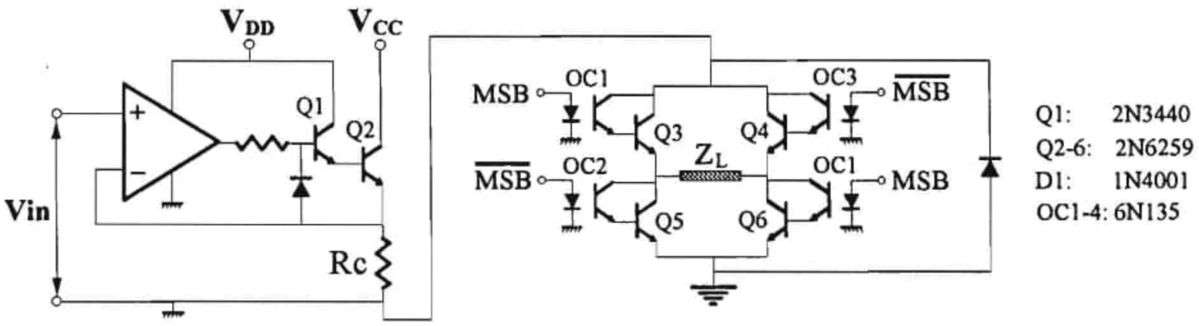


Fig. 4: Schematic of the output stage. The input voltage (Vin) comes from DAC and is converted to a current which is directed to the output load (Z_L). The biphasic currents can be applied using a single positive supply.

RESULTS

Simulation results (place and route, back annotation, etc.) prove the functionality of our proposed architecture. ACTEL FPGA /10/ has been used to implement the logic circuitry under *View Logic* environment. After implementation on FPGA using ALS software, the final design used 98% of the modules available in the device. Three laboratory prototypes have been successfully fabricated and tested. The DAC has been realized using AD7523 (Harris Semiconductor). The output stage has been realized using only a single high voltage (V_{CC}) and generates positive and negative stimulation signals.

DISCUSSION

A multi-purpose multichannel programmable stimulator for FES applications has been proposed. Stimulation channels are similar and totally independent. Each stimulation channel has been miniaturized using RAM, FPGA, and DAC devices and is able to generate any type of stimulation waveform and a very flexible timing pattern. This characteristics facilitate to investigate new stimulation strategies and the device may be used for many FES applications. It is actually used in developing new bladder control stimulation algorithms.

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DUAL CHANNEL IMPLANTABLE SYSTEM

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SUMMARY

A novel dual channel implantable stimulator system has been developed. One of the problems of selective activation of nerve fibres is solved with this device - to activate muscles selectively and obtain a functional movement in certain applications. The stimulator comprises an implantable receiver and an external transmitter providing power and stimulus information for the receiver. The stimulator is small, low cost and potentially useful for various applications. Animal implantation experiments are in progress in order to measure different parameters and to test selective activation of the muscles, technology of our system in vivo (reliability, functionality, repeatability) and to make some histological examinations. Some preliminary results are presented.

STATE OF THE ART

It is well known that many surface as well as implantable functional electrical stimulation devices for the control of paralysed muscles have been developed since the widely known first published Liberson's idea of using a functional electrical stimulation /1/. Among them the stimulators used as orthotic devices for correction of the foot drop in hemiplegic patients have been the most popular devices. A great advance in technology has been made /2/. Various electronic devices for permanent total implantation have been made since the first implantable cardiac pacemaker. However, implantable functional electrical stimulators for the control of paralysed extremities are by far not as successful as cardiac pacemakers. Only a few stimulators have been used for human implantation. Such devices are open-loop control systems usually because of some problems and limitations regarding the use of closed-loop control systems /3/. In spite of this fact, good results have been achieved with implantable peroneal nerve stimulators in Ljubljana. Research and experiences of a single channel implantable stimulators and some successful human implantations /4/ resulted in development of different dual channel devices /5,6/ , and further in development of multichannel devices /7,8,9/ where more precise and complex movement is achieved by activation of more paralysed muscles. Experiences and results from clinical rehabilitation of gait using surface electrical stimulation systems /10/ contributed to design and development of implantable systems. Dual channel implantable stimulator has been used for many years with different aims /11/.

MATERIAL AND METHODS

The presented implantable system is an open-loop control system with no sensors and no feedback signals except a heel switch giving the information about the position of the leg. We tried to develop simple, small, low cost device with minimum number of channels for designated application. What can be done with two channels? One idea was to improve the push-off phase of the gait with the second channel /11/. Our idea is to get reliable, functional and useful selective activation of the nerve fibres using two channels with variable pulse parameters.

Purpose. The purpose of our dual channel implantable FES system is to provide neuromuscular control in two muscles and thus accomplish better correction of gait. The main aim is reliable selective stimulation of the common peroneal nerve. Thus it would be possible to control ankle dorsiflexion and eversion respectively and achieve more normal gait pattern. The system could be equally used in some other applications. Our approach is to solve problems consequently. In this phase of development we try to apply dual channel stimulator to solve the electrode positioning problem in single channel implant where excessive eversion of the foot usually dominated dorsal flexion /4/.

Description of the system. Our system consists of three main parts: an implantable receiver (implant) with three electrodes, a small microcontroller based external programmable control unit with a transmitting antenna and a portable programmer/stride analyser (Figure 1). The microcontroller is a Motorola M68HC11 with internal memory. An asynchronous serial communications interface is used for communication between the programmer and the control unit. One heel switch is used to synchronise the stimulation with gait cycle. The antenna of the control unit transmits the operating power for the implant and all stimulus parameters. The control unit is simple for use: it has four keys to select the amplitude of the stimulating pulses, one switch for power on and a LED indicator. All other adjustable parameters of the pulses can be set by means of the programmer.

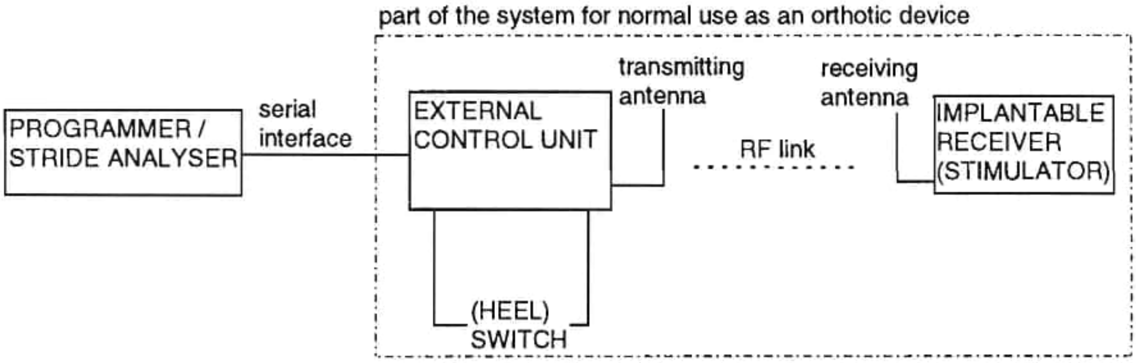

Figure 1. Block diagram of the complete system

In addition an auxiliary stimulator with auxiliary stimulating electrodes has been developed as an implantation tool. By changing software in the control unit different stimulation sequences can be obtained.

Stimulating pulses. Trains of rectangular biphasic constant current stimulating pulses with adjustable net charge flow can be triggered by internal timer or synchronised with gait cycle using one heel switch. Figure 2 shows the shape of the pulses used for the stimulation. The output stage of the implant gives the constant current pulses up to the load impedance of 1000 Ohm. The delay between the positive and negative part of the pulse is zero. Pulse parameters are collected in Table 1. The pulse of the second channel is delayed after the pulse of the first channel because of the encoding and the modulation of the transmitted signal.

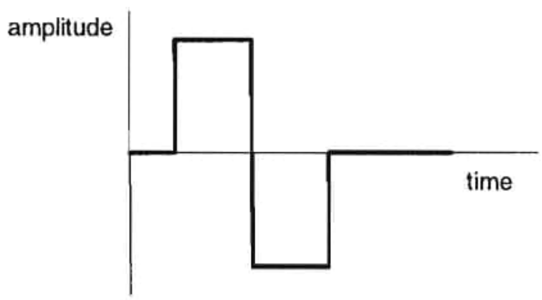

Figure 2. Stimulating pulse

Implant description. Figure 3 displays the implantable stimulator with electrodes. The stimulator is made of biocompatible materials. The encapsulation procedures against the depredations of body fluid have been known for long time /12/. The implant was designed according to different criterion: anatomical, surgical, functional and dimensional.

pulse parameter	from	to
amplitude (current)	**0**	**10 mA**
pulse width (positive part)	**80 μs**	**500 μs**
pulse width (negative part)	**80 μs**	**500 μs**
frequency	**10 Hz**	**60 Hz**
intermittent stimulation (cycle)	**2 s**	**12s**

Table 1. Adjustable stimulating pulse parameters

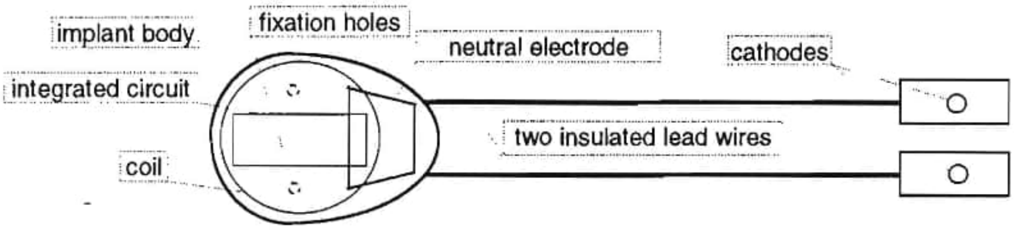

Figure 3. Scheme of the implantable stimulator (implant)

A body of the implant contains the receiving antenna (coil), a hybrid integrated circuit and electrode connectors. The dimensions of the body are: 29mm x 24mm x 5mm. A neutral electrode (cathode) is mounted and fixed on the one side of the implant body. Two stimulating electrodes are connected to the body by means of biomedical wires (stainless steel). They are disc-shaped and imbedded in the silicon fixation sheets. Peripheral nerve electrodes for selective activation of muscles /13/ and monopolar excitation technique is used for selective stimulation of superficial peripheral nerve trunk regions /14/. The complete electronic circuit of the implant is integrated into a 14 pin dual in-line ceramic-metal package. The main part of the electronic circuit is realised as a novel custom designed chip. Only the receiving antenna (coil) and electrode lead wires are connected to the integrated circuit.

RESULTS

The system passed preliminary testing and experiments in vitro. Long-term test has been carried out to determine the stability of the materials used in the implant and the operational stability, reliability and durability of the implant. The biphasic charge density for electrodes is much smaller than maximum allowable for the geometric areas of the electrodes and is in the safe range for the stimulation of the nerve tissue /15/. Two systems have been implanted in two experimental animals. A special implantation technique of the stimulating electrodes has been used to get optimal functional response. Electrophysiological and biomechanical measurements are done during periodical experiments. Goniometers, EMG recorders, dynamometers, special electronic brace for measuring ankle torque, data acquisition systems, X-ray are used. The response dependence on different stimulating pulses and different stimulation parameters is observed an d measured. Periodical tests are done to track the operability and the functionality of the systems. All results are recorded by means of data acquisition systems. Both implanted systems are operable. The effect of the tissue encapsulation of the stimulating cathodes can be overcome by changing the stimulus parameters.

DISCUSSION

Restoration of the function of paralysed limbs and rehabilitation of various forms of neuromuscular dysfunction is possible by using functional electrical neuromuscular stimulation. Reliable, selective, reproducible force recruitment characteristics with determined electrode-muscle recruitment characteristics can be obtained by developing different approaches to the stimulation. Two channels can assure reliable selective activation of peripheral nerves by using proper stimulating electrodes, correct positioning of the electrodes (which depends on the application), good fixation technique for the implantable part of the system, rest period after the implantation and changing the intensity of the stimulation of each channel. This is only one step in development of the useful stimulator. Instead of the open-loop control systems the closed-loop control systems could be used. Sensory nerve signals could be used as a feedback signal in the closed-loop control /16/. After obtaining good results from animal implantation experiments we will be able to extrapolate our experiences to human implantations. The dual channel implantable sistem could be useful also for other applications, for example in hemiparetic patients with persistent improper quadriceps muscle strength which disturb walking. It would demand relatively minor surgical procedure.

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20 CHANNEL IMPLANTABLE STIMULATOR FOR EPINEURAL NERVE STIMULATION

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INTRODUCTION

Beginning with 1982 in four cases of paraplegia two 8-channel stimulators each have been implanted to reactivate knee- (infragluteal nerve, quadriceps muscle) and hip-extension (femoral nerve, gluteus muscle). Active standing up, sitting down, swing through and 4 point gait with crutches and riding a special training bicycle were the main results. A limiting factor was the lack of active flexion. This was one of the main reasons for the decision to develop the new 40-channel system based on two 20-channel implants. The extended number of channels should improve gait and enable stair climbing providing the user with knee- and hip-flexion. Technological improvements concern reliability, bioresistance and biocompatibility. Technology and technical characteristics of the implantable stimulator and results of preclinical animal experiments are described in the following. The subsequent paper (Bijak et al.) deals with biocompatibility of electrodes and functional results of the whole system.

MATERIALS AND METHODS

The basic system requirements for the leg-pacemaker include 20 output channels for each implantable stimulator and the capacity of simultaneously controlling two implants for the external control unit. Power and control commands are transmitted from the external unit to the implanted stimulators through two radio-frequency links. Multi-contact connectors are installed between stimulator and electrode leads. The configuration of the complete system is shown in figure 1, the communication protocol for pulse-to-pulse parameter control in figure 2.

Implantable stimulator, stimulation parameters: The receiving antenna couples into the externally produced electromagnetic field. The induced RF-signal is rectified and regulated to form the internal power supply.This power source is used to provide the output stage with sufficient voltage and current capabilities to output stimulus pulses. It is also used to form a low-voltage power supply for the control logic. The receiver demodulates the information containing stimulation constant current amplitude, pulse width, impulse frequency, polarity, and target electrode outputs (figure 2). The parameters are not affected within a transmitter to receiver distance range as great as 10 cm. The current amplitude range covers 0-5 mA with 8 bit resolution (256 steps), impulse duration varies between 0.05 and 1.0 ms, and the upper limit of the frequency range is 200 Hz when stimulating 3 nerves simultaneously.

The electrode outputs are DC-decoupled via capacitors and are programmable as anode, cathode, or switched off from impulse to impulse within one electrode group (5 electrodes). The whole stimulator circuitry has been implemented in thick film hybrid form including two gate-array circuits containing part of the control logic.

The packaging and encapsulation of the implantable stimulator must provide suitable long-term protection for the electronic circuitry which is compatible with the body's internal environment and meets all requirements for proper operation. Encapsulation procedures should not adversely affect the stimulator circuitry during construction, and provide all the appropriate interfaces to the tissues. Materials used for the package must be sterilisable, have sufficient long-term bioresistance, not evoke excessive tissue response, and provide maximum circuitry protection without unnecessary volume or weight.

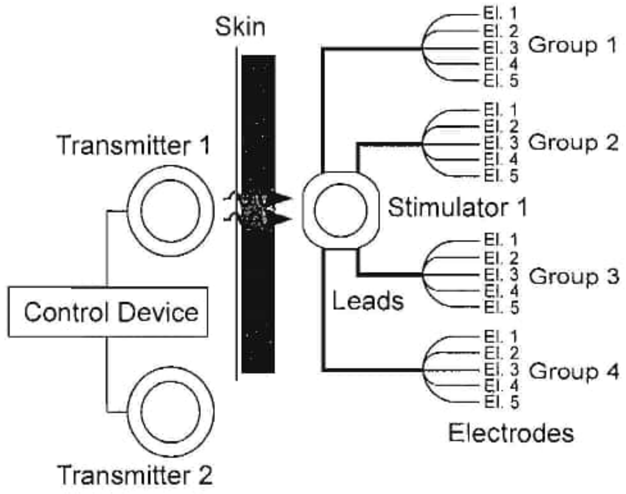

Figure 1
System configuration, block diagramm

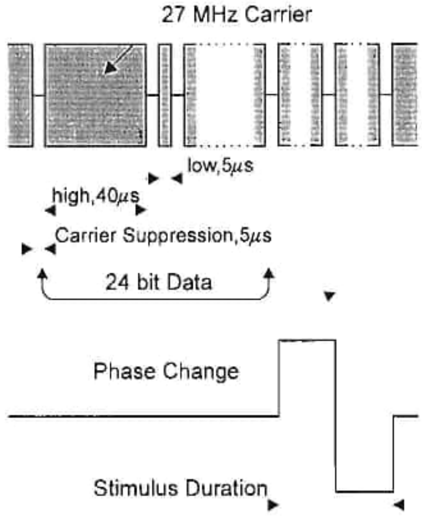

Figure 2
Carrier modulation / single stimulus

The niobium package for encapsulation of the stimulator electronics has been developed in our laboratory. This package design utilizes 24 feedthrougs emerging from the base plate of the package. The hybrid circuit is attached to the base plate and connections are made to the feedthroughs (gold wire bonding to tantalum pins). The capsule is sealed with the lid being welded to the base plate using pulsed YAG laser welding in a helium atmosphere. The overall hermeticity is verified using a helium fine leak test. Electrode connectors and the niobium made single turn antenna are connected directly to the feedthrough pins using electrical compressive spot welds. The whole assembly is encapsulated with the epoxy resin Hysol (figure 3). For a monopolar version the upper surface of the lid is left exposed to form the reference anode.

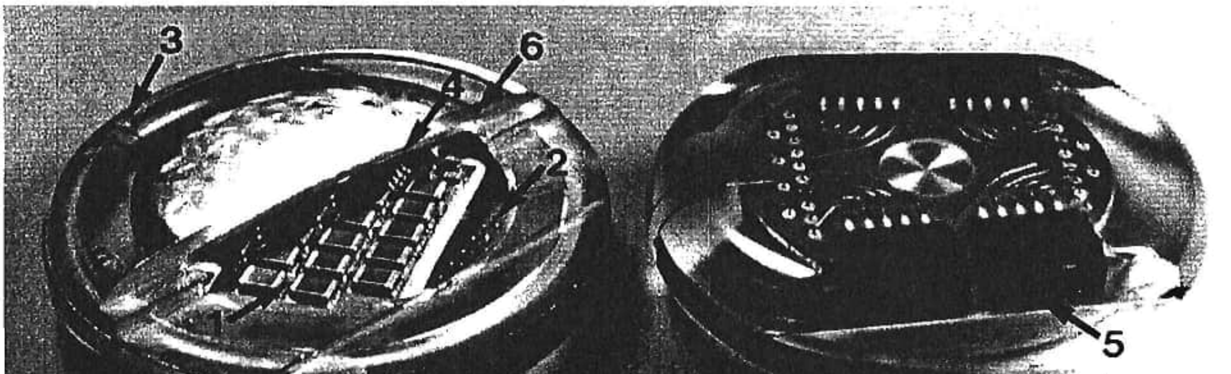

Figure 3: 20-channel implant: (1) hybrid, (2) tantalum pins (feedthroughs), (3) antenna, (4) niobium case, (5) electrode connectors, (6) epoxy (Hysol)

Animal evaluation has been undertaken to address the overall system performance. The parameters of primary interest were long-term behavior of threshold level of stimulation, force recruitment characteristic, selectivity of recruitment via epineural stainless steel electrodes and effects on tissue interfaces. Electrodes were attached to the femoral nerve to induce knee-extension, nervus gluteus caudalis for hip-extension, nervus glutaeus cranialis for hip-flexion,

nervus tibialis for knee- and ankle plantar-flexion, nervus peroneus for ankle dorsi-flexion, and additionally to the sciatic nerve to compare knee- and ankle-flexion via different electrode sites. The study included 6 sheep, mechanographic and EMG-data were collected through the investigation period of 6 months.
Both, the tissue interfaces and the surfaces of the implanted components were analysed at the end of the experiments. Samples of the tissue envelopes of the stimulator and the electrode leads and electrode-nerve samples were fixed in formalin-ethanol, embedded in polymethyl-methacrylate, and then cut and ground to 70 to 100 µm thick sections and analysed by light microscopy after modified Paragon-staining.
The technical system performance was observed through the investigation period, especially the reliability of stimulation parameters and long-term stability of the RF-link.

RESULTS

All 6 implanted systems worked without any disturbance during the whole evaluation period of 6 months. No change in technical data was observed except the slight drop of the resonance frequency we had to exspect. Figure 4 demonstrates the shift of the frequency characteristic associated with the penetration of moisture into the epoxy resin. After 2 to 4 weeks this effect saturates and the characteristic stabilizes.

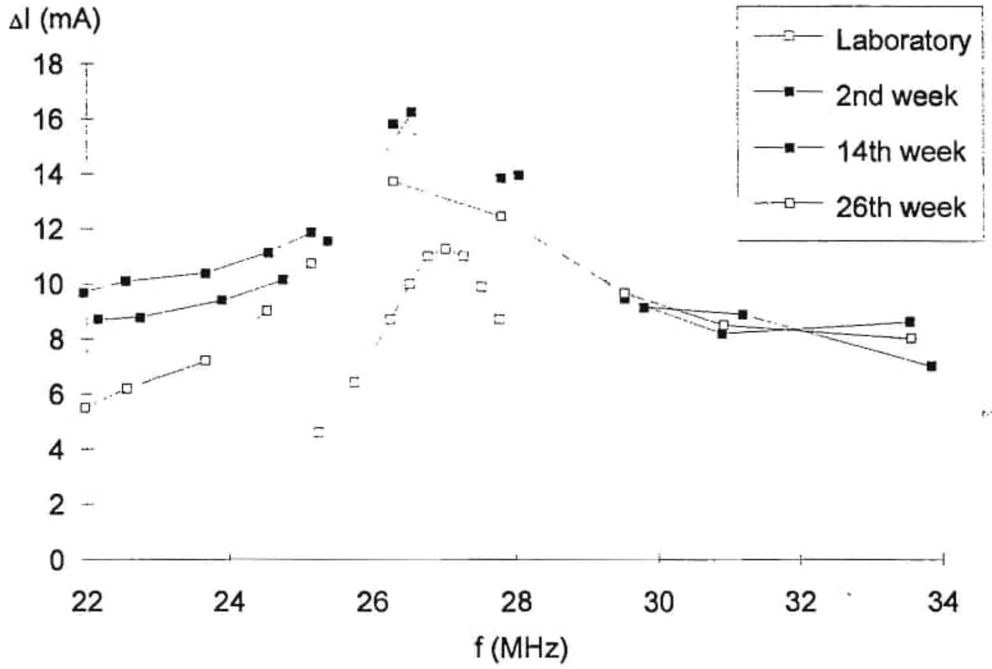

Figure 4: Frequency characteristic of the RF-link
ΔI = current uptake of the loaded minus unloaded transmitter

At the tissue/implant-interface a pseudosynovial layer with macrophages and multi-nucleated giant cells is formed, followed by multiple fibrous and fatty tissue layers (figure 5 and 6). This normal foreign body reaction was found to be stable and constant over the whole implant surface and in all animals. Neither pathological changes of the surrounding tissue nor signs of degregation of the implant surface were observed.

DISCUSSION

The animal study has shown that the 40-channel leg-pacemaker system is usable for FES of multiple lower extremity muscles via their supplying nerves. The implantable stimulators as well as the electrodes have proofed to be reliable and long-term biocompatible. The implant design

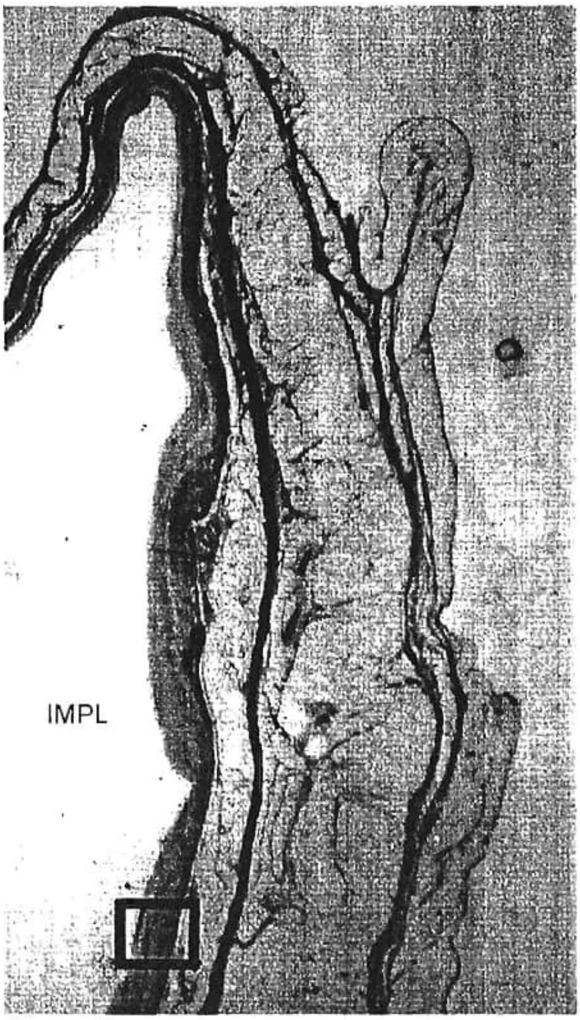

Figure 5
Connective tissue envelope after removal of the stimulator/receiver (IMPL)
magnification: 7

Figure 6
Enlarged detail showing a pseudosynovial layer (PSL) with macrophages and multi-nucleated giant cells at the implant-interface, followed by multiple fibrous and fatty tissue layers (FL) and a vascular layer (VL)
magnification: 100

with all components encapsulated in a hermetic niobium case in combination with a single turn niobium antenna seams to provide remaining stability of the RF-link and optimum life-time.
The above results will bring our plans closer to clinical trials. The external hardware is undergoing marked modifications so that the paraplegic subject will have a belt-worn microprocessor with programs that enable individual muscles or groups of muscles to be stimulated for exercise, standing and walking.

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20 CHANNEL IMPLANTABLE NERVE STIMULATOR, PRECLINICAL TESTING

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INTRODUCTION

In 1981 the "Vienna Working Group of Functional Electrostimulation" developed an 8-channel implantable nerve stimulator. This FES implant in conjunction with epineural electrodes /1,2/ is up to now used for phrenic pacing /3,4/. In addition "Carrousel Stimulation" /5/ helps to avoid diaphragm fatigue. In 1982 the same 8-channel device was implanted to mobilise paraplegics (leg-pacemaker) /6/. Active hip- and knee-extension could be restored so the patient was able to stand up, walk (4-point-gait, swing-through-gait with crutches) and ride a bicycle. The lack of active hip- and knee flexion led to the development of a 20-channel-implant (4 groups with 5 electrodes each). For easy handling of all the 20 electrodes a five in one electrode lead was produced. After finishing the technical part /7/, the device was tested in an animal study. Pacemaker and electrodes were implanted in six sheep and permanently observed over a period of six months. Finally the histology of tissue interfacing electrode leads, electrode tips and stimulator were investigated.
The animal study itself and the results will be described in the following.

MATERIALS AND METHODS

20-channel implantable nerve stimulator (20 channel implant)

The electronic circuit is located in a hermetically sealed (laser-welded) niobium case. Glass to metal seals link electrode connectors and receiving coil to the electronic circuit. All parts are embedded in hysol. The 20 channels are organised in 4 groups 5 electrodes each. Only electrodes out of the same group can be activated at same time either as anode or cathode.

Electrodes

The electrodes and the electrode leads are made of stainless steel (316L) stranded wire with 12 strands, 50µm in diameter each. The five electrode leads are coated with teflon for electrical isolation, helically coiled into a silastic tube. This multi electrode lead is split up into spiralled single leads at the end. Ring-shaped electrode tips with a diameter of 1mm form the interface to the nerve.

Implantation

The experiments were carried out using 6 female sheep. The implant was placed close to the spinal column. From the implant the electrode leads run to the nerves of the left hind leg. With microsurgical techniques the electrode tips were fixed to the epineurium of the nerve. Different electrode configurations were chosen to find an optimum, referring to the clinical application of the implant for the lower extremities.

Time schedule

For every sheep the study lasted 26 weeks. Surveys were carried out 2 weeks, 14 weeks and 26 weeks after implantation.

Survey

The sheep was anaesthetised and lay on his back. To find out the *threshold currents* each electrode was switched as cathode, the remaining four of the entire group as anode. Starting with 0mA the current amplitude was continuously increased until the first muscle response occurred. Maximum isometric force vectors in horizontal and vertical direction evoked by different electrode combinations were investigated next. For force measurement the hind limb was connected to a metal truss that holds two orthogonally mounted load cells. Stimulation current was further increased until the force saturates. *Maximum force* and related *saturation current* were recorded.
These measurements were performed with hip and knee extended for hip and knee flexion force and 90° hip- and knee-flexion for hip and knee extension force.
The stimulation parameters were 26 Hz and 0.6ms, the stimulation current varies.
At the end of the third survey stimulator and electrodes are explanted and samples of the tissue interface, nerve and muscle were investigated histologically.

Time between measurements

To operate the stimulator as close as possible to the perspective conditions the system was active for 8 hours per day. Every electrode was cathodically activated once per minute for 1 second. To avoid irritation of the sheep subthreshold stimulation with 80% of the threshold current was carried out.

RESULTS

Threshold current

The threshold behaviour during observation time is shown in Fig. 1. Two weeks after implantation the threshold current had its highest value. Due to the healing process in the electrode area the threshold current decreases until a stable electrode tissue interface was configured. The final threshold value usually keeps stable for years /2,4/. A sudden increase of the threshold current would indicate electrode dislocation or other electrode problems.
The mean threshold current of all 120 electrodes was initially 0.76±0.1mA, after 14 weeks 0.67±0.05mA and after 26 weeks 0.58±0.06mA (Values: Mean±SEM).

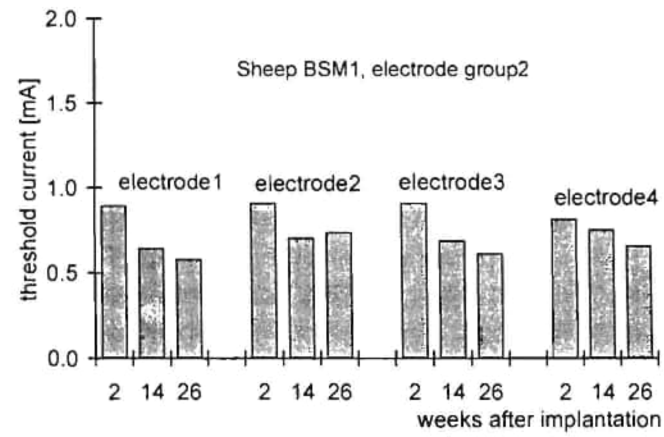

FIGURE 1
Threshold current vs. time for
4 electrodes of a group

Force

Figure 2 shows a typical follow up of vectors. The related stimulation currents are 2.7mA, 2.8mA, 2.6mA in the left diagram and 2.0mA, 2.7mA, 1.9mA in the right diagram.
The left diagram indicates forces evoked by stimulation of the trunk of n. femoralis, the right one of a branch of n. femoralis. Both show hip and knee extension as generally recorded with high force amplitude. Flexions generate small forces only.
The accuracy of force measurement is limited due to fixation of the limb to the transducer and the animal to the operation table without hurting it.

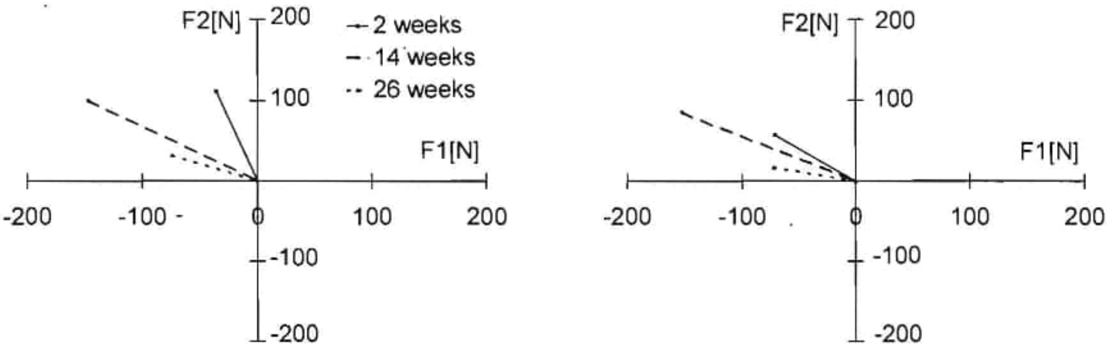

FIGURE 2
Force vector caused by stimulation of trunk (left) and branches (right) of n. femoralis

Histologic Findings

Figure 3 shows the cross section of two multi-electrode leads. In the left part of the picture five stranded, teflon coated, electrode leads embedded in the silastics can be seen. The silastic tube is surrounded by fibrous tissue.
Figure 4 presents the cross section of the epineural electrode close to the stimulated nerve. The electrode itself is covered with connective tissue.
Normal tissue reaction and no signs of nerve damage or electrode corrosion were observed after six months of stimulation eight hours per day.

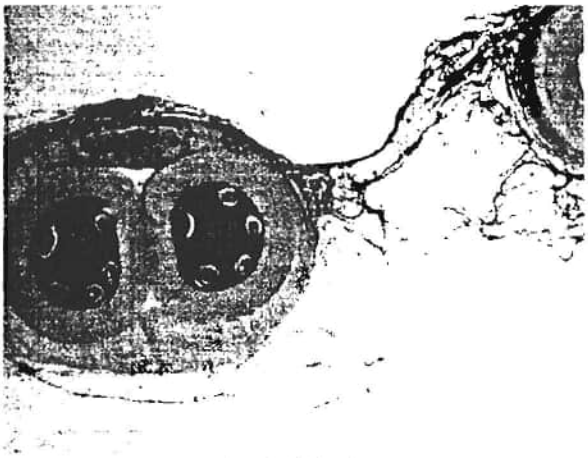

FIGURE 3
Cross-section of two electrode leads(EL) with surrounding fibrous and fatty tissue. (mag.:9)

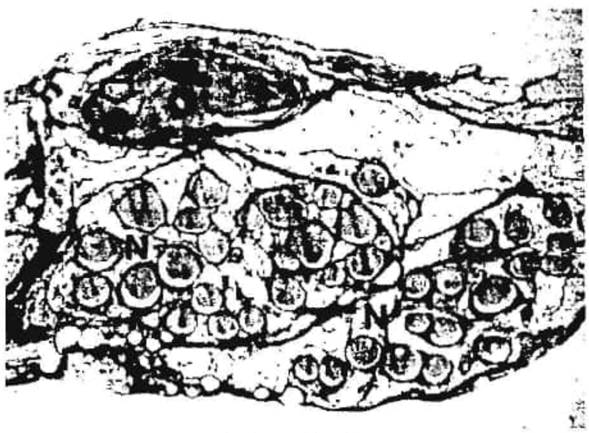

FIGURE 4
Cross-section of two electrode ends (arrows) close to the stimulated nerves (N) in a separate connective tissue. (mag.:17)

Electrodes

120 electrodes have been implanted during this study. In no case any electrode dislocation, electrode corrosion or broken wires occurred.

DISCUSSION

In all experiments extension as well as flexion of hip- and knee joint could be demonstrated with useable recruitment characteristic and force level.
The animal model provides only a rough approximation of the human anatomy. The final decision of electrode sites cannot be determined until the first clinical application. Care must be taken when choosing the electrode location to avoid recruitment changes due to moving electrodes.
The 20-channel implant and the electrodes have passed the preclinical animal study and proofed to be reliable and biocompatible.

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Simulation of the Electrically Stimulated Auditory Nerve

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SUMMARY

The electrically generated firing pattern in the fibers of the primary auditory nerve is simulated for a monopolar stimulating electrode. Using an analogous input speech signal the spiking pattern produced with a single electrode has a simple structure which makes no use of the two important coding principles used by nature. By computer simulation it is possible to obtain an approach of the firing pattern of the auditory nerve fibers. Listening to the information carried by the compound action potential of the auditory nerve demonstrates that speech signals with dominant high frequency components are difficult to discern - or it is not possible at all.

A strategy for speech processing is presented which seems to improve speech understanding for single-channel implant patients, because thereby neural patterns consisting of more temporal information can be generated.

1. SPEECH REPRESENTATION IN THE AUDITORY NERVE

Acoustical signals are represented in the auditory nerve both by place-rate information and by the fine structure of the time differences in the spiking pattern.

The place information (tonotopic principle) is mainly caused by the mechanical properties of the basilar membrane which changes from the base to the apex: Every place along the basilar membrane has its characteristic frequency. This means that stimulation with a pure sinusoidal tone results in high amplitude vibration only within a small area. It is interesting that the frequency difference limen of 0.2% at 2000 Hz /1/ corresponds to just a little more than 10 µm between two places of resonance. This is about the distance between two neighboring inner hair cells (3500 inner hair cells standing in a line of 35 mm length lead to a 10 µm distance).

The temporal information results from the physiological properties of the hair cells: Every pressure wave of the inner ear fluid causes the hairs (stereocilia) of the receptor cells to be bent, ionic currents enter the cell and the small variations of inner hair cell potentials produce transmitter release which generates action potentials in the axons of the auditory nerve. In this way acoustical signals up to 4000 Hz have synchronized responses in the neural signal. In contrast to the inside potential of a single hair cell, which is able to directly follow the pressure variations of the acoustical signal, the hair cell information is distributed to 8 fibers/cell, because the maximum firing frequency of a single fiber is essentially below 1000 spikes/second. (Electrically stimulated fibers can fire with frequencies just above 1000 spikes/s.)

The ear is able to make use of the sharp tuning properties of the basilar membrane only in the case of periodic signals which are presented for several periods, because the first pressure waves move nearly the whole basilar membrane, and it needs time to make vibration maxima sharper /2/.

Therefore there is a fundamental difference in the neural coding of pure tones or combination of tones and the aperiodic parts of a speech signal: The temporal principle is of high importance for speech representation in the auditory nerve and the place representation is not sharp /2/. Neurograms of the auditory nerve are dominated by a capture effect, i.e. the formant frequencies of the speech signal capture fibers with caracteristic frequencies from a band which has a width up to one octave and even more (Fig. 1). Note that the 120 Hz frequency (f_0) is present in all the fibers.

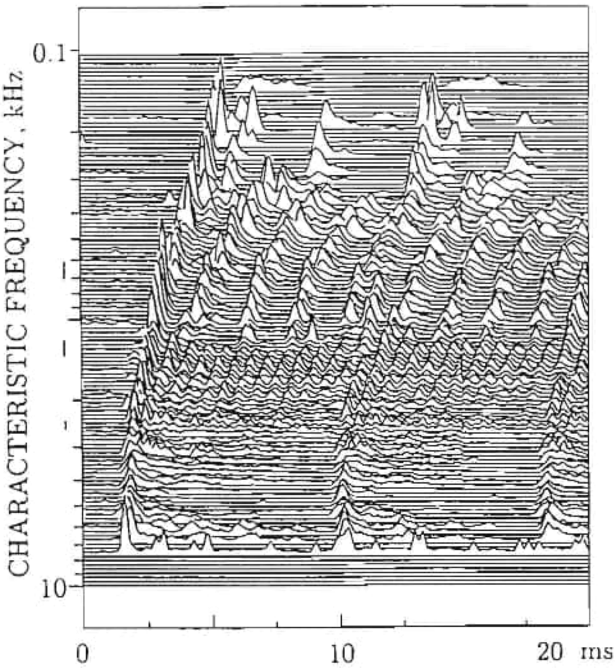

Fig. 1. Firing behavior from 223 acoustically auditory nerve fibers from a single cat with characteristic frequencies between 100 Hz and 10 kHz. The stimulus was the synthetic speech signal /da/ consisting of the frequencies f_0, f_1, f_2, f_3, which are slowly changing as marked by bars on the left side. The 69 dB stimulus lasted 100 ms, but reactions are displayed for the first 20 ms (10 ms of delay dropped).
Every line represents a histogram of the firing times of a single fiber. The lowest line corresponds to a fiber with a characteristic frequency of 10 kHz. Note that the delay, which includes a mechanical (pressure wave) and neural component, increases for lower frequencies.

Adapted after /3/.

2. SIMULATION OF ELECTRICALLY STIMULATED NERVE FIBERS

Several models are available to simulate reactions of electrically stimulated human nerve fibers, however, a slightly modified Hodgkin-Huxley model (with a temperature factor k=12 and reduced hyperpolarization) is best suited in the case of the auditory nerve /4-6/. At first glance other membrane models for myelinated fibers should be more adequate. By detailed investigation it turned out that the Hodgkin-Huxley model is the only one which reflects the following features known from experiments:

(i) It is able to respond with multiple spiking within a period of low frequency stimuli.
(ii) It fits a maximum firing rate of 700 spikes/s.
(iii) Chronaxy of 340μs is very close to the measured ones.
(iv) There are some accumulation effects which were tested in a double pulse experiment: A signal consisting of two 100μs pulses (amplitudes: I_1, I_2), which are separated by a 100μs interval, was alternatively offered to a cochlear implant patient with a single impulse of strength I_1. If the second impulse leads to another perception, additional fibers more distant to the electrode will also produce spikes. These fibers would react in a subthreshold manner by the single pulse experiment, but nevertheless, their membrane potential arising from the first impulse must be considerable at the beginning of the second pulse, because in the just discernable case I_2 is less than 10% of I_1. For details see /4, pp. 217-219; 5/.

This effect (iv) seems to be the only one that allows a single channel implant to generate short time differences in the spiking pattern of the auditory nerve. Such time differences below 1ms are important for speech decoding, however, they are rare or even missed in the coding pattern generated by single channel implants (Fig. 2).

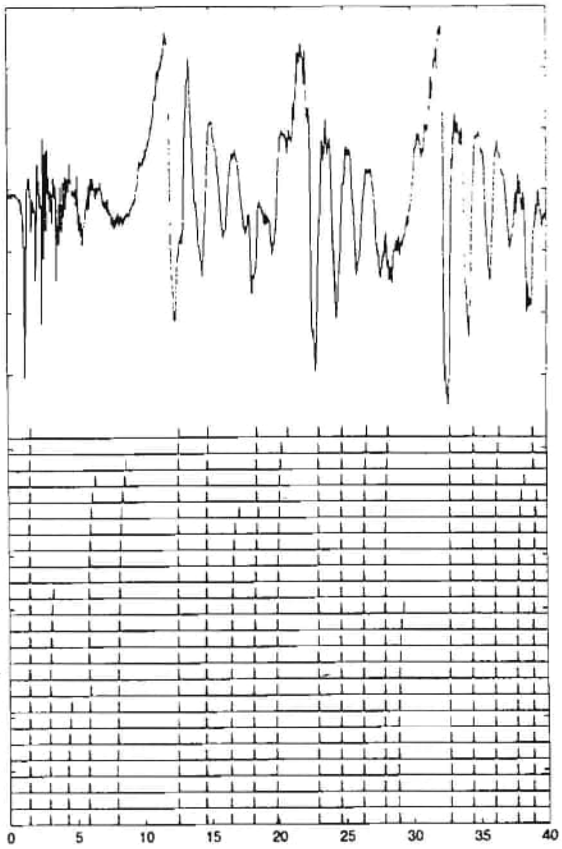

Fig. 2. The electrically stimulated fibers of the auditory nerve are sharply synchronized with the minima of the stimulus. First 40ms of /da/ from a female speaker (top) are used as stimulus with varied signal strength in order to simulate fiber reactions (bottom lines). Different lines correspond to fibers with different distances to the stimulating electrode. Although the naturally spoken /da/ has more temporal irregularities than the synthetic one, the temporal information in the electrically stimulated nerve is poor. Even the sum of all the fiber activities (compound action potential) carries less information than e.g. the 1kHz fibers shown in Fig. 1.

3. LISTENING TO THE COMPOUND ACTION POTENTIAL OF THE AUDITORY NERVE

The compound action potential reflects the temporal behavior of its components, i.e. the overall information about the spiking times of single fibers is present. With the help of a sound blaster card we used this attribute in order to hear the information which may be available to a patient who is supplied with a single channel cochlear implant. To obtain the acoustical information of the auditory nerve we used the following procedure: The speech signal enters the Hodgkin-Huxley model, which predicts the nerve responses of 25 fibers at different distances to the electrode. They produce a spiking pattern corresponding to Fig. 2. By summing up the spiking times we generate a histogram which is comparable to the compound action potential. Listening to these computed neurograms demonstrates the poor temporal information which is available by the usual single channel stimulation.

4. A SINGLE-CHANNEL SIGNAL PROCESSING STRATEGY

Cochlear implant patients can obtain better perceptions, if the auditory nerve pattern carries more information. In single channel implants more temporal information can be generated in the fibers of the auditory nerve by making use of the accumulation effect described at (iv) in section 2. Fig. 3 demonstrates that it is possible to produce a firing pattern which follows the temporal structure of a speech signal. In this case a pulsatile technique is used. For details see /4, pp 222-229; 7/.

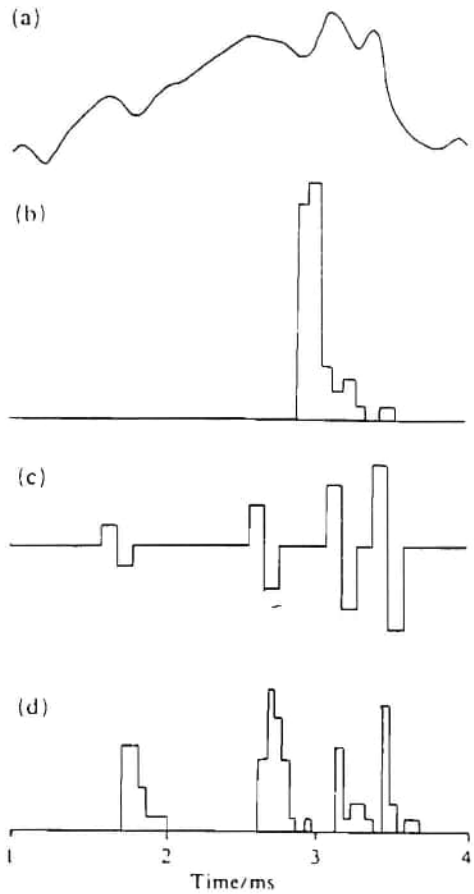

Fig. 3. Comparison of computed neural answers generated by normal analogous speech input and results of a refined pulse strategy coding. (a) Half wave of speech signal /i/. (b) the total nerve response in the form of a poststimulus histogram generated by normal analogous stimulation of 50 auditory nerve fibers with different distances. (c) Sequences of bipolar pulses corresponding to the maxima of the speech signal. (d) Histogram of the computed responses of 50 fibers stimulated with signal (c) shows that it is possible to obtain a fine temporal resolution even with singel channel electrodes.

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Fast stimulator cochlear implant systems
The Wuerzburg experiance using the MED-EL COMBI-40
Surgical considerations and preliminary results

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A significant amount of progress in the cochlear implant field can be achieved through further development of speech coding strategies. The MED-EL COMBI-40 fast stimulator cochlear implant system is a new device which is available since January 1994. The surgical procedure does not present any particular difficulties for the well trained otologist, however some technical details may simplify the surgical procedure and reduce the number of possible complications. The surgical technique which is used in Wuerzburg minimizes the danger of trauma during insertion of the COMBI-40 electrode which is softer than other cochlear implant electrodes. Therefore some extremely deep insertions have been achieved.
The Wuerzburg experiance is based on 29 patients which have been implanted with this new device since January 1994. We were pleased by the speed with which the patients achieved an open speech understanding. For the monosyllable word tests (Freiburger Einsilber, Vestra-CD No. 1) the patients scored (mean monosyllable word score)

33 % two days post fitting.
48 % at the one month test interval
66 % at the six months test interval.

Maximum score reached in the monosyllable test so far is 90 % at the 6 months test.

EXPERIENCE WITH A NEW COCHLEAR IMPLANT IMPLEMENTING THE CONTINOUS INTERLEAVED SAMPLING STRATEGY

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SUMMARY

Since April 1994 18 patients underwent cochlea implant surgery, supported with a MED EL Combi 40 device. This new cochlea implant implements a new speech coding strategy, called continous interleafed sampling (CIS). There are eight pairs of active electrodes over a length of 20.6 mm at the electrode array. Through this strategy, at any defined time there is one defined spike in one defined part of cochlea. Stimulation rate by CIS is 12500 pulses per second.
In postlingual deafened adults postoperative speechtestresults are excellent and better than known up to now. In praelingual deafened adults and in children results are encouraging and interesting in future development.

STATE OF THE ART

Worldwide there are implanted around 12000 patients up to now. Out of them 1700 children. Vienna Medical School was one of the very first, starting in 1978. Now we are responsible for 140 cochlea implant patients (25 children). After epoxy, 3M-Vienna, single and different multichannel devices, we can call very fast stimulator cochlea implants like the Combi 40, which are available since last year, third generation implants. These third generation implants (MED EL Combi 40 (TM) or Clarion (TM)) have an enormous increased pulse rate (6 kHz-12.5kHz), compared to former devices. Individual fitting, changes of mapping laws and the possibility of special tuning each channel, bring advantages and more postoperative success.
Also surgical technique improved. Cochleostomy, cochlea-endoscopy, deep insertion surgery and intraoperative stapedius reflex are perfect tools in correlation to patients clinical effort and personal benefit of cochlea implants.

MATERIAL AND METHODS

We implanted ten postlingual deafened adults (age 34 years to 65 y.), mean duration of deafness 7.5 years (half a year up to 24 years), five praelingual adults (age 15 years to 31 y.) and three children (age 24 months, 48 m. and 54 m.). All patients were supported with a MED EL Combi 40 cochlea implant. Surgery was performed through cochleostomy. Cochlea endoscopy was done in 15 cases. Intraoperative stapedius reflex levels were measured and recorded whenever possible (condition: intact stapedius muscle and tendon; for example not possible in otosclerosis). In all patients except one, complete insertion of all electrodes was done. Seven times deep insertion of 30mm was possible. In one case, because of complete cochlea ossification caused by meningococcal meningitis, just five electrodes could be inserted 11 mm.

RESULTS

postlingual adults: seven of ten patients had open set speech understanding after initial fitting. Already established tests like noise detection, speech or word detection, were too simple. In all postlingually deafened adults we started after initial fitting with Freiburger number test (german language), Freiburger monosyllable word test (german) and Sotscheck-test (word-rhyme test). After initial fitting mean score of Freiburger number test was 70% correct answers (50%-100%). Mean score of Freiburger monosyllable word test was 56% (30%-80%) correct answers. Mean score of Sotscheck test was 55% (0%-72%) correct at initial fitting. All tests were performed without lipreading at comfortable loudness levels between 70dB(A) and 80dB(A). Six months after initial fitting mean score of Freiburger number test is 93% correct answers, mean of Freiburger monosyllable 82% correct answers and mean of Sotscheck-test 76% correct answers. Subjective all patients are very happy and use their implant all over the day.

praelingual adults: All patients could score and determine noise recognition and detection tests after initial fitting. Compared to the group of postlingual deafened there is not this surprisingly, astonishing immediate effort. Of course there is a difference to former times of first and second generation implants, but even CIS cochlea-implants are not a guarantee to have fast progress in speech production and control in praelingually deafened adults. All patients are implantuser, especially in their job and subjective they are satisfied. The implant helps voice control and together with lipreading it is a benefit in word recognition and speech understanding.

children: Immediately after initial fitting (especially using intraoperative stapediusreflex-levels) there is a good and safe answer to noise detection and pure tone audiometry. Pure tone audiometry thresholds are between 500 Hz and 4000 Hz within 30dB(A) up to 45dB(A). Compared to children supported with other devices, we expect these three children in regular school, first because of the good pure tone result and second because of their young age (24-54 months). Frequent postoperative training will start speech production and auditory skills which allows regular education in an auditory environment.

DISCUSSION

Third generation cochlea implants, like the Combi 40 (MED EL company TM), implementing CIS strategy bring a new, better standard and clinical efforts and benefits in the large field of cochlea implantation. Fast stimulation combined with individual variability of fitting parameters open a new perspectives of rehabilitation and personal patients benefit. Especially postlingually deafened adults are winner of these circumstances. 70 % of postlingual deaf patients will have open set speech understanding after initial fitting. Within seven months after surgery nearly each patient will have open set speech understanding and will be back from isolation, because of his disease or accident, in his used auditory environment and probably in his former profession. Short term deafness additionally increases chances of fast and very successfull rehabilitation. It is an aim to implant postlingually deafened patients as soon as possible. Children will have very good chances as well. Our`s and international results show, that cochlea implant surgery under the age of four allows auditory education, independent if there is congenital, praelingual, perilingual or postlingual deafening. Frequent rehabilitation should lead to regular school education. Nowadays it is a medical and ethical necessity to implant a child before the age of four, independent of etiology.

Ambivalent and not generally convincing can be seen cochlea implant surgery in praelingually deafened adults, even with third generation implants. Obviously neurobiological basics still can not be fooled by sophisticated technical tools. Implants in these group can be a benefit in single cases, but generalisations in praelingually deafened adults should be avoided. All our patients use and wear their implant, especially in their job. They are good in noise recognition and noise detection and the implant supports word understanding by lipreading. Up to now, after ten months implant time, we have not seen real speech production and no word understanding without lipreading. Singularely number understanding is possible. Generally we should not recommend cochlea implantation in all praelingual deaf people. This is a very special topic and in these patients cochlea implant surgery just should be done under very special considerations and circumstances.

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The Influence of Stimulation Rate and Number of Stimulation Channels on Speech Understanding with CIS Strategy Cochlear Implants

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The MED-EL COMBI 40 fast stimulation cochlear implant system implements the CIS (Continuous Interleaved Sampling) strategy according to B. Wilson of RTI (USA). The CIS stimulation strategy generates multi-channel non-simultaneous biphasic stimulation pulses at a constant rate. The amplitude of each pulse depends on the output of an envelope detector (rectification and low pass filtering stages) for each of a number of frequency bands which together cover the speech range. The frequency bands correspond to the number of contacts in the intra-cochlear electrode. For good speech recognition, stimulation rates above 800 p.p.s. are necessary, yet at 1500 p.p.s. there was still improvement observed.

Non-simultaneous stimulation is instrumental in achieving good communication capabilities since it greatly reduces field interaction problems leading to channel cross talk and overlapping which has hampered multichannel analogue stimulation strategies.

Several parameters of the CIS-strategy can be varied and optimized. The most important ones are the stimulation rate per channel and the number of channels. The overall sampling rate of the COMBI 40 is 12.120 p.p.s. corresponding to approx. 1500 p.p.s. per channel with all 8 channels active.

In the COMBI 40 standard fitting, for smaller numbers of channels the stimulation rate automatically increases accordingly.

Systematically switching off channels, starting from 8 and decreasing down to 2, while keeping the stimulation rate constant at 1500 p.p.s., results in only slight deterioration of speech understanding down to 4 channels, yet a rapid decay below.

In contrast to this, decreasing the stimulation rate while keeping the number of channels constant (i.e. at the maximum possible with a particular patient) results in about a linear decay of speech understanding.

ELECTRICAL STIMULATION OF NERVE CELLS IN BRAIN SLICES: A MODEL FOR MULTI-CHANNEL-AUDITORY PROSTHESIS

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SUMMARY

The brain slices technique was used to measure the effects of different stimulus configurations of a multichannel electrode on neuronal tissue. The use of an in-vitro system permits an easy access for determing potential field and current flow generated by the electrode as well as the activity of nerve cells.

STATE OF THE ART

Electrical stimulation of the cochlear via a cochlea implant has become an important aid for the profoundly deaf providing acoustic information. Different electrode systems and stimulation strategies for cochlear as well as brainstem implants have been developed to optimize speech recognition of implantees. One problem in respect to multichannel stimulation results from the interaction of neighbouring channels /1/. The current spread of simultaneously activated electrodes leads to a loss of spectral resolution /2/. To compensate or reduce current spread processor strategies like lateral inhibition or continuous interleaved sampling (CIS) have been developed /3/.

For designing new multichannel implants it is necessary to get information about current distribution around the electrodes and within the surrounding neuronal tissue. Several studies exists describing current distribution in and around the cochlea of man and mammals aquired by measuring and modelling /4/. We have started an approach to investigate this problem using in vitro brain slices of young rats. The in-vitro experiments make it possible to measure field distribution of the electrode as well the evoked activity of nerve cells under defined and visually controlled conditions.

MATERIAL AND METHODS

Preparing of slices

Young rats (3-4 week) of either sex, were decapitated and the brains were rapidly removed and placed in ice-cold physiological saline solution (ACSF). The dorsal or ventral parts of the hemispheres were cut coronally using a vibratom. The 350 µm thick slices containing visual or auditory cortex were incubated in a chamber perfused with carbogen gas at room temperature for one hour. After incubation slices were placed in the recording chamber which was continuously perfused by warm (30°C) oxygenated ACSF.

Stimulation and recording system

For stimulation a 28-channel electrode array with a concentric design (s.fig.1d) was constructed. Each channel consists of a varnished silver wire with a diameter of 100 µm. The bundle of single channels were coated by epoxy resin. Each channel could be activated independently via optically isolated current sources.

The activity of cortical cells was recorded intra- and extracellulary with microelectrodes filled with 3M potassium acetate or a fluorescence tracer (Lucifer Yellow, LY) dissolved in 1M LiCl. The resistance was in between 1-3 (extracellular) and 80-250 MΩ.
Recording and stimulation systems were controlled via a computer (PC).

Experimental procedure

- Determination of potential fields of the electrode in respect to different stimulus configurations. To measure potential fields the electrode was fixed in the recording chamber which was installed on a motorized scanning stage mounted on an inverted microscope. The recording electrode was fixed on a motorized micromanipulator and located at the opposite side of the stimulus electrode. The reference electrode (AgCl pellet) was integrated in the slice chamber at a great distance (20 mm) to minimize disturbances of the measured field. The positioning of both electrodes were under computer control. This arrangement allowed an automatic 3-dimensional scanning of potential fields within the recording chamber with a resolution of 1 µm. The measuring procedure consists of scanning planes parallel to the surface of the stimulation electrode with succesively increasing distances. Examples of the distribution of potential fields within a plane are shown in fig.1a-c

-Cell activiy
The stimulus electrode was placed on the white matter of the slices. Recordings were made from cortical layers III to V. At the begining of experiments gross stimuli (biphasic pulses 100 µs/phase, maximal distance between channels, repetition rate 1 Hz, amplitude 100 µA) were used. Cells with stable resting potential and clear responses (APs, PSPs) were used for further experiments. Intracellular activity of a neuron could be measured for 30 min. Successfully recorded cells were labeled with LY to identify location and morphology. Labeled cells were imaged by a CCD-camera to calculate 3D-reconstruction of the cell. The orientation of the cell as well as the knowledge of current disribution are important requirements for determination of the efficiency of stimulus configurations (orientation of field vectors vs orientation of the activated fibers or cells).

RESULTS

Measurement of potential fields

Fig.1a-c shows the results of 3D field potential measurements in the saline filled slice chamber. For demonstration one single plane with a distance of 100 µm from the electrode surface (fig.1d) is selected. Three different stimulus configurations with the multichannel electrode were testet. Channels used for stimulation are indicated by small characters. The electrical field are described by their equi-potential contours (continuous lines) and the current density depicted by arrows (projection on the xy-plane). Length of arrows characterizes current strength, arrowheads give the direction of current flow. The field potential in fig.1a belongs to a simple bipolar stimulation caused by the electrode pair xx. The current distribution shows a dipole character with a maximum of current density between the two electrodes. Above the electrodes the maximum current vector is directed perpendicular to the xy plane so that only a spot is seen. Bipolar stimulation with the electrode pair yy resulted in a similar current distribution (fig 1b). According to the position of electrodes the field is rotated by nearly 90°. Simultaneous stimulation of both channels produced strong current densities at different locations (fig.1c). The asymmetric distribution of current densities found in all cases could be an effect of an inhomogeneous surface of the stimulation electrodes. Furthermore if the electrode is not parallel to the measurement plane distortions of the field distribution result.

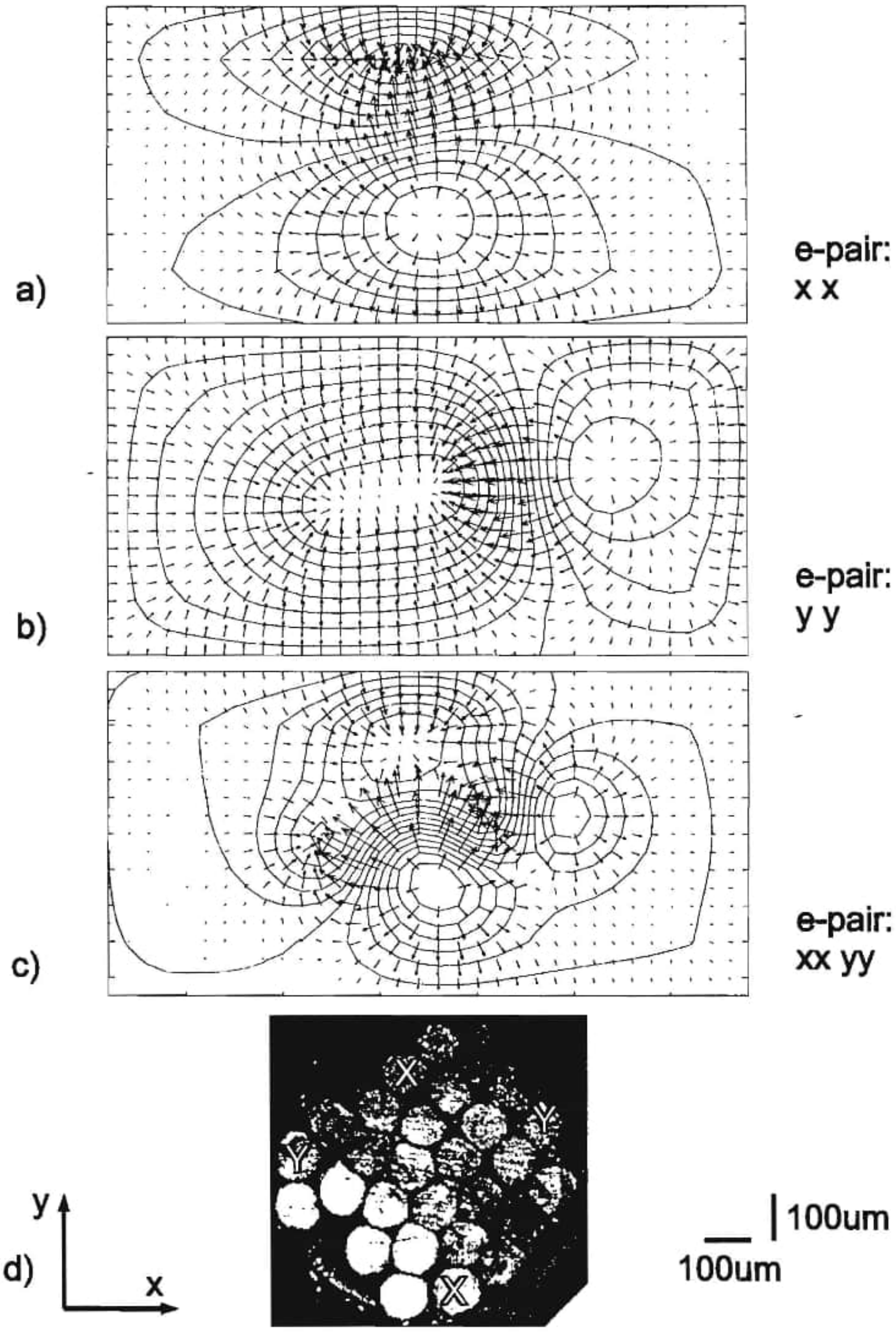

Fig. 1 a-c: Equi-potential contours and current density distribution of a multi-channel electrode measured within a saline filled slice chamber. a,b: bipolar-stimmulation, c: simultaneous bipolar stimulation with two pairs of electrodes.

Fig. 1 d: Surface of the multi-channel electrode. Orientation and scale corresponds to the measurements in fig. 1 a-c.

Measurement of cell activity

Spontaneous activity was rare but was frequently obtained when cells were penetrated. Spike activity could be induced intracellularly by depolarisation with current application via the recording electrode or extracellularely via stimulus electrodes. Most neurons responded with EPSPs. IPSPs were found only in a few cases. Latencies varied from 2-90 ms whereby 5-10 ms were measured most frequently.

Fig. 2a+b shows the response of two neurons from the auditory cortex to bipolar stimulation of the white matter. (Distance of electrodes 1 mm) Recordings were located in layer III. In the first case biphasic pulses of 1 Hz and 100 µA evoked a small EPSP (fig.2a) in the second case a neuron responded with an IPSP (fig.2b) to the same stimulus.

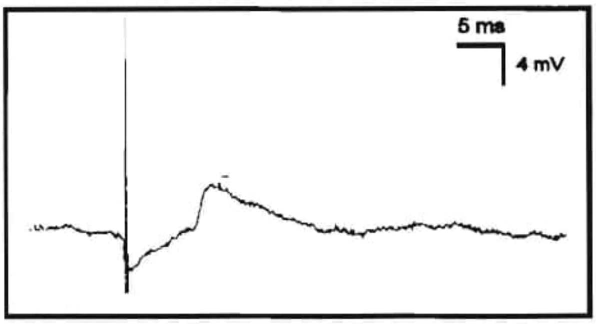

Fig. 2a

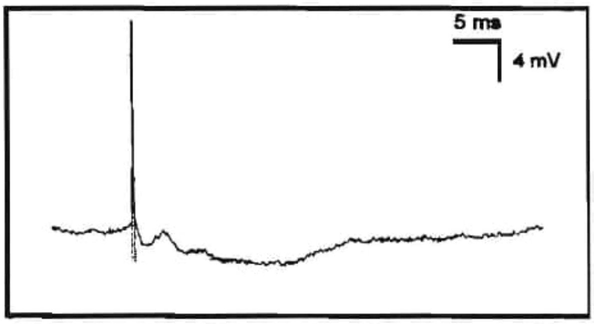

Fig. 2b

Fig.2a+b Activity of two auditory cortical neurons from layer III after bipolar stimulation of the white matter. First peak marked the stimulus artefact. a: EPSP, b: IPSP.

DISCUSSION

The electrical field of the multichannel electrode can be formed by simultaneous activation of different channels. Beam forming decreases the current spread and increases the selectivity of stimulation. Within the brain slice neurons could be stimulated with different directions of the current vector, e.g. parallel or perpendicular to cortical layers. This will be important with respect to the stimulation of brainstem e.g. the selective activation of subnuclei (VCN).

Conclusions from in vitro measurements may be transferred to other systems of neuroprothesis where efficency of artificial electrical stimulation on excitable tissue is investigated.

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FOUR-POLE-ELECTRODE STIMULATION OF THE PHRENIC NERVES IN TETRAPLEGIC PATIENTS - INDICATION, TECHNICS, RESULTS

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SUMMARY

Since 1987 we treated 9 patients with an implantation of a diaphragm pacemaker. 7 could be evaluated, 2 are still in the follow-up-procedure. Three month after surgery all patients achieved total independence from conventional ventilators. Follow-up is hardly to predict because of technical and nontechnical complications. 3 patients died within periods of 0,7 - 3 years after implantation. 2 persons are discharged at home, 2 are waiting for that. All are able to speak and have independence from ventilation still.

STATE OF THE ART

1.200 spinal-cord-injured patients are treated in Germany p.a., 40 % are tetraplegics /1/. At a rough estimation we think of 2,5 persons per million and year suffering a high lesion with paralysis of the diaphragm. Most of them get their lesion by trauma. So we have to treat an increasing number of these patients since 1987 in Hamburg. The installation of a subdepartement was necessary even as the development of special treatments in medical, nursing, PT and OT affairs.

First aid: Patients are admitted intubated and with stable vital functions. So - without knowledge about recovery in future - we have to treat them under the rules of traumatology. They get stabilization of the spine and intensive care. Three month waiting give certainty of missing recovery. Then we have two possibilities: to supply them with conventional ventilators and discharge them mobilized and supported with aids to any nursing institution or to implant a diaphragm pacemaker. We report about our experiences with the latter method.

Indication: Implantation is possible if the moto-neuron is working. So we include patients after testing percutaneously the nerves of both sides. Excluding criterias are damage of the nerves, respiratory failures, pulmonary tissue damage, mental insufficiency and other various risks /2/. Motor ability to speak should be proved and motivation of the patient. Possibilities of social reintegration should be checked. The therapeutical team should have experiences not only in pacing-procedure but in rehabilitation, too.

METHODS

We use a four-pole-stimulation device working with the carousel-system /3/, to get non-fatigue-stimulation all over the day. Intracorporal parts (electrodes, cables, receivers) are stimulated via transduction by extracorporal parts (antennas, stimulator, programming module). We do implantation ourselves using the intrathoracical way (second ICR) on both sides. A pouch of the pleura parietalis fix the electrode-tongues, one over and one below the nerves. Cables are drawn subcutaneously to another pouch in the ribcage-region where the receivers are situated. Before ending surgery testing of all electrode-poles is necessary /2/. Two weeks after we start the stimulation procedure beginning with 2 to 3 minutes per hour up to 12 times the day. Increasing times are used for conditioning the diaphragm changing the mixed composition into a maximum of slow-twitch-fatigue-resistant fibres which are best suitable for continuous stimulation. After conditioning-period permanent stimulation is possible.

RESULTS

Since 1987 we treated 11 patients with a lesion-level below C 0 to C 3. 9 persons got an implantation of a pacemaker, one was supported with a conventional ventilator, one died before further treatment. Two of these patients are within the conditioning period. So we report about 7 patients, 2 female and 5 male with an average age of 39,8 (19 - 59) years. 6 got their lesion by trauma, one by disease. Lesion was in C 0-level in 2, in C 2 in 4 and in C 3 in one person. Implantation was done in the average 5,4 (3 - 10) month after the lesion onset. All got the intrathoracic procedure on both sides. Conditioning period differed between 4 - 12 weeks (6). Three month after implantation 6 patients were stimulated and breathing continuously and independent from ventilator, one changed stimulation and ventilator from day to night.

Complications: Technical defects and failures we got in our first patient. Both receivers must be changed. Infection of the left side caused explantation, followed by neck-implantation, nerve damage and reimplantation after recovery. Mechanical ventilation could not be ended because of insufficient nerve function. After this we never had technical defects of the intracorporal parts in the other patients (since 1991). Three patients got complications not depending to the devices. Our first case could not swallow up and had no function of his vocal cords by cerebral defects. The third patient two years after implantation and living at home got a basalic atelectasis followed by abscess, sepsis and death. The sixth patient died - 7 month after surgery - by his disease.

Follow-up and functional outcome: Three of our patients died, the first case after three years suffering several complications, not able to speak and to swallow up, hospitalized without hope and demotivated, wishing his death. The third suffered lung complications as mentioned above, the sixth got recidivation of his main disease. So four patients are still alive, the second case about four years. All have four-pole-stimulation and use mechanical assisted ventilation only in case of respiratory infects (two of them). Case 2 is still living at home, case 4 is studying at the high school. Case 5 is prepared for discharge at home, case 7 was transferred to another SCIC. He waits for discharge, too. All have their tracheostoma left. Concerning quality of life we proved three items /4/. All patients got better functions (ability to speak, independence from conventional ventilator). Their expectations concerning the stimulation could be fulfilled. Independence from nursing instituts is given to two of them, the other are waiting for it.

CONCLUSIONS

1. Sequential four-pole-stimulation in high tetraplegic patients enable to speak, make possible independence from conventional venti-

lators and medical institutions. These are the only points of interest for the patient concerning quality of life.

2. Medical indications (better physiological breathing, possibility to close the tracheostoma (?)) should be mentioned.

3. Results and functional outcome are hardly predictable. So a sophisticated indication should be performed. Therapeutical concepts should be very clearly, staff well-trained. Nevertheless expectations concerning the outcome should be ranged at a low level.

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„VIENNA PHRENIC PACEMAKER" - EXPERIENCE WITH DIAPHRAGM PACING IN INFANTS AND CHILDREN

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SUMMARY:

From 1987 to 1994 the „Vienna phrenic pacemaker" was implanted in eight children, five boys and three girls, aging from 2 to 13 years (M=9+/-3). One child suffered from partial ventilatory insufficiency due to central alveolar hypoventilation syndrome. Seven children suffered from total ventilatory insufficiency due to high cervical cord or brain stem lesion. Implantation of the device was performed in a standardized procedure. Four electodes were applicated to each phrenic nerve via sternotomy. Increasing duty cycles were applied to conditioning the hemidiaphragms for chronic electrophrenic respiration. Simultaneous pacing of both hemidiapragms could be performed in all children but one. Four children could achieve chronical EPR, one is in conditioning period. Two patients could not be discharged from hospital due to parental neglect and died after two and three years of intermittent stimulation. Six children could be discharged from hospital, two of them died after one and four years of chronical pacing. In one case tracheotomy could be closed definitely.

STATE OF THE ART:

Diaphragm pacing now is more than 20 years in clinical practice (6). Treatment of ventilatory insufficiency due to central alveolar hypoventilation syndrome and high spinal cord injury or brain stem lesion is state of the art even in infants and children, provided the phrenic nerves are functioning (1,2,5,). The „Vienna Phrenic Pacemaker", which differs distinctly in some aspects from other commercially available products (7,8) has been implanted in 25 patients since 1983 (9). Fifteen of these patients were quadriplegics, suffering from total ventilatory insufficiency. Eight of all 25 patients were under the age of 13 years at the time of implantation. Special interest was given to these group in order to evaluate the validity of diaphragm pacing in infants and children.

MATERIALS and METHODS:

Patients:

Since 1987 eight children, five boys and three girls underwent implantation of a „Vienna phrenic pacemaker". Children aged from 2 to 13 years with a mean age of 9+/-3 at the time of implantation. Patients suffered from ventilatory insufficiency due to central alveolar hypoventilation syndrome (CAH) in one case and due to high spinal cord- or brain stem lesion (SCI) in the other cases. The girl suffering from CAH required mechanical ventilation not only during sleep but also often when she was awake. The seven other children were quadriplegics, totally dependent on mechanical ventilation. Tetraplegia was caused by brain stem lesions - incurative but stable tumor and encephalitis - in two cases. In five cases tetraplegia derived from trauma with level of SCI-injury above the origin of the phrenic nerves (C1/2, C2/3).

All children were ventilated mechanically over a period from 4 to 48 months (M=20.1 months) before implantation of pacemaker. All children received a tracheotomy a few weeks after onset of ventilator dependency. No other severe deseases were present in these children beside from the main disease.

Device:

The „Vienna phrenic pacemaker" consists of external and implanted components (manufactured by Medimplant Inc., Vienna, Austria). An external control unit provides adjustement of individual parameters for synchronuous bilateral pacing of the hemidiaphragms. Stimulus energy and -information is transmitted through the intact skin and underlying tissue via loop antenna to the implanted part of the device. This part consists of the radio receiver which actually is an eight-channel implant, and eight electrode leads in two trunks, each carrying a sling in a pocket for lateron elongation and eight ring shaped electrodes with an inner diameter of 0.8mm. Four electrodes are applicated to each phrenic nerve for performance of a special kind of stimulation named „Carousel-stimulation". Device and „Carousel"-stimulation have been published more detailly in previous reports (3,8,9,12).

Implantation:

Evaluation of phrenic nerve and diaphragmatic function using percutaneous nerve stimulation was performed prior to operation. Burst stimulation was applied to achieve tetanic diaphragm contraction and tidal volume was measured with a respirometer. Cases with unclear results underwent evaluation of phrenic nerve latency (11).

Implantation was done under general anesthesia in a standardized procedure. Median sternotomy was performed and both phrenic nerves were exposed in the upper part of the mediastinum and again tested by direct nerve stimulation. The receiver was placed in a subcutaneous pocket at the abdominal wall and electrode leads were pulled through subcutaneously into the mediastinum. Four electrodes were fixed to the epineurium of each phrenic nerve with a single 8-0 monofile suture in helical manner using microsurgical techniques.

Postoperative treatment:

Pacing of the diaphragm was started 2-3 weeks after surgery. Respiratory rates and tidal volumes were adjusted individually to the patient's comfort, usually in accordance to mechanical ventilation. Increasing duty cycles with respect to muscle fatigue were used to conditioning the hemidiaphragms. Children were disconnected from ventilator for performance of electrophrenic respiration (EPR) from the very beginning of conditioning program. Oxygen saturation was monitored by a pulse oximeter permanently. In addition tidal- and minute volumes were measured at regularly intervals using a Wright respirometer connected to tracheotomy.

RESULTS:

Preoperative testing revealed normal phrenic nerve- and diaphragm function in all cases but one. This patient exhibited severely reduced function of his right phrenic nerve due to the initial trauma. Implantation in this case was done in order to establish unilateral pacing during day.

The implantation procedure was without complication in any case.

Synchronuous pacing of the hemidiaphragms was possible in all seven children with intact phrenic nerves. EPR could provide adequate ventilatory support in all these children from the very beginning of stimulation. Respiratory rates ranged from 10 to 20 breaths per minute (M= 14+/-3) and tidalvolumes ranged from 7 to 19 ml per kilogram bodyweight (M= 13+/-5). Thus the overall ventilated minute volume ranged from 142 to 192 ml per kilogram bodyweight (M= 167+/-26). Oxygen saturation measured by pulse oxymeter was kept over 90 %. Unilateral pacing was tried in one patient and produced tidalvolumes between 3 and 4 ml per kilogram bodyweight. In this case diapragm pacing was not suffizient for ventilatory support, even not at high respiratory rates. Values concerning respiration did not change to a major extent during conditioning period and lateron time course.

Conditioning the diaphragm led to chronical fatigue free EPR around the clock in four patients. A mean time of 13 months was needed, minimum time for conditioning was 6 months and maximum time exceeded up to 24 months. These four children are off mechanical ventilation totally and use EPR chronically since 10, 28, 38 and 48 months (M=31). One child is in conditioning period. In two cases EPR provided sufficient ventilation but chronical performance could not be established. One child simply refused the pacemaker the other child frequently suffered from severe intercurrent pulmonary infections, which always necessitated interruption of stimulation.

Tracheotomy is maintained in seven children. One of these childs uses a speech cannula permanently. In one child tracheotomy could be closed definitively.

Six children were discharged from hospital and live permanently at home within their families. Five of them use chronical EPR, one of them is still dependent on mechanical ventilation due to his non functioning right phrenic nerve. Two children could not be discharged from hospital due to parental neglect. In these two children full time chronical EPR could not be achieveded.

Four out of eight patients have died. Severe pneumonia followed by general septicemia was the reason in all cases. Two of this children never left hospital after implantation. Two children acquired their pneumonias during routine check up in hospital.

DISCUSSION:

According to other authors we consider therapy of ventilatory insufficincy due to CAH and high SCI with diaphragm pacing a safe and useful technique in adults and even in children (1,2,5). In fact treatment with a phrenic pacemaker seems to be much more difficult in children than in adults: In our first series, published 1993 (9), mean age at time of implantation was 19.5+/-11 years. 11 patients out of 15 could achieve chronical EPR, which means a „success-rate" of 75%. In the present study mean age at time of implantation was 9+/-3 years and 4 out of 8 patients achieved chronical diaphragm pacing, which means a decrease in „success-rate" to 50%. Focusing on the „failures" reveales one case of incorrect indication (nonfunctioning right phrenic nerve) and two cases of parental neglect (with impossibility to discharge the children from hospital). Thus a strong medical and even social indication seems mandatory for treatment with phrenic pacemaker.

Time course of conditioning is also an indicator for a higher amount of problems with diaphragm pacing in children than in adults. Most of these problems are not related to EPR or health but to psychological and, as mentioned above, to social reasons. Two situations may illustrate the range of possibilities: Diaphragm conditioning took time 6 months in a boy with strong motivation to get off mechanical ventilation. Another boy refused the pacemaker and EPR out of psychological and social reasons and although the pacemker provided sufficient ventilation chronical EPR could not be achieved.

Diminished diaphragm contractility due to prolonged disuse, as described by other authors (10) we did not observe in our series, even not after 48 months of mechanical ventilation prior to implantation. However, the two long term ventilated children reacted different from the other children concerning oxygen saturation: Even very small reductions of duration of inspiration or respiratory rate were promptly followed by declination of oxygen saturation, thus probably indicating reduced pulmonary function due to long term mechanical ventilation.

EPR, as a physiologic way of artificial ventilation, creates physiologic intrathoracic pressure values. Thus it can reduce some of the problems related to long term positive pressure ventilation. The „Vienna phrenic pacemaker" can provide full time ventilatory support with near physiologic breathing parameters in any case, even in children. In conclusion EPR should be considered as alternative to long term mechanical ventilation in any case of CAH and high SCI, provided both phrenic nerves and hemidiaphragms are functioning.

Several authors consider tracheotomy in these patients mandatory (4,7). We could support one child with a speech cannula and we could close tracheotomy definitively in another child, both meaning a tremendous increase in quality of children,s life. Due to the warnings against such a procedure we selected patients very carefully. Both patients are quadriplegics with C2/3 level of SCI, which means that these patients have static and dynamic control of their head and that they can breath spontaneously for at least half an hour.

Diaphragm pacing probably will not lengthen life of severely injured children. But it will increase the quality of their lifes by increasing their mobility and sometimes by returning them back to normal speech.

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COMPUTER AIDED ADJUSTMENT OF THE PHRENIC PACEMAKER: AUTOMATIC FUNCTIONS, DOCUMENTATION AND QUALITY CONTROL

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SUMMARY

Electrical stimulation of the phrenic nerves of patients with complete ventilatory insufficiency with the Vienna Respiratory Pacemaker has been in clinical use since 1983. During adjustment of stimulation parameters with the existing device the following disatvantages occur: (1) For some measurements like the recruitment curve, series of complete inspiration cycles have to be stimulated. This causes the danger of muscle fatigue for unconditioned patients. (2) Documentation is done mostly by hand, taking time and increasing possibility of error.

As a first step to solve the above problems we developed a new stimulation and measurement system. It consists of a PC with data aquisition hardware, the necessary sensors and amplifier circuitry. The implanted stimulator is controlled via the parallel interface. The new system offers some advantages: (1) Computer control shortens the time for measurement and documentation. The stress on the patient and the risk of error is reduced. (2) Synchronized measurement makes it possible to use single stimulation pulses instead of bursts and ramps to reduce diaphragm fatigue. (3) Digital signal processing improves measurement results and reproduceability. (4) Help functions and self tests are provided, together with a graphical user interface.

We use sensors for air flow, diaphragm EMG and acceleration, on up to 8 channels simultaneously. Combined samplerates of up to 100kS/s are possible. The system can be adapted for other uses involving functional electrical stimulation with our implantable nerve stimulators.

Using this equipment saves a lot of effort, the adjustment process can be focused on improved stimulation results and better performance for the patient. Current research is going into implementation of automatic functions like aquisition of stimulation thresholds. This might result in a mostly automated adjustment of the phrenic pacemaker, and even in the future in a closed loop controlled system.

STATE OF THE ART

The Vienna phrenic pacemaker has been in clinical use since 1983, leading to major improvements in life quality for the patients /1/. Clinical studies on 23 patients showed that with the method of „carrousel stimulation" electrophrenic respiration can be maintained for 24 hours a day without diaphragm fatigue /2/. Adjustment of the stimulation parameters and documentation is done manually. During adjustment and optimization of stimulated inspiration cycles of unconditioned patiens there is the danger of muscle fatigue due to repeated stimulation of the same muscle fibers without longer recovery. Carrousel stimulation can not be used in this phase. It is therefore necessary to shorten and faciliate the adjustment process.

This implies (1) further development of the involved hard- and software and (2) research into possibilities of automation. As (1) is regarded, studies of the „man-machine interface" or „user interface" like /3/ can be helpful to achieve additional functions without confusing the user.

As for (2) there are groups doing research into automated tuning of FES systems like in /4/ - /6/. Durfee and MacLean suggest methods for aquiring recruitment curves automatically /7/, Fodstad mentions results of clinical trials with „computer optimized" phrenic pacing /8/.

MATERIALS AND METHODS

Stimulation and Measurement Hardware

Based on the existing 8 channel phrenic pacemaker implant we developed a new control system, consisting of a controller unit connected to an IBM compatible PC via the parallel interface (see Fig. 1). All stimulation parameters are under program control and can be changed from pulse to pulse. The stimulation can be synchronized to the mechanical ventilator to avoid asynchronous stimulation and raise the comfort of the patient.

The signals are aquired with a National Instruments (NI) AT-MIO 16L-9 data aquisition board, preamplifier circuits and the necessary sensors. The following signals can be aquired: (1) air flow with a Hamilton flow sensor and Motorola pressure transducer, (2) diaphragm EMG, and (3) movement of the abdominal wall with an acceleration transducer. The electronic amplifier circuitry was developed at our department. Additionally a pulseoximeter with RS232 interface can be connected to the PC for monitoring and documentation. Other signals can be aquired with minor adaptions to the system, if necessary.

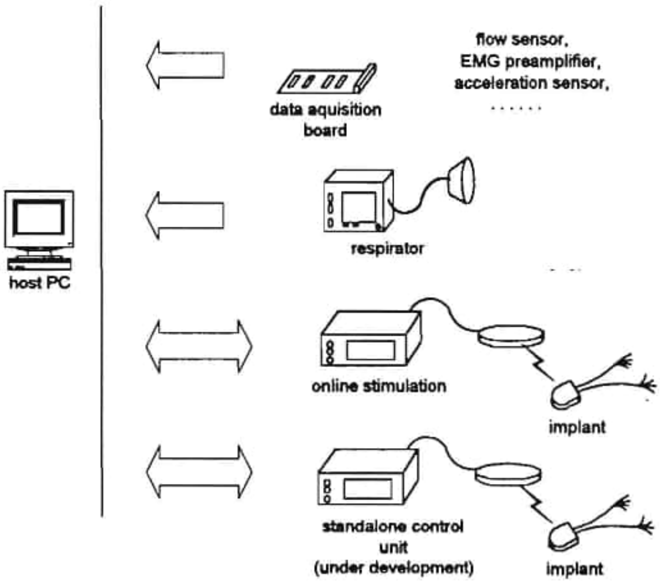

Fig 1: Schematic diagram of the stimulation and measurement system

Graphical User Interface

The graphical user interface was programmed in ANSI C for Windows, using a NI LabWindows CVI compiler. This environment is especially designed for the concept of virtual instruments. The user no longer turns real knobs and pushes buttons to activate the system, but chooses directly from controls (virtual instruments) on the computer screen by mouseclick or keyboard. The appearance of the screen can be changed and optimized to user demands. Further experiences can be implemented. This amount of flexibility would not be possible with a conventional control unit with hardware buttons, knobs and switches.

Our user interface was designed with the intention to keep the manipulation of a complex system as simple as possible. The controls are divided into groups for stimulation and measurement. The screen is adapted to the current mode of function by program control, for example, it is impossible to change the stimulation frequency in single pulse stimulation mode. To minimize input errors unnecessary controls are hidden, the user sees only the controls that are currently important. Help functions and default values for every function are provided by the push of a button or a mouseclick. Input errors are indicated by pop up messages on the screen.

Functions of the System

The following stimulation modes are supported by the system: (1) continuous stimulation, (2) single pulses, (3) bursts, (4) ramps, and (5) carrousel stimulation. Fiber recruitment can be controlled by amplitude or pulse width modulation. All stimulation parameters can be changed online.

The measurement system works either synchronized with the stimulation, or continuously. Inspired air volume, minute volume and breathing frequency are calculated online. An advantage of synchronized measurement is that muscle answers to single stimulation pulses can be measured even in noisy environments. Digital signal processing like filtering or averaging can be used for further improvement of the waveforms.

Adjustment of the phrenic pacemaker starts with the computer aided detection of stimulation thresholds for all electrode combinations. Single pulses are used, the amplitude is raised and the user has to decide from the flow, EMG or acceleration curves when threshold is reached. The thresholds are used to decide which configurations are adequate for stimulation. Then the stimulation amplitudes for maximal force are detected in a similar way. Threshold and maximum are starting points for the optimization of ramp parameters for each hemidiaphragm. Finally both sides are matched for bilateral stimulation.

In this process the stimulation parameters found in one stage are automatically forwarded to the next one, there is no need for manual documentation. All aquired signals are displayed immediately to faciliate optimization, and saved to disk for further processing. Once a satisfying stimulation result has been achieved, there is no need for further measurements. Fatigue is decreased by the use of single pulses for a wider range of measurements. Comfort for the patient is raised by synchronizing the stimulation to the mechanical ventilator and by a shortened adjustment process.

DISCUSSION

The equipment as described above offers some new advantages in the use of the phrenic pacemaker: (1) Compared to the existing system the number of equipment necessary for measurement and stimulation has been reduced. Further reduction can be achieved by miniaturization and by the use of a laptop PC. This allows follow up examinations outside the clinic, at patients home. (2) Additional measurements like the movement of the abdominal wall can improve the parameter optimization process. (3) Digital signal processing offers the possibility to use single pulses for a wider scope of measurements like the recruitment curves.

These features prepare the process of adjustment and training in phrenic pacing for consequent quality control, with automated, reproduceable documentation as an important basis. Computer controlled measurement and stimulation with sufficient user guidance makes it easier to follow the predefined adjustment protocols and shortens the process. Both are great benefits for the patients.

The possibility to save, review and compare relevant waveforms can raise the standard of phrenic pacing in clinical practice. Optimization can be aimed on the shape of the flow curve. The data aquired from spontaneous and from stimulated inspiration cycles can be used to define „standard inspiration cycles“ with corresponding curves for air flow, diaphragm EMG, and movement of the abdominal wall. Areas of tolerance, error functions, maximum air flow and remaining ripple can be useful parameters for the optimization process.

Current research goes into automation of the adjustment process. As a first step different methods for aquiring stimulation threshold and recruitment curves are studied. Different signals and algorithms are tested to find out how to achieve accuracy and reproduceability with minimal stress for the patient. This will serve as a starting point for adaptive control of inspiration cycles, with closed loop control as a long term aim of our studies.

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ABDOMINAL MUSCLE FES ASSISTS VENTILATION: A FEASIBILITY STUDY

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SUMMARY

In eight male neurologically intact adult subjects assistance of ventilation was performed with functional electrical stimulation (FES) of abdominal muscles in synchrony with naturally occurring breathing. The stimulation of mainly rectus abdominis via surface electrodes was performed in supine position. Significant augmentation of ventilation due predominantly to increase in tidal volume was observed. The results provide a basis for further studies with patients in borderline ventilatory failure.

STATE OF THE ART

Ventilation as a part of respiration is a key function in maintaining efficient gas exchange in the lungs. Inspiration is brought about by the contraction of diaphragm, and expiration occurs passively due to the elastic recoil of the lungs. However, in the cases of apnea, acute ventilatory failure, and impending ventilatory failure, patients are at risk, and may be considered for mechanical ventilation (MV). MV typically consists of introducing a fixed volume of air into the lungs under positive pressure or with generated negative pressure distends the chest and allows inspiration. One patient population in which long-term MV is mandatory are those with high-level complete spinal cord injury [1].
The present study provides preliminary data indicating that it may be feasible to use electrical stimulation of abdominal muscles to increase tidal volume, which might be favorable for the patients who are candidates for MV.

MATERIALS AND METHODS

Subjects: Eight neurologically intact male subjects (avg. age 40 years, 84 kg of body weight and 178 cm height) with no known medical complaints were studied. Standard pulmonary function tests values were measured with standardised procedure and were within normal limits. Tidal volume, respiratory rate, oxygen

consumption and carbon dioxide production were measured with an Oxycon Sigma apparatus. Minute ventilation and respiratory quotient were computed from measured values. Data obtained by these measurements were transferred by diskette to a personal computer for statistical analysis (SPSS/PC+). Means and standard deviations were computed and tabulated for all variables by subject and condition. A one-way analysis of variance (ANOVA) was performed for each variable to determine if there was a significant difference between conditions. If the ANOVA showed such a difference existed at the 0.01 level, post-hoc tests were performed to determine specifically which groups were different.

Electrodes: Commercially available neuromuscular stimulation electrodes (3x8 cm rectangle; PALS, Axelgaard Mfg.) were placed on abdomen symetrically along the mid-line, just under the costal margine and above syphysis bone, so the rectus muscles were predominantly stimulated.

Stimulator: A custom built microprocessor controlled electrical stimulator with an a/d converter, continuously monitored the analog signal from an air flow sensor at 10 samples per second, to determine when the stimulation pulse train should be delivered. From the data signal of zero, minimum, and maximum flow during normal breathing the microprocessor set a threshold at 15% of maximal expiratory flow. The stimulus pulse train, once triggered, began at 25 μs pulse width and linearly increased to 350 μs over the 1 s burst of stimulation at 50 Hz. This mode of stimulation intensity allowed gradual rather than abrupt onset of stimulation and acceptable comfort of the subjects.

Protocol: Subjects were studied in supine position. A ten minute period of quiet, normal, breathing was recorded, followed by ten minutes of triggered stimulation of expiration, followed by 10 minutes of normal breathing, followed by 10 minutes of manually assisted expiration by manual compression of the abdomen.

RESULTS

Tidal volume increased on the average from approximately 667 (sd=188) ml to 1100 (sd=387) ml during periods of FES assisted expiration. The respiratory rate during assisted ventilation was greater for avg. 2 breaths/min (16 to 18.6). Average ventilation was 10.3 (sd=2.7) l/min during normal breathing, increasing to 17.5 (sd=6.5) during electrically assisted expiration and 18.3 (sd=8.0) during manually assisted expiration. All variables measured showed statistically significant differences between conditions. Post-hoc tests revealed that in general the periods of normal breathing were comparable, but that these two groups were different from electrically and manually assisted. There were no difference between last two groups.

DISCUSSION

The application of FES is not new. Large research efforts have been underway in restoration of upper and lower extremity function [2] in maintenance of bladder control (micturition) [3], and in respiratory or phrenic pacing [4]. The experiences in these fields suggest that there is a reasonable probability for clinical success of electrically assisted expiration, if it can be shown to be clinically beneficial.

The device and technique used in this experiment is intended to cause contraction of the major muscles of expiration (abdominals) and is based entirely on surface electrodes. In a sense, this is a reversal of traditional methods of assisted ventilation which have tended to emphasize an active or assisted inspiratory phase, with expiration being passive.

In related studies one group of investigators [5] has reported that abdominal muscle stimulation increases intra-abdominal pressure, and could provide effective coughs. The other group [6] has reported peak expiratory flow increased in 15 out of 25 patients with abdominal stimulation. Both indicate that electrical stimulation of abdominal muscles have ventilatory consequences.

Electrical stimulation for ventilatory assist during expiration should not be confused with existing devices for phrenic pacing. Phrenic pacing is intended to cause contraction of the diaphragm, the major muscle of inspiration and usually requires an invasive procedure [4]. The results presented in this paper suggest that stimulation of expiratory muscles during expiration increases tidal volume in normals. The next stage of this work will be to study this possibility in actual patients, both in candidates for MV and those actually on MV.

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ELECTRICAL STIMULATION OF ABDOMINAL MUSCLES FOR INCREASING COUGH EFFICACY IN TETRAPLEGIC PATIENTS

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SUMMARY

In tetraplegic patients there is a restrictive pulmonary impairment with reduced clearing of secretions by cough. The most common complications are respiratory infections and consequentially atelectasis. The aim of the study is to evaluate whether the electrical stimulation of abdominal muscles in the early phase of expirium and adequate respiratory muscle training can improve the respiratory capacities and efficiency of cough of tetraplegic patients. Five tetraplegic patients were included in the study. Every patient had three periods of treatment, each lasting one month: inspiratory muscle training, expiratory muscle training and without training. Two respiratory tests (RT) - forced vital capacity (FVC) and forced expiratory volume in the first second (FEV1) - were measured before and at the conclusion of each monthly period in four different ways. The measured RT were larger after the period of respiratory muscle training and also the combination of voluntary effort with either manual assistance or FES has proven to be efficient as well. The conclusion of the study is that both respiratory muscle training and electrical stimulation of the abdominal muscles can improve the cough in tetraplegic patients.

STATE OF THE ART

Tetraplegia resulting from acute cervical spinal cord trauma often significantly damages respiratory functions. Injures at or above the C3 to C5 level involve phrenic nerves and cause partial or complete hemidiaphragmatic paralysis. Intercostal muscle paralysis inflects inspiration and paralysis of abdominal and other expiratory muscles inflects the expiration. The reduced both inspiratory and expiratory functions results in patients inability to generate adequate vital capacity (VC) as well as cough inability /1/.

Patients with lower lesions can contract their diaphragms to a variable extent due to the completely or partially intact phrenic nerve. However the daily intercostal muscle inactivity affects the inspiration. As other higher level patients these tetraplegics have also lost their voluntary control of abdominal and other expiratory muscles. These deficiencies result in patients cough inability. The cough is too weak to enable the clearing of the lung secretions what causes hazardous and chronicle lung infections.

The aim of our study is to find out whether electrical stimulation combined with adequate muscle training can be used to replace the physical therapist's manual assistance in ensuring proper tetraplegic's cough. This would make a tetraplegic more independent from medical assistance /2/ as until now therapist's manual assistance was the only way to produce cough. The paper discusses the preliminary results of the tests conducted on five patients.

MATERIALS AND METHODS

Each patient has undergone three phases of treatment each lasting for approximately one month. One month was chosen as a period that would hopefully yield some improvements. The patient entered the first phase after admittance to the Institute for Rehabilitation. The patient was in full medical care but no respiratory muscle training were taking place in this period. The second and third phase were training of expiratory and inspiratory muscles. The exact sequence of training was chosen arbitrary. Both training sessions consisted of seven different exercises with each being repeated ten times with short rest period between each effort. The session was conducted twice a day, six days a week. Usually one session has lasted for about 30 minutes /3/.

Expiratory muscle training consisted of simultaneous application of electrical stimulation and expiratory muscle exercise. Electrical stimulation was provided by a portable battery powered stimulator with two pairs of surface electrodes which placement is shown in Figure 1. During each expiratory effort one stimulation pulse burst was applied. The stimulator was triggered by a physical therapist with a pushbutton. The pulse burst consisted of monophasic rectangular pulses lasting for 0.75 s and with a pulse width of 0.3 ms at a frequency of 50 Hz. The maximal amplitude is 110 V. The amplitude was adjusted at the level where a strong and visible contraction was achieved or just below the level that caused irritation to the patient. The stimulation with same parameters was applied in training and measurement and only the amplitude was adjusted for each exercise independently. Inspiratory muscle training did not involve any kind of stimulation and only inspiratory muscles were trained for both strength and endurance.

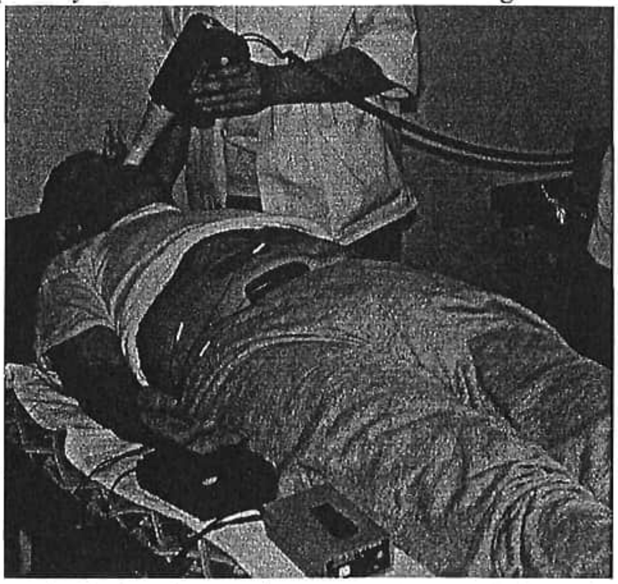

Figure 1: Performing respiratory test in tetraplegic patient

To assess the efficacy of electrical stimulation and training several quantities were measured at the end of each phase. The quantities measured were:

- forced vital capacity (FVC),
- forced expiratory volume in the first second (FEV1),
- maximal inspiratory and expiratory pressure in the mouth (Pi_{max}, Pe_{max}).

The results for only FVC and FEV1 are shown. All this measurements were taken in both sitting and lying position with a combination of four sets of conditions:

- patient's own unassisted effort,
- patient's own effort and therapist's manual assistance,
- patient's own effort and electrical stimulation triggered by a therapist,
- patient's own effort and electrical stimulation triggered by the patient himself,

Only incomplete or lower level tetraplegics are able to trigger the stimulator by themselves which was not the case for all our patients. Therefore the results shown only for unassisted effort, therapist's assistance and

Patient	Sex	Age	Lesion	Artificial ventilation	Time after injury
1. M.S.	m	23	C4 (complete)	6 weeks	11
2. J.J.	m	20	C6 (complete)	3 weeks	10
3. G.I.	m	30	C4 (complete)	4 weeks	10
4. C.D.	f	45	C3 (incomplete)	0 weeks	5
5. S.A.	m	26	C5 (complete)	0 weeks	13

Table 1: Data on patients

therapist triggered electrical stimulation.

FVC and FEV1 were measured with an electronic flowmeter (SpiroSense 1000, Futuremed inc., USA) that was through a serial port connected to a PC. A volume is obtained by numerical integrating the sampled flow data. A custom made filtering program was used to transfer the data directly to the commercial spreadsheet program which was used for data processing and visualization.

The data for the five patients that completed the whole program is shown in Table 1. The patients voluntarily entered this research program.

RESULTS

The results assessed are shown in Figures 2 to 5. Figure 2 presents the results for FVC in sitting position, Figure 3 for FVC for lying position, Figure 4 for FEV1 in sitting position and Figure 5 displays the FEV1 for sitting position. All quantities were measure before therapy (BT), after inspiratory training (PI) and after expiratory training (PE). Patient's own effort (AL), patient's own effort combined with therapists manual assistance (MA) and patient's own effort with electrical stimulation triggered by a therapist (ES) were record each time. Each measurement was repeated three times under the same condition and only the best results are presented in the graphs.

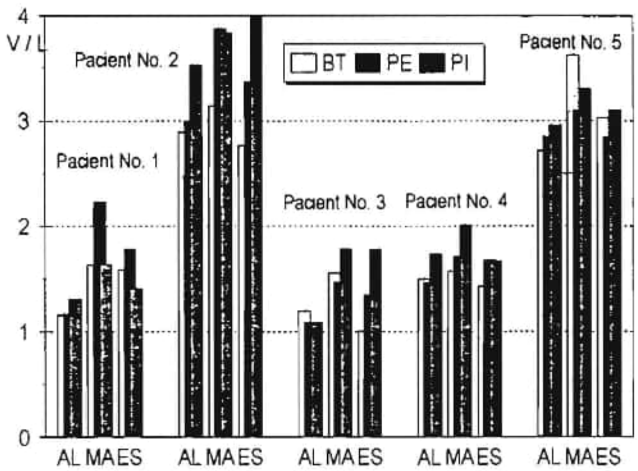

Figure 2: FVC sitting

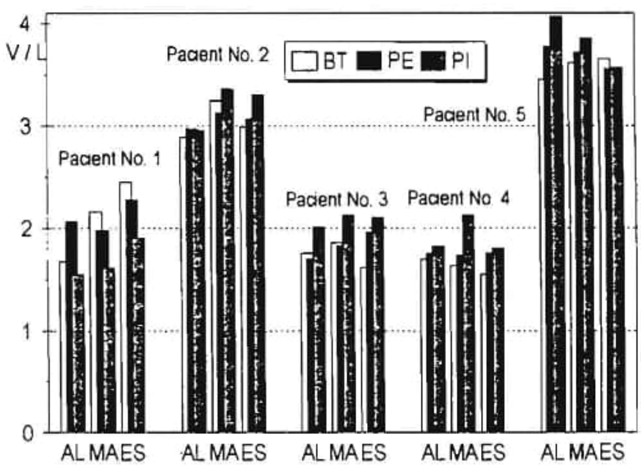

Figure 3: FVC lying

Results show that any kind of training improves patient's respiratory functions. Has the best performance, is much dependent on the patient state but training modalities need to be further investigated to determine ways of optimizing. However inspiratory training tends to be more effective particularly for patients with severe respiratory malfunction. The results achieved in the lying position are also better since in this position the intercostal muscle activity is no longer necessary to stabilize the rib cage which in sitting position performs pressure on hemidiaphragms which therefore can not function properly. The sitting/lying position affects more the patients with severe respiratory restrictions.

Therapist's manual assistance is more effective in lying position. The reason is that the therapist can easier apply the force to the patients abdomen and also because the patients generally achieve better results when lying as explained above.

The most interesting conclusion is that applying electrical stimulation to an untrained patient generally does not at all improve vital capacity. After any kind of training the efficacy of electrical stimulation nearly reaches the efficiency of therapist's manual assistance. Therefore we might be able to produce stimulation induced cough only in well trained patients. Influence of electrical stimulation on patients with minor respiratory obstruction is nearly negligible.

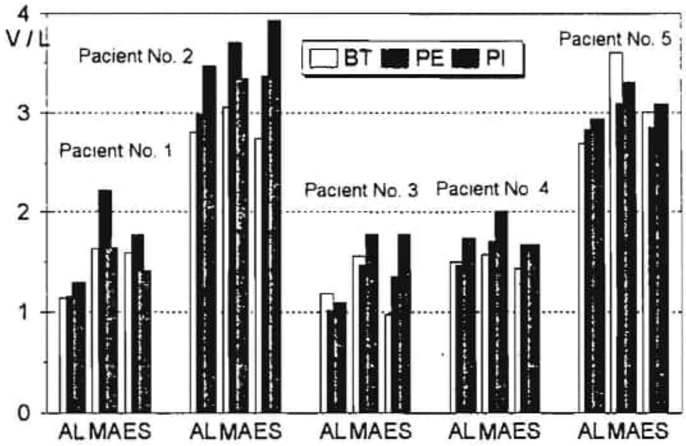

Figure 4: FEV1 sitting

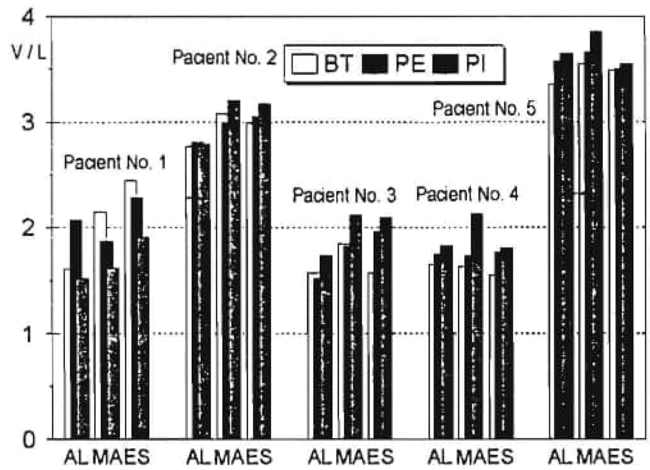

Figure 5: FEV1 lying

Another interesting fact is that the FEV1/FVC ratio, which is normally used as a respiratory system health indicator is extremely high and it usually exceeds 95% compared to the 80% in normal heath adult. This might be due to the fact, that the expiratory volume is so small that the tetraplegic can easily expire it all within a second and it still does not reach the FEV1 or maximum expiratory flow (FEF_{max}) of a healthy subject.

DISCUSSION

Our preliminary results indicate that it is absolutely necessary to apply electrical stimulation to a trained patients. Its efficacy increases with decreasing patient's FVC. The problem still remains as patients with severe respiratory disfunction usually have high level lesions. Therefore they might not be able to voluntary control their hands and a special triggering mechanism has to be developed.

In our following work we will first document the achieved improvements of respiratory system function and thoroughly evaluate the clinical impact of the obtained results. We will also concentrate on optimizing the stimulation triggering methods and timing what could enable us to set the basic requirements for achieving a functionally useful expectoration.

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SKELETAL MUSCLE CHANGES IN CHRONIC RESPIRATORY FAILURE.

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SUMMARY

Our experience on the influence of chronic obstructive pulmonary disease (COPD) on the skeletal muscle morphology is reported. Fifteen male patients (mean age 64.8) with moderate degree of chronic respiratory failure have undergone a needle Vastus lateralis muscle biopsy under local anaesthesia. Results have been compared on normal parameters from healthy subjects. Morphological, enzyme-histochemical and morphometric evaluation of muscle specimens showed a generalized fibre hypotrophy, occasional degenerative changes and reduction of type I and IIB muscle fibres. Morphology and distribution of intramuscular capillaries were normal. The immuno-histochemical in situ detection of apoptotic DNA fragments did not demonstrated apoptosis in muscle fibres. SDS PAGE analysis of myosin/actin ratio (a molecular marker of muscle fibre atrophy) showed increased values in CODP patients if compared to healthy subjects. Data suggest that the impairment of gas excange at rest and during exercice in CODP patients may play a role in skeletal muscle morphology and in fibre type composition .

STATE OF THE ART

Chronic obstructive pulmonary disease (COPD) is defined as a disorder characterized by evident chronic airflow limitations with abnormal tests of expiratory flow that do not change over periods of several months of observation (1). Chronic bronchitis, emphysema and peripheral airways disease are included in the more generic term COPD. Other causes of chronic airflow obstruction, such as bronchiectasis and localized disease of the upper airwais , are excluded (2).
The major symptom of COPD is a chronic respiratory failure with limitation in the exercice capacity caused by dispnoea. Recent studies suggested that the impairment of gas exchange at rest and during exercice may play some role in skeletal muscle fibre function (3). Since the functional impairment of the skeletal muscle seems to be related to the entity of the functional damage, nutritional status and exercice capacity, we have studied the influence of the chronic respiratory failure on morphology, fibre type composition and on some molecular aspects of skeletal muscle from COPD patients with different exercice oxygen desaturation (EOD).

MATERIALS AND METHODS

Fifteen male patients (mean age 64.8 years) with COPD, after their informed consent, have undergone a needle Vastus lateralis muscle biopsy under local anaesthesia. patients were in steady condition,including the medical therapy and the rehabilitation program, with the exclusion of any exercise reconditioning one. Pulmonary function was impaired showing chronic respiratory obstruction with FEV1 80% of predicted and a reversibility after inhaled salbutamol 10%.

Arterial blood gases were normal or showed slight or moderate hypoxiemia and (or not) hypercapnia. Patients with severe respiratory failure, chronic use of corticosteroids ,cardiovascular or metabolic disorders, and neuro-muscular diseases were excluded from the study, as well as patients with regular physical activity. A division into 2 groups of patients was performed: 6 COPD patients with oxygen desaturation during exercice (EOD 1) and 9 COPD patients who didn't desaturate (EOD 2).

A part of muscle specimens was fixed in formaline, embedded in paraffine and utilized for haematoxylin and eosin, modified Gomori trichrome stain and for immuno-histochemical in situ detection of DNA fragments (4) indicating apoptotic phoenomena (ApopTag method, Oncor). A small muscle specimen was fixed in Karnovsky fluid for electron microscopy. Some muscle specimens were frozen in isopentane cooled at - 170° C in liquid nitrogen and utilized for enzyme-histochemical studies (NADH, COX, ATPase pH 9.6 and 4.6) ,for histochemical investigations (PAS stain for glicogen and Oil red O for lipid demonstration), for the determination of the percentual of the myosin heavy chains (MHC) and of the MHC/actin ratio (5). Morphometric investigation on intramuscular capillaries was also performed using previously detailed methods (6). Results have been compared on normal muscular parameters from our laboratory.

RESULTS

All patients showed reduction of the muscle fibre size and occasional degenerative changes of fibres. No architectural or nuclear changes, cellular reaction and fibrosis was observed. In some patients, isolated or small groups of type 1 fibres showed atrophy. Abnormalities of distribution of fibre types were seen in numerous patients of both studied groups . In table 1 are reported the results of the enzyme-histochemical analysis of fibre type composition, of the electrophoretic study of myosin heavy chain isoforms (MHC 1) and of the myosin-actin ratio (a marker of muscle atrophy) in COPD patients with and without EOD. All patients showed a reduction in type 1 fibre percentage (determinated by both enzyme-histochemical and electrophoretic methods) and in type IIB fibres, if compared to normal healthy subjects. Comparing group 1 vs group 2, group 1 has a more reduction of type IIB fibres; the reduction of type 1 fibre percentage was similar in both subsets of patients. In both studied COPD groups, SDS PAGE analysis of myosin actin ratio showed increased values if compared to normal muscles, but not significant differences were observed between COPD groups. No apoptosis in muscle fibres was seen. Quantitative and morphological analysis of intramuscular capillaries of studied groups did not revealed significant changes in respect to normal parameters.

Table 1. Fibre type diameter (%) and composition (%) (ATPase pH 4.6); MHC1 content and Myosin/actin ratio in vastus lateralis muscle from COPD patients with and without exercice oxygen desaturation (Group EOD1 and EOD2).

COPD patients group	Fibre type diameter I	II	Fibre type composition I	IIA	IIB	MHC1	Myosin/actin
EOD 1	38+4.6	42+2.8	35+4.8	45+2.6	20+1.8	37+16	2.7+0.2
EOD 2	40+3.8	48+3.6	32+3.8	42+2.8	26+2.4	36+14	2.9+0.5
Normal values	52+3.6	56+3.0	39+4.4	21+3.6	40+2.8	40+11	2.2+0.2

DISCUSSION

The airway and pulmonary abnormalities of COPD have for many years distracted attention from the importance of the exercice limitation caused by dyspnoea and from the possible hypoxemic impairment of the skeletal muscle. As pointed out by De Troyer ,the main studies on skeletal muscle were performed on respiratory muscles (7). In the present study, some morphological and molecular abnormalities of skeletal muscle of COPD patients with moderate respiratory failure were described. These changes were generally confined and moderate in degree and were observed in almost all COPD patients. Although the number and morphology of intramuscular capillaries were normal, the functional deficient oxygenation of skeletal muscle in COPD appear to provide the described muscle fibre damage. Moreover the condition of exercice oxygen desaturation in COPD patients didn't seems to made an additional disadvantage to muscle fibre morphology and function. Some influence on the fibre type pattern, particularly on the type IIB glycolitic fibres, seems to due to muscle inactivity also, as demonstrated in humans and in experimental conditions (8,9). Studies are now in progress to assess the possible efficacy of a rehabilitative treatment on skeletal muscle abnormalities described in CODP patients.

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IMPLANTABLE TOMOGRAPHY TECHNIQUE AND MINIATURIZED STIMULATOR FOR TOTAL BLADDER CONTROL

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SUMMARY

This paper describes a new miniaturized implantable bladder controller which is composed of four main parts: a volume monitoring device (VMD) based on the tomography approach, a fully programmable miniaturized central processor and stimulator (CPS), a bidirectional data and power link (BDPL) and an external controller (EC). The proposed system is intended to restore both normal bladder functions (retention and voiding) to spinal cord injured patients. The system contains a mixed-signal (analog/digital) feedback loop to command the bladder functions through neuromuscular stimulation techniques. The implantable circuitry is powered by a single encoded radio frequency carrier and may have up to 8 independently controlled monopolar (4 bipolar) channels. The microstimulator is able to generate a wide range of stimulation patterns including selective stimulation waveforms. In addition, an optical link transmits the state of the implant and volume monitoring results to the external controller.

STATE OF THE ART

Electrical stimulation is becoming a promising method of bladder management for the spinal-cord-injured patients /2,5,6/. The majority of commercially available implantable stimulators lack different adequacies, especially the restricted patterns of stimulation and the external control of stimuli /1-6/. Therefore, they are not allowed to run new stimulation algorithms that may improve the quality of treatment. In a second hand, the stimulations are nearly never applied at the right time because the patient does not sense his bladder volume variations. In addition, the stimulation to avoid incontinence is constantly at its maximum strength, even when the bladder has just been emptied. Moreover, several methods have been used to measure the degree of fullness of the bladder, but unfortunately, most of them do not offer an adequate precision and present artifacts /3,4/. Therefore, the circuits needed to process the signals generated by these sensors cannot be implanted.

The advantages of reprogrammable neuroprosthesis to measure the volume and then deliver electrical stimuli to address mixed urinary dysfunctions are obvious, and error detection becomes critical issues for the system. The reprogrammability is also necessary to keep the stimulated nerve from getting used to a fixed pattern of stimulation. The proposed device in this paper is intended to measure and send out the state of the bladder volume and to generate feedback signals for a central processor and stimulator (CPS). The volume monitoring device (VMD) is based on a tomography approach, while the CPS consists of a programmable stimulator supporting a wide range of neuromuscular stimulation algorithms. The system requires a bidirectional data and power link (BDPL) providing immunity to interference from external sources.

MATERIAL AND METHODS

The full system is based on inductive coupling technique for programming and powering the implant and optical coupling for telemetry (Fig. 1). It includes external units (physician's and patient's controllers) and an implantable part. The physician's controller is used to control and reprogram the implant. The patient's controller is simplified and used just to trigger the stimulation. Both of them power transdermally the implant via the magnetic link.

The implant is composed of three main parts: (1) BDPL including a demodulator and voltage regulator to recuperate the incoming data and provide a stable power supply, (2) VMD, based on tomography technique, is composed of a signal conditioning and telemetry modules to sample the biological information and send them to the physician, (3) CPS contains a data and clock decoder and the internal controller to verify the state of the patient, a processor which directs all operations of the implant and finally the output stage to interface the electrodes. At the level of CPS, one bipolar channel is powered by a lithium battery in order to stimulate the nerve controlling sphincter for avoiding the incontinence. This channel provides continuously a low frequency stimulus to contract the sphincter. The characteristics of these three main modules are the following:

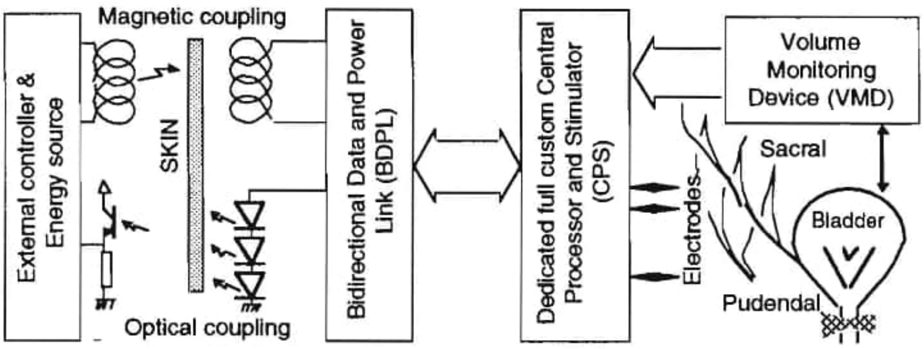

Fig. 1: Simplified block-diagram of the global system dedicated to bladder control.

a. The Volume Monitoring Device (VMD)

The main goal of the tomography is to make an impedance mapping of a biological environment. By injecting low intensity currents into the environment and measuring the produced electrical field, the impedance can be deduced /3,4/. When electrodes are diametrically placed on the bladder wall, an increase in the measured impedance is related to an increase in the bladder's volume. In order to get higher precision, several electrode pairs can be placed elsewhere on the bladder wall.

A 50KHz oscillator drives a voltage controlled current-source at 1 mA of magnitude to two opposed electrodes on the bladder wall. Voltages at those electrode pairs are scanned using an analog multiplexer, and the levels are adjusted by the programmable amplifier. The amplified signals are then demodulated and filtered. The demodulator produces DC voltage levels proportional to the distance between the injecting current electrodes, hence the volume of the bladder. A control bloc implemented by a dedicated finite states machine (FSM) selects the appropriate electrodes, programs the amplifier gains as well as the parameters of a signal processor block.

In order to eliminate artifacts produced by patients cough, laugh, etc., several signal processing steps must be done. An analog to digital converter (ADC), produces digital output values which represent the evaluated bladder volumes. Each recorded volume is sent to the central processor and stimulator (CPS), which starts the stimulation when requested by the patient. The stimulator maintains the retention process and transmits the measured volume to the user through the communication interface. In order to initialize the device, a physician can program the control parameters using the external controller.

The variation of the power-supply due to the bidirectionnel RF/optical link must not affect the operation of the stimulator. For this reason, the programmable preamplifier has been designed with a complementary differential input stage, which increases the common mode input range, therefore permitting lower supply rails. In order to start in-vivo experiments, an in-vitro evaluation of the tomography system has been done following the construction of a model for the bladder impedance. This model is made of a rubber balloon with 4 electrodes attached to its inner wall (two on each side). When the balloon is filled with sterile serum, it acts like the bladder being filled with urine and the tomography can be performed with the 4 electrodes.

b. The Central Processor and Stimulator (CPS)

The CPS comprises the following modules (Fig. 2): (1) an interface to VMD, (2) a Manchester decoder which separates the input data and clock, (3) a serial to parallel data converter and error corrector block which detects and corrects single bit error in each command word, (4) an operation-mode decoder block, (5) an optimized fully testable finite state machine (FSM), (6) registers, channel selectors and frequency divider, and (7) four stimulus waveform generators (SWG) inluding current-sources. Each SWG is programmable by means of an SRAM cell which contains the stimulation parameters and the basic waveform. 16 samples of the half wave of the basic waveform are programmed, as well as the amplitude and the sign of each sample. In addition, up to four different frequencies can be combined in each generated train wave.

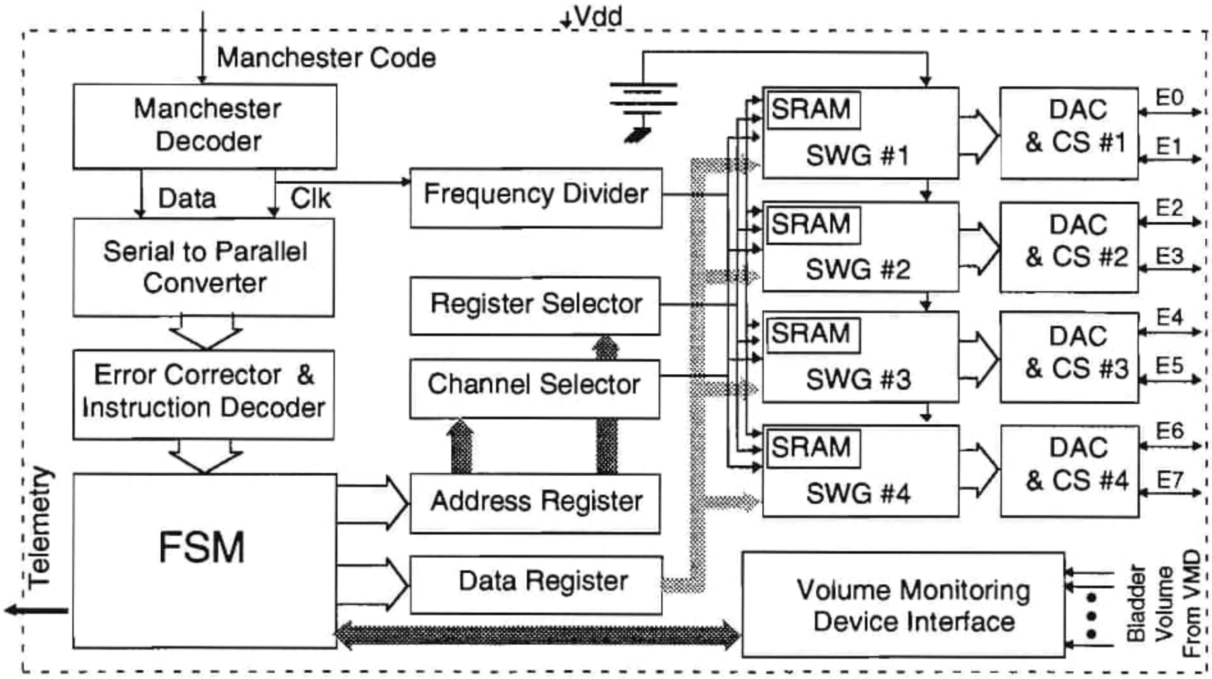

Fig. 2: Block diagram of the central processor and stimulator (CPS).

The FSM of the CPS receives 8-bit data, 3-bit instruction codes and 2 control bits and directs all operations of the implant. The output driver module consists of four optimized bipolar current sources. Each one includes an 8-bit current mode digital-to-analog converter (DAC) and an analog switching circuit (ASC) to determinate the direction of the current in the related electrode. In addition to the first channel, all SRAMs are supplied by an implanted battery to store the data.

Three operation-modes can be supported by the implant. The command mode in which the 8 data bits define a command to be accomplished. In this mode, the physician may accomplish DAC calibration by slight adjustment in Vdd level, trigger the stimulation, test the electrodes functionality, and verify the state of patient through the BDPL. In the second mode, the programming is carried out by receiving both address and data consequently. The third mode is similar to the second except, the chip generates the required address. This mode is appropriated for whole system programming.

c. The Bidirectional Data and Power Link (BDPL)

Since the implant must be permanently powered using RF amplitude shift keying (ASK) link during its operation, an independent optical link is employed for telemetry which eliminates the interference during programming phases /5/. This optical link is powered by the RF link. The implant may be also used to send out the state of patient including physiological parameters.

RESULTS

The microstimulator is optimized using circuit techniques to reduce power dissipation and to save battery power. The power estimation predicts that the minimum cell operating voltage will be reached up to 10 years. The stimuli frequency can be programmed from 1 to 2000 Hz and the pulse duration can vary from 10 μs to 2000 μs. A wide range of stimulation waveforms can be generated. The simulation results prove the functionality of the implant.

The CPS providing several new features: forward error correction block, new mixed-technique link, high level of flexibility of stimulus, etc. This part of the system has been fabricated using 1.2 μm CMOS4S technology of Northern Telecom of Canada (NT) through the Canadian microelectronics corporation (CMC) and occupies around 19 mm^2 of silicon area. Regarding the VMD, two steps of this project have been done so far; the programmable amplifier and the bladder tomography model. This model has been successfully completed and preliminary results have been obtained. More descriptive results are currently taken using that bladder model.

DISCUSSION

An implantable system for monitoring the bladder volume has been presented and a model for bladder impedance has been tested. The system is based on the tomography principle and offers a feedback loop to control the stimulation. When coupled with the stimulation implant, the whole circuit forms a highly autonomous system. Using many electrodes, the device can be improved and the form of the bladder can be deduced. This information could be of interest for urological researches. The new programmable neuromuscular miniaturized stimulator system is adaptable to the patient's needs and to future development in stimulation algorithms, without changing the implant.

The characteristics of the implant exceed the requirements of actual FES applications. It can be used to any neuromuscular applications (pacemaker, pain control, cochlear implant, etc.). The telemetry link allows the physician to optimize the stimulation parameters after implantation. The device is an important tool for neuromuscular stimulation investigations and represents a significant progress in the development of new generation neural prosthesis. The implantable microstimulator presented in this paper has been dedicated to recuperate normal bladder functions. It is the unique microstimulator that addresses both bladder dysfunctions.

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INTRAMURAL ELECTROSTIMULATION OF THE URINARY BLADDER

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SUMMARY

Electrostimulation of the bladder detrusor has been utilized for the treatment of hypocontractile or acontractile detrusor. We investigated the effect of chronic intramural stimulation of the detrusor in 8 mongrel dogs with muscular needle electrodes (TME 60-Z; Osypca Ges.m.b.H.), considering changes in intravesical pressures, bladder histology and smooth muscle histochemistry. For the chronic stimulation period biphasic pulses were applied twice a day for 3 min in all cases (50Hz, 70mAmp, pulse width 2.5msec). All canines were cystometrically evaluated prior to and after a 3 week stimulation period with a 50% and 90% filling status. Hereto intravesical pressure changes during pelvic nerve stimulation (20Hz, 10mAmp, 2.5msec) were recorded with a polygraph. Biopsies for histology and histochemistry were taken in all cases prior to and after chronic stimulation.

All dogs tolerated the chronic stimulation well without requiring anesthesia during the whole procedure. Intravesical pressures secondary to pelvic nerve stimulation increased by 56.2% at 50% filling and 39% at 90% filling. Histology of the bladder did not show significant alterations of the mucosal or muscular order. A moderate or severe inflammatory reaction at the implantation site was not seen. Histochemical staining of smooth muscle's oxidative phosphorylation, glucose metabolism and myosin quality revealed normal findings.

We finally present a patient with hypocontractile detrusor who underwent transient chronic intramural electrostimulation for 3 weeks. By stimulating with the same parameters as in the initial experiment urodynamic investigations during and after the stimulation period showed improved urinary flow rates and decreased residual urine volumes. However, an increase in intravesical pressures was not seen.

STATE OF THE ART

Electrostimulation of the bladder detrusor has been performed as a diagnostic and therapeutic tool. Direct muscular stimulation of the detrusor has been investigated in experimental and clinical trials /1-6/. Initial results in patients with neurogenic bladder disorders appeared encouraging, although, due to dislocation of electrodes, local spread of currency causing detrusor-sphincter dyssynergia, local pain, concomitant activation of motor neurons and erections, direct muscular stimulation of the detrusor did not become an established therapy in patients with voiding dysfunctions /1,4-6/.

In cardiac surgery temporary wire electrodes are regularly used for muscular stimulation of the atrium or ventricle to avoid postoperative bradycardia or tachycardial arrhythmias. These electrodes are implanted in the cardiac muslce, transcutaneously linked to an external pacemaker and can be removed without additional surgery /7/.

By using those electrodes we investigated the capability of chronic detrusor stimulation and evaluated the histological and histochemical alterations of the bladder detrusor and changes in intravesical pressures secondary to chronic intramural electrostimulation. Due to the good results of our initial experiment we report on one patient with bladder hypocontractility who was treated by transient intramural electrostimulation.

MATERIAL AND METHODS

Initially intramural electrostimulation of the bladder detrusor was investigated in a chronic study on 8 female mongrel dogs (median weight 17.5kg, range from 12.4kg to 21.9kg).

Animals were premedicated with Azepromazine (1mg/kg body weight) and anesthesized with Ketamine (100mg/kg body weight) and Xylocainhydrochloride (20mg/kg body weight). Intraoperatively, animals were kept on a heating matrace to keep rectal temperature above 38°C.
Via a median laparotomy, the bladder was exposed and 2 unipolar intramural wire electrodes (TME 60-Z; Osypca Ges.m.b.H.) were implanted on either side of the lateral bladder wall. The intramural electrodes were led subcutaneously to the nuchal region and the endings of the electrodes were fixed in the cutis through a small incision. A cystostomy was placed to record intravesical pressure changes via a Polygraph. Additionally, the right pelvic nerve was prepared and supported with a cuff-electrode for stimulation.
After cystometric evaluation of the bladder capacity, in each individual case the bladder was filled with both 50% and 90% of total capacity and stimulation of the pelvic nerve was performed. Stimulation parameters were 10Hz, 20mAmp with an impulse width of 2.5msec. The intravesical pressures after pelvic nerve stimulation were recorded. Finally, a biopsy from the bladder dome was taken for histology.
The procedure took no longer than 45min and all dogs survived the operation without any complications.
All dogs underwent chronic temporary intramural electrostimulation of the detrusor twice a day for no more than 3 minutes thus not requiring anesthesia. Stimulation parameters were biphasic pulses (50Hz, 70mAmp, pulse width 2.5msec) applied in bursts of 1.2sec duration. Complications of stimulation and accidental micturition during stimulation were registered.
After 3 weeks of chronic stimulation all animals were reevaluated by the same procedure and identical bladder fillings as prior to stimulation. To avoid an influence of the stimulatory response due to a possible surgical lesion of the right pelvic nerve now the left pelvic nerve was used for stimulation. Again stimulation of the pelvic nerve (10Hz, 20mAmp, pulse width of 2.5msec) was performed and intravesical pressures were recorded. A rebiopsy from the dome of the bladder was taken for histology. All biopsies were stored in liquid nitrogen and finally evaluated histologically and histochemically. Histologic examination was performed after standard Haematoxylin-Eosin staining. For histochemistry, qualitative analysis of enzymes considering smooth muscle cell's oxidative phosphorylation (NADH, Succinatdehydrogenase, Cytochrome C-Oxidase), glucose metabolism (Periodic acid Schiff) and myosin quality (acid and alkaline ATPase) were investigated. To find alterations in smooth muscle cells a morphometric analysis of each specimen was carried out using cryosections. The perimeter and area of the smooth muscle fibres were ascertained by means of a computer assisted morphometric analysis (Unigraph, IBM PS/2 80).
Changes of the pre- and poststimulatory intravesical pressures after stimulation of the right (initial phase) and left (late phase) pelvic nerve were compared.

Statistical analysis

For comparative statistical analysis of changes in smooth muscle cellular diameters and intravesical pressures a nonparametric Wilcoxon test ($p<0.05$) was performed.

RESULTS

Biopsies taken prior to and after chronic stimulation did not show a change of the order of mucosal or muscular layers. Poststimulatory histology showed a regular urothel with 5 or 6 epithelial layers and cubic umbrella cells in all cases. The muscular layers were in regular order revealing no evidence of degeneration or inflammation. A submucosal increase of collagen was not seen but an increase of collagen was found in all cases at the muscular implantation site of the electrodes. A severe inflammatory reaction at the muscular implantation site was observed in one dog. In all other biopsies there were no signs of inflammation found. Smooth muscle histochemistry for oxidative phosphorylation, glucose metabolism or myosin quality did not reveal any changes in poststimulatory cellular function. Comparison of the staining pattern for NADH and cytochrome C, the initial and end-stage enzymes of the oxidative phosphorylation showed no alterations. Histochemistry did not reveal lesions of cellular mechanisms after chronic intramural stimulation.
Computer-assisted evaluation of smooth muscle cellular diameters did not verify a significant increase in cellular diameters, however, graphical analysis showed a shift of diameters to thicker ranges. The mean diameters of pre- and poststimulatory SMCs were 5.19µm±1.46SD and 6.52µm±2.01SD ($p=0.32$, n.s.).
A statistically significant mean increase of intravesical pressures by 56.2% ($p=0.042$) at 50% filling status and an increase by 39% ($p=0.31$, n.s.) at 90% filling was found during pelvic nerve stimulation.

Complications of stimulation were dislocation of the electrodes in 1 case on the second postoperative day. In this case no further stimulations were performed. In 2 animals a dislocation was suspected on the 12th and 15th postoperative day due to muscular contraction of the abdominal wall during stimulation. Stimulation was interrupted and a dislocation of one electrode each was found at reoperation. Accidental micturition occured in some instances during stimulation. Mechanical problems of the electrodes were not seen.

CASE REPORT

A 41 year old female with chronic urinary infection and residual urine of 500-600cc presented to our department. In her history she had undergone several operations due to vesicoureteral reflux as a child. Due to systemic lupus erythematodes she was treated with chronic steroids since 1990. Investigations of the upper urinary tract revealed normal findings. Initial urodynamics showed a hypocontractile detrusor with a bladder capacity of 400cc, average flow rates of 2.5ml/s and a maximal detrusor pressure of 28cmH_2O. The patient was able to spontaneously void 41cc. As a combined neural and muscular lesion of the detrusor was suspected we initially tried to improve bladder contractility by intravesical electrostimulation as the least invasive procedure. She performed intravescal stimulation on a daily basis for 14 days. Following urodynamic investigations did not show any improvement, the amounts of residual urine maintained at mean values of 354cc±139.6cc. Due to our experimental results with transient intramural electrostimulation we subsequently decided to implant 2 extraperitoneal unipolar muscular electrodes (TME 60-Z; Osypca Ges.m.b.H.) after obtaining an informed consent from the patient. The electrodes were each located on the lateral bladder wall, leading the wire transcutaneously to an external stimulation device. Intraoperatively it was seen that there was nearly no residual detrusor muscle attached to the mucosa. Although the patient required chronic steriods no postoperative complications occured and stimulation was initiallized on the 6.postoperative day. Stimulations were performed via an external supply by the patient twice a day for 21 days. Stimulation parameters were the same as in our canine study. The patient tolerated the stimulation without any pain sensations, stimulatory induced micturition as seen in the canine experiment was not observed. Immediately after starting the protocoll residual urine decreased to a mean of 256.2cc± 82.1SD. After 3 weeks of intermittent stimulation mean residual urine further decreased to a mean of 193.8cc±41.7SD. Urodynamics showed an improvement in urinary flow rates (8ml/s), a increase in micturition volumes to 200ml (3 portions) and a reduction of residual urine, however, intravesical pressures (20cmH_2O) were not changed compared to the initial findings. Due to the improvement in bladder emptying the electrodes were finally withdrawn without requiring surgery. The patient is now spontaneously voiding with clean intermittent self catheterization once a day and average residual urine volumes of 200cc.

DISCUSSION

Direct electrostimulation of the bladder detrusor has been investigated experimentally in various models. Mechanical complications of the electrodes or local spread of currency restricted the use in humans. With the improvement of intramural wire electrodes in cardiac surgery, a renaissance of direct stimulation of the detrusor might be feasable.

The intramural wire electrode is made of a short zig-zag shaped stimulatory part of stainless steel supplied with a needle and a long isolated part with either a straight or curved needle. Its placement can be easily performed and the leads can finally be removed only by gentle pulling as reported in cardiac surgery. Since the implantation is a standard procedure in cardiac surgery only minimal to moderate histological changes were suspected in the bladder detrusor /7/. The examination for histological alterations of the detrusor after chronic intramural stimulation showed only a slight increase in leucocytes and collagen at the implantation sites of the electrodes which appears encouraging for longer stimulatory periods. These results are conform to Bradley et al. reporting on minimal tissue reactions after 3 months of muscular stimulation /3/. Due to their data a prolonged protocoll for chronic stimulation could be undertaken without a diminishing in transduction of currency due to local enhancement of collagen at the implantation site.

Although poststimulatory investigations revealed an increase in intravesical pressures of more than 50% compared to prestimulatory results we did neither find an increased number of blood vessels in the muscular layers nor a measurable increase in bladder density in histological investigations. However, morphometrical analysis of the smooth muscle cells revealed a thickening according to the

distribution at the Gauss' curve but this was not statistical significant. A longer stimulatory phase might have led to a significant increase in cell diameters. Malmquist et al. reported on smooth muscle cell hyperplasia in rat detrusor by an increase in bladder weight after chronic subvesical obstruction already after 10 days /8/. They also found a change of actin and desmin filaments contents and an alteration in myosin subspecialities. Samuel et al. saw alterations in the distribution of smooth muscle cell type I to type II from 1:3 to 1:1 after chronic subvesical obstruction in hypertrophic detrusor /9/. The reason for the rapid changes of the smooth muscle subtypes within several days in obstructed bladders is not clear yet. Pathogenetically either hypertrophia or hyperplasia or a combination of both are discussed. As we have seen in our canine experiment a significant increase of intravesical pressures were found without alterations of detrusor's histology. At least by histochemistry we expected to verify any deleterious effects of chronic electrical stimulation on the cells. Yet, this was not found.
The good results of chronic intramural electrostimulation in canines were not repeatable in our single case report. Although there was an improvement in bladder emptying we did not see an increase in intravesical pressures in the postoperative urodynamic investigations. Since the patient already had a long history of large amounts of residual urine a deterioration of the detrusor muscle seems most likely. The intramural electrostimulation might place a new model in the treatment of hypocontractile or acontractile detrusor especially in patients after Wertheim' operations or some cases of extended bladder surgery.

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SELECTIVE DETRUSOR ACTIVATION BY ELECTRICAL STIMULATION OF THE HUMAN SACRAL NERVE ROOTS

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SUMMARY

The purpose of this study was to investigate the feasibility of selective detrusor activation without activation of the urethral sphincter by sacral root stimulation in patients. The sacral roots were stimulated using a tripolar electrode. An anodal block was used to prevent the urethral sphincter from contraction. Using square current pulses (700 μs, 6-7 mA) no increase in intraurethral pressure was measured while a normal increase in intravesical pressure occurred. The minimum pulse duration to obtain a complete block was 550 μs. The study shows that anodal blocking of action potentials is possible in humans and can result in selective detrusor activation when used in sacral root stimulation.

STATE OF THE ART

Spinal cord injury patients with a suprasacral lesion usually suffer from detrusor hyperreflexia and detrusor-sphincter dyssynergia which can cause incontinence and renal failure. The therapeutic goal is to establish a bladder with a high storage capacity at low pressure and periodic emptying with low urethral resistance. One of the current approaches is twofold, deafferentation of the detrusor by cutting the dorsal sacral nerve roots eliminates the reflex detrusor contractions while a detrusor contraction to induce voiding is elicited by stimulation of the ventral sacral nerve roots using implanted electrodes /1/. However, the selectivity of stimulation technique is insufficient. Both the urethral sphincter and the detrusor are simultaneously activated resulting in little or no voiding.

In clinical practice this problem is overcome by interrupting the stimulus pulse train. As the striated urethral sphincter muscle relaxes faster after a stimulus burst than the smooth detrusor muscle, bladder emptying is achieved between the pulse trains due to the sustained high intravesical pressure. However, in this artificial micturition pattern voiding occurs in spurts with possible supranormal intravesical pressures. The latter may be harmful to the kidneys.

Several attempts to eliminate the sphincter contraction have been reported and include i.a. a pudendal nerve neurotomy /2/, blocking the motor signals in the pudendal nerve either by a collision block /3/ or by a high frequency block /4/, fatiguing the urethral sphincter /5/ and a selective rhizotomy of ventral sacral rootlets /6/. The drawbacks of these techniques have been discussed in Rijkhoff et al. /7/.

The micturition pattern would improve if the detrusor could selectively be activated. Since the urethral sphincter is innervated by relative large diameter somatic fibers while smaller parasympathetic fibers innervate the detrusor /8/ the problem comes down to selective activation of the smaller nerve fibers.

Selective activation of small fibres is possible using an anodal block /7/, /9/, /10/. Using a tripolar cuff electrode consisting of a cathode flanked by two anodes, all fibers (small and large) are activated close to the cathode. Close to the distal anode, the propagation of the AP's in the large fibers is blocked by a selective anodal block. As the AP's in the smaller fibers can pass unhindered, the net result is selective small fiber activation.

Simulations with a computer model /7/ showed the theoretical possibilities of this stimulus technique for activation of the detrusor without activation of the urethral sphincter. Based on these theoretical results, tripolar cuff electrodes have been developed and successfully tested in acute experiments on dogs /11/, /12/. In this abstract we report the first experience with the stimulus techniques in patients.

MATERIALS AND METHODS

In 10 spinal cord injury patients, who underwent implantation of a Finetech-Brindley sacral root stimulator /1/ in combination with a complete sacral dorsal rhizotomy (S2-S4/S5), the intradural sacral ventral roots (S3 or S4) were stimulated after the dorsal rhizotomy. During the operation, the roots were stimulated using a symmetrical tripolar electrode (a cathode flanked by two anodes). Since the electrode contained both S3 or S4 roots bilateral stimulation was used. The electrode was connected to a selfmade stimulator consisting of two synchronized current sources with a common cathode. A two channel transurethral pressure catheter was used to measure intravesical and intraurethral pressure. The urethral pressure sensor was positioned at the level of the external sphincter so that -in response to suprathreshold stimulation, a maximum pressure response was measured. Pressures were sampled at 8 Hz, displayed on a monitor and stored in a portable datalogger. Prior to the stimulation phase the bladder was filled with approximately 200 ml saline.

RESULTS

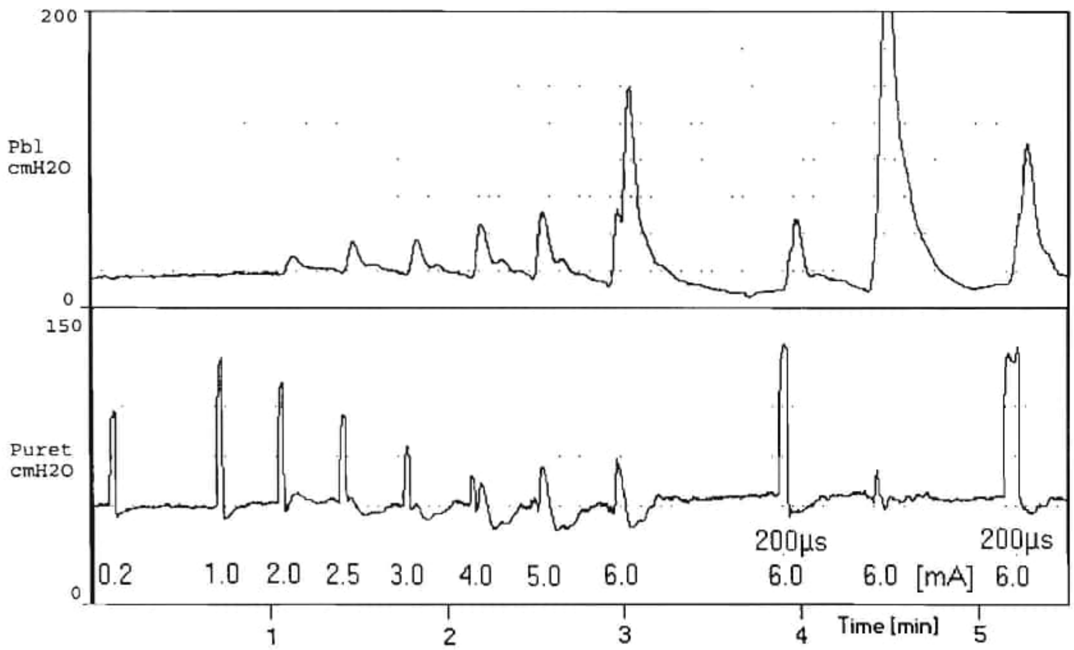

Fig. 1: Intravesical (Pbl) and intraurethral (Puret) pressure responses to stimulation of an intradural sacral root pair (25 Hz, pulse duration: 700 µs). Given stimulus is the cathodal current. Stimulation with 200 µs wide pulses results in a normal sphincter response.

Fig. 1 shows a typical stimulation induced pressure response in the urethra and in the bladder. The relation between the stimulus current and the urethral pressure is depicted in Fig. 2. The stimulus threshold (pulse duration: 700 µs) to elicit a sphincter contraction was about 0.15 mA. Beyond the stimulus threshold the pressure responses increased until all innervating motor fibres were activated at about 0.5 mA. An increase of the stimulus to 1 mA did not change the pressure response while above 1 mA the response started to decrease as the current at the distal anode exceeds the blocking threshold for fibres innervating the sphincter. Increasing the current from 1 to 6 mA resulted in a gradual decrease of the urethral pressure response as more and more fibres are blocked. At 6 and 7 mA the square shaped pressure response (caused by activation of the striated sphincter muscle) disappeared totally, a complete block is achieved. The still visible pressure response is transmitted from the intravesical pressure.

To show that the reduction of the intraurethral pressure response is due to anodal blocking and is not due to other causes as muscle fatigue, the pulse duration was twice reduced from 700 μs to 200 μs. Since a pulse duration of 200 μs is to short to obtain blocking effects /8/ the intraurethral pressure response should be about the same as the maximum response obtained with 1 mA. Fig. 1 shows that just by switching the pulse duration between 200 and 700 μs the block could be switched on and off which proves that the urethral pressure response reduction was caused by anodal blocking.

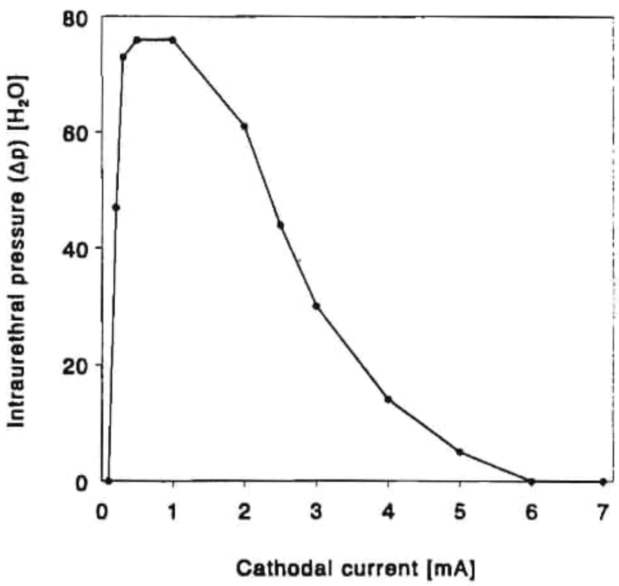

Fig. 2: Intraurethral pressure response (deviation from baseline pressure) as a function of the cathodal stimulus current (700 μs pulse duration).

The threshold for a bladder contraction was about 1 mA. With increasing current, the intravesical pressure response gradually increased as more and more small fibers innervating the detrusor were activated. At 6.0 mA, 700 μs the detrusor was activated while the urethral sphincter muscle was not activated, so selective activation of the detrusor muscle occurred.

At 6.0 mA the pulseduration was varied to determine the influence of the pulse duration on the urethral sphincter activation. Below 200 μs no blocking effects could be observed. Between 200 and 550 μs the block was incomplete while a complete block could be obtained beyond 550 μs.

DISCUSSION

Anodal break excitation at the end of the rectangular pulses did not occur in our experiments. This is in contradiction with the literature concerning blocking of peripheral nerves (e.g. /10/) which stresses the necessity of a slow current decrease at the end of the pulse (0.2-1 ms) to suppress anodal break. In experiments using dogs, we often observed that anodal blocking was possible without anodal break excitation, using a current just above the blocking threshold. A further increase of the stimulus usually led to break excitation which could be suppressed by a gradual current decrease at the end of the pulse. It is therefore likely that break excitation will also appear in the patients when higher currents are used.

The detrusor response to 6 mA, 200 μs is less than the response to 6 mA, 700 μs. There are to possible causes. The first is that the current needed to excite a fibre increases with decreasing pulse duration (strength-duration relation). So if 6 mA, 700 μs does not recruit all the fibers innervating the detrusor then 6 mA, 200 μs will certainly recruit less fibers and therefore result in a smaller pressure response. The second cause is that the stimulation duration at 200 μs was shorter. There is therefore less time for the bladder to build up the pressure.

This study shows that the technique of anodal blocking can be used in human sacral root stimulation for bladder control. The combination of cathodal excitation and selective anodal blocking leads to selective activation of the detrusor muscle. In addition to blocking the fibers innervating the urethral sphincter, the large motor fibers innervating muscles in the lower limbs are also blocked. Hence movement of lower limbs during stimulation is reduced. When this technique can be used in implanted systems, bladder emptying by sacral root stimulation will be more physiological and at lower intravesical pressures because the outlet resistance is largely reduced.

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ELECTRICAL MODULATION OF SACRAL NERVES FOR TREATMENT OF VOIDING DISORDERS AND INCONTINENCE

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SUMMARY

We evaluated neuromodulation as a treatment for severe voiding disorders such as urgency, frequency, urine retention, urge-incontinence and pain in combination with urge or urge-incontinence. The patients in this studies were so-called 'urological cripples' and were at the end-stage of treatment. Following a positive effect of a percutaneous nerve evaluation test the patients were operated and a Medtronic, Inc. Urological Nerve Stimulation System was implanted. In total 41 patients were treated with a neuromodulator with an average follow-up of 27.8 month (4 years maximum). The success percentage was 83.5 %. The urodynamic investigations of patients with urge-incontinence showed significantly decreased instable bladder contractions, leakage episodes and residues. Furthermore increased bladder volumes were found. The quality of life was better in more than 80 % of the patients. The overall benefit, recorded with questionnaires, was approx. 90 %.
With a high success rate and only minor adverse events we conclude that neuromodulation is a good alternative for patients with severe voiding disorders.

STATE OF THE ART

Voiding dysfunction is a frequently encountered urological problem. Trials of electrical control of the bladder function began in the 1950s. Since then, extensive experimental and clinical trials had been performed at different central and peripheral levels, including the spinal cord, pelvic nerves, detrusor muscles and pelvic floor muscles, to explore the most successful way to achieve bladder evaluation [1234]. Each technical approach had its limitations and disadvantages. Currently, neural stimulation at the S3 level has shown promising results[1-234]. Most cases of voiding dysfunction are associated with some degree of hyperactivity of the pelvic floor and external urethral sphincter muscles, which are controlled mainly through S3. Since neural stimulation minimizes spastic behaviour of the striated muscles, it was believed that stimulation of S3 could modulate the spastic behaviour of the pelvic floor and external urethral sphincter with improvement in voiding pattern.

In this paper we will present the results of 4 years treatment by the use of neuromodulation. The patients were first tested with the use of a percutaneous nerve evaluation (PNE) test. After a successful treatment period of 3-5 days patients were scheduled for implantation. In total 41 patients were treated with a neuromodulator with an average follow-up of 27.8 month (4 years maximum). The patients were included in two clinical trials (1990-1993 and 1993-1994). The voiding disorders consists of urgency, frequency, urine retention, urge-incontinence and pain in combination with urge or urge-incontinence. The treatment was evaluated with the use of voiding dairies, Quality of Life assessments and urodynamic investigations.

MATERIALS AND METHODS

PNE test

The percutaneous nerve evaluation (PNE) has two separate phases, an acute phase for response confirmation, and a sub-chronic phase for evaluation of therapeutic effect. *Acute phase*; in order to establish the functional integrity of the sacral nerves, to locate and identify the nerve responsible for specific responses, and to confirm the proper muscle responses. Acute percutaneous electrical stimulation of the ventral ramus at the level of he third sacral foramen (S3), and possibly S2 and S4. Insulated needles, a ground pad and an external hand-held neurostimulation will be used. *Sub-chronic phase*; if adequate responses are obtained during the acute testing, sub-chronic test stimulation will be conducted for a minimum of three days. The acute stimulation needle will be replaced by a temporary percutaneous lead wire which is connected to the external stimulator. After wound dressing and securing the lead with tape the patients returns to their home.

Before, during and after (one week) the PNE voiding diaries for a minimum of 3 days will be complete by the patient. In this diary voided volume, leaking episodes, replacement of pad/diaper, felt empty and degree of urgency are noted. Analysis of baseline, PNE and post-PNE diaries makes it possible to evaluate the treatment. With an improvement >50% the patient will be scheduled for definitive neuromodulator implantation.

The Medtronic, Inc. Urological Nerve Stimulation System consists of a Lead, with four separate electrodes, an Extension, a neurostimulator (Itrel II IPG), and two control magnets. The Itrel II IPG can be programmed to provide stimulation with a wide range of parameters. The stimulation parameters to be used in this treatment will be approximately as follows: pulse amplitude 0 to 10 volts, pulse rate 5-20 pulses per second, pulse width 120-270 microseconds, pulse mode continuous or cyclic and daily usage from a few hours to 24 hours per day. With the use of a extension wire the Itrel II is connected to the lead. The Medtronic, Model 3886 PISCES-Quad, lead has the following specifications; four electrodes placed circumferentially around the lead, each electrode is 3mm wide and spaced 3mm from one another. Electrode material consists of platinum-iridium, lead material MP35N quadrifilar coil, each conductor individually insulated and the lead insulation consists of polyurethane.

Operation

Under general anaesthesia, the patient is positioned prone on the operating table with the hips and knees flexed. The surgical area is draped and prepped. Test neuromodulation is performed to identify and confirm nerve location and muscular responses. An incision over the sacrum is carried out down through the fascia on the side that produced the best response in the percutaneous nerve evaluation (test). The muscles are the separated to permit access to the foramen. Acute testing is repeated, and if adequate, the permanent foramen lead is inserted into the foramen. Following positioning of the lead, the attachment sleeves are fixed to the sacral periosteum or bone to secure the lead in position. The lead is brought to the flank of the patient to be connected to the extension wire. Through a subcutaneous tunnel the extension wire is threaded to a lower quadrant of the abdomen.

In the lower quadrant of the abdomen a pocket is made in which the stimulator, connected to the extension wire, will be placed and secured with sutures.

Stimulation is normally activated the next day. With the use of impedance measurements and sensations felt by the patient the most effective electrode position and stimulation parameters will be determined.

Evaluation

Analysis of voiding dairies (3-6 month intervals) during the treatment with neuromodulation. Urodynamic investigation before and after 6 month treatment were conducted.

RESULTS

The success percentage, more than 50% improvement, was 83.5 % with an average follow-up of 27.8 month. The urodynamic investigation, performed 6 month after the implantation, show a significantly decreased instable bladder contractions which resulted in decreased leakage episodes ($p=0.000$). Furthermore an increase in bladder volume ($p=0.006$) and a decreased residue ($p=0.000$) was found.

Urodynamic investigation	baseline	6 month follow-up
bladder volume (ml)	147.1	192.7
bladder empty after voiding (%)	54.3	89.2
leakage episodes / 3 days	23.4	11.3

Other positive side effects were found in 13 of the 15 patients with pain in combination with incontinence. The pain was reduced or not present any more due to the neuromodulation treatment. Furthermore from 5 patients with defecation problems 3 were cured.

Quality of Life assessments

Question: how would you rate your overall quality of life now as compared to the time before you received your stimulator ?
36.6 % much better, 36.6 % better, 13.3 % slightly better, 3.3 % the same, 3.3 % slightly worse.
Question: how would you rate the overall benefit of the neurostimulation therapy ?
50 % great benefit, 30 % moderate benefit, 10 % slight benefit, 3.3 % slightly worse.

Three types of complications did occur, firstly technical problems like wire isolation damage (3 times), repositioning of the lead (5 times) or battery problems (3 times). The second group of complications consists of patients (6) with good reactions in the beginning return to baseline problems after a few month. No wound infection developed after the operation.

DISCUSSION

Neuromodulation is a new technique to treat patients with sever bladder disorders. Many patients can't be treated with conventional treatments or can only be treated with invasive methods like bladder removal or other major surgery.

By applying a current on the sacral nerves, especially the nerves in foramen S3, stimulation of pelvic floor and bladder develops. From the 105 patients treated with the use of neuromodulation a success rate of 83.5 % was reached. Quality of life assessments showed major improvement.

With this treatment modality we have a new and promising technique in the treatment of micturition disorders. A randomized study is started in 1993. Results until now looks very promising.

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ACTUAL STATUS OF EXTERNAL FUNCTIONAL ELECTRICAL STIMULATION IN THE MANAGEMENT OF FEMALE URINARY INCONTINENCE

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SUMMARY

The actual status of functional electrical stimulation (FES) in the management of female urinary incontinence (UI) results from the development of technology and medical science, especially over the last 20 years. Technical progress has provided the determination of efficient parameters of FES. Stimulus: rectangular and biphasic to prevent corrosion of electrodes; duration of impulse: 1 msec; frequency: 20 Hz; current: between 35 mA and 100 mA, depending on the effect to be achieved. We have designed plugs for vaginal and rectal use which maintain a better contact with tissues. We also use materials more suitable for long term FES application: a high-quality plastic for plugs and prochromium for electrodes which prevents corrosion. New stimulators maintain unchanged intensity of current throughout stimulation duration regardless of the tissue impedance. Improved medical knowledge has proved principally reflexogenic activity of FES applied on the pelvic floor muscles. Clinical studies have enabled precise determination of the indications for management of UI with FES. The most important indication is unstable detrusor, manifested as urge incontinence. Treatment with FES provides far better results than any drug treatment, and there have been no contraindications encountered, not even in elderly women. FES has proved more efficient in the management of sensory than of motor idiopathic urge incontinence (cured and improved 87.5% vs 75.0%).

STATE OF THE ART

To understand the actual status of functional electrical stimulation (FES) in the management of female urinary incontinence (UI), it is necessary to review the development of FES, especially over the last 20 years. This development has followed two directions: technical and medical, and has been mainly performed in Ljubljana.

Numerous technical problems had to be solved to provide the actual indication area, efficacy and safety of the treatment of female UI. As the parameters taken from literature proved inappropriate, we had to establish new ones. Corrosion of electrodes after a longer use of stimulators did not only initiate the search for new materials, but also resulted in transition from monophasic to biphasic stimulation. We designed more physiological plugs for vaginal and rectal use, and new electrodes. The automatic vaginal simulator, vagikon-x, also resulted from our research. New stimulators for acute maximal functional electrical stimulation (AMFES) have been made to maintain unchanged intensity of current throughout the 20 minutes of stimulation, regardless of the tissue impedance. Our modern stimulators have the following parameters of electrical stimulation: impulse is rectangular and biphasic, duration of impulse is 1 msec, frequency of impulse is 20 Hz, intensity of current ranges between 35 and 100 mA, depending on the type of UI. Only stimulators for external application, vaginal or rectal, are currently in use.

Medical knowledge in this area has been improved by numerous clinical, neurophysiologic and urodynamic findings. Neurophysiology has contributed the important finding that FES applied on the pelvic floor muscles has a predominantly reflexogenic effect. FES stimulates afferent nerves of the pelvic floor, the impulse continues to the centre in S2 to S4 and returns via efferent fibres to the pelvic floor muscles, which contract. The important clinical and urodynamic finding was that the response of the micturition centre in S2 to S4 is physiological. Its response to the stimulus is the contraction of the pelvic floor muscles and relaxation of the bladder detrusor. All these findings helped to find the indication areas for the management of female UI. Clinical investigations confirmed the efficiency and reasonableness of the treatment of individual types of female UI with FES.

MATERIAL AND METHODS

The aim of our study was to classify the indications for treatment of micturition disturbances with external application (vaginal or rectal) of FES, and to evaluate the outcome of treatment. For this purpose we analyzed the data on patients treated at the Unit of Gynecologic Urology, Department of Obstetrics and Gynecology Ljubljana over the last 10 years.
All the patients underwent precise diagnostic procedures to obtain the exact diagnosis of a micturition disturbance, and of UI in particular, in order to be enrolled in a suitable diagnostic group. In all the patients a precise medical history was taken and laboratory tests made (urinary test, bacteriological Sanford's test, blood sugar test). The patients underwent a pelvic examination, especially with regard to genital statics problems, followed by urologic and neurophysiologic examinations (EMG of the pelvic floor muscles), and by multichannel urodynamic investigations (urethral pressure profile, cystometry, urodynamic stress profile, provocative tests for urge incontinence and uroflow). After making the exact diagnosis of UI the PAD test for objectivization of UI was made at 2/3 and full capacity of the urinary bladder. Only the patients conforming to the criteria of UI set by the International Continence Society were enrolled in the study and underwent further treatment. All these examinations were repeated 3, 6 and 12 months after the concluded treatment. In this way we obtained subjective (provided by the patients) and objective evaluations of treatment.
In the treatment of stress incontinence stimulators for the so-called chronic stimulation were used. Stimulation lasted for 1.5-2 hours per day, and had be continued for at least three months. The above parameters were used, the intensity of current applied was 35 mA.
Idiopathic urge incontinence was treated with AMFES. The parameters used were the same as indicated above, while the intensity of current had to exceed 65 mA in case of vaginal application, and 40 mA if applied rectally. The intensity of the applied current should be individualized and should not exceed the threshold of pain. The current was applied 20 minutes per day for 5 consecutive days. The intensity was gradually increased so that the recommended intensity was achieved within 2-4 minutes.
The studies performed over the last five years have proved that the successful outcome of treatment can be achieved if the intensity can after the initial rise, i.e. after 2-4 min, be constantly maintained throughout the remaining 16-18 min. Tissue impedance change during the time of stimulation, and thus stimulation can be done with much lower intensity, which essentially affects the outcome of treatment. Therefore our new stimulators have been made so as to maintain constant current intensity throughout the time of stimulation.

RESULTS

The treatment with FES was applied with the following indication areas: stress incontinence, urge (motor and sensory) incontinence, some types of neurogenic bladder incontinence, vesicourethral dyssynergia and frequency. The results of treatment are presented with regard to the type of a micturition disturbance and/or UI.

The patients were considered cured, if after the terminated treatment they did neither have subjective problems, nor signs of urodynamic UI on objective evaluation (PAD test). The patient's condition was considered improved when they subjectively claimed to have been cured (experienced no related problems) or their condition essentially improved, but objectively (PAD test and urodynamic investigations) we still found some parameters indicating the existence of UI, although of a milder degree.

The results of treatment of **stress incontinence** by FES: of 111 patients 56 (50.5%) were cured, 26 (23.4%) improved, and in 29 (26.1%) the conditions remained unchanged.

The results of treatment of **idiopathic urge incontinence**: of 88 patients 65 (72.7%) were cured, 8 (9.0%) improved, and in 16 (18.3%) the condition remained unchanged.

Further, our aim was to find the respective reactions of both urodynamic types (motor and sensory) of idiopathic urge incontinence to the treatment with FES.

The results of treatment of **motor urge incontinence** with FES: of 40 patients 22 (55.0%) were cured, 8 (20.0%) improved, and in 10 (25.0%) the condition remained unchanged.

The results of treatment of **sensory idiopathic urge incontinence** with FES: of 48 patients 42 (87.5%) were cured, none improved, and in 6 (12.5%) the condition remained unchanged.

The results of treatment show no significant difference between the types of idiopathic urge incontinence (X = 2.29, p =<0.13). Had the cured patients alone been taken into account, the difference would have almost been significant (X = 4.22, p =<0.04).

After 3 months the recurrence of idiopathic urge incontinence was registered in 26% of patients. In these patients AMFES was applied again with the same outcome of treatment as before.

The results of treatment of the **unstable urethra** with AMFES: of 39 patients 22 (56.4%) were cured, 9 (23.1%) improved, and in 8 (20.5%) the condition remained unchanged.

Micturition disturbances related to unstable urethra were in 6 patients (15.4%) manifested as urge incontinence, in 5 (12.8%) as stress incontinence, and in 24 (61.5%) as mixed (stress and urge) incontinence.

The results of the treatment of **neurogenic urge incontinence** proved to be unfavourable and short-lived. A transient success was achieved only in 20 to 30% of patients. The outcome of treatment basically depended on the primary neurologic disease.

DISCUSSION

When analyzing the results of treatment of micturition disturbances, and of UI in particular, the indication areas became evident.

Stress incontinence is treated with external FES mainly in patients with mild and moderate degree of UI. Treatment proved efficient only in 50% of patients and improvement was achieved in 23.4%. The results of treatment of mild stress UI with FES do not significantly differ from the ones achieved with physiotherapy (Kegel exercises).

The results of treatment of urge UI with external FES show considerably different percentages: 72.7% of patients were cured and 9.0% improved which are essentially better results than the ones achieved by drug treatment, most frequently used until now.

It is of extreme importance that external FES can easily be applied in elderly patients (over 65 years) with no contraindications, frequently encountered with drug treatment.
External application of FES is practically no longer used in the treatment of micturition disturbances with neurogenic bladder, since the outcome has not been favourable. On the other hand, favourable results have been achieved with direct stimulation of sacral roots.

CONCLUSIONS

Over the last 20 years the indication areas for the treatment of micturition disturbances, and female UI in particular, with external application of FES, have been clearly defined. With modern stimulators, which maintain unchanged intensity of current, and with optimal stimulation parameters, extremely favourable results have been achieved, especially in the management of urge incontinence (81.7%). It is also important that external FES may be applied in elderly patients with no contraindications whatsoever.

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INVESTIGATION ON ARTIFICIAL PROPRIOCEPTION: A STIMULATOR FOR TACTILE PHI PHENOMENA

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INTRODUCTION

This work presents a 3-channel stimulator based on Tactile Phi Phenomena /1/. The computer-controlled stimulator is applied to the study of artificial proprioception in C5-C6 tetraplegic patients.

MATERIALS AND METHODS

Tactile Phi Phenomenon is a non-explored method for tactile communication . It consists in evoking a moving fused image through only two or more pairs of electrodes close to each other. The intensity of the stimulating currents vary temporally and in complementary fashion. The three channel, computer-controlled pulse amplitude modulation (PAM) system generates two different wave forms: triangular and elliptical. It was designed to elicit a Saltation Effect (yielding bursts of rectangular pulses). In this application, the delays between the bursts in the three channels can be adjusted. The system also allows programming and monitoring of its main parameters: pulse width (10 μs to 5 ms), pulse frequency (0.1 Hz to 50 kHz), modulation frequency (0.1 Hz to 10 Hz), current intensity (up to 20 mA), and the amplitude modulation index (0% to 100%). Further, the system provides up to 8 predefined protocol sequences corresponding to 8 images.

An IBM-PC-compatible computer controls the whole system by processing the programmed wave form patterns and parameter values, and by yielding the required wave form. It uses hardware interruption, defines counters programming and dialogs with external board circuits though a parallel port interface. The counters are programmed by software and generate the carrier pulses of the PAM circuit. D/A converters generate a voltage that is related to the wave form pattern set by the user. The channels are independently programmed. The amplifiers yield current intensities up to 20 mA. An analog switch block constitutes the PAM system. The isolation and protection circuits are the electronic parts responsible for isolating the digital block from the analog and high voltage ones for providing safety to the patient. Excitation currents are transmitted to the patient by means of skin electrodes.

The software (developed in C-language) is responsible for generating and controlling the stimulation parameters. It also allows visual inspection of the latter and of the selected protocols on the PC-monitor screen. A user-friendly interface allows changes in parameter values. Two or three channels can be used to elicit the Phi Phenomenon or the Saltation Effect. A training option allows up to 8 independent stimulation sequences. Active and rest times can be programmed by the experimenter. When the experimental method is selected, the parameters to be stored during stimulation are shown. The Help command shows a menu of basic system operations. An Exit command resets all stored values and ends the stimulation session.

Preliminary experiments were performed using ECG electrodes (A=76 mm^2) placed 5.5 cm apart, coupled with gel, and held on the shoulders by strips of adhesive clinical bandage. The subjects were seated on a comfortable chair. Stimulation was controlled by the observer through the computer keyboard. The parameters used were: pulse width of 200 μs, pulse frequency of 500 Hz, modulation frequency from 0.5 to 2.0 Hz, and amplitude modulation index from 24% to 100%. Current intensities were adjusted independently until the subject acknowledged a moving fused image. Image sensation behavior and variations on it were observed having in mind an improvement in the images (better resolution and homogeneity along the skin).

RESULTS

Tests on a prototype have been performed. Psychophysical experiments have also been performed with phantom images. The tests indicate that the prototype provides a pulse width from 0.01 ms to 5.0 ms, a frequency from 100 Hz to 50 kHz, current intensity from up to 20 mA, envelope frequency from 0.1 Hz to 10 Hz, and an amplitude modulation index up to 100%.

Experiments with five normal subjects have shown that it is possible to elicit a better moving fused phantom image with this system than with a 2-channel one. Triangular envelopes are good for straight line sensations, while elliptical envelopes are more comfortable and have better resolution for all kinds of moving images.

DISCUSSION

A phantom sensation electrotactile stimulator designed to investigate artificial proprioception was described. Experimental results indicate that: 1) it is possible to elicit a moving fused image; 2) a triangular envelope is good for straight line sensations, while an elliptical envelope evokes oval (or circular) images; 3) sensations are stronger under the electrodes; and 4) the 3-channel stimulator can generate better images than a 2-channel system.

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NATURAL VS. ARTIFICIAL SENSORS APPLIED IN PERONEAL NERVE STIMULATION

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SUMMARY

We have attempted to quantify the performance of natural verses artificial sensors when used in a closed-loop, functional electrical stimulation system. Peroneal nerve stimulation was applied during gait to a Multiple Sclerosis subject with a drop-foot. Stimulation was applied only during swing phase to provide artificially induced dorsiflexion of the foot. Detection of the onset of stance phase was accomplished using a standard heel contact switch mounted inside the subject's shoe (the artificial sensor), and using processed nerve signals derived from an implanted nerve-cuff electrode (the natural sensor). A heel contact detection percentage of at least 85% was achieved using the afferent nerve signal information only. When additional information about the gait cycle was incorporated, detection ratios approaching 100% were achieved, confirming that natural sensory information can, indeed, be used in a functional neuroprosthetic system to replace an artificial sensor.

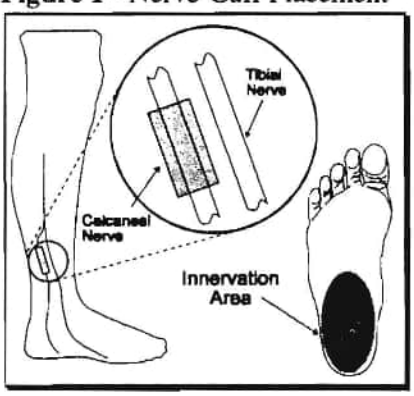
STATE OF THE ART

Peroneal nerve stimulation has proven effective in reducing or eliminating drop-foot in humans [1]. One drawback of typical peroneal nerve stimulators is that an external sensor (usually a pressure activated switch mounted in the subject's shoe) is required for the system to differentiate between the swing and stance gait phases, since stimulation is only required during swing phase. The development of a fully implantable drop-foot correction system using an artificial sensor would thus require some kind of implantable pressure sensor. An alternative approach is to use the afferent nerve signals originating from the skin's natural touch receptors as an indicator of foot contact [2]. An implantable drop-foot correction system using such a natural sensor would overcome many of the reliability problems inherent in artificial sensor based systems, while eliminating the inconveniences of an externally worn system.

MATERIAL AND METHODS

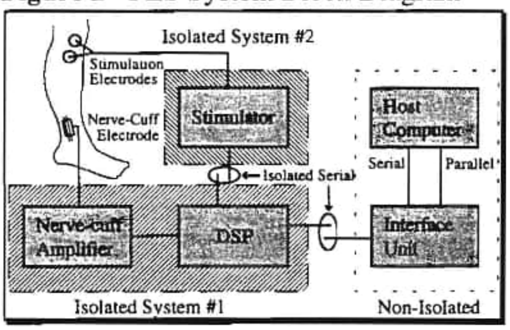
A 42 year old male who has been mildly paralyzed, hemiplegically, for the past 6 years due to Multiple Sclerosis, had a nerve-cuff electrode implanted around the calcaneal nerve, 5cm proximal to the left medial malleolus. This electrode was constructed of a 3cm long piece of insulating, bi-compatible silicone tubing with a 2.8mm inner diameter, which was split laterally to facilitate implantation [3]. Five equidistant loops of de-insulated, multi-standed, stainless-steel wire function as electrodes within this tubing. The remaining insulated length of these five electrode leads was routed subcutaneously up and around the calf, to a lateral exit site 10cm distal to the knee joint. The leads exit through individual transcutaneous openings, attaching to a 5 pin, external connector. A common, superfluous, epineurium surrounded the calcaneal nerve and other branches of the tibial nerve. This epineurial sheath was opened, the calcaneal nerve separated from the others, and the cuff electrode placed around it. The calcaneal nerve, which innervates the heel area, is believed to transmit purely afferent (sensory) signals. One day after implantation, the actual area of innervation was determined, as shown in figure 1, by mechanically stimulating the region. This is precisely the area from which sensory information is desired for use in both drop-foot and gait restoration systems (to derive heel contact force, for example).

Figure 1 - Nerve-Cuff Placement



The nerve-cuff electrode was connected in a tri-polar configuration to an amplifier providing an overall gain of 110,000. This amplifier consists of a standard audio transformer, which provides impedance matching and an initial, passive signal gain [4], coupled to a low-noise instrumentation amplifier powered by two 9V batteries. The output of this amplifier was then connected to a portable, battery operated, Digital Signal Processing (DSP) system [5]. A ground electrode, connected to the amplifier common, was placed 2cm proximal to the nerve-cuff. Two self-adhering, surface stimulation electrodes were placed over the peroneal nerve, 2cm and 6cm distal to the knee joint, on the lateral side of the left leg. No skin preparation was performed. These electrodes were then connected to a monophasic, constant current, microprocessor controlled stimulator. Figure 2 diagrams the complete drop-foot correction system. With the patient seated, the required stimulation intensity (current) required to achieve proper foot dorsiflexion was determined using a simulated gait stimulation pattern. The stimulation pulse width was linearly ramped up/down at onset/offset over 350ms to a maximum (plateau) level of 300μS. This ramping was designed to minimize patient discomfort. A constant 30Hz pulse rate was maintained throughout. Once the required stimulation level was determined, the "baseline" noise level of the processed nerve signal during stimulation was observed on an oscilloscope. During this time, no mechanical stimuli were applied to the innervated area recorded by the nerve cuff. Thus, any observed activity was the result of either tonic nerve firing, or system noise, both of which should be neglected during operation. Once the baseline noise was determined, the DSP algorithm's starting noise threshold level parameter was manually set to an appropriate value above this baseline. During system operation, the DSP algorithm periodically (between stimulus pulses) calculates a 16-bit value proportional to the energy content of the nerve signal within the frequency band of interest (1.2 to 1.6 kHz) which is above this noise threshold. This value can then be used as the input to a detector, designed to determine gait phase. In the simplest algorithm (used for these experiments), a fixed threshold detector may be used. Values of the processed signal above the threshold indicate a change of gait phase (from swing to stance, or stance to swing). Some of the dynamic properties of the system, manifested as increasing or decreasing signal-to-noise ratio (SNR), can be compensated for by automatically adapting the noise threshold. The noise threshold was varied from the manually preset value based on apriori knowledge and assumptions about the human gait cycle, and was, thus, not optimally adapted in the true signal processing sense. In these experiments, it was assumed that no nerve signal of interest was present during swing phase. Thus, the "signal" energy during swing phase was considered pure noise. A moving average of the swing phase energy value over the previous 8 steps was used to determine a new noise threshold value for each new gait cycle. An external heel contact switch mounted in the subject's shoe was use to generate a reference artificial sensor signal, by which the detection accuracy of the natural sensory based system could be judged. The unprocessed nerve signal, the external heel switch output, and an analog representation of the DSP's internally calculated signal energy value were recorded during gait. The DSP started or stopped stimulation based on information from either the external heel switch, or the calculated signal energy, depending upon which was desired as the reference. Additional experiments were conducted, in which the subject was seated and artificial mechanical stimuli were applied to the heel area. During these, the calculated signal energy was always used to turn the stimulator on/off. These experiments were designed to eliminate the effects of spurious heel contact detection during swing phase, presumably resulting from unpredictable skin/shoe contacts, and provided a more consistent and controlled mechanical stimulus. Both types of experiments were performed over several, non-consecutive days. The subject walked on a variety of surfaces during the gait experiments.

Figure 2 - FES System Block Diagram



RESULTS

In figure 3, the processed nerve-cuff signal is shown in relation to the force applied (using a 2cm diameter, flat, strain-gauge probe) to the heel area. Although the intention was not to show the absolute value of the applied force but rather the timing of application/removal, it should be noted that all applied forces were under 100N (10kg), or roughly 1/10th the dynamic forces present during gait. It is interesting to note that the recorded nerve signal corresponds mainly to a measure of the change (derivative) in applied force, rather than the absolute force value. Thus we assume that it is primarily the contribution of type FAI receptors (Meissner corpuscles) that is recorded by the cuff electrode. This is also consistent with previously developed nerve models [6]. Data recorded during actual gait provides more interesting (and relevant) information. In figure 4, the processed nerve-cuff signal is shown in relation to the output from the artificial reference sensor. In this case, the force applied to the receptive area is not as well defined. An analysis of over 1100 steps (25 minutes) showed that 85% (with a std.

dev. of 6% over 12 trials of approx. 100 steps each) of heel contacts could be detected using the afferent nerve signal information alone. When using a threshold detector, this percentage depends upon the percentage of false positives (heel contact detections during swing phase) that is deemed acceptable. Using no other knowledge about the gait cycle, this 85% heel contact detection results in an 8% false positive rate. Fortunately, these erroneous detections can be entirely eliminated if some assumptions are made about the gait cycle. If it is assumed that the swing/stance phase timing is short time constant, then apriori knowledge about when the next heel contact is expected can be used to ignore false detections outside of a window around the predicted heel contact time. Naturally, false detections occurring within this window might still result in the stimulator being turned off prematurely. If this window is made sufficiently small, the practical effects of such premature detections during gait are negligible, and erroneous detections during swing phase can be easily eliminated. Analysis of the gait cycle did, indeed, show that swing/stance timing was surprisingly constant (57%/43%, with a std. dev. of only 1% over the 12 trials spread over several days). During these trials, the subject was asked to walk normally, over a variety of surfaces. It should be noted that the heel contact switch used did not function perfectly. An average false detection percentage of approx. 2% was seen, where false detections were defined as premature or spurious switch closures during swing phase. These were, in all cases, attributable to insufficient heel clearance (which could not be corrected by peroneal nerve stimulation). Although the subject's gait speed was also very constant (varying no more than 5%), no restrictions on this were imposed. The algorithm was easily able to adapt to these slow variations in speed.

Figure 3 - Heel Force vs. Processed Nerve Signal

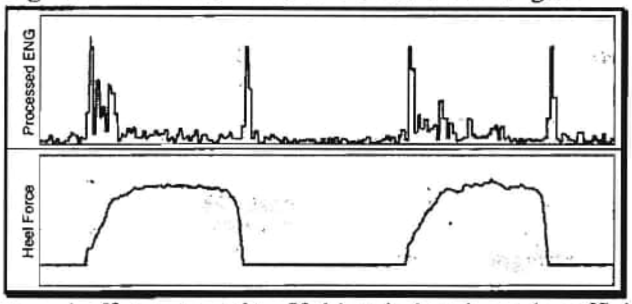
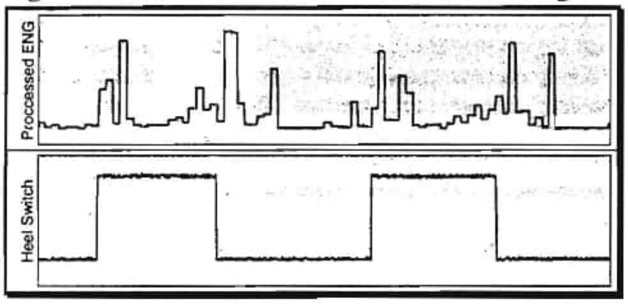


Figure 4 - Heel Contact vs. Processed Nerve Signal



Detection of push-off has proven to be a substantially more difficult problem, unless, again, additional information is utilized. When the 25 minutes of gait data was analyzed for detection of push-off purely based on the afferent nerve signal, either the detection percentage was unacceptably low (<40%), or the false positive rate unacceptably high (>50%). If, again, a window was applied using knowledge of the gait cycle timing, this percentage increased to more that 60%, which was still not deemed acceptable. Many of the problems in detecting push-off may be attributable to the mechanical properties of gait. The change in force applied to the heel (to which the receptors primarily respond) is higher during the transition from swing to stance than from stance to swing phase, explaining the lower push-off nerve signal amplitudes typically seen.

DISCUSSION

One of the most significant problems in correlating ENG signal activity with the applied mechanical stimulus is the elimination of noise. Although a variety of sources contribute to the overall noise, two dominate. The first can be attributed to the electrical path, through the body's fluids, between the stimulation electrodes and the nerve-cuff, which causes a large stimulation artifact voltage to be induced in the cuff for the duration of the stimulation pulse. In general, the stimulation amplitude is at least 140dB (10^7x) greater than the nerve signals appearing inside the cuff. This tremendous amplitude difference manifests itself in the cuff as a large image of the external stimulation pulse. Indeed, this artifact is usually large enough to saturate the nerve-cuff amplifier. Although it has been suggested [4] that it is necessary to "blank" the amplifier (i.e. switch its input to ground during the stimulation pulse), we have not found this to be a requirement as long as the amplifier's saturation recovery time is short (under 500µS or so). The second major noise source is more difficult to remove. During electrical stimulation (or natural activation, voluntary or involuntary) of the muscles adjacent to the cuff electrode, a significant electromyographic (EMG) signal is present inside the cuff. The amplitude of this contaminating EMG signal usually ranges from 100 to 1000 times the ENG signal of interest. Fortunately, the peak energy of this interfering EMG signal is in a significantly different frequency band (2 octaves lower) than the nerve signal of interest. It can therefore be significantly removed by standard filtering techniques. It is, however, not sufficient to simply filter the nerve-cuff signal to obtain directly usable detection information. Consider that a 30dB power (60dB amplitude) difference between the noise and desired signal corresponds to loss of 10 bits when digitized. Even if very good digitizing circuitry is utilized, resulting in true 16-bit resolution, the ENG signal after ideal filtering would be represented in only the 6 least significant bits! In addition, there is not a complete separation of frequency bands between the EMG "noise" signal and the nerve signal. Indeed, even when steep (91st order FIR) filters are used, this overlap results in a SNR of, at best, 0dB. Fortunately, it is not necessary to have high accuracy, instantaneous ENG information. In a typical closed-loop control system, the processed ENG signal is used at the system loop rate (usually the stimulation frequency). Thus, it is possible to improve the amplitude resolution of the ENG signal (reducing temporal resolution) by digitally integrating the filtered signal over the stimulation inter-pulse period. Additional experiments have shown that the EMG noise present in the cuff electrode arises primarily from soleus activity, and, thus, is present only during stance phase (neglecting any low level activity due to antagonistic contraction), with the largest activity present during push-off. Although, in figure 4, it appears that the nerve signal amplitude during push-off is quite significant (and therefore detectable), much of this signal is, in fact, due to the overlapping EMG noise which could not be filtered out. Since it is not possible to distinguish between the afferent nerve signal and the contaminating muscle signal components based on their frequency content alone, more sophisticated methods for accomplishing this are now being investigated. If this distinction is not made, and the combined signal is used in the detection of push-off, timing errors will result. The extent to which these errors impact the functional operation of the system is still being investigated. In addition, the potential for this combined signal to resolve some system ambiguities by providing synchronization at system startup is also under investigation.

It is likely that further improvements in the consistent detection of both heel contact and push-off can be achieved through the use of more sophisticated electrode designs [7] which may yield increased nerve signal amplitudes. However, unless a significant improvement (between 100 and 1000 fold) in the "raw" SNR is realized, it is likely that some form of advanced processing will continue to be required. It must also be noted that, in a practical system, a trade-off between the required processing and electrode size/complexity must be made. It may be desirable to actually reduce this raw SNR using much shorter (or smaller) cuff electrodes, as long as the resulting SNR after processing remains acceptably high. There may be several advantages in using such electrodes in humans, such as: ease of implantation, reduced risk of nerve damage, and the possibility of using such less obtrusive electrodes in smaller spaces. This last point may be of considerable importance for the use of natural sensory feedback in hand-grasp restoration systems.

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EMG FEATURE EXTRACTION FOR REAL-TIME FES CONTROL

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SUMMARY

Measurements of the EMG activity of tibialis anterior (TA) of control subjects and the most affected legs of disabled subjects during walking to a slow metronomic beat have been recorded. Simultaneously, heel position information was recorded using a foot switch /1/. An algorithm has been developed which can extract the envelope of EMG activity. The envelope obtained from control subjects has been modelled using a "double-trapezoidal" profile. For normal subjects, relationships between variations in the timing parameters of this profile and variations in stride time have been derived. For subjects with varying levels of disability, the EMG envelopes have been analysed to determine how the processed EMG may be used to trigger and control a microprocessor-based electrical stimulator.

STATE OF THE ART

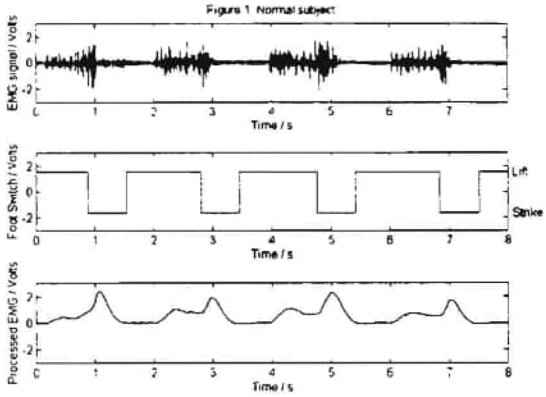
The work presented here forms part of the European TIDE programme FESTIVAL (Function Electrical Stimulation To Improve Value Ability and Lifestyle) which aims to apply electrical stimulation to those with disability. In general, it seeks to develop new, effective means of functional muscle stimulation, and is currently addressing the problem of footdrop in patients with neurological disorders or peripheral nerve injury (PNI).

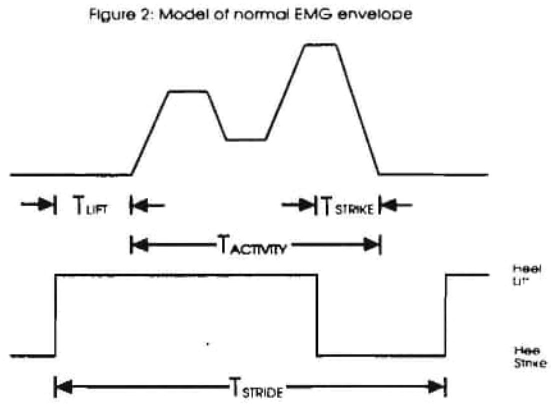
The first generation of footdrop stimulators were produced some 40 years ago and systems currently employed use a foot switch to trigger a relatively simple pre-defined variation in stimulator output. The required stimulator duty cycle is often generated using discrete dedicated analogue and digital circuitry. Choices concerning type of trigger, timings, amplitude variations, and walking pace must be set up by a trained clinician by selecting miniature switches or presets, or by cumbersome signal selection systems.

The development of microprocessor-based stimulators offers a more flexible approach with easier programming of waveforms and parameters /2/. In addition, position and EMG transducer inputs provide the possibility of parameter adaptation in response to factors such as variations in walking pace, terrain, muscle fatigue, etc.

MATERIALS AND METHODS

Surface EMG signals from healthy subjects and those with disabling conditions have been recorded from TA, the muscle primarily responsible for toe lift during walking. Using an electronic metronome (Seiko DM-20) it possible to set the cadence to a range of different pace rates. A period of pace training was performed before the EMG recordings were made.





The top trace of figure 1 shows the EMG signal from a normal subject for a single leg heel-lift-to-heel-lift step time of 2s (metronome set to 60 beats per minutes). The centre trace presents corresponding heel position information. For a slow walking pace, the envelope of the EMG shows a characteristic double burst of activity signal (see bottom trace of figure 1). At higher cadence rates the envelope merges into one activity period. There is a delay between heel lift and start of EMG activity (T_{DELAY}). The initial burst of activity is required to overcome joint inertia and lift the toe after the heel lifts. There is then a period of decreased EMG activity during the swing phase where the forward momentum of the leg holds the foot in the correct position. The second burst of activity at the end of the swing phase controls foot placement and the forward movement of body weight onto the foot. There is no significant EMG activity during the stance phase.

An algorithm has been developed to detect the envelope from normal EMG signals. The algorithm was optimised in software, with the constraint that it could be implemented using simple analogue hardware. The current algorithm comprises rectification, noise thresholding and low-pass filtering. This algorithm has been applied to data obtained from patients with footdrop. Compared with normal EMG the signals patients' data may have various features "missing" depending on the type and degree of disability. We have sought to determine the range of differences and the level and type of EMG features that could be used to trigger or control a stimulation cycle.

We modelled the normal EMG envelope using a "double-trapezoidal" profile (figure 2) with timings and relative amplitudes derived from data measured from 10 normal subjects. Sets of recordings were made for each normal subject walking in time to the metronome. The metronome was first set at 109 beats per minute to give an approximate heel-to-heel stride time (T_{STRIDE}) of 1.1s. Further recordings were made with the metronome frequency reduced so as to produce 100ms increments in the stride time up to a maximum of 3.5s. Relationships between EMG signal activity timing parameters as a function of stride time were then derived from the data.

RESULTS AND DISCUSSION

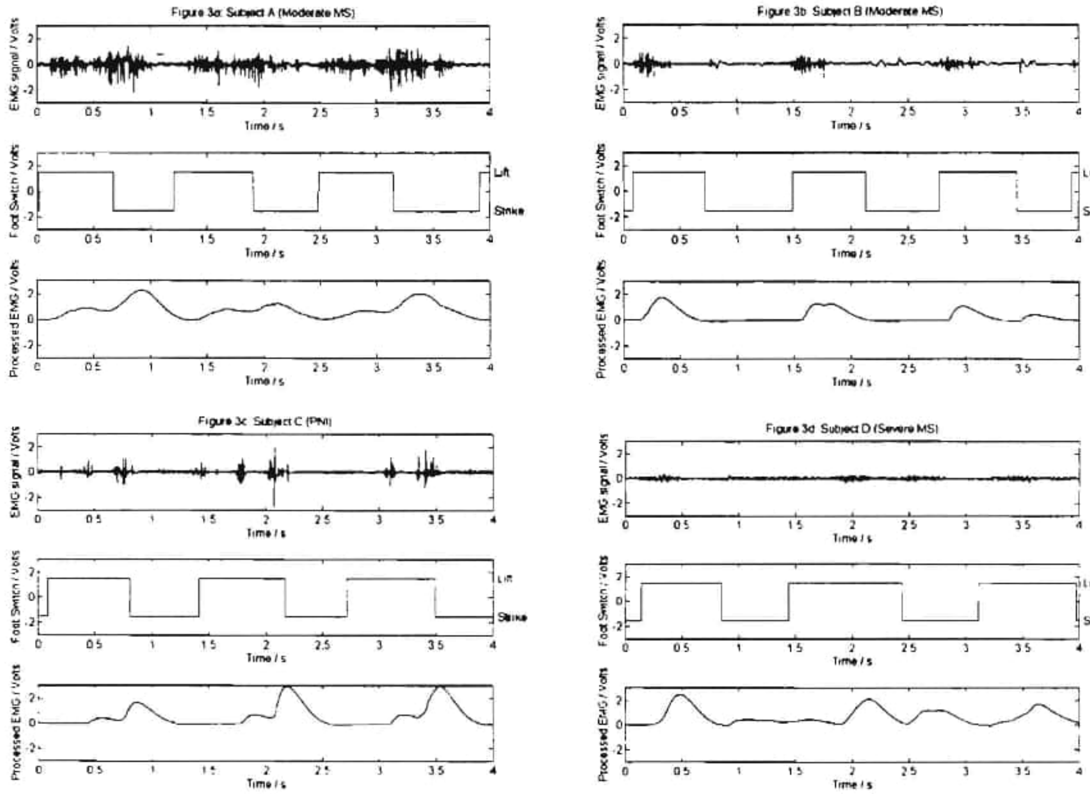
No one person has an absolutely regular stride duration even when walking in time to an externally regulated stimulus, so each heel-lift-to-heel-lift stride time (T_{STRIDE}) was measured from the heelswitch data and plotted with the associated EMG timing parameter of interest; linear regression was then performed.

For one normal subject, whom we studied in detail, the following relationships (valid for $1s < T_{STRIDE} < 3.5s$) were derived:

$$T_{LIFT} = 0.207 + 0.361T_{STRIDE} \quad \text{(R-square = 0.914)}$$
$$T_{ACTIVITY} = 0.195 + 0.390T_{STRIDE} \quad \text{(R-square = 0.901)}$$
$$T_{STRIKE} = -0.0199 + 0.114T_{STRIDE} \quad \text{(R-square = 0.657)}$$

where T_{LIFT} is the delay from the heel lift to the start of the EMG signal activity; $T_{ACTIVITY}$ is the total duration of the EMG signal activity present during the step; and T_{STRIKE} is the delay after the heel strike to the end of the EMG signal activity. To be responsive to variations in walking pace an intelligent stimulator could start with a default walking pace, then measure heel switch timings to determine timings of the next stimulation cycle waveform.

Differences between four patient recordings are illustrated by the following:



<u>Subject A: Moderate MS (Figure 3a)</u>
For subject A, with moderate multiple sclerosis (MS), the start and end of EMG activity during the swing phase can be determined and so can be used to start and halt an EMG initiated stimulus control routine.

<u>Subject B: Moderate MS (Figure 3b)</u>
In subject B, however, there is only one burst of EMG activity at the commencement of the swing phase which was inadequate to dorsiflex the foot sufficiently to clear the ground. There is no second burst of EMG activity indicating foot placement. In this case the first burst could be used to trigger a fixed-pace stimulation routine.

Subject C: PNI (Figure 3c)
This peripheral nerve injury (PNI) patient shows similar timing of EMG activity to a normal subject, but the initial burst is shorter and was insufficient to dorsiflex the foot. There is a marked period of inactivity which may be due to the attempted incomplete recruitment of motor units. EMG activity associated with deceleration of the foot can be detected. Thus there is sufficient EMG activity to allow a reliable detection of the commencement and conclusion of the swing phase of gait for control of the stimulation cycle.

Subject D: Severe MS (Figure 3d)
There is a near complete absence of detectable EMG activity from the TA muscle in this patient. Because of the difficulty in distinguishing these signals from background noise, the simple envelope algorithm implemented is not reliable. The use of advanced digital signal processing (DSP) techniques, which offer the potential of extracting information "hidden" in the noise, may resolve this difficulty.

The next phase of the research will investigate the use of turns analysis, zero-crossings and various frequency domain techniques for characterisation and parameter extraction of EMG signals during walking.

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EVALUATION OF HUMAN KNEE JOINT ARTICULAR NERVES FOR NERVE CUFF RECORDINGS

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SUMMARY

The purpose of this study is to determine the feasibility of recording from articular afferents in the human knee joint, which may be able to provide a feedback signal in a lower extremity functional electrical stimulation (FES) system. A surgical approach has been developed to access articular branches of the tibial nerve in human cadavers. Since the main articular branch of the tibial nerve contains a branch projecting distal to the knee joint capsule, the best location for a neural recording interface (for example a nerve cuff electrode) appears to be the well defined ramifications of the articular branch that penetrate the joint capsule. Nerves resected from eight cadavers were examined histologically. The branch most appropriate for a neural recording interface contains approximately 650 myelinated fibers. Fiber diameter distributions computed for nerves from three cadavers display a peak at 3 or 4 μm, and in one specimen there is an additional peak at 9 μm. Since the fibers are predominantly group III (diameter = 1 - 6 μm) /1/, with fewer group II fibers (diameter = 6 - 12 μm) and virtually no group I fibers (diameter > 12 μm), the ability of a nerve cuff electrode to record from these fibers is unknown. Another neural recording interface, such as a microelectrode array, might be more suitable for this application.

STATE OF THE ART

Numerous animal studies have been conducted to determine if recordings from articular afferents can be used to detect joint angle. Many studies have focused on the cat posterior articular nerve (PAN), a branch of the tibial nerve which primarily supplies the posterior knee joint capsule /2/. Burgess and Clark /3/ found limited afferent activity in whole nerve recordings from the cat PAN when the knee joint was held at intermediate angles; dorsal root recordings showed that most neurons were slowly adapting and were activated only at the extremes of joint range of motion (ROM). Grigg /2/ also found that PAN afferent output was confined to the extremes of knee joint ROM in dorsal root recordings. All neurons were slowly adapting and the majority were activated by knee extension although forcible flexion could also activate many of the same receptors. However, during high quadriceps activation (which stretches the posterior joint capsule), joint afferent neurons could be made to discharge at intermediate joint angles. Grigg documented torque relaxation during maintained knee extension with corresponding adaptation of the receptors. Similar results were obtained in both dorsal root and whole nerve recordings from the monkey knee PAN /4/. In the monkey, Grigg found an exponential relationship between single afferent discharge rate and static knee joint angle; however there was hysteresis in this relationship dependent on the direction of joint movement.

Ferrell /5/ also made dorsal root and whole nerve recordings in the cat knee PAN. The majority of whole nerve recordings displayed nonmonotonic joint angle vs. afferent discharge rate relationships, with the highest discharge rates occurring at the extremes of joint ROM. Unlike the other studies, Ferrell always recorded afferent activity at midrange joint angles. A later study by Gregory /6/ demonstrated that tendon organ afferents and possibly spindle afferents from the popliteus muscle may have contaminated the joint afferent recordings made by Ferrell.

In an extensive review of the animal literature and psychophysical testing done in humans, Proske /7/ suggested that joint receptors serve three primary functions: 1) to signal joint movement, 2) to act as limit detectors, and 3) to act as nociceptors. The question we asked is, can information from joint receptors be useful as a feedback signal in an FES standing system? Since joint afferents are active at the extremes of joint ROM, could they be useful in sensing when the knee joint starts to flex from a fully extended position, which could occur when the quadriceps muscles fatigue during prolonged standing?

We describe here a preliminary investigation to determine the feasibility of recording from joint afferent neurons in the human knee. Articular branches of the tibial nerve were chosen for study since they are the largest and most consistent articular innervation in the human knee, innervating the posterior joint capsule /8/, which Grigg /4/ believes is stretched when the knee joint is extended. The main articular branch of the human tibial nerve corresponds anatomically to the PAN in cat. The goals of this study were: 1) to determine a suitable surgical approach for accessing articular branches of the human tibial nerve, 2) to determine the number of myelinated fibers present in these nerve branches, and 3) to determine the myelinated fiber size distribution. Knowledge of the number of myelinated fibers and their distribution will aid in determining if a suitable signal could be expected to be recorded from this nerve using a neural recording interface.

MATERIALS AND METHODS

Dissections were performed on 11 knees (8 right and 3 left) from 11 different fresh cadavers. The surgical procedure involved a direct posterior approach to the popliteal fossa. The tibial nerve as well as the peroneal nerve were identified in the popliteal fossa. A fine branch (1-2 mm in diameter) running along the medial side of the tibial nerve within the same connective tissue sheath was identified as it branched from the tibial nerve proximal to the joint line. The tibial nerve branch takes a sinuous path coursing distally and anteriorly, lateral to the popliteal vessels. Dissection was continued along this nerve while retracting the popliteal vessels medially without any observed damage to these structures. Deep to the vessels the nerve courses medially and branches extensively before innervating the joint capsule. Well defined branches 0.5 - 1.0 mm in diameter ramify into branches less than 0.5 mm which penetrate the joint capsule. In all cadavers we found a branch that travelled distal to the joint capsule. In one cadaver we had the opportunity to mark this branch and identify it in a later dissection.

We removed the main articular branch of the tibial nerve and as many of its ramifications as possible. Nerves were placed in fixative for at least 24 hours following removal from the cadaver. The majority of nerves (8 of 11) were fixed in 4.9% glutaraldehyde with Sørensen's phosphate buffer (pH = 7.3 - 7.4). Two nerves collected at the University of Aarhus were fixed in 3% glutaraldehyde and 1% paraformaldehyde in 0.1 M cacodylate buffer (pH = 7.4). The remaining nerve was initially fixed in 10% phosphate buffered neutral formalin; this was followed by storage in 2.5% glutaraldehyde in 0.1 M phosphate buffer (pH = 7.3) which facilitated subsequent embedding in Epon. Following fixation, nerves were postfixed in 1% osmium tetroxide for one hour, dehydrated in ascending concentrations of ethanol, and imbedded in Epon. Semithin sections (approximately 1 μm) were cut with a glass knife and stained with 1% tolouidine blue.

Using light microscopy, nerve branch cross sections from 8 of the cadavers were magnified and viewed on a computer screen at a final magnification of 2836 x. Numbers of myelinated fibers were counted in the following articular branches of the tibial nerve: the main articular branch of the tibial nerve (tibial nerve branch), the branch where all subsequent ramifications penetrated the joint capsule (the ideal location for a neural interface (recording branch)), the branch travelling distal to the joint capsule (distal branch), and small branches that didn't ramify further and penetrated the joint capsule (individual capsular branches). The cross sections of all fascicles within a nerve branch were randomly, yet systematically sampled; an unbiased counting frame /9/ was used to count all myelinated fibers within this known fraction of the nerve branch cross sectional area. An estimate of the total number of fibers within the nerve branch was then calculated from this fraction[1]. In the three best preparations a point-counting system was used to estimate the areas of the myelinated fibers that had been sampled. These area measurements were converted to equivalent diameters (this assumes circularity of the fibers; although the majority of the fibers were not circular, this transformation allows comparison with fiber diameter distributions reported in the literature).

RESULTS

We have developed a surgical approach allowing consistent identification of articular branches of the tibial nerve without damage to any major structures in the knee. All nerve specimens exhibited a branch travelling distal to the joint capsule. In one cadaver we identified that this branch had one proximal ramification that appeared to penetrate the joint capsule, while 9-10 much more distal ramifications penetrated the popliteus muscle. Therefore this distal branch contains afferents from structures other than the knee joint capsule. Thus the best location for a neural recording interface appears to be the well defined

[1] In large nerve branches, at least 100 myelinated fibers were counted during the sampling /9/. In nerve branches with less than 100 myelinated fibers, all fibers were counted.

branches 0.5 - 1.0 mm in diameter with projections travelling only to the joint capsule. These dimensions should be large enough to accommodate a nerve cuff electrode.

Table 1 displays the number of myelinated fibers present in the nerve branches counted. Histograms of

nerve branch	avg. number fibers	range	standard error
tibial nerve branch	2280	1949 - 3184	154
recording branch	658	225 - 1018	103
distal branch	688	167 - 1210	109
individual capsular branches	279	43 - 544	34

Table 1. Numbers of myelinated fibers in various articular branches of the tibial nerve in human.

myelinated fiber diameters were constructed for nerve branches from three cadavers. The top row of Figure 1 displays histograms obtained from the tibial nerve branches. All histograms display a peak at 3 or 4 μm; the histogram from subject b also displays a peak at 9 μm. The bottom row of Figure 1 displays histograms obtained from nerve branches where a neural recording interface would be placed; in many cadavers these branches contain multiple ramifications which penetrate only the joint capsule. In the data displayed here, capsular histograms for subjects a and c are for a single branch penetrating the capsule that didn't appear to ramify further (these were the only capsular branches resected from these specimens), while the capsular histogram for subject b contains fibers from two of three separate capsular branches which would be recorded by a cuff electrode (one branch was damaged upon removal and so the data could not be included). Capsular histograms also display peaks at 3 or 4 μm. The histogram for subject c displays an additional peak at 9 μm.

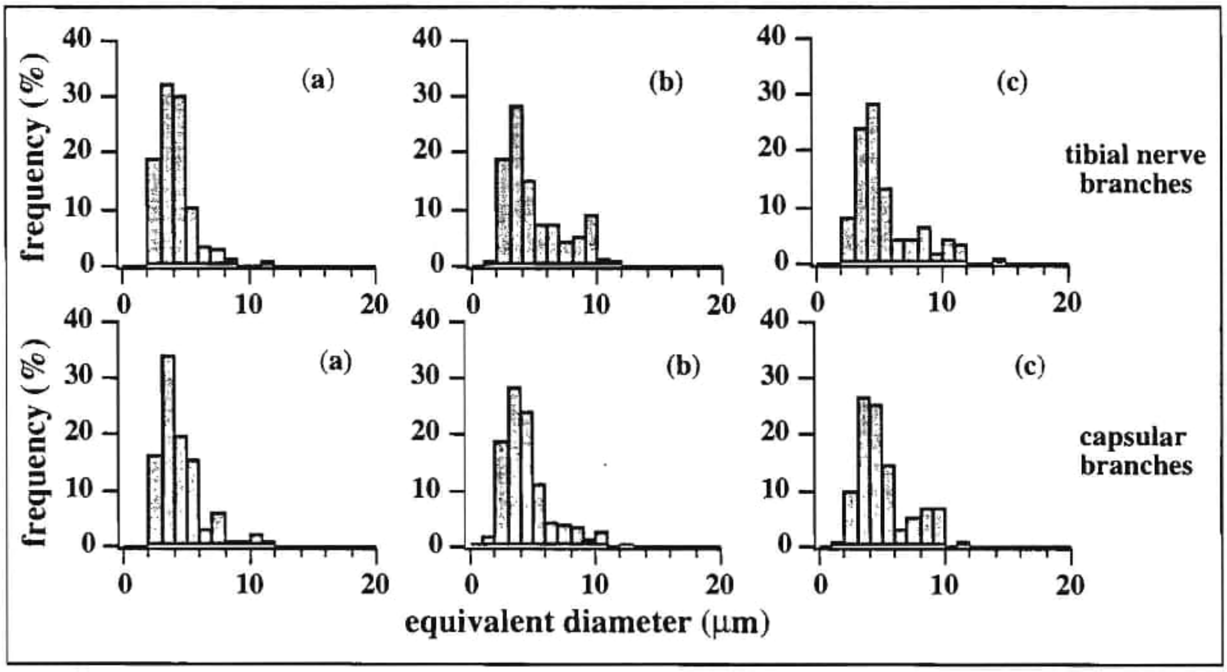

Figure 1. Fiber diameter histograms from subjects a - c. Top row: histograms obtained from tibial nerve branches. Bottom row: histograms for branches supplying only the joint capsule.

DISCUSSION

In one cadaver we found that the distal branch of the main articular branch of the tibial nerve contains projections to the popliteus muscle. This coincides with the findings of Gregory et al. /6/ who verified that primary and secondary spindle afferents and tendon organ afferents from the popliteus muscle are frequently contained in the cat PAN. Whether the distal branch of the main articular branch of the tibial nerve in humans consistently projects to the popliteus muscle remains open to speculation. However, if a neural recording interface were placed on the main articular branch of the tibial nerve, it would certainly contain afferent information from structures distal to the knee joint, which might not respond similarly to capsular afferents when the knee joint is moved. Thus we recommend placement of a neural recording interface on branches ramifying only into the joint capsule.

Bimodal fiber diameter histograms from PAN nerves in the cat knee (peaks at 3 and 9 μm) /1/, and monkey knee (peaks at 4 and 8 μm) /10/ have been found (these correspond to the tibial nerve branch histograms shown in this paper - animal histograms have not been made for individual capsular branches). A unimodal distribution is present in the rat knee PAN (peak at 3 μm) /11/, and the monkey finger joint nerve (peak at 2 μm) /12/. In all distributions there are few (if any) fibers over 12 μm in diameter (group I). Thus the fiber distributions we have found share many similarities with those determined from animal studies. Whether suitable nerve recordings can be made from these small diameter fibers is an open question. Marshall and Tatton /13/ demonstrated that their nerve cuff recordings from cat PAN contained little activity from group III and IV afferents. These constitute the majority of fibers present in the histograms found in humans. A neural recording interface other than a cuff electrode might be more suitable in this application.

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COMPARISON OF SIMULATION AND EXPERIMENTS OF DIFFERENT CLOSED-LOOP STRATEGIES FOR FES. PART 1: SIMULATION MODEL

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SUMMARY

A detailed biomechanical model of the lower extremity was developed in order to predict knee motion induced by functional electrostimulation (FES). This model was applied to the design and test of neural prostheses. A discrete-time model is used which characterizes the relationship between stimuli (pulse width, pulse amplitude, interpulse period) and muscle activation. Muscle fatigue and recovery were also considered. The model takes into account nonlinear musculotendon dynamics of all muscles spanning the knee joint and nonlinear body-segmental dynamics. Main parameters are identified by standardized procedures. The model was validated in FES experiments with paraplegic patients. The presented simulation tool enables the user to test and optimize different open- and closed-loop strategies, thus avoiding troublesome and time-consuming experiments.

STATE OF THE ART

Currently existing neural prostheses have proven that standing and walking by means of FES is feasible. However, a system has not yet been developed which achieves sufficiently good control of movement. To improve the performance of conventional FES systems, many investigators apply biomechanical models /3/ /4/ /7/. These models which describe the behavior of artificially stimulated muscles, are limited by their neglect of major effects that occur during FES (e.g., muscle fatigue). Another deficiency of existing FES-related models is that they take only a limited number of muscles into consideration, so that the choice of muscles to be stimulated cannot be optimized. Furthermore, only a few investigators compared mathematical simulations with experimental data.

The rationale of this paper is to present an experimentally evaluated biomechanical model of the lower extremity that can be employed in the design and optimization of FES systems for persons with upper motor neuron lesions. This model accounts for muscle fatigue, artificial multi-input stimulation, as well as optimized muscle selection.

MATERIALS AND METHODS

The model consists of three main parts: *activation dynamics, contraction dynamics,* and *body-segmental dynamics. Activation dynamics* connects the FES input to the activation needed by muscles to generate desired force. The FES input is described as a set of rectangular pulse trains characterized by three parameters: pulse amplitude, pulse width, and interpulse period. Muscle force is controlled by adjusting pulse width or pulse amplitude (recruitment modulation) and interpulse period (frequency modulation). To take into account discontinuous force generation due to single, successive stimulation pulses, a discrete-time model is required. Therefore, we use an activation dynamics model that is similar to the one proposed by Hatze /2/. Additionally, we have accounted for nonlinear recruitment characteristic of artificially stimulated muscle /6/. Furthermore, we have introduced a normalized fitness function $fit(t)$ in order to describe muscle fatigue and recovery:

$$fit(t) = 1/T_{fat}\,(fit_{\min} - fit(t))\,a(t) + 1/T_{rec}\,(1 - fit(t))(1 - a(t))\,; \quad fit(t),\, a(t) = 0 \ldots 1$$

In this equation $a(t)$ denotes muscle activation, fit_{min} is the minimum fitness, T_{fat} and T_{rec} are the time constants for fatigue and recovery, respectively. We distinguish between slow and fast fiber types. *Contraction dynamics* generate tendon force. The lines of action of 13 musculotendon actuators of the lower extremity are defined based on their anatomical relationships to 3-D bone surface representations /1/. Each muscle is in series with tendon and is modeled as a composition of elements with nonlinear passive viscoelastic and force-generating properties /3/. The contractile element of muscle accounts for the force-length and force-velocity property of muscle, which also depends on muscle activation. We use a method developed by Zajac /8/ to scale the musculotendon actuators. In contrast to other investigators /1/ /2/ /3/ /7/, we pay special attention to the viscous property of muscle: we describe muscle damping force as a nonlinear relation of muscle velocity /6/. In *body-segmental dynamics* the moment arms are determined as a function of knee flexion angle. Moment arms and tendon forces yield joint torque. Finally, movement of the lower extremities is obtained by applying equations of motion. To identify patient-specific parameters, a passive pendulum test is performed to determine elastic (e.g., musculotendon lengths) and viscous properties (e.g., damping coefficients) in muscles and joints. Standardized stimulation experiments allowed us to identify the recruitment curve of muscle and contraction/relaxation as well as fatigue/recovery time constants. Remaining parameters were estimated from the literature.

RESULTS

The simulation program is based on an identified model and can be used to simulate FES-induced isometric knee flexion/extension moment or shank motion. In Fig. 1 simulated and measured isometric knee extension moments are compared for a predefined stimulation pattern. This figure illustrates the influence of single, doublet, and triplet bursts on the moment output. Pulse width as well as pulse frequency were not modulated. Note that intermediate bursts accelerate joint moment generation.

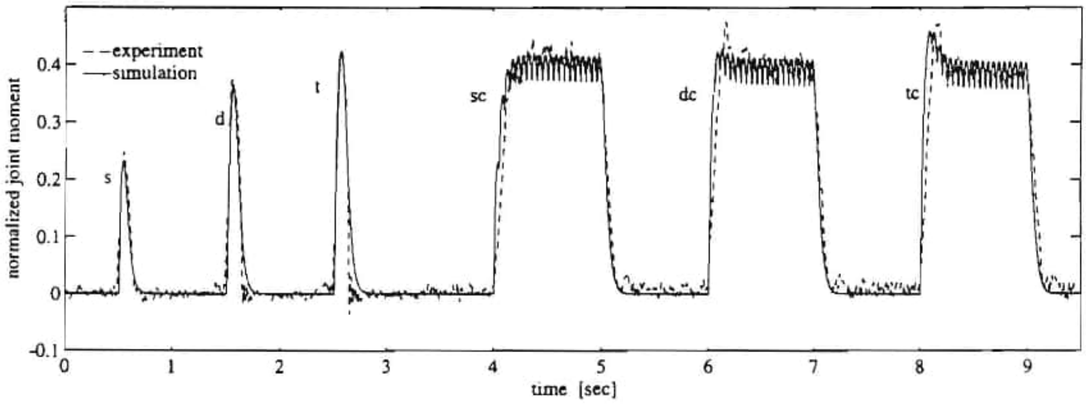

Fig. 1. Comparison of simulated and measured isometric moment in the knee joint. The abbreviations s, d, and t mean single, double, and triple stimulation pulse, respectively. sc, dc, and tc mean that after an initial single, double or triple burst, respectively, stimulation bursts follow with continuous interpulse periods (50 msec). The interpulse period in the double and triple bursts are 10 msec.

We also investigated different stimulation patterns for freely swinging shank and compared motions generated in the simulation model with motions traced in FES experiments. Fig. 2 shows such a comparison for rectangular and triangular pulse width modulation. The results of the simulation model agree sufficiently well with the data obtained by measurements.

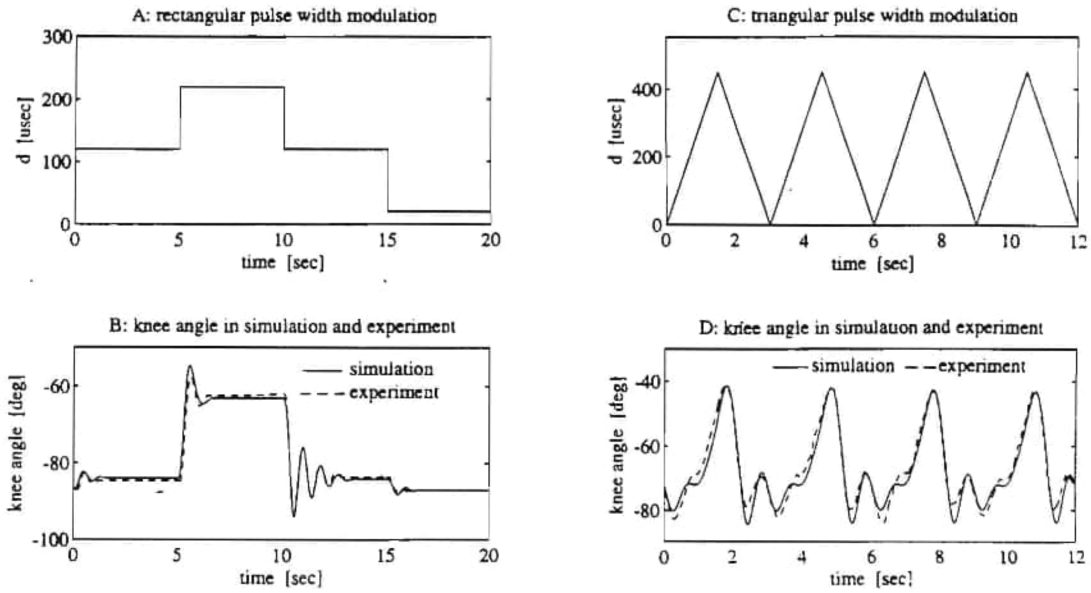

Fig. 2. Comparison of simulated and measured knee flexion angle of freely swinging shank. The measurements were performed in two different patients with complete spinal cord injury. The upper graphs show the time course of the modulated pulse width; the figures below present the resulting knee angles in simulation and experiment. (A), (B) Rectangular pulse width modulation and resulting knee flexion angle. (C), (D) Triangular pulse width modulation and resulting knee flexion angle.

DISCUSSION

The objective of this study was to develop an experimentally evaluated biomechanical model of the human knee which can be employed for designing and testing open- and closed-loop strategies for neural prostheses on the basis of FES. One difficulty of our model appears to be its complexity, which requires many parameters to describe the musculoskeletal system. Figs. 1 and 2, however, show that simulation and measurements correspond well. One could argue that it would be easy to fit the simulated and experimental trajectories by iteratively modifying one of the various parameters, arbitrarily, without any physiological basis. This, however, does not hold true in our case, because on the one hand parameters that do not significantly differ among individuals or that are difficult to determine were taken from the literature. They were assumed to be equal in all subjects and, thus, they were not changed during the studies (e.g., parameters describing muscle paths, joint geometry or musculotendon properties such as the force-length and force-velocity relation). On the other hand, the remaining parameters describing viscoelasticity of joint and muscles, fiber recruitment behavior, muscle fatigue, anthropometry, etc., were identified with standardized procedures.

Since the musculoskeletal system is very complex (many nonlinear effects) and due to the high number of input quantities (pulse width, pulse amplitude, interpulse period, muscles to be stimulated) which control or influence human body motion, we believe that detailed modeling is indispensable for this kind of engineering problem. One advantage of the model's complexity, e.g. the large number of muscles, is that the user can investigate the stimulation of different combinations of muscles and thus determine which combination develops optimum joint loading during FES in order to avoid overstress of joints and ligaments. The present simulation model is an effective tool for such investigations, because such quantities cannot be measured noninvasively. Furthermore, effects such as muscle fatigue or nonlinear muscular viscosity are required for a realistic simulation of FES-related tasks. Muscle fatigue is a significant problem that occurs during FES. Taking this effect into consideration, it is possible to optimize muscle stimulation patterns so as to allow only minimum muscle fatigue.

Compared to others /5/, our approach to describing muscle fatigue is more general and thus it has the advantage that it can be applied to any shape of stimulation input. Since we use a discrete-time model to describe multi-input activation dynamics as realistically as possible, our model can also deal with various kinds of FES modulation patterns. Not only recruitment and frequency modulation can be modeled in our simulation. It also allows the user to study the influence of variable interpulse periods on the generated joint moment, for example by adding intermediate stimulation bursts. Such stimulation patterns have many advantages for the performance of neural prostheses as regards muscle fatigue and the properties of force generation. Our comparisons of model predictions and experimental data have shown good agreement, which encourages us to conclude that the modeling of the human musculoskeletal system will advance the development of neural prostheses.

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COMPARISON OF SIMULATION AND EXPERIMENTS OF DIFFERENT CLOSED-LOOP STRATEGIES FOR FES. PART 2: EXPERIMENTS IN PARAPLEGICS.

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SUMMARY

Open-loop and closed-loop stimulation of the knee extensors for the control of knee joint angle and torque were tested as a potential basis for more complex functional electrical stimulation (FES) systems used in human locomotion. The output of the biomechanical simulation model described in part 1 was compared with stimulation experiments in patients with complete thoracic spinal cord injury. A good correspondence between simulation and experiments could be obtained for both isometric conditions and conditions with freely swinging shank. For closed-loop control, a simple proportional-integral-derivative (PID) controller yielded sufficient performance only in isometric conditions, especially if combined with (linear) feedforward. Due to additional nonlinearities of musculotendon and body-segmental dynamics more complex strategies have to be applied to the control of unconstrained movements. An inverse model was derived from the direct biomechanical model in order to compensate for these nonlinearities. This inverse model yielded satisfactory agreement between the measured knee angle and the desired trajectory already in an open-loop condition. A combination of the inverse model in the feedforward part of the control loop and of a PID controller provided robust and precise control of knee angle. Further improvement may be achieved by including elements of spasticity into the simulation model and by controlling both, the agonistic and the antagonistic muscles.

STATE OF THE ART

The feasibility of standing up and sitting down, gait, and stair climbing in paraplegic patients using FES has been demonstrated in several laboratories /1/. However, clinically used FES systems today are all open-loop and the implemented stimulation patterns are derived empirically. With these systems the weight-bearing muscles have to be stimulated excessively in order to provide a margin of safety. Therefore, the resulting movements are not harmonious even in the ideal case of non fatigued muscles. Additionally, open-loop systems can not compensate for external disturbances (e.g. stumbling) or changes of internal parameters (e.g. loss of muscle force caused by fatigue). Numerous approaches to closed-loop control with FES have been tested in different laboratories, for example linear and nonlinear lead-lag controllers, adaptive control /2/, finite state control and cycle control /3/. A combination with linear feedforward improved the performance of lead-lag controllers /4/ especially in isometric conditions. Due to the numerous nonlinearities of the motor system, however, linear components are not appropriate for the control of unconstrained movements. For the development of enhanced control systems, these nonlinearities must be considered. The aim of the present paper is, to verify if mathematical models of the motor system (electrode, peripheral nerve and musculoskeletal system) may improve motor control with FES. Direct models of the motor system may be used in computer simulations in order to optimize stimulation patterns and parameters of the closed-loop controller without requiring cumbersome experiments in patients. It should also be tested to what extend inverse models will compensate for the nonlinearities of FES-induced movements.

MATERIALS AND METHODS

Stimulation experiments were performed in five patients with complete thoracic spinal cord injury. The patients were laying supine with the thigh supported and the shank hanging down. The quadriceps femoris muscle was stimulated by surface electrodes. Pulse width modulation with constant current and a stimulation frequency of 20 Hz was used. Under isometric condition the knee torque was measured with a strain-gauge based transducer. Under condition with freely swinging shank the knee angle was measured with an electrogoniometer. The sampling rate amounted 160 Hz. For open-loop experiments the modulation waveforms (rectangular, sinusoidal, and triangular) were applied to the pulse width. For closed-loop experiments with a PID controller and for experiments with the inverse model the modulation waveforms were applied to the controlled variables (knee torque or knee angle). Prior to closed-loop stimulation experiments the parameters for the PID controller were optimized by computer simulation with the direct model described in part 1 in a standardized iterative procedure with the mean square error as optimization criterion. The inverse model was derived from a simplified version of this direct model. The input to the inverse model was the desired trajectory of knee joint, the output was the stimulation pulse width. The inverse model contained the following components and provided the following intermediate quantities (in parenthesis): equations of motion ($\Rightarrow$ knee moment), varying lever arm of the quadriceps femoris muscle ($\Rightarrow$ tendon force), force-length relation of the muscle ($\Rightarrow$ muscle activation), release of calcium ions and synaptic signal transmission ($\Rightarrow$ number of recruited motor units), and recruitment curve ($\Rightarrow$ stimulation pulse width). This inverse model was only used in the feedforward part of the control loop, in some experiments it was combined with a PID controller.

RESULTS

Open-loop stimulation experiments with freely swinging shank and triangular (linear) pulse width modulation revealed that the system is highly nonlinear in space and time (Fig. 1A). The time course of the measured knee joint angle differed considerably from the time course of the stimulation pulse width. With an inverse model most of these nonlinearities could be neutralized (Fig. 1B). For the ascending part of the curve (knee extension movement) there is a good agreement between the desired and the measured knee angle. During knee flexion movement however, the measured value was always higher than the desired value.

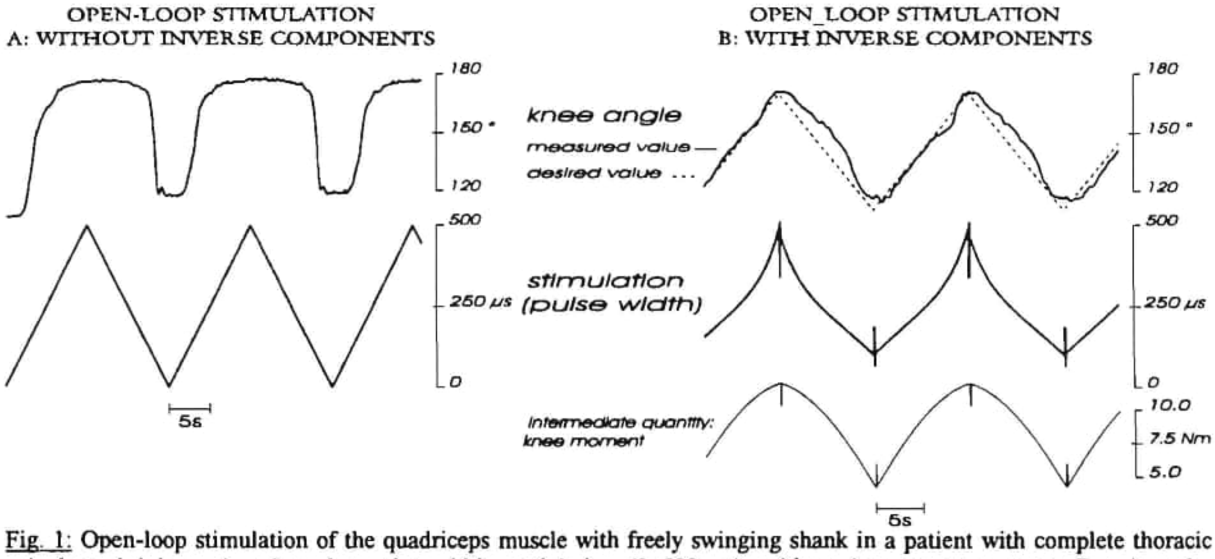

Fig. 1: Open-loop stimulation of the quadriceps muscle with freely swinging shank in a patient with complete thoracic spinal cord injury. A: triangular pulse width modulation (0..500 µs), without inverse components. B: triangular modulation of the desired knee joint angle (dashed line) as input to the inverse model. The output of the inverse model is the stimulation pulse width (middle trace). The calculated knee moment is also displayed as an example for intermediate quantities derived from the inverse model.

Closed-loop stimulation experiments proved that control of knee torque (under isometric condition) and control of knee angle (under condition of freely swinging shank) are both possible with a PID controller. For both conditions the best results were achieved using controller parameters, which have been optimized by computer simulation. Under condition of freely swinging shank (Fig. 2A) control was less robust and the time lag (330 ms) was higher than under isometric condition (130 ms). Additional linear feedforward improved the performance of the system only under isometric condition. For condition of freely swinging shank an excellent performance could be achieved by a combination of feedforward with the inverse model and a PID controller (Fig. 2B). There was almost no time lag (30 ms) and only a slight overshoot at the extreme positions.

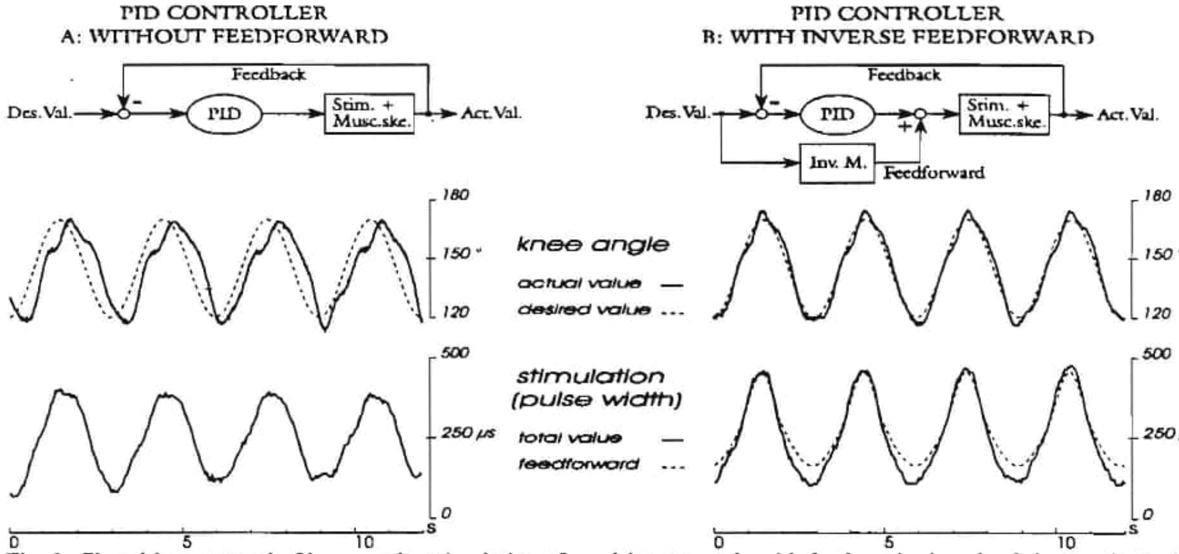

Fig. 2: Closed-loop control of knee angle; stimulation of quadriceps muscle with freely swinging shank in a patient with complete thoracic spinal cord injury. A: PID-controller without feedforward. B: Combination of a PID-controller and feedforward with the inverse model. *Des.Val.*, desired value; *Act.Val.*, actual value; *PID*, PID controller; *Inv.M.*, inverse model; *Stim.+Musc.ske.*, plant (stimulator, nerve and musculoskeletal system). The upper curves represent the knee angle (dashed, desired value; solid, actual value). The lower curves represent the stimulation pulse width (dashed, output of the inverse model = feedforward part of pulse width).

DISCUSSION

This paper stresses two aspects of mathematical modeling: direct models and inverse models. Direct models have been used in computer simulations in order to predict knee motion induced by FES. In that way different controllers can be tested and optimized prior to stimulation experiments in patients. We found good agreement between predicted and measured knee motion, when a careful identification of the model's parameters had been performed.

Inverse models have been used as part of the control loop. Although not all components of our direct model were used in our inverse model, this inverse model considerably improved feedforward control of knee motion. Inverse models have several advantages compared to empirically derived stimulation patterns. Inverse models compensate for nonlinearities of the system, e.g. nonlinear recruitment of motor units, nonlinear force-length relation of muscle contraction, changing lever arms, and influences of inertia. If the trajectory of the desired value is steady, inverse models can also make up for delays and nonlinearities in time. In multijoint movements inverse models consider coupling of moments between joints. The hardware requirements for inverse models are considerably lower than for artificial neural networks /2/, even multijoint inverse models can be implemented on current microprocessors.

However, one important limitation for such models is spinal reflexes, which are preserved or even exaggerated in patients with upper motor neuron lesions. It is difficult to predict accurately the occurrence and the effects of phasic, polysynaptic reflexes, e.g. flexor withdrawal reflexes in patients with spasticity. Thus, modeling of these reflexes seems hardly be possible. It also seems unlikely that motion induced by these powerful reflexes may be completely counterbalanced by stimulation of antagonistic muscles. Because phasic reflexes usually occur only during the first seconds of stimulation it is more desirable to find stimulation patterns that do not elicit these reflexes at the onset of stimulation. A second aspect of spasticity is the increased muscle tone. When muscle tone or stiffness is considered, one has to differentiate intrinsic and reflex components /5/. Although there is evidence, that changes of intrinsic muscle properties contribute to increased muscle tone in patients with upper motor neuron lesions /6/, also tonic stretch reflexes have to be taken into account. As tonic stretch reflexes are more predictable than phasic reflexes, modeling these reflexes may improve the simulation and control of lengthening contractions (e.g. knee flexion movement, see Fig. 1B).

Other limitations for feedforward control of FES induced movements are external disturbances and changes of internal parameters due to fatigue. These phenomenons can only be compensated by closed-loop control. If applied to the control of unconstrained movements, conventional lead-lag controllers have several disadvantages, such as a substantial time delay and a lack of robustness. It could be shown in this work, that a combination of linear feedback controllers with inverse feedforward eliminates many of these disadvantages. Further improvement can be achieved by controlling also the antagonistic muscles and using adaptive algorithms /2/ in order to compensate for variations of parameters.

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Closed-loop control for functional electrical stimulation with percutaneous electrode in paraplegics

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SUMMARY

A closed-loop control system for functional electrical stimulation (FES) with percutaneous electrode is described. The system consisted of ultrafine percutaneous electrodes, multi-channel stimulators (16 and 32 channels) and sensors (pressure sensor, flexible goniometer and stretch sensor) for detection of knee buckling. In comparison with three sensors during standing, the stretch sensor was superior to other sensors in both ease of use and response. Two completely paraplegic patients could stand and walk stably with this closed-loop control system. No complications occurred in clinical use. This system reduces muscle fatigue by electrical stimulation and prolongs upright activities in complete paraplegics.

STATE OF ART

Restoring independence in performing daily functions is the main goal in treating paraplegia. Recent advances in computer technology has made it possible to control paralyzed muscles by electrical stimulation. We have used FES to restore paralyzed muscles in the lower extremities since 1990/1/. A major limitation of FES is that of muscle fatigue. The amount of fatigue of the muscles can be reduced using the closed-loop control. Although some investigators have already developed the closed-loop control systems using surface electrodes for paraplegics, there is no available system for percutaneous electrodes /2,3/. We have developed new stimulators and sensors for closed-loop control with percutaneous electrodes. Here we describe our system and the clinical use in two complete paraplegic patients.

MATERIALS AND METHODS

The indwelling electrode was formed from 19 strands of a helically wound Teflon-coated stainless steel (Nippon Seisen Co.Ltd.). Electrodes were percutaneously implanted into the motor point of muscles. Two stimulators were developed for the percutaneous electrodes. Akita stimulator I had 16 channels, including two channels for swinging the leg by stimulating the iliopsoas muscles and two for the continuous stimulation. Rectangular pulse trains consisted of a pulse width of 200 microsecond, a pulse interval of 50ms, and a pulse amplitude from 0 to -15 V. This stimulator equipped an interlocking circuit to prevent simultaneous reactions in both legs (Fig 1). Akita stimulator II had 32 channels and could vary pulse frequency from 20 Hz to 100 Hz to apply high frequency stimulation to achieve quick response to knee buckling. Akita stimulator II can be used for not only FES but also therapeutic electrical stimulation (TES) in training paralyzed muscles to achieve sufficient muscle strength for standing and walking (Fig 2).

Pressure sensors on the grip of the walker were connected with a stimulator for initiating standing-up or swinging the leg. In restoration of standing, a pressure sensor (Click BP) on the anterolateral site of the proximal shank, flexible goniometer (P&G) attached on the axis of the femur and tibia, and stretch sensor (Biotech) attached at the posterior of the knee were used to detect knee buckling caused when the floor reaction vector shifts behind the knee joint. Since the command algorithm includes some time delays, we compared three sensors with the response to the time delay under 20Hz stimulation. Two completely paraplegic patients were requested to remain standing with the hybrid FES system. Then electrical stimulation was cut to induce knee buckling artificially or they were requested to voluntarily buckle the knee. When knee buckling was detected with a knee sensor, hip and knee extensor muscles were stimulated for 2 seconds to recover from knee buckling. We measured accuracy of response to knee buckling in each sensors and time delay from knee buckling to the start of recovery stimulation in the flexible goniometer and stretch sensor. Time delays were measured ten times in each sensor.

The algorithm for control during walking was as follows: when the grip sensor was on, the iliopsoas muscle was stimulated to swing the leg and the ipsilateral hip and knee extensor muscles were not stimulated but the contralateral hip and knee extensor muscles were stimulated for limb support. When the grip sensor was off, the hip and knee extensor muscles were stimulated to maintain limb support but the iliopsoas muscle was not stimulated. The hip and knee extensor muscles were stimulated when the knee sensor was off and not stimulated when the knee sensor was on. The grip sensor always had priority over the knee sensor to prevent the falling.

This closed-loop control system using Akita system I was implanted in a T6 completely paraplegic patient (case 1) and that using Akita system II in a T8 completely paraplegic patient (case 2) to restore the function of standing and walking. Both cases involved spinal cord injury.

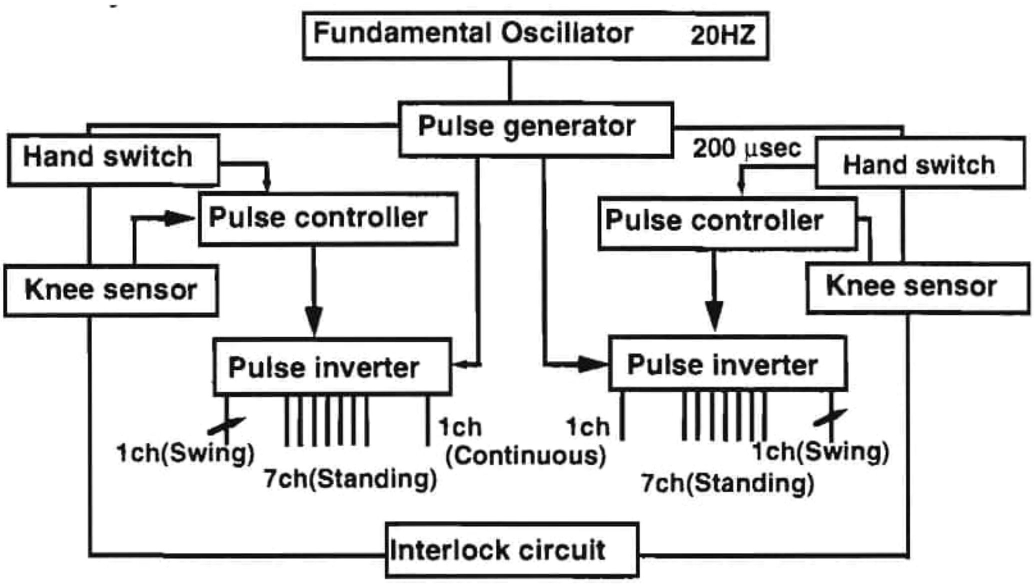

Fig.1

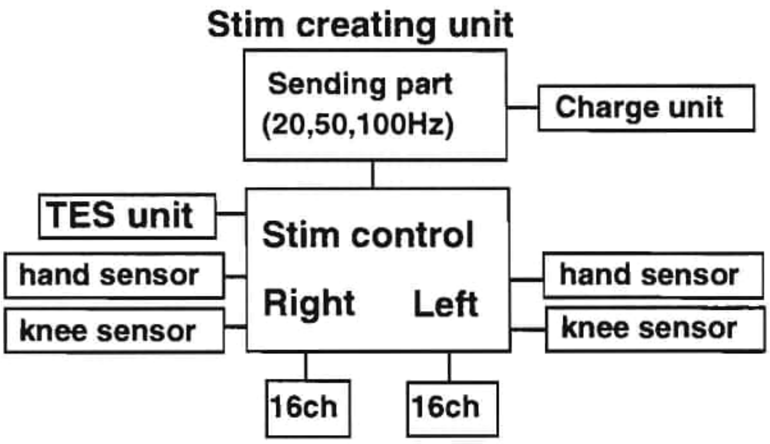

Fig.2

RESULTS

Both complete paraplegic patients could stand and walk stably with this closed-loop control system. Maximal duration of standing by electrical stimulation with closed-loop control was 25 minutes in each patient. Maximal distance of walking was 25 meters in case 1 and 30 meters in case 2. No complications such as falling occurred in either case.

To detect knee buckling during standing, the pressure sensor sometimes presented false-negative response due to the incompatibility between sensors and orthosis. The accuracy of response by the pressure sensor was not reliable in detecting knee buckling. Although the flexible goniometer could set the threshold of knee angle for detecting knee buckling precisely, it needed to be set each time and determining the appropriate threshold was difficult. The appropriate threshold of knee angle for the flexible goniometer to control standing efficiently was 12 degrees. The stretch sensor had an advantage in that threshold did not need to be determined each time because of active current control. The threshold was automatically determined when stretch strength became fixed each time. The average time delay from the start of knee buckling until initiation of recovery electrical stimulation was 0.53±0.17 sec (Mean±SD) in the flexible goniometer and 0.18±0.04 sec in the stretch sensor. There was a 0.35 sec difference in time delay on average between the two sensors. The maximal time delay was 0.8 sec in the flexible goniometer and 0.23 sec in the stretch sensor. The stretch sensor was superior to pressure sensor and flexible goniometer in both ease of use and response.

DISCUSSION

For paraplegics, FES-induced muscle fatigue and withdrawal reflex habituation are two of the factors that limit control and endurance of standing and ambulatory activities. The presently available clinical FES standing systems involve continued activation of the lower limb extensors resulting in rapid muscle fatigue. The amount of muscle fatigue can be reduced using the closed-loop control. It is possible for the paraplegic patient to remain standing without muscle activity of the lower limb as long as the floor reaction vector is in front of the knee joint, with hip hyperextension. This "C"-posture allows the patient to stand stably using a hybrid FES. When the floor reaction vector shifts behind the knee joint, knee buckling occurs. In case of buckling, the knee sensor detects it, and knee extensor muscle is stimulated. This closed-loop control reduces muscle fatigue and prevents falling due to knee buckling. To reduce knee motion during buckling, it is necessary to shorten the time delay by detecting knee buckling as soon as possible and stimulating the muscle immediately to induce rapid muscle contraction. Although a pressure sensor has been commonly used to detect knee buckling, the accuracy of its response was not reliable. The stretch sensor was most useful for closed-loop control of knee buckling during standing both in ease of use due to active current control and in response. In addition, it was cheap and durable.

Although the sequential phases of locomotion in the 4-point gait pattern with the hybrid FES were described by Andrews /4/, it was difficult to reproduce these phases in complete paraplegia. Problems with high energy requirements, lack of trunk and hip stability requiring the use of a walker and complexity of care and maintenance of the system remain to be resolved. We have restored the reciprocal gait pattern in the swing of the leg by stimulating the iliopsoas muscle and providing limb support by stimulating hip and knee extensor muscles. The stride length has been regulated by the stimulation time of the iliopsoas muscle. This simple control restores stable walking without falling and reduces muscle fatigue in complete paraplegic patients. However, more complex systems are needed to prolong the walking distance and completely prevent falling. Further expansion of these systems would facilitate the independence of complete paraplegic patients in daily living.

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ON THE USE OF SENSORS FOR FES CONTROL

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SUMMARY

Preliminary results are presented of recent studies using machine learning to extract data from sets of sensors for use with FES controllers. These methods allow flexibility in choosing and locating sensors. Examples of suitable external sensors suitable for FES are presented. Although the examples involve the lower limb with external sensors and electrodes the techniques are general in scope.

Keywords: Sensors, FES Control, Machine Learning, Paraplegic Locomotion

BACKGROUND

Sensors are often selected for FES on the basis of experiential knowledge or intuition as to how the signal could be processed to give the desired gait control variable or, in the case of event or intention detectors, how discrimination algorithms can be formulated. Such heuristic knowledge is deep and can be very robust, however, the approach is limited by the availability of sensors and the ability to formulate the algorithm. Preliminary results illustrate new possibilities for extracting information from sensors for use in various components of the neuroprosthetic system including: interpretation of user commands; detection of user intentions; discrimination locomotor events and phases; feedback data for control loops; data for hand crafted rule based controllers; data for self adaptive controllers; data for system diagnostics; patient compliance and functional outcomes; supplementary sensory feedback to the user. The present sensory system is being developed for a hybrid system (Davis et al. in these proceedings) to assist transfers, standing, obstacle negotiation and short range locomotion in paraplegia. The hybrid system comprises an external sensory system, control computer, implanted electrodes and ankle foot orthoses.

METHODS

Modular General Purpose Sensor System In order to minimize encumbrance and improve reliability, cosmesis and ease of use the sensory system comprises external artificial sensors that are restricted to and integrated within the AFO's and a low profile waistband. The robust, miniature and low cost sensors presently being investigated are: single chip accelerometers with a dc response type ADXL05, Analog Devices, force sensing resistors (FSR's, Interlink Electronics Inc.), strain gauges and a simple, purpose designed, magnetic field transceiver position and relative angle sensor. Up to six accelerometers are distributed in the waistband and three in each AFO. The FSR's are integrated into the footplate of the AFO's and the strain gauges attached to the anterior surface (to estimate the ankle dorsiflexion restraining force actions). The accelerometers are rich in information on inclination with respect to the gravity and inertial components up to +/-5g. The device is sensitive at 0.5V/g, with good resolution at 5mg, low drift at +/-0.5%, highly linear at 0.2% full scale, 0-1.6 kHz bandwidth, robust up to 1000g shocks, low weight 5gm and low power. A simple, low cost, non-inertial magnetic position sensor comprises three 12kHz transmitters in the waistband and three receivers in each AFO. Each transmitter coil is activated in turn and the corresponding signal strengths from each receiver are sampled to provide information on relative angle and position of the relative motions between the transmitters and receivers. The transmitters and receivers also incorporate magnetoresistors that provide inclination signals relative to the earth's magnetic field. Single multicore cable connects each AFO sensor cluster to the waistband cluster. The methods described below do not require precise alignment of these sensors. The set is overdetermined and can be reduced depending on the FES control tasks.

Skill Grafting, Detecting Gait Events & User Intentions In many learned motor tasks involving there are associated preparatory movements or postural changes. These are often subcognitive (as opposed to those process of which the subject can give an explicit account) and a computer can learn by imitation from behavioral recordings from a trained patient (or clinician), then reproduce the learned skill when subsequently performing on its own, and finally deliver an articulate account of the given acquired skill in the form of rule-structured expressions. For example, in the simplest manual handswitch control of FES as described by Kralj & Bajd the patient (or clinician) is often observed to progressively improve the gait by learning exactly when to press the control switch during late stance to evoke the flexor reflex. Patients can become skilled in learning when to press the switch to accommodate for delays such as those associated with the flexion reflex. This learned subcognitive skill can be approximately modeled in the form of production rules from repeated instances of its use. In this way, skill is cloned since these rules logically mimic the skill of the CNS and can be readily transferred or grafted to a computer. During these examples behavioral and system signals are recorded. In this case, the handswitchs together with the sensor signals such as: insole pressures and crutch force sensor signals. In principle, if there is a strong coupling between volitional motions and control signals then there is the opportunity for an improved *cybernetic interface* the machine (FES controller) also has the ability to adapt, for example by using reinforcement learning /1/, then mutually adaptive learning occurs the interface may be further improved. For this reason the system sensors are selected to be rich in information on the related volitional preparatory movements and postural changes such as body weight shifts and crutch advancement and loading.

Machine learning for FES control was first described in 1988 by Kirkwood & Andrews /2/. Skill grafting for FES control was subsequently presented at the 3rd Vienna workshop using the *Disciple* algorithm based on Quinlan's ID3 rule induction algorithm /3/. The method allowed the designer freedom to chose sensors and position them without a priori reasoning on how to extract rules or be concerned about precise anatomical alignment. Also the contribution from each attribute is quantified in information theoretic terms. Indeed, it has been found that human experts do not do as well when asked to select or rank the importance of sensors /4,7/. The method is more fully described by Kostov et al. in these proceedings. In supervised learning, a major concern is how well the model (rules, neural nets etc.) generalizes. Here the handswitch is used not only to initiate flexion but also the degree of flexion by how long the switch remains pressed (preset stimulus intensity). This control is used by the patient in many subtle ways: to initiating and terminating gait; negotiate obstacles or uneven terrain; turning on the spot; back stepping; negotiating a stair or step. The patient also introduces inconsistent time lags and errors due, for example, to distractions or lack of concentration. These inconsistencies will confuse and degrade the quality of learning. Since the trained model only represent shallow knowledge of the system, one can only reasonably expect it to correctly extrapolate or interpolate situations that are close to or within the hyperspace clusters formed by the training examples. The other regions of the hyperspace being essentially unknown i.e. shallow models are not endowed with common sense! These uncharted regions of the hyperspace could be patched or locked out by integrating other information such as hand crafted rules and, for given training examples, the model's prediction accuracy can be optimized by trial and error selection of sensor attributes. However, this cannot improve the detectors generalization for events that are underrepresented in training, especially if these events are absent or only weakly represented in the sensor signals. Therefore, generalization performance of a model is influenced by the quality of training data and breadth of the training experience i.e. the correlation of attributes with teacher signals and the statistical significance of the training examples to the population of possible instances..

To illustrate the issue, Table 1 presents data from for the spinal cord injured person (male born 1963, height 1.9m, C6 incomplete ASIA grade C, Brown-Sequard, injured 1981, left unilateral 2 ch FES, muscle grades less than ASIA 1) using the same FES system with forearm crutches and handswitch mounted on the left handgrip as described in the original reports. These data were recorded in Oct. 1991 in five consecutive walking trials in a single 2 hr session, each time starting from standing at rest and with rest periods between each trial /5/. In four of the trials he was asked to walk at his preferred rate and in the fifth at a faster rate. The sensors were:- FSR's, four per insole, heel, med. & lat. metatarsal and big toe described in /6/; strain gauges measuring axial crutch forces; goniometers (Penny & Giles, M180) positioned to measure flexion and extension of the hips and knees. The amplitudes of these 14 sensors were (50Hz, 12 bit A/D) used as attributes to the *Empiric* rule induction algorithm /7/. The corresponding handswitch signals were also recorded and used to train the decision tree using the data of trial C. Training was repeated at for preset error rates 5, 10 and 15% (used with the number of classes, output levels - here 2, to calculate the required information level /7/) and the corresponding number of decision tree nodes are also indicated. Figure 1 shows the decision tree (10%) and the 4 attributes selected by the algorithm. The top to bottom position of an attribute ranks the relative importance.

Error Rate (%)	*# of Nodes*	*Misclassifications (%)* *A*	*B*	*C*	*D*	*E*
5	37	18.4	14.5	0.2	8.0	24.6
10	9	7.0	14.8	5.4	8.2	45.1
15	5	9.5	10.5	6.4	8.5	45.1

Table 1. *Results from FES walking trials: A-D are the slow walking trials, C is the training data and E faster walking trial.*

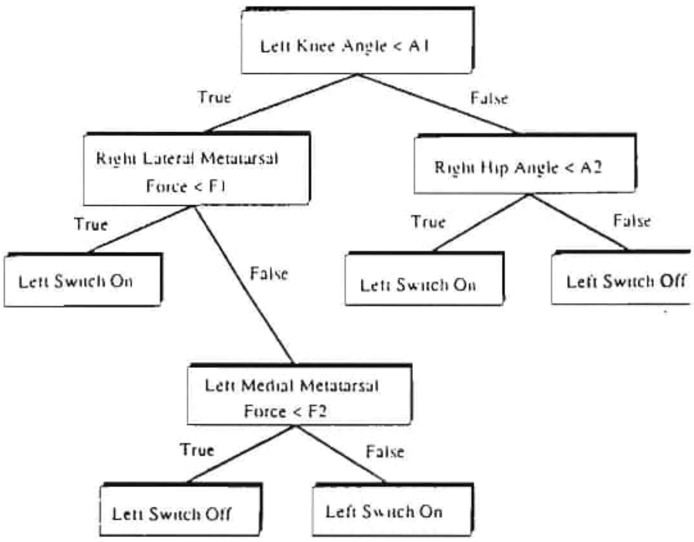

Figure 1. *Decision tree produced by* **Empiric**. *Note only 4 out of 14 attributes were used.*

the training set and, as expected, larger on the other trials at similar speed A-D. However the errors are unacceptable at 45.1% for the faster walking trial E. Examination of the actual data for trial D shown in figure 2 reveals that the errors occurred mainly during the start up phase. This example serves to make the point that a decision tree trained with the attributes of one speed of walking did not generalize well to other speeds by the same subject. Further study is required to discover the limits to generalization of this technique in terms of combinations of sensors, attributes and models (the number of combinations can readily become large and is best optimized using algorithms like *Predict* that uses genetic algorithm to expedite the process).

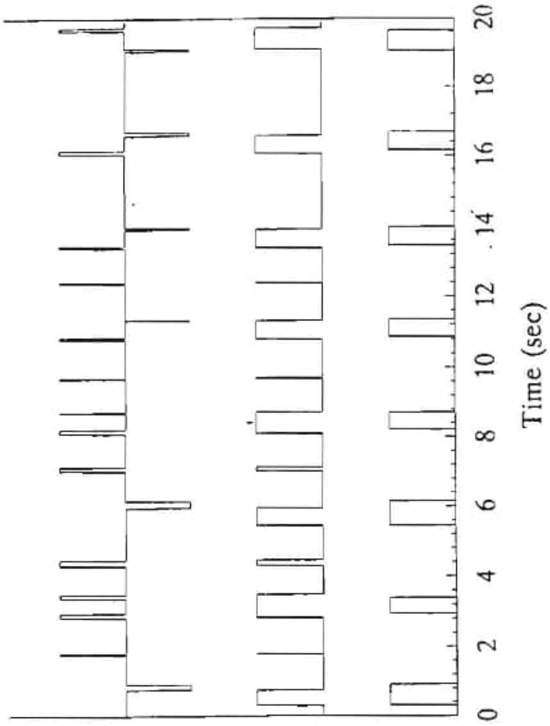

Figure 2. *Generalization errors for walking trial D. Top trace the error. Bottom trace actual switch data. Middle trace* Empiric *prediction.*

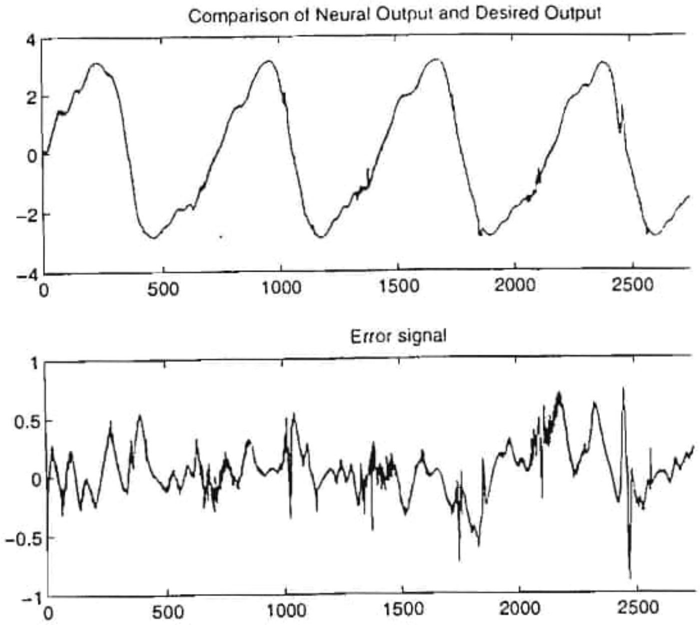

Figure 3. *Top: video derived forward velocity (dotted) & superimposed* Predict *output (solid line). Bottom: the difference.*

Sensor Simulation using Gait Analysis The actual choice and location of sensors in the above scheme is limited by availability and the need to conduct repeated clinical tests. An alternative approach is to perform a comprehensive gait analysis in which the segmental kinematics (and kinetics) are determined. It is then possible to recalculate the data to determine the kinematics for any point on the body. In this way a hypothetical set of sensor signals can be quickly and conveniently obtained that can then be input to trainable networks. This enables candidate sensors to be examined and assessed before a commitment is made to specific sensors and the effort and resources needed to conduct clinical tests. This method was used to explore the required sensors for control of swing-through FES synthesized gait /7/. Using this method discovered the importance of a new sensor, one that would detect the instant the swinging shanks cross the crutches. This sensor has yet to be developed but could be implemented optoelectronically, however, this example serves to illustrate the power of the technique.

Intelligent state variable "Observer" There is the requirement for specific biomechanical variables that are not directly monitored. These "hidden" variables may be observed by the use of a trained neural network that maps sensor derived features onto the required variables. During training the desired variables must be directly monitored (using specific transducers such as goniometers of general purpose motion analysis equipment) and used as examples for the supervised learning. The trained neural network may be regarded as an intelligent observer (In some ways this has some similarities to the observer technique used in modern control theory to estimate state variables that are not available from the actual system. Unlike the above modeling this is simply a transformation of one set of system outputs to another and thus should be less affected by the time varying inconsistencies in the CNS and neuromuscular system and higher level planning. To illustrate the method consider the following task to determine the forward velocity of the foot of an able bodied subject from two accelerometers (ADX05, Analog Devices, sampled at 1kHz, 12 bit A/D) attached to the shoe of an able bodied subject one approximately aligned with the heel and toe with the other approximately radial. The forward velocity teaching data was determined by numerical differentiation the displacement of a reflective marker positioned on the toe using a 60Hz video based motion analysis system. Each acceleration signal was low pass filtered (10Hz, 8th order Butterworth double pass to cancel phase) to a similar bandwidth as the teacher signal. The filtered acceleration signals one accelerometer to indicate stance and swing phase. The Kalman filter learning rule option was selected and the five signals were input to the *Predict* program which automatically applied a number of potential data transformations, to improve the correlation with the teacher signal, to each feature signal. A genetic algorithm is used by Predict to select the optimal feature set most suitable data transformations. The algorithm was thus trained using 70% of the first 1900 data points and the generalization error tested on the remaining unseen data points. *Predict* selected four of the five features and applied either Tanh or linear data transformations, the results were encouraging and are shown in figure 3.

DISCUSSION

The development of techniques to improve the generalization of models derived from supervised learning is now a priority, no matter if they are implemented as various paradigms of artificial neural networks or various rule induction schemes. This is a largely a matter of improving the quality and degree of training. Once trained, the generalization should be exhaustively tested. Regarding the training of static models the following techniques may be considered: **Optimizing Sensors and Attributes** This can only be achieved on a trial and error basis. As a guide, training data should be as clean as possible and have a high correlation with the teaching data. To further improve these correlation's the data can be scaled and transformed. This can rapidly lead to an enormous number of possibilities to try out which can be very time consuming and tedious. Programs like *Predict* have largely automated this process by using a genetic algorithm to search for synergistic sets of input variables which are good predictors of the output. Once learned *Predict* produces C code that aids implementation of the FES controller. **Localized Modeling** The dynamics of the locomotor system changes with the phase of the gait cycle e.g. in single support the leg resembles an inverted pendulum whereas during swing it is a compound pendulum. This is expecting a lot from a single model. Intuitively it would seem more appropriate to restrict the hyperspace by having at least two models trained on data localized around specific events or phases. **Sequential Ordering** In many motor tasks, events and phases are normally sequential ordered. This knowledge can be included by implementing the models as a sequential state machine to lock out or trap abnormal state transitions. In addition, the probability of occurrence of the next events can be statistically determined based on the historical pattern of occurrence in recent cycles. For example, the "probability of occurrence" function can be used to window or weight out false detection's. **Integration of Hand Crafted Rules** A priori knowledge of the biomechanics of neuromuscular system and movements during gait may be articulated or extracted by an expert and embodied in the form of hand crafted rules (Boolean, fuzzy or rough). This human reasoning or "common sense" is deep as opposed to the shallow knowledge extracted from input output data. A number of machine learning algorithms allow these hand crafted rules to be readily incorporated into the trained model.

CONCLUSIONS

These neurocomputing and AI methods allow flexibility in selecting and locating sensors and removes the need to know explicitly how the sensor signals relate to control variables. Learning algorithms that incorporate genetic algorithms can expedite the process of optimizing attributes/features. Machine learning raises issues of Generalization and Overfitting (not discussed here). There are concerns about generalization for these methods that require further work to resolve. Many machine learning algorithms allow for incremental learning i.e. additional training examples can be taught without having to start the learning process from the beginning. It is perhaps asking too much of the technique to successfully learn a statistically representative selection of all the various control situations encountered in everyday FES usage. An intuitively more attractive approach is to use a self adaptive approach such as reinforcement learning to implement a continuously self adapting fuzzy controller as described in /1/. This latter approach offers the potential to supply partially trained (using a computer model, hand crafted or supervised learning) controllers that can then continuously adapt to an individual patient.

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A FES Controller with Artificial CPG for Biological Systems

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SUMMARY

A central pattern generator (CPG) of biological systems has excellent characteristics such as adaptivity or generation of various motion patterns. The purpose of this research is to propose and develop a new control method configured by the biological simulator, sensory feedback and the artificial CPG which is constructed by recurrent neural network (RNN) and genetic algorithm (GA). This FES control system would have a possibility to realize more effective and emergent motion control for severely physically handicapped persons such as the quadriplegics or paraplegics. A recurrent neural network (RNN) is used to construct the artificial CPG. The synaptic weights of this RNN are modified/changed by the genetic algorithm (GA) to achieve more adaptive and effective learning. This FES controller which has genetic algorithm and sensory feedback to the artificial CPG enables to realize emergent learning under various circumstances. By the actual experiments using animals with sensory feedback (in this case, angular displacement and angular velocity) and the computer simulations considering circumstances and biological aspects, we could confirm the excellent adaptivity and emergence for the motion control. This FES control concept might be regarded as essential for the total motion control.

Keywords *FES, CPG, Genetic Algorithm, Recurrent Neural Network, Self-Organization, Adaptivity*

STATE OF THE ART

FES technology might be essential methods to control or manipulate the muscle of biological systems. Most of FES controllers would be "feedforward manipulation" or "visual feedback control". These traditional ways can realize to move or manipulate the human's arms or legs etc. But, we need more suitable and adaptive feedback control. On a posture control of patients, I propose a decentralized sub posture control system which controls the patient's posture by itself. The special mark of this research shown in Fig.1 is *cybernic FES controller* which consists of *self-organized artificial CPG = Recurrent Neural Network(RNN) + Genetic Algorithm(GA)*. It would have an excellent and emergent adaptivity. The basic concept of this research is illustrated in Fig.1. Motion pattern or trajectory or adaptive controller are obtained according to the performance indices in the uncertain circumstances including systems.

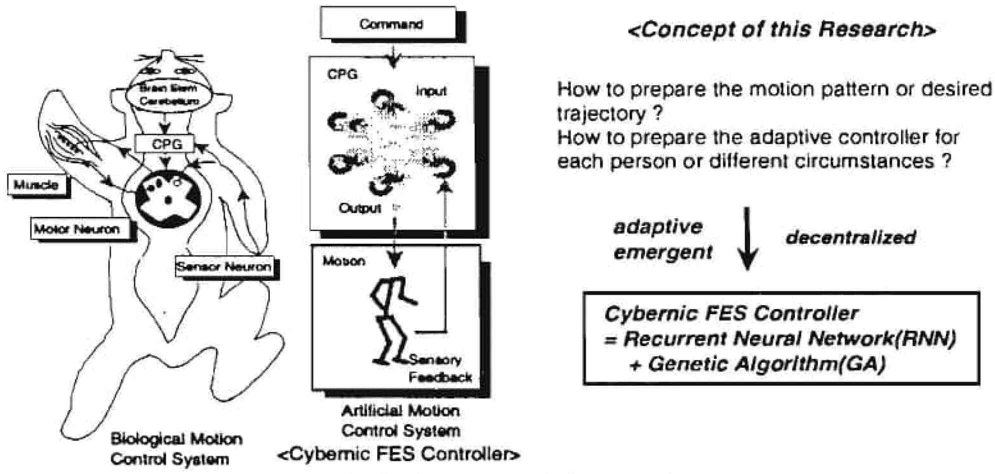


Fig.1 Concept of this research

MATERIAL AND METHOD

The configuration of the cybernic/biocybernetic FES controller is shown in Fig.2. Artificial central pattern generator (CPG) or pattern generators (PGs) are main part of this FES control system. Sensory signal such as displacement, velocity, acceleration, tactile information etc are fed back to the CPG/PGs to perform the self-organization. In this level, we can chose the status in the CPG/PGs, i.e., we can use the plain CPG (no learning) or pre-learned CPG by use of the bio-simulator of the human body described as virtual human or biological system. The purpose of this virtual biosimulator is to realize pre-learning and to reduce the actual repetition. It is very similar to the image training.

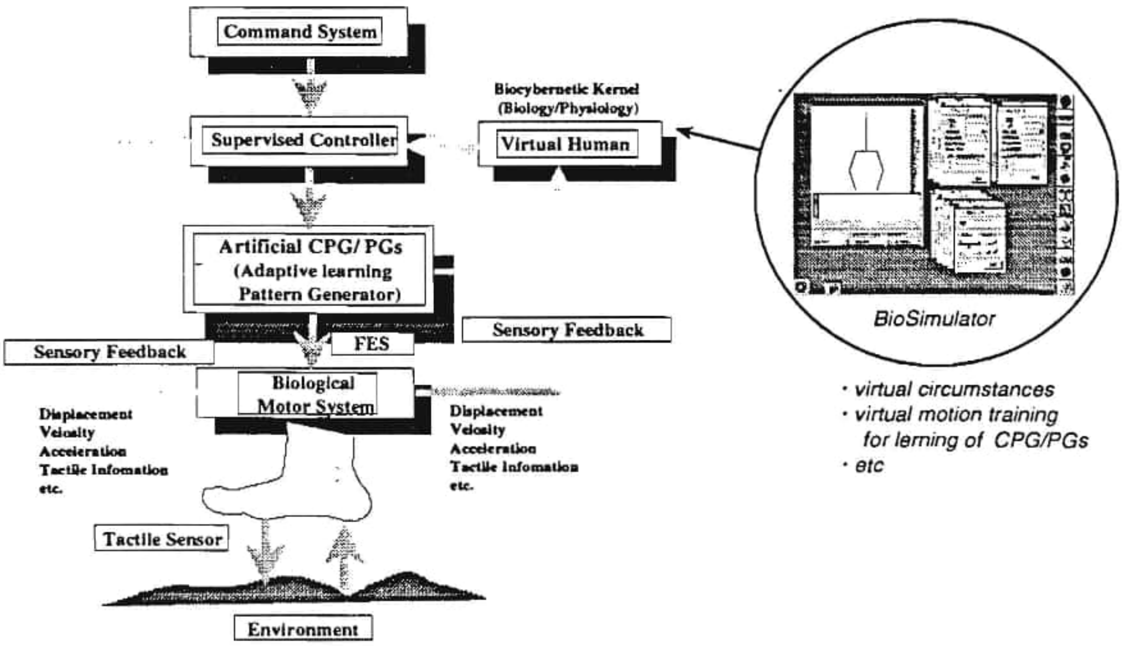
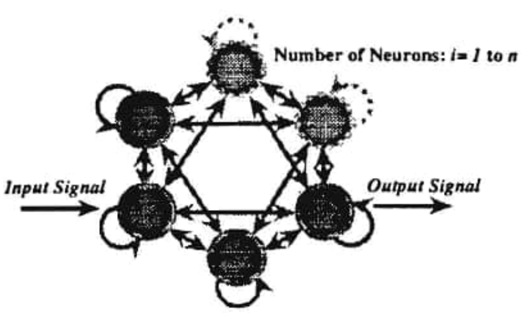


Fig.2 Configuration of cybernic FES control system

The neuron model adopted here is recurrent neural network (RNN). Furthermore, each neuron has a time constant and mutual linkages. Therefore, this network can learn the dynamic motion pattern. The state equation of *ith* neuron is shown in Fig.3. The synaptic weights and time constant are modified by using genetic algorithm (GA). Genetic algorithm is a stochastic optimization search method based on the principle of biological evolution. Many theoretical foundation of genetic algorithm is based on a binary string representation of genetic pattern. In this research, RNN weight matrix as the gene is not integer but real number. Therefore, number of combination is countless and there would be few possibility to fall into local minimum. Fig.4 is GA calculation and the algorithm in this research.



State Equation of i th Neuron:

$$\tau_i \frac{dx_i}{dt} = -x_i(t) + \sum_{j=1}^{n} w_{ij} y_j(t) + u_i(t)$$

$$y_i(t) = f(x_i(t)) \qquad f(x) = \frac{1}{1+e^{-x}}$$

$x_i(t)$: state of i th neuron, $u_i(t)$: input signal to i th neuron,
$y_i(t)$: output from j th neuron to i th neuron
τ_i: time constant of i th neuron, w_{ij}: synaptic weight coef. of i th neuron
$f(x)$: sigmoid function, n: number of neurons

Fig.3 State equation and neuron architecture

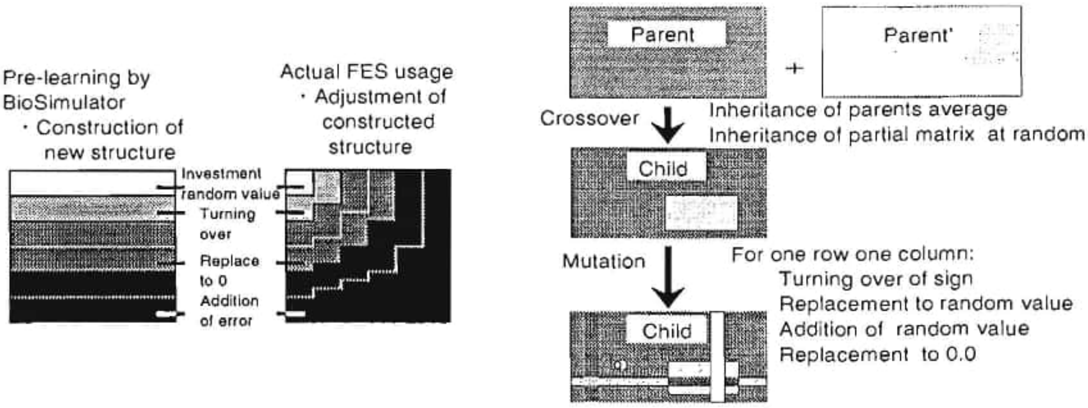


Fig.4 Genetic Algorithm in this research

RESULTS

Experiments have been performed for twenty frogs as shown in Fig.5. Every spinal cord of frog's lower back was cut and every leg below knee was connected to FES controller. In these experiment, the degree of freedom is one. Parameters and conditions in these experiments are set as follows; RNN[number of neuron unit=8, reset inner states of CPG=0], GA[number of pieces=64, mutation rate in pre-learning= 0.15(cf. |error|>10% then 0.3), mutation rate in after-learning=0.05(cf. |error|>10% then 0.3), performance index of fitness=only regulation(desired value=50 degree)]. Example results are shown in Fig.6. In this case, pre-learning of the artificial CPG by use of the simulator was performed previously before the actual experiment.

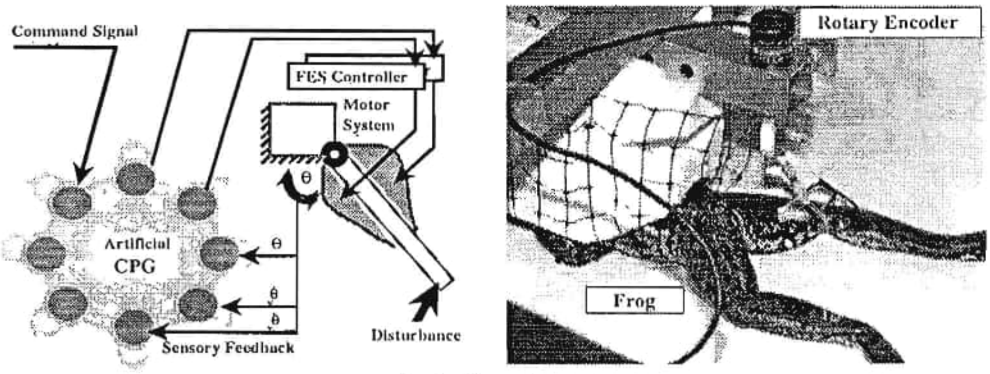


Fig.5 Experiment

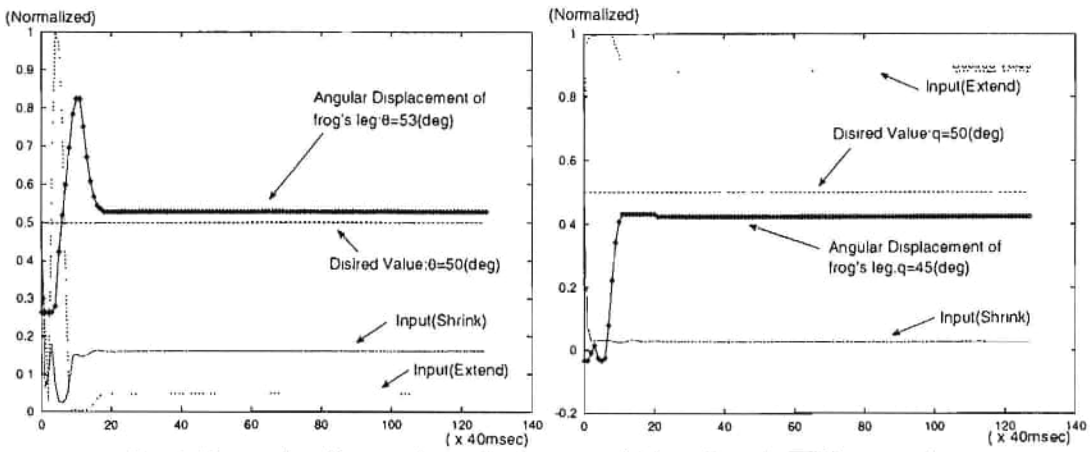


Fig.6 Example of control results by use of this cybernic FES controller

In the simulation, we confirm the advantage of this method for parameter perturbation (e.g.30%). Therefore, relatively fine results are obtained only several trails (19 generation = 19 trials) as shown in Fig.6. In the left figure(FIg.6), we can find a overshoot, but amplitudes of input signals are relatively small. In the right figure(Fig.6), there is no overshoot, but amplitudes of input signals are relatively large. In this experiment, performance index is only regulation value. If we need other indices, we can prepare some indices for judgment of fitness, e.g., "regulation, overshoot, input amplitude".

DISCUSSION

We could confirm the excellent adaptivity and emergence for the motion control by using this cybernic FES controller. Especially, pre-learning by use of the simulator is effective method. If the artificial CPG is plain, we need many trials as shown in Fig.7. Of course, parameters of living frogs are different from parameters of virtual frog simulator. So, the system structure in Fig.2 would be suitable structure. But it is not clear which structure is better for more complex systems, i.e., centralized CPG structure or decentralized structure. We must get the working of the structure uncovered.

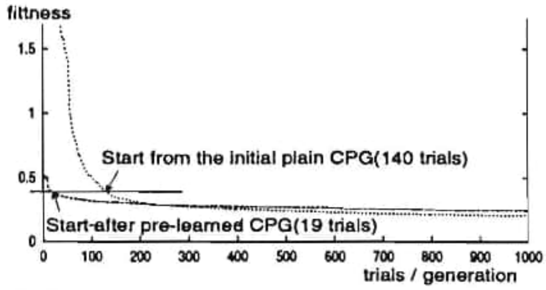


Fig.7 Advantage of pre-learning by use of biosimulator

This FES control concept might be regarded as essential for the total motion control. And in the near future, we would like to apply this control method to the paraplegics. Stable and adaptive posture control will be expected.

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AN ARTIFICIAL NEURAL NETWORK BASED SYSTEM FOR NMES-INDUCED GAIT

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SUMMARY

An intelligent algorithm was used for controlling stimulation signal amplitude and pulse width. The control algorithm consisted of an artificial neural network trained on data from the subject for whom each device was made.

One version of the system used feedback information from a knee goniometer, while an improved version read signals from an ankle goniometer as well. Controller output for the former consisted of percent changes in signal amplitude, while the latter produced pulse width changes. Both systems were designed to induce swing only.

Results suggest that an artificial neural network can be trained for adequate control of electrical stimulation-induced swing.

STATE OF THE ART

In spinal cord injured (SCI) patients, communication between the brain and muscle tissue below the injury level may be completely absent. However, supraspinal centers do not need to intervene in the generation of level, rhythmic walking: There exists an internal representation of the motion. Such internal representation consists of neural circuitry acquired mainly through the process of phylogeny, and throughout the early stages of individual motor learning. The latter process can be simulated, at least in part. This work relies on this fact and introduces an artificial neural prototype based on supervised learning for closed loop control of gait generated via neuromuscular electrical stimulation (NMES). Input comes from a single knee electrogoniometer for one device (S1), while a second system (S2) also uses an ankle goniometer. In S1 output for the system is the amplitude control signal for a portable stimulator unit /1/. The output for S2 produces changes in the stimulation pulse width (PW) .

Supervised learning schemes, such as Backpropagation /2/, and other neural algorithms /3,4/ have been employed with some success in the study of sensorimotor phenomena. None of the latter, however, have so far presented a control system for human gait whose simplicity and required computation time would allow real time control of locomotion in SCI patients. In addition, existing closed-loop NMES control systems /5/ fail to meet the needs of individual patients. These systems also fail to accommodate for non-stationary input-output relationships between monitored biomechanical variables and NMES signal characteristics.

MATERIALS AND METHODS

The first functional version of the system is illustrated in Figure 1. A computer-based neural network uses signals from a knee electrogoniometer (an earlier version included data from FSR foot reaction force sensors, but they were found to interfere with stance in ways that compromised the patient's safety). The output signal consists of percentage amplitude changes in the control signal leading to a portable NMES unit.

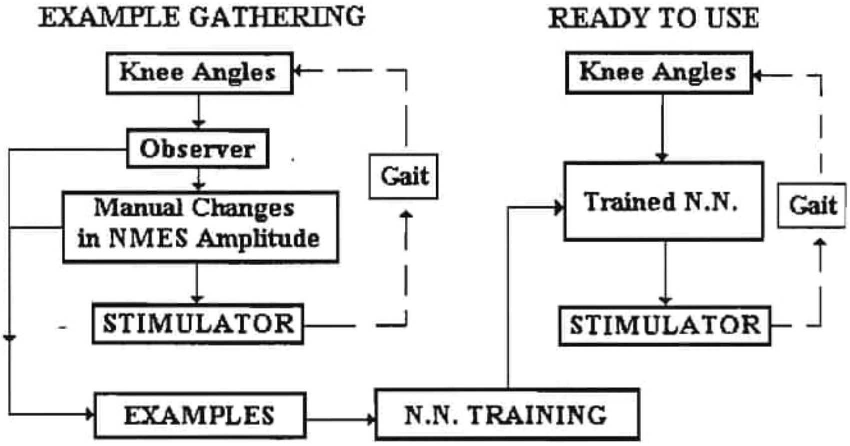

FIGURE 1 - Functional schematic of the artificial neural system for closed-loop control of NMES-generated gait. N.N. stands for a three layer artificial neural network.

In this work, the femoral and peroneal nerves are stimulated. For testing purposes, the swing phase in the left leg is controlled by the neural prototype, while the right leg uses a traditional portable, stand-alone NMES unit.

During the "Example Gathering" phase (Figure 1), a swing cycle is produced with an untrained neural network. In this phase, an observer makes the desired changes in NMES amplitude via computer keyboard based on gait cycle-to-gait cycle observations. The history of sensor inputs and the corresponding NMES signal changes for many gait cycles are recorded. This information is then used for training the neural network. The "Ready to Use," trained network is later employed in automatic control of NMES signal output. It is important to note that each trained network is unique to each patient. Also, the "example gathering" process needs to be repeated only if the trained network is found to malfunction. Otherwise, a single session for gathering examples should be enough (on-line learning is now being added to the system).

RESULTS

Preliminary clinical tests have been run with system S1. A complete (C6 level) SCI subject underwent NMES on the peroneal and femoral nerves, respectively. Swing of the left leg was effected by production of the triple withdrawal reflex followed by knee extension. The swing phase ended when peroneal stimulus was turned off. Amplitude values for both stimulation channels were initially preset to arbitrary values. The produced swing motion was analyzed by an experienced observer. Then, the latter adjusted the stimulation amplitudes in both channels until a suitable motion was observed. Meanwhile, four cycles of angle data and NMES amplitudes were recorded and used for posterior training of a neural network. Ideal swing for this subject was observed when NMES amplitudes were as follows: 60V at the femoral nerve; 30V at the peroneal nerve.

Later, the same subject underwent NMES as described above. This time, however, stimulation amplitudes were adjusted by an artificial neural network. Beginning with amplitude values of 20V and 0V for the femoral and peroneal nerves, respectively, predictions were made for ideal NMES amplitudes. An untrained network suggested values of 120V (the maximum output for the stimulation hardware) for both the femoral and peroneal channels, whereas a network trained on the four recorded examples above suggested values of 58V (femoral) and 6V (peroneal).

In a second test, system S2 was used in similar fashion to produce swing in the left leg of an incomplete C6-level SCI subject. Fifteen example files were gathered. Of those, twelve were selected for network training. The remaining three files were arbitrarily chosen for network performance evaluation. This was of necessity as no stimulation was produced with a trained network for the reasons listed above. The best cycle was produced for a stimulation PW of 300 μs for the quadriceps, and 650 μs for the peroneal nerve. Network training took 21800 iteration cycles (30 min in a DX2/66 MHz machine). The trained network was then presented with data points from the three example files not used for training. Results are shown in Table 1.

TABLE 1 - PW changes produced by a neural network trained off-line. **Per** denotes stimulation to the common peroneal nerve, while **Quad** refers to quadriceps contraction produced by femoral nerve stimulation. Updated values are the sum of pre-set and change values.

TEST CYCLE	PRE-SET PW (μs)		PW CHANGE* (μs)		UPDATED PW (μs)	
	Quad	Per	Quad	Per	Quad	Per
1	50	50	200	747	250	797
2	250	100	67	653	267	753
3	300	400	16	283	316	683

* Given by trained network based on goniometer history resulting from Pre-set PW

DISCUSSION

This work introduces the use of an auto adaptive, intelligent system for control of locomotion produced by NMES. Preliminary results show that an artificial neural network is capable of learning to make appropriate NMES amplitude changes. However, predictions for the peroneal nerve stimulation with S1, as compared to ideal values (6V versus 30V), suggest that network training on four examples only is inadequate.

Results for S2 are more encouraging. A look at pre-set and updated PWs in Table 1, as compared to best cycle values (Quad= 300 μs, Per = 650 μs), suggests that corrections made by the trained neural network are reasonable. Best results were obtained from test cycle 3. This may be related to the fact that pre-set values for this cycle were closer to best cycle values than pre-set values for cycles 1 and 2.

Better results obtained from system S2 (as compared to S1) can be attributed to the use of an extra goniometer feedback and to a larger number of training sets. It does not appear that changing the controller output from amplitude changes to PW changes was a significant factor.

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PREDICTED AND MEASURED MUSCLE FORCES AFTER RECOVERY OF DIFFERING DURATIONS FOLLOWING FATIGUE IN FES

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SUMMARY

Using ^{31}P NMR spectroscopy, the bioenergetics of paralyzed muscles activated by FES were studied *in vivo* during fatigue and recovery on paraplegic subjects. During the activation phase of the muscle, the muscle force was also monitored. The phosphorus metabolites were found to vary systematically during fatigue and to slowly recover to their rest state values after cessation of FES. During fatigue a good correlation was found between the decaying force and each of the profiles of phospho–creatine, inorganic phosphorus and intracellular pH. A musculo–tendon five element model was proposed for the activated muscle to predict its force generation capacity. A fatigue recovery function, based on the metabolic profiles, was introduced into the model. This model allowed to predict the force expected to be developed as a function of time after recovery of given time durations. Validation experimental measurements of force were carried out and included recurrent fatigue tests, both in the initially unfatigued state and at various times in the post–fatigue stage of the muscle. Comparison of the predicted and measured forces indicated satisfactory agreement of the results. It is believed that the developed model of muscle dynamics will help to design a strategy for reducing muscle fatigue under FES.

STATE OF THE ART

Two major issues are associated with Functional Electrical Stimulation (FES) of a muscle; the mechanism of force generation by the recruitment of the muscle fibers, and the decay of muscle force with time as a result of muscle fatigue /6,8/.

The musculo–skeletal system of the human limbs is normally treated as dynamically indeterminate, if the forces in the individual muscles are to be determined, due to the larger number of unknowns as compared to equations. In a paralyzed limb activated by electrical stimulation the degree of mechanical indeterminacy can be reduced, since the muscles of this limb are isolated from voluntary control and the number of activated muscles and the level of excitation can be controlled /3/. This is a unique situation since it allows the calculation of the actual muscle force from the externally measured torques, and the correlation of this direct muscle output to parameters of other nature, such as metabolic or myoelectric.

Metabolic parameters monitored by ^{31}P magnetic resonance spectroscopy and including phosphocreatine (PCr), inorganic phosphorus (Pi) and intracellular pH were shown to indicate muscle force capacity in FES /2,3,5/. The decaying force and pH level were found to correlate to each other and this correlation /5/ was used as a basis for the incorporation of a fatigue function into a musculo–tendon model of the activated muscle /3/.

In the present study the relations between muscle force in FES and metabolic parameters are studied to enable the development of a model of the activated limb, by which the force output can be predicted.

MATERIALS AND METHODS

The set of measurements in this study were made on five paraplegic subjects. Transcutaneous electrical stimulation of the paralyzed muscles of paraplegic subjects was of tetanic form, given by a microprocessor controlled current-output stimulator /7/. The stimuli were rectangular with 0.25 ms duration and frequency of 20 Hz /10/. The stimulation intensity was supramaximal and was obtained in each subject from the recruitment curves. Thus, it could be expected that all the muscle fibers became activated at the onset of stimulation, producing, within a time period of seconds, maximum muscle activation. From this initial condition, a gradual decay of the muscle output followed as a result of fatigue.

Mechanical Measurements

With the thigh attached to the seat, the lower leg was attached, by hinging the foot at the level of the ankle joint, to a load cell. The torque about the knee joint was measured isometrically versus time at 30° of knee flexion angle. The torque was on-line digitized at a sampling rate of 2000 samples/sec. To ensure unfatigued conditions of the muscle, each test was made at the beginning of the training day, before any electrically induced activity took place. Each test included two contractions, one of 3 min and one of 100 s, separated by rest periods of differing durations: 3,6,9,12,15 and 30 min.

^{31}P NMR Measurements

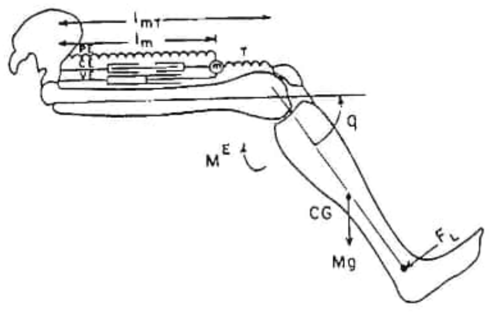
A detailed description of the metabolic measurements is given elsewhere /5/. Briefly, these measurements included metabolic spectra and force measurements. The continuous stimulation, the force recording and the ^{31}P NMR measurements were sampled simultaneously within the MR clinical 1.9T instrument operating at 32.9 MHz for ^{31}P spectroscopy and at 81.3 MHz for ^{1}H imaging. A hydrogen/phosphorus, doubled tuned, surface coil served for both imaging and spectroscopy. The coil operated in a transmit/receive mode. Field shimming was performed on the ^{1}H signal.

MUSCLE MODEL

By solving the dynamic equations for the lower leg, it is possible to obtain the quadriceps tendon force, given the external loads and the anatomical and anthroprometic data. The musculo-tendon model which was used for this study is shown in Fig. 1. The muscle's active element is represented by the muscle contractile element (CE). The passive elements in the muscle fiber are represented by the passive parallel-elastic component (PE) /4/. The muscle viscosity caused by the presence of the fiber fluids is represented by the viscous element (VE) /1/. The variable l_m represents the average muscle fiber length. The tension present in the parallel muscle element (PE) depends on the muscle length l_m. This tension, when combined with the tension produced by the contractile element (CE), yields the total muscle force for a particular level of activation /9/. The forces in the tendon (F_t), the PE (F_p) and the VE (F_d) elements were analytically represented by the following relations:

$$F_t = f_t(l_t) = f_t(l_{mt} - l_m) \quad F_p = f_p(l_m) \quad F_d = f_d(\dot{l}_m) \tag{1}$$

The variables l_t and l_{mt} indicate the tendon length and the length of the musculo-tendon, respectively. The force in the CE element was represented by the products of the following length-tension, velocity-tension, fatigue-recovery (normalized) and activation functions (a):



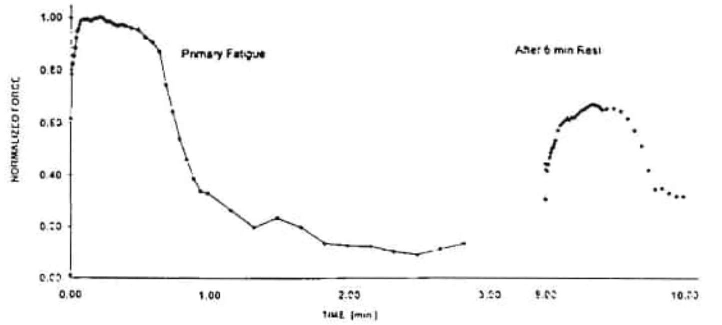


Fig. 1: Musculo–Tendon model of the system.

Fig. 2: Typical fatigue curves

$$F_l = f_l(l_m) \quad F_v = f_v(\dot{l}_m) \quad F_{pH} = f_{pH}(pH(t)) \quad a = a(t) \tag{2}$$

The intracellular pH level was designated to represent fatigue within the active contractile element. The procedure used included least square curve fitting of the pH decay with respect to time t during electrical stimulation and recovery, respectively,

$$pH^F(t) = c_1 - c_2\tanh[c_3(t - c_4)] \quad ; \quad pH^R(t) = d_1 + d_2\tanh[d_3(t - d_4)] \tag{3}$$

with constant parameters c_1, c_2, c_3 and c_4 for fatigue and d_1, d_2, d_3 and d_4 for recovery. The balance equation yields the following musculo–tendon model:

$$\ddot{l}_m(t) = \frac{1}{m\cos\alpha} f_t(l_t(t)) - \frac{1}{m}[f_p(l_m(t)) + f_d(\dot{l}_m(t)) + f_l(l_m(t)) f_v(\dot{l}_m(t)) f_{pH}(pH(a,t)) a(t)] \tag{4}$$

It should be noted that the musculo–tendon length l_{mt} is treated here as a measurable constant since the experimental trials analyzed in this study were performed isometrically.

RESULTS AND DISCUSSION

Typical fatigue curves of force are shown in Fig. 2, in two conditions: the initially unfatigued and after a rest period of 6 min. The metabolic results of 5–6 measurements performed on each of the tested patients are demonstrated in Fig. 3. The tetanic stimulation induced very prominent changes in the steady state levels of the phosphorous metabolites. There was a decrease in the intracellular pH to about pH=6.2, which was found to correlate to the decay in the quadriceps force during stimulation.

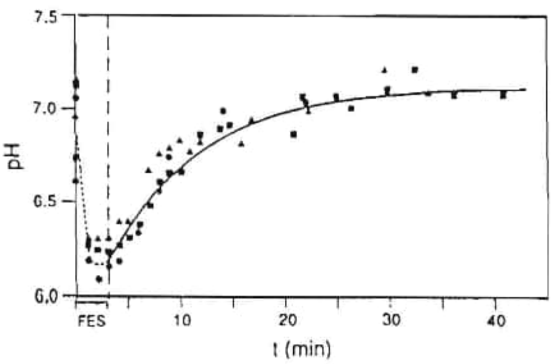


Fig. 3: Variation of Intracellular pH in Fatigue and Recovery.

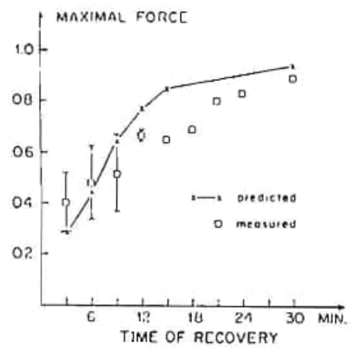


Fig. 4: Model and Measured Results

The recovery process is also illustrated in Fig. 3. The pH values returned gradually to their steady state levels after about 35–40 minutes of recovery. There was a similarity in the behavior of the quadriceps muscles of all the patients.

The model was run for two FES contractions, one of 3 min and one of 1 min, separated by rest periods of 3,6,9,12,15 and 30 min. A predicted maximal force trajectory was obtained indicating a steady increase of the force with recovery time (Fig. 4). The results of parallel experiments are also indicated in the figure and show that there exists a good correspondence between the predicted and measured maximal forces.

The comprehensive approach combining mechanical and metabolic parameters has been presented to identify and resolve the major difficulties associated with artificial muscle activation. The proposed mechanical model provided means to predict the force production capability of the muscle under different stimulation conditions. It is believed that learning the dynamic model of the muscle will enable to design a strategy for reducing the muscle fatigue during FES. Additionally, the task of a feedback controller becomes simplified, since the feedback errors can be reduced and the stability of the system can be increased.

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GLYCOGEN DEPLETION IN FAST AND SLOW MUSCLES OF RAT DURING ELECTROSTIMULATION

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SUMMARY

We studied the effect of electrostimulator "Stimul-1", widely used for treatment of neuro-muscular diseases and trauma, on glycogen content in fast m.tibialis anterior and slow m.soleus of rat. The direct muscle stimulation was performed with alternating 2000 Hz sinusoidal current interrupted 50 times$\cdot s^{-1}$ for 10-40 min in regimen: 5 s maximal intensity stimulation - 5 s rest. To increase muscle glycogen level at rest, some animals were injected with glucose and insulin 24 hours before the study. As rest, glycogen content in m.tibialis anterior was higher, than in m.soleus: 40.1 ± 1.9 and 33.3 ± 1.8 mmol$\cdot$kg w.w^{-1}, respectively. The rate of glycogen depletion in both muscles was maximal during the first 10 min of electrostimulation, than it declined and was approximately constant for the further 20 min. Regardless of initial glycogen content, the glycogen depletion rate was higher in m.tibialis anterior, than in m.soleus: for example, during the first 10 min 70% and 50%, respectively. The rate of glycogen depletion in each muscle was positively correlated with the initial glycogen content.

INTRODUCTION

Besides its practical application, such as treatment of the neuro-muscular disorders and trauma /1/, electrostimulation is a useful research method. It can activate simultaneously all the fibers in a muscle, thus allowing to standardize the conditions of contraction in the fibers of the various types by eliminating the recruitment pattern effect. Therefore, the intrinsic properties of the muscle fibers can be studied under the stimulation conditions.

It was shown previously, that the muscle glycogen depletion during exercise is positively correlated with the initial glycogen content /2,3/. The aim of our investigation was to study this relation in muscles of various composition (slow m.soleus and fast m.tibialis anterior) in rat during maximal evoked contractions.

MATERIALS AND METHODS

Male Wistar rats (160-230 g) were anaesthetized i.p. with pentobarbital (50 mg$\cdot$kg^{-1} b.w.). Calf muscles of one extremity were stimulated through the surface circular electrodes. Proximal electrode was on poples. Alternating 2000 Hz sinusoidal current interrupted 50 times$\cdot s^{-1}$ from stimulator "Stimul-1" was used in regime 5 s maximal intensity stimulation - 5 s rest for 10-40 min. To increase muscle glycogen level at rest, some animals were injected i.p. with insulin (10 mE$\cdot$ 100 g b.w.$^{-1}$) and glucose (0.5 g$\cdot$100 g b.w.$^{-1}$) 24 hours before the study. Immediately after cessation of stimulation, muscles of both extremities were excised and frozen in liquid nitrogen. Glycogen was assayed in a muscle sample of 3-5 mg by anthrone method /4/. The remaining part of muscle was grinned to powder and deproteinized with perchloric acid. Glucose-6-P and lactate were assayed in supernatant enzymatically /5/.

RESULTS

At rest, glycogen content in m.tibialis anterior was higher than in m.soleus: 40.1 ± 1.9 and 33.3 ± 1.8 mmol$\cdot$kg w.w^{-1}, respectively. The rate of glycogen depletion in both muscles was maximal during the first 10 min. of stimulation, than it declined and was approximately constant for the further 20 min.

The analysis of changes of glucose-6 phosphate and lactate allow to conclude, that the decrease in glycogen depletion rate was not due to their inhibiting effect on glycogenolysis enzymes. Indeed, although the lactate accumulation was higher in m.tibialis, than in m. soleus - 14.0 and 5.1 mmol$\cdot$ kg $^{-1}$, respectively,- the rate of glycogen depletion in the former was higher, than in the latter. We didn't register any considerable accumulation of glucose-6-phosphate: 0.5 and 0.3 mmol$\cdot$kg^{-1} in m.tibialis and m.soleus, respectively. The fact infers, that the inhibition of phosphofructokinase reaction was hardly probable.

The effect of initial glycogen content upon the rate of its depletion was investigated on a mixed group of animals. Rats of various age and size were used to broaden the range of muscle glycogen content at rest. Besides, 10 animals were injected with glucose and insulin, that led to some increase of glycogen content: in m.tibialis anterior of rats without injection it ranged from 24.8 to 64.0 mmol $\cdot$kg w.w.$^{-1}$, and after injection - from 45.8 to 84.8; in m. soleus the corresponding values ranged from 8.5 to 45.3 mmol $\cdot$kg w.w.$^{-1}$ without injection and from 25.9 to 51.9 after injection. According to glycogen content, the muscles were divided into two groups: glycogen-rich and glycogen-poor. For m.tibialis anterior the border was 43 mmol $\cdot$kg^{-1}, and for m.soleus - 31 mmol$\cdot$kg^{-1}.

The rate of glycogen depletion was found to be positively correlated with the initial glycogen content both in slow and fast muscles: r = 0.656 and 0.863, accordingly. The same relation was clearly seen when comparing glycogen-rich and glycogen-poor muscles (see table 1): the mean rate of depletion was higher for former, than for the latter .

Table 1. Glycogen content (mmol·kg^{-1}) and depletion rate (mmol·kg^{-1}·min^{-1}) in m.tibialis anterior and m.soleus during 10 min. and 30 min. evoked contractions (n=11)

Indices	M.tibialis anterior		M.soleus	
	glycogen-rich	glycogen-poor	glycogen-rich	glycogen-poor
1. At rest glycogen content	53±2.4	33.7±1.1	40.6+2.2	19.6±1.9
2. Glycogen content after 10 min of contractions	19.2±2.4***	9.9±1.4*	28.4±1.3**	9.9±1.7
3. Depletion rate for 10 min	4.02±0.17	2.38±0.17	1.72±0.17	0.99±0.14
1. At rest glycogen content	55.2±4.0	33.7±1.8	36.4±1.7	24.9±1.3
2. Glycogen content after 30 min of contractions	9.2±2.0***	3.8±0.5***	16.7±2.2*	11.3±1.7
3. Depletion rate for 30 min	1.54±0.09	0.99±0.06	0.66±0.07	0.44±0.06

Significances for the glycogen content values (in one group): * - $p< 0.05$, ** - $p<0.01$, *** - $p< 0.001$.

On the other hand, the glycogen depletion rate in m.tibialis anterior was higher than in m.soleus. The difference can't entirely be attributed to the higher glycogen content in m.tibialis anterior than in m. soleus. Indeed, in glycogen-poor m.tibialis anterior the depletion rate was higher than in glycogen-rich m.soleus, although the initial glycogen content in the former was less, than in the latter (see table 1). That means, that the difference in glycogen depletion rate depends both on metabolic pattern and initial glycogen content.

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SATELLITE CELLS IN ELECTRO-STIMULATED MUSCLE

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SUMMARY

The rat soleus muscle was maintained in an extended or in a shortened position and simultaneously electrically stimulated at low frequency for some hours to 3 days. The ultrastructure of those muscles was examined. More satellite cells were recognizable in all stimulated muscles (particularly in the muscle stimulated in extension) while compared to the controls, as soon as after 6h of experiment. The possible reasons of this phenomenon are discussed.

STATE OF THE ART

Satellite cells, identified by an electron microscope, are mononucleated fusiform cells lying beneath the external laminae of muscle fibres. The satellite cells are postulated to be the sole source of myonuclei added during the postnatal growth /1/. In the work-overloaded skeletal muscle the anabolic processes are accelerated and the number of muscle nuclei and of satellite cells increases /2/. In the muscle maintained in a shortened or in an extended position some reorganization of the contractile structure takes place /3,4/, while by work-overloading those processes are accelerated /5,6/. However, work-overloading in extension is a condition of muscle damage /2,7/. In the present work the number of satellite cells was evaluated in a muscle that has been electrically stimulated for some hours up to some days, and simultaneously maintained in an extended or in a shortened position.

MATERIAL AND METHODS

Adult female albino Wistar rats (160-180 g of body weight) were used. The soleus muscle was maintained in an extended or in a shortened position by immobilization of the ankle joint at an angle of about 90 or 160 degrees, respectively. Simultaneously the sciatic nerve was stimulated for some hours to 3 days by pulses of 0.3 msec of duration at a frequency of 20 Hz. In some experiments overloading of the soleus muscle in extension was also obtained by partial tenotomy of the synergistic muscle, gastrocnemius and by stimulation of the sciatic nerve. The following muscles served as controls: the soleus of the contralateral leg, the soleus of nonexperimental animals of the same group (intact) and the soleus stimulated at a free position. Immediately after the rats were decapitated, their complete soleus muscles were excised, while their length was maintained. The muscles were attached to plastic rods, fixed in glutaraldehyde-paraformaldehyde and embedded in Epon. All procedures were described in detail previously /4,6/. The ultrathin sections were inspected in a JEM 100B or a JEM 1200EX electron microscopes.
For quantitative evaluation of the satellite cells all muscle nuclei seen in the section were examined and counted. The number of the satellite cells was related to the number of muscle

fibre nuclei. It was expressed in per cent of the total muscle nuclei, i.e. those present within the external laminae of muscle fibres (muscle nuclei and satellite cells together).

RESULTS

The length of the control soleus (contralateral and intact) was about 20 mm. The length of the experimental muscles changed to 110 ± 2% and 82 ± 5% of the contralateral value for the muscle stimulated in extension and in shortening, respectively. The length of the muscles stimulated at free position was within the range of the contralaterals.

In all the stimulated muscles signs of the increased biosynthetic activity were found. Muscle nuclei were enlarged and made round with decondensed heterochromatin and prominent nucleoli, i.e. the so-called 'activated' nuclei (Fig.1). They were still situated in the subsarcolemmal space or sometimes translocated to central areas of the muscle fibres. Golgi apparatus and rough sarcoplasmic reticulum were frequently seen. Numerous polysomes were located both in the region of nuclei and among myofibrils (Figs.1,2). These characteristic features suggested the increased both transcriptional and translational activity. Numerous lysosomes were present showning the increased katabolic processes.

More satellite cells were recognizable (Fig.3) in all stimulated muscles while compared to the controls. They were, as a rule, larger and more round, and contained more cytoplasm compareing with the satellite cells of controls. The space between satellite cells and muscle fibres was often enlarged and it contained some material (Fig.4). The increased number of satellite cells was found as soon as after 6h of stimulation and remained at a similar level after 3 days of stimulation. The highest increase of the satellite cells number was observed in the muscle stimulated in an extended position (Table 1). Several irregularities of the contractile structure were observed, as previously described /4,6/.

TABLE 1

Number of satellite cells in the stimulated muscles

Treatment	% of satellite cells*		
	-	6h	2-3 days
Control (intact)	3		
Stimulated natural		9	7
Stimulated extension		11	10
Stimulated shortened		4.5	6

*Total number of muscle nuclei (present within the external lamina) was taken as 100%

DISCUSSION

The increased number of the satellite cells in overloaded muscle is a well-known phenomenon /2/. However, such a quick increase, after 6h, is very surprising and difficult to explain. In

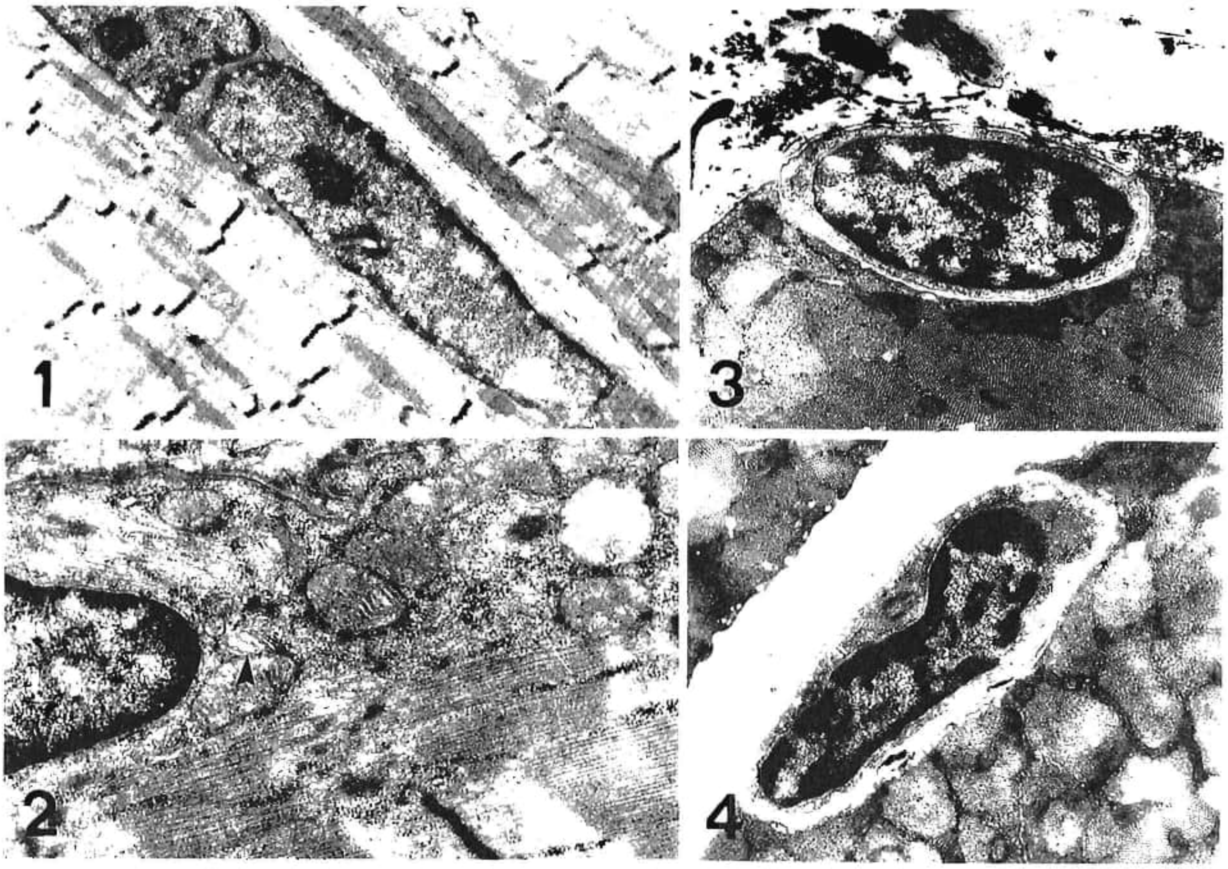

Fig.1.
Muscle stimulated in shortening for 4h; longitudinal section. Two 'activated' nuclei with decondensed heterochromatin and prominent nucleoli; the contractile structure irregular. X 6.000

Fig.2.
Muscle stimulated for 2 days; longitudinal section. Subsarcolemmal area. "Activated" nucleus (left-hand side); cisternae of Golgi apparatus (arrow); lysosomes (right-hand-upper corner); granular material, resembling polysomes in the subsarcolemmal space and between myofibrils. X 17.000

Fig.3.
Muscle stimulated in a natural position for 6h; transverse section. The satellite cell (central region); numerous collagen fibres in the intracellular space. X 12.000

Fig.4.
Muscle stimulated in extension for 6h; transverse section. The satellite cell; space between it and the muscle fibre enlarged, containing some material. X 13.000

literature /1,2,8/ some suggestions could be found, but no explanation of this phenomenon. Several alternatives might be considered here.

1) Satellite cells are much easier to get rcognized in the stimulated muscle than in any normal muscle. That could occur, for example, because of the enlarged space between the satellite cells and the muscle fibres. However, such enlarged space was also sometimes observed in the intact muscles.

2) It is likely that the increased volume of the satellite cells in the stimulated muscles, causes the presence of one satellite cell in the more numerous slides observed under electron microscope. However, the volume of muscle nuclei (to which satellite cells were related) seems to be increased as well.

3) Mitotic division of satellite cells. It is rather impossible: according to the present knowladge 6h is much too short for a mitotic division.

4) Not all the satellite cells, identified in this work according to the ultrastructural criteria, are the genuine satellite cells. For example, some cells of blood or blood vessels or of connective tissue could turn into satellite cells. Such possibility was suggested in the past; however, there is no evidence so far.

5) Another possibility is that some small split fragments of muscle fibres, containing nucleus, resemble the satellite cell.

Considering the above, we believe that the question is still open and under study.

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MEASURING OF SKELETAL MUSCLE'S DYNAMIC PROPERTIES

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SUMMARY

Many studies have been made to answer a polemical question - how do muscles work. One of the aspects is to study the muscle response - but how to measure it? Our main aim was to build a measuring system that would be simple to use, non-invasive, and would measure the muscle response direct to the muscle.

The measuring method that was used is based on a magnetic displacement sensor measuring the muscle belly radial displacement. The sensor is placed adjacent to the skin over the muscle and measures radial movements of the muscle belly. We observed the muscle response to electrical stimulation.

Different muscles or muscle groups have different responses. The parameter that was found to be interesting for studying was the rise time of the muscle belly response. Comparison of muscles' responses due to normalized rise time parameter confirms known division to 'slow' and 'fast' muscles. The parameter of a 'fast' muscle was four times greater than the parameter of a 'slow' muscle.

The aim of the study is to estimate how the measured data obtained with recent knowledge about skeletal muscles dynamics.

The proposed measuring method contributes to a better understanding of skeletal muscles' dynamic properties. It offers a possible way of studying the muscle structure from the muscle's response to electrical stimulation.

STATE OF THE ART

Skeletal muscles move the body and produce a force by shortening the muscle fibres. There are some methods for measuring a muscle force itself but these methods are invasive methods. Many different methods have been proposed and tested to measure muscle force indirectly. In dystrophic patients muscle responses have been measured by measuring the torque around a specific joint /1/. The early muscle changes in such patients are notified in tibialis anterior muscle. When the muscle response on electrical stimulation is measured, also an antagonistic group of muscles is activated. Therefor the torque around the ankle joint is a result of many muscles' responses. In standard procedure a doctor detects a muscle response visually and by touching the muscle belly with fingers.

This is also the idea of the measuring method based on a displacement sensor. The sensor is placed radial to the measured muscle directly to the skin over a muscle belly.

The advantages of this method over the torque measuring method are selectivity of measured muscles' responses and also general usage of the same equipment for all skeletal muscles laying close enough to the skin. The sensor measures muscle responses very near where the muscle contraction takes a place.

Previous measurements were made in muscle tibialis anterior in healthy subjects /2,3/ and in muscle gluteus maximus in persons after above-knee amputation /4/. In Rehabilitation Institute of Slovenia the measuring method is used in standard procedure in persons after above-knee amputation /4/.

MATERIALS AND METHODS

In our study, muscles' responses of one subject were measured. Responses of five different muscles were compared. The subject was male, 25 years old.

Electrical stimulation was provided by a single DC stimulus of 100 V and 1 ms duration. The two surface electrodes (self-adhesive rectangular 4 × 9 cm) were fixed to the skin 5 cm distal from measuring point toward both muscle insertions. The joint that specific muscle moves was left loose.

The measuring sensor was pressed to the skin above the measured muscle with the pressure of about 0.2 N/cm^2. The sensor was fixed to the bed on which the subject was laying during the measurement. The sensor was placed radial to the skin surface onto the measuring point. In the previous studies /2/ the position of a measuring point has been studied. The best results in long slim muscles were noticed on the point where the highest muscle belly displacement was detected. Measuring point of the measured muscles was on the proximal third of the specific muscle length.

The measured muscles were chosen by their muscle-fibres characteristics. Muscles quadriceps and brachioradialis have more 'fast' muscle fibres, muscle soleus is known as a 'slow' muscle. For comparison muscles gastrocnemius and tibialis anterior were also chosen.

The muscle belly response has been analysed by means of time parameters. The most interesting parameter for our study is rise-time of the muscle-response. The rise-time (Δt_r) is the time between 10 % and 90 % of maximum value of the muscle response (Figure 1).

$$v_b = \frac{\Delta d_r}{\Delta t_r}, \tag{1}$$

where v_b is a velocity of a muscle belly response, Δt_r is the rise time and Δd_r is a value of a muscle belly displacement during a rise time; it is 80% of a maximum value of the muscle belly displacement.

To compare rise time of different muscles it has to be normalized to a maximum value of a certain response (Equation 1). Normalized rise time Δt_r is connected with tangens of a response rise angle and estimates a velocity of a muscle belly response.

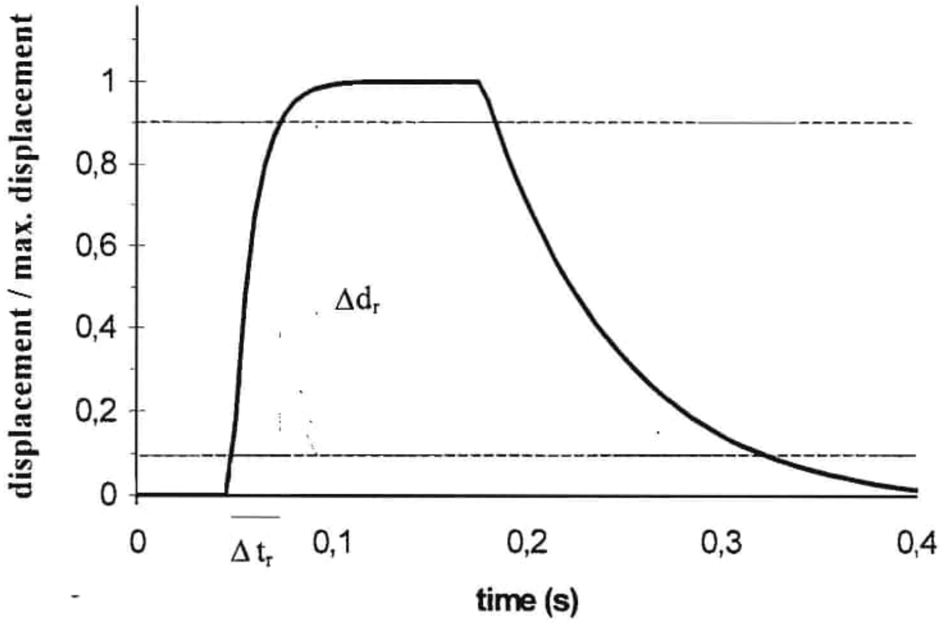

Figure 1: Muscle belly response to an electrical stimulus of 1 ms duration. The two parameters used for analysis are Δt_r- rise time and Δd_r - displacement during a rise time.

RESULTS

The results of the measurements were printed on the paper. The resolution error was estimated to be less than 5 ms on the time axis and less than 5 % full scale on the displacement axis.

Velocity parameter has been measured in five muscles (Figure 2, Table 1).

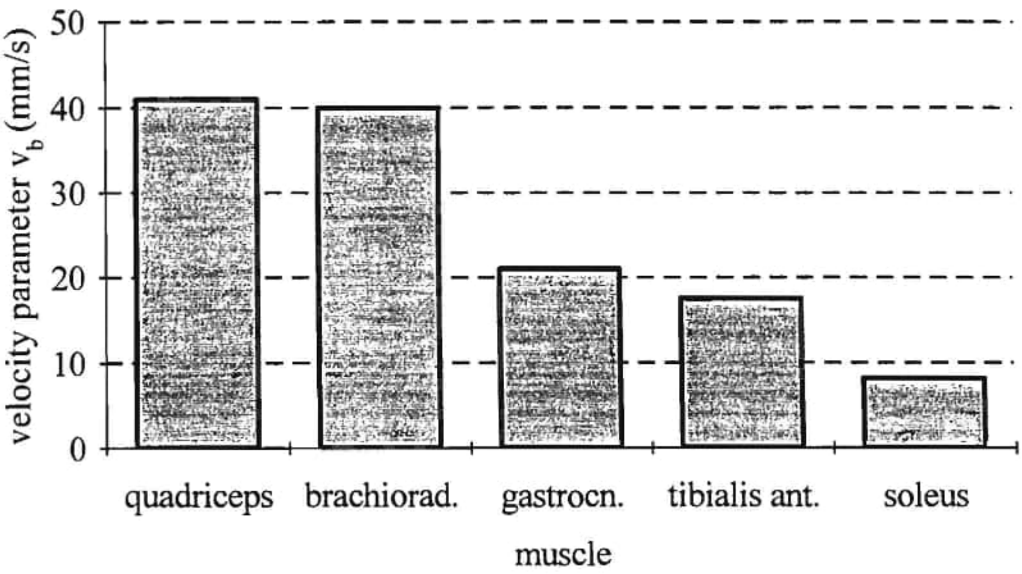

Figure 2: Velocity parameter v_b in five muscles.

MUSCLE	quadriceps	brachioradialis	gastrocnemius	tibialis anterior	soleus
v_b (mm/s)	41	40	21	17.5	8.2

Table 1: Velocity parameter v_b in five muscles.

DISCUSSION

Measurements of the muscle belly responses to an electrical stimulus revealed a difference between muscles. Most significant difference between muscles' responses is due to different muscle structure. In muscles quadriceps and brachioradialis we found velocity parameter v_b to be four times higher than in muscle soleus. Both, muscle quadriceps and muscle brachioradialis are known as fast muscles with more fast muscle fibres. Muscle soleus on the other hand is a slow muscle with a higher portion of slow muscle fibres. In muscles gastrocnemius and tibialis anterior the value of velocity parameter was in-between.

We believe measuring the muscle belly response with displacement sensor can be a valuable information of muscle structure in means of muscle fibres.

In this particular study it has been shown that the measured values of a velocity parameter v_b agree with recent knowledge about skeletal muscles dynamics.

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MUSCLE FATIGUE DURING MULTI-CHANNEL AND SINGLE-CHANNEL FES

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INTRODUCTION

FES (functional electrical stimulation) is used to restore lost muscle or organ functions. One of the major problem in FES is muscle fatigue during chronic or prolonged stimulation. Single channel stimulation is commonly used in most of the stimulation devices /2/. In single-channel applications controllability of the electrical field is limited to variation of electrical intensity (impulse parameters). Four to five electrodes are used in multi-channel stimulation, which enables the position and the extension of the electrical field within the nerve to be varied /5/. Therefore we evaluated an experimental model in sheep to compare the effect of single- and multi-channel stimulation on muscle force and fatigue.

MATERIALS AND METHODS

Experiments were carried out in 7 adult female sheeps. Anesthesia was induced by Thiopental and maintained by Halothane. The rectus femoris muscle was exposed on both hindlimbs and its distal tendon was attached to a strain gauge. Temperature was kept constant at 37°C. The femoral nerve was dissected on both sides. The branch to the rectus femoris muscle was localized and all other branches were transected. A cuff carrying 4 electrodes was positioned to the surface of the nerves. In case of single-channel stimulation only one pair of electrodes was used. For multi-channel stimulation four bipolar electrode combinations were selected to be changed from stimulation burst to stimulation burst /4, 6/. Stimulation parameters were identical for both configurations except the current amplitude (Tab. 1). At the beginning of each experiment maximal tetanic tension was detected for both muscles by varying the current amplitude. After 30 minutes pause for muscle recovery for both muscles the fatigue index according to Burke /1/ was determined in a two minutes stimulation sequence with maximum force contractions. For both nerves 4 electrode combinations with similar maximum force were selected and current amplitudes to evoke 25 to 50% of maximum force were determined. After another 30 minute pause a stimulation sequence over a period of one hour with registration of stimulation current and isometric contraction forces of both hindlimbs was performed. Data were scanned with a frequency of 300 Hz and stored for later analysis.

Table 1. Stimulation parameters.

Stimulation frequency	40 Hz
Pulse width	0.8 ms
Duration of stimulation	475 ms
Pauses between stimulations	1025 ms
Stimulation current amplitude range	0.5 - 4 mA

Mean force of one stimulus was evaluated every minute for the first 20 minutes of the experiment and later on every 5 minutes (FIG. 1). Fatigue indices were calculated using the following equation /1/:

$$FI(t) = \frac{F(t)}{F(0)}$$

where

FI(t) fatigue index at time t,
F(t) force at time t,
F(0) initial force.

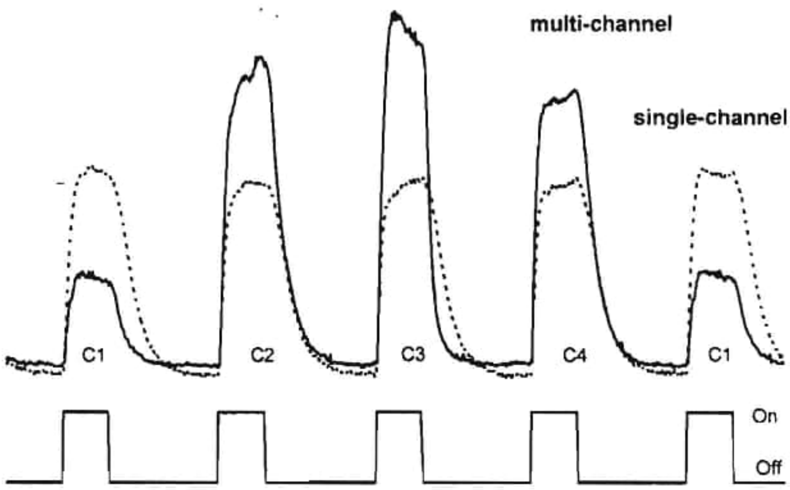

FIGURE 1
Stimulation (bottom) and evoked contraction forces (top) during multi-channel (normal line) and single-channel (dash-lined) stimulation (C1 - C4 indicate the different electrode combinations).

The mean value out of four subsequent contractions (4 electrode combinations) in multi-channel mode were compared to the samples from the single-channel side. Statistical comparison of fatigue index at different points of time was done with student's t-test. A probability of less than 5% ($p=0.05$) was considered to be significant.

RESULTS

Mean muscle force was higher in all cases at the multi-channel side compared to the contralateral side with single-channel stimulation. Therefore also the fatigue indices of the multi-channel stimulation were significantly ($p<0.05$) higher for all investigated time intervals (see Table 2).

Table 2. Fatigue indices of single- and multi-channel stimulation after different time intervals.

time / min	fatigue indices single-channel stimulation	multi-channel stimulation	
0	1	1	
5	0.54±0.26	0.75±0.11	*
10	0.47±0.19	0.67±0.11	*
20	0.35±0.17	0.54±0.15	*
60	0.21±0.10	0.41±0.21	*

(values: mean±SD, *: p<0.05)

Mean fatigue indices of multi-channel stimulation stayed approximately 20% higher beginning with the 5 minutes sample till the end of the sequence (60 minutes). The fatigue curves for both stimulation modes showed a saturation effect after 20 minutes (FIG. 2).

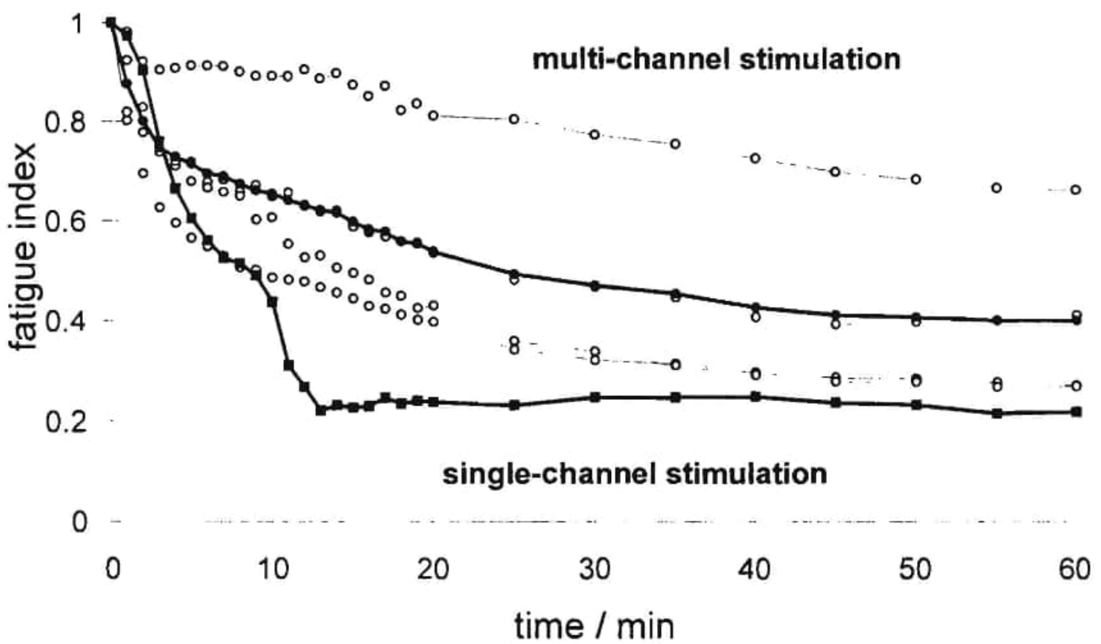

FIGURE 2
Example of fatigue curves: single-channel stimulation (■), multi-channel stimulation/4 electrode combinations (○) and multi-channel stimulation/mean (●).

DISCUSSION

Multi-channel FES leads to persisting higher muscle force and less muscle fatigue compared to single-channel stimulation at submaximal force levels /3/. Single-channel stimulation is still used for several chronic applications /2/. In clinical practice of chronic diaphragm pacing single-channel stimulation limits stimulation frequency to 8 to 10 Hz and respiration frequency to 8 to 10 per minute, whereas multi-channel pacing can provide physiological stimulation and respiration frequency /4/. We expect even greater differences between the two methods by optimizing the electrode combinations and impulse parameters.

The presented data show, that under our experimental conditions 20 minutes after the onset of stimulation no further fatigue occurs and that the remaining force level stays significantly higher for the multi-channel method. Considering also the clinical data of phrenic pacing we conclude, that multi-channel stimulation shows clear advantages compared to single-channel stimulation

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EFFECT OF MONOPHASIC AND BIPHASIC CURRENT TYPES ON TONIC AND PHASIC MUSCLE FIBRES. A COMPARATIVE IN VITRO STUDY

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SUMMARY

Several types of current (T.C.) can stimulate innervated striated muscle fibres. We used mainly mono- and biphasic rectangular currents for functional electrical stimulation (F.E.S.). The two types were compared for tonic and phasic muscles at several durations, varying between 50 and 600 μsec.
At the same intensity and pulse duration, a highly significant isometric contraction was obtained for phasic muscle with the biphasic T.C. when compared with the monophasic T.C.

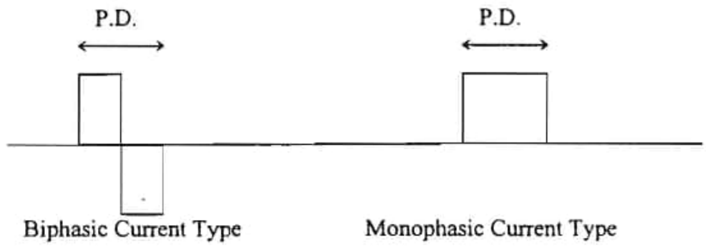
INTRODUCTION

By definition transcutaneous electrostimulation of innervated striated muscle fibres in F.E.S. is an indirect stimulation. The influence of the T.C. on the depolarisation of α_1 and α_2 motor neurons has hitherto not been investigated.
So far, a monophasic rectangular type of current has been used for stimulating the peroneus nerve.
The purposed aim of our in vitro study was to determine possible differences in effect between monophasic and biphasic T.C. at the same pulse duration and intensity.

MATERIAL AND METHODS

The soleus (a 99.9% tonic muscle) and the extensor digitorum (a > 90 % phasic muscle) were dissected in toto from the right hind leg of ten guinea pigs (8 ± 2 weeks old).
The muscle preparations were suspended in toto between two parallel platinum electrodes in Krebs' solution (95 % O_2, 25°C).
Prior to stimulation, the optimal tension of the preparation was determined. Afterwards the preparation was calibrated during one hour. Each preparation underwent at random 24 stimulation sessions of 10 sec. each. The intensity of the current was fixed at four times the rheobase of the preparation; frequency of current was 50 Hz. The pulse duration varied from 50 to 600 μsec. as well for the monophasic as for the biphasic rectangular T.C..

VISUALISATION OF THE CURRENT TYPES USED
Biphasic and monophasic current type



(The pulse-duration (P.D.) in the experiment ranged from 50 to 600μs (50, 100, 150, ..., 600 μs).)

Stimulation was done with a constant current stimulator. The electrically induced isometric contraction force was recorded on a linear graphic recorder. The isometric force was expressed in millinewton/surface x sec. The two tailed Wilcoxon test was used for statistical analysis.

RESULTS

The mean rheobase for the soleus muscle was 6.45 ± 2.2 mA (n = 10) and 6.33 ± 2.1 mA (n = 10) for the extensor digitorum muscle.
The same isometric contraction force was obtained with both T.C. for the tonic soleus muscle. However, a significantly higher isometric contraction force was recorded for the phasic extensor digitorum muscle after stimulation with the biphasic T.C., and this at all pulse durations tested.

DISCUSSION

It has been suggested in the literature that the inversed phase in the pulse current does not led to contraction, but it is important to simulate an apolar T.C..
Our study, however, shows that the inversed phase induces a contraction in both types of muscle fibres. The greater isometric contraction force recorded for the biphasic T.C. applied to the phasic muscle suggests that the abrupt reversion of polarity leads to an increased depolarisation of α_1 motor neurons.

In conclusion

With the same intensity and pulse duration a higher isometric contraction force is obtained for phasic muscle with a biphasic rectangular type of current than with a monophasic one.

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EFFECTS OF SURFACE ELECTROSTIMULATION ON HUMAN SKELETAL MUSCLE

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SUMMARE

Adaptative changes in skeletal muscle following surface electrical stimulation (SES) were investigated in the group male (n=8) volunteers between the ages of 25-33 years. SES was performed on the tibialis anterior (TA) muscle. The procedure was carried out for 7-weeks, using his technique of high frequency electrical stimulation (2500 Hz). A 7-weeks SES training was held every day for days with 2 days of rest. The effect a long-term frequency of SES on the force production and cross-sectional area (CSA) of the TA were investigated. Contracile properties of TA were tested before every week cycle. Maximal voluntary contraction (MVC) and electrically evoked contraction (EEC) at 100 Hz were increased by 18.6% and 27.6%, respectively ($p<0.05$). The highest increase of MVC and EEC is noted in 24 trainings and the effect maintains for 4.5 months. CSA of TA increased by 10% ($p<0.05$) and the highest increase is achieved after 20 trainings. A positive correlation ($r=0.90$) between MVC and CSA has been detected. After 7-week of SES procedure absolute voluntary force muscle made up by 40.6 N/cm^2 vs. 35.0 N/cm^2 before training and the highest value was detected in post-SES period 43.8 N/cm^2 ($p<0.01$). In post-SES period 165 days of MVC continues to increase with some decrease of EEC. During this period of CSA of TA decreases and reaches its initial value, that is, 6.95±0.68 cm^2.

STATE OF THE ART

In recent years a lot of works investigating of SES effrect on muscles both in clinical /1/ and actually healthy subjects have been published /2/. It is known that muscular loading /3/ is required to achieve optimal muscular force increase. In this case SES is considered to be a more effective than voluntary contractions to highten muscular contraction force /4/. Previosly developed method of SES included 15-19 trainings /5/. The purpose of this in investigation was to evalute the adaptative changes taking place in skeletal muscle following of more prolonged an SES program.

MATERIAL AND METHODS

A group of 8 healthy men aged 25-33 years were examined. Each subject was tested once before and after each exerimental condition.

SES consisted of isometric contractions of the TA of one of the limbs of the tested subject in response to the direct electrical stimulation induced by the device "Stimulus-01". Subjects were stimulated with a 2500 Hz alternating sinusoidal current surged at a frequency of 50 Hz with a 10-ms interval between each train /5/. The electrodes (7 cm x 2 cm x 2 mm) were placed at the proximal and distal margins of the belly of the TA, using a bipolar technique. The subjects trained while in the sitting position with the knee held in 90° flexion. The SES period encompasses ten sessions of electrical stimulation with one training session per day over a period of 7-weeks during which stimulation procedure was held daily for 5 days in succesion (from Monday till Friday inclusive). Then two days rest (Staturday and Sunday). Ten electrical stimulation induced maximum isometric contractions each lasting 10 s with a 50 s rest period, were performed. Every tested subject had 32 trainings.

The contractile properties of the TA were tested every week cycle (on Monday). Bipolar electrodes (their centres 18 mm apart) were placed on the skin abone the peroneus (fubularis) communis nerve, active electrode at the point of the lowers level - near the of the fibula. Rectangular pulses of 1 ms duration and supramaximal voltage with of 100 Hz were used to irritate the nerve. The recording two of Ag-AgCl surface electrodes (8 mm diameter) were placed on the lower part of the TA belly. The muscle surface action potentials were recorded and for measurement on a storage oscilloscope.

Maximum voluntary contraction was determined during three contractions of 2-3 s duration separated by 3 min. The largest of three contractions was cousidered as the MVC.

Method of ultrasonic echolocation was used to measure cross-sectional area (CSA) of the TA muscle /6/.

For the analysis, a paired Student's *t*-test was used.

RESULTS

After 10 of SES procedures the MVC increase more by 10%, and after 20 procedures more than 20% ($p<0.05$). Major MVC increase is achieved after 5 weeks (24 SES procedures) by 18.6% (243.3±37.3 N vs 289.4±51.0 N, respectively; $p<0.05$). Subsequent SES period don't cause substantial muscular force increase - MVC growth value has increased only by 2.9% ($p>0.5$). For the total SES training period MVC has increased up to 296.3±53.0 N ($p<0.05$). The absolute voluntary muscle force during the whole period of SES training was increasing and after 7-weeks of SES procedures and made up an average 40.6±1.2 N/cm^2 vs 35.0±1.5 N/cm^2 before the training. The greatest value of absolute voluntary force by 43.8±1.5 N/cm^2 was noticed of post-SES period ($p<0.01$).

After 24 of SES procedures (the 5h week) the EEC increase from 159.9±18.6 N to 204.0±41.1 N ($p<0.05$). Our results indicated that the EEC increases even to a more extent as compared to MVC by 27.6 % ($p<0.05$).

CSA of the muscle after 1-2 weeks of SES procedures increases by 10% from the initial value 6.95 cm^2 to 7.55 cm^2 ($p<0.05$). Moreover, the dynamics increase of CSA during the first 29 SES with the dynamics of muscular force growth. After 24 of SES procedures muscular CSA gradually decreases and by the end of the 32nd SES procedure (the 7th the week) amounts by 5.8% of the initial value.

When SES of the muscle ends the achieved effect of the MVC increase maintains during rather a long period for 165 days. At the same EEC somewhat decreases. Thus, for the first 32 days after the stimulation is over EEC growth decreases approximately twice as compared to largest growth during SES period (the 5th week) and further maintains as this level in an average for about 4.5 months. During post-SES period CSA of the TA decreases and reaches its initial level.

DISCUSSION

The adaptation on muscle contraction to SES training can be results of changes which occur within the nervoue command of muscle contraction and/or at peripheral sites. Among peripheral factor(s), working hypertrophy obviously, plays the role either due to the increasing of myofibrills constituting muscular fibres /7/, or due to the fibre splitting and their quantity increase /8/. Histological study showed the increase of myofibrills in the stimulated muscle or, in other words, muscular force increase resulted from high frequency stimulation is connected, first of all, with the development of intermuscular type of muscular hypertrophy /9/.

Physiological data obtained by us also support the concept of the peripheral factor. First, in the process of SES training muscular force increase is accompanied by CSA increase of the stimulated muscle. The results completely agree with the previously by the observation, according to which muscular force is proportional to muscular CSA /10/. Second, both MVC and EEC of the stimulated muscle simultaneously increase in response to SES. However, it should be noted that relative increase of EEC developed by the TA in response to the tetanic electrical irritation of the motor nerve at 100 Hz surpasses relative MVC increase. Supramaximal tetanic irritation of nerve allows us to assume that increase is resulted from peripheral factors solely, i.e., from changes in the properties of peripheral neuromuscular system /11/.

Morphological study reveal CSA changes in muscular fibres and, particularly, in type II fibres in case the training is the development of force properties /12/. In this connection from physiological point of view electrical training is the most effective one /9/. As in type of training larger and smaller motoneurons that innervate fibres type II and I, respectively, are activated according to the excitability of their axons /13/ while during voluntary contraction they are recruited according to the size principle /14/. Therefore, type II fibres are activated first and much more contribute to the general strain growth developed by the muscle /15/. This, is in contrast to the normal recruitment pattern, in when the smallest motoneurons (supplying type I fibres) are first recruited, the larger ones being recruited with increasing voluntary force. Thus, these facts support the concept of the decisive role of working hypertrophy of the TA fibres in the increase of MVC.

However, the analysis of the results obtained in post-SES period indicate that, evidently, another factors than muscle hypertrophy alone /16/ promotes the increase of voluntary force in the process of SES /17.

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WAVEFORM OPTIMISATION IN FES-EFFICIENCY STUDIES

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SUMMARY

This study describes experiments performed with an in-house, constant voltage stimulator able to deliver different pulse shapes applied to the muscles of normal volunteers, to indicate which types of waveforms would be the most comfortable, least fatiguing and most efficient in terms of the electrical power required to elicit a particular movement. The electrical efficiency of waveforms has been evaluated for Biceps using a comparison of stimulation levels required to achieve a fixed amount of elbow flexion for different stimuli. Further studies have been carried out on Tibialis Anterior by using a comparison of force/time profiles in response to different stimuli with the amplitude set each time to achieve dorsiflexion of the foot to a defined force level.

STATE OF THE ART

For successful functional electrical stimulation (FES), the stimulus waveform must be able to induce a smooth tetanic contraction with minimal discomfort whilst maximising the muscle torque and minimising fatigue[1,2]. Other studies have investigated stimulation modalities by using random tests on normal subjects with a range of differing stimuli[3,4,5,6]. With increasing emphasis on compact design, the electrical efficiency of a waveform is important especially for the development of body worn devices. It would seem logical to attempt to maximise battery life by improving the characteristics of the stimulation waveform. In this study, experiments have been performed to evaluate different shapes of stimulation waveform with respect to their electrical efficiency and comfort with a view to maximising design. This is part of a more broad EEC funded project, FESTIVAL, to develop key aspects in a closed loop FES control system.

MATERIALS AND METHODS

Waveform pulse shapes were generated on an HP8904A waveform generator and act as input to a high voltage amplifier (constant voltage stimulator) of Bristol design. Voltage and current waveforms at the skin surface were rectified and sampled on an HP54505B digitising oscilloscope. These two waveforms were multiplied and the resulting "power" waveform averaged over one pulse width in real time. This is a measure of stimulation waveform efficiency.

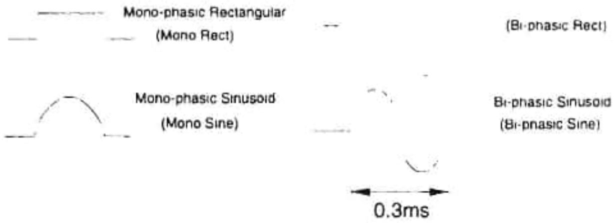
Stimulation of Biceps

For biceps the subject was seated with forearm resting on the table. The skin surrounding the muscle was cleaned with alcohol. A pair of 5cm diameter stimulation electrodes (PALS) were placed over the humerus. The stimulation amplitude was then increased slowly until the forearm lifted and increased further until the arm continued to rise and then pushed lightly against a fixed rod, thus transcribing an arc of approximately 45^0. At this point a power measurement was logged. The arm was allowed to rest and the study repeated for a range of stimuli. From this study, waveforms were chosen as a basis for further experiments on Tibialis Anterior and are shown in Figure 1. Inspection of Figure 2 suggested that 300μs pulses at 30Hz would be the most efficient waveforms for these experiments.

Stimulation of Tibialis Anterior

The subject was seated in a Tornville physiological measurement chair. An area of approximately 16 cm^2 of the proximal two thirds of the muscle bulk of Tibialis Anterior is cleaned with alcohol to minimise impedance. Two adhesive silver/silver chloride were applied over the proximal third, spaced vertically apart by approximately 1 cm. A third earth electrode is place nearby on the shin bone. These electrodes are connected to a differential input EMG preamplifier and used to monitor muscle electrical responses during voluntary and stimulated contractions. Two stimulation electrodes of 5cm diameter are placed over the muscle, one near the motor point, approximately at the mid length point of the muscle and the other at the distal end of the muscle.

Figure 1 Stimulation Waveforms selected for Tibialis Anterior Experiments



To establish the exact stimulation sites and stimulation levels the foot was first allowed to rest in the neutral position by placing the heel on the edge of a footplate and raising the stimulator output until dorsiflexion of the foot was achieved. If inversion or eversion was apparent with increasing stimulator output, the stimulating electrodes are repositioned such that minimal deviation was seen when the foot assumed dorsiflexion. The electrode sites were mapped onto an acetate sheet, marked with a 1cm grid, for future reference. The foot was then strapped to a force sensor attached to the foot plate. The height of the plate was adjusted for each subject so that hips, knees and ankles were at right angles and straps were used to retain the hips and knees in fixed positions. The subject was asked to produce a maximum voluntary contraction (MVC) for 20 seconds and allowed to rest for 10 seconds and EMG and force data were logged on the computer. The stimulator was switched on and its output raised to a level to produce a contraction equal to half the maximum voluntary dorsiflexion at which point both the average electrical power of the stimuli and the force generated were noted. The stimulation level was kept constant until the force had dropped to 50% of the starting force, and was then switched off. The subject was then asked to produce a second MVC for 20 seconds and the muscle allowed to rest for half an hour. This was repeated until all waveforms had been tested. EMG and MVC data were logged on the computer during this experiment to provide some indication of fatigue. However this analysis is not presented in this paper.

RESULTS

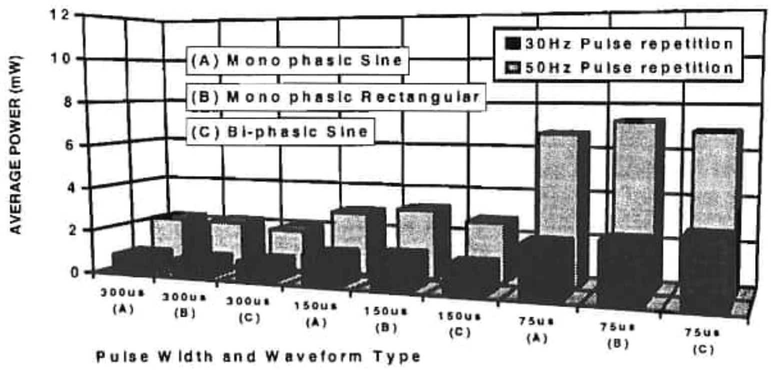


Figure 2 Comparison of three waveform types for Biceps

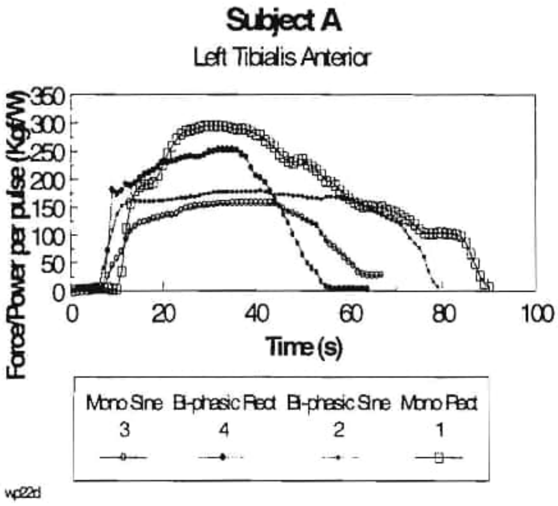


Figure 3 Force Profile, Subject A

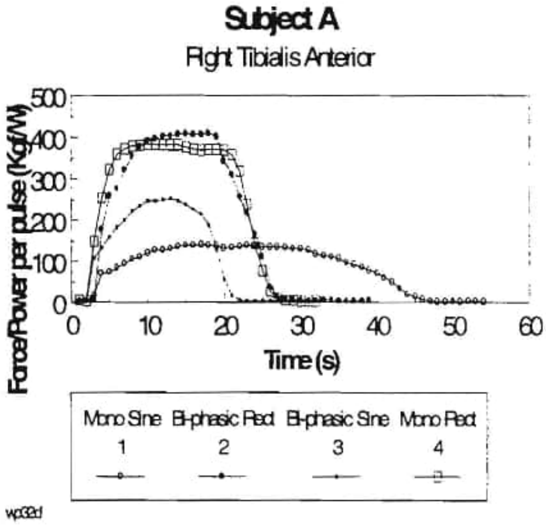


Figure 4 Force Profile, Subject A

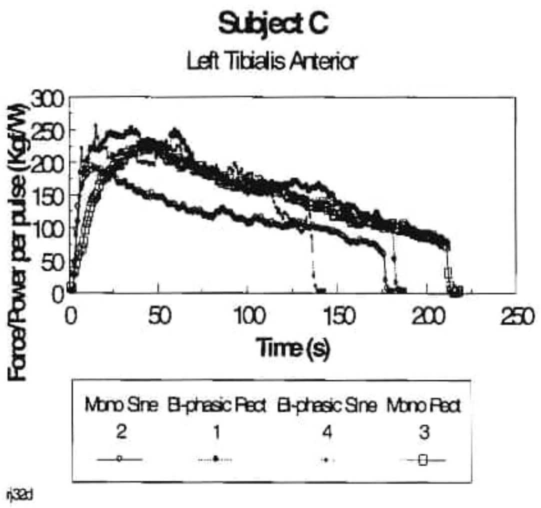


Figure 5 Force Profile, Subject C

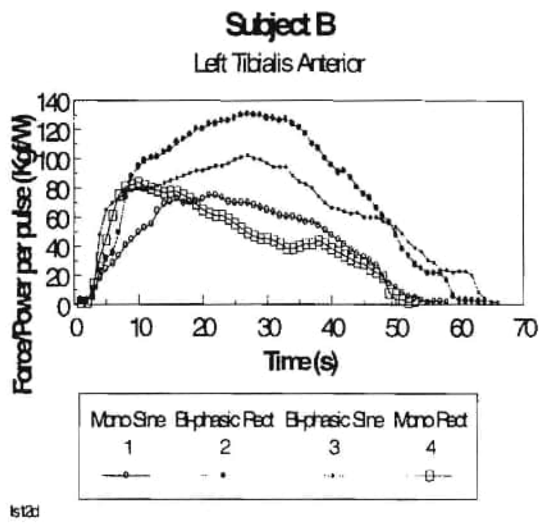


Figure 6 Force Profile, Subject D

DISCUSSION

For Biceps, the experiment was performed with waveforms having pulse widths of 300μs, 150μs and 75μs, at both 30Hz and 50Hz pulse repetition. Figure 2 shows average power dissipated at the skin surface for these waveform types. The average power was calculated by multiplying the power measured for one pulse by the pulse width and the square of the repetition frequency. All waveforms with the same pulse width show similar levels of average power. Waveforms showing the lowest average power are the more efficient. Therefore the most efficient methods of stimulation for this data were the 300μs pulse shapes at 30Hz repetition. The average power increases for all waveforms at 50Hz repetition simply because there are more pulses in one second.

Figures 3, 4, 5 and 6 show force profile plots for experiments performed on Tibialis Anterior. The force data has been scaled by dividing by the power per pulse. For these experiments the pulse width and repetition frequency was kept constant at 300µs and 30Hz respectively. A more efficient waveform would show up as having the highest peak force and the least fatiguing would have the longest time to 50% force drop. Figures 3, 4 and 5 suggest that the bi-phasic rectangular waveform was the most efficient and the mono phasic sine was the least. Figure 6 shows that the mono phasic sine was the least efficient and all the other waveforms displayed similar characteristics. For all volunteers in this trial it was a common feature that the mono phasic sine was by far the most comfortable and the bi-phasic rectangular the most distressing. The bi-phasic sine and mono phasic rectangular waveforms were perceived as having similar comfort ratings and lay somewhere between the bi-phasic rectangular and mono phasic sine.

In conclusion, it has been shown that for biceps, different waveform shapes show similar electrical efficiencies, but when used to generate force using Tibialis Anterior, some force profiles show different responses. Further work will be to continue with experiments, to more closely define these differences with a wider group of normal subjects and those with Multiple Sclerosis.

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HALF-DAY ELECTROSTIMULATED SHEEP LD IS FATIGUE RESISTANT IMPLICATIONS FOR DYNAMIC CARDIOMYOPLASTY

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SUMMARY

The sustainable working capacity of fatigue-resistant muscle is a constraint of dynamic cardio-myoplasty. Fatigue-resistance at relatively high sustainable power output is achieved by different electrostimulation patterns which are implementable in clinical settings. We are testing the effects on functional and structural characteristics of the sheep LD of a half-day protocol which strictly mimics for any other parameter the clinical protocol actually tested in FDA trials. Results are encouraging, since the muscle maintains its mass and an intermediate state of fast to slow transformation. With the actual protocol we find only minor changes of power output in comparison to the standard protocol. Major result is the demonstration that the life-span of implantable devices is more than doubled. Resting the muscle each day for periods of several hours decreases risk of muscle damage. Accidental experiences demonstrate that periods of several hours or days of LD resting are not detrimental to patient's cardiac function, but questions remain if the new pattern of cardiac assistance, which open new options (muscle hypertrophy oriented, included), is acceptable on regular basis in clinical settings.

STATE OF THE ART

Fatigue resistance at moderate power output is achieved in two-three weeks and is dependent from increased oxidative metabolism, calcium handling, but not changes in contractile machinery /1/. The level of sustainable power output of fatigue-resistance-converted muscle is one of the major constraint of skeletal muscle-cardiac assistance /2,3/. Fatigue resistance at relatively high sustainable power output could be achieved by different patterns of muscle stimulation, and long-term fatigue resistance is maintained in spite of short-term (hour or day) changes in overall muscle activity. Evidence are: 1) for long-term changes the conditioning-deconditioning experiments in rabbit /4/ and sheep /5/; 2) for short-term changes: i) anecdotes of clinical experience of electrostimulation disconnection without detrimental effects or major worsening of hemodynamic results during or after one-day of cessation of electrostimulation /6-10/; ii) animal experiments with 8 or 12 hrs per day electrostimulation (for review see /1/); 3) for very short-term changes: the data here reported and those of others during sessions of power and fatigue testing /11-13/.
We are studying the effects on power output and on anatomical and molecular characteristics of the sheep latissimus dorsi (LD) of a half-day electrostimulation protocol which strictly mimics for any other parameter the clinical protocol which is under FDA testing /14,15/. Preliminary data show that an intermediate state of muscle transformation can be maintained if muscles are activated height-ten hours per day. The results are interesting, since: i) the muscle maintains its mass and the half-day electrostimulation prolongs the life-span of the devices; ii) interrupted electrostimulation (one hour on / one hour off) is known to be less damaging than continuous electrostimulation /16,17/, being the slow fibres more susceptible to exercise-induced muscle damage /18/; and iv) partially transformed muscles are expected to be more powerful /19,20/.

MATERIALS AND METHODS

Surgical procedures and measures of dynamic characteristics of sheep LD were performed at the Experimental Surgery Unit, Cardiovascular Institute, University of Bologna, S. Orsola Hospital, Bologna; histochemical and molecular analyses on muscle specimens were accomplished at the Department of Biomedical Sciences, University of Padova. Methods are detailed in /21/.

RESULTS

Three sheep were implanted and final stimulation protocol according to /14/ was achieved in two sheep. After four and six months of ten hours per day electrostimulation at 3 V, 130 msec train at 30 Hz every 1.5 sec (40 tetanic contractions per min) major results are: i) Muscle gross mass does not decrease, as is the obligatory results of all-day electrostimulation patterns. Myoglobin, a molecular marker of oxidative

Table 1. Sheep LD conditioning: 24 vs 12 hrs per day cardiac-like electrostimulation

	Weight (gr)	MHC1 (%)	Myoglobin (%)
24 hrs per day electrostimulation			
Control unstimulated LD		14	0.72-0.59
2-month stimulated LD		95	0.35-0.98-0.80
12 hrs per day electrostimulation			
Sheep Bo94-1			
Control LD	180		
axilary edge biopsy		8	0.88
central biopsy		20	n.d.
Four-month stimulated LD	185		
axilary edge biopsy		68	0.85
central biopsy		60	n.d.
Sheep Bo94-2			
Six-month electrostimulated LD			
ascellar border biopsy		65	0.27

myofibers, only slightly increases (it remains near to 4 % of total muscle proteins, that is near to 0.6% of tissue weight). MHC1 (the peculiar marker of slow-type, fatigue-resistant myofiber /22/) increase from 20% of normal LD to 60-65%, but does not achieve the 100% transformation which usually occurs in continuous electrostimulation (Table 1). These results are in keeping with the rabbit 12 hr per day experiments discussed in Pette and Vrbova /1/ vs the 24 hrs per day electrostimulation experiments performed by Salmons and collaborators /4/. The contractile characteristics are also incompletely converted: in the normal LD tetanic fusion was obtained at stimulation frequencies higher than 40 Hz, while after one month of 24 hrs per day conditioning the tetanic fusion was complete at 20 Hz /2/, after half-day electrostimulation the tetanus is unfused at 20 Hz /21/. After half-day electrostimulation sustainable power output is similar to that extractable from a 24 hrs per day electrostimulated LD (about 0.5 watts per LD, i.e., more than 2.5 watts per kg /2/). When the power output was doubled either by increasing duration of the tetanic contractions or the in-burst frequency, a fatigue index of about 80 (that is there was a loss of 20% power) was present after 3 min. If the power output was maintained four times higher than that continuously sustainable, the muscle fatigued in less than one minute. Sustainable level of power was obtained after short-time rest (a few minutes), that is, a moderate power out-put (30-50% of left ventricle mean power output) is maintained in spite of short-term (20-30 sec) increase of work demand up to four times the sustainable power output. During several hours of measurements the sustainable power output was maintained, even after manifested fatigue due to increased demands. Interestingly, the sustainable power was achieved with electrostimulation parameters very close to those of the final setting of the conditioning protocols. Questions worth to be tested are: could the muscle be conditioned with more demanding electrostimulation protocols? Could such an increased activity be imposed without long-term muscle damage?

DISCUSSION

Our results confirm that an intermediate state of muscle transformation can be maintained by half-day electrostimulation even in species, like the sheep, in which full conversion to slow type contractile properties and to slow myosin is achieved with tetanic cardiac-like electrostimulation or even with 2 Hz continuous electrostimulation, but applied all the day around. Resting the muscle each day for periods of several hours would decrease the risk of muscle damage. Experimental studies in rabbit show that substantially less muscle damage than in continuous electrostimulation had been observed in one hour on / one hour off electrostimulation /16/. Chekanow confirms that after dynamic cardiomyoplasty there is no need to stimulate the LD every heart contraction, and suggests that hour-periods of muscle rest could be introduced in the stimulation regimen. We here demonstrate that the Magovern enthusiasm for such a proposal could stand on experimental evidence. The question remains if the patients could accept such a pattern of cardiac assistance. Occasional experiences of a few surgeons demonstrate that such an approach (which open a full set of new options) is not detrimental /6-10/. The higher freedom in activating the patient's LD could add to pre-operative physical training /23/ the long-standing advantages of muscle hypertrophy-oriented daily electrostimulation sessions. In any case, a major result of our preliminary observations is that the life-span of implantable devices could be more than doubled.

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EFFECT OF ADAPTIVE PULSE TRAIN DURATION ON LATISSIMUS DORSI BLOOD FLOW

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SUMMARY

Blood flow, intramuscular pressure, and stroke work of the trained latissimus dorsi muscle (LD) were measured during electrical stimulation at contractions rates between 20 and 160 per minute using pulse trains of 2 to 6 pulses in length. Epimysial electrodes and intramuscular pressure sensors were implanted in the LD of five dogs. The muscle remained *in situ*. After 12 weeks of a progressive training protocol, LD blood flow (BF) was measured using an ultrasonic flow probe and work (SW) was determined from the measured force and shortening. For pulse trains of 2 or 3 pulses, BF increased with rate and SW was maintained at all rates. For 4 pulses, BF and SW decreased when the contraction rate exceeded 120 per minute. SW decreased above 100 per minute and 80 per minute for 5 and 6 pulses respectively. An upper rate limit dependent on the pulse train duration exists above which BF and SW decline. Exceeding these upper rate limits should be avoided in cardiomyoplasty. Excessive stimulation rates could be detrimental to the muscle by creating a metabolic insufficiency or ischemia. The cardiac assist benefit is compromised as SW declines during high contraction rates of long pulse train duration.

STATE OF THE ART

The latissimus dorsi muscle (LD) is used in cardiomyoplasty to assist the failing heart. The LD is surgically wrapped around the heart and stimulated with a cardiac-synchronized, 30 Hz pulse train, typically six pulses in duration. We have found previously that for this pulse train duration, contraction rates of 80 per minute or more result in reduced power output and decreased LD blood flow /1/. First generation cardiomyostimulator systems do not allow flexiblity in programming shorter pulse trains. The LD, therefore, has historically been stimulated every other heart beat to prevent contraction rates that exceed the sustainable work rate of the muscle as the heart rate rises. The upper rate limit of the LD, however, is expected to be dependent on the duration of the pulse train. The new Transform™ Cardiomyostimulator (Model 4710, Medtronic, Inc.) allows the number of pulses in the pulse train to be programmed. It also has the feature of adaptive duration which automatically shortens the pulse train by truncating the number of pulses. Theoretically, the LD may provide greater cardiac assist if it is contracting with every heart beat. With adaptive duration, the LD may be able to contract at higher rates without impaired performance. The present study was undertaken to determine the upper rate limit for varying pulse train durations.

MATERIALS AND METHODS

Experimental methods
Five mongrel dogs (20 to 25 kg) underwent implantation of epimysial electrodes (Medtronic, Inc.) on the left LD over the main thoracodorsal (TD) nerve. The electrodes were connected to a pulse generator (Itrel II, Medtronic, Inc.) implanted in a subcutaneous pocket over the abdomen. A pressure sensor (Model 4321, Medtronic, Inc.) was implanted in the mid-region of the oblique segment of the LD for later monitoring of intramuscular pressure (IMP). It was connected to a percutaneous access port implanted in the abdominal region. Needle electrodes were later used to gain connection to an external amplifier.

After a two week healing period, the muscles were stimulated *in situ* according to a 10-week progressive training protocol. A 30 Hz train of 6 pulses (210 μsec pulse width) was initially delivered at a rate of 5 pulse trains per minute (ptpm). The rate was increased every two weeks up to 46 ptpm. The stimulation amplitude averaged 1.5 V and was selected to be the minimum amplitude at which stroke work was maximal.

At the end of the training period, the TD neurovascular pedicle was again surgically isolated and a 2-mm ultrasonic flow probe (Transonic, Inc., Ithaca, NY, USA) was placed around the TD artery. The wound was closed, and the forelimb was attached to a contraction monitoring system that incorporated a force transducer (Model LCF-25, Omega Engineering Inc., Stamford, CT), a linear displacement transducer (Model LD600-25, Omega Engineering Inc., Stamford, CT), and an adjustable afterload weight. Force (F), shortening (ΔL), TD blood flow (TDBF) and IMP during afterloaded contractions were simultaneously recorded on a PC using CODAS data acquisition software (DATAQ Instruments, Akron, OH) at 500 Hz per channel. The afterload weight was typically 0.5 to 1 kg and was selected during each monitor such that shortening was maximal but within the range of the linear displacement transducer.

The pulse generator was programmed to deliver 30 Hz pulse trains, or bursts, of 2 to 6 pulses at rates of 20, 30, 60, 80, 100, 120, 140, or 160 ptpm in a random order. TDBF, F, ΔL, and IMP were recorded continuously for 60 seconds. A resting period of 5 minutes was allowed between stimulation episodes to prevent prolonged fatigue and allow TDBF to return to resting levels.

At the end of each experiment, biopsies were taken from the oblique section of the left and right (control) LD and snap frozen in methyl butane pre-cooled in liquid nitrogen. Myosin ATP-ase staining was performed to assess fiber-type transformation.

Data analysis

The peak F and ΔL were determined at the onset of stimulation and after 60 seconds of stimulation. The mean TDBF and IMP during a 10-second interval were determined after 10 seconds and 60 seconds of stimulation. The pressure sensor measured relative pressure changes. All results are reported as the mean $\pm$ standard error. ANOVA factorial analysis was performed to determine the effect of rate and pulse number on BF and SW. Paired t-tests were performed to determine change in fiber type percentages. A p-value less than 0.05 was considered statistically significant.

RESULTS

Transformation to 100% Type I fibers occurred in three dogs. Partial transformation occurred in the remaining two resulting in an average of 80 $\pm$ 13% Type I fibers in the left LD (stimulated) compared to 31 $\pm$ 4% Type I fibers in the right LD (unstimulated).

Resting TDBF was 6.8 $\pm$ 0.2 ml/min and did not vary over the course of a study. The muscles weighed 104 $\pm$ 3.8 grams. Since blood flow supplied by collateral vessels remained intact but was not measured, TDBF can not be accurately expressed in a per gram basis. TDBF increased 52 $\pm$ 11% during the least demanding stimulation mode, 2 pulse bursts at 20 ptpm. The highest increase was 480 $\pm$ 129% which occurred at a rate of 120 ptpm when 5 pulse bursts were delivered. TDBF increased with rate over the entire range tested for pulse trains of 2 and 3 pulses ($p = 0.03$, Figure 1). TDBF increased with rate up to 120 ptpm during 4 and 5 pulse bursts ($p = 0.01$ and $p < 0.001$, respectively). TDBF decreased at rates above 100 ptpm when 6 pulses were used.

Similarly, ΔL decreased above 100 ptpm for 6 pulses ($p \leq 0.01$), 120 ptpm for 4 pulses ($p \leq 0.05$) and didn't change with rate for 2 pulses. The highest SW for all rates combined was achieved when 5

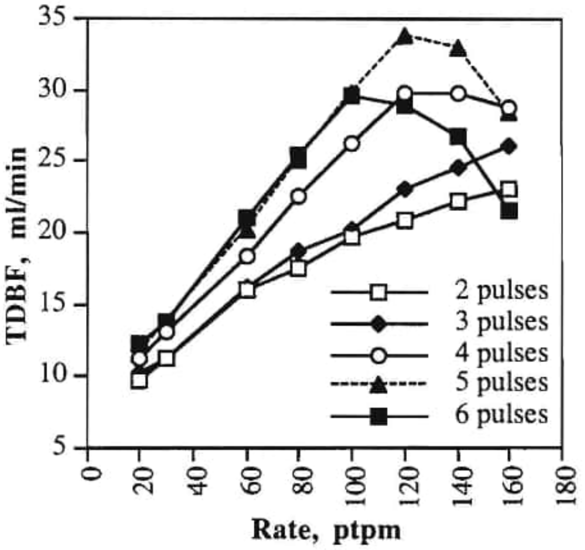

Figure 1. TDBF is shown at each stimulation rate for pulse trains of 2, 3, 4, 5 and 6 pulses.

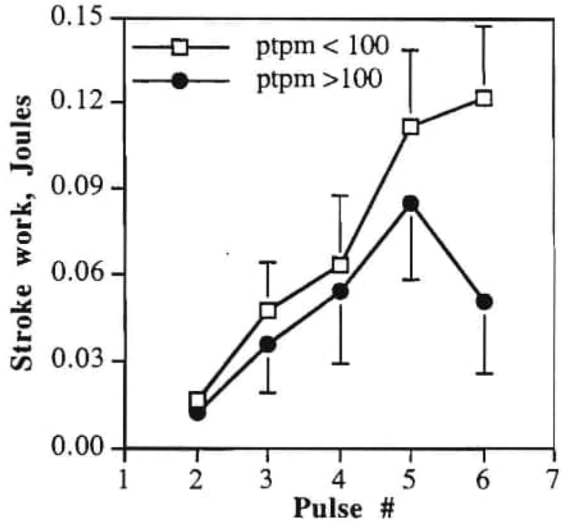

Figure 2. SW increases with pulse number at rates less than 100 ptpm (p = 0.01). When the rate exceeds 100 ptpm, the SW decreases during 6 pulse bursts.

pulses were used. For rates less than 100 ptpm, SW increased with pulse number (p = 0.01) ranging from 0.016 $\pm$ 0.004 Joules during 2 pulse bursts to 0.122 $\pm$ 0.036 Joules for 6 pulse bursts (Figure 2). However, when the pulse train rate exceeded 100, the highest SW occurred when 5 pulses were used . The maximum rate at which SW was maintained was 80 ptpm for 6 pulses, 100 ptpm for 5 pulses, 120 for 4 pulses and greater than 160 ptpm for 2 and 3 pulses.

Mean IMP increased significantly with rate ($p < 0.01$) and pulse number ($p = 0.03$). IMP increased 46 $\pm$ 27% during the least demanding stimulation, 2 pulses at 20 ptpm, up to 470 $\pm$ 212% during 6 pulse bursts at 160 ptpm. Even though SW declined during this most demanding mode, IMP remained high suggesting an elevated tension was maintained without cyclic shortening. The increase in IMP is shown versus total pulses per minute (ppm) in Figure 3. Corresponding values for the increase in TDBF are plotted. TDBF begins to decrease when the total ppm exceeds approximately 600. This corresponds to the upper rate limit at which TDBF was maximized for each duration; 120 for 5 pulses (600 ppm) and 100 for 6 pulses (600 ppm).

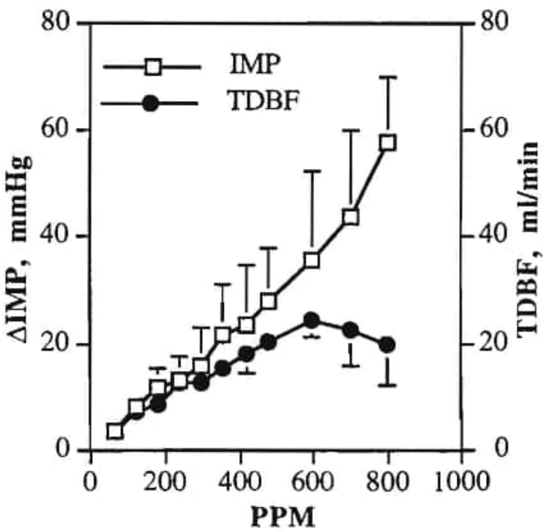

Figure 3. The increase in IMP and TDBF is shown against the total pulses delivered per minute.

DISCUSSION

An upper rate limit exists above which the LD is incapable of sustaining a constant work rate and TDBF declines. This upper rate limit depends on the duty cycle of the pulse train. For very short pulse trains, 2 or 3 pulses delivered at a frequency of 30 Hz, the upper rate limit is greater than the maximum rate of 160 ptpm tested in this configuration. As the pulse number is increased, the upper rate limit decreases. An upper rate limit of 80 ptpm was found previously when the LD was configured into a skeletal muscle ventricle and stimulated with 6 pulse bursts /1/. This limit is lower than the limit found in the present study suggesting that the upper limit will also depend on loading conditions. In the current study, the LD worked only against an afterload. When the muscle is preloaded, as in our previous study, increased resting tension will cause a higher resistance to BF. Resting BF decreases with increasing preload /2/. This decrease in resting flow likely imposes further limitations on the maximum sustainable work rate of the LD.

Mean IMP, averaged over time during stimulation, increased with both contraction rate and pulse number. Mean IMP was proportional to the total time that the LD is contracted. The rise in IMP is a likely cause of decreased TDBF at high duty cycles. Incomplete relaxation occurs at high rates of long duration resulting in a continuously elevated IMP, increasing the resistance to blood flow. Upon cessation of stimulation, a hyperemic response was always observed. This hyperemic response did not occur as long as stimulation was being delivered even when fatigue was apparent. At high rates of longer duty cycle, shortening did not occur after 60 seconds of stimulation, but some level of developed tension and elevated IMP was maintained, probably restricting TDBF.

The reduction in TDBF at high duty cycles could also be a normal autoregulatory response to reduced work output. Since the muscle is performing less work, the demand for blood flow is reduced. The reduction in external work could either be the result of the inability of the metabolic capacity, not associated with reduced substrate delivery, to keep up with the contractile demand or inappropriate myosin-actin overlap. After the initial contractions, the slow-twitch muscle no longer reaches complete relaxation between contractions making the next contraction less efficient due to inappropriate sarcomere overlap.

Understanding the efficient working limits of the trained LD is important in optimizing its ability to assist cardiac function in cardiomyoplasty. Stimulation patterns that result in reduced work performance and reduced TDBF should be avoided. Using adaptive muscle burst duration reduces the work performed during each contraction but allows the muscle to contract at a higher rate and still perform within its sustainable working capacity. Wtih adaptive duration, stimulation with every heart beat is feasible rather than every other heart beat as done previously, potentially increasing the benefit of cardiomyoplasty during increased physical activity.

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INFLUENCE OF THE FREQUENCY OF STIMULATION ON MECHANICAL PROPERTIES OF CANINE LATISSIMUS DORSI MUSCLE

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SUMMARY

The mechanical properties of canine Latissimus Dorsi (LD) were studied with two protocols of stimulation: 30 Hz (F_{30}; duty cycle = 0.20) and 100 Hz (F_{100}; duty cycle = 0.07) in isometric and isotonic contractions. Isometric Tension, velocity of shortening and shortening displacement were measured in control and after repetitive stimulation (fatigue test). In control state F_{30} group developed greater isometric tension than F_{100} (8.4±1 vs. 7.5±0.9 Ncm^{-2}) with smaller rate of tension development (49.7± vs. 73.7±4 $Ncm^{-2}s^{-1}$). F_{30} and F_{100} showed similar mean peak values of velocity of shortening and displacement (28.7±1vs.32.3±3 cm/s and 3.9±0.3 and 3.2±0.3 cm, respectively). Fatigue induced 19% decrease in F_{30} and 10 % in F_{100} in isometric tension. Shortening decreased to 46.5±7 and 64±10% and velocity to 48±6 and 63±9% in F_{30} and F_{100}, respectively. These results showed that repeated contractions with shortening induced greater fatigue than isometric contractions. Accordingly, F_{100} group showed smaller fatigue suggesting that this protocol may be more beneficial to the muscle in cardiomyoplasty.

STATE OF THE ART

The first clinical application of electrically stimulated Latissimus Dorsi muscle as an autologous pump to assist the failing heart /1/ was followed by its application in several centers /2/. Based upon its favorable clinical results this technique, called dynamic cardiomyoplasty, has been indicated as a treatment for heart failure. However, many aspects of the contractile behavior of the electrically stimulated LD muscle have not yet been thoroughly studied. In this work, evaluation of some of the canine LD muscle's mechanical properties was performed in isometric and isotonic contractions.

MATERIALS AND METHODS

Surgical procedures were performed on anesthetized and artificially ventilated mongrel dogs (17±1 kg body weight). Blood gases and pH were monitored and maintained within

adequate levels. Body and muscle temperature were monitored and maintained at 37-40°C and 30-33° C, respectively with the help of a water filled heating pad beneath the animal and a heating lamp nearby the muscle. The LD muscle was dissected free of surrounding tissues while preserving its main blood supply and nerve after which two intramuscular electrodes were implanted. For more detailed description please refer to /3/.
After surgery, a period of 1 h was allotted for stabilization of the preparation. Two frequencies of stimulation were utilized: 30 Hz with a duty cycle of 0.2 (F_{30}) and 100 Hz with a duty cycle of 0.07 (F_{100}). The remaining parameters of stimulation for both groups were the same (1 ms pulse width, supramaximal amplitude at a rate of 60 contractions per minute). Animals were divided in two groups for isometric (n=3,30 Hz and n=3,100 Hz) and isotonic (n=4,30 Hz and n=5,100Hz) tests.
In isometric contractions, force measurements were performed in control and after fatigue stage. Optimal muscle length was determined /3/ and five contractions were elicited with muscles at this length. After 30 min. interval, fatigue test was performed with stimulation provided for 2 min.
In isotonic contractions displacement and velocity of shortening were measured for loads adjusted to 13, 27, 53 and 80 N. After 30 min rest, a fatigue test was performed (2 min) with 27 N load.
Values are presented as mean ± SEM with isometric tension normalized to muscle cross-sectional area /4/. Statistical comparisons between means of different groups were made by independent t tests and a repeated analysis of variance (ANOVA) was performed on the fatigue data and isotonic contractions at increasing loads.

RESULTS

Peak isometric tension (IT) in control was similar for both groups F_{30} and F_{100} with the latter showing greater rate of tension development (T/ t_{50}: ratio of tension at 50% amplitude by its respective time interval). Fatigue index (ratio of tension at 120 s to initial tension) was greater for F_{30} These results are shown in table 1.

Table 1. Isometric characteristics

	F_{30}	F_{100}
IT(Ncm^{-2})	8.4±1.1	7.5±0.9
FI	0.9±0.03	0.8±0.02
T/t_{50} (Ncm^{-2}/s)	49.7±5	73.7±4*

Values are means ± SEM, * $p \leq 0.05$

Displacement and velocity of shortening obtained for the different loads studied are shown in Figure 1 and Figure 2, respectively.
After fatigue, shortening displacement decreased to significantly smaller values compared to their controls (46.5 ±7.2% in F_{30} and 64±10% in F_{100}) and so did velocity (48.2±6.2 % and 63±9% in F_{30} and F_{100}, respectively).

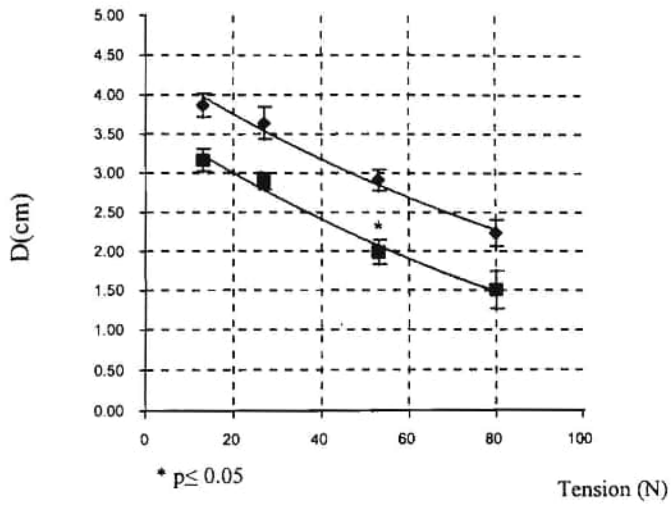

Fig.1. Displacement (D) for increasing loads (Tension) at 30 Hz (◆) and 100 Hz (■).

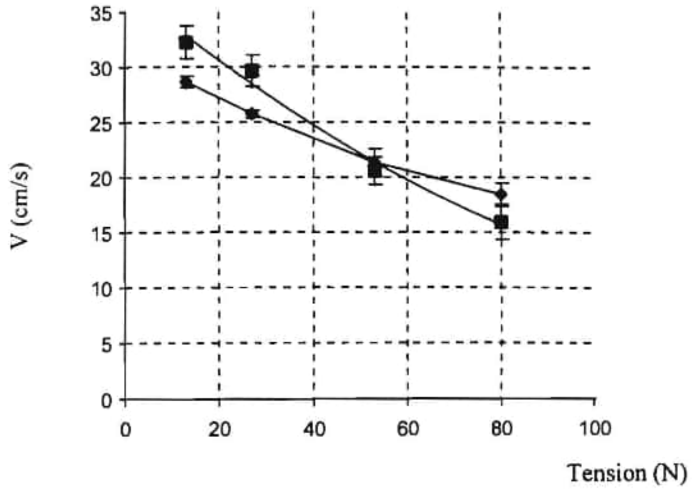

Fig.2. Velocity (V) for increasing loads (Tension) at 30 Hz (◆) and 100 Hz (■).

SUMMARY AND DISCUSSION

Two protocols of stimulation were studied using 30 Hz stimuli with 0.2 duty cycle and 100 Hz stimuli with reduced duty cycle of 0.07. In control state both protocols of stimulation resulted in similar mean peak values for the mechanical properties studied either in isometric or isotonic conditions. Comparing the variations induced by fatigue after 2 min. of repetitive contractions, it was seen that isotonic contractions produced variations of greater magnitude compared to contractions with no shortening. These findings are in agreement with results obtained from the mouse diaphragm /6/ and canine diaphragm/7/. Even though comparing these two types of contractions is not direct due to the many differences in muscle energetics, our results suggest that shortening contractions represent an increased demand for the muscle. Since mean peak values of velocity of shortening and displacement were the same for and F_{30}. Also, smaller reduction due to fatigue was found in F_{100}. These preliminary results suggest that this latter protocol may be more beneficial to the muscle used in cardiomyolplasty although further investigation is necessary for more decisive results.

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FES OF M. LATISSIMUS DORSI FOR CIRCULATORY ASSIST IN SHEEP

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Summary

Three series of experiments concerning circulatoy assist by skeletal muscles were undertaken. First a conditioning program for the transformation of the latissimus muscle into a fatigue resistant one was developed. Secondarily cardiomyoplasty using a divided latissimus muscle was perforemd. Finally a new skeletal muscle ventricle consisting of a kryopreserved aortic homograft and the latissimus muscle was designed.

State of the Art

Circulatory assist by skeletal muscles has been carried out mainly in two different forms [1]: Skeletal muscle ventricles (SMVs) consisting of various prostheses and a stimulated muscle wrapped around have not been applied clinically so far due to the unsolved problems of the artificial surface of the prostheses. Cardiomyoplasty has been carried out in more than 300 human patients. This method was introduced about 10 years ago as therapeutic approach to end stage cardiac failure [2]. The latissimus dorsi muscle is wrapped around the heart and stimulated chronically. However the final results of this procedure are in general inconsistant. An objective recording of an improvement of circulatory parameters due to the contribution of the stimulated muscle has always been difficult [1,3-5].

Circulatory assist by skeletal muscles requires a muscle which is able to contract without fatigue over long periods of time. Thus one of the main goals of cardiomyoplasty and other methods of muscle powered devices for circulatoy assist is the induction of adaptive changes in the original, fatigueable latissimus dorsi muscle by means of chronic electrical stimulation [1,6,7].

Several institutions of the University of Vienna are working together in order to improve the results of muscle assisted circulation by improving stimulation techniques and muscle positioning around the heart and by the construction of new forms of skeletal muscle ventricles. The alternative concept of indirect multichannel stimulation of the muscle by electrodes connected to the nerve has been introduced by Thoma. As the active electrodes are changed after each contraction, this multichannel technique has been introduced as "carousel-stimulation". It has been successfully applied for limb and diaphragm stimulation in para-and tetraplegic patients [1,8,9]. A further intention was its application in cardiomyoplasty.

In a second step we tried to improve the results of cardiomyoplasty by extending the knowledge of muscle transposition in other fields of plastic surgery to this particular problem.

Thirdly we tried to construct a new skeletal muscle ventricle consisting of a skeletal muscle wrapped around a kryopreseved cadaver aorta (homograft).

Materials and Methods

Our scientific group has performed 3 steps of experiments

Muscle conditioning by multichannel stimulation in an in situ model

In 6 adult sheep 4 stimulation electrodes were sutured to the epineurium of the left thoracodorsal nerve. Muscle conditioning was performed by multichannel ("carousel") stimulation according to a newly developed stimulation protocol consisting of 2 different phases [10].

Phase 1: Carousel-Stimulation with 10 contractions per minute. We started with 10 min/hour work and 50 min/hour rest. The duty cycles ("on" periods) were adapted to the fatigue resistance of the muscle until 10 contractions per minute could be performed during 24 hours.

Phase 2: The frequency of contractions was increased from 10/min to 70/min adding each week 10 contractions per minute.

Stimulation parameters were: Burst stimulation, burst duration 330 ms, burst frequency 28,8 Hz, single impulse duration 540 µs. The amperage was adapted to the respective stimulation thresholds in order to achieve maximal muscle strength.

Final experiments

Electrodes were sutured to the thoracodorsal nerve of the contralateral unconditioned latissimus muscle, too. The tendons of the latissimus dorsi muscles were exposed bilaterally and fixed in a force transducer. The following parameters were determined:

On both sides the electrode combination which produced the strongest muscle contraction was selected. These electrode combinations were used to compare ***maximum tetanic muscle tension*** of the conditioned and the contralateral unconditioned muscle at different resting tensions.

A ***test of muscle fatigue*** during 20 minutes of chronic multichannel stimulation (50/min) was carried out.

Cardiomyoplasty with a divided latissimus muscle

In 8 sheep acute experiments were done. The left latissimus was raised. A thoracotomy was done and the muscle was transposed into the thorax. Afterwards the muscle was divided into two parts according to its vascular anatomy. It was wrapped around the heart in two different configurations.

a.) Intercostal Extension

The tendon of the muscle was fixed to the third rib. The two parts of the divided other end were lead out through the intercostal muscles. The heart was captured between the two parts of the muscle. The longitudinal axis of the muscle was parallel to the coronary sulcus of the heart. The fixation of the muscle to two opposite areas of the thoracic wall allowed an individual adaption of the resting tension.

b.) Double wrap-around configuration

One part of the muscle was wrapped around the heart from dorsal to ventral, the other one from ventral to dorsal. The two parts were fixed to each other.

The resting tensions of the muscles were controlled by ultrasound monitoring to avoid impairment of the diastolic filling of the heart.

Contraction of the muscle was achieved by ECG-sychronized stimulation. We used a stimulation device which was developed in our own laboratories. Stimulation parameters were: Burst duration 200ms. R-wave-stimulus interval 20ms; maximal frequency of stimulation 30/min.

Circulatory parameters were measured by intravasal catheters. Data from nonsupported heartbeats were compared to those from heartbeats which were supported by a contraction of the muscle. Heart insufficiency was induced by rapid infusion of a betablocker (Ismolol, Breviblock®)

Aortic homograft as skeletal muscle ventricle (SMV)

A skeletal muscle ventricle (SMV) was constructed from a sheep cadaver aorta which was enlarged by the insertion of two patches of glutaraldehyde-preserved pericardium. In acute experiments the SMV was connected to the thoracic aorta by two end-to-side anastomoses. The left latissimus muscle was wrapped around and stimulated during the diastolic phase (counterpulsation) (Fig.5).

Results and Discussion

1.Muscle conditioning by multichannel stimulation

In the final experiments the conditioned muscles revealed an average maximal tetanic force of 96.5N at 20N resting tension and 128.3N at a preload of 40N. The respective data for the contralateral, unconditioned muscle were 144.5N (preload 20N) and 191.3N at 40N (Fig. 1). Supposing that both muscles were of equal force at the beginning of the stimulation program, the loss of force caused by muscle conditioning amounted about one third of the initial force. During 20 minutes of chronic carousel stimulation performing 50 contractions per minute the maximal tetanic force of the conditioned muscles decreased from 87.7N to 71.5N, which means an average loss of 18.5%. This loss of force was mainly confined to the first 3 minutes of this particular test. On the contrary the unconditioned muscles lost 68.8% of maximal force in the same period of time (Fig.2).

Although the conditioned muscles were stimulated for at least 2 weeks with 70 contractions/min without visible fatigue, a small loss of force occurred in each case. This phenomenon -even to a higher extent- is also described by other authors after the application of different conditioning schemes [1,7]. Therefore these basic experiments showed the possibility of muscle conditioning by carousel stimulation resulting in excellent fatigue resistance and an acceptable loss of maximal force on the other hand.

Figure 1: Average maximal tetanic tension of the conditioned and the unconditioned latissimus muscles at different resting tensions.

Figure 2: Comparison of the maximal and the mean tetanic tensions between a muscle transformed by multichannel stimulation [Max and Mean cond](full and broken line) and an unconditioned [Max and Mean uncond] muscle (dotted line and line with asterisks) during continuous stimulation over 20 minutes performing 50 contractions per minute.

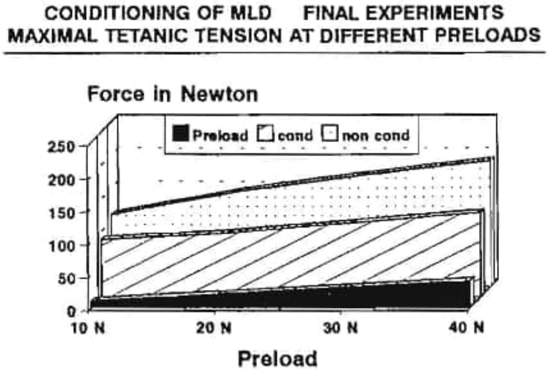

Fig.1

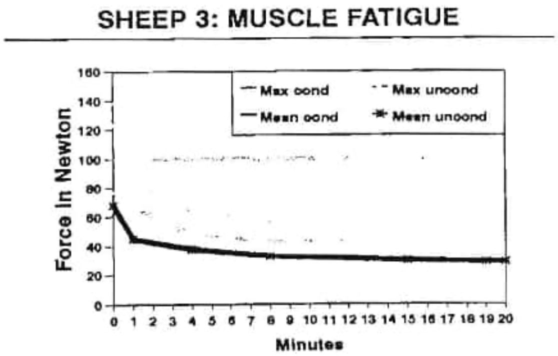

Fig.2

Cardiomyplasty with a divided latissimus dorsi muscle

The data of the average systolic arterial, maximal left and maximal right ventricular pressures with and without stimulation in the intact heart can be seen from the following table.

Table 1: Intact heart

	Intercostal Extension		Double wrap-around	
Simulation	off	on	off	on
Arterial pressure	78	86	93	104
Left ventricle pressure	74	83	92	104
Pulmonary artery pressure	20	25	22	28

The respective data recorded after induction of heart insufficiency can be seen from the figures 3 and 4.

Figure 3: Cardiomyoplasty after induction of heart insufficiency. Systolic pressure (Artery), maximal left ventricular pressure (Ventr sin), maximal right atrial pressure (Atr dext) and maximal pulmonary artery pressure (PAP) without (full bars) and with (hatched bars) support by the stimulated latissimus muscle. The two parts of the muscle are capturing the heart in between. The distal free ends are led out intercostally.

Figure 4: The same as figure 3, but the two parts of the muscle are wrapped around the heart in opposite form.

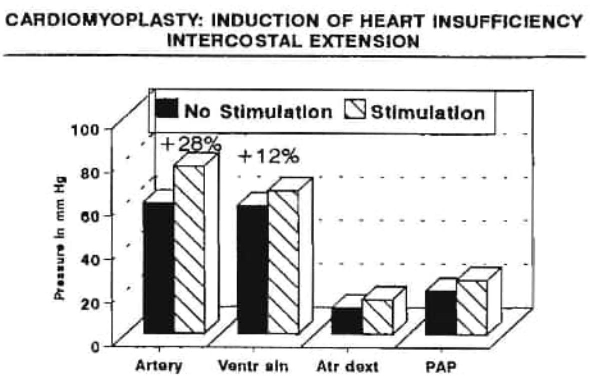

Fig.3

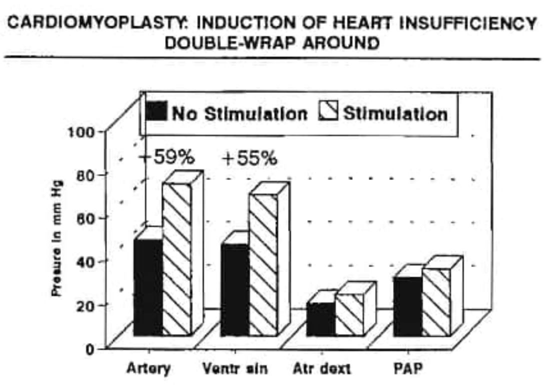

Fig.4

The divided latissimus muscle flap has been used for many reconstructive procedures in other fields of plastic surgery. The importance of pretension of a muscle which is transposed for functional reasons has been emphasized before. The division of the muscle in both configurations of our experiments offered us the possibilty of stretching the muscle until a certain amount of resting tension was obtained.

Both configurations of the transposed muscle resulted in a marked increase in systolic pressures. The differences between the stimulated and the nonstimulated beats were more distinct when the parts of the muscle were wrapped around the heart with a certain amount of resting tension. Furthermore we could emphasize the importance of the whole procedure for the insufficient heart.

Aortic homograft as skeletal muscle ventricle (SMV)

Stimulation of the muscle which was wrapped around the SMV augmented the abdominal aortic blood flow and the diastolic pressure. The mean systemic pressure was slightly augmented. Nevertheless further experiments with different positioning of the SMVs are necessary to show the impact of this newly configurated device for circulatory assist.

Figure 5: Skeletal muscle ventricle consisting of a cadaver aorta with a latissimus muscle wrapped around.

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THORACODORSAL ARTERY BLOOD FLOW DURING SYNCHRONIZED BURST STIMULATION (Abstract)

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Muscle damage has been reported in latissimus dorsi (LD) muscle flaps following experimental and clinical cardiomyoplasty (CMP), and an ischaemic origin has been suggested. This study aimed to document the effects of synchronized muscle stimulation on thoracodorsal (TDA) blood flow.

Material and Methods: In-situ LD muscles of 5 sheep (weight range 45 - 54 kg) were preconditioned with 2 Hz continuous stimulation for 8-9 weeks to achieve fatigue resistance. In a final experiment the muscles were stimulated (5V, 30 Hz), using a burst duration of 21% or 35% of the R-R interval. Stimulation was in either 1:1 (heart : muscle) or 2:1 synchronicy with the cardiac cycle. TDA blood flow and thoracodorsal venous (TDV) lactate concentration were monitored during, and immediately following a 3-min period of stimulation.

Results: A significant rise in TDA blood flow was seen with all protocols of stimulation ($p<0.001$). The increase in blood flow following stimulation with a 2:1 ratio and 21% burst was significantly less than when a 1:1 regime was used (88.8% [90% CI: 60.4% - 120.5%] and 138.9% [90% CI: 103.8% - 180.1%], respectively). This effect was more pronounced for a 35% burst duration (123.2% [90%CI: 90.4% - 161.8%] and 167.0% [90%CI: 127.6% - 212.9%], respectively). Timing of stimulation with the systolic or diastolic phase of the cardiac cycle (1:1 ratio, 21% burst) resulted in a similar rise in TDA blood flow. Following cessation of 1:1 stimulation, a further increase in blood flow was seen in 3 out of 5 animals with a 21% burst duration, and in all animals following a 35% burst. Reactive hyperaemia was never present following 2:1 regimes. TDV serum lactate levels tended to rise after 1:1 stimulation with a 21% burst, and fell compared to base line following 2:1 regimes (3.7% [90% CI: -12.7% - 23.1%] and -14.5% [90%CI: -28.0 - 1.6%], respectively). These changes reached statistical significance when a 35% burst duration was used (34.9% [90%CI: 13.6% - 60.2%] and -15.0% [90%CI: -29.2% - -0.001%], respectively).

Conclusions: 1:1 Assist ratios, even in the absence of muscle mobilization, may adversely affect TDA blood flow. This may have important implications for CMP.

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THE EFFECTS OF CARDIOMYOPLASTY ON CARDIAC GROWTH (Abstract)

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Cardiomyoplasty (CMP) has been considered for paediatric patients, but there is concern that a latissimus dorsi (LD) wrap could restrict ventricular growth. This possibility was investigated by performing CMP in an immature animal model.

Material and Methods: Six-week-old male Sprague-Dawley rats underwent CMP (Group I, n=7). To assess the effects of anaesthesia and surgical intervention alone, a sham thoracotomy was performed in Group II (n=8). Animals in Group III (n=7) underwent no procedure. The animals were electively sacrificed 20 weeks later.

Results: Pre-operative body weights were similar between the groups (Group I: 202.3 $\pm$ 8.8g, Group II: 209.6 $\pm$ 5.5g, and Group III: 198.6 $\pm$ 13.8g [Mean $\pm$ SEM], p = ns). There was no statistical difference between the final body weights of animals that underwent surgery (Group I: 558.0 $\pm$ 21.5g and Group II: 617.3 $\pm$ 20.3g), but these were less than those of the control animals (Group III: 727.6 $\pm$ 13.3g, $p<0.001$ and $p<0.01$ respectively). The cardiac ventricular weights in the CMP group were significantly less than those recorded for control animals (Group I: 1.21 $\pm$ 0.06g and Group III: 1.45 + 0.04g, $p<0.01$), but were not statistically different from those of the sham thoracotomy group (Group II: 1.36 $\pm$ 0.05g). There was no statistical difference between in left ventricular end-diastolic volume between the groups (Group I: 0.67 $\pm$ 0.07ml, Group II: 0.06 $\pm$ 0.07 ml and Group III 0.69 $\pm$ 0.10 ml).

Conclusions: No significant impairment of ventricular growth by a LD flap was demonstrated in this study, but further studies with stimulated muscles are indicated before CMP can be applied in paediatric clinical practice.

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LUMBAR ROOT STIMULATION FOR RESTORING LEG FUNCTION. METHODS: STIMULATOR AND MEASUREMENT OF MUSCLE ACTIONS.

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SUMMARY

We are studying the feasibility of restoring lower limb functions to paraplegics by stimulating their lumbar anterior roots (L2-S2). The potential advantages of placing electrodes at the roots, at the cauda equina, were set out by Rushton /1/ and our results so far are in a companion paper by Rushton *et al.*. The procedure we have used for selecting suitable subjects for this experimental prosthesis is described in another companion paper by Barr *et al.*. In this paper we describe briefly the stimulator system and a special apparatus we call the Multi-Moment Chair. The stimulator is a development from an earlier design of implantable peripheral nerve stimulator /2/ and has features which make it easier to use. The Multi-Moment Chair enables us to gather simultaneously isometric joint moments from 14 axes of the legs during stimulation while the body is fixed in a posture between sitting and full-extension. Such rapid data collection is essential to discover the effects of multiple-root stimulation and therefore the functional possibilities.

STATE OF THE ART

Unless there is a reflex response, the effect of stimulating peripheral motor nerve is confined to the target muscle or muscles, and so each stimulation channel usually gives a local response. For example, stimulating the quadriceps muscles gives knee extension with some hip flexion due to rectus femoris. Each leg has at least six degrees of freedom (axes) of movement at the three joints. When the lumbar roots are stimulated, the response from each root extends to many of these axes. Root stimulation therefore has a special difficulty: in order to set the stimulation intensities, so as to obtain a good approximation to any required combination of moments at these axes, models which relate the intensities to the moments are required. These models can be mappings between coordinates in moment space (7-dimensional in our models) and those in stimulation space (6-dimensional), assuming that each side of the body is independent. To be practicable, we have to be able to collect enough data to create such a mapping before the muscles become too fatigued. At present, we collect the responses to hundreds of stimulus patterns for each model and this is possible because the Multi-Moment Chair allows us to simultaneously measure all 14 leg moments while the subject is in a posture which can be set between sitting and near full-extension. As we find the responses depend on posture, several models will be necessary. Radial Basis Functions can be used to model the dynamic behaviour of stimulated muscle /3/: in this case we use RBFs to approximate the static mapping between moment space and stimulation space.

MATERIAL AND METHODS

Stimulator System

The implant and the external "Control Box" are both modular. The implant has two circular hermetically-sealed ceramic assemblies /4/. One carries the receiving coil and contains the receiver and decoder circuits; the second contains the de-multiplexor, blocking capacitors and terminates four

4-wire output cables. Each cable has one anode wire and three separate cathode wires. Three of the cables go to 3-slot "book" electrodes but one goes to a 2-slot book with a short extension to a further 1-slot book to facilitate placement at L2 level within the spinal canal. Each book contains three electrodes in a tripole configuration but all the anodes (the outer electrodes in each book) are connected together. The two ceramic assemblies are jointed back-to-back and encapsulated in silicone rubber.

There are two 68HC11 microprocessors in the Control Box. One, the Link Processor deals with the implant while the other, the Control Processor, executes FES application programs. This division simplifies the task of writing application programs. It also makes the system easier to expand as more powerful Motorola processors could be substituted if they have the SPI high-speed serial interface which is used for transferring messages.

The electronic design was described in reference /5/. The main features of the implant system are as follows.

- The stimulator is a flattened ellipsoid of diameter 58 mm and thickness 14 mm.
- The output current is 5mA.
- Pulse widths are set on an exponential scale from 2.1 to 992 s in steps with a fractional increment of 1/16th. In addition to these 142 steps there is also a zero pulse width step. For convenience we translate the 143 steps onto a logarithmic intensity scale of 0-100%.
- Reflected impedance /6/ is used to measure the coupling between the transmitter and receiver coils. The transmitter drive is adjusted to provide sufficient power as the coupling changes. The link will tolerate lateral displacements of the transmitter up to approximately 25mm.
- The coupling is displayed on an LCD and a warning buzzer sounds if the coupling gets excessively weak (when there is a risk of communication failure).
- The LCD not only displays warning information from the Link Processor program but also other short message strings generated by the control program.
- The Control Box is small enough to be carried by the user (120*80*45 mm) and weighs 372 grams. It is separate from a battery pack which weighs 528 grams and gives a running time of 14 hours before recharging.
- There is an RS232 interface to the Control Processor which can be used for down-loading programs or for sending stimulation patterns generated elsewhere (this allows experiments to be run from the PC which records and displays data from the Multi-Moment Chair (see below).
- There are 20 analogue inputs for goniometers, etc, 8 digital inputs for switches, and two external SPI ports in case simultaneous surface stimulation is required.
- The Control Processor has an operating system in EPROM and 32 kbytes of battery-backed RAM for programs.
- At present the Control Program modes include (i) exercising of muscles at home, (ii) manual adjustment of the 12 intensities from an array of linear potentiometers, (iii) stimulating with sequences of short bursts with intensity patterns received by RS232, and (iv), open-loop standing.

Multi-Moment Chair

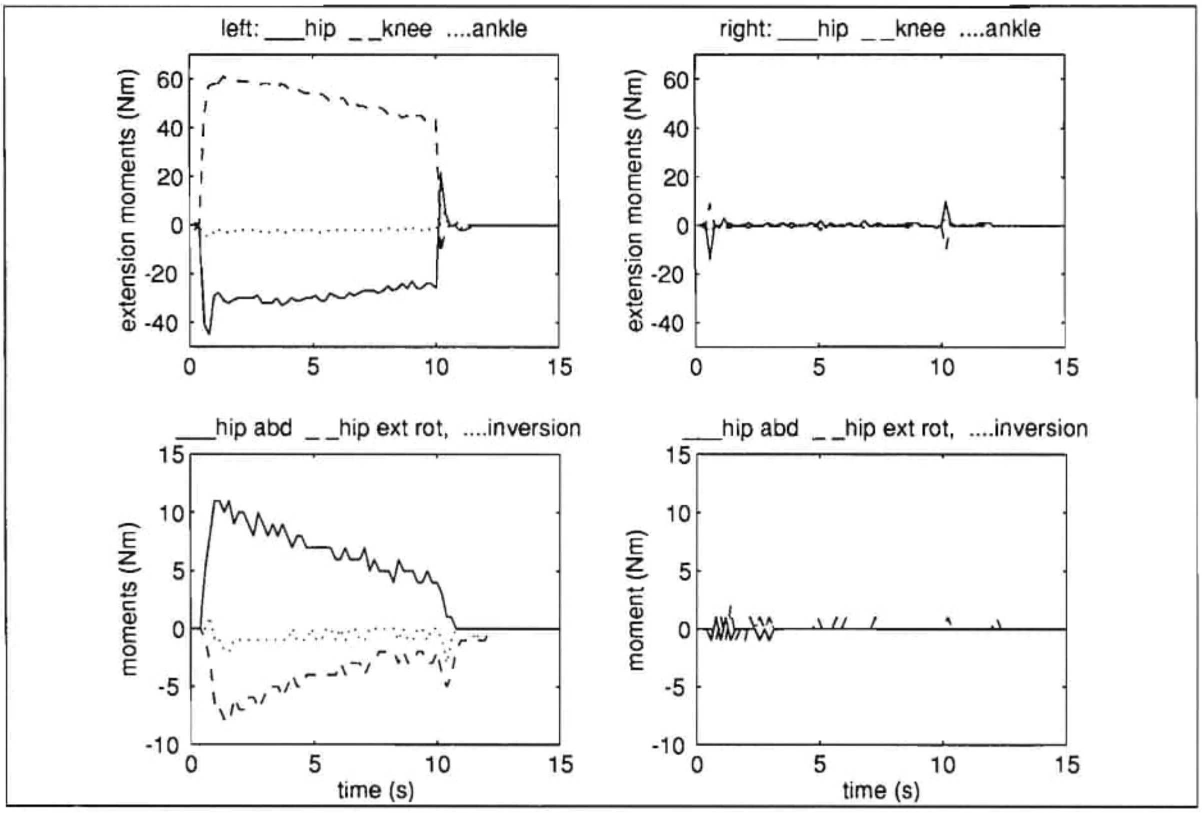
The subject sits on a chair which, like dentists' chairs, has adjustable height and inclination of the back. The seat is always horizontal. Straps hold the subject in place. Shoes are joined to plates which bolt into "shoe boxes" which are themselves pivoted on the plantarflexion axes of the ankles but then fixed at some angles to the horizontal. The shoe boxes are joined to 6-axis transducers which can be fixed at some horizontal distance from the chair. By adjusting the height of the seat, the inclination of the shoe boxes and the distance from the seat to the shoe boxes, the ankle and knee angles are determined. The inclination of the seat back gives the common hip joint angles. For convenience, we always arrange the thighs to be horizontal. The hips and knees can be set at any angle between full extension and 90 degrees of flexion. When the pelvis is restrained and the feet are in the shoes, only sideways movement of the knees remain possible. This is prevented by padded plates on both sides of each knee. These plates are fixed to beams which have strain gauges to measure the horizontal restraint forces.

Each leg is thus fully-restrained and as nearly isometric as possible without there being an unacceptable risk of skin damage. The 6-axis load cells were designed to withstand forces up to 2 kN and moments to 200 Nm. Each load cell was calibrated by loading on the line of the plantarflexion axis of the ankle. Twelve loading arrangements were necessary to cover the three orthogonal forces, three orthogonal moments, and for positive and negative signs. Calibration gave a matrix which relates the forces/moments at the ankle to the bending moments at the sites of the gauges on the transducer. From these and the lateral force at the knee, the internal moments in the leg are calculated. These moments are: hip extension, knee extension, plantarflexion, hip abduction, ankle abduction, hip external rotation and inversion of the ankle.

The strain gauge bridge signals are amplified and sampled by a 12-bit A/D card (DAS1600) in a PC486. A "C" program reads the strain words, calculates the joint moments, displays the moments in real time, and saves the moments records as text files. Usually the sampling rate is set to 5 Hz. For all the calculated joint moments, the worst-case resolution is 1.25 Nm. The program also can run experiments, sending stimulation patterns by RS232 to the Control Box and storing information about the experiment (e.g. posture). MATLAB is used to plot the results and for finding the Radial Basis Function models (Neural Network Toolbox).

RESULTS

The figure shows the measured responses to stimulation of the left quadriceps group of muscles of a normal subject with large surface electrodes. These responses are reasonable and show little cross talk between the legs.



Given that our subject can produce knee extending moments of nearly 100 Nm, we have found it impossible to prevent some movement occurring during strong contractions. Strong knee extension moments, with the leg extended, push the trunk up the back of the chair despite the straps. It order to maintain the accuracy of the moment records, we now use goniometers at the knees so that the results of this movement, which would otherwise introduce significant errors, are corrected in the calculations. Another problem has occurred during strong plantarflexion when the ankle is forced out of its shoe a little way. If this vertical movement is resisted at the knee, due to friction with the knee plates, the calculated hip extension moment is erroneous. We avoid this error by using slippery pads between the knee and each plate. It is important to pre-filter the strain gauge bridge signals or significant ripple in the calculated joint moments can occur due to aliasing of the mechanical vibration present at the stimulation frequency (20 Hz).

DISCUSSION

As we intended, the Multi-Moment Chair enables us to collect data rapidly in each or several postures. Although the transducers are calibrated for ankle joint forces, we have no comprehensive method of validating the calculated joint moments. However, data such as that presented in the figure is reassuring. At present, we expect that once the muscles have finished strengthening by training with the implanted stimulator, enough data to characterise the individual patient will take six half-days to collect. As we are primarily interested in the mechanical effects of the stimulation, we normally do not make EMG measurements but these can be made in conjunction with the moments in experiments to discover how or why the moments occur.

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SAMPLING DEVICE FOR TIMEPARAMETERS IN GAITANALYSIS

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SUMMARY

During gaitanalysis with elektromyography (EMG) and videometry, groundcontact events are used for time normalisation of multiple steps. Single sensors, taped at the foot, turned out to be inaccurate because of contact area variability. Moreover the timing of contact events of different sole areas during stance phase is of interest in functional footdiagnostic.
For this purpose we developed a datalogger, sampling contact events at an insole array of 64 pressure sensors. The battery operated device is carried at a hip belt without cabling. The system is microcontroller driven. The contact events in up to 8 maskable areas are logged in onboard RAM and are additionally available as an amplitude coded realtime signal, ready to be plugged in every EMG measurement unit as event channel. When used as stand alone device the logged data is sent off line to a PC over a serial interface, which is also used to mask and calibrate the insole sensors. The sampling frequency is 200 Hz. Depending on the number of areas the sampling time is 5 to 40 min. Two synchronised loggers are used for bipedal analysis. The device shows reliable preliminary results.

STATE OF THE ART

In functional gaitanalysis there are kinematic/kinetic and EMG measurements. These parameters are able to give information, how activity of muscles generate moments at the joints and finally lead to angular movements of bodysegments. A single gaitevent is not significant for interpretation due to high stride to stride variability, especially in pathologic gait and EMG [1,2]. It is necessary to take means of multiple gaitcycles. For this purpose a normalisation in time is needed. The groundcontact of the foot define events to split the cycle into phases. The main phases are stance and swing, identified with initial contact (heel strike) and toe off events. Full forefoot load and heel lift are subevents in the stance phase (Fig. 1).

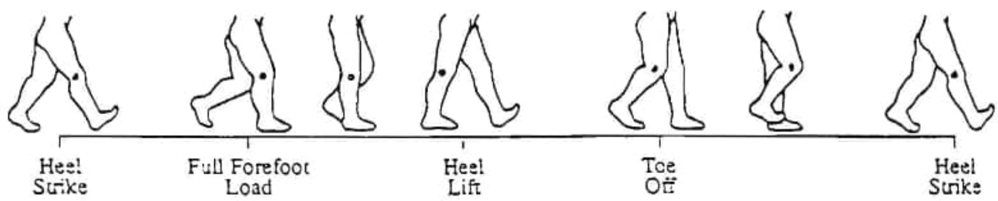

Figure 1: phases of gaitcycle

Up to now we use 4 pressure sensors at one foot to measure these events in clinical gait analysis. They are taped at the bare foot. When the foot is loaded the sensors change conductivity. This rapid change triggers the gaitevents. The commercially available systems are costly and do not offer realtime and logging function at the same time. The inhouse single sensor tape method is time consuming in handling and sensors are damaged easily because of mechanical stress during taping. The foremost shortcoming of the present method is inaccuracy with pathologic gait. If the patient varies the initial or final groundcontact area to an area without sensors taped on, the trigger fails. This leads to normalisation errors in time and misleading timing.

MATERIAL AND METHODS

To deal with this problem we developed a device able to collect pressure distribution of the entire foots, small enough to be carried at a hip belt and providing a realtime channel. This datalogger may be used in combination with any EMG measurement system to generate a trigger channel. It may also be used as stand alone system in order to measure the timeparameters in gaitanalysis. Every cunductivity sensor matrix within the limits of 8 x 16 elements may be used with this datalogger. The prototype is equipped with a 64 sensor insole (Interlink Elektronics, CA, Santa Barbara) because of commercial availability (Fig. 2).

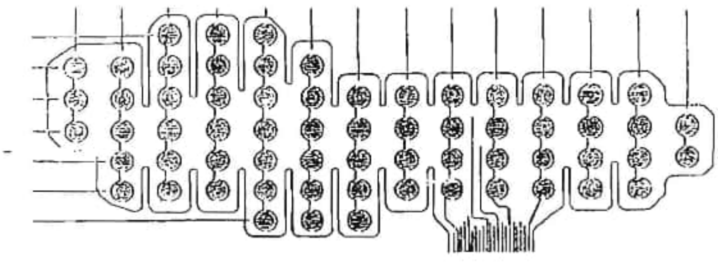

Fig.2: Sensor insole matrix

This sensor is built up in a partly filled 7x14 matrix. To save time only present sensors are scanned and dataprocessing is multiplexed with the sampling time of the next sensor. Virtual mass is adjusted to those sensor columns, which are not sampled during scan of one sensor in order to avoid crosstalk within the matrix.The sensormatrix may be masked in up to 8 free selected groups. The group is active if at least one of the groupsensors are loaded. The groupdefinition and the switching levels are generated by a PC-program. The switching level is adjusted to the bodyweight. The groups are defined with a graphic tool and may be saved for further use.

The system is driven by a 80C535 microcontroller (Fig.3). The Sensor Matrix is multiplexed in columns and rows. Each sensor conductivity is A/D converted with 8 bit resolution. The switching situation is calculated by comparing these values with a zero adjust table. This calibration table is generated during an unloaded zero adjust situation. Damaged or bend sensors are given a higher switching level in accordance to their preload.

The system unit contains 12 keys and a LCD display with 2 rows of 16 alphanumeric characters each. Following functions are controlled by these elements: Receive group definition and switch level from PC, zero adjust, realtime test with display of group activity, logging data in RAM and send data to PC. Tree LEDs indicate system status and battery low.

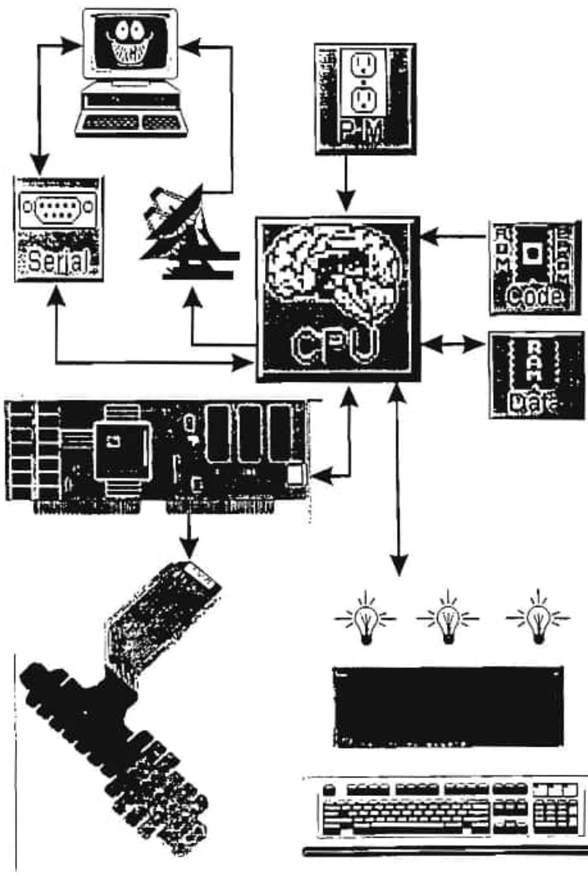

Fig.3: Datalogger unit

A fullscan needs 5 ms. The real time signal and the switching events in each of the 8 groups are updated in 200 Hz cycles. The statusbyte is saved in a 64 kB RAM. This gives more than 5 min sampling time. This time may be split in up to 32 trials. The microcontroller programcode is based in an EPROM.There is an off-line RS232 interface to the PC and a real time output. The later one shows the switching situation of the insole with a 200 Hz amplitude coded Signal without bias, able to be fed as event channel in every EMG unit. The standard output include cadence and duration of stance and swing phase. The start/stop trigger may be done additionally by light switches. With distance measurement the system is able to calculate gait velocity and step length.

VALIDATION METHOD

To evaluate the sensor insole and logging system we compared the switching events with the ground reaction force measured with a force plate (AMTI, Newton, MA). The measurements were taken after a zero adjust in unloaded situation without additional adjustment for different tasks. All sensors were masked in one single group. The switching level had an offset of 1/10 of the dynamic range. The realtime signal of the datalogger and the vertical component of the ground reaction force (GRF) were sampled at 1000 Hz simultaneously (Fig.4). The realtime signal was identical to the logged signal time expanded with factor 5.

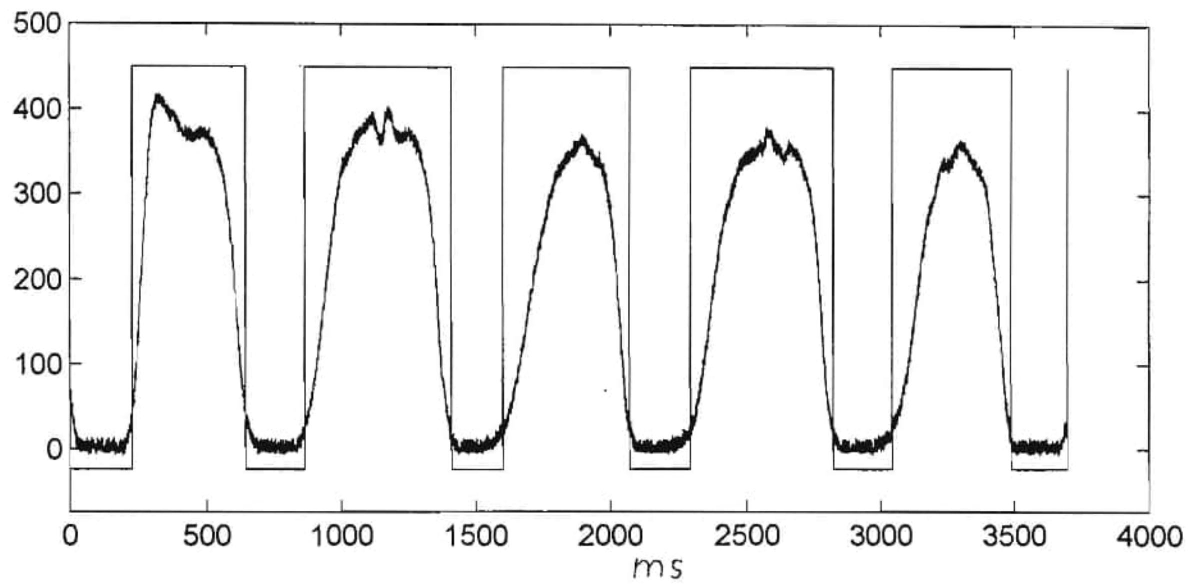

Fig.4: ground reaction force versus start and end of stance phase with gait logger

Start and end of stance phase were defined as the crossover of GRF at 1/10 of bodyweight. The time difference to gait logger events was identified as Δ begin and Δ end. Negative values indicate early, positive values indicate late definition of the gait logger events in respect to GRF events (Tab.1).
High variations of gait patterns were tested in this evaluation. 60 trials of a healthy person in 6 simulated variation groups were taken. The gait pattern varied in initial heel contact and initial toe contact. The stance varied in medial, lateral and symmetric loading.

RESULTS

group:	Δ begin mean(ms)	Δ begin std (ms)	Δ end mean (ms)	Δ end std (ms)
ini.heel - sym.	-0.13	2.5	18.3	4.1
ini.heel - medial	1.6	3.2	2.6	5.0
ini.heel - lateral	2.5	3.3	-15.6	14.0
ini.toe - sym.	12.3	4.3	6.2	4.8
ini.toe - medial	-4.0	13.6	12.2	25.6
ini.toe - lateral	16.5	5.4	14.4	10.5

Table 1: Event errors of gait logger in ms

DISCUSSION

The switching error of single sensors was found to be +/- 10ms for the start and +/- 22ms for the end of stance phase in previous studies[3]. These errors were tested with normal gait pattern. The overall results for high variability in gait in this study show similar findings. Roughly for heel strike events the error is under +/- 5 ms and for toe strike and toe off events under +/- 20 ms. There is a light shift of ~2 ms towards late definition in heel strike. This is due to the scan period of 5 ms, which leads to delayed output of switching events. There is little difference between loading patterns, showing good reliability of the system. The unloading pattern show later definition in the initial toe strike events. This may be due to high pressure in the toe area after unloading because of toe walk. The trial number is to small to discuss more details.

The handling of the system was easy in respect to the datalogger. The betaversion of the PC software was unusual to handle but will be debugged within next months.For quick use the update will include a sample of predefined masks for different walker types.

There is a need for studies with patients to proof reliability in real pathologic gait. As there was no adjustment for foot contact type and bodyweight in this pilotstudy we have good reason to expect reliable results in further studies.

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APPLICATION OF BALLISTIC WALKING MODEL TO FES ASSISTED GAIT ANALYSIS

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SUMMARY

In order to produce successful gait in paraplegic individuals using Functional Electrical Stimulation, muscle activation patterns must be found. These patterns are often complex, and must be precisely tuned to each specific individual. The development and tuning of control systems is a time consuming process, requiring numerous clinical trials. The effort on the part of researcher and patient is great.

Walking models can be effectively used to aid the development of such control systems in three ways: (1) The feasibility of a particular control strategy can be evaluated before any clinical testing begins; (2) The behaviour of a control system can be simulated beforehand, and anticipated when patient testing begins; (3) Control systems which are known to work can be coarsely tuned using model simulations, and later fine tuned during patient testing. In these ways, modeling can greatly speed up the development of FES control systems.

In this study, the swing phase of gait is simulated. A very simple control scheme is applied to the quadriceps muscles of the swing leg with the objective of improving swing leg extension at heel-strike.

STATE OF THE ART

Dynamic walking models come in many forms, and range in complexity from very simple to very complex (c.f. Mochon and McMahon /1/, Onyshko and Winter /2/, Siegler et al /3/, Pandy and Berme /4/, Yamaguchi and Zajac /5/). The walking human is modeled as a series of links, each having a characteristic mass and moment of inertia. The links represent one or more skeletal segments of the human body. Joints are often modeled as restrained pin connections with elastic and/or damping elements to simulate internal joint reactions. Isolated muscles are modeled in a vast variety of ways (Zahalak /6/). Muscle models are often incorporated with the joints of walking models and act essentially as torsional actuators.

Basic walking models with a low number of degrees-of-freedom are appealing for their fast computation speed, low number of vital parameters, and simple output. This study focuses on the 3 degree-of-freedom ballistic walking model (Mochon and McMahon /1/) which simulates the swing phase of gait. The input to the model is a set of six initial conditions referring to the position and initial angular velocity of each segment at the start of swing phase (toe-off). The output is the kinematics of all three segments represented as functions of time. A numerical integration technique is used to solve the equations of motion.

MATERIALS AND METHODS

The ballistic walking model of Mochon and McMahon /1/ was used with the following revisions:

(1) Non-linear torsional springs and linear dampers were attached to the knee joint and the hip joints to produce realistic joint reactions. The non-linear elastic functions were taken from Davy and Audu /7/.

(2) The knee-lock mechanism of the swing leg knee was removed.

(3) The feet were modeled as simple triangles with vertices at the heel, toe and ankle joint. The swing leg shank and foot remained one rigid segment (assuming an AFO was being used).

(4) The quadriceps muscle of the swing leg was modeled as a first-order response to a given stimulus according to Ferrarin et al /8/. The muscle model is defined by the following equation

$$\tau\dot{M} + M = M_{max}x(t)$$

where M is the moment produced at the knee by the quadriceps, M_{max} is the maximum moment capable, τ is the time constant of the muscle response, and $x(t)$ is the stimulus function.

The revised ballistic walking model has three degrees-of-freedom and consists of three segments: the stance leg, the swing leg thigh, and the swing leg shank and foot. The upper body mass is modeled as a sizeless mass at the hip joint. Figure 1 shows how the angles, ϕ_1, ϕ_2, and ϕ_3 are defined.

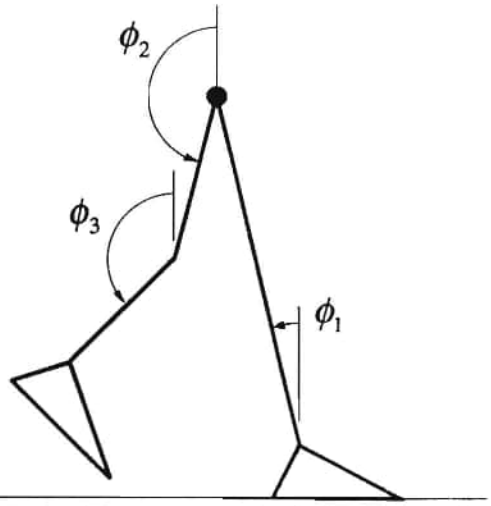

Figure 1: Schematic diagram of revised ballistic walking model

A basic control scheme was chosen to demonstrate the ability of the model to determine if and when quadriceps stimulation during swing phase can improve gait. First, it is necessary to describe the goal of the control scheme.

A successful simulation is defined as one in which (1) the swing foot remains above the ground at all time between toe-off and heel-strike, (2) the swing leg knee is extended no less than 10 degrees from full extension at the moment of heel-strike, and (3) the distance between the stance leg toe and the swing leg heel at the moment of heel-strike is no more than 10% different from the distance between the swing leg toe and stance leg heel at toe-off. In short, the three criteria for a successful swing phase are (1) foot clearance, (2) critical extension at heel-strike, and (3) step length consistency.

In order to test the ability of the model to verify and optimize muscle stimulation patterns, four sets of initial conditions were selected which produce failed gait when no muscle stimulation is applied. These initial conditions are listed in Table 1. Each trial chosen fails to result in adequate swing leg extension at heel-strike. Activation of the quadriceps muscle should aid knee extension. Therefore, a step stimulus was applied to the quadriceps at a time, t_{on}, after toe-off. The model was then used to optimize t_{on} with the goal of producing the best knee extension at heel-strike.

Table 1: Initial conditions for optimization trials

trial	ϕ_1 (rad)	ϕ_2 (rad)	ϕ_3 (rad)	$\dot{\phi}_1$ (rad/s)	$\dot{\phi}_2$ (rad/s)	$\dot{\phi}_3$ (rad/s)
1	0.18	2.90	2.15	-1.1	6.0	-5.0
2	0.18	2.90	2.15	-1.1	5.0	-4.0
3	0.25	2.90	2.25	-1.2	5.0	-4.0
4	0.25	2.90	2.25	-1.3	5.0	-4.0

An iterative step approach was used to optimize t_{on}. Iterations were repeated until a minimum value for knee angle at heel-strike was found. Trials which resulted in good knee extension at heel-strike but failed the other criteria for successful swing phase were discarded. For all simulations, the body parameters of a normal male were used (Vaughan et al. /9/).

RESULTS

Approximately 60 simulations were executed for each trial. The iterative search found optimal values of t_{on} for all four trials. Table 2 summarizes the results of the search. The second column in Table 2 lists the values of knee angle at heel-strike when no quadriceps muscle stimulation is applied. The third column contains the knee angles at heel-strike when optimal quadriceps stimulation is applied.

Table 2: Model simulation results

trial	Final knee angle $(\phi_2 - \phi_3)$ without quad. stim.	Final knee angle $(\phi_2 - \phi_3)$ with quad. stim.	optimal t_{on}
1	23.6	4.6	0.03
2	10.8	6.1	0.36
3	35.0	7.7	0.38
4	23.2	8.9	0.34

Figure 2 plots the value of knee angle at heel-strike versus t_{on}. The data in figure 2 is taken from trial 2.

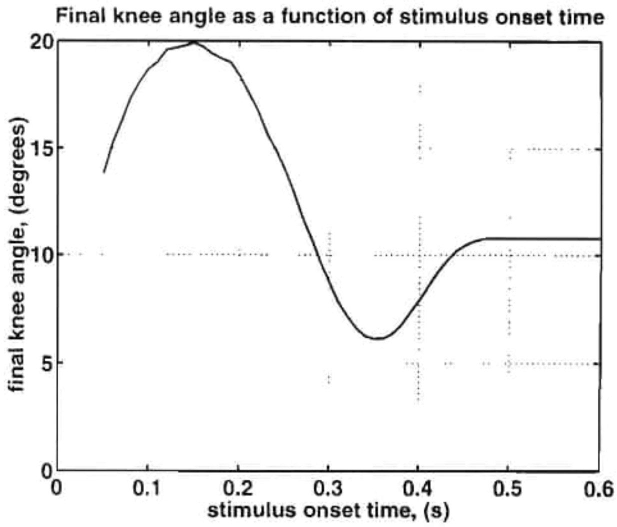

Figure 2: Knee angle at heel-strike as a function of quadriceps stimulation onset time

DISCUSSION

The results demonstrate that swing leg knee extension can be aided by activation of the quadriceps muscle at some instant during swing phase. With the exception of trial 1, optimal quadriceps muscle stimulation onset time is approximately 0.36 s. This is roughly 65% through swing phase. The optimal onset time may be associated to some detectable event during the swing phase, and a control system devised which begins quadriceps activation when the event is detected. Since quadriceps stimulation is desirable during early stance phase, the results of this study suggest that the quadriceps can be stimulated some time before heel-strike in paraplegic walking.

The ballistic walking model can be easily employed to test other muscle control schemes. For example, a muscle model of the hamstrings could be used to improve trials for which the foot clearance criterion is not satisfied. Larger scale models can be similarly employed.

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CHARACTERIZATION OF CUTANEOUS NERVE RESPONSES FOR CONTROL OF NEUROMOTOR PROSTHESES

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SUMMARY

The objective of this study is to determine the suitability of using the afferent activity recorded from cuffs implanted around cutaneous nerves to provide feedback control in neuromotor prostheses. The data were obtained using chronically implanted, tri-polar recording cuffs placed around a branch of the common palmar digital nerve innervating the radial side of the index finger in a quadriplegic volunteer subject. Precisely controlled mechanical stimuli stretched the digital skin at the distal phalange of the index finger. The stretch was delivered by means of a force servo apparatus that produced trapezoidal force profiles. Investigation using force rates of 1, 2, 4, 8, 16 N/s and amplitudes of 0.5, 1, 1.5, 2, 2.5 N showed an approximately linear increase in the rectified and smoothed ENG activity with increasing rate of stretch over the range of 2-16 N/s or increasing amplitude from 1- 2.5 N. These results are in agreement with behavioral studies of the regulation of the force of the precision grip when normal subjects were asked to restrain a grasped object that exerted unpredicted pulling loads (see ref [9,10]). In those studies, the subjects automatically increased the grip force in proportion to the rate and amplitude of the pulling force. Furthermore, this automatic reflex behavior seemed to be based on cutaneous output since the lawful grip force regulation was totally disrupted when an anesthetic was injected around the digital nerves to block cutaneous sensation. The demonstration in our present studies of the same proportional increases in digital nerve activity when the skin was stretched, supports the hypothesis that the cutaneous activity plays a major role in driving the automatic grasp force regulation system. The significance of these findings is that they provide a foundation for developing neuroprosthetic hand grasp control schemes that are adaptive for the rate and magnitude of an imposed load force perturbation. Further studies are required to develop means to reliably distinguish changes in the nerve activity that are only attributable to changes in skin stretch imposed by load changes during the lifting or restraining of grasped objects.

STATE OF THE ART

Activation of paralyzed muscles by means of electrical stimulation is being developed to restore motor function in individuals with spinal cord injury. Although research has indicated that the application of "closed loop control" [1,2] can improve these systems, there is a need to provide sensors which can monitor such factors as finger contact, grip force, object slippage or foot-floor-contact and limb loading. Efforts to develop artificial sensors have demonstrated a number of problems including poor cosmesis; difficultly in maintaining calibration and interference with the act of grasping due to mounting the sensors on the fingers and the presence of the lead wires [3]. An alternative approach which we are developing is to try to utilize the biological natural sensors that are present within the skin, joints and muscles to furnish feedback information for FES control [4,5,6,7,8].

The present studies aim to determine the response properties of the cutaneous mechanoreceptors present over the surface of the fingers to mechanical stimuli that stretch the skin at defined rates and amplitudes. These stumuli attempt to isolate the components of mechanical skin deformation that occur when a passive object is lifted, or when an active object (such as an umbrella in the wind) exerts a pulling load. These studies should provide a better understanding of the signal content of the whole nerve responses that result from functional grasping activities so that effective real-time signal processing techniques (cf. ref [8]) can be developed. The role of cutaneous information in grasp control has been well established from previous behavioral studies [9,10] where it was shown that the rate and amplitude of a pulling load modulates the automatic grip force increase that occurs to keep an object from slipping. The rate and amplitude dependent characteristics of the whole nerve afferent activity observed from the present studies are consistent with those behavioral observations.

MATERIALS AND METHODS

A tri-polar nerve cuff (Fig. 1) was used to record the sensory nerve activity. The cuff had an overall length of 20 mm and was installed circumferentially around the radial branch of the palmer digital nerve as shown in the figure insert. The three lead wires from the cuff were routed subcutaneously to the dorsum of the forearm where they exited and terminated in a pin connector. A thirty-five year old male with C6 level spinal injury served as a volunteer subject for these studies. Informed consent was obtained, and the study was approved by the local ethics committee.

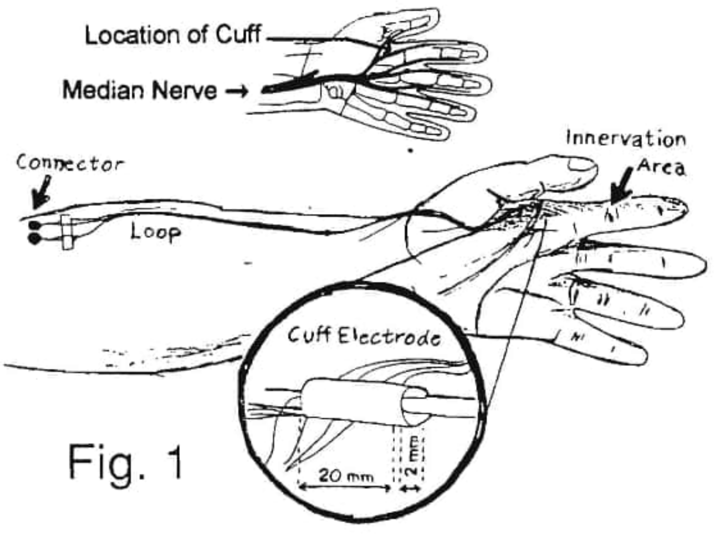

Fig. 1

The signal from the nerve was differentially amplified; band pass filtered (1KHz-5KHz); rectified; filtered again; digitally sampled (20kHz) and later integrated off-line using a 23 msec sliding window. Mechanical stimuli were provided using the two axis servo system shown in Fig. 2. The solenoid motor was used to provide a constant 1 N contact force normal to the finger surface throughtout the application of the stretch trials. The contactor surface (rectangular, essentially flat and 15mm wide) was positioned over the distal phalanx, and the stretch was dorsal to volar. Blocks of ten consecutive pulling loads were applied by activating the torque motor using symmetric trapezoidal command profiles.

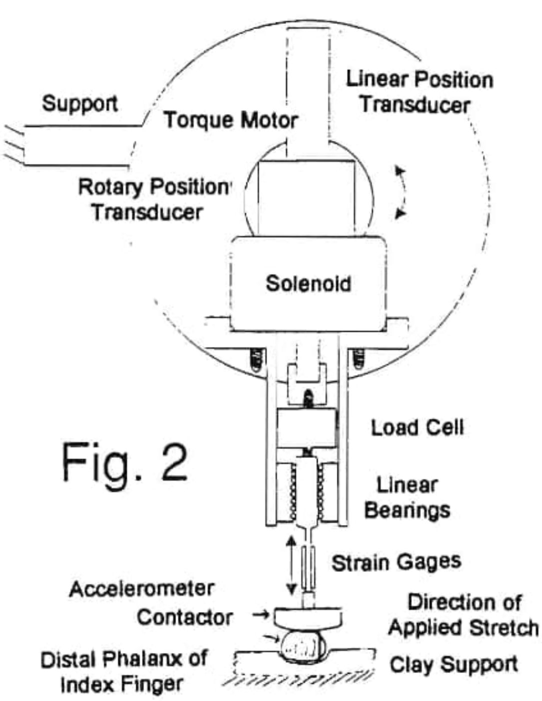

Fig. 2

Double face tape (3M Company #136) applied between the contactor and the finger increased the friction and extended the range of tangential loads that could be applied to stretch the skin without slippage. Load profiles included ten trials at each of five different rates (1, 2, 4, 8 and 16 N/s) and five different magnitudes (0.5, 1, 1.5, 2 and 2.5 N), totaling 250 trials. Mechanical signals (sampled at 400Hz) including contact force, normal and tangential displacement of the contactor, load force, and the output from an accelerometer were registered along with the nerve activity. Blocks of ten congruent trials were averaged together by super-imposition before being compared to other averaged trials. Data were examined at each of the time or event marks shown in Fig 3. This included: 300ms prior to the ramp to access baseline activity; 50,100 and 150 ms from the onset of the ramp; the peak of the load force rate (df/dt) near the top of the ramp; the start of the plateau phase; every 100ms throughtout the plateau; the onset of the load force ramp declining phase.

RESULTS

Effect of Stretch Rate -The effect of rate of skin stretch (16, 8, 4, 2 and 1N/s) at a constant amplitude of 2N is shown in Fig. 4. Each trace is the average response for ten successive trials. The contribution the whole nerve activity from the dynamic sensitivity of the mechanorecptive afferents is clearly evident from the stretch applied at the three hightest rates. Note that the steep overshoot of the response during the loading ramp as compared to the activity level immediately after the onset of the plateau phase. In contrast, the low rates of 1N/s showed no phasic activity at the ramp onset and instead displayed a "tracking" behavior throughtout the ramp stretch. The overall effect of increased rate of stretch is to evoke a more rigorous response. This rate sensitivity is also apparent from the details of the average response during a given ramp, as subtle changes in load rate (evident from the time derivative signal) are reflected in the neural discharge activity. An "off" response is also present near the end of the stretch relaxation phase for the two highest ramp rates tested, but the off response is considerably less rigorous then the response during the increasing stretch stimulus.

Effect of Stretch Amplitude - The effect of increasing the amplitude of the stretch at a slow rate of 1N/s is shown in Fig. 5. Each trace represents the average responses for ten trials. Note that the responses have been offset in the display for clarity (the baseline activity or "start" of each trace in reality represents the same level of about 1uv.). A "threshold" effect is observed between the 0.5N stimulus where no response occurred and the 1N stimulus for which the response is clearly discernable. Again note the prominant tracking quality of the response to stretch at the low (2N/s) rate as the rising phase of the ramp proceeds.

Early Responses to Stretch -Figure 6 shows the sensitivity of the nerve activity to stretch rate when this is evaluated soon after the onset of the load ramp (i.e. at 50 and 150ms). The figure summarizes the averaged responses across all stretch rates and amplitudes. The individual responses are scaled so that the highest amplitude response has a value of unity and the baseline response is zero. The rate of stretch is taken from the *Load Force Time Deriviative.* The results show that a lawful relation between stretch and nerve activity is established very soon after the onset of the stimulus but only if the rate is above about 2N/s. Furthermore, the relationship between the nerve activity and the rate of stretch appears to be approximately linear and constant over this interval.

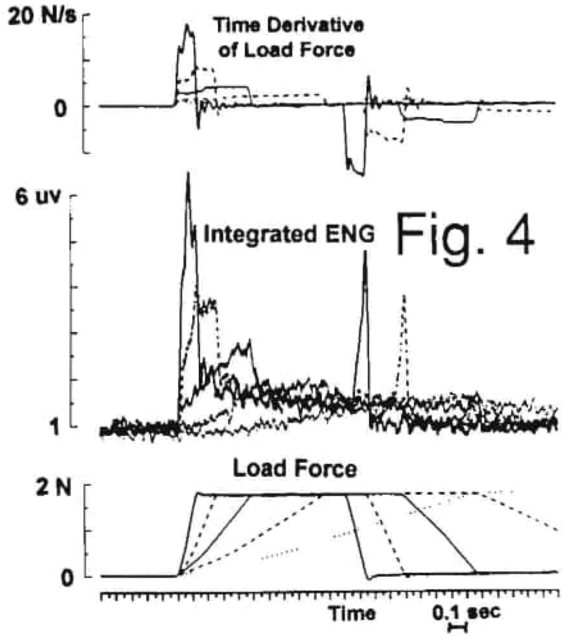

Fig. 4

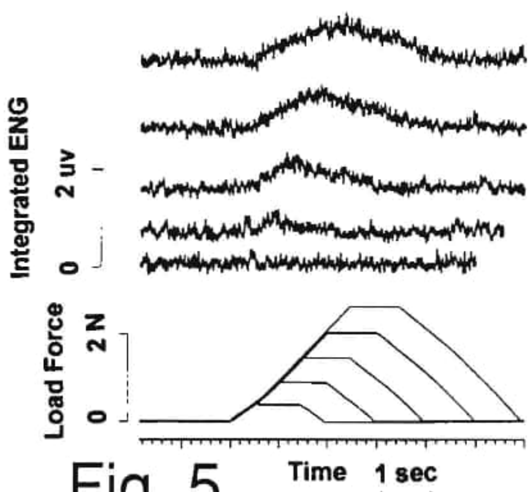

Fig. 5

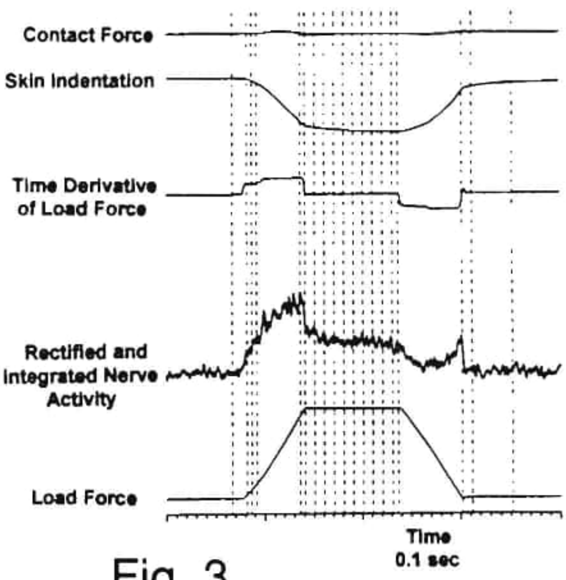

Fig. 3

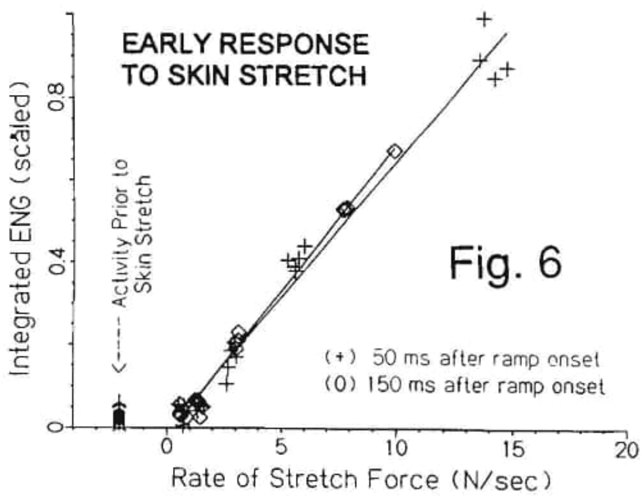

Fig. 6

DISCUSSION

These studies demonstrate that it is possible to record whole nerve ENG from the digital nerves in the palm of a quadriplegic subject on a chronic basis with a circumferential cuff. Stretching the skin near the end of the index finger results in an increase in nerve activity that is approximately linearly related to the rate of stretch applied. Furthermore, this lawful relationship is established already only 50ms following the onset of the skin stretch. These findings are in agreement with the behavioral studies of Johansson et al. (ref [9,10]) which showed that normal human subjects increase the grip force when a grasped object exerts an unpredicted pulling load. In those studies, increasing the rate of pull evoked a grip force increase of proportionally higher magnitude. Our present findings are significant for the control of FES hand grasp systems: It seems possible that the cuff recorded responses to skin stretch could be used to drive an "automatic reflex" in which skin stretch that exceeded an arbitrary threshold would produce an upgrade of the muscle stimulation parameters and increase the grasp effort to avoid object slippage. Furthermore, the gain for the reflex could be adaptive since greater rates of skin stretch (which would imply increased risks of object slippage) evoke more intense nerve responses which could be used to drive larger upgrades of the grip force. Continued research is necessary before a functional "grasp reflex" can be put into clinical practice because the fingers receive a variety of mechanical stimuli during the manipulation of objects and this can result in a complex pattern of nerve activity. A major challenge for researchers is to identify unique features for nerve activity that will permit distinguishing skin contact, slippage and stretch. Our studies further demonstrate that some information about static loads is also present in the cuff recorded signals. However, because of the adaptation that is seen in the nerve activity during the studies of the plateau region, this aspect of the control will require considerably more evaluation.

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Restoration of Lateral Hand Grasp using Natural Sensors

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SUMMARY

A closed loop control system for controlling the key grip of a C6 tetraplegic patient was developed. Natural sensors served as the source of the feedback signal. The neural signals from cutaneous receptors were picked up by an implanted cuff electrode placed around the radial branch of the median nerve innervating the lateral part of the index finger. Mechanical stress applied to the skin, like pressure and slips, resulted in an increase in amplitude of the recorded neural signal. The goal of the study was to show whether the recorded neural signals are able to indicate a slip of an object during lateral grasp, and whether the slip can be stopped by increasing the grasp force through functional electrical stimulation of the thumb adductor and flexor.

STATE OF THE ART

Compound activity in a peripheral nerve can be recorded with a chronically implanted cuff electrode. It has been of interest to investigate if the activity mediated by mechanoreceptors in the skin can be recorded from a cutaneous nerve and used for feedback for an FNS system. We have previously reported on animal experiments indicating that this might be possible. We have also shown in a hemiplegic patient with a dropfoot that it is possible to use the nerve signal from the sural nerve for heel contact detection /5/. In this paper we report on the first attempt to show whether it is possible to use this technique to provide a useful feedback signal for a hand neuroprosthesis.

Previous results have show that in both cat and human /1,3/ the properties of the signal recorded from a nerve supplying glabrous skin are such that standard linear feedback of skin contact force is not straight forward. This is caused in part by temporal adaptation of the cutaneous receptors together with the non-linear property of increasing signal during both increases and decreases in a perpendicularly applied force. However, the studies have shown that it is possible to extract information about slips across the skin from the nerve signal. This information might be possible to use for control of an FES system for hand grasp by means of an "event-driven" controller /1/. In the present paper we describe the results from a study aimed at implementing such a controller in a human tetraplegic.

MATERIALS AND METHODS

The study was performed on a 27 year old male C6 level tetraplegic patient (8 years post-injury). The patient gave his informed consent and the study was approved by the local ethical committee. This patient had good control of shoulder motion, elbow flexion and some wrist extension, but had no voluntary control over his hand muscles. He had sensation in his forearm and to some extent in his thumb and index finger.

In May 1994, the left hand of the subject was instrumented in a surgical procedure with a tripolar cuff electrode around the digital branch of the palmar nerve innervating the lateral part of the index finger. The cuff electrode was an insulating silicone-tube, 23 mm long and 2 mm inner diameter with 3 circumferential electrodes inside the cuff (10mm inter-electrode distance) /4/. The wires of the cuff electrode were routed subcutaneously to an exit site on the volar side of the forearm, where they were attached to a small external connector. During a short stay in Cleveland, Ohio, in August 1994, 11 intramuscular electrodes /2/ were implanted percutaneously at the following locations: FPL (thumb flexor), EPL (thumb extensor), AbPB (thumb abductor), FDS (finger flexor), EDC (finger extensor) and the ulnar nerve at the wrist (thumb adduction, AdP).

Finger flexors and thumb adductor (FDS and AdP) were conditioned via the percutaneous electrodes (approx. 4 hours per day, using cyclic stimulation, 2 sec on, 2 sec off), since the patient did not tolerate surface stimulation very well.

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RESULTS

The first observation that was noticed when stimulation started was that there was significant pickup of compound muscle action potentials (EMG) in the nerve signal (50-100μV). This was removed by simple blanking in the bin-integrator as previously reported /1/, but it was found that max. 17ms out of the 50ms between stimuli could be used because of EMG contamination caused by both direct muscle stimulation and an apparant reflex activated by the stimulation.

Experiments were performed to investigate if the system was capable of reacting to small slips of the object with respect to the skin of the index finger, so that the grasp force could be increased. For this purpose we instrumented a rectangular object (80x60x20mm) with a sensor to measure the grasp force.

The experiment was performed by initially stimulating the muscle to produce a secure grip. The grip was then slowly released by reducing the stimulation intensity at a slow constant rate. At some arbitrary time, the experimenter briefly pulled the object away from the grip, resulting in skin deformation (decrease in Hall transducer signal) and a slip across the skin (increase in Hall transducer signal). When this happened, the nerve signal increased and was detected by the computer, which reacted in order to increase the grip force on the object. This was done by increasing the command level to 100% for a single pulse and afterwards settling at a command level 50% higher than before the slip occurred. This was repeated a few times until the object had moved out of reach. At the time of this experiment, only the ulnar nerve electrode could be used to produce thumb flexion/adduction (FPL-electrode was broken), and the AdP muscle was too weak to stop a slip even at highest stimulation intensity. These slips were caused by rapid and relatively large movements of the object (2-3cm). It was our observation that small and slow slips were not possible to distinguish from background noise.

It was also of interest to know if hand or forearm movement could produce nerve responses that would wrongly be identified as a slip. We asked our subject to supinate and pronate several times, while the thumb was strapped away from the index finger to avoid skin contact (the pronator was not under voluntary control, but by moving his shoulder the subject was able to produce forearm pronation). The result was that voluntary forearm movement caused enough passive stretching of the skin of the index finger to produce several false detections of slip, without any object touching the finger.

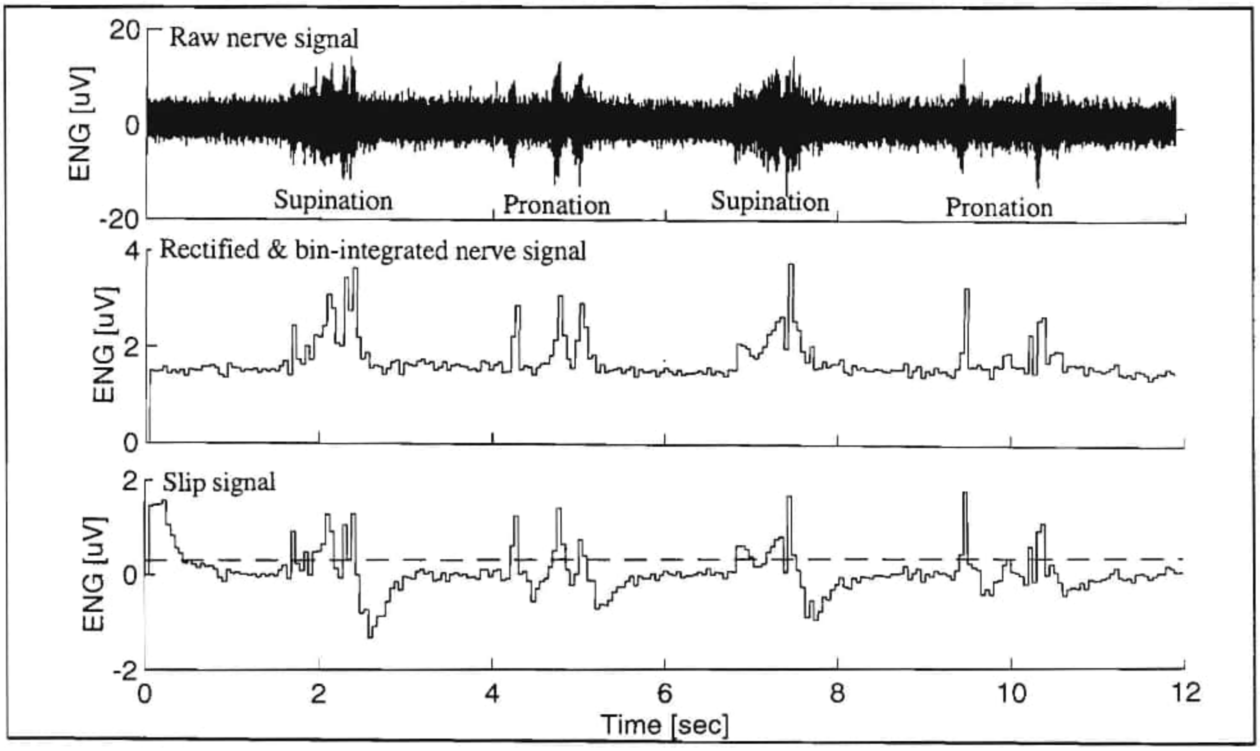

Figure 2 Raw and bin-integrated nerve signal recorded while the hand was actively supinated and passively pronated two times. No stimulation was applied.

DISCUSSION

The experiment clearly demonstrated that chronical recordings from natural sensors in the index finger of a tetraplegic patient can be used to detect when an object slips across the skin during an FES controlled

A PC-controlled stimulator delivered current-controlled, biphasic, charge balanced pulses at a rate of 20 Hz. Stimulus intensity was varied by modulating the pulse duration between 0 and 255 μsec. The stimulation pulses for the different muscles were delivered sequentially with a temporal spacing between the pulses of 1 msec. The output from the controller was translated into individual pulse widths for each muscle by using a lookup-table for the activation of the muscles, where 0% corresponded to 'open hand' with full thumb extension, and 100% corresponded to 'maximal force generation' with full thumb flexion and adduction.

The nerve signal was amplified with a battery powered amplifier (MicroProbe Inc.) with a gain of 100,000 and passed through an isolation amplifier. The signal was then bandpass filtered (4^{th} order Krohn-Hite) with a lower cut-off frequency of 1000 Hz (to remove EMG contamination) and a higher cut-off frequency of 4 kHz, and then sampled at 10 kHz. The nerve signal was digitally rectified and bin-integrated to produce the envelope of the nerve signal at 20Hz sampling frequency.

We attempted to measure the movement of the object relative to the finger by equipping the object with a permanent magnet and tape a Hall effect transducer to the skin on the opposite side of the index finger. However, since the skin moved around the finger when the object was pulled, the output from the transducer not only signalled the position of the object with respect to the skin (positive change when object was pulled) but also the change in angle of the skin (negative change when object was pulled).

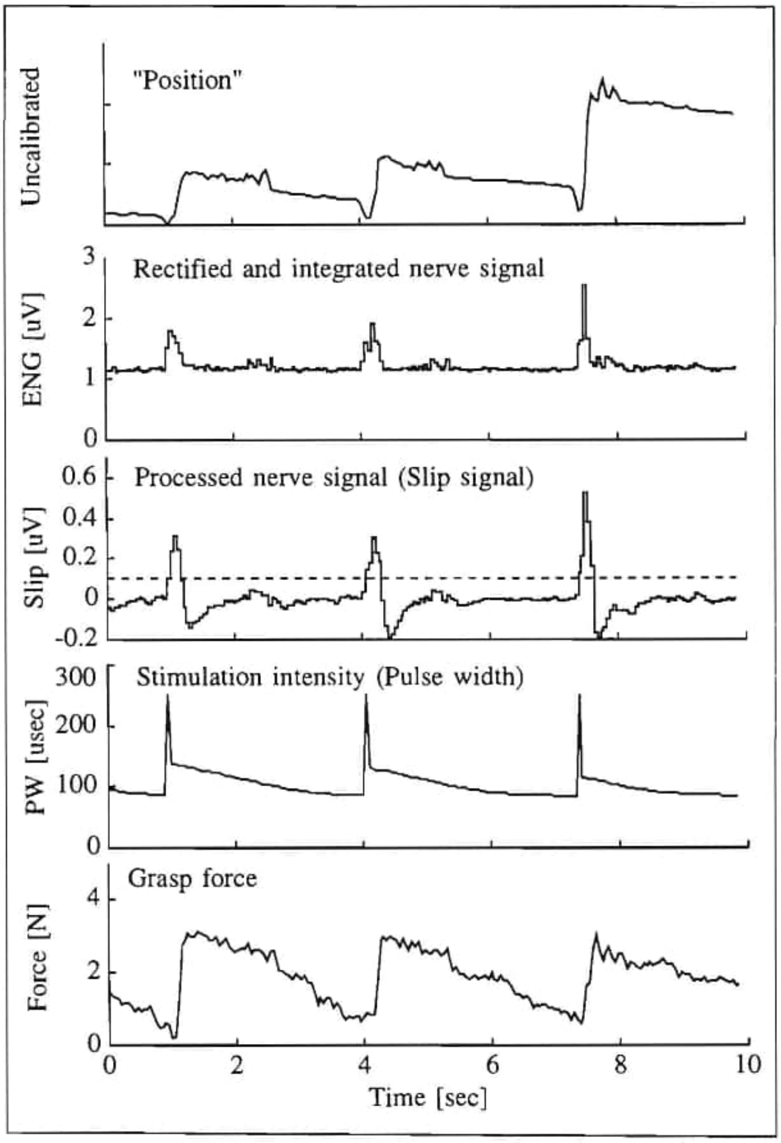

Figure 1 Slip detection and compensation. The test object was held in a key grip that was partially passive and partially produced by stimulation. Three times the object was briefly pulled away by the experimenter, causing skin deformation and slip. Top trace shows the position of the object measured by a Hall-effect transducer stuck to the skin on the opposite side of the index finger. A slip was detected when the processed nerve signal crossed the threshold value marked as a dashed line, at which time the stimulation intensity (PW=pulse width) increased to produce an increased grasp force.

To extract information about occurrence of slips from the rectified and integrated signal, a simple peak detection scheme was employed, similar to the algorithm previously used in cat experiments /1/: To remove slow changes in signal amplitude caused by changing noise-level and background activity, a lowpass filtered (0.7 Hz) and delayed (0.2 s) version of the signal was subtracted. A slip was detected when the signal passed a fixed threshold value.

Several of our recording sessions were dedicated to obtaining information about the nerve response to different mechanical stimulations of the skin (perpendicular and lateral forces and slip). The results of those studies will be presented elsewhere. Here is presented results from experiments with a more practical purpose, i.e. to find out whether the signals recorded during stimulation of muscles producing a grasp could be used as feedback information that would improve the grasp.

lateral grasp, and that this information can be used to increase the grasp force to secure the grip. However, there were also a number of problems. Many of the percutaneous stimulation electrodes broke earlier than expected, making it difficult for us to really investigate the usefullness of slip-information as a feedback signal. Within the first three months after implantation, 5 out of 11 electrodes broke. This was a much higher rate than expected and was attributed to the very active lifestyle of our patient. Also, one wire from the cuff electrode broke after 244 days of implantation, at which time we chose to stop the experiments and explant all electrodes.

It was possible to extract information about the occurence of a slip across the skin and use the information in a "near practical" situation to increase the stimulation intensity in order to secure the grip. However, because of the weak force available from the stimulated thumb muscles, it was not possible to show whether this would have any practical significance for the patient. This should of course be possible to avoid by better muscle conditioning and better placement of stimulation electrodes. Also, it was observed that with the relatively simple processing of the nerve signal that we used, slow slips, even large ones, were practically impossible to distinguish from background noise in the nerve signal.

It has not so far been possible to distinguish between real slips and other transient mechanical events applied on the skin. In order for a practical system to work in the presence of hand movements such as pronation and supination, it will be necessary to find ways to identify these movements and disable the slip-compensation during periods of predictable disturbances. This may be possible to do by use of information from the stimulator and EMG picked up by the stimulation electrodes. If the stimulation intensity continuously is slowly reduced as suggested in /1/, a false detection will only cause a too high grip force for some time. The occurences of this should of course be reduced as much as possible, but will not necessarily disable the functionality of the system.

If more information is to be extracted from the nerve signal to distinguish between different types of events, it is important to develop cuff electrodes that shields better against external noise, since at the present pickup of stimulation artifacts and EMG severely limits the quality of the nerve signal.

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ASSESSMENT OF TRI-STATE MYOELECTRIC CONTROL FOR BILATERAL UPPER EXTREMITY NEUROPROSTHESES.

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SUMMARY

Detection of myoelectric signals from muscles under volitional control for persons with tetraplegia is proposed for the provision of control of bilateral upper extremity neuroprostheses. A computer simulation was used to assess the ability of persons to use both right and left sternocleidomastoid muscles (SCMs) to control their corresponding ipsilateral hand. A tri-state myoelectric signal was used where maintaining a low level causes hand closure, a high level causes hand opening, and zero level maintains the current hand configuration. Six subjects (five non-injured, one C5/C6 spinal cord-injured) were tested in their ability to use their right and left SCMs to independently move computer-generated indicators of right and left hand opening. Myoelectric signals, detected with surface electrodes, were amplified with a gain of 1000 and filtered with a bandwidth of 15-150 Hz before their sampling at 400 Hz. The rms value of the signal was obtained at approximately 10 Hz and used to update on-screen indicators of virtual hand position. Assessment was made by measuring the subjects time to complete a tracking task, the integral of position error and the percentage of incorrect commands in that task. The effect on these assessment parameters of varying target positions, speed of indicator movement and open/close command thresholds was measured. All six subjects were able to manipulate the dual on-screen indicators using their right and left SCMs without apparent differences between the performances of non-injured and injured subjects.

STATE OF THE ART

Myoelectric control of the upper extremity neuroprosthesis has been demonstrated to be adequate for users completion of activities of daily living /1/. This approach has been readdressed here with a modified control strategy and extended in order to enable the use of bilateral neuroprostheses for the control of the right and left hand grasp. Demonstration of the detection of myoelectric signals for the purpose of bilateral control of neuroprostheses using sternocleidomastoid muscles has been made and has shown the appropriateness for this approach /2/. Applying this strategy here, six subjects (1 C5/C6 spinal cord injured, 5 non-injured) have been assessed in their ability to control on-screen indicators that simulated hand opening and closing. This is in order to demonstrate the ability of persons to use this control methodology and to measure the sensitivity of the control to setup parameters.

MATERIALS AND METHODS

Myoelectric signals were detected by placing three skin surface electrodes each over the right and over the left sternocleidomastoid muscles. The skin was prepared by washing with soap and water, followed by the application of redux paste (Hewlett-Packard, CA) to reduce the skin resistance. Pre-gelled, single use surface monitoring electrodes were then held with tape to the skin surface. The differential electrodes were placed approximately 1 cm apart and close to the clavicular end of the muscle. This placement reduced the influence of the muscle moving under the skin during head turning. A third, indifferent electrode was placed off the muscle at the base of the neck at the shoulder. Signals were amplified with gain of 1000 and filtered with a pass-band of 15 Hz to 150 Hz. The conditioned signals were then sampled at 400 Hz and processed in real time by a routine that utilised Labview software (National Instruments, TX).

Subjects were presented with a computer screen which showed a vertical bar graph on the left and another on the right. These bar indicators could be moved by the flexing of the left or the right sternocleidomastoid respectively to show virtual hand position. A strong flexing of the muscle (above a high threshold) would result in the bar rising and a weak flexing of the muscle (above a low threshold, but below the high threshold) would lower the bar. This position indication, when applied to the neuroprosthesis, would correspond to degrees of hand opening and closing, respectively. The experimental trials involved tracking tasks by the manipulation of this on-screen hand position indicator. Only one side was allowed to be moved at a particular instant. The low and high thresholds incorporated hysteresis and filtering in order to reduce the occurrence of accidental state changes. These thresholds could be changed between trials via the computer keyboard.

Muscle Command	**Command Response**	
	left	**right**
both off	none	none
right low	none	down (close right hand)
right high	none	up (open right hand)
left low	down (close left hand)	none
left high	up (open left hand)	none

Table 1. Tri-state command control strategy for on-screen hand control simulation (indicator bars showing degree of hand opening) and proposed hand grasp control (in parentheses).

At the commencement of an experiment, the subject would flex strongly their right and then left sternocleidomastoid muscle as prompted on the computer screen. The RMS voltage level of these signals was used to normalise all the following signals to be processed by the computer. All thresholds for strong and weak commands were relative to this. The normalisation also compensated for variations between the right and left signals due to electrode placement and resistance. Although, in the flexing of the sternocleidomastoid without head movement, a co-contraction of the right and left muscles occurs, it has been shown /2/ that the command directed to one side or the other can be differentiated. This property was exploited by the system software to differentiate the subjects commands and to, subsequently, decide in which direction to move one of the indicator bars. Beside the indicator bars were bars showing the target position to which the subject was required to match with the right and left sides. The position of the target bars was varied for some trials in the experiment. A tracking task was considered to be successful and subsequently stopped when both the right and left tracking bars were within five percent of the target position. The threshold for the weak and strong flexing commands was varied in some experiments as was the speed of the indicator bars. Signals acquired by the data acquisition board (National Instruments, TX) were sampled at 400 Hz and then processed in windows of width 0.05 s. A moving average RMS algorithm was applied to consecutive windows. The RMS signal level measured in each window was compared to the preset command thresholds and a decision was made in the software as to the current command state. Subsequently, the tracking bar would move as required.

Ten trials of each experimental test were made for each subject and these are expressed as (mean ± standard error of the mean).

RESULTS

All subjects (6/6: one spinal cord injured, five non-injured) were able to complete the tracking tasks. Three subjects (one spinal cord injured, two non-injured) were immediately able to operate the on-screen indicators using both right and left sternocleidomastoid muscles. The remaining three were taught to do this using a training method incorporating head movements to increase their consciousness of the flexing of these muscles. After approximately half an hour of this training, these remaining three were able to control the on-screen indicators at a performance level that would be sufficient for hand control and was comparable to the three, immediately successful, subjects.

The investigation involved a precision tracking task which consisted of moving right and left on-screen indicators to their respective targets. For the slowest subject the trials for the initial tracking task took (7.4 ± 1.8 s; n=10) whereas the mean over all the subjects was (4.1 ± 2.1 s; n=6). The slowest subject also had the largest error rate which was (23.2 ± 3.8 %; n=10) of commands issued and the mean error rate over all six subjects was (13.4 ± 5.8 %; n=6)..

In the first experiment above, the subject was required to control the indicator bars such that the left bar moved in a positive direction and the right bar moved in a negative direction (although subjects weren't required to move these simultaneously). The second experiment reversed this and required that the left bar be moved in a negative direction and the right bar be moved in a positive direction. The outcome values are expressed relative to those obtained for the first experiment. For three subjects, changing the direction of the bar movements required to make the targets, did not significantly effect the time to complete the tracking task. For two of the subjects there was a significant improvement in the second experiment with regard to the time required to complete whereas one subject took (46 ± 0.4 %; n=10) longer with the second tracking task. In the second tracking task the number of errors increased significantly with this particular subject as well as with two of the subjects whose task completion time did not change significantly with the target position change. Two subjects had less errors with the second experiment whilst one had no significant difference.

The third experiment involved the increasing of the speed of the indicator bar movement during commands. The outcome values are expressed relative to those obtained when the speed was set at 100 Hz. The results indicate that for four of the subjects, a significant improvement in completion time was made by increasing the speed with that improvement being lost when the speed was increased to 300 Hz and above in one of these subjects. Overall, the fastest speed at which subjects could reliably control the indicator bars for tracking purposes was 500 Hz. It would be expected that with the increase in speed of the tracking bars the number of errors made would increase accordingly. This was the case in four subjects with no significant change in the relative amount of errors made in the remaining two. Generally, 300 Hz was the preferred speed for subjects as it produced mostly improved completion times although the increase in the number of errors would need to be considered with respect to acceptability for the functional tasks to be performed by the user of electrically stimulated hand grasp .

The final experiment involved the modification of the command thresholds for examination of the sensitivity of tracking to these parameters. Firstly the lower command threshold was increased and decreased from 30% of the normalising command to 40% and 20% respectively while maintaining the upper threshold constant at 80% (5 subjects). Secondly, the upper command threshold was increased and decreased from 80% of the normalising command to 90% and 70% respectively while maintaining the lower command threshold constant (6 subjects). The outcomes are expressed relative to that obtained with the low threshold set at 30% and the high threshold set at 80%. For the variation in the lower threshold, reducing the threshold did not significantly change the relative completion time although increasing it increased the relative time to complete in three of five of the subjects. Reducing the lower threshold here was also seen to increase the relative number of errors in one of five subjects and increasing the lower threshold increased the relative number of errors in two of five of the subjects. Reducing the upper threshold increased the relative time to complete the task in only one of the six subjects and had no significant effect on the remaining five. This subject also was the only one showing an increase in the relative number of errors occurring as the result in the reduction in the upper threshold. Increasing the upper threshold reduced the time for tracking task completion for three of six of the subjects and increased it in one case. This increase in the upper threshold also reduced the relative amount of erroneous commands in the three subjects who had shown a reduction in relative completion time here. The remaining three showed no significant difference in the errors made as the result of this. These results indicate that best performance may be obtained by making the low command window (between the low and high threshold) as large as possible while ensuring the low signal is above the background signal resulting from head movements and the high threshold is not so high as produce unacceptable fatigue during the issuing of a high command.

DISCUSSION

Control methods of the upper extremity neuroprosthesis have been reviewed /3//4/ and the approach taken by researchers to solve this problem is usually in the form of state controllers or proportional controllers. The most popular proportional controllers are the joint angle controllers and those for state control being switch, respiration and voice. Myoelectric control, although mainly used in prosthetic applications, but previously explored for upper extremity neuroprostheses by Peckham /1/, is most suited to state control /5/. In considering a control method that is suited to the control of bilateral neuroprostheses, myoelectric control is a method which can provide the C5/C6 spinal cord injured user with a control method that allows the use of the users remaining volitional faculties (such as sternocleidomastoid activation) without interfering with the performing of functional tasks with the instrumented hands themselves. This is not the case with the joint angle controllers (say shoulder and wrist) or in the switch controller. Voice and respiration control if applied to the control of bilateral neuroprostheses would increase control complexity in a system that is limited in its intuitiveness. Myoelectric control allows the control signal source to control the ipsilateral hand thereby improving the intuitiveness of the control method. This study demonstrates that simultaneous hand grasp and release can be robustly controlled on both the right and left sides by the use the sternocleidomastoid muscles. It was also seen that the performance of the C5/C6 spinal cord injured subject in this control was not worse and in most cases better than his non-injured counterparts.

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ENHANCED REACHING BY MEANS OF FES

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SUMMARY

A method for determination of stimulation parameters for control of elbow movements in humans with spinal cord injury at C_4-C_5 cervical levels was developed. The study considered the design of a hierarchical controller for the elbow joint for reaching tasks. The coordination, higher control level is assumed to follow the synergistic strategy based on scaling of angular velocities in the plane of movements, and it uses an expert system. The actuator, lower level is a closed-loop control using production rules based on mapping of the angular velocity vs. stimulation parameters in subjects in whom the system is to be applied. Results of the study suggest that the look-up table for selection of stimulation parameters is appropriate for subjects lacking voluntary control of elbow movements, but having preserved at least partial innervation of biceps and triceps muscles. The time sampled feedback uses present and past values of the angular velocity at the elbow joint.

INTRODUCTION

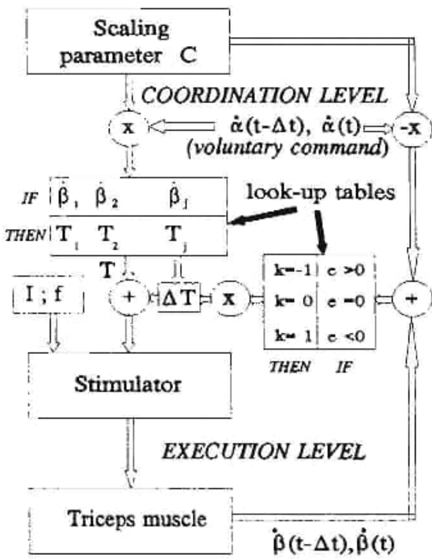

Fig. 1: The generalized form of a hierarchical controller for arm movements. $\dot\alpha$ and $\dot\beta$ are the shoulder and elbow angular velocities, and e is the error at the elbow joint.

Two approaches to control assistive systems for reaching and grasping are described in the literature: 1) analytic /1-4/, and nonanalytic /5/. An analytic method uses a complex biomechanical model of a system of rigid bodies powered by a redundant set of muscles and a preferred trajectory given in advance. A human upper extremity is a system with seven degrees of freedom at the arm and 19 degrees of freedom in the hand, powered by about 30 pairs of muscles; thus, this is a highly redundant system in which movements are highly dependent on the task. A convenient control method to control movements relies on synergistic actions, and great simplification /4/. An approach developed earlier for control of artificial arms uses extended physiological proprioception, and this method has been tested for control of reaching /6/. The evaluation of this approach has been verified using optimal control simulation which considers the dynamics and includes nonlinear characteristics of both agonist and antagonist muscles /7,8/.

A rule-based system can be used for both levels of control, and it has two parts: 1) nonanalytic control using sensory feedback at the actuator level, and 2) nonanalytic, feed-forward control at the coordination level (Fig. 1). Even though the lower level of control is nonanalytic it has to consider many biomechanical properties of the system. This part of the control requires individual neuro-musculo-skeletal parameters of the arm for different tasks. A nonanalytic hierarchical method is favorable for the dynamic control because it decouples the system to single joint controllers, and simplifies the single joint regulation by using a look-up table generated through input-output observations equivalent to a non-parametric identification of the system. Note, that the upper part in Fig. 1 is open-loop control. The parameter C for scaling between the angular velocities of the shoulder and elbow joint is determined from the initial and terminal position of the hand. The lower part of the scheme is a sampled data feedback control, and e is the error between the desired and actual value of the elbow joint angular velocity.

The aim of this research was to develop a method for determination of individual characteristics of a tetraplegic subject to be used for the actuator level of control of an assistive system. The hypothesis adopted in this development is that, for the control of the elbow joint using a rule-based method, it is sufficient to determine the mapping between the angular velocity in the elbow joint and corresponding stimulation parameters. The nonlinearities of the neuro-musculo-skeletal system are inherent characteristics when the system is mapped in output space. Since the mapping can be done for different environmental conditions, and different loadings the dynamic variability becomes also an intrinsic property of the mapping determined. Hence, even though the synergistic approach based on scaling of angular velocities can be classified as a kinematic method, it considers the dynamic properties of both the control object and the process.

METHODS AND MATERIAL

Subjects. Five volunteer tetraplegic subjects with a SCI at the cervical (C_4,C_5) level resulting in loss or disorder of motor and sensory functions, absence of strongly manifesting spasms, preserved lower motor neurons, sufficient balance while sitting, and no cardio-vascular problems participated in the study. In subjects we estimated: 1) the muscle response to electrical stimulation; and 2) the level of pain and discomfort during surface FES. If a good muscle contraction was observed in muscles relevant for manipulation, and the pain elicited with surface FES was tolerable, then a subject was accepted in the study. Each subject signed the informed consent approved by the local ethics committee, and all measurements were done at the "Dr. Miroslav Zotović" Rehabilitation Institute in Belgrade. The paper presents only one subject data, because it is not possible to generalize results due to differences between subjects. The representative set of recordings presented here is very similar to patterns found in all four other subjects, but numerical values are different. The optimal control based on the minimal tracking error and limited actuator torques simulation of grasping in other subjects when actuator torques are limited has been performed, and a very good correlation was found /8/.

Determination of a look-up table. The triceps brachii muscle was electrically stimulated using surface electrodes, and the elbow joint angle was measured using a two-axial flexible goniometer. The angular velocity was calculated off-line using techniques described elsewhere /7/. The following characteristics were assessed: 1) the elbow joint angular velocity vs. pulse duration; and 2) the elbow angular velocity vs. time using the stimulation parameters and initial elbow joint angle as parameters. The frequency of electrical stimulation was constant at f = 20 Hz, while the amplitude was set at a level that ensures that a train of pulses, each lasting T = 150 μs, generates maximal torque. We measured the elbow joint torque /7/, but these results are not included in this paper due to space limitations. In all subjects the limitation of the maximal electrical charge was limited by the spreading of the stimulation to antagonistic muscles, e.g., biceps brachii m. The amplitude of the stimulating monophasic, charge compensated, pulses was between 45 and 75 mA.

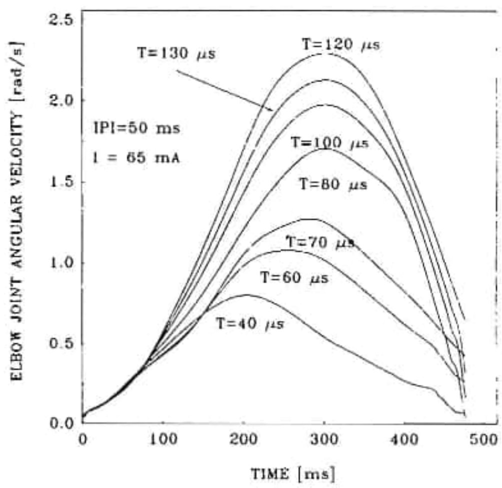

Fig. 2: The elbow angular velocity vs. time. At longer pulse durations the maximum velocity starts decreasing because of the spread to biceps brachii m.

RESULTS

An example of recordings in D.J., a tetraplegic subject (Fig. 2), shows the angular velocity vs. time with the pulse duration used as a parameter. Note that for different pulse durations the initial slope of the curves reaching different maximum angular velocities is almost the same, indicating that the delays imposed by the muscle and inertial characteristics of the system are playing the major role. As expected the maximal velocity is increased when a larger charge is delivered to the muscle. Once the stimulation starts spreading to antagonistic muscles the maximum velocity starts decreasing as is shown for the pulse duration of 130 μs. The set of data presented (Fig. 2) is only one from a large series of recordings. It is necessary to capture similar sets of data in order to generate look-up tables for mapping in various dynamic conditions (e.g., for the arm moving in the horizontal and vertical planes, tilted planes for various angles with respect to vertical, with different loads in the hand, and starting the movement in various angular positions). The pulse amplitude and frequency of stimulation were kept constant during the experiments.

The maximum angular velocity which the elbow joint reaches vs. pulse duration for three different initial positions is presented in Fig. 3. These plots were obtained by processing several series like the one depicted in Fig. 2. where the initial joint angle was invariant ($\beta = 60^o$)

DISCUSSION

It is known that the usage of controlled patterns of electrical pulses will cause the muscle to contract, and in some cases this leads to a functional device for restoration of movements /9/. However, there is no effective way to control muscles, even though many biomechanical and motor control studies addressed this issue. A suggestion that the hierarchical control method using the rule-based skill expert system for coordination between joints, and closed-loop control system at the actuator level is the alternative best suited to biological control /5/ has been verified for some applications, but is still controversial. The specific reason that this control is believed to be the best approach is that for the variation of many parameters within the system, adaptation to changes of the environment can be easily taken into account. This study was dedicated to develop a methodology for estimating parameters relevant for the implementation of functional electrical stimulation when using a rule-based controller.

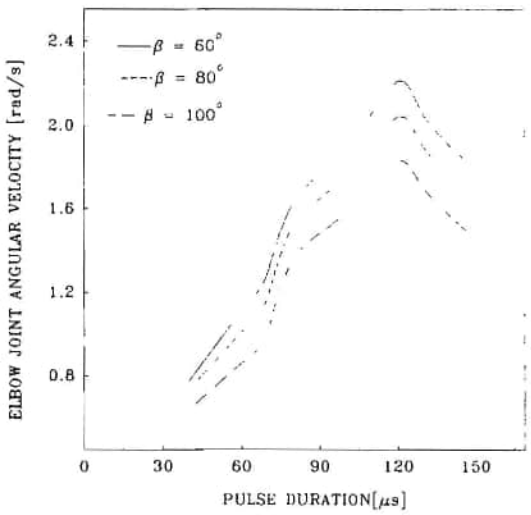

Fig. 3: The maximum elbow joint angular velocities for different initial elbow joints and pulse durations.

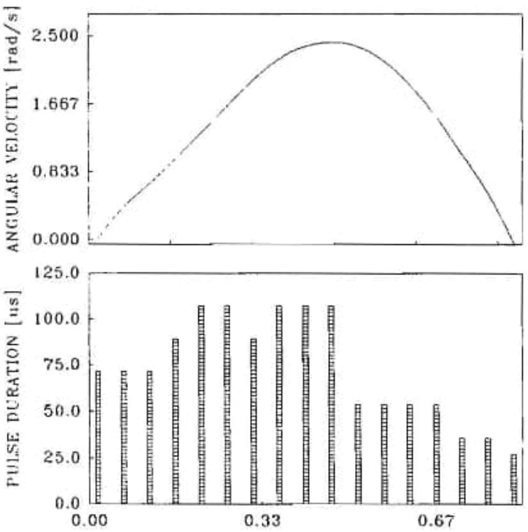

Fig. 4: The estimated profiles of pulse durations for a given elbow angular velocity vs. time. The controller, as shown in Fig. 1, will select duration based on the past and present velocities.

Muscle activation is variable from subject to subject, but also in the subject at various times. The fatigue of the muscles is excluded from this study, but it is relevant and it has to be incorporated at a later phase of the design of a controller. The fatigue will typically change the response by slowing it down and decreasing the maximum torque. Since we use normalized activation, the fatigue, if detected, can be included relatively simply, because it will only change the ratio of stimulation parameters to normalized activation.

The analysis of data obtained when stimulating the triceps brachii m. showed that the look-up table can not be a simple set of pairs of pulse durations and joint angular velocities, because of the delays in muscle responses and inertia of "actuators". The look-up table must include a past value of angular velocity in addition to instantaneous velocity. The procedure for assessing parameters is schematically presented in Fig. 4. The diagram shows the angular velocity in parallel with the estimated triceps m. activation for an elbow extension of 1.2 radian lasting 1.06 seconds. The elements used for estimation of this profile of activation are the past and present angular velocities presented in a look-up table similar to Table I. The actual implementation follows the methodology of production rules, i.e., *If-Then* conditional expressions are used, where the *If* part of the rule is formed with an exclusive *and* of the past and present values of the elbow angular velocity, and the *Then* part of the rule is the pulse duration; hence, it can be easily mastered in real-time. Note that the stimulation parameters are adjusted in real time.

Table: 0.32 rad/s

$\dot{\beta}(t-\Delta t)$ [rad/s]	$\dot{\beta}(t)$ [rad/s]	T [μs]
0.32	0.32	50
0.32	0.34	60
0.32	0.36	70
0.32	0.40	80
0.32	0.44	90
0.32	0.50	100
0.32	0.57	110

Table: 0.40 rad/s

$\dot{\beta}(t-\Delta t)$ [rad/s]	$\dot{\beta}(t)$ [rad/s]	T [μs]
0.40	0.32	0
0.40	0.34	10
0.40	0.36	20
0.40	0.40	30
0.40	0.44	40
0.40	0.50	60
0.40	0.57	90

Table I: An example of two, from many, look-up tables formed by mapping the recorded sets of maximum velocities and corresponding stimulation parameters.

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THE USE OF ELECTRICAL STIMULATION TO PREVENT SHOULDER SUBLUXATION POST STROKE

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SUMMARY

A prospective randomised controlled study was used to determine the efficacy of electrical stimulation in preventing shoulder subluxation in post CVA patients. Forty patients were selected and randomly assigned to a control or treatment group. They had their first assessment within forty-eight hours of their stroke and those in the treatment group were immediately put on a regime of electrical stimulation for four weeks. All patients were assessed at four weeks post stroke and then again at twelve weeks post stroke. Assessments were made of shoulder subluxation, pain and motor control. The treatment group had significantly less subluxation and pain after the treatment period but at the end of twelve weeks there was no significant differences between the two groups. It appeared that motor score at the beginning was a good predictor of subluxation. Electrical stimulation can prevent shoulder subluxation but after the withdrawal of treatment there was a tendency towards subluxation.

STATE OF THE ART

Shoulder pain in hemiplegic patients is a common complication which causes distress to the patient and obstructs the rehabilitation process. The inherent instability of the glenohumeral joint places great importance on the musculotendinous sleeve which surrounds it to maintain normal alignment /1/. The loss of activity in these muscles which occurs following a stroke can result in inferior subluxation of the glenohumeral joint; this may cause stretching of soft tissues and contribute to the problematic painful hemiplegic shoulder. Prevention of secondary complications which impairs functional recovery must be a priority in rehabilitation. At present the treatment and prevention of subluxation is dependent on the use of slings which support the arm in a restricted position. The complications associated with the use of slings has led to interest in the use of electrical stimulation as an alternative.

There have been two studies on the use of electrical stimulation in reducing shoulder subluxation. Baker and Palmer /2/ showed that electrical stimulation could reduce existing subluxation but that it did not help to regain a full reduction. Faghri et al /3/ conducted a randomised control trial, with a six week treatment period, on a total of 26 patients starting treatment at a mean of 17 days post stoke. In this study it appeared that the patient group had significant subluxation at the start of the programme. They demonstrated that further subluxation could be reduced and further subluxation, after treatment, prevented.

There have therefore been no reports which have assessed the prophylactic effect of electrical stimulation in preventing the development of subluxation immediately post stroke. This aim of this study was to investigate the effectiveness of using electrical stimulation in preventing this significant problem.

MATERIAL AND METHODS

Forty patients were selected. The main inclusion criteria was that the patient has suffered a CVA resulting in a significant motor deficit in the upper limb (grade 2 or less on the MRC scale). Patients were recruited within 48 hours of admission to the Acute Stroke Unit of the Western Infirmary, Glasgow in order to commence the programme before complications arose. Informed consent was obtained and patients were randomly allocated to treatment and control groups. All patients in the treatment group received a four week course of electrical stimulation immediately after the first assessment session [s1].

Electrical stimulation was applied to the supraspinatus and posterior deltoid muscles four times each day. Treatment sessions were increased from thirty minutes to one hour over the four week period. The duty cycle was 15 seconds on, including 3 seconds ramping up and 3 seconds ramping down, and 15 second off. On several occasions an X ray was taken of the shoulder whist stimulation was applied to ensure the correct movement was being achieved.

Measurements were made of; subluxation (by use of one A-P radiograph), pain, motor function and upper arm girth. These measurements were made on three occasions; before commencing programme [s1], after four weeks, at the end of the treatment period [s2], and three months post stroke [s3]. At each assessment session a single A-P radiograph was taken and consistency of positioning was ensured by having the same person present throughout all assessments. X-ray magnification was repeatable to within 1mm. The X-rays were evaluated in two ways. One method was a categorisation of subluxation /4/ which was performed by an independent blinded radiologist. The categories were: 0 - normal humeral alignment, 1 - V shaped widening, 2 - moderate subluxation, 3 - advanced subluxation and 4 - dislocation. The second method involved measuring, from the X-rays, the distance from the most superior aspect of the humerus to a line bisecting the glenoid. Pain was assessed using two methods. The first followed a protocol to assess pain-free range of lateral rotation /4/. A reduction in range reflected an increase in pain. The second method was a verbal rating score. Motor function was assessed using the upper arm section of the Motor Assessment Scale /5/. Pain and motor function were evaluated by an independent blinded physiotherapist.

Non parametric statistical analysis [Wilcoxon] was used to compare the changes, between the two groups, over the treatment and follow-up periods.

RESULTS

There were no differences between the treatment and the control group in the motor scores for any of the sessions although there was a improvement over the sessions [means of whole patient population at each session were: s1 = 1.00, s2 = 2.93, s3 = 3.35]. Motor scores for session one are shown in figure 1.

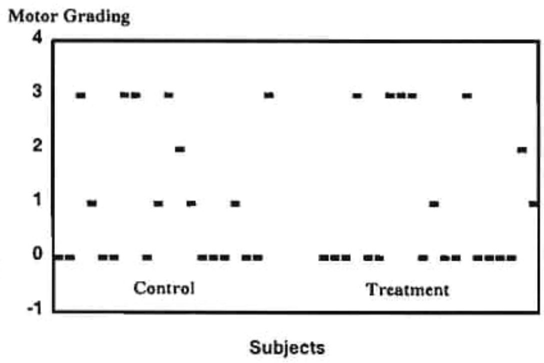
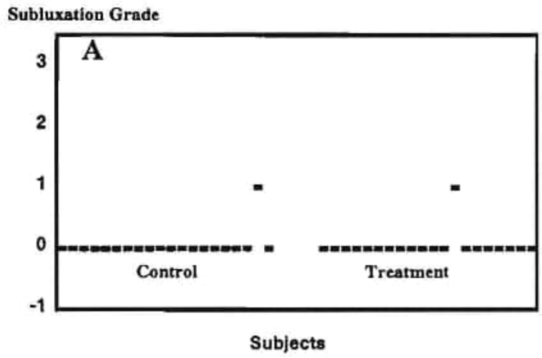
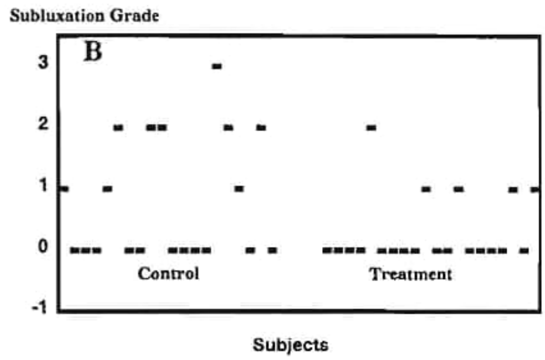


Figure 1 *Motor grading of all patients at the first assessment session [s1] prior to the start of treatment. There is no significant difference between the groups.*

There was no subluxation at the end of the programme in the 14 subjects (7 in the treatment group and 7 in the control group) who had a motor scale of 3 or 4 at the start of the programme. Of the 21 subjects (10 in the treatment group and 11 in the control group) who had a motor scale of 0 in the first assessment 14 had subluxation at the end of the programme. It appears that initial motor score is a strong indicator for shoulder subluxation.

The results for subluxation grading are shown in figure 2. There was a significantly greater increase in subluxation in the control group over the treatment period [$p = 0.067$]. This changed over the follow-up period when the treatment group had significantly greater subluxation [$p = 0.020$] Over the whole programme there was no significant difference in the change in subluxation grading between the groups. Subluxation as measured by the distances on the radiographs showed similar results. The mean distances for the treatment group were: s1 = 2.51, s2 = 1.88, s3 = 1.89. The mean distances for the treatment group were: s1 = 2.40, s2 = 2.18, s3 = 1.87. The control group had more subluxation than the treatment group over the treatment period [p = 0.064] but this trend reversed over the follow-up period the treatment group [p = 0.023]. Over the whole programme there was no significant difference, between the groups, in the change in subluxation measurement.





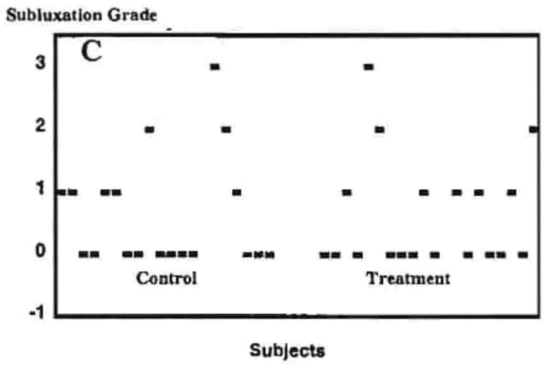


Figure 2 *Subluxation grades of all subjects in the treatment and control groups at all three assessment sessions. Figure A shows the values at session s1 prior to the treatment period, figure B shows the values at session s2 after the treatment period and figure C shows the values at session s3 after the follow-up period. The individual subjects are in the same order in all the figures and in the same order as in figure 1.*

There were no changes in the verbal rating of pain. However, over the treatment period, from s1 to s2, the pain free range of lateral of rotation (figure 3) of the treatment group decreased less than the control group [p = 0.015]. There were no other significant changes in the measurement of pain.

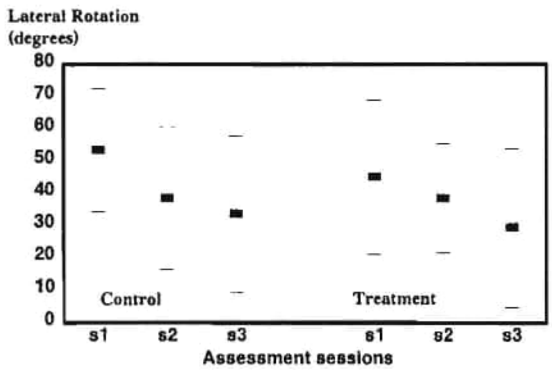


Figure 3 *A comparison of pain free range of lateral rotation for each for the control and treatment group at each session. Means and standard deviations shown.*

DISCUSSION

This study recruited forty patients very soon after CVA and only two had any sign of shoulder subluxation at the initial assessment [figure 1A]. There was clear effect over the treatment period but two months after the withdrawal of electrical stimulation the treatment group were indistinguishable from the control group. It is unclear from this study what would be required to maintain the benefits post treatment. However it is reasonable to assume that commencing stimulation immediately post stroke on a prophylactic basis is advantageous. The results over the treatment period are consistent with previous reports however unlike Faghri /3/ this study did not detect any long term gain. This could be due to the shorter treatment period of this study, the longer follow-up period, the different patient population (this study applied electrical stimulation immediately post stroke) or the different techniques of assessment. It is interesting to note that treatment significantly prevented the reduction of the pain free range of lateral rotation over the treatment period. It is this effect that may be of major importance to the stroke patient.

Motor control /5/ seemed to be a good predictor of shoulder subluxation. This study looked at 40 patients recruited over a ten month period. In 14 patients it would have been possible to predict that they were not prone to subluxation and this may have diluted the power of this study.

ACKNOWLEDGEMENTS

The funding of the Scottish Office [K/RED/6/23/14] is gratefully acknowledged.

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EFFECTS OF ELECTRICAL STIMULATION ON THE STIFFNESS OF THE WRIST POST STROKE.

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SUMMARY

The efficacy of electrical stimulation [ES] in reducing contractures in post stroke hemiplegia was investigated in a single case study design with repeated measures on eleven subjects over a period of six weeks. Treatment with ES was associated with an increase in the range of movement and reduction in the resistance to passive extension.

STATE OF THE ART

The loss of motor activity, secondary to a CVA, is often associated with the formation of contractures on the affected side, in spite of the many prophylactic measures in practice /1/. Although there is some degree of controversy on the actual cause /2,3/, a contracture is defined as a pathologic condition of soft tissues characterized by stiffness associated with loss of elasticity and fixed shortening of the involved tissues leading to a reduced range of movement [ROM] about the joint /4/.

Previous studies on the effects of ES on the hemiplegic wrist /5/ have reported an increase in the ROM. In this study we examined the effects of ES on contractures after stroke and quantified changes in ROM, resistance to passive extension and fixed shortening in the flexors.

METHODOLOGY

Eleven subjects with flexion contractures or reduced ROM at the wrist, secondary to a CVA, were recruited for this study. The group consisted of 3 female and 8 male subjects who were 4-weeks to 13-years post stroke. All subjects gave informed consent to join the study. The study, which was six weeks long, comprised of control, treatment and follow-up periods, each lasting two weeks. In the treatment period the subjects received four 30-minute sessions of ES each day along with their normal rehabilitation therapy. In the control and the follow-up period the subjects received their normal rehabilitation therapy. Surface electrodes were used to stimulate the wrist extensors.

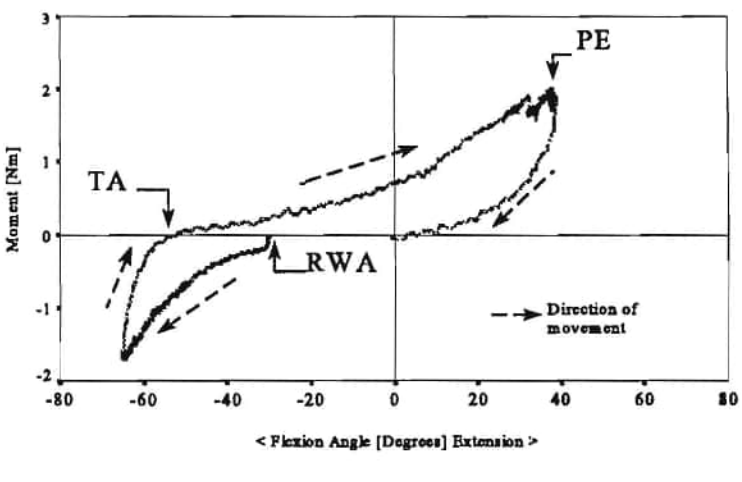

Figure 1. Sample moment angle curve.

Outcome measures

The outcome measures used in the pilot study were the Resting Wrist Angle [RWA], maximum extension angle [PE], Threshold Angle [TA] and the measure of the average work done [WD] in extending the wrist. The RWA was defined as the angle at which the wrist came to rest when placed on the measuring device. PE was the angle at which there was maximum resistance to movement or pain. The TA was defined as the angle, when stretching from full flexion to extension, at which a positive moment in the direction of extension was first applied. The average WD is defined as the area under the curve from the TA to PE divided by the difference between PE and TA [Fig 1].

The outcome measures were recorded at the start of the study [D0], end of the control period [D14], end of the treatment period immediately after the last ES session [D28/0], end of the treatment period one hour after the last ES session [D28/1], end of the treatment period 24-hours after the last ES session [D29] and end of the follow-up period [D42]. The outcome measures on nine subjects were taken using an electro-goniometer mounted on a mechanical device and on two subjects using a protractor goniometer.

RESULTS

The changes that occurred at the end of the treatment period were defined by the changes in the RWA, PE, TA and the average WD. The Wilcoxon's matched pair rank test was used to test for significance.

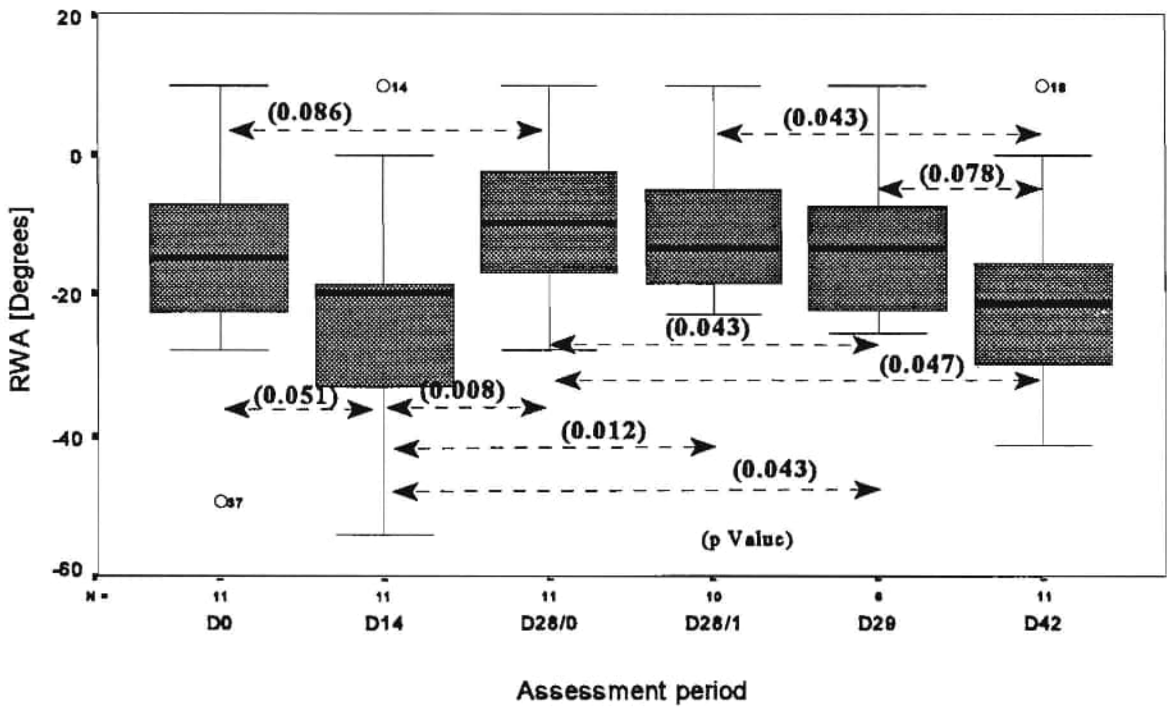

Figure 2. Box and whisker plot of the changes in the RWA. This had moved closer to neutral at the end of the treatment period.

The changes in the RWA [Fig 2] and TA followed a similar pattern. At the end of the control period these values had moved towards flexion and at the end of the treatment period they had moved towards neutral. However these changes started deteriorating from 24-hours after discontinuing ES and the general trend was continued deterioration to the end of the follow-up period. There were no significant difference in TA between the assessment periods.

There was an increase in PE [Fig 3] immediately after treatment was discontinued, however a reduction in PE was recorded at one hour after treatment was discontinued.

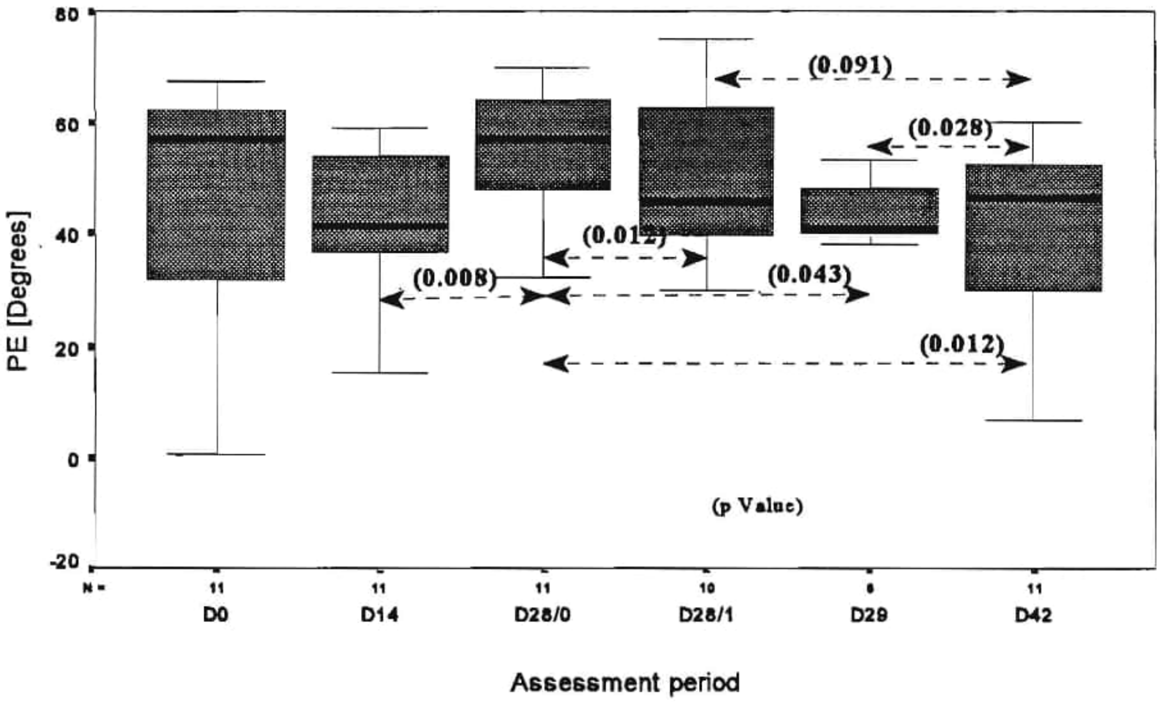

Figure 3. Box and Whisker plot of the changes in PE over the study period. There was an increase immediately after treatment was discontinued. However a reduction was apparent at one hour after treatment was discontinued.

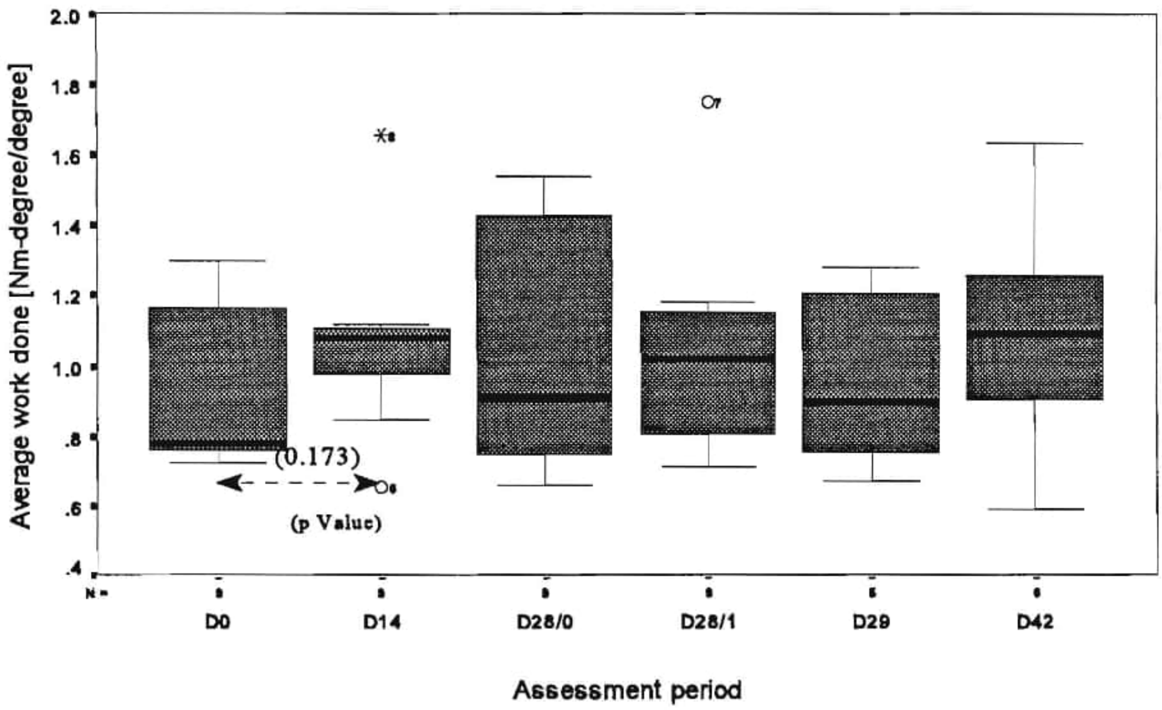

Figure 4. Box and whisker plot of changes in average WD in moving the wrist from the TA to PE. There was an increase over the control period and a subsequent decrease at the end of treatment.

There were no significant difference, in the average WD, between the assessment periods [Fig 4]. The changes showed an increase in average WD over the control period and a decrease at the end of the treatment period. An increase in the average WD would imply an increase in resistance to passive extension and a decrease would indicate a decrease in resistance to passive extension. These changes deteriorate at one hour post ES.

DISCUSSION.

The changes observed for the group at the end of the treatment period are consistent with a reduction in the formation of flexion contractures, i.e. there was an increase in the range of passive extension associated with a decrease in the resistance to passive extension. The decrease in the RWA and TA would also be consistent with a reduction in the adaptive shortening of the wrist flexors. However in hemiplegia these changes could also be associated with a decrease in spasticity and / or flexor tone. Any decrease in the flexor tone would manifest as a reduction in the resistance in the passive stretch and an increase in the RWA. The decrease in spasticity will manifest as a reduction in the resistance to a passive stretch and this reduction could be velocity dependent. Hence, as no attempt was made during the course of this study to quantitatively monitor tone and spasticity, it is difficult to state conclusively that the changes that were observed reflect a change in contracture formation only.

This study has indicated that ES may reduce the formation of contractures and flexor tone at the wrist in post stroke hemiplegia.

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Electrical stimulation exercise to improve hand function and sensation following chronic stroke.

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Summary

Twenty chronic Stroke subjects received electrical stimulation exercises of the hand and wrist muscles. Wrist and finger extensors were stimulated reciprocally with lumbricals, finger flexors or triceps. Subjects exercised twice a day for two periods of up to one hour for a period of three months. Three assessments were made, the Jebson-Taylor hand function test, static two point discrimination and palmer, pinch and key grip strength measurements. **Results.** 15 subjects improved their Jebson test score while 3 reduced their score and 2 were unchanged. The 16 subjects who were unable to complete the full test at the start of the trial, were able to complete an average of an additional 3.4 tests, an increase of 24.7% ($p<0.001$) There was a significant increase in key grip of 38 % ($p < 0.01$). The mean two point discrimination score increased from 1.80 to 2.44 ($p<0.02$). There was a significant difference between groups at the start of the trial but no statistical difference at the second static two point discrimination score.

While statistically significant differences were found in function, sensation and grip strength, it is not clear if these benefits were carried over into activities of daily living. Some subjects however reported improved function in activities such as fastening trouser buttons using both hands, and writing. Further investigation now required to verify these results.

Introduction

A seventy year old right CVA subject, seven years post CVA was referred to our department for electrical stimulation exercises to strengthen and improve the fatigue resistance of his wrist extensors. The wrist extensors were exercised using a Raymar Pocket Orthotron neuromuscular stimulator using 300 micro second pulses at twenty pulses a second, for two periods of twenty minutes a day. The stimulator gave a duty cycle of eight seconds on and ten seconds off. After one month the subject reported a significant improvement in not only wrist function but also finger extension. The subject reported improved hand function such as doing up buttons, putting on his reading glasses and tying shoe laces. He also believed his ability to feel had been improved. These reports, while subjective, convinced us that the use of electrical stimulation exercises to improve CVA hand function should be investigated further.

Materials and Method

Twenty chronic CVA subjects received electrical stimulation exercises of the hand and wrist muscles. Wrist and finger flexors were stimulated together with lumbricals, finger flexors or triceps. Subjects exercised at home for up to one hour a day. Three assessments were made. The Jebson - Taylor Hand

Function Test [1] consists of seven individual tasks and is performed by each hand. Each task is timed and if not completed, the number parts of the task completed recorded. The tasks are:

Writing. A standardised text is copied.
Turning 5 cards (75mm x 100mm).
Picking up and placing in a tin (180mm x 100mm dia) two bottle tops, two USA pennies and two paper clips.
Stacking four draughts pieces on a board (20mm thick).
Simulated feeding. Using a tea spoon, five kidney beans are lifted and dropped in to a tin.
Lifting empty 1 lb. baked bean tins (115mm x 75mm dia) on to a board, open end down.
Lifting full tins. As above but with unopened tins.

It was found that most subjects were unable to perform the writing test so this was omitted.

Sensation was tested using static two point discrimination [2]. The hand was divided up into 24 areas, four palm areas and four areas per digit. The subject was blindfolded and asked to say whether they perceived one point or two when the hand was touched with the probe. The hand was scored as follows:

0 = no sensation,
1= sensation but no discrimination or ambiguous answers given,
2 = 10mm discrimination
3 = 6mm discrimination
4 = 4mm discrimination
5 = 2mm discrimination

Each area was tested using the 10mm probes first and the probe size reduced until no discrimination was possible. The subject was also tested with one point randomly throughout the measurement. The mean two point discrimination (the sum of the scores divided by 24) was recorded for each hand.

Grip strength was recorded using an MIE Grip Strength Analyzer. Power, pinch and key grip were tested for each hand. Subjects were allowed three attempts and the greatest measurement recorded.

Subjects were tested prior to exercise and again between two and three months after exercise. Results are given below. It was not possible to record all measurements on all subjects. Subject numbers have been given in each case.

Results

Jebson test.

Overall, 15 subjects had improved scores, 3 deteriorated and 2 had no change. Four subjects completed all the tasks before and after, reducing their mean time per task by 37.9%. The 16 subjects unable to complete all the tasks, were able to complete on average 3.4 additional tasks by the second measurement, an increase of 24.7% (paired T test $p < 0.001$). There was no significant change in the unaffected hand.

Grip strength.

There was a significant increases in key grip (n=9 38.3% increase, $p<0.01$). There was also an increase in the power grip of the unaffected hand. (n=13, 15.1% increase, $p < 0.01$.)

Two point discrimination.

The mean two point discrimination score changed from 1.80 to 2.44 between the assessments ($p < 0.02$). Using a paired T test, 7 subjects increased their score, 4 were unchanged and 0 reduced their score. No significant change was found in the unaffected hand, 2.91 to 2.78. There was a significant difference between groups at the start of the trial but no statistical difference at the second measurement.

Discussion

While overall statistically significant improvements were recorded in all three measurements, it is not clear if these improvements were carried over into every day life. Some subjects reported improved function, for example one subject was able to do up his trouser buttons and belt using both hands, another was able to use a knife and fork, another manipulate a pepper grinder, and another was able to write all the families Christmas cards where previously they had only been able to do one or two. However some subjects received no improvement and none had a returns to normal function. No relationship can be found between the performance in the tests and the time since CVA, age or side of hemiplegia. There is also no indication that subjects with an initial very poor hand function improved their test scores any differently to subjects with initially reasonable hand function.

Baker et al. [3] noted an increase in the wrist extension of spastic hemiplegic subjects who used electrical stimulation to exercise the wrist and finger extensors. This would be consistent with increased hand function. However, the group could not find any change in skin sensation. Kraft et. al. [4] showed an improvement in hand function measured using the Fulg-Meyer test after similar exercises. They also showed that when the stimulation was triggered by the subject using emg that the improvement was increased.

It is not clear what the mechanisms behind these changes may be. The fact that a change in two point discrimination was recorded suggests that neural-plastic changes in the brain may have occurred and this may be due to increased activity in the hand while performing the exercises. While some increase in grip strength was recorded it is important to remember that the typical stroke subjects has significantly more difficulty in releasing his grip than in making a grip. A further trial would attempt to quantify the spastisity in the wrist and finger flexor muscles. Further work is required to validate these results in a more rigorously controlled trial and with a greater number of subjects, to establish which patient group can best benefit from this treatment and determine if the benefits are translated into improved function in daily living.

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RESIDUAL EFFECTS OF FES ON PATIENTS WITH CEBERAL PALSY

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SUMMARY

The objective of this research was to examine the effects, both during the treatment phase and after the termination of, functional electrical stimulation, FES, on children with cerebral palsy. Three boys with spastic hemiplegia participated; one boy also exhibited dystonia. The three underwent FES programs targeting the distal upper extremity for a period of at least a year during which time they were periodically tested for range of motion, strength, and dexterity. When the subjects' performance reached a plateau, electrical stimulation was terminated and the participants' function observed over the next 6 months. By the end of the FES programs, all three had improved their voluntary wrist extension by over 60º and grip strength by more than 10 lbs, or 60%; the times required to complete certain tests of manual dexterity fell by 20-80%. Two subjects maintained the gains they had made during the FES program within 20% of those recorded at the end of the treatment period. The third participant, who is dystonic, maintained wrist extension, but became hampered by an uncontrollable hyperextension of the interphalangeal joint of the thumb to such a degree that FES was reinstated.

STATE OF THE ART

Functional electrical stimulation, FES, has been employed in efforts to either correct or compensate for a number of neuromuscular disorders, such as dropfoot, plegia, and spasticity. Thus, cerebral palsy, CP, a condition often accompanied by dropfoot and spasticity, would seemingly be a potential area for FES treatment. However, the number of studies conducted on the effects of FES in CP patients is relatively small and the results have been mixed at best [1-6]. Some of the studies conducted have questioned the merits of using FES on the CP population, often citing a lack of any long-term or residual effects [7,8].

This paper summarizes the results obtained both while an FES program was being conducted and for 6 months after FES was concluded. The FES treatment focused on the distal upper extremities of children with CP. Quantitative data was collected in conjunction with qualitative observations to better gauge any changes that might have occurred.

MATERIALS AND METHODS

Subjects

This research involved three boys, DS, CR, and ME, aged 12, 15, and 9 years at the beginning of the respective studies. All three had spastic hemiplegia; CR also exhibited dystonia.

DS was affected on his left side. Before the advent of the electrical stimulation he held his hand with the wrist flexed and the fingers curled in the typical spastic CP posture. A cortical thumb inhibited grasping and pinching motions. A breech baby, he was not properly diagnosed until age 12.

CR displayed spasticity and dystonia on the right side. At the start of this study he pinched by using the second and third digits as pincers. From the age of 14 months until 3 or 4 CR participated in physical therapy.

ME was spast6ic on the right side of his body. He had a fairly good lateral pinch at the beginning of the study, but performed grasping and palmer pinching movements more poorly.

FES protocol

Surface stimulation was chosen because the boys were still growing and were too active for percutaneous or implanted electrodes and wanted to avoid the highly invasive nature of those electrodes. Commercially available Medtronics Respond II stimulators generated the stimulation pulses, each of which was 300msec. in duration. Pulse frequency was set to 53 Hz based on empirical findings examining maximal performance for a given level of comfort since the boys still had pain sensation.

The FES programs were tailored to meet the individual needs of each participant. DS received electrical therapy for 21 months. The stimulation generated wrist and thumb extension and thumb abduction. CR's 12-month FES program sought to produce wrist and thumb extension, thumb opposition, and finger flexion. ME underwent a 12-month program focused solely on improving wrist extension. The subjects were involved in 5 stimulation sessions per week at the boys' homes under parental administration and supervision. Session durations gradually were increased from 10 min. to 30-45 min. The percentage of time the Respond II devices were on during the on-off cycle was increased from 8 sec. on and 15 sec. off to 20 sec. on and 8 sec. off. The subjects were exhorted to help the stimulation contract the muscle as much as possible.

Testing

The participants were tested approximately once every three weeks. Voluntary range of motion of the wrist and thumb was assessed with a goniometer. Grip strength was evaluated using a JAMAR hand dynamometer. A pinch gage was employed to perform three tests of manual dexterity [developed to suit the CP subjects]. One task required the removal of a quarter, dime, nickel, and penny, one at a time, from a cardboard box. The second called for picking 5 pens out of a cardboard box and placing them into a cup. The third task entailed picking 5 small rubber balls out of a cardboard box.

Post-Stimulation

The three boys eventually reached a state in which their performances of a number of the aforementioned tests leveled. At this point it was decided to end the electrical therapy and monitor the subjects for 6 months. The subjects were instructed to continue the exercises, which had been part of the FES programs, without the stimulation. Measurements were still taken once every few weeks.

RESULTS

Table 1 shows the average scores for each subject during the course of the study. The first column represents the average of the first two testing sessions. The second column contains the mean values of the measurements recorded during the two testing dates prior to the discontinuation of the stimulation. The last column gives the mean scores for all of the data taken during the period when no FES was administered. Dashed lines indicate an inability to perform the listed task.

DISCUSSION

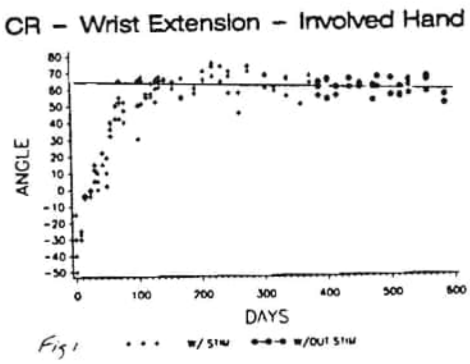
All three participants demonstrated substantial improvement while in the FES programs. Wrist extension increased by at least 60º. Grip strength rose by at least 10 lb (>60%). The time necessary to perform the given dexterity tasks dropped 20-80% with some decrease of over 150 seconds. DS and CR developed palmar pinching motions. The palmar pinch enabled CR to pick up small objects, such as coins. The data in the table attests to the extent of the improvement. Figures 1 and 2 indicate that the pattern of amelioration tended to be logarithmic. Improvement went beyond the test setting to everyday life. The boys began to use their involved hands which previously they had not to hold and pick up items, reel a fishing rod, open doors, dribble a basketball, or tie shoes.

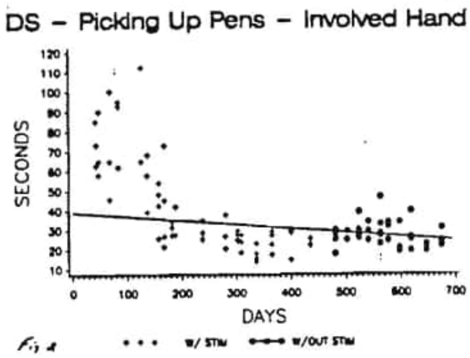
DS and ME showed considerable carry-over effects of the electrical stimulation treatment over the 6 months. Decreases in ME's performance as measured by the difference between average post-stimulation and end-of-stimulation test scores were < 20%. Table 1 values actually show improvement in lateral pinch strength, picking up pens, and picking up coins. Post-stimulation data for the task entailing picking up the balls showed a statistically significant linear increase in time ($p<.05$), but the average increase was only 2.6 seconds. DS's post-stimulation performances were

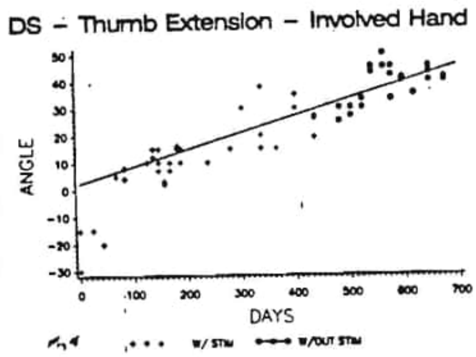
TABLE 1

TEST	START			END OF STIMULATION			POST STIMULATION		
	DS	CR	ME	DS	CR	ME	DS	CR	ME
WEXT (^{o})	-5	-29	-3.3	79	63	64	77	59	61
GRP (lb)	9	3.8	15.5	34	33	25.6	30	26.3	22.8
PPST (lb)	---	2.0	4.2	5.8	8.1	5.6	5.6	6.7	5.4
LATST (lb)	3.7	3.6	5.5	11.2	11.9	6.	9.4	8.4	8.5
PENS (sec)	72	250	83	25.0	64.2	35.9	28.3	133	33.2
CCNS (sec)	202	---	167	33.8	185	128	43.4	4.8	73.3
Balls (sec)	16.9	63	29	11.2	30.5	15.5	13.3	52	18.1
Text (^{o})	-20	---	---	25	---	---	39	---	---

WEXT = wrist extension; GRP = grip strength; PPST = palmer pinch strength; LATST = lateral pinch strength; PENS = picking up the 5 pens and placing in cup; CNS = picking up quarter, nickel, dime, and penny; BALLS = picking up 5 rubber balls; TEXT = thumb extension.







within 20% of end-of-stimulation values in all but one case. Only the lateral pinch values led to a regression line with a slope signifying a decline in performance at p=.05. The average decrease in strength, however, was only 16%. His thumb extension continued to improve.

CR maintained his level of maximal wrist extension, but demonstrated statistically significant declines in strength and dexterity. Difficulty seemed to stem from involuntary hyperextension of the thumb IP joint which translated into problems with curling the thumb in order to grasp and pinch. Electrical stimulation was reinstated with only the flexor pollicis longus targeted. Preliminary results give signs that he is improving once again. CR has dystonia as well as spasticity; the FES treatment may prove more effective with certain types of CP.

In all three cases implementation of the FES program corresponded with very visible improvements in range of motion, strength, due to the attainability of a more mechanically advantageous posture, and dexterity. While definite progress was made during the FES programs, the advances cannot be unequivocally attributed solely to the electrical stimulation. Maturation, practice, and greater attention being paid to the involved limb may have played a role in the amelioration seen.

Significant residual effects were seen even 6 months after the conclusion of the electrical therapy. The degree of successful carry-over of the FES treatment seemingly will vary within the CP population, but certainly it has been shown that it is possible.

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EXPERIENCE OF CLINICAL USE OF THE ODSTOCK DROPPED FOOT STIMULATOR (ODFS)

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SUMMARY

The ODFS is a simple FES device for the correction of dropped foot. Improved reliability, fine control of stimulation parameters and careful application and follow-up have led to 80% compliance. Data on 56 patients (27 hemiplegics, 5 MS and 1 SCI) who have used the system for between 6 and 18 months is presented and shows a statistically significant increase in walking speed, with the stimulator, at 3 months, of 14% ($p<0.001$). Decreased effort of walking, measured as Physiological Cost Index (PCI), of 39.5% ($p<0.001$) and statistically significant improvement in functional mobility tests and questionnaires. No statistically significant carry-over was seen, although 4 subjects had sufficient improvement in active ankle control and gait parameters to no longer need the stimulator.

6 patients who use the stimulator all day everyday have had a problem with skin irritation which we have not yet been able to solve. Two patients have discontinued after experiencing increased spasticity in the calf.

STATE OF THE ART

Since the work of Liberson /1/ in 1960 the use of common peroneal stimulation, timed with swing phase by a pressure sensitive heel-switch, has had a chequered history. A number of published studies have reported poor subject compliance/2/ and inadequate system reliability /3/ and poor subject selection /4/ and poor follow-up /5/ so that, despite improved function, the dropped foot systems are not widely used; particularly in Great Britain. The interim results of a clinical trial and data recorded from patients attending the FES clinic show better compliance. This paper will suggest reasons for this and for the failure for the system to be useful in certain cases.

MATERIALS AND METHODS

Stimulation is applied through skin-surface electrodes placed over the Common Peroneal nerve and the Tibialis Anterior motor point. A pressure-sensitive heel switch triggers the stimulation with the swing phase of the gait cycle. Stimulation parameters such as ramp, timing, duration and output levels are easily adjusted to suit the individual persons needs. A bi-phasic asymmetrical wave form is used, pulse width 0.3 ms and a stimulation frequency of 40Hz. We have found that a variable pre-set a ramp at the beginning of the stimulation cycle is useful for patients who find the sensation of stimulation uncomfortable, or who walk very slowly. It is particularly useful in patients who have high levels of calf spasticity. Gradual recruitment of motor units thus achieved seems to reduce calf spasm, the mechanism is not entirely understood, but it may be that a slower muscle contraction of Tibialis Anterior and the Peronei is less likely to elicit a stretch reflex in the calf. Stimulation can also be triggered by either heel rise or heel strike, our experience has been that faster walkers respond better to heel strike and, when heel rise is used, careful positioning of the heel switch can control very precisely the moment of stimulation; moving the switch forward in the shoe delays the trigger time and allows a more normal movement for slower walkers.

Timing can be set to 'fixed time' or switch dependent, except with very slow, unsteady walkers switch dependent timing is more effective.

Of the 56 patients who have been using the ODFS for a period of between 3 and 18 months. 20 hemiplegics were part of the randomised, controlled trial

Criteria for selection:

Suitable patients suffer from a variety of Upper motor neuron diseases, most commonly Stroke and Multiple sclerosis, and have a dropped foot resulting in:

i) Toe catch during swing phase,

ii)Hip hitch or circumduction to avoid toe catch,

iii)Passive range of ankle movement to allow a heel strike,

iv)Effective ankle dorsiflexion with stimulation and without undue discomfort,

v) Improved walking with ODFS assessed by gait analysis.

Suitable patients are asked to attend the FES clinic for two sessions on consecutive days. During the first session the stimulator is set up to provide the most effective gait pattern. The patient is carefully instructed in it's use and application, this is considered to be of utmost importance as failure to apply the device correctly has been shown to be a common reason for non-compliance/2/. The patient is asked to attend the second session using the stimulator, this ensures that either they or their carer are able to set up the system and gives an opportunity to overcome any problems.

Patients are given a simple clear instruction manual which explains how to set up the system, and includes a list of safety precautions. We encourage users to contact us immediately if the stimulator is not working well.

Clinical assessment to evaluate the effectiveness of the system.

i)Walking speed, measured over 10 metres with and without the stimulator (the average of three walks is taken whenever possible)

ii) Physiological Cost Index, a measure of the effort of walking, is the ratio of increased heart rate (from resting heart rate) over the speed of walking, also measured over 3, 10 metre walks.

iii) Questionnaires : Hospital Anxiety and Depression (HAD) scales, Nottingham Quality of Life Profile and a mobility questionnaire.

iv) 10 simple mobility tests

Some patients benefit from a short course of Physiotherapy. Many patients develop an abnormal gait pattern as a result of their dropped foot. Physiotherapy can make them aware of this and of the fact that with the stimulator they can walk more normally. The stimulator, through increasing speed and efficiency can also give the potential of a more rhythmic, balanced gait, but patients need to be given confidence to achieve this. Sometimes, practising the components of the gait cycle, can make a patient aware of the abnormalities and when correct movements are practised in a secure environment their confidence can be improved. For any change in gait pattern to be effective it must be automatic, conscious changes in gait therefore need time and practise.

Patients are reviewed after six weeks, sooner if they have problems. Walking speed and PCI tests are repeated and adjustments sometimes made to the stimulation parameters. At three months patients are reviewed again and complete a questionnaire which asks about how much and when they use the stimulator and what problems, if any they have encountered. Patients are then followed-up at six monthly intervals.

RESULTS

When the stimulator is first set up the alteration of the gait pattern can cause a reduction in walking speed. The rate at which patients adapt to a new gait pattern varies. By 3 months all the patients had adapted and the improved gait pattern is reflected in the walking speed.

Although the mean change in walking speed without stimulation was not significant it is important to notice that 5 out of the 16 subjects walked more slowly without stimulation after 3 months. There may be a tendency to become dependent on the stimulator, adaptations made to the gait pattern which are effective with stimulation may cause problems when the stimulator is withdrawn.

Changes in walking speed with and without the ODFS, measured over 10 metres at three months (n=56) 5 subjects walked more slowly, 42 more quickly (mean increase in speed was 14%, 27 subjects increased their speed by > 10%) 9 walked at the same speed. (A significant difference was shown in walking speed with and without the stimulator, Paired T Test $p<0.001$) No significant change was seen in walking speed over three months either with or without the stimulator.
Not all patients benefit, 15 had less than 10% improvement, 9 no change and 5 walked more slowly.

Changes in PCI with and without ODFS, (n=56) 8 subjects had a higher PCI, 7 no change, 41 a decrease in PCI (mean improvement was 39.5% with 32 subjects having an improvement of >20%) (Significant difference with and without stimulator, Paired T Test $p<0.001$) No change was seen in PCI over three months either with or without the stimulator. Improvement in PCI was immediate.

The mobility questionnaire asks about use of wheelchair and walking aids, distance walked without stopping to rest, ability to walk outside, alone, on even and uneven surfaces. Changes in scores on the mobility Questionnaire, A significant difference was seen between the treatment and control group after 3 months, n=24 Fisher exact probability test $p<0.0498$.

Objective tests include: standing from a wheelchair, stepping onto a block, standing unsupported and balancing on the affected leg, lifting the knee to touch a bar, walking with or without aid, and ability to, and style of, climbing stairs. Tests are carefully controlled in the laboratory.
Changes in scores on the mobility tests, a significant difference was seen between the control and treatment group after 3 months use of the ODFS Fisher exact probability test $p<0.0189$

Conclusion
56 patients who have used the ODFS over a period of at least 3 months have shown
1. An average 37% less effort in walking.
2. An average 15% increase in walking speed.
3. 86% compliance.
4. Statistically no significant influence on recovery of active movement, although this has been seen in a few patients, enough in three, for them to no longer need the device.

It has not been shown to have any statistically significant influence on recovery of active movement, although some patients (3) have experienced an improvement in voluntary control of ankle movement which has so far been retained despite discontinuing stimulation.

DISCUSSION

51 patients are continuing to use the system. 7 have discontinued, 3 because they have had sufficient improvement in voluntary control to enable them to walk as well without it.
Problems: 3 patients are, at present unable to use the system regularly because of skin irritation. We do not know why. Heat and / or electro-chemical toxins may be a cause and we are about to experiment with a symmetrical bi-phasic pulse to avoid a charge imbalance. In some cases hygiene or changing make of electrodes has solved the problem.

Factors which adversely affect the use of the stimulation system need to be addressed. Why do some patients *not* show an improvement in the effort or speed of walking? could this be related to an increase in calf spasticity? A system to measure spasticity levels in the calf is being developed to answer this question. A two channel stimulator is also being developed to give a more normal gait pattern.

A small change in the stimulator design now enables ramp at the beginning and end of swing to be adjusted independently producing in some patients a more normal gait and corrects foot slap.

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A SIMULATION MODEL OF FES INDUCED GAIT REHABILITATION IN HEMIPLEGIC PATIENTS

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SUMMARY

The advantages of multichannel functional electrical stimulation (MFES) therapy for gait training and relearning in hemiplegic patients compared to conventional therapeutic methods (CONV) have already been proven. The purpose of this study was to evaluate on what levels and to what extent do the effects of different therapies take place. Three models of gait rehabilitation process were proposed: exponential, logistic and mixed. The non-linear regression of experimental data was used for parameter estimation for each model respectively. A correlation coefficient was used to evaluate which model fits best. Gait speed during CONV and MFES therapy in 20 hemiplegic patients was used as a measure of gait recovery. The mixed exponential-logistic model showed the best fit to experimental data. The model incorporates two parameters which represent: direct effects of therapy to muscles (functional movements, weight bearing, etc.) and afferent effects of therapy to CNS (motor learning, plasticity, etc.). The comparison of group averages of calculated model parameters for CONV therapy and MFES therapy showed that both, direct and afferent effects during MFES therapy, are approximately 5 times greater compared to CONV therapy.

INTRODUCTION

Since it's introduction functional electrical stimulation (FES) has been widely accepted as a supplementary therapeutic method as well as an orthotic aid in patients with upper motor neuron dysfunction /1/. In rehabilitation of gait the effects of FES were investigated on two levels: instantaneous or direct effects can be observed in functional movements as a consequence of FES elicited muscle contraction, and long-term or indirect effects which manifest in permanent FES induced modification of gait even after the use of FES was discontinued.

The direct effects were clear and easy to demonstrate since the beginning /2/. The reported results related to the study of long-term effects of FES therapy were somehow ambiguous. Some authors /3, 4/ reported prolonged effects of FES on one isolated parameter: the isometric ankle torque. On the other hand Maležič et al. /5/ failed to demonstrate long-term effects of multichannel FES (MFES) therapy for correction of gait pattern in ambulatory hemiplegic patients. The results did show significant difference between the stimulated and control group at the end of therapy. However, after period of 6 to 12 months the difference between groups was not significant any more. The preliminary study of application of MFES in non-ambulatory patients with the purpose not to correct the anomalies of an existing gait pattern but to re-establish a new one, showed very promising results /6/.

Vodovnik /7/ tried to explain the long-term effects of FES on the nerve-synapse-nerve level by a mathematical model. He considered muscle force to be proportional to a product of the volitional signal transferred by the nerve and a presynaptic potential that exponentially increases during activity. Diminished volitional signal in patients with upper motor neuron dysfunction could be replaced via the afferent nervous pathways by employing FES and thus increasing presynaptic potential. The presynaptic potential was assumed to remain higher for a period after FES. Thus the experimental data /4/ obtained for the isolated volitional movement were interpreted. However, the effects of FES on complex movement (e.g. gait) have not been experimentally clarified yet.

Since the standard statistical approach with tested and control groups proved to give inconclusive results /5/, probably due to large inter-patient variance in hemiplegic population, an alternative experimental model has been utilized in our study. Each patient served as his/her own control by testing both therapeutic modalities on each patient. To eliminate the effect of sequencing different therapies, two groups were randomly formed with reversed order of therapeutic modalities. The primary purpose of the presented study was to demonstrate the advantage of the MFES therapy for re-learning of gait in hemiplegic patients, compared to the corresponding "conventional" therapeutic methods. The results proved MFES to be significantly superior to the existing therapeutic methods /8/. The purpose of his paper is to present a mathematical approach to explanation of the MFES therapy effects.

SUBJECTS

Twenty non-ambulatory hemiplegic patients were included in the study. They were randomly assigned to two groups (10+10 subjects), one group starting with 3 weeks of MFES therapy followed by 3 weeks of conventional therapy and the other group with reversed sequence of therapies. Their gait and general physical status was evaluated in the beginning of our program, at switch over of therapies and at the end /8/. The step length, gait velocity and cadence were measured by the stimulator during each session of MFES therapy and 4 - 5 times during the conventional treatment.

MATHEMATICAL MODEL

After stroke the CNS centers responsible for gait are generally severely disorganized. During the period of rehabilitation a combination of spontaneous self-organization of CNS and applied therapy result in subsequent more or less functional gait pattern. From the control point of view the process of recovery can be described by equation (1):

$$\dot{x} = f(x,u,v,k,t) \tag{1}$$

where $x = x(u,v)$ is the state vector, u is the set of input vectors (e.g. therapy), v represents voluntary control, $k = k(t)$ is the vector of time dependent parameters and f is the non-linear function. Although this law is stated in general, its application could be accomplished e.g. by measuring the relevant gait variables.

It is of primary importance to find an explicit model of equation (1), to estimate the time when the variables reach the stationary level and to determine how the switching between different therapy modalities affect the results. Various experiments show that time series describing gait variables have a general sigmoidal or exponential shape /9,10/. Therefore the equation (1) can be written as:

$$\dot{x} = k(x,u)(x_s - x) \tag{2}$$

$$x(t_0) = x_0$$

where x_s is a stationary state dependent on the physical properties and recovery level of the system, x_0 is initial value, and $k(x,u)$ is system gain dependent on the rehabilitation method u and on the state of the system. Expanding k in Taylor series and dropping terms of degree greater than one gives:

$$k(u,x(u,v)) = a - bx \tag{3}$$

where $a = a_1 + a_2 u$ and $b = a_3$. Substituting equation (3) in equation (2) we obtain:

$$\dot{x} = (a + bx)(x_s - x) \tag{4}$$

Equation (4) represents state transition consisting of exponential and logistic law of motion. When $b = 0$ (k independent of system state and therapy method) we have a linear system of first order, and when $a = 0$ we have a logistic equation. For all three cases the analytical solution is known /11/.

All three models: exponential, logistic and mixed have been verified on the experimental data. Gait speed was selected as a representative variable. It was measured and averaged during each therapy session. The moving average of lag 3 was applied for experimental data filtering. The non-linear regression was used for the comparison of the proposed models.

RESULTS AND DISCUSSION

Fig. 1 represents raw data of gait velocity measurements in two typical subjects from each experimental group. The non-linear regression of all three models was performed on each patient's data. The correlation coefficient r^2 was used as a measure for selection of the most appropriate model. In the CONV/MFES group there were no differences between combined and logistic model. Both, however, describe experimental data much better compared to exponential model. For combined model the average correlation coefficient was $r^2=0.88$ (range 0.71-0.98), for logistic model $r^2=0.86$ (range 0.73-0.98) and for exponential model $r^2=0.65$ (range 0.45-0.84). In the MFES/CONV group the correlation coefficients were $r^2=0.95$ (range 0.86-0.99), $r^2=0.93$ (range 0.85-0.98) and $r^2=0.91$ (range 0.85-0.98) for combined, logistic and exponential model. According to these results the combined model was selected as best fit.

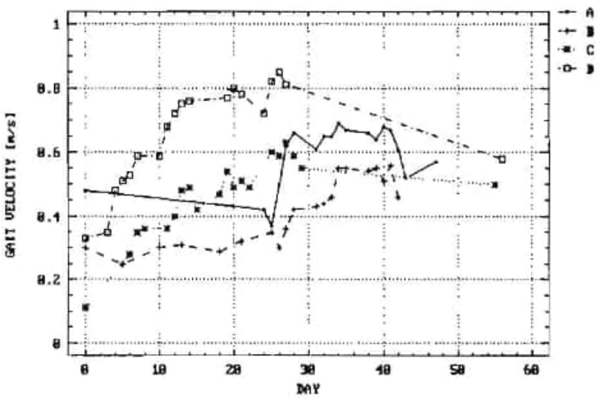

Figure 1: Gait velocity curves (raw data) during therapy for four subjects participating in the study (subjects A and B started with MFES and continued with CONV therapy, subjects C and D had reversed order of therapies).

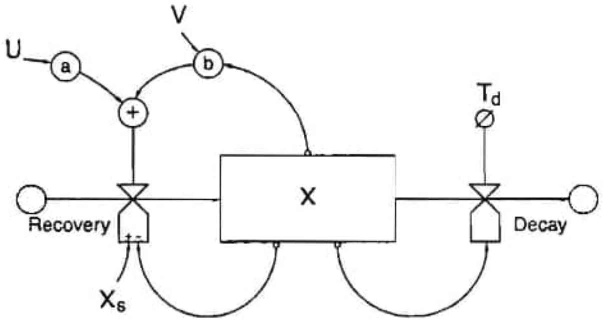

Figure 2: Simulation model of stroke patients recovery during therapy.

In order to explain sensitivity of applied methods on functional recovery with possible neurophysiological implications a simulation model has been proposed. It was derived from equation (4) by integrating both sides and replacing the results of operation with formal blocks, which are used in system dynamics. The state of the system is the difference between the recovery rate and decay rate. The recovery rate consists of two parts: direct influence of therapy on muscles which is represented by $u \in U$ multiplied by constant a; and influence on muscles by voluntary control represented by $v \in V$ multiplied by state of system organization x and constant b. The latter should be equivalent to post-synaptic strength of the motor neuron, where gain factor b can represent sensory influence on the motor neuron via interneuron /7/. Variables u and were chosen as unit step functions, while a and b represent " gain" depending on the system input sensitivity. The decay rate determined as ratio of state of organization x and decay time constant, has been added to equation (4) to incorporate the disorganization process, which is imminent for such a system. The structure of the simulation model is presented on Fig. 2.

For simulation purposes constants $a_M, a_C \in a$ and $b_M, b_C \in b$(indexes M and C represent MFES and CONV therapy) were obtained by non-linear regression of experimental data in each patient and for each therapeutic modality respectively. Generally after therapy and especially after MFES the value of x fell to a new equilibrium, from which parameter T_d was determined. By setting constants a,b and T_d all experimental results were simulated. Fig. 3 presents the gait velocity simulation results for the same subjects as presented in Fig. 1. The results show good alignment with the experimental data.

The obtained simulation constants a and b were averaged over the patients for each therapy modality respectively. The statistical t-test between the constants showed that both constants are significantly higher for MFES therapy ($p < .001$). The calculated ratios between the average constants show that $a_M / a_C = 4.64$ and $b_M / b_C = 4.36$. Constant a represents direct effects of therapy. It was expected to be much higher during MFES therapy, because of the effective functional movements produced by FES. The constant b represents indirect or afferent effects of therapy. At the current state of art these effects are impossible to be measured or assessed. Indirect effects are triggered by enriched sensory inflow to CNS and by higher motivation of the patient, which may affect CNS plasticity and motor learning.

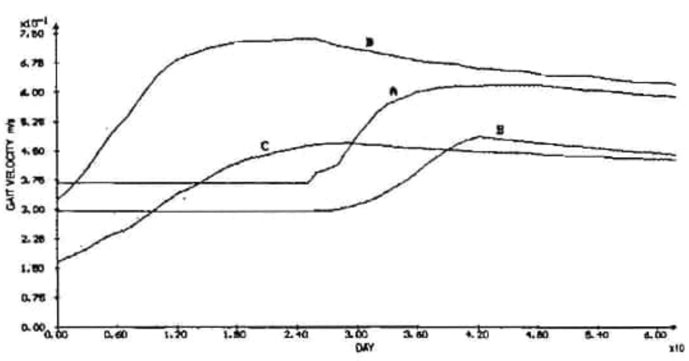

Figure 3: Results of gait velocity simulation for the same patients as presented on the Fig.1.

It premature to give a definite judgment about the therapeutic effects of MFES on the basis of presented results. However, the results presented on a simple simulation model give us an insight into the impact level of two different therapy modalities to neuro-muscular system and CNS, which could be a good basis for further research.

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A FORWARD ERROR CORRECTING TECHNIQUE FOR CONTROLLED IMPLANTABLE SYSTEMS

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SUMMARY

This paper presents a reliable communication protocol permitting an implant to recuperate safely the data and clock coming from external controllers over a noisy link. A forward error correction (FEC) technique using (15,11) Hamming code with a minimum distance of 3 has been employed and a novel implementation has been proposed. The presented protocol provides wireless communications for an implantable bladder stimulator and can be used for any implantable prosthesis. The proposed architecture has been designed using CMOS 1.2µm technology.

STATE OF THE ART

Recent advances in miniaturization techniques made it possible to design advanced multifunction implantable prostheses which result in a high quantity of data to be communicated to the implant. Presently, more than 1.5 million peoples have pacemakers implanted worldwide /1/. Extracorporal controllers need to communicate with implanted systems for both programming /2/ or delivering stimuli /3/ using wireless digital communications. Since we deal with human being, the reliability of the communication is of great concern. The data transmitted to implant over a noisy link, programs the device or specifies stimulus parameters and can affect the health of the implant host, therefore error detection and data verification become critical issues for the implantable systems. Unfortunately, the majority of existing implantable prostheses suffer from the lack of an error detection and correction protocol and are susceptible to noise /1/. The aim of this work is to develop a secure communication protocol and the related architecture having multiple means of error detection and correction.

MATERIALS AND METHODS

In this section we present the design and implementation of the proposed clock and data separator and the error correction approach.

Digital Data and Clock Decoder

During wireless asynchronous communication, data and clock are combined at the transmitter and are sent to the receiver. A technique that has received considerable acceptance is called Manchester coding. Fig. 1 shows the simplified circuit schematic of the proposed Manchester decoder. It is based on detection of bit-center transitions. The incoming Manchester encoded data (MED) is passed through a Schmitt trigger to obtain a digital signal. When a bit-center transition is occurred the incoming MED is sampled after ¾T, where T is the clock period. Therefore, the MED is decoded with a delay of ¼T. The f_{REF} is recuperated from the carrier frequency of the incoming AM modulated signal. The Manchester decoder has been tuned to a data rate of 300 Kb/s.

Communication Protocol and Error Control Strategy

Implanted devices utilize either an inductive /2-3/ or an optic link /4/. In both cases, the data transferred to the implant are serially organized and transmitted using digital communication techniques.

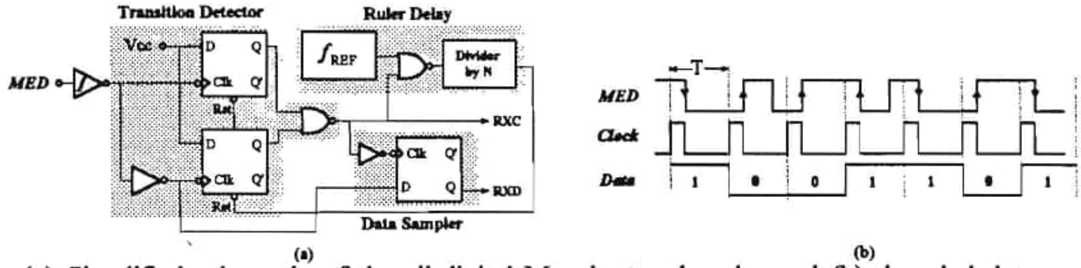

Fig. 1: (a) Simplified schematic of the all-digital Manchester decoder and (b) decoded data and clock from the received MED.

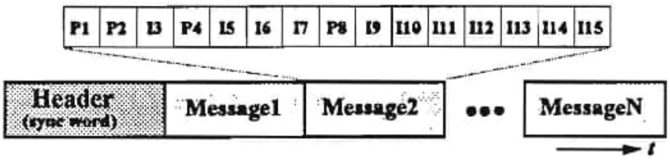

Fig. 2: Data frame for the implant receiver.

Fig. 2 illustrates our proposed data frame. A key word establishes the communication and data are sent serially in 15-bit message words. The header is used to synchronize the data frame. Each message word contains 11 information bits (8 data bits and 3 op-code bits), and 4 parity bits. In order to reduce the transmission errors and increase the reliability of the system a conventional 15-bit Hamming code with a minimum distance of 3 (15,11) has been employed for single-bit error detection and correction. Hamming code is a linear block code and is an optimal choice because it has a satisfactory error correction performance with a very simple decoding hardware. Other coding strategies such as cyclic and convolutional codes result in complicated decoding hardware /5/ which is not desirable in miniaturized implants. Using (15,11) Hamming code, the probability of an undetected error is the same as the original probability of error in two or more of 15-bits. The probability of error in n or more bits of an N bit command word can be calculated using binomial distribution as follow:

$$p_n = \sum_{i=n}^{N} \frac{N!}{i!(N-i)!}(p_1)^i (1-p_1)^{(N-i)} \tag{1}$$

where p_1 ($\approx 10^{-6}$) is the probability of an error in any one bit. In our case, by assuming that p_2 is much bigger than p_3, ... , p_{14}, and p_{15}, the probability of an undetected error is reduced to p_2 which is approximately:

$$p_2 \approx 105(p_1)^2(1-p_1)^{13} \tag{2}$$

At the transmitter, the check bits are determined from the following set of equations:

$$\begin{aligned} P1 &= I3 \oplus I5 \oplus I7 \oplus I9 \oplus I11 \oplus I13 \oplus I15 \\ P2 &= I3 \oplus I6 \oplus I7 \oplus I10 \oplus I11 \oplus I14 \oplus I15 \\ P4 &= I5 \oplus I6 \oplus I7 \oplus I12 \oplus I13 \oplus I14 \oplus I15 \\ P8 &= I9 \oplus I10 \oplus I11 \oplus I12 \oplus I13 \oplus I14 \oplus I15 \end{aligned} \tag{3}$$

At the implant, upon receipt of a valid header (key word), the incoming bit stream is shifted into a serial to parallel converter; then on time FEC is performed.

Design of Error Correction Module

Fig. 3 depicts the block diagram of the proposed error corrector module. The decoding procedure is performed based on syndrome calculation /5/. Other techniques like trellis decoding /6/ are not suitable for hardware implementation and normally require soft decisions.

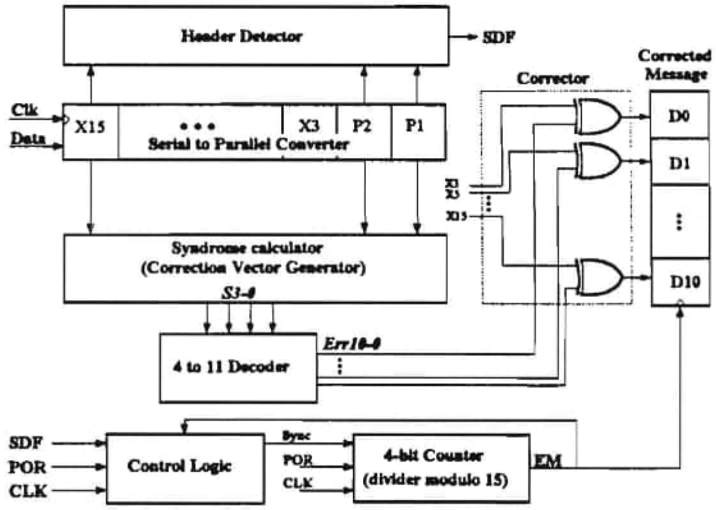

Fig. 3: Complete block diagram of the error corrector module. (SDF: Start of data frame, POR: Power on reset, EM: End of 15-bit message).

The implemented structure operates as follow. The serial to parallel converter recuperates a 15-bit message (*Mess*) and then the syndrome calculator generates the corrector vector (*S3-0*) from the received message, based on equations 4, indicating whether the received message contains an error or not.

$$\begin{aligned} S0 &= P1 \oplus I3 \oplus I5 \oplus I7 \oplus I9 \oplus I11 \oplus I13 \oplus I15 \\ S1 &= P2 \oplus I3 \oplus I6 \oplus I7 \oplus I10 \oplus I11 \oplus I14 \oplus I15 \\ S2 &= P4 \oplus I5 \oplus I6 \oplus I7 \oplus I12 \oplus I13 \oplus I14 \oplus I15 \\ S3 &= P8 \oplus I9 \oplus I10 \oplus I11 \oplus I12 \oplus I13 \oplus I14 \oplus I15 \end{aligned} \tag{4}$$

The 4 to 11 decoder looks up the assumed error vector (*Err10-0*) stored in the table 1 which represents the relationship between the syndrome vector (*S3-0*) and the error vector. Error vector addresses the erroneous bit. The sum *Mess* + *Err* implemented by the corrector (exclusive-OR gates) finally generates the corrected data. If there are no errors then *S3-0* = (0000) and so the received message is not affected. In order to minimize the hardware, the elements of error vector related to parity check bits have been omitted because they are of no further interest.

Table 1: Correction table for the (15,11) Hamming code with a minimum distance of 3.

S3-0	Erroneous Bit	*S3-0*	Erroneous Bit
0000	none	1000	P8
0001	P1	1001	X9
0010	P2	1010	X10
0011	X3	1011	X11
0100	P4	1100	X12
0101	X5	1101	X13
0110	X6	1110	X14
0111	X7	1111	X15

The divider modulo-15 separates the messages. When a message word is completed the correcting procedure is accomplished in less than one clock cycle and at the next clock cycle the signal EM is activated to latch the corrected message (D10-0) in the output register. The control logic is a simple three states finite state machine and synchronizes all operations.

RESULTS

The layout was generated using Cadence® tool based on CMOS 1.2 μm technology of Northern Telecom of Canada. The proposed architectures occupy a very small area of silicon (0.41 mm^2) in comparing with other techniques /6-7/. The circuit has been designed for structural testability by means of scan-based test approach. This technique guarantees high structural fault coverage. Since the small power dissipation is an important characteristic for implantable systems, the circuit has been especially optimized for low power. The proposed structures have been also successfully implemented on a single ACTEL Field Programmable Gate Array (FPGA).

DISCUSSION

A new clock and data separator for programmable implanted devices has been proposed. The Manchester code has proved to be a robust choice for digital communications addressing implants. A forward error correction communication protocol for implantable prostheses using (15,11) Hamming code has been also presented. This module increases significantly the reliability of implants and protects them against existing noise in the data link. To our knowledge, it is the first error correcting architecture dedicated to implantable devices. Its architecture is quite simple and requires a very small silicon area in comparing with other decoding techniques.

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DETOXICATION PROPERTIES OF SYNTHETIC CARBONS APPLIED AS ELECTRODE MATERIALS

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SUMMARY

In order to intensify detoxication processes, one way is through direct electrochemical oxidation-reduction on the surface of carbon, wich serves as a fluidized-bed electrode. The investigations on the electrochemical detoxication of patient plasma showed the possibility to intensify this processes for several metabolites,free-radical products and products of peroxide oxidation.The modification influence on carbon materials upon its electrochemical behaviour in a saline electrolute solution was studied.

STATE OF THE ART

The active synthetic carbon SCN are distinguished from natural raw materials by their biocompatible, phisicomechanical and sorption properties /1/. An extention of previous work /2/ on SCN sorbents has led to the conclusion that the usage of electrochmical factors besides sorption was found to extend the application area of activated carbons and allow us to increase the selectivity and depth of extraction of various organic substanses from biological fluids.

The peculiarity of molecular structure of carbons,presence chemically bonded heteroatoms predefine the electrochemical behaviour in oxygen containing solution.Therefore changes in the surface structure of synthetic carbons caused by the modification of various metals can result in an alteration of sorption and electrocatalytic action.

Taking into account mentioned above we have worked out a mass exchanger-electrolyzer ''EChO-2'',where spherical-granular sorbents act as a fluidized-bed electrode.

MATERIAL AND METHODS

Electrodes

Standard haemosorbents SCN-1K,SCN-2K,oxidized synthetic carbon (SCNo) and non-porous SCN-placebo (SCNpl) used as a working electrode were balanced in a saline solution to create a stationary potential.The polarization of fluidized-bed electrode was provided by potentiostate ПИ-50.1.1 through the platinum current-carrier.

The haemosorbents have been modified by hemosorption of the ions of transition metals (Cu^{2+},Zn^{2+},Ni^{2+},Fe^{3+}).

Device

Electrochemical investigations were carried out in electrolyzer ''EChO-2''(working volume 30 ml^3).This device contained platinum current-carriers and semipermeable membrane.

A fluidized-bed layer was created by the direct circulation of electrolute solution in the central camera of the device.

RESULTS

Measuring stationary electrode potentials in patient plasma were -0.14V(nhe) for SCN-2K and -0.32V for SCNpl.

We have examined the possibility of electrochemical detoxication of middle mass molecules, cyclic immune complexes and malondialdehyde at the catode potentials from -0.2V to -0.7V in comparison with the sorption without an external potential (Fig.1 a,b).

We have also specifically studied a stationary potential value on the surface of activated carbons SCNo and carbons modified by ions of transition metals (Cu^{2+},Zn^{2+},Ni^{2+},Fe^{3+}) in the volume of the electrode (see table).

DISCUSSION

The results of the investigations suggest the possibility of employing activated carbons as an effective electrodes to control the elimination processes of several metabolites, free-radicals products

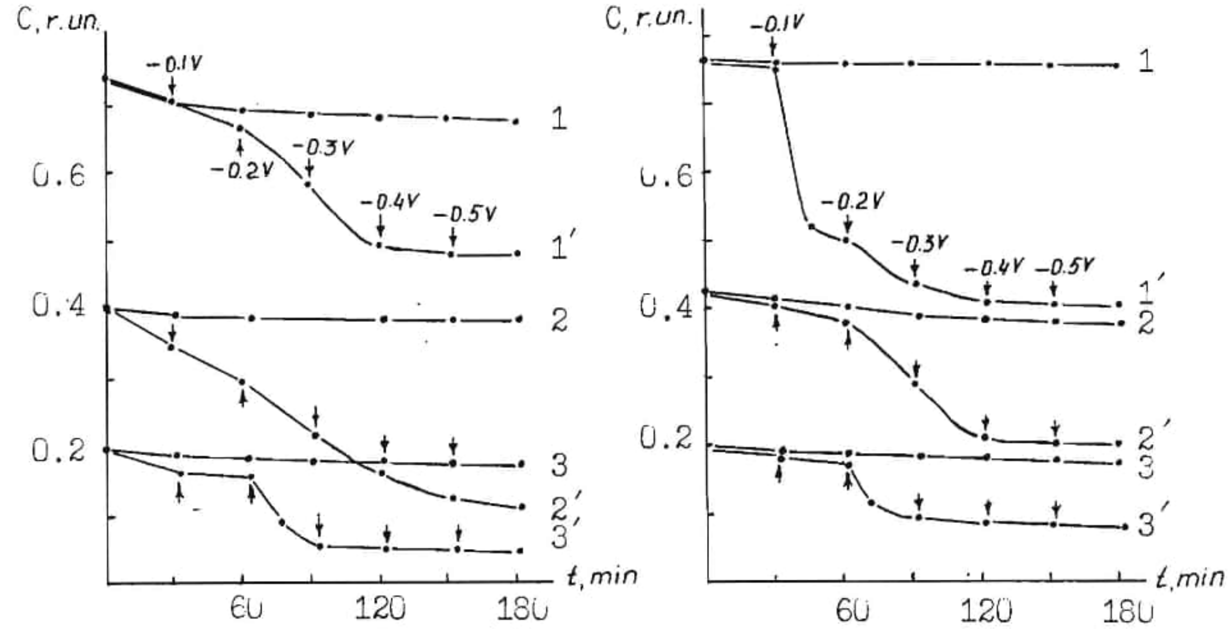

Fig.1.Kinetic curves of removal of cyclic immune complexes (1'),middle mass molecules (2'),malondialdehyde (3') from blood plasma after perfusion: a) through SCN-2K, b) through SCNpl, step catode polarized from external electric source;and without external potential (1,2,3,).

Table 1

Sorbent type	Stationary potential,V(nhe)	Sorbent type	Stationary potential,V(nhe)
SCNpl	0.080	SCNo(Cu^{2+})	0.165
SCNpl(Cu^{2+})	0.226	SCNo(Fe^{3+})	0.296
SCNpl(Fe^{3+})	0.271	SCNo(Zn^{2+})	0.400
SCNo	0.060	SCNo(Ni^{2+})	0.141

and products of peroxide oxidation on the surface of carbon fluidized-bed electrode.We have found the step-shifting catode polarization of haemosorbents increases the elimination of cyclic immune complexes,middle mass molecules and malondialdehyde (Fig.1).
The experiments carried out on SCN-2K and non-porous SCNpl made it possible to eliminate a sorption component and prove the existance of electrochemical ones in the removal processes.
Chemical modification of haemosorbents by transition metals as well as electrochemical polarization from the external power source allows us

to change the electrochemical potential on the surface of carbon (Table 1) in order to direct elimination of various metabolites.
In using electrochemical method it is possible to obtain the following: inhibition of free-radical reactions, fast correction of antioxidational ability of the organizm to exert protectional adaptation reactions against disease-producing factors.

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A WIRELESS LINK FROM CRUTCH INTEGRATED SENSORS TO FES CONTROLLERS

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INTRODUCTION:

In 1982 the Vienna Working Group of Functional Electrostimulation started to mobilize paraplegics by use of FES[1]. This leg pace maker system consisted of two eight-channel implantable nerve stimulators[2] with epineural electrodes[3,4,5], external antenna and external control device. External and internal parts were radio-linked. The stimmulation sequence for stand up, stand and walk was controlled by the patients with crutch integerated switches[6], which were connected to the control device by wires.

For several reasons the leg pacemaker system required a redesign. Active hip-knee-flexion was now added in the 20 channel sytem[7,8] to the active hip-knee-extension of the older eight channel system. In the scope of this revision we also renewed the connection of the crutch-integrated command switches and the control device. To increase patient's comfort we replaced the hindering wire connection by a radio remote control system.

MATERIALS AND METHODS:

Demands:

The following points had to be considered during the development of the remote control system:

- As a transmitting frequency of 27Mhz is required to supply the implant with power and information, the frequency of the remote control system must be far beyond from this.
- The whole arrangement must be integrateable in an on market crutch.
- As the energy is supplied by battery, the energy consumption should be on a lowest possible level.
- The digital input of four on/off command switches must be read.
- Four analog channels must be read and digitized.
- The complete channel information (four switches, and up to four analog channels) has to be passed on digitally to the transmitter module using a RS232 protocol.

Structure of the remote control system:

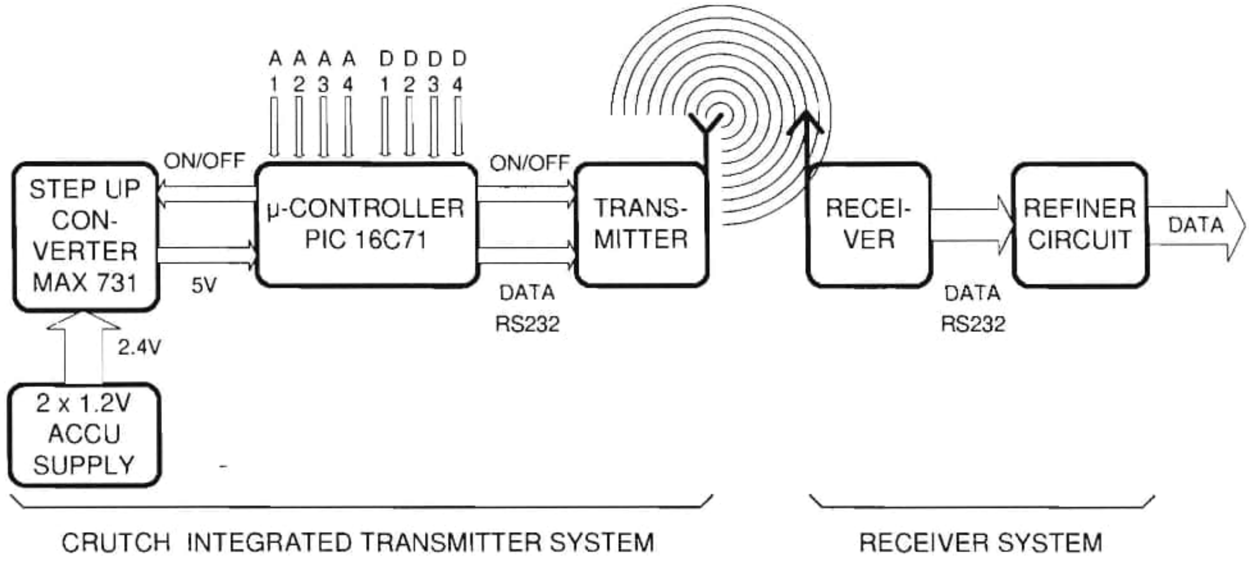

Fig. 1: Block diagram of the transmitter and receiver system

The crutch integrated transmitter system:

Power supply:

Two rechargeable batteries are stored in the grip of the crutch. The accommodation in an already existing narrow space in the grip enables an easy exchange of the batteries and keeps the origin appearance of the crutch almost unchanged. The voltage provided by the batteries is too low to supply the chosen transmitter module. Therefore a MAX 731 step-up-converter doubles the supply voltage up to 5V. A maximal current of approximately 200 mA can be drawn from this DC/DC converter. The status of the converter (on/off) can be controlled via its shutdown-pin.

µ-controller:

The µ-controller PIC 16C71 is the central device of the transmitter system. It offers an internal eight bit real time counter, 13 I/O pins including an external interrupt pin and four analog input pins. The analog module multiplexes four analog channels into the 8-bit A/D converter. Further useful features are the power on reset, and the power saving sleep modus.

Transmitter module:

The transmitter module transmits the RS232 protocol frequency modulated with a transmitting rate of 9600 Baud at a carrier frequency of 433.92 Mhz.

Receiver system:

The receiver system consists of an on market available receiver module and a signal refining circuit. It is located close to the external control device. The refiner circuit ensures the faultless data recognition by compensating the receiver entrance low pass, which limits the transmission rate to 10 kBaud. Due to this low pass, the edges of the rectangular data pulses are flattened. The refiner circuit restores the edges and enables the exact temporal recognition of the RS232 protocol. Logic schmittriggered components shut down the data output when the carrier is lost.

Operation of the crutch integrated transmitting system:

The µ-controller is the central element of the crutch integrated transmitting system. It controls the reception of information its transmission and also the power supply by switching the step up converter on or off. As any output pin is able to source 20 mA, the transmitter module is supplied via a processor output pin and can be easily shut off to minimize power consumption. Leaving the command switches inactive for approximately 30s will lead the controller and also the complete transmitting system to the energy saving sleep modus. This efficient energy saving modus is revoked by pressing any of the command pushbuttons. During one interrogation cycle the state of the digital channels (command pushbuttons) and the value of one of the analog channels are read and coded into the following two bytes:

The INFOBYTE:

bit7	bit6	bit5	bit4	bit3	bit2	bit1	bit0
R0	A7	C0	C1	S1	S2	S3	S4

The DATABYTE:

bit7	bit6	bit5	bit4	bit3	bit2	bit1	bit0
R1	A6	A5	A4	A3	A2	A1	A0

Fig. 2: The configuration of the two bytes information package

The bits S1 to S4 show the status of the command switches. A0 to A7 represent the 8-bit value of the analog channel belonging to the channel number shown in C0 and C1. The status of the bits R0 (=0) and R1 (=1) destinguishes the two bytes. The processor delivers the two bytes result of one interrogation cycle in form of a RS232 protocol to the transmitter. The number of the transmitted analog channels as well as a special succession of them can be easily arranged by software.

Using a transmission rate of 9600 Baud 480 DATA- and 480 INFOBYTES could be transmitted each second. The following table shows how often a channel is sampled and its value is transmitted per second depending on the number of the used analog channels:

Number analog channels:	Digital channels D_X (x: 1,2,3,4) (1/s),	Analog channels A_X(x: 1,2,3,4) (1/s),
1	480	480
2	480	240
3	480	160
4	480	120

Tab1.: Sample rate of the digital and analog channels

CONCLUSION:

With this new development we simplified the use of the leg pacemaker system. Now patients are not hindered by wires connecting the crutch integrated command switches to the control unit any longer. Due to its flexibility the new remote control system can be used for other applications as well. Simple software changes adapt the remote control system to other user defined subjects. So it can be used for any purpose concerning remote controlled devices.

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ELECTROPHYSIOLOGICAL EVALUATION OF LOWER LIMBS IN PARALITICS USING MACRO EMG

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SUMMARY

Functional electrical stimulation (FES) is used for the restoration of locomotion in paraplegics, including thoraco-lumbar spinal injury (TLSI) patients who have damaged to both upper and lower motor neurons. The purpose of this study is to explain how to detect mixed lower motor neuron damage in paraplegics. Macro EMG, a quantitative electromyography technique described by Stålberg in 1980, was used in our evaluation. Two parameters, the area and the amplitude, of macro MUPs from the tibialis anterior (TA), the vastus lateralis (VL), and the vastus medialis (VM) of 12 paraplegic patients that included 6 TLSI patients, were compared with those of 41 normal subjects. The mean values of median areas in normal subjects were 372.4 ± 100.2 (± SD), 629.4 ± 120.7, and 480.0 ± 98.2 nV•s in T.A, V.L, and V.M ; the amplitudes were 145.0 ± 35.2, 242.1 ± 29.2, and 218.1± 42.8 μV, respectively. In patients, only the TLSI patients had a significant increase of parameter values, and showed insufficient contraction of muscles by electrical stimulation because of denervation. Our results suggest that macro EMG is useful in detecting denervated muscles in FES patients.

STATE OF THE ART

Functional electrical stimulation (FES) has been performed at Akita University Hospital, mainly for the restoration of locomotion of the lower limbs of paraplegics, since 1990 /1, 2/. In some FES patients, especially in the TLSI patients, electrical stimulation is not effective in contracting strongly paralytic muscles /2/. In these patients, mixed damage of both upper and lower motor neurons exist, so that muscles stimulated by FES are actually denervated. In our study, denervated muscles were evaluated by electrophysiological examinations, particularly by electromyography. It is difficult to detect slight denervation, however, using the conventional EMG. Therefore, a quantitative electromyography technique called macro EMG, that was described by Stålberg /3/ in 1980, is used for the evaluation of denervated muscles in this study.

MATERIAL AND METHODS

Subjects

Forty one normal adults, ranging in age from 24 to 76 years (average age : 38 years) were NORMAL group. They were tested by macro EMG to define the normal (for Japanese) limit of EMG parameters (area and amplitude) at three muscles : the tibialis anterior (TA), the vastus lateralis (VL), and the vastus medialis (VM). Twelve paralytics, ranging in age from 22 to 63 years (average age : 44 years) years were the PARALYTICS group, and were examined by both macro EMG and conventional EMG. Three of these patients had cerebrovascular disease, and nine had spinal injuries (including six TLSI patients).The 12 patients were devided into two subgroups : the "TLSI"group, and the "UPPER INJURY" group (Table 1).

Procedure and equipment

The macro EMG electrode /3, 4/ consists of a modified single fiber EMG (SFEMG) electrode with a steel cannula, insulated except for 15 mm proximal to the tip, and a platinum wire exposed in a sideport of the bared cannula. Recordings were made on two channels ; one channel records from a "single fiber" electrode with the cannula as a reference, for triggering the recording of the cannula potentials. The other channel records the signal between the bared cannula "macro" electrode, using the surface electrode, placed at least 30 cm away, as a reference. After averaging approximately 256 times, until the signal no longer changes and the baseline becomes smooth, the cannula potentials could be defined as the macro motor unit potentials (macro MUPs) at each individual site (Fig.1).

Most of macro EMG examinations were performed according to the procedure described by Stålberg /3-5/. Macro MUPs were recorded from at least 20 different sites in each muscle during slight voluntary contraction (being less than 30% of maximal force). Parameters of measurements of the given wave shape were the area and the peak-to-peak amplitude.

The equipement used included the MYSTRO MS25 (Medelec, England), the macro EMG electrode (No. 17915, Medelec, England) and the Blue Sensor (P-00-P, Medicotest, Denmark) as a surface reference electrode, in macro EMG.

Table 1.Paralytic subjects

	case	diag.	age (years)	sex	periods (Yrs, Mos)	manual muscle testing Tibialis Anterior Rt.	Lt.	Quadriceps Rt.	Lt.
"Upper injury" group	1	C.H	44	female	16Y	N	F+	N	N-
	2	C. I	47	female	2Y 2M	N	T	N	N-
	3	C. I	53	male	6M	N	T	N	G+
	4	C 5 S. I	22	male	1Y 6M	G	P	G+	G+
	5	T 8 S. I	43	female	5M	G+	G+	N-	N-
	6	T10S. I	48	male	10M	T	T	P+	P
"Thoraco-lumbar spinal injury" group	7	T12S. I	63	female	10Y	Z	Z	G+	N-
	8	T12S. I	38	male	1Y 2M	Z	Z	G	G-
	9	L 1 S. I	33	male	1Y 6M	Z	Z	P	P-
	10	L 1 S. I	22	male	4Y 1M	Z	Z	G-	F+
	11	L 1 S. I	57	male	1Y 2M	G	G+	G+	N-
	12	L 1 S. I	56	male	7Y 2M	P	P+	G-	G+

C.H : Cerebral Hemorrhage C. I : Cerebral Infarction S. I : Spinal Injury

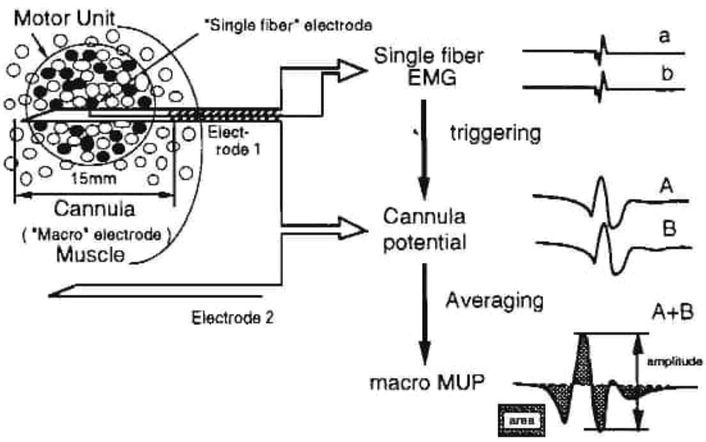

Fig. 1 Principle of macro EMG. The macro EMG electrode has a "single fiber" electrode in the middle of the bared cannula, "macro" electrode. a, b : Signals from "single fiber" electrode with cannula. A, B : Cannula potentials from "macro" electrode with a reference (electrode 2). A+B : Macro MUP is the average of cannula potentials.

Definition of abnormality

The following two procedures suggested by Stålberg /4/, were used to define the upper and lower limits of "normal value". 1) "Median method" : A mean value of 20 macro MUPs in an individual subject is not very useful because of a skewness in the distribution of the macro MUP parameters; the "median" value, however, is useful. If the "median" value of an individual paralytic subject is outside the normal maximal value and minimal "median" values of the normal subjects, the subject is defined as abnormal. 2) "Outlier method" : The extreme values at each end of the parameter range are discarded in each normal subject; the normal range is then defined as being between the (new) maximal and minimal values remaining in the normal subjects. If more than one value of the individual paralytic subject is outside the normal range, the subject is defined as abnormal.

Table 2. Macro EMG results in the normal subjects

	Tibialis Anterior	Vastus Lateralis	Vastus Medialis
No. of tested muscles	40	40	41
No. of MUPs	784	831	861
Area (nV • s)			
Median ; mean ± S.D	372.4 ± 100.2	629.4 ± 120.7	480.0 ± 98.2
upper ~ lower limits	210.0 ~ 687.0	412.0 ~ 935.0	266.0 ~ 706.0
Outlier ; upper ~ lower limits	70 ~ 1300	110 ~ 1700	120 ~ 1800
Amplitude (μV)			
Median ; mean ± S.D	145.0 ± 35.2	242.1 ± 29.2	218.1 ± 42.8
upper ~ lower limits	78.4 ~ 241.0	187.0 ~ 327.5	117.0 ~ 316.0
Outlier ; upper ~ lower limits	30 ~ 400	70 ~ 640	60 ~ 560

RESULTS

The mean values of the median of the area in normal subjects were 372.4 ± 100.2, 629.4 ± 120.7, and 480.0 ± 98.2 nV•s in TA, VL, and VM; the amplitudes in normal subjects were 145.0 ± 35.2, 242.1 ± 29.2, and 218.1 ± 42.8 μV, respectively. The suggested normal limits are shown in Table 2.

In the upper injury group, no muscle was defined as abnormal according to either the macro EMG or conventional EMG (Table 3). In the TLSI group, most subjects had a significant increase in parameter values according to macro EMG data. Twenty-five muscles out of the examined twenty-eight were defined as abnormal, denervated muscle (Table 3). In both the area and the amplitude parameter, the results were almost the same. In the case where only one parameter was abnormal, the muscle was eventually considered abnormal. According to conventional EMG, denervation potentials were found in seven muscles; five of these were completely paralyzed. Neurogenic findings of the MUP shape were found in seventeen muscles. Eleven muscles had normal MUPs (Table 4), of which, eight muscles, most being moderately or slightly paralyzed, were defined as abnormal by only the macro EMG technique.

Table 3. Macro EMG results in the paralytic subjects

			TA	VL	VM	total
Upper injury group	No. of tested muscles		5	9	9	23
	No. of abnormal muscles		0	0	0	0
	Increase of parameter	area	0	0	0	0
		amp.	0	0	0	0
Thoraco-lumbar spinal injury group	No. of tested muscles		4	12	12	28
	No. of abnormal muscles		3	12	10	25
	Increase of parameter	area	2	11	10	23
		amp.	3	12	9	24

TA : tibialis anterior VL : vastus lateralis VM : vastus medialis

Table 4. Conventional EMG results in the paralytic subjects

		TA	VL	VM	total
Upper injury group	denervation potentials				
	No. of tested muscles	9	9	9	27
	No. of abnormal muscles	0	0	0	0
	neurogenic findings				
	No. of tested muscles	5	9	9	23
	No. of abnormal muscles	0	0	0	0
Thoraco-lumbar spinal injury group	denervation potentials				
	No. of tested muscles	12	12	12	36
	No. of abnormal muscles	5	2	0	7
	neurogenic findings				
	No. of tested muscles	4	12	12	28
	No. of abnormal muscles	2	8	7	17

TA : tibialis anterior VL : vastus lateralis VM : vastus medialis

DISCUSSION

In the early period of denervation, denervation potentials can usually be observed. In the late denervation period (when reinnervation occurs as peripheral sprouting from survival motor neurons), neurogenic potetials begin to appear clearly. Finally the motor unit has much more muscle fibers than before the injury. This innervation ratio increase causes EMG parameter value changes; these values usually increase. But in most conventional EMG examinations, and occasionally in the case of TLSI patients, it is difficult to clearly locate these abnormal potentials because of following reasons.

1) Lower limb muscles, such as the quadriceps femoris are innervated by neurons from several nerve roots. 2) Lower limb muscles are larger than upper limb muscles, and their motor unit size is also larger. 3) In a traumatic spinal injury, reinnervation occurs in only part of the muscle. 4) The concentric needle electrode picks up signals from fibers within only 1 mm radius, and can not cover the entire motor unit territory (it being 5 ~ 10 mm diameter). 5) In TLSI patients with both upper and lower motor neuron damage in various grades and portions, the complexity of neuron damage makes it difficult to detect the denervation.

On the other hand macro EMG electrode territory is larger than concentric needle electrode territory, and should preferably cover the entire motor unit. The macro MUP shapes, therefore, reflect more sensitively the minimal changes of the motor unit, when reinnervation occurs /3 - 5/ . In this investigation, eight denervated muscles of TLSI patients were detected using only macro EMG.

Electrical stimulation to those patients defined as abnormal by macro EMG, could not cause sufficient contraction of muscles because of denervation. Our results, therefore, suggest that macro EMG is useful in detecting denervated muscles in FES patients prior to surgery.

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BIDIRECTIONAL INTELLIGENT TELEMETRY SYSTEM (BITS)

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SUMMARY

A microprocessor based telemetry system has been developed which will enable a controller of an FES system to acquire analog and digital signals necessary for the control of stimulated muscle motion in the hemiplegic or hemiparetic patient. The signals will be derived from transducers positioned on the patient's body, such as foot sensors, goniometers and accelerometers. The system can pre-process these signals and either upon demand or in a regularly timed report format send the content of those signals to the FES controller. The FES system would consist of multiple physically identical units. Each unit will be individually programmed for a certain task or function. Several working prototypes of the telemetry system were fabricated and tested. The performance of the RF sections and the operating system characteristics are described.

INTRODUCTION

Functional Electrical Stimulation is a rehabilitation method to restore function of paralyzed limbs in patients with cerebral or spinal cord injury. By applying electrical pulses to paralyzed muscles or their innervating nerves, functional limb motion can be achieved. A typical FES stimulation system consists of a stimulus generator/controller, electrodes and sensors. External electrode wires can be eliminated by being implanted together with the stimulus generator under the skin, thus constituting an implantable stimulator. To make an FES system even more attractive to potential users, sensor wires should also be eliminated and the stimulation system must be as easy to don and doff as possible. The objective of this project was to eliminate these sensor wires by developing bidirectional telemetry transceivers which can process sensor data and send appropriate information to the stimulation controller.

MATERIALS AND METHODS

The transceiver contains three major subsystems, a digital microcontroller, a VHF receiver, and a VHF transmitter. In normal operation the transmitter portion of the transceiver may send data to a remote location, or it may receive data from the remote location. It cannot transmit and receive simultaneously, and must use a transmit receive protocol that insures proper half-duplex operation. The receiver and transmitter share a common loop antenna. A digital microcontroller controls DC power to the transmitter and receiver, as well as receiving the digital output from the receiver, and provides digital modulation for the transmitter. It receives information from the external device providing the data requiring the telemetry, ie, sensor status, etc. Since the required range for the system will never exceed a few meters, the antenna need not provide exceptional performance.

In the absence of a real transmission, the remote receiver will still have a steady stream of random data at its digital output. Noise from the receiver's front end has sufficient amplitude to provide random threshold crossings at the receiver's data output. Most, if not all, of this random data will generate framing errors, overrun errors, or noise flag errors in the microcontroller's serial input circuitry. Occasionally a random valid start condition could occur. A message CRC or checksum provides immunity from this condition.

A valid transmission will "quiet" the receiver for at least one data frame in length. From this startup condition the receiver can detect the conclusion of the transmitter's start up condition, and unambiguously determine the first start bit of the actual data stream. After correctly decoding a message from the transmitter, the receiver becomes the transmitter and then sends an acknowledge message back to the original sender.

RESULTS

The prototype transceiver operated from a raw power source of 2.0 to 4.5 volts DC. A voltage converter generates a regulated 5.0 volts from the raw input which then powers all of the systems in the transceiver. The actual current consumption from the 5.0 volt regulated source for the subsystems follows: Microcontroller (MH68HC805B6 @ 2.0 MHz Crystal): 4.3 mA, Transmitter: 5.4 mA, Receiver: 5.6 mA. The receiver will start providing error free data at quieting levels of 10dB or greater. A quieting level of 10 dB occurs at about a 15 microvolt signal level. Full quieting occurs at about 22 microvolts. Error free detection of any transmit signal starts at the 15 microvolt level.

The transmitter must provide a range of 1 to 2 meters. At this range the receiver and transmitter operate in the "near field" range of any antenna used. This close range greatly reduces the necessity for an efficient antenna. At no point out to a range of 84 inches (more than 2 meters) does the transmitter's signal level drop below the receiver full quieting threshold of 22 microvolts. The above transmit power levels would extrapolate to an effective maximum range of about 16 to 20 feet (six meters).

The microprocessor chosen for this project has allowed us to realize a single chip solution to the design of the telemetry controller. All program, data storage, A/D, I/O capabilities are available to us on the microprocessor chip, the MC68HC805B6. The major reason for choosing this particular microprocessor were its low power consumption, the high level of function integration (analog to digital conversion, timing, storage options), and its memory structure, allowing a sealed factory released device to be programmed in the field for the particular application at hand and for it to receive and execute downloaded code transferred to it over the RF link.

The firmware of the proposed project was designed around a model patient to demonstrate the abilities of the telemetry system. Our model was a hemiplegic patient with disabilities in the ankle and the knee, and using a cane. Four pressure sensors mounted in the sole of the shoe of the affected leg, goniometers in the ankle and the knee, a pressure sensor in the cane and two finger controlled switches on the cane grip. (These signals were all simulated during the development with potentiometers.) Accordingly, the transceiver locations will be the ankle, the knee and the cane and the FES controller. Based on the sequence of events, the telemetry system would detect standing and walking patterns and convey relevant information to the FES controller.

In its minimal configuration, the system is able to support a communication link between two sites, one sensor site and one FES controller site. The sensor site transceiver is able to provide eight digital and eight analog data signals either on request from the FES controller transceiver or in preprogrammed intervals. Analog data has eight bit resolution. In its expected maximum configuration, the telemetry system can consist of (but will not be limited to) eight telemetry sites. Again, each of the seven sensor sites is able to provide eight analog and eight digital signals. Multiple patients will be able to operate their systems in close proximity by appropriate channel selection. The FES controller site will either request individual sensor data or automatically receive data from the remote sensors in a sequential pattern.

The ankle transceiver measures analog data from four force sensors located in the sole of a shoe and analog data from the ankle goniometer. From these data the microprocessor in the transceiver can detect, encode and transmit the following events:

> Gait phase: heel strike, support phase, push-off, swing phase; Ankle position: neutral position, slight dorsiflexion, moderate dorsiflexion, excessive dorsiflexion, slight plantar flexion, moderate plantar flexion, excessive plantar flexion. The knee, foot and cane transceivers will obtain data likewise detect and encode relevant events.

The model requirements above drove the design of the command and interrogation structure of the system software. Commands were designed which would describe the signal boundaries for the sensors processed and allow the slave devices to assemble status byte information for the model requirements. The flexible bit test opcodes of the 6805 microcontroller greatly enhanced the ability of the system to store and act on this information. Because of the compact nature of the encoded information only a small amount of information needed to be transferred to the host controller to give an updated report of sensor status.

DISCUSSION

Throughout the development and testing of the telemetry transceiver, many details of the expected approach changed as the design evolved. The prototype circuit implementation allowed for a great deal of flexibility in final configuration, and many different variations of the original design were evaluated. For instance, the voltage tuned input filter and quadrature tuning, although working, were discarded in favor of a more straightforward approach using trimmer capacitors. Most tradeoffs involved choices that reduced the system component count and/or current consumption.

The prototype design achieved all initial design goals, and resulted in a configuration suitable for further miniaturization. The design demonstrates the feasibility of developing a human worn telemetry transceiver that can provide reliable two way wireless digital communications between a belt worn controller unit and sensor units located elsewhere on the body. The testing indicated that the demonstrated transmission range far exceeded the requirements for the system. This fact validated the decision to use a simple single chip receiver configuration.

All of the circuitry comprising the transceiver can operate from a 3.0 power source directly. The feasibility system used a 5.0 volt supply for the actual circuitry. A practical transceiver may use a 3.0 volt lithium coin cell battery directly to provide system power. In addition, the MC68HC805B6 microcontroller can operate from a 32,768Hz clock oscillator rather than the prototype's 2.0MHz crystal. The combined effect of these two changes will reduce the average current consumption to a level 161 microamps with the receiver and transmitter in the standby mode; 3.3 milliamps with the receiver on, and 6.7 milliamps with the transmitter and receiver both on. This would seriously impair the data transfer rate and processing time of the telemetry device however and would not be of sufficient benefit to warrant the savings in power consumption. Other methods of current reduction are possible - using the microcontroller's slow mode and WAIT instructions to reduce overall consumption to a minimal level. The actual average current will also depend on the duty cycle of operation for the receiver and transmitter. A lithium coin cell (Panasonic CR2477) could provide as much as 24 hours of continuous service at the 6.7 milliamp drain. At a more reasonable transmission duty cycle of 10 to 25% the battery life easily increases to about one week with 12 hours per day of use.

The system software provided a flexible operating system supporting device addressing, single byte command parsing, polled or interrupt data status reporting, CRC and checksum support, downloadable and sensor specific program language support. High data transfer rates were achievable with the prototype devices.

The only serious technical problems encountered during the development of the system were mechanical. The multipin connector chosen for the system uses 0.025" center to center contacts and is surface mountable. This connector turned out to be much too fragile and additionally too small to be practical for the user or care-giver of a user of this system to easily manipulate. For this reason, the next iteration of the transceiver will use more robust and smaller pin count connectors. We will have to sacrifice the quantity of analog and digital events that can be transduced and probably make use of a jumper header to select the functionality of the connector chosen. This should still support the processing of the desired signals as well as support the interfaces to the host controller.

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A MATHEMATICAL MODEL MEASURING ENERGY COST FOR RESTORATION OF STANDING-UP IN PARAPLEGICS

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SUMMARY

The energy cost of the quadriceps, which chiefly generate the knee extension torque, was calculated in healthy adult men during the standing-up motion under various conditions. When subjects stood up without fixation of the ankles during the motion, the results indicated that 0° of the ankle angle was most efficient. When subjects stood up with the anterior ankle-foot-orthosis (AFO) during the motion, the results indicated that the AFO with 0° of ankle angle was most efficient. In the restoration of standing-up by using the functional electrical stimulation (FES), the AFO of 0° may be most efficient.

STATE OF THE ART

In the practical restoration of motions by using FES in paraplegics, it is significant to minimize muscle fatigue. The standing-up motion from a chair and wheel chair is the most common and repeated motion everyday. Paraplegics have to make more effort to stand than healthy persons since muscle fatigue appears quite soon. In the restoration of standing and walking by using FES, the AFO, which is fixed at the planter-flexion (PF) 5° of the ankle angle, has been applied. It has been considered that the AFO is effective from the point of view of ground reaction vector. But no report has described the ankle angle of the AFO during the standing-up motion. For paraplegics to stand up, FES must create sufficient knee torque. The source of the knee torque is the quadriceps. The purpose of this study is to estimate the energy cost of the quadriceps under various conditions of standing-up in healthy persons in order to find the most efficient condition.

MATERIALS AND METHODS

Subjects

The group A consisted of ten healthy men with their ages ranging from 23 to 29 years (mean 25 years). Their weights ranged from 52.4 to 72.6 kg (mean 63.3 kg), and their heights ranged from 162 to 182 cm (mean 171 cm). The group B was five healthy men with their ages ranging from 24 to 30 years (mean 27 years). Their weights ranged from 59.4 to 63.5 kg (mean 61.4 kg), and their heights ranged from 164 to 175 cm (mean 169 cm). None of the subjects had any previous disease or injury of their musculoskeletal systems and no abnormalities were found by examination.

All subjects provided an informed, written consent to participate in the study.

Test procedures

Subjects sat with their feet 0.25 m apart on a force plate embedded in the floor. The seat was at the height of each subject's knee level. Subjects were asked to stand up with their arms crossed in front of their chests. The speed of movement was not controlled. In group A, the initial ankle angle was set at dorsiflexion (DF) of 10°, 5°, 0° and planter flexion (PF) of 5°, 10°. In group B, subjects were asked to wear an AFO of PF 10°, 5° and 0° during the motion. The standing-up time was determined from the first hip angle motion (more than 0.5° during 1/60 second motion) to the last hip angle motion (more than 0.5° during 1/60 second motion).

Instrumentation

Automatic coordination system (Quick-MAG system, Ohyo Keisoku Kenkyusyo Inc. Japan) was used to find each joint angle. Markers were stuck on 1) the lateral malleolus, 2) the lateral side of the knee joint lines midway between the patella and popliteal fold, 3) the great trochanters of the femurs, and 4) the acromions of the shoulders.

A Kistler force plate (9281B) was used to collect the vertical and the antero-posterior forces.

The joint angle and floor reaction force were synchronized with time.

Calculation

The three-segment link model, as described by Yukawa /1/, was used for the numerical analysis. We calculated the hip, knee and ankle joint torque and the angular velocity of each joint during the standing-up motion.

The musculoskeletal model described by Yamazaki /2/ was used. The model included the nine lower limb muscles: gluteus maximus, iliopsoas, vastus lateralis and medialis, short head of biceps femoris, soleus and tibialis anterior (all one-joint muscles) and, rectus femoris, hamstrings, lateral and medial heads of gastrocnemius (all two-joint muscles).

Both muscle force and energy cost were calculated with Ehara's method /3/ from each joint torque, angular velocity of each joint, and Yamazaki's model. The relationship between force and contraction velocity on the muscle, as described by Hill /4/ (and modified by Mashima /5/), was considered in Ehara's method.

We examined the data in the Fisher's Protected Least Significant Difference test.

RESULTS

In group A, the energy cost of the quadriceps of DF 10°, 5°, 0° and PF 5°, 10° were 18.8 ± 5.6, 12.6 ± 4.3, 9.7 ± 4.9, 11.7 ± 5.3, 19.2 ± 6.6 (± S.D.) cal/kg/min, respectively. Both DF 5° and 0°, and PF 5° were significantly smaller ($p<0.05$) (Fig.1). In group B, the energy cost of the quadriceps with the AFO of PF 5°, 10°, 0° were 0.79 ± 1.0, 1.98 ± 1.4, 2.04 ± 1.8 cal/kg/min, respectively. The AFO of 0° was significantly smallest ($p<0.01$) (Fig.2).

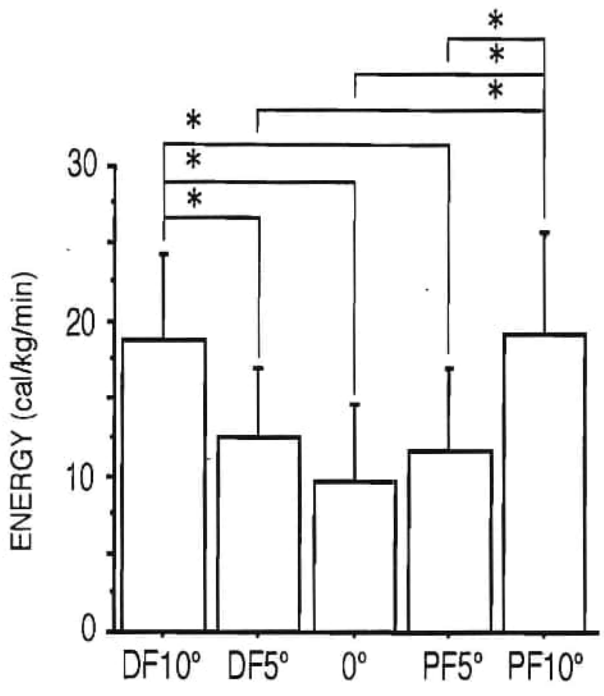

Fig.1 The energy cost of the quadriceps in group A. (∗p<0.05) (mean ± S.D.)

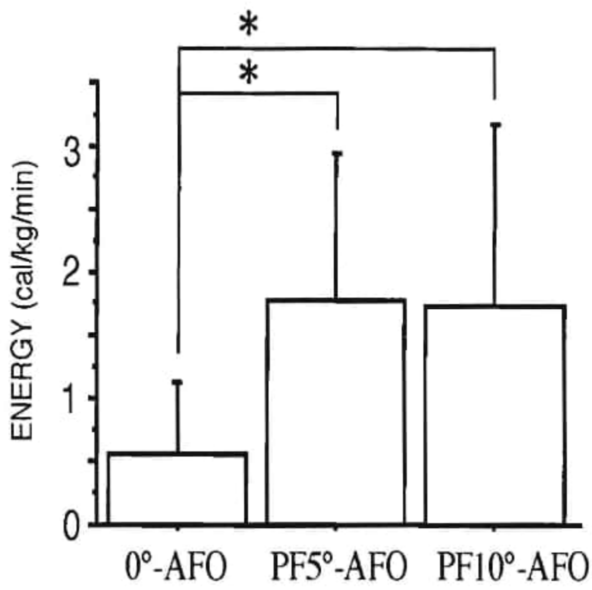

Fig.2 The energy cost of the quadriceps in group B. (∗p<0.01) (mean ± S.D.)

DISCUSSION

When subjects stood up without fixation of the ankles during the motion, the results indicated that 0° of the ankle angle was most efficient. When subjects stood up with the AFO during the motion, the results indicated that the AFO of 0° was most efficient. The energy cost of the quadriceps with the AFO was much smaller than without the AFO. We think the AFO decreases the energy cost of the quadriceps during the standing-up motion. The results suggest that the most energy efficient manner of standing-up for paraplegics can be found by this method.

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The Value of EMG-Triggered Electrostimulation in Spastic Hemiparesis Following Stroke

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Abstract

The therapy of spastic paresis has two aims: Spasticity has to be reduced, voluntary movement and contraction force shall be improved. The method of EMG-triggered electrostimulation intervenes in the circuit of "planning - performance - feed-back of quality/quantity of movement" in so far as an initiated voluntary movement is completed by means of electrical stimulation. We report on preliminary results of a current investigation of patients with spastic hemiparesis following stroke. At present, the majority of patients show a distinct reduction of spasticity and a slight improvement of mobility.

State of the art

A unilateral cerebrovascular lesion leads to a central, spastic hemiparesis. Although the peripheral nerve-muscle-apparatus is intact, a normal movement is impossible because the central nervous pathways are interrupted, and the central mechanisms of movement control are damaged. Spasticity developes with increased tendon reflexes, pyramidal signs and increased muscle tone. Paresis and increased muscle tone both impair the normal voluntary mobility.

There are several therapeutical concepts to counteract this development, such as antispastic drugs, physiotherapy, massage, physical therapy and various forms of electrotherapy, most of them reducing spasticity as a short-term effect.

"Conservative" electrotherapy aims to reduce spasticity by making use of inhibiting processes on the spinal level. Hufschmidt tried to imitate the locomotion activity, hoping that an adequate afferent flow of information would induce a functional reorganisation (4). Alfieri stated that electrotherapy of the antagonists leads to a better reduction of spasticity than stimulation of the spastic agonists (1). He thought that areas in the supplementary motor cortex could be reached via an afferent pathway of a long-loop reflex, the pyramidal tract being the efferent pathway.

The EMG-triggered electrostimulation is not a new type of conservative electrical therapy, it aims at a functional goal. The initial situation is as follows: A movement is cortically initiated, but it cannot be performed due to the lesion of the efferent central nervous pathways. Thus, an always negative feed-back is sent from peripheral receptors to the cortex saying "I wanted to perform this movement, but I was not able to". This circuit now shall be interrupted, and the afferent information shall be replaced by a positive feed-back: The patient intends and starts a movement, the maximum muscle tension is measured and the value is stored by the stimulation device. After a short period of complete relaxation, the patient again performs this movement as strongly as possible. When the maximum possilbe value of muscle tension is reached, the device automatically starts to stimulate the muscle for several seconds, thus completing the movement and sending a positive information to the brain. This positive feed-back is thought to activate populations of neurons and pathways in and around the area of infarction that are still intact or can be reactivated or reorganized.

Material and Methods

The entire study compares the value of EMG-triggered stimulation with the "conservative" coninuous electrostimulation, all patients receiving a basic program of physiotherapy and occupational therapy. A control group only receives this basic program without electrotherapy. At present, two groups of patients with spastic hemiparesis following stroke were treated: Group 1 (EMG-triggered electrostimulation and basic program): n=12, 10 males, 2 females, age 51.7±11.9 years (33-69), duration of disease 4-104 weeks. Group 2 (control group, basic program): n=4 males, 64.5 ± 6.0 years (56-58), duration of disease 4-8 weeks.

Stimulation is performed by a special device (Per-Y Rehabilator, NeuroCareUnits, Rheurdt). Sensitivity of EMG is 0.1-1000 µV, the stimulation impulse is asymmetric-biphasic, duration 0.3 ms, frequency 20-100 Hz, intensity 0-90 mA. The parameters of sensitivity, impulse intensity and frequency were chosen individually different, always reaching the same clinical effect (completion of movement). Stimulation was performed on four muscle groups, being antagonistic to the spastic muscle groups: Triceps muscle and extensors of the forearm, biceps femoris and anterior tibial muscle. During the whole session, the patient was asked to relaxe and to concentrate. Each muscle group was stimulated about 10 times within 15 minutes, the duration of one single stimulation was 3-9 seconds.

Control investigations were performed immediately before and four weeks after the onset of therapy. For estimating the ADL (activities/abilities of daily living) and the psychological status, we used the modified Ashworth scale, dynamometry (Myometer, Penny & Giles, Christchurch), the Barthel index, the Hamilton depression scale (HAMD) and the v. Zerssen feeling scale (Bf-S). Optionally we used the pendulous test (6) and the H-reflex.

Results

All of the patients indicated a subjective improvement of spasticity. Most of the patients showed a distal spasticity without major pathological findings in the pendulous test. An increase of spasticity, only was found in the control group. In both groups, Barthel index increased (group 1: 0-35, group 2: 15-25 pts). Both groups improved in the HAMD and Bf-S (HAMD: 7.3 ± 3.5 vs. 7.5 ± 3.6 pts, Bf-S: 11.7 ± 6.3 vs. 7.3 ± 2.3 pts). Dynamometry showed a distinct increase of contraction force in group 1 (shoulder: abduction 2.0 kp, anteversion 1.4 kp, retroversion 1.3 kp; ellbow: flexion 2.8 kp, extension 3.2 kp; hip: abduction 3.0 kp, flexion 3.6 kp; knee: flexion 2.7 kp, extension 2.2 kp; foot: flexion 3.3 kp, extension 4.7 kp) and only a slight increase in group 2 (shoulder: abduction 0.6 kp, anteversion 2.4 kp, retroversion 4.4 kp; ellbow: flexion 2.0 kp, extension 0.2 kp; hip: abduction 3.5 kp, flexion -2.0 kp; knee: flexion 1.5 kp, extension 1.1 kp; foot: flexion 1.1 kp, extension 3.3 kp).

None of the results shows statistical significance.

Discussion

Patients receiving EMG-triggered electrotherapy showed a higher increase in contraction force than patients from the physiotherapy group. This is not necessarily equivalent with a better mobility, and the Barthel index did not show clear differences between the groups. Barthel index, however, is a very simple scale, and thus allows only a rough estimation of the abilities of daily living.

In this study, patients were able to perform voluntary movements against their spasticity. In such cases, each motor command is implemented incorrectly, thus reinforcing the deficient central programming. The replacement of this negative information by a positive feed-back can often help in clinical routine therapy to improve the patient's mobility (2, 3, 5). So was the result in this study. Possibly due to the small number of subjects, no statistical significance was found. The clinical experience of a positive effect on mobility and force, however, seems to be confirmed.

Wartenbergs pendulous test (6) which is thought to be of greater value in estimating chronic spasticity did not prove very valuable in these cases, probably because of the preponderantly distal spasticity that occurs in early stages of stroke. For this, other methods have to be developed.

Measuring the outcome of electrotherapy is not the same as estimating its value for the patient. There are patients with a distinct increase of muscle force, reduction of spasticity and increase of mobility, which, however, will never be content with their results, and others might be happy with an only small improvement of their abilities of daily living. Clinically there is a general acceptance that features of the patient such as depression or low motivation might have a major influence upon outcome. We hope that the HAMD and Bf-S scales will be able to demonstrate a possible influence of mood upon therapeutical success, or vice versa, resp. Patients that receive EMG-triggered electrical stimulation seem to profit from this type of therapy. After four weeks of therapy they "feel better" (Bf-S) than patients from the physiotherapy group. Much further research is needed, however, to develop clinically useful, valid measures of handicap and quality of life.

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Walking orthosis for paraplegics

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Abstract: *Walking orthosis of a new kind (Parapodium PW) for paraplegics is described. Parapodium is operated by still active muscles of the disabled person (upper limbs). There is no need to use crutches while walking. During breaks in walking both hands are free and different tasks might be performed.*

Keywords: Parapodium, Walking orthosis, Paraplegic, Man-parapodium system

Introduction

Walking orthoses for paraplegics can be supplied from external sources of energy or operated by still active muscles of the disabled person. Although a tremendous progress in the development of the first group of devices has been observed recently they are expensive and rather out of reach for an average invalid. In the second group, only one device, as a matter of fact, based upon the invention of Louisiana State University (L.S.U. device) found practical application [1]. Some limitations and drawbacks of that device stimulated our recent research in this field. In 1994 four variants of a new kind walking orthosis were built and tested by our group. The most mature variant is described in this paper.

Walking with the parapodium.

(Device patented in Poland in 1995. Patent number P 307 620)

In Fig. 1 and 2 the usage of parapodium is illustrated. Gait in this device differs from the normal human gait since knee joints are fixed here (no flexion of the knee). Foot platforms are all the time parallel to the floor. Easy to learn, slight swinging along horizontal axis is necessary to initiate gait. It is also accompanying all the steps, while using the device. That swinging is decreasing load on the activated leg and enables its movement without a friction between the foot and the floor. Parapodium is activated by hands using two lewers. Specially designed, patented mechanisms enable user to make turns. During the turning legs turn round the vertical axis passing through hip joints. Comparison between normal gait and gait in parapodium is given in Fig. 3.

In case of normal human walking two main phases are present: stance phase (~ 60 % of the whole cycle) and swing phase (~ 40 %). Such a normal walk is depicted in Fig. 4a [2]. In the same figure (Fig. 4b) phases of walking while using parapodium are also shown.

Parapodium is depicted in Fig. 5. Torso frame (vest) made of composite might be adjusted to the size of the user. The same concerns both legs. Total weight of the device now equals 11 kg, but will be reduced in the future.

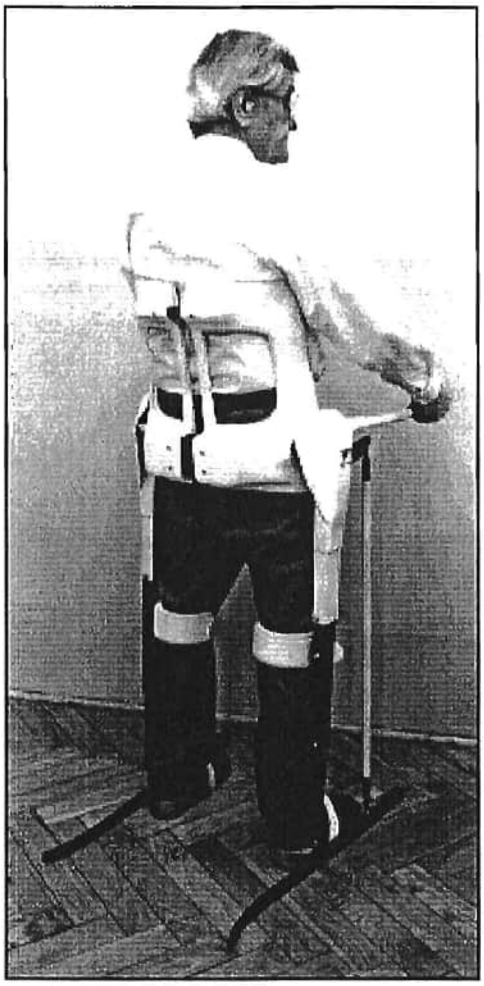
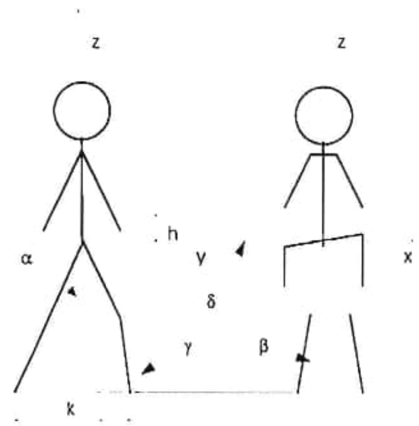
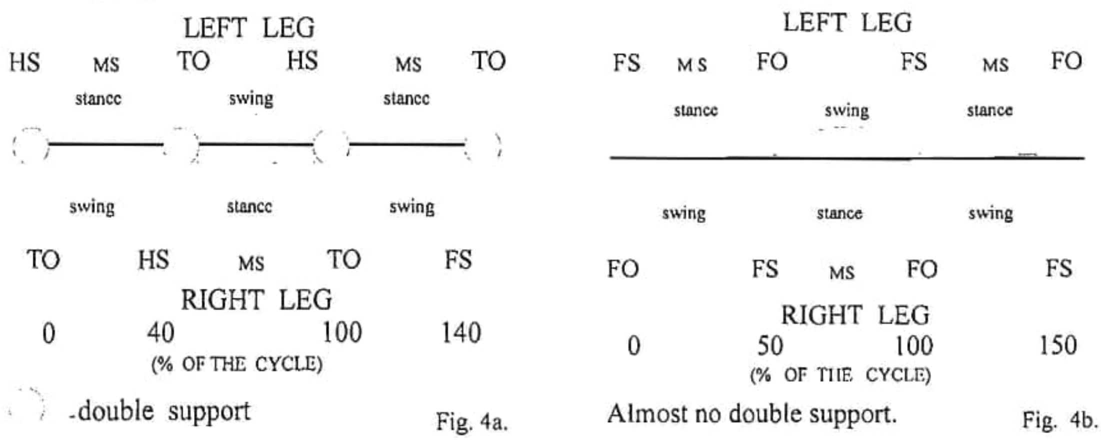


Fig. 2 Back side of parapodium.



	Normal human gait	Gait with parapodium
α - swing of a leg	20°	15°
β - side flex of a leg	changeable	fixed (5°)
γ - flex of a knee	0^{o} - 65	0^{o}
δ - vertical pelvic rotation (axis y)	4°	0°
horizontal dip of pelvis (axis z)	8°	0°
h - vertical displacement of the pelvis	50 mm	max. 54 mm
k - length of one step	660 mm	500 mm

Fig. 3. Comparison between normal human gait [2] and gait with parapodium.



Normal human gait | Gait with parapodium

TO - toe off; FO - foot off; HS - heel strike; FS - foot strike; MS - middle stance.

Fig. 4 Phases of walking

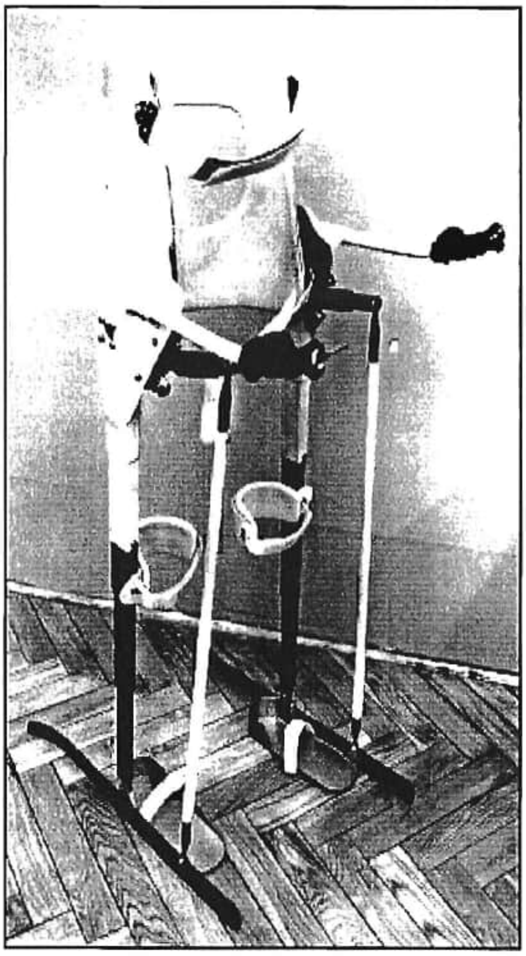


Fig. 5 Parapodium PW.

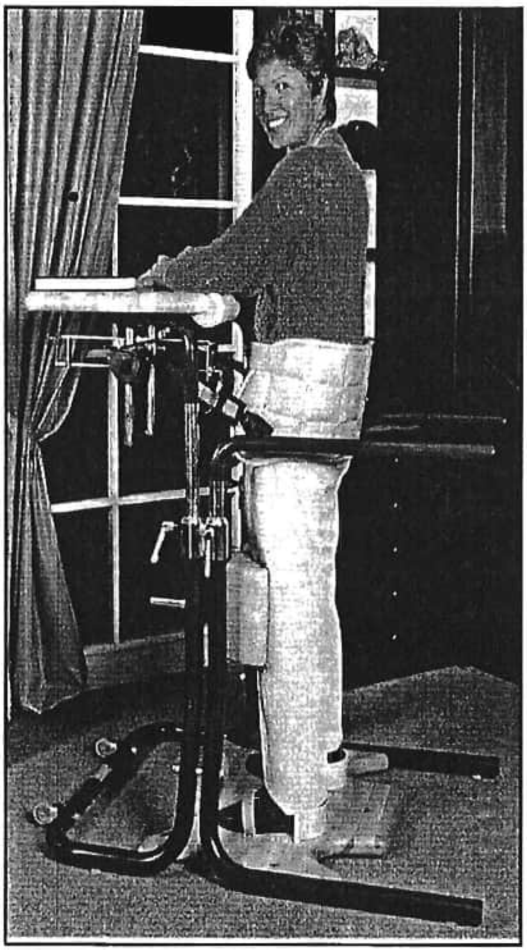


Fig. 6 Device of the firm „Rollsthul Richter"

Future plans.

At the moment our device needs some external help of the additional person to be used by an invalid.
In the nearest future we plan to build improved version of the device which will enable self-reliant standing up of the disabled person (probably with a surface electrostimulation). It will have similar properties as a well known device of the firm „Rollstuhl Richter" (Fig. 6) [3] and in addition to that will enable walking without crouches.

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AN IMPROVED NERVE CUFF RECORDING CONFIGURATION FOR FES FEEDBACK CONTROL SYSTEMS THAT UTILISE NATURAL SENSORS

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SUMMARY

In recent efforts, researchers developing techniques to record ENG activity using nerve cuffs have employed a recording configuration described by Stein /1/ (1975) and his colleagues /2,3/ which we will refer to as "quasi-tripolar" arrangement. While a cuff containing three electrodes is used, the outer electrodes are connected to each other before being led to one end of an amplifier. The other amplifier input is connected to the cuff central electrode. We compared this "quasi-tripolar" configuration with our tripolar configuration in terms of the ability to suppress interference currents through the cuff caused by biopotentials (EMG) or FES-Pulses. Our tripolar configuration consists of a tripolar cuff-electrode that is connected to two first stage high-impedance amplifiers with adjustable gain. The outer electrodes are not shunted together, as is done in the "quasi-tripolar" configuration. In a second stage the outputs from the two instrumentation amplifiers are in effect subtracted from each other. An investigation in an animal preparation demonstrated that the tripolar configuration suppresses interference currents through the cuff substantially better (27.1 dB) than the "quasi-tripolar" configuration.

STATE OF THE ART

In a typical tripolar nerve recording cuff, the three electrodes are mounted on the inside of a cylinder made of an insulating material such as silicone which electrically isolates the nerve from the surrounding tissue. To perform well in rejecting the registration of EMG-activity, the outer electrodes are shunted together and a bipolar amplifier is employed to measure the potential difference between the middle and outer electrodes ("quasi-tripolar configuration"). The tissue impedance of the nerve itself ($\underline{Z}t1$ and $\underline{Z}t2$) and the impedance of the nerve-electrode interface ($\underline{Z}e1$, $\underline{Z}e2$ and $\underline{Z}e3$) are connected to the amplifier, as modeled in Fig. 1a.

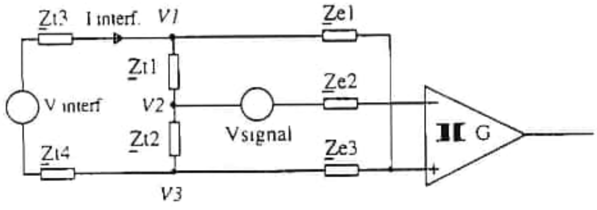

Figure 1a

Assuming $\underline{Z}t1=\underline{Z}t2$ and $\underline{Z}e1=\underline{Z}e3$

$$V_{quasitri} = G\cdot\left(-V2+\frac{V1+V3}{2}\right) \quad (1a)$$

$\underline{Z}t3$, $\underline{Z}t4$ ...Tissue impedance between interference source (V interf.) and recording cuff

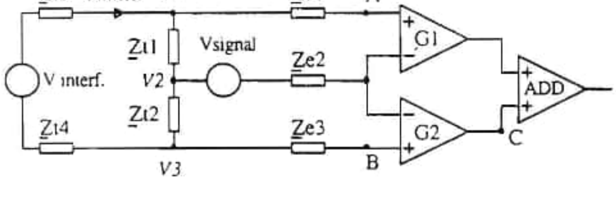

Figure 1b

Assuming G1=G2=G

$$V_{tri} = 2\cdot G\cdot\left(-V2+\frac{V1+V3}{2}\right) \quad (1b)$$

In theory, external interference currents passing through the cuff are rejected if the two voltage dividers consisting of $\underline{Z}t1$, $\underline{Z}t2$ and $\underline{Z}e1$, $\underline{Z}e3$ are well matched. In practise, however, considerable artefacts caused by muscle activity and by FES pulses are still present in the cuff recordings, because such precise impedance matches are not realisable.

In our recording configuration the outer electrodes of the tripolar cuff are not shunted together, rather they are connected in pairs to two first stage high-impedance instrumentation amplifiers with adjustable gain (Fig. 1b). The outputs from the two amplifiers are then in effect subtracted from each other in a second amplifier stage. When our tripolar arrangement is used, the interface-impedance ($\underline{Z}e1$, $\underline{Z}e3$) mismatch becomes negligible because of the high input-impedance of the amplifiers, and the remaining imbalance of the nerve-impedance ($\underline{Z}t1$, $\underline{Z}t2$) can be matched by adjusting the gain of the first stage amplifier. As will be shown, this recording arrangement performs well at rejecting interference currents passing through the cuff.

MATERIALS AND METHODS

A tripolar nerve recording cuff was implanted around the sciatic nerve in two rabbits. The cuff was formed using a silicone tube having an overall length of 22mm. Three circumferential platinum foil rings (1mm wide x 3mm diameter) attached to the inner wall of the cuff with a centre to centre separation of 10mm formed the electrode surfaces. Three stainless steel lead wires extended from the cuff, and a 19 gauge needle placed subcutaneously and 25 mm lateral to the cuff, provided a reference for the amplifier. Two AMP-01 (Analog Devices Inc.) units formed the first stage (gain 100 or 500). The adding stage (TLC 2201, Texas Instruments Inc.) permitted adjustable weights for the gains from the inputs. Two switches allowed the amplifier to be configured from "quasi-tripolar" to tripolar (ie. points **A** and **B** were shunted and one input (point **C**) from the adder stage was connected to the circuit ground). The two configurations were thus studied sequentially, and in either case, a secondary amplifier and 1st order bandpass filter (1-6kHz) was applied before storing the data on DAT-recorder (sampling freq.=24kHz).

To provide a defined and equal level of nerve activation for both measurement situations, we used supramaximal stimulation applied through hook electrodes in an oil bath to the transected and isolated peroneal nerve just distal to the knee.

The ability of the two alternative recording configurations to reject artefacts was studied by driving constant current pulses (100 µs, various amplitudes) through the tissue. These were delivered in the vicinity of the nerve cuff using a pair of needle electrodes positioned first parallel to and then transverse to the long axis of the recording cuff and about 2 cm from the cuff.

RESULTS

The results of the noise measurements are presented in Table 1a. The rows "Amp1" and "Amp2" refer to data taken when values of 100 and 500 were used, respectively, for the first stage amplifier gains. RMS noise measurements for the whole system (recording cuff and amplifier) were performed for both recording configurations and several different gain settings using a Keithley 2000 multimeter with the animal deeply anaesthetised and no externally applied interference currents present.

While the tripolar configuration showed a higher absolute noise level (Table1a) compared to "quasi-tripolar" configuration, the former has a superior signal-noise ratio (S/N), because the signal output of the tripolar configuration is two times higher than the quasi-tripolar configuration. This can be seen from Figure 2 where the behaviour of the tripolar and "quasi-tripolar" configurations are compared for supramaximal stimulation of peroneal nerve.

Despite our using an additional instrumentation amplifier (in the first stage) the S/N is not degraded, as shown in Table 1b. This occurs because the signal output for the tripolar arrangement is double that of the

Input Noise [in μV RMS]		
Amplifier Type	Quasi-tripolar	Tripolar
Amp 1	1.05	1.63
Amp 2	0.795	1.476

Table 1a

Comparison of Signal*/Noise Ratio [in dB]		
Amplifier Type	Quasi-tripolar	Tripolar
Amp 1	-2.416	-0.065
Amp 2	0**	0.797

* peak-to-peak value of signal response for supramaximal stimulation of peroneal nerve

** S/N values are normalized (0dB) to the quasi-tripolar configuration using Amp2

Table 1b

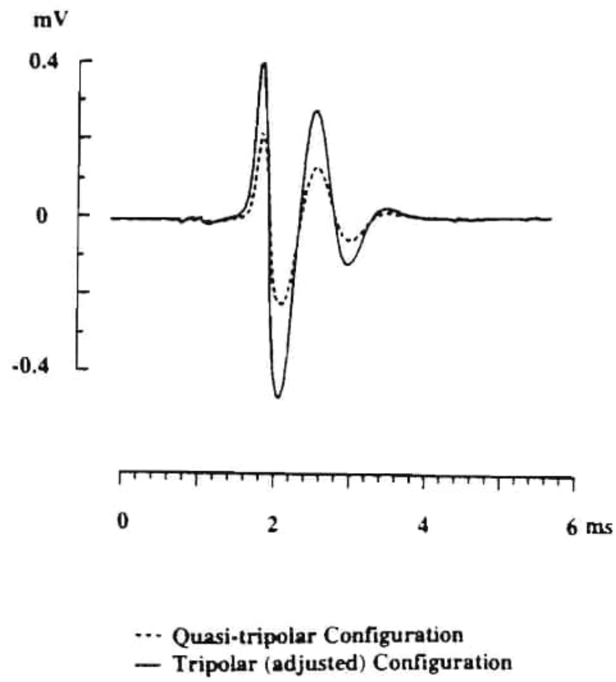

Figure 2

"quasi-tripolar " arrangement, while the noise added by the amplifier is only increased by the square-root of 2. Since the noise from the resistive components of the cuff-impedance is approximately doubled for the tripolar arrangement, depending on the contribution of amplifier noise (Vamp) and noise coming from the cuff (Vcuff), itself the S/N can be improved up to a factor equal to the square root 2. Moreover, in the worst case the tripolar configuration will still perform at least as well in terms of S/N as the "quasi-tripolar" configuration.

To realise the benefits of the tripolar configuration the gain of the weighing stage was adjusted (Fig.3) to obtain a minimal response to current pulses (100μs , 5mA , 2,5 kHz) applied in the vicinity of the recording cuff.

Figure 4 compares the performance of the "quasi-tripolar" and properly adjusted tripolar configuration during application of 100μs stimulation pulses at various amplitudes. For currents up to 5mA (cases **A**, **B** and **C**) the tripolar configuration suppressed the stimulation pulses much better than for the "quasi-tripolar" arrangement. Note that the tripolar configuration showed no further suppression ability when the amplitude of the interference pulses reached 5.5 mA, because the first stage amplifiers saturated. In that case it still performed as well as the "quasi-tripolar" configuration, however it had another advantage in that the system recovered from saturation more quickly (i.e. compare point **a** with point **b**), because only the first stage amplifiers were affected.

The average interference suppression ratio (10.28) was calculated by comparing the peak to peak voltages of the signal outputs during the application of interference currents. Since the signal output for the nerve response of the tripolar arrangement is approximately double that of the "quasi-tripolar " arrangement (In this case the adjusted tripolar configuration had a factor of 2.2), after taking this into account, we obtained a normalised interference suppression ratio of 27.1dB (20 log (10.28 x 2.2)).

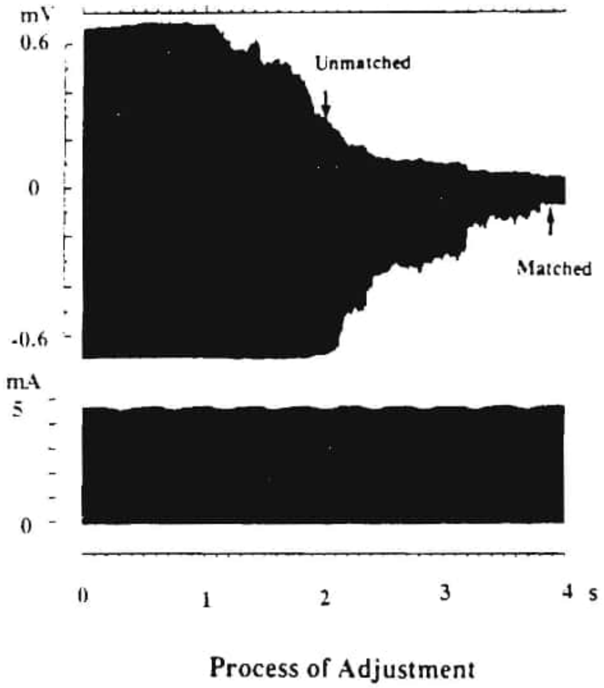

Figure 3

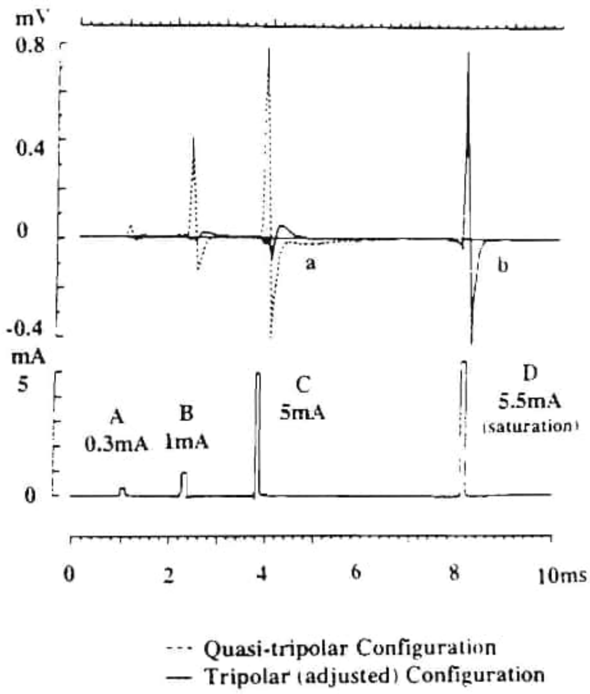

Figure 4

DISCUSSION

In this paper we showed that the tripolar configuration has a superior ability to suppress interference currents passing through the cuff, and the S/N is improved. This may be especially useful to compensate for the increased amplifier noise associated with operational amplifier components for implatable hardware because of their extreme low bias currents. We look forward to confirming these results in the near future in a human volunteer subject who has a chronically implanted nerve recording cuff.

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LASER WELDING TECHNIQUES FOR IMPLANTABLE CASES

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INTRODUCTION

Packaging and encapsulation of implantable electronics must provide suitable long-term protection for the electronic circuitry which is compatible with the body's internal environment and meets all requirements for proper operation. Encapsulation procedures should not adversely affect the stimulator circuitry during construction, and provide all the appropriate interfaces to the tissues /1/. Materials used for the package must be sterilisable, have sufficient mechanical stability and chemical resistance, not evoke excessive tissue response, and provide maximum circuitry protection without unnecessary volume or weight. Multi-channel applications like complex nerve stimulators or measurement devices require multiple electrically isolated feedthroughs.

Excellent biocompatibility and bioresistance are provided by pure metals of group IV and V of the table of elements, especially titanium, tantalum and niobium. A self healing oxide film protects them against corrosion. Neither excessive foreign body reaction nor release of metal ions occur an, implant stays incorporated even in case of inflammation of the surrounding tissue.

In the following an example for the construction of a hermetic titanium case with 12 electrical feedthroughs is presented, where the application of CNC-laser techniques led to a flexible and economical solution.

MATERIALS AND METHODS

The implant case consists of a deep-drawn cup and a base plate. The base plate forms an exact seat for the cup and carries the feedthrough seals, elements for mounting the electronic circuit and the battery on the inner side and a perforated element for fixation of the electrode connectors outside.

Beside deep drawing and milling, laser-cutting and-welding plays an important role in the manufacturing process. It is used for cutting titanium parts to size, mounting the different fastening means to the baseplate, weld-in the prefabricated feedthrough seals (figure 1) and welding the lid to the base plate to seal the whole implant.

A pulsed neodyn-YAG laser (Yttrium/Aluminium/Garnet) with a wavelength of 1,06µm and equipped with numeric control is used (LASAG LP300, NUM570). This machine provides excellent reproducible results in cutting or welding titanium or the other above-mentioned metals as long as a suitable protective gas is used to avoid reaction of molten metal with oxygen. Therefore the workpiece is moved relative to the laser beam inside a chamber filled with argon for welding and filled with helium for hermetic sealing of the case.

Machinability of materials with lasers can be estimated by the socalled „difficulty factor S", based on optical, physical and thermal properties of the worked material /2/.

$$S=\frac{\lambda . Ts.p.C}{A^2}$$

λ heat conduction, Ts melting temperature, ρ density
c specific heat, A coefficient of absorption

The factor „S" should be as small as possible to achieve high welding quality. For titanium the difficulty factor is about 0.006, for niobium 0,011 and for stainless steel 316L 0,05. In comparison for gold „S" amounts 11,15.

Quality of a welding seam is investigated via metallurgical micrographs for parameter optimization and microscopical inspection during manufacturing. Hermeticity of the whole implant case is checked via helium fine leak test after the sealing procedure.

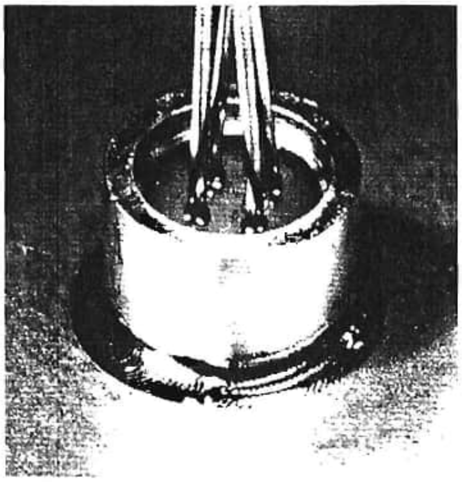

Figure 1: Welded-in feedthrough seal

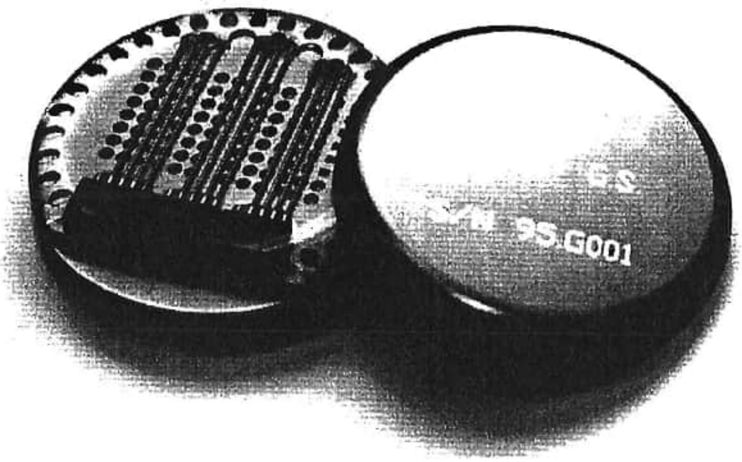

Figure 2: Implantable battery operated stimulator

RESULTS

To give an example the following parameters were optimized for the welding seam between base plate (0.8mm titanium) and lid (0.5mm):

objectiv focus	**150 mm**	**aperture**	**5.8 with 90 mm**
expander	**20/200**	**final mirror**	**type 44.008 with 190 mm**
tuning out mirror	**type 44.076 with 190 mm**	**voltage**	**350 V**
duration of impulse	**1.05 ms**	**frequency**	**8 Hz**

Figure 2 shows a battery operated implantable stimulator based on the described titanium case. The leak rate of the laser sealed cases amounts between 10^{-9} and 10^{-12} mbarls^{-1}.

DISCUSSION

The neodyn-YAG laser serves as a useful tool in the construction of hermetic cases for implantable electronics, providing high flexibility in design, minimal thermal and mechanical stress to the feedthroughs and the sealed electronic components and reproducible results.

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Concept of a Retina Implant for Ganglion Cell Stimulation Applicable for Patients Suffering from Retinitis Pigmentosa

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Summary

This work describes the concept of an implant for electrostimulation of retinal ganglion cells applicable for patients suffering from retinitis pigmentosa. The proposed system is based on a novel combination of microelectronic and micromechanical methods that will allow the fabrication of miniaturized flexible silicon multielectrode structures with integrated CMOS circuitry, e.g. for power and data transfer as well as stimulation pulse generation.

Introduction

Biological research on disease of retinitis pigmentosa as well as macula degenerations has shown [1, 2] that visual sensations can still be achieved by electrostimulation of ganglion cells despite photoreceptor degeneration [3, 4]. In this contribution we propose a system for stimulation of retinal ganglion cells for patients suffering from retinitis pigmentosa (RP) which can be divided into two major components: The implanted stimulator unit and an external retina encoder. Both are coupled by a combination of radio frequency (RF) and optical links for power supply and data transmission. The implantable part, the *Retina Stimulator Unit*, can be realized only by applying advanced methods of microelectronics and micromechanics, e.g. flexible silicon multicontact stimulation arrays with integrated CMOS microelectronic circuits and lithographically formed (LIGA) [5] contact electrodes. The structure of the system architecture is shown in Fig. 1.

Implantable Retina Stimulator

The implantable retina stimulator itself will be divided into the telemetry receiver unit that will be placed inside the eye in the position of the crystalline lens and the multicontact electrode which is a flexible structure of a few millimeter diameter. The latter is placed on the retina surface for epiretinal stimulation and coupled to the receiver by a highly flexible silicon ribbon cable for power and serial data transfer inside the eye. The telemetry receiver unit provides wireless link between the stimulator and the external encoder. It transforms RF-transmitted power into regulated supply voltage and decodes electrical patterns for the stimulator. Both receiver and stimulator will be fabricated on silicon substrate and can be processed using our in-house CMOS technology to implement integrated CMOS circuitry for contact selection and stimulation pulse forming. Although the stimulator itself carries circuitry, it also forms a flexible silicon structure. This is achieved by applying a novel

[1]The authors Dr. M. Schwarz, Prof. R. Eckmiller, and Prof. B.J. Hosticka are members of the Retina Implant Team that also worked out a scenario for a Retina Implant device in the study "Neurotechnology-Report I" contracted by the German Federal Ministry of Research and Technology, Bonn.

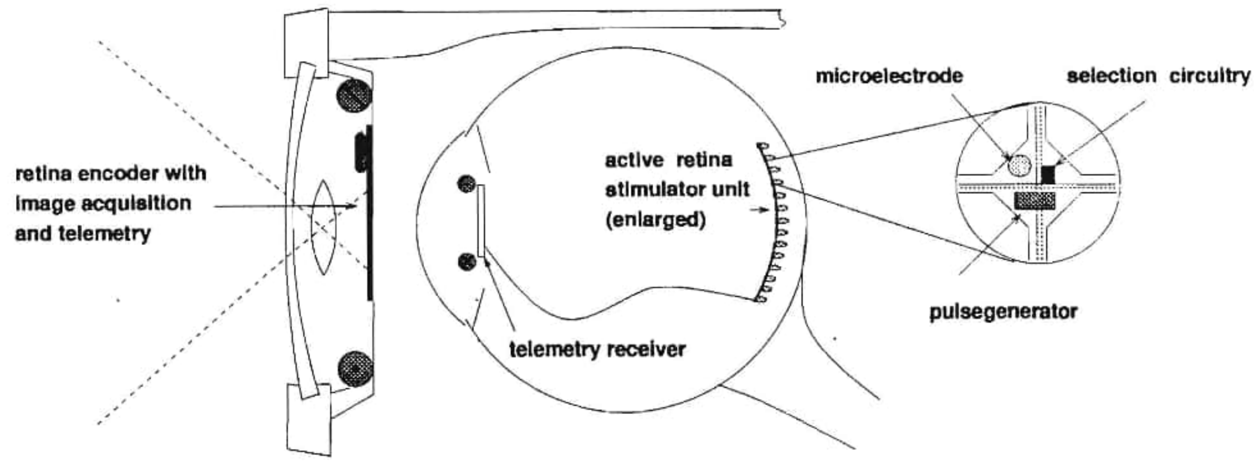

Figure 1: Architecture of a retina implant system for epiretinal ganglion cell electrostimulation

etching process which allows mechanical decoupling of substructures while creating small "islands" of silicon keeping single or small groups of electrodes and their associated CMOS circuits (Fig. 2). This is in contrast to approaches pursued by some U.S. researchers who use passive polymide plastic electrodes [6]. It has been estimated that for the first experimental phases 20 to 200 microelectrodes with electronic contact selection and pulse generation are realistic. Encapsulation, biocompatibility, surgery and fixation methods, as well as long time stability of the implantable retina stimulator are subject of extensive investigation by associated research groups.

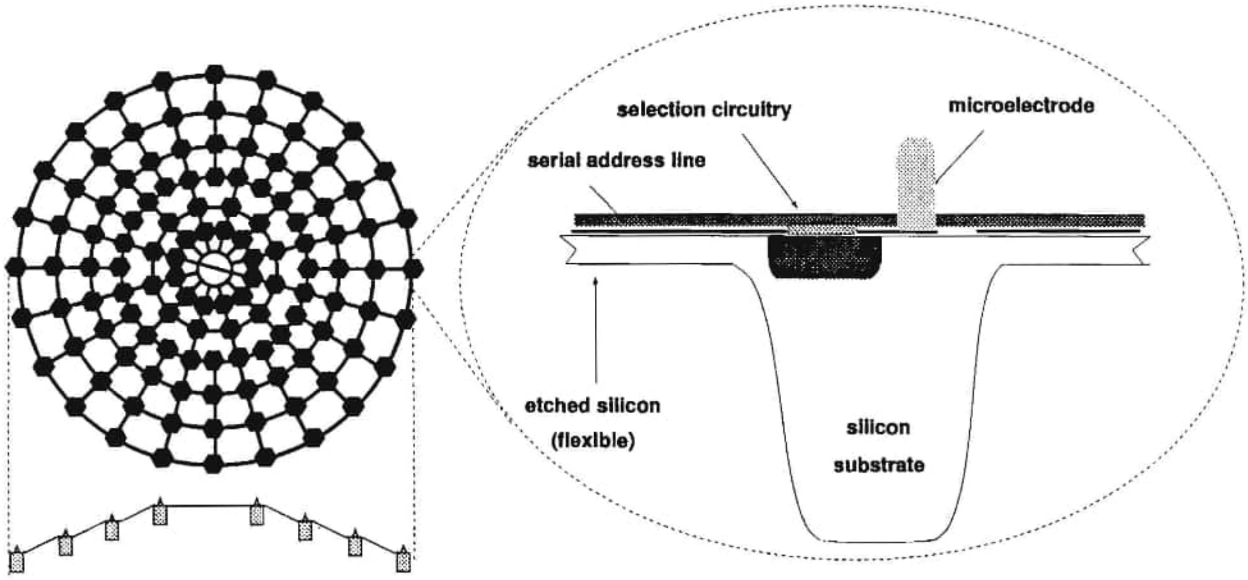

Figure 2: Microelectronic multielectrode structure for intraocular epiretinal stimulation

Retina Encoder

The major tasks that will be performed by the external *Retina Encoder* include image acquisition, computation of receptive field functions, encoding of the stimulus pattern for telemetric transmission of command sequences for stimulation, and common steps for channel coding and data integrity test (Fig. 3). At input to the Retina Encoder a dedicated microelectronic photodetector-array will be attached, which implements all functions of an image acquisition subsystem on a single chip. A CMOS-photodetector array with a hexagonal grid structure, optimized for receptive filed computation was proposed for this purpose and seems to be realistic since comparable structures have been fabricated and tested successfully at our institute [7]. On-chip readout electronics perform addressable readout of single gray values as well as fast collective readout of all gray values within a definable hexagonal region. In contrast to CCD-devices with full frame serial readout, our method allows a more efficient spatio-temporal filtering inside the retina encoder. Additionally, nonlinear mappings of space for the purpose of resolution adjustment according to the distance from fovea center, can be carried out by the on-chip hardware.

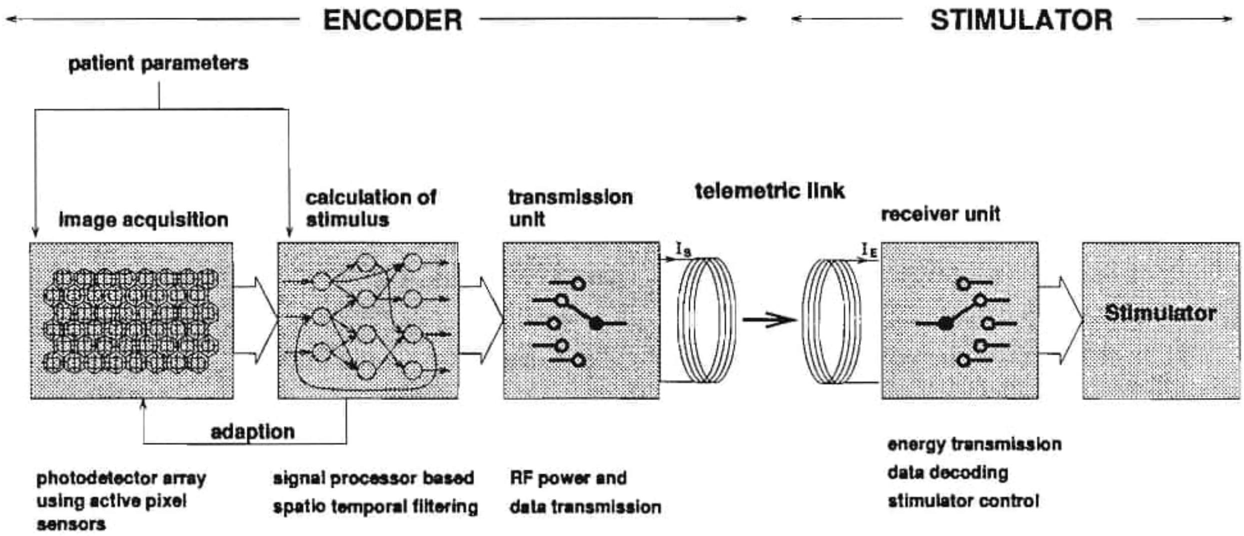

Figure 3: Structure of the retina encoder with image acquisition and telemetric link for power and data transmission to the intraocular stimulator

For a prototype system all spatio-temporal filtering for implementation of receptive field functions will be performed by a programmable signal processor (DSP) (Fig. 3) which is powerful enough to emulate neural encoding of visual signals in real-time. This programmable Retina Encoder System, which emulates an adaptive neural net using a DSP, gives us a great flexibility and thus allows extensive testing of various receptive field functions, which is necessary, since patient feedback will not be available in the first project phase. All results will be proven using animal models, e.g. mouse and rabbit, by acquisition of optical nerve and cortical signals.

Perspective and primary goals

Although no tests on patients are planned in the first phase, we assume that we can show feasibility of a ganglion cell stimulation system for retinitis pigmentosa patients within the next decade. First steps include the design of a variety of flexible and light-weight implantable stimulator structures made of silicon, which allow the integration of CMOS microelectronic circuits, e.g. for electrostimulation, data and energy transfer, into the stimulator substrate as a novel feature. Accompanying medical research performed by associated groups will concentrate on optimization of the implantation ophthalmological surgery and long-time implant fixation with minimal penetration of the retina. Biomedical research will test biocompatibility and stability of encapsulated implants in cell culture, penetration of stimulated cells and stability of the implant itself, especially for electrodes and encapsulation.

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EMG-CONTROLLED WRIST EXTENSION.

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SUMMARY

In order to restore an EMG-controlled key grip in spinal cord injured C5-C6 tetraplegics, a system using surface electrodes has been developed which measures the patient's voluntary EMG from the forearm muscles, and through proper signal processing applies an electrical stimulation to the same muscle. A filtering routine has been developed to extract the patient's voluntary EMG from the recorded signal, and the entire system has been implemented in a microprocessor controlled device.

STATE OF THE ART

Much work has been published using implanted electrodes for restoring functionality in SCI-patients, but the literature on using surface electrodes for restoring a hand grip is sparse. The work presented here is mainly based on /1/, /2/ and /3/.

The purpose of this study is to restore a useful hand grasp for C5-C6 tetraplegics with partly paralyzed forearm muscles. By stimulating the forearm wrist extensor muscles and making use of the so-called tenodesis effect it is possible to obtain a key grip which will be useful in daily living.

The key grip is obtained by stimulating *m. extensor carpi radialis (longus/brevis)* in the forearm. This is causing a wrist extension followed by a passive finger flexion and thumb adduction. A hand grasp is thus obtained by stimulating one muscle only. The grip can be strengthened by simultaneous stimulation of the finger flexor muscles and/or the thumb adductor muscles.

Since the wrist extensor muscles are innervated from the C5 to the C8 spinal nerves, a C5-C6 tetraplegic will have some voluntary control of the wrist extensor muscles, but not sufficient to achieve a normal function. It is possible to detect this weak activity and use it for controlling the stimulation of the same muscle. By using visual feedback the patient is able to control the position of the wrist by activating his/her extensor muscles. The system provides the patient with a more natural control of the established grip.

The system, using surface electrodes, has been implemented in a 2-channel microprocessor controlled device. The system has been tested on 3 tetraplegic patients.

MATERIAL AND METHODS

Functional Electrical Stimulator. The system is implemented as a 2-channel device consisting of 2 EMG-amplifiers with a shut-down facility, 2 constant-current stimulators and a digital signal processor, which takes care of the signal processing and the control of amplifiers and stimulators. In the following only one amplifier and one stimulator is considered as shown in fig.1.

When the patient wishes to establish a grip or alter an existing grip, he/she contracts or relaxes his/her wrist extensor muscles. The amplifier records the muscle activity at the recording electrodes, and feeds the signal to the digital signal processor. The signal processor first performs a filtering of the recorded signal in order to extract the patient's voluntary EMG. The extracted signal is then used to calculate an appropriate stimulation current and the stimulator is activated. The resulting muscle

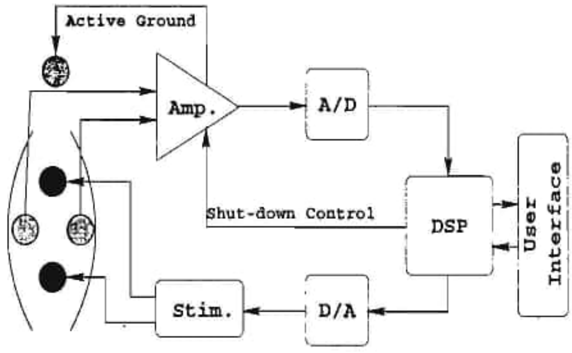

Figure 1: Schematic overview of the FES-system

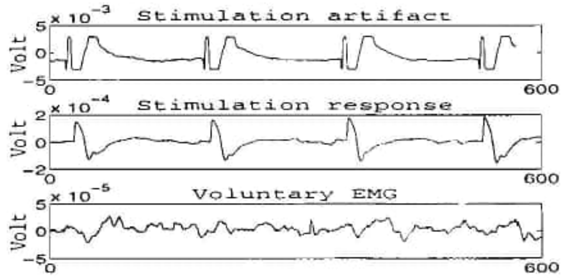

Figure 2: Decomposition of the signal measured at the recording electrodes. Top: Stimulation artifact. Middle: Stimulation response. Bottom: Voluntary EMG.

contraction is thus a result of the recorded EMG-activity in the same muscles as being stimulated.

When recording the EMG from a muscle, which is being simultaneously stimulated, the measured signal will consist of 3 components as shown in fig.2: 1) a stimulation artifact, which is due to the direct spill-over from the stimulation electrodes to the recording electrodes 2) a stimulation response, which arises from the synchronous activation of many muscle fibers due to the stimulation 3) the patient's voluntary EMG, which can be regarded as a bandpass filtered white noise signal. This signal contains the patient information regarding the desired hand movement. The filtering task is then to separate the voluntary EMG from the stimulation artifact and the stimulation response.

Suppression of stimulation artifact. The stimulation artifact (top of fig.2) is due to the direct spill-over from the stimulation electrodes to the recording electrodes. This artifact is usually much larger than the other components of the signal. If it was applied directly to the type of EMG-amplifier used here, the amplifier will, due to the large gain, saturate typically with a recovery time which is larger than the stimulation period. In order to maintain the large amplification of the voluntary EMG, the stimulation artifact must be suppressed before entering the amplifier. The EMG-amplifier is therefore equipped with a switch, which is controlled from the signal processor. During the stimulation pulse the amplifier is shut-down and opened again during recording. The result of the shut-down is shown in the middle of fig.2. The amplifier is here not saturated and therefore active in the entire recording period, and the signal now only consists of stimulation responses and the voluntary EMG.

Suppression of the stimulation response. The stimulation response is due to the simultaneous activation of many motor units; therefore the stimulation response is dependent on both the amplitude of the stimulation and of the electrode position relative to the muscle. The response will vary in both shape and amplitude during change in stimulation and during movement of the hand. The stimulation response is therefore a highly non-stationary signal, and in order to deal with the non-stationarity an adaptive filter solution is necessary. The stimulation response is suppressed effectively by an adaptive linear prediction filter as depicted in fig.3.

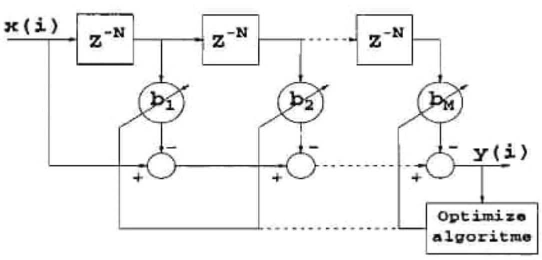

Figure 3: Adaptive linear prediction filter

The filtering idea is to divide the input signal into frames of N samples, where N is the ratio between the sampling frequency and the stimulation frequency. Each frame will then consist of exactly one stimulation response (cf. middle of fig. 2). The stimulation response in a given frame is predicted from a number M of previous stimulation responses and subtracted from the actual response. This leaves (after some scaling) a signal which has the same rms-value as the voluntary EMG. This procedure is carried out by means of a FIR filter as shown in fig.3. It is a classic adaptive filtering problem, and the optimal filter coefficients can uniquely be determined by solving the normal equations obtained by using the method of Least-Squares /4/:

$$\mathbf{\Phi}\mathrm{b} = \mathbf{\Theta} \Leftrightarrow \mathrm{b} = \mathbf{\Phi}^{-1}\mathbf{\Theta} \tag{1}$$

where $\mathbf{\Phi} = \begin{bmatrix} \phi(1,1) & \phi(1,2) & \cdots & \phi(1,M) \\ \phi(2,1) & \phi(2,2) & \cdots & \phi(2,M) \\ \vdots & \vdots & \ddots & \vdots \\ \phi(M,1) & \phi(M,2) & \cdots & \phi(M,M) \end{bmatrix}$

$$\begin{aligned} \mathbf{\Theta} &= [\phi(0,1), \phi(0,2), \cdots, \phi(0,M)]^T \\ \mathrm{b} &= [b_1, b_2, \cdots, b_M]^T \\ \phi(j,k) &= \sum_{i=1}^{N} x(i-Nj)x(i-Nk) \end{aligned}$$

The term $\phi(j,k)$ can be interpreted as the cross correlation between frame j and frame k except for a scaling factor. The normal equations are solved for each new frame arriving, and therefore the filter is always in its optimal stage, provided that the stimulation responses have the same shape in the observed blocks. If the shape of two consecutive stimulation responses are approximately the same, a filter with M=1 will often be sufficient.

RESULTS

An example of a filtering with M=1 of a sequence, where the stimulation amplitude is applied as a ramp is shown in fig.4.

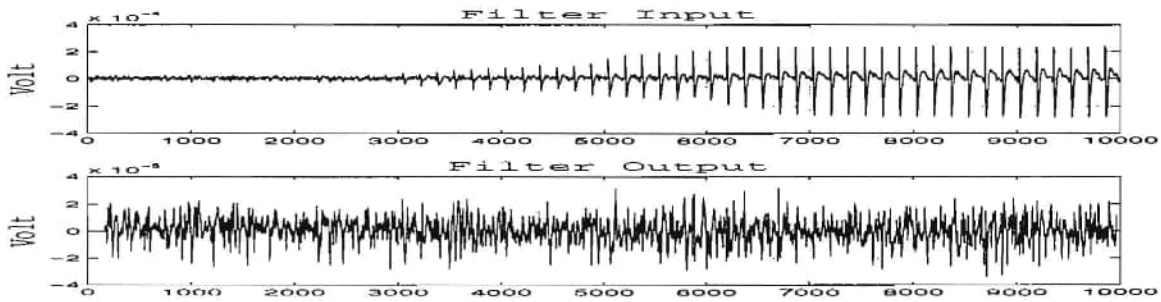

Figure 4: Filtering (M=1) of a sequence with increasing stimulation. Top: The input sequence consisting of voluntary EMG mixed with muscle responses. Bottom: Filtered sequence.

Fig.4 shows the filter performance during no stimulation (0-3000), increasing stimulation (3000-6000) and constant stimulation (6000-10000). Note that the stimulation responses are effectively eliminated, even during the sequence of non-constant stimulation. The effectiveness of the filter is dependent mainly on the difference in shape between the observed stimulation responses. The filter allows fast and large variations in the amplitude of the stimulation response, as long as the shape exhibits only slow variations compared to the observed time window.

Since the filter uses the information of M+1 frames to predict the output-signal a delay of M+1 frames is introduced. At 20 Hz stimulation the delay equals 100 ms for a system with M=1 and 150 ms for a system with M=2. The parameter M should be kept as low as possible to ensure a short reaction time for the total system.

With increasing M. the filter has more parameters to adjust when trying to fit the frames to the actual stimulation response. It is therefore capable of tolerating more variations in the shape of the stimulation responses and the over all performance improves.

ID	Age	Time of Injury	Injury	Muscle Str.
JBS	31	July 1994	Incompl. C5	1-2
HJ	40	May 1994	Compl. C5	1-2
KTN	39	1970	Incompl. C4	2

So far the entire systems has been tested on 3 tetraplegics. All 3 patients had unconditioned wrist extensor muscles, and all of them were able to control the stimulation to some degree. By altering their voluntary EMG, JBS and HJ were able to turn the stimulation on and off, but had difficulties graduating it. KTN could easily start and stop the stimulation, and could furthermore graduate the stimulation to at least four intermediate levels. In this case the stimulation was applied as a staircase function of the voluntary EMG. His maximum EMG was about 3-4 times the background noise (the EMG from the relaxed muscle and amplifier noise), and he could easily and reproducibly control the stimulation by altering his EMG to the following levels: 62%, 75%, 87% and 100% of his maximum EMG. Since his muscle was very weak, it was tired out relatively fast, and it has not yet been possible to test the system with a larger number of intermediate levels.

DISCUSSION

Some of the difficulties concerning extraction of the voluntary EMG from the mixture of artifacts arising, when doing simultaneously recording and stimulation at the same muscle, have been solved. The filter effectively eliminates the muscle responses and leaves a signal with the same rms-value as the patients voluntary EMG. This is true also during changes in stimulation amplitude and slow movements.

The 3 test individuals had all unconditioned forearm muscles, therefore the obtained maximum rms-value of the voluntary EMG is only 2-4 times the background noise. Still it was possible to use the EMG for turning the stimulation on and off for all 3 individuals, and one was even capable of adjusting the stimulation to several intermediate levels. The system performance might improve, when it operates on conditioned patients, who are capable of developing a larger EMG.

Two of the test individuals expressed that it was an unusual task to relax a muscle, when it is being stimulated at the same time, and they had to concentrate to relax it. This was especially difficult, when the muscle started to fatigue. Both individuals had the impression, that changing the activity in the muscle during EMG-controlled stimulation can be improved by training.

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MINIATURISATION TECHNIQUES FOR IMPLANTABLE ELECTRONICS

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SUMMARY

During the last fifteen years different implantable stimulation systems for FES were developed at our department. The field of application for these implants reaches from the first 8-channel phrenic pacemaker to a battery powered cardiomyoplastie implant. After finishing the electronics and the first tests of an implantable stimulator the miniaturisation process can be started. Important for a successful design is a close cooperation of the circuit design team and the case design team.
Three different miniaturisation methods are used: the SMT (surface mounted technology), the thick film technique and thin film technique. The choice between these methods dependents on the production cost and time and the desired degree of miniaturisation. SMT is the best method for prototyping of implant circuits because it is cheap and produces fast results. SMT combined with COB (chip on board) increase further the component density and leaves all advantages of SMT. Thin or thick film substrates in conjunction with customized chips are used for the final version of standard implants.

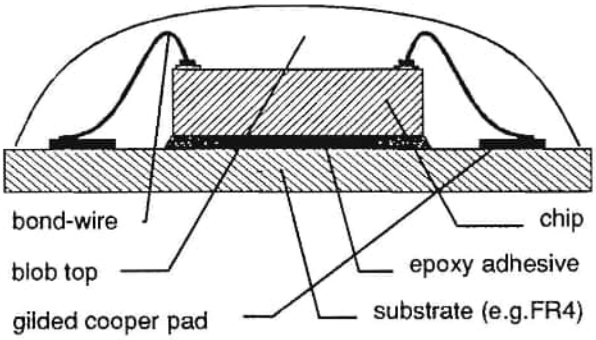
MATERIALS AND METHODS

An implantable stimulator consists of the miniaturised circuit, the hermedically sealed case, the electrodes and their connectors. An important demand for the electronic design is the reduction of used components and the simplification of the circuit. This keeps the required case volume and the amount of electrical connection low and the durability is increased.

SMT-Surface Mounted Technology:
The cheapest way to miniaturise electronic cercuits is the use of double side attachment in SMT, which is a standard production method. This technology provides fast results and is sufficient for simple implant circuits and prototypes The layout design can be done with standard CAD-systems. The equipment for the production as well as the SMT components are problemless available. These components need approximately the half or third of the area than standard components, except condensators. Condensators limits the reduction ratio for all miniaturisation methods. To reduce the attachment area of condensators they can be placed in upright position (Lit.1.).

COB-Chip on Board:
COB is a technology to connect uncased chips to an SMT board or a thick film substrate. This reduction technology is a new production method in combination with SMT circuits. First we use COB by our 20-channel thick film substrate (Lit.2.). Due to the complexity of the implant it was necessary to connect a customized CMOS chip to the hybrid. Second we used this method for the batterypowered cardiomyoplastie implant (Lit.3.). During the development of these implant three electric components with SO20 SMT case should be used. All this components together need an area of 0,6 in^2 ($387mm^2$), to much for the desired case. The use of caseless chips reduced the needed area to 0,17 in^2 ($109mm^2$) and solved this problem. The principle of COB (fig. 1) is to diebond a chip to an ceramic-substrate or an epoxy plate (FR4) using a thermally

conductive epoxy. After the cure time the chip is bonded with 1mil (25µm) thick gold-wires. To bond direct to a SMT-board (FR4) the cooper conductor must be metalised with 0.1-0.3mil (3-8µm) nickel and more than 0.04mil (1µm) gold (Lit.4.). After the bonding procedure the chip area is covered with an epoxy blob top to protect the sensitive part against mechanical and environmental shocks.



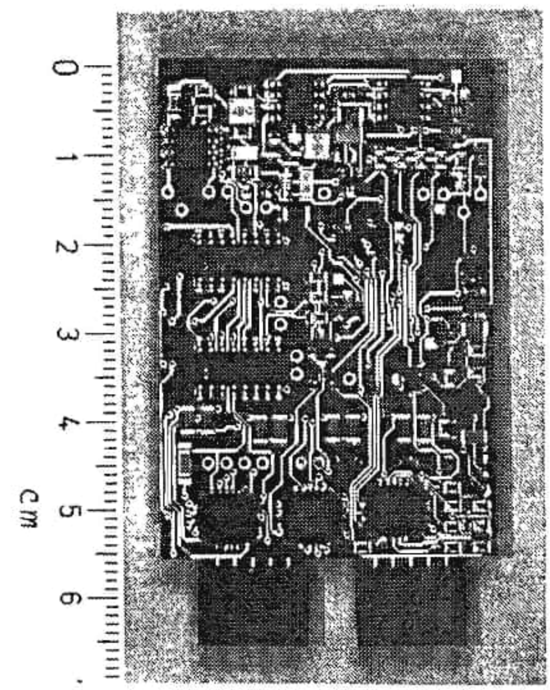
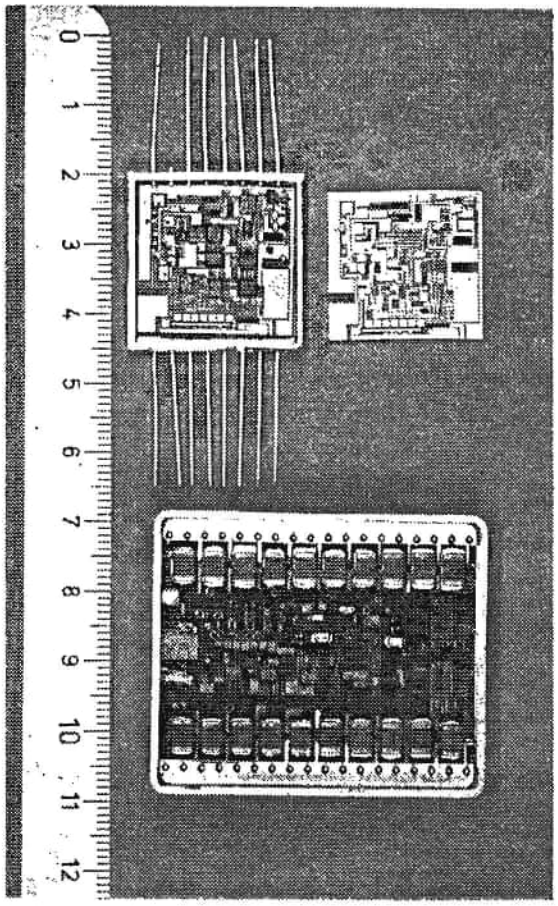


Fig.1.: left: principle structure of COB (chip on board)
right: SMT-prototype of the cardiomyoplaty implant with COB

Thick film substrates:
A mechanically robust and safety technology is realised with the thick film substrates. The substrates were made of ceramic plates. The layout of the conductors and resistors were silk-screen printed on the ceramic plates with different thick film pastes. Then the substrates were sintered in a furnace corresponding to a defined temprature profil. This temprature profil defines the temperatur coefficient of the resistors. The resistors were trimmed with a laser to their desired value. The on board resistors reduces the attachment costs and tolerances and is an advantage compared to SMT-boards. The thick film substrates have the similar reduction ratio as SMT-boards and can be realised in single or double side attachment. If COB will be used on a thick film layer it is necessary to make bondable gold pads with special pastes. Figure 2. shows our 20 channel stimulator in thick film technology and double side attachment.

Thin film substrates:
The highest reduction ratio (10-20 to standard components) apart from customized chips can be reached with thin film technology. The substrates are made of coated glass plates. The coating is built up of a resistance layer (0.004mil Ti+Pd(100nm)) and a bondable gold layer (0.06mil (1.5µm)). For the coating procedure a metal-mask will be provided. The thickness of the resistance layer and its geometric design defines the values of the resistors on the substrate. The layers can be drawn with a standard CAD program. Relative resistor tolerances are defined by the CAD system precision. All electronic components are uncased attached with adhesives. An electrical adhesive for the diebonding of capacitors, diodes and transistor and a nonelectrical adhesive for integrated circuits is used. After the diebond procedure the electrical connection are made with a thermosonic ball-wedge bonder using a gold wires. Every bond is mechanically and electrically tested according to MIL-STD-883 (e.g. bond pull test, Lit.5.). All

described steps are performed by hand. Therefore the production costs of thin film technology are very high. Additional the working tools and the necessary cleanroom are to expensive equipment to manufacture only a few number of pieces. Figure 2. shows our 8 and 20 channel stimulator in thin film technology.



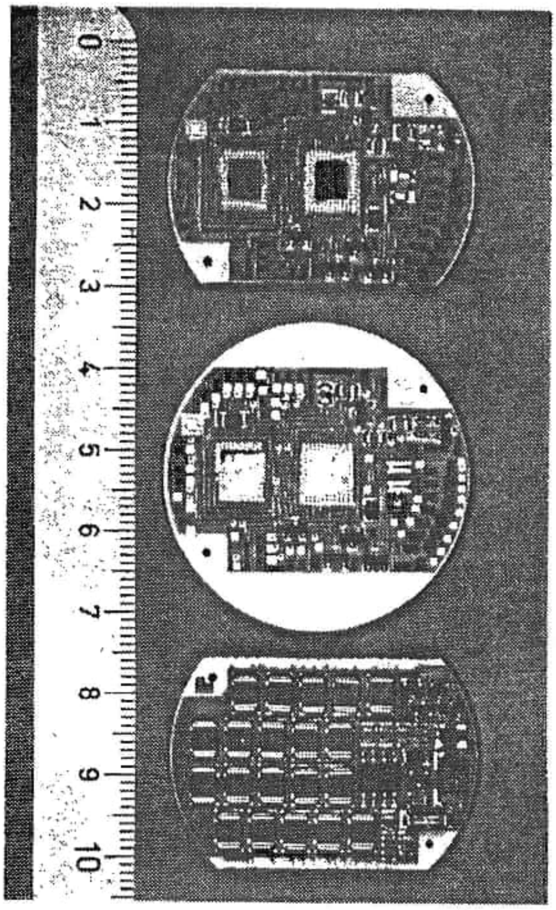


Fig.2.: left: 8 and 20 channel stimulator in thin film technology
right: 20 channel stimulator in thick film technology

RESULTS

	SMT	thick film	thin film
resistor size	R0805 3875mil^2 / 2.5mm^2	on board 3100mil^2 / 2mm^2	chip resistor 1600mil^2 / 1mm^2
capacitor size	same	same	same
chip size	NAND 4093 0.085in^2 / 53mm^2	NAND 4093 0.085in^2 / 53mm^2	chipform 0.004in^2 / 2.5mm^2
typ. wire with	10mil / 0.25mm	8mil / 0.2mm	2mil / 0.05mm
reduction ratio	2-3 to standard	3 to standard	10-20 to standard
attachment	double side	double side	single side
layout costs	ATS 1800.- / 2 layer	ATS 10000.- /10 layer	ATS 17000.-
substrate costs (100pcs)	ATS 23000.-	ATS 50000.-	ATS 45000.-
attachment time	1 day	3 days	10 days

Fig.3.: overview of the production costs

Figure 3 gives an overview of the production costs and the results of the described technologies. The thin film technology reduces the circuit area to 10% of a SMT-board. But also the costs for material and reproduction costs are raised to by a factor of ten. The middle curse is the use of thick film technology, which has distinct fewer reproduction costs. Additional thick film technology in combination with COB is a well proofed technique in comparison to SMT. The thick film substrates are not so fragile as compared to the thin film substrates. Therefore the ideal miniaturisation method is the thickfilm technology with or without COB, if the reduction factor is sufficient. But for the prototyping of these circuits the cheap and fast SMT technology with the possibility of the COB is an ideal addition for cicuit design.

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