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3rd VIENNA INTERNATIONAL WORKSHOP

ON

FUNCTIONAL ELECTROSTIMULATION

BASICS, TECHNOLOGY AND APPLICATION

BADEN / VIENNA (AUSTRIA), SEPTEMBER 17—20, 1989

PROCEEDINGS

DEPARTMENT OF BIOMEDICAL ENGINEERING
UNIVERSITY OF VIENNA

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POSTER PRESENTATION

EVALUATIVE AND REGULATIVE ASPECTS OF THE BIOCOMPATIBILITY OF ELECTRODE MATERIALS

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SUMMARY

The materials used for electrical stimulation of muscular or nerval tissue have to be, obviously, compatible to the surrounding tissues, so to fulfil their intended function. In contrast to other, more frequently implanted devices such as orthopaedic, surgical or dental implants, no specific regulations seem to exist for testing the safety and suitability of the various materials and material combinations when used as electrodes, conductors, stimulators, receivers, etc. There is, however, increasing attention to the analysis of retrieved implants also in this field of biomaterials application. Taking examples from recent publications and the author's own experiences, the modes of failure presently under discussion are compiled and discussed together with the state of the art modes of evaluating the biocompatibility and the safety of such devices.

FAILURE MECHANISMS OF STIMULATION ELECTRODES

Mechanical Failure

According to their nature, stimulation electrodes are usually small and delicate, sometimes with an increased surface area at the tip. The most significant influences of the body environment, into which the electrode is implanted, are the corrosive and degradative effects of the body fluids and constant (relative) motion. In addition, such delicate structures are prone to mechanical damage during handling, before, during and after implantation, or at implant retrieval.

Percutaneous stimulation of muscle imposes severe mechanical demands on both, electrodes and lead wires. It is general experience that electrodes made by coiling up length of fine stainless steel wire typically survive for only a few weeks before braking off (1). Some improvement was expected from using multistranded wire and plastic fillings, but fatigue failures are still a problem.

As an example, the retrieval analysis of epineural electrodes which failed after only 9 months of function, can be presented here (2). 5 of the 8 electrode leads of an 8-channel phrenic stimulator were found broken, and the SEM-analysis showed mainly mechanical failure of the 7 filament(50 um) stainless-steel leads (ETHICON 611P) with silicone filling and tubing, due to vibration and tension, the latter possibly also exerted during retrieval. The corrosive attack visible on some of the filaments could have taken place only after freeing of the broken ends from the silicone cover.

Dissolution and Corrosion

In this example, stainless steel was apparently chosen as electrode material because of its favourable mechanical properties, combined with adequate corrosion resistance and biocompatibility. It failed, however, mainly from mechanical fatigue, and not so much from corrosion, as expected (1,3). In vitro fatigue tests of the metallic wires alone and in combination with plastic fillings and/ or tubings, performed in simulated body fluids, can be regarded as a prerequisite to in vivo implantation testing. As it will be shown later, the mechanical properties and the behaviour in the aggressive body environment of both, the electrode metal and the insulating plastics forming the lead, mutually influence each other.
Electrode failure by dissolution (=corrosion) seems primarily a problem for nonnoble metals. There exist nonnoble metals with superior corrosion resistance (and equally good mechanical properties) such as titanium and tantalum, but the insulation by their corrosion-stable oxide film prevent faradaic charge transfer and thus limit their suitability as stimulation electrode materials (1). They can, however, form capacitor electrodes and are then even safer electrode materials as the noble metals gold and platinum (4). In order to achieve useful levels of charge injection with the former metals, high surface areas at the electrode tips (=porous electrodes) have been fabricated and successfully used e.g. in cardiac pacemaking. Factors such as roughening of the surface, bending stresses, and the electrical stimulation itself can dramatically increase the corrosive attack even in noble metals (1,4). Silver electrodes, for example, corroded during only 2 months of service as nerve stimulators and first the impedance increased and then the wires became brittle and broke (5). Also with platinum and its alloys, pitting corrosion can occur during electrical stimulation, but rarely to the extent of electrode failure. It could be though the reason for impedance changes, as discussed after in vitro experiments (4).

Tissue Encapsulation and Foreign Body Reactions

Encapsulation of electrodes with fibrous connective tissue has to be encountered after implantation into or onto central nervous tissue, near to peripheral nerves, or into muscular tissue. It seems evident that this encapsulation becomes thicker solely by electrical stimulation, and this effect is used for improving wound and bone healing. For the stimulation it has a negative effect, since increased ionic resistance of this capsule (or new bone formation around an auditory prosthesis) requires increased power to produce a given current. Also the current distribution can be altered, producing unpredictable effects around the electrode.

Naturally, the sole presence of the electrode material plays an important role for the tissue response, as does the type of tissue in the implant bed. While, for example, titanium and tantalum cause a decreasing, but persistent foreign body reaction in contact with soft tissues, bone tissue attaches directly to these highly reactive metals. On the other hand, corrosion of nonnoble metals and also of the noble metal silver will release metal ions into the surrounding tissue, which can be toxic and cause cell necrosis, thereby increasing and prolonging the foreign body response.

The same applies principally for the polymers in use for insulating and packaging electrodes and stimulators etc. The so-called "nonbiodegradable" polymers polytetrafluorethylene, silicone rubber, epoxy resin, poly-paraxylene or polyurethane are encapsulated by a thin layer of fibrous tissue (1), the lining with flat foreign body cells only detectable by light and transmission electron microscopy after appropriate fixation and plastic embedding. More severe foreign body reactions can usually be related to the leaching out of stabilizers and other nonpolymeric constituents which provoke the toxic, allergic or other undesirable reactions. An important factor for the tissue response to both, metallic and polymeric implants, are the surface conditions. Analysis of the surface layers of materials and of the interfacing layers of the surrounding tissues is in progress and will hopefully bring us new and better insight into the basic mechanisms of implant-tissue interactions. The effects of more obvious surface properties such as roughness (=microstructures) or porosity (=micro- to macrostructures, depending on pore size) are already better understood. It has been demonstrated that a roughened surface makes a given material more irritating than with a smooth, polished surface (5,6). On the other hand, cells and intercellular matrix can grow into such surface irregularities, providing a better stabilization of the implant and preventing the also deleterious effect of motion to the interface.

This latter aspect is particularly important for stimulation electrodes in muscular tissue. A comparison of so-called "traumatic" (screwed-in) and "nontraumatic" (passive ingrowth fixation) cardiac pacemaker electrodes (7) showed thicker fibrous encapsulation and increased tresholds for the "traumatic" type. The former type should prevent electrode dislocation and consecutive pacing failure, but the tissue damage due to the traumatic insertion of the corkscrew tip caused only a deleterious fibrotic scar tissue formation without better fixation.

Electrode fixation directly on peripheral nerves is also controversial, since the trauma of insertion and the exerted pressure shall damage the nerve fibres (1). Experiences with epineural electrodes seem to be quite good here in Vienna (2), and we will hear about morphological findings in experimental animals at this symposium. We could also evaluate some electrodes retrieved after years from human patients, and different dislocations of the electrode tips from the adjacent nerve bundle, to the epineurium of which the wire loops were initially sutured, could be observed. In addition, foreign body giant cells and round cell infiltrates were observed at the interfaces of both, the stainless steel wire and the silicone tubing, followed by fibrous tissue encapsulation. Only such long-term histomorphological observations and comparison to the clinical performance of the implant will provide us with data suitable for judging the safety of the system.

Insulation Failure through Polymer Degradation

Electrode failure can also be caused by failure of the insulating polymer, resulting in entry of body fluid, metal corrosion, and a low-impedance path between lead and indifferent electrode (3). With regard to metal corrosion, the only one paper presented at the Symposium on Retrieval & Analysis of Surgical Implants and Biomaterials in Snowbird,UT, 1988, about retrieved cardiac pacing leads (8) introduced an interesting aspect and up-to-date methods of evaluation. The polyurethane leads which were thought superior to silicone leads because they are thinner and easier to handle, showed often premature failure due to polymer degradation. This process was not only demonstrated morphologically by cracks in the insulation, visible in the scanning electron microscope (SEM), but also by chemical changes such as chain cleavage in the bulk polyurethane and at the surface, using Fourier-transform infrared spectroscopy and attenuated total reflectance techniques (FT-IR/ATR). Often the damaged areas coincided with stressed segments in the leads, finally leading to perforation of the insulation. The penetration of conductive body fluids to the electrode will lead to electrochemical effects with the production of oxidants which in turn will enhance polymer degradation. In vitro experiments confirmed this degradation mechanism of polyurethane.

Besides the already mentioned corrosive effect of such electrochemical reactions to the metallic electrode, they have surely effects upon the surrounding biological environment, causing all kinds of oxidation/reduction reactions (1).

CONCLUSIVE REMARKS

The biomaterial related problems with stimulation electrodes are obviously very complex. As it was stated recently in the regulations published by the International Standardisation Organisation (9), a biomaterial is a non-viable material intended to be in contact with living tissue to perform a function for medical purposes. A biomaterial should be biocompatible, but may be biodegradable. Biocompatibility is a state of desirable reaction of living tissues to non-viable materials. The biocompatibility of a given material may vary depending on its end-use application. Since it is accepted that no non-viable material is likely to be absolutely biocompatible, the clinical necessity requires and will continue to require the use of materials and devices which may not be fully biocompatible. A minimal test programme is recommended which will enable to establish a reasonable level of confidence concerning the biological response to materials and devices. Experienced and expert judgement is essential in determining the extent of testing required to establish the safety of a material for use in a particular implant.

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THE HARD WAY TO IMPLANTABLE MULTICHANNEL NERVE STIMULATORS

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SUMMARY

Functional electrostimulation (FES) requires chronic approach to to the biological system. Meanwhile opinions whether a stimulation system should use surface electrodes or totally implanted electrodes have settled on the fully implanted ones. Also demands for totally implantable stimulation systems can be defined clearly, there are only a few groups trying to solve the immense technological problems attached with implantable multichannel nerve stimulation units. An ultimate design for an 'ideal' stimulator cannot be offered by neither research group up to today! Nevertheless there are some remarkable promises, one of them is based on the 20-channel implant developed by the Vienna Group.

INTRODUCTION

After many years of efforts by several groups the feasibility of using electrical stimulation to provide functional movement of limbs of paraplegic or tetraplegic subjects has been proven. But there is still a great gap between some successful applications of FES in laboratory research and the broad acceptance in clinical practice. The reasons are manifold and are well described by criterias for practical FES systems which were established by Marsolais /1/. Without going in detail one demand among a lot of others refers to a totally implantable permanent system which should fulfill the following features:

* Easy to use with a simple interactive, responsive control system, incorporating non-visual feedback,
* stimulator and all electrodes surgically implanted,
* radio frequency controlled from an external unit,
* a belt which contains an antennae for sending signals to the implanted devices and for receiving signals from feedback transducers located elsewhere on the body,
* batteries small enough to be fixed to the belt,
* a number of channels between 32 and 48.

Additionally reliability and durability of the system must be comparable to the standard which has been reached with the heart pacemaker.

AN ABSTRACT OF SOLUTIONS FOR IMPLANTABLE MULTICHANNEL STIMULATORS

Without any claim of completeness the following survey gives an impression what is (or was) done in the field implantable multichannel stimulation units (restricted to implants for FES of limbs).

In 1981 an 8-channel system was presented by Hildebrandt et al /2/ which had used a gate array electronic circuit in an all ceramic hermetically sealed housing with inserted titanium stimulator electrodes. Although technology used was very high and laboratory results were

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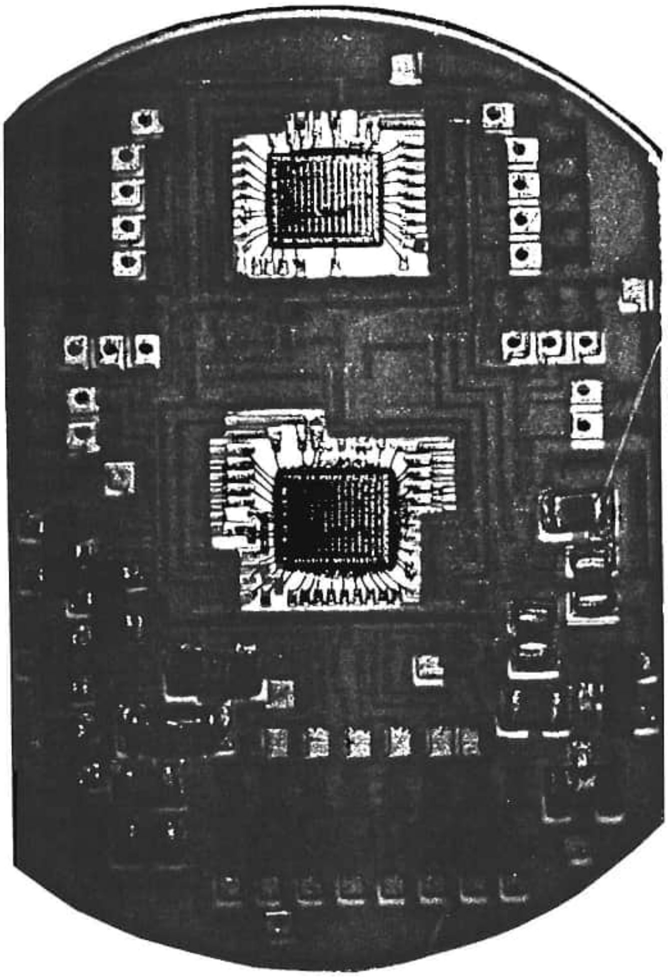
* constant current, DC-decoupled outputs, mono-phasic or bi-phasic impulses,
* stimulation current adjustable 0 - 8 mA, solution 8 bit (256 steps),
* max. stimulation voltage > 12 volts,
* impulse duration 10 - 1000 microseconds (4 usec step),
* impulse frequency up to 80 Hz,
* each output can be floating (inactive), positive or negative.
* Size of circuit is round with a diameter of 28 mm. All electronic parts are contained on the thickfilm substrate which is assembled on both sides. Most area is used for the 20 decoupling capacitors with low leakage current and high capacity (2.2 uF).
* Power supply as well as adjustment of all parameters is done via an RF-link (20 Mhz approx.) using a pulse modulation technique. Power transmitted can be controlled using a feed back RF-signal indicating amplitude of power supply voltage in the implant.

The hybrid circuit module as well as the custom designed IC was developed in our own laboratory and is now produced by the Austrian company KAPSCH in low quantities for own further applications (Fig.1).



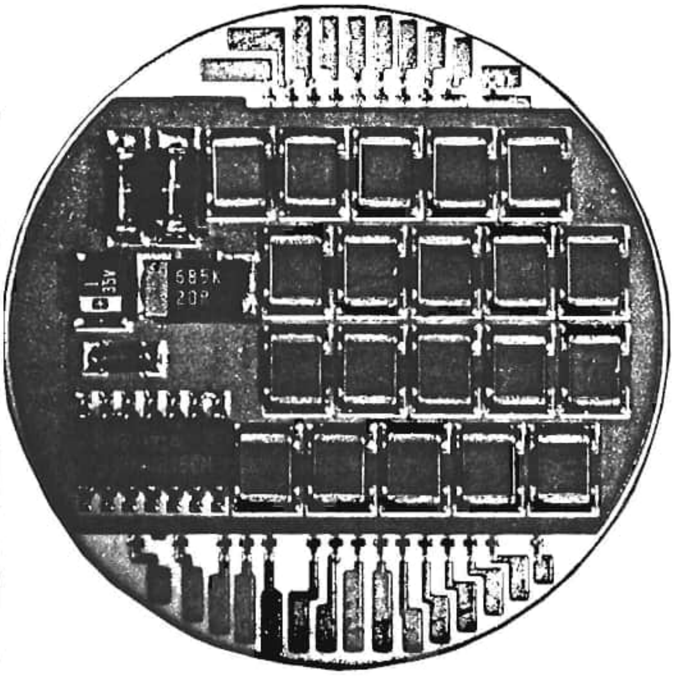


Fig.1:
Both sides of the hybrid circuit of the 20-channel stimulator.

First prototypes of the housing for the electronic circuit are now ready for testing too. The round housing is produced of niobium with glass-feed-throughs offering best bio-compatibility and resistance to corrosion.
Programming and controlling of such sophisticated implants demand special computerized tools for rationalized handling even for technically non-trained physicians. The solution developed consists of a portable device (12 x 4 x 6 cm) which can program and supply two implants via

encouraging the development program was stopped and the research group was broken up.
The Rancho Rehabilitation Engineering Center (Meadows et al /3/) developed an implantable stimulation system to generate charge balanced biphasic pulses from 0-2.25 mA in sixteen steps. Pulse width is controllable from 30-300 usec in 0.17 usec steps. The implantable stimulator utilizes a three chip set of integrated circuits developed at Stanford University Integrated Circuits Laboratory. The electronic parts are enclosed inside a titanium, hermetically sealed can, with eight tantalum feedthroughs for electrodes and three feedthroughs for antenna connections. Information and power is received by a modulated 20 MHz transmitter. The implant package is approximately 1.75 inches in diameter and 0.375 inches thick.
At Veterans Administration Medical and Regional Office Center, Togus, USA, Davis at al /4/ have modified the Nucleus multichannel implantable hearing prosthesis (Nucleus Ltd., Sydney, Australia) into a 22-channel neural stimulator. It delivers biphasic current pulses adjustable in 3 percent steps from 25 uA to 2.3 mA. Pulse width is adjustable in 0.4 usec steps from 20 usec to 0.4 msec for each phase.
Smith, Peckham et al /5/ are using an 8-channel stimulation unit produced in thickfilm technology and using a gate array. The outputs generate negative discharge impulses from output capacitors, with impulse widths from 0-255 usec. The electronic circuit is housed in a titanium capsule. Size of the whole implant is 25 mm by 50 mm approx.
A further proposal was presented by Donaldson /6/. He developed a 24-output stimulator with 70 mm in diameter.

OWN DEVELOPMENTS OF MULTICHANNEL STIMULATION UNITS

The first design of an 8-channel implant was already presented in 1978 /7/, which was improved using thinfilm technology and discrete electronic circuit design. These implants were implanted in human for mobilization after paraplegia four times /8/ and are still used as "lung pacemaker" to stimulate the phrenic nerve in cases of high lesion of the cord /9/.
The implant is designed to be used for round-about stimulation (carousel-stimulation) and stimulates two nerves via 4 electrodes each.
Meanwhile two succeeding developments of implants are ready to be used. One is a redesign of the 8-channel implants, the other is a new 20-channel implant which is assigned for future applications in paraplegic subjects.
Because of the complexity of electronic design of the implant a gate array integrated circuit was developed to simplify reproduction of the implants. Number of discrete electronic parts for the implant was decreased immensely so that thickfilm instead of thinfilm techniques can be used which decreases reproduction costs. The gate array allows implants to be configured either as stand-alone stimulation units but also chained together with up to 80 outputs. Each gate array chip (complexity 840 N- and P-channel array transistors) has 10 outputs which are grouped in twice 5 outputs. Each group is dedicated to stimulate one nerve according to the principle of the round-about electrode /7/.
Because the chip is produced in CMOS-technology supply voltage can be 3-18 volts, while supply current is negligible. The chip consists of all stages to encode serially transmitted information which is modulated on a high-frequency carrier for energy supply of the implant. According to the operating mode of the chip information is transmitted using an impulse train with up to 24 bits. The interval between two successive blankings of the RF-carrier determines the logical state of bit (> 50 usec. = HIGH, < 15 usec. = LOW).
In detail the technical features of the new 20-channel are:

* 20 channel output, i.e. 4 groups with 5 outputs each,

two transmitting coils. Thus the system consisting of two 20-channel implants and one extracorporal supply unit represents a 40-channel system, capable to stimulate 8 nerves.
The supply unit which can be attached to a belt and worn by the patient consists of a CMOS microcomputer (80C51) with 32kB EPROM, 32 kByte RAM, an 8-channel ADC, a watchdog, a real-time clock, an acoustic signal, an 8-character display and a RS232 link to communicate with a PC either directly or via a modem. The RAM holds all parameters and stimulation patterns. Battery capacity contained in the portable device allows continuous stimulation for 2 - 4 hours. Using the PC stimulation patterns necessary for different phases of a movement can be programmed interactively (Fig. 2).

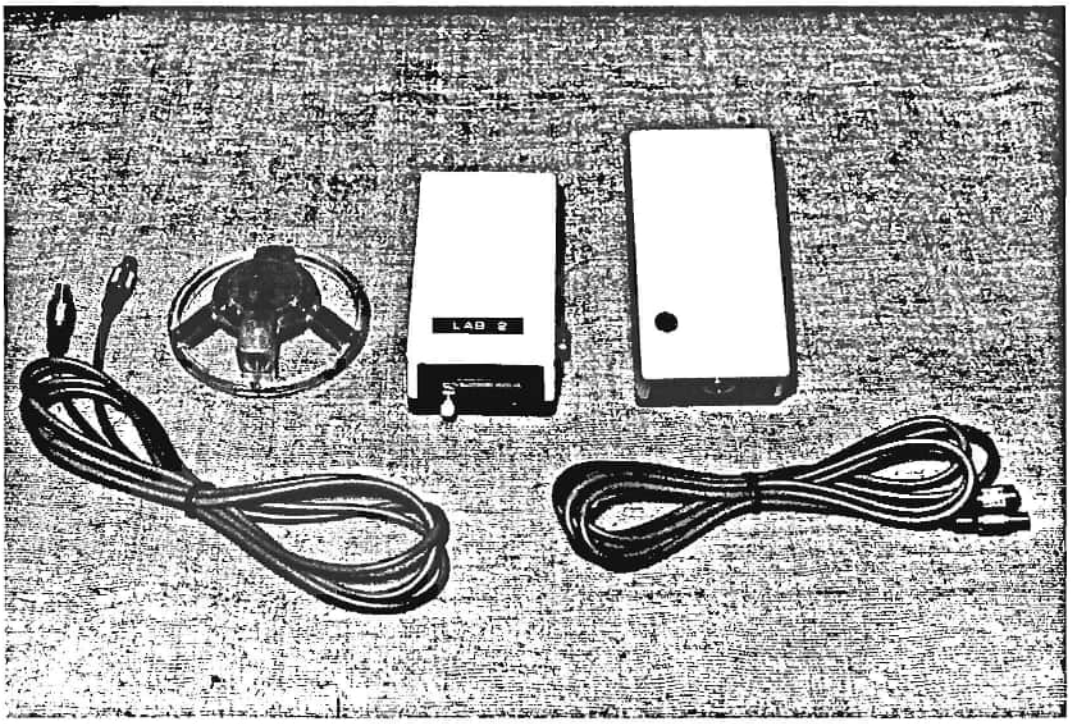


Fig.2: Supply unit for two 20-channel implants (LAB 2), transmission coil, charging unit.

DISCUSSION

The short summary of multichannel implants shows that there some steps taken in the right direction. But a final product is not available by neither group. Beside this further problems, not mentioned in this paper, like shape and material of electrodes, electrode connection, controlling algorithms, closed loop feedback, motion sensors and so on are still in discussion and development. It is still a hard way to implantable multichannel nerve stimulators!

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DIMINISHING SPASTICITY BY PERIPHERAL ELECTRICAL STIMULATION CLINICAL APPROACH AND THEORETICAL CONSIDERATIONS

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INTRODUCTION

Functional Electrical Stimulation (FES) has been developing for the past 30 years. The goal is restoration of movements for paralyzed handicapped patients. The road leading to it may be divided into two parts. Firstly the patient has to be brought into a ready state for applying FES and secondly the FES itself has to be installed. The first part includes the well developed clinical procedures of rehabilitation. Assuming there are no complications one may start with the reconditioning of the paralyzed muscles and pass over to FES. Often the patient will not be in such a state at the beginning of therapy, especially if the paralysis has existed for some time. Then malfunctions as decubitus, contractures or spasticity have developed, the later two perhaps in conjunction, which may prevent the application of FES. In those cases one therefore has at first to cure or at least to ease these malfunctions.
Spasticity is a symptom accompanying a number of different diseases resulting in paralysis. If the paralysis is of a larger systemic extent a moderate level of extensor spasticity is often useful to the handicapped as it contributes to the stabilization of body position and allows him upright standing. However, a patient developing severe spasticity is restricted in many respects, possibly inclusive for using his residual functions.
When applying FES in a clinical environment one is often faced with these problems and therefore in many cases has to extend the therapeutical approach to 3 sections:

1. therapy of malfunctions
2. restrengthening of the atrophied muscles
3. FES

The intention of antispastic stimulation is different from that of FES. In FES the motor nerves are stimulated in order to generate muscle contractions whereas in the case of antispastic stimulation one tries to alter the spastic activity pattern of the spinal motorneurons by directly modulating the sensory input to the spinal cord and/or indirectly via the stimulated muscle activity.
Since the early sixties FES has been investigated systematically with the aim to restore basic functional performances of paralyzed patients /13,18/. The application of FES,

however, was restricted, or even prevented in many cases through an exaggerated reflex activity of the paralyzed muscles resulting in poor control of the stimulated muscle contraction.

Experiences in the stimulation of the drop foot syndrome revealed the possibility of reducing muscle spasticity and improving joint mobility /7,16/. To quantify the effect of anti-spastic therapy various methods have been used, e.g. EMG activity and the 'pendulum drop test' developed in Ljubljana /2/. The frequencies applied to relieve spasticity mediated by stimulated muscle activity were in the range of 20 - 50 Hz and about 100 Hz in the case of direct stimulation of the afferent nerves.

The results obtained in the stimulation of different types of spasticity had been doubtful to positive /1,6,7,11,12/. The same applied to the so called carry over effect, i.e. an effect persisting for hours, or even for days after cessation of stimulation.

Only in moderate cases of spasticity stimulation parameters commonly used in FES are effective (Bajd, personal communication). However, the severe cases of spasticity resistent to nearly all common therapy are of a more clinical significance.

This paper deals with the feasibility of reducing spasticity by electrical stimulation.

Our institute has been working in the field of FES for approximately 13 years and incidentaly found in a few cases a reduction in spasticity sometimes associated with a change in spasticity pattern. Because we had been successful in some cases of severe spasticity with the application of a specific intermittent stimulation of the antagonists at 20 Hz, we started a systematic survey study of the possibilities to diminish spasticity by electrical stimulation.

METHODS

The factors causing spastic patterns and probable changes in the neural organisation of the spinal cord and upper sensomotoric centres are still unknown. The spastic patterns are similar to those of polisynaptic reflexes arising, enhancing and persisting after loss of upper motor control.

A review of results obtained in animal and human experiments showed that there are spastic related pathways in the interneuron pool of the spinal cord, or in the case of incomplete paralysis or lesions of the CNS, this pool, besides other neural structures, at least is involved in the process /4,5/. Direct evidence for spasticity related structural changes concerning synaptic contacts or axonal sprouting was missing.

Assuming that spasticity is basically caused by functional changes in the organisation of the spinal cord, then the observed relief in spasticity and the carry over effect are probably related to a modified programme of the neural network. In this case specific stimulation pattern applied via afferent nerves should be more effective.

This concept was systematically examined.

Testing procedure

For patients with varying grades and different etiology of spasticity parameters had been evaluated which turned out to be effective in reducing or enhancing spasticity. The efficacy was assessed by the intensity and duration of spasticity after stimulation , its threshold for response, its intensity in resting position and by changes of joint mobility. The following parameters were modified:

- frequency: 0.5 - 40 Hz, current constant, rectangular pulses
- pulse width
- stimulus intensity
- stimulation site: agonist, antagonist of the spastic muscle groups as well as their synergetic muscles;
  the corresponding cutaneous areas (dermatoms) or their functionally related areas, respectively
- combinations of stimulation sites
- duration of application per session
- stimulation pattern: continuous / intermittent with various stimulation frequencies
- repetition of sessions per day, possibly with regard to a carry over effect

An important precondition is to position the patient correctly that all spasticity eliciting stimuli are avoided.
At first the direct and the nearby antagonists of the spastic muscle groups are stimulated, if possible on both sides of the body. For each of the selected stimulation sites stimulation frequency and amplitude are varied individually and in combination until a spastic movement has started in order to separate the range of reducing from the range of increasing spasticity.
According to the results of these tests the determined stimulation parameter frequency and amplitude, if possible with a sufficient distance to the limiting values, are used to ascertain the best position for the electrodes, are tested in continuous stimulation and are observed in different combinations of the stimulation site.
Every 10 minutes it is checked whether a spastic movement can be triggered. In the case of an improvement stimulation is continued until no further improvement can be obtained in the 10 minute period.
It is important to observe especially adverse effects of the stimulation. If such effects occur the stimulation parameters and areas are changed.
In case of fatigue of the untrained muscles the stimulation has to be interrupted for an adequate resting period. A stimulation leading to exhaustion of the muscle should definitely be avoided.
The testing procedure is repeated with varying electrode combinations until a satisfying

result is obtained or the procedure is terminated if any improvement is missing. In the latter case, provided spasticity is not intensified, the procedure may be repeated for a number of days as sometimes positive effects may occur.
In case of instantaneous relief the duration of the carry over effect is evaluated and the stimulation continued.
As a next step it is investigated whether an intermittent stimulation pattern of 5-10 sec on/off cycles with a slow linear rise and decay of the stimulus is more effective than continuous stimulation.
Finally it is checked whether several stimulation sessions per day give a better effect than only one.
Obviously there aren't any universal rules for the selection of the above listed stimulation parameters. But from our observations and from the experiences of other groups the following instructions for counteracting spasticity by electrical stimulation may be extracted:
- in many cases the stimulation of cutaneous areas associated to antagonistic muscles is successful, sometimes the direct stimulation of the spastic muscles turns out to be more effective, e.g. in the case of extensor spasticity of the thigh the stimulation of the m. quadriceps possibly in combination with stimulation of the glutei muscles may be effective whereas the stimulation of the antagonists (ischiocrural muscles) fails.
- extreme low frequencies may be inefficient compared to those of about 2 Hz; higher frequencies tend to elicit spasticity
- stimulation sessions of long duration seem to be less effective than short ones
- the spasticity reducing effect of electrostimulation may be highly dependent on the number of stimulation sessions per day, e.g. in one of our patients, a severe spasticity eliciting effect of stimulation was observed when repeatedly applied after cessation of the carry over effect (ca. 3 hours), whereas a single session per day was successful. In another case of severe spasticity of the flexor and adductor muscles of the hip a stimulation programme of 30 minutes, repeated every 2 hours during night, was so effective that daytime stimulation could be reduced to a single session.

Application of antispastic stimulation - phase I

After the evaluation of the individual stimulation procedure has been successfully completed, it must then be discussed with the patient how he can integrate this into his daily living routine.
To manage the stimulation independently the patient has to become fully acquainted with the procedure which may take up to one or two weeks in more complicated cases.
The progress in treatment should be followed up by regular ambulatory inspection, which should include checking of the patient's correct handling of the stimulation system.
Following the inspection and testing of the effectiveness of the hitherto used stimulation

programme and of variations to its parameters, the programme may then be modified.
We have so far dealt with phase I of antispastic stimulation in which an improvement of spasticity is probably obtained with low frequencies of 0.5 to 6 Hz. As those frequencies are not effective in strengthening atrophied muscles, a reconditioning programme -phase II- has to follow if functional use of the muscles by FES is intended.

Application of antispastic stimulation - phase II

The main goal of phase II is to evaluate a stimulation programme capable of restrengthening the muscles needed for functional use by carefully increasing stimulus amplitude and frequency without impairment of its spasticity reducing effect.
This special kind of approach in antispastic therapy is founded on the following considerations:
Assuming the validity of the hypothesis that spasticity is mainly caused by the development of wrong pathways in the spinal cord, than it would be reasonable to remove these pathways if ever possible, thus 'fixating' the therapeutic effect of stimulation.
The integration of the spastic muscles in a stimulated movement pattern while applying FES may promote this process. In a case of spasticity in a tetraplegic, for example, it was observed that the spasticity pattern of the finger extensors gradually changed into the movement pattern of the stimulated grip.
Thus, the second goal of antispastic stimulation, i.e. the fixation of the antispastic effect by gradually increasing stimulation amplitude and frequency may simultaneously be part of an FES preceding reconditioning period and vice versa.
The changes in spasticity pattern may occasionally transform into just their opposite. We observed, for instance, a severe spasticity of the adductor muscles of the hip changing to a moderate tonic abductor spasticity which was easy to control by electrical stimulation.
Obviously, the functional structure of the interneural network of the spinal cord can be modified by electrical stimulation, probably because of inhibiting and facilitating effects.
How much time the described 'reprogramming' by electrical stimulation will take can't be said exactly; it may require several weeks or even more.
The application of antispastic stimulation of phase II also requires periodical routine check-ups in order to:

- modify the stimulation programme in accordance with the improvements obtained
- determine the time of proceeding to functional stimulation if intended
- prevent potentially unfavourable future developments.

DISCUSSION

Taking into account the results of other groups working in the field of FES it has to be realized that in most cases spasticity is influenced positively by electrical stimulation. Actually we cannot predict which specific treatment will be successful for the different types of spasticity. This may be due to lack of method in application. A wrongly chosen stimulation frequency could e.g. be the cause of a great number of failures.
In the case of 40 patients with severe spasticity, who were stimulated for FES by a frequency of 20 Hz from the beginning, half of the group showed no effect with respect to spasticity, while spasticity of the other half of the group diminished considerably at different stages partly only after a long time of stimulation.
However, the reducing of spasticity was occasional. If the spasticity was not influenced it could have been due to an insufficient frequency or an amplitude which was too high.
Hufschmidt /9,10/ seems to have the richest clinical experience, and he reports good success in stimulating spasticity in all types of deseases except spinal cord injuries. Unfortunately it is difficult to gather exact information from his publications about the number of cases successfully treated, the amount of reduction of spasticity achieved and the continuation of the success after suspending stimulation. Moreover, Hufschmidt as far as we are informed, did not proceed to higher frequencies to achieve functional use of the muscles.
In the cases of 24 patients with spasticity of different etiologies and primarily treated with antispastic stimulation, we recognized a diminishing of spasticity, but in different grades. The short duration of treatment and the inhomogenity of our small group of patients does not allow reliable conclusions.
As far as the etiology of spasticity and the influence of stimulation on it is concerned there are, up to now, no reliable models.
The following hypothesis are under discussion:

1. servo control hypothesis with modification of gain characteristic
   - Renshaw inhibition
   - reciprocal inhibition
   - praesynaptic inhibition
2. nerve sprouting hypothesis
3. disturbed balance of descending motor systems
4. stretch activation of muscle

If one distinguishes between tonic and phasic spasticity /17/ the tonic one would be due to a shift of the operating point of the servo loop and the phasic one to an alteration of its gain characteristic.
A change of the operating point of the servo loop has to be executed at the spinal cord level by reorganisation of the interneural pool. Until now the spinal reprogramming has

been carried out with rather simple periodic stimulation patterns which are especially effective at low frequencies, whereas frequencies above 10 Hz tend to elicit spasticity.
This suggests that their spasticity reducing ability is based on rather simple facilitating effects.
As a working hypothesis it is proposed that within the spinal cord preferential circuits along reflex pathways are established if motor control and coordinating functions of the upper motor centres have been lost. These circuits tend to stabilize themselves on the basis of self-organizing effects of the interneural cell pool as described with synergetic model by Haken /8/.
Afferent pulse patterns as induced by the periodic stimulation sequences seem to disturb the newly established neural organisation and to inhibit it. The carry over effect may be found on the same mechanism.
The primary functional reorganisation which causes spasticity leads eventually to a secondary synaptic fixation underlying the functional organisation. This is suggested by the persistance of a latent readiness for spasticity which may exist over a long period without any symptoms.
If such a mechanism exists the functional reprogramming of the contraction pattern is the best way to cure spasticity permanently.
However, the question arises if a sophisticated stimulation pattern - an 'intelligent afference' - could induce more effectively the desired reorganisation of the interneural network or even cause a distinct stimulus of the activation of certain functional structures. For the time being this is highly hypothetical.
There is possibly an indication of a potency of programming of rather simple movement patterns in the spinal cord. It was demonstrated that spinal cats despite their transsected spinal cord learned to perform coordinated movements like walking on a belt /14/, and with Vojta therapy it is possible to cause movements in completely paralyzed persons by pressing on defined cutaneous areas /19/.
However, it remains doubtful whether the spinal cord got the potency for organizing more complex control systems which could be reached through specific inputs. Looking at the cybernetic organisation of the senso-motoric system it seems more likely that in humans these functions are located in the upper CNS /20/.
Structural changes in the paralyzed muscles may also have an influence on spasticity as reported by Mayer and Young /15/ and Dietz et al. /3/. Our investigations suggest, however, that the histochemical changes in the muscle cells are a secondary effect of spasticity while primary the reorganisation of the interneuron pool and the formation of the specific reflex pattern are decisive for the occurence of spasticity.
Additional consequences of the described process are alterations of the gain characteristic and shifts of the operating point of the servo loop control system. However, this model cannot explain the different types of spasticity and their preferences seen by the clinician.
In practice we posses at present only a vague idea how to influence the mechanisms of

spasticity. However, it becomes more and more evident that there exist possibilities to reduce spasticity so that at least, if no other treatment was successful, electrical stimulation should be tried.

As in every heuristic procedure a considerable part of the success is founded on the comprehensive collection of clinical experience demanding accurate observation, systematic proceeding and intuition.

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The present state of patients who have had sacral anterior root stimulators for between 5 and 11 years

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Implantation of a sacral anterior root stimulator, usually with simultaneous sacral posterior rhizotomy, is a means of achieving low-pressure micturition with little residual urine, curing reflex urinary incontinence, and improving bladder compliance in patients with spinal cord injury or spinal cord disease. The stimulator often also improves defaecation and allows implant-driven penile erection.

The first sacral anterior root stimulator was implanted in 1976, but was unsuccessful. Two were implanted in 1978, and both of these are still in use. Four more followed in 1979, two in 1980, two in 1981, 9 in 1982, 17 in 1983, 21 in 1984, and more in each subsequent year than in the year before. The first 50 patients, of whom all but 2 have spinal cord injuries, were reviewed in 1985 (J. Neurol. Neurosurg. Psychiatr., 49, 1104, 1986). Two died, in 1982 and 1988. Findings at necropsy will be reported. In July 1989 questionnaires were sent to the remaining 48, and findings at clinical examination and the results of intravenous urography and culture of urine specimens were assembled. All these will be reported.

FES IS PREVENTING THE DEVELOPMENT OF SECONDARY PATHOLOGIES IN JOINTS x)

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SUMMARY

The biomechanical principles of long bones bending stressing and joint compressive stressing are utilized for developing of a hypothesis which is used as a guide for proving that if long bones are stressed as in normals also the joints are not critically loaded. Consequently an analysis is made for long bones bending loading in spinal cord injured patients and compared to normals. Because of nearly identical bending stressing profiles the conclusion is made that grossly the joints in SCI patients which utilize FES are not overstressed and it is very unlikely that secondary pathology in joints may develop. Subjective experience in a group of about 100 patients utilizing FES for standing and reciprocal walking from one to ten years is supporting the presented hypothesis and presented conclusions.

INTRODUCTION

Functional electrical stimulation FES has been in utilization for 20 years while for spinal cord injured SCI patients FES has been about 10 years in use /1,2,3/. In SCI patients FES is enabling standing and simple patterns of walking. With the enhancement of FES systems the functions are improving and also the extent of daily use. Improved functionning results also in greater load and dynamic stressing of long bones and joints. The later is increasing the possibilities for secondary pathology development in joints. At the present state of FES development the composition of stimulation control sequences is subjective and does not take into account the joint mechanics and principles for preventing pathological developments. The developments in the FES field did not bring formal and theoretical means for stimulation control sequences synthesis /4/. Also no means were developed for the prevention of pathological developments. There are no formalized clinical experiences but subjectively we are aware that inadequate FES indications and FES prescriptions can enhance pathological developments. Owing to the complexity and rather complicated not yet completely understood mechanisms of joint pathology developments /8/ it is too ambicious and impossible to compose an universal discussion of problems related to joint pathology development. The problems are even more difficult if we take into account the primary pathologies in a SCI patient /9/. Therefore we will limit our discussion to biomechanical factors which are related to joint pathology development. According to /5/ it is evident that muscles activate and stabilize the joints while in the same time provide also stress reduction for long bones. Muscular action is selected in such a way that proper joint loading is ensured. From this aspect we are going to discuss the prevention of secondary pathology developments in joints.

Excessive stressing and secondary pathology development in joints

Improper and excessive loading of the ligamentous structures of a joint and overstressing of the cartilage covered load bearing surfaces of joints is according to the extent of superseding the limiting values and duration increasingly facilitating the pathogene factors which very soon provoke pathonomic signs and simptoms of changes in joints. The later may develop in short time pathological structural and functional changes in

x) Supported by RSS, Ljubljana, Yugoslavia, and NIDRR, Washington, USA.

the joints. Quantitative limits and other influencing parameters with their quantitative data are not known yet for SCI patients joints. What we know are the fundamentals of joint mechanical principles which must be obeyed also in FES. By doing so we are to an extent limiting the loading to be within the values of normal man functionning. Excessive bone loading goes along with improper joint stressing. The said can be recognized from Figure 1. Here in different phases of standing-up or sitting down (roughly reversed sequence) the gravitational bone bending torques are presented. Bone and joint structures are built primarily to withstand large compressive stressing while bending stressing of long bones and shear force stressing of joints can be dangerous. Following the theory of muscle action /5/ for providing efficient reduction of bending stressing logically as a consequence the compressive stressing in joints is drastically increased. According to the definition of compressive stressing being the pressure between the joint surfaces the following equation applies $p = F/S$, where p is compressive stressing in N/cm^2, F force in N and S surface in m^2. Observing Fig. 2a, where

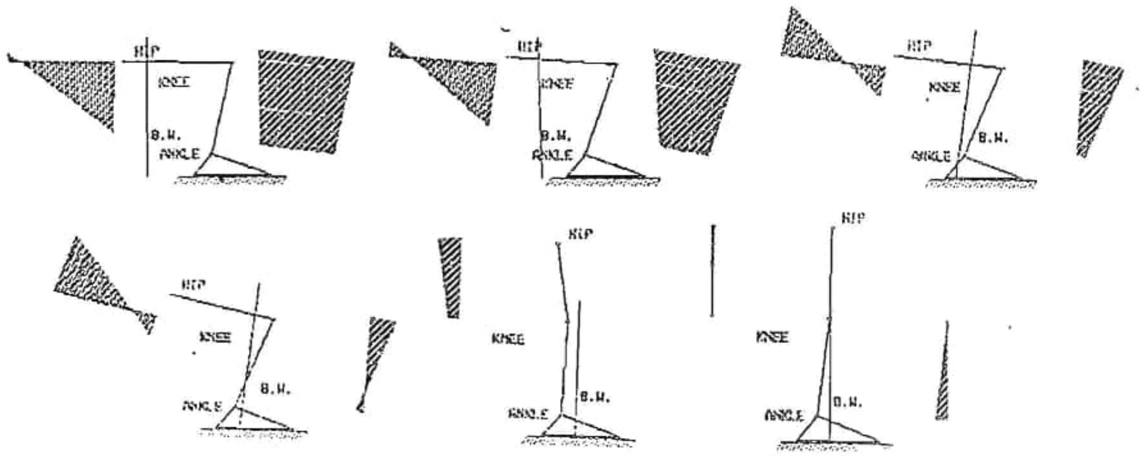

Fig. 1

the joint is presented flexed to a limiting angle, the contacting surfaces are reduced and consequently to it and to R high stressing is the result. If R may be converted to R' this may not be the case. According to the equation for p and the given force F=R the stressing of joint cartilage layers on the edge of joint (Fig. 2a).

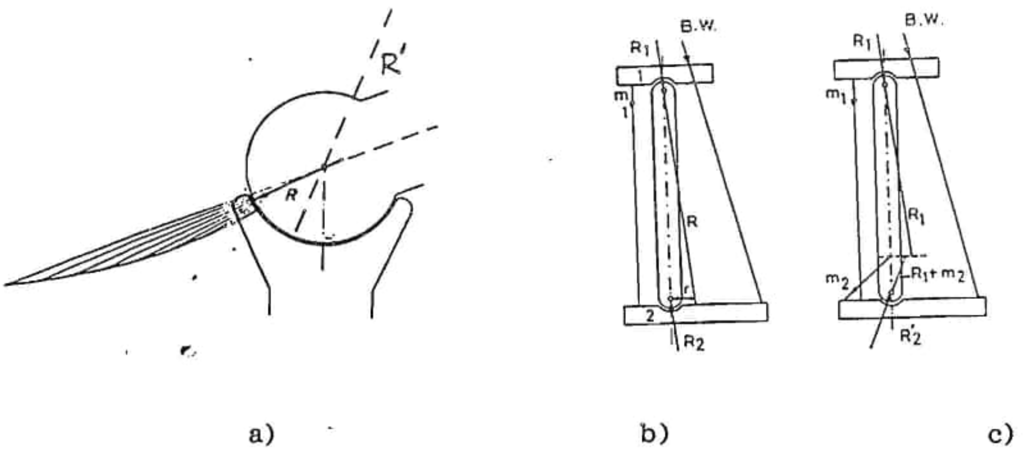

Fig. 2

Therefore in normals the muscular action is adjusted in such a manner that the resultant force is never passing too close to the boarder of the contacting surfaces but more centrally of the joint. Biomechanically this principle can be explained by means of Figure 2b and c. In Figure 2b the resultant force R_1 is bypassing the joint 2, while according to the rules for equilibrium the reaction force R_2 must pass the 2 joint and through the center of rotation. For obtaining stability in joint 2 additional muscular action provided by m_2 was selected to counterbalance the 2 joint force couple moment $M = R.r$. The addition of m_2 to R_1 provided stabilization of 2 joint, favoured central loading, but also increased comressing stressing of the 2 joint ($R_1 + m_2$ and R_2'). The described biomechanical principles are usable for guidlines for FES control and sequence composition. We may also estimate that if the bending loading of long bones obtained with FES is by shape and magnitude similar to the one in normal man, than also to a large extent for safe and acceptable joint stressing is taken care. Such a hypothesis is very difficult to evaluate in quantitative terms. Also there are very rare studies which tackle the problems of joint loading in FES enabled activities. Owing to the said we believe if the hypothesis is applied to FES control it may provide at least grossly improved joint loading in comparison to the present practice.

RESULTS AND DISCUSSION

For clinical practice and chronic home use of FES systems in SCI patients it is important that the probability for patients to develop secondary pathology in joint is checked and minimized. Owing to it we have made a study for evaluation the long bones bending loading in patients utilizing FES enabled standing. In our case the patients use only m.quadriceps stimulation for standing /1,6/. For balance and transitions assistance hands are used. After Panwels /5/ the profiles of bending loading of long bones in a standing man are given in Fig. 3a. Here Mg is gravitational or load, Mm-muscular in Mr resultant torque. The model for normal subject standing is stabilized by quadriceps, gastrocnemius and soleus muscles. It is interesting to note that the femur bending stressing is small (Mr), while for the fibula-tibia bones Mr has a triangular shape, being zero at the ankle joint and maximal at the knee joint. This Mr torque at the knee joint is counterbalanced by the muscular action and in the center of knee joint rotation it is zero. Detailed presentation is omitted here due to space

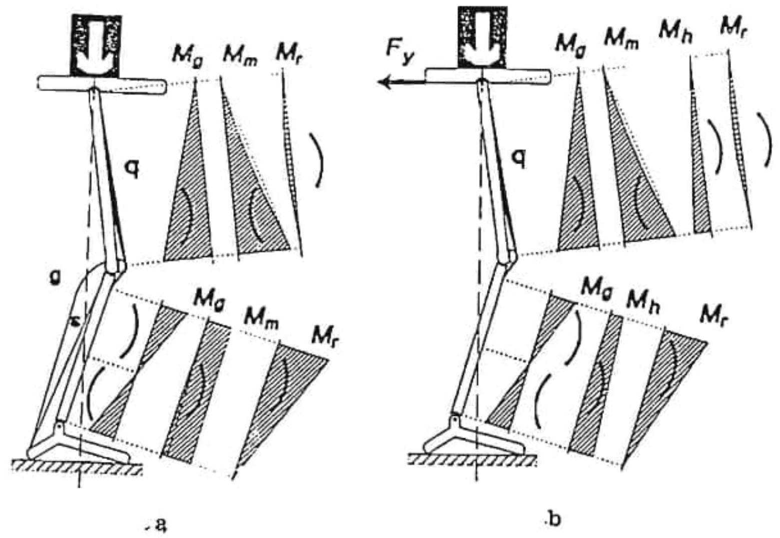

Fig. 3

limits. In Fig. 3b the bending loading of long bone is presented for a SCI patient standing by m.quadriceps stimulation. Mg torque is gravitational torque, Mm caused by muscular action, Mh torque being the consequence of hands balancing force Fy and Mr - the resultant bending stressing. Comparing Fig.3a to the bending stressing of long bones in SCI patient standing by means of FES shows, that the resultant stressing profiles are very alike /7/. But there is an important difference. For the tibia-fibula bones the resultant bending stressing in normal man was produced by the action of gravitational loading, and the action of muscles. In the SCI patients model the bending stressing results because of hand action and gravitational loading, but still the ankle joint and hip joint torque is balanced to zero and also the knee joint has comparable loading. Therefore according to the stated hypothesis in the former paragraph we may expect that joints are proper loaded also in patients utilizing FES and that in chronic use it is very unlikely that secondary pathologies in joints may develop. Subjective there is also a proof for the said, because in about 100 patients /1,6/ who utilized FES from several months and up to more tha 10 years we have not observed any joint problems yet. We may extrapulate further. Also in patients who have been using FES for ambulation no joint problems have been observed so far. This is indicating that also during the FES enabled reciprocal gait pattern the joints are not overstressed. Observing Fig. 1 and the large bending loading during transitions gives rise to thoughts that during transitions and when dynamical forces are present the joints loading may be critical and therefore should be investigated in detail.

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ON THE SIGNIFICANCE AND LOCALIZATION OF MYOSIN TRANSITIONS IN CHRONICALLY STIMULATED MUSCLE

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SUMMARY

Myosin genes are re-expressed in muscles that are subjected to a long-lasting increase in their overall activity. Changes in the predominant myosin isoforms have important consequences for the therapeutic application of chronic electrical stimulation, because they affect the speed of the muscle, its resistance to fatigue, and its power-generating capacity. With the use of immunogold electron microscopy it is possible to map the sites of exchange of these isoforms within the sarcomere.

SIGNIFICANCE OF MYOSIN TRANSITIONS

Under physiological conditions, motor units are recruited in a fixed hierarchy in which fatigue-resistant units sustain the more continuous, low-level activity. No such selective activation occurs when a motor nerve is stimulated electrically. Moreover, a supramaximal electrical stimulus activates all the muscle fibres in synchrony, so it is necessary to use unnaturally high stimulation frequencies in order to achieve adequately fused contractions. The combination of these two effects results in early onset of fatigue. This poses a serious problem in some potential clinical applications, which include: stimulation of nerves to muscle groups in the lower limbs to restore posture and locomotion in patients paralysed by a spinal cord lesion; stimulation of the phrenic nerve to restore diaphragmatic function in cases of inadequate, intermittent or absent ventilation; maintenance of tonus in an artificial sphincter for the control of incontinence; and the use of skeletal muscle as an autologous source of contractile tissue for repairing, enlarging or otherwise augmenting the function of the heart.

Fortunately for the future success of such applications, skeletal muscles turn out to be capable, in the long term, of accommodating such demanding patterns of use to a quite unexpected extent. This adaptive capacity was discovered in the course of experiments in which muscles of the fast-twitch, fatiguable type were subjected to a chronic increase in aggregate activity by indirect electrical stimulation. Under these conditions, a complete transformation of type occurs whereby the fast muscle acquires all the physiological, biochemical and morphological attributes of a slow-twitch muscle. In the process such muscles become remarkably fatigue-resistant, largely as a result of changes in the metabolic pathways responsible for the generation of ATP. These consist of a reduced dependence on anaerobic glycolysis and a switch to oxidative pathways, particularly those involved in the breakdown of fat and fatty acids (1, 2). There is an associated increase in capillary density (3) and a marked increase in mitochondrial volume fraction (4). We have studied the bioenergetic correlates of the induced fatigue-resistance in latissimus dorsi muscles of the dog by means of *in vivo* ^{31}P-nuclear magnetic resonance (NMR) spectroscopy (5). A decline in phosphocreatine and an accumulation of ADP and inorganic phosphate, the usual hallmarks of muscle fatigue, were clearly evident in control muscles but absent in muscles that had been stimulated chronically for 8 weeks. The stimulated muscles could therefore meet even the extreme increase in ATP utilisation imposed in this test with a corresponding production of ATP. In other experiments we have shown that such muscles consume less oxygen per gram of tissue than control muscle for a given amount of internal work performed (6). Thus chronic stimulation produces more efficient coupling between the development and maintenance of tension and the consumption of oxygen.

Changes in contractile speed

In terms of the mechanical behaviour of the muscle, the overall response to chronic stimulation is a reduction in contractile speed, seen as a marked prolongation of the contraction and relaxation phases of the isometric twitch, a higher twitch:tetanus ratio and a lower fusion frequency for tetanic stimulation (7,8). As a consequence, smooth and forceful tetanic contractions can be generated at lower frequencies of stimulation, which are less taxing to the muscle. Two main mechanisms are involved in bringing about the changes in speed. The first, affecting the kinetics of release and uptake of calcium within the fibres, consists of changes in the calcium transport ATPase (9), calcium-binding proteins (10) and the extent of the sarcotubular membrane system (4). The second involves replacement of fast with slow muscle isoforms of myosin (11-13). This results in less rapid cycling of the propulsive cross-bridges formed between the thick and thin filaments of the muscle, and hence a reduction in overall contractile speed. Such muscles use ATP more efficiently in sustained contractions (14), a fact that undoubtedly contributes in an important way to the observed increase in fatigue resistance.

Power considerations: the problem of slowness

The transformation that results from chronic stimulation goes far beyond a mere increase in endurance: it amounts to a fundamental alteration in the characteristics of the muscle as an actuator. These characteristics are governed by a series of curves relating calcium sensitivity to sarcomere length, force to length, force to frequency, force to velocity of shortening, and power to velocity. We have designed a digitally-controlled electrohydraulic apparatus to generate data on these relationships in control mammalian muscles and in muscles which have been subjected to stimulation for various periods. Our studies have shown that the curves shift and change shape markedly during transformation (15). These fundamental relationships are crucial to the power that the muscle can deliver, and the working conditions under which it can perform to best advantage. With the new apparatus we can use the force-length, force-frequency, force-velocity, and power-velocity curves to specify the conditions for a fatigue test in which the control and the contralateral stimulated muscle are arranged to contract cyclically, each delivering the same time-averaged power output and each shortening at the velocity for which its instantaneous power output is maximal.

These experiments show that the extreme resistance of the muscle to fatigue, which makes sustained activity possible, has to be set against a decrease in power-generating capacity. A major component of this decrease – which can be as much as 8-fold in rabbit fast muscles – is the reduced intrinsic speed of shortening, which itself may be undesirable for applications where there are constraints on the time available for contraction and relaxation. For these applications there is a need to seek patterns of activation that produce a less extreme alteration in contractile characteristics while preserving the necessary resistance to fatigue.

SUBCELLULAR LOCALISATION OF NEWLY INCORPORATED MYOSIN

Since changes in speed are due in large part to the switch in myosin heavy chain isoforms, it is appropriate to extend our basic knowledge of the re-expression of these proteins in response to stimulation. There is now good evidence that myosin heavy chain transitions are the result of regulatory events occurring at the level of the gene (16). Recently we have been using electron microscopy in conjunction with an immunogold labelling procedure to map the distribution of slow (SM) and fast (FM) muscle myosins as they are replaced in the sarcomeres of rabbit tibialis anterior muscles undergoing stimulation-induced transformation and recovery.

The technique involves a light glutaraldehye fixation followed by low-temperature embedding in Lowicryl. In general, only sites at the surface of sections are revealed during post-embedding labelling methods. The sensitivity of the technique is therefore dependent upon exposure and antibody recognition of epitope which has survived both cross-linking due to fixation and the effects of dehydration and polymerization of resin. Fortunately, the monoclonal antibodies we have developed are specific to characteristic epitopes which tolerate these procedures. The following is a summary of results which will be reported in detail elsewhere (17).

Well-defined differences in the distribution of label within the A-band suggested that the monoclonal antibodies bound to different parts of the myosin molecule; this was confirmed by Western blots of subfragments prepared from FM and SM. Muscles stimulated for 4 weeks, and muscles allowed to recover for 3 weeks after 7 weeks of stimulation, were labelled positively for both anti-FM and anti-SM. The distribution of gold particles was always characteristic of the antibody and independent of the origin or history of the fibres (Figure 1). This observation points to the conclusion that newly synthesized myosin is capable of being incorporated throughout the length and cross-section of the A-band, probably by a process of continual exchange between intact myosin filaments and a soluble pool of changing isoform composition.

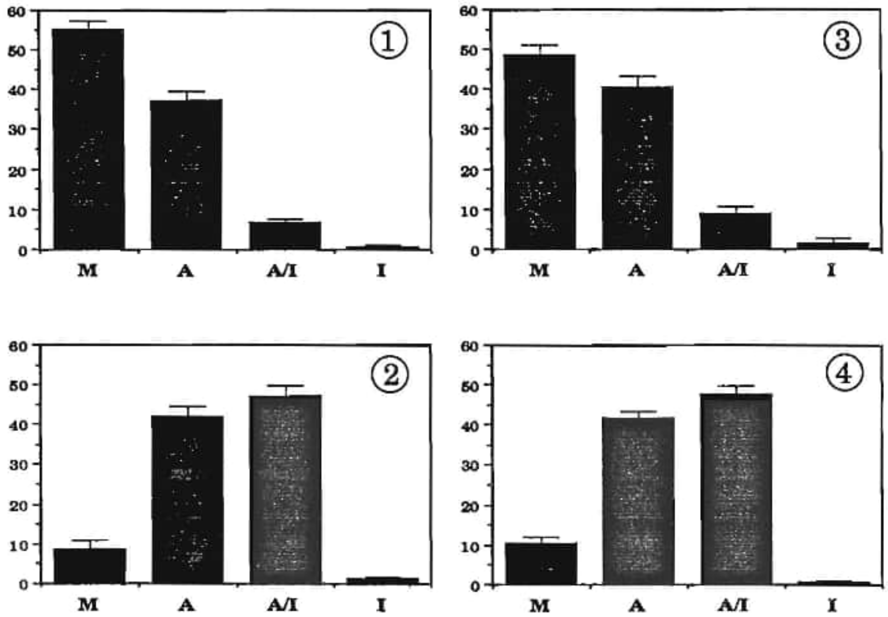

Figure 1. Percentage distribution of gold particles in sarcomeres of rabbit muscles: (1) control TA (2) control soleus (3,4) TA stimulated for 4 weeks. Samples were labelled with anti-FM (1,3) or anti-SM (2,4). Particles were counted in 4 zones - M, A, A/I, I - each equivalent to 1/10 of an A-band in width. The stimulated muscle is labelled with both antibodies and is therefore partially transformed, but the gold particles are distributed in patterns characteristic of the antibody, with no evidence of preferred sites of incorporation.

In a previous study, direct immunofluorescence labelling was used to demonstrate that fast and slow isoforms of myosin coexisted within individual fibres that were at an intermediate stage of stimulation-induced transformation (18). This was achieved by reacting serial transversely-cut frozen sections with the different antibodies and examining the sections for coincidence of labelling. These observations could be extended rather elegantly to the level of individual sarcomeres if it proved possible to examine thin sections which had been double-labelled by exposure to both primary antibodies followed by sequential application of immunogold probes with different particle sizes. Although such an approach presents technical difficulties, we have been able to conduct preliminary trials of a technique in which the section is labelled on one of its surfaces with an anti-FM–5nm immunogold sequence, followed on the other surface by anti-SM–15nm immunogold. When this technique was applied to the samples that were at an intermediate stage of transformation or recovery, both sizes of gold particle were found in the A-band, with the same distribution as that of the primary antibodies used separately. This result supports our contention that newly incorporated myosin is not spatially segregated within the sarcomeres.

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DOES FES DAMAGE THE PATIENTS JOINTS?

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Direct stimulation of the agonist muscle can result in motion that may be satisfactory for rehabilitation purposes. Several studies from our laboratory on normal subjects demonstrate that during movement, low level of activity is present in the antagonist muscle. One of the reasons for such antagonist activity is thought to prevent joint subluxation and uneven articular surface pressure that may damage the joint.

Cadaver knees were mounted horizontally, and fixed at various angles. The quadriceps tendon was attached to a cable and loaded up to 60 NT at 10 NT steps to simulate FES tension. Sequential loading of the hamstring tendon also up to 60 NT was performed while x-ray photos of each condition taken. Three metal markers set in the femoral bone head and two in the tibial head. Geometric calculations shows that up to 4.5 mm anterior displacement of the tibia occur with quadriceps loading only, and that uneven spacing of the joint space is present. Less than 20 NT of hamstrings load can correct the anterior displacement and can provide even joint spacing. The results warn against agonist only stimulation for the fear of joint damage under long term chronic use of FES.

FES OF THE LOWER EXTREMITIES BY STABILISATION OF THE ABDOMINAL, HIP AND KNEE JOINT REGION VIA SURFACE ELECTRODES

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SUMMARY

The method which would enable paraplegic patients to stand and to walk using reciprocal gait, has to stabilize all joints of the paralyzed part of the body. Otherwise the subject will find his standing balance in an unphysiological posture with extreme loading on the spine, knee and arm joints. The basic principle of the described method is to fix actively nearly all involved joints by FES via surface electrodes and an 8-10 channel stimulation. For practical daily use the number of channels should, however, be limited.

INTRODUCTION

The standing human is an upright body with at least eight joints which have to be stabilized: head-thorax, thorax-pelvis, hip-, knee-, and ankle joints. Even such a powerful controller as the brain seems not to be capable to control this essentially unstable chain if each joint is moving in an unpredictable independent manner. The brain solves the control task by fixing most of the joints during a movement or by stabilizing them dynamically in such a manner, that it is able to build a model of the dynamics of the movement pattern to be executed. Even if the model matches the actual dynamics of the body well, there are always enough perturbations the nervous controller has to compensate in order to keep equilibrium - and often enough it fails to succeed.

A paraplegic patient has lost at least control of the lower three pairs of these joints. In the technical sense this implies the controllability, the voluntary control, of the hip and leg muscles, and the observability, the loss of the sensory feedback of the limbs themselves. Stiffening the paralyzed legs and pelvis passively by bracing or actively by FES is one prerequisite to stand up and walk again but does not solve the problem to keep equilibrium. To the remaining part of the still voluntarily controllabel body the artificially stiffened lower segment of the body appears as a foreign matter, which has to be stabilized additionally like stilts.

The result is known, having not enough actuators left to compensate dynamically for the

perturbation movements the paraplegic is falling down. Because of this the dynamic control problem is converted into a static one: the handicapped uses crutches to gain a four to three point support. The equilibrium obtained this way is only semistatical because the human body is still moving in itself. The linkages between the limbs on one side and the body and the crutches on the other side are not fixed, especially when the handicapped wants to walk.
One task of FES to obtain standing and walking is therefore to bring the not voluntarily controllable joints into such a fixed position, that the center of gravity of the human body remains between the points of support.
(The control problem of keeping the body of a paraplegic handicapped in an upright position without additional support will not be considered in this paper).
Securing the joints to keep equilibrium might be done by using a mixed active-passive fixation scheme, leading off with the knee joint by bringing it into a blocked position through the stimulation of certain muscles. The angles of the other joints are adjusted around the force vector generated in this way /7/. This method needs only very few stimulation channels. The disadvantages are: The body is not kept straight, the already restricted reserve of compensation is diminished, and the upper extremity has to produce more force.
Another way is to control the joints actively in a more extended manner. This procedure needs more stimulation channels. Its advantages are: Each joint might be actively controlled allowing a straight upright position, the equilibrium is easier kept and one hand is extensively free for daily use, and the energy consumption is less. In addition it provides the possiblity to gain a better active overall stability of the whole body.
The system requires to control the lower extremities by FES in such a way, that they fit as smooth as possible into the reduced voluntary control of equilibrium executed by the upper part of the body. In order to meet this requirement the static and dynamic properties of the hip and legs have to operate in a predictive manner. They have to be stable in a wide range and support the stability of the entire system.
The basic principle applied by the Ljubljana Group since 1971 /2,5/, is to stimulate the knee extensors blocking the knee joint. The body is then positioned in such a way to compensate for the force vector of the leg. The fixation of the hip and knee joint is that way achieved in an active-passive combination. That means ,however, a limited controllability including the danger of insufficient posture resulting in hyperlordosis and hyperextension of the knee joints.

MATERIALS AND METHODS

In this paper a way is pointed out to actively control and move the joints . During standing and walking one would have to control at least two degrees of freedom in the abdominal region, three degrees of freedom at the hip, and two at the knee and ankle joints. To performe this at least 16 stimulation channels are required for one leg without those serving the flexor reflex. The time taken to donn and doff all the required electrodes would be inconvenient and tedious for the handicapped in the daily routine.
Therefore we use the smallest number of channels which allow the stabilization of the trunk, hip, knee, and ankle joints /9/.

The ankle joint is usually stabilized passively, the abdominal region is only stimulated in cases of high thoracic level of lesion (above T_6),when the residual control of linkage between thorax and pelvis is not sufficient.
An advantage of surface electrodes is the possibility to coactivate synergistic muscle groups via one stimulation channel. However, proper positioning and sufficient size of the electrodes are essential.
This method allows us to stabilize the hip and knee joint with only three stimulation channels. Via one pair of electrodes the mm. glutaei max. med. et min. and perhaps the tensor fasciae latae are coactivated. By a second and third channel the hamstrings and quadriceps are stimulated. The flexor reflex with an ankle dorsiflexion is triggered via a 4. channel. If neccessary in the abdominal region, a 5. channel is added with the electrodes attached dorsal lateral, and ventral touching the rectus abdominis laterally.
Doing so we stabilize the trunk by stimulating the rectus abdominis and obliquus ext. et int. (the latissimus dorsi is voluntarily activated.). The sagital plane of flexion/extension movements by stimulation of the glutaei max. and the hamstrings, and as an antagonist, the rectus femoris. This provides a muscular fixation of the hip joint extension and lessens the hyperlordosis. The lateral stabilization is achieved by stimulation of the mm. glutaei med. et. min., and keeps the pelvis horizontal during the single stance phase. We stabilize the knee joint not only by locking it through an activated quadriceps, we also stimulate the antagonists, and thus prevent an unbalanced hyperextension.
The patients have to pass an initial training program in the hospital. All muscle groups, needed for performing functional movements and stabilization, are restrengthened simultaneously, if neccessary selectively, to get a comparable level of muscle force /9/.
For this multi-channel application an 8-channel stimulator is commercially available, a 16-channel stimulator is developed at our institute /1,3/.

RESULTS

Up to now 17 outdoor patients are participating in the program. There are 3 females and 14 males, all traumatic paraplegics with ages ranging from 20 to 51. The level of spinal cord lesions varies from T_1 to T_{12} with complete motor and sensory loss. Time post injury ranges from 6 monthes to 10 years. All of them are able to position the electrodes and performe the training competently, they stand up, walk, and sit down without assistance in parallel bars. One young man is able to walk with the support of ellbow crutches.

DISCUSSION

The method has proved to be effective in providing a good stabilization of all involved joints. During standing only a minimum of upper limb support is required to maintain the balance. During walking the patients effort and the overloading of his upper limb are reduced. It is even possible for T_1 paraplegics to walk secured by parallel bars in a somewhat normal posture.

The disadvantages are still:

1. fast occurence of muscle fatigue limits the time of FES enabled functions.
2. the flexor-reflex is often found to be insufficient to raise the leg and performe the step.
3. circulatory disturbances arising during quiet standing are occasionally observed.

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PILOT STUDY ON THE EFFECTS OF FNS ON THE QUADRICEPS MUSCLE IN 6 SPINAL CORD INJURED PEOPLE

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SUMMARY

Research into FNS began in this country in 1983. By 1986 three projects were completed: the use of trunk EMG for control of FNS of the lower limb (1); the development of a quadricycle (Paracycle) (2); and the development of a six channel computer-based programmable stimulation system (3). The latter two were integrated in a trial at Conradie Hospital, Cape Town on a small group of recently injured paraplegics. After this trial proved sucessful, Project RESTAND was initiated at the close of 1986. The aim was the establishment of standing in paraplegics whose lesions were of less recent origin. Three studies were initiated, namely: the development of a FNS muscle training and fitness program in preparation for standing; the design of a biomechanical model of standing using FNS and thirdly, the design of the necessary FNS control systems to stimulate the standing process.

This paper reports on the results of a pilot study to determine the effects of FNS on the quadriceps muscle bulk and on its contractile ability including fatigue and endurance. This experience was utilised in the development of a FNS muscle training program, suited to our particular situation and needs, to prepare the paraplegics for standing.

MATERIALS AND METHODS

Subject Selection

Prospective participants were informed of the aims, proposed program and potential benefits of the research project and were provided with literature on similar research projects wordwide. After an initial FNS muscle response test and a medical examination to determine any conditions that may preclude participation, six subjects were selected.

Each subject was supplied with a portable two-channel FNS muscle stimulator. The stimulation parameters were 25Hz, 200µs and a maximum of 100mA. The waveform was symmetrical biphasic with an "on" and "off" time of 10 seconds each and a ramp time of 5 seconds. The amplitude was preset for each individual to produce full knee extension. Carbon - rubber surface electrodes (10cm x 5cm) were used with electrolyte gel. Padded ankleweights were designed for ease of load adjustment in order to optimise the training effect.

The program was geared to use in the home . This was convenient for both the subjects and the limited staff. The subjects performed their exercises at home and were relied upon to keep a log of their exercise data on the forms provided.

Assessments

Each subject was assessed at the laboratory approximately every three weeks for changes in strength and fatigue. The stimulation was provided by the programmable computer-based stimulation system (3). The subject was first driven passively on the Paracycle (2) for 10 minutes, then seated in the testing chair for the measurement of the strength of each leg using a straingauge system attatched to the subject's ankle. This measured the resulting force of the quadriceps contraction. The parameters of the test stimulus were 25Hz, 80mA and a pulsewidth that increased from zero to the set maximum over the 20 second duration of the test. A built-in safety feature of the stimulation program terminated the stimulus when a force of 100N was reached.

Funded by Dr H Goldberg, the MRC and UCT

Muscle fatigue and endurance was measured as the droop (decrease) in knee extension over a 3 minute period. The test stimulus was a constant current of 25Hz, 80mA and 600us. After calibration of the goniometer over the 0 to 90 degree range, the leg was raised manually to the full knee extension position (0 degrees). The stimulation was initiated and the decrease in knee extension was monitored for the duration of the test. The analysis of the fatigue curves presented a problem. After many attempts to find a suitable method, an adaption of the T50% index used by some authors (4) was used. The index %TD(ht) denoted the percentage of the total droop in knee extension that had occured by the half-test mark (90 seconds). A decrease in %TD(ht) indicates an improvement in the muscle fatigue response.

Magnetic Resonance Imaging (MRI) scans of the cross section of the leg at midthigh level were taken approximately six monthly. The scans were digitised to determine the areas of the following compartments: anterior (quadriceps), posterior and medial, bone, marrow and subcutaneous fat. The changes in the relative areas of these compartments as a percentage of the total cross-sectional area of the leg were examined.

The study was not originally intended as a statistical study and the heterogeneity of the present group is thus not suited to tight statistical analysis.

RESULTS

The details of the subject group are presented in Table one. The mean age of the group was 28 $\pm$ 10 years. The SCI's were all due to trauma which occured during their scholar/ student years. Motor vehicle/cycle accidents accounted for 83% of their injuries. The mean age at injury was 17,5 $\pm$ 4 years. To date, post-injury time was 11,1 $\pm$ 11 years. The level of injury ranged from C5,6 to T9. Subjects DH (C5,6) and AZ (C7) (tetraplegics) had lesions that were beyond the suggested range for FNS use, namely T3-T12.

Table 1: Subject Characteristics

SUBJECT	SEX	AGE	DATE	CAUSE	LESION
DH	F	48	2/1955	diving	C5,6
HV	F	26	7/1984	MVA	T5,6
AZ	F	25	7/1982	MVA	C7
TW	M	27	2/1984	M-cycle	T4
RM	M	26	2/1973	MVA	T8,9
SB	M	17	12/1986	M-cycle	T9

Subjects improved in strength to varying degrees depending on their individual circumstances. Figure 1 shows the result of subject SB. The mean ($\pm$SD) improvement in quadriceps muscle strength for the paraplegics (TW, HV, RM, SB) was 53N $\pm$ 29N (=97,8 $\pm$ 59,6%) for the left leg and 41 $\pm$ 19N (=171.21 $\pm$ 118.1%) for the right leg. This increase was significant for both legs (p<0,05).

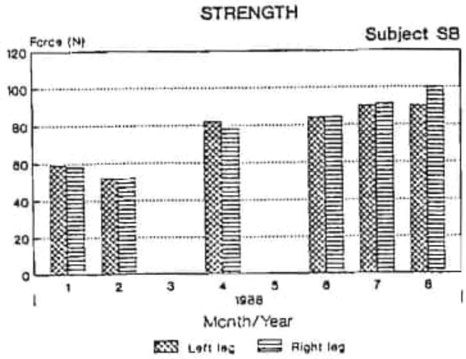

Figure 1: Quadriceps strength of subject SB

Figure 2 indicates the fatigue response for subject SB . Figure 3 (subject HV) also shows the effect of a period of absence from FNS on the fatigue response. The mean improvement in %TD(ht) for the 6 subjects was 16% and 3,9% for the left and right leg respectively. There was wide variation in the individual responses. The significance level for the improvement in the left leg fell within $0,05<p<0,1$.

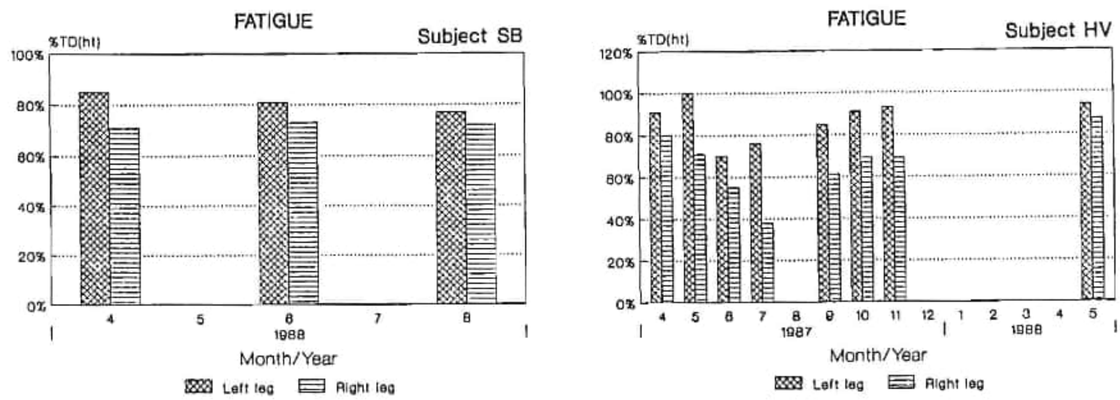

Figure 2 and 3: Quadriceps fatigue response for subjects SB and HV.

Three subjects (TW, HV, AZ) particpated in the muscle bulk tests. The means of the results showed no significant change in the posterior and medial, bone and marrow compartments. The anterior compartment showed a trend ($0,05<p<0,1$) towards an increase in the area, that is an increase in the muscle bulk, by 4,4% and 2,7% for the left and right leg respectively. The subcutaneous fat compartment decreased in area by 4,7% (left) and 3,4% (right) ($p<0,05$). Figure 4 presents the results of the left leg of subject HV.

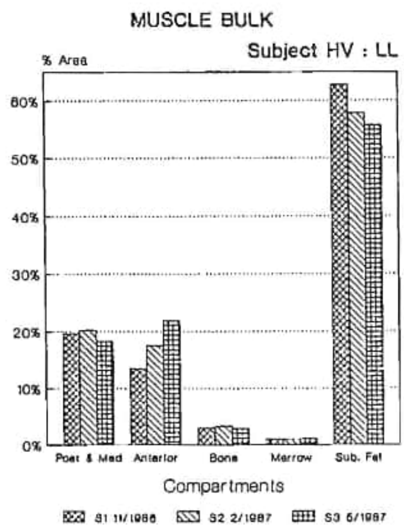

Figure 4: Muscle bulk results for subject HV

The results were initially analysed as six individual case studies as each subject had to be viewed in the light of his/her individual circumstances such as time since injury, degree of muscle atrophy, initial response to FNS and regularity of FNS sessions. The following general observations were noted from these six case studies:

Subjects with more recent injuries (TW, HV, AZ and SB) had higher initial quadriceps strength those (DH and RM) whose injuries were of a longer duration.

In subjects HV and RM, the right leg was consistently weaker than the left.

Three subjects underwent temporary periods of discontinued FNS use (two to six months). After six months, TW had maintained the muscle strength. After two months break by HV, the strength in the left leg was maintained, but that of the right leg (weaker) had

decreased by 20%. The force increased when FNS was resumed. After a second longer break the force in the left and right legs had decreased by 35% and 45% respectively. RM responded by a decrease in strength in both legs of 19% and 41%, left and right (weaker) legs respectively.
Quadriceps muscle strength increased after FNS in all the paraplegics (TW, HV, RM, AZ).
The tetraplegics response: DH experienced some discomfort (incomplete lesion) and the tests were therefore performed with voluntary effort only. Muscle strength improved in both legs. AZ had a strong initial response to FNS but after an initial rise in strength, little futher increase was measured.
There appeared to be a pattern between the strength and the fatigue responses in that an increase in the muscle strength was generally accompanied by an improvement in the fatigue response.
Muscle fatigue often increased during periods of discontinued FNS use despite a maintainance in strength.
Using the %TD(ht) index, TW, HV and AZ showed overall improvements in varying degrees in both legs. RM,DH and SB showed improvement in the left leg while the right leg had a varied response (DH) or showed no real change (RM, SB).
Subjects TW, HV and AZ showed a consistent pattern of response in the muscle bulk section, namely an increase in quadriceps muscle bulk and a decrease in the quantity of subcutaneous fat at the mid-thigh level.

DISCUSSION

Our subjects were fully rehabilitated and employed. As the study progressed this presented a previously hidden problem in that the subjects led such active lives that they had limited time to devote to FNS. The "home use" situation meant that the subjects had to be relied upon to exercise regularly without supervision and to record the exercise data as this was the only avaliable record. Exercise sessions at the laboratory may have solved this problem but they were impractical due to the nature of our subject group.

The results of the study showed that quadriceps muscle strength, bulk and fatigue (endurance) were improved after FNS use. The study provided experience in many aspects of FNS such as the use of electrodes and stimulators and the effects of stimulation parameters. It highlighted the need for suitable selection criteria, such as time availability, the level and nature of the lesion and the absence of contractures of the lower limbs, when examining prospective participants. The study led to the development of a device, the Inclistand, which can be used for FNS exercise and as a frame for inclined standing under FNS control. The experienced gained will help to develope the present program as we procede to the standing phase of the program.

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SYMMETRY OF FES ACTUATION IN PARAPLEGIC SUBJECTS x)

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SUMMARY

Symmetry of FES responses was studied in the knee extensors of a group of ten paraplegic subjects. Recruitment curve and fatigue index were assessed in right and left lower extremity. An average symmetry over 70% was found for both stimulated muscle strength and fatigability allowing, thus, the reducement of complexity of the control approach in FES locomotor aids.

METHODS

Because of many natural or artificial obstacles, gait is less automatic and periodic process as it appears when studying normal ground level walking. Paraplegic subject's walking must be to a large extent under patient's voluntary control. The control of the simple four-channel walking pattern was accomplished only by a hand switch built into a handle of a crutch and providing transition from the double into the single stance phase of walking /1/. Later the potentiometers were added into the handle allowing, thus, appropriate adjustment of stimulation amplitude for each particular channel. More complex approach has been proposed by Thoma /2/. Here, both hip and knee joints are controlled by the movement of single knuckles of two fingers. Less learning is required with the method described by Graupe /3/. The command to initiate a step is represented by an EMG signal originating from the upper trunk above the level of the lesion.

To lessen the burden of voluntary control, the symmetry of walking can be taken into account. Symmetric motion of the legs requires symmetric FES actuation /4/. Here, we have in mind the symmetry of the right and left gait parameters such as occuring during steady walking. Our interest will be concentrated on the symmetry of stimulated muscle strength and fatiguing.

Ten completely paralyzed SCI subjects were randomly selected to participate in the investigation. They all displayed upper motor neuron lesion between L1 and C6. All of them were able to walk when assisted by four-channel FES. Half of them were using FES rehabilitative devices for several years at their homes for daily standing and walking exercise. The rest of the paraplegic subjects were, at the time of this investigation, completed successfully the FES walking program /1/ at the rehabilitation center. The age distribution was between 17 and 40 years. The time passed after the accident was from 4 months up to 8 years.

All the measurements were performed in the knee extensors of the right and left extremity by the help of a measuring device built in our research laboratory. The strength of the stimulated muscle group was evaluated by assessing the recruitment curves. The slope K [Nm/V] of the linear part of the recruitment curve was considered as most important for stimulator control and was used in further consideration.

x) Supported by RSS, Ljubljana, Yugoslavia, and NIDRR, Washington, USA.

Fatiguing of electrically stimulated knee extensors was studied during continuous train of stimuli. The muscle fatigue was estimated by means of fatigue index f [%] expressed by the help of initial torque M_0 and the torque value assessed after 30 seconds of continuous electrical stimulation M_{30}:

$$f = \frac{M_0 - M_{30}}{M_0} \cdot 100\ \%$$

Surface electrical stimulation was applied in the investigation. Stimulation frequency of 20 Hz and pulse duration of 0.3 ms were used.

RESULTS

The slopes of the recruitment curves belonging to the right and left knee extensors of each SCI subject are shown in Fig. 1. An average slope of 1.79 Nm/V (±0.75) was found in right knee extensors and 1.59 Nm/V (±0.95) in the left knee extensors. Insufficient symmetry can be observed in two subjects (patients no.: 1,4).

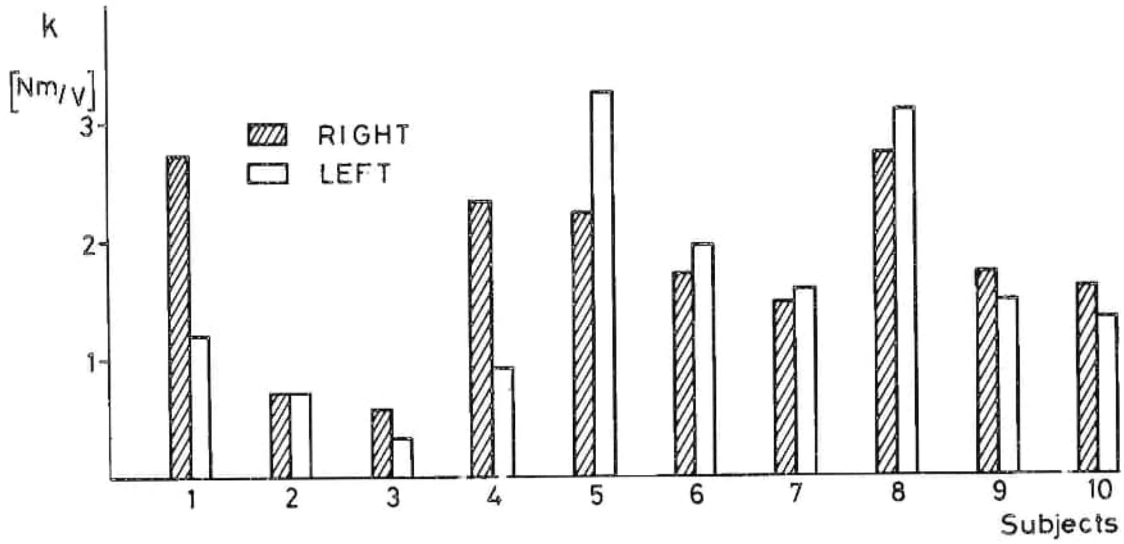

Fig. 1. Recruitment curve slopes belonging to the right and left knee extensors

Fatiguing of electrically stimulated muscle is seriously limiting the successfulness of FES assisted standing or walking in completely paralyzed persons. It can be overcome to some extent by increasing the stimulation amplitude from time to time during standing or walking. The symmetry of fatigue indices can be observed in Fig. 2. In the right extremity 22.3% (± 10.4) of fatiguing was found as compared to 24.3% (± 11.6) in the left leg. Inadequate symmetry can be claimed in two patients only (patients no.: 4 and 8).

Symmetry can be further quantitatively estimated by calculating the quotients of the measured parameters appertaining to the right and left extremity. The greater of both values was considered as denominator. In this way symmetry values between 0 and 1 were found what made statistical comparison easier. An average symmetry for the recruitment curve slope of 0.74 (± 0.21) was found while it was 0.72 (±0.18) for the fatigue index.

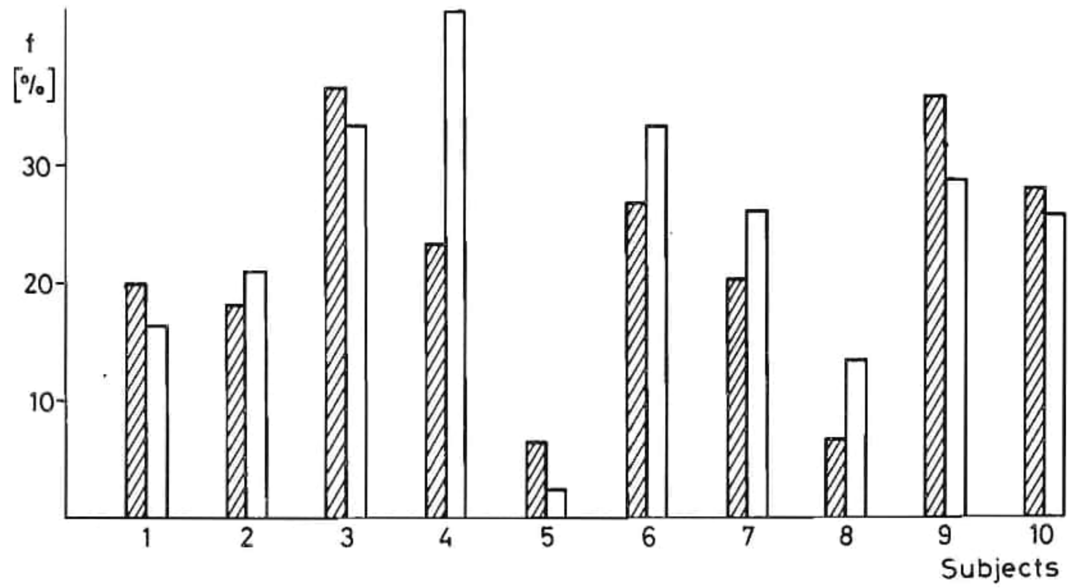

Fig. 2. Fatigue indices belonging to the right and left quadriceps muscles

DISCUSSION

The symmetry of FES responses in the lower extremities of paraplegic subjects allows reduction of complexity of a control module of a multichannel FES rehabilitative aid providing restoration of walking in completely paralyzed subjects. In this way, two potentiometers in the handles of the right and left crutch, controlling the stimulation amplitude of the right and left knee extensors, can be replaced by a single potentiometer. A small turn of this potentiometer knob will result, for example, in an increase of 10 Nm in one extremity and an increase of 7 Nm in the contralateral extremity. Taking into account relatively poor selectivity of surface FES, such an approach of the gait control is quite acceptable.

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ARTIFICIAL-REFLEX STIMULATION: CLINICAL POSSIBILITIES IN PARAPLEGIC STANDING.

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SUMMARY

A non-numerical or finite state control scheme has been developed to decrease average quadriceps activation during FES induced paraplegic standing. To assess the clinical possibilities of this strategy it was tested for providing both sufficient stability and adequate reduction of muscle fatigue. Stability was evaluated during paraplegic standing in a special frame to guarantee reproducible external stand conditions. Impact on muscle fatigue was estimated by comparing maximum stand-time with and without using the controller.
Some preliminary results are given.

INTRODUCTION

Current clinically applied FES systems are based on open-loop control of stimulation. Knee locking during standing is usually realized by continuously supramaximal stimulation of the quadriceps muscles [1]. This results in early fatigue due to ischemia and limits standtime and walking distance. Feedback of kinematics may reduce these problems [2], but will be clinically accepted only when providing both sufficient stability and adequate reduction of muscle fatigue.
We proposed and tested a modified on/off (or ramp-down) control strategy based on finite state feedback of knee angle and angular velocity. To assess the dynamics of the FES controlled leg when using this strategy experiments were done on a special bench with the patients in supine position [3].

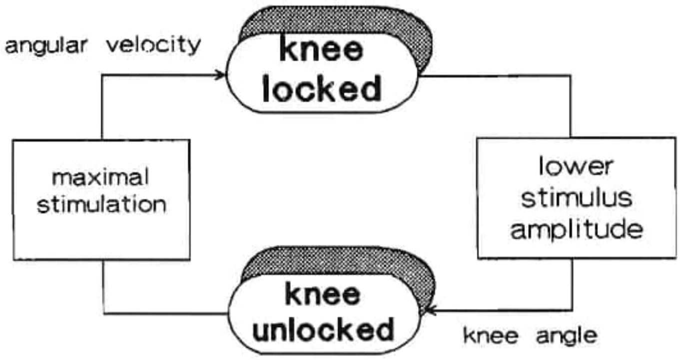

Figure 1. State-diagram of the applied control strategy.

Figure 1 shows the state diagram of the controller. The control strategy recognizes two different states: knee-lock and knee-unlock. The transition from lock to unlock is detected using knee angle data, obtained from a goniometer. Knee flexion over a defined minimum will cause the transition from the knee lock to the unlock state. The transition from unlock to lock is detected by determining zero knee angle velocity during a specific time interval. The use of angular velocity allows the system to calibrate automatically the lock position since the zero velocity situation is independent of any DC shift. During the unlock state the most

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important thing is to stop further bending of the knee. Therefore the stimulation amplitude is switched to a high prefixed level. Following transition to the lock state the pulse amplitude is reduced exponentially in order to maximally lower muscle activation and thus postpone the occurrence of fatigue. The time constant can be chosen to yield a maximal reduction of fatigue. Using this strategy the average stimulation amplitude is adapted to changes in the stimulus versus force relation and to changes in external load.
Experiments in the experimental set-up with the patients in supine position have shown that the strategy may provide continuous dynamic activation of muscle and robust control of knee angle [3]. Dynamic muscle activation is supposed to increase muscle blood flow compared to constant supramaximal stimulation, and restore some muscle pump function. Robustness of the system to muscle fatigue and load changes is gained by introducing a limit-cycle; i.e. a non-damping system oscillation around the target position. In this way average quadriceps activation can be minimized without direct feedback of muscle force (although the knee is in full extension) and repeated calibration of the locked position is possible.

In conclusion, the control strategy looks promising from a systems point of view. However, introducing a limit-cycle may effect the clinical possibilities of the system in standing. Finally, the true impact of the controller on local muscle fatigue must be evaluated. This paper describes the assessment of these two clinical aspects in standing paraplegics.

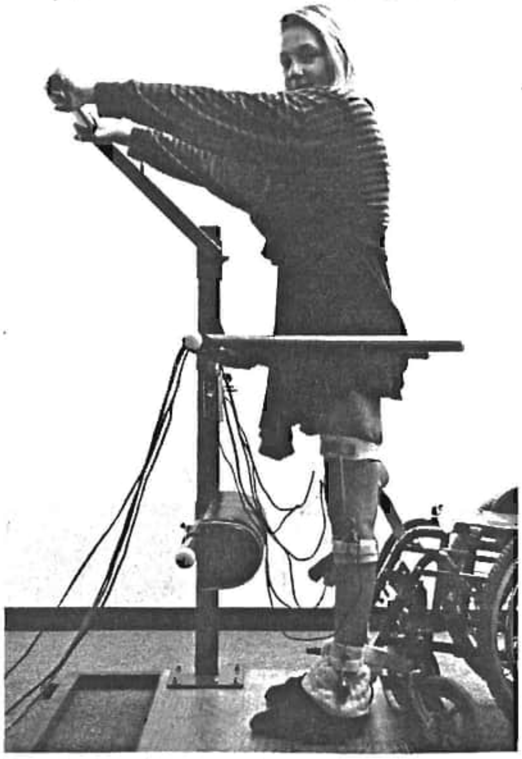

Figure 2.
The artificial-reflex controller used by a standing paraplegic.

METHODS

System dynamics.
System dynamics was evaluated during standing in a special frame to guarantee reproducible external standing conditions. See figure 2. The subject is standing while the trunk is stabilized in a vertical position by a hip belt and the patient's arms, both in a horizontal position. In this way the trunk can move in a vertical direction, not being influenced by the patient.
The experiments were carried out on paraplegics, complete T5-T6. Subjects had normal excitability of quadriceps muscle. Surface electrodes (4x7 cm, Intra Medical, adhesive) were placed on the motor point of the rectus femoris and near the patella. Stimulation was controlled by an IBM-XT computer with AD-facilities.

Monophasic rectangular current pulses (duration 300 us, pulse rate 20 Hz) were applied. Knee angle was measured with an electro goniometer (MCB pp27c). The goniometer signal was sampled at 100 Hz and low pass filtered at 15 Hz. Angular velocity was calculated digitally from angle inter-sample difference.
Knee angle, angular velocity and stimulation data could be recorded continuously, or in intervals for later evaluation. Knee angle disturbances relative to the locked position as well as the locking velocity were measured continuously in each stimulus cycle.

Fatigue.
For our purpose local muscle fatigue is defined as the relative loss of muscle force evoked by stimulation. Unfortunately quadriceps force can not be measured directly during standing. Therefore loss of quadriceps force is quantified by measuring 1: standtime and 2: knee flexion and locking velocity in each stimulation cycle.

RESULTS

Figure 3 shows as typical example three 10 second intervals out of one stimulation trial. Shown are knee angle (solid line) and stimulus amplitude (dotted line) from the left leg of a patient with a rather poor condition of the quadriceps muscles (right leg: 15 Nm, left leg: 12 Nm). It can be seen how the knee joint continuously switches between the lock and unlock state and how the average knee flexion slowly increases in time. Average knee flexion during unlock was 3.1° for the right leg and 2.3° for the left leg, corresponding to a vertical hip movement of 0.37 mm (right) and 0.20 mm (left). Average locking velocity was 42°/s (right) and 24°/s (left). This can also be seen in figure 4, which shows as a continuous registration every maximum knee flexion during unlock relative to the locked position (solid line) and the corresponding locking velocity (dotted line). It can be seen how the dynamic response of the knee varies slightly around a rather constant average.
The maximum standtime when using the controller was 271 sec. After recovery (24 hrs) maximum standtime was found to be 78 sec. during continuous supramaximal stimulation. This means that with the controller standtime increased a factor 3.5.

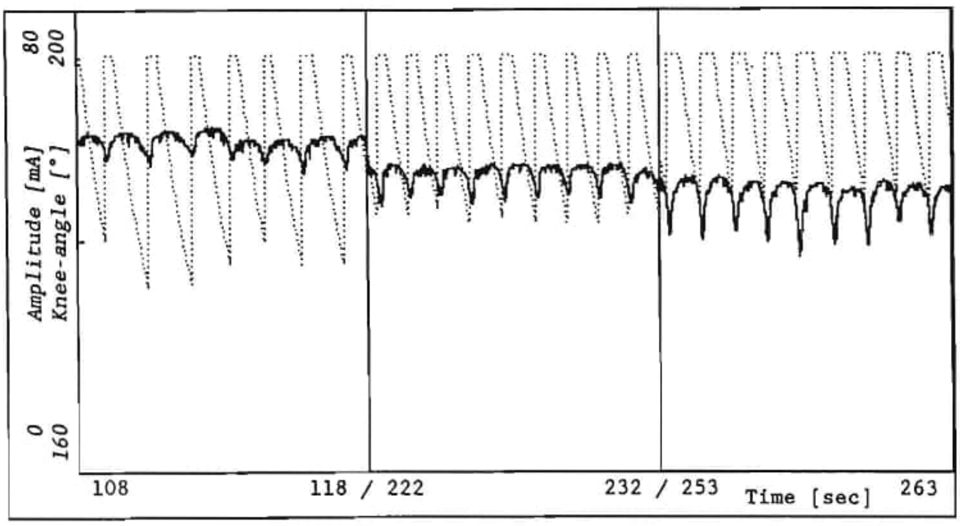

Fig 3. Three 10 sec intervals from one trial of art.-reflex controlled standing. Solid line: knee angle; Dotted line: stimulus amplitude. Left leg; stimulation frequency 20 Hz; pulse duration 300 us; angular deadband 1.8°; ramp-down time-constant: 1.5 sec.; maximum amplitude 80 mA.

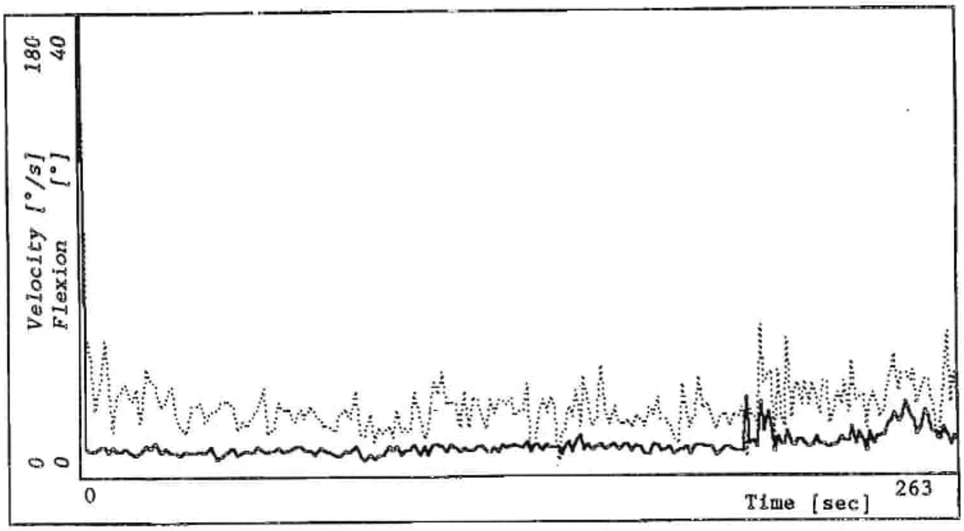

Fig 4. Time course of maximum knee flexion during unlock (solid line) and locking velocity (dotted line) for the stimulation trial of figure 3.

DISCUSSION

The main items depicting the functional and clinical possibilities of artificial-reflex control of knee joint in standing paraplegics are system dynamics (does the presence of a limit-cycle introduce unacceptable knee jerks for the patient) and the ability of the controller to postpone local muscle fatigue. The present control strategy looks promising on these points. For the non-hyperextended situation the generated knee movements (although patient dependent) are acceptable both from a functional and a 'comfort to patient' point of view. Standtime increased nearly a factor 4 compared to continuous supramaximal stimulation, even in a patient with poor muscle condition. In the hyper-extended situation stand-time will increase even further and will be proportional to the periods of hyper-extension.
For a more fundamental knowledge of the impact of artificial-reflex stimulation on muscle blood flow, muscle pump and muscle fatigue, further experiments will be done during dynamic isometric contractions. This should also determine the optimal control parameters under dynamic load conditions.

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CONTROL OF FUNCTIONAL ELECTRICAL STIMULATION WITH EXTENDED PHYSIOLOGICAL PROPRIOCEPTION.

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Summary

The force output (and hence joint position) obtained by stimulation of a muscle varies over a considerable range as a result of such factors as temperature, fatigue, movement of the motor point, and joint position. The design of an interface between patient and neuroprosthesis should provide a means of compensating for such variation (1). Furthermore, the accuracy of joint positioning depends on the amount of information flow across the interface, and this may be improved when some form of feedback is supplied to the user (2).

This paper describes preliminary results from the application of a technique known as Extended Physiological Proprioception (EPP) to the control of joint-positioning with FES. In this method, the control and paralysed joints are mechanically linked by means of a Bowden cable, such that a consistent relationship exists between force, position and velocity at each joint. The tension in this cable is used to control the muscle actuator, and proprioceptive sensations arising from the slave limb are thus transmitted to the controlling joint via the normal sensorimotor pathways (3).

The performance of the system was assessed by testing the accuracy of limb positioning with vision excluded, and was compared with open and closed-loop position-servo systems. The EPP system performed significantly better than the other two methods.

Materials and Methods

In order to develop and test the EPP-FES principle, the experimental apparatus shown in fig. 1 was assembled, in which a paraplegic subject controls his paralysed knee joint with FES applied to the quadriceps muscle group by shoulder protraction-retraction.

A trans-scapular harness similar to that used to control upper-limb prostheses was worn, and a Bowden (Perlon) cable linked shoulder motion to knee-joint motion by its attachment to a pulley on the joint of a knee brace. The arrangement was such that shoulder protraction caused tension in the cable to rise and the knee to tend to extend (although actual extension was difficult without stimulation

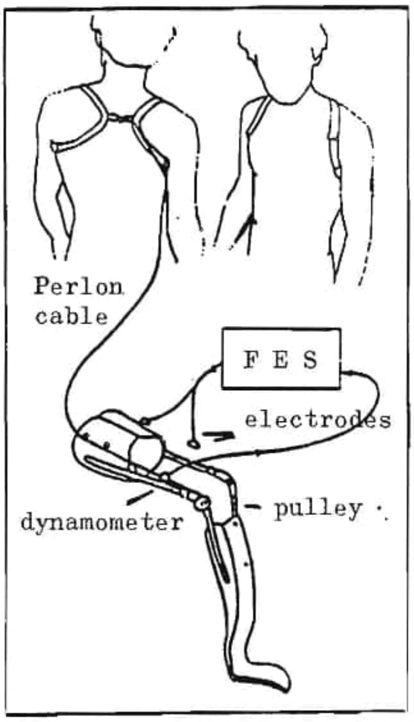

Fig. 1: apparatus for EPP control

Acknowlegements

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because of the small mechanical advantage given by the pulley radius, 25 mm). Tension in the cable was monitored by an inline strain-gauged proving-ring type dynamometer. The amplified signal, was input to the Analogue-Digital converter of an IBM-PC Compatible microcomputer, and used to generate the control signal to a constant-current stimulator (developed at this site). The stimulation train was pulse-width modulated at a constant inter-pulse-interval (40ms) between the threshold level of the muscle (typically 50 - 100μs) and a limit, arbitrarily set at 500μs and applied using "Pals +" surface electrodes (Axelgaard Manufacturing Co. Ltd., Fallbrook, California). Current level was adjusted to give full extension at this limit, and the force transducer was calibrated for cable tensions produced when comfortable levels of force were applied through the harness.

Controller Synthesis: Using a simple proportional relation between transducer output and pulse-width, it was found that the system was unstable, with unacceptable large oscillations ocurring at around 1Hz. This might be expected, since in linking input and output joints by the cable a closed-loop system is created with a large time-delay caused by the inertial effects of the limb together with muscle excitation-force coupling delays. System modelling, by analysis of the step response characteristics ("Matlab", ...) revealed the following input-output relationship:

$$G(z) = \frac{K_o (z+1)^4}{(z^2 - 1.78z + 0.15)(z^2 - 1.86z + 0.92)}$$

where K_o is a measure of the overall loop-gain
and z is the unit delay operator (sampling interval = 40 ms)

Analysis of the root locus of this equation disclosed two dominant poles very close to the unit-circle, which rapidly cross this into the unstable zone as the loop is closed and gain increased from zero. To stabilise the system, a PID controller was designed in which two zeros cancel these poles and draw the locus away from the unit circle to increase gain margin (4). The resulting algorithm was as follows:

Desired controller zeroes at $(0.9 + 0.25j)$

$$\text{Controller} = K(z) = \frac{u(z)}{e(z)} = \frac{v * (0.875 * z^{-2} - 1.8 * z^{-1} + 1)}{(1 - z^{-1})}$$

$$u(k) = u(k-1) + v(e(k) - 1.8 * e(k-1) + 0.8 * e(k-2))$$

where $u(k)$ = controller output at k'th time interval
$e(k)$ = cable tension at k'th time interval - $u(k-1)$
and v = velocity gain (tuned to give optimum performance)

This controller proved effective in practice, with an acceptable dynamic response (velocity in response to step input = 60 deg./s).

System Assessment: The supposed advantage of EPP over conventional (open and closed-loop) control is better control of limb position because of the ability to sense limb position. In order to test this hypothesis, the apparatus shown in fig. 2 was constructed.

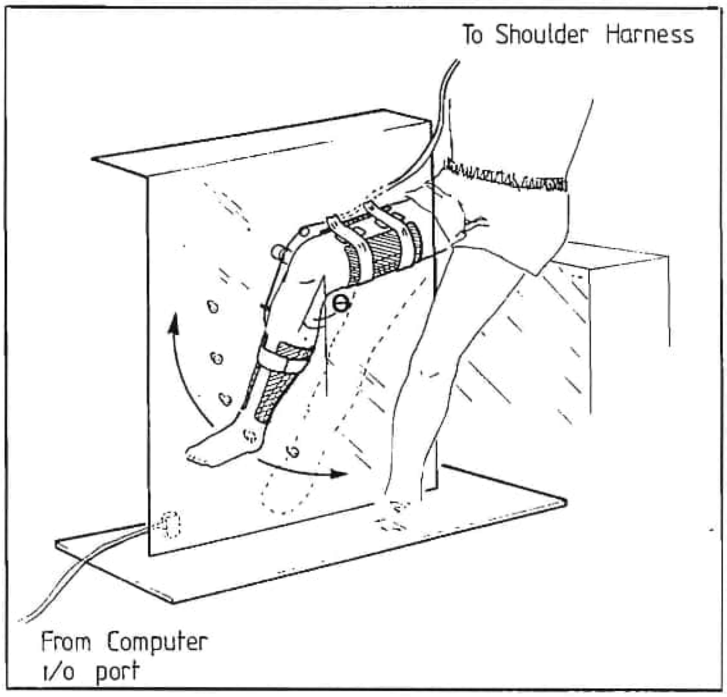

Fig. 2: experimental setup for controller assessment (modified from (5)) angle measured by electro-goniometer is denoted by Θ.

This is a modified version of that used to assess kinaesthetic sensing of the Boston arm (5). The controlled limb is hidden behind a screen, on the visible side of which are mounted indicator LEDs at five equidistant points around a quadrant whose centre is approximately colinear with the subject's knee-joint axis. The LEDs were switched on at random by the controlling computer, and the subject instructed to move his leg (using the FES controller) to a point at which he felt the shank was opposite the illuminated LED. He then pressed a switch and the computer recorded the position achieved by an electro-goniometer on the knee. Following a three second rest period another LED was illuminated. This was repeated until all five LEDs had been selected five times each. Prior to each test session, a two minute practice period was allowed, during which the LED nearest to the shank position was illuminated. The subject was instructed to move the leg freely in order to "get the feel of the system".

The performance of EPP control against conventional open and closed-loop control was compared. For these latter two methods the Bowden cable was detached from the pulley and made to operate a linear-action sprung potentiometer. In the open-loop case the signal from this potentiometer alone provided the input to the controller, whilst in the closed-loop case the difference between this and the goniometer output was used. The assessment was performed on three paraplegic subjects, who had sustained complete thoracic-level lesions. On questioning subjects during the tests, they reported finding the task very difficult with the conventional systems because they had "no idea" where the leg was. All preferred the EPP controller

Results

The results of the assessment are displayed in fig. 3. An analysis of variance shows that the EPP control system performed significantly better ($p < 0.25\%$) than both the conventional control schemes in all leg positions except those at the extremes of joint motion. This finding might be expected, since these angles could be approximated by setting the stimulation either fully on or fully off, no judgment of knee angle being required.

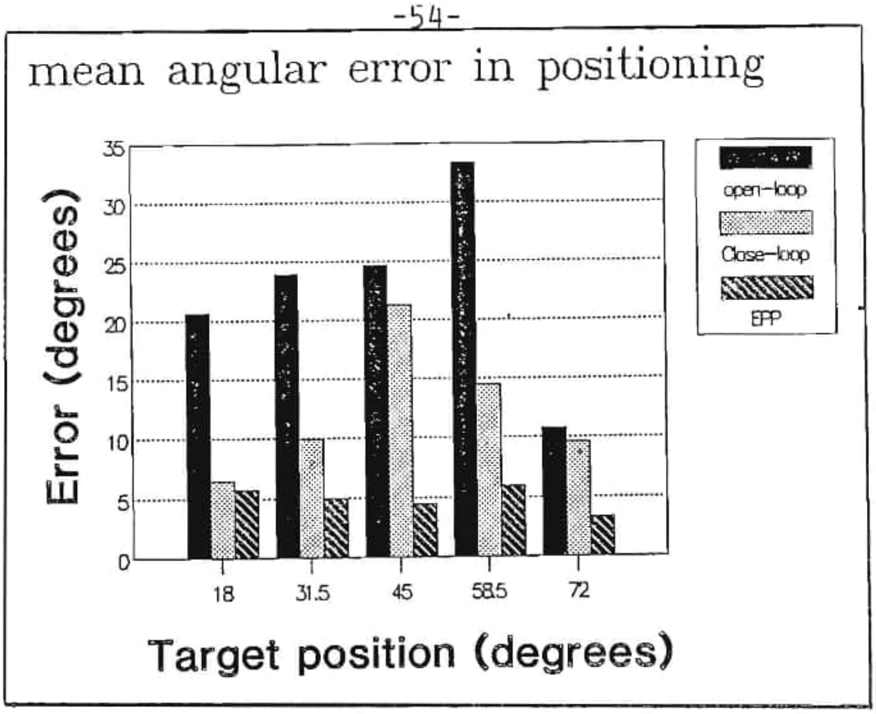

Fig. 3: results of an assessment of joint-positioning accuracy with the three controllers (open-loop, closed-loop and EPP).

Discussion

The reasons behind the improvement in performance with EPP compared to conventional closed-loop control are not obvious. It is possible that without proprioceptive feedback the patient's reference position may drift, and the mapping between control and slave joint lost (6).

Although in experiments the shoulder was used as the control joint, the technique of EPP-FES is versatile, and can in principle be applied to the augmentation of any passive mechanical orthosis, providing that a measure of the force put into the brace by the patient's vestigial musculature can be transduced. The more natural control achieved by EPP should facilitate subconscious operation and improve patient acceptance in future FES systems.

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REMODELLING OF NMJ: MORPHOMETRY OF SYNAPTIC STRUCTURES FOLLOWING INDIRECT ELECTRO-STIMULATION *)

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SUMMARY

The effect of continuous indirect electro-stimulation at low frequency on neuromuscular junction (NMJ) structure was investigated in EDL muscle of young adult rats. The endplate was visualized by light microscopic AChE staining and by transmission electron microscopy. Continuous low frequency electro-stimulation of the fast muscle resulted in a reduction in histochemically determined endplate perimeter and width which was appreciable by day 10. Transmission electron microscopy revealed small intact terminals associated with a larger expanse of clefts, several terminals within the same primary clefts, a large variability in the architecture of secondary folds. Quantitation of ultrastructural features confirmed that the magnitude of changes was the same in either 10 or 30 days stimulated EDL. Besides evidence of mature synapse plasticity, data from the present investigation are suggestive of functional relationships and, thus, may have relevance to biochemical and molecular changes occurring in fast twitch muscle when subjected to continuous low frequency stimulation.

MATERIAL AND METHODS

Young adult male Wistar rats weighing 200 to 300 g were used. Under thiopental and ether anaesthesia stimulating electrodes were implanted on the sciatic nerve of one side and indirect low frequency (10 Hz) electro-stimulation was continuously applied (24 h/day) as previously described (1). At day 4, 10 and 30 stimulated EDL muscles were removed and processed for transmission electron microscopy (2). Contralateral EDL and SOL muscles served as controls. In some experiments, stimulated and control muscles were processed for the histochemical demonstration of AChE activity (3), and then teased into small bundles of fibres which were mounted in Aquamount mounting media between two standard cover-slips. The method described in (3) was slightly modified in order to prevent muscle contractures and shrinkage and to make more reliably comparisons of endplate dimensions in different experimental conditions (details will appear elsewhere). Morphometric analyses of NMJ structure in experimental and control muscles were performed on either electron micrographs of cross-sectioned nerve terminals, printed at calibrated magnification or on camera lucida drawings of positive areas on cholinesterase-stained whole mounts. Measurements were done using a semi-automatic image analyzer (Mini-Mop, Kontron Bildanalyse). The parameters

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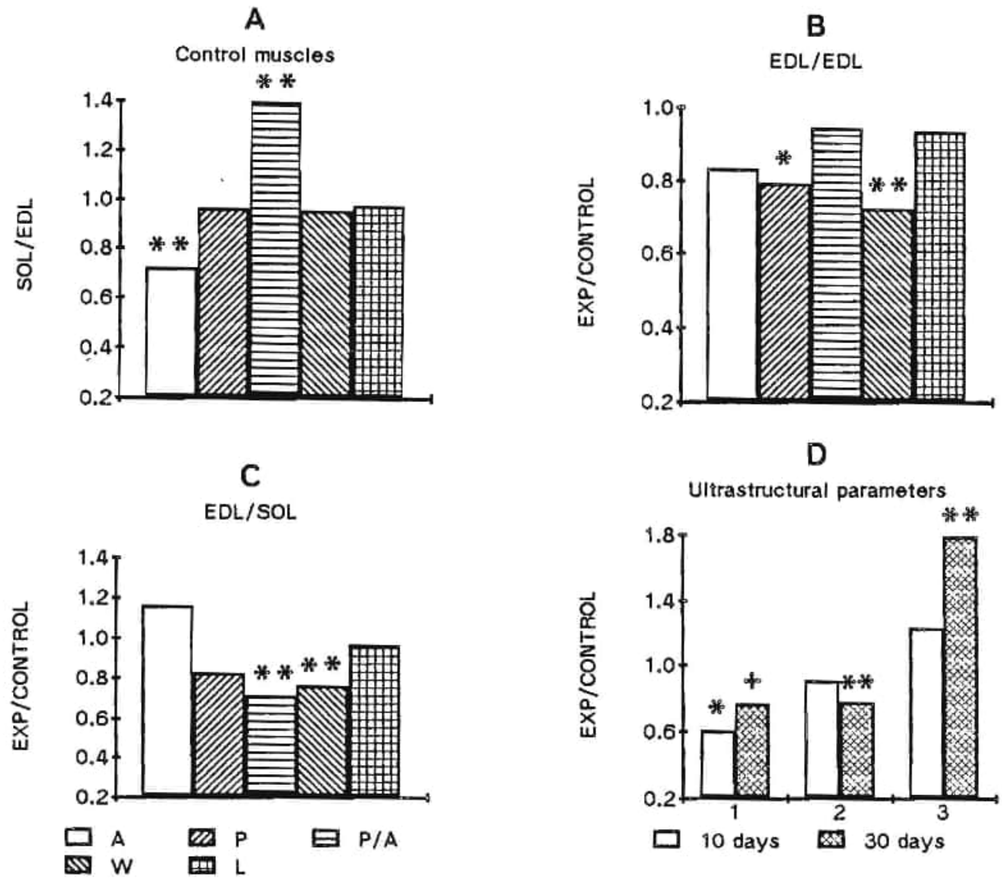

Figure 1 - Quantification and morphometry of NMJ structure in stimulated and control rat skeletal muscles as seen in cholinesterase-stained whole mounts (A-C) and in electron microscopic composites (D). **A-C**: bar graph of differences in endplate dimensions of control SOL (A) or of 10-day indirectly electro-stimulated (10 Hz) EDL muscle fibers (B, C) relative to contralateral EDL and SOL control muscles. Evaluations of the following parameters are shown: endplate area (A), endplate perimeter (P), perimeter to area ratio (P/A), endplate width (W) and length (L). **D**: bar graph of changes in ultrastructural features of nerve terminals from EDL muscle fibers continuously stimulated for 10 and 30 days relative to contralateral EDL controls: 1, number of synaptic vesicles/unit area of the terminal; 2, percent length of the primary groove in close unobstructed contact with the pre-synaptic axonal membrane; 3, spacing between secondary clefts. +, $p<0.05$; *, $p<0.025$; **, $p<0.001$.

evaluated on camera lucida representations included: endplate perimeter (the continuous length of the complete outline of all AChE-stained regions); endplate area (the integrated are within the endplate perimeter) endplate width and length (the maximum circumferential and longitudinal extent, respectively of the stained region). Ultrastructural parameters measured on electron micrographs included: number of synaptic vesicles/unit area of the nerve terminal; length of the primary cleft membrane in close unobstructed contact with the pre-synaptic membrane; spacing between secondary clefts. The data were treated statistically using ANOVA analysis of variance.

RESULTS AND DISCUSSION

By light microscopy after staining for AChE activity, endplates in SOL and EDL control muscles of young adult rats were found to differ in shape and size. In SOL NMJs primary clefts appeared mainly rectilinear, with branches variably oriented in respect to the long axis of the fibre. In most EDL fibres the configuration of primary clefts was revealed by continuous rows of distinct patches outlining a large and long oval area parallel to the main axis of the fiber. In 10-day stimulated EDL muscle the endplates appeared less complex, with regular and smooth outlines. By morphometry it could be seen (Fig.1, A) that endplates in fast and slow rat muscles were significantly different in area and in perimeter/area ratio, while they had similar length and width. In other words, primary clefts in rat SOL NMJs were found narrower that those in EDL muscle. In EDL continuously stimulated at low frequency, AChE-positive areas were significantly reduced both in circumferential extent (width) and perimeter (Fig.1, B); when compared with control SOL (Fig.1, C) stimulated EDL endplates showed a nearly 30% difference in width and complexity (perimeter/area ratio).
At the electron microscope, cross-sectioned profiles of NMJs from unstimulated contralateral EDL muscles were characterized by the presence of numerous nerve terminals localized on the muscular surface at a short distance from each others. Each bouton, deeply implanted in the synaptic cleft, was rich in clear vesicles with a few and small mitochondria. The secondary clefts, generally deep and straight, opened at an almost regular spacing all along the primary cleft. In the sole plate, myonuclei and small clusters of mitochondria and sarcoplasm were present. Conspicuous accumulations of these substructures to form a "raised area", typically found in SOL and also present in EDL of the mouse (4), were very occasionally observed.
As already reported for muscle fibres (1), in NMJs from stimulated EDL degenerative changes were nearly absent at any stimulation time considered and indirect signs of focal degeneration were seen in form of scanty lysosomal vacuoles. The most striking abnormalities observed at both 10 and 30 days after stimulation regarded the occurrence of several terminals within the same primary cleft and of small intact terminals associated with a larger expanse of clefts, often accompanied by a multilayered basal lamina of the Schwann cell. More frequently in 30 than in 10 days stimulated EDL muscle the architecture of secondary folds appeared involved by a great variability in shape, size, orientation and number. In addition, a very peculiar structure was observed in the area of the sole plate, built up by stacks of secondary clefts which were deeply embedded in the sarcoplasm and did not open into the outside space. Such a structure was of smaller size and less frequently encountered at day 10, while it appeared large and even bulging from the perimeter of the muscle fibre at longer time of stimulation.
By quantitative analysis (Fig.1, D), it resulted that nerve terminals of stimulated muscles contained a reduced number of clear vesicles/unit area, with a trend to recover; the percent length of the primary cleft in close unobstructed contact with the pre-synaptic membrane was significantly decreased, while the spacing of secondary clefts was increased.

From these results it is clear that, when subjected to long-term functional stimulation NMJs in fast muscle of young adult rat undergo pronounced morphological modifications. Taking into consideration the nearly absence of degeneration accompanying sprouting and retraction of nerve terminals (5) we can also argue that the great majority of the changes are part of a dynamic process of remodelling, thus giving once more relevance to the plasticity of the adult synapse. We would also point the attention on the concomitant modifications which are occurring in the muscle fibre (1). It has been shown that long-term stimulation of a fast muscle at a frequency which mimics the slow nerve firing transforms such a muscle in a slow one, in which a complex pattern of modulations is achieved as adaptive response to new activity demands (6). It has also been shown that by the use of the same stimulation protocol on the same type of muscle (EDL) in the rat a dramatic increase in slow myosin is induced when stimulation is directly applied to the denervated muscle (7), while an equally dramatic disappearance of fast 2B myosin heavy chain (MHC) is fully substituted by MHC 2A, but not by MHC 1 when stimulation is brought to the muscle through the nerve (1). Should this last be an intermediate step towards the complete adaptation of stimulated muscle, achieved without damage, it could give even more importance to the permanence of the nerve which while remodelling itself, controls and regulates the muscular trophism.

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QUANTITATIVE ASSESSMENT OF NERVE LESIONS CAUSED BY EPINEURAL ELECTRODE APPLICATION IN RAT SCIATIC NERVE- A PRELIMINARY REPORT

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INTRODUCTION

Since the beginning of Functional Electrical Stimulation (FES) of peripheral nerves for recovery of muscular function, many authors have investigated upon the question, whether this technique causes any morphological changes in the stimulated nerves. Especially the effects of cuff, coiled wire and intraneurally implanted electrodes on nerve integrity have been explored in many histological studies.(1,2,3)

The application of epineurally fixed ring electrodes used in this study is not very common, compared to other methods like cuff electrodes. Clinical (4,5) and experimental (6) experiences have already revealed excellent functional results of this method. The present study was done in order to quantify the extent of lesions caused by suturing annular stainless steel electrodes to the epineurium of a peripheral nerve.

MATERIALS AND METHODS

Animals
36 female Sprague-Dawley rats with an average weight of 255,7g underwent electrode implantation under general anaesthesia (12-14 mg Ketamin-hydrochloride/100g body weight).

Electrodes
Ring shaped electrodes (Inner diameter 1 mm) in connection with an electrode lead of 1 cm length were used. Electrode and lead were made from stainless steel (Ethicon 612 P). The lead was covered with a silicone tube (Dow Corning Silastic 602).

Implantation
In all animals the left sciatic nerve was exposed. Under microscope using microsurgical techniques four electrodes were positioned around the left sciatic nerve. Each electrode was sutured to the epineurium of the nerve separately.

Groups
Three investigation groups, called group 1, group 2 and group 3, each consisting of 12 animals, were formed. In each group all 12 animals had received electrode implantation to the left sciatic nerve; two rats had received microsurgical exposure of the right sciatic nerve (sham operation) and two animals had received a crush of their right sciatic nerve. The periods of electrode implantation were *10 days in group 1, 3 weeks in group 2* and *3 months in group 3.*

Explantation
In each animal both sciatic nerves were exposed and excised between the sacrum and the knee joint. Under microscope the four electrodes were removed from the epineurium of the left sciatic nerves. In all left sciatic nerves specimens situated 8 mm proximal, 8 mm distal and directly at the site of the electrodes were used for histological evaluation. The nerves of the right thigh served as controls and were harvested for histology at corresponding levels.

Processing
The nerves were fixed in 3% glutaraldehyde, postfixed in 2% buffered osmium tetroxide and embedded in Epon. For quantitative evaluation, 2 μm semithin cross-sections were cut on an ultramicrotome and transmitted via TV camera from the microscope (ZEISS-Axiomat) to a personal computer (IBM PS2/80) for image analysis. Cross-sections of the sciatic nerve at the three levels mentioned above were examined in regard to either signs of degeneration or signs of regeneration.
Following parameters were measured for each cross-section of the sciatic nerve :
- total cross-sectional area of neural tissue within the perineurial sheath
- area of nerve segments showing signs of de- or regeneration
- diameter of 500 normal-appearing nerve fibers
- diameter of regenerating and remaining intact nerve fibers in pathologically altered segments.

From these measurements the *altered area proportional to the total area* of neural tissue within the perineurium (percentage of altered area) was calculated.
Nerve fiber diameters were evaluated to confirm

the classification in normal appearing and pathologically altered regions of the sciatic nerve.

RESULTS

GROSS FINDINGS

At the time of autopsy a distinct increase in connective tissue around the electrodes was found in 6 of the 35 rats (one animal of group 2 died one week after electrode implantation), independent of investigation group. In 6 cases one electrode and in one animal (of group 3) three electrodes had not preserved their original position in contact to the epineurium and were found more distant to the nerve.

HISTOLOGICAL FINDINGS

Alterations

- Number of altered nerves

The number of sciatic nerves showing pathologically altered segments was 9 in group 1, 8 in group 2 and 5 in group 3. Lesions were seen in all levels of examination. Proximal to the electrodes only one specimen showed an altered region. At the level of the electrodes 14 of 35 nerves exhibited alterations. Distal to the site of the electrodes the number of sciatic nerves exhibiting pathologically altered segments was 9 in group 1, 6 in group 2 and 3 in group 3. In 4 cases (2 in group 2, 2 in group 3) alterations at the electrode level were not followed by altered nerve segments distal to the electrodes (Table 1).

- Appearence of lesions

Lesions referred to electrode application were usually arranged in segments and never widely disseminated over the whole cross-sectional area of the sciatic nerve.

Regions classified as pathologically altered appeared different in different examination groups.

10 days after electrode implantation (gr. 1), the injured sectors exhibited fragmented myelin sheaths, myelin globules, signs of myelin phagocytosis and a reduction of nerve fiber density due to slight increase in connective tissue or edematous swelling. Within these sectors a small amount of relatively large, normal-appearing nerve fibers could be observed (Fig. 1B).

3 weeks after electrode application (gr. 2), damaged nerve segments usually contained a lot of small nerve fibers with thin myelin sheaths and remnants of degenerated myelin sheaths.

3 months after the implantation procedure (gr. 3) remnants of degenerated myelin sheaths in combination with small nerve fibers indicated pathologically altered areas in an advanced state of regeneration in 4 cases (Fig. 1C). On the contrary, the altered segments still exhibited small nerve fibers and an increase in connective tissue in two specimens of this group.

- Extent of lesions

At the site of the electrodes between 3,46 and 12 % of the total area were damaged by elctrode implantation in group 1. Pathologically altered areas ranged between 0,7 and 13,03 % in group 2 and between 0,38 and 4,96 % in group 3.

Distal to site of electrodes the injured sectors occupied between 0,39 and 25,5 % of the total area of neural tissue within the perineurium in group 1. Corresponding ranges were 0,24 to 5,74 % for group 2 and 0,21 to 2,36 % for group 3.

Pooling all animals of one group the *average pathologically altered areas* at the electrode level captured 4,74 % (gr. 1), 2,18 % (gr. 2) and 0,57 % (gr. 3) of the total fascicular area. Corresponding values evaluated from cross-sections distal to the electrodes were 6,43 % in group 1, 2,62 % in group 2 and 0,27 % in group 3 (Table 2).

	GROUP 1 10 days	GROUP 2 3 weeks	GROUP 3 3 months
Total number of animals	12	11	12
Total number of left sciatic nerves exhibiting lesions	9	8	5
Lesions prox. to electr. level	0	1	0
Lesions at the electr. level	7	4	3
Lesions dist. to electr. level	9	6	3

Table 1: Number of sciatic nerves showing altered sectors after different periods of electrode implantation.

	GROUP 1 10 days	GROUP 2 3 weeks	GROUP 3 3 months
at the level of the electrodes	4,74%	2,18%	0,57%
distal to the electrodes	6,43%	2,62%	0,27%

Table 2: Mean altered areas, expressed in per cent of the total fascicular areas pooling all rat sciatic nerves of one examination group.

CONTROLS

Right sciatic nerves, which had not received any treatment, appeared similar to areas in left sciatic nerves classified as normal.
No signs of de- or regeneration could be detected in 6 right sciatic nerves, which had been just exposed but not received electrodes.
In all three investigation groups the qualitative appearance of alterations due to electrode application was well corresponding with the specimens of the right sciatic nerves, which had been crushed with a forceps.

DISCUSSION

In nearly all previous studies dealing with electrode-nerve interactions electrodes and electrical stimulation had been applied to the nerves prior to histological examination. The question remains, whether the influence of current or mechanical factors are responsible for the degeneration of nerve fibers during FES. (2,6) Relevant investigations revealed that peripheral nerves are resistent against the influence of electric current on condition that correct stimulation parameters are applied. (7)
In 5 years of clinical experience with the Vienna Phrenic Pacemaker a loss of phrenic nerve function was never observed. The present study was done in order to quantify morphological lesions caused mechanically by epineural electrode application.
10 days after implantation the sciatic nerves exhibited distinctly visible lesions. But only in 2 cases the extent of altered areas exceeded 12 % of the total area of the nerve. 3 months after electrode implantation none of the damaged nerve segments covered more than 5 %. Pooling all specimens distal to the electrodes in group 3 on the average more than 99 % of the total area of neural tissue were seen intact. In addition, all pathologically altered nerve regions in group 2 and group 3 exhibited signs of nerve fiber regeneration. Thus a long-term impairment of peripheral nerve function by the application of epineurally sutured electrodes is improbable.
The number and the extent of damaged areas in group 1 and the distinct decrease of these two parameters in group 2 and 3 lead to the conclusion, that the implantation procedure is the most important factor influencing nerve integrity. Persisting electrodes neither lead to new alterations nor prohibit nerve fiber regeneration.
These morphological investigations suggest that the epineural application of electrodes as described above does not alter the nerve to a higher extent. Thus epineural electrode application might help to overcome the problems seen with many other types of electrodes used for FES.

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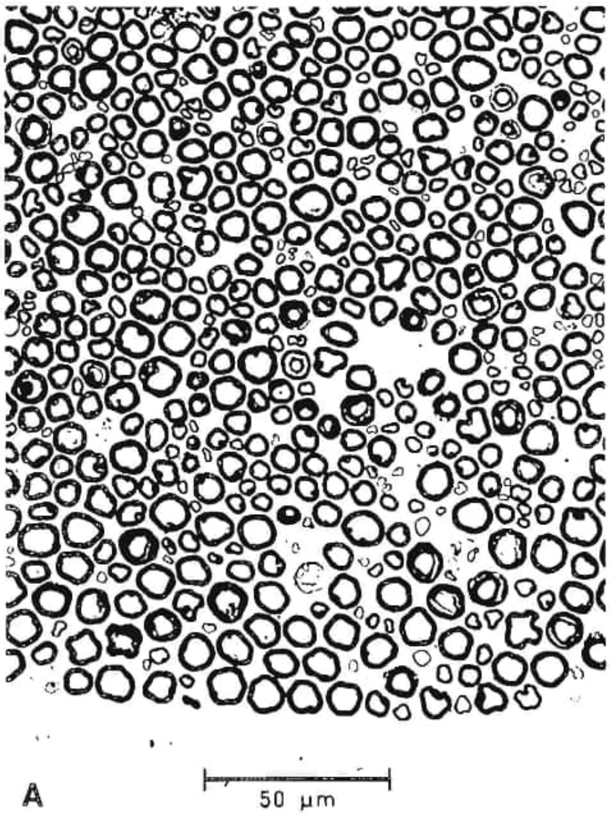

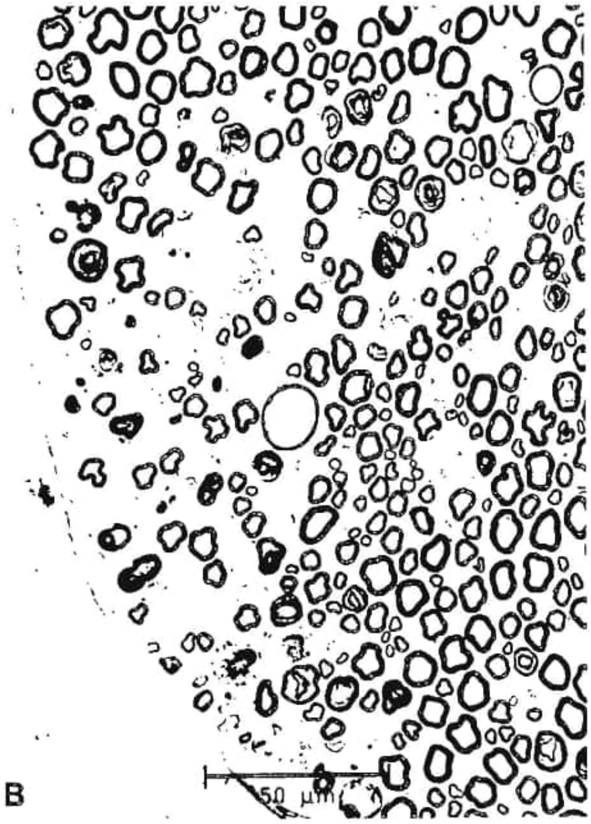

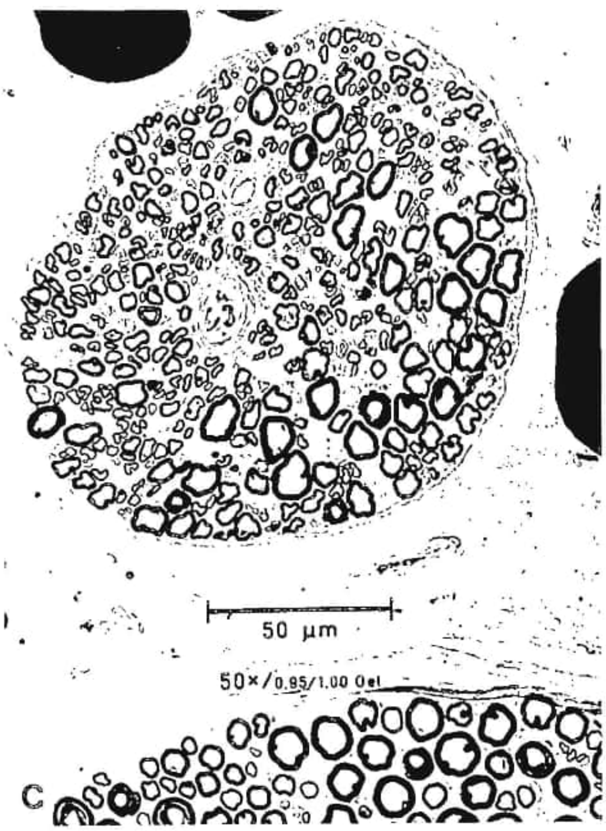

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Fig. 1: Semithin cross-sections of rat sciatic nerves 8 mm distal to electrode application

A: *10 days after implantation. No signs of degeneration*

B: *10 days after implantation. Segment of the common peroneal branch exhibiting signs of degeneration; the surrounding neural tissue is intact*

C: *3 months after implantation. Segment of a small fascicle with distinct signs of regeneration, the surrounding tissue and the fascicle at the bottom of the photomicrograph are intact*

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ULTRASTRUCTURE OF THE STRIATED MUSCLE ELECTROSTIMULATED IN EXTENTION.

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SUMMARY

The ultrastructure was studied in the rat fast extensor digitorum longus muscle maintained in extended position and stimulated at low frequency. Several anomalies were found in the contractile apparatus of this muscle: the length of sarcomeres was variable, individual myofibrils were dislocated, Z-line became wavy and it lost its continuity, the "Z-line streaming" and "rod-like structures" appeared frequently. A lot of polysomes were present between myofibrils. Contraction bands and other "degenerative" changes of the contractile structure were found occasionally. The majority of these anomalies may have been connected to the adaptation and remodeling of muscle fibers, but degenerative and necrotic processes took place in the studied muscles as well.

INTRODUCTION

It is well known that in the muscle maintained in excessive extension or in excessive shortening, a number of sarcomeres increase or decrease, respectively, to reach the sarcomer length optimal for function. Increased activity induced by indirect electrical stimulation of such muscle accelerates these processes /1, 2/. In the present work the fast muscle maintained in excessive extension was electro stimulated at low frequency and ultrastructure of the contractile apparatus was studied.

MATERIAL AND METHODS

Adult female albino rats (160 -180 g of body weight) of Wistar strain were used. Fast muscle, extensor digitorum longus (EDL) was maintained in extended position by immobilization of the ankle joint at an angle of 130-160 degrees. The sciatic nerve was stimulated for 4 - 12 hrs by pulses of 0.3 msec of duration at a frequency of 20 Hz. The following muscles were used as controls: EDL from controlateral legs and from normal rats, EDL and soleus muscles stimulated without immobilization of the ankle joint.
To evaluate the frequency of the ultrastructural anomalies of the contractile apparatus, muscle samples were randomly selected and studied as described /3/. All the fibers

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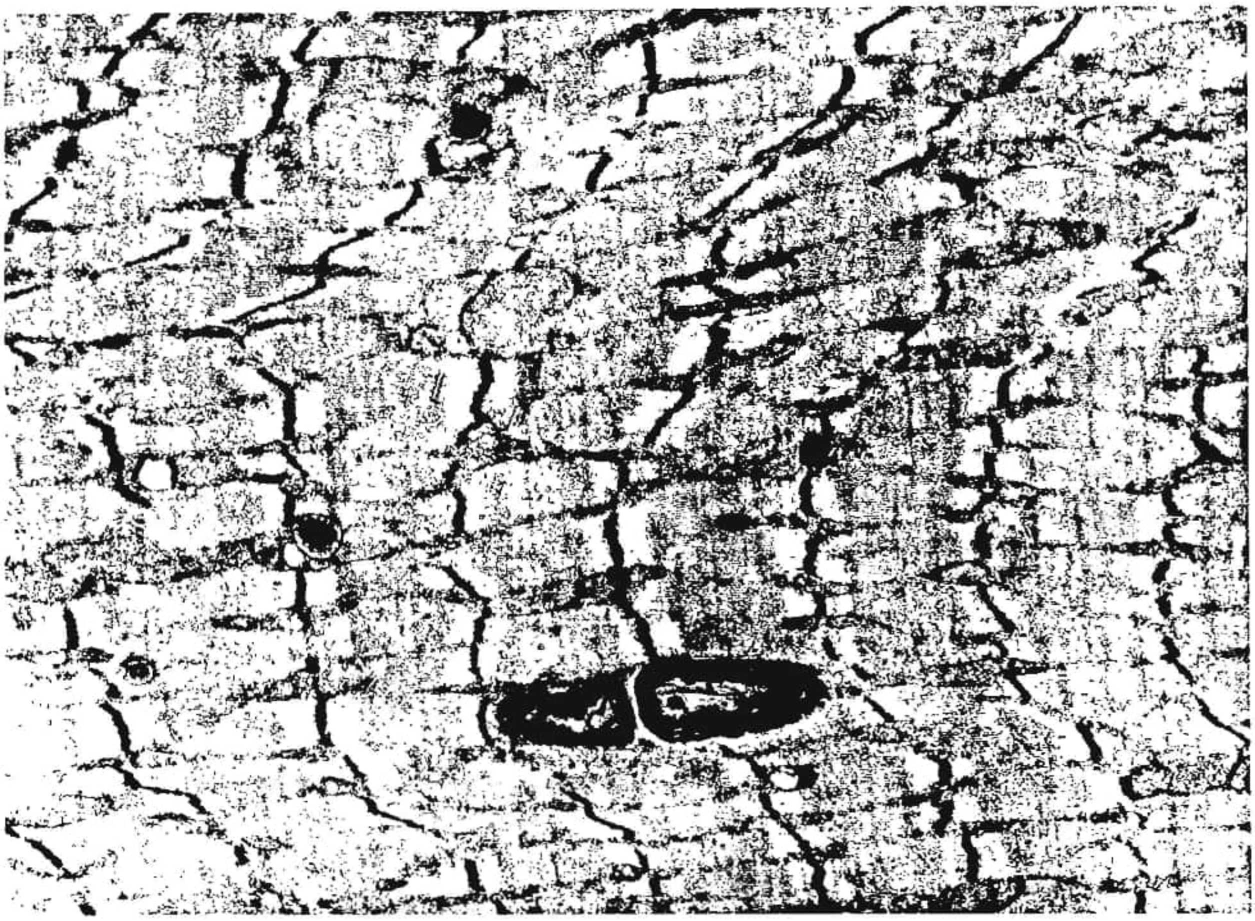

Fig. 1. EDL muscle stimulated in extended position for 12 hrs. Sarcomeres of nonuniform length, the Z-line wave and irregular, lysosomes present.

present in the sample were observed and used for quantitative evaluation. More than 700 fibers were studied; a minimum of 100 in each group.

RESULTS

EDL muscles stimulated in extended position increased in length to 112-130% of the contralaterals, while the length of EDL muscles stimulated without immobilization of the joint remained unchanged.

In the majority of the fibers the contractile apparatus of the extended-stimulated EDL muscle became irregular, showing several anomalies. Length of sarcomeres was not uniform (Fig. 1) within individual fibers and between fibers. Individual myofibrils or groups of myofibrils were dislocated in 46% of the fibers studied. The Z-line lost its continuity and became irregular or wavy (Fig. 1). "Z-line streaming" and "rod-like structures" were frequent (Fig. 2): "rods" were observed in 13% of the fibers. Triads became irregularly placed and dilated. Contraction bands (Fig. 3) were found in 7% of the fibers, total disorganization of the myofibrillar order in 5% of the fibers. "Post-mortem-like" changes, as well as empty fields within the contractile structures were seen occasionally. Only about 30% of the fibers studied looked normal (Fig. 4a), however polysomes between myofibrils and also lysosomes were observed practically in all the fibers. Mitochondria were well preserved in some fibers, while they were swelling or

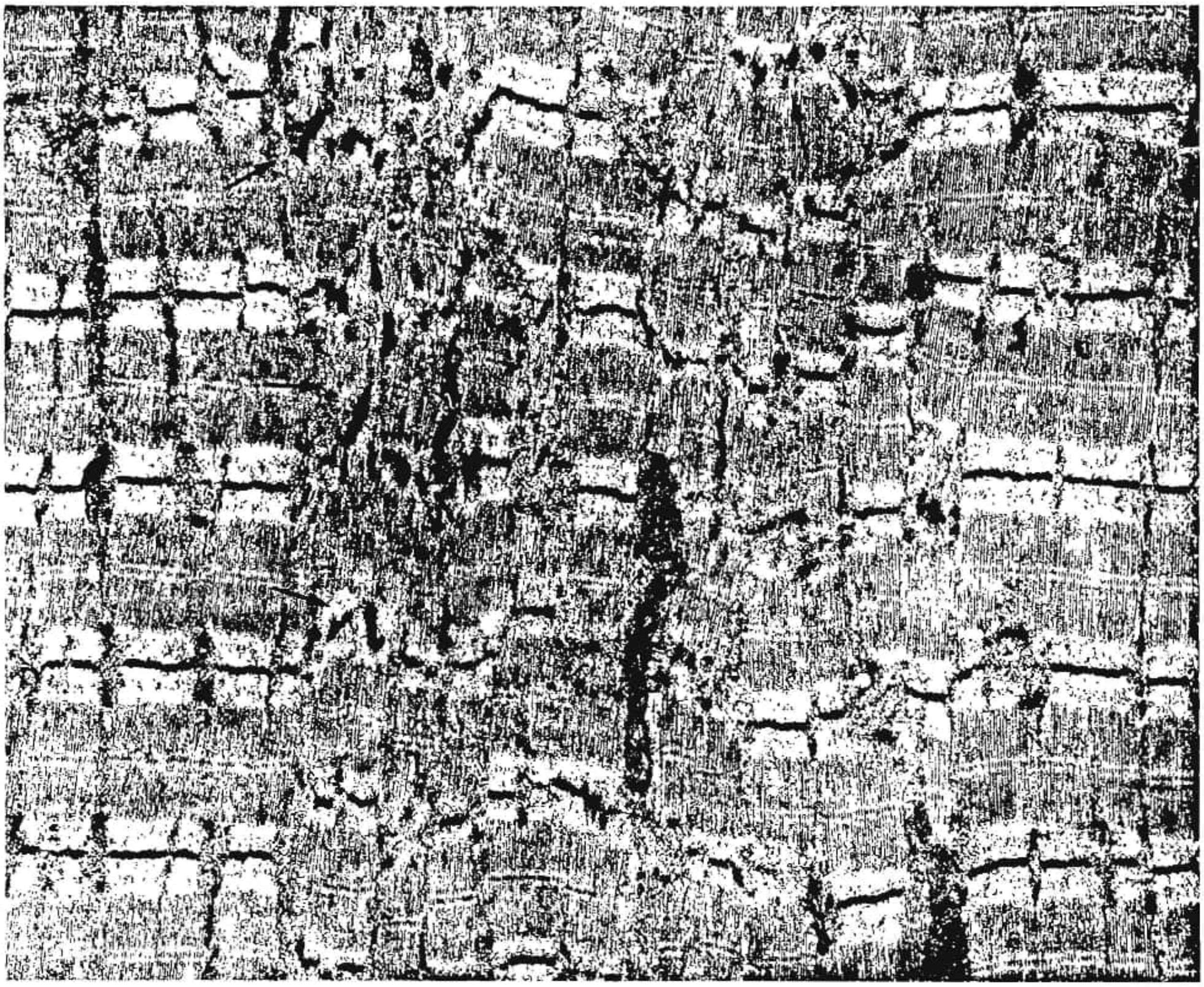

Fig. 2. EDL muscle stimulated in extended position for 6 hrs. "Rod-like structures" (arrows) present within irregular groups of myofibrils in which sarcomeres are shorter than in neighbouring regular myofibrils.

disrupted in others. These anomalies were observed as soon as 4 hrs after stimulation and they were still present in 12 hr stimulated EDL muscles.

Some of the above mentioned anomalies of the contractile apparatus were also present in lower quantities in the EDL muscles stimulated without immobilization, but "post mortem-like changes" and total disorganization of filaments were absent and contraction bands

were found only in 1% of the fibers. Thus, in contrast with the extended-stimulated EDL, the contractile apparatus of both EDL and soleus muscles stimulated without extention (Fig. 4 b and c) were in general well preserved, though less regular than in normal EDL muscles.

DISCUSSION

Several different processes concomitantly take place in the EDL muscle maintained in extended position and continuously stimulated at low frequency. Both the anabolic and

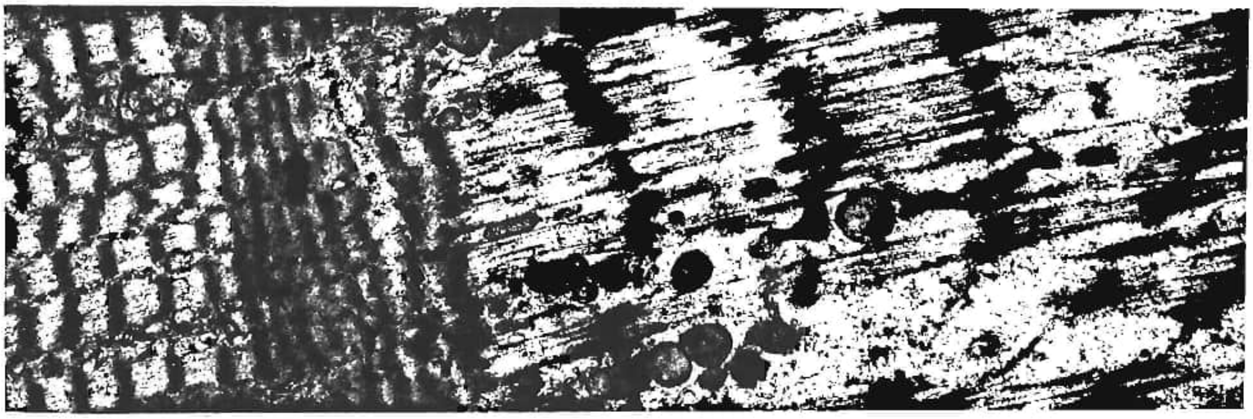

Fig. 3. EDL muscle stimulated in extended position for 4 hrs. Damage of the contractile structure: contraction bands (left side), overstretching of sarcomeres and loss of contractile structure (centre and right side).

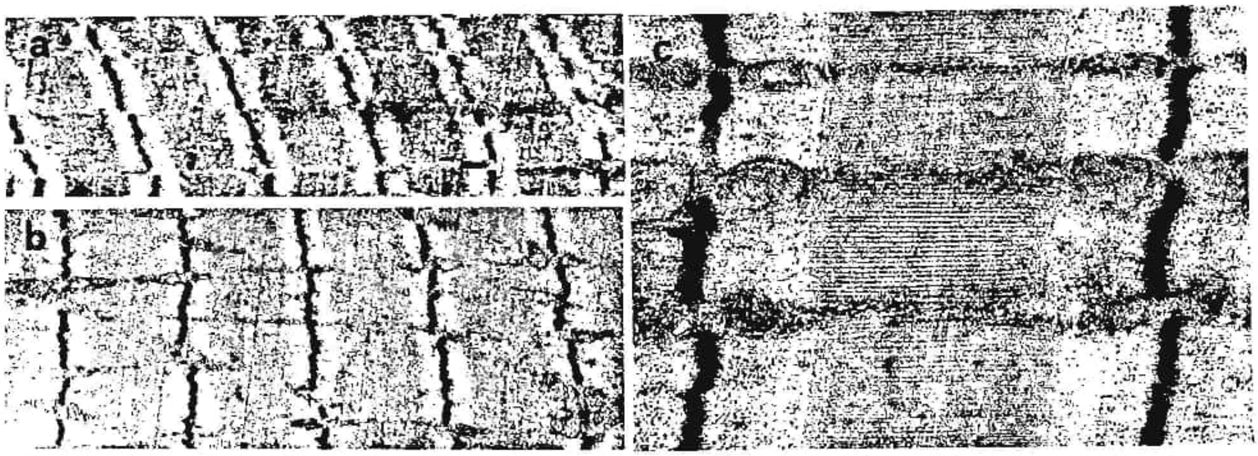

Fig. 4. (a), EDL muscle stimulated in extended position for 4 hrs; (b), EDL and (c) soleus stimulated for 6 hrs without joint immobilization. The contractile structure looks normal, some irregularities of the Z-line.

catabolic processes seem to be accelerated in such a condition as it is suggested by the increased amount of polysomes and lysosomes in the myofibers.

In this paper we have focused our attention on the ultrastructure of the contractile apparatus. We have found changes suggesting both adaptation and damage of it. One must take into consideration that the stimulation protocol used imitates the activity of slow-fatigue resistant motor units and therefore impose an unusual pattern of activity to the EDL. Indeed the pattern of stimulation we used is similar to that usefull to induce fast to slow transformation in rat, rabbit, mouse, dog, sheep and humans fast muscles /4 - 7/. Furthermore, since the EDL is overextended during work its sarcomere number is known to increase. For both these mechanisms a remodelling of the contractile apparatus must be expected. Indeed dislocation of myofibrils, irregularities of triads, nonuniform length of sarcomeres, and "rod-like structures", which we found in the EDL stimulated in extension, are also common in the nonstimulated fast muscle maintained in excessive extension, but only after some days /3/. Thus, in the electrostimulated muscle these anomalies seem to be connected with an accelerated reconstruction of the contractile apparatus (i.e. addition of new sarcomeres) in the muscle maintained in

extended tension. As far as the effect of acute stimulation alone is concerned, our preliminar conclusion is that the Z-line waving (similar to that presented in Fig. 1) is probably the most peculiar ultrastructural anomaly of contractile apparatus referable to the effect of increased contractile activity. Indeed this feature is common of stimulated muscles in shorten /2/, free and extended position.
On the other hand, some observations ("post mortem-like" changes, total disorganization of filaments and contraction bands) show that the contractile apparatus could be damaged, particularly in extended-stimulated EDL. Meaning of these observations is open to discussion. If they are steps towards fiber necrosis, they would confirm observations of other authors /8/ that muscle fiber damage takes place in stimulated muscle, and that the degree of damage is also related to the degree of eccentric contraction /9/. In any case our results may help to understand the meaning of ultrastructural observations in muscle subjected to unusal contractile activity, which can occurs in functional electrostimulation of muscles or in muscle pathology.

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LOW-FREQUENCY ISOTONIC STIMULATION ON DENERVATED MUSCLES OF THE MOUSE*

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SUMMARY

The isometric contraction characteristics of 4-month denervated and intact contralateral soleus (SOL) and extensor digitorum longus (EDL) muscles of mice were investigated *in vitro*. Transcutaneous electrical stimulation for 3 weeks (5 Hz, 1 hour/day) resulted in largely reduced twitch and tetanic forces in denervated SOL (65% and 59% of control denervated muscles) and EDL (53% and 46%) muscles, and in prolongation of contraction time (41%) and increase in ACh sensitivity in EDL muscles. Denervated-stimulated solei had significantly fewer muscle fibers per muscle than intact (-19%) and denervated (-14%) control muscles as well as significantly smaller muscle cross-sectional area than denervated controls (-27%). The data show that low frequency isotonic electrical stimulation has negative effects on denervated muscles most likely as a result of both muscle fiber loss and enhancement of fiber atrophy.

MATERIAL AND METHODS

Female C57Bl/6J mice (3 months of age; Charles River - Germany) were used. The animals were kept in standard plastic cages and received water and standard food *ad libitum*. Under deep narcosis (Nembutal, 40-60 mg/kg i.p.), a ligature was set around the right sciatic nerve and a large distal piece of the nerve was removed. To exclude reinnervation, the animals were controled every 3 weeks and the nerve was resected whenever necessary.

After a 4-month denervation period electrical stimulation was carried out in one group of animals under deep Nembutal narcosis daily for 1 hour, 5 days in the week for 3 weeks. Two electrodes made of thin silver wire and wrapped by moist tissue were put around the uppermost part of the thigh and around the ankle. Contact with the skin was assured by repeated moisturing with isotonic saline. Single pulses (5 Hz) gradually increasing in voltage until rythmic contractions of the foot were visible were applied. In the first 5-10 minutes voltage amplitude was constantly adapted to maintain optimal contractions without nociceptive reactions /3/. During stimulation and recovery from the anaesthesia the animals were kept warm by applying red light. Control animals were treated as the stimulated ones except for the application of current.

Acute experiments were performed 24 hours after the last stimulation. Muscles were isolated under anaesthesia and isometric tension measurements were performed *in vitro* as previously described /1/. Parameters studied were twitch and tetanic (50 Hz for SOL, 100 Hz for EDL) force, twitch contraction and half-relaxation time, twitch-tetanus ratio, ACh-induced contracture amplitudes (5 and 50 mg/l ACh), wet muscle weight and tetanic force/muscle weight ratio. After tension recordings, the muscles were frozen and cryostat sections were stained with toluidine blue and for glycogen phosphorylase activity /5/. Absolute numbers of muscle fibres in SOL were determined in videoprints

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(final magnification 250-390 x) of selected sections containing all muscle fibers. The total muscle cross-sectional area was calculated from the mean of the orthogonal axes of the section's contours in the videoprints as is described for single muscle fibres /9/.

RESULTS

The contractile characteristics of control denervated SOL and EDL muscles were typically changed as compared to intact muscles. The changes (not shown) consisted of: loss of twitch and tetanic force (in the magnitude of 4-7 times), increased twitch-tetanus ratio (1.5-2.1 x), prolonged contraction and half-relaxation time (1.6-4.2 x), presence of extrasynaptic ACh sensitivity, decreased muscle weight (about 3x), specific and normalized force (tetanic force per unit muscle wet weight and per unit cross-sectional area, respectively; about 2-fold). These results are comparable to data previously reported for the mouse /10/. Isometric force in stimulated denervated SOL muscles was further reduced and the twitch-tetanus ratio was additionally increased as compared to unstimulated muscles (Table 1). EDL muscles appeared even more heavily affected by stimulation since also contraction time, ACh sensitivity and muscle weight were significantly changed (Table 1). Time to peak and half-relaxation time did not differ significantly in stimulated and control denervated muscles (not shown).

Table 1. Contractile parameters and muscle weight of denervated and denervated-stimulated soleus and EDL muscles.

PARAMETER	SOLEUS Stimulated	SOLEUS Control	EDL Stimulated	EDL Control
Tetanic force (P_o, mN)	21 ± 1 + (4)	35 ± 8 (6)	21 ± 4 # (4)	46 ± 4 (4)
Twitch force (P_t, mN)	12 ± 1 + (4)	19 ± .4 (6)	12 ± 3 # (4)	22 ± 4 (4)
Twitch-tetanus ratio	.61 ± .02+ (4)	.55 ± .02 (6)	.55 ± .06 (4)	.47 ± .05 (4)
Specific force (N/g)	4 ± 1 + (4)	7 ± 2 (6)	7 ± 1 # (4)	13 ± 1 (4)
Normalized force (N/cm2)	7 ± .3+ (4)	8 ± 1 (4)	/	/
ACh contracture (50 mg/1,%P_o')	102 ± 8 (3)	92 ± 6 (5)	112 ± 15* (4)	75 ± 21 (4)
Muscle weight (mg)	5.5 ± .9 (4)	5.2 ± .5 (6)	3.1 ± .1+ (4)	3.5 ± .1 (4)

Values are mean ± SD. Number of observations in parentheses.
* - $p < 0.05$, + - $p < 0.01$, # - $p < 0.005$ compared with control denervated muscles (t-test). Specific force - tetanic force / muscle weight. Normalized force - tetanic force / muscle cross-sectional area.

The number of muscle fibers that could be identified at the light-microscopic level in denervated-stimulated SOL muscles (703 ± 31 SD, n=4) were significantly less than in control denervated (821 ± 49, n=4, $p < 0.01$, t-test) and intact contralateral (865 ± 100, n=4, $p < 0.025$, t-test) muscles. Muscle fibers in denervated SOL muscles appeared very atrophic with the impression of generally smaller muscle fibers in stimulated than in control denervated muscles. The total muscle cross-sectional area of denervated-stimulated SOL (0.31 ± 0.01 mm2, n=4) was significantly smaller than that of denervated controls (0.49 ± 0.13, n=4, $p < 0.05$, t-test). The area of contralateral muscles was 1.82 ± 0.13 mm2 (n=4). Signs of muscle fiber necrosis and phagocytosis or regeneration were not found in stimulated or control muscles.

DISCUSSION

Effective counteraction of denervation atrophy by direct muscle stimulation requires generally high amounts of applied activity, patterns that "mimic" normal nerve activity and different frequencies for fast and slow muscles /2,4/. One could expect that the "mild" stimulation (1 hour/day, 5 days/week) at low frequency applied in this study would be ineffective in counteracting muscle atrophy /see 4/. Unexpectedly, we found markedly negative effects in both the fast-twitch EDL and the slow-twitch SOL muscles. The influence on EDL was stronger than on SOL muscles which can be explained by the fact that EDL is more superficially positioned and thus stronger affected by the transcutaneously applied current. Another possibility is that the applied pattern of activity was much less "suitable" for the faster EDL muscle.

The strong decline in force of stimulated denervated muscles is readily explainable by the significantly smaller number of muscle fibers and muscle cross-sectional area. Muscle fiber degeneration had probably occured early during the stimulation period as no signs of accute degeneration, necrosis or phagocytosis were found at the time of the experiments. It cannot be excluded, however, that the "missing" fibers exist but are too small to be identified in the light microscope.

Physiological amounts (5% of daily time) of both high- and low-frequency stimulation of the innervated peroneus longus muscle of the cat causes a decrease in tetanic force and mean fiber diameter /6/. According to Hennig and Lømo /4/, low stimulus frequencies mimic more the spontaneous contraction of denervated muscle fibers (fibrilation) than the high activity of normal innervated muscles. It can be speculated that the applied stimulus frequency and amount of activity (about 4% of daily time) in some way trigger the acceleration of muscle catabolism and/or reduction in synthetic activity necessary to maintain the muscle fiber volume. However, such an effect might be species specific as in larger animals 1-Hz stimulation (predominantly isometric) appears to bring beneficial effects /8/.

Extrajunctional acetylcholine sensitivity appears to be primarily regulated by evoked activity /7/ and it is therefore difficult to interpret the increased sensitivity of denervated stimulated EDL muscles. Among other possibilities /7/, a simple explanation would be that the relatively stronger ACh contractures of stimulated muscles result primarily from relatively lower efficacy of the direct muscle stimulation, e.g. due to the presence of isolated muscle fiber fragments. This at the same time could explain the difference to SOL muscles which might be less damaged than EDL.

A major difference between the present and most other experiments on electrostimulation is that we have produced predominantly isotonic rather than isometric muscle contractions. It can be speculated that this condition alone might account for the pronounced negative effects found here since also innervated muscles in suspended animals show marked muscle wasting /11/. Clearly, the underlying mechanisms deserve further elucidation.

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THE EFFERENT MYOKINETICALLY STIMULATED SKELETAL MUSCLE IN ISCHEMIA AND REPERFUSION

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SUMMARY

There is evidence that the postischemic electrostimulation of the skeletal muscle might be a possible therapeutic approach to reduce multiple postischemic injuries (10). We investiated if the efferent electrical stimulation of skeletal muscle during ischemia might influence the energetic situation and the early inflammatory reactions during the reperfusion period. We obtained no evidence that electrostimulation during ischemia would improve the energetic state of the muscle or suppress inflammation considerably in the reperfusion period. For clinical applications resting conditions of free muscle flaps might be considered as most suitable for best postoperative results in plastic surgery.

INTRODUCTION

Skeletal muscle ischemia resulting from a disturbed blood perfusion causes pathological changes in the biochemical status of the system (3,4,7,8,9,11,12,13,14). Recently, skeletal muscle ischemia is considered as being responsible for early inflammation especially in reperfusion (2,3,6,8,11,12,14). After a maldistribution of blood or a no-flow-situation of certain muscle areas pathological concentrations of oxygen free radicals are generated which - among others - might induce migration of polymorphnuclear neutrophile leucocytes (PNML),(14). Activated PNML may further aggravate the pathological conditions by multiple tissue damage caused by excessive production of reactive oxygen spezies (1,2,3,5,6,7,8,14). There is evidence that the postischemic electrostimulation of the skeletal muscle might be a possible therapeutic approach to reduce postischemic injuries (10). We investiated if the efferent electrical stimulation of a skeletal muscle during an ischemic period might influence the energetic situation and the early inflammation during the reperfusion period.

MATERIAL AND METHODS

The studies were performed on the M. gracilis of 24 mongrale dogs (18 ± 3 kg B. W.). Under Valium-Ketanest(R)-anesthesia and during a common shock prophylaxis with HEAS-steril(R) 10% the ischemic period was induced by use of atraumatic microvessel clamps. After separation from the connective tissue the skeletal muscle was removed from its origin and insertion in order to avoid collateral supply to the muscle. The vascular bundle and the nerve were prepared up to 2 cm distal of its penetration in order to allow the proper application of the vessel clamps and cover electrodes for electrical stimulation (Anapulse-Stimulator, WPI-Instruments, New Hamden, USA.; stimulation at 20 V, 20 Hz, impulse duration 0.1 msec). Venous effluate was taken from the femoral vein via an abbocath catheter. After the preperation a preischemic resting period followed. In other to obtain comparable conditions for the activated as well as the resting muscle two groups of experiments were performed:
<u>Group 1:</u> 60 min ischemia during electrical stimulation immediately followed by a reperfusion period of 60 min under resting conditions.

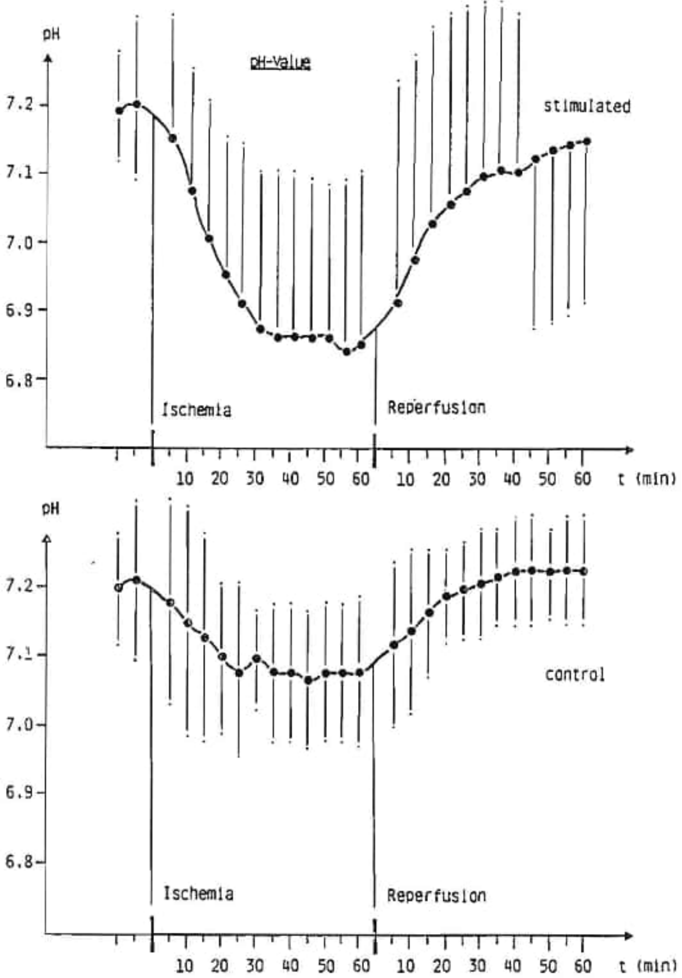
Group 2: 60 min ischemia under resting conditions immediately followed by 60 min perfusion under resting conditions for control.
In both groups the following parameters were measured:
(a) In 5 minute-intervals during the whole experiment: pH (electrode No. 83334), redox potential (electrode No. PT 4804 M6, both electrodes: Ingold, Frankfurt, FRG), temperature (digital temperature probe, type Impac, Philips)
(b) During the preischemic control period and during reperfusion (after 1, 5, 30, 60 minutes) the specific chemiluminescence was measured in the venous blood of the muscle (PMA-induced chemiluminescence (1) by using a Biolumat (LB 9500, Berthold, Wildbad, F.R.G.)

RESULTS

Although distinct interindividual differences are found in the measured parameters, obvious tendencies in the results obtained can be recognized. The mean pH is found to be in range of 7.20 in the resting ischemic skeletal muscle, decreasing in the preischemic period down to 7.08 after the beginning of the ischemic period about 25 min later. In the stimulated muscle the acidosis is found to be even more striking: after about 25 min. a maximal pH drop down to 6.85 can be observed. The postischemic period in both groups recovers from the acidosis up to the preischemic control level. The redox potential shows deviations of about 20 % in the resting and of about 40 % in the stimulated ischemic muscle compared to preischemic values. The postischemic recovery is found in both groups though a slight tendency towards elevating the redox potential during the late reperfusion period of the ischemic stimulated skeletal muscle is considered. A temperature decrease of about 1.8° C is obvious only in the stimulated skeletal muscle. The 'Specific Chemiluminescence' (CL) in group 2 decreases 1 min after the onset of reperfusion to about 95 % of the preischemic values, rising again after 5 min. up to 99 %, then reducing again after 30 min. down to 85 %, increasing once more after 60 min. up to the preischemic level. In group 1 a decrease of the CL 1 min after reperfusion down to 85 % of the control values is observed followed by a continuous increase up to 94 % within 60 min of posischemia.

DISCUSSION

The relatively distinct decrease of pH compared to the control might mainly be caused by the lactacidosis resulting from a forced anaerobic glycolysis (4,9,13). In general, there is evidence that the biochemical situation of stimulated muscle is turning worth during ischemia as compared to the control. This is underlined also by a deterioration of the redox potential which increases significantly in the stimulated muscle. This might further indicate an obvious shift of cellular redox processes towards the production of reduced metabolites (4,9,11,12,13). Mainly postischemically the reversibility of pH and redox potential might be a further hint to the hypothesis that the vital biochemical steady state in both groups is readjusted independently of stimulation. However, electro-stimulation cannot inprove the ischemic as well as the postischemic metabolism concerning the investigated parameters.
So far, an explanation for the temperature decrease during ischemia in the stimulated muscle remains open.
In spite of different ischemic conditions the leucocyte activity is suppressed in the first min of postischemia in both groups. Afterwards, it behaves in group 2 without any clear tendency. In contraste to group 2, the continuous recovery during postischemia in group 1 may indicate that leucocyte suppression is reversible after 1 h of reperfusion. However, concerning the CL, we found no evident relationship between the leucocyte activity and recently described postischemic inflammatory processes (1,3,6,14).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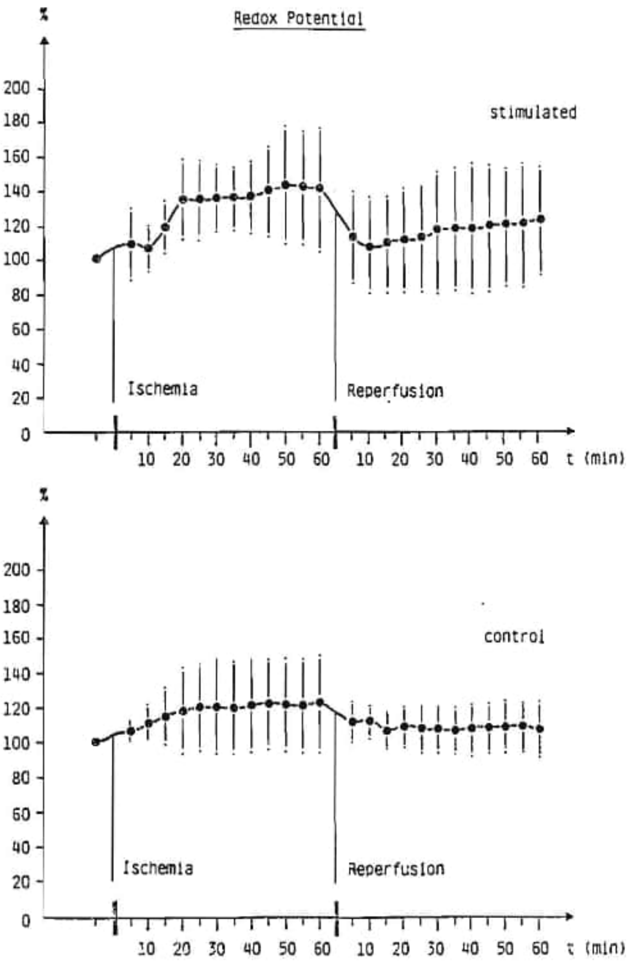
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Ischemia
Reperfusion
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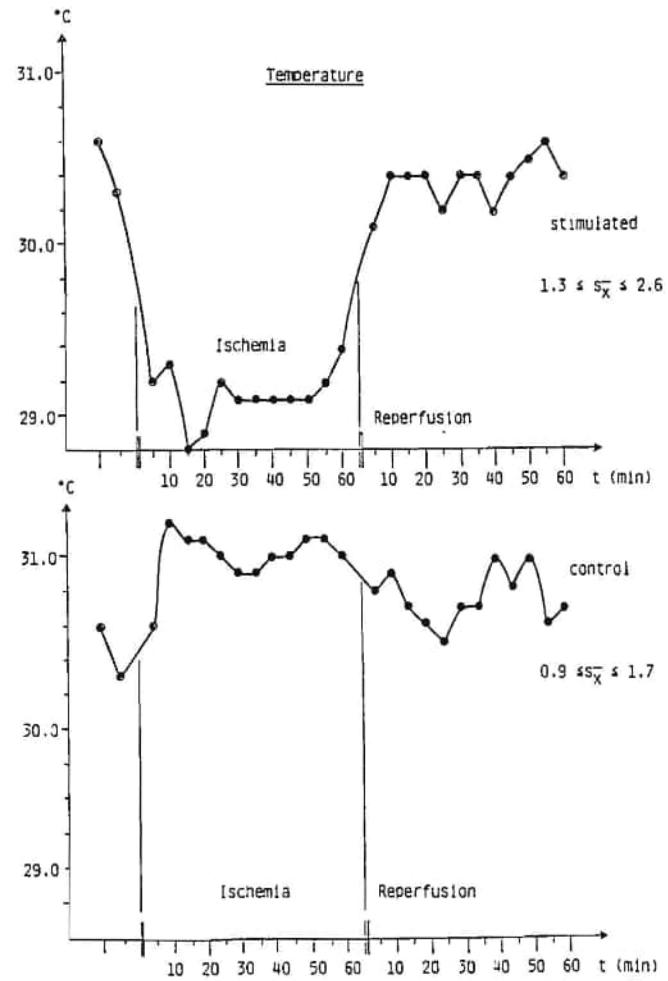
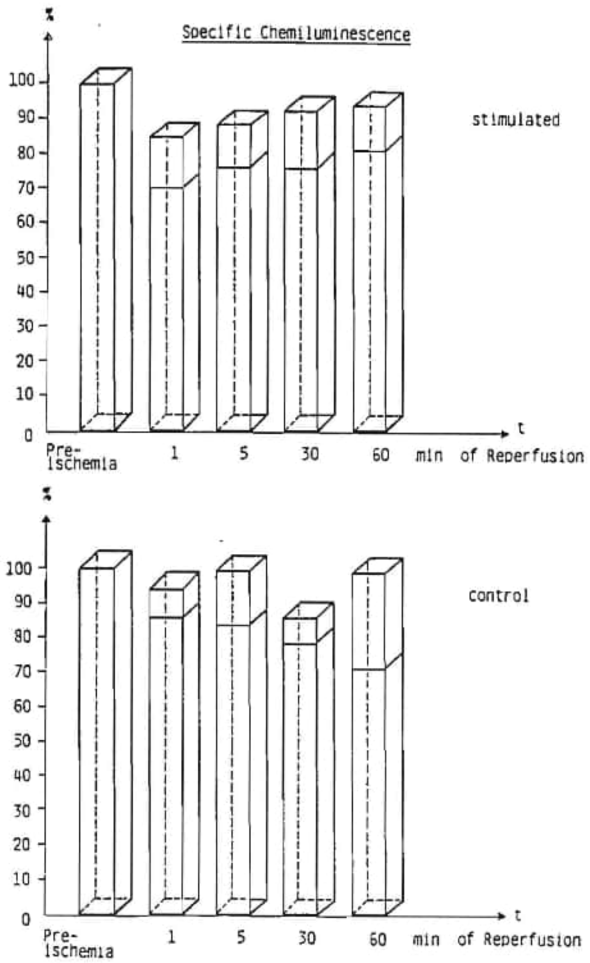

Temperature
°C
stimulated
$1.3 \le s_{\bar{x}} \le 2.6$
control
$0.9 \le s_{\bar{x}} \le 1.7$
Ischemia
Reperfusion
t (min)


Specific Chemiluminescence
%
stimulated
control
Pre-
Ischemia
min of Reperfusion

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AN ANALYSIS OF SWINGING GAITS AND THEIR SYNTHESIS USING FES

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SUMMARY

It is proposed to use Functional Electrical Stimulation (FES) to synthesise swing-through walking in paraplegics who otherwise cannot perform this gait. Preliminary to this study is a thorough understanding of swing-through in normals and those paraplegics with low enough lesions to be able to walk in this fashion.

In this study a sagital plane model of swing-through and swing-to gaits was used to investigate three different gaits: a normal performing swing-through, a lumbar lesion paraplegic performing swing-through and a thoracic level lesion performing swing-to.

It was found that the less the disablement, the faster the gait and the less energy that had to be supplied during the swing phase (by the arms) as opposed to the stance phase. The peak ground reaction force on landing is no higher than normal gait values and it was found that the moments required at the hip are within the ranges obtainable by surface electrical stimulation of paralysed muscle.

MATERIALS AND METHODS

Gait Analysis

The gait analysis system used was manufactured by Sakai in Japan and is based around a solid-state Charge Coupled Device (CCD) camera. It gives a resolution of 800 pixels horizontally and 500 vertically, which represent distances of approximately 5 mm and 6 mm respectively in the object plane. Joint positions were tracked by means of retro-reflective markers attached to the subject, which reflected an infra-red strobe towards the camera. Due to the symmetrical nature of the gait the analysis was performed in the sagital plane only. The sampling rate used was 30 Hz. The kinematic data thus collected was synchronised with the output of a Kistler force-platform to obtain ground-reaction forces (this was not performed for subject A). The human body was modelled as a multiple rigid link planar system with revolute joints, the number of links depending on the degree of disability. Static and dynamic loads were calculated using the body segment parameters of Contini and Drillis (1) and those of Braune and Fischer (2). A finite-impulse-response differentiator with a 6 Hz cut-off frequency was used to obtain velocities and accelerations.

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Subjects

Subject A was a 22 years old, 1.69m tall, male paraplegic with a T6/7 lesion, who weighed 55Kg. He performed a swing-to gait using a rolator, but preferred to use a wheelchair outside the laboratory.
Subject B was a 45 years old, 1.75m tall, male paraplegic with an L1/2 lesion who weighed 85kg. He was a skilled swing-through walker with elbow crutches and this was his gait of choice.
Subject C was a 25 years old, 1.85m tall, male weighing 73 kg, who was able-bodied. He was experienced in the use of elbow crutches for swing-through gait.

RESULTS

The results for a series of 6 tests with each subject are summarised in table 1. Following Shoup (3) the figures have been non-dimensionalised with respect to body height, weight or percentage of the gait cycle as appropriate. The peak ground reaction and hip moment are halved in the assumption that both feet contact the force plate simultaneously and that only the force on one foot is of interest to compare with the values for normal walking.

subject	mean speed (m/s)	stride length / height	peak ground reaction / weight	swing time / gait period	peak hip flexion moment in swing (Nm)
A	0.42	0.37	N/A	0.256	0
B	0.81	0.74	0.54	0.438	20
C	1.48	1.16	0.82	0.432	30

DISCUSSION

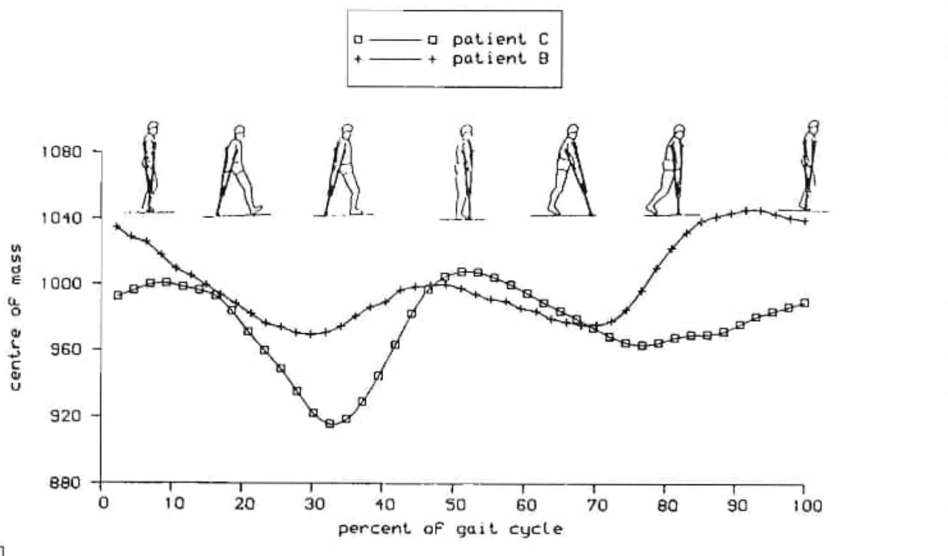
Swing through gait is fast but unstable. For those paraplegics with low enough lesions to be able to perform it, it is often the gait of choice. Attempts have been made in the past to produce it by means of FES (4) but these seem to have been largely intuitive, an approach which must be limited given the inherent instability of the gait and hence the need for an effective control strategy.
The purpose of this study is to prepare the ground for a programme to synthesise swing-through gait in paraplegics by means of FES. The chosen approach is to take the gait of trained normals as a measure of excellence, obtain their muscle moment histories by means of dynamical analysis and emg studies and then use these as the classes for an inductive learning algorithm (5) to automatically generate the rule base and hence select the best sensor set to recognise these classes. The sensors would then be used by the rule base in the synthesised gait to determine which state the subject is in and hence determine which control strategies should be selected.
The study of normals will also allow us to safely explore different strategies that may improve the efficiency of the gait, eg the use of

'Canadian' rather than elbow crutches. (6)

As would be expected these results show gait speed decreasing with level of lesion. The normalised ground-foot reaction forces are within the values quoted by Goh(7) for both normal walking and one-leg swing-through gait and hence should not be any more detrimental to the patients joints.
Wells (8) working with artificially disabled subjects (braced) found that the proportion of time spent in double support increased as disability increased. Whilst this is certainly true for subject A there is little difference between subjects B and C.

The peak hip moment required during the swing phase, which is critical in enabling the legs to swing through, is again within the range for normal gait as quoted by Peizer(9) and also within that obtainable by surface stimulation of hip flexors (10).

Figure 1 shows the variation in the vertical coordinate of the whole body centre of mass for subjects B and C, this is proportional to potential energy. Even though the total variations throughout the cycle are similar, subject C (the normal) injects most energy during stance (at about 30% of the cycle) hence the energy must come from his legs, this gives him a potential energy peak which is higher than the peak in mid swing, and means that the swing phase can be mainly ballistic. However, subject B must raise his centre of gravity considerably more to provide extra ground clearance, due to the loss of leg flexion, and this must take place in late stance/ early swing (about 70% of the cycle) and so this energy must come from his arms, the equivalent of doing a push-up once every cycle! This indicates the potential benefits to be gained in reduction of upper limb effort from FES augmentation of swinging gaits.



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FES POWERED RECIPROCATING GAIT ORTHOSIS FOR PARAPLEGIC LOCOMOTION: I. EXPERIENCE WITH A PATIENT GROUP.

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Eight paraplegics ranging in age from 18 to 41 years and injury level from T-1 to T-10 and postinjury period of 1 to 20 years were fitted with the LSU-RGO (reciprocating gait orthosis) and a 4-channel FES unit to alternate power to the quadriceps and contralateral hamstring such that swing phase and contralateral push-off are produced during locomotion. Locomotion experience was initiated after six weeks of FES therapy to the muscles to reverse atrophy of disuse.

Results show that effortless standing balance could be maintained indefinitely and locomotion was possible continuously for 1.2 and up to 4.25 hours. Maximal speed locomotion over 70 ft. resulted in velocities ranging from 31.1 ft/min and up to 68.6 ft/min at a cadence of 41 to 50 steps/min. Patient experience at home points out that additional improvement are need to allow safe and functional use on ramps, stairs, reaching down etc...

FES POWERED RECIPROCATING GAIT ORTHOSIS FOR PARAPLEGIC LOCOMOTION: II. ENERGY CONSUMPTION.

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Six paraplegics fitted with the LSU-RGO (reciprocating gait orthosis) powered with quadriceps and hamstrings FES were studied for the energy (O_2) consumption during locomotion with the RGO, RGO-FES and FES alone.

Energy consumption (Kcal/kg-min) and efficency (Kcal/kg-m) data demonstrate that reduction of cost and increase in efficiency for locomotion in the RGO-FES mode as compared to RGO alone. Heart rate data also confirm reduction of stress (12b/min) when using RGO-FES compared to RGO alone. Comparison with similar data of locomotion with FES alone further demonstrate the superiority of the FES-RGO mode.

STABILITY IN FES AND ORTHOSES ASSISTED PARAPLEGIC STANDING[1]

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SUMMARY

A study was undertaken of the relative stability during standing afforded by 3 different lower limb braces in a paraplegic, using measurement of centre of pressure (CofP) variations while standing on a Kistler force plate. The three braces used were a knee ankle foot orthosis (KAFO), functional electrical stimulation (FES) and a hybrid functional electrical stimulation floor reaction orthosis (FROH). Several parameters were calculated from the data: the mean speed of travel, mean radius, mean frequency of sway, and maximum and mean displacements in the anterior-posterior (A/P) and the medio-lateral (M/L) directions. Results indicated that the body weight was being carried through the legs and not through the upper limbs and hand support. Study conditions included standing using both hands, only the right hand, only the left hand, with eyes open and with eyes closed, and no hands for support with the eyes open. Stability with no hands was much less than with both hands for support in all cases. Using either hand for support afforded an intermediate degree of stability. Overall stability using some kind of hand support was comparable in the KAFO and the FROH. The poorest overall performance was with the sole use of FES to brace the knees. The best performance without using hands for support was given by the FROH. The KAFO performed poorly under this condition. FES was not tested without the use of hands for support.

MATERIALS AND METHODS

Subject.

One adult (age 22 years) male, T5-6 sensory and motor complete paraplegic, 5 years post lesion, who stands regularly in his KAFO. He also exercises daily using electrical stimulation to strengthen his quadriceps. He is in good health and does not take medication or suffer from vestibular or other disturbances that might impair his balance. He is right-handed.

Protocol.

The volunteer was asked to stand on the central area of the force plate, in a his usual posture. He was asked to fix his vision on a point ahead of him. He used an instrumented rolling walker as upper limb support. He was asked to stand quietly.

Data were sampled from the instrumented upper limb support and the force plate simultaneously for 15 second periods at 50 Hz using a 16 channel analog to digital converter (Amplicon PC-26) and recorded on to a portable personal computer (Compaq II).

Seven different conditions were tested in the KAFO and in the FROH, and only one condition with FES. The 7 conditions were: 1) standing using both hands on the upper limb support and keeping the eyes open, 2) both hands on the support with eyes closed, 3) only the right hand on the support with eyes open, 4) the right hand on the support with the eyes closed, 5) only the left hand on the support with eyes open, 6) left hand with eyes closed, 7) no hands on

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the support with eyes open. With FES just the first condition was tested. During the no hands condition, the subject did touch the support occasionally, usually with just one finger.

A given brace was tested under all its corresponding conditions twice. The first time, the instrumented handle of the upper limb support was on one side, the second time, it was put on the other.

Two different braces were tested in a session, trying no to test the same pairs tested together before or altering the order of testing if they had been tested together before. One session was carried out per week. The study took 4 months to complete.

Analysis.

For the force plate and upper limb support data collected, different analyses were done.

a) Force Plate Data. The data were filtered digitally with a low-pass finite impulse response filter at a cut-off frequency of 7.5 Hz, a span of 50 and using a raised cosine bell window. A number of parameters were calculated: the mean speed of the CofP displacement, the mean radius of the CofP, the mean frequency of the travel, and the mean and maximum displacements in the A/P and the M/L directions [3,4].

The mean speed is an indicator of the regulatory activity of the balancing system. The mean radius is a reciprocal measure of the effectiveness of balance, ie a measure of stability. The frequency is the ratio of mean speed and mean radius. The maximum displacements give an estimation of the size of the base of support used. The mean displacements indicate the relative stability in each of the A/P and M/L planes.

b) Hand Grip Data. The three orthogonal forces and the three corresponding moments were measured by the strain gauged transducer built into one of the two handles of the upper limb support [5]. The raw data were first filtered digitally with the filter described above. The mean, maximum and minimum values for each trial were calculated for all forces and moments. No large discrepancies between the minimum and maximum values were found. (e.g. no forces greater than the weight of the hand, were found in the vertical direction). The small horizontal forces and corresponding moments at the handle were considered to be due to balancing activity.

RESULTS

Table 1 contains the means and standard deviations of the resulting parameters of the CofP variations for each of the three braces for all hand support and vision conditions. The large standard deviations found indicate a large variability in the 15 s of data collection. Yet, the mean values found from session to session and brace to brace were very consistent, indicating good repeatability.

DISCUSSION

In all cases where the number of hands for support are varied, the use of both hands for support gave the most stability, as indicated by the smaller radius measurements, and smaller maximum displacements. The use of only the left hand was next followed by the use of only the right hand on the support. The use of no hands for support proved to be the least stable. The results in the

a) KAFO RESULTS

eyes open	KAFO	Two hands mean	Two hands stdev	right hand mean	right hand stdev	left hand mean	left hand stdev	no hands mean	no hands stdev
speed	mm/s	3.8	1.8	4.1	1.7	3.7	1.7	13.3	14.6
radius	mm	1.1	1	1.6	0.6	1.3	0.6	2.3	2.2
freq	Hz	0.7	0.35	0.44	0.17	0.48	0.12	0.85	0.21
max A/P	mm	5	4.6	6.3	3.1	4.8	2.2	13.5	15.2
max M/L	mm	2.8	0.9	4.2	1.1	4.9	3.4	6.1	3.8
mean A/P	mm	0.9	1	1.2	0.6	0.9	0.5	1.9	1.9
mean M/L	mm	0.5	0.2	0.7	0.1	0.8	0.3	1	0.7

eyes closed	KAFO	two hands mean	two hands stdev	right hand mean	right hand stdev	left hand mean	left hand stdev
speed	mm/s	2.3	0.3	4	3	3	0.8
radius	mm	0.6	0.2	1.3	1.2	1.1	0.6
freq	Hz	0.6	0.08	0.55	0.2	0.49	0.18
max A/P	mm	2.3	0.7	5.9	4.5	4.6	3.2
max M/L	mm	2	0.3	4.5	3.3	4.1	1.6
mean A/P	mm	0.4	0.1	1	1.1	0.8	0.7
mean M/L	mm	0.4	0.1	0.6	0.4	0.6	0.2

b) FES RESULTS

eyes open	FES	two hands mean	two hands stdev
speed	mm/s	7.3	3
radius	mm	1.9	2.2
freq	Hz	0.89	0.57
max A/P	mm	9.4	13.1
max M/L	mm	5.9	4.3
mean A/P	mm	1.5	2.2
mean M/L	mm	0.9	0.6

c) FROH RES

eyes open	FROH	two hands mean	two hands stdev	right hand mean	right hand stdev	left hand mean	left hand stdev	no hands mean	no hands stdev
speed	mm/s	3.4	2	4.2	2.1	2.5	0.1	5.5	1.5
radius	mm	1.4	0.8	2.5	1.4	1.2	0.2	2.3	0.4
freq	Hz	0.38	0.02	0.28	0.02	0.35	0.07	0.37	0.04
max A/P	mm	7.2	5.8	12.9	6.4	5	1.5	9.9	2.2
max M/L	mm	4.4	3.5	7.9	4.1	3	0.8	6.1	1.5
mean A/P	mm	1.2	0.7	2.1	1.2	1	0.2	2	0.3
mean M/L	mm	0.7	0.4	1.3	0.7	0.6	0.1	1.2	0.3

eyes closed	FROH	two hands mean	two hands stdev	right hand mean	right hand stdev	left hand mean	left hand stdev
speed	mm/s	1.7	0.3	4.3	0	2.5	0.5
radius	mm	1	0.9	1.5	0.1	0.9	0.5
freq	Hz	0.44	0.35	0.45	0.02	0.51	0.18
max A/P	mm	4.3	4	8.8	0.3	4.1	1.7
max M/L	mm	2.7	2.4	5.2	0.1	2.4	1.1
mean A/P	mm	0.8	0.7	1.3	0.1	0.7	0.4
mean M/L	mm	0.5	0.5	0.8	0	0.5	0.3

Table 1. a) KAFO means and standard deviations.
b) FES means and standard deviations.
c) FROH means and standard deviations.

parameters using the FROH tended to vary much less throughout the different conditions, including the no hands test. This could be due to the inherent stability of the brace itself. The relatively higher speeds recorded using FES suggest that a greater amount of regulatory activity is present than in the other cases.

The lowest and highest mean speeds were recorded in the KAFO tests. The lowest speeds were found in the hand supported tests, suggesting a minimal amount of regulatory activity was necessary. In the no hands condition, the increase in speed together with an increase in radius indicate that greater regulatory activity was needed, but was not enough to compensate for the adverse conditions and the stability still decreased.

The reduction in the mean radius and maximum displacements seen in most of the eyes closed results, compared to their eyes open counterparts reflects the higher dependence on vision that the paraplegics have in maintaining their balance since the proprioceptive posture control mechanisms are impaired. This is explained as a voluntary reduction of movements to a minimum to ensure they stay well within their base of support.

The largest base of support was found in the KAFO without hands followed by the use of FES with hands. The M/L displacements using FES are substantially larger than in any of the other braces. This could be due to instability caused the lack of ankle bracing.

The results of the FROH compared to those of the more conventional KAFO are very promising as they afford a comparable degree of stability using hands for support, and a superior degree of stability when not using hands for balance during standing. The FROH is smaller and lighter than the KAFO, and easier to don and doff. The FROH combining the characteristics of FES and the FRO proved to be the superior alternative in most cases. The paraplegic volunteer expressed a preference to use the FROH over his KAFO in his regular standing session.

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DEVELOPMENT OF PRACTICAL HYBRID FES SYSTEMS

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INTRODUCTION

Our clinical experiences point out that only small number of patients give increased functional status as the main motive for using FES. More often the stated motives to persevere with FES at home are of an esthetical, sportive or therapeutical origin. This finding is due to limitations of the system we can offer.
To be clinically applicable a system should:
- improve standing/locomotion function,
- be reliable/safe,
- be easy in use, and
- be cosmetically acceptable.

Our results with FES as well as the reported clinical results from other groups indicate that at this moment the total balance on these points is inadequate for the majority of patients. Presently the focus of our shortcomings seem to be the first two points.
The FES system most often used (4 channel stimulation: Quadriceps and flexion reflex) has two serious drawbacks. First the application of open loop stimulation fatigues the muscle too early and therefore limits the functional application and diminishes its reliability. Secondly most patients have problems with stability of the hip and trunk and we have not been able to overcome these problems with surface FES only.
Also inter patient variability requires a range of solutions to be able to optimize the system to each patient.
Therefore our clinically oriented research will be directed to the development of a modular hybrid system, which we see as the best mid-long range solution. With such a system the functions needed for standing and walking, i.e. body weight support, joint stabilization and movement, may be allocated to the orthosis or to the electrical system. As a first start-off the orthosis may be allocated to the stabilization function and FES to the movements but a syntheses of both capabilities may improve the overall functions quite considerably.
Presently our philosophy (with complete lesions) is to start of with a complete orthotic system, to enable safe long term standing. As a next step we will try to exchange the mechanical for electrical support as much as possible. This should result in an increase of function and cosmesis without loosing reliability and ease of use.
Important in this process will be a standardized method for feedback of clinical results, to come to a patient dependent optimization [1].

METHODS

Considering the control of the system both a high level and a low level control may be discerned (figure 1). The low level control is focussed on specific joints and has the function to stabilize or move the joints in pre-determined ways when enabled from the higher level. In the high level the control patterns have to be generated according to the patient's conscious commands and detected intentions. Additionally safety rules and an advanced patient control interface can be build in.

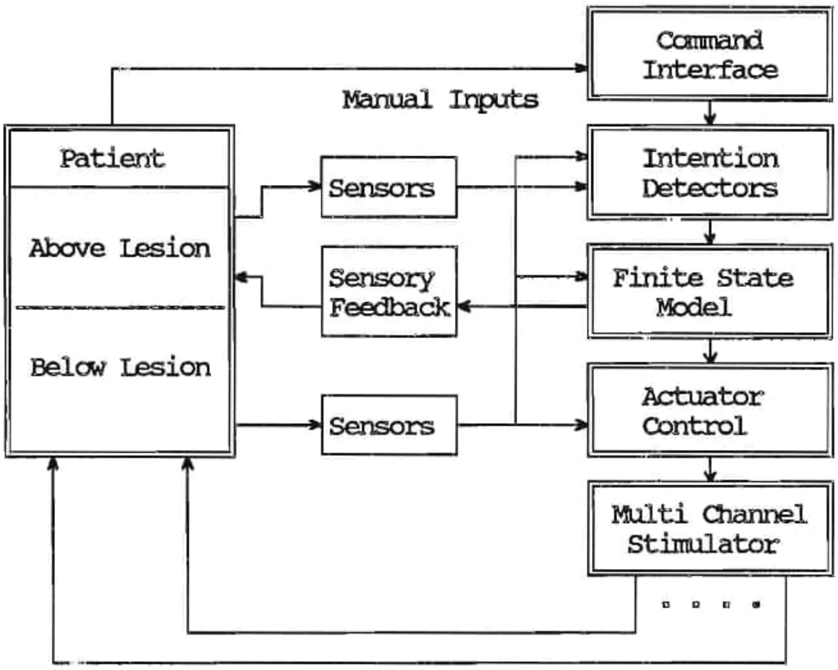

Figure 1. Block diagram of the hierarchical control system.

Control of ankle joint.

The paralysed leg may be mechanically stabilized, without FES, by limiting ankle dorsiflexion. Compared to electrical stimulation, mechanical bracing has the disadvantage of limiting dorsal flexion and therefore ground clearance requiring the foot to be lifted higher during swing phase.
Dorsal flexion of the foot can be obtained by stimulation of the flexion reflex or by efferent stimulation of the peroneal nerve.
Plantar flexion of the foot is attractive because propulsion may be obtained by evoking a good push-off of the swing leg. Also it may be useful to push-off the stance leg. This may facilitate the swing phase of the other leg, but it has the serious disadvantage that the stability of the patient decreases due to the small contact area with the ground, which makes the patient feel himself less safe.

Control of knee joint.

Much attention has been focussed on the knee because knee extension is crucial in obtaining and keeping a standing position. Traditionally the knee is extended by mechanical bracing, which undoubtedly still is the safest solution. Yet it has the serious drawback of necessitating also walking with locked knees. This compromises footclearance during swingphase and requires higher upperlimb force actions. It actually transfers the fatigue problem to the upper

part of the body.
For orthotic knee locking this means that an auto-releasing knee joint is favorable. We can also choose for FES induced knee locking. However, in that case closed loop control is needed in order to prolong standing for more than five minutes.
At this moment two systems are being investigated for their clinical possibilities, both based on finite state control algorithms:
1. the FRHO system.
2. the ARCK system.
Both systems were originally developed to prolong standing but may be incorporated easily in walking systems.
The FRHO system provides mechanical stabilization of the leg, when wheightbearing, by enabling the ground reaction force (GRF) to be directed ahead of the knee joint. Stability is conditional on the GRF not passing behind the knee joint axis. An artificial reflex was implemented to provide full stabilization. In this system, the action of the GRF at the knee joint is sensed and quadriceps stimulation is applied only when required [2]. The advantages of the system are that FES induced quadriceps fatigue is avoided, the knee joint is free to flex and the ankle joint may plantarflex.
The ARCK system uses a modified on/off (or ramp-down) control strategy based on finite state feedback of knee angle and angular velocity [3]. A repeated short time switch-on of stimulus amplitude stabilizes the knee joint. This reduces average muscle force independent of additional mechanical bracing or specific posture, and results in continuous dynamic activation of quadriceps. Preliminary results indicate good knee stabilization as well as quadriceps fatigue being significantly reduced.

Control of hip and trunk.
At this moment there is no electrical system that can be applied to stabilize the hip and trunk joints in the clinical or home situation. However, hip stabilization is needed for most patients (T12 and up). One of the problems is that the preferred musculature cannot be stimulated using surface electrodes (and there are no implantable systems readily available). Another problem is that there is no real joint end position (like in case of the knee) which would facilitate the control.
For the time being our attention will be focussed on improvement of the orthotic approach. One particular interesting system is provided by reciprocally coupling the hip joints as used in the LSU brace [4, 5]. Non-reciprocal movements are inhibited thus vertically stabilizing the trunk. Reciprocal movement may be initiated by voluntary trunk movements of the patient and can be facilitated by activation of hip extensors/flexors by (various combinations of) afferent and/or efferent stimulation. Our experience is that combining reciprocally linked hip joints (using cables as in the LSU RGO or by using a Bowdenflex flexible linearbearing as used in the Strathclyde systems) with this type of stimulation results in a considerable increase in step length.
With this component we have focussed on reducing hip friction (flexible linear bearings), reduction of weigh (carbon fiber) and adding modularity. We have also recognized that lateral stability of the upper part of the brace is a disadvantage during sitting in a wheelchair or car.

High level control.
At the University of Strathclyde experience is gained considering the 'translation' of the patient wishes into stimulation patterns. This is described in [2, 6].
At the University of Twente experience is gained with an operating system which was specially developed for implementation of finite state control schemes. The system uses path expressions do describe states and state transitions. The description format enables depicting concurrent or parallel processing. Through simulation performance of the system can be analyzed.

DISCUSSION

In this paper a number of methods have been described which are either a subject of research or are already clinically applied in one or both cooperating institutes. From this it will be clear that we do not aim at a particular solution of each problem. Due to the variety of patient characteristics it is needed that a variety of solutions are present. If hybrid systems are to be accepted in significant numbers we recognize the need to minimize all encumbering hardware that is donned and doffed (e.g. mechanical bracing, electrodes, sensors, electronic enclosures and interconnecting wires). This emphasizes the problem of an optimization procedure to fit the hybrid system to the wishes/demands of a particular patient. Also from the research point of view, with in mind the clinical application, it is important to know the present problems and to quantify the impact of modifications on the functionality of the system. This requires a systematic evaluation procedure considering the relevant aspects as mentioned in the introduction.

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SELECTIVE STIMULATION OF REXED'S SPINAL CORD LAMINAE IN RATS

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SUMMARY

In an animal test model for human spinal cord injury, a stimulation experiment for spinal cord motoneurones was developed.Caudally to a lesion microelectrodes were inserted into Rexed's lamina 9 of lumbar segments.By multisegmental intermittend stimulation a coordinated pattern of movements was induced in the lower extremities.The stimulation effect was measured by means of an integrated multichannel EMG recording from the muscles as well as by 2-dimensional estimation of the induced movement against a test weight.The stimulation of the first lumbar segments produced mass movements of the leg with extension and flexion in the hip-and knee-joint.Several muscles were contracted in their agonist or antagonist groups.The EMG-activity and the muscle power was found to be ranged according to the strength of the stimulation current.

MATERIAL AND METHODS

For the experiments 24 adult female Wistar rats of 300g body weight were used.All animal got a traumatic spinal cord lesion at the level of segment T 9 followed by a complete paraplegic syndrom without any motor control or movements in the lower extremities.The surgical technique was performed according the defined model experiment of spinal cord injury descibed by (2) and (4).21 days after the lesion, the stimulation experiments were carried out.In deep anaesthesia (Ketamin 20 mg/kg and Diazepam 10 mg/kg i.m.), in the level of segment T 13/L 1 a laminectomia was performed leaving the dura mater and spinal blood vessels intact.Especially for that purpose developed (4) fine microelectrodes were inserted transdural into the gray matter of lamina 9 of Rexed using a stereotaxic equipment. On both sides, one electrode was placed in each of the segment (T 13, L 1) in such a way that the stimulation current could be applikatet bilaterally over 4 electrodes at maximum. The stimulation current was provided by a computer-assisted (Z 80 processor) device, allowing freely programmable temporal application as well as control and various modulation of the current's amplitudes. Unipolar rectangular pulses (duration of a single pulse: 100 mic.sec., frequency: 80 Herz, current intensity: 20-200 mic.A.) were applicated.
The stimulation effect was recorded mechanically over a 2-dimens. measurement of direction and power of the movements induced in the hind-leg of the rat. Flexions and extensions movements were recorded against a constant resistance of 0,4 Newton.
Simultaneously, by bipolar needle-electrodes the EMG-activity was recorded over an EMG-multiplier (band-wide: 10-1000 Herz) from the following muscles: M.tensor fasc.lat., M.gluteus max., M.vastus lat. M.rectus fem.. All signals were digitally registered and further processed by a 16 bit-IBM-compatible computer,allowing a synchronuous demonstration of the movements completed by the integrated activity of muscles.

RESULTS

By one-channel stimulation of motor neurons in the gray matter of spinal segment T13 a flexion movement of the hind-limb was induced. This movement impones as a complete tetanus with considerable power development. In analogy to this, stimulation in the first lumbar segment resulted in an extension movement. Both effects were highly dependent on the electrode localization in that deviations from the position of the electrodes produced uncoordinated movements by contraction of different muscle groups, despite identical stimulation parameters. A positive correlation between stimulation current intensity and muscle achievement was found to exist within a certain range of stimulation (20-200 micro A). An enhancement of the stimulation current beyond this range resulted in sudden decreases of the muscle performance, mainly due to co-innervation of additional muscle groups (Fig. 1). By means of a 2-channel and temporarily seperated, sucessive stimulation with modulated current intensities, an intermittend flexion and extension movement can be evoced (Fig. 2).

Fig. 1

Muscle performance as function of current intensity

Ordinata: rel. ext. of movement
Abcissa : time (ms)

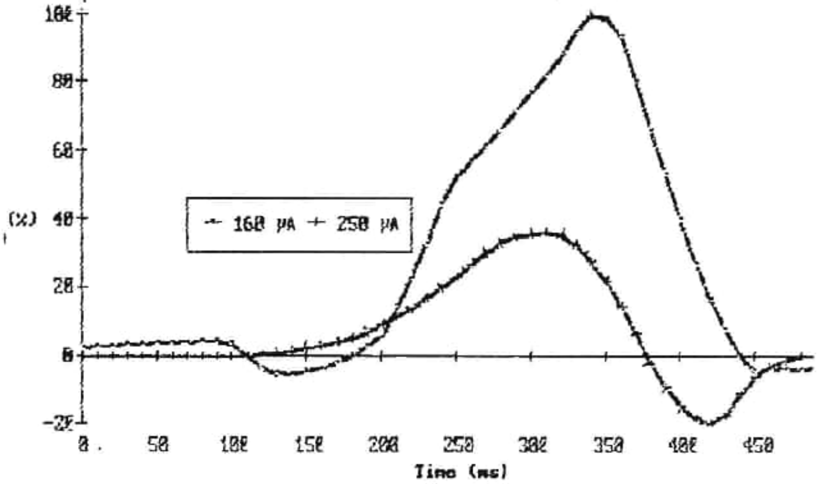
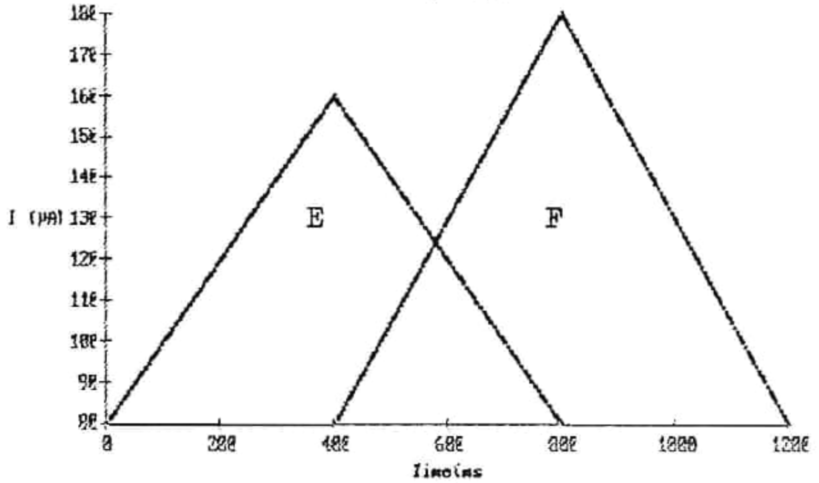
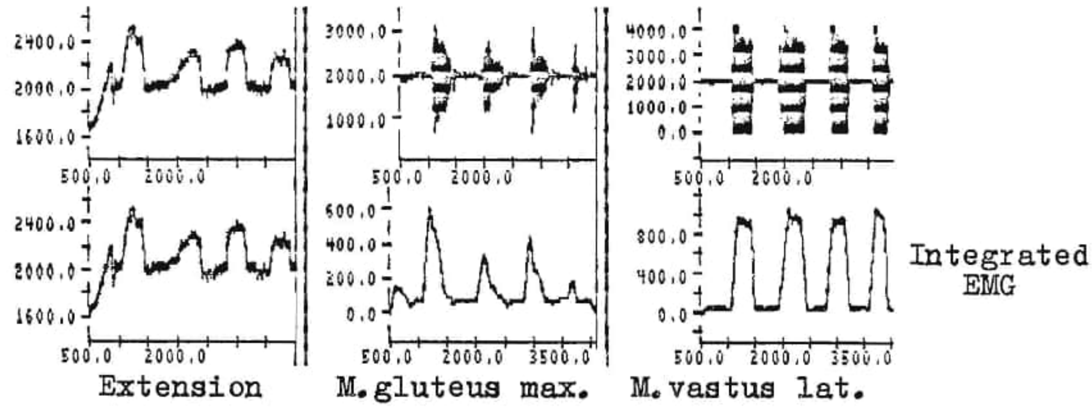


Fig. 2

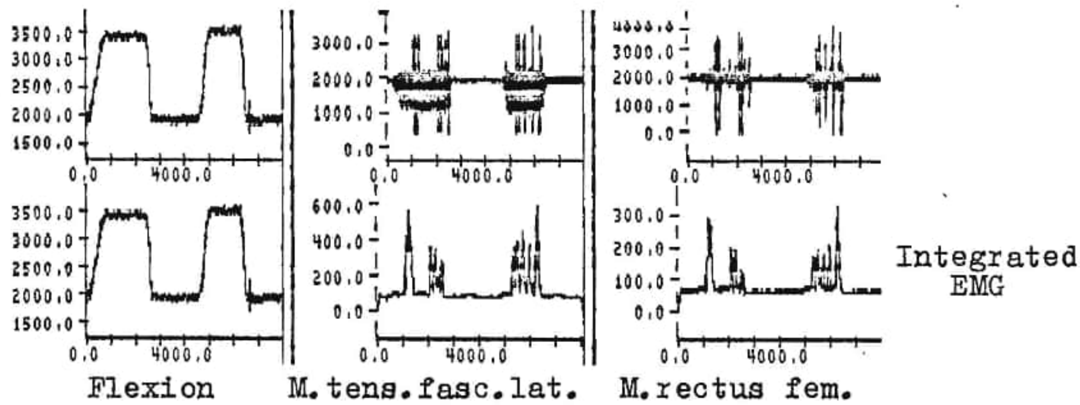
Inducement of extension (E) and flexion (F) by temporarily delayed stimulation



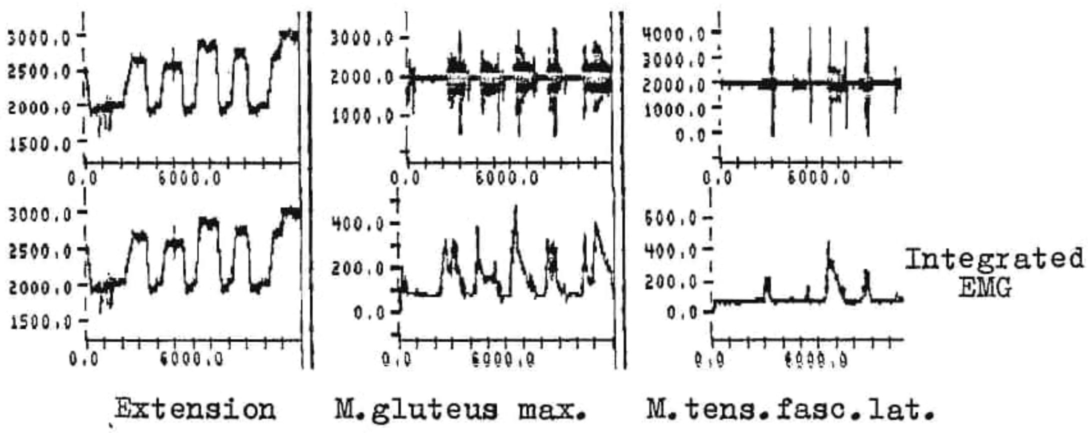
The EMG-activity of the muscle groups is correlated with the corresponding movement. So, the extension of the leg is characterized by the simultaneous activation of the gluteal muscle as well as vastus lateralis (Fig. 3: Ordinata: movements or muscle activity resp., Abcissa: time, 800 points = 1sec.). The level of innervation in the vastus lat. muscle surmounts that in the gluteal muscle, also when the current intensity is ranged.

Fig. 3


The flexion of the leg is produced by a simultaneous activation of the M.tensor fascia latae and the M. rectus femoris. However, in both muscles the strengh of contraction is different (Fig. 4)

Fig. 4


Agonist and Antagonist action is characterized by remarkable differences in the EMG-activity as is demonstrated in an extension movement (Fig. 5).

Fig. 5


DISCUSSION

The method of functional electrostimulation in some aspects might successfully intervene with motor insufficiency due to a traumatic lesion of the spinal cord (3). The unspecific epidural stimulation (5) is mainly used to influence spastic side-effects. The direct stimulation of the peripheral motor nerves or muscles is aimed to induce a compensatory locomotion in paraplegic patient. However, several factors are limitating the quality of the induced movements. A multitude of stimulation electrodes and channels are necessary to activate such a high number of motor units and muscles to obtain a movement pattern of sufficient high compexity as is required for the functional stability of the whole sytem. Therefore, as a third possibility we used the direct segmental stimulation of the lumbal spinal cord motor laminae making benefit from the intraspinal regulatory neuronal circuits and close arrangement of the neurons for the induction of mass movements in the lower extremities.
Corresponding to the segmental arrangement of motoneurons in the rat spinal cord and their innervation area (1), the stimulation of the upper segment T13 evoced contractions of the hip-flexors, that of the lower L1 segment contractions of extensors.
In contrast to the unspecific epidural stimulation of the motor pathway, the method of direct segmental stimulation offers a new possibility to induce a phasic agonist-antagonist action. Further investigations will show if a step-by-step walking can be obtained.

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DIAGNOSTIC AND MEDICAL EFFICIENCY OF SPINAL CORD ELECTROSTIMULATION IN PATIENTS WITH SPINAL TUBERCULOSIS

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SUMMARY

The work was performed with purpose to search for the suitable technique for diagnostics and treatment of "incurable" patients with spinal tuberculosis. The electrodes were implanted into posterior epidural space at lumbar, thoracal and cervical levels. The conductance of the ascending pathways was estimated by the presence of ESP at the C 6-7 level induced by lumbar enlargement stimulation. The descending pathways were tested by cervical enlargement stimulation with the recording of evoked responses in lumbar enlargement and leg muscles. This technique improves the results of surgical intervention due to more presice diagnostic. The antero-lateral decompression followed by the course of electrostimulation gave satisfactory results in patients who were considered "incurable".

METHODS

For the determining of functional state of the spinal cord the electrodes were implanted into posterior epidural space at lumbar, thoracal and cervical levels 10-15 days before the operation. EMG-activity of leg muscles during their voluntary activity, H-reflexes, evoked spinal potentials (ESP) at the C 6-7 level in response to lumbar enlargement stimulation, and ESP in lumbar enlargement induced by cervical stimulation were recorded. The potentials were amplified by electromyograph (DISA) and averaged by computer (ANOPS-101).The intensity of stimuli of 1 ms duration was selected individually.

The sceletation of vertebrae bodies, anterior and lateral decompression of spinal cord, meningoradiculolis, electrode implantation into anterior epidural space,anterior spondilodosis by autotransplantates were performed during the operation. The posterior (when necessary) decompression of spinal cord were reached by resection of posterior parts of vertebrae bodies. 1-2 weeks after the operation the electrodes were reimplanted into posterior epidural space at the same levels. The postoperative diagnostics was followed by the course of stimulation consisted of 15-64 daily procedures each of 45-55 min duration.For better acquaintance with the methods used see Fig.1-2

RESULTS

90 patients of 5 to 60 years old were examined and treated.The effect of electrostimulation was estimated by the regress of neurological sympthomatology as revealed by clinical

and electrophysiological methods.Under conditions of spinal cord compression the effect of electrostimulation was transitory or none. In contrast, in operated patients electrostimulation gave the steady effect even in 2-7 years after the decompression. As a rule the antispastic effect may be reached by 30-100 Hz stimulation but the cases of muscle super- hypertonus need 0.5-1 Hz stimulation. The prolonged low-frequency stimulation of 1-7 Hz results in 1-1.5 marks increase in muscle strength broadening of leg movement volume. The disturbances of pelvic organs function (enuresis) can be cured in two steps: the low-frequency stimulation leading to the persistent contraction of urinary sphyncter and the following high-frequency stimulation until the normalisation of urination. Under conditions of sough lesions postoperative stimulation of 0.5-70 Hz was most effective when applied locally to the anterior epidural space at decompression zone. The positive effect of the stimulation was confirmed both by electrophysiological tests and by subjective evidence.

DISCUSSION

At present time there are many patients, endured tuberculosis spondylitis, with rough deformations of spinal column resulted from prolonged compression of spinal cord and its roots by residues of vertebra bodies, caseosus masses, sequesters and epidural abscesses/1/. The conservative methods of treatment are not effective and lead to the spreading of neglected cases. So, the operative treatment is now the basic way to the reabilitation of such patients/2/. The estimation of functional state of the spinal cord is nessesory for development of the optimal tactics of the operative intervention. Our diagnostic method allows to estimate the degree of the spinal cord conductive pathway's lesions quite satisfactory. For instance, when testing the descending systems by the cervical enlargement stimulation, we recorded both ESP at lumbar enlargement and EMG-responses of leg muscles. While ESP might be induced both by orthodromic and antidromic impulses/3/ the leg muscles contraction strongly evidences in favor of conduction along the descending pathways. The method revealed that as a rule patients with spinal tuberculosis have the lesions of the descending spinal pathways. At the same time the peripheral reflex arc revealed by H-reflex characteristics, and motoneurons excitability is normal. The data shows that patients with spinal tuberculosis have the deficit of supraspinal influences. As a result of operation, the essential regress of spinal disorders is reached in 81.2% of cases. However, the simptomatology of spinal cord lesions retains to some extent, moreover , the rough disturbances of spinal cord are remained incurable (such as the deep paraparesis and paraplegia, the distribuces of pelvic organs functions). The conventional methods of post-operative treatment are ineffective in such cases. The course of stimulation led to the recovery of conductance in spinal cord pathways due to the "beating" phenomenon.

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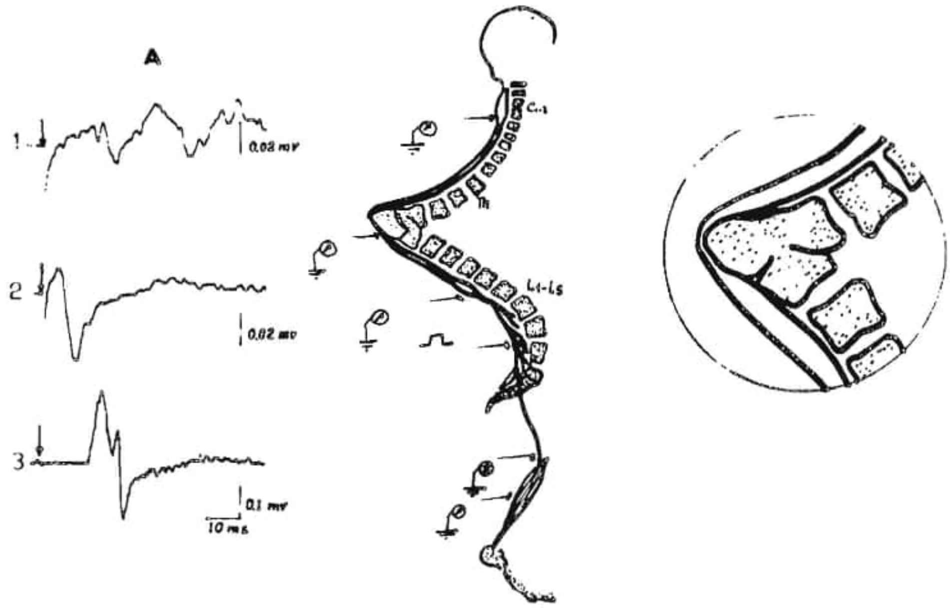

FIG. 1 THE TESTING OF ASCENDING PATHWAYS OF SPINAL CORD IN PATIENTS WITH SPINAL TUBERCULOSIS. (BEFORE OPERATION) A. THE POTENTIALS RECORDED FROM THE POSTERIOR EPIDURAL SPACE AT TH-12 (2) AND C-6 (1) LEVELS AS WELL AS FROM M. GRACILIS(3) IN RESPONSE TO LUMBOSACRAL ENLARGEMENT STIMULATION.

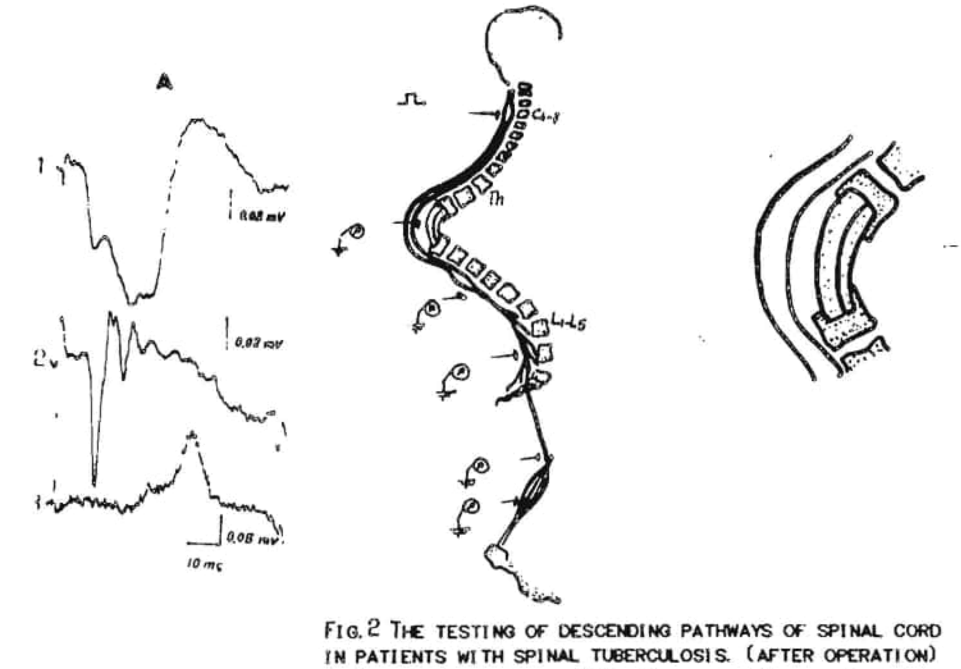

FIG. 2 THE TESTING OF DESCENDING PATHWAYS OF SPINAL CORD IN PATIENTS WITH SPINAL TUBERCULOSIS. (AFTER OPERATION) A. THE POTENTIALS RECORDED FROM THE ANTERIOR EPIDURAL SPACE AT TH-6 (1) AND POSTERIOR EPIDURAL SPACE AT L-3 (2)LEVELS AS WELL AS FROM M. GRACILIS(3) IN RESPONSE TO CERVICAL ENLARGEMENT STIMULATION.

INDUCED ELECTRIC FIELDS BY MAGNETIC STIMULATION IN CONDUCTING MEDIA

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SUMMARY

The electric fields and current densities induced by a time-varying magnetic field have been calculated using the concept of mutual inductance. The spatial derivative of the electrical field generated by a coil located below and parallel to a semi-infinite conducting medium has been evaluated along lines parallel to the plane of the coil. The electric field and its spatial derivative induced by a coil perpendicular to the surface of a semi-infinite conducting medium were also calculated using the method of images. The results have been verified experimentally and are important for the understanding of the mechanisms of magnetic stimulation.

INTRODUCTION

Magnetic stimulation can used to achieve non-invasive excitation of neural tissue in both the peripheral and the central nervous system[1]. Although this is a potentially important technique for non-invasive stimulation of the nervous system, the mechanisms underlying this type of stimulation are unknown and in particular, the spatial distribution of the current density induced by the imposed magnetic fields is not understood. The solution for the current density generated by a coil placed parallel or perpendicular to a semi-infinite conducting medium is presented.

RESULTS

1) Coil parallel to the surface of a semi-infinite conducting medium.

The induced current density is given by:

$$\mathbf{J} = \sigma \mathbf{E}$$

and

$$\mathbf{E} = -(M/2\pi r).\ (di/dt)$$

where $\mathbf{E}$ is the induced electrical field, $\mathbf{M}$ is the mutual inductance between the magnetic coil and a concentric imaginary coil in the conducting solution of radius r, i the current in the magnetic coil and σ conductivity of the medium. $\mathcal{M}$ can be calculated by the following equations[2] (see Fig.1):

$$\mathbf{M} = \mu\sqrt{R.r}\left[\left(\frac{2}{k}-k\right)K(k)-\frac{2}{k}E(k)\right]$$

where:

$$k = \frac{4Rr}{d^2+(R+r)^2}$$

K(k) and E(k) are complete elliptic integrals of the first and second kind respectively, (R, r) the radii of the two coils and d the distance between them.

The results show that **J** has only one component $\mathbf{J}_\phi$ tangent to the circle of points in a plane parallel to the magnetic coil. The y component of the current density generated along a straight line positioned above the coil is monophasic and peaks at a point closest to the center of the coil as shown in Fig.1. Since it is the change in the electrical field which is important to excite a axon[3], the derivative of the electric field (second derivative of the induced voltage) was also calculated. The induced field (E_y) and its derivative (dE_y/dy) generated by a coil with 20 turns, a maximum rate of change (di/dt) of 40 MA/s and a radius of 1.75 cm, is plotted for a plane located 1.25 cm above the coil (Fig. 2). The second derivative is spatially biphasic but the distance between the peaks is large suggesting that only long axons can be excited. The results also indicate that the optimal orientation of an axon for maximum excitation is at a 45 ° angle from the tangent to the stimulation coil.

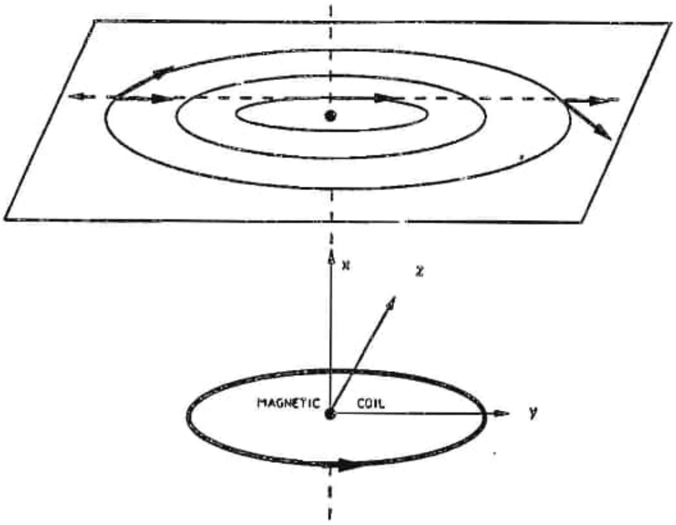

Fig.1: Induced currents in a semi-infinite conducting medium by a magnetic coil parallel to the surface. The induced electric field generating the current is independent of the conductivity of the medium and can be calculated from the mutual inductance between the magnetic coil and the imaginary coil in the solution.

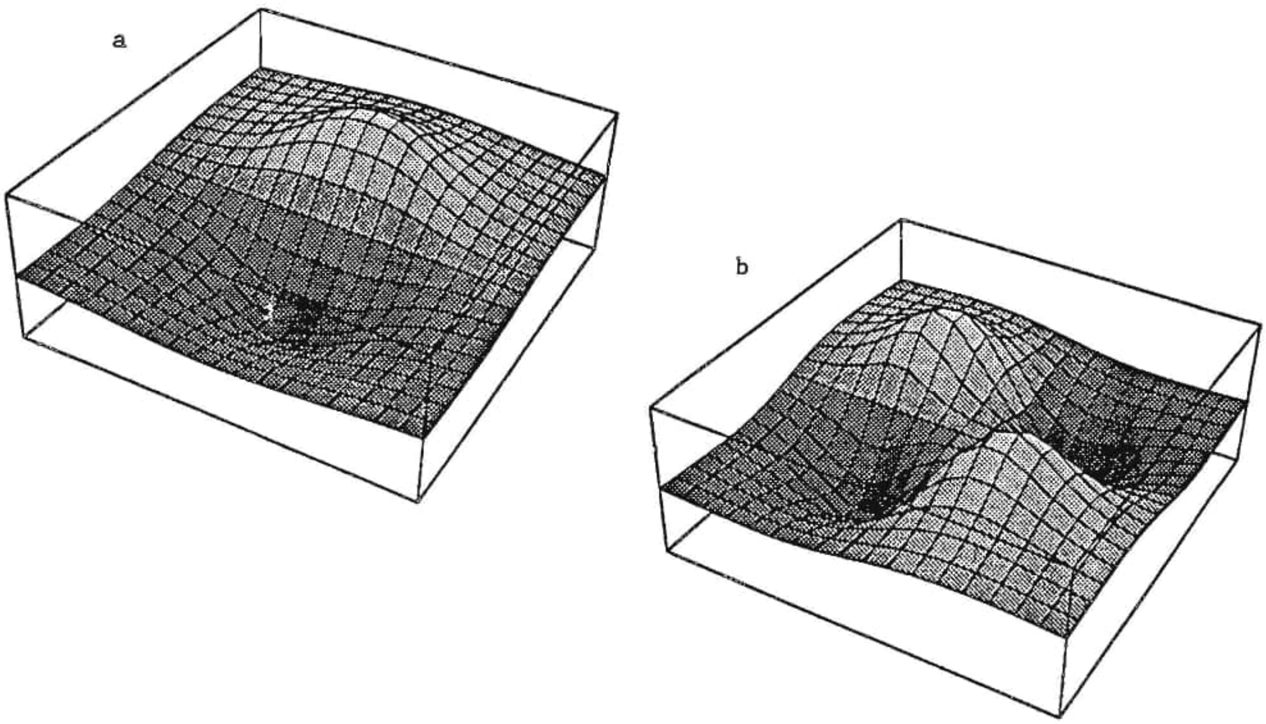

Fig.2: y component of the induced electric field (a) and its derivative (b) in a plane parallel to the coil and located 1.25 cm above the coil. The horizontal and depth axes are the y and z axes respectively (-5,+5 cm). The vertical axis is the current density for (a) and has a range of -100 to 100 A/m^2. In (b), the range is -3000 to 3000 A/m^3.

2) Coil perpendicular to the surface of a semi-infinite conducting medium.

The coil can also be located perpendicular to the non-homogenous medium as shown in Fig. 3a. Because of the lack of axial symmetry, the solution in this case is more difficult to compute. The solution to Maxwell Maxwell's equations in this case is:

$$\mathbf{J}_{Total}=\mathbf{J}_{Source}+\mathbf{J}_{Ohmic}$$

$\mathbf{J}_{Source}$ is the source generating the currents: $-d\mathbf{A}/dt$ where **A** is the magnetic vector potential. **A** is defined by:

$$\mathbf{B}=\nabla\times\mathbf{A}$$

is related to the mutual inductance **M** by:

$$\mathbf{A}=\mathbf{M}.I/(2\pi r)$$

$\mathbf{J}_{Ohmic}$ is the ohmic current generated by the sources. Since the total current must be divergence free, then:

$$\nabla\cdot\mathbf{J}_{Total}=\nabla\cdot\mathbf{J}_{Source}+\nabla\cdot\mathbf{J}_{Ohmic}=0$$

Therefore:

$$\nabla\cdot\mathbf{J}_{Ohmic}=-\nabla\cdot(-d\mathbf{A}/dt)=d(\nabla\cdot\mathbf{A})/dt$$

The solution of this Poisson equation is known in an homogenous medium and is given by:

$$\mathbf{J}_{Ohmic}=\frac{1}{4\pi\sigma}\int\frac{\frac{-d(\nabla\cdot\mathbf{A})}{dt}}{R^2}dv$$

The theory of images was then used in order to replace the inhomogeneous medium by a homogeneous one as shown in Fig. 3b. The perpendicular component of $\mathbf{J}_{Total}$ at the interface is then zero and the current density can be evaluated by first calculating the magnetic vector potential **A** and its divergence using the mutual inductance formula, then solving numerically the volume integral for $\mathbf{J}_{Ohmic}$ and adding the component $\mathbf{J}_{Source}$. Since the divergence of the vector potential is zero everywhere in space except at the surface discontinuity, the volume integral is replaced by a surface integral.

The results show that the current density vector is no longer contained within a plane parallel to the coil but has components in all three directions. In Fig. 4a, the y component of the induced electric field is shown in a plane perpendicular to the coil and located as in the previous case 1.25 cm above the coil (see Fig. 3a). The y-derivative of the induced current in the same plane (Fig. 4b) show that an axon located in this plane is less likely to be excited as in the parallel case but the sharp slope in the z-direction suggest that the perpendicular configuration is more selective.

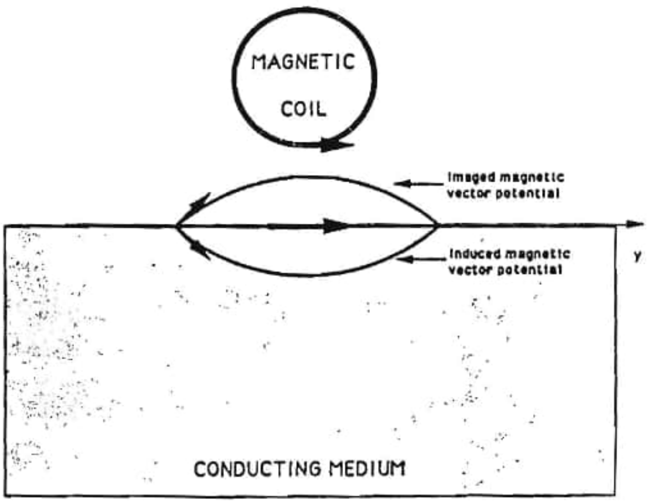

Fig.3: The coil is located in a plane perpendicular to the surface of the conducting medium . The y component of the induced current is calculated in a plane located 1.25cm above the tip of the coil. The homogenous medium is replaced by an homogenous medium by adding image sources

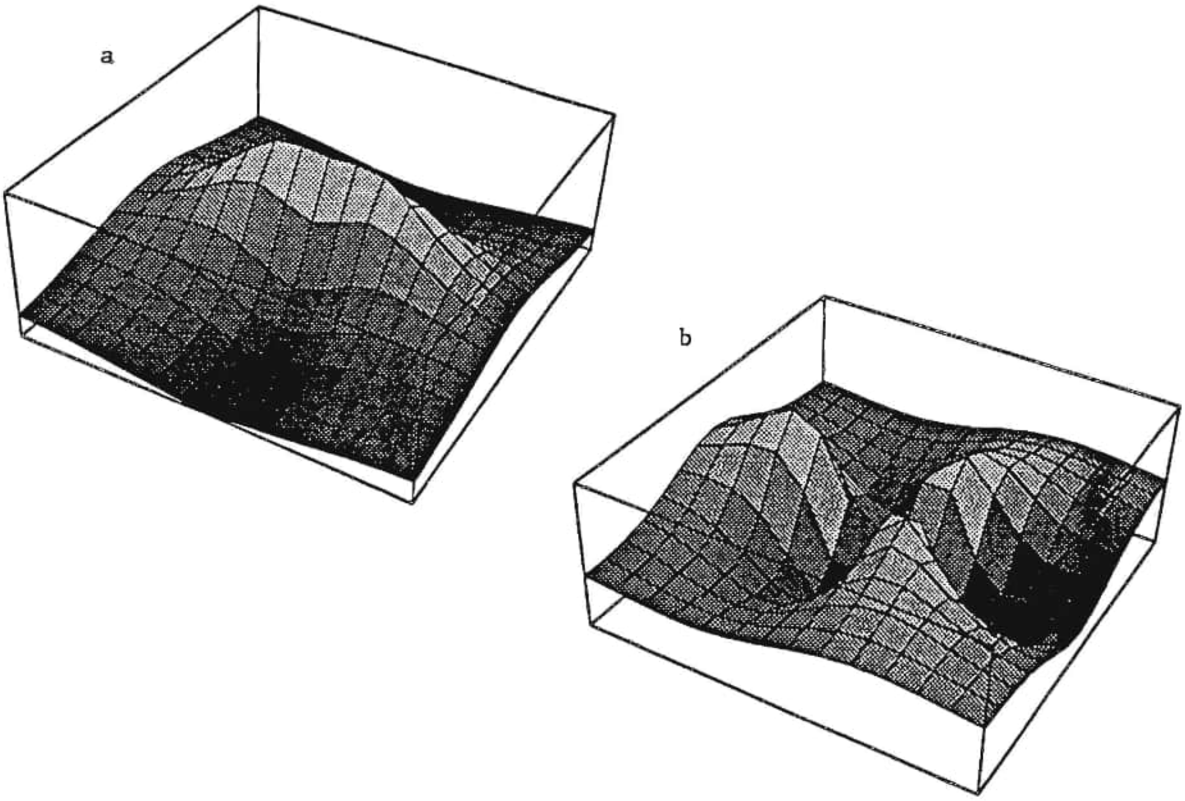

Fig.4: y-component of the induced electric field (a) and its spatial derivative in the y direction (b) for a coil perpendicular to the surface and in a plane perpendicular to the coil . The axes are similar to Fig. 2. The range in (a) is -5 to 40 A/m^2 and -500 to 700 A/m^3 in (b).

CONCLUSION

This method allows a simple and direct calculation of the induced current density resulting from magnetic stimulation and should therefore be very useful not only for the determination of the effects of the induced fields on various orientations of axons but also on the design and optimization of the coils. Preliminary experiments using a specially designed probe have confirmed the computer results.

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EFFECTS OF ELECTRICAL STIMULATION ON EDEMA FORMATION x)

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SUMMARY

Many clinicians are using electrical stimulation (ES) for the purpose of reducing post-traumatic edema and joint effusion. However, although empirical evidence supports the use of such treatments, the utility of ES for edema control has not been scientifically documented. Reed recently demonstrated that high voltage pulsed galvanic stimulation (HVS) reduces microvessel permeability to fluorescent labelled dextran following topical application of histamine to hamster cheek-pouches /1/. Thus, HVS may be able to modulate edema formation by impeding the movement of proteins into the interstitium. We initiated a series of experiments to test the influence of ES on post-traumatic limb volume changes. Hind limbs of anesthetized frogs were injured by dropping a weight onto plantar aspects of feet or by hyperflexing ankles. One hind limb of each subject was randomly selected to receive ES at intensities 10% lower than those needed to evoke muscle contraction; the other limb served as a control. Treatments were begun immediately after trauma, or delayed 4.5 hours and were administered in a series of four 30-minute sessions or in a single 6-hour block. Limb volumes were measured by water displacement. ANOVA with repeated measures and post hoc tests were used to determine significance of limb volume changes. Cathodal HVS, applied below motor threshold and at 120Hz, seems to be capable of modulating post-traumatic edema formation. Low voltage pulsed stimulation (LVS) applied under essentially the same conditions, however, did not significantly influence post-traumatic limb volumes.

MATERIAL AND METHODS

The four experiments described in this paper share numerous common features. In each, 20 bull frogs were anesthetized by immersion in an aqueous solution of MS222, and remained anesthetized throughout data collection. Both hind limbs of each animal were injured to induce edema formation, but only one

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x) Stimulators were provided by Chattanooga Corp., P.O. Box 4287, TN, 37405 and NTRON Electronics, Inc., San Rafael, CA 94912-7000.

limb (selected randomly) received ES treatment. Changes from pretrauma limb volumes were determined by water displacement and recorded in ml/kg body weight. ES was always applied by immersing one leg and foot into water into which the cathode was placed; the anode was affixed to skin over the ipsilateral hip. Intensity of stimulation was 10% below visible motor threshold. Measurements were made regularly during the first 8 hours after trauma and up to 24 hours post-trauma. Skin incisions were made at time of sacrifice to assure absence of hematoma. Significance of treatment effects was accepted at the 0.05 level.

Each experiment had unique characteristics as follows. Test #1 measured the effects of cathodal HVS following impact injuries induced by dropping a 450g mass from 1.1m. Starting immediately after injury, four 30-minute treatments were administered, with one-hour rest periods between each treatment. Test #2 was identical to test#1 except for mode of trauma. Here, ankles were mechanically hyperflexed to 90^{o} to simulate sprain. Test #3 was also identical to test #1 except force of impact was reduced to guard against hematoma (and associated elimination of data),low voltage pulsed direct current was applied by rectifying the output of a portable neuromuscular stimulator, and rest periods between treatments were reduced to 30-minutes. In Test #4, cathodal HVS was applied in a single 6-hour block that began 4.5 hours after injury. Although the treatment lasted 6-hours, intensity of stimulation was adjusted every 1.5 hours, when limb volume measurements were made.

RESULTS

Figure 1 shows the results of Tests #1 and #2. Mean volumes of limbs treated with cathodal HVS were significantly less than control limbs starting after the first treatment (about 1 hour post-trauma) and continuing throughout data collection. Values shown at hours 1, 3, 5 and 7 were recorded after treatments 1, 2, 3 and 4 respectively. Figure 2 shows the results of Test #3. Mean limb volume changes increased following impact injuries, but were not influenced by treatment with LVS ($p=.66$). Figure 3 shows the results of test #4. Treated limb volumes were significantly less than those of untreated limbs from hour 6 through hour 22.

DISCUSSION

Cathodal HVS was effective in limiting edema formation in frog hind limbs following two different forms of mechanical injury; differences in limb volumes were significant ($p<0.01$) even after the first 30-minute treatment, and remained so for ten or more hours after the conclusion of treatment. Because stimulation intensity was less than that needed to evoke muscle contraction, it is unlikely that periodic

Fig. 1 Modulation of Acute Edema via HVS

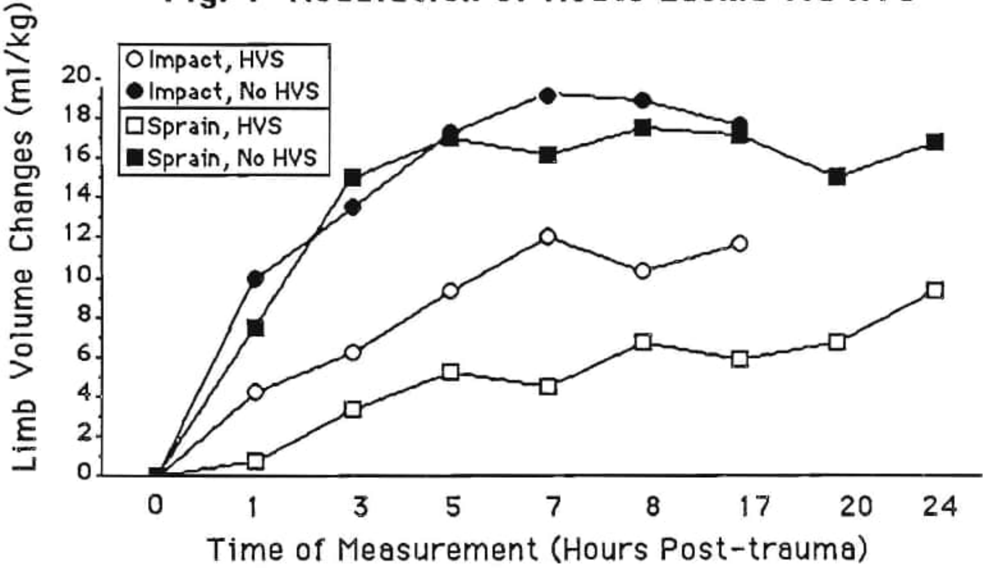
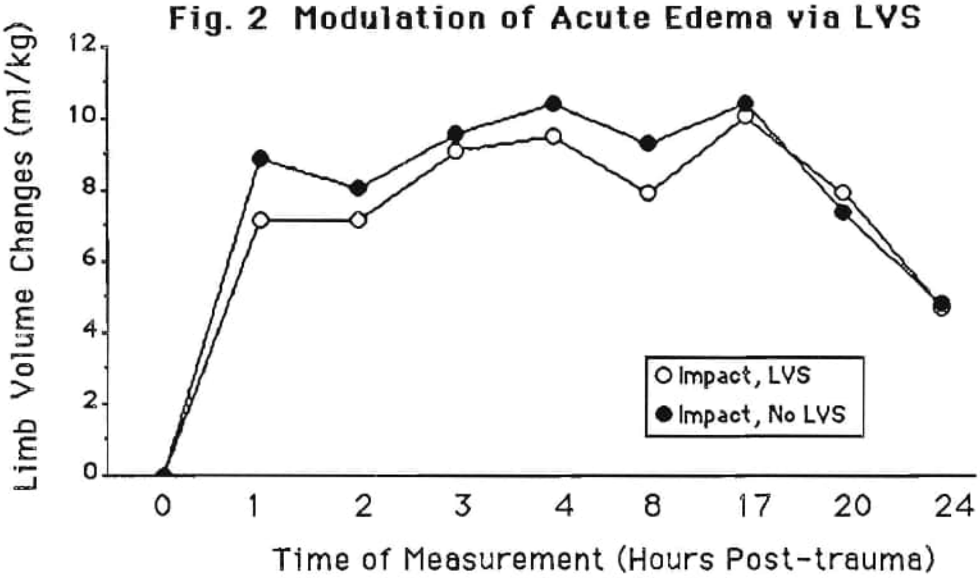
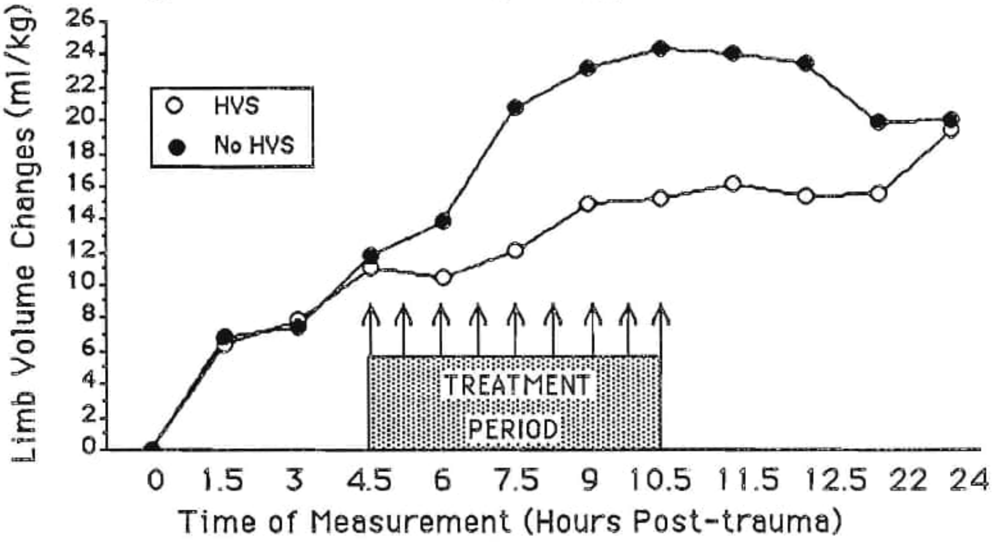


Fig. 2 Modulation of Acute Edema via LVS



compression of veins and lymphatics contributed to the treatment effect. The recent findings of Reed suggest that ES may result in changes in microvessel permeability /1/. This may account for treatment effects. Low voltage pulsed direct current (LVS) also applied at 10% below motor threshold and over a similar time course was not effective in limiting limb volume increases after impact injuries. Thus, waveform characteristics seem to be of considerable importance. Cathodal HVS applied in a 6-hour block beginning 4.5 hours after trauma limited the further progression of edema formation relative to

Fig. 3 Effect of Delayed Application of HVS.



control limbs. This corroborates the findings in tests #1 and #2, i.e., that HVS can limit edema formation, and shows the utility of HVS for this purpose even when treatment is delayed. Analysis of limb volume changes during treatment sessions and during rest periods has suggested that the mode of action of ES in edema modulation is short-lived, i.e., control of limb volume is only observed during ES administration. Despite this, ES has cumulative effects that may ultimately be shown to be of benefit to humans. Limbs treated with HVS did not exhibit rebound to higher limb volumes at the conclusion of treatment. We are now conducting experiments to test the influence of polarity, the utility of HVS for edema modulation in a mammalian model (rat paw), and the relative effectiveness of ES applied at intensities above motor threshold. Ultimately, we plan to conduct clinical trials to determine the utility of ES in controllin edema in humans.

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ELECTROSTIMULATION ON POSTOPERATIVE INTENSIVE CARE PATIENTS

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SUMMARY

Due to muscular inactivity, sepsis, parenteral nutrition with lack of enteral nutrition, the catabolic metabolism of patients who underwent large abdominal surgery causes remarkable muscular atrophy. Additional factors are inconsciousness, respiratory therapy, sedation and pain. Atrophy was the main reason for establishing electrostimulation (ES).

It was the purpose of the present study to test whether ES could prevent a loss of contractile tissue. This would be important for a faster mobilisation.

MATERIAL AND METHOD

Since the very first day following surgery, ES was applied exclusively to the left legs of the patients for 90 minutes daily, during two weeks. The equipment was a Bentrofit F 14 (Bentronic, München FRG) with modulated current supply. The daily program consisted of a frequency of 30 Hz, a contraction period of 5 seconds, a resting period of 25 seconds resulting in 180 contractions each muscle.

For a maximal development of strength, a uniform bloodflow and simultaneous minimal standard of sensible irritation, we used broad flat electrodes consisting of silicone rubber with a diameter of 7.5 cm. The electrodes were placed at the Musculus rectus femoris, tibialis anterior, triceps surae and at the ischiocrural musculature. The stimulation of agonists and antagonists worked alternatingly.

The current provoked a visible contraction ensuring, however, a tolerable stimulus for the patient.

For the first collective (of 11 patients: 3 women, 8 men aged between 48 and 78), a computertomography was done of both thighs at 20 cm proximal of the superior patella margin. Additionally, we measured the leg circumferences at 15 and 30 cm proximal of the medial articular space of the knee and at 15 cm distal of the lower leg.

For the second collective, lactate concentration in the capillarized earlobe was determined before and after ES.

The first question was to find out whether ES of the postoperative status has the same effect as there is by normal training in healthy people. Secondly, we wanted to see whether the lactate concentration is influenced by the intensity of FES. There was a total of 62 pairs of blood lactate tests (1 - 9 pairs of each patient). The treatment was according to a method published by the Köln Institute of Sports Medicine (FRG): Before and after ES, the hyperemized ear was incised by a haemostiletto; 20 ml of capillar blood were aspirated. The protein structures denaturated in 200 µl of 0.6 molar perchloroacid at a centrifugal speed of 12,000 rotations/min. 100 µl of the resulting deposit were aspirated and frozen. The UV test showed a lactate concentration with an increased extinction, as per the established model:

$$L - lactate + NAD \xrightarrow{LDH} Pyruvate + NADH_2$$

$$Pyruvate + L\text{-}Glutamate \xrightarrow{GPT} L\text{-}Alanin + 2\text{-}Oxoglutarate$$

We applied the Behring Testomar[R] with full enzyme activity and photometered, type Eppendorf[R], at a wave length of 366 mm Hg. This was verified by the serum Precinorm[R]. We ascertained a standard lactate of venous blood in healthy individuals at 1.00 - 1.78 mmol/l. Plasm and arterial blood levels were 20% higher.

RESULTS

The first collective manifested a significant atrophy in 10 of 11 cases. The circumference of the **unstimulated right** leg decreased by an average of 6.2 %, (0 -15.1%) in the upper leg, by 5% (1.5 - 11.3%) in the lower leg. The CT evaluation resulted in a mean decrease of 9.9% (2.7 - 18.3%). The circumference of the **stimulated left** leg, however, only decreased by an average of 2.4%. This is significantly less than at the right side. At the left lower leg, there was no difference: we measured 2.2%. The total decrease of the sectional muscular area in the left leg was significantly lower, i. e. 9.7%, than in the unstimulated right one.

In the second collective, we measured lactate concentrations between 0.4 and 4.2 mmol/l before and 0.7 - 5.4 mmol/l after stimulation. The mean value before stimulation was 1.61 mmol/l $\pm$ 0.1 mmol/l and 2.15 $\pm$ 0.13 mmol/l afterwards. The average difference calculated between the pairs of results was 0.54 $\pm$ 0.09 mmol/l.

For statistics, we verified one of the results in each patient, at random. Foi those 17 pairs of numbers, $\bar{X}$ PRE was 1.60 $\pm$ 0.18 mmol/l, $\bar{X}$ POST was 2.30 $\pm$ 0.22 mmol/l. The Wilcoxon test for bound random tests showed a significant difference ($p = 0.001$) between the pre and poststimulation lactate concentration. Only 69% of the results increased and only 48% increased by more than 0.5 mmol/l. Especially those increases did not relate to certain days of stimulation. Even previous data were insignificant.

In 3 cases, the lactate concentration increased by more than 1.5 mmol/l exceeding the aerobes-anaerobes limit. In such cases, the intensity of training should be reduced.

Tests of the lactate concentration in venous blood enable us to manage training intensity thus preventing transgressions beyond the aerobes-anaerobes limit as well as lactacidosis.

We did not observe a correlation between the number of previous training days, body temperature, or the quotient of urea to blood creatinine.

NEUROANATOMY OF THE ANAL CONTINENCE ORGAN: DIRECT NEUROSTIMULATION - FIRST EXPERIENCE

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Incontinence can be defined as the inability to control voluntarily the passage of enteric content. Anal continence is provided by the anorectum, a reservoir system with a outlet resistance amenable to reflexive or voluntary control. The tubular, distensible rectum functions as the reservoir ; the sphincters of the anal canal and their surrounding pelvic floor musculature function to obstruct the outlet appropriately.
Anal continence as a controllable act depends on the integrity of the voluntarily contractible muscles of the external anal sphincter and levator ani, especially the puborectalis muscle, and their nerve supply.
Two basic mechanisms of anal continence are provided by those muscles: sufficient anal closure pressure of the anal canal in situations of increased intrarectal or intraabdominal pressure and the angulation of the bowel at its rectoanal junction. (1-4)
The purpose of our study was to demonstrate the innervation of these muscle complexes and to show the implications of the neuroanatomy for the use of direct neurostimulation.

MATERIALS AND METHODS

In human cadavers the striated pelvic floor muscles and nerve supply were exposed by dissection.
Direct neurostimulation with a percutaneous or operative approach was performed in patients undergoing diagnosis and treatment of lower urinary tract dysfunction (5). The effect of neurostimulation on the rectoanal angle was documented by X-ray after inserting a contrast filled balloon into the rectum. Changes in anal canal pressure to neurostimulation were recorded with a water

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filled double balloon catheter attached by a non-distensible polyethylene tube to transducer, amplifier and a recording unit.

RESULTS

The striated anal continence mechanism is innervated by a common source: the sacral roots S2-S4. Neurostimulation demonstrates that the nervous supply of the two different continence mechanisms of the striated muscles differs: the rectoanal angle is influenced by direct nerve fibers splitting from the sacral nerves and running on the inner surface of the levator muscle; whereas the anal canal pressure is governed by muscle structures innervated by the pudendal nerve.

DISCUSSION

Whereas anal incontinence consequent to muscular lesions of the pelvic floor and the sphincteric system can usually be treated surgically with success the treatment, and even the diagnosis, of neuromuscular disorders of the pelvic floor in general and the anal continence mechanism in particular remain difficult and unsatisfying.

Direct neurostimulation of the sacral and pudendal nerves gives us the chance to test neuromuscular components of the anal continence mechanism together or separetely, depending on the level of stimulation. The value of permanent neurostimulation in the treatment of patients with anorectal dysfunction needs further assessment.

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CERVICAL EPIDURAL MULTIPOLAR SPINAL CORD STIMULATION

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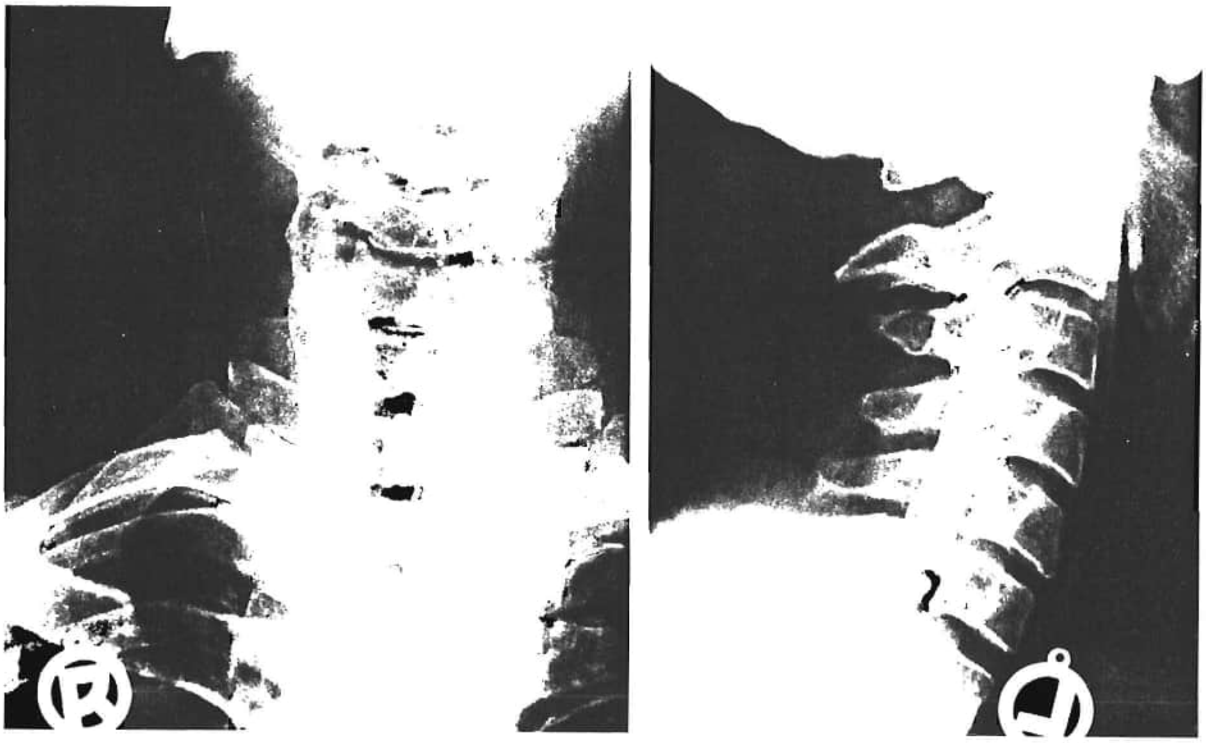
SUMMARY

The method of epidural spinal cord stimulation, inaugurated by Norman Shealey (4) is applied nowadays mainly for the treatment of deafferentation pain (e.g. stump and phantom limb pain, persisting pain after laminectomy). This method also is used for the treatment of central nervous disturbances, especially to improve a (spinal) spasticity. The electrodes (leads) are placed in the lower thoracic epidural space (D9 - D12) for the treatment of pain and to improve a spasticity in the lower extremities.
Cervical lead implantation is recommended in therapy resistant (deafferentation) pain in an upper extremity, also in spasticity followed by hemi- or hemiparesis (3). The use of multipolar leads for cervical stimulation seem to be of special advantage.

MATERIAL AND METHODS

Cervical placement of spinal cord stimulation leads is more hazardous and therefore demands more technical skill than lead placement at the thoraco-lumbar level. The lead can be placed percutaneously by inserting the canula (TUOHY - needle) in strict median (a.p.) position, as we perform it, or in setting the canula in a 30-45° angle to the midline. The latter method is often preferred because lead damages or decubital ulcera, caused by the bending

Fig.1: Epidural (MEDTRONIC SIGMA QUAD) electrode for cervical multipolar spinal cord stimulation. X-ray images in a.p. and lateral view show the lead tip at the level C5.



lead are less often found (1). In cervical epidural spinal cord stimulation the electrodes usually are placed in the dorsomedian or mediolateral epidural space at the level C3-D1 (Fig.1). Cervical epidural spinal cord stimulation was performed in 16 patients within a time period of 8 years (1981-1989) at our pain therapy unit.

RESULTS

In seven patients one epidural lead was placed (Fig.2). Two patients still show good to excellent long term results, one patient a moderate long lasting improvement and one patient a temporary improvement. In three cases stimulation was terminated within the test stimulation period because of non-improvement.
In five patients two leads each were implanted (Fig.2). Four of them still show a moderate improvement, one only a temporary improvement.

Fig.2: Uni-, bi- and multipolar cervilal epidural spinal cord stimulation (Diagnostik & Therapiezentrum-Neurologie/LKH Mauer, 1981-1989).

YEAR	(PAT)	DIAGNOSIS	ELECTRODE POSITION	RESULT
			UNIPOLAR	
83	(EM)	THALAMUS SYNDROME	C7	0
85	(GB)	INCOMPL.TRANSSECT.CORD LESION	C6	++
85	(HM)	INCOMPL.TRANSSECT.CORD LESION	C7	(+)
85	(WW)	PLEXUS CERVIC.LESION LEFT	C6	0
86	(KJ)	PARASPASTICITY (ST.P.MYELITIS)	C6	+
87	(EA)	THALAMUS SYNDROME	C5	0
87	(ZL)	THALAMUS SYNDROME	C6	++
			BIPOLAR	
81	(BJ)	PLEXUS CERVIC.LESION RIGHT	C5/C7	+
81	(TW)	AMPUTATION RIGHT ARM	C6/D1	(+)
86	(SL)	INCOMPL.WALLENBERG'S SYNDROME	C5/C7	+
88	(KT)	PLEXUS CERVIC.LESION LEFT	C6/C7	+
89	(SJ)	SYRINGOMYELIA/PARAPARESIS	C6/D1	+
			MULTIPOLAR	
85	(RH)	PLEXUS CERVIC.LESION (R.)+PARAPARESIS	C5-C7	0
88	(HA)	APALLIC SYNDROME/QUADRUPARESIS	C6-D1	0
88	(TR)	PLEXUS CERVIC.LESION LEFT	C5-C7	++
89	(GA)	PLEXUS CERVIC.LESION LEFT	C4-C6	++

LEGEND
0 = no improvement during test stimulation.
(+) = initially improved, stimulator implanted, now stimulation terminated (stimulator explanted).
\+ = still stimulating - with fair result.
++ = stimulating with good to excellent result.

In four patients a multipolar lead (one 4 and one 8 channel lead (NEUROMED); two MEDTRONIC PISCES QUAD leads) was implanted (Fig.1,2). In two cases with deafferentation pain due to peri-

pheral nerve (plexus cervicalis) lesion a good to excellent result could be achieved during an observation period of six and 20 months with the MEDTRONIC PISCES QUAD system.
In none of the 16 patients a spinal cord lesion, an epidural bleeding or infection following the lead implantation was observed.

DISCUSSION

Results of cervical epidural spinal cord stimulation depend on correct indication, exact lead position and, what should be pointed out in this article, on the possibility to vary the site of stimulation. Also we obtained the best results in patients with deafferentation pain due to plexus cervicalis lesions and in incomplete transsectional cord lesions (1,3). The advantage of a multipolar (MEDTRONIC PISCES QUAD) electrode is the possibility to choose from 18 variable electrode switching positions after having implanted the system (2). The desired stimulus sensation can be more dependibly achieved. These leads were used successfully in two patients.

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THERAPEUTIC BENEFITS OF AN FES PROGRAMME FOR INCOMPLETE SPINAL CORD INJURED PATIENTS

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SUMMARY

The therapeutic value of applying electrical stimulation (ES) to both efferent and afferent nerves has been studied to a large extent on subjects with complete spinal cord injuries. The effect of muscle strengthening has been extensively investigated [1]. The effect of ES on the reduction of spasticity has been investigated [2] and it was shown that the Relaxation Index (RI) as measured by the pendulum test may be affected by dermatome stimulation, agonist or antagonist stimulation. However this has not been demonstrated to have a significant long term effect.

In an FES programme the therapeutic benefit may be incidental to the main aims but these benefits have been cited as supportive. It has been remarked [3] that it is quite difficult to draw a demarcation between therapeutic and functional ES. For the purposes of this study functional benefit will be defined as the direct improvement in function whilst using an FES system and therapeutic benefit as that which the subjects receives from having participated in an FES programme.

The aims of this study was to investigate the therapeutic benefits of an FES programme of rehabilitation designed specifically for the restoration and improvement of gait for subjects with Incomplete Spinal Cord Injuries (ISCI).

METHOD AND MATERIALS

Six subjects with ISCI of 2 or more years post injury were selected with the criteria of: Lower limb muscles and flexion withdrawal reflex excitable with ES, some degree of ambulation after having completed a normal rehabilitation programme. This group comprised of 3 females and 3 males of age range 19 to 40 years; their details and lesion levels are shown in table 1

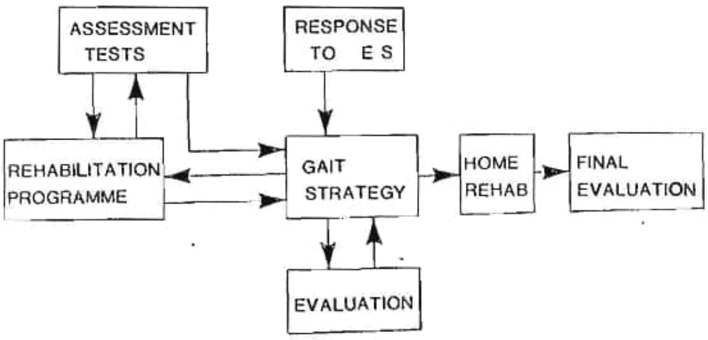
Table 1

subject	Age	Sex	Lesion	Date	Cause
A	19	M	C4	05.86	Diving accident
B	32	F		03.78	Laminectomy after car accident
C	35	M	T12	03.84	Fall from ladder
D	35	M	C3/4	11.69	Rugby injury
E	39	F	T5/6	04.83	Car accident
F	28	F	T12	07.83	Car accident

Evaluation tests for therapeutic benefits were performed at the start, middle and end of the FES programme. This programme ran for a period of twelve months. An overall strategy of the programme was planned (fig. 1). In this, the specific requirements of each subject were assessed in order to formulate 1. a rehabilitation programme using FES the aims of which were derived from a battery of assessment tests, and 2. a strategy for the production of gait based on the results of the assessment tests, rehabilitation programme and responses to ES. The responses to ES investigated were in relation to the flexion withdrawal response, in which the frequency, train of pulses, and site of stimulation which produced the least habituation and shortest latency period were identified.

Fig 1

OVERALL STRATEGY



In the rehabilitation programme, exercises were devised using ES for the following rehabilitation aims; 1. strengthening of muscles, 2. increase of endurance of muscles, 3 .reduction of tone and increase of extensibility of muscles, 4. improvement of posture. Gait was synthesised using a programmable 8 channel stimulator developed at the Bioengineering Unit. The gait was evaluated and stimulation parameters and channels changed accordingly. This process was continued for a period of three to five months until the most natural gait possible was achieved. A stimulator with appropriate parameters for gait was supplied to each subject and a home rehabilitation programme was carried out in which the subjects received regular domiciliary visits from a physiotherapist. During these visits the subjects were instructed on the use of their FES system to improve on their mobility and level of independence using FES. At the end of this period the subjects were re-evaluated. At the commencement of the tests at this stage none of the subjects had used ES for a period of at least 24 hours.

The areas evaluated were:-

1. Spasticity. The Relaxation Index (RI) of the pendulum test [4] was used to determine quadriceps spasticity. In this test a preconditioning routine was adopted and then ten separate measurements of RI made. Extensibility of all major muscle groups at the hips, knees, and ankles was clinically evaluated. The values of extensibility were scored for each joint in terms of range of movement. Subjects also reported in a daily diary any change in the intensity, frequency or effect of function of their spasms.
2. Maximum Voluntary Contraction of the quadriceps muscles measured as the isometric moment about the knee
3. The physiological cost [5], speed and cadence of the subject's gait. The subject was required to walk around a standard track the length of which was individually determined. This was made with the walking aids used at the start of the programme. This test was repeated on five separate occasions both before and after.
4. Their degree of independence in aspects of activities of daily living (ADL) was subjectively determined by means of a questionnaire in terms of time and assistance to perform a number of activities.
5. Psychological assessment of anxiety and depression using the General Health questionnaire.

RESULTS

The pendulum test results are presented in fig 2 the bars representing the mean of 10 measurements. All changes shown are significant at the 0.001 level. For this group of subjects there has been a decrease in spasticity as measured by the RI of the pendulum test ($p < 0.004$).

Fig 2

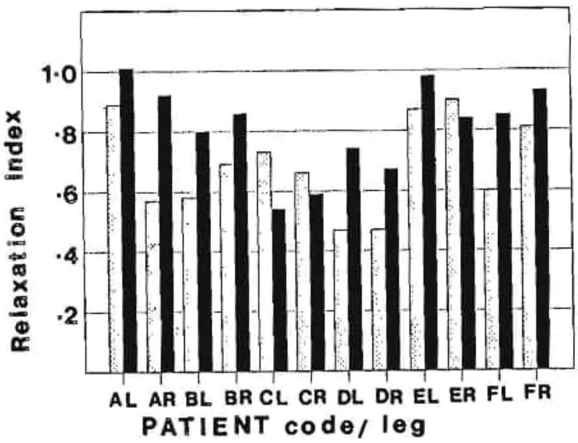


Fig 3

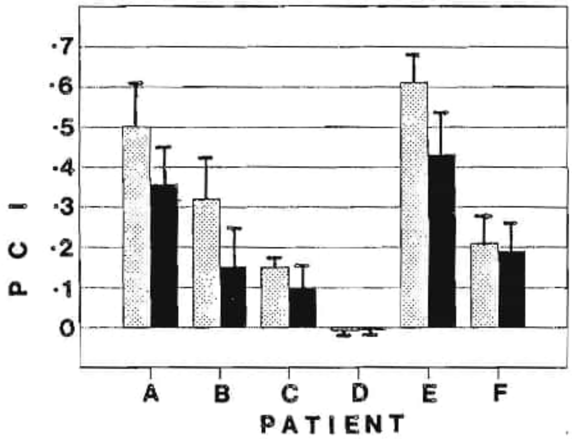
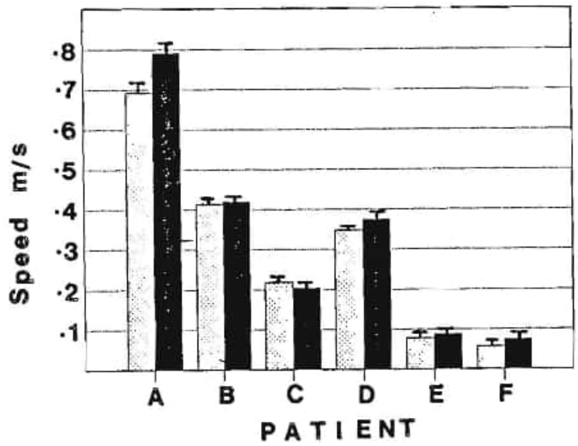
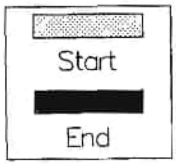


Fig 4





In 5 subjects, there was an increase in the range of motion of the joints the other subject having full range in all joints at the start of the programme. An example of this was subject D who had tightness of the hamstrings in his right leg restricting full extension of the knee. After strengthening, the quadriceps full range of extension was gained and maintained. Using the Wilcoxon matched-pairs sign ranks test it was found that there was a significant increase in extensibility ($p < 0.05$).

Three subjects reported a decrease in spasms in their daily diary and this coincided with periods of greatest use of stimulation. Three subjects reported no subjective change.

The results from the start to the middle and the middle to the end show a similar trend to the above.

The PCI was reduced (fig 3) for 5 of the 6 subjects. Across the subject group there was a significant decrease ($p < 0.05$) in PCI.

Changes in speed [4] of walking were very individual there being a small but significant increase in subjects A, E and F but no change significant changes in the others.

Reported changes in the performance of ADL tasks were generally very small but positive. There was no real change in the scores for the psychological tests to 4 of the patients and a slight improvement in 2.

DISCUSSION

The FES programme was designed for restoration of gait and as such, all exercises instituted were to meet this basic aim.

In all cases, the subjects have received measurable benefit from the programme outside of the general aim of restoring or improvement of gait. If an intensive research programme is conducted using FES we have to be sure that, as a minimum, the subject will not have any adverse effects. Indeed it would enhance the programme if we could be reasonably certain that the subjects would derive benefits not associated with the use of FES as a walking aid. This is the case as far as the ISCI population used in this study is concerned.

The general improvement in tone has always been a goal in rehabilitation of the SCI and in this area it is clear that the FES programme has some positive benefits.

The general improvement in objective testing is not always closely borne out by the subjects answers to the questionnaires. The impact of the programme to ADL was low. However all subjects felt at the end that they had benefited from the programme in some way.

ACKNOWLEDGEMENTS

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EXPERIMENTAL DYNAMIC CARDIOMYOPLASTY IN THE SHEEP

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SUMMARY

During later years there has been a growing interest in using transformed skeletal muscle, i.e. after chronic electrical stimulation, to augment or replace ventricular function (8,2). However there are contradictory results about the hemodynamic effects of the transposed muscle (1,2).

This report describes the hemodynamic influence of the latissimus dorsi muscle (LDM) in the sheep as well as the histo- and biochemical changes seen in the muscle after 6 and 12 weeks duration of electrical stimulation of the muscle when it had been wrapped around the heart as a pedicle.

In our study the stimulated muscle fibres were rounded and varied more in diameter. Peri- and endomyseal collagen tissue was increased. After 6 weeks of stimulation more fibres were rich in the oxidative enzyme succinate dehydrogenase and poor in myofibrillar ATPase. After 12 weeks stimulation almost all fibres were transformed to the slow-twitch oxidative type. Biochemical findings indicate increase in citric acid cycle metabolism and the breakdown of fatty acids but a decrease in glycolysis for the energy need which is in agreement with the histochemical result.

With normal heart function there were no hemodynamic effects from the LDM.With depressed heart function (esmolol i.v.) contraction of the stimulated muscle gave a slight increase in CO (cardiac output), but the difference was not significant.

MATERIAL AND METHODS.

Nine sheep weighing 50 to 65 kg were operated. The left LDM was mobilized as a pedicle with preserved nerve and blood supply. A thoracotomy was made under the 5th rib and the muscle was passed into the chest cavity through a defect created by partial resection of the 3rd rib. An implantable pulse generator (Medtronic Model SP 1005) with leads for muscle stimulation and sensing was used. The LDM was wrapped around the left and part of the right ventricle and sutured to the peri- or epicardium.with non-resorbable sutures.

Two weeks after surgery, when the muscle was supposed to have adhered to the heart, the electrical stimulation was started with single pulses on every 2nd beat. The stimulation was increased every 14th day (in 4 steps) until pulse trains of 240 msec. (30 Hz bursts, 6-8 pulses each period) were given on every heart beat. After 6 and 12 weeks of electrical stimulation the experiments were terminated. Hemodynamic measurements were done with normal and depressed heart function after infusion of esmolol (Brevibloc) i.v.

Histochemical methods: Biopsies from the normal and the stimulated LDM were frozen in liquid propane cooled by liquid nitrogen. Cross-sections, 20 µm thick, were cut at 25°C using a microtome in a cryostat. Some sections were used for demonstration of myofibrillar ATPase (mATPase) (6). Type I fibres were dark following preincubation at pH 4.5 and light at pH10.4. The reverse was true for type II fibres. Other sections were used for the demonstration of the oxidative enzyme succinate dehydrogenase (SDH)(5).

Biochemical methods: Biopsies from the stimulated and the normal LDM were also used for quantitative analysis of glycolytic and oxidative enzymes.

RESULTS

Surgical results: In three animals the muscle was detached from the apex of the heart but still it was covering most of the left ventricle. In one sheep the muscle was very fibrotic probably due to compromised blood flow through the pedicle. Another sheep had a wound infection which was cured by local treatment. All muscles were firmly adherent to the myocardium but there were also adhesions between the muscle and the thoracic wall at the site of thoracotomy especially in two cases.

Hemodynamic results: During normal heart function no hemodynamic effects could be measured when the LDM was stimulated. When the heart function was depressed due to infusion of esmolol stimulation of the muscle gave a higher cardiac output (CO), most pronounced in sheep 4 (Fig. 1).

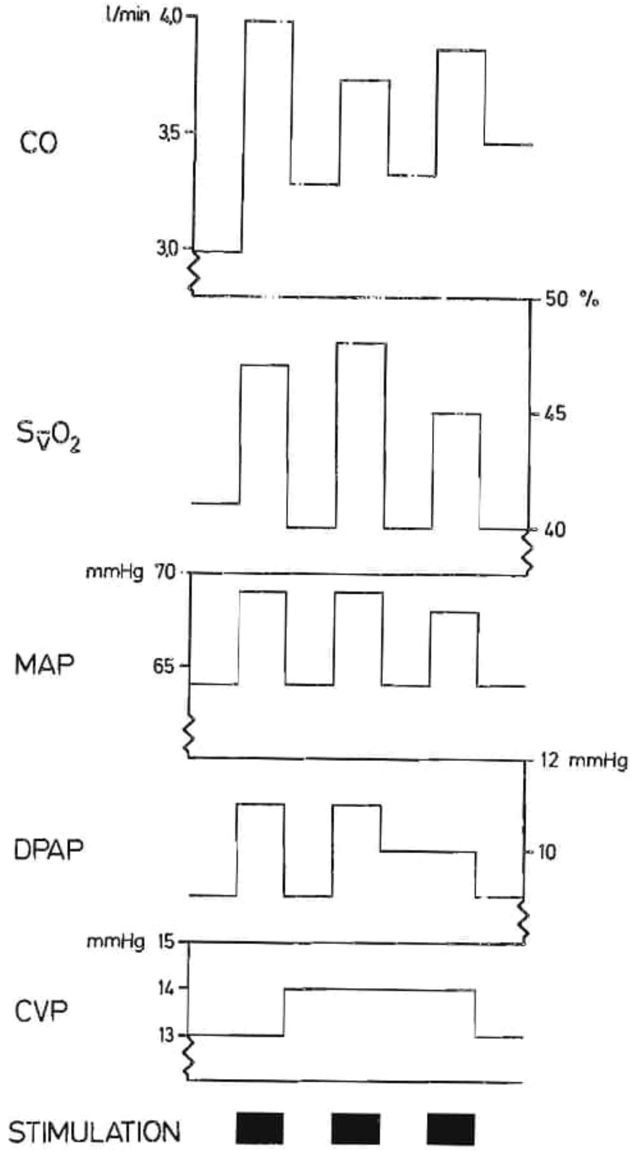

Fig. 1. Cardiac output (CO), oxygen saturation of mixed venous blood ($S_{\bar{v}}O_2$), medium pulmonary artery pressure (DPAP) and central venous pressure (CVP).

Histological and histochemical results: Cross-sections of the stimulated muscle showed smaller fibres which varied more in size compared with the control muscle. Peri- and endomyseal connective tissue was increased. The regular distribution of type I and type II fibres seen in the normal muscle was disturbed with a relative increase in the former type after 6 weeks of stimulation(2a). At that time many fibres also displayed an intermediate staining intensity in the ATPase preparation. and more fibres were rich in SDH. Later at 12 weeks almost all fibres were rich i SDH and stained darkly at pH 4.5 indicating a near complete transformation to slow, type I fibres (2b).

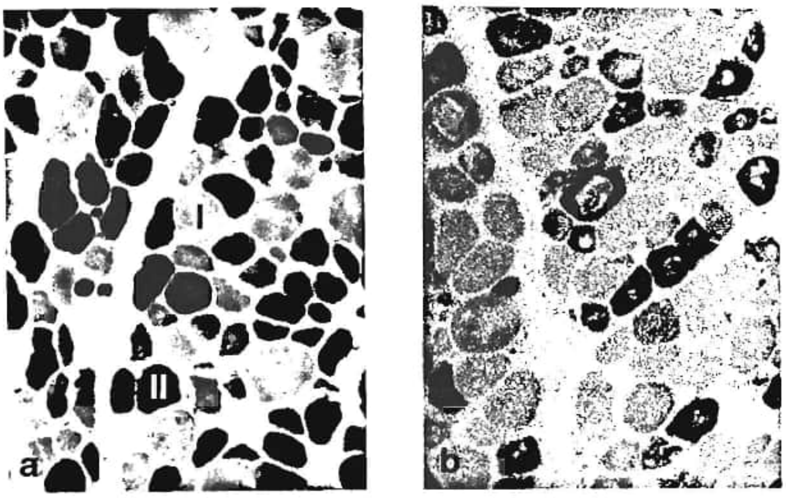

Fig. 2. Stimulated muscle after 6 weeks (a), and after 12 weeks (b). There is a gradual increase in type I fibres (light). ATPase, pH 10.4, x110.

Biochemical results: After 12 weeks stimulation there were changes in both glycolytic and oxidative enzymes. Phosphofructokinase showed a decrease to 14% of the initial value. Citrate synthase and hydroxyacyl CoA dehydrogenase were increased with 60 and 93% respectively, compared with the control. The values were corrected for the protein content.

DISCUSSION

The skeletal muscle has a considerable capacity for accomodating changes in demand. Thus, chronic electrical stimulation of a predominantly fast muscle like the LDM changes the metabolic and contractile properties in the direction of those found in a slow muscle, i.e. increase in oxidative enzymes, capillary density and decrease in glycolytic enzymes and fatiguability (7). The histochemical results indicate a fast-to-slow transformation of muscle fibres which is supported by the biochemical measurements. This transformation was near complete after 12 weeks when very few fibres rich in mATPase were found, which is later than reported by others who stimulated the muscle in situ (3, 4) .

The muscle did not fatigue during the hemodynamic measurements which lasted for about 2-3 hours for each animal.

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ENERGY METABOLISM OF CANINE LATISSIMUS DORSI MUSCLE DURING CHRONIC ELECTRICAL STIMULATION *

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SUMMARY

Application of the latissimus dorsi (LD) muscle for dynamic cardiomyoplasty requires its transformation into a fatigue-resistant muscle. Electrical stimulation of canine LD muscle during 24 weeks induced an increase of immunohistochemically assayed type I muscle fibers from about 30 to 70-80%. Concomitantly, the anaerobic glycolytic capacity of the LD muscle declined markedly, but the capacity for oxidative energy production remained unaffected. This difference in adaptation of contractile and oxidative metabolic properties may relate to a rise in the efficiency of force generation of the stimulated LD muscle.

INTRODUCTION

In recent years the latissimus dorsi (LD) muscle has gained much attention because of its suitability for dynamic cardiomyoplasty. This latter concept involves the use of an electrically stimulated skeletal muscle wrapped around part of the heart to restore or augment ventricular contractility (1,2). The electronic device is composed of an implantable pulse generator, together with intramyocardial sensing and muscular pacing electrodes. Experimental studies have been performed mostly on goats and dogs (3,4). In addition, since the first successful clinical case, described in 1985, over 30 cases have been reported.

Successful application of the LD muscle for this biomechanical assist system depends largely on the efficacy with which electrical stimulation can transform this mixed-type fatiguable skeletal muscle into a slow-twitch fatigue-resistant muscle. For this, adaptations are likely to be necessary of both the energy generating system (metabolic capacities for aerobic and anaerobic energy production) and of the contractile system (myosin isoforms and myofibrillar ATPase activity).

We studied the effect of 24 weeks of continuous electrical stimulation on metabolic and contractile properties of the in situ LD muscle of adult mongrel dogs. At regular intervals biopsies were taken from both the stimulated and contralateral control muscles for metabolic flux measurements, assay of enzyme activities and of the contents of adenine nucleotides and endogenous substrates, and for histochemical assay of muscle fiber type composition. Chronic electrical stimulation was found to induce changes in some parameters while leaving others unaffected.

* Study carried out in collaboration with the Bakken Research Center, Maastricht, the Netherlands, and supported by the Netherlands Heart Foundation, research grant no. 37.003.

MATERIALS AND METHODS

Experimental protocol

An ITREL™ (Medtronic Model 7420) myostimulator, allowing burst pacing, was implanted and connected to the left LD muscle by means of a pair of intramuscular electrodes (Medtronic SP 5528). The right LD served as control. Electrical stimulation was started about three weeks later and was carried out according to the protocol described by Chachques et al. (3). Briefly, in 10 weeks the contraction rate was increased gradually from 30 to 80 per min using burst pacing with a stimulus duration of 0.25 sec (the rest period between two bursts decreasing from 1.75 to 0.50 sec). At regular intervals two open transmural biopsies were taken from both the stimulated and the contralateral control LD muscles. One specimen was immediately freeze-clamped and used later for analysis of the contents of adenine nucleotides (HPLC) and endogenous substrates. The other sample was used for metabolic and histochemical examinations.

Metabolic studies and histochemical analysis

The muscular capacity for fatty acid oxidation was measured radiochemically in freshly prepared whole homogenates, as described elsewhere (5). The experimental conditions were chosen so that the oxidation rate was maximal with respect to substrate availability and the presence and concentration of cofactors. Activities of metabolic enzymes were assayed in supernatants of sonicated homogenates, using routine spectrophotometric methods.

Fiber type composition of the LD muscle was monitored immunohistochemically using the mouse monoclonal antibody R11D10 (raised against ß-myosin heavy chain; Centocor Europe) applied either to aceton fixed cryostat sections or to sections of formalin fixed and paraffin embedded biopsies. Type I muscle fibers show an intense immunoreactivity with the antibody, type II fibers no reactivity and fibers of intermediate type (IC and IIC) a reactivity in between (M.G. Havenith et al., submitted).

RESULTS

Oxidative capacity of the LD muscle, measured in homogenates as the maximal rate of palmitate oxidation and expressed per g muscle, was about half as high as that of canine left ventricular tissue, and did not change significantly during the stimulation period (Fig.1, left panel). Similar observations were made on the activity of the mitochondrial marker enzyme citrate synthase (Fig.1). In contrast, electrical stimulation caused the capacity of the anaerobic glycolytic pathway to decrease markedly, as appeared from a lower activity of the key-enzyme fructose-6-phosphate kinase and a lower content of lactate dehydrogenase isozym-5 in the stimulated when compared to the control LD muscle (Fig.1, right panel). In both LD muscles the contents of the nucleotides ATP, ADP and AMP, and hence the energy charge calculated from these, and the contents of the endogenous substrates creatine phosphate, glycogen and lactate all remained unaltered during the entire stimulation period (data not shown), indicating that the energized state of the muscle cells was maintained.

Immunohistochemical analyses revealed that the mixed-type LD muscle gradually transformed towards a muscle containing predominantly type I (oxidative) fibers (Fig.2). The transient appearance of intermediate type fibers suggests a change from type II via intermediate type (IIC and IC) to type I fibers. This order agrees with data on electrical stimulation of rabbit skeletal muscles (6).

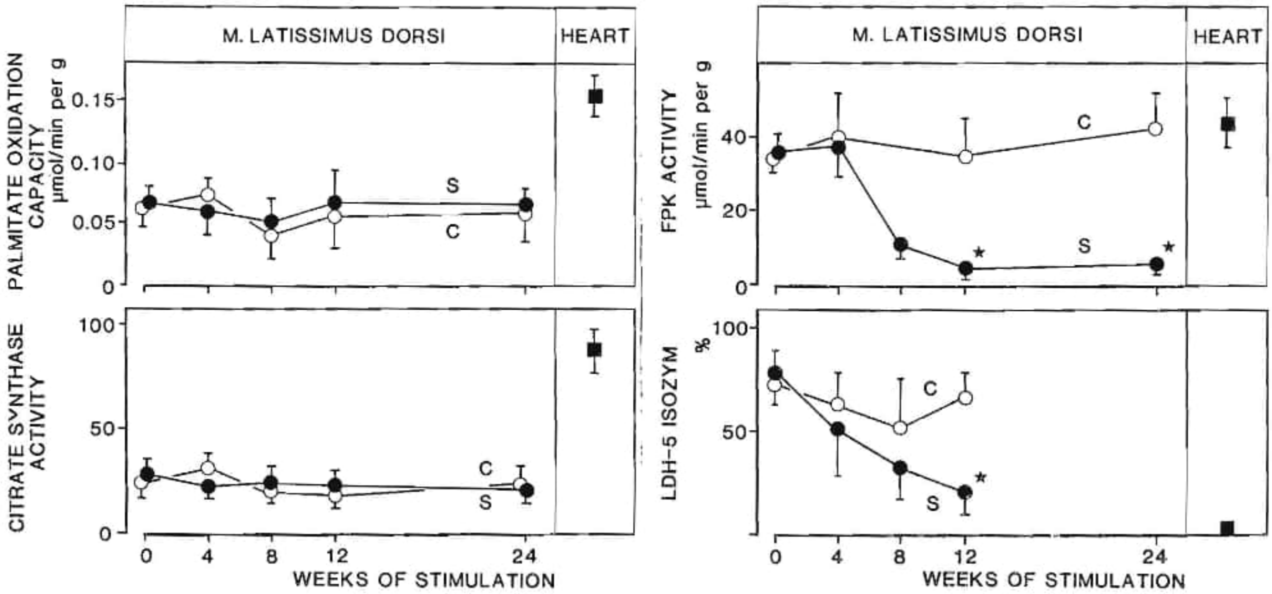

Fig. 1. Effect of chronic electrical stimulation on parameters of oxidative (left panel) and anaerobic glycolytic energy production (right panel) in dog m. latissimus dorsi. Values for left ventricular tissue are given for comparison. Data represent means ± SD for 4 (24 weeks) or 6-10 animals. S, stimulated muscle; C, control muscle.
* Significantly different from control muscle ($p < 0.01$).

DISCUSSION

Metabolic flux measurements are particularly suitable for obtaining insight into the capacity of a muscle for energy production through oxidative catabolism, as the complete conversion of a substrate by tissue specimen is measured, rather than the activity of individual enzymes from that catabolic pathway. Furthermore, since the oxidative capacity of a skeletal muscle determines its susceptibility to fatigue, metabolic flux assays can be used to directly monitor the latter.

The present study shows that chronic electrical stimulation of canine LD muscle induces marked changes in its contractile properties (myosin ATPase) towards a more oxidative, fatigue-resistant muscle, consistent with observations by other workers (4,7). During this process fast-twitch oxidative glycolytic (type IIA) fibers transform into type I fibers, since purely glycolytic (type IIB) fibers are not found in the dog (8). Consistent with these findings, the muscular capacity of the anaerobic glycolytic pathway decreased markedly; the decline of the content of type II fibers by about 65% after 24 weeks of stimulation corresponds well to the decline of FPK activity by about 80%. However, upon electrical stimulation the oxidative capacity of the LD muscle did not increase, but remained at its initial level. Hence, during the process of transformation the type II(A) fibers apparently lost (part of) their glycolytic capacity, did not gain oxidative capacity but yet expressed more of the type of myosin ATPase adapted to perform sustained work.

The observed disparity of changes in myofibrillar proteins and adaptations in functional metabolic properties of the dog LD muscle during chronic electrical stimulation contrasts to similar studies on rabbit tibialis anterior muscle, in which changes in the myosin ATPase type were found to parallel those in the activities of enzymes of oxidative metabolism (6,9). The lack of increase of the oxidative capacity of the dog LD muscle may indicate that as a result of electrical stimulation energy production and demand were not imbalanced so as to require such an adaptation. The latter may be explained by a higher effi-

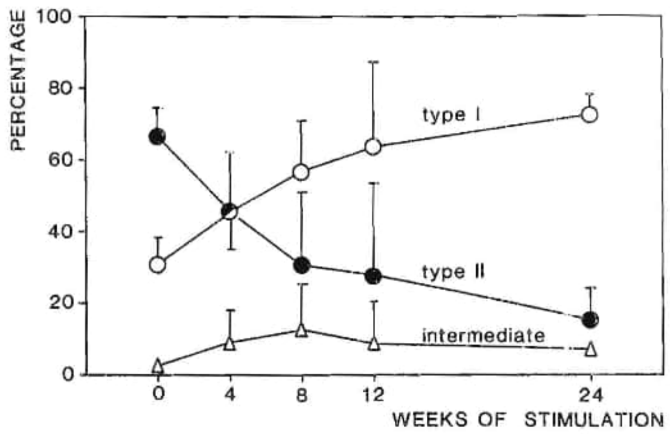

Fig. 2. Electrical stimulation induced changes in fiber type composition of dog m. latissimus dorsi. Results (means ± SD for 4-6 animals) are given for the stimulated muscle only.

ciency of force generation of the stimulated than that of the control LD muscle.In this respect it should be noted that in the left ventricle a change of the myo sin heavy chain subunit from the fast ($\alpha\alpha$) to the slow (ßß) form is correlated with a decrease in speed of muscle contraction with, in parallel, an increase in efficiency of force generation (10).

The energy demands imposed on the LD muscle during the stimulation period are likely to be not as high as those necessary to assist or functionally replace a failing heart. Therefore, it would be of interest to further study the metabolic adaptation, if any, of the LD muscle after transpositioning into the thoracic cavity.

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FORMATION OF A NON-FATIGABLE SKELETAL MUSCLE FOR CARDIOMYOPLASTY BY NEUROMYOSTIMULATION.

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A method of training of a skeletal muscle for cardiomyoplasty with the aid of a Soviet original teleguided neuromyostimulator with the programmable burst of impulses from 2 to 7 impulses, with the sparse of amplitude from 0,1 to 5 V and the stimulus/cardiac rhythm correlation from 1/8 to 1/1. The training regimen of muscle stimulation began with the frequency of 20-40/min.,depending on stimulator type, and then rose during 15-20 days to 80-90/min. After the second step of the operation -the trained muscle's implantation on the myocardium - the degree of the transformed skeletal muscle's contractive capacity efficacy was assessed. After long periods of the training stimulation the skeletal myofibrils'structure slowly changed into the myocardial myofibrils'structure. The developed pressure was: $Pw=98\pm12,6Hg$; $dP/dt=1850\pm112$; $ET=0,20\pm0,003$ sec; at $CV=2430\pm347,2$ ml/min. Today the maximal time of the muscle functioning without fatigue signs is up to 4 months.

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ELECTROPHYSIOLOGICAL RESPONSES OF THE DIAPHRAGM TO THE ELECTRICAL STIMULATION OF THE PHRENIC NERVE WITH TWO TYPES OF DIAPHRAGM PACEMAKERS

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An experimental study was carried out to investigate the electrophysiological response of the Diaphragm (evaluation of muscle fatigue) after electrical stimulation of the phrenic nerve with two types of diaphragm pacemakers.

We studied the spirometric and electrophysiological responses of the diaphragm after stimulation of the phrenic nerve in dogs with two types of tottaly implantable diaphragm pacemakers. We have analized the electromyographic response of Diaphragm and the gastric, esofagic and transdiaphragmatic pressures.

We have used 12 pacemakers wich characteristics are

	High Frequency	Low Frequency
Inspiration Rate:	20 resp.min.	10 resp.min.
Pulse Delay:	0.94 - 0.96 msec.	1.04 mesc.
Inspiration Duration:	1.25 - 1.35 sec.	1.32 - 1.35 sec.
Pulse Interval:	100 - 110 msec.	40 - 41 msec.

The results of our experiences have shown diaphragm fatigue when use the diaphragm pacemakers of high frequency but not when the low frequency pacemakers were used.

We observed a progressive reduction of the gastric, esofagic and transdiaphragmatic pressures corresponding with diaphragm fatigue when high frequency pacemakers were used, and no pressure reduction was shown with the low frequency pacemaker.

No differences were noticed in phrenic nerve conduction and in the width and timing of evoqued potentials of de diapragm, either with high or low frequency pacemakers. In reference to the electromyographic response of the diaphragm in spontaneous respiration, the width and timing of the action potentials was not changed between the two types of pacemakers.

Finally, we find it convenient to use pacemakers of low frequency because they do not cause alterations as are shown when muscular fatigue of the diaphragm appears. At the same time we believe that the determination of gastric and esofagic pressure are an easy way to analize the diaphragm function during and after pacing the phrenic nerve.

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Morphostructural alterations of phrenic nerve and diaphragm muscle after electrostimulation with experimental diaphragm pacemaker.

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Summary

The chronic permanent stimulation of the phrenic nerve was achieved with a programmable and totally implantable diaphragmm pacemaker and with 3 models of stimulation parameters:

Group 1.-High frequency pulses stimulation (25 Hz.) and 10 r.p.m. respiratory rate.

Group 2.-High frequency pulses stimulation (25 Hz.) and 20 r.p.m. respiratory rate.

Group 3.-Low frequency pulses stimulation (10 Hz.) and 10 r.p.m. respiratory rate.

For these experiments were needed 15 dogs.

We researched the following objectives:

a)Diaphragm fatigue induced with the 3 diferent groups of chronic experimental electrostimulation.

b)Phrenic nerve alterations induced by the 3 groups of electrostimulation.

c)Diaphragm muscle alterations induced by the 3 Groups of electroestimulation.

These studies were done comparatively with the phrenic nerve and diaphragm muscle of counterlateral and non stimulated nerve and muscle.

We achieved the following conclusions:

1.-The diaphragm fatigue with group 1 was produced between 10 to 20 weeks.

2.-The diaphragm fatigue with group 2 was caused between 4 to 10 weeks.

3.-The group 3 has not suffered diaphragm fatigue after 6 months of permnent stimulation.

4.-The distribution rate values of fibre diameter and myelin sheath thickness of phrenic nerve were displaced to bigger values in both parameters.

5.-The hemidiaphragm electrostimulated achieved lower weight and volumen in relation to the non stimulated muscle.

6.-The hemidiaphragm electrostimulated had lower surface and perimeter than the non stimulated muscle.

7.-The diameter of muscle fibres of electrostimulated diaphragm was shorter than the non stimulated.

8.-All these alterations were greater in groups 1 and 2 than in group 3.

9.-In group 3 from the point of view of ultrastructural changes it is proved a transformation of type II,fast twitched fibres in type I,slow twitched fibres.

10.-After these experiments we can assert that low frequency pulses stimulation (10 Hz.) is less deletereous to the muscle and suitable for chronic and permanent electrostimulation to avoid muscle fatigue.

11.-The structural alterations of the muscle produced by permanent low frequency pulses stimulation of the diaphragm muscle could be reduced by mean a conditioning period.

INTRODUCTION

The investigation about the diaphragm pacemaker could be divided in three parts in order to be understood,when the biological consequences of the clinical application of the method are analysed.

1.-Results of the chronic electrostimulation on the phrenic nerve(1,2).

2.-Changes of diaphragm muscle which could be found in relation to the stimulation parameters (3,4).

3.-What consequences has the phrenic nerve electrostimulation and the resulting diaphragm activity on the lung structure and ventilation.

The main purpose of the investigation was to avoid the diaphragm muscle fatigue.For this reason we have concentrated our effort in the following objectives:

1.-Development of the experimental model of animal "in vivo".

2.-Histomorphometric study of phrenic nerve after muscle fatigue due to chronic electrostimulation of the former.

3.-Morphostructural alterations in the muscle and histomorphometric variations of the diaphragma muscle fibres in a state of fatige caused by chronic phrenic nerve electrostimulation.

MATERIAL AND METHODS

1.-Development of experimental model of animal "in vivo".

The experimental model developed in our investigation was that proposed by Glenn and cols.(4).

The animals were divided in three groups:

Group 1.-The animal were stimulated by high frequency pulse stimulation (25 Hz)and respiratory frequency of 10 r.p.m.

Group 2.-The animals were stimulated by high frequency pulse stimulation (25 Hz)and respiratory frequency of 20 r.p.m.

Group 3.-The animals were stimulated by low frequency pulse stimulation (10 Hz)and respiratory frequency of 10 r.p.m.

The pacemaker used was a totally implantable and programmable device with Lilly type stimulation pulses,160 microseconds of stimulation amplitude,1.4 seconds of inspiration time and programmable intensity.Monopolar electrode.The applied intensity was submaximum.

5 dogs were studied in each group.Only the phrenic nerve of one side was stimulated leaving the other side as an experimental control.

The follow-up controls were done every 15 days.Spirometric results during follow-up to diaphragma fatigue were obtained with a digital spirometer (Bourns ventilation monitor Model LS 75-Bear Medical Systems,Riverside California 92503) with anesthesised and endotracheally intubated animals ,causing the spontaneous respiration inhibition with controlled hyperventilation.Once reaching the state of fatigue the animals were sacrificed.

2.-Histomorphometric study of phrenic nerve after muscle fatigue due to chronic electrostimulation of the former.

Phrenic nerve specimens were extracted from both sides and processed (Mosey-84).

The histomorphometric studies were done with optical microscope and cuantifications of parameters with an Apple IIe Computer.

Morphostructural alterations in the muscle and histomorphometric variations of the diaphragma muscle fibres in a state of fatigue caused by chronic phrenic nerve electrostimulation.

A.-Weight and volume of each hemidiaphragma was determined.

The surface and perimeter were determined as for the trapezoidal formula of Sympson.To facilitate the calculations a Fortran II programma was used.(Univac 1008 Computer.)

B.-Microscopic and ultramicroscopic studies of the diaphragma muscles.

Specimens of both hemidiaphragmas were fixed in formaldehyde,embedded in paraffine and dyed with conventional methods for microscopic study.

For the ultramicroscopic study the specimens were fixed in 2.5 % gluteraldehide in Sorensen buffer at Ph 7.2.Postfixation in osmium tetroxide and embedded in epoxy ressin (Araldit),Reichert Ultracut ultramicrotom and Philips 400 electronic microscope were used.

RESULTS

1.-Development of the experimental model of animal "in vivo".-

Group 1.-This experimental group reached the reversible diaphragm fatigue between 10th and 20th week.(Graph 1).The animal were sacrificed 2 weeks later and during this period with no stimulation at all in order to observe the irrecuperability of the fatigue or its eventual slow regression.One dog was sacrificed prematurely in a state of reversible fatigue after 8 weeks of stimulation and the rest between 20 and 30 weeks.

Group 2.-The irreversible diaphragma fatigue was reached after 4 to 10 weeks.The animals of this group were sacrificed between 10 and 12 weeks of stimulation (Graph 2).

Group 3.-After 30 weeks of stimulation none of the animals showed any sign of diaphragm fatigue.(Graph 3) 2.-Histomorphometric study of phrenic nerve after muscle fatigue due to chronic electrostimulation of the former.

a.-The results of the histomorphometric syudy of the diameter of phrenic nerve fibres are shown in figure 1.

The range of distribution moves towards greater thickness values of the fibres in stimulated in relation to non stimulated nerves ($p<0.05$).

b.-The same tendency was observed in thickness of the myelin sheath ($p<0.01$).

The groups looked at individually have all statistically significant differences.

3.-Morphostructural alterations in the muscle and histomorphometric variations of the diaphragm muscle fibres in a state of fatigue,caused by chronic phrenic nerve electrostimulation.

The results are shown in figure 2 and 3:

a.-Weight decrease of stimulated hemidiaphragm ($p<0.01$),(figure 2).

b.-Volume decrease of stimulated hemidiaphragm ($p<0.025$)(figure 2).

c.-Perimeter decrease of stimulated hemidiaphragm ($p<0.04$).Group 1 look at individually is highly significant ($p<0.004$)(figure 3).

d.-Surface decrease of stimulated hemidiaphragm ($p<o.04$)(figure 3),where group 1 is highly significant ($p<0.008$)and group 3 not having modified its surface (figure 3).

B.-Microscopic and ultramicroscopic results.

The main alteration observed in the stimulated hemidiaphragm was muscle atrophy,most significant in group 1 and 2.

In the ultramicroscopic study of group 3 can be observed well preserved sarcomers but with decrease in its width and increase of the interfibrilar sarcoplasm.The mitochondrias with irregular morphology have increased in size (megamitochondrias).The Z band seems to be wider in the stimulated compared to the non stimulated diaphragm.

In group 1 and 2 can be seen a deorganization of myophilaments with loss of spatial disposal and disapperance of the sarcomers.

c.-The histomorphometric study of muscle fibre diameter is shown in table 4:

A decrease of stimulated muscle fibre diameter is observed ($p<0.01$)(figure 4).In group 1 it is highly significant ($p<004$) but not significant in group 3.

DISCUSSION

The results obtained with the experimental model animal "in vivo" are similar to those of Oda T.and cols.(4).

The histological changes of electrostimulated phrenic nerve has been studied by Kim J.H.and cols.(1,2)being emphasized alterations in the phrenic nerve as a result of the electrode implantation,more deleterious with bipolar electrodes.

Our results show a displacement of the modal curve of nerve fibre diameter and myelin thickness to the right.The interpretation of this fact is not clearly defined.

Bering in mind the already known scientific facts the following new statements can be made:

1.-The phrenic nerve changes could be related to the preservation of fibre type I (fatigue resistant fibres)after stimulation of the diaphragm.

2.-The diaphragm muscle fatigue cause decease of weight,volumen,perimeter and surface,specially with high frequency electrostimulation,but insignificant changes in those with low frequency electrostimulation.Our results do not agree with those of Oda T.and cols.(4)because the stimulation periods are not continuous and permanent as in our experiment.

We consider our results as consequences of muscle atrophy observed in groups 1 and 2,with decrease of fibre thickness and fibre number.

It can be demonstrated by electrostructural study the transformation of fibre type II (fast twitch)in fibre type I (slow twitch)being evident the increase in size and amount of the mitochondrial material as well as the amplification of the Z band width.This changes are actually specifically being investigated.

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THE VIENNA PHRENIC PACEMAKER
5 YEARS OF EXPERIENCE WITH "KARUSSELLSTIMULATION"

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SUMMARY

An implantable 8-channel stimulator for functional stimulation of the phrenic nerves has been developed. "Karussellstimulation" provides fatigue-free stimulation of both hemidiaphragms for 24 hours a day.
Between 1983 and 1988 10 patients have been treated with the "Vienna Phrenic Pacemaker". 9 of them suffered from total ventilatory insufficiency due to high cervical cord lesions. One patient is partially respiratory insufficient due to central hypoventilation syndrome.
Both hemidiaphragms are stimulated simultaneously, tidal volumes as well as respiratory rates are kept within physiological ranges. Chronical stimulation is performed successfully in eight of these patients, in one case since 5 years. The tracheostomy has been closed in 4 cases. 7 patients are living at home. Two patients died from pulmonar embolism and septicemia.
The system of "Karussellstimulation" can help to overcome the electrically induced fatigue of the diaphragm.

INTRODUCTION

Functional electrical stimulation of the phrenic nerves for the purpose of chronical artificial ventilation first was mentioned by Sarnoff in 1948 (9). The developement of the modern technique of diaphragm pacing was based upon the work of Glenn and Coworkers (5). Meanwhile chronic ventilatory insufficiency due to either central alveolar hypoventilation syndrome or high spinal cord lesion indicates treatment with a phrenic pacemaker (1,2,3). The Vienna group has own experimental and clinical experiences on FES since 1971 (6). Result of this work is an implantable eight-channel stimulator for functional stimulation of the phrenic nerves, which first was implanted in 1983 (8).

MATERIALS AND METHODS

Pacemaker

The external system consists of a control unit and a transmitter, which supply the implanted part with stimulus information and energy, a radio receiver, electrode leads and 8 electrodes. Calibration of respiratory rate, duration of inspiration and tidal volumes - by adjusting the electrical current - can be performed programming the external control unit.

The system of "Karussellstimulation" (7,10) provides fatigue free stimulation of both hemidiaphragms at high respiratory rates and adequate tidal volumes for 24 hours a day. 4 ring shaped electrodes are positioned around each phrenic nerve. Configuration and polarity of these four electrodes is changed after each inspiration, only a part of the neurons is activated at a time.

Patients
Between 1983 and 1988 9 quadriplegics have been treated with the "Vienna Phrenic Pacemaker". All patients suffered from complete ventilatory insufficiency due high cervical cord lesion.

Implantation
Prior to implantation phrenic nerve function was evaluated in all cases by means of percutaneous stimulation.
The implantation was done under general anaesthesia. A median sternotomy was performed. Both phrenic nerves were located in the upper mediastinum and function of the nerves and the hemidiaphragms was finally tested by use of direct nerve stimulation. The receiver was placed underneath the fascia of the right rectus abdominis muscle and the electrode leads were pulled through subcutaneously into the mediastinum.
Four ring shaped steel electrodes were fixed around each phrenic nerve. The electrodes were fixed with 8.0 sutures to the epineurium of the nerve under the microscope using microsurgical techniques.

Conditioning the diaphragm
Synchronous pacing of both hemidiaphragms was started two weeks after operation. Respiratory rates and tidal volumes were adjusted individually to the patients comfort, usually in accordance to mechanical ventilation.
Electrophrenic respiration at first was performed four times 15 minutes a day. In an individual program to conditioning the diaphragm time intervals of mechanical ventilation decreased, untill full time ventilatory support could be provided by EPR.

RESULTS

At the follow up EPR was performed chronically in 8 patients. Bilateral synchronous pacing provides appropriate ventilation, tidal volumes ranging from 9 to 15 ml per kg bodyweight and respiratory rates between 10 and 16 per minute.
Blood gas analyses in all cases revealed a compensated respiratory alcalosis, paO_2 ranging from 86 to 95 mmHg, $paCO_2$ from 25 to 30 mmHg and ph of 7,4.
7 patients are entirely independent of a convential respirator, pacing full time since 53, 30, 25, 6, 6, 4 and 1 months. One patient uses mechanical ventilation one night a week, although fatigue of the diaphragm could not be detected. Tracheostomy was finally closed in four of these cases. One patient has just one phrenic nerve functioning and is fully dependent on mechanical ventilation for unilateral pacing does not provide adequate ventilatory support. Seven patients are living at home. One patient is still in hospital for final rehabilitation. Recently two patients died because of pulmonar embolism in one case and pneumonia followed by general septicemia in the other case.

DISCUSSION

Ventilatory insufficiency due to brain stem or high cervical cord lesion above the origin of the phrenic nerves indicates the treatment with a phrenic pacemaker (1,2,3,4,5). EPR means physiological ventilation and should be preferred to mechanical ventilation (6).
The "Vienna Phrenic Pacemaker" provides fatigue free stimulation of both hemidiaphragms at high respiratory rates and adequate tidal volumes. Closure of tracheostomy is possible, which means an essential improvement in quality of the patients life.

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Electrophrenic stimulation in 9 patients with Ondine's curse

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SUMMARY

This report describes elektrophrenic pacing in 9 infants with Ondine's curse. Ondine's curse is characterized by an adequate ventilation when awake, but falling asleep, the infants "forget" to breathe. There is no ventilatory response to hypercapnia or hypoxia, correspondent to a failure of the automatic control of ventilation. The age at the time of implantation of the pacing unit ranged from 4 months to 22 years. Seven patients were supportet by mechanical ventilation since birth, except for two, having an acquired central hypoventilation.

In one patient the electrophrenic stimulation failed, in eight patients the system works effective now for more than eight years in the first patient. They could be weaned off the respirator and are able to live under home care with their families. Cooperation of a well informed and understanding family contributed to the continued success of the program after infants were discharged from the hospital. Careful patient selection is very important. The phrenic nerve conduction time has to be intact, as well as the diaphragmatic action potentials. Follow up is available on all patients from 4 months to nine years postoperatively.

The pacing unit consists of the external components, i.e. one transmitter and two antennas. The implanted components are bilateral electrodes attached to a segment of the intrathoracic phrenic nerve, with perineural blood supply. Also implanted is the receiver, in the abdominal area on the left and right side. The phrenic nerve is stimulated by radiofrequency transmission of a programmed train of electrical impulses.

In infants a bilateral stimulation is necessary to provide sufficient ventilation. In order to prevent obstructive apneas all infants needed a tracheostomy. In our experience electrophrenic pacing showed to be a successful mode of therapy in Ondine's curse in infants.

MATERIAL AND METHODS

Nine infants were treated for central hypoventilation, Ondine's Curse, with diaphragmatic pacing, between March 1980 and September 1989.Their ages ranged - at the time of implantation - from 4 months to 22 years. The central hypoventilation was congenital in seven infants, acquired in two.

In all patients automatic control of ventilation is lost, while voluntary breathing remains possible. There is no primary pulmonary, thoracic, cardiac or neuromuscular disease. In Ondine's Curse neither the structural abnormalities nor the pathophysiology is clear. The presenting symptoms are:

-apnea, cyanosis or pallor during sleep, severe hypoxia and hypercapnia

-making immediate mechanical ventilator therapy necessary.

-there is no increase of ventilation when breathing 3 % carbon dioxid in air

-no, or only inadequate ventilatory response to hypercapnia or hypoxemia. Thediagnosis of Ondine's Curse has been established by evaluating lung function during daytime or overnight, measuring blood gases, respiratory frequence volume and amplitude. Continuous monitoring of the patients ECG, heart rate transcutaneous partial pressure of oxygen (PO_2), transcutaneous partial pressure of carbon dioxid (PCO_2), oxygen saturation and depth and frequency of breathing was performed.

Evaluation of phrenic nerve and diaphragmatic function using percutaneous nerve stimulation was also performed prior to operation. The positive proof of the viability of the phrenic nerve and its conduction time was mandatory, as well as the motility of the diaphragm under fluoroscopy.

The pacing unit consists of several components (manufactured by Avery Laboratories, Farmingdale, NY). The external transmitter supplies the stimulus information to the receiver through a radio frequency electromagnetic coupling, by means of an external antenna. The receiver is an hermetically sealed integrated circuit implanted in a subcutaneous pocket in the abdominal area. The electrical current produced by the receiver is carried by an electrode to the phrenic nerve. The electrode contains one (unipolar) or two (bipolar) platinum band embadded in a silicon rubber cuff. In children these electrodes are implanted on the thoracic portion of the phrenic nerve, using a thoracotomy. It is very important to avoid any mechanical lesion to the nerve and to provide a good blood supply by the perineural tissue. The output signal of the external radio generator consists of repetitive series of modulated pulse trains of a carrier frequency of 2.05 MHz. The respirator rate is adjusted by the time interval between each series of pulses. The depth of inspiration is determined by the current amplitude which is depending on the width of each radiofrequency pulse train. Diaphragm excursions are produced by gradually increasing the energy of the pulse train, in order to stimulate slowly more nerve fibers.

RESULTS

All nine patients needed pacing during sleep only and had adequate spontaneous breathing during the awake state. In eight of nine patients a unipolar electrode was implanted; in the first patient in 1980 a bipolar electrode was used. Since in experimental animals the unipolar electrode was found to produce less nerve damage, it has replaced the bipolar electrode. The healingperiod, after implantation will take about 12 - 14 days, then pacing can be started. The initial threshold current should be determined under fluoroscopy, to avoid high frequency impulses or excessive stimulation. We started with very short stimulation periods (5-15 min), measuring blood gases, transcutaneous partial pressure of carbon dioxid(PCO_2), and, according to the patients sleep state and tolerance of pacing, the stimulating time was increased. In order to provide sufficient ventilation, we varied the respiration rate and pulse width according to the PCO_2. After 5 weeks up to 4 months it was possible to wean the patients off the respirator and maintain sufficient ventilation only by pacing. For some patients in this period a limiting factor were recurrent upper airway infections. The duration of continuous pacing was limited to 12 hours per day.

Seven of nine patients could be discharged home for the first time in their life after the pacemaker was implanted and functioned well. None of the patients developed a cor pulmonale, and the systems of right heart hypertrophy in two patients disappeared under electrophrenic respiration. One patient developed two times an acute right heart failure, when he contracted severe upper airway infection. The application of digitalis and diuretics, and if necessary mechanical respiratory support resulted in a rapid improvement. The most common reasons for rehospitilisation were upper respiratory infections. The patients recovered usually soon with a clinical trial of antibiotics, diuretics and digitalis. In some cases pacing had to be discontinued and replaced by mechanical respiration. After recovery they could be discharged home, maintaining the same pacemaker settings. Due to the manipulation of the nerve during the operation, the threshold, initially used, could be diminished after a short period of continuous stimulation and did not increase significantly since then in any patient.

Phrenic nerve conduction time and diaphragmatic action potentials revealed no evidence of nerve injury or muscle dysfunction.

Malfunction of the pacer unit occured in three patients:

After 3 years successfully pacing the receiver had to be exchanged bilaterally in the eldest patients. In another patient the left unit didn't work adequately right after implantation. First we tried a new transmitter, next a new receiver was implanted, and finally after one year of pacing with high amplitude, the whole left unit was exchanged, since then there were no more difficulties. In another patient, who could not be paced sufficiently, the phrenic nerve conduction time was normal, but on the left side an adequate ventilation was not achieved. Consequently the left receiver was exchanged, but revealed not to be the reason for the malfunction. Subsequently the parents did not agree to any further operation, so that in this patient the electrophrenic stimulation was abandoned.

DISCUSSION

Phrenic nerve pacing is applied successfully in certain forms of acquired chronic respiratory insufficiency, like poliomyelitis, encephalitis and especially in traumatic lesions of the spinal cord. In infants, only few cases have been reported (see literature).

In our experience, diaphragmatic pacing is safe and has no major side effects. Selecting the appropriate candidates is very important, the phrenic nerve has to be intact as well as the diaphragmatic motility, there should be no primary pulmonary disease. To provide successful pacing and avoid nerve damage, the operative technique is as important as the accurately assessed stimulating current. The electrodes are implanted at the intrathoracic portion of the phrenic nerve, and care has to be taken on the preservation of perineural blood supply.

A tracheostoma is mandatory in all infants, to avoid upper airway obstruction caused by failure to activate laryngeal and upper airway muscles during pacing. In the first patient a unipolar pacing system was employed, but showed a similar effect as unilateral diaphragmatic paralysis in infants, i.e. paradoxical movements of the contralateral diaphragm and insufficient ventilation. Consequently a bilateral pacing system is mandatory in infants. Follow up of the nerve conduction time and diaphragmatic motility revealed no damage or fatigue, verified by transcutaneous stimulation, transtelephonic monitoring and fluoroscopy. In order to obtain these results, we didn't exceed a stimulation time of 12 hours and applied the lowest current amount possible. Malfunction from the technical point of view could be resolved by removing the failing part and implantation of a new one.

Electrophrenic pacing showed to prevent or reduce cor pulmonale. In our experience the phrenic pacemaker is an appropriate therapy in Ondine's curse, allowing the patient a near normal life, by discontinuation of the respirator and effective ambulation and rehabilitation.

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TRANSCUTANEOUS VOLUME MEASUREMENT IN CASE OF ELECTROPHRENIC RESPIRATION

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INTRODUCTION

Chronical electrical stimulation of the phrenic nerves has become a clinical method for the rehabilitation of tetraplegic patients suffering from respiratory insufficiency. A stimulation method developed in Vienna, the socalled "carrusel" or "round-about" stimulation, offers chronical respiration avoiding muscular fatigue.

It is based on a fully implantable multichannel implant and a set of 8 electrodes, 4 of them placed around each phrenic nerve. The electrodes can be used as an anode or a cathode or switched off. Each electrode combination innervates a certain group of nerve and muscle fibers; a part of the fibers is active while the rest of them recovers. Control information and power supply are provided by an extracorporal supply and control unit via a RF-transmitter.

Up to now an open loop system is used. To begin to close the loop two different measurement methods were evaluated:
- -transcutaneous impedance measurement
- -diaphragm excursion measurement

MATERIAL AND METHODES

1) Transcutaneouse impedance measurement:
The sensor consists off 4 single use EKG-electrodes. A constant current 40kHz rectangular signal is applied on two off them. The voltage drop at the other two is used to analyse the impedance.

2) Diaphragm excursion measurement:
This system is based on a piezoelectric strain gauge element mounted on a textile belt.

Respiration flow was measured with a differential pressure device, the volume curve results from analogous integration of the flow curve. The sensor was connected to the cannula (early training phase) or to a mask (after decannulation).

RESULTS AND DISCUSSION

One example is shown in Figure 1. Five different electrode combinations were measured. The impedance sensor was situated at the left hand side of the thorax. For the secound and the third inspiration cycle only the right phrenic nerve was stimulated.

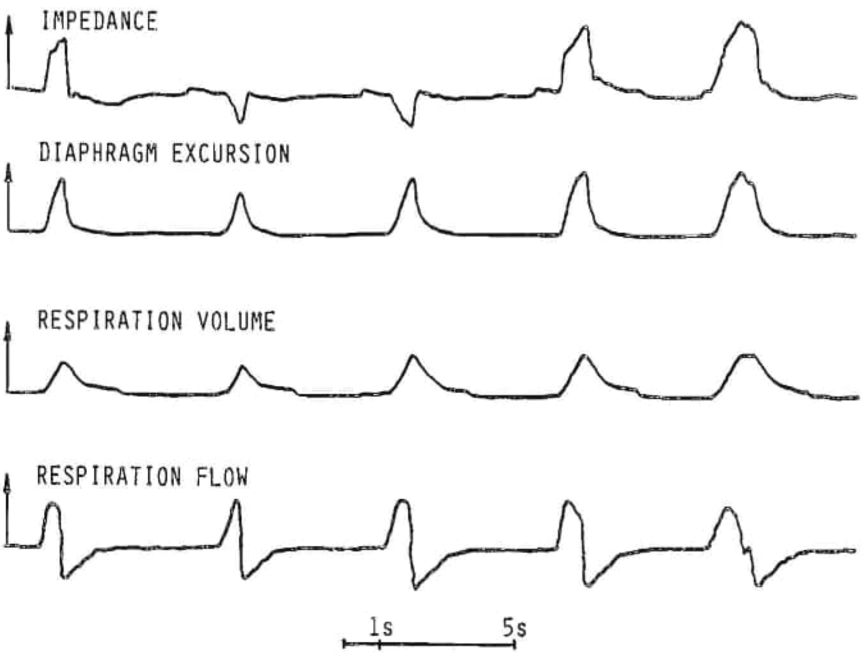

Figure 1: 5 respiration cycles with different electrode combinations (sensing electrodes/left thorax)

The impedance signal roughly approximates the shape of the real respiration volume. It quantitativly strongly depends on the positioning of the surface electrodes. The advantage of the impedance methode is its selectivity concerning activity of the hemidiaphragms. For example it clearly identivies discontinuities in the contraction of one hemidiaphragm and a smooth contraction of the other one at once.

The strain gauche methode shows clear advantages concerning long term stability and reproducibility. It offers a useful approximation to the respiration volume.

ELECTRICAL STIMULATION OF MYELINATED NERVE FIBERS: A MODELLING STUDY

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SUMMARY

Effects of electrical stimulation with point sources on myelinated nerve fibers were calculated, using a model of mammalian nerve fiber and a simple (homogeneous) volume conductor model. The sensitivity of the fiber model to variations in model parameters was evaluated by the threshold stimulus (rheobase) and the propagation velocity of action potentials. Anodal and cathodal stimulus conditions giving rise to membrane excitation and subsequent propagation were investigated, as well as the conditions by which propagation could be blocked. In addition to straight fibers the effect of stimulation on curved and bifurcated fiber models was investigated, especially with regard to their threshold stimulus.

METHODS

The model of myelinated nerve fiber stimulation, introduced by McNeal in 1976 [1] (Fig.1) was used in combination with the equations of the non–linear, voltage dependent nodal resistance (Rm) of rabbit myelinated nerve fiber, presented by Chiu et al. [2]. According to McNeal the change of nodal membrane potential was described by:

$$\frac{dV_{a,n}}{dt} = \frac{1}{R_a \cdot C_m}\left[\{V_{e,n-1} - 2V_{e,n} + V_{e,n+1}\} + \{V_{a,n-1} - 2V_{a,n} + V_{a,n+1}\}\right] - \frac{V_{a,n}}{R_m} \qquad (1)$$

Thus the field parameter related to nodal membrane potential (Va) is the second order difference of the nodal field potential (Ve): the **activating– or driving function**.

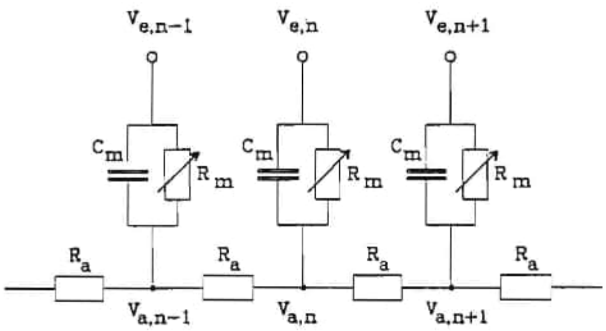

Figure 1. *McNeal model of myelinated nerve fiber stimulation.* ***Ra:*** *internodal intracellular resistance,* ***Rm:*** *(variable) nodal membrane resistance,* ***Cm:*** *nodal membrane capacity,* ***Va:*** *nodal intracellular potential,* ***Ve:*** *nodal field potential.*

Nodal field potentials, generated in an infinite, homogeneous, isotropic medium (conductivity σ) by an anodal or cathodal point source with current I, were calculated analytically [3]:

$$V_e(x,y,z) = I \,/\, 4\pi\sigma\,(x^2+y^2+z^2)^{\frac{1}{2}} \qquad \text{(source at } x = y = z = 0) \qquad (2)$$

For this type of stimulus field the **activating function** along a straight nerve fiber is maximal at the node closest to the electrode and has two areas of opposite sign at both sides [3,4] (Fig.2). Using a cathode the maximum is positive, resulting in local membrane depolarization, while at the negative "side–lobes" hyperpolarization will occur. An anode has the opposite effects.
Usually a 10 μm diameter myelinated nerve fiber, consisting of 60 nodes of Ranvier at intervals of 1 mm was modelled. The nodal membrane current in (1) (Im=Va,n/Rm) was calculated by Hodgkin-Huxley–like kinetics [2]:

$$I_m = \pi.d.l\,[\,\bar{g}_{Na}.h.m^2.(E-E_{Na}) + g_L.(E-E_L)\,] \qquad (3)$$

with d the axon diameter, l the nodal gap width and E (=Va–Ve) the nodal membrane potential. Chiu et al. [2] found that repolarization in mammalian myelinated fibers is only due to a leakage current. Usually the electrode(s) were at nodal positions at a distance of 1mm from the fiber. For each set of parameters the threshold stimulus (rheobase) was calculated. Nodal membrane potentials were calculated and plotted as time–series and spatio–temporal contour maps (after interpolation).
Fibers with a bifurcation were modelled in the same way.

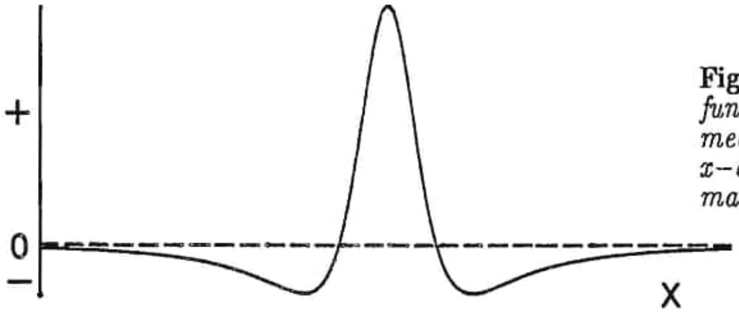

Figure 2. *Cathodal (continuous) activating function (mV) in a homogeneous, isotropic medium. X–axis: position along nerve fiber; x–coordinate of electrode corresponds with maximum.*

RESULTS

The sensitivity of the nerve fiber model to changes in model parameters was evaluated by varying these parameters in the same range as the variations in experimental data from literature (–50% and +100%) and calculating the rheobase and propagation velocity. Table I shows that their values vary considerably with most model parameters.

Table I

(1: axon/fiber diameter=1.0)

model parameter	standard value	rheobase – 50 %	rheobase + 100 %	propag. velocity – 50 %	propag. velocity + 100 %
nodal gap	1.5 μm	– 22 %	+ 43 %	+ 53 %	– 38 %
nodal capacitance	0.02 F/m²			+ 44	– 36
min. nodal conduct.	1280 S/m²	– 30	+ 56	+ 31	– 70
max. nodal conduct.	14450 S/m²	+ 18	– 15	– 43	+ 37
axon/fiber diameter	0.6	+ 52	– 19 [1]	– 38	+ 36 [1]
nodal interval	1.0 mm	+ 44	– 15		
intracell. conduct.	0.7 Ω.m	– 22	+ 35	+ 53	– 40

When stimulating, not only the peak value of the activating fuction is important, but also the amplitude of its side–lobes. At **cathodal stimulation** a fiber could be excited and the action potential propagated in two directions (Fig.3A, velocity 57 m/s), but at a stimulus of 5.3 x rheobase the hyperpolarizing effect of the side–lobes blocked propagation (Fig.3B). At **anodal stimulation** the depolarizing side–lobes excited the fiber at a stimulus of 5.2 x cathodal rheobase, while in–between the side–lobes a strong hyperpolarization occurred (Fig.3C).
Blocking of a propagating action potential by an **anode** (Fig.4A) was only possible by pulses having a minimal duration corresponding with the action potential. The anodal blocking threshold was 1.8 x the cathodal rheobase of the fibre, but due to the depolarizing effect of the side–lobes propagation could not be blocked any more at a stimulus of 2.2 x this anodal blocking threshold. Outside this small blocking range there only was some extra delay, which could be shown more clearly if an array of anodes was used. In Fig.4B the propagation velocity in the anodal region is reduced from 57 to 21 m/s. At varying electrode distance some ratios of excitation– and blocking thresholds also varied, but the ratio of upper– and lower anodal blocking threshold was almost constant (≈ 2).
In contrast with a straight nerve fiber, thresholds decreased markedly at increasing curvature in a direction away from the electrode, as shown in Fig. 5.

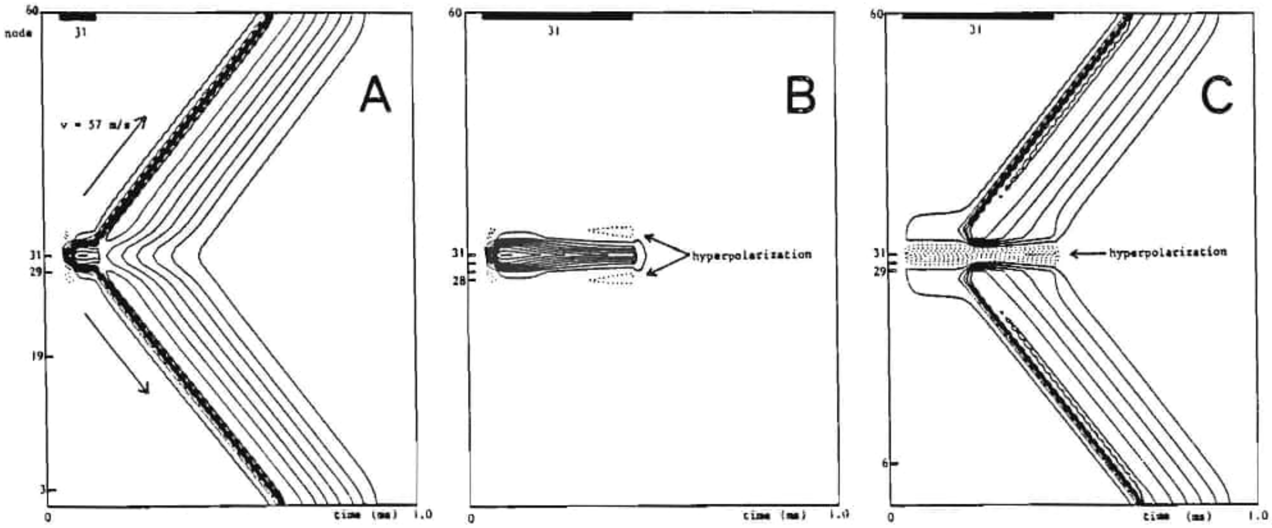

Figure 3. *Spatio–temporal contour maps of nodal membrane potentials. 10 µm fiber, 60 nodes, nodal interval 1 mm, electrode at 1 mm from node 31.* ***A****: cathodal excitation,* ***B****: cathodal block,* ***C****: anodal excitation.*

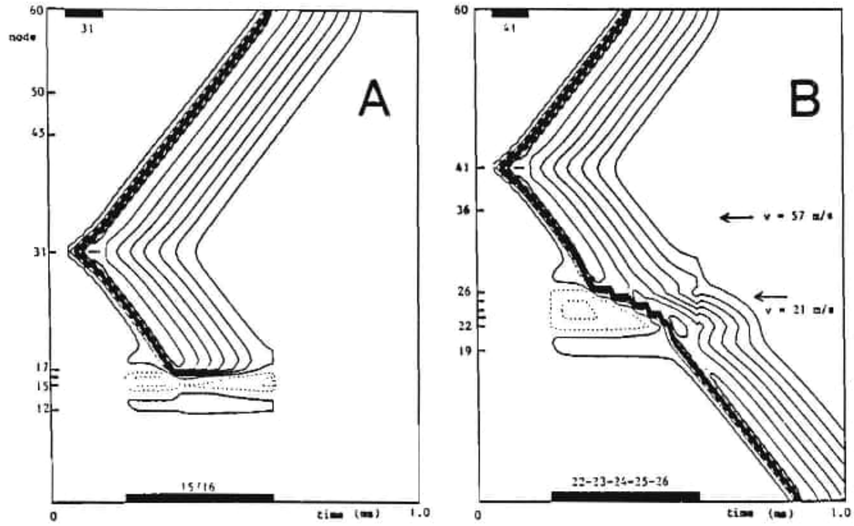

Figure 4. *Contour maps of nodal membrane potentials (cf. Fig.3).* ***A****: anodal block (anode at 1 mm from node 15),* ***B****: anodal delay (5 anodes at 1 mm from nodes 22–26).*

threshold	value (mA)	normalized values 1	2	3	4	5
cathodal excit.	– 4.318	1.00	0.84	0.75	0.51	0.39
anodal excit.	+18.663	1.00	0.84	0.76	0.70	0.75
cathodal block	–32.260	1.00	0.80	0.70	0.56	0.56

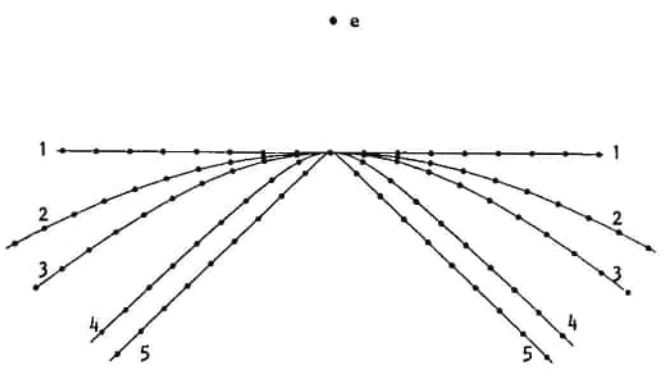

Figure 5. *Thresholds of straight and curved, 10 µm myelinated fibers; minimal distance from the electrode is 4 mm.*

Simulations were also executed on a straight fiber model (10 μm diameter), having a **collateral** perpendicular to the fiber. When the electrode was in line with the collateral (10 μm) at 1 mm from the bifurcation node, the cathodal excitation threshold was 0.80 x the value without a collateral. When using a smaller collateral diameter or a larger surface of the bifurcation node, this threshold was increased. At cathodal stimulation above threshold an action potential could be generated, which propagated in the main fiber but was blocked in the collateral. At anodal stimulation the opposite effect could be obtained.

DISCUSSION

The sensitivity study showed that the behaviour of a nerve fiber largely varies with changes in model parameters. Because experimental data on these model parameters in the literature also vary considerably, there is a need for more reliable data.
The next step in this investigation will be the analysis of the various responses to anodal and cathodal stimulation as a function of fiber diameter and electrode distance, in order to develop a fiber– diameter–selective stimulation strategy. Furthermore, the theoretical results of this modelling study will be verified by experiments.
The effects of fiber–curvature and –bifurcation on excitation and blocking thresholds are primarily of interest to stimulation techniques for the brain and the spinal cord [5–7].

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MUSCLE SELECTIVE NERVE STIMULATION FOR FES

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SUMMARY

Results of intrafascicular nerve stimulation in rat are presented. The sciatic nerve, consisting of two or three fascicles, was stimulated at a level proximal to its bifurcation into tibial nerve and common peroneal nerve. Twitch forces and electrical responses of the extensor digitorum longus and soleus muscle were measured. The recruitment threshold of these muscles appeared to differ much when one fascicle or another was stimulated. Therefore, intrafascicular stimulation seems to be a promising method for the realization of muscle selective nerve stimulation. The results justify the continuation of a thorough study of intrafascicular stimulation.

MATERIAL AND METHODS

Introduction

One of the aims of research on FES is the development of methods for electrical nerve stimulation by which a better (inter– and intra–) muscle selectivity can be obtained. In this study the possibilities of fascicle selective nerve stimulation are investigated.
Human peripheral nerves are composed of a large number of fascicles, separated by connective tissue, the epineurium. Number and size of the fascicles vary along the nerves, because fascicles fuse and divide repeatedly. By this redistribution of nerve fibres among fascicles, the composition of fascicles gets more muscle–specific towards the periphery [1].
It is obvious to make use of this anatomical subdivision of peripheral nerves for the selective stimulation of muscles. It was also suggested by Bowman and Erickson [2] that intraneural electrodes may be of great value for this purpose.
In a previous study simulations have been performed, using a model of the human deep peroneal nerve with realistic cross–sectional geometry [3,4]. The results predict that fascicle selective stimulation is difficult to attain when using small extraneural electrodes or epineural electrodes just outside a fascicle, but may well be realized using small intrafascicular electrodes. Furthermore, a mixed recruitment of nerve fibres with different diameters seems to be favoured by intrafascicular electrodes, but not by extrafascicular ones.
Experiments were started in order to verify the results obtained by this modelling study. A first series of acute experiments were done on rat, having nerves with relatively few fascicles.

Experimental methods

The sciatic nerve in the upper hind leg of the rat, consisting of two or three fascicles, was used for stimulation experiments. Figure 1 illustrates the experimental setup. At some distance proximal to the knee joint this nerve bifurcates into the tibial nerve and the common peroneal nerve. The tibial nerve contains the motor fibres of both the soleus and gastrocnemius muscle. The common peroneal nerve innervates the extensor digitorum longus (EDL) and tibialis anterior muscle.
The sciatic nerve was stimulated monopolarly by intrafascicular wire electrodes (ϕ 25 μm), isolated except at the tip. The reference electrode was placed at some distance between the muscles of the upper hind leg. Cathodic monophasic rectangular current pulses, having a pulse width of 60 μs, were used. The pulse amplitude was varied during the experiments.
In order to measure twitch forces of the EDL and soleus, the distal tendon of each muscle was cut and connected to a force transducer. Fixation of the proximal tendons was obtained by cutting and clamping, or by fixation of the femur.
In one experiment the electromyogram (EMG) of each muscle was also measured, using intramuscular wire electrodes (ϕ 50 μm), isolated except 2 mm from the tip.

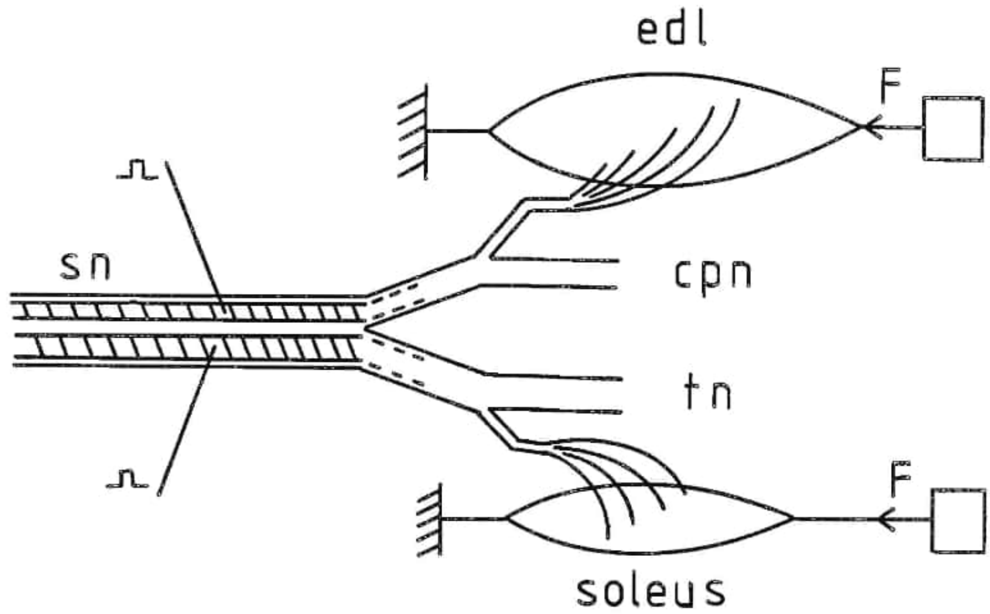

Figure 1. *Experimental setup. Stimulating wire electrodes are positioned in the fascicles (shaded) of the sciatic nerve (sn). The fascicles pass into the common peroneal nerve (cpn) and the tibial nerve (tn), innervating the EDL and the soleus muscle, respectively. Muscle forces (F) are measured.*

RESULTS

Figure 2 shows recruitment curves (twitch force versus stimulus amplitude) of the EDL at five different (intrafascicular) positions of the cathode in two rats. In three cases the stimulating electrode was positioned in the fascicle that passes into the common peroneal nerve. In these cases the threshold stimulus was about 10 μA. In the other two cases the stimulating electrode was placed in the fascicle that enters the tibial nerve, and the threshold stimulus of the EDL was much higher (about 80 μA). In some cases there was a slight overlap of the recruitment curves. However, this will be of minor interest, because it occurred at almost maximum force.

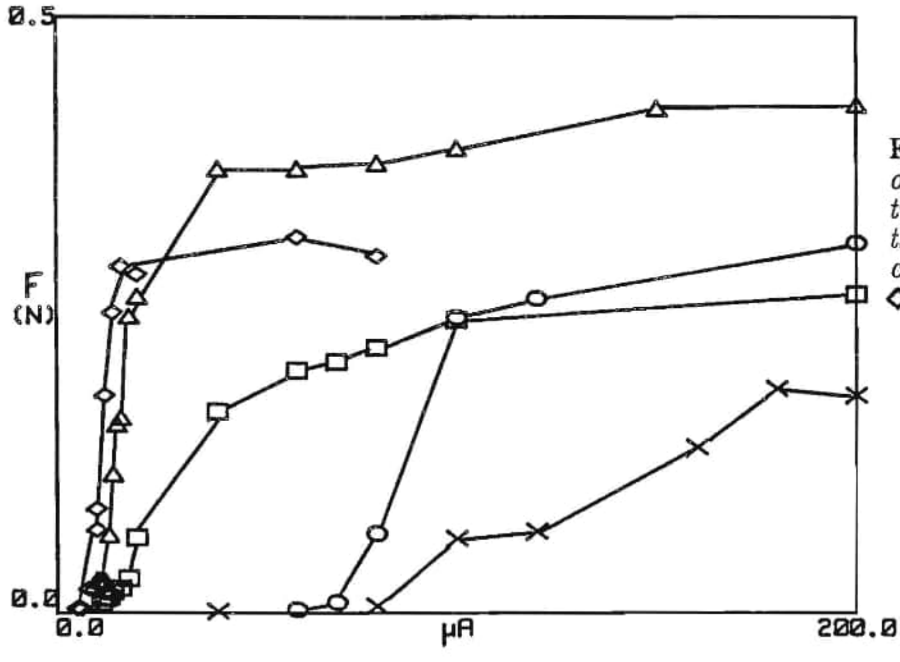

Figure 2. *Recruitment curves of the EDL. Stimulating electrode positioned in a fascicle of the sciatic nerve, entering the common peroneal nerve (△, □, ◇) or the tibial nerve (○, ×).*

Some results of EMG measurements are also presented. Because it is not obvious which EMG parameter should be taken as a quantitative measure of muscle activity, the peak–to–peak amplitude of the M–wave was chosen. Identical results were obtained when the area of the M–wave was used. In figure 3 the peak–to–peak amplitude of the M–wave of four muscles is presented as a function of the stimulus amplitude. The stimulating electrode was placed in the fascicle that passes into the common peroneal nerve. The results show that the threshold stimulus of the EDL and the tibialis anterior were much lower than those of the soleus and gastrocnemius muscle.

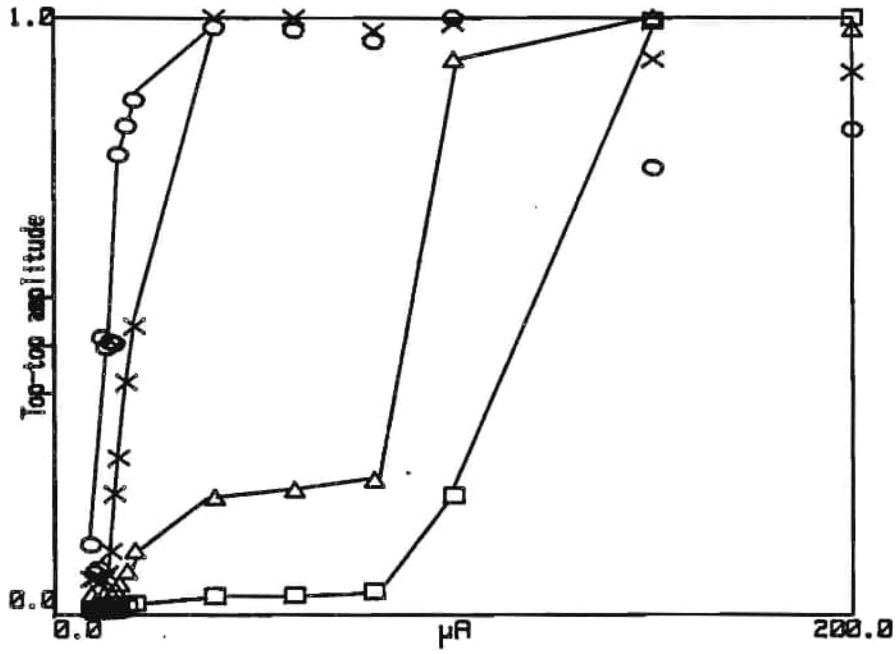

Figure 3. *Peak–to–peak amplitude of the M–wave of four muscles as a function of stimulus amplitude; EDL (x), tibialis anterior (o), gastrocnemius (□) and soleus (Δ). The maximum peak–to–peak amplitude was normalized at 1.0 for each curve.*

DISCUSSION

From both the recruitment curves and the EMG measurements it appears that the threshold stimulus is low for a muscle innervated by the fascicle directly stimulated by an intrafascicular electrode. A muscle innervated by another fascicle has a much higher threshold. This result is in agreement with the results of simulations [3,4], which predict that it will be possible to recruit all fibres in a fascicle by an intrafascicular electrode without recruiting fibres in neighbouring fascicles. The main reason is the large distance between the cathode and the nerve fibres in neighbouring fascicles as compared to the fibers in the stimulated fascicle. Furthermore, the low conductivity of the epineurium is an important factor.

The rat sciatic nerve is a rather simple experimental model. Every fascicle in this nerve lies close to the surface of the nerve. Therefore, it will be possible to stimulate a fascicle selectively by an extraneural electrode too. In larger mammals, however, having nerves which consist of larger numbers of fascicles, it will be more difficult to attain muscle selectivity using extraneural electrodes [5].

We determined the number of fascicles in the sciatic nerve, common peroneal nerve and tibial nerve of rat, rabbit and cat. Rabbit nerves consist of about the same number of fascicles as rat nerves. In the cat, however, the number of fascicles is of the order of 10. Therefore, the sciatic nerve of the cat seems to be appropriate for further experiments on intrafascicular stimulation.

The recruitment characteristics and fascicle selectivity of intrafascicular stimulation will be compared with those of extrafascicular and extraneural stimulation. It seems a drastic surgery to insert a wire into a fascicle. Therefore careful chronic experiments will be necessary.

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Model of Nine Different Muscles Tested with FES.

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The model of a muscle is necessary for the design of accurate, precise FES based closed loop control systems for the rehabilitation of spinal cord injured patients. Based on the large difference in twitch response, fiber pennation, tendon and muscle length proportions and associated viscoelastic stiffness, large variations in the model of different muscles is expected.

Using FES with orderly recruitment of motor units simultaneously with rate increase, nine different muscles in the hindlimb of the cat were tested. The results show that all muscles resulted in a linear, second order model with double poles as follows: L. Gast - 1.5 Hz, soleus - 1.8 Hz, M. Gast. - 2 Hz, Peroneus B. - 2.1 Hz, Peroneus L. - 2.1 Hz, EDL - 2.15 Hz, Tibialis P. - 2.15 Hz, EDL - 2.5 Hz and Tibialis A. - 3 Hz. The two fold increase in the poles of the model of the muscles indicate that special care should be taken when designing a closed loop control system for a specific muscle and warns against the use of a single general model.

The Use of the Tensor Network Theory for Funcional Neromuscular Stimulation

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Comuter programs for motor control have been developed using a multidimensional geometric theory of neural systems. (Tensor Network Theory by A. Pellionisz.) Here this programs are applied for functional neuromuscular stimulation. An intended movement of a limb specified in 3D Cartesian coordinates must be converted into change of the length of each muscle that contributes to the movement. The theoretical solution to such problems have been elaborated.(Pellionisz 1984: Tensor Geometry: Mathematical Brain theory for Neurocomputers and Neurobots, A Paralell Algorithm for Functional Neuromuscular Stimulaton. In: Proc. of 9th Annual Conference IEEE Engeniring in Medicin and Biology Society, Boston Nov 13-17 , 1987)
The developed computer programs (Laczkó et al. 1987 Neurosci. Absts. 13:372) yield a poosibility for simultaneous stimulation of muscles using surface electrodes. A video will be presented. At present the next step, carrying mathematical pardigms and software simulation into a hardware basis is being planned.

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MULTI-CHANNEL INDIRECT STIMULATION REDUCES MUSCLE FATIGUE

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ABSTRACT

Isometric contraction forces were registrated in sheep rectus femoris muscles at two different types of stimulation through the femoral nerve. Conventional single-channel nerve stimulation (2 electrodes) on one leg was compared with multi-channel stimulation (4 electrodes with rotating activity) on the contralateral leg. Fatigue indices were evaluated according to BURKE et al.(1973) with stimulation parameters modified for the larger dimensions in sheep. Fatigue indices were calculated after 2, 4, 10, 20, 40 and 60 min. After 2 min. submaximal multi-channel stimulation resulted in at least 14% less muscle fatigue compared to single-channel stimulation. Accordingly, after prolonged stimulation up to 60 min. higher contraction forces were recorded at multi-channel stimulation. The fatigue indices were 0.43 for single-channel and 0.66 for multi-channel stimulation respectively. The data clearly indicate that multi-channel stimulation results in 23% less muscle fatigue. The experimental results are proving the advantages of multi-channel stimulation in patients.

INTRODUCTION

FES has been used for years at different muscles for the restoration of lost function. In case of tetraplegia, paraplegia and cardiac insuffiency the diaphragm, urinary bladder, muscles of the lower leg and the latissimus dorsi muscle wrapped around the heart have been successfully stimulated.[1,2,3,4] One of the main problems in FES is muscle fatigue during prolonged stimulation. This is the reason why an experimental model has been developed to compare different methods of indirect muscle stimulation (single- and multi-channel stimulation) in one and the same animal and under identical conditions in respect to muscle fatigue.

METHOD

The experiments were carried out in 10 adult female sheep. The animals were anesthetized initially by Thiopental and anesthesia was maintained by Halothane.
On both hindlimbs the rectus femoris muscle was exposed and its distal tendon was attached to strain gauge. Temperature was kept constant at 37° C. On both sides the femoral nerve was dissected free and all branches were transected exept the nerve to the rectus femoris muscle.

Silicone cuffs containig 4 ring-shaped stranded steel wire electrodes (each of 0.5mm diameter) were exactly adapted to the surface of the nerves. To prevent movements, the hip of the sheep was fixed to the stable frame bearing the two strain gauges. A control and supply unit for the RF induction-powered multichannel stimulator, discribed by Thoma[5], was used for indirect stimulation. At single-channel stimulation 2 opposit electrodes are acting during the whole stimulation period. During multi-channel stimulation after each stimulus train the active electrode combination was changed to the next (1 - 2, 2 - 3, 3 - 4, 4 - 1). The same equipment is also in clinical use.[2]

Strain gauges and the control- and supply unit were connected through an analogue interface to an Z80 microprocessor. This system was controlled by the main processor (IBM AT3) for driving stimulation and mechanograhic realtime data sampling.
Stimulation parameters and electrode combinations could be programmed at the PC for each side.

Isometric muscle force and fatigue indices were evaluated according to Burke & al.[6]

with stimulation parameters modified for the larger dimensions in sheep: Pulse width 0,8msec., 40 Hz stimulus trains 475 msec. on and 1025 msec. off. Fatigue was calculated, after 2, 4, 10, 20, 40 and 60 min. of continuous supramaximal and submaximal stimulation for both, single and multi-channel stimulation.

$$\text{Fatigue Index} = \frac{\text{initial force}}{\text{force after x min.}}$$

RESULTS

After 2 min *supramaximal* single-channel as well as alternating multichannel stimulation the maximal tetanic tension (Po) of the rectus femoris muscle was reduced to 48% of the initial tension.
In each experiment also *submaximal* starting levels of 10 to 70% of Po were chosen. 2 min, submaximal alternating multi-channel stimulation - switching from one electrode combination to another after 1 min. - resulted in at least 14% less muscle fatigue compared to single-channel stimulation (Tab. 1). Accordingly, after prolonged stimulation up to 60 min. higher contraction force was recorded by multi-channel stimulation. The fatigue indices were 0.43 for single-channel and 0.66 for multi-channel stimulation respectively. The data clearly indicate that at a submaximal level multichannel stimulation results in less muscle fatigue.
All mechanographic data evaluated for corresponding single- and multi-channel stimulation were compared statistically by variance analysis. The differences between the two types of stimulation were significant (p>0,02) after all stimulation periods (2, 4, 10, 20, 40 and 60 min). The calculated muscle fatigue was 12 to 23% less at multichannel stimulation compared with single-channel stimulation.

		STIMULATION PERIOD						
STIMULATION		1 min	2 min	4 min	10 min	20 min	40 min	60 min
Single-channel n=12	FI 100 St.Dev.	0,76 0,13	0,49 0,20					
Single-channel n=6	FI 29 St.Dev.	0,82 0,19	0,75 0,19	0,70 0,18	0,62 0,17	0,53 0,18	0,46 0,14	0,41 0,14
Multi-channel n=7	FI 28 St.Dev.	0,96 0,07	0,91 0,06	0,89 0,08	0,82 0,08	0,74 0,12	0,71 0,14	0,66 0,14

Table 1. Fatigue indices and their standard deviation of the sheep rectus femoris muscle. Comparison of fatigue at single-channel and muti-channel stimulation after stimulation periods of 1 to 60 minutes.

CONCLUSION

The programmed multichannel stimulator used in all experiments was acting with 4 predetermined electrode combinations and no attempt of optimizing out of 64 possible programmable combinations was made. We would expect that testing out the optimal combinations - as is done routinely in clinical application of this system - could achieve even further reduction of muscle fatigue.

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CONSTRUCTIVE TECHNOLOGY ASSESSMENT OF FUNCTIONAL NEUROMUSCULAR STIMULATION IN PARAPLEGICS

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INTRODUCTION.

Functional Neuromuscular Stimulation (FNS) has been developed in the last decades for restoration of standing and walking in paraplegics. Allthough the number of research groups worldwide involved in the research on this and related topics is still increasing, the clinical applicability improves only slowly. In the last five years there is a tendency towards the development of complex (totally) implantable systems. Due to limited financial resources, emancipated patients and the awareness of scientists of their responsibility for the society, an increasing interest has arisen about the social implications of this new method.

We applied a for the Biomedical Engineering suitable form of Constructive Technology Assessment as an instrument to investigate the future clinical and social impact of FNS for restoration of walking in paraplegics.

In Enschede the Rehabilitation Centre Het Roessingh and the University of Twente carry out research on FNS. For the application of FNS, the Roessingh Rehabilitation Centre has developed a clinical program.[1]

METHODS.

Traditionally Technology Assessment (TA) was used to systematically identify, analyze and evaluate the potential secondary consequences (whether beneficial or detrimental) of technology in terms of its impact on social, cultural, political, economical and environmental systems and processes, and was intended to provide a neutral, factual input into the decision-making process.[2] This form of TA was strongly scientific oriented, since people had high expectations of technological developments, and the decision-making process was seen as a rational one. During the seventies however the idea of technology-development being a continuous transformation-process became more realistic. Technology-development was not longer seen as an autonomic process but as a process continuously influenced by societal processes.

A specific form of TA became Constructive Technology Assessment (CTA), which also includes the tracing and formulating of social needs and useful technological applications. CTA provides possibilities for every person concerned to take part in the process of decision-making and to take part in the process of feedback to the design of a technology.[3]

For Biomedical Engineering we designed a scheme according to which CTA could be applied. This Biomedical Technology Assessment (BMTA) scheme is presented in figure 1.

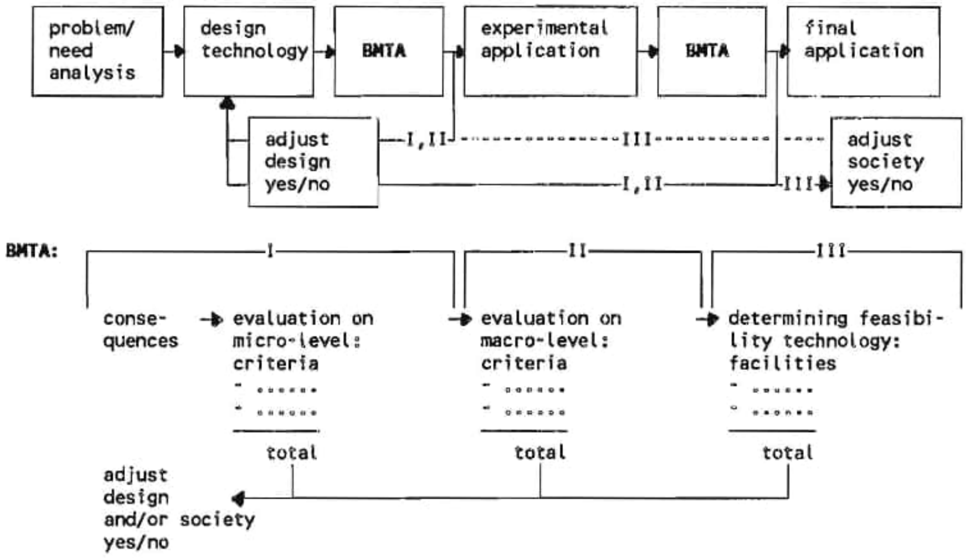

Figure 1 Biomedical Technology Assessment (BMTA).

The BMTA-part of this scheme comprises three phases, each determining the consequences at complementary levels. Each phase provides feedback information concerning the technology-design and feed-forward information for societal changes.

At the Roessingh Rehabilitation Centre 13 patients were or have been in the experimental stage of applying FNS in the observed time period. The evaluation of consequences of FNS at micro-level has been performed by interviewing those 13 patients according to a specially designed questionnaire. Also others concerned with the implementation of FNS, i.e. a rehabilitation physician, physiotherapists, researchers and people from the Dutch Medical Insurance Board, have been interviewed to evaluate micro- and macro-level consequences. Part III could not be performed due to little information present at this stage of the research and due to the present stage of technological possibilities of FNS. When the development of FNS comes near to a final introduction in the society, part III becomes more important and most certainly more information will be available at that stage.

In part I, 9 different consequences have been evaluated. In part II, four different consequences have been evaluated with the information which was provided by the evaluation at micro-level and by the interviews.

RESULTS.

Each of the consequences at micro- and macro-level are shortly evaluated below.

Consequences at micro-level (part I), derived from patients interviews.

1. The physical consequences of FNS. The majority of the patients finds FNS in general positive for their bodies. The only negative bodily aspect was the influence of FNS on spasms (50%).
2. The mental consequences of FNS. There were no negative psychic consequences of FNS for the patients.
3. The work-situation of patients. FNS has no influence on the work-situation of the patients. At present FNS is not being used in a working environment.
4. The consequences for the living situation of patients. Houses do not need adjustment to make the application of FNS possible. Most houses already have been adjusted for the use of wheelchairs.
5. The consequences for daily life. The application of FNS brought no change at all in the functions of normal daily life which could be performed by the paraplegic patients. At the present state of FNS a negative remark is that is does not leave the hands free, so their are activities which better can be done without the application of FNS.

Consequences which may influence the decisions of the patients to applicate FNS, are:

6. The costs of FNS for the patients. Time-investment and strain are reasonable according to the patients. Improvements are suggested in increasing the efficiency of training-programmes with FNS and improving the logistics of these programmes. Patients are in general well motivated to apply FNS, although it sometimes is hard to keep a good motivation.
7. Expectations of the patients. For 50% of the patients the expectations with regard to FNS have come out. The non-fulfillment of expectations hardly seems to influence the reasons for patients to quit with FNS.
8. The user-friendliness of FNS. The user-friendliness of the stimulator has been positively appreciated by all patients. Some remarks have been made concerning the attachment of wires to the electrodes. These remarks already have led to improvements of the design of those electrodes.
9. The safety of FNS. The patients experienced FNS as a safe technology.

Consequences at macro-level (part II).

It is estimated that for The Netherlands the number of patients eligible for the application of FNS will stabilize at about 50 patients per year. This number already suggests the little influence to be expected for the four consequences.

1. Consequences for primary health care. Primary health care includes family doctors, district

nurses, and home helps. Since none of the interviewed patients uses professional help, their is no impact on this part of primary health care. Also the visits to family doctors hardly will change when FNS is applied. The only effect observed in some patients that may influence the number of visits to family doctors is the better emptying of the bladder with FNS which may result in less cases of inflammation of the bladder.

2. Consequences for secondary health care. One little consequence for secondary health care concerns the lesser cases of decubitus. The financial savings however seem very low.
3. Consequences for employment. Employment for paraplegics does not change. Since expectations are that 50 paraplegics will come up every year their may be a little increase in the employment situation of physiotherapists (1.5 fte) and rehabilitation physicians (0.5 fte).
4. Consequences for the societal, financial costs. Hardly any consequences.

DISCUSSION.

Feedback to the design of the technology of FNS concentrated on the following aspects:

- small technical improvements could be made, especially concerning the attachment of the wires to the electrodes.
- the logistics around the FNS-programme.
- research could be done on the effectivity of FNS-training, to enlighten the burden of the patients.

Consequences 1 - 5 at micro-level were, among other aspects, used to determine macro-level consequences. Due to a small-size patientgroup macro-level consequences (at this stage of the development of FNS) can hardly be identified.

Applying BMTA during the process of developing and introducing new biomedical technologies can be useful in early identifying suggestions for improvements of the design, problems with the implementation of the design, and suggestions for necessary societal changes. Applying BMTA in the way it was applied here probably will be more effective when large patient groups are at stake.

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INVESTIGATION OF SURFACE ELECTRODE CURRENT DENSITY AND FIELD CONTROL WITH APPLICATIONS TO UPPER AND LOWER LIMB FES

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SUMMARY

The electric field and current density distribution within the tissue and at the skin-electrode interface are investigated in terms of the shape, feedpoint, and resistance of the surface electrodes, and the conductance and permitivity of the skin layers and tissue. Applications are from the areas of ambulation control for partial and complete paraplegics, upper limb motion rehabilitation for quadraplegics, and spasticity reaction in patients with cerebral palsy.

Patients are evaluated for gait pattern, dynamic stability, and fatigue limits with gait laboratory and Cybex facilities, compared to normals and to other mechanical orthoses.

INVESTIGATION OF CURRENT DENSITY DISTRIBUTION

Introduction

We will describe the use of mathematical solutions of electrostatic field problems for the investigation of the factors which determine the current density distribution within the tissue and at the skin-electrode interface. We characterize the current density distribution in terms of the shape, feedpoint, and resistance of the surface electrodes and the conductance of the skin and subcutaneous tissue. The current density distribution on the surface of the electrodes is generally not uniform but can have peaks which are several times larger than the average current density. The current density is maximal at the interface between the tissue and the electrodes. Burton et al. (1) have estimated the threshold for thermal damage of the skin to be about $50 mA/cm^2$ for current pulses of pulsewidth 300μs and repetition frequency 20Hz. We can predict the current density distribution for rectangular resistive electrodes applied to a homogeneous medium, circular resistive electrodes applied to a multilayer medium and for an arbitrary arrangement of disk electrodes applied to a homogeneous medium.

Methods and Results

For the rectangular resistive electrode applied to the homogeneous medium of Fig. 1, we use a hybrid finite difference/integral equation method to solve the Laplace equation for the electrostatic field. The results, Fig. 2, indicate that current density peaks can occur both at edge of the electrode as is typical for metal electrodes, or near the feedpoint on the electrode. If the conductivity of the electrode material is poorly matched to the effective conductivity of the tissue, the feedpoint-peak can be five times the average current density.

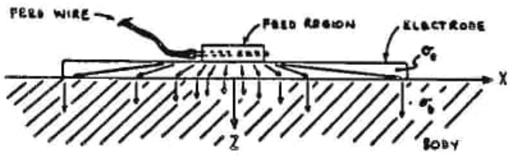

Fig. 1: Model used in computing the surface current density of a rectangular conductive rubber electrode applied to the human body.

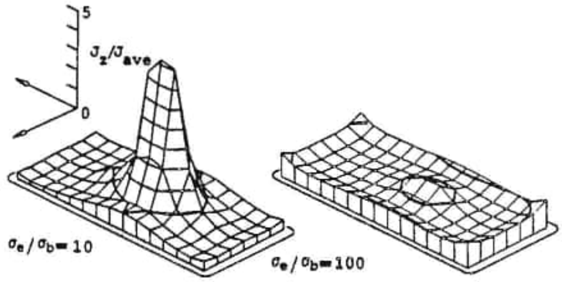

Fig. 2: Typical plots of surface current density J_z relative to average current density J_{ave} for a 1 mm thick center-fed electrode (Medtronic #3793) for various values of σ_c/σ_b.

For circular disk electrodes we first consider a uniform thickness resistive electrode applied to a two-layer medium in Fig. 3 in order to investigate the effects of the electrode conductivity and of the skin on the current density distribution. A set of dual integral equations for the electrostatic field distribution is solved by means of the method of moments. The results in Fig. 4 indicate that the surface current density could have a feed region peak. The peak is low for large skin thickness, low skin conductivity, high electrode conductivity and an extended feed region covering about 40% of the back of the electrode. We also consider an electrode with variable conductivity and derive an ideal electrode conductivity profile which would give a uniform current density distribution for an electrode applied to a homogeneous medium, Fig. 5.

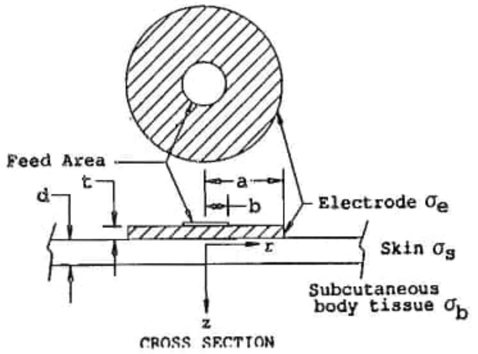

Fig. 3: Two layer medium, disk electrode

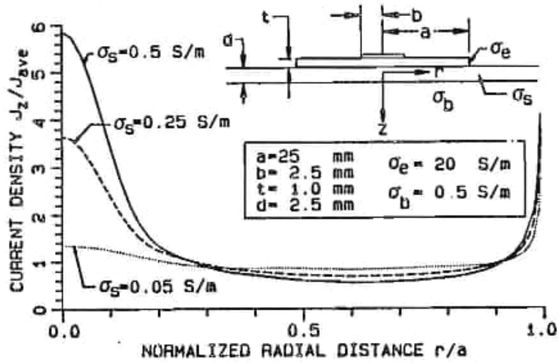

Fig. 4: Variation skin conductivity

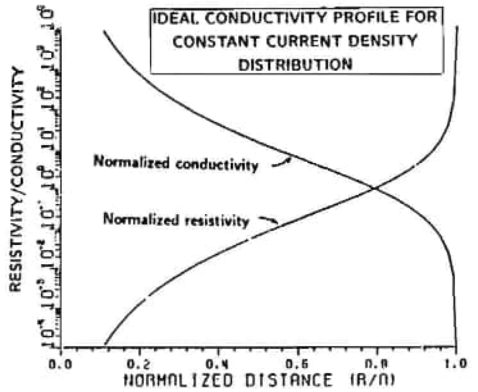

Fig. 5: Ideal constant current conductivity profile.

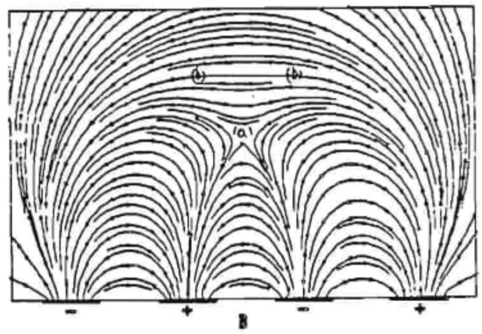

Fig. 6: Field line plots for two excitation patterns of four identical disk electrodes in a row. The interelectrode (center-to-center spacing is 4a.

The multiple electrode problem was analyzed to determine how the interaction between electrodes affects the field distribution of the electrodes and thus to be able to compare monopolar with multipolar stimulation. We also investigated the extent to which the current density distribution of multiple electrodes can be combined to selectively stimulate particular nerves, Fig. 6. The configuration we consider is that of multiple coplanar disk electrodes applied to a homogeneous medium. The results are obtained by three-dimensional moment method solution for the quasistatic field problem. We found an increase in the surface current density on the edge closest to a nearby electrode if the center-to-center spacing of the electrodes is less than 3 times the electrode radius. The field underneath the electrode is approximately uniform over the region between the electrodes when the center-to-center spacing of the electrodes is three times the electrode radius. By comparing the fields of disk electrodes with that of point electrodes, it was found that the point electrode approximation is within 10% of disk electrode if the observation point is more than three electrode radii from the nearest electrode.

Application to Individuals with Paraplegia, Partial Quadriplegia, and Cerebral Palsy

Functional Electrical Stimulation (FES) with skin surface electrodes, has been used successfully in ambulation training of spinal cord injured (SCI) individuals [4] and a cerebral palsy (CP) individual [5] at The Ohio State University. The areas stimulated include the quadriceps femoris muscles, the glutenus maximum muscles and the flexor withdrawal reflex. Positioning of the electrodes for the quadriceps and gluteal muscles is not critical due to the large size of the muscles. Positioning for the withdrawal reflex is critical, as an indirect pathway to the muscles is being stimulated which tends to change periodically. Quantitative measures of progress are obtained through gait analysis techniques with the Vicon video motion analysis system and torque produced at the knee and ankle joint is measured with a Cybex II dyanometer.

Subject T.P. is a C5/C6 incomplete quadriplegic with a functional level of T10/T11. He has been in the FES program for four years, and walks with four channels of stimulation, used only on his left leg, and two forearm crutches. He walks at a rate of 0.2 - 0.4 m/s, up to 200 meters without a rest. See Table 1.

TABLE 1: TIME / DISTANCE STATISTICS
Subject T.P. --- February 15, 1989

	Raw Data	Normal
Velocity	0.42 m/s	1.52 m/s
Stride	0.79 m	1.59 m
Left Step	0.41 m	0.79 m
Right Step	0.37 m	0.79 m
Cadence	1.09 steps/s	1.92 steps/s
Step Width	0.12 m	0.07 m

Subject J.W. is a T6 complete paraplegic, and has been involved in the program for two and one half years. Six channels of stimulation are used, three per side, as well as ankle-foot orthoses and a reciprocal walker. He has walked up to 9.5 meters in 155 seconds (without a rest), a rate of 0.07 m/s. In a 90 minute session, J.W. usually walks 30-40 meters. Cybex measurements indicate that a torque of 20-35 Nm at a velocity of 30 degrees/sec. is produced at the knee joint when the quadriceps muscles are stimulated.

Cerebral Palsy is a pathology of the motor centers of the brain which can result in monoplegia, hemiplegia, paraplegia, diplegia or generalized rigidity. Spasticity is common, leading to contractures and deformation. The goals of the FES program include determining optimum stimulation parameters for individuals retaining sensory function and to improve gait and prevent bone contractures through: reduction of spasticity with stimulation of antagonistic muscles, conditioning and strengthening of appropriate muscle groups, increased range of motion at the knee and ankle joint, improved posture at the hip joint, and retraining gait patterns through sensory feedback.

Subject R.Z. has spastic diplegic CP and has been in the FES program for one year. He ambulates with six channels of stimulation and two forearm crutches. R.Z. has walked up to 725 meters in 18 minutes without a rest, a rate of .67 m/s. His voluntary range of motion at the knee joint has increased 27%, range of motion at the ankle has increased 15%.

Application of FES to upper limb function was directed to the problem of increasing the peak range of motion as a result of surface electrode FES in quadraplegic individuals. The work extended over a period of six months, during which elbow flexion was increased 44%, wrist extension increased 32 percent, and wrist flexion increased 48 percent. Surface electrodes were critical to this study to permit movement of the stimulation points during the experiment.

CONCLUSION

We have developed several mathematical models to determine the critical parameters that affect the current density distribution of surface electrodes and to predict the current density distribution for a number of idealized electrode configurations which are more realistic than those available in the literature. By an extension of the methods used in these models it would be possible to compute the current density distribution for arbitrary shaped electrodes applied to a multilayer model of the body. Application to several FES needs demonstrate the feasibility of surface electrode controlled stimulation.

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VEHICLES FOR EXERCISING PARALYZED LIMBS x)

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SUMMARY

Persons with spinal cord injuries are provided effective mobility by wheelchairs and other wheeled devices, but these generally fail to promote any exercise or even passive movement of paralyzed lower limbs. Consequently, use of standard wheelchairs and other wheeled vehicles results in continued atrophy and other potentially adverse sequelae such as osteoporosis, venous stasis, and decubitus ulcers. To minimize these deliterious effects, we are developing vehicles designed to provide regular and habitual exercise of both normal and paralyzed limbs whenever a user moves his/her vehicle from one locale to another. Voluntary movements of upper limbs propel these vehicles, but paralyzed limbs moving synchronously with uninvolved limbs are exercised by electrical stimulation and thus augment propulsion. The induced exercise of the paralyzed and voluntary use of normal limbs is, from the user's perspective, incidental to the task of locomotion just as exercise of lower limb muscles in incidental to walking in persons without such disabilities.

MATERIALS AND METHODS

Current designs include wheelchairs for children and adults and tricycles for children. All vehicles have hand and foot cranks that turn synchronously. Thus, voluntary movements of upper limbs control timing and duration of stimulation (via portable electrical stimulators) to paralyzed lower limbs.

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x) Supported by New York State Science and Technology Foundation

RESULTS

Wheelchairs

Hand and foot crank assemblies are applied as accessories to standard wheelchairs. Several different drive mechanisms are currently being investigated, but all are designed to allow maintenance of all normal wheelchair functions and features. Modified wheelchairs can be operated by standard means as well as by hand and foot cranks, thus maintaining their maneuverability for use in home and work settings, but also allowing efficient, relatively fast (approximately 25km/hr) transportation in more open areas. As with a standard wheelchair, power is provided by normal upper limbs of the user and is therefore under voluntary control. Position and rate of movement of upper limbs determine those same variables for paralyzed lower limbs, i.e., they are not dependent on a timer or preset program. As muscles of paralyzed limbs increase in strength and endurance, they will contribute more to locomotion. In turn, exercise of paralyzed limbs should be increased, which should further contribute to limb and cardiovascular health as well as efficiency of the vehicle. However, because power from paralyzed limbs is not essential to drive this wheelchair, it may be used before paralyzed limbs are strong enough to provide torque; indeed, the vehicle can be used to train those limbs and then to maintain them. Should the stimulation system fail or paralyzed muscles fatigue, upper limbs should provide sufficient power to propel the vehicle by standard means or by handcranks.

Tricycles

Tricycles for spinal cord injured children are also under development. These vehicles are also fitted with linked hand and foot cranks and are designed to train and maintain paralyzed lower limbs while developing and taxing upper limbs and heart. Built low to the ground, they provide good stability and easy accessibility so that children may mount and dismount with little or no help. This ease should provide young users with a measure of independence, which seems to be an important element in determining the extent to which riders will choose to use the vehicle over and above time prescribed by clinicians. Another critical feature from the user's perspective is the ability to ride with other children on a vehicle that looks and functions much like everyone else's.

Stimulators

Current models of wheelchairs and tricycles are designed to use commercially available neuromuscular stimulators, but more flexible, portable multichannel stimulators are under development. Stimulation is delivered by commercially available transcutaneous electrodes.

Controlling and safety mechanisms

A microprocessor-based stimulus distribution/safety system receives input from angular sensors on the foot cranks and permits stimulation to occur during variable arcs of motion programmed by a clinician. Safety mechanisms will prohibit stimulation when the vehicle is not moving forward, if torque produced by paralyzed limbs is outside prescribed limits (range adjustable by clinician), when the number of pedal revolutions exceeds a number set by clinician, or if bale switches on handgrips are released. A tilt-sensor also prohibits stimulation should the vehicle tip over.

DISCUSSION

The benefits of repeated and habitual exercise of paralyzed limbs are well known /1/, but most current FES systems require the user to undergo long training programs that are designed to bring the involved limbs into a state of readiness. Once ready, the limbs must be maintained. Both the training and maintenance are typically achieved by use of stationary exercise devices. Such devices are not readily available, are typically hospital or laboratory based, are expensive, and require long and frequent use and therefore much time dedicated exclusively to exercise. Many spinal cord injured persons simply lack the time necessary to devote to such an enterprise or fail to appreciate the potential value of exercising limbs that serve no utilitarian function. The vehicles described here are designed to incorporate FES induced exercise of paralyzed limbs into normal daily activities in such a way that the user perceives the exercise as incidental to the task of locomotion. These vehicles are patented in the U.S.; patents in other countries are pending.

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MAXIMIZATION OF ARM FUNCTION IN THE C4 QUADRIPLEGIC

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SUMMARY

An FNS-based system has generated hand prehension-release plus arm mobility in the upper limb of C4 quadripelgics. Voluntary shoulder girdle movements transmitted through the arm contribute to the arm motion. A variety of techniques have been developed to compensate for the limited range of mobility and to maximize the number and quality of arm functions regained.

MATERIALS AND METHODS

The Stimulation System

The system (1) is voice activated and microcomputer controlled. The output of the computer modulates each of the twelve channels of stimulation with dual parameter (current intensity and pulse frequency) control. Stimulation intensity can be controlled directly on each channel, or coordinated temporal sequences may be activated from either the voice input, or the computer keyboard. A remote control analogue unit can further modulate the stimulation intensity. The latter modulation parameters can be input to the computer through the A/D input to program the temporal sequences (2). The stimulation is delivered to bipolar, conductive rubber surface electrodes arranged on the hand segment (thenar group, 1st interosseous); on the forearm segment (extensor digitorum, extensor pollicis brevis, extensor pollicis longus plus extensor indicis, flexor carpi radialis, flexor digitorum profundus, flexor digitorum superficialis, flexor pollicis longus; and where not denervated extensor carpi radialis brevis and extensor carpi ulnaris); and on the upper arm segment (triceps; and where not denervated, biceps).

Mechanical Constraints

Where the wrist extensors respond insufficiently, an active wrist extension splint is used. The forearm is constrained to move in a horizontal plane by a two link arm support attached to the wheelchair.

Quadriplegic subjects

Three subjects who have used the system are C4/C5 quadriplegics. All can voluntarily activate the rhomboid muscle giving shoulder girdle protraction, retraction, and the upper trapezius muscle giving shoulder girdle elevation/depression. Figure 1 shows the utilization of these voluntary articulations together with the arm support to achieve left/right and forwards/backwards motion respectively of the hand.

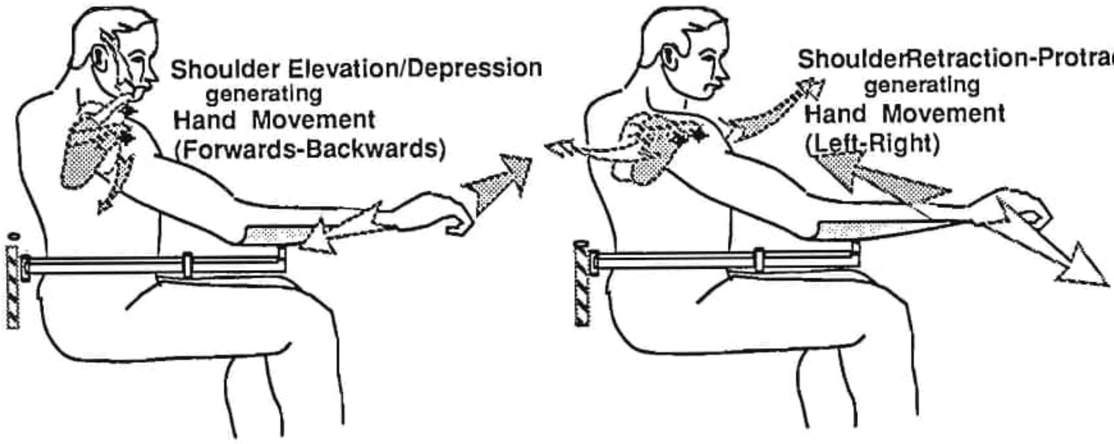


Figure 1: Voluntary Limb Motion

In figure 2 the stimulation generated motions are shown. Activation of the triceps generates forward/sideways reach. The flexor carpi radialis gives a few centimetres of vertical motion at the palm of the hand, utilized for writing and for picking up utensils. This vertical motion can be magnified to 30 cm by use of a long handled utensil (figure 4). The OPEN and CLOSED hand position is shown for the three prehension-release patterns generally preprogrammed for each subject.

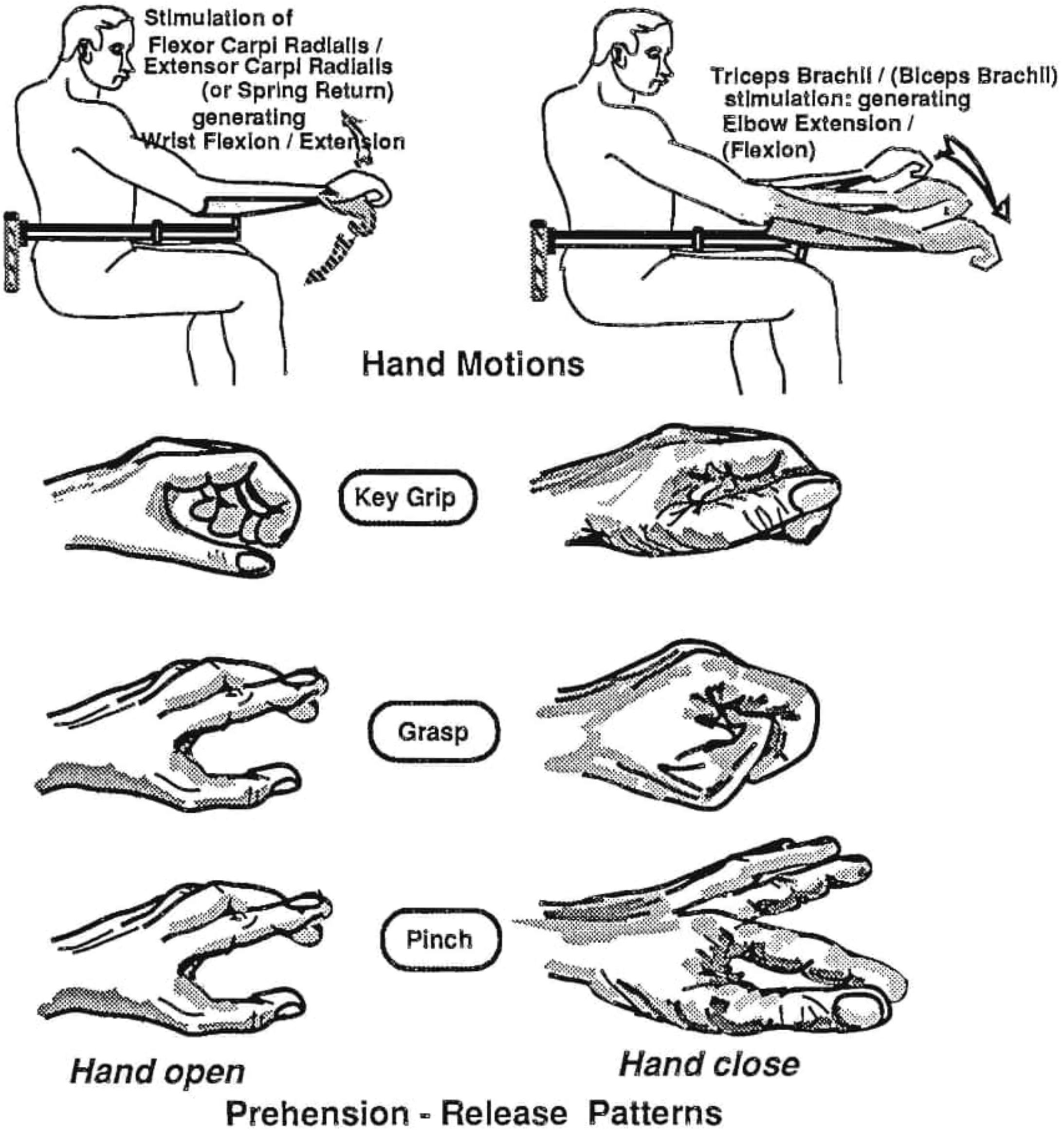


Figure 2 : Stimulation Generated Motion

Peripheral Utensils

An instrumented pen (figure 3) monitors gripping force and pen/paper pressure. A cup (figure 4) is fitted with a horizontal swivel handle and a drinking straw. Various instruments for cosmetic activities in the facial region (lipstick, hairbrush, toothbrush) have been fitted with extended handles. Eating utensils have also been fitted with extended handles enabling lifting of food to the level of the mouth by wrist flexion (figure 4). Control of the height of the endpoints of all the utensils is by wrist flexion/extension.

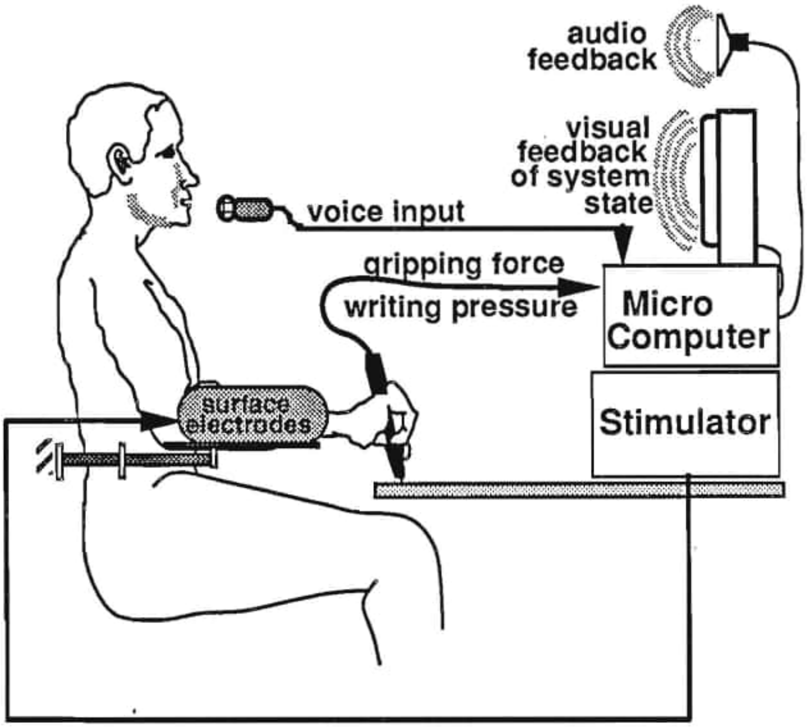
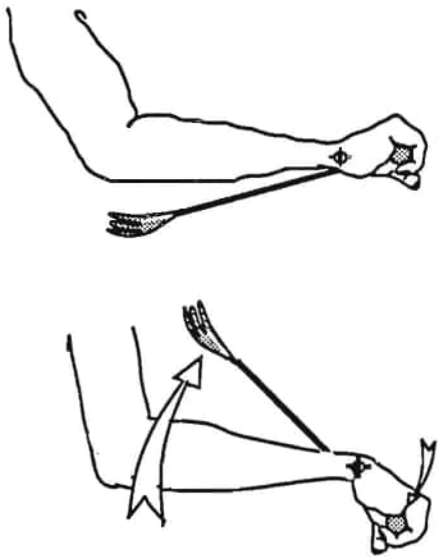
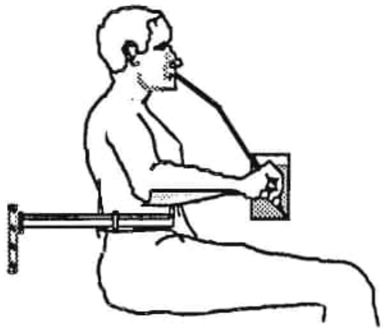


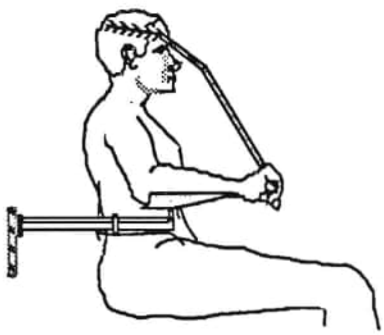
Figure 3 : The Stimulation System and Closed Loop Writing System



Eating Motion
Generated by Wrist
Flexion



Drinking



Hairbrushing, Toothbrushing,
Makeup

Figure 4: Generation of Activities of Daily Living

RESULTS

Writing

Closed-loop control of the gripping force has enabled a constant, controlled grip to be maintained. Closed-loop control of the pen-paper contact pressure has simplified and improved the writing ability. Raising and lowering the pen between strokes is simplified, and the evenness of the contact pressure results in a smoothing of the horizontal force component required to overcome pen-paper friction and to carry out the pen stroke. Equation parameters for the control system are systematically optimized by repeated tests with standard forms. The standardized tests are timed. The pen can be picked up from and replaced in a holder.

Eating

The eating utensil is held with the head pointing towards the body. Shoulder girdle elevation moves the hand and the head of the utensil backwards, shovelling or skewering food in the plate. Wrist flexion now raises the food to the mouth (figure 4).

Other ADL's

Drinking, hairbrushing, brushing of teeth and application of makeup have been carried out. Utensils can be taken from and replaced in stands.

DISCUSSION

The C4 quadriplegic subjects participating in this research have been very similar one to another in their neuromuscular abilities and disabilities. A deadband of upper limb articulations, unobtainable both by surface stimulation or voluntarily, include forearm supination, elbow flexion, and shoulder joint motion. Hoshimiya and Handa (3) are examining the use of intramuscular electrodes in the generation of these latter articulations.

Our approach to the design of the system has been non-invasive, integrating FNS generated movements with non-energized peripheral devices to enhance the number and quality of activities of daily living achieved in the laboratory environment.

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A HYBRID ORTHOSIS OF HAND:MECHANICAL AND FUNCTIONAL ELECTRICAL STIMULATION OF HAND MUSCLES

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SUMMARY

Three types of upper extremity functional orthosis for patients with cervical spine injuries and disturbances were applied in the University Rehabilitation Center in Poznań /Poland/. These three types of orthoses i.e. 1/ biomechanical, 2/ electromechanical, 3/with electrical stimulation were evaluated as to their usefulness. Indications for their application were also elaborated.

INTRODUCTION

The most serious disability for patients with spinal cord disturbances below C_4 is the lack of hand grasping abilities. Hand muscle dysfunction makes these patients dependent on other persons in their daily living activities such as eating, washing etc. It also makes it impossible for them to perform such simple activities as writing, dialling numbers, operating computers etc. Thus, communication with other is impaired. This is why rehabilitating treatment aims at maximal restoration of hand functions with the help of various means and technical aids.

MATERIAL AND METHODS

In the Rehabilitation Department of the University of Poznań, a patient J.K. after the injury of cervical spine C6-C7, was provided with a functional biomechanical orthosis. This orthosis links active movement of wrist extension with passive movement of fingers in MP /metatarso-phalangea/ joints. This patient has paralysed long and short muscles of both hands and only his extensors of wrist are active.

In the orthosis - reciprocator, active extension of wrist and its passive palmar flexion is transformed into flexion - grasping movement of paralysed fingers towards the thumb in opposition. The precondition for making use of the biomechanical orthosis of that type is the presence of passive thumb opposition and the ability of positioning of the thumb in maximal abduction in addition to the posibility of full passive movements in MP, PIP, DIP joints.

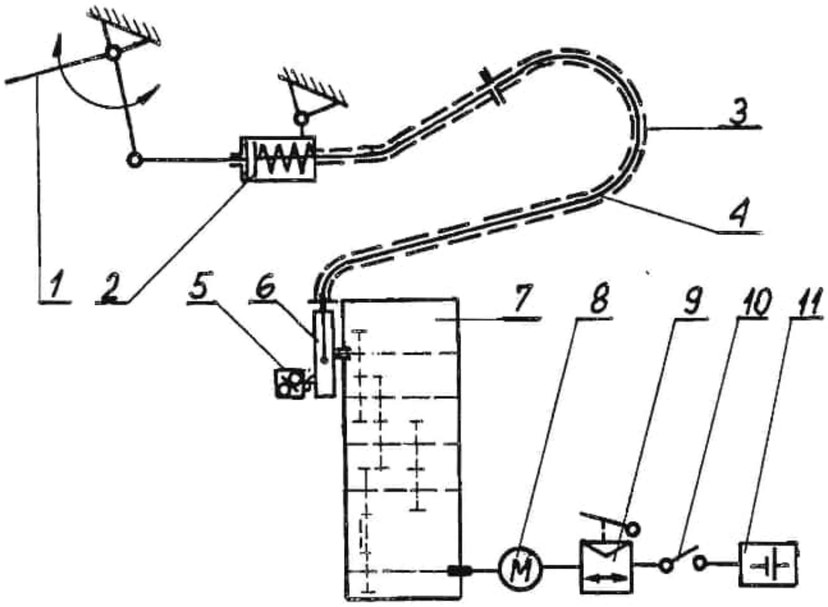
The reciprocator consists of a number of elements - shells made of plastic, which permanently stabilize the thumb in opposition and fix the fingers in the position of flexion equal 45° in the PIP joints and 20° in the DIP joints, leaving the MP joints free. A hard wire connects the fingers with another shell on the forearm, so that the active movement of wrist extension makes the finger tips come closer and touch the tip of the fixed thumb. Passive flexion of the wrist makes the fingers open.

Thanks to this type of orthosis - reciprocator applied to both hands, the patient may eat unaided making use of a spoon, a fork, he may grab a cup, write, and comb his hair.

For a patient after the injury of C4 - C5 a functional electromechanical orthosis was made. The patient has both short and long hand muscles paralysed and has a paralysis of wrist muscles. He is able to move actively elbow and arm joints.

Making use of the orthosis in this case depends on: a/ presence of full passive abduction of thumb, b/ ability of passive movement in MP joints /metatarso-phalangea/, c/ presence or only insignificant impairment of passive movement in PIP and DIP joints.

This electromechanical orthosis consists of an appliance and a motive - steering device. The appliance consists of: 1/ a shell stabilizing the wrist joints and metacarpus, 2/ a thumb shell stabilizing it in abduction and in opposition; this shell is connected with the wrist shell, c/ a shell for 2-nd and 3nd fingers which is linked with the wrist shell at the MP joint level. The construction of the motive - steering device and its operation has been presented on the diagram.



The electromechanical orthosis has been applied to the patient's right hand, he may switch the device with the movement of his left wrist.

This orthosis lets the patient eat unaided, he can also write and make use of a personal computer.

The Rehabilitation Department together with the Institute of Electronics of the Poznań Technical University created a 4-channel equipment for functional electrostimulation. This device was applied to a patient after the injury of C4. This patient was also provided with a light orthosis stabilizing his wrist and fingers which made grasping possible by electrical stimulation. This equipment for functional electrostimulation is now being tested and we assume it will serve as a therapy to improve muscle force, as well as a hybrid hand orthosis.

CONCLUSIONS

1. The biomechanical orthosis - reciprocator gives the ability of grasping to patients with the disturbances of spine on the level of C6-C7, when the long and short hand muscles are paralysed but the extonsors of wrist are active.

2. The electromechanical orthosis or the orthosis with functional electrostimulation facelitate grasping in patients with the disturbances of spine on the level of C4-C5.

INDUCTIVE LEARNING TECHNIQUES APPLIED TO THE RULE-BASED CONTROL OF FUNCTIONAL ELECTRICAL STIMULATION

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SUMMARY

Previous rule-based FES control systems employed 'hand crafted' rules for the detection of gait events. The method described here uses the artificial intelligence technique of inductive learning from examples to analyse a manually operated FES control system, measuring signals from shoe insole and crutch load sensors, in order that such a system may be automatically controlled. The rules obtained inductively are compared with those which were hand crafted and the advantages of such an approach to FES control are discussed.

INTRODUCTION

Past rule-based control systems for functional electrical stimulation (FES) have utilised 'hand-crafted' rules derived by intuition and the examination of gait records to detect specific gait events for determination of the low-level control strategy to be applied [1,2,3].

In a previous publication [4] we reported preliminary results of the application of artificial intelligence inductive learning techniques to the problem of the recognition of static postures.

We have made two major developments since then : (1) the construction of an inductive learning program (DISCIPLE) which gives greater flexibility in learning and testing rule sets and (2) the application of inductive learning techniques to the recognition of dynamic 'postures' (sections of the gait cycle) [5].

THEORY

The inductive learning program, DISCIPLE (one who is taught), is based on the hierarchical mutual information classifier of Sethi & Sarvarayudu [6] which uses the information-theoretic method of calculating average mutual information gain, defined as:

$$I_k(C_k,X_k) = \sum_{C_k,X_k} P(c_{ki}, x_{kj})*\log_2[P(c_{ki}/x_{kj})/P(c_{ki})]$$

where C is the set of pattern classes and X is the set of possible events (above or below threshold)

The algorithm performs a hierarchical partitioning of the n-dimensional attribute space (i.e. n attributes) using hyperplanes perpendicular to the attribute axis which they intersect. Thus the attribute space is sectioned into hypercuboids each of which is designed to contain members of only one class.

ACKNOWLEDGEMENTS
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DISCIPLE uses the algorithm to produce decision trees (directed graphs) which provide a classification of the training data. Alternatively, a decision tree can be expressed as an equivalent rule set. The program allows for both the construction and testing of decision trees.

MATERIALS AND METHODS

Having previously shown the efficacy of this technique in the identification of gait events [5] the next development was to evaluate the applicability of this technique to deriving rules for controlling an FES system. To this end, the following problem was investigated.

A subject with an incomplete lesion at the C6 level (male, year of injury 1981) is able to walk with elbow crutches using a two channel peroneal stimulator on the left leg. The stimulator is controlled by a hand operated switch mounted on the crutch.

In order to synthesise a smooth, continuous gait the subject has learned to 'anticipate' the reflex delay of the peroneal stimulation by pressing the switch to activate the withdrawal response in advance of the response being required during the gait cycle.

The problem for a control system is to be able to 'mimic' this anticipatory action and activate the switch at the same time as the subject would.

In terms of the inductive learning strategy there are two classes in this problem: (1) switch on and (2) switch off. Ten attributes were used to characterise the subjects gait, the load on each crutch (2 attributes) and the force pattern on each foot (8 attributes - 4 forces per foot) measured using a pair of force sensing insoles [7].

The subject performed a number of walks manually controlling the stimulation. The data recorded using a Compaq II PC sampling at 50 Hz, from independent runs, was divided into training and testing sets to evaluate the performance of the rules derived in recognising when the switch was on and off.

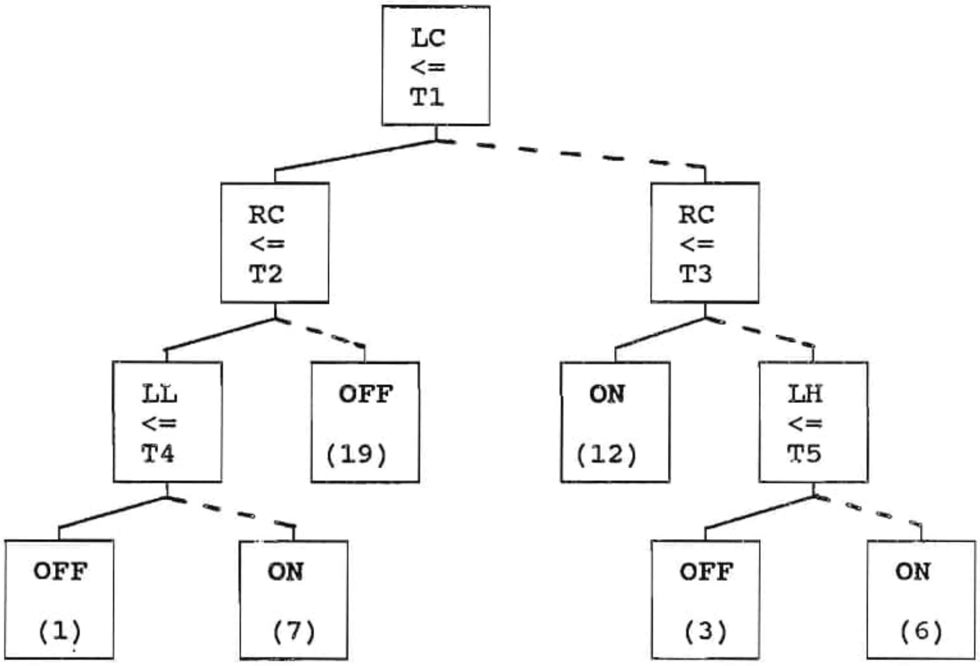
RESULTS

The decision tree obtained by DISCIPLE from the training set is shown in figure 1. (next page)

Using this decision tree to classify the testing set gave an accuracy of 97.917% with the confusion matrix as shown in figure 2

		Actual	
		ON	OFF
Predicted	ON	23	0
	OFF	1	24

Figure 2. Confusion Matrix



———— = True, - - - - - - - = False
LC = left crutch force, RC = right crutch force, LH = left heel force, LL = left lateral metatarsal force, Tn = threshold n, ON = switch depressed, OFF = switch not depressed, (n) = number at that leaf

Figure 1 Decision Tree For Testing Data

DISCUSSION

Examination of figure 1 shows that only a subset of the available attributes are used in the decision tree (four out of a possible ten). Thus redundancy in the attribute set is identified. Therefore deriving rules by induction offers the possibility of creating fault tolerant control systems [5] whereby multiple decision trees, each using only a subset of available attributes, would be available to the controller allowing the controller to select the appropriate tree based on information about the fault status of sensors.

The rule set from the decision tree of figure 1 can be written as:

```
IF (left crutch force <= T1)
    THEN IF (right crutch force <= T2)
            THEN IF (left lateral metatarsal force <= T4)
                     THEN (switch off)
                     ELSE (switch on)
            ELSE (switch off)
    ELSE IF (right crutch force <= T3)
         THEN (switch on)
         ELSE IF (left heel force <= T5)
              THEN (switch off)
              ELSE (switch on)
```

The accuracy of this classification method is seen from figure 2, with only 1 example out of 48 being misclassified. It should be possible to further improve the classification accuracy by using a larger training set from more runs. Therefore inductive learning techniques represent an efficient and accurate method of deriving rules for the control of FES. In the example described the knowledge gained by the subject's experience of controlling the stimulator (by pressing the switch) is effectively captured by the program.

A previous system for this subject which used hand-crafted rules [3] was found to result in a reduced speed of gait because intuitive rules did not take account of the reflex latency, whereas the inductively derived rules encode the subject's anticipation of the delay. Examination of the gait data recorded shows that the subject presses the switch as the crutches are crossing over, whilst the previous, intuitive, strategy activated stimulation once the crutch had been loaded. Therefore the intuitively obvious method of activating stimulation is not always the most efficient.

Such control systems, using inductively derived rules, have application to hybrid FES orthoses [8]. This would combine the reduction in fatigue offered by such a system together with an efficient and robust control strategy thereby improving both speed and maximum walking distance. They are also applicable to alternative gait strategies such as swing-through gait.

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Fast step response of electrically stimulated paralyzed quadriceps.

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It is often desirable to elicit an instant action from a muscle; but there is always some delay between the start of stimulation and the development of useful muscle force.

We have investigated two ways of reducing this delay. The first comprises stimulating the muscle at pulse widths below functional levels before the start of the required action, then stepping up the pulse width when the action is required. This might be expected to reduce those components of the delay attributable to the stretching of series elastic elements. The prestretching phase used pulse widths between 20 and 150 microseconds at 20 Hz

The second method comprises a short period of stimulation at a high frequency followed by a more normal frequency. This is comparable with the 'catch mechanism' described by Wilson et al (1968) (1) and by Burke et al (1970) (2). A catch frequency of 100 Hz was applied for periods varying between 20 and 100 ms.

We measured knee moment while stimulating the quadriceps of complete paraplegics through surface electrodes, isometrically. The trial strategies were compared with 300 microsecond pulses at 20 Hz.

Pre-stimulating at low pulse widths offers no advantage over the conventional stimulation parameters. The 'catch' method yields a significant reduction is step response time, provided that the duration of the high frequency burst is limited to 20 ms.

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CONTROL OF MUSCLE CONTRACTION BY INVERSION OF A DISCRETE TIME MODEL OF MUSCLE DYNAMICS

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INTRODUCTION

Control of muscle contraction during artificial muscle stimulation has been described by several investigators /1/../4/. However, these control strategies were based on knowledge about muscle dynamics /5/../8/ only in a limited way. We studied an open loop nonlinear compensator for control of muscle contraction, obtained by inversion of a muscle dynamics model.

THEORY

A discrete time model of the muscle-skeleton-load system

The system considered is an artificially stimulated soleus muscle of a cat, in which the ankle joint is controlled against a second order linear load. The discrete time model of the muscle-skeleton-load system is given by:

3-factor muscle dynamics model /9/:	$M_{a,k} = A_k f_\varphi(\varphi_k) f_{\dot\varphi}(\dot\varphi_k)$	(1)
critically damped activation dynamics:	$A_k = 2aA_{k-1} - a^2A_{k-2} + (1-2a+a^2)u_{k-1}$	(2)
total joint torque:	$M_k = M_{a,k} + M_{p,k}$	(3)
passive torque:	$M_{p,k} = M_{p0} - \varphi_k/C_p$	(4)
second order load:	$\varphi_k = l_1\varphi_{k-1} + l_2\varphi_{k-2} + l_3M_{k-1} + (1-l_1-l_2)\varphi_{nom}$	(5)
derivative of φ is approximated by:	$\dot\varphi_k = (\varphi_k - \varphi_{k-1})/T_{IPI}$	(6)

The time step of this discrete time model equals the interpulse interval T_{IPI} of the stimulation. The three factors of the muscle dynamics model (1) are: activation dynamics (2), angle-torque function f_φ and angular velocity-torque function $f_{\dot\varphi}$. Bernotas et al. /10/ used second order linear activation dynamics (2) to model isometric muscle contraction ($\dot\varphi = 0$). u_{k-1} is the recruitment input ($0<u<1$). A_k and $f_{\dot\varphi}$ are normalized. f_φ and $f_{\dot\varphi}$ have been described as part of the Hill model /5/,/8/. We m::deled f_φ piecewise linear. We took $f_{\dot\varphi} = 1$ for $\dot\varphi_k < 0$ (lengthening muscle). For $\dot\varphi_k >= 0$ $f_{\dot\varphi}$ was modeled in two ways:

piecewise linear:	$f_{\dot\varphi}(\dot\varphi_k) = \max(h_1-h_2\dot\varphi_k, 1-h_3\dot\varphi_k)$	(7)
or linear + 1st order dynamic process for small $\dot\varphi_k$:	$f_{\dot\varphi}(\dot\varphi_k) = h_1-h_2\dot\varphi_k + (1-h_1)y_k$	(8)
with: $y_k = qy_{k-1} + (1-q)(1-\dot\varphi_k/\dot\varphi_{small})$ if $\dot\varphi_k < \dot\varphi_{small}$; $y_k = 0$ if $\dot\varphi_k > \dot\varphi_{small}$		(9)

The total joint torque M_k (3) is composed of the active torque $M_{a,k}$ (1), generated by muscle contraction, and the passive torque $M_{p,k}$ (4), contributed by the internal load of the cat's paw. The internal load is modeled as a linear compliance C_p with offset M_{p0} for $\varphi=0$, which is a reasonable approximation in the range where the passive torque is relatively low. The relation between torque and angle is determined by the second order linear external load (5). At the nominal angle φ_{nom} the steady state torque is zero.

This research was supported by NIH-NINDS contract NO1-NS-6-2303 and the Dutch Foundation for Technical Sciences STW, and was carried out at the Applied Neural control Laboratory, Case Western Reserve University, Cleveland, OH 44106, USA.

Open loop nonlinear compensator

A nonlinear compensator can be derived by inversion of the muscle-load model, and substitution of φ_k by the reference input $\varphi_{r,k}$. We obtain:

$$u_k = (A_{k+1} - 2aA_k + a^2A_{k-1})/(1-2a+a^2) \tag{10}$$

with:

$$A_i = (M_{i,k} - M_{p,i})/[f_\varphi(\varphi_{r,i})\, f_{\dot\varphi}(\dot\varphi_{r,i})] \quad , \; i = k+1,\; k,\; k-1 \tag{11}$$

$$M_{r,i} = [\varphi_{r,i+1} - l_1\varphi_{r,i} - l_2\varphi_{r,i-1} - (1-l_1-l_2)\varphi_{nom}]/l_3 \tag{12}$$

$$M_{p,i} = M_{p,0} - \varphi_{r,i}/C_p \tag{13}$$

The reference signal $\varphi_{r,k}$ must be known two time steps in advance. This results in a 2 time step delay between reference signal $\varphi_{r,k}$ and the actual angle φ_k. The recruitment is varied by modulation of the stimulus pulse width $T_{PW,k}$, which is determined from u_k via the inverse of the recruitment curve R_C:

$$T_{PW,k} = R_C^{-1}(u_k) \tag{14}$$

METHODS

Experimental methods

Identification of the system model and the control methods were developed and tested in seven acute cat experiments. Sodium Pentobarbitol was used as an anesthetic. The soleus muscle was stimulated at 10 Hz via the sciatic nerve using a spiral cuff electrode /12/. Branches of the sciatic nerve to other muscles were cut, and the sciatic nerve was crushed proximally to the site of stimulation. The pulse width T_{PW} of the cathodic rectangular current pulses was modulated. The distal tendons of the medial gastrocnemius and plantaris muscles were cut. The cat paw was connected to a servo controlled rotational motor system. The ankle joint angle was measured by a potentiometer and the torque by strain gauges. A second order linear load was implemented by real time computation (at 100 Hz) of the angle from the torque signal, and applying the angle via the servo system /12/.

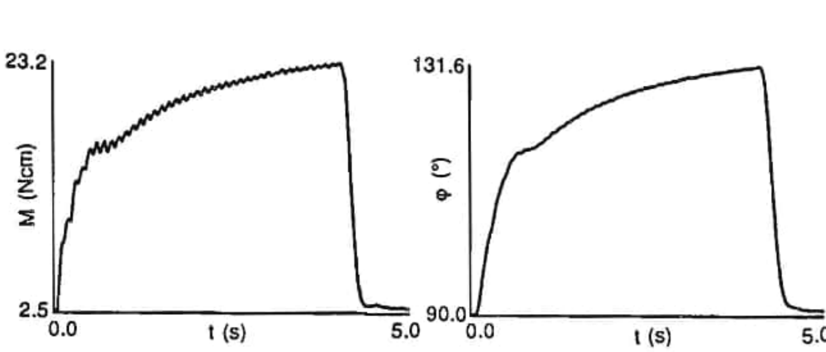
Identification

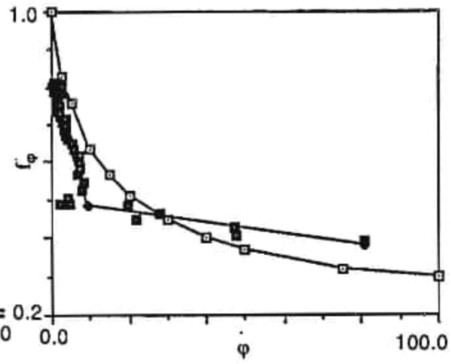
We identified the model components in the range of operation of the controller as follows:

- A piecewise linear approximation of the recruitment curve R_C was determined from isometric burst responses at seven values of the pulse width (PW) between threshold and saturation.
- The compliance of the internal load C_p was determined by linear regression from the torque response to a 0.5 Hz sinusoidal angle perturbation in the angle range of operation, with no stimulation.
- The angle-torque function f_φ was measured by burst responses at 5 recruitment levels (load attached).
- The angular velocity-torque function $f_{\dot\varphi}$ was determined from a burst response at supramaximal stimulation with the load attached. The active torque M_a was found by subtraction of the passive torque $M_p(\varphi)$. M_a was divided by the angle function f_φ, and by the step response of the activation dynamics A. The derivative of the joint angle signal between subsequent stimulus pulses was determined by linear regression from the angle signal. $f_{\dot\varphi}$ was found by the relation between the processed torque signal and the angular velocity. Parameter 'a' of the activation dynamics was taken such that hysteresis was minimal. The angular velocity-torque function was also determined by responses to isokinetic ramps at maximal stimulation. Torque was measured in a 10° range around the same angle /6/.

RESULTS

Figure 1 shows an example of a burst response at supramaximal stimulation. We took $f_{\dot\varphi} = 1$ for lengthening muscle ($\dot\varphi$ is negative): lengthening only occured when the active torque decreased due to decreased recruitment. This torque decrease is fast and mainly determined by the activation dynamics.

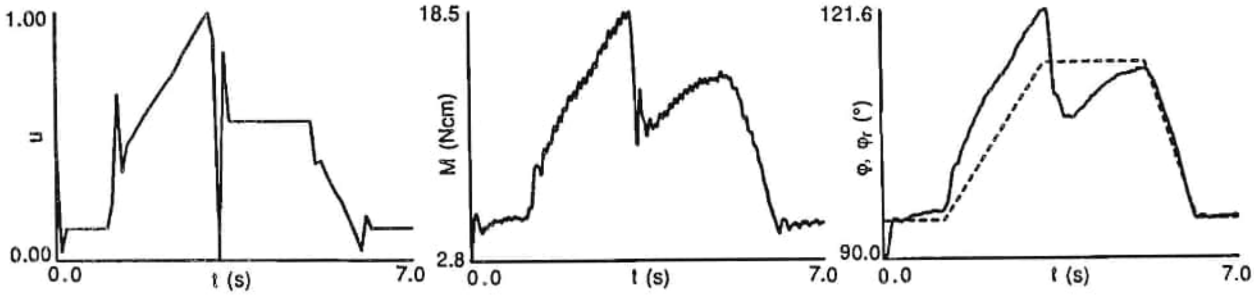




1a. 1b. 2.

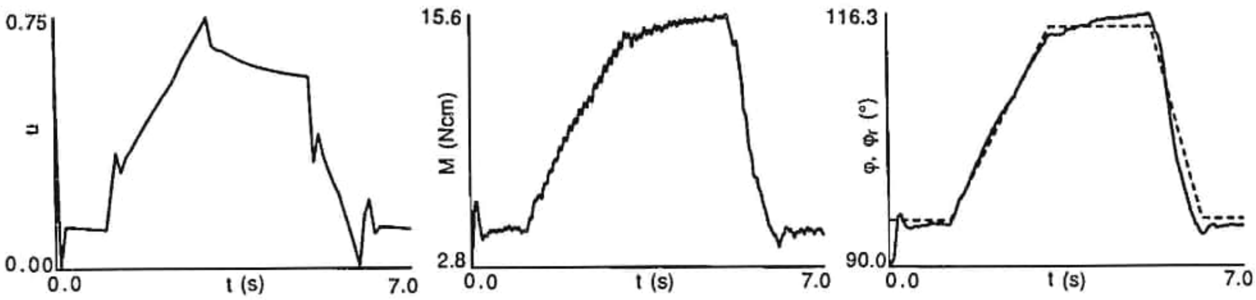
Figure 1. *Response to a 4 s. burst stimulation at maximal recruitment (Load: compliance: 2°/Ncm; natural frequency: 4 Hz; damping ratio 1.0). a: torque, b: angle.*

Figure 2. *Angular velocity-torque function $f_{\dot{\varphi}}$, as determined from the burst response of figure 1 (scattered dark squares), and from ramp trials (light squares connected by solid line). The piecewise linear approximation (7) is indicated by 2 linear line segments determined by linear regression from the dark square points.*



3a. 3b. 3c.

Figure 3. Example of the nonlinear compensator response, using the parameters of the angular velocity-torque function (7) as found from the burst response with load (two llnear ine segments in figure 2). The load parameters are the same as in figure 1. a: recruitment u, b: torque, c: actual angle (solid line) and reference angle (dashed line). The reference angle was plotted two timesteps delayed.



4a. 4b. 4c.

Figure 4. *Example of the open loop nonlinear compensator response, with adapted angular velocity-torque function (8),(9) and a higher value of $f_{\dot{\varphi}}$ for the first ramp (10 °/s). a, b, c: see figure 3.*

A typical example of the angular velocity-torque function $f_{\dot\varphi}$, as found both from the burst response of figure 1 and from the ramp responses is given in figure 2. $f_{\dot\varphi}$ for shortening muscle was estimated from the burst response by two linear segments, as indicated in the figure. For low velocities of about 10 °/s the angular velocity function found from the burst response was always lower than the angular velocity function found from the isokinetic burst responses.

The performance of the nonlinear compensator is shown in figure 3. With the angular velocity-torque function derived from burst responses with load we systematically found too high responses during the first ramp, and large undershoots in torque after the first ramp (increasing angle means shortening muscle). The first aspect points to an underestimate of the angular velocity function. The second aspect appears to be caused by the fact that the Hill-type muscle model /5/,/9/ assumes that the torque at zero angular velocity can be generated instantaneously when the angle change stops. However, it takes some time before the maximal torque is reached. This was also reported by Joyce et al. /7/,/8/ and corresponds to the limited rate in which bonds can be made between the contractile filaments (sliding filament theory). We modified the Hill type angular velocity-torque function by adding a first order system for small angular velocity (8),(9). The time constant of this system was found from the slowly increasing part of a burst response (figure 1). Also, a higher value of the angular velocity-torque function, close to the value found from the isokinetic ramp trials, was taken for the first ramp of the reference angle signal. These modifications systematically improved the tracking performance of the nonlinear compensator, as is shown in figure 4.

CONCLUSIONS AND DISCUSSION

The experimental results show that control of joint angle by inversion of a nonlinear model of the systems dynamics of muscle and load is feasible. However, the performance of this control strategy largely depends on the model structure and the parameter values being used. Like Joyce et al. we found that the angular velocity-torque function can be different for different circumstances, and that maximal torque for zero angular velocity needs some time to develop.

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Control of complex movements by closed-loop electrical orthoses

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The purpose of this study was to analyse the problems which occur when complex movements have to be restored using closed-loop functional electrical stimulation (FES) systems. Electrophysiological and biomechanical experiments were performed in healthy subjects during stair climbing, raising from a chair, and sitting down. The results were used for the design of computer controlled FES-systems for paraplegic patients.

Problems on the sensory or muscular level are well known to scientists working in the field of FES. For multi joint movements interactions between different joints have to be taken into account. During the different phases of complex movements the stimulation and controller parameters but also the regulated variables may change. In our view the most significant problems of movement control with FES are however interactions between the FES-system and the patient himself: additional input to the muscles by spinal reflexes (spasticity) and coordination between voluntary movements and the FES-system.

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AUTOMATIC STANCE – SWING PHASE DETECTION FOR PERONEAL NERVE STIMULATION BY ACCELEROMETRY.

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SUMMARY

The use of a peroneal nerve stimulator to correct footdrop is hampered by continuing problems regarding the footswitches and their connection. The development of implantable stimulators has further increased interest in new, preferably implantable, sensors. Theoretically we showed that accelerometers can be used to distinquish between stance and swing phase. Therefore the potential of accelerometers for the automatic stance–swing detection was investigated.

Placing accelerometers between ankle and knee joint we calculated the equivalent acceleration of the ankle joint. This resulted in a typical and reproducible signal in which the different walking phases were identified. Automatic detection algorithms, based on cross correlation calculation were developed and tested.

Measurements from four healthy and one hemiplegic subject showed that a high accuracy can be achieved profided that the subject has a reasonable push–off phase. We could further show that using only one accelerometer closely below the knee joint simular results can be achieved. This could lead to a combination of sensor and stimulator into one implantable device.

MATERIAL AND METHOD

Introduction

Since the first experiments to correct footdrop by electrical stimulation of the peroneal nerve [1] this technique has developed to a point where, for a selected group of patients, it can be used as an almost routine therapy. Some of the problems remaining with todays peroneal stimulators [3,4] may be solved by using a fully implantable peroneal stimulator for which first trials have been reported [2,4]. However in these trials only the stimulator itself was implanted whereas the power–supply and the detector were still attached externally. Conventionally the onset of a step is detected by a footswitch. Although footswitches are used satisfactorily, except for mechanical robustness, they can not be implanted. In this paper we study the possibilities of accelerometers as detectors to replace footswitches. Accelerometers have the potential of implantation.

Theory

Considering rigid–body dynamics, an idealized ball and socket ankle joint and using a seismic accelerometer attached to the lower leg the equivalent acceleration of the ankle as measured by an accelerometer is given by [5]

$$\vec{a}_0 = \vec{g} - \ddot{\vec{R}} \qquad (1)$$

with $\ddot{\vec{R}}$: Linear acceleration contribution.

$\vec{g}$: Gravitational acceleration contribution.

$\vec{a}_0$: Measured acceleration at the ankle.

Obviously $\ddot{\vec{R}} \simeq \vec{0}$ during the stance phase and $\ddot{\vec{R}} \neq \vec{0}$ during the swing phase of walking so by calculating the modulus of the equivalent acceleration we should be able to distinguish between the stance and swing phase.

$$|\vec{a}_0| \quad \begin{matrix} \simeq g \text{ (stance)} \\ \neq g \text{ (swing)} \end{matrix} \qquad (2)$$

Instead of placing an accelerometer at the ankle joint, which might be difficult for implantations, the equivalent acceleration can be calculated also by placing two accelerometers between the ankle and knee joint using [5]

$$\vec{a}_0 = \vec{g} - \vec{R} = \frac{r_2\ \vec{a}_1 - r_1\ \vec{a}_2}{r_2 - r_1} \tag{3}$$

Measurements

To measure the tangential and radial components, four one–dimensional accelerometers (Kyowa AS–5G) were attached to a PVC bracket which was then attached to the lower leg using VELCRO straps. Footswitches were placed under the shoe at the heel and the first metatarsal head to detect the different walking phases. The signals were amplified, low–pass filtered (100 Hz) and sampled at 500 Hz for 10 seconds.

First, measurements were made with a group of healthy subjects to establish a 'normal' equivalent acceleration pattern. A total of 39 measurements each 10 s long were made. The same measurements were done on one hemiplegic subject. The accelerometers were attached to the leg also carrying the peroneal stimulator. Measurements were performed both with and without peroneal nerve stimulation on this patient. A total of 15 measurements were made.

RESULTS

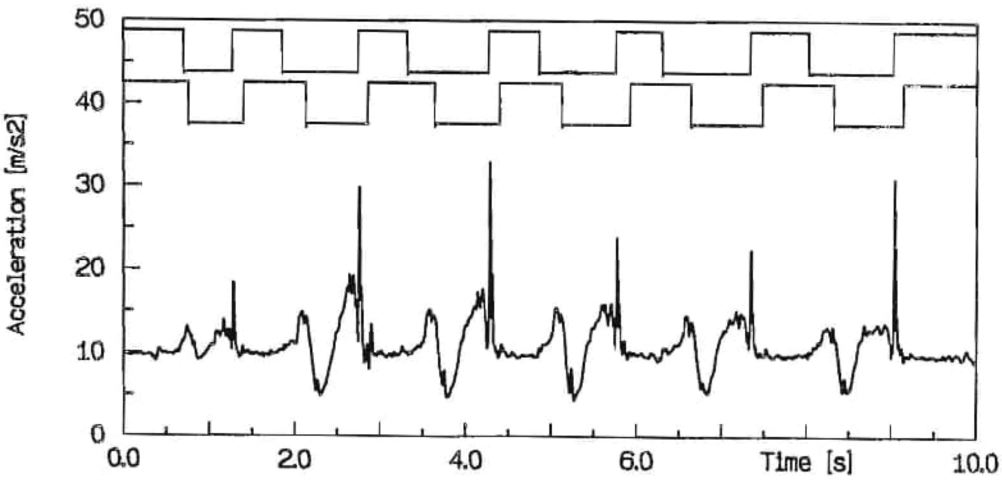

Fig. 1. Acceleration of the ankle in combination with footswitches at the heel (top) and toe (below), during normal walking.

Signal description

In figure 1 a typical example of $|\vec{a}_0|$ is shown together with the signals from the footswitches. Figure 1 starts with erect standing after which the first step is performed with the leg with the attached accelerometers. Four walking phases were distinquished.

- Stance (heel–switch signal and toe–switch signal high). During stance the equivalent acceleration approximately equals g in accordance with equation 2.
- Push–off (heel–switch signal low, toe–switch signal high). The push–off phase is characterized by an increase of the equivalent acceleration. A first maximum is within 50 ms of the end of the push–off phase. Typically, the first push–off phase (standing to walking transition) is different from the following push–off phases.
- Swing (heel–switch signal and toe–switch signal low). The swing phase is characterized by a down–up course of the equivalent acceleration, ending with the heel–strike.
- Foot–down (heel–switch signal high, toe–switch signal low). The foot–down phase starts with the heelstrike which usually is clearly visible as a peak in the equivalent acceleration. The end of the foot–down phase can not be detected directly because the ankle hardly moves during this phase (linear acceleration contribution $\simeq 0$).

We found the radial accelerations to be very similar to the equivalent acceleration, except for the last part of the swing phase and the heel–strike, which are lower. In contrast the tangential accelerations are not very simular to the equivalent acceleration. Considering this simularity we decided to compare the result of an automatic stance–swing phase detector based on either signal.

Detection algorithm

A peroneal nerve stimulator normally starts its stimulation in the push–off phase, detected by a heel–switch in combination with a time–delay. It ends its stimulation shortly after the heel–strike. We can therefore use the equivalent acceleration as a trigger for a peroneal nerve stimulator provided that the push–off and the foot–down phases can be detected automatically. Both the push–off and swing phase were detected using cross–correlation techniques. By including a detection algorithm of the swing–phase the chance of a false push–off or foot–down detection during this phase can be minimized. The last 0.4 s. of each push–off (as defined by the toe switch) was extracted from the data and the average push–off time course was calculated. This was then used as a template for the detection of the different push–off phases. A linear template of 0.2 s. was used for the detection of the descending and ascending part of the swing phase. The heel–strike was detected by level detection of the first derivative. To correct false detections, causing e.g. stimulation during stance phase, as fast as possible, control and correction routines were included. We used maximum times for the detection of both the swingphase and heel–strike (0.5 s.). This gives the state transition diagram as shown in figure 2 with four normal change–state paths and three correction paths.

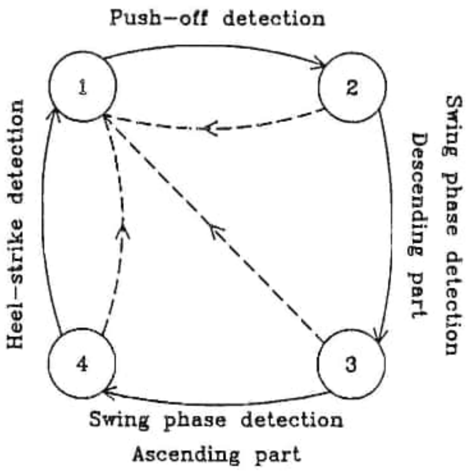

Fig. 2. State–transition diagram for the automatic waling phase detection.

Accuracy of detection

Half of the measurements were used as a reference data base to optimize the detection and to establish a template for the push–off detection (i.e. the average push–off time–course) while the other half was used as an evaluation data base. The equivalent acceleration signal used was either the (total) equivalent acceleration or the radial component only (as measured closely below the knee joint).

A step was considered detected accurately (no error) only if all four phases were detected. A step could be missed completely (no detection) while the heel–strike could be missed (no heel–strike) or detected to early (early detection). Figure 3 shows a typical result with the different transitions. The results are summarized in Table 1. The average time from heel–off to toe–off, as measured with the footswitches, was 0.20 s while the average time from heel–off to push–off detection was 0.08 s.

TABLE 1. Automatic step detection results.

Subjects	Healthy		Hemiplegic	
Source	$\lvert \vec{a}_0 \rvert$	a_r	$\lvert \vec{a}_0 \rvert$	a_r
Steps	110		45	
Errors				
No detection	1	1	0	1
No heel–strike	1	4	0	0
Early heel–strike	2	2	0	0

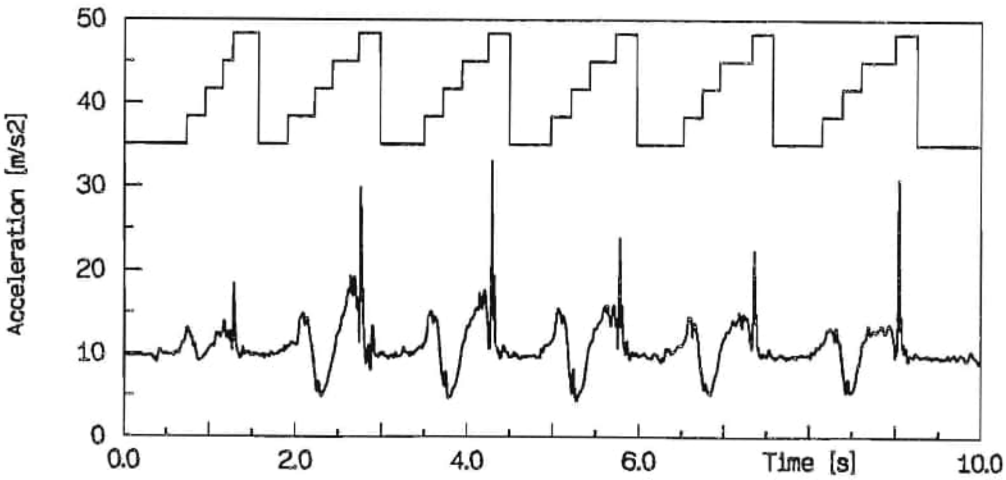

Fig. 3. *Automatic walking phase detection from accelerometer data. Phases are : stance, push–off, swing–down, swing–up, heel–strike.*

DISCUSSION

Accurate push–off detection is essential for peroneal nerve stimulation. As shown (Table I) our method resulted in only 1 missed detection. We found more errors for heel–strike detection. However their effect may be small. Missed heel–strike detection will result in stimulation during the first part of the stance phase. By using a minimal "stimulation–on time" a same effect can be reached for early heel–strike detections. The advantage of a detection using the signal of one accelerometer only, placed closely below the knee, would be the possibility to integrate the sensor and stimulator into one implantable package. As shown, this resulted in a quality comparable with a detection using all four accelerometers, except for the number of missed heel–strike detections. This is probably caused by some form of damping. For a small, lightweight accelerometer better result may be anticipated.

For the limited amount of measurements the only systematic difference between the hemiplegic, either with or without stimulator, and healthy subjects was the higher heel–strike, which is probably caused by the different type of footwear. The detection result for the hemiplegic patient were comparable with those of the healthy subjects with better results for the heel–strike detection.

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AN IMPLANTABLE SENSOR FOR REAL–TIME GAIT ASSESSMENT FOR CLOSED–LOOP FES.

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SUMMARY

A method is presented for the calculation of the lower extremities angles using accelerometers which have the potential of implantation. Relative angles (i.e. angles between segments) can be calculated without integration, thereby solving the problem of integration drift normally associated with accelerometry. The feasibility of this method is demonstrated by calculation of the knee angle of a healthy subject. Measurements during standing–up, sitting–down and walking showed that shock (heel–strike) and vibration are main error sources. Additional signal processing, e.g. low–pass filtering, can be used to diminish these errors. The accuracy of the knee angle found is shown to be high enough to be used in a feedback controller for functional electrostimulation of the lower extremities.

MATERIAL AND METHODS

Introduction.

Functional electrostimulation (FES) of paralyzed muscles for the restoration of walking can benefit from closed–loop control strategies. Relevant parameters are the angle, angular velocity and angular acceleration of the lower leg segments. Conventionally these are measured using a electrogoniometer. However size, handling and mechanical robustness limits their use to laboratory circumstances. Furthermore their potential for implantation is very limited.
Because accelerometers show a potential for implantation and because their use for the assessment of the angular velocity and angular acceleration is well documented, we decided to investigate the possibilities of accelerometers as sensors for closed–loop controlled FES. Previously [1,2] we described a method for the calculation of absolute angles, e.g. the angle between sensor and gravitational field, during the stance phase of walking. However the calculation of the leg segment angles during swing was still hampered by integration drift problems. In this paper we will discuss the possibility of calculating relative angles, i.e. the knee angle.

Theory

Considering rigid–body dynamics, an idealized ball and socket joint and using seismic accelerometers, the equivalent acceleration ($\vec{a}$) at a distance r from the joint is given by [3]:

$$\vec{a} = \vec{g} - \ddot{\vec{R}}_0 - r\vec{\Omega} \qquad (1)$$

with $\ddot{\vec{R}}_0$: linear acceleration contribution (of the joint).

$\vec{g}$: gravitational acceleration contribution.

$r\vec{\Omega}$: rotational acceleration contribution.

The equivalent acceleration of the knee can be calculated by placing 2 accelerometers on the lower leg (a_{l_1} and a_{l_2}) at distances r_{l_1} and r_{l_2} as well as by placing 2 accelerometers on the upper leg segment (a_{u_1} and a_{u_2}) at distances r_{u_1} and r_{u_2}. Eliminating the rotational contributions by multiplying by r_{l_2} and r_{l_1} for the lower leg and by r_{u_2} and r_{u_1} for the upper leg yields:

$$\vec{a}_{l_0} = \frac{r_{l_2}\,\vec{a}_{l_1} - r_{l_1}\,\vec{a}_{l_2}}{r_{l_2} - r_{l_1}} \qquad (2a)$$

and:

$$\vec{a}_{u_0} = \frac{r_{u_2}\,\vec{a}_{u_1} - r_{u_1}\,\vec{a}_{u_2}}{r_{u_2} - r_{u_1}} \tag{2b}$$

The components of $\vec{a}_{l_0}$ and $\vec{a}_{u_0}$ are the acceleration of the knee as measured by the accelerometers in the upper and lower body–fixed frame coordinates respectively (2a).
Assuming the lower leg movements during walking to be two–dimensional their relationship is given by:

$$a_{u_{0,y}} = \cos(\theta_0)\, a_{l_{0,y}} + \sin(\theta_0)\, a_{l_{0,z}} \tag{3a}$$

$$a_{u_{0,z}} = -\sin(\theta_0)\, a_{l_{0,y}} + \cos(\theta_0)\, a_{l_{0,z}} \tag{3b}$$

where $_y$ and $_z$ denote the y and z component of the acceleration and θ_0 is the knee angle.

After substitution of (2a) and (2b) into (3a) and (3b) they can be solved for θ_0. Note that this solution is valid during both stance and swing phase. Also, the knee angle has been obtained from the accelerometer data without integration.

Measurements

To use (3) we have to measure the y and z coordinates of the acceleration at two places for both the upper and lower leg segment. The method was evaluated in two ways

1. By comparing with goniometer data obtained from a two articulate pendulum. In this case the assumption of an ideal joint and of completely rigid attachment of the accelerometers was assumed to be valid.
2. By compared with goniometer data on a healthy human subjects during standing up and walking. For this, four uniaxial accelerometers (Kyowa AS–5GA) were attached in pairs on a PVC bracket, which was then fastened to the lower leg. The same was done for the upper leg segment. We used a flexible goniometer (Penny + Giles G180) as a reference for the knee angle. The signals were amplified and low–pass filtered at 100 Hz.

RESULTS

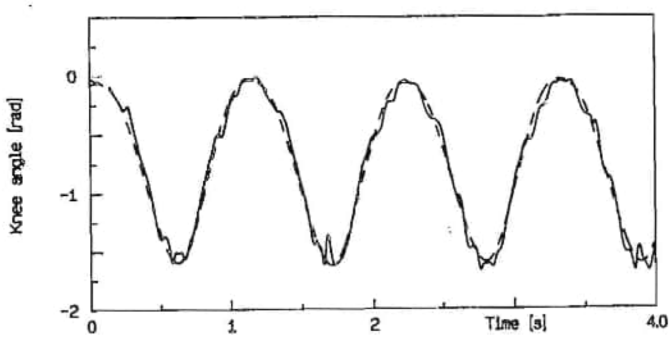

Figure 1.
Knee angle during pendulum measurement, as calculated from accelerometer data (solid line) and as measured by a flexible goniometer (broken line).

The angles were calculated from the accelerometer data using (3) and compared with the joint or knee angles as measured with the flexible goniometer. Non zero average errors (± 0.05 rad) were considered to be systematic and were compensated for. The standard deviation was used as a measure of the remaining error.
A typical result for the pendulum measurements is shown in Fig. 1. The standard deviations for the difference between calculated and measured knee angle ranged from 0.005 to 0.030 rad. For

standing–up (Fig. 2) as well as for sitting–down of a healthy human subject standard deviations ranged from 0.02 to 0.05 rad. Results for walking were greatly influenced by the effects of the heel–strike which gave appreciablete errors (Fig. 3a). They could be reduced by filtering as is demonstrated by using a digital fourth–order low–pass Butterworth filter with a cut–off frequency of 5 Hz. The filtered knee angles are shown in Fig. 3b. The standard deviation then ranged from 0.05 to 0.10 rad.

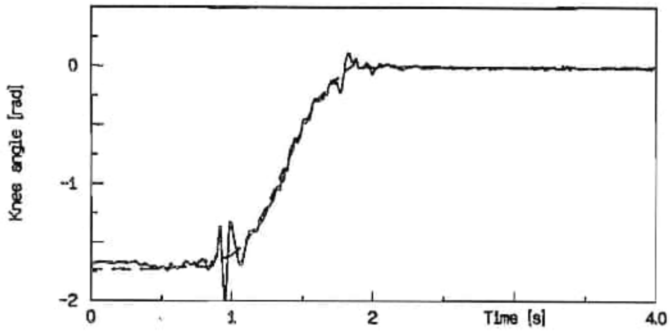

Figure 2.
Knee angle during standing up, as calculated from accelerometer data (solid line) and as measured by a flexible goniometer (broken line).

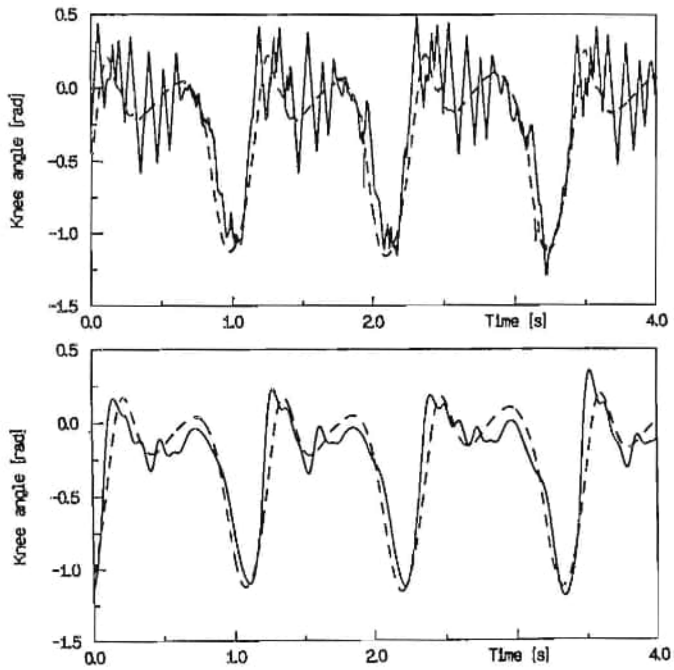

Figure 3.
Knee angle during walking as calculated from accelerometer data (solid line) and as measured with a flexible goniometer (broken line).
A: no filtering,
B: after 5 Hz low–pass filtering.

DISCUSSION

Three main errors could be identified. In the human subjects a systematic component was found, which showed up as an average error. This error could be caused by the non–ideal knee joint, by not fulfilling the rigid–body condition, by errors in the calibration of the accelerometers or by systematic componenents of the remaining errors. Because systematic errors can easily be compensated, however, this was not investigated further. A second error source was the non rigid attachment of the accelerometer during heel–strike. In general at heel–strike large accelerations occur. There is however a significant difference between the accelerations of the leg segments and of the accelerometer because of their attachment on the soft tissue of thigh and calf. Because the resonance frequency of the attachment is much higher then the frequency of the knee angle during

walking this problem can reduced by filtering as was demonstrated. A third error source is the movement of the muscle tissue which is detected by the accelerometers and interpreted as a change of the knee angle. An example of this is shown in Fig. 2 were a disturbance in the knee angle can be seen before the movement actually starts. A same effect is visible for walking. This means that, as long as a implantation of the accelerometer with fixation to the bones is not yet possible, great care should be taken to insure optimal fixation of the accelerometers. The use of accelerometers in a hybrid system, with the possibility of fixation to the orthosis, would thus be less critical.
The error ranges given are a function of speed. Because the movements of a paraplegic walking with FES are usually slow, we expect the lower range to be a good estimate of the results that can be achieved with these patients. Preliminary data collected by Crago *et al.* [1] indicates errors of 0.015 rad (standing) and 0.05 rad (walking) to be tolerable for closed–loop control of the knee joint by FES, which is comparable with the results we found. We conclude that the assumptions made (rigid–body dynamics, 2–dimensional movements and a ball and socket knee joint) do not lead to inacceptable errors and that our method for calculating the knee angle from accelerometer data can be used in feedback controlled FES systems.

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CONTROLLED FUNCTIONAL NEUROMUSCULAR STIMULATION OF PARALYSED MUSCLES

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SUMMARY

This paper is concerned with the design and development of a closed–loop controller to control the lower limb joint, using an electrical stimulation system. A model, describing the dynamic behaviour of the unloaded electrically stimulated knee joint was developed. This model consists of a nonlinear part, describing the motor unit recruitment order and a linear dynamic part, described by a deterministic ARMA model. Identification of the model was performed on the linear part, and three criteria; minimum square error, independence of residuals and the Akaike Information Criterion were used to estimate model order. An existing Model Reference Adaptive Controller was modified and implemented to control the unloaded knee joint of paraplegics. Nonlinearity compensation and a high closed loop damping had to be incorporated to overcome spastic reflexes in the paralyzed muscle. Controller implementation is detailed including experimental results.

MATERIAL AND METHODS

Model Development

The extrenally stimulated paralyzed muscle/joint system can be modeled as is depicted in Fig.1.

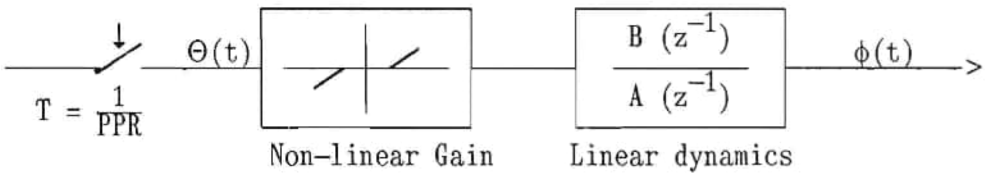

Fig. 1. A model of the paralyzed muscle/joint system

$\Theta(t)$ is the input stimulation pulsewidth (PW) and $\phi(t)$ the output angle, as provided by an electro–goniometer system.The nonlinear block represents the nonlinear motor unit recruitment characteristic. The recruitment relationship consists of a load and angle dependent dead–zone, i.e. pulsewidths below the dead–zone do not result in an angular change of the joint. Earlier trials on normal subjects have shown [1,2] that a simple threshold nonlinearity, followed by a linear relationship between stimulation PW and joint angle provides a sufficiently accurate representation of the recruitment characteristic.
The linear block represents the linear dynamics of an unloaded knee joint, described with a deterministic Auto Regressive Moving Average (DARMA) model.

Identification of the paralyzed muscle/joint system

The quadriceps and hamstring muscle pair of a paralyzed person were stimulated seperately with increasing PW, to determine the PW threshold of the dead–zone. Succesively the muscle pairs were stimulated with a Pseudo Random Binary Sequence (PRBS) of input PW for a period of 50 seconds, so as to not invoke muscle fatique.
The sampled angular data was linearized for each muscle pair seperately by setting below threshold PW to zero and substracting from the remaining above threshold PW an amount proportional to

the measured threshold.
The muscle/joint system after input–output linearization was described by the following equation, relating output joint angle $\phi(t)$ and stimulation pulsewidth $\Theta(t)$,

$$\phi(t) = -\sum_{j=1}^{n} a_j \, \phi(t-j) + \sum_{j=0}^{m} b_j \Theta(t-j-d) \qquad t \geq 0 \, , \, d \geq 1 \tag{1}$$

with a_j the time varying autoregressive model coefficients, b_j the time varying moving average coefficients, d the integer time delay (in steps of 50 ms), n the denominator order and m the numerator order. The basic system identification includes determination of the model order (n,m), the time delay (d) and the DARMA parameter set (a_j,b_j), given a set of input/output sequences $(\Theta(t), \phi(t))$.
The first criterion to identify the muscle/joint system order is the Least Square Error (LSE) criterion, which is obtained when the sum of the squared residual signal is minimized. As the LSE is a monotonically decreasing function for increasing model order, numerator and denominator orders must be chosen for which any further increase in model order is accompanied by a decrease in LSE that is too small to justify the extra complexity of a higher model order. Using this criterion, the system was identified as an DARMA model with a zero order numerator, a third order denominator and a time delay of one sample.
The second criterion to identify the system order is the independence of the residuals. We expect that for the optimal model order the autocorrelation function to have near–zero values for time lags greater than zero. Using this criterion the system was also identified as a DARMA model with a zero order numerator, a third order denominator and a time delay of one sample.
The third criterion to identify the system order is the Akaike Information Criterion (AIC). The difference between the AIC and the other criteria is that the AIC gives an objective result, whereas the other criteria give a subjective result. The optimal model order is given by the minimum of a function, proportional to the variance of the residual. However, so far, the AIC function did not give conclusive results about the model order due to large variance of the error even with high model order, so for the Model Reference Adaptive Controller (MRAC) a third order controller routine was implemented, as was concluded from the first two criteria.

The implemented model reference adaptive controller

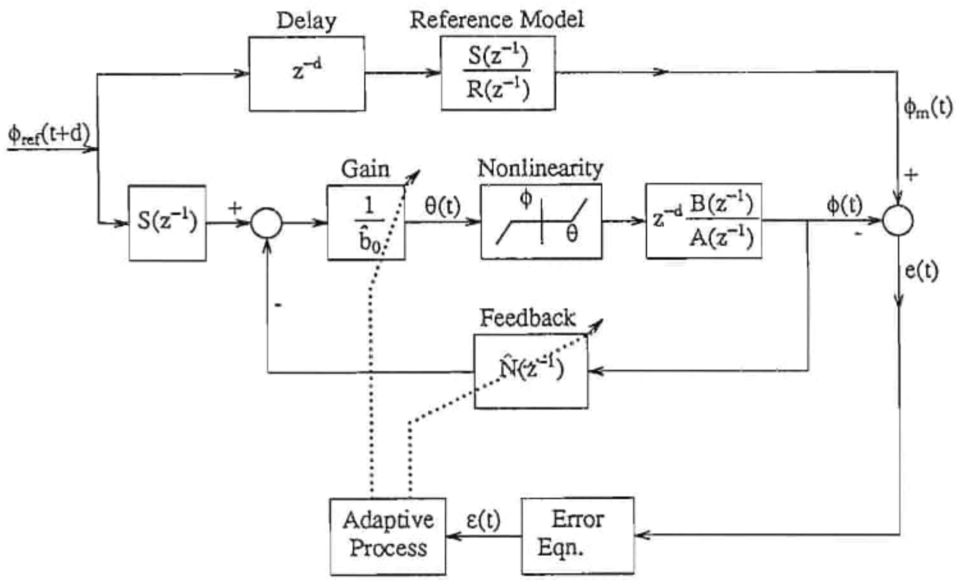

Fig. 2. The implemented MRAC algorithm

The implemented MRAC algorithm was based on a series–parallel design described fully in Landau et al. [4], the block–diagram of the MRAC algorithm is given in Fig. 2.
The closed–loop system dynamics could be determined by choosing the reference model parameters. The adaptation algorithm, as described fully in [3] adjusted feedback filter and gain parameters, according to the augmented filtered plant–model error. The parameter adaptation rate was chosen so as to impose a slow adaptation. Compensation for the non–linear input–output characteristic had to be implemented in the controller algorithm. Threshold estimation was performed before control experiments were carried out. The non–linearity compensation consisted of switching off the parameter estimator in the MRAC algorithm for stimulation PW within the nonlinear region.

The experimental setup

The identification and controller trials, involving both healthy and paraplegic subjects, were performed with a computer–based stimulation system. The system is centered around a PC/XT computer which operates as the controller in a feedback loop around the knee joint. In all experiments, the stimulation variable was the PW; pulse amplitude (appr. 80 mA) and repetition rate (20 Hz.) were maintained constant. Joint angle information, provided by an electro–goniometer system was sampled at a rate of 20 Hz. The coded MRAC control signal was sent from the PC to a decoder, containing information about the muscle pair to be stimulated and the PW. The decoder distributes the stimulus PW information to the high–voltage battery operated stimulators.
Identification and controller trials were carried out with the subject in seated position. The stimulator outputs were connected via surface electrodes to the main extensor (quadriceps) and flexor (hamstrings) muscle groups of the knee joint. More detailed information about the experimental setup is given in [3].

RESULTS

In order to meet the control rate constraint, a compromise had to be found between a reference model giving, on the one hand , a high enough bandwith to allow good tracking of the reference signal, while on the other limiting change of the control signal. A rapidly changing control signal induces spastic reflexes [3].Fig 3. shows the tracking of the reference input, as well as the control signal for a 30 seconds experiment.

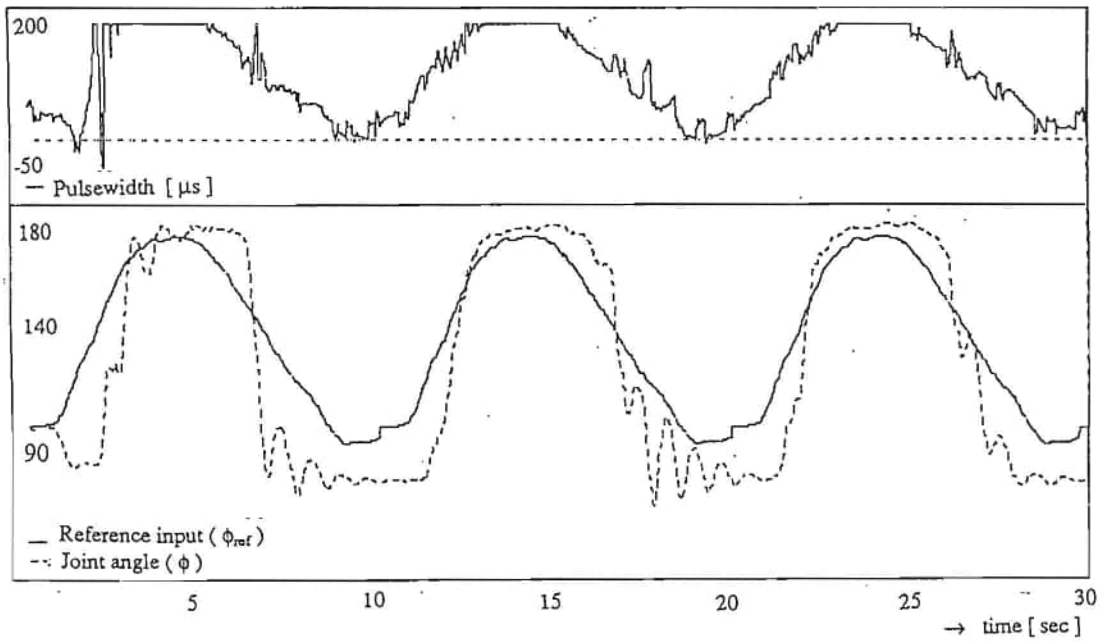

Fig. 3. Input–output results of MRAC for the paralyzed knee joint

The change in parameters occurs most extensively in the first 5 seconds of the experiment, as parameters are updated from their initial values. Optimal tracking as well as a slowly changing control signal can be seen from Fig.3.

DISCUSSION

The identification results of the paralyzed muscle/joint system show that the system can be identified as a third order DARMA model, although spastic reflexes invoked in the identification procedure produced large residual errors. Future identification trials may be carried out so that spasticity is not invoked, or even an attempt could be made to incorporate spasticity into the model of the muscle/joint system.
The results from controller experiments show that perfect tracking of the reference trajectory could not be reached, because of the high damping choosen for the reference model in order to eliminate spastic activity. A constraint on the control signal is that it has to be of a very low frequency content, as not to invoke spastic reflexes. The dependency of the dead–zone region on the angle of the knee joint was not incorporated into the model, tracking improvement may be obtained estimating the threshold PW during the control trials.
Different types of controllers may be implemented in the future to control the non–linear muscle/joint system

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LARGE SCALE TWO-DIMENSIONAL FINITE DIFFERENCE MODEL OF SACRAL BED SORE

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SUMMARY

The varied stimulation currents ranging from DC and tetanizing current to pulsed electromagnetic fields were applied to wounds in order to obtain a positive influence on progress of the healing /1,2/. Mostly integral data about electrical currents or voltages of bipolar surface electrodes were mentioned in the reports. Rough data are reported about the electrodes or induction coils geometry, particularly when electromagnetic stimulation is performed. Also, the data about magnetic flux densities, electrical field strengths and current densities, as the most relevant differential electric parameters of stimuli, which may have influence on understanding of the healing mechanisms, were not described precisely and consistently. Therefore, the parameters of stimuli are not satisfactory compared by different authors. The major reason lies in the lack of the data available, and in extended variety of geometry and anisotrophic and inhomogeneous properties of the conducting tissue. Direct measurements of electric fields inside and around chronic wounds are difficult to perform in humans. In addition, the available measuring methods may disturb the electric fields when low current densities are used and thus the accuracy of measurements is not guaranteed. A reasonable method to obtain the parameters of electric fields inside the volume conductor of biological tissue is two-dimensional or more realistic three-dimensional modelling.

The numerical determination of the field distribution in the stimulated biological structures around ulcers has primarily practical value for optimal electrodes design and their positioning relative to the wound. Finally, comparisons with data reported in various references are possible in order to define external parameters of stimulation and eventual understanding of the mechanisms.

MATERIAL AND METHODS

Sacral bed sore finite difference model

A two-dimensional large scale finite difference model of pressure sores in sacral region of the back has been created. The model is valid in both for the direct constant and the tetanizing stimulation, because of the quasi static approach. The electrodes are positioned on the healthy skin lateral to the wound about 2 cm away from the edge of the wound. Just for model purposes the normalised voltage of 1000 mV is applied to the electrodes. Because of linearity of the model the results may always be scaled to any other value of the actual stimulation current or voltage sources.

The basic geometry of the sacral part of the back has been taken off from the anatomic atlas. Four inhomogeneities have been considered in the model: interface between electrodes an skin, fat tissue, skeletal muscle tissue, and bones. The anisotrophic conductivity of the skeletal muscle has been considered. The conductivity of skeletal muscle is 0,4 S/m longitudinal and is 0,1 S/m in transversal relative to the major direction of muscle fibres cells. The fat has conductivity of 0,5 S/m, the bone has 0.001 S/m in all directions. The skin conductivity is 0,0025 S/m in tangential directions and 0,005 S/m in all directions normal to the skin surface. It is evident that such a large scale of inhomogeneities and anisotrophies have to be considered in any approximation of the more or less realistic volume conductor model of the biological system. The various tissues electric properties are known from many classic references /3,4/.

Discretization and numerical solution

Discretization of the volume conductor has been performed in resolution of 0.5 cm. Because the symmetry of the wound and surrounding tissue has been supposed in this first two-dimensional approximation, only the right half of the whole model needs to be calculated numerically. The transversal section of the wound in size of 8 cm in diameter has been modelled. The depth of the sore is varying from zero on the edge to maximum 1.5 cm in the centre of the wound.

The numerical solution of the potential distribution is based on finite difference approximation of scalar Laplace equation for inhomogeneous and anisotrophic media. Both Neuman and Direchlet boundary condition have been considered properly. Because of an extreme variety of the geometry of biological structures in human, our own Pascal programme have been developed for these specific needs. The programme for Biological Models Computer Edit Design (BMCAD) includes extended graphics and an original fast algorithm has been developed in order to solve the large system of finite difference equations. The maximal number of points where potentials inside volume conductor can be calculated is up to 60.000 when XT or AT personal computer with minimum 640 kB of memory and with mathematical coprocessor is build in the system. The inhomogenious mesh of the discretization can be used for large scale models. Programme run interactively or can be controlled by predetermined beach files. Basic geometrical shapes are entered by digitiser. The method is described in details by reference /6/.

RESULTS

The isopotential lines in steps of 20 mV are plotted in Fig. 1. The inhomogenous distribution of the potentials is evident. From potential distribution all strengths of the electric field can be calculated in any point of tissue. In addition, numerical determination of the current densities are possible by applying the Ohm's law in differential form. These data about the electric field need to be known because of the purpose mentioned in the introduction. Just for an illustration, the amplitude of the electrical field strength is at the region near the wound surface approximately 0.2 V/cm, and corresponding current densities are in the range up to 200 mA/cm . These values are somewhat higher than data reported and suggested in most references /7,8/, but are still in the same range of the magnitude.

DISCUSSION

This two-dimensional model is only a crude approximation of the reality. The data available about parameters of electric and current field are compared with those calculated with the proposed model. An optimisation of the electrodes size and position will be possible when more realistic three-dimensional model of pressure sores will be developed. No unified theory regarding healing mechanisms has been accepted so far. Better understanding of electric properties obtained by

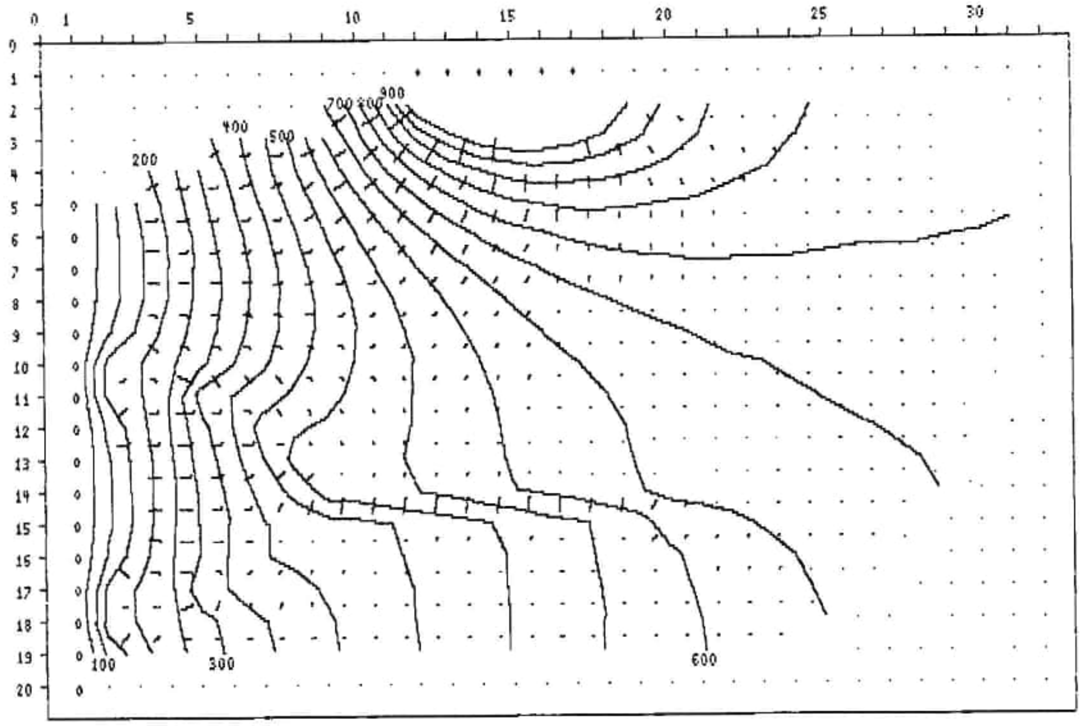

Figure 1. The plot of isopotential lines and vectors of the electric field strengths into the tissue surroundings the sacral decubitus ulcer when electrical stimulation of 1000 mV is applied by bipolar surface electrodes. The electric field strength is calculated from known field as a numerical derivative of the potentials Because of symmetry only a right half side of the two-dimensional model is shown. The inhomogenious distribution of the potential due to bones and sore geometry is evident.

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MONOPHASIC HIGH VOLTAGE GALVANIC STIMULATION ALSO IN VETERINARY MEDICINE

U.G. Zechner-Trummer, G. Zechner

The first time high voltage galvanic stimulation was used in veterinary medicine, and tested under everyday conditions and in the stable.
Biophysical principles and clinical findings in human medicine are described, and some cases of veterinary use are shown:
an ulcer on the pastern of a riding horse which had been treated for three years without effect healed compleatly after 20 TENS applications within one month.
the second case we want to tell about is the rehabilitation of a hunting dog after a deep wound on the foreleg with infection with anaerobic germs.

MATERIALS AND METHODS

In our veterinary praxis dogs and horses are treated with high voltage galvanic stimulation.
commom indications are:

1. woundhealing and posttraumatic edema.
2. lameness in horses according to osteochondrosis tendiniosis and tendovaginitis chronica.
3. muscle relaxation in the back muscle of horses.

I want to pic aut two cases:

1. A 10 jears old stud had an ulcer on its right posterior pastern, it was 30mm to 15mm wide and 6mm deep next to a 40mm to 18mm large keloid. It had been treated for three years with ointments and bandages without effect.
2. The second case is a 4 years old huntingdog which came with a gasedema on his foreleg up to the ellbow 3 weeks after a bite-lesion. Beside wound-toilette and antibiotic treatment we started high voltage galvanic stimulation.

We use two types of high voltage generators (DIA) with an output of 500 volts (one for clinical use and a portable one). They produce an exactly monophasic twin-peaked pulse with a duration of 65 microseconds and an intensity up to 2.0 amperes, the average current is as high as nanoamperes.
It is possibe to choose the following variables:

1. frequency of the double impulses from one up to one hundred per second
   We used:

12	for healing of the ulcer
8 - 12	for resorption of edema and musclestimulation in the dog
80 -100	for painrelief
12 -100	for musclerelaxation

2. the polarity of the electrodes:
   In the most veterinary cases we used the first time bipolar treatment with two pads with the same extension (48x48 or 48x97 mm).

3. Next one can choose the time 20-25 minutes are minimum in the acute stadium every day or every other day.

4. The current flow can be chosen continous or alternative between two therapeutic pads.

5. We increase the voltage continuously by hand until reaction; treatment takes place under this threshold. The horse was treated with 300 volts. The dog was treated with 150 to 220 volts.

The rubber pads are easy to clean and to desinfect. They were placed with elastic bandages.

RESULTS

Case one:
First the ulcer grew, got soft and humide, and after one week we could see young epithel-tissue spreading into the ulcer, after 4 weeks the ulcer was closed, and we finished therapie. Two months later the scar was smooth and pliant.
Case two:
Edema diminished after the first current application. The dog stood on his leg immidiately after the first application because of pain reduction, he did also allow to touch the leg, what he did not before. After two current applications (that is one week after beginning of treatment) he ran with 4 legs, and showed only little lameness. After 14 days the wound had healed without restlameness.

It is difficult to verify the results of the most treatments of arthrosis and chronical tendovaginitis in horses under everyday conditions in the veterinary praxis and in the stable of the owners.
Because the owners often ride the horses despite the order as soon as they go better, and on the other hand there are too few cases of the same diagnosis for statistical evaluation.

DISCUSSION

The fields of indication and the clinical results of high voltage galvanic stimulation correlate with those of human medicine.
I want to give a view over the illnesses and symptoms which have been investigated in Austria in the Ludwig Boltzmann Institute for physical diagnostic by AMMER /1,2,3/
1. chronic posttraumatic syndromes
2. acute posttraumatic syndromes
3. musclerelaxation
4. muscletraining
5. periarthropathia humeroscapularis
6. arthrosis
7. neuralgia

The polarity:
ROSS and SEGAL /5/ used a pseudounipolar treatment: that means that there are one, two or more small pads with high current density beneath (they are called "different" pads), and one large (indifferent or dispersive) pad. They found, that positve treatment pads make sedation, vasodilatation

and healing, and on the other hand negative polarity beneath the treatment electrodes leads to vasoconstriction and desinfection. In veterinary medicine we applicated the first time bipolar (as described above).
And also Ammer /1/ did not find a significant difference due to the polarity by treating periarthropathia humeroscapularis.

The biological effects of direct high voltage currents had been collected by BINDER /4/and Shauf et al./6/:
There is no thermal effect because of the tiny average current flow; thus we cannot use high voltage galvanic stimulation for diathermie.
There do not occur chemical reactions such as coagulation because of the short duration of the current impulses; therefore this form of current is not used for iontophoresis.
Like any other form of current action potentials of nerv- and muscle-cells are evoced, and there should be noted, that the nerv's reaction comes before that of the musclecell.
The amplitude required to excite a nervecell is inversely proportional to the fibre's diameter.
Pain fibres are of small diameter, whereas the other afferent fibres are more myelinated. They answer the electrical stimulus before the pain fibres and block the gate for the pain fibres (Gate control theory of pain reduction).
Peripheral circulation is said to depend on musclekontractions (beeing stimulated with 8 to 32Hz) and on the other hand by inducing an autonomic response with vasodilatation.

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RELAXANT INDUCED NEUROMUSCULAR PARALYSIS IN THE RAT TIBIALIS MUSCLE AND THE DIAPHRAGM: QUANTIFICATION BY EMG AND MMG *

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SUMMARY

For monitoring of neuromuscular (nm) transmission during anaesthesia qualitative evaluation of muscle tone is widely applied. A more accurate, but semiquantitative technique is manual or visual assessment of evoked twitch responses of a peripheral skeletal muscle following indirect stimulation of the respective motor nerve. Quantitative determination of the degree of nm depression is based on the measurement of such responses. However, clinical applicability of the method of choice, i.e. the isometric measurement of evoked contraction, is restricted to certain muscles only. Since muscle groups also differ in their sensitivity to nm blocking drugs, monitoring a peripheral muscle appears to be of limited value especially when assessing the extent of (residual) respiratory muscle paralysis. Thus in order to quantify the different relaxant sensitivities of the tibial muscle and the diaphragm, an animal model was developed. Using this model both the electrical surface compound action potential (EMG) and the isometric contraction (MMG) were determined simultaneously in order to elucidate any differences between the measurement techniques itself. From the results obtained with increasing bolus doses of intermediate acting nondepolarizing muscle relaxants, it is concluded that the dose response curve in the diaphragm is right-shifted compared to that of the tibial muscle. Nm block determined by the EMG technique is deeper and recovery from nm depression slightly prolonged which results in a curvilinear relationship between EMG and MMG during the offset phase of nm blockade. Unlinearity was more pronounced in the tibial muscle than in the diaphragm. Though correspondence with isometric MMG is lacking, proper EMG measurement nevertheless appears to be a reliable monitoring technique.

MATERIAL and METHODS

14 Sprague Dawley rats were anesthetized (thiopentone) and ventilated. Heart rate, arterial blood and airway pressure, core and peripheral temperature were continuously monitored; hind limb temperature was kept constant within ±0.2 deg. Blood gases and blood electrolytes were checked intermittently. Nm depression was measured electromyographically in the tibial muscle (TIB) and diaphragm (DIA) by a special relaxation monitor described previously /1/. Responses were elicitated by single (0.2 msec, 0.1 Hz) pulses and intermittent train-of-four (TOF)

* Supported by Hochschuljubilaeumsstiftung of the City of Vienna

stimulation of both phrenic nerves and the tibial branch of the sciatic nerve. Vecuronium (VEC) and ORG NC8764, a VEC derivative, were applied using bolus doses of 1, 2- and 3-fold ED_{90} (VEC: 300, 600 and 900ug/kg; ORG NC8764: 4800, 9600 and 14400ug/kg). In addition, a continuous infusion of VEC was administered and adjusted to depress twitch contraction by approx. 90% in the tibial muscle. Due to the cardiovascular side effects of ORG NC 8764 this relaxant was not infused continuously. Complete recovery (also verified by missing TOF-fade) was allowed before subsequent relaxant application. For statistical comparisons ANOVA and Wilcoxons difference test were employed; a significance level of $p<0.05$ was chosen. For comparison of MMG and EMG during offset of paralysis a regression analysis was carried out.

RESULTS

Tables 1 and 2 summarize the pharmacodynamic parameters calculated from the time course of nm depression following increasing bolus doses of VEC or NC8764. Onset of nm block is similar with both measurement techniques. In the two muscle groups maximal depression of the surface compound action potential (EMG) was enhanced compared with the mechanical twitch (MMG) depression. Statistically significant differences in maximal block were found in the diaphragm. Figures 1 and 2 depict the time periods from drug injection to twitch recovery of 25, 50, 75 and 90% of their respective control values. Comparing the offset phase of nm depression in the diaphragm and tibial muscle nm transmission is restored earlier in the diaphragm no matter whether the measurement is effected mechanographically or electromyographically. The mechanical twitch recovered earlier to its pre-drug control than the EMG responses yielding a curvilinear relationship between simultaneously measured EMG and MMG in TIB. This relation is approximated by a 2nd order poly nomial in the range between 20 and 95% twitch height (MMG; $y=-2.66+0.345x+0.0057x2$; $r=0.941$). The best fit for the EMG and MMG data

Tab.1: Onset (sec) and maximal block (%) measured by MMG and EMG in the tibial muscle and the diaphragm after increasing bolus doses of VEC

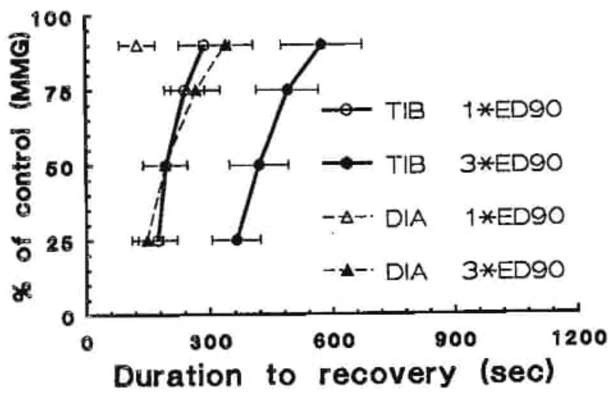
	TIB				DIA			
Dose	Onset		Max.block		Onset		Max.block	
	MMG	EMG	MMG	EMG	MMG	EMG	MMG	EMG
ED_{90}	79±10	69±15	84±13	89±14#	53±7#	48±7#	27±7##	76±14#
$2*ED_{90}$	55±12*	50±8 *	99±3*	97±5*	53±5	48±9	60±14#*	87±13#
$3*ED_{90}$	44±7 *+	38±10*+	100±0*	100±0*	55±5#	50±10#	86±13#*+	92±9*#

Tab.2: Onset (sec) and maximal block (%) measured by MMG and EMG in the tibial muscle and the diaphragm after increasing bolus doses of ORG8764

	TIB				DIA			
Dose	Onset		Max.block		Onset		Max.block	
	MMG	EMG	MMG	EMG	MMG	EMG	MMG	EMG
ED_{90}	90±13	90±12	91±7	93±6	53±7##	49±8	68±14##	86±10
$2*ED_{90}$	55±8*	45±9*	100±0*	100±0*	59±8	38±7*	91±7#*	99±3
$3*ED_{90}$	39±4*+	36±5*+	100±0*	100±0*	40±10	36±8*	96±6#*	100±0*

Onset in seconds; maximal block in %; mean ± sd, n=7
TIB vs. DIA: # $p<0.05$ ## $p<0.01$
ED_{90} vs. $2*ED_{90}/3*ED_{90}$: * $p<0.05$; $2*ED_{90}$ vs. $3*ED_{90}$: + $p<0.05$

recorded from the diaphragm is governed by a similar regression ($y=-12.2+0.54x+0.0064X2$; $r=0.924$). During continuous VEC infusion nm transmission was only slightly impaired in DIA (block: 11±2% MMG, 13±5% EMG) in contrast to TIB (block: 91±3% MMG, 98±2% EMG; $p<0.05$).



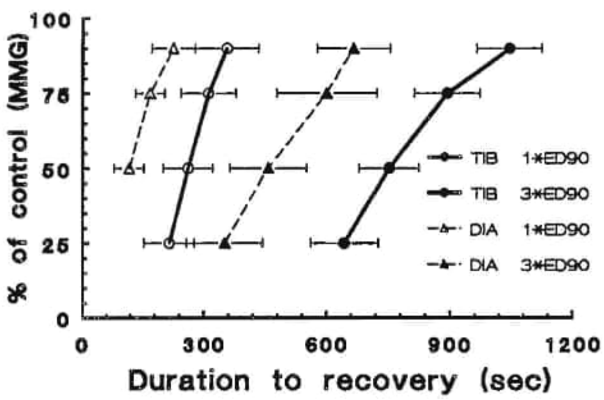


Fig.1 and 2: Time course of mechanical twitch recovery: Nm block was induced by VEC (fig.1, left) and ORG NC8764 (fig.2, right) in TIB and DIA by ED_{90} and $3*ED_{90}$ bolus doses (ED_{90}: open, 3-fold ED_{90}: closed symbols). Mean ± sd; n=7. The ED_{90} of VEC induced a nm block of less than 30% in DIA (left figure). Duration of blockade lasts significantly longer in TIB than in DIA indicating a higher relaxant sensitivity of the tibial muscle.

DISCUSSION

We have developed a rat animal model for quantitative determination of nm blockade not only in peripheral muscle but also in the diaphragm. There might be some concern in respect to quantifying nm depression by the EMG technique employed. Mechanical twitch measurement is still the preferred choice for nm transmission studies /2/ in spite of numerous reports indicating a close relationship between EMG and MMG. Our finding of a measurable mechanical contraction, even though the evoked EMG was completely suppressed, appears to be in contrast to what is expected from the mechanism of excitation-contraction coupling. This discrepancies may be explained by the fact that the total summated output is measured by the MMG, whereas the compound action potential (EMG) strongly depends on the ratio between the size of the recording and the muscle surface area /3/. In our experiments a varying ratio can be neglected since the same recording technique was used throughout the investigations. Another objection against the EMG is an eventual lack of long-term stability. This error can be ruled out here since EMG amplitudes recovered to their pre-drug control at least within ± 5%. Also any influence of physiological variables, like temperature changes and/or alterations in flow distribution, can be disregarded in our experimental set up: body and limb temperatures were kept constant and only those experiments were evaluated in which hemodynamics remained stable and no alterations in pH or blood electrolytes were apparent. Thus, under well controlled conditions, the EMG technique employed has to be considered as accurate as the mechanical force measurement.
The most important finding in this study is the rather large difference of nm block in the two muscles. In respect to VEC it should be emphasized that the maximal depression measured in the tibial muscle was far

deeper than in the diaphragm both after a ED_{90} bolus dose (84 vs 26%) and during continuous infusion (91 vs 11%). A similar difference in the extent of muscle paralysis was observed by Tran et. al. /4/ during steady state VEC infusion in the same animal species. Those results, showing only 5 to 10% depression of mechanical twitch response in the diaphragm, are therefore in excellent agreement with the present data. Differences in maximal block are less pronounced with NC8764 indicating also drug specific discrepancies. Onset of the drug effect was significantly shorter in DIA than in TIB, but without any evidence for a drug specifity. For explanation, a higher blood flow, a faster drug transfer into this biophase or varying drug transport delays have to be taken into consideration. Since the time interval between drug injection and appearance at the different sites should not exceed more than 20-30 seconds (circulation time) and not vary by more than a few seconds in a small animal like the rat, this delay is considered unimportant. The effects due to a higher perfusion or a reduced drug crossing time (from blood to the receptor), however, cannot be differentiated with the present measurement technique. Thus, further studies are needed to clarify the relative contribution of these factors.

Shortening of onset was observed with increasing bolus doses in the tibial muscle in contrast to the diaphragm; in this muscle the time from drug injection to peak effect did not change significantly. The observed reduction in onset is clearly due to the complete block (in all but one animal) caused by the 2-fold ED_{90} bolus in the tibial muscle. It may be hypothesized that an even larger bolus dose would not further reduce the onset, the limit being approx. 40 seconds, apparently needed for drug transport and diffusion into the biophase. With regard to DIA the onset tended to shorten only with the highest dosage of NC8764 causing nearly complete block of nm transmission.

After single ED_{90} bolus application, the difference in maximal paralysis was smaller than during continuous relaxant infusion and duration of action was also significantly shorter in DIA, both facts indicating a decreased drug sensitivity of the diaphragm. This sensitivity difference apparently is masked at least in part during the drug distribution phase: Since the onset in DIA is faster, the concentration in this effect compartment (cpt) may be higher than in a "slower" cpt. Thus the higher initial biophase concentration to some extent compensates for a right-shifted dose-response relation causing a smaller difference in maximal blockade.

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ELECTRIC, VIBRATION, MAGNETIC STIMULATION OF CHILDREN' SCOLIOSIS.

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Electric, vibration, magnetic stimulation were used for substantiation of a nosologic diagnosis and for treatment of 20 children with scoliosis I-II degree (up 30°), aged 8-12 years. We hade good results in every children: correction of deformity was 5-25°. Electric stimulation: for diagnosis - H-reflex, M-replay, evoked potentials of spinal cord; for treatment - noninvasive and invasive stimulation of paraspinal muscles on the side of curvature. Vibration stimulation: for diagnosis - tonic vibration reflex of paraspinal muscles; for Treatment - vibration of this muscles in defective places with different freqency. Magnetic stimulation: for diagnosis - evoked potentials of spinal cord and peripheral nervous (2-4 T); for treatment - impulsive magnetic field to the back' muscles.

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AFFERENT STIMULATION IN THE TREATMENT OF LOWER LIMB SPASTICITY

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SUMMARY

Thirty patients with lower limb spasticity, all resistant to medical treatment, were treated with electrical stimulation. The flexor reflex arc was stimulated with repetitive puls train applied to the posterior tibial nerve behind the medial malleolus of the ankle. After two days the stimulation of the peroneal nerve behind capitulum fibulae was initiated. After a period of one year, 24 patients still had subjective improvement and thus continued stimulation. Measurements of reflexes were evaluated just before start of stimulation and again after 4 weeks. In 22 legs a significant increase of the flexor reflex was seen.

INTRODUCTION

More than 70 patients, with various pathologies, were treated with electrical stimulation with the aim of reducing spasticity and rigidity. In this paper the experience from the first investigation will be described.
Since 1983 an extensive research on functional stimulation has been carried out at the Department of Neurology, Århus Municipal Hospital. The aim was to apply the fundamental knowledge which we have obtained during 15 years of reflex studies in our laboratories. Medical treatment of lower limb spasticity may not always be sufficient and quite often adverse side-effects, such as drowsiness and decreased voluntary power (1,2), may counteract the clinical effect. In 1983 a Danish Neurostimulator was developed for peroneal nerve stimulation (3), and more than 1000 patients are using this stimulator at present. A lot of these patients have obtained a depression of their spasticity. To utilize this positive effect further a special dual stimulator has been developed for use in spasticity treatment.

MATERIAL AND METHODS

Thirty patients, 15 men and 15 women (mean age 40 years? range 18-60 years) were included in the study for a period of 2.5 years. In 5 patients walking was still possible. The diagnoses were multiple sclerosis (MS) in 16, traumatic paraplegi in 5, of whom 2 were incomplete, cerebral thrombosis in 3, cervical neurinoma in 2, and in the remaining 4 contusion cerebri. All patients displayed typical, clinical signs of spasticity, increased stretch reflexes, clonus, flexor spasm and muscle hypertonia. The duration of the symptoms varied from 2.5 to 10 years, and MS patients had remained stable for more than 2 months. There were no alterations in the medical treatment during the study. The treatment was performed by means of balanced monophasic impulses, with a pulse duration of 250us and a frequency of 40Hz. The stimulation was applied to the posterior tibial nerve behind the medial malleolus and was carried out on one or both legs simultaneously. The duration of the stimulation was set to 5-8 s followed by a pause of 15 s. Each treatment lasted for 25 min and was performed twice daily. After two days the stimulation site was altered to the peroneal nerve behind the capitulum fibulae. In the cases of double stimulation the stimulation was altered to asynchronous mode.

Acknowledgement: This study was supported by the Danish Multiple Sclerosis Society

The stimulators were either Neurostimulator KDC 2000, a single-channel peroneal stimulator, or KDC 5000, a dual-channel neurostimulator.

The patients' evaluation of the treatment was carried out by registering the condition of the legs after stimulation, especially in connection with everyday activities. The patients were asked to record improvements, if any, of their spasticity and to note when the improvement disappeared.
Clinical evaluation consisted of registration of spasticity during a standardized neurological examination, and Kurtzke's scale (4) was used for the MS patients.
Flexor spasm was evaluated as absent, slight, or severe relative to mass reflex. Clonus was evaluated as absent, exhaustible, or nonexhaustible. Spasticity was evaluated as normal muscle tonus, muscle tonus higher than normal with strong resistance to passive movement, or very high tonus with limited passive movement of the joints.

In 15 consecutive patients quantitative measurement was performed corresponding to a sample of 22 legs, before and after a stimulation period of approximately 1 month.
Counting of flexor spasms were performed during one night by rectified (EMG) registration from the tibial anterior muscle, according to the method described earlier (5).
Flexor reflex threshold was elicited by electrical stimulation applied to the posterior tibial nerve behind the medial malleolus. The EMG response was recorded from the tibial anterior muscle.
T-reflex measurement (6) was elicited from an electromagnetic hammer. The patient was in the supine position with the foot placed on a transducer pedal, enabled for isometric measurement, with dorsiflexion at a position obtained by a torque of 300 p-m. The reflexes were recorded both by EMG and by the transducer pedal.
T-reflex inhibition measurement was elicited by afferent flexor reflex stimulation at the medial malleolus at low level, only allowing allowing a slight movement of the toes. The flexor reflex input was elicited 2000 ms before the T-reflex was elicited, and this time interval was then gradually reduced by 100 ms at a time. In the inhibition area this interval was further reduced to 5-10 ms. In normal persons the inhibition of the T-reflex is complete when flexor reflex input is applied in the area of 50-300 ms (7). Resistance to passive movements in the ankle joint was measured by a sudden release of a rubber band, enabling the transducer pedal, to which the foot was strapped, a torque of 500 p-m. The ankle joint was in a fixed starting position.

RESULTS

After a mean observation time of 1 year 24 patients continued daily stimulation. The subjective improvement was a decrease or elimination of spasticity for 6-14 h after each treatment. During daily activities i.e. bathing, dressing, and physical therapy excitation of spasms was decreased or eliminated and/or the legs were less stiff. Four patients reported a total relief or diminished pain in the legs. Two patients (MS) had stopped the stimulation due to lack of effect of the spasticity. Four other patients (2 spinal lesions and 2 cerebral lesions of the nervous system) had stopped stimulation because the decrease in spasticity only lasted for 1-2 h after stimulation.

Neurological evaluation of the 16 MS patients varied from 3.5 to 8.5 (mean 6.7). After the stimulation treatment the disability score for the MS patients was unchanged or only slightly decreased.

Clinical evaluation after stimulation treatment showed depression of resistance to passive movement and decreased hypertonia, clonus and flexor spasms.
The result of the quantitative measurements are shown in Fig. 1. The number of flexor spasms counted during one night showed a slight decrease. Three patients reported undisturbed sleep for the first time in many years.
The threshold of the flexor reflex was significantly increased. The T-reflex movement area showed an insignificant increase.
Resistance to passive dorsiflexion of the foot showed an insignificant increase in maximal speed. Ten of the patients reported subjective improvement, and in these patients a significant decrease of resistance to passive dorsiflexion was obtained and the T-reflex movement area was significantly increased. The T-reflex inhibition measurement was incomplete or impossible in 12 cases. In 5 of these cases the inhibition became normal (Fig. 2). In the remaining 10 cases the pattern was unchanged or slightly normalized after stimulation.

DISCUSSION

A majority of these patients, suffering from long-lasting spasticity, which was resistant to drug treatment, reported decreased spasms and spasticity and less stiffness of the legs. This improved their everyday activities several hours after the stimulation treatment. Other authors have described a similar effect.
We find the behaviour of the flexor reflex very important in the understanding of spasticity. It is well known that flexor reflex thresholds in normal persons increase with the increasing stimulation cycles, and that these increased thresholds will last for some time before returning to normal. The same effect seemed to play a major role in the suppression of hyperactive reflexes in the lower limbs. The flexor reflex is a polysynaptic reflex travelling in the interneurons between several spinal segments. Through propriospinal tracts this suprasegmental suppression could propagate to, and change, sensitivity in gamma motors and alpha motor neurons. This inhibition can also be observed on the T-reflex by measuring the T-reflex inhibition evoked by afferent inflow over the flexor reflex arch. The optimal suppression effect is seen by stimulating the posterior tibial nerve behind the medial malleolus. In an anti-spasticity treatment this stimulation site is less convenient than stimulation of the peroneal nerve behind the capitulum fibulae, and although this renders a smaller afferent contribution in the flexor reflex arch we find that this stimulation site renders sufficient effect after two days of treatment at the posterior tibial nerve. Decreased inhibition has been reported to be responsible for the increased excitation in spasticity. In this study many patients showed an abolished presynaptic inhibition which could be settled or normalized in some of them by intensive inflow of the IA afferent pathways of the flexor reflex arch.
T-reflex responses are often reduced in spastic patients and after stimulation this reflex tends to show an increase, as previously seen. It is remarkable that stimulation of the flexor reflex arch abolishes both extensor and flexor spasticity in the lower limb. The results of this study strongly support the hypothesis that many paths in the spinal cord are opened for afferent influence, reducing abnormal reflex activities in many patients.

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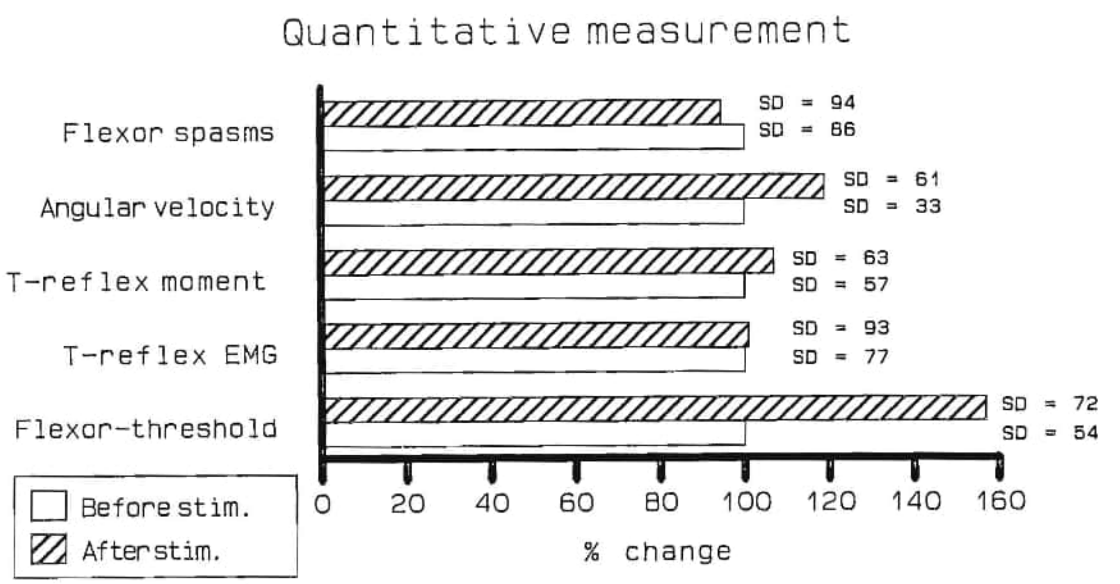
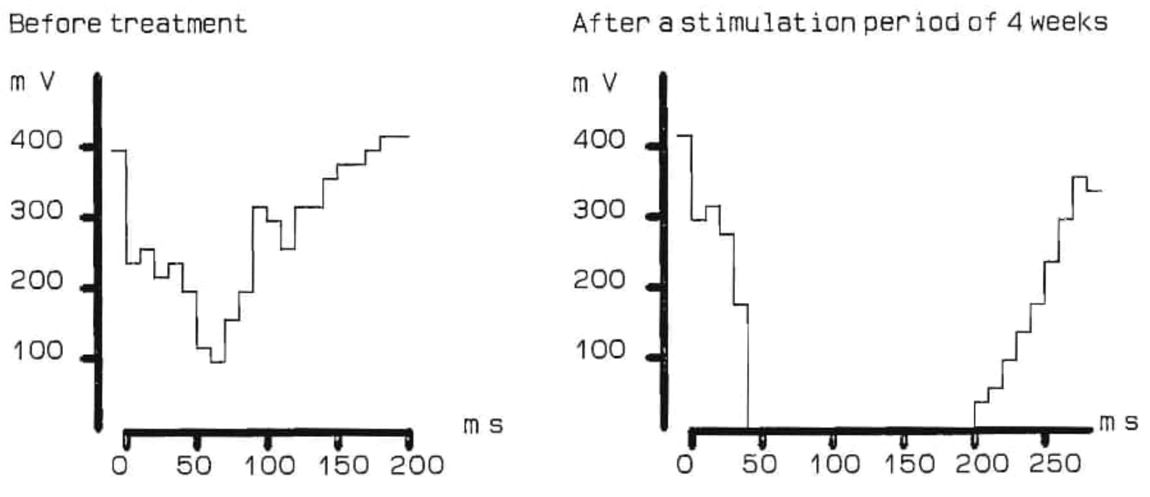


Figure 2.



T-reflex inhibition. Time scales indicate the interval from eliciting a flexor reflex to eliciting a T-reflex

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Reconstruction of the damaged spinal cord with transplantation of muscle and omentum mayus

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Apart from rehabilitation mesures highly improved in the last 15 years, the direct reconstruction of injured fibres of the spinal cord is still almost impossible to realize.

It appeared in the last 10 years' research work that in traumatic paraplegia there is particularly a damaged microcirculation. Many examinations had been done to improve the microcirculation.

The most successful methods in treating injured spinal cord tissue seemed to be the transplantation of muscles or of omentum on the spinal cord.

The author's research work has shown that priority has to be given to the direct transplantation of omentum on the damaged spinal cord structures particularly in the acute phase. Within a few weeks histologically collateral vessels from the omentum proliferate in the spinal cord. This is the more stronger the stronger the lesion is. If there is a better vasculare state the regeneration of damaged nerve fibres is more possible on the one hand and on the other hand it also appeared that the necrosis of the spinal cord's tissue can partly be stopped if the vascular circulation is improved.

THE SACRAL ANTERIOR ROOT STIMULATOR (BRINDLEY) - OWN EXPERIENCE IN THE MANAGEMENT OF UNBALANCED REFLEX BLADDER

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SUMMARY

Implantation of sacral anterior root stimulator (SARS) in combination with sacral deafferentation (SDAF) has become an established therapeutic concept in the management of unbalanced reflex bladder. Our own experience with 11 females and 2 males demonstrates, that detrusor hyperreflexia and its consequences can be controlled and balanced voiding be achieved. Prerequisites are a complete suprasacral lesion with an intact sacral efferent neuron and a detrusor capable to contract. Complete SDAF is essential to abolish detrusor reflex contractions to gain continence. In case of incomplete rhizotomy a second deafferentation at the level of the conus can be necessary, as in three of our patients. Technical problems with the implant, which could be repaired, occured sofar in 4 of our patients.

INTRODUCTION

Electromicturition by stimulation of the anterior sacral roots was performed in animal experiments since 1969 (1,2), in 1978 the first sacral anterior root stimulator was implanted in a human (3). Meanwhile worldwide about 300 patients had been treated by implantation of SARS. This device is appropriate to patients with complete suprasacral spinal cord lesions with otherwise not treatable unbalanced reflex bladder. Detrusor - sphincter dyssynergia and detrusor hyperreflexia cause urinary reflex incontinence, residual urine and subsequent urinary tract damage. This treatment strategy includes implantation of SARS and posterior sacral root rhizotomy (sacral deafferentation) to render the detrusor areflexic when it is not electrically stimulated. In this way balanced voiding and urinary continence can be achieved.

MATERIAL AND METHODS

The Finetech - Brindley bladder controller is driven by an external radio transmitter. Electrode mounts are placed around the anterior sacral roots intra- or extradurally. They are connected with the subcutaneously implanted radio receiver block by silicone coated cables. The external stimulating device consists of a stimulator box and a transmitter, which has to be held over the implanted receiver block for stimulation. Intraoperatively the sacral roots as well as the anterior and posterior compartments are identified by intraoperative electrostimulation together with simultaneous intraoperative urodynamic monitoring. The posterior sacral roots from S_2 down to $S_{4/5}$ are transsected, they all may contain afferent parasympathetic fibres. This rhizotomy has to be done proximal to the spinal ganglion. The anterior sacral roots of S_2, S_3 and $S_{4/5}$ are trapped in three electrode books. This allows the independent stimulation of three groups of nerve roots.

Postoperatively the parameters of stimulation can be adjusted under urodynamic control to achieve balanced voiding. The problem of simultaneous stimulation of the detrusor and the external sphincter is overcome by stimulation in bursts with intervals inbetween. Thus the fast reacting striated muscle of the sphincter relaxes intermittently while the slow reacting smooth detrusor muscle remains in contraction resulting in more or less intermittent voiding.

PATIENTS

From 1985 - 1989 13 patients had been operated, 11 females and 2 males. 5 suffered from tetraplegia, 8 from paraplegia, all had complete spinal cord lesions. The mean age at the time of operation was 26,8a, the youngest being 17a, the oldest 45a. The mean duration after the trauma was 5a with a range between 1 and 27a. All patients suffered from an unbalanced reflex bladder, which was 9x normocontractile, 4x hypercontractile. Preoperatively 10 patients had anticholinergic drugs and emptied their bladder with self intermittient catheterisation, the rest used either catheter alone or combined with reflex micturition or reflex micturition alone. Despite therapy 9 patients suffered from total, three from moderate urinary incontinence, 12 had relevant amounts of residual urine. Vesicoureteric reflux I was recorded in 3, reflux II - III in one patient. The procedere, which was performed by the neurosurgeon, was done intradurally in 10 cases and extradurally in 3 patients. The extradural approach was necessary, because the sacral roots could not be separated intradurally (in one patient after myelography with oily contrast medium, in one because of severe deformation of thoracolumbar spine and in one patient because of severe arachnitis of unknown reason). Sacral deafferentation was performed in all patients. All roots S_2 - S_5 have been cut in 6, incomplete deafferentation was done in 7. Two patients sofar needed a second deafferentation at the level of conus medullaris because of persisting detrusor hyperreflexia, a third patient will need it too.

RESULTS

All 13 patients can empty their bladder with the bladder controller, 12 with minimal or no residual urine after stimulation. In one patient assistance by abdominal straining is necessary. In 12 patients the detrusor pressure is physiologic during stimulation, in one patient maximum detrusor pressure goes up to 150 cm H_2O, sofar without reflux or changes in the radiologic bladder outfit. Despite sacral deafferentation very weak detrusor contractions up to 20 cm H_2O at high filling volumes can be registered in 3 patients. Nevertheless 12 patients remain dry during day and night. In one patient urine leakage occurs at night. In this patient a second deafferentation is planned. Technical problems were observed in four patients sofar. In two the receiver block became defect and had to be changed. This may be the case in one patient in whom shortly a previous excellent electromicturition failed. Receiver block exchange is planned. In one patient a cable brake had to be repaired after a wheel chair crash.

DISCUSSION

The aim of this treatment is to improve bladder emptying and to achieve continence in para- or tetraplegic patients with unbalanced reflex bladder and uncontrollable urinary incontinence. Furthermore subsequent urinary tract damage should be prevented.
Electromicturition achieved by so called "poststimulus voiding" in combination with deafferentation is functionally sufficient. Our patients have efficent micturition with minimal or none residual urine and with physiologic detrusor pressure in 12 of 13.
From our experience some technical problems with the receiver block occured. We exchanged two receiver blocks and, as stated above, it is very likely that a third is defect. Cable defects are seen very rarely, in our patient one was caused by trauma.
Usually stimulation of the roots S_2 and S_3 is most effective, but we also found a patient whose main nervous supply of the bladder was accomplished by $S_{4/5}$.
As stimulation is painful SARS can be used only in complete or nearly complete spinal cord lesions with absence of pain sensations. The sacral efferent peripheral neuron has to be intact and the detrusor has to be contractile.
Chronic stimulation should not cause tissue reaction of the nerves being in contract with the electrodes, so far there is no clinical sign of tissue fibrosis.
Cutting of the posterior sacral roots is necessary to abolish spontanous reflex bladder contractions. This is essential for continence and for preventing progressive destruction of upper urinary tract. Sofar we could not observe detrusor hypertrophy or an increase of bladder trabeculation in our patients. In one patient a vesico-ureterorenal reflux grade III ceased after deafferentation and electromicturition with physiologic detrusor pressure. We could achieve complete detrusor areflexia in 10 patients (in 2 patients relevant detrusor contractions required a second deafferentation), in one more patient second deafferentation has still to be done. Up to now the effect of deafferentation lasts on, propably due to the fact that the deafferentation is performed proximal to the spinal ganglion, where the seperation of the anterior and posterior roots is relatively easy to perform. A negative effect of cutting the posterior sacral roots is the loss of vaginal lubrication in women and - more important - the loss of reflex erection in men. Only in about 30% of males an erection can be induced by electrostimulation with this device.

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Direct sacral or pudendal nerve stimulation in patients with urinary incontinence.

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Direct sacral nerve stimulation has been used as a tool for evaluation as well as treatment in patients with voiding dysorders and predominant urge incontinence. Whereas patients with low maximal closure pressures (urethral) and predominant stress incontinence would rather be candidates for surgical repair, a group of patients is suffering from incontinence despite reasonable maximal urethral closure pressures. Many of these patients show a lack of coordination of the different muscles of the pelvic floor and involuntary relaxation of the urethral closure mechanism or urethral instability.
Patients who can benefit from chronic direct nerve stimulation were defined by percutaneous placement of a temporary wire-electrode in the S3 foramen, connected to an external stimulator box. The decision whether or not to implant a sacral or pudendal nerve electrode for chronic stimulation is based on the evaluation of 2 to 5 days of temporary stimulation.
Of 43 patients who received an electrode and a stimulator implant because of their urge symptoms, 35 (81%) reported a significant improvement after initiation of chronic neurostimulation.

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A NEW APPROACH TO TREATMENT OF URGE INCONTINENCE BY FES

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SUMMARY

The author describes a way of treatment of urge incontinence and urgency by FES. He uses acute maximal functional electrical stimulation (AMFES). The parameters of stimulation: impulse is rectangular, its duration is 1 msec, frequency of impulses 20 Hz, the impulse is biphasic. He uses a single plug-electrode (vaginal or rectal), gradually increasing the applied current beyond 65 mA by vaginal application and beyond 40 mA by rectal application. The current is increased up to the threshold of pain. Due to gradually increased current the application is not painful. The duration of application is 20 min. daily for 5 successive days. A new stimulator that he is using, is a current impulse generator, which maintains the power of applied current regardless of changing impedance of the tissue. Thus he treated 88 women patients and obtained a complete recovery in 72,7% and notable improvement in 14,8% of patients; so he obtained favourable effects of treatment in 87,5% of patients. In his oppinion the AMFES is the treatment of choice of the urge incontinence, because of its simplicity and absence of counterindications.

INTRODUCTION

The urge incontinence (UI) and urgency are very common ailments in women. We can find very different data about the prevalence of this ailment in literature. Its pathophysiological substrate is very often an unstable bladder (m. detrusor). Common estimate being that some 15 to 20 % of women complain of ailing with UI or urgency. The treatment of UI and urgency is very difficult and often without success. Ways of treatment are numerous, the commonest being medicaments. As drugs are mostly used anticholinergics. The drug treatment is generally some 60% successful, very often recurrency appears. The drugs treatment has numerous counterindications, for general effects of the medicaments to the vegetative nervous system. Jeffcoate and Francis have brought the training of the bladder into the treatment of the UI. Frewen has reported of improvement and recovery in 82,5% of cases in his 1978 paper. Bio-feedback and psychotherapy are also finding its way into treatment of UI with some 60% of successful cases. Surgery is very seldom used and only in patients who are resistant to other therapy. We are treating the UI and urgency with functional electrical stimulation (FES). It is known that m. detrusor is effected only by currents of greater power applied to the muscles of the pelvic floor. This way of treatment with FES we call acute maximal functional electrical stimulation - AMFES.

MATERIALS AND METHODS

To check the results of treatment with AMFES we included into the study

88 women patients with UI and urgency. In all the patients UI was confirmed by patient's history, tests for objectivisation of urinary incontinence and with urodynamics. Excluded were neurogene illnesses, local illnesses that could cause UI or urgency were treated before; so we only had patients with idiopathic (non-neurogene) UI in the study.

All the patients were treated with a new i.e. changed way of treatment with AMFES method, and with a new stimulator of pelvic floor muscles.

The parameters of stimulation: the impulse is rectangular, duration of impulse is 1 msec, frequency of stimulation 20 Hz. The impulse is biphasic (to exclude corosion of the electrodes, and ensure absolute safety from tissue damage). The new stimulator is a current generator, which retains the same current power by changeable tissue impedance for the duration of stimulation. We are using a single plug-electrode (vaginal or rectal). The applied current is gradually increased, so that the stimulation is painless, to maximal power, that is to the threshold of pain. We stimulate daily for 20 min. for 5 successive days.

RESULTS

The results of our treatment of urge incintinence:

Unchanged	11 patients	or	12,5%	
Improved	13 patients	or	14,8%	}87,5%
Cured	64 patients	or	72,7%	
Total	88 patients	or	100,0%	

Valuation of results: As cured were considered those patients, that had no more complaints of urge incontinence in the patient's history, or whose condition improved in such a way that UI presented no problem any more, and all these patients had negative results in test for UI. As improved were considered the patients, who still had insignificant subjective complaints, but the tests significantly improved. As unchanged were considered the patients that did not show neither subjective nor objective improvement.

Recurrences of urge incontinence or urgency were found after 3 to 6 months in 18 patients (23%).

DISCUSSION

This treatment of UI and urgency with AMFES was already described in 1977. Then three pairs of electrodes (vaginal, rectal and needle electrodes) were applied to the pelvic floor. The current was immediately applied to full power till the boarder of endurance. The parameters of stimulation were: impulse was rectangular, duration 1 msec, frequency of stimulation was 20 Hz. Average applied current on all three electrodes was 94 mA. Thus 25 patients were treated and complete recovery was noted in 23 patients (92%). In all patients AMFES was applied only once but in 6 patients we had to repeat the treatment after 3 to 6 months.

This way of treatment of urge incontinence with AMFES was very successful, but also painful for the first 2 to 3 min. of application, due to immediate application of current to the boarder of endurance. So we changed the method of application in next years to gradual increasing the current. Thus the application is not painful and in 2 to 3 minutes the maximum power is reached. Simultaneously we found, that satisfactory power of current can be obtained with application of one plug-electrode only (vaginal or rectal). The needle electrodes were dropped, as their resulting average power never exceeded 15,8 mA. But the results of such treatment decreased (81,9 cured and improved patients), especialy decreased the number of cured patients (59,5% - Kralj, 1985). We found that the impedance of the tissue changed respectively increased during the application and thus reduced the power of applied current. So a new stimulator was developed with a current generator, which retains a constant power of current in spite of the tissue impedance. Thus the results of treatment were improved again (87,5%), especially the portion of completely cured patients (72,7%) and with completely painless application of electrical current.

After longer use of vaginal and rectal plug-electrodes the corosion of these was noted, even if they were made of best prochrome. So we changed from monophasic to biphasic stimulation. Even after several years of usage of biphasic stimulation with plug-electrodes of prochrome no corosion of electrodes was noted. So we can conclude that biphasic stimulation is better for electrode protection, which never corode and the tissue of vagina or rectum is completely safe from any damage. Results of treatment are quite the same as by monophasic stimulation.

Due to satisfactory results the parameters of stimulation were retained, as described already in 1977, i.e. stimulus is rectangular, duration 1 msec and the frequency 20 Hz. Changed was the impulse from monophasic to biphasic (prevention of corosion of electrodes and absolute safety from the tissue damage), and application of three pairs of electrodes to a single plug-electrode (vaginal or rectal) by which we obtain a current in vaginal electrode over 65 mA and in rectal over 40 mA. The duration of application was retained at 20 min. a day. AMFES is applied now 5 days successively.

Of the utmost importance is the fact that there are no counterindications for treatment with AMFES. Also elderly women can be treated by AMFES, which normaly are counterindicative to drugs treatment. In elderly women the urine incontinence is very frequent (57,2%), particularly frequent is UI (47,2% - in generative age 15 to 20%). The results of treatment with AMFES in elderly women are identical to those in women in generative age (Kralj, 1987). For these reason AMFES is the treatment of choice for elderly women with UI and urgency. It seems that most important for favourable results (87,5%) in treatment with AMFES is the current impulse generator, which keeps unchanged the current power for the total time of application i.e. 20 min., regardless of tissue impedance.

CONCLUSION

The treatment with AMFES is simple, not counterindicated, can be used in elderly women. The results of treatment are very satisfactory (cure, or significant improvement in 87,5% of women). So we consider that AMFES treatment is the method of choice in treatment of urge incontinence and urgency.

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Functional Electrostimulation of the Bladder by Sacral Anterior Root Stimulation (SARS)

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Detrusor - external sphincter - dyssynergia is responsible for unbalanced voiding and urinary reflex incontinence of patients with supraconal spinal lesions.
Sacral deafferentation **(SDAF)** restores the **areflexicity** of the detrusor. A normal compliant bladder with subsequent urinary continence is achieved. An implanted sacral anterior root stimulator **(SARS)** is able to controll a **balanced voiding**. We used the Brindley device.

These new surgical treatment was performed in 40 mainly posttraumatic para- and tetraplegic patients between 1986 and 1989 in our center.
We present our intraoperativ findings convening the influence of **parasympathic fibers** of roots **S 2 to S 5** on the innervation of the smooth muscle of the bladder. Our results are contrary to the functional patterns described in the textbooks and will be compared to those of so far longterm follow up studies.

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USES OF THE COMPUTER IN NEURO-UROLOGY

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Neurological procedures in urology usually consist of single-channel recordings of, for example, the bulbocavernosus reflex arc. These are made on a polygraph with a paper chartrecorder. Proper paper speed and exact amplification of the biosignal are essential for successful studies. Once recorded, curves cannot be altered for certain points of interests such as amplitude or higher time axis resolution. Commercially available neurologic equipment is now beginning to incorporate the advantages of computer storage and recall. Software programing and RAM (random access memory) are the main obstacles that set limits on the capabilities of these systems.

A state-of-the-art use of the computer is presented for neuro-urological applications. EMG , pressure and flow studies and combinations thereof are made directly into the computer memory. Both continuous recordings and averaged responses are placed into computer memory. Advantages come from postprocessing capabilities and memory availability. The equipment consists of an Apple Macintosh II™ computer with an 8 Mbyte RAM and a 144 Mbyte hard disk. The software program provides a capability for a one-million-fold resolution factor (i.e. seconds to microseconds) and a ten-thousand-fold amplitude adjustment. EMG/pressure tracings can be compressed or expanded for later analysis without repeating the study. Statistical analysis is therefore highly selective.

This methodology has particular advantages in the recording of evoked responses because it allows a continuous follow-up of the changes during continous stimulation with different patterns, which might be related to muscle fatique or lack of metabolism. An additional advantage is the financial attractiveness of combining the latest computer technology with existing analog amplifiers.

FIELD EFFECTS VIA INFLUENCES ON SECOND MESSENGER PATHWAYS

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Continuing the work on field stimulation, we currently investigate the effects of EM-stimulation on the model neuron NG108C-C15, a hybrid cell.

When treated with cAMP, cell division ceases, the cells show action potentials and extend processes which form synapses with nearby cells. We could show that the treatment with cAMP leads to an increase in ^{45}Ca uptake. The data support conclusions from electrophysiological measurements indicating a regulation of Ca metabolism during differentiation via voltage sensitive ion channels.

Since calcium may act as a second messenger to control cell function, a modulation of the activity of the associated channels by EM-fields could possibly explain the earlier observed functional alterations during maturation and differentiation. The experimental evidence of Sisken and Blackman supports this working hypothesis.

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PROGRESS IN THE DESIGN OF AN ARTIFICIAL URETHRAL SPHINCTER

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SUMMARY

A new class of composite materials made of a polyelectrolyte gel and an electron conducting polymer has been prepared and used to develop a prototype of an artificial urethral sphincter which ,in its final implementation, will be electrically driven.The composite is an interpenetrated network made of polyacrylonitrile (PAN) thermally cross-linked and loaded with polypyrrole (PPY), polymerized by a gas state technique. The samples, in fiber form, show an electronic conductivity of the order of 10 S cm^{-1} in the dry state and mechanochemical and electromechanochemical response in aqueous baths. The material has been tested in mechanochemical experiments showing elongation and contraction as high as 30% under isotonic condition and an isometric force generation higher than 10 Kg/cm^2 with a response time of a few seconds.A demonstration device was constructed , driven by the composite fibers, capable to close and open a silicone-made model of urethra under an hydrostatic pressure of a water column of 45 centimeters.The electrical stimulation of the material also leads to a mechanical response without gas evolution , but with lower isometric force , smaller isotonic length change and longer response time.The electrochemical mechanism of activation is examined and possible improvements are discussed.

MATERIALS AND METHODS

A demonstrative prototype of the artificial urethral sphincter was constructed by using a triangular perspex body with three Teflon pistons acting on a silicone-made urethra-like tube, 6 millimeters in external diameter with a central conduit, 1 centimeter long, purposely shaped (fig.1).
The device was used to control the water flow from a reservoir under a water-head of 45 cm .
The contractile fibers were assembled on the external part of a fiber holder, kept in place by the piston heads.
At the present stage of our work no attempt is made to reduce the device dimensions , to make them compatible with the human anatomical site.
Polyacrylonitrile (PAN) in form of fibers (Mitsubishi Rayon CO. , Silpalon, 30 filaments, each 25 µm in diameter) was annealed at 220 °C in air for 5 hours to cross-link it and then boiled in 1N NaOH aqueous solution for 30 min. to obtain a partially ionized carboxylic structure /1/.

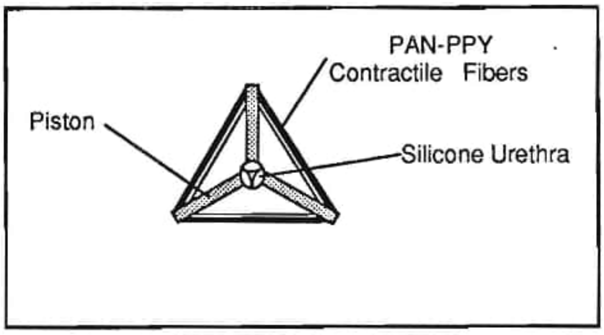

Fig. 1 Schematic drawing of the artificial sphincter .

The fibres were then immersed for 24 hours in an aqueous solution of ferric chloride (40% by weight) brought to pH =0.5 by adding hydrochloric acid. Pyrrole was polymerized into the PAN hydrogel fibers by a gas state technique suggested by Ojio and Miyata /2/.

The fiber bundle was put in a pyrex flask under saturated atmosphere of water and pyrrole vapors at a temperature of 10 °C.

The pyrrole was left to diffuse and polymerize into the host gel for a time period ranging from 5 to 20 hours.

The conductivity was measured by a four-point technique, having dried the fibers at 20 °c for 24 hours in air (R.H. 50%).

The artificial sphincter was operated by chemical stimuli:

The mechanochemical experiments were performed by changing the pH of the solution surrounding the fibers by alternate addition of 0.1 M HCl and 0.1 M NaOH solution.

Experiments were also performed on isolated fiber bundles to evaluate their performance.

The electromechanochemical measurements were executed using the composite material as working electrode immersed in a 0.05 M NaCl solution ; a few centimeter apart, a platinum counter electrode was immersed in the bath to close the electrical circuit.

The isometric and isotonic measurements were performed by using an isometric transducer (Universal Transducing Cell UC2m, Gould Statham, Oxnard, CA , USA) and an isotonic one (Isotonic Transducer 7006, Ugo Basile, Comerio, Italy).

During the electromechanochemical experiments the applied voltage and resulting electric current were also simultaneously recorded.

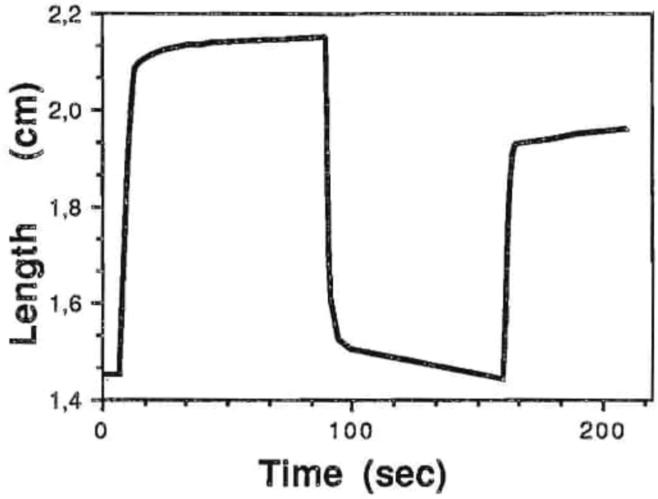

Fig.2 The isotonic length of the PAN-PPY (pyrrole polymerization time of 5 hours) gel fibers as a function of time when the pH is changed from 1 to 13 and viceversa.

RESULTS

The device opening and closing sequence was found to follow the same time course of the isolated fiber bundle under isotonic mechanochemical experiments.

In fig. 2 the fiber length as a function of time, under isotonic condition, is reported following chemical stimuli.

The fiber length change was about 30% relative to the contracted state.

In this first serie of experiments the artificial sphincter was only operated by chemical stimuli.

The device was completely closed (no flow under 45 cm of water head) when the fibers were at pH 1 and fully open when at pH 13, with a resultant water flow of 1.5 cm^3/sec .

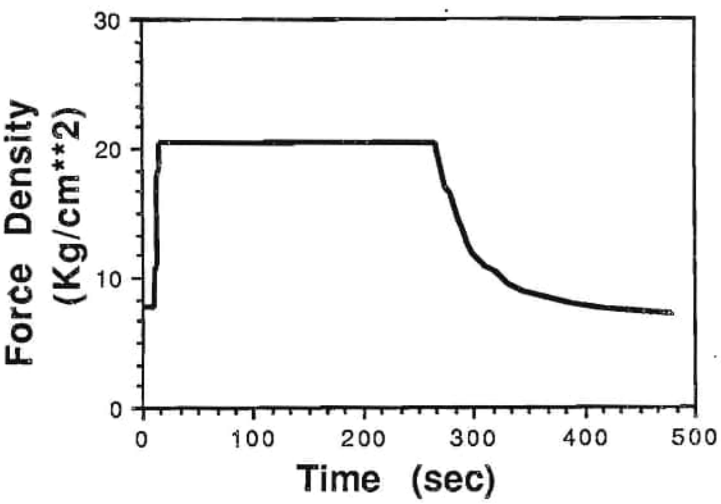

Fig. 3 The isometric force density exerted by PAN-PPY fibers with a pH step change between 13 and 1 and viceversa .

In fig 3 we report the force per unit sectional area (as measured in the dry state) exerted by the gel fibers versus time when the bath pH was changed from basic (pH =13) to acid (pH=1) and viceversa .
The electrical conductivity , measured as a function of pyrrole polymerization time, resulted to saturate to the value of 10 S cm^{-1} .
The electrical activation of the material showed a behavior qualitatively similar to the chemical one, outlining the electrochemical origin of the activation.
A negative electrical potential (in respect to the platinum electrode) applied to the sample caused its elongation, a positive one caused a contraction, without apparent gas generation.However, the generated force and length variation were smaller and slower than those obtained by chemical activation .

DISCUSSION

We have reported here the preparation and preliminary functional characterization of a material which can actuate a sphincter-like device.The conductive polymer moiety can transfer electrical power through electrochemical reactions without gas bubbling (4,5,6) , when properly driven, substantially increasing the device lifetime.
The electrocontractile performances of the new composite material,however, are still inadequate to drive the prototype in a satisfactory manner.
An understanding of the processes occurring at the conductive polymer-electrolyte interface is instrumental in improving these performances.
These mechanisms are discussed in detail elsewhere /3/, here it is sufficient to note that the pH and the ionic strength of the solution which permeates the gel network change by the following reactions

$$P + OH^- \Longleftrightarrow (P^+ OH^-) + e^-$$

$$P + Cl^- \Longleftrightarrow (P^+ Cl^-) + e^-$$

Two antagonist effects occur : a decrease of pH causes the gel to shrink while contemporary lowering the ionic strength would induce gel swelling ; since , in polycarboxylic gels,the pH effect dominates /7/ the overall result is sample contraction.
The slow time response is ascribed to the low electrical conductivity of PPY limiting the number of moles of counter ions (OH^-, Cl^-) adsorbed or released into the gel solution by the PPY, which is proportional to the charge flown through the sample .
Improving electromechanochemical performances to properly drive the artificial sphincter passes necessarily through the following steps: a) increasing polymer conductivity to achieve a faster response; b) investigating the role of the dopant ions in the electrical conduction of the metal-like polymer and in the gel contraction mechanism to obtain the full force response from the contractile part of the composite material.
Work is in progress along these directions.

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AN OPTICALLY PROGRAMMABLE, IMPLANTABLE MUSCLE STIMULATOR

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SUMMARY

A battery powered, single-channel, implantable stimulator has been developed for long-term muscle stimulation research. The system generates up to twenty different stimulation patterns, of which eight may be initiated after implantation via a percutaneous optical link. A suitable physical size and a very low power consumption have been achieved through the use of an application-specific integrated circuit. An optically tranparent, ceramic package, to house the stimulator circuit and the battery, has been developed as well.

INTRODUCTION

There is an increasing interest in clinical applications that involve long-term activation of skeletal muscle by electrical stimulation. In paralyzed patients for instance, some degree of motor function can be restored by FES /1/. To help patients with end-stage cardiac failure, skeletal muscle may be redeployed as a means of augmenting or replacing the function of the heart /2/.

A constraint on most of these applications is that they require skeletal muscle to perform sustained work at a level well beyond their normal capacity. However, mammalian skeletal muscle has the capacity of changing its properties in adaptive response to increased functional demand /3/, /4/. To study this behaviour, implantable devices for long-term stimulation with growing complexities are required. Devices using discrete components and multilayer thick film circuits are no longer acceptable, due to their large size and power consumption. In the present work we have sought to overcome these problems by developing an application-specific integrated circuit for the stimulation system. This system had to be capable of generating at least 8 different programs of stimulation, with provision for initiating or changing these after implantation. The device, with its self-contained battery power supply, had to be small enough to be implanted into rabbits and yet provide an operating life of at least 6 months. We present a system that meets these requirements.

CIRCUIT DESCRIPTION

The stimulator has a single channel with a voltage output drive. Two sorts of waveforms are generated: continuous pulses and repetitive bursts of pulses. In both cases, the output pulse width is 200 μs. Two options for the bursts can be established by hard-wired links. The repetition frequency of the pulses in a burst can be either 40 Hz or 80 Hz and the duration of the burst can be either 100 ms or 200 ms. All available patterns are summarized in Table 1.

A schematic of the circuit is provided in Figure 1. The heart of the chip is a 20 kHz, externally trimmable, low power oscillator. This, combined with a 17-bit divider, generates all the timing needed for the circuit operation. A specific pattern is selected by means of a shift register. This shift register contains only one logic "1". The position of the "1" determines the actual pattern selected. When the "1" moves out of the shift register, the latter is preset to its initial state by a monostable multivibrator.

On the basis of previous favourable experience /5/ we elected to use an optical control link, so that the clock pulses for the shift register are in fact derived from light flashes delivered percutaneously to the stimulator. A phototransistor and an on-chip resistor convert the flashes to voltage pulses. A differentiating network then eliminates the DC component, so that ambient lighting cannot trigger the circuit. Next a Schmitt trigger converts the input signal to full logic levels. Since the width of this pulse still depends on the shape of the input pulse, its trailing edge is used to trigger a monostable multivibrator, which generates a stable 1 ms clock pulse for the shift register.

Waveform	Repitition interval	Options
continuous	0.1 s	none
continuous	0.2 s	none
continuous	0.4 s	none
continuous	0.8 s	none
burst	0.8 s	40/80 Hz-100/200 ms
burst	1.6 s	40/80 Hz-100/200 ms
burst	3.2 s	40/80 Hz-100/200 ms
burst	6.4 s	40/80 Hz-100/200 ms

Table 1: Summary of the stimulation patterns available

The repetition frequency of the stimulation pattern is selected through a series of NAND and NOR gates. For continuous pulses, the frequency to be selected is gated through two NOR gates to the output monostable multivibrator, which generates the 200 µs output pulses. For the bursts, the repetition frequency is directed first to a monostable multivibrator, which generates the duration of the burst according to the logic state of the input designated SA ("1" = 100 ms, "0" = 200 ms). The output of this multivibrator serves as a time window during which pulses can pass at the burst repetition rate to the output monostable multivibrator. The repetition rate is 40 Hz or 80 Hz, according to the state of the input designated SB ("1" = 40 Hz, "0" = 80 Hz).

The output of the circuit is disabled during selection of a new pattern by means of a two-bit up counter. Provided that the input pulses are delivered at intervals less than 200 ms, the output will be inactive during the selection of a new pattern; the desired output will then be available not more than 400 ms after the last input pulse. This design accommodates programming with light

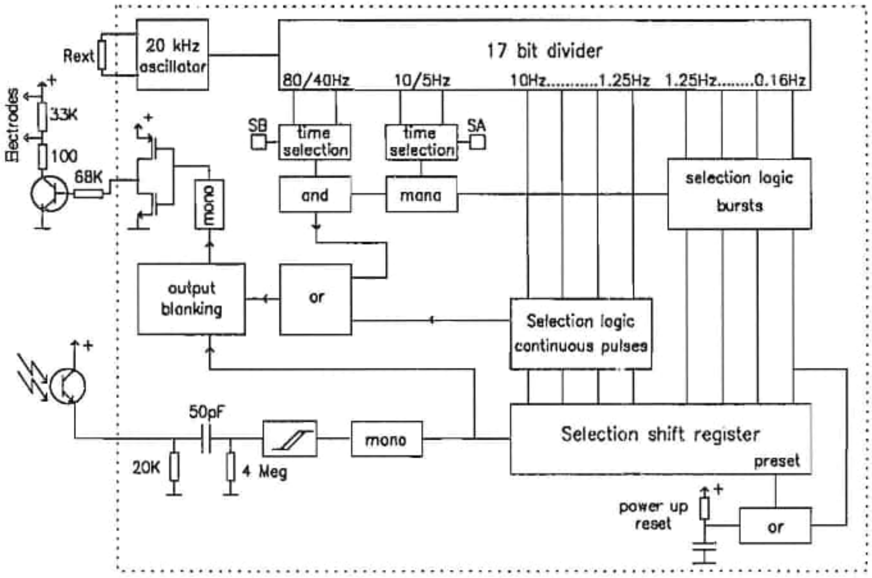

Figure 1: Circuit diagram of the stimulator.

flashes from a source firing repetitively at 5 Hz, with no output generated during programming, while permitting the programs to be cycled manually if desired.

The integrated circuit can operate on a supply voltage ranging from 2.5 V to 7.5 V. For this particular application, the power supply was fixed at 3 V (one 200 mAh lithium cell). The average current consumption in the absence of an output load is 3.5 μA. As the current from the on-chip output stage is not sufficient for stimulation at this supply voltage, an off-chip bipolar output stage had to be added, as shown in figure 1.

The integrated circuit has been implemented in a 3 μm p-well CMOS process. This process had been modified to incorporate the large resistors needed for the differentiating network. The dimensions of the chip are 1.5 mm by 2 mm.

The entire circuit is mounted on a thick film substrate on which a gold conductor pattern interconnects all components. Extra attention has been paid to the electromagnetic noise immunity of the circuit, by adding several Schottky-Barrier protection diodes. After mounting all components, the phototransistor die is covered first with a transparent epoxy resin. Since CMOS chips are light sensitive, the stimulator chip has to be protected against exposure to light. It is therefore covered with a dark epoxy. The hybrid circuit measures 8.5 x 8 mm^2, and its height is about 2 mm.

STIMULATOR PACKAGE

An entirely new package has been developed in order to meet the requirements for implantation, such as: biocompatibility; hermeticity; optical transparency; electrical isolation; provision of output terminals; low physical profile; easy replacement of batteries.

Figure 2 illustrates the package in cross-section. A machineable glass ceramic (MACOR) is used to manufacture the can. The base of this cylinder is machined down to a thickness of 0.5 mm, allowing light to penetrate freely and diffuse in all directions inside the cylinder. Two stainless steel feedthrough plugs drilled and tapped from the outside permit electrical connections to be made using small (M1) screws. After the hybrid circuit is connected to the stainless steel plugs,

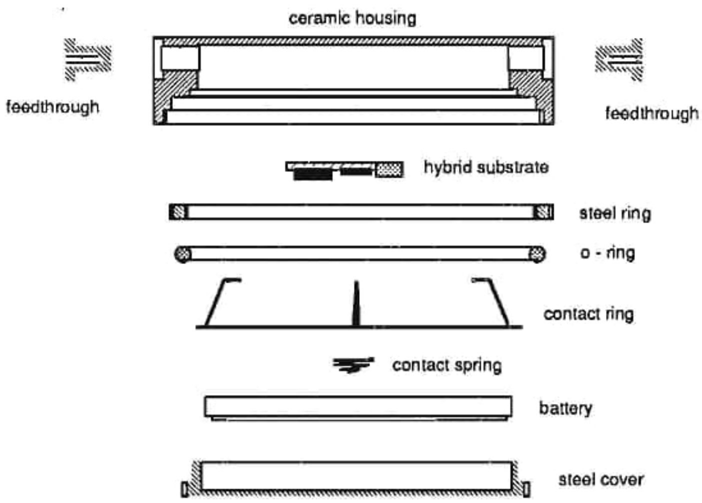

Figure 2: Cross-section of the package

the circuit is embedded in a transparent silicone resin to protect the circuitry and to isolate the battery from the plug connecting wires. A stainless steel ring is fitted in the package in which the lid, which is also made of stainless steel, can be screwed in and out. This allows an easy and safe replacement of the batteries, without deteriorating the ceramic housing. An O-ring prevents fluid from entering through this metal-ceramic interface. The package has a diameter of 35 mm and a height of 8 mm. Figure 4 shows a photograph of the assembled device. Before implantation a piece of Dacron mesh is added to facilitate suturing and the entire device is covered with a biocompatible silicone rubber. It is then immersion-sterilised for at least 24 h prior to surgery.

In vitro as well as in vivo testing of the stimulator is currently in progress. At the time of this writing, the new device was implanted intraperitoneally in a rabbit for a period of 4 weeks. The optical link proved very reliable in all experiments.

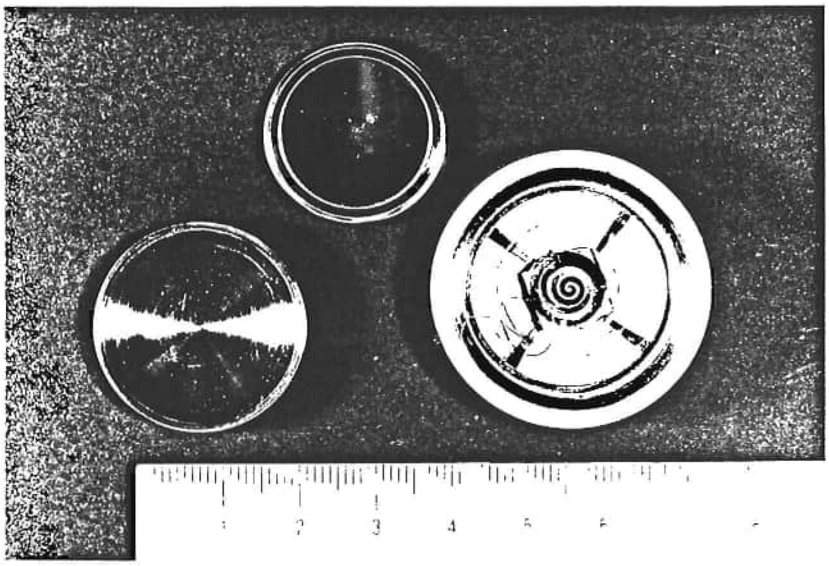

Figure 3: Photograph of the assembled device

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THIN-FILM STIMULATION ELECTRODE: MECHANICAL AND ELECTRICAL TEST RESULTS

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SUMMARY

Under conditions of prolonged electrical stimulation in-vitro, it has been observed that the thin-film electrode array which was constructed of titanium-platinum conductors between two layers of polyimide substrate, delaminated. There were two modes of failure (a) metal/polyimide and (b) polyimide/polyimide. In this paper, the results of tests designed to measure the adhesion between the conductor (titanium-platinum) of the thin-film electrode and the substrate (polyimide) are given. The adhesion between two layers of polyimide deposited and cured at different stages in the fabrication process are also provided. Tests carried out with a shape-memory alloy (NITINOL) to assist the insertion of the electrode into the cochlea are discussed.

MATERIALS AND METHODS

The advantages of using thin-film technology for the production of stimulating electrodes for cochlear implants has been recognised [1-3]. The major advantages are the flexibility of the electrode configuration, the potential cost savings of labour, high yield and reliability.

Fabrication Technique: The basic technique is to deposit liquid polyimide on a silicon wafer (substrate) and to spin it so that it forms a thin film. The polyimide film is cured by increasing the temperature in stages up to a maximum according to the manufacturer's instructions. The film together with the substrate are placed in a sputtering machine and covered with a layer of platinum. A photo-mask, positive photoresist and ultra-violet light are used to expose the parts of the platinum layer to be removed in order to define a pattern of connection pads, feedlines and stimulating tips of the electrode. The device is placed in the sputtering machine and the exposed parts of the platinum are removed by sputter etching. A second layer of liquid polyimide is deposited on the structure so that the platinum is sandwiched between two layers of a thin film of insulating and biocompatible polyimide. "Windows" are opened through the top layer of polyimide to expose the connection pads and stimulating tips of the electrode. The silicon substrate is removed to give a flat thin-film electrode [3,4]. The flat electrode is rolled to form a cylinder 0.5 mm diameter and 70 mm long using a die to hold it in that form while medical-grade silicone rubber is injected into the hollow cylinder formed by the electrode. When the silicone rubber is cured, the electrode array can be withdrawn from the die [5,6].

Electrical Test Procedure: In theory the electrode will operate at 37 °C. But testing it at this temperature for the expected life-time of 20-25 years is unrealistic. By elevating the temperature a shorter period of testing will give results which can be used to predict the long-term performance of the electrode. A rule-of-thumb commonly used is: for every 10 °C increase in temperature of the test environment, the device can be considered to have survived for a period equal to twice that of the test.

The amount of stimulating current required to reach the threshold in implant patients varies from patient to patient. It also depends on the electrode design and on the proximity of the electrode tips to the neurons. However, a commonly accepted charge transfer criterion is 100 nC/phase of pulsatile stimulation [3]. It has been determined that for platinum in a saline solution, the limit for safe stimulation is 300 μC/geometric cm^2/phase [7].

In order to ensure that the electrode meets the life-expectancy criterion, the tests were started at room temperature in a saline bath with ion concentration approximately equal to that found in the cochlea. The initial current stimulation was equivalent to 50 μC/geometric cm^2/phase. The electrode array was removed from the bath once every 7 days for a visual inspection for cracks in the polyimide, changes of colour and delamination at the metal/polyimide interface which shows up as wrinkles in the metal. A test of the integrity of the insulation between the individual electrodes is also carried out. If the electrode array shows no signs of failure, the temperature or charge density is increased. The aim is reach a temperature of 85 degrees C with a current stimulation equivalent to 250 μC/geometric cm^2/phase and to find out how long the electrode will survive under these conditions. If the electrode array fails, a detailed examination is carried out to determine the mode of failure.

<u>Failure Modes</u>: There are two basic ways in which the electrode fails when subjected to <u>in-vitro</u> electrical accelerated life-time test. The first is the delamination of the structure at the metal/polyimide interface. It is easy to detect this form of failure by the wrinkles in the platinum. About 5% of the electrodes tested so far, failed in this mode. The second is due to the delamination at the interface between the top and bottom layers of polyimide. This accounts for about 95% of the failures and it is generally catastrophic. It is most easily detected by applying a small quantity of water-soluble dye to the stimulating tips after the electrode has been withdrawn from the saline solution. The dye quickly spreads in the saline between the two layers of polyimide.

It would appear that current stimulation <u>in-vitro</u> promotes the delamination of the electrode. A technique for measuring the stress required to cause rupture at the metal/polyimide and polyimide/polyimide interfaces has been devised. A specimen of the material is glued between two cylindrical pieces of stainless steel (3.81 mm diameter) using a quick-setting epoxy. A force applied to the pieces of stainless steel is increased until the specimen fails.

<u>NITINOL Experiments</u>: The thin-film cylindrical electrode array has a tendency to buckle when a compressive force is applied to it. To counteract this tendency, a fine stainless steel wire was placed in the hollow cylinder formed by the polyimide before the silicone rubber was injected. Fig. 1 shows a cross-section of the electrode. It became evident that if the stainless steel wire was bent roughly into the shape of the cochlea, it would facilitate the insertion operation. The situation could be improved tremendously if the wire could be made of some other material which would take the shape of the cochlea when it was brought up to the human body temperature of 37 ^{o}C. A material that has shape-memory which can be triggered at this temperature is NITINOL.

NITINOL, an alloy of nickel and titanium, can be bent into any given shape and annealed at about 460 ^{o}C. It can then be reshaped at about 0 ^{o}C and when the temperature is subsequently brought up to the transition temperature of 37 ^{o}C, it will assume the shape in which it was annealed [8]. The annealing, reshaping and transition temperatures vary depending on the composition of the alloy. This phenomenon is to be used to pre-program the electrode array to take the spiral shape of the cochlea during the insertion

RESULTS

Preliminary tests showed that before the electrode was subjected to current stimulation, it took a stress of 7.5 MPa to cause the metal/polyimide interface to fail and 6.0 MPa to cause the polyimide/polyimide interface to rupture [9]. The next step is to determine the effect of current density and the length of the stimulation period on the force of adhesion at the two interfaces. The effect of raising the temperature for accelerated ageing has also to be determined.

Fig. 2(a) shows the electrode in its "straightened" form at about 0 ^{o}C. Fig. 2(b) shows the electrode at 37 ^{o}C. Fig. 3(a) and 3(b) show two different shapes of bare NITINOL wire compared to the shape of the electrode after the NITINOL was bonded to it. It is clear that in order for the final assembly to assume a given shape, the bare NITINOL wire will have to be pre-distorted.

DISCUSSION

A method of measuring adhesion at the metal/polyimide and polyimide/ polyimide interfaces in a thin-film cochlear electrode has been developed. This will enable the process of delamination to be tracked accurately so that action can be taken to avoid this mode of failure.

Preliminary results show that the electrode can be pre-programmed to take the shape of the cochlea using a shape-memory alloy. This will facilitate the insertion operation.

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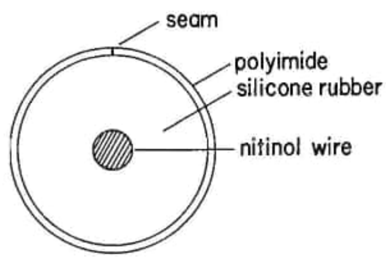

Fig. 1

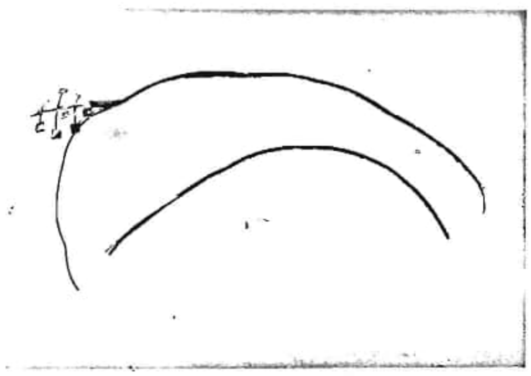

Fig. 2(a)

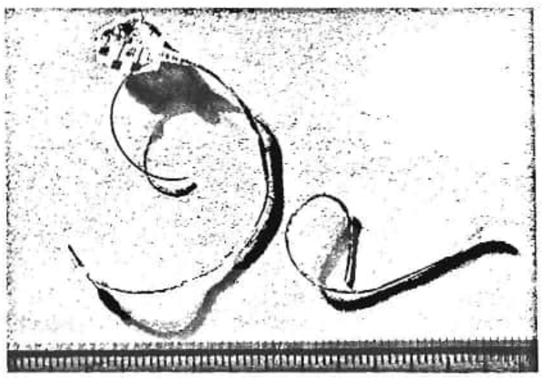

Fig. 2(b)

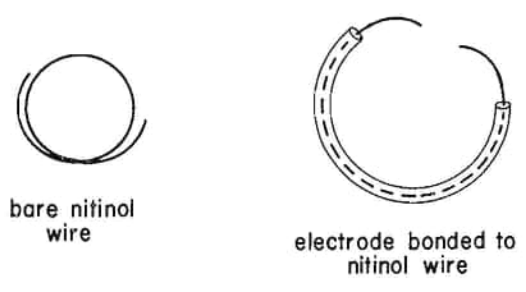

Fig. 3(a)

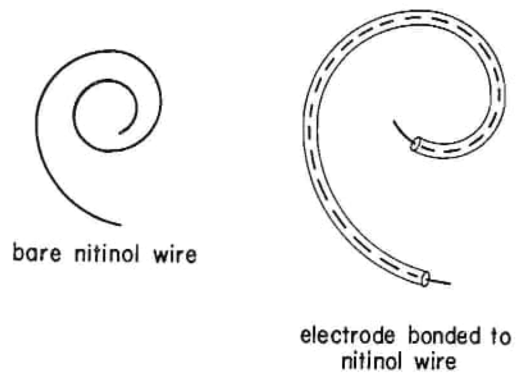

Fig. 3(b)

REAL-TIME CEPSTRAL ANALYSIS IMPLEMENTATION; A SPEECH PROCESSING STRATEGY FOR THE COCHLEAR PROSTHESIS

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SUMMARY

Cochlear implant systems consist in general of five blocks: analog interface, speech processing unit, transmitter, stimulator and an electrode/1/. This paper presents real-time cepstral analysis implementation as a speech processing strategy for the auditory prosthesis using the TMS320C25. The cepstral system tracks the first three formants of speech and their respective amplitudes, along with the speech pitch period. The system is tested for algorithm correctness, method validity and cochlear implant requirements.

MATERIALS AND METHODS

Speech Processing Requirements

Any speech processing method considered for the cochlear implant should conform to two main restrictions. Firstly, fast execution time is required to minimize the delay between the speech input and the output to the electrode. Secondly, efficient hardware implementation is required to minimize power consumption and size. The choice of a speech processing dictates the speech features available for extraction. The tonotopical nature of the cochlea suggests the extraction of frequency information as an input to the electrode stimulating the cochlea.

Speech Processing Methods

Advances in microprocessor technology has enabled the coding of complex speech processing algorithms for real-time applications/2/. Linear predictive coding may be used for formant and pitch extraction/3/. Filter banks provide frequency energy representations/4/. Unprocessed speech may be used to provide an overall speech energy level/4/. Cepstral analysis is proposed as an alternate speech processing strategy for the cochlear implant, to track speech formants and extract the pitch period/5/.

Cepstral Analysis Implementation

Cepstral analysis was introduced as a speech processing system for formant tracking and pitch extraction by Rabiner and Schafer/5/. Cepstral analysis stems from the cepstral model of speech which considers voiced speech to be the convolution in the time domain of the pitch pulses and the vocal tract characteristics. The cepstral analysis system involves the separation of the pitch period and vocal tract characteristics from speech,

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whereby the pitch period exhibits a large peak that may be filtered out to retain only the information of the vocal tract characteristics. Figure 1, outlines the steps taken to implement the cepstral system using the TMS320C25. Speech is windowed and transformed into the frequency domain, to transform the convolution of the pitch pulses and the vocal tract characteristics in the time domain into a multiplication. Applying a logarithm routine, the multiplication is transformed into a simple addition. An IFFT is employed to obtain the cepstrum, which is the waveform representation of the sum of the waveforms of the pitch pulses and vocal tract characteristics in the qufrency domain (time transformed by the logarithm operation). The cepstrum exhibits a large peak indicating the pitch period. This peak is filtered out using a fourth order Blackman-Harris window centered at 600Hz; the remaining waveform represents the vocal tract characteristics, and an FFT yields the spectral envelope of the speech sample.

The cepstral system was implemented using a 256 point speech input frame sampled at 8kHz, 32msec intervals. Table 1 displays the memory space used for implementation along with the execution time for the major routines.

Table 1

Routine	Prog. Mem	Exe. Time (msec)
FFT	784 bytes	3x(4.5 msec)= 13.5
LOG	530 bytes	1x(4.9 msec)= 4.9
ISR	27 bytes	256x(2.7 μsec)=0.7
Others	397 bytes	1x(3.98 msec)= 3.98
System	1738 bytes	23.08 msec

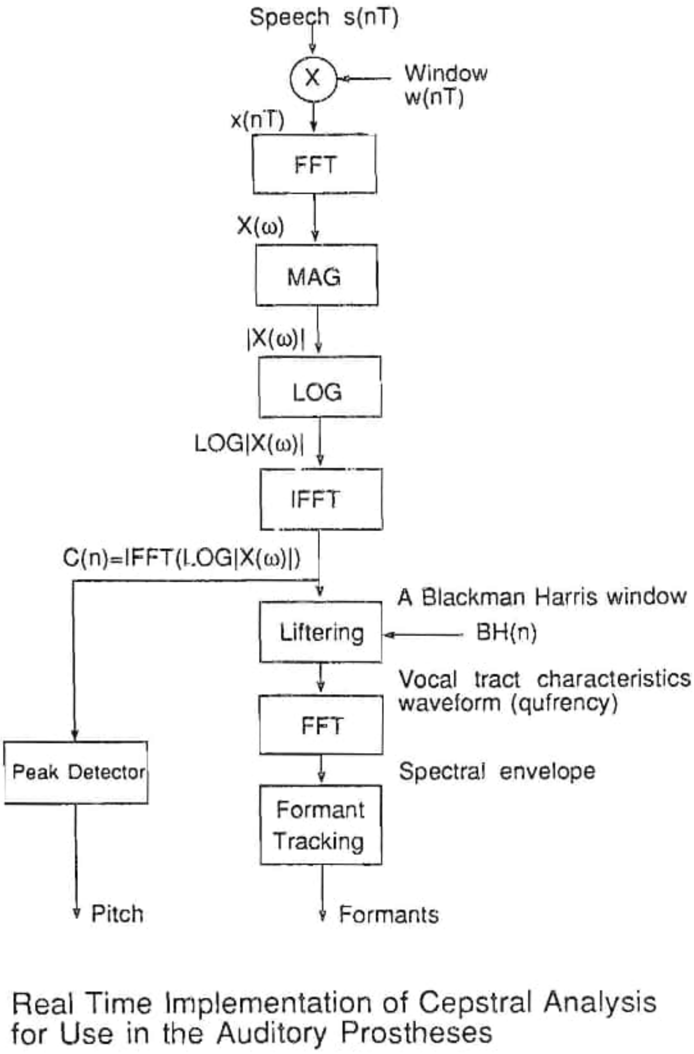

figure 1: Cepstral Analysis Implementation

The available time is 32msec, and the hardware is designed to accomodate 4kbytes of memory, it is observed that the idle processor time and unused memory space are in excess of 25% and 50% respectively which may be used for other routines.

RESULTS

The cepstral analysis system was subjected to three types of tests; the aim of these tests was to check the correctness of the algorithm, validity of its implementation and the system's performance with test speech samples used to evaluate cochlear implant's speech processing capabilities. The first test consisted of analyzing a defined electrical signal with accurate pitch and dominant frequencies values. The second test was a comparison between the cepstral system and a 14-pole LPC analysis system from a commercial software package, ILS/6/. The test was performed on the speech sample "we were away a year ago", and figure 2 shows the formant tracking of both systems; which validates the cepstral system's results as a formant tracker. The third test was catered to the discriminatory ability of the cepstral system with speech sample inputs that are difficult to lip read; since, lip-reading plays an important role in the rehabilatory process of a cochlea implantee/7/. The results as processed by the cepstral system were different for these speech samples; thus, the system displayed high discriminatory capabilities/8/.

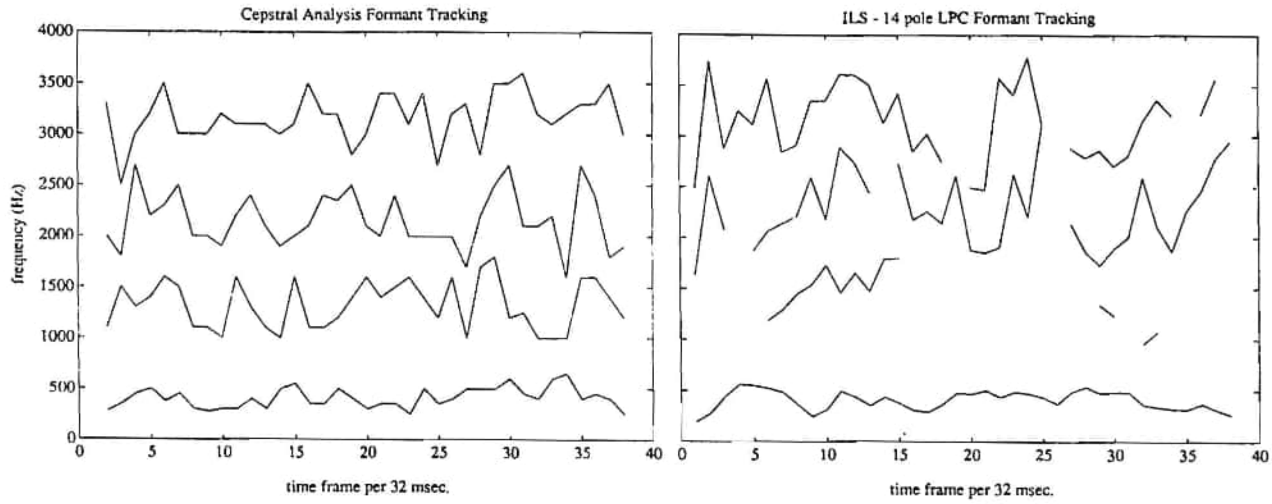

Figure 2: formant tracking of the speech sample "we were away a year ago" using the cepstral system and a 14-pole LPC analysis from ILS.

DISCUSSION

An accurate real-time speech processing system has been implemented in fixed point for use in the cochlea implant. The system's validity has been checked on three levels: algorithm correctness, compatibility of results with other speech processing methods and discriminatory tests for lip-reading purposes. The hardware used to implement the system is small (70X120X25mm) and low-power. The remaining time and memory space may be used for additional routines, the authors have implemented a current spread corrective routine as part of the speech processing system/9/.

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Improved Electrode Garment for Physician Prescribed F.E.S. Ambulation in S.C.I.

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Wright State Univ., Dayton, Oh., U.S.A.**

Recently, surface electrode technology in combination with commercially available electrical muscle stimulators and a lower extremity orthosis (HKAFO) has resulted in F.E.S. ambulation systems that can be prescribed by physicians. The medically prescribed system requires that 14 surface electrodes be individually applied to the lower extremities. In order to simplify this procedure, our group originally proposed an electrode garment which contained the requisite electrodes and could be conveniently applied and removed with minimal time and effort. Recently we have improved this electrode garment as an integral part of our physician prescribed F.E.S. ambulation system. The improved garment has: 1) larger electrode surface areas in order to keep current densities below 1 milliampere per square centimeter; 2) rearranged the gluteal electrode configuration so as to optimize stimulation of the gluteus maximus muscles; and 3) rearranged the hamstring electrode configuration so as to optimize stimulation of the semitendinosis muscles. The electrode garment described herein is commercially available from Bio-Stimu Trend Corp., 14851 N.W. 27th Ave., Opa Locka, Florida, U.S.A. 33054

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DUAL CHANNEL IMPLANTABLE STIMULATOR

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SUMMARY

A dual-channel implantable neuromuscular stimulator was designed, fabricated and preliminary tests carried out /7,9/. The dual-channel implantable system was designed to be used as an orthotic stimulator primarily for correction of drop foot. The use of low-cost, readily adaptable packaging technology permits customizing the implant to other desired applications. As we have used rectangular constant current biphasic pulses in controlling the charge applied to the nerve, the current density in the tissue is under control and the amount of charge introduced into the tissue is independent of the electrode impedance. We correlated the applied charge density with the potential excursions of the voltage transient in both stimulating cathodes and the common anode induced during controlled current pulsing in vitro (0.9 % NaCl solution). The dual-channel implantable system was implanted in a goat for two months with the aim of getting information about the fixation of the stimulating electrodes, the response due to dual-channel electrical stimulation, estimation of the suitability of the dimensions and shape of the implantable stimulator in the tissue, and finally about the parameters of the stimulation pulses. Here we report the results obtained from stimulation of the goat's common peroneal nerve and a appropriate muscle near the peroneal nerve for eight weeks at a 0.1 μCb/mm^2 per phase per channel.

MATERIAL AND METHODS

The complete dual-channel implantable system comprises three sections: (1) An external stimulator and antenna which is encapsulated in silicone rubber that generates and transmits radio frequency signals through the skin to the implanted assembly: (2) a surgically implanted passive receiver which receives the signal from the external stimulator and converts it to two trains of electrical pulses: and (3) two monopolar stimulating electrodes. An external stimulator (Fig. 1) with stimulus controls was constructed to allow high flexibility in the stimulus controls. It transmits both stimulus information and the operating power inductively to the implant. 2 MHz was selected as a suitable transmitting frequency for energy transfer. On the external transmitter it is possible to select stimulation pulses with different parameters for each channel. It is possible to adjust the current amplitude of primary (cathodic) and secondary (anodic) half of the stimulus for each channel at the same time, and the pulse width of the primary and secondary half of the stimulus separately for each channel. To circumvent the fluid ingress problem, the electonic circuit of the dual-channel implant developed last year was encapsulated in a casing made of machinable ceramic (MACOR). The final dimensions and shape of the dual-channel implantable stimulator were formed by machining of the implant body casted in epoxy resin (HYSOL) on ordinary equipment and additional grinding. The circuit of the dual-channel implantable stimulator was miniaturised by using a hybrid thin-film technique. The type of the stimulus pulse for both channels is a rectangular biphasic constant current pulse with zero net charge flow, as shown in Fig. 2.

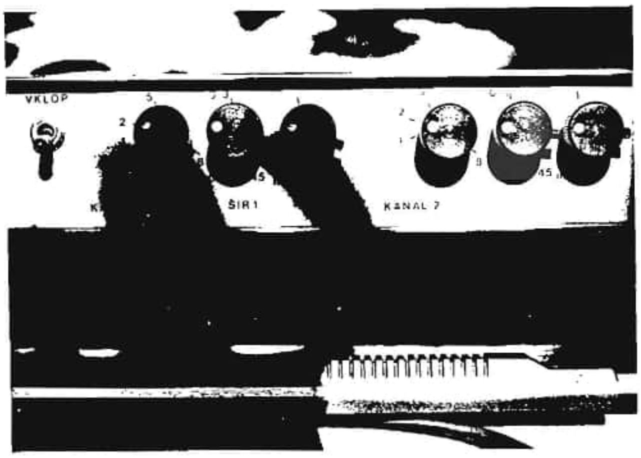

Fig. 1. An external stimulator.

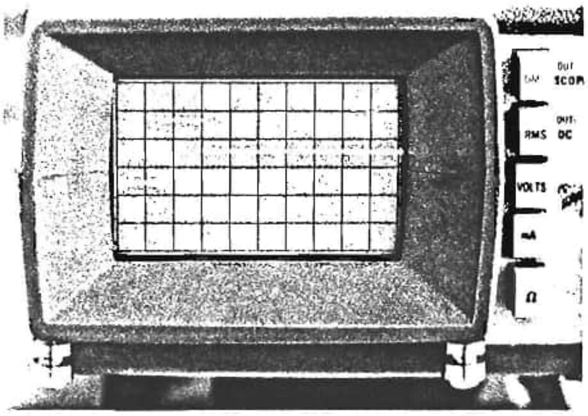

Fig. 2. The stimulus pulse.

The polarity of the stimulus pulse is changed after every pulse. The delay between the primary and secondary half of the stimulating pulse is zero. The output current to the electrodes is adjustable from 0 to 6 mA. The current delivered to the electrodes varies by not more than 5 % when the electrode impedance changes from 100 to 1000 ohms. The disc-shaped stimulating electrodes (Fig. 3) are manufactured from pure platinum sheet and imbedded with biocompatible medical silicone adhesive. The interconnecting cable is of a helical three strand wire design made of stainless steel /1,5/. The development of stimulation electrodes involved determining the "safe" charge which may be injected in a pulse without electrolysing the electrolyte and evolving gas. The geometric area of the stimulating electrode disc is 12.5 mm^2 and the real surface area is 1.4 times the geometric area (17.6 mm^2). With the maximum available current density of 0.33 mA/mm^2 (geom.), the charge density becomes 0.1 $\mu Cb/mm^2$ (geom.). It is obvious that the above limits do not restrict the use of these Pt electrodes in the nerve and muscle stimulation. In order to minimize the selectivity of the electrode when using two stimulation sites a monopolar structure was used. A

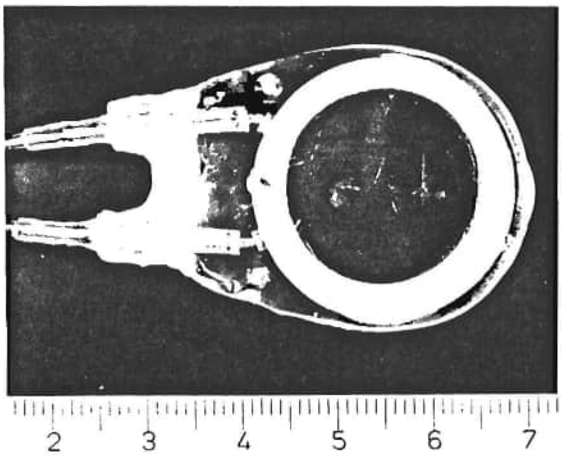

Fig. 3. The disc-shaped stimulating electrode.

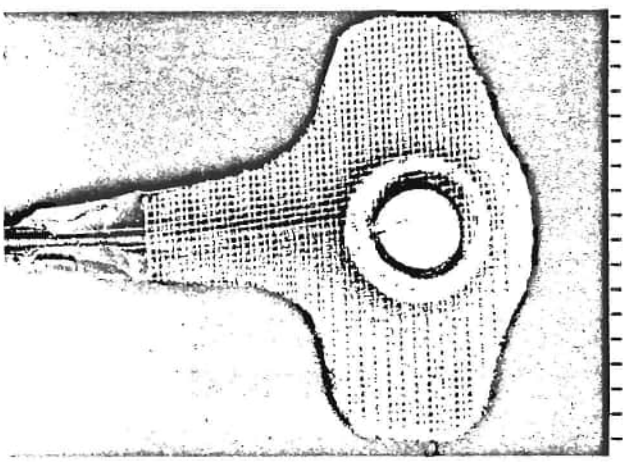

Fig. 4. The dual-channel implant.

indifferent electrode was made of titanium with great geometric surface and suited on the one side of the implant body. The flat shape of the stimulation electrodes was designed to accomodate the shape of the human peripheral nerve and the shape of the muscle.
The procedure for implantation of dual-channel implant (Fig. 4) was as follows.
The first channel was used for stimulation of the common peroneal nerve, whereas second channel was used for stimulation of the chosen muscle near the common peroneal nerve. The latter was surgically isolated for a length of 3-4 cm. The muscle to be stimulated was identified by stimulation during surgery with one of the stimulating electrodes. A relatively low stimulus level was required to effect nerve or close to the nerve entrance on the muscle. During surgery both of the stimulating electrodes were sutured using 2-0 sutures at each of the two prolonged sides of the electrode silicon substrate. The achievement of activation of the desired muscle to near maximum levels without exciting neighbouring muscles, was found to be difficult.

RESULTS

The maximum, biphasically applied charge which can be injected without electrolysing water has been determinated for a Pt electrode: when Pt is used as the cathode, the theoretical limit is $3.5 \pm 0.5\ \mu Cb/mm^2$, independent of current density in the range of $\pm$ 0.5 to $\pm$ 4.5 mA/mm^2.
It is obvious that in our case the biphasic charge density of 0.1 $\mu Cb/mm^2$ in both channels is much lower than maximum which can be injected without electrolysing water and is in the range safe for stimulation of the nerve tissue /3,4,6,10/. Since electrochemical reactions depend mostly on the range of electrode -electrolyte voltage over which the electrode cycles from pulse to pulse, the potentials of both stimulating cathodes and the potential of the common anode during pulsing and the value of the potential for an electrode passing no current were measured against a Ag/AgCl reference electrode. Dummy platinum electrodes with the same shape and surface as the real electrodes were connected to the corresponding receiver circuitry and immersed an 0.9% NaCl solution. The separation between the receiver and transmitter antenna, the frequency of pulses and pulse widths were equal in all measurements and were 1 cm, 30 Hz and 0.2 ms, respectively.
The findings from the animal experiment where stimulating electrodes were encapsulated in a moderately thick accumulation of dense connective tissue has important implications for the extrapolation of these results to human use /2,8/. The effect of the encapsulation is to move the electrode away from the "optimal" location which results in decreased selectivity, recruitment rate and relative gain. An increased stimulus amplitude is required and increased length dependence can be expected. Gross examination of the electrode sites and implant body site showed no evidence of infection or haemorrhage.

DISCUSSION

Packaging of the device involves utilisation of the unique properties of several biomedical materials. Epoxy resins exhibit good strength and hardness characteristics, while evoking minimal adverse tissue response. The use of these materials is necessitated by the constrains imposed by the stimulator electronics, including nonmetallic encapsulation due to RF coupling, hermetically sealed electronic circuitry and a minimum of 5 years working lifetime after implantation. Epoxy resins are also admirably suitable to cold ethylene oxide sterilisation, provided proper degassing procedures are adopted.

However they are not impervious to water vapour and this fact must be considered when designing the implant circuitry. In itself the presence of water vapour in an implanted package is not a problem, providing the design implementation uses components that are insensitive to vater vapour. However, if voids are present in the encapsulant, water vapour can condense and cause failure due to saline bridges between components. Due to facts mentioned above, the next step in improving the dual-channel implant will be changing the encapsulation procedure. The modified model of encapsulation technology, encapsulation of the electronic circuitry in a metal case will be used instead of encapsulation in a ceramic housing.

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DUAL CHANNEL ORTHOTIC ELECTRICAL STIMULATOR WITH STRIDE ANALYZER FOR CORRECTION OF GAIT *

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SUMMARY

A dual channel orthotic electrical stimulator for gait correction has been developed. The whole set consists of two devices: the microprocessor controlled stimulator and the program unit. The stimulator is designed to be handled by the patient alone. All stimulation parameters are preprogrammed by the therapist through the programming unit exept stimuation amplitudes for both channels which is controlled by patients themselves.
Preliminary results of dual channel stimulator evalvation has been obtained on groups of 10 CVI and 10 TBI patients. Significant improvements of relevant gait parameters has been observed.

INTRODUCTION

Functional electrical stimulation (FES) has been introduced in the rehabilitation of plegic and paretic patients for more than twenty years /1/. Numerous stimulators have been designed for the surface stimulation of gait, from the simple single-channel to very sophisticated multichannel units. But only a few devices are convenient enough for home use /2/. There are some reports on development of laboratory oriented dual channel devices /3/, but recently some of them appeared on the market. These are all handsome cyclic stimulators, which are very convenient for therapy in rehabilitation institutions, but less applicable for gait for everyday homeuse. In the last few years multichannel electrical stimulation has been applied in severely involved patients, who could hardly walk or could not walk at all without considerable help from a physiotherapist /4/. It has been shown that these patients started walking after two to three weeks therapy with stimulation, using a crutch and some assistance from a physiotherapist. After finishing therapy such patients would in most cases need a dual-channel device for furthert stimulation. There is also a large group of patients who can walk, but have considerable problems with insufficient ekstension or with hyperextension of knee during the stance phase, or with insufficient ekstension of knee during the swing phase. Such patients are also candidates for dual channel stimulator as an orthotic aid /5/.

MATERIAL AND METHODS

Characteristics of stimulator

While developing the main concept of the hardware of the stimulator, we decided that the stimulator set should consist of two units: a stimulator and a programmer. Both units have been designed to be easy to handle. In the stimulator, which is used by the patient at home, there are on/off switch, amplitude knobs and connectors for electrodes and heel-switches which are accessible to the patient. There is also an indicator light, which emites green light when the stimulator is on and the battery is full, or it emites red light when the battery is low and indicates that the battery should be replaced within an hour of operation. All other parameters of stimulation are preprogrammed by the therapist with the programming unit and can not be altered by the patient, even when removing the battery. The stimulator has two independent channels with intermittent current stimulation pulses with amplitudes from 0 to 50 mA. There are two modes of operation: cyclic mode and walking rate dependent mode (WRD). When neither heel-switch is connected the stimulator operates in cyclic mode. The preprogrammed stimulation sequence is repeated in preprogrammed time interval. This mode is used for selecting the stimulation sites, for exercising of muscles, for pain relief stimulation, etc. When one or both heel-switches are connected, the stimulator operates in WRD mode, which is used for walking. In this case the same stimulation sequences are optionally triggered by left or right heel-switch. The duration of the stimulation sequence is adapting to the patients speed of gait. According to the information from one or both heel-switches the following statistical parameters of gait are also measured: number of steps, average stride time with its standard deviation, average stance phase times with standard deviations for both legs and their symmetry. The programming unit has been designed to be handled by the therapist. through alpha-numeric display. Therapist can change different menues by pressing pushbuttons and set the following parameters for both channels together: stimulation frequency from 5 to 120 Hz, duration of the cycle from 2 to 12 sec and the following parameters for both channels separately: pulse width from 0.05 to 0.5 msec, stimulation sequence, pulse shape (monophasic or biphasic) and triggering of each channel by left or right heel-switch. The chosen parameters can then be programmed through cable connection to the stimulator, or the programmed parameters could be read from the stimulator in order to check the setting. The statistical data could be read and displayed from the stimulator or the statistics could be cleared for a new measurement. The stimulation sequence setting is graphically represented for both channels separately with 8 software switches for the stance and with 8 software switches for the swing phase. When the switch is on, the stimulation is on in the corresponding stance or swing time increment.

Subjects

Severlely involved patients with the upper motor neuron lesion after CVI and TBI have been included in the therapy for testing the functionality of the device. Besides of peroneal nerve or pretibial muscle group for ankle dorsal flexion, one of the following muscle groups are added: quadriceps muscle for knee extension, hamstring muscle for knee flexion or gluteus maximus muscle for the hip extension.

Instrumentation

The functionality of dual channel orthotic stimulator have been evaluated by electrokinesiological measurements: the forse shoes /6/, 3D goniometrics system besides space and time gait parameters. Average value and standard deviation are computed for evaluation purposes.

RESULTS AND DISCUSSION

10 hemiplegic patients and 10 brain injury patients are involved in this study. Significant improvements of step lenght, step time, gait velocity and gait symmetry as well as correction of joint angles and posture due to stimulation were observed. So far, the most sensitive

gait parameter influenced by stimulation are ground reaction pattern. In Figure 1, the results of gait of hemiplegic patient (case No.7) without stimulation (dashed line) and with stimualtion (solid line) are shown. It is obvious dramatical change in point of action (POA) of vertical force due to stimulation of muscle peroneal and muscle quadriceps. Foot contact area are transfered from lateral metatarsal side to the heel area and running along anterior-posterior foot axis, similar to those of the unimpared leg. Better heel strike and trajectory of POA mean smooth body transfer on the impared leg. This correction are also reflected in improvements in symmetry, velocity and step time. Similar results are achived on each examined patients. Information obtained from gait analyzer are very important for the therapists as a feedback about course of patient rehabilitation.

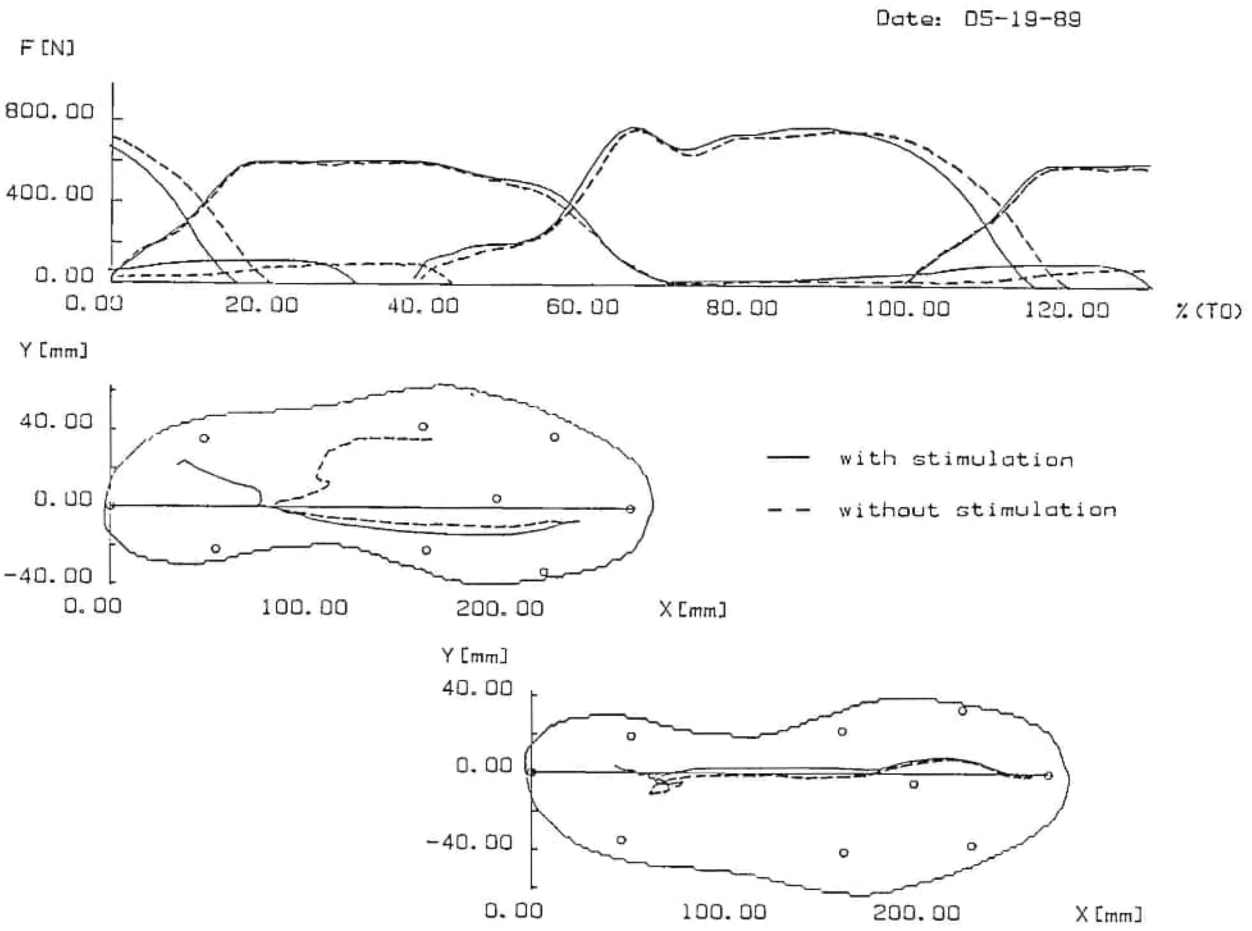

Figure 1. Gait pattern of a hemiplegic patient without stimulation (dashed line) and with dual-channel stimulation (solid line).

The stimulator described and evaluated is a new orthotic aid for the correction of plegic or paretic gait, which can be used outside the clinical environment. It has been designed in the light of experiences from multichannel therapeutic stimulation, which indicated the need for a multichannel orthotic device. Implementation of that idea was enabled by VLSI technology and CMOS microcomputers integrated in a single chip. Some unique features, like walking rate dependent stimulation or the way of setting and representing of the stimulation sequences, are implemented in the dual channel stimulator. The preliminary evaluation on CVI and TBI patients clarified its orthotic and research usefulness.

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THE ROLE OF RATE RESPONSIVE PACING IN HEART STIMULATION

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SUMMARY

Authors rewiew the history of the last decade of cardiac pacing, which is clearly dominated by the emergence of clinically reliable rate-responsive heart stimulation.
The merits and drawbacks of the different systems using different physiologic parameters (tidal volume, central venous temperature, activity, QT intervals, pH, O_2) were compared and no clinical solution was found to the controversy which system should be prefered.
The possibility of combining different sensors is extensively explored and model experiments were carried out with mixed results: no better results for combination emerged, the practical and economic considerations favoured simpler systems.
Authors conclude from their own experience that economic trends for small pacemaker implanting centers allow only slow and gradual rise in the relatively small percentage of rate responsive models in a totally free of charge health care system.

MATERIAL AND METHODS

Introduction

The 4 decades of cardiac pacing has milestones in every decade. The fifties produce the first wearable external pacemakers (PM), in the sixties the implantable PM gets into widespread use, multiprogrammability arrives in the seventies and in the eighties dual-chamber pacing and rate responsive pacing introduce hemodynamic benefits to patients.

The history of physiologic pacing

The evolution of cardiac heart stimulation has 3 major stages. At first the aim was to provide a minimum heart rate. The concept of "demand" function enabled to use PM implantation as a safe therapy in millions of patients. The recognition of the hemodynamic role of the atrium and its use in physiologic or dual chamber models was the great leap in the last two decades. The third step is the introduction of rate responsive pacing, meaning that devices are implanted which increase their rate in response to effort, using physiologic sensors to make the best adoption of rate to metabolic requirements.
Very early in the history of cardiac pacing the great

benefits of physiological control of heart rate were demonstrated by hemodynamic and clinical studies /1/. With constant advances in technology for 20 years reliable dual-chamber atrial synchronous models are in clinical use. The only problem is that about 50% of all pts requiring a PM implantation are not suited for a system depending on atrial signals, or the progression of their disease may limit the long term use in patients. Also atrial lead systems were for a long time typical for producing malfunction and the two leads for both chambers are still a potential for problems. This and economic causes are behind the fact, that world wide implanting physicians still use 6 fold more single chamber units as compared to dual chamber PMs.
The concept of a new atrial synchronous single lead rate responsive PM is more than 20 years old /2/, with the first model implanted 12 years ago /3/.
In the last decade and especially in the last 5 years lots of different sensors and models were developed and experimented with. Different systems emerged on the market and are now in clinical use.

Biological sensors

The functioning atrium is still the best biological sensor and still now atrial sensors are less perfect, therefore all such devices present a higher level of complexity, both medically and technically. There are many possibilities and sensores can be classified differently: QT interval, respiratory rate, activity, O_2, pH, temperature are those mostly used.
If we look at all parameters necessary for optimal rate responsive pacing the specifity, sensitivity of a sensor has to be assessed, beside the speed of response and a host of technical features (feasibility, longevity, reliability, current consumption, the complexity of the necessary algorythm, case and cost of the system) /4/. The most important factor is the relationship between rate and the parameter used for its regulation. To achive a truly physiologic rate response some PM systems offer a solution of different responsive curves, individualising therapy, howewer this makes the actual setting complicating and time consuming.

DISCUSSION

Till now the merits and drawbacks of the different systems using different physiologic parameters as sensors were compared in many tests /5, 6/ and no clinical solution was found to the controversy which system should be prefered.
The possibility of combining different sensors was extensively explored and model experiments were carried out with mixed results. No better results for combination emerged, the practical and economic consideration favoured simpler systems. However there are experts favouring the use of more than one parameter for rate control, especially those combining two complementing parameters in a sense that potential limitations of one can be compensated for by

the other, making the system more reliable /4/. Stangl et al. described their practical multisensor system /7/ last year.

Rate responsive pacing is a true revolution. The controversy of demand versus fixed rate generators two decades ago ended with now nearly all PMs having demand capacity. The same applies for rate responsive capability /8/. If fully developed it allows pacing at a hemodinamically optimal rate. Althoughs rate responsive models are in competition with dual-chamber PMs at present, logically they surely will be combined and the future optimal PM will have multisensor capabilities.

We conclude from our own experience, that financial limitations allow for small implanting centers in a free of charge health care system with limited resources only a slow and gradual rise in the small percentage of rate responsive models.

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TWO PARAMETERS IN ONE RATE ADAPTIVE SENSOR
QT-INTERVAL AND T-WAVE AMPLITUDE

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A single sensor for rate adaption has certain disadvantages: lack of sensing and oversensing, or sensing of false originals may occur.
Double sensor technique may overcome these problems and may also improve the rate response. A simple alternative is two parameters derived from the pacing-evoked response. In 7 pts with the latest generation of QTinterval (QTi) sensing pacemakers, the QTi and the T-wave amplitude (TWA) was measured both during exercise (X) at a fixed rate and at rest, using pacing rates from 50 till 120 bpm. The QTi was measured on a high speed ecg recorder simultaneously with the TWA (with a TP2 programmer). During pacing (50-120 bpm) no change in TWA ($\pm$0,1 mV) was noticed, but during X the TWA showed a linear increase from average 1,4 mV till 3,3 mV at maximum X. (p
The QTi varied with both rate and X as has been reported by other investigators.

Conclusions:

1. The TWA is independent from pacing rate and is linearly correlated with X.
2. The TWA seems to be an independent parameter from the QTi.

Implications:

The TWA can be used as a single or additional parameter for rate adaption in the QTi (evoked response) sensing pacemaker.

THE TECHNOLOGY OF A TEMPERATURE CONTROLLED PACEMAKER

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SUMMARY

Recent trends in cardiac pacemakers have resulted in the development of a number of rate responsive pacemakers. These physiological pacers use several different types of sensors. This paper looks at a pacemaker which uses blood temperature as a physiologic indicator. During exercise, muscle generates a considerable amount of heat causing an increase in the temperature of venous blood. In order to detect these temperature changes and to analyze the results, many new and unique technological advances were required. These included the reliable measurement of blood temperature, the digitizing of the temperature data, and the processing of this data in an algorithm. In addition to these requirements, the pulse generator must be totally programmable and have a lifetime of over 5 years.

BACKGROUND

After a great deal of research, it was determined that the temperature response to activity or stress can be characterized in terms of brief dips in blood temperature followed by a temperature rise back to baseline. In most cases, the temperature continues to rise to some maximum and then decreases to baseline after the exercise stops.

It was also found that the temperature profiles vary among patients. The magnitude of each component of the temperature response varies with the individual patient and the level of activity. Some patients tend to exhibit pronounced drops, while others exhibit no drop or only a slight drop.

In order to develop a pacemaker system which would detect and analyze small changes in blood temperature, it was necessary to develop a number of special purpose circuits. These circuits are discussed below.

TEMPERATURE MEASUREMENT

The temperature measurment system was the most unique and challenging part of the pacer. It consisted of a bead thermistor mounted approximately 3 cm from the tip of the pacing lead. This thermistor was biased with a low current and the changes in voltage were digitized in a voltage controlled oscillator (VCO).

The thermistor had a nominal value of 10K ohms at room temperature. The usable range was from 5K ohms to 6K ohms. This corresponded to a five degree temperature range at body temperature. Power was applied to the thermistor every 10 seconds. The voltage across the thermistor was applie to a voltage controlled oscillator with a nominal center frequency of 25 KHz. The output of the VCO was then gated with a precise crystal controlled time base of 250mS.

The number of pulses was then totalized in a 12-bit counter. With this system, a typical response of 250 counts per degree centrigade was achieved.

This system had to operate over a wide range of battery voltages and also had to function while pacing pulses were delivered. In order to ensure reliable operation during these events, the complete temperature measurement system was powered by a band-gap reference and voltage regulator. This allowed the system to operate down to 2.0 volts. The measurement was also syncronized with the pacing event. Following a pacing event, power is applied to the temperature measurement system. The actual measurement of temperature is then delayed for 50 mS to let the circuitry stabilize.

Using these techniques small changes in temperature were measured over the life of the pacer with a high degree of reliability.

MICROCONTROLLER

The microcontroller had three main functions. These include:

(1) Operating System

(2) Temperature Algorithm

(3) Programming and Telemetry

The operating was designed to keep the microcontroller in a low-power state most of the time. A separate timer generated an interrupt every 5 seconds. The microcontroller then made decisions on what action was to be taken. Some of the actions include; reading temperature, executing temperature algorithm, keeping track of real time, and conducting system tests every 24 hours.

In addition to the timer interrupts, the microcontroller could also be interruped by the programming circuit. In this interrupt the microcontroller would analyze the serial data which was demodulated in the RF detector circuit. The microcontroller would count the number of pulses detected, look for proper parity, and finally check five bits against a preset access code. If all three requirements are met, then the microcontroller would accept the incoming data and send out an accept signal and program the pacer. The range of programming operations include:

* Program or Read any RAM location
* Change Pacing Parameters
* Change Temperature Parameters
* Request Telemetry Data
* Request A System Test Command
  (i.e.: Read Temperature)

The large amount of flexibility in the programming and telemetry system enables the physician to obtain a great deal of data back from each patient. And he is therefore able to obtain detailed temperature profiles and responses.

The microcontroller chip is constructed with CMOS technology and it consists of a CPU, RAM, ROM, timer, and I/O parts.

PACING CHIP

The timing for pacing was generated in a separate custom CMOS chip. The microcontroller could adjust the parameters but all of the timing was controlled in separate timing sections for the pulse genrator, refractory circuit, and pulse width circuit. Also included on this chip was the VCO, the output amplifiers, the programming and telemetry interface circuitry, the crystal controlled main oscillator, and rate limiter.

PROGRAMMER

The external programmer is an integral part of the complete pacing system. This programmer is portable and battery powered and is made up of two LCD displays, keyboard, printer, and programming wand. The programmer allows the physician to have access to all pacing parameters, all temperature parameters, and the complete RAM memory.

In addition to the normal programming features, the programmer also has an RS232 port on its rear panel. This port enables the programmer to be linked directly to an IBM PC computer. Complete temperature data can then be transferred from the programmer to the personal computer. The personal computer is then used to analyze the temperature data and make recommendations on optimum pacing settings.

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RELIABILITY OF EVOKED QT PRINCIPLE FOR AUTOMATIC PACING

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SUMMARY

In order to determine the reliability of the Automatic Rate-Responsive 919, a QT driven rate pacemaker using the evoked St-T interval and the calculated T slope.

10 patients have been investigated.

The rate-responsive mode was switched on 1 month after implantation. Automatic slope adaptation was monitored by regular interrogation at months 1 and 3.

Pacemaker status, in-built 24 H Holter, treadmill test, conventional 24 H Holter were performed at the same time.

Preliminary results indicate :

- an improved rate response to exercise, compared with previous devices.
- better efficiency in rate modulation, depending upon automatic slope adaptation.
- easy follow up provided by in-built Holter and analysis functions.

MATERIAL AND METHODS

Introduction:

It was already well known that the QT interval was influenced by changes in heart rate (1). The principle of using the paced evoked QT interval to determine pacing rate was established by Rickards et al (2.3). This parameter has been used in successful development of a QT sensing pacemaker (Quintech TX, VITATRON Medical B.V.), which is one type of rate responsive pacemaker. The QT interval is altered by two destructive factors : metabolic demand and heart rate.

In 1987, Perrins discovered that, in individual patients the relationship between the QT interval and the pacing interval was non linear and, created thereby the basis for several major improvements in QT driven pacemakers (6.7). At the end of 1987, VITATRON introduced the third generation of QT driven rate responsive pacemaker : 919 (8).

Study objective:

The objective of the clinical evaluation study was to :

1) confirm safe and effective operation of the device.
2) investigate whether the automatic slope adaptation provides a stable and adequate response to exercise.
3) investigate the accuracy of the built in heart rate holters.

Patients:

The study group consisted of ten patients (two females and 8 males) aged 55 to 86 years (average 67.5 yrs). The indications for pacing were 2nd or 3rd degree AV Block in seven patients and sick sinus syndrome in three (3) patients. All patients were pacemaker dependent. No changes in drug prescription were undertaken during the study period. All patients had normal serum electrolyses throughout the study. This report is based on data obtained from ten implanted 919, different type leads were used: Telectronics 030.281 (x3), Intermedics 4930.5 (x1) (porous surface structure), Medtronic capsure 4003 (x2), ELA 0860 (x4) and no screw in leads were used..

Study Protocol:

The clinical evaluation of the 919 consisted of three different phases. During all phases data was collected concerning the following items : Age, sex, medications, indications for pacing, implantation data, pacing lead data and measurements : voltage pacing threshold, current pacing threshold, endo-cardial QRS amplitude ane evoked T-wave with TA1 analyser.
The lower rate limit was programmed to values 70 bpm. The rate drop at night feature was used in 80% of the patients. The programmed rate drop at night ranged from 5 to 10 bpm.
The upper rate limit was programmed to 120 bpm. The programmed T-wave sensitivity at the last follow up was 0.5 mV in 20% of the patients and 1.0 mV in 80% of the patients.
Stim T interval measurements was used to calculate the numerical values of the dynamic slop during the first week, after one month's and three months' implantation.

Built-in Event Recording (9):

The pacemaker is equiped with two different Holter functions. The 24 hour heart rate Holter calculates the average heart rate over 7.5 minute periods and subsequently stores this information over a 24-hour period.
In addition, a 1 hour heart rate Holter has been implemented which can be used during exercise stress testing. The pacemaker calculates the average heart rate over 20 second periods and stores these values continuously over 1 hour period.

RESULTS

Exercise stress testing and one hour heart rate Holter:

The rate response to a standard exercise stress test has previously been evaluated using Stim T driven rate adaptive pacemaker of the previous generation together with investigational software (10). It was found that the initial rate response was significantly faster than with the previous generation.

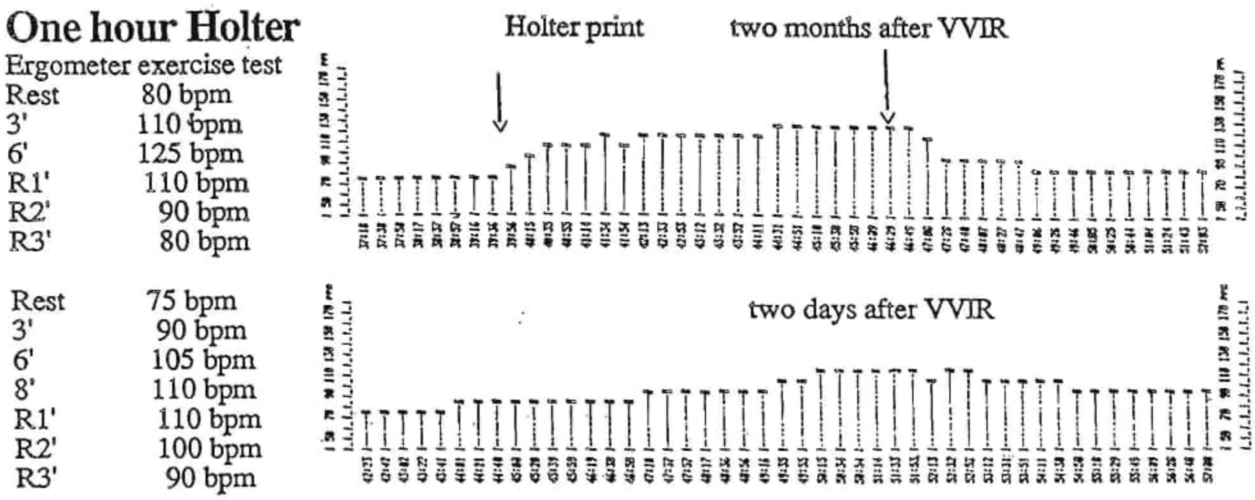

Fig. 1. Part of an interrogated 1-hour heart rate Holter during an exercise test of a patient with a model 919 rate responsive pacemaker, demonstrating the response time of the new algorithm. One week after implantation the rate responsive parameters are still set at conservative values. Two months later, the pacemaker has automatically adapted the rate responsive parameters to the individual optimal values.

Fig. 1 shows an example of two identical exercise stress tests performed at different stages of the automatic slope adaptation. Initially the PM shows a relatively slow and limited response due to the low dynamic slope values. Thereafter the automatic slope adaptation causes the dynamic slope to increase daily until after 8 weeks when the dynamic slope has settled, a correct rate response is obtained.
The correlation between the 919 Holter and the manually recorded heart rate is high.

24 hour heart rate Holter:

The in-built 24 hour rate Holter proved to be very useful in analysing the performance of the pacemaker during daily life.
Example of a Holter print out is shown in Fig. 2.
From this figure it can be seen that :

- Rate variation correlate closely to activities in daily life.
- The magnitude of rate variation is proportional to the level of exercise.

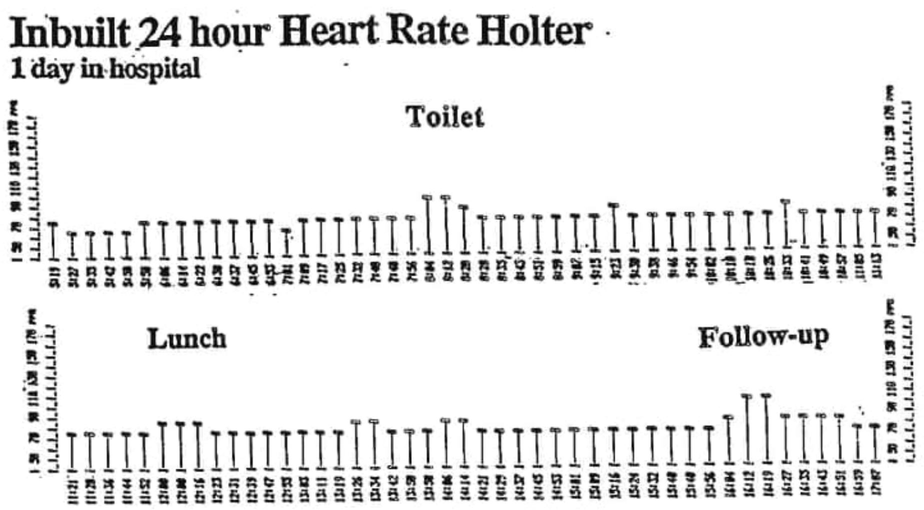

Fig. 2 shows part of a 24 hour Holter print out and demonstrates the results of prolonged and repeated exercises.

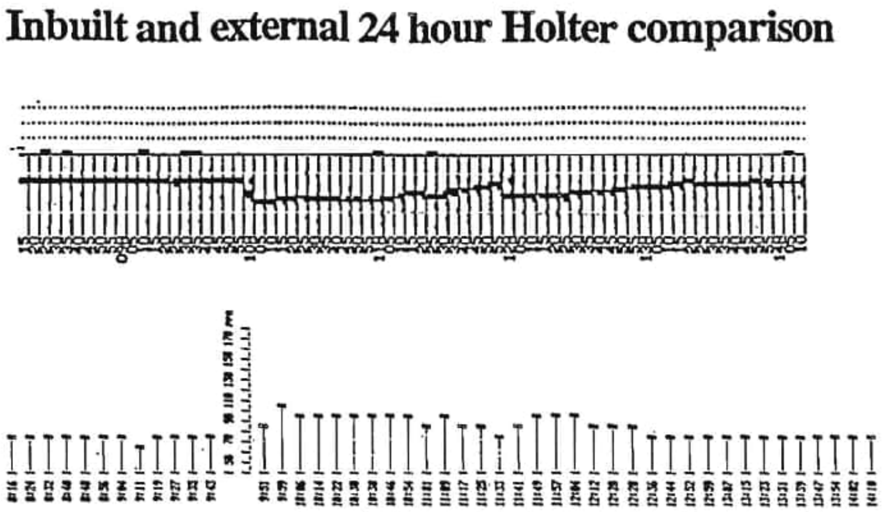

Fig. 3. Comparison between conventional Holter and pacemaker Holter during a quarter of a day.

In addition to the heart rate Holter functions two separate event counters are available:

- the percentage paced counter provides information on the pacemaker dependency of each patient.
- the percentage sensed T-Wave counter indicates whether reliable T-Wave sensing is present.

DISCUSSION

It is often difficult and time consuming to program the rate responsive parameters to such values so that adequate rate responsiveness is obtained.
Furthermore, it may be necessary to change these parameters in the long term because conditions may change the patient's physical condition, drug treatment.
It is necessary to check rate responsive pacemakers with exercise stress testing and 24 hour Holter recording. Both increase work pressure on medical staff.
Automatic slope adaptation provides a stable and adequate rate response to exercise.
Built-in heart rate Holters have proved to be a useful and time saving tool in the follow up of TX 919 patients.

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AN ATTEMPT TO UNDERSTAND THE UTILITARIAN VALUE OF LOCALIZED *IN VIVO* ELECTRICAL STIMULATION IN ATROPHIC MUSCLES

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SUMMARY

The standardized program of electrical stimulation was applied to the control and denervation atrophied muscles of frog and the pattern of changes in the contractile kinetics were observed in the gastrocnemius muscles. Total twitch time, contraction time and half relaxation time were observed to be higher in denervation atrophied muscle than the control. The program of electrical stimulation applied to the atrophic muscles has restored its conditions nearer to the control level.

MATERIAL AND METHODS

Healthy frogs belonging to the species *Rana hexadactyla* of 30±2 g were collected from ponds locally. They were maintained in clean glass aquaria and fed with cockroaches regularly *ad libitum*. The frogs were acclimated to laboratory conditions and they were divided into three groups of 12 animals each as:

GROUP I : Normal Sham-operated frogs (C);

GROUP II : Sciatic denervation - denervation atrophied (DA) and

GROUP III : Electrical stimulation for DA animals-denervated stimulated (DS)

Sciatic denervation: Sciatic denervation was performed under aseptic conditions. Nerve supplying the shank was carefully separated and about 2 cm length of the nerve was cut at the posterior part of the thigh. Sham operated normal animals were maintained as controls.

Induction of exercise into the denervated frogs through electrical stimulation: Denervation atrophied gastrocnemius muscle of frogs was stimulated with platinum electrodes using an electrical stimulator. Regular pulses of 5v; 2c/sec frequency and 100 ms pulse duration was given for 20 min daily for a period of 15 days.

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Kymographic recordings of muscle: C, DA and DS animals gastrocnemius muscles were isolated carefully and washed repeatedly with amphibian Ringer's solution and kept for few minutes to recover from shock effects. In Vitro muscle contractions were recorded on a kymograph. The twitch properties and the associated contractile kinetics were analysed by the kymographic method as adopted (1). The amplitude of contraction, total twitch time, contraction time (CT) and half relaxation time (HRT), twitch tension rate (or) Vtmax were calculated.

RESULTS

Total twitch time of DA muscle was higher than the (C'. Similarly CT and HRT were also more or less increased to the same extent. Twitch tension, twitch tension rate (Vtmax) and fatigue time in the DA muscle were lowered than that of 'C'. Total twitch time, CT and HRT were depleted in the DS muscle from that of 'DA' muscle. Vtmax was increased remarkably and the onset of fatigue was also increased similarly in response to the electrical stimulation applied to the 'DA' muscle. Total twitch time in DS muscle had significantly decreased in comparison to that of 'DA' muscle. HRT/HCT ratio was higher in DS muscle over that of DA muscle. Thus the denervation atrophied muscle is subjected to standerdized electrical stimulation almost it restored to normal conditions.

DISCUSSION

Denervation atrophied muscle: Total twitch time was more in denervated muscle suggesting the passive mode of contraction of this muscle owing to disuse due to lack of trophic influence of the nerve. The contraction time was known to depend on the rate of activation of actinmyosin interactions (2), the rate of release of Ca^{2+} from sarcoplasmic reticulum and the affinity of calcium to bind with troponin. The increased contraction time observed suggests the inefficiency at the above factors. The relaxation time on the other hand was known to depend on the rate of Ca^{2+} sequestration. Hence, decreased rate of uptake of Ca^{2+} into the sarcoplasmic reticulum in the denervated muscle might be responsible for the observed decrease in HRT. Earlier findings have shown that the decrease in rate of aerobic and anaerobic breakdown of carbohydrates and proteins, in 'DA' muscle supports such a possibility.

Denervated stimulated muscle: The 'DS' muscle had significantly decreased total twitch time in comparison to that of 'DA' muscle. This indicates increased contractile efficiency of the muscle. The decreased HRT suggests increased rate of calcium uptake so as to lead to an early sequestration of Ca++. Vtmax was higher in DS muscle than 'DA' which suggests its efficient force generating capacity and it might be due to the supply of energy to the muscle. In the 'DA' muscle, energy generating capacity seems to be affected due to the lack of trophic stimulus, leading to muscle disuse. In conclusion, it can be stated that the standardized program of electrical stimulation to 'DA', has restored the functional efficiency and structural organization to normal condition.

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TABLE

Total twitch time, Contraction time, Half relaxation time, HRT/HCT, Twitch tension, Twitch tension rate and Fatigue time in Control (C), Denervated atrophied (DA) and Denervated stimulated (DS) Muscles.

(Values are mean ± SD of 12 individual observations)

Component	Control muscle(C)	C Vs DA	Denervated muscle (DA)	DA Vs DS	Denervated stimulated muscle (DS)
Total twitch time (m.sec)	119.51 ± 4.56	+53.17 P < 0.001	183.06 ± 5.95	-34.40 P < 0.001	120.06 ± 6.25
Contraction time (CT) (m.sec)	41.42 ± 1.84	+43.07 P < 0.001	59.26 ± 3.34	-28.34 P < 0.001	42.46 ± 1.68
Half relaxation time (HRT) (m.sec.)	42.14 ± 1.26	+35.02 P < 0.001	56.9 ± 2.96	-24.05 P < 0.001	43.21 ± 2.0
HRT/HCT (m.sec.)	2.034 ± 0.09	-5.6 P < 0.001	1.92 ± 0.01	-5.98 P < 0.001	2.035 ± 0.08
Twitch tension (g)	25.00 ± 1.69	-44.0 P < 0.001	14.00 ± 0.99	+67.78 P < 0.001	23.49 ± 2.0
Twitch tension rate (or) Vtmax (g/m.sec)	1.207 ± 0.09	-61.06 P < 0.001	0.47 ± 0.002	+135.31 P<0.001	1.106 ± 0.07
Fatigue time	2.85 ± 0.1	-22.45 P < 0.001	2.21 ± 0.099	+26.24 P < 0.001	2.79 ± 0.09

LARYNGEAL PACEMAKER: RESPIRATION CORRELATED STIMULATION OF THE DENERVATED PCM IN SHEEP+)

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SUMMARY

In 5 sheep a diaphragmatic myogram-controlled direct electrical stimulation of the denervated posterior cricoarytenoid muscles (PCM) was performed. The abduction movement of the vocal cords was documented by means of video laryngoscopy. Sufficient bilateral vocal cord abduction was obtained though the training effect of chronic direct electrical muscle stimulation was not utilised.

MATERIAL AND METHODS

In 5 sheep both posterior cricoarytenoid muscles were denervated by resecting an approximately 2 cm long piece of the inferior laryngeal nerve. Bipolar electrodes were implanted into the muscles with atraumatic sutures, their connecting leads being positioned at the skin surface of the animal's neck.

After carrying out a median laparotomy, four myogram electrodes with extra-corporal leads at the right thoracic wall were placed on the right muscular part of the diaphragm.

The diaphragmatic EMG signals were amplified and analyzed for triggering the PCM stimulation units (Fig. 1)

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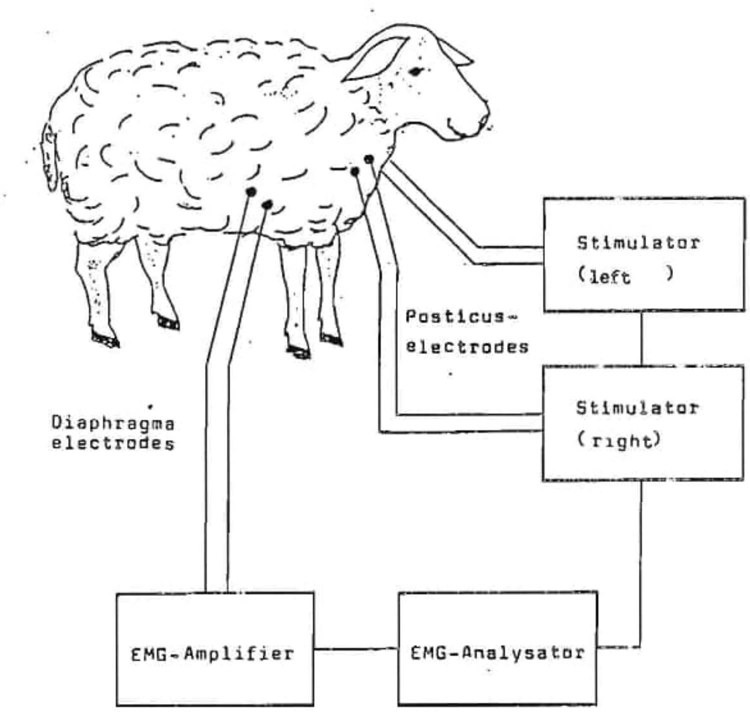

Fig. 1: Scheme of the diaphragmatic EMG, respiration correlated, stimulation of the PCM in sheep.

The stimulation effect was documented by the help of a 70° magnificy laryngoscope and a fiber endoscope connected to a video camera (fig. 2).

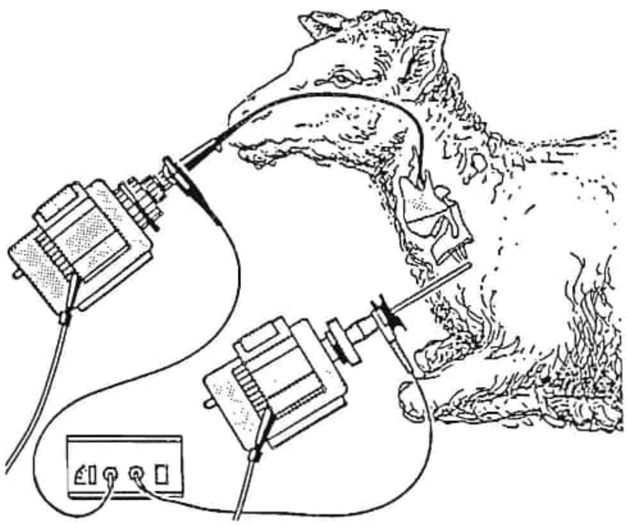

Fig. 2: Scheme of vocal cord abduction documentation with a fiber endoscope and a magnificy laryngoscope.

The laryngoscopic video documentation was performed via a tracheostomy, the fiberoptic was inserted through the nose.

RESULTS

In all 5 animals sufficient bilateral vocal cord abduction was obtained by means of inspiration correlated direct electrical stimulation (fig. 3,4).

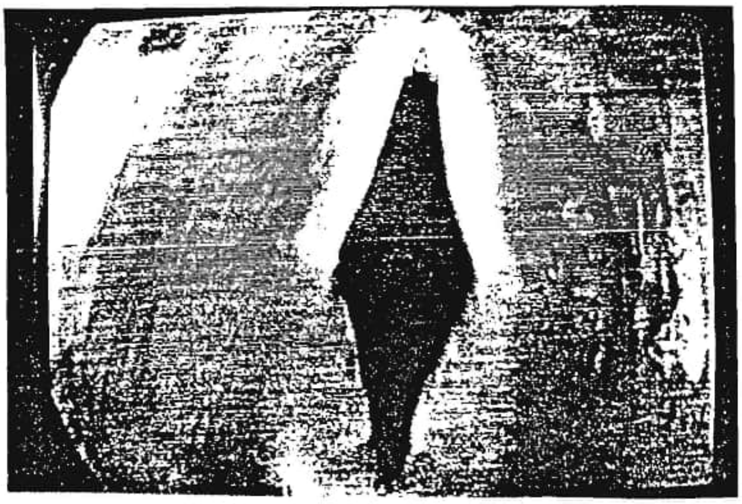

Fig. 3: Magnificy laryngoscopic view of a sheep glottis in rest.

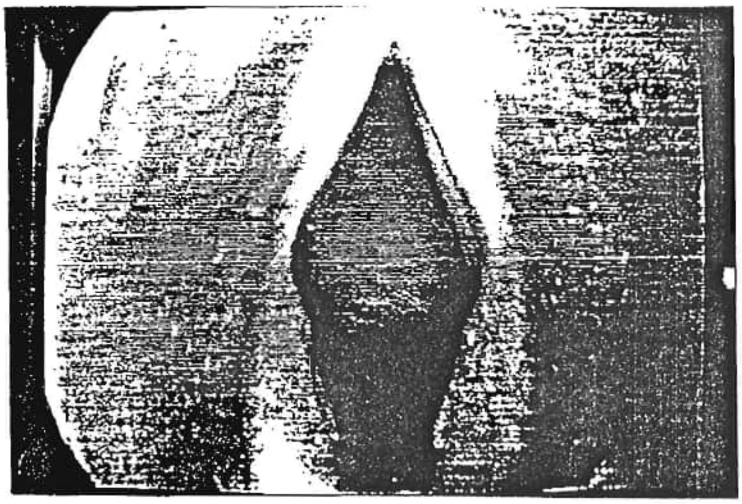

Fig. 4: Magnificy laryngoscopic view of a sheep glottis during bilateral direct electrical stimulation of the denervated PCM's.

In one animal without tracheostomy no respiration problems occurred during bilateral direct electrical stimulation of the denervated PCM.

DISCUSSION

Our experiments show that diaphragmatic myogram-controlled direct electrical stimulation of both paralytic PCM's is possible for a short period of time.

Since in sheep the majority of inspiration cycles shows a common onset or a leading edge of up to 40 ms for the PCM, no negative effects on respiration need be anticipated.

The supposition that human respiratory cycles show similar behaviour leads to the conclusion that a direct electrical stimulation of the glottis opening muscles with a diaphragmatic myogram physiological trigger controlled device becomes feasible for humans.

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THERAPEUTICAL EFFECTS OF DIRECT ELECTRICAL STIMULATION IN FLACCIC PARALYSIS

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Summary

Conventional electrical stimulation (ES) is not very effective in preventing atrophy and loss of force in flaccid paralysis. Based on some new ideas, we had invented a new stimulation mode, delivering bidirectional rectangle impulses of a longer duration than normally used. In extensive animal experiments, this new current form had proved efficacy morphologically and physiologically, and in addition had not produced any muscle damage. Preliminary results in 2 patients show, that atrophic changes and changes of contractility, occurring after denervation and/or stimulation, are reversible. In one patient with cervical root avulsions, ES led to an increase of muscle force, strong contractions of flexor and extensor muscles of the wrist were possible. After withdrawal of therapy, usual atrophy appeared and muscle force decreased dramatically. In a 17 years old female with a traumatic flaccid paraplegia of both legs, six months after the onset of therapy, ES was able to lift the calf up to a horizontal position, with the patient sitting on a chair. Based on these observations, we intend to apply our therapeutical regimen now on a greater amount of patients.

Introduction, Materials and Methods

In a lot of animal studies from the last 150 years, completed by a few clinical investigations, conventional ES had failed to prove efficacy in preventing atrophy and loss of force in flaccid paralysis (5,7). Considering the great variety of current forms, impulse durations, impulse frequencies and training regimens, which had failed to be effective, and those, which had shown some specific effects on muscle fiber contractile properties, we had decided to test a new current form, with the question, if it might be capable of inducing strong tetanic contractions even a long time after denervation, and if it could be applied by skin electrodes with a minimal expense.

Opposite to continuous stimulation techniques, we set up an experimental regimen in animals analogous to strength training in man, where intense periods of activity are undertaken for only a few hours several times a week. Presumably a long-lasting increase in protein synthesis is initiated during these periods of stimulation (8), which might be a possible mechanism of action. We used rectangular impulses, because they are thought to be most effective, and only modified them in two aspects: Firstly, opposite to "physiological", very short impulse durations we chosed durations of at least 20 ms, considering membrane changes occurring after denervation, and secondly, current direction was changed during every single impulse, thus producing one 10-ms-rectangle, immediately followed by another 10-ms-rectangle of the other polarity, and this total impulse being followed by a 20-ms-break. With this management, a cathodal overload under the electrodes was impossible.

Denervated rabbit muscles were stimulated every twelve hours with an effective stimulation time of 6, 7.5 or 9 minutes/session. A 1-minute continuous stimulation was followed by a 5-minute break. With this regimen, fatigue during training was low. Contractions were isometric or isotonic, always tetanic and strong over the total period of the experiments up to eight months.

In patients, the regimen was similar. Using the same current form, the only difference was that at the onset of therapy impulses had to be longer (50-70 ms) to produce strong contractions, but could be shortened to 30-40 ms after several weeks of stimulation.

Results

In over 50 animals it had been shown by means of histology and force measurements, that typical denervation-induced atrophic changes could be avoided and even were reversible after a delayed onset of stimulation. After a reduction to 20 % of the initial, pre-denervation values within one month in a non-stimulated muscle, an increase of force was observable during the following stimulation, reaching values comparable to those before denervation (2,4). Typical histochemical changes have been reported (3,5), major signs of muscle damage have never been observed.

Now, as these most interesting facts have been shown in the animal experiments, demonstrating only positive effects and no disadvantage for the muscle, it should be urgent to investigate a larger quantity of patients. Although we have some experiences with single cases from the last decade, including results of other investigators using our technique (Kern and coworkers, Vienna), we really do not know at this moment, where will be the limits for our therapeutical success in future. Some possibilities can be shown by two examples:

Case 1:

A 16-year-old male suffered from a flaccid paralysis of the right arm due to root avulsions of C5-8 after a bicycle accident. The onset of ES was one month after trauma. Inconstant ES was performed approximately six times a week, in each session stimulating one muscle group (extensor and flexor muscles of the wrist) for three minutes. During seven months of training, muscle strength increased continuously. In addition, the force of the flexor muscles of the wrist increased at a rate of 20% during an intensive training of one hour daily within 11 days. This means, that the movement was so powerful, that it possibly could be used functionally. After the seven months of stimulation, the patient underwent a neurosurgical treatment (nerve grafting) and stopped his training. Reasons were: "lack of time" and "returning sensitivity". Two and a half years later, the same muscles had become clearly atrophic, and so, a reproducible force measurement was no longer possible. Sensitivity had come without any motor function.

Case 2:

17-year-old female. She had fallen from a horse, and a comminuted fracture of the first lumbar vertebra had been operated with dorsal spondylodesis. Neurologically she showed a persisting flaccid paraplegia of both legs and a total sensory deficit beginning at D11. 16 months later, Magnetic Resonance Imaging (MRI) documented a distinct atrophy ot the muscles in both legs. We began a direct muscle stimulation of all muscle groups of the thigh and the calf, using surface electrodes. Initially, the patient´s muscle strength was low (measured by a MYOMETER, Penny & Gilles), increased during the first three months of stimulation at a rate of about 20%, and six months after the onset of ES, the calf could be lifted up to a horizontal position, with the patient sitting on a chair. MRI documentation now showed a significant increase of muscle volume. During the following three months, muscle force and volume did not further increase. The only change of circumstances had been, that the patient now was vegetarian, there was no loss of body weight. Additional three months later, there even was a slight decrease of 5-10% of muscle strength. The patient told us, that she had stopped to perform the stimulation twice daily, and stimulated only once in the evening, because she prepared for some important school examinations. Effective stimulation time now was 1 minute/muscle group daily. She now received a more comfortable 8-channel stimulation device with a 3-fold effectivity of stimulation during the same time, the effective daily training time increased, and muscle strength increased too (e.g. the flexor muscles of the calf to about 100N).

Discussion

These two cases show in an exemplary manner, that 1) an adequate training can be very short and is able to maintain muscle force, which - in a paralytic arm - possibly can be used functionally. If longer training times are possible, the contraction force can be improved dramatically within a few days. The stimulation effect is reversible and does not seem to depend from the amount of stimulation time alone, but also from the kind of nutrition; 2), a very important factor for the efficacy of ES is the patient´s motivation. All of our young patients seemed to be enthusiastic about the possibilities of ES in the early phase of therapy. Later on, most of them became a little depressive, they felt hopeless because a normal function of their paralyzed extremities would never come back again, and reasons of time were pretended why they had reduced or finally stopped their training. The last reason why an effective ES sometimes had to be stopped is the sensory reinnervation, which always occurred after the neurosurgical manoevers. With growing sensitivity, strong stimulation becomes painful.

In total, however, these cases show that in flaccid paralysis an effective ES might be possible from technical view, and an induced movement, which is strong enough to be used in the sense of functional electrical stimulation seems to be available, at least in the small muscle bulks of the forearm. It is, however, very important to stimulate the patient´s *motivation* too. His interest in all steps of therapy is a not negligible fact. We should learn together with every single patient, to find the individual limits of our therapy, which are set up from technical and personal reasons equally. The next decade then will show, where are the limits in general.

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FLEXOR RESPONSE ELICITED IN SPINAL CORD INJURED PERSONS' LOWER EXTREMITIES [1]

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SUMMARY

In paraplegic patient's FES enabled walking the swing phase is performed by eliciting flexor reflex. To increase maximal responses, the reflex behavior was studied in eleven SCI patients with lesion in the thoracic and one in the cervical region. Submaximal electrical stimulation was applied to stimulation sites above n.suralis, n.tibilis and n.peroneus. Hip, knee and ankle joint goniometric assessments, and separately isometric hip and ankle joint torque measurements were performed. The trajectories of the joints, toe and heel were calculated from goniometric data and evaluated with respect to obstacles such as stairs. In some patients EMG reflex activity was studied.
In patients with higher lesions (Th2 to Th6) EMG activity was recorded also in leg joint extensor muscles.The supposition was made that coactivation of agonist and antagonist muscle groups during reflex movement might be the reason for weaker biomechanical responses in this group of patients.

INTRODUCTION

In paraplegic patient's ground level walking enabled by a four channel surface Functional Electrical Stimulation (FES), the swing phase is performed by eliciting flexor reflex (FR) which results in synergistic movement of the whole leg [1]. In stair climbing higher hip, knee and joint angles are required (appr. 40, 65, and 20 Deg respectively) as well as higher joint torques in joints produced by responsible muscles. Single muscle response to electrical stimuli has been intensively investigated by neurophysiologists, but the behavior of a leg as a complex biomechanical system during flexor reflex response (FRR) to electrical stimulation is rearly reported in the literature. The aim of this study was to screen the abilities to increase FRR (flexor reflex responses) to electrical stimulation in order to enable higher number of paraplegic patients to ascend and descend stairs.

MATERIALS AND METHODS

PATIENTS

Twelve patients (see Tab.1) with complete (PL) or incomplete clinically determined level of spinal cord lesion were involved in the study, participating (Y) in isometric (ISO) hip and/or ankle joint torque measurements, goniometric (GON) assessment and surface EMG study (EMG).

ELECTRICAL STIMULATION

Surface monophasic electrical stimulation was delivered through button electrodes (20 mm diam.) by a laboratory made stimulator with variable pulse amplitude(0-130V), frequency(f=20-100Hz), duration (d=0.1-1ms) and adjustable pulse train interval (t=0.5-2s) . The time interval between two consecutive stimulation trains was at least 10s, and 20 minutes rest was taken before each new set of measurements.Stimulation sites above n.peroneus communis in the fossa poplitea region, n.suralis and n.tibialis at an ankle joint region were chosen.

EMG OBSERVATIONS

Submaximal stimulation (f=20Hz,t=0.8s,d=0.3ms) was applied to described sites with the pulse ampli-

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tude adjusted to 130threshold voltage in order to elicit FRR. Beckmann AgCl disc electrodes, 50mm2 were attached to m.rectus femuris (RF), m.biceps femuris (BF), m.tibialis anterior (TA) and m.gastrocnemius (G). Medelec ER94/SENSOR system was implemented for EMG recordings. Eight consequent registered EMG FR (flexor responses) were rectified, averaged, and the area of EMG signal was estimated for each muscle. Muscle activity was classified into H-high (100 μVs), M-medium (50 μVs-100 μVs), L-low (50 μVs), and 0- activity.

INIT	SEX	TYPE LESION	LESION LEVEL	LESION DATE	REASON	AGE	FES STATUS	M EASUREMENTS ISO	GON	EMG
MZ	M	PA	C6	06/86		30				Y
DA	F	PL	Th2-4	01/87	SH	36		Y		
DS	F	PL	Th4-5	06/87		18	WA	Y		
SP	F	PL	Th5-6	**/82	TR	28	CR,S	Y		
AM	F	PL	Th5-6	10/86	TR	18	CR	Y		
SV	M	PA	Th6-9	04/87	TR	29	CR	Y		
SZ	M	PL	Th7-9	03/87	OT	30	CR	Y		Y
GK	M	PL	Th8	10/87	FA	42	WA	Y	Y	
FC	M	PL	Th9	05/87	TR	32			Y	
RK	M	PL	Th10-11	03/87	FA	37	WA	Y	Y	
DR	M	PL	Th11	11/86	TR	22	CR	Y		Y
DO	F	PL	Th12	12/84	FA	18	CR,S	Y	Y	Y

LEGEND: M-male, F-female, PA-paretic pat., PL-plegic pat. SH-shot, TR-traffic accident, FA-fall, OT-other CR-FES with crutches, WA-FES with walker S-in FES stair climb.prog., Y-involved

Table 1: Population of the involved SCI patients

ISOMETRIC MEASUREMENTS

FRR were elicited above n.peroneus and n.suralis. Laboratory made isometric hip joint torque brace mounted on a tilt table and an ankle joint torque brace with a specially designed chair were used in torque assessment. Both braces were instrumented with strain gauge transducers. Hip and ankle joint assessment were performed at different days.The recruitment curve characteristics T=T(U) were sampled one trial at each point, separately for each nerve and then with a simultaneous stimulation above both nerves.

GONIOMETRIC MEASUREMENTS

Patient was positioned on a tilt table in an upright position with a tested leg at the tilt table site. 3-D goniometers (TRIAX Chattex,USA) were mounted unilaterally to a patient's randomly selected leg. Goniometric data were sampled by the PC-based TECMAR data acquisition system. FR recruitment curve characteristics A=A(U,f,d,L) were sampled three times at each point. Toe and heel point trajectories were restored from raw data. Electrical stimulation with the pulse amplitude at 130the threshold voltage was applied. It should elicited reflex activity resulting in sufficiently high leg joint angles to overcome 14cm raiser of testing stairs.

RESULTS

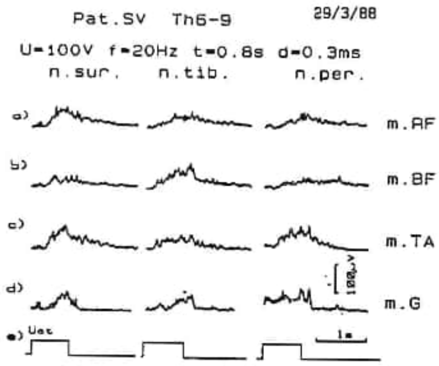
EMG OBSERVATIONS

An example of registered rectified and averaged EMG activity as a consequence of eliciting FR for patient SV is presented in Fig. 1. EMG response was quantitatively assessed for all patients as shown in Fig. 2 (EMG INTEN). M.TA becomes highly active (H) whenever FR is evoked. In patients with higher lesion (patients MZ,AM and SV) also the extensor m.G shows high activity with the EMG area larger then 100 μVs (H).The same is with the m.RF in patients MZ and SV. In lower lesion patients Th7-Th12 only low or no activity was registered in muscles other then m.TA.

ISOMETRIC MEASUREMENTS

The recruitment curve shown in Fig. 3 displays saturation of ankle joint curves at much lower stimulation

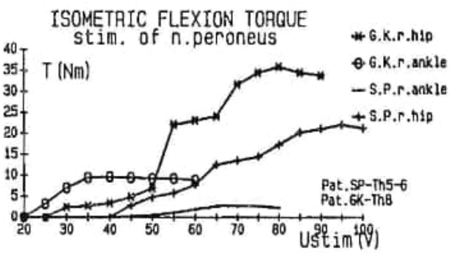
voltages as hip joints. Torques produced by patient GK (with lower thoracic lesion than SP) are generally higher (see Fig. 3), also with larger inclination than for the patient SP.
In Fig. 4 patients involved in ankle joint torque measurements (see Table 1) were ordered according to the level of lesion. Peak torque values in general increase with the decrease of the lesion level. This is valid especially in case that FR was elicited simultaneously above n.peroneus and n.suralis. Exception is the patient SZ with the highest torque values in all three stimulation variants.



PAT. INIT	TYPE LESION	LESION LEVEL	NERVES INVOLV.	EMG INTEN. RF	BF	TA	G
HZ	PA	C6	S	H	H	H	H
AM	PL	Th5-6	T	M	L	H	H
SV	PA	Th6-9	P,S,T	H	H	H	H
SZ	PL	Th7-9	P,S,T	L	L	H	L
RK	PL	Th10-11	P,S,T	0	L	H	0
DR	PL	Th11	P,S,T	0	0	H	0
DO	PL	Th12	P	0	L	H	L

LEGEND:
Lesion: PA-paretic pat. PL - plegic pat.
Nerves: P-peroneus S-suralis T-tibialis
EMG intensity: H-high,M-medium,L-low
Muscle:RF-rect.femuris,BF-biceps femuris
TA-tibialis anter.,G-gastrognemius

Figure 1: Rectified and averaged EMG elicited by stimulation above three nerves in Th6-9 patient.
Figure 2: Data on patients involved in EMG measurements with indicated level of EMG activity in four muscles, elicited by the stimulation above P,S,T nerves.



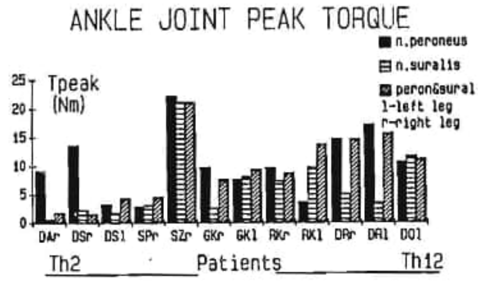
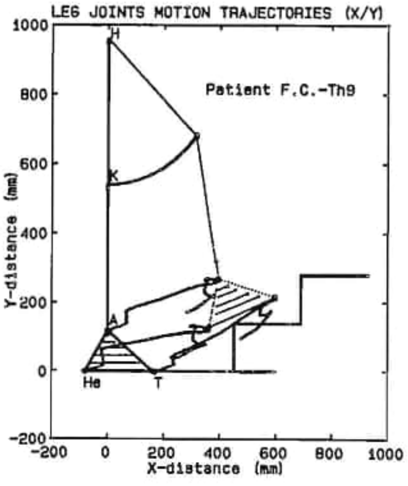


Figure 3: Results of isometric torque measurements in ankle and hip joint for patients GK ant SP.
Figure 4: Peak torque values produced in ankle for SCI patients ranged to their clinically established lesion level.

GONIOMETRIC MEASUREMENTS

Due to the limited sise of the paper raw data of goniometric measurements (see Table 1 - GON) are not reviewed. In order to prove the findings of extensor muscle activation during FRR reported above, only an example of restored knee (K), ankle (A), heel (H), and toe (T) trajectories for single measurement is presented in Fig. 5. The angles produced during FRR were high enough that the leg would this time move above an imaginary step with 14 cm raiser. As the stick figure shows, the leg position at the toe peak position expresses an active extension in the knee joint. In Fig. 6 differences in ankle and knee joint horizontal displacement are shown during four consequent FRR. Each time the value (Xa -Xk) is positive, ankle joint proceeds the knee joint: in other words, knee is extended. Early after the stimulation (Ustim)



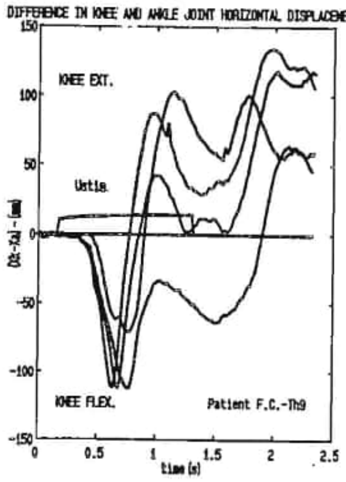


Figure 5: Stick figure presentation of flexor reflex response with computed trajectories calculated from goniometric data.

Figure 6: Difference in ankle and knee joint horisontal movement during four consequence flexor reflex responses. Above sero-line part of all curves indicates knee extension.

occurs, knee is flexed, becomes then extended, and remains extended to the end of the measurement. The lowest curve in the chart belongs to the smallest FRR, which would result in bump of a foot at a stair.

DISCUSSION

EMG activity in extensor muscles registered during electrically elicited FRR in higher spinal cord lesion was an initiative to investigate the consequences of coactivation of agonist and antagonists muscle. The presence of EMG in extensor muscles highly correlates with the low torque values produced in the ankle joint in all higher lesion patients (compare Fig. 2 and results in Fig. 4). Also the torque values in Fig. 3 are higher for patent GK with lower lesion compared to results of the patient SP. One of the possible explanation might be, that with higher values of stimulation in patients with higher thoracic lesion a mass response is elicited with both agonist and antagonist muscles activated in the knee and the ankle joint. The expected movement of the stimulated leg is therefore suppressed. This is not the case in lower lesion patients (Th8-Th12). The results of goniometric measurements further confirm the undesired role of knee extensors in FRR.

In FES enabled stair climbing trials [2] knee extension prevents good hip flexion during swing phase of climbing sequence. Patient SP (Th5-6) was also able to climb and descend several stairs but with considerable hand support. On the other hand, FES rehabilitation praxis shows that patients with higher lesions are appropriate candidates for ground level walking where large flexion angles in H,K,A are not required (see Table 1, column "FES STATUS").

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CHARACTERISATION OF THE FLEXION WITHDRAWAL RESPONSE

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SUMMARY

The flexion withdrawal response is a spinal reflex which results in flexion of the limb in response to a potentially harmful stimulus. Attempts to restore locomotion in paraplegics by means of Functional Electrical Stimulation (FES) often use flexion withdrawal reflexes to produce the swing phase of gait (1). However certain problems have been encountered when using this response these being :- long latency of the reflex and a decreasing response to repeated stimuli known as habituation. Previous studies (2,3) of this reflex in man have concentrated on EMG of the lower limb muscles and as such there are limitations in its usefulness in FES where actual movement of the limb is of more interest. The present study was intended to examine the response in terms of joint angles. In addition if this response is to be used functionally then there is a need to define a baseline of variability of the response both between subjects and day to day variability in each subject.

Different patterns of response to the repeated stimuli are presented and the significance of these differences in relation to production of gait are discussed.

MATERIALS AND METHODS

Penny & Giles flexible goniometers were attatched to the subject's hip, knee and ankle with adhesive tape or velcro straps. To approximate to a normal limb position in stance the tests were performed with the subjects vertical. This was obtained with the subject either between parallel bars, if an incomplete SCI or strapped to a tilt-table if a complete SCI with the feet in contact with the floor or footplate of the tilt-table. During the tests the subjects were instructed to stay as upright as possible while looking straight ahead.

The response was elicited by surface stimulation of the common peroneal nerve, as it passes around the head of the fibula using Myocare 3M electrodes (size 35x25mm) or Pals Plus electrodes. The stimulus parameters used were frequency 25Hz, pulsewidth 300μs, stimulus train duration 0.5s repeated every 2s. This was produced using an 8 channel stimulator controlled by a BBC microcomputer. The electrode site and level of stimulation were adjusted with the subject in a vertical position until approx 30 degrees hip flexion or the maximum stimulus intensity that could be tolerated by the subject was reached.

The joint angles and timing of the stimulus pulses were recorded on a Compaq computer with an Amplicon PC26A 12bit A/D converter using a data collection program.

ACKNOWLEDGEMENTS

This work was funded by the Scottish Home and Health Dept. MRC and SERC. The help of the staff and patients at the Spinal Injuries Unit Philipshill Hospital Glasgow is acknowledged.

Due to memory size of the computer the amount of data that could be collected sampling 5 channels at a high frequency was limited. Therefore it was decided to carry out 2 tests on each leg as follows :-
Test 1. Response to 10 stimuli sampling at 200Hz to allow examination of the response in detail and measure it's latency. .
Test 2. Response to 100 stimuli sampling at 20Hz to study the effect of repeated stimulation on the maximum angle of flexion obtained. With some subjects Test 2. was stopped before 100 stimuli if limb movement in response to stimuli had ceased.

Two subjects with complete lesions of the spinal cord and four subjects with incomplete lesions were studied. (see table 1) The tests on each subject were repeated at the same time of day on at least 3 occasions.
Table 1.

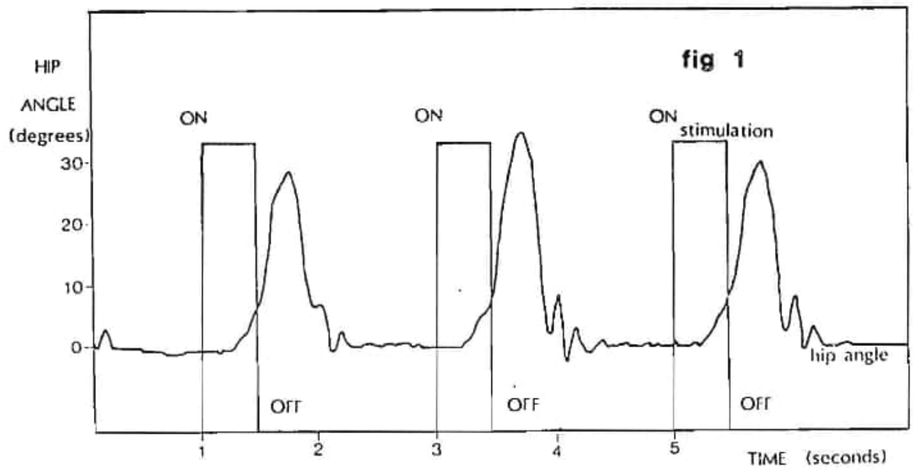
Subject	Level of Injury		No of Times Tests Repeated
A	T5/6	I	4
B	C5	I	4
C	T12	I	5
D	C4	I	5
E	T6	C	4
F	T6/7	C	3

The data was analysed using a program which defines the start of stimulation and finds the maximum angle reached in the 2 seconds following the onset of stimulation. (fig 1) This is repeated for each train of stimulus pulses.

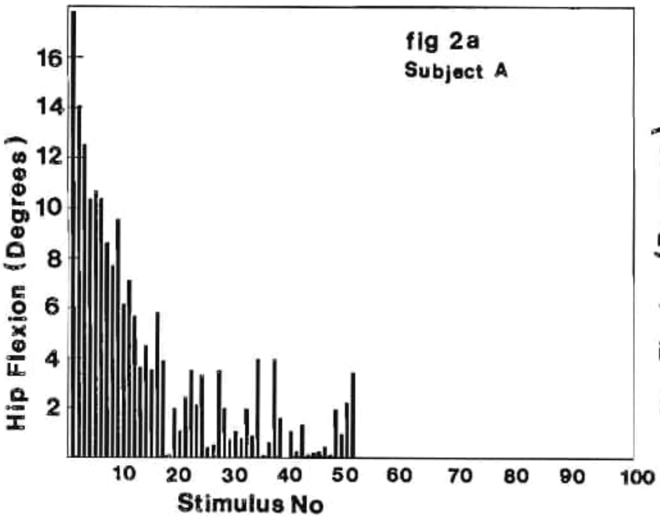
The maximum angles of flexion reached during each stimulus train (Test 2.) were plotted against stimulus No. (fig 2a, b, c.)

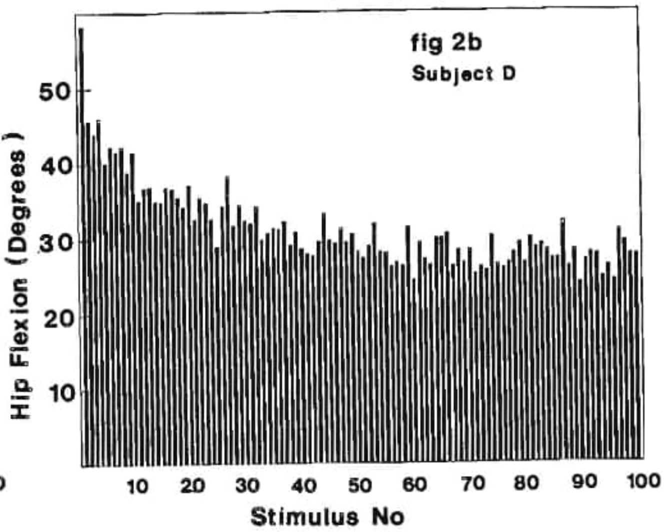
RESULTS

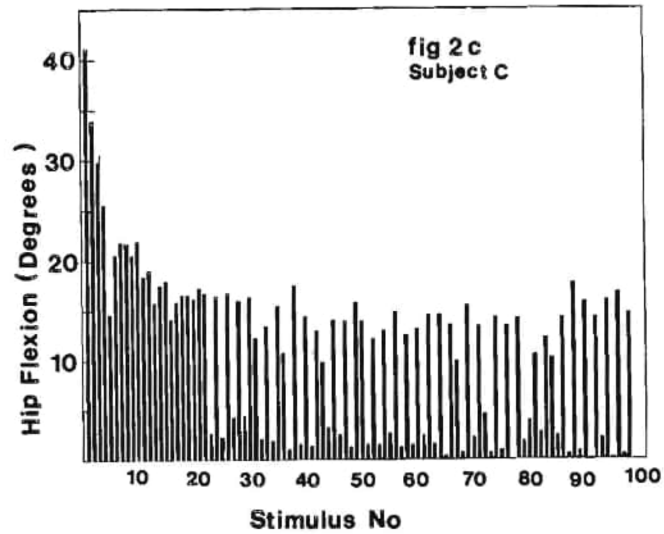
fig 1. shows stimulation strategy and recording of hip angle. fig 2a, b&c shows resulting angle of hip flexion with repeated stimulation. Stimulus parameters 25Hz, 300μs, stimulus trains 0.5s repeated every 2s.



Typical plot of hip angle with stimulation







DISCUSSION

With each of the subjects tested different patterns of hip flexion were obtained in response to repeated peroneal nerve stimulation. Whilst all subjects show a decline in the amount of hip flexion over the first 10 stimuli there is considerable variation there after. fig2a,b&c shows three of the different patterns of decay that were obtained.

Initial hip flexion of 16 degrees was obtained in subject A with the response rapidly decaying to less than 5 degrees after 15 stimulus trains. Data collection was stopped after 50 stimuli. In contrast subject D exhibits greater hip flexion at a lower stimulus intensity than subject A with initial hip flexion of greater than 50 degrees. Although decay of the response is still present after 100 stimuli it is a much slower decline with hip flexion of 30 degrees occuring at the end of the test. A third variation in the pattern of response occured in subject C . During the first 20 stimulus pulses rapid decrease in hip flexion is shown (fig 2c) ; thereafter the response alternates between little or no hip flexion and 20 degrees of hip flexion. When it occurs hip flexion of approx 15 degrees is recorded and this level of hip flexion remained over the 100 stimuli. However no hip movement resulted from every second or third stimulus pulse although the stimulus was still perceived by the subject. The continued decay of the response shown in subject A. This alternating pattern was recorded on several days in subject C. Subject E and F exhibited rapid decay of the response. Subject B showed an increasing response with time.

The latencies of the reflex response will be discussed in a future publication.

Future FES control systems will have to accomodate both the long latency of this response and it's variability in terms of functional hip flexion. It is likely that this reflex response will have to be measured on an individual basis if it is to be used functionally in gait using electrical stimulation.

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EFFERENT ELECTRICAL STIMULATION OF HIP FLEXORS USING SURFACE ELECTRODES

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SUMMARY

In gait, hip flexion is essential for the effective production of the swing phase (2,4,5). Afferent stimulation by eliciting limb flexion is currently the most commonly used stimulation pathway to obtain this (2). The problem with afferent stimulation is habituation, variability of response and long latency periods (1,3). The efferent stimulation of hip flexors using surface electrodes has the potential advantage of reducing latency and variability and avoiding habituation and thus improving the controllability of response.

Tests were conducted on 3 complete spinal cord injury subjects (T4-T7) to determine :-
a. Optimum motor point locations,
b. Isometric hip moment responses,
c. Isometric hip moments vs. pulse width recruitment curves and

Electrical stimulation was applied to 5 surface motor point locations to recruit hip flexors individually and in combination. Measurements were taken using a test rig which maintained the subjects in an upright posture in order to simulate a walking situation.

This method of hip flexion has been tried in a complete and in an incomplete spinal cord injury subject to assist in the swing phase of gait and is being applied in walking at home.

MATERIALS AND METHODS

Outline of Experimental Setup

The hip flexor rig maintained the subject in an upright posture in a half seat and two upper limb support configuration (refer fig1). The test limb was locked at the knee with a brace and was free to assume varing degrees of hip flexion.

Isometric hip moments were calculated from the tensile force measurements in the restraining cable. Abduction was detected by the change in alignment of the restraining cable. A pulley-potentiometer connector transducer detected rotational displacement of the thigh.

The test setup used one microcomputer for stimulation control and another for data aquissition. The stimulator control microcomputer triggered the commencement of data collection via a printer-A/D link.

Acknowledgement: Dr. Delargy, staff and patients of the Spinal Injuries Unit, Philipshill Hospital, Glasgow, U.K.

The Strathclyde 8 Channel Computer-Controlled Stimulator System

The stimulator system used in this project was the Strathclyde Research Stimulator which is a constant current Functional Neuromuscular Stimulator. The particular model employed was an 8 Channel model controlled by a BBC ACORN microcomputer (6502 microprocessor and 6522 I/O).

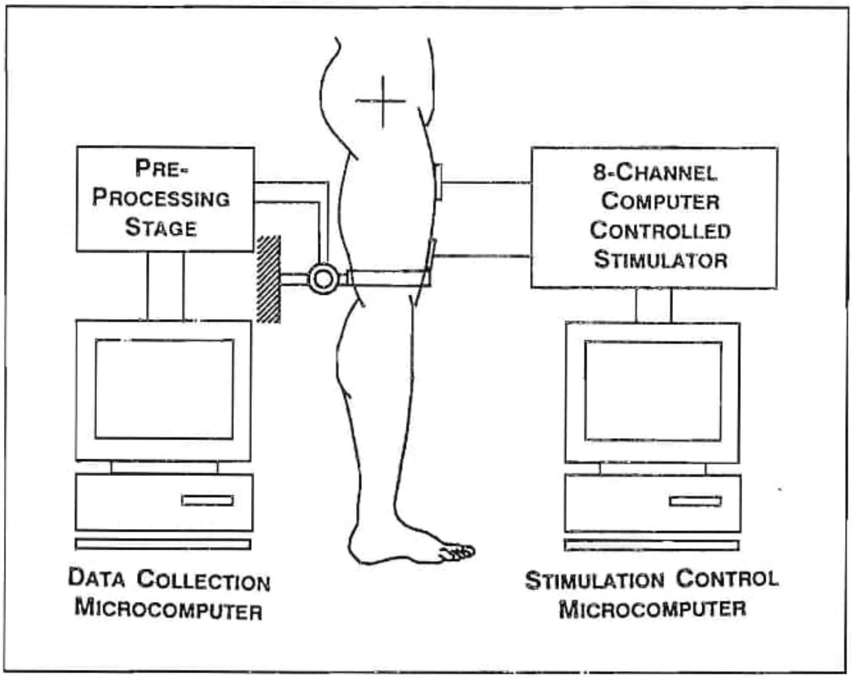

Figure 1 : Experimental Layout

The stimulator delivers asymmetric monophasic pulses under the specifications :

Stimulation Parameters	Operating Range	Normal Range
1. Current	0-150mA	120-150mA
2. Voltage	180V	4180V
3. Pulse width	2-500μs	0-300μs
4. Inter-Pulse Interval	10-500ms	50ms
5. Frequency	2-100Hz	20Hz

Surface electrodes used were 3M self-adhesive conductive rubber elecrodes.

Hip Moment Stimulus
A one second transient pulse train at 300μs pulse width.

Recruitment Stimulus
For the hip moment recruitment test, the pulse train consists of :-
a. ramping up pulse width from 0μs to 300μs at 2μs per 20ms (7.5s duration)
b. constant at 300μs for 2.5s and
c. ramping down pulse width from 300μs to 0μs at 2μs per 20ms

Hip Flexor Muscles and Motor Point Locations

With reference to known muscle and nerve motor points, optimum hip flexor motor points were mapped by motor point probing. The results refer to the motor point located rather than specific hip flexor muscles. The motor point positions are labelled by their anatomical proximity :-

a. adductor longus,
b. femoral nerve,
c. gracilis,
e. rectus femoris and
f. tensor fasciae latae.

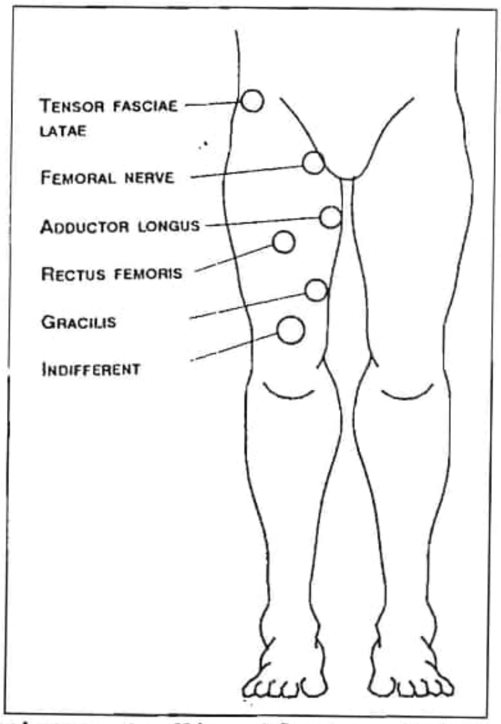

Figure 2: Hip Flexor Motor Point Locations

RESULTS

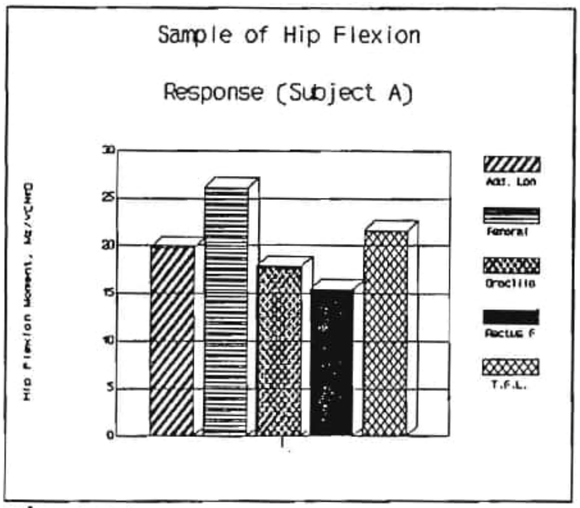

Figure 3

Hip Flexor Application

Application of hip flexors in gait used the Strathclyde Research non-programmable 2-channel stimulator which in the sit/stand mode, outputs 20Hz transient pulse trains controlled with hand held switches.

Subject A

Complete T4, 40 year old male,
No motor or sensory function.
4 years post injury

For everyday mobility, subject A walked with a reciprocating gait using calipers and a rolator. He relied on trunk muscle and the inertia of the lower limbs to implement the swing phase. Stimulus applied to the femoral nerve motor point produced hip flexion which improved the swing phase of gait. The subject expressed an improvement in the effort required in walking using FES assisted hip flexion and the faster response which allowed him to maintain a more costant walking speed.

Subject B

Incomplete T6/7, 40 year old female.
Partial motor and sensory function in both lower limbs. Normal proprioception.

5 years post injury.
Subject B was able to walk using the peroneal reflex and quadriceps stimulation with the aid of a rolator. The gracilis motor point was implemented and produce hip flexion and knee flexion, with no undesirable adduction (improving ground clearance). The subject expressed that by comparison with peroneal stimulation, there was a preference in stimulus sensation and noted the faster response obtained.
Subject B accepted the use of gracilis stimulation for FES assisted walking at home and after a few weeks began to regain some voluntary hip flexion.

DISCUSSION

Hip moment values obtained for individual motor points indicate that they are of sufficient magnitude for consideration in assisting in the swing phase of gait. Used concertedly, their response could be adjusted to meet individual needs.

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Functional Training in Flaccid Paralysis With Multichannel Electrostimulation

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Functional electrical stimulation is applied in spastic paralysis with good success, the lost function is partially restored using surface or implanted electrodes. The handling in flaccid paralysis is much more difficult due to the different physiological status in the periperally denervated muscle. We present a "Measure-and-training-unit", a bicycle, based on an especially adapted "Home-trainer". Denervated muscles are stimulated using surface electrodes, the computer system varies its stimulation parameters according to the actual state of the pedals and pedal movements. Secondly, a 24-channel stimulation device is presented, which can be used by outpatients easily at home. The current forms are bidirectional rectangle impulses with 20-100 msec duration up to 70 mA intensity. Different indications for both stimulation systems are discussed. Preliminary results are encouraging.

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A GENERAL PURPOSE, PROGRAMMABLE, MULTI-CHANNEL, IMPLANTABLE STIMULATOR

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SUMMARY

A flexible, implantable stimulator, which can easily be adapted for various stimulation applications, has been developed. This device significantly reduces both cost and development time for a new stimulator. The device is based on a full custom waveform generator chip, which generates all desired stimulation patterns. This chip combines a high degree of programmability with a low power consumption and small dimensions. The waveform generator chip interfaces directly with the commercial 68HC11 microprocessor. Several stimulation patterns can be stored in the microprocessors EEPROM. The processor also takes care of all communication with the outside world, for which an infrared link is used. The stimulator can be controlled and even reprogrammed through this link. The use of error correcting codes for the data transmission strongly reduces the possibility of transmission errors, and increases the action radius of the IR link. The overall power consumption of the stimulator is minimised by making extensive use of the low power sleep mode of the processor, so that battery operation is possible. Provisions for multiple channels are available.

INTRODUCTION

Electrical stimulation has numerous applications in medicine nowadays, such as restoration of movement for paralyzed patients with FES /1/, pain reduction with TENS /2/, reduction of skeletal deformities in scoliosis stimulation /3/ and reduction of spacticity through spinal cord stimulation /4/.

Research is still in progress in most of these fields. This research requires stimulators specifically adapted to the particular needs of the application. Developing a new device for each application is both very costly and time consuming. It can be observed however that most stimulators are a subset of a general stimulator architecture /5/. The design effort for each new application with such a general stimulator is limited to the development of the application specific output drivers, which is relatively easy and can be done quite fast and cheap.

We present a general stimulation system that is extremely flexible and that is suitable for most stimulation applications. This stimulator is based on a waveform generator chip which has great programming flexibility. This waveform generator as well as the entire stimulator will be discussed.

FULL CUSTOM WAVEFORM GENERATOR CHIP

A full custom waveform generator chip has been developed for the stimulator. This chip is designed to interface directly with a microprocessor. The block diagram of the chip is shown in figure 1. The waveform generator can generate four types of waveforms: continuous pulses, pulse trains, continuous voltages and repeating sequences of voltages. The difference between voltages and pulses is that pulses always return to their baseline, while voltages do not.

The timing for these patterns is generated by a number of counters. Each counter is combined with a latch that holds the value of the parameter to which the counter is assigned. Six counters are provided: a pulse width counter (16 bit), a pulse period counter (16 bit), a train period counter (24 bit), a rise time and a fall time counter (8 bit) and finally a counter for the number of pulses in a pulse train (8 bit).

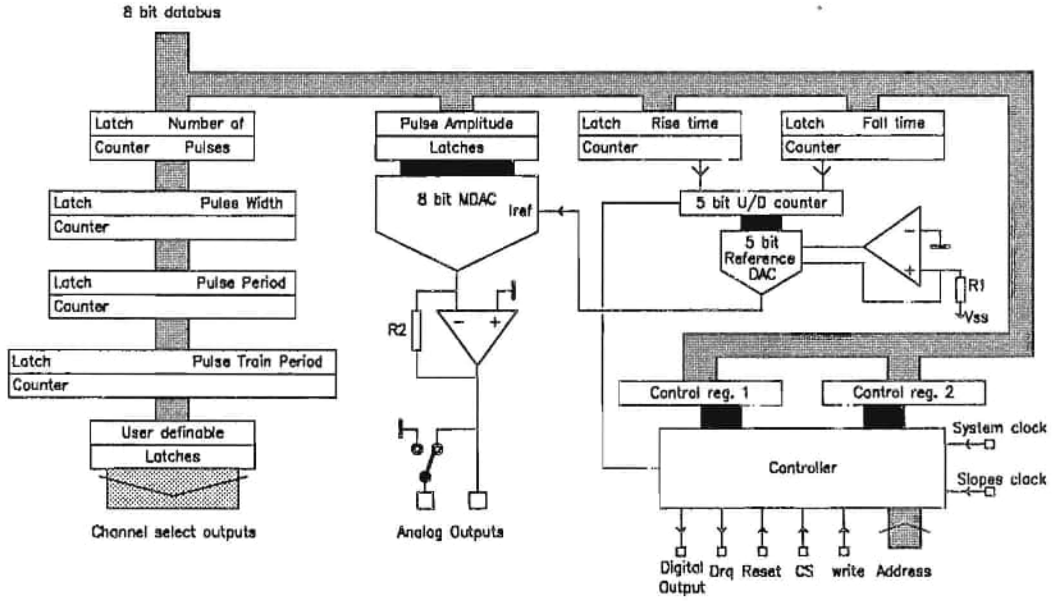

Figure 1: Block diagram of the waveform generator chip

The amplitude of the output pulse (or voltage) is generated by an eight bit multiplying digital to analog convertor (MDAC). The value to be converted is contained in a double latch. The processor can write to both latches. The value in the bottom latch is converted immediately, while the value in the top latch is transferred to the bottom latch at the start of each sequence, and is then converted. This allows for changing the output voltage without the counters being active.

The reference current for the MDAC is supplied by a five bit digital to analog convertor (DAC). This DAC is controlled by an up down counter, which counting speed is controlled by the rise and fall time latches. The output of the DAC is a current with the desired slopes but with a fixed amplitude. This fixed amplitude is generated by an operational amplifier and a resistor R1, and scales with the supply voltage. The current pulse is then multiplied in the MDAC with the desired amplitude. The result is a pulse with the correct slopes and the correct amplitude. The amplitude of the output pulses is thus proportional to both the value in the latch and the supply voltage. A

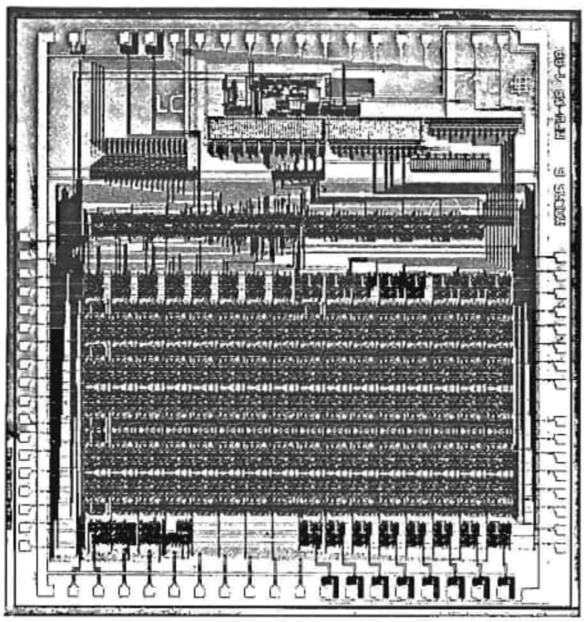

Figure 2: Microphotograph of the waveform generator chip

digital output is provided as well, for cases where no variable amplitude is needed. The pulses at this output have the desired timing, but have an amplitude equal to the supply voltage.

A double latch is provided which has a user definable purpose. The outputs of this latch are available off chip, an can for instance be used to select multiple channels. The entire circuit operation is controlled with two registers. The values contained in these control registers determine the operating mode of the circuit.

At the start of each pulse the data from the latches is loaded into the counters and the data request line (drq) is enabled, thus signaling to the processor that new data can be written into the latches. At the beginning of the next pulse this new data is used. This means that all parameters can be different for every pulse. For instance, a pulse train with increasing pulse widths can be generated. As another example, an eight bit approximation of a sine wave can be generated if the voltage mode is selected.

The power consumption of the chip is minimized by automatically disabling all circuits that are not used for a particular mode. The analog portion of the circuit can also be switched off, if only the digital output is needed. This reduces the current consumption from about 400 μA to less than 80 μA for a 5V supply voltage and a 100kHz system clock. The waveform operates on supply voltage ranging from 3 to 15 Volt. The chip has been realized in a 3 μm nwell CMOS process. The dimensions are 6 by 7 mm^2. Figure 2 shows a microphotograph of the waveform generator chip.

THE STIMULATOR CIRCUIT

The waveform generator chip works in close cooperation with a microprocessor, as has been mentioned previously. The selected processor for the stimulator is the Motorola MC68HC11, because of its excellent hardware features (on board communications interface, watchdog function, EEPROM, RAM,...) and its low power modes. Figure 3 shows a block diagram of the stimulator.

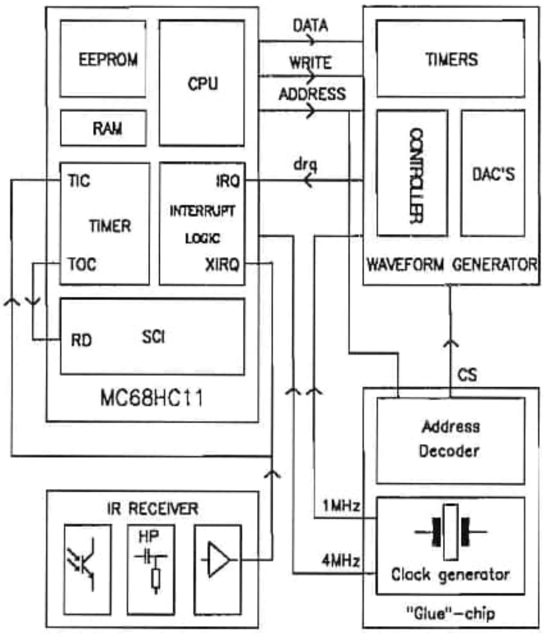

Figure 3: Block diagram of the complete stimulator

The stimulator is controlled through an infrared link /6/. The IR pulses are detected with a phototransistor. The background lighting is filtered out with a high pass filter, and the resulting signal is amplified to the full logic levels. These pulses are then shaped with the on board timers of the processor and are directed to its serial communications interface (SCI). This type of link has been chosen because the necessary hardware can easily be miniaturized and the link is both relatively fast and reliable. An error correcting code has been used for all data communication. This coding does not only considerably reduce the possibility of transmission errors, but also doubles the range over which the IR link can be used, as a limited number of transmission errors are now allowed.

All necessary interface logic, such as a low power clock generator and an address decoder, has been integrated on another full custom "glue"-chip. Provisions have been made to allow multiple waveform generator chips to operate in parallel. Completely independent multiple channels can be created this way, in contrast to the slightly dependent multiple channels that can be created using the user definable outputs of the waveform generator.

The processors average current consumption is reduced to a few microamps by making extensive use of its sleep mode. The 68HC11 is only pulled out of the sleep mode by either a data request from the waveform generator or an interrupt from the IR receiver.

The necessary stimulation patterns can be stored in the EEPROM of the processor. A desired pattern can then be initiated or changed with the IR link. The stimulator can also be completely reprogrammed through this IR link. An entirely different set of stimulation patterns can for instance be transferred to the stimulator. As the hardware is extremely flexible and all parameters of the system are software adjustable, the possible applications for this stimulator are virtually unlimited.

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Ideal frequency parameters for chronic neural stimulation in voiding dysorders

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The pudendal nerve was stimulated with a surgically implanted cuff electrode, coupled to a Medtronic receiver. A fixed amplitude and pulse width were used and frequencies that varied stepwise from 2 to 185 PPS. EMG responses picked up from the sphincter ani were recorded with a MacIntosh II computer and later analyzed. A complete loss of appreciable muscle contraction occured above 100Hz, associated with complete flattening of the action potentials. Muscle fatigue was noted with any frequency above 30Hz.
The optimal frequency for chronic stimulation appears to be 15 Hz. This setting provides the best combination of fused muscle contractraction for augmentation of urethral closure, inhibition of detrusor instability, patient comfort and tolerance minimal fatigue of the muscle contraction and preserved sense of awareness of the stimulus. The analysis of the EMG recording provided a profile of neuromuscular integrity.
This type of study will be of value in identifying patients who can be treated with electrical assist devices.

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A HANDGRASP DYNAMOMETER FOR MEASUREMENT OF MOMENTS AND FORCES GENERATED BY THE FINGERS

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SUMMARY

A dynamometer was developed to monitor isometric forces or moments applied by the fingers and thumb. The dynamometer was included in a closed loop system with computerized electrical stimulation. Preliminary measurements were carried out on the isometric moment response of the M.P and P.I.P joints to several stimulation functions. The controllability of application of predefined force functions by the finger and thumb segments was also examined.

MATERIALS AND METHODS

A grasp dynamometer was developed that measures the isometric moments applied by the M.P and P.I.P joints in the hand. The dynamometer can be adapted to measure isometric forces applied by the fingers and thumb.

The dynamometer contains 10 strain gauge bridges, two for each finger. They are connected through amplifiers (SGA-300, CIC electronics) to the A/D of an APPLE-2 computer.

The dynamometer for measuring moments

The measured joints are arranged directly over the strain gauges.

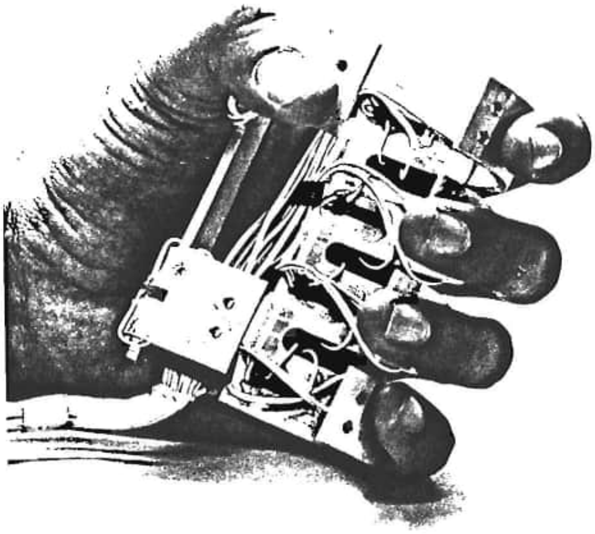

Figure 1: Grasp dynamometer measuring joint moments.

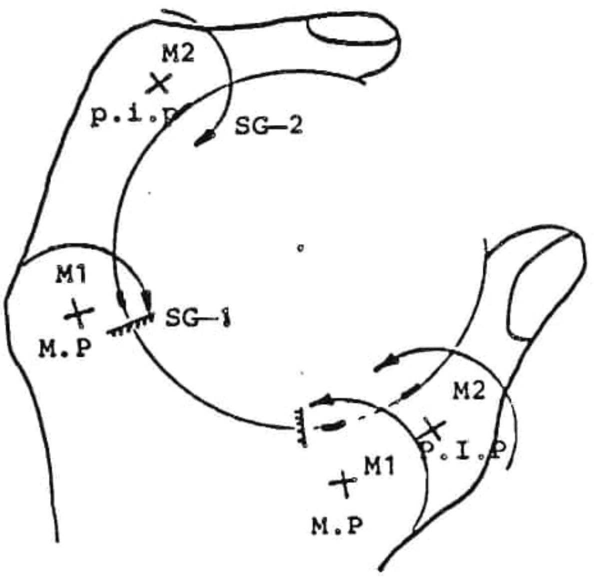

Figure 2: Diagram of moments applied to grasp dynamometer.

Moments applied at M.P joint are directly transferred to the dynamometer tongue and are measured directly by SG-1. SG-2 measure directly the moment at the P.I.P joint, and are converted to units of [Kg·m].

The dynamometer for measuring forces

For measuring forces an extension is connected to each tongue as shown in Figure 3.

Figure 3: Grasp dynamometer measuring applied force.

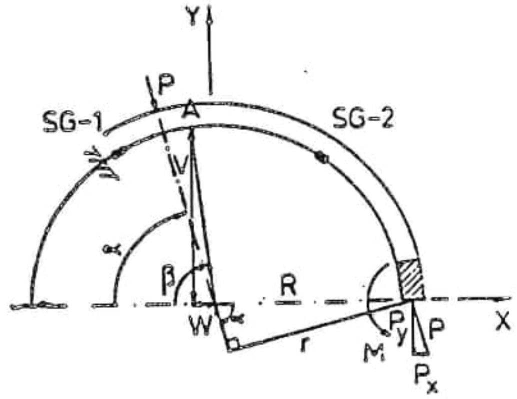

Figure 4: Diagram of forces dynamometer.

The extensions transfer the moments of the total resultant force generated by each finger to both strain gauges as seen in Figure 4.

We have, for the x and y components of a radially acting force P

$$V = R \sin \beta \qquad (1) \qquad\qquad W = R \cos \beta \qquad (2)$$

$$P_x = P \cos \alpha \qquad (3) \qquad\qquad P_y = P \sin \alpha \qquad (4)$$

giving a moment at the distal end of the tongue,

$$M = PR \sin \alpha \qquad (5)$$

For any point A on the inner tongue.

$$\Sigma M_A = P_y(R + W) - M - P_x V = PR \sin \alpha(1 + \cos \beta) - PR \sin \alpha - P \cos \alpha \, R \sin \beta$$

$$\Sigma M_A = PR \sin(\alpha - \beta) \qquad (6)$$

M_A is positive if $\alpha > \beta$

Strain gauge - 1 measures M_1 where

$$M_1 = PR \sin(\alpha - \beta_1) \qquad (7)$$

Sg - 2 measures M_2 where

$$M_2 = PR \sin(\alpha - \beta_2) \qquad (8)$$

and R, β_1 and β_2 are constants of dynamometer geometry. α is eliminated between equations (7) and (8). This gives P

$$P = \frac{M_1}{R \sin\left(tg^{-1} \dfrac{M_1 \sin \beta_2 - M_2 \sin \beta_1}{M_1 \cos \beta_2 - M_2 \cos \beta_1} - \beta_1\right)} \qquad (9)$$

RESULTS

An average scatter of ±2% was found during calibration of the dynamometer. The stimulation system includes surface electrodes, and an 8 channel stimulator controlled through D/A of an APPLE-2 computer.

A mass activation of the forearm flexor muscles caused the grasping action.

Fig. 5 shows the isometric moment response of the M.P and P.I.P joints using surface electrical stimulation of the forearm flexor muscles, for a step current input of 10 MA amplitude.

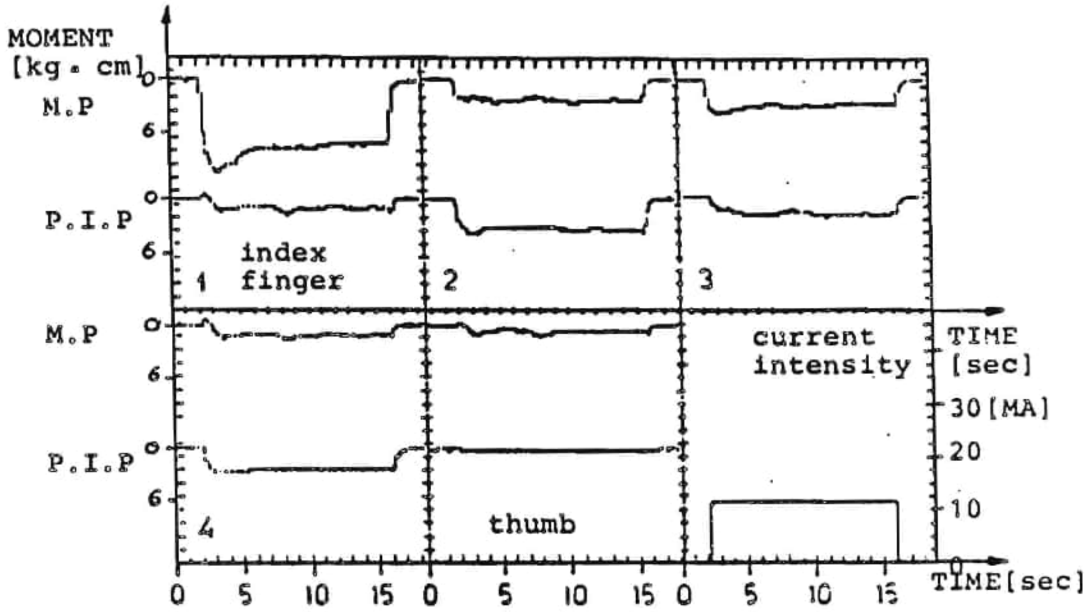

Figure 5: The finger joint moment response to step current input.

Fig. 6 shows for a frequency of 0.2 HZ the response for a sinusoidally modulated current of 10 MA amplitude.

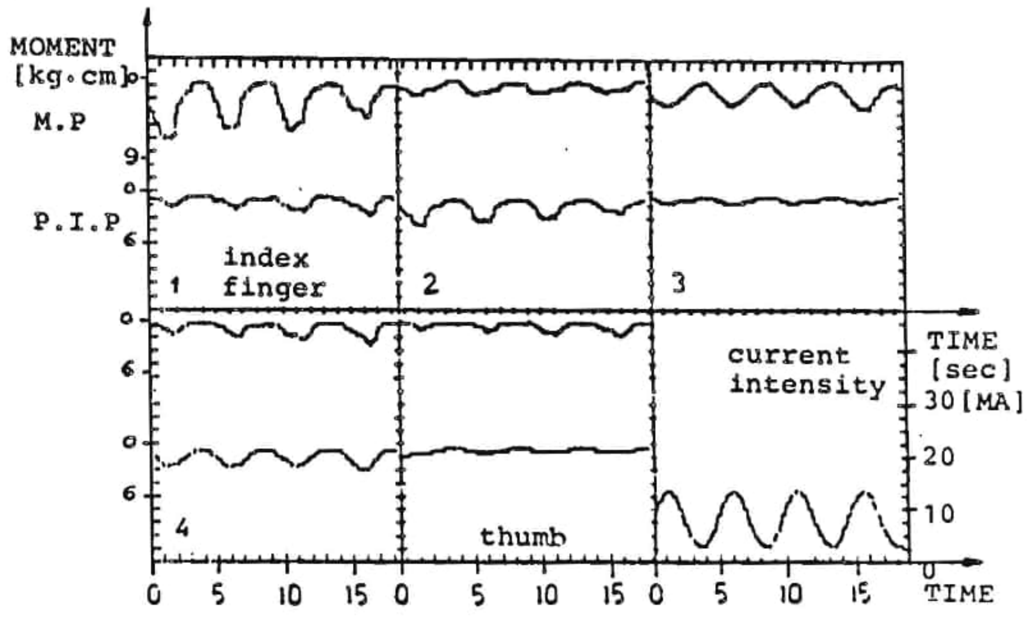

Figure 6: The finger joint moment response to sinusoidal current input.

A closed loop control system was developed for generating a preset total force: the sum of the five resultant forces in the fingers and thumb. Fig. 7 is the response for a 3 kg preset force. Other parameters of interest may be calculated and displayed on-line. Figure 7 shows examples of these: the resultant force, its angle and height, applied by the four fingers are displayed separately from the thumb force. The vectorial sum of these two forces will be equilibrated by a force applied by the palm of the hand.

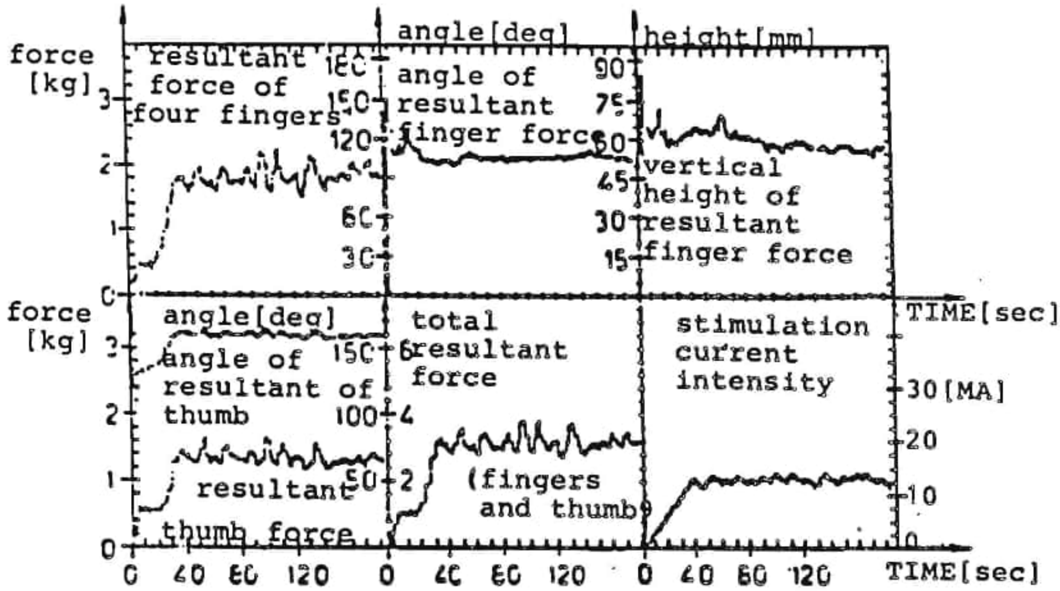

Figure 7: Closed loop force response for preset gripping force.

DISCUSSION

The dynamometer has been used in research to monitor the isometric moments and forces during FNS of both healthy and paralyzed hands. Tethering each finger to the dynamometer tongue allows measurement of finger extension. Abduction/adduction cannot be measured. A low friction interface (Double PVC film) was used between the hand and the dynamometer to ensure that forces are acting perpendicularly only to the dynamometer tongue. The present dynamometer has strain gauges in fixed positions necessitating careful arrangement of the hand configuration with each measurement to ensure the finger joints overlay the strain gauges exactly. A universal dynamometer with adjustable tongues is being designed.

The system is designed to allow research into muscle response and gripping actions under FNS. It has been used on research of the transfer function of the system with healthy and paralyzed muscle and for assessment and monitoring of the pathological condition of the hand. It could also be used in sports research.

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EFFECT OF MAGNETIC RESONANCE IMAGING ON IMPLANTED NEUROSTIMULATORS

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The use of magnetic resonance imaging (MRI) for diagnosis continues to increase, as does the number of patients in whom therapeutic neurostimulators are being implanted. Although the present policy of health care facilities is to prohibit MRI in patients with neurostimulators, the interference from the MRI fields may not necessarily pose a problem. Thus, we designed a study to investigate the effects on neurostimulator receivers of the static and changing magnetic fields and the radio frequency (RF) electromagnetic field generated by the MRI scanner.

Four models of implantable neurostimulator receivers (two single-channel, one dual-channel, one single-channel/four-contact) were mounted on a support and placed in the tunnel of MRI scanners from two different manufacturers. The receivers were connected to resistor terminations and their voltage output was monitored on an oscilloscope as they were moved from the target site out toward the tunnel edge.

For one single-channel receiver, the amplitude at the target site of the output pulses induced by one MRI model was 6 V; from another, more powerful, MRI model, it was 13 V. These amplitudes could cause discomfort and possibly harm if the normal therapeutic value was 1-3 V. In contrast, there was no significant output from a single-channel/four-contact receiver that depended upon coded pulse-width-modulated signals to control its output. As expected, the amplitude of the receiver's output decreased as it was moved away from the target site.

Theoretical calculations were also made to estimate the amount of signal that the MRI fields would produce at the output of implanted lead wires in the patient. The effects on the receivers of the strong static magnetic field, the changing magnetic gradient field, and the strong RF electromagnetic field were calculated. The computed neurostimulator-induced voltages produced by the maximum pulsed magnetic gradient was less than 0.20 V for the four receivers.

In conclusion, important factors in determining the safety of MRI in patients with an implanted neurostimulator include:

1) the type of neurostimulator receiver;
2) the power of the MRI scanner;
3) the frequency separation between the receiver-tuned RF and the MRI's transmitted RF;
4) the distance of the receiver from the RF coils in the scanner; and
5) the therapeutic amplitude of the stimulator.

VIBRATORY MOTOR STIMULATION IN PATIENTS WITH POLYNEUROPATHY. A PRELIMINARY REPORT

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Vibratory motor stimulation has been used during two months twice daily for 20 min in 8 patients /5 women and 3 men/ with diabetic polyneuropathy to facilitate a wear voluntary contraction and to improve sensory impairment.

A pair of cylindrical vibrators with a frequency of 150 Hz and a vibration amplitude of 2.5 mm was secured ower the tendon of triceps surae muscle by rubber bauds. Sensory impairment was tested on scale of 5 degrees and volitional motor control by manual muscle testing and EMG at the begining and at the end of this study. After two months there was a stati sticaly significant improvement of volitional motor control by manual muscle tes ting as a result of vibratory motor stimu lation. There was also a significant increase of action potentials amplitude /$P<0.05$/ between first and second EMG investigation. The results obtained can be used as a base for further study.

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WIRE-FREE SWITCH SYSTEM FOR ELECTROSTIMULATION IN PARAPLEGIC LOCOMOTION

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SUMMARY

A system, using infra-red transmission has been developed to provide on/off switching of electrostimulation from switches on the crutch handles.

The system is used with 'hybrid' reciprocal gait in paraplegia using a mechanical orthosis in conjunction with electrostimulation. A flat switch is wrapped around the crutch handle and connects to a transmitter clipped onto the shank of the crutch. The receiver, with integral infra-red detector diode is attached to the side of the mechanical orthosis. Interference of infra-red radiation from any source other than the transmitter is rapidly detected and the receiver output is switched off, preventing misinterpretation and inappropriate stimulation.

The system is compact and mechanically robust. It is resistant to transmission interference and could be adapted to provide 8 switching channels and used for a range of applications. An attempt has been made to reduce the inconvenience of one aspect of electrostimulation and this may improve the acceptability of the technique outside the laboratory.

INTRODUCTION

Functional Electrostimulation (FES) is being used increasingly for rehabilitation in paraplegia. FES techniques have been applied with the aim of helping restore reciprocal gait in people suffering complete or partial loss of lower limb function. To be clinically acceptable it is important that any equipment must be as convenient to use as possible.

Patients at our unit have been using FES of gluteal muscles to augment the use of the ParaWalker (a mechanical orthosis which allows reciprocal gait in paraplegia) in order to offset some of the effort provided through the arms. The stimulus is switched on and off by the user with finger switches and the strength is adjusted at the outset. Interconnecting wires between the switches and the stimulus generator are inconvenient and a possible source of fault. In order to avoid the need for such interconnecting wires a short range wire-free switch system using infra-red transmission has been developed.

Described here are the components necessary to relay the states of the finger switches. The outputs of which may then be connected to an electrostimulus generator, however, this is not described or illustrated.

Acknowledgement is given to the Medical Electronics Laboratory, School of Electrical Engineering, Bath University for advice on infra-red transmission.

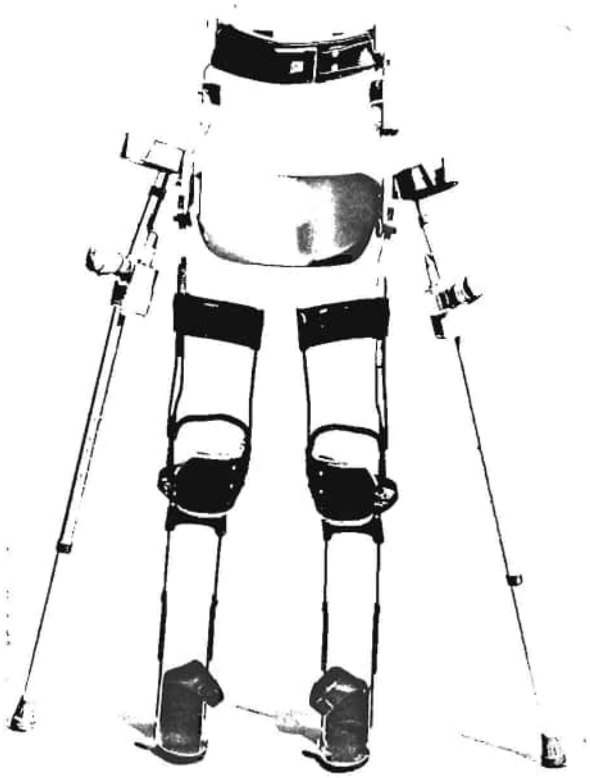

Fig. 1 Wire-free switch system (not including electrostimulus generator) ParaWalker orthosis and crutches.

TECHNICAL DESCRIPTION

The system consists of a transmitter (100 x 60 x 25 mm, 130 g), attached to the shank of one or both crutches and a receiver (145 x 90 x 33 mm, 270 g), attached to the orthosis. The switches themselves are incorporated into bands which wrap around the crutch handles without any modifications being necessary. Transmission is through coded infra-red radiation (950 nm) and the receiver has an integral infra-red detector diode. The infra-red emitting diodes, which are incorporated into the body of the transmitter, have a wide emission cone (half angle of 45o) making the system tolerant of a wide range of relative positions. Each transmitter or receiver draws 10-20 mA from a PP3 battery (alkaline or rechargeable Ni-Cad). Switch states are transmitted via an 8 bit word of duration 10 ms which is continuously repeated during transmission. The state of each bit is indicated by the presence or absence of a pulse at a fixed delay after the start of the word. This contrasts with pulse width modulation where the bits and words vary in duration. The decoding system uses a phase locked loop technique to synchronise to the source, introducing a delay of < 0.2 s before the switch states can be output at the receiver. In the present arrangement 4 bits are used as a code to identify the source, 2 bits indicate the states of 2 finger switches and 2 bits are spare. A 'high' state at the output indicates that the corresponding switch is depressed and it remains 'high' until the switch is released. The 'high' output state is selected only if the correct 4 bit code is received and if the corresponding switch bit is present on 3 consecutive words.

Any interference in the infra-red signal which could contaminate the code word is immediately detected and the outputs returned to their low states, corresponding to a fail safe condition.

The system may be used in 2 modes of operation:

<u>Mode 1</u>: Single transmitter with 2 switches on one crutch. Transmission and synchronisation of the receiver is continuous but the user must learn which finger corresponds to which stimulation channel.

<u>Mode 2</u>: Two transmitters may be used, one on each side. A second diode detector is required on the opposite side to the receiver but this is permanently attached to the orthosis. Transmission is initiated by depression of the switches resulting in a delay of up to 0.2 s. However, use of switches on each side may seem more natural for reciprocal, paraplegic locomotion. This arrangement is illustrated in the figures.

DISCUSSION

The system provides a compact means of relaying switch states from finger switches on the handles of the crutches or other support to an electrostimulator attached to the orthosis. When used in conjunction with the ParaWalker reliable transmission is maintained at all positions of the crutches during reciprocal gait. Transmission is not subject to radio-frequency interference and any extraneous infra-red radiation is rapidly detected and the outputs are switched off. Coding based on pulse width modulation, more usually found with remote control systems, was found to be prone to channel miss-selection in the presence of interfering pulses. Instead, coding with fixed word length is used with the result that it is highly unlikely that spurious interfering pulses would be interpreted as data. Any second source of pulsing infra-red radiation aimed at the diode detector is interpreted as interference and the outputs are switched off.

The 4 bit identification code can distinguish up to 16 transmission sources to prevent cross switching between different users in close proximity. However, if this facility is not considered necessary then these 4 bits would be available to indicate switch states, making a total of 8. This would make it suitable for a range of applications including the voluntary input to complex feedback control systems.

The transmitter and receiver have been constructed using off-the-shelf electronic components. Increasing the degree of integration, for example using gate arrays, could lead to further miniaturisation and possibly the integration of the receiver into the stimulus generator box.

Clinical acceptance of electrostimulation techniques depend on a balance between increased function and the inconvenience of use. The wire-free switching system goes some way to improve convenience by removing interconnecting wires between the support handles and the electrostimulus generator.

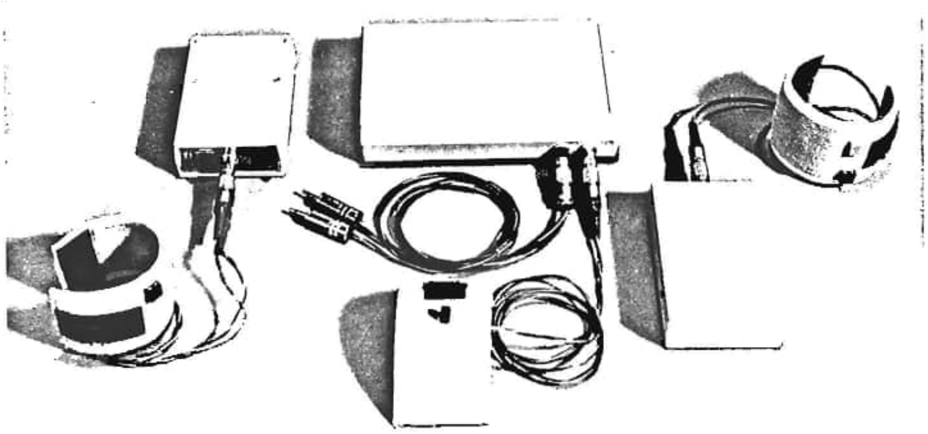

Fig. 2 Components of wire-free switch system

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THE BIOMECHANICAL CHILD GROWTH FACTORS x)

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SUMMARY

The biomechanical parameters of lower legs were measured in 77 healthy children .It was concluded that the period of free oscillation of lower leg is constant , independent on the children age although: the moment of inertion, stiffness and damping of the muscles acting on the knee joint are increasing functions of child's age.

MATERIAL AND METHOD

In the analysis of motor system it is often of interest to describe its transfer functions ; it means to determine the relationship between the output and input signals . The problems of the biological system motion combine the changable structure of the limb segments under multilevel nervous control. The human limb segment motion is described with the following equation:

$$I \ddot{x} + D(t) \dot{x} + C(t) x - G(x) = M \tag{1}$$

where:

- I -represents the inertial properties of segment
- D,C -represent the viscoelastic properties of the active and passive elements acting on the segment(damping and stiffness respectively)
- G -represents the grawitional forces acting on the segment
- x -generalised coordinate of motion
- M -external forcing

To use the linear system tools it's usually assumed;especially in the metrological applications that the viscoelastic properties of muscles are constant (relaxation or steady effort) and grawitional forces are zero or constant (unloading or constant loading conditions).The different methods of identification (the measurement of the linearised eq.1 parameters) depend on the complexity of the used model ,the input functions, methods of motion analise applied and the limb segment choosen for , identification procedure. The anthropometric methods of the moment of inertion measurements of different human body are based on the geometrical models of the segments with assumed body density /1,3,11/.
The results of such calculations are commonly used some the biomechanic applications but they don't cover the dynamics of the system.The most commomnly used input functions in the identification procedure are step and sinusoidal signals.The suitable arrangements are rather complex and are usually equipted with special motors.The segments which are preferable in such investigations are forearm /17/ and foot /9,10,18,20/.Constant velocity forcing also need special devices /4,13/. The static methods of stiffness measurements are also used /5/.
The aim of our studies was to evaluate the changes of the passive biomechanical parameters in children of different age with noninvasive, safe method. We used the free oscillation technique / 1,12/. The method is safe and useful in the identification of different distal limb segments fingers , forearm and lower leg in healthy /7,16/ and diseased children / 8 /.
In our investigations subjects were laying on theirs back with lower legs hanging over the special table with regulated height

(fot.1).The leg under investigations was attached to the strain-gauge beam at the ankle joint . The small oscillations of the whole system (in the direction perpendicular to the segment axis) were elicted mannualy with a hit (impulse forcing).The displacement signal was transformed in strain-gauge bridge CMT - 83 , amplified (Tektronix AM5Ø2) and fed to the after preamplifier input III of electromyograph Disa 15ØØ . Monopolar, surface electrodes were attached over skin projections of mm . quadriceps and biceps femoris to control the muscles relaxation . The EMG signals were fed to the channels I and II of electromyograph respectively. The periods of free oscillations were measured with external mass loading(Ø.5,1,2 kg) and without it . The mean values for up to ten oscillations for each loading were calculated and the function m=f(T /4II) C was plotted.The linearity of that function was estimed with the correlation coefficient .The function slope was considered as the overall stiffness of the whole system and the reduced mass was found as the function value for the zero mass.Linear stiffness of the elements acting on the knee joint(reduced to the ankle joint) was calculated as a result of subtruction of the arrangament stiffness from the overall system stiffness.Lower leg(with foot) moment of inertion was calculate according to the formula : I = m r(where:m-mass reduced,r-radius of reduction.The linear viscous damping of the elements acting on the knee joint (reduced to the ankle joint)was calculated from the decrement of damping. The frequency of lower leg free oscillations was calculated according to the formula:f = 2II C /m.The accuracy of those parameters measurement depends on the correlation coefficient value but never was worse then 15 % (damping) and can reach 2% (moment of inertion, stiffness).

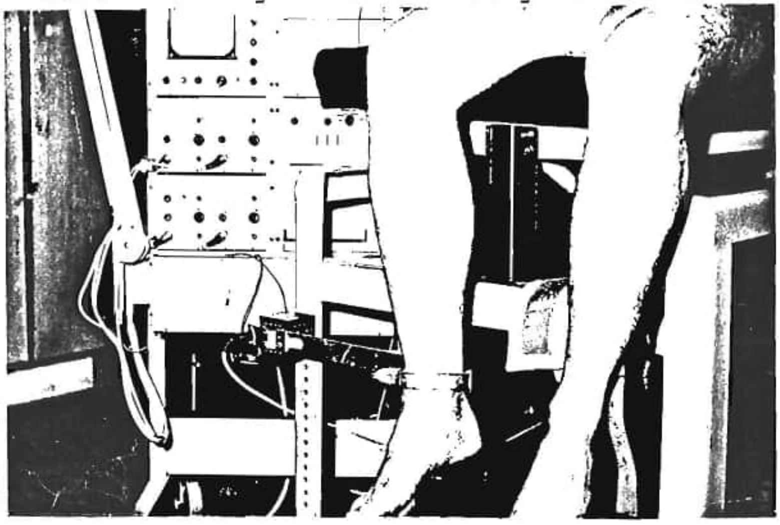

Fig.1 The arrangement for lower leg biomechanical parameters identification.

77 healthy children from Warsaw schools were evaluated in the studies . There were 26 girls and 51 boys aged 6 to 18 years.

R E S U L T S

The indyvidual results of measurements for : moment of inertion of lower leg stiffness and damping of the elements acting on the knee joint and the frequency of the free oscillations of lower leg are displayed in figures 1,2,3,4 . The functions are plotted against child's height since it was found that the dispertion of the results was less against that parameter then for the age.The lower leg (with foot) moment of inertion is an increasing function of child's height I = f(H) (fig.1) .The lower leg moment of inertion changes from Ø.Ø5 kgm to Ø.8 kgm (the mean values for the extremal height groups) (fig.1). The linear (reduced to the ankle joint) , passive stiffness of the elements acting on the knee joint is also an increasing function of child's height C = f(H) and varies from 22Ø N/m to 75Ø N/m (the mean values for the extremal height groups)(fig.2).

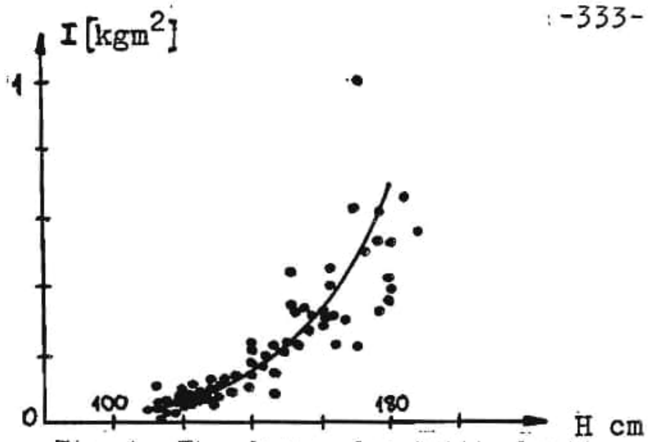

Fig.1 The lower leg(with foot) moment of inertia(I) as a function of child's height (H).

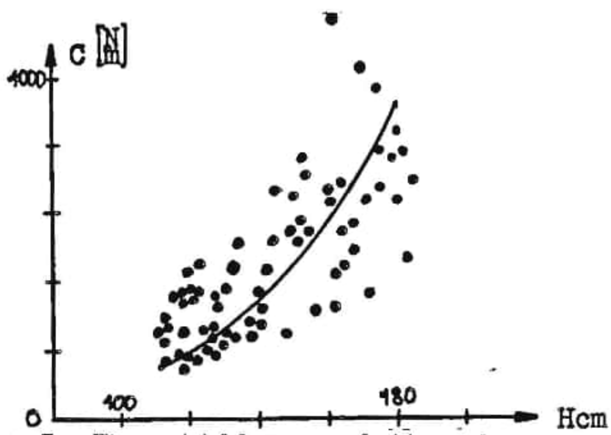

Fig.2 The stiffness of the elements acting on the knee joint (C) as a function of child's height (H).

The passive viscous damping of the muscles acting on the knee joint (linear reduced to the ankle joint) is also an increasing functions of child's height D = f(H) and varies from 3 Ns/m to 10 Ns/m respectively for the extremal height groups(fig.3).The frequency of lower leg free oscillations is constant , independent on child's height f = 2.21 + 0.28 Hz (fig.4).

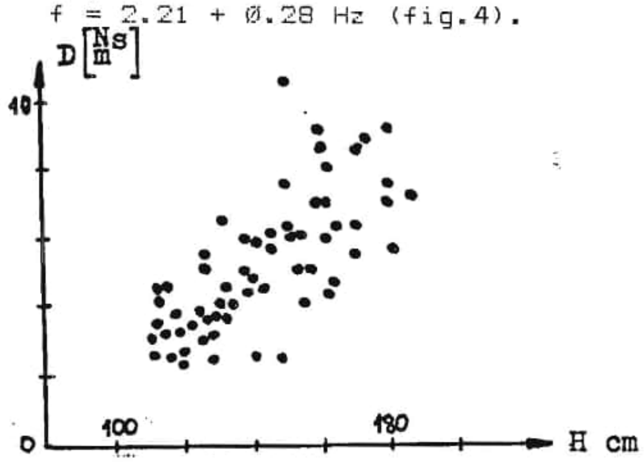

Fig.3 The damping of the elements acting on the knee joint (D) as a function of child's height (H .)

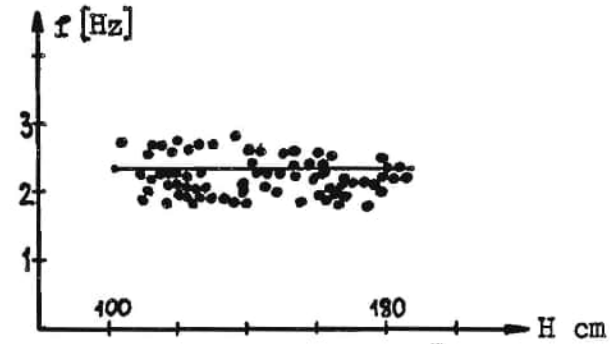

Fig.4 The frequency of lower leg free oscillations (f) as a function of child's height (H).

The dispertion of all parameters except the frequency of free oscillations inrease with child's height (fig.1,2,3)

D I S C U S S I O N

The increase of the lower leg moment of inertion function represents the increase of the segment dimension and it's mass, what is with agree with the results of anthropometric studies /1,11/. The increase of the stiffness and damping represent the changes of active and passive elements acting on a knee joint.Since it was shown that most of the stiffness reside in the soft tissues namely in the muscles /15,21/ it can be concluded that the changes in the viscoelastic parameters are due to the growing of the muscles acting on a knee joint.The increase in the dispertion of the parameters with height is with agree with the increasing variability of the anthropometric dimesions with age .It has been stated that although all biomechanical parameters of human limb segment are changing during the child's growth from 6 to 18 years the frequency of free oscillations of segment is constant, independent on child's age. It can be concluded that there is no need to adapt the motor control parameters to the increasing biomechanical parameters of the limb segments during child growth.It's with agree with the fact that one of the basic parameters of neural control : peripheral and central conduction velocity is slightly changing in children after age 8 years/19/.

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LOW-COST FES EXERCISE BICYCLE FOR HOME USE.

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SUMMARY

To efficiently train paraplegic muscles as a preparation for functional use or for therapeutic or cosmetic purposes, regular (daily) use of stimulation is advisable. Bulky, complex and expensive exercise equipment therefore should be avoided: it restricts exercising to a clinical environment.
Based on previous work concerning computerized FES exercise cycling we devised an inexpensive easy to use and compact bicycle ergometer for home use. It is based on a commercially available ergometer which is equipped with a simple device for the synchronization of the stimulation with the leg movement and precautions for joint protection. The patient can use the exerciser while sitting in his own wheelchair. For stimulation basically any (switch controlled) muscle stimulator can be used. At this moment the device is used by 4 paraplegic patients on a regular basis at home.

INTRODUCTION

The success of FES exercise programs for training paraplegic muscles depends highly upon the regularity of the patients exercise performance. To enable the paraplegic patient to stand up from the wheelchair and to keep standing for longer periods of time, especially the Quadriceps muscles must be trained extensively [1]. One of the items is restoring fatigue resistance. Although FES bicycle exercisers are well accepted for endurance training the expenses of the commercially available types restricts exercising to the clinical environment for most patients. Especially as long as health insurances do not reimburse this type of equipment. Therefore we felt a strong need for developing a reliable, easy-to-use and inexpensive cycling device suited for home-use.
For use at home mechanical aspects, security and joint protection are of great importance. Besides, the exerciser must be easy to operate by the patient without outside assistance. Also the total expenses of the system should be kept low. Therefore it was decided to use a commercially available bicycle exerciser, and to modify this to be used from the patients own wheelchair. In this way a safe and easy accessible system is guaranteed.

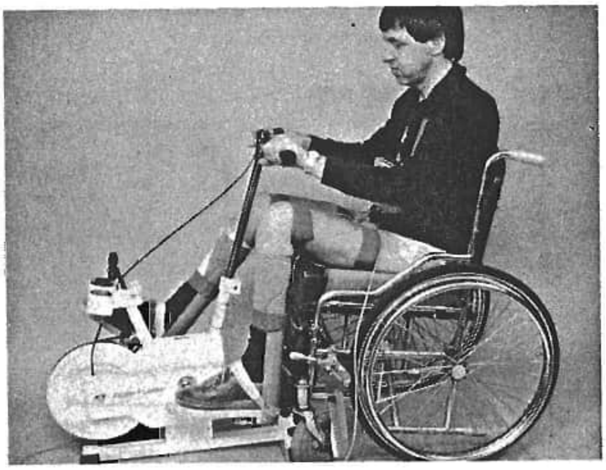

Figure 1. Paraplegic patient using the bicycle ergometer from his wheelchair.

Acknowledgement: Our work on FES is supported by the Dutch foundations: STW, IOP-HG, and St. Joris Stichting.

MATERIAL AND METHODS

Mechanical setup

For the exerciser we chose a Tunturi(TM) bicycle ergometer which is compact and has a safe construction. The pedalling resistance is adjustable from the handlebar. It has a timer and a speedometer and is equipped with a flywheel of 8 kg. The saddle of the exerciser was removed. During cycling the wheelchair is placed behind the exerciser. To prevent the patient from tumbling backwards or pushing the exerciser forward, the wheelchair has to be stabilized. Therefore a groundplate is introduced (70x70 cm), fixed to the rear stand tube of the bicycle. VELCRO straps mounted on the front of the groundplate enable the patient to fix the wheelchair. The handlebar of the exerciser is placed in the saddle tube to serve as a handhold. Two rigid low leg braces mounted on the pedals protect the ankle joints and prevent the legs from moving sidewards. Each leg is fixed to the pedals by two VELCRO straps, one across the ankle joint and one over the tibia.

Synchronization

To develop a device for the synchronization of the stimulation with the leg movements, experiments were carried out with computer controlled cycling in spinal cord injured patients [2]. In these experiments the stimulation bursts could be given any particular shape or timing related to the pedal position and pedal velocity. Several experiments were carried out, stimulating the quadriceps muscles on both sides. From the experiments the timing of the stimulation related to the pedal position showed to be the crucial point. The envelope of the stimulus pulse amplitude could be shaped simply rectangular, to perform good pedalling.

To find the right timing of the stimulation, the leg muscle activity of healthy subjects during cycling was monitored using surface EMG. As an example figure 2 shows the mean integrated absolute value of the right-leg-Quadriceps activity over 7 rotations. The patterns give a good indication of the desired timing. It can be seen how the Quadriceps activation starts around the point of maximum knee flexion and ends about 40° before maximum knee extension.
From figure 2 it can be seen that in healthy subjects the onset of muscle activity is related not only to the pedal position but also to the rotation velocity: The higher the rotation velocity the earlier the muscle activation starts. This may be a caused by changes in the motor program to compensate for the delay of 50-100 ms between electrical activation and muscle force onset, which results from the dynamic characteristics of the muscle.

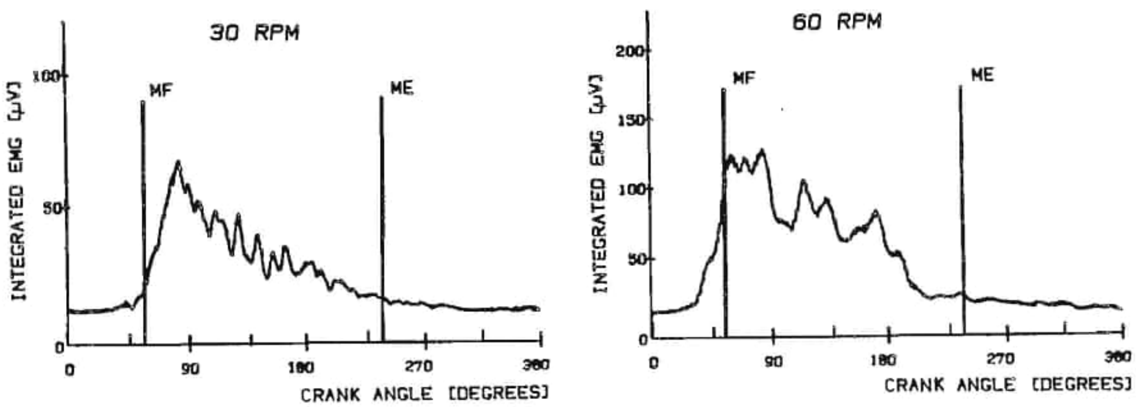

Figure 2. Quadriceps activity of a healthy subject during cycling: mean integrated EMG for 30 rpm and 60 rpm (MF: max. knee flexion; ME: max. knee extension).

In FES induced cycling we can use the delay in muscle force onset to guarantee system stability with respect to load changes and muscle fatigue without needing an active control mechanism in the stimulation equipment: When we stimulate the leg muscles according to fixed positions of the pedal arm, there is a negative feedback of the rotation velocity to the effective on-period of muscle force. This effect together with the negative feedback of the muscle contraction velocity to the generated muscle force (i.e. the Hill relationship) enable the use of simple switches with a fixed on/off timing for synchronization. On and off moments must be related to the point of maximum knee flexion as mentioned above (the dead points in the movement).

For use in the clinic we realized a special reedswitch synchronizer with an adjustable timing. The idea is based on [2]. A total of 36 reedswitches are placed in a circle and a permanent bar magnet is attached to the pedal arm to activate the switches (figure 3). Each of the switches can be selected to switch the stimulation current on or off. This enables to determine the optimal timing (for which the highest rotation velocity is reached) for the individual patient within 10°, which has shown to be efficacious. The optimal timing mainly depends on the seat position which determines the point of maximum knee flexion.

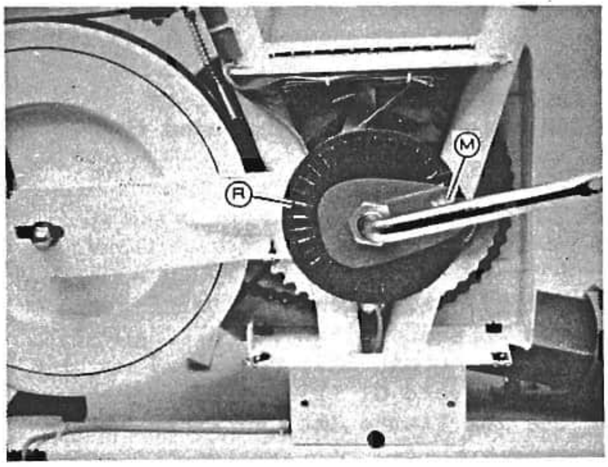

Fig 3. The reedswitch synchronizer in the opened gear-case. R: reedswitch; M: bar magnet.

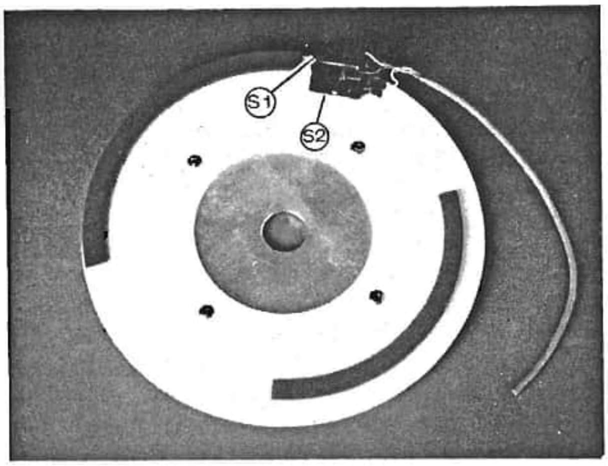

Fig 4. The microswitch synchronizer. A two-channel realization for activation of the quadriceps left (S1) and right (S2).

Once adjusted, for the home-use exerciser we use a microswitch synchronizer which is mounted inside the gear-case of the exerciser. It consists of a set of switches, one for each channel, which are activated by a partially thickened plastic disc that rotates with the pedals (figure 4).
In most patients the optimal timing is found to be when the quadriceps muscles are activated each from 0° to 140° after maximum knee flexion. However, as long as some patients prefer pedalling forward as well as backward, in practice we stimulate with a more symmetrical pattern, i.e. from 40° to 140° after maximum knee flexion. Although less efficient, this pattern has the advantage that it enables both pedalling directions without adjustment.

Operation

Before exercising, the patient first fixes his wheelchair to the groundplate. He fixes his legs to the pedals and starts rotating his legs by hand. Now the stimulation amplitude is turned up and the legs will take over the movement. Inertia drives the pedals over the dead centre, resulting in smooth pedalling.
At our centre FES patients use a 4-channel current output stimulator (freq. 20 Hz, pulse 300 us, amplitude up to 100 mA) for quadriceps exercising, standing(up) and

walking. Besides the normal controls this stimulator has a digital switch input for each channel to switch stimulation on and off. We use this stimulator for cycling but in fact every commercially available muscle stimulator can be used: The microswitches can switch the high voltage stimulation output directly.
As an extra feature the stimulation can also by controlled using hand-switches. In this way the patient can get a good hand-to-leg coordination which is important as a preparation for switch controlled walking.

RESULTS AND DISCUSSION

The exercise bicycle was used by four patients at home for more than half a year now. Cycling was performed for up to one hour, from two times a week up to two times a day, depending on the patients daily activities. The patients report a good motivation to exercise.
Besides muscle training the device additionally provides a dynamic exercise of knee and hip joints.
To evaluate the effect of cycling three indoor paraplegics started their FES exercise program with resistantless cycling for two times a day. After 6 weeks they showed 1. increase of maximum cycling time from less than 5 minutes up to 30 to 60 minutes and 2. no significant increase of muscle force. It was concluded that there is a strong need to combine bicycle exercising and muscle force training within one exercise program.
The system is inexpensive and can be used by the patient from the wheelchair without outside assistance. It can be used with any two channel stimulator to activate the quadriceps muscles on both sides. When more channels are needed the exerciser can be easily modified.

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AUTOSTIMULATION IN PSYCHOKINESITHERAPY FOR CHILDREN WITH CEREBRAL PALSY

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Subjecting children with cerebral palsy to kinesitherapy has the aim of formulating and stabilizing motorial patterns. Frequent and longlasting repetitions of the exercise may result in waking out a permanent and correct performance of a given motorial activity. The purpose of this process is practicing a pattern which is typical for normal children. It has been observed, that physical exercises, organized in such a way, force these children to be physically active, though there motorial activity is limited to some extent and the children are not fully conscious of this process. A combination of elements of kinesitherapy with psychotherapy gives new broader possibilities of having efficient influence on the child and mainly on its central nervous system in order to produce and stabilize new, non-existing motorial patterns. Thus, the whole process may be conceived as psychomotorial autostimulation which impels the body to increased effort. Provocation of the autostimulation in case of case of a child is possible when it is involved in the interesting game. A will to participate in the game, the strong wish to win makes the child perform some movements difficult for it. The author has presented a methodical and technical description of means of evoking partically controlled autostimulation at a special laboratory unit equipped with a motorial set for upper limbs.

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The Strathclyde Research Stimulator for Surface FES.

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Most stimulators are designed for specific applications, and lack the flexibility needed for research purposes. The design of a research stimulator must facilitate applications in scenarios which may not be envisaged at the time the equipment is conceived.

The essential technique for such a design is modularity. The system as a whole is decomposed into layers comprising, for example, stimulator hardware, computer hardware, low-level software, application-level software, and user-interface level software.

The system designer has to define the interfaces between the layers. These must be defined in such a way that the implementation of each layer is transparent to other connecting layers.

The stimulator system developed and used at the University of Strathclyde will be described. The interface specifications are made public in the hope that modules developed at different research centres may be usefully combined.

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FATIGUE TESTING OF A DILATABLE PROSTHESIS, FOR BANDING THE MAIN PULMONARY ARTERY

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Initial experimentation has determined the efficacy of using a prosthesis, which consists of a metallic helix encased in a silastic sheath to band the main pulmonary artery. This prosthesis is capable of serial dilatation using an intraluminal balloon dilator.[1]

Physical measurements were conducted on the prosthesis using an Instron universal apparatus to measure the extension force deformation curves of the prosthesis. Throughout the maximal range of elongation required for human application, no significant work hardening occurred. 60% +/- 3% of each unit of lengthening was non-recoverable.

An apparatus for simulating the forces experienced by the prosthesis in its human application was designed and constructed.

Preliminary fatigue experiments demonstrate no alteration in the physical characteristics of the prosthesis following a simulated human use. No failure of the prosthesis occurred.

Ref. 1 Journal of Thoracic and Cardiovascular Surgery, 1989; 97:421-427.

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LASTING RELAXATION OF HEMIPLEGIC SPASTICITY BY PERIPHERAL ELECTRICAL STIMULATION. A NEUROPHYSIOLOGICAL HYPOTHESIS.

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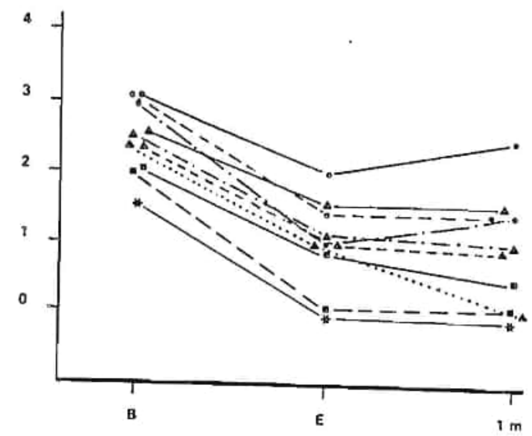
Our previous experiences, started in 1973, show that electrical stimulation (**ES**) of the antagonistic muscles of the spastic-ones in selected hemiplegic patients, performed for a sufficiently long time, is fit to provoke a reduction of spasticity lasting at least one month after the end of treatment (1, 2. Fig. 1). The follow-up after one year shows that about 60 % of the controlled patients maintain the result in a certain extent.

The following mechanisms can be hypothesized.

Fig. 1 = Spasticity of flexors of wrist and fingers of 10 hemiplegic patients. B: beginning of treatment. E: end of treatment. **1m**: one month after end. Ordinate: **Ashworth scale.**



Besides excitation of Ia fibres of the stimulated muscle -producing a transient reciprocal inhibition-, the **ES** excites the II group afferent fibres as well, coming from the spindle secondary endings (so as motoneuronal and gamma fibres are excited).

These fibres are the afferent limb of a **long loop transcortical reflex mechanism of motor regulation** (9, 11. Fig. 2) and their afferences are known as powerful evokers of responses by motor cortex neurons (3, 4).

The ascending pathways, run along by these fibres, include the **spino-reticular**, the **spino-cervical**, the **spino-cerebellar** and the **spino-thalamic tracts** (5, 6, 7, 8

10, 11, 12, 13. Fig. 3); their afferences are integrated in a complex way between 3 and 4 cortical areas and with the supplementary motor area (5). The efferent limb of this long loop is the pyramidal tract (11. Figs. 2 and 3).

Zarzecki and Asanuma (13) demonstrated that the II group afferences, both from skin and muscles of a forelimb af a cat, project to the motor cortex also along a di= rect thalamo-motorcortical path (Fig. 3), while the I group afferences from spindles, that reach the cortex as well even if in a smaller extent (12), pass through the cor=

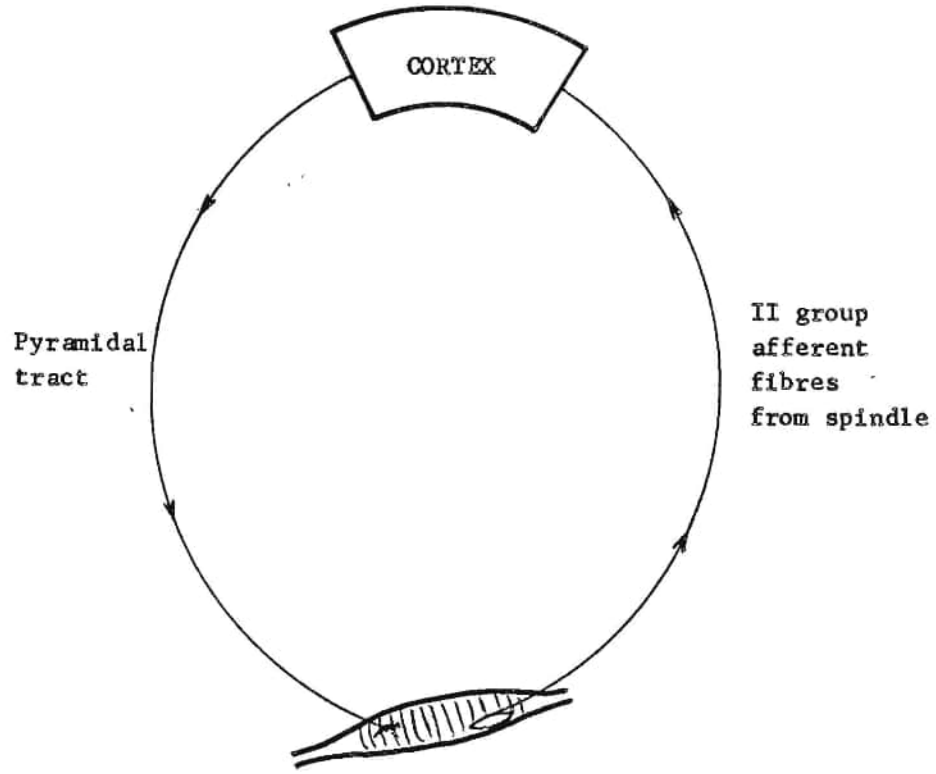


Fig. 2 = LONG LOOP TRANSCORTICAL REFLEX MECHANISM.
Phillips, 1969; Wiesendanger et al., 1975.

tical 3 area. These two pathways are involved in the control of the motor cortex output (13).

The II group fibres, coming from the spindle secondary endings, have two main func tions (beside the other-ones):

1) to make conscious the sensation of muscle contraction, of movement and of the reci procal position of the segments of a limb;
2) to supply an accurate regulation of the movement, modulated at cortical level, and to provoke corrective changes in the cortico-motor output, facing unexpected vari=

ations of the motor programme.

The fine regulation of cortico-motor output **implies necessarily a great amount of inhibitory activity**, in which the passage through the cerebellum by the **spindle-transcortical-motoneuronal long loop**, take a sure, important part.

The prolonged and repeated excitation of the II group spindle fibres could be able

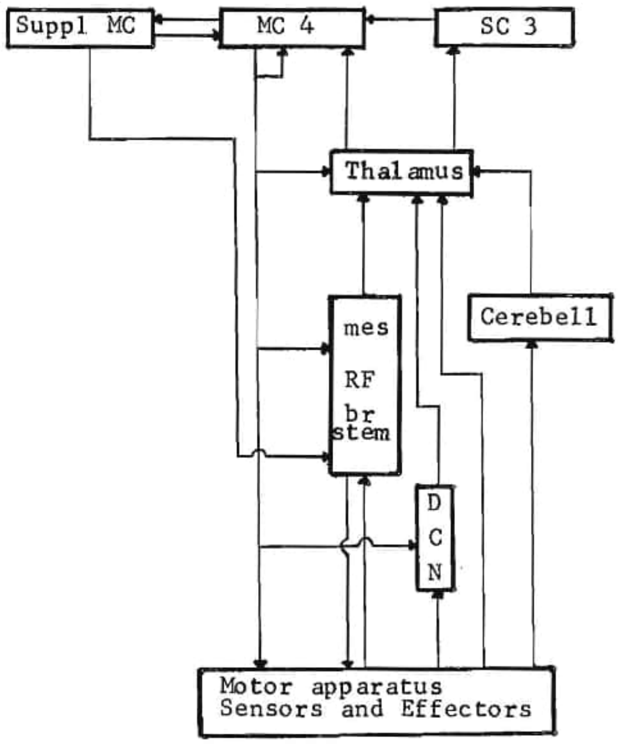


Fig. 3 = Diagram illustrating the pathways run along by afferences from neuromuscular spindles (mostly from secondary endings) to the higher centres. Derived from: Lundberg & Oscarsson, 1961; Oscarsson, 1973; Phillips et al., 1971; Evart & Tanji, 1974; Wiesendanger et al., 1975; Kniffke et al., 1977; Willis, 1979; Zarzecki & Asanuma, 1979.

to trigger a complex inhibitory mechanism, involving basal ganglia, rubro-spinal tract and what remains of the pyramidal tract, thus leading to the fixation of a better automatic process of regulation of the muscle tone.

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