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POSTER PRESENTATION

FEASIBILITY OF A VISUAL PROSTHESIS FOR THE BLIND UTILIZING INTRACORTICAL MICROSTIMULATION

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SUMMARY

Microelectrodes with exposed tip sizes approximating the size of cortical neurons were implanted into the human visual cortex and used to activate small populations of neurons. Phosphenes were produced at currents as much as 1000 times lower than required with electrodes placed on the cortical surface. Within rather narrow limits the brightness, size and color of the visual sensations could be varied with changes in the stimulus level. Phosphenes produced by simultaneous stimulation through two electrodes 500 microns apart could be resolved, but not when electrodes were spaced at 250 microns. A subject, totally blind for 22 years, could recognize simple patterns with the limited number of electrodes available, but complex image recognition experiments must await future implants with larger arrays of electrodes. These results are compatible with the possibility of a visual prosthesis for the blind.

Acknowledgements

The authors would like to express their sincere appreciation to our research subjects whose identities must remain anonymous but whose courage and enthusiasm will never be forgotten. We would also like to thank Dr. Eugene Streicher, Dr. Robert Burke, Dr. Edward Oldfield, Dr. Roger Porter and Dr. Murray Goldstein for their encouragement and for providing the support of the National Institute of Neurological Disorders and Stroke, National Institutes of Health.

STATE OF THE ART

The concept of a cortical visual prosthesis for the blind is based on the fact that localized electrical stimulation of the visual cortex excites topographically mapped visual sensations called phosphenes. Cortically evoked phosphenes can be produced in the normally sighted and in individuals who are totally blind following lesions of the eyes or optic nerves. Such a prosthesis would utilize a miniature television camera, an electronic processor to convert the camera output to a signal suitable for controlling a multichannel stimulator, and an array of visual cortical electrodes.

Early experiments by Brindley, Dobelle, Pollen and others studied the effects of visual cortical stimulation with electrodes placed on the pia-arachnoid surface. /1-3/ The results indicated that a prosthesis of only very limited usefulness could be expected because of phosphene interactions and other phenomena resulting from the large number of neurons excited and the limited control of these neurons by surface stimulation. As an alternate approach, investigators in the Neural Prosthesis Program and the Laboratory of Neural Control at the National Institutes of Health began the systematic design, development and evaluation of safe and effective means of microstimulating cortical tissue. The expectation is that by implanting microelectrodes with exposed tip sizes the same order of magnitude as the excited neurons, much more selective stimulation can be achieved resulting in more precise control of neuronal function. For a visual prosthesis, it is hoped that this will result in reduced phosphene interaction and higher information transfer rates into the visual system.

To derive engineering design data for a prototype chronic implant, acute intracortical microstimulation studies were performed in sighted patients. Results from these studies encouraged us to pursue a long-term implant in a blind subject. Specifically we needed to know what a person blind for a long period of time would experience during intracortical microstimulation of the visual cortex and whether spatial patterns of phosphenes could be recognized in a timely fashion.

MATERIAL AND METHODS

Subject Selection

Four volunteers, three normally sighted and one totally blind, have been used as research subjects. The sighted subjects were undergoing occipital craniotomies under local anesthesia for excision of epileptic foci and were studied for approximately one hour each./4/

Although we did not actively solicit a research subject, over 50 blind individuals contacted us following several articles about our work in the popular press. From this group, 20 were felt to be seriously interested in being research volunteers, did not have unrealistic expectations about their sight being restored, and had no significant

medical problems other than their blindness. We brought four of them to the National Institutes of Health (NIH) Clinical Center for preliminary medical and psychological evaluation. Part of the evaluation included non-invasive stimulation of the occipital lobe with a magnetic stimulator to obtain more information on the viability of visual cortical tissue, but because of the exploratory nature of this test we did not rule out any subjects if they did not see magneto-phosphenes.

From the final group of four candidates, a 42 year old woman was selected who had been blind for 22 years without light perception secondary to glaucoma. Following implantation of an electrode array in the right occipital cortex, she underwent daily testing for four months.

The procedures and risks were fully explained to all of the subjects prior to the experiments and informed consent obtained. Each subject was aware that they would receive no direct benefit from these experiments and that the main purpose was the knowledge that would be gained about the future possibility of a visual prosthesis for the blind.

Electrodes and Stimuli

The microelectrodes were activated iridium, fabricated from 37.5 um diameter iridium wire that was microwelded to a 25 um gold lead. The free ends of the microelectrodes were electrolytically sharpened to a diameter of approximately 2 um./5/ In addition to single microelectrodes, two and three microelectrode groupings were fabricated by attaching single electrodes together at spacing of 250 to 1000 um. Immediately prior to inserting these intracortical microelectrodes, a .75 mm platinum ball stimulating electrode was moved around on the pial surface of the visual cortex to map regions capable of producing phosphenes near the central or foveal region of the subject's visual field.

In the blind volunteer, a total of 38 microelectrodes, fabricated as either single microelectrodes or pairs, were implanted to a depth of 2 mm in a region near the right occipital pole. In the sighted subjects, the single, double and triple microelectrodes were inserted at various depths up to 6 mm, also near the occipital pole. All microelectrodes were insulated with Parylene-C, and the tip insulation removed with a high voltage arc discharge to leave exposed microelectrode contact areas of from 40 to 800 sq. microns in the sighted subjects and 200 sq. microns in the blind subject.

Regulated current, capacitor coupled stimulators generated biphasic waveforms whose pulse duration, pulse frequency, pulse amplitude, train duration, and train repetition rate could be varied while maintaining the electrodes within safe electrochemical limits./6/

Surgical Procedures

For the chronic implant in the blind individual a two stage surgical

procedure was designed. The first stage, the craniotomy, was done under general anesthesia and included the cutting of four separate ramp-like channels in the skull and bone plate.

The second stage was performed under local anesthesia with the original intention of mapping the visual cortex with the large surface electrode prior to inserting the microelectrodes. The 38 microelectrode leads had been previously packaged into four separate pieces of silicone tubing with silicone strain relief pads attached to the outside of the tubing. The four pieces of tubing with their associated leads were tunnelled through the scalp and exited through four separate scalp incisions. The portions of the leads outside the body terminated in four multicontact connectors which were not attached to the skull or scalp. Following a failure to produce phosphenes during stimulation with the surface electrode, we passed the 38 microelectrodes and their leads through their respective ramps in the skull and implanted them in an unsymmetrical wedge shaped region of the occipital cortex with the apex of the wedge at the occipital pole. The unequal length sides of the wedge extended from the pole about 1 cm adjacent to the sagittal sinus and about 3 cm adjacent to the lateral sinus. We tried to place the microelectrodes on the crests of gyri to maximize the likelihood of penetration parallel to cortical cytoarchitectonic columns. We also avoided obvious pial blood vessels. At the completion of four months of testing, our subject underwent a final surgical procedure. At this time several microelectrodes were removed, the percutaneous leads were cut, and the scalp incisions were closed.

Testing

The sighted patients were positioned on their sides during surgery and looked directly at a white tangent screen. During stimulation they reported details of the phosphenes including the size and position by reference to calibrated markings on the screen.

Our blind subject established an imaginary central fixation point by directing her eyes forward. While holding her eyes in this position and imagining that she was looking at her nose, she gave the angular position of each phosphene relative to a clock face and the radial position as a linear interpolation between 0 and 90 degrees, the former being the fixation point and the latter being the most peripheral visual experience she could remember.

RESULTS

Visual sensations, called phosphenes, were produced in all patients during electrical stimulation of the visual cortex. The phosphenes were generally described as small spots of light from about the size of a pinpoint to as large as a U.S. five cent coin at arm's length. Stimulation was never associated with pain or any other discomfort.

In the sighted patients the electrical current thresholds for phosphene production were determined as a function of cortical depth

by testing during microelectrode insertion. These ranged from 2 ma at the surface using the surface mapping electrode to 20 uA when the much smaller microelectrode tip was located at about 2-3 mm beneath the surface (.2 ms per phase, 100 pps, 1 s train length). The intracortically evoked phosphenes were described as steady, i.e. did not flicker, and had a crisp onset and offset that corresponded to the stimulus train as judged by the subject when given a simultaneous auditory clue. Almost all of them were mapped in the contralateral visual field within 10 degrees of the central visual fixation point. When stimulating currents were near threshold they often had distinct colors, e.g. blue, red, or yellow. Increasing the stimulus intensity made the phosphenes brighter and often somewhat smaller. Time did not permit evaluation of temporal or spatial pattern recognition in the sighted patients.

In the blind patient-volunteer, initial testing with the surface mapping electrode during the second stage of the two part surgical implantation procedure under local anesthesia was discouraging because the subject did not experience any visual phenomena with stimuli up to the electrochemically safe level. However, during testing over the first month following surgery, stimulation of 34 of the intracortical microelectrodes produced phosphenes. All phosphenes were located in the left visual field within 45 degrees and most within 25 degrees of the imaginary central fixation point. The phosphenes were close to the horizonal meridian, with most if not all, above the meridian. On a clock face as imagined by the subject the phosphenes were located between 9:00 and 10:30. Thresholds ranged from 2 ua to 20 ua with biphasic, cathodic first, capacitor coupled pulses (pulse frequency = 200 Hz, pulse width = 200 us, train length = 125 ms, train repetition rate = 1/s). Near threshold the phosphenes were often reported to have colors such as yellow, lavender and violet. At higher levels of stimulation the phosphenes generally became white.

The phosphenes were sometimes reported to appear at different distances in front of the subject depending upon which electrode was activated. When two microelectrodes which produced phosphenes at different distances were activated simultaneously with interlaced sequential stimuli, the two resulting phosphenes tended to become co-planar at one of the two distances. At low levels of stimulation phosphenes were usually single, but when the current was increased, a second would sometimes appear in close proximity. They did not flicker but did have an initial period of diminution of brightness. Typically a phosphene might decrease to about 1/2 its original brightness over the first one to two minutes of stimulation at which point it would stabilize in brightness or extinguish.

The phosphenes were reported by the subject within 400 ms or less of the start of stimulation. Allowing for the subject's motor reaction time of 220 ms as determined by asking the subject to press a button after hearing a tone, we estimate that the phosphenes appeared within 200 ms of the start of stimulation. Except in two instances of continuous, repetitive stimulation for several seconds, they immediately extinguished upon cessation of stimulation. In the two instances when the phosphenes did not extinguish, they continued for

up to 10 minutes after stimulation stopped. In one of these instances the phosphene expanded to cover the entire left visual field before it spontaneously extinguished.

Individual phosphenes moved with eye movements. When two microelectrodes were stimulated, each of which produced single phosphenes when activated alone, the two phosphenes that resulted also moved with eye movements and retained their same relative position with respect to each other except at the extremes of eye movement or if the subject was asked to converge her eyes.

Six simultaneous phosphenes, arranged approximately in a vertical row, could be produced by simultaneous stimulation of four separate electrodes. This pattern was identified as a letter "I" by the subject. During the latter stages of the experiment, when we intended to perform more sophisticated image recognition tests, lead breakage prevented testing of more than four microelectrodes at one time.

Thresholds remained essentially stable over the three month period except for microelectrodes whose leads fractured resulting in high microelectrode impedances and the abrupt failure to evoke phosphenes.

At the planned conclusion of the experiment after four months of implantation in the visual cortex, the microelectrodes were found to still be in place and had produced no gross signs of tissue reaction or hemorrhage. Some of the microelectrodes had advanced up to 1 mm further into the cortex which was the thickness of the portion of the microelectrode that originally protruded above the cortical surface.

DISCUSSION

An important finding in this study was that cortical phosphenes could be produced in a subject who had been totally blind, with no light perception, for 22 years at a current level as low as 2 ua. This compares to minimal thresholds of 1-2 ma reported in the literature for cortical surface stimulation. It is also encouraging that phosphenes produced by microelectrodes as close as 500 microns could be resolved. With surface electrodes significant interactions were reported for electrodes as far apart as 2-3 mm. These findings combined with the smaller size of microelectrodes should make it possible to utilize many more electrodes in an intracortical prosthesis as compared to a cortical surface approach.

The decrease in the brightness of the phosphenes during continued stimulation may be a problem. Brindley claimed that the phosphenes experienced by his first blind subject did not fade /7/, but Dobelle noted significant accommodation effects in both sighted and blind patients /2, 8/. It is not clear whether the duration of blindness might have an affect on the degree of accommodation and the possibility exists that repeated stimulation over a period of time might reduce this effect.

The occasional continuation of visual phenomena for a period of time after cessation of stimulation has been reported by Brindley /1/.

Pollen studied the activation of single units in cat visual cortex by electrical stimulation and feels that the persistence of phosphenes represents an afterdischarge of visual cortical neurons. It most commonly occurred with repetitive stimuli presented in long pulse trains. He found that the threshold for producing afterdischarges was inversely proportional to train length and that the threshold for afterdischarges could be greatly increased by administration of Dilantin. /9/ Our blind patient was initially on Dilantin but was off the drug when the afterdischarges occurred. It is likely that Dilantin or a similar drug would control afterdischarges in individuals with visual prostheses, but the effect of these drugs on cortical phosphenes is unknown. It is possible that the reason our blind patient did not see phosphenes with surface stimulation was because she was on Dilantin at the time of the second surgical procedure.

The lead breakage problem was due to the use of excessively extensible silicone tubing around the bundles of percutaneous leads which when accidently stretched transmitted some of the strain directly to the leads rather than entirely to the strain relief pads on the sides of the tubing. This should be easy to correct in future devices by using either a percutaneous connector rigidly fixed to the skull or by using a transcutaneous radio-frequency coupling system with no leads or connectors passing directly through the skin.

The results of the simple pattern identification studies are encouraging, but are not conclusive. More sophisticated image recognition studies are needed in blind subjects with many more than 34 functional electrodes.

Plans for the future are focused on designing an implant that has a sufficient number of microelectrodes to permit more complex image recognition experiments. If these experiments are encouraging we would like to be able to provide a degree of function to a blind subject by interfacing an implant with a portable television camera and image processing electronics.

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TECHNOLOGY TRANSFER OF AN UPPER EXTREMITY NEUROPROSTHESIS FOR RESTORATION OF HAND FUNCTION

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SUMMARY

A multi-site evaluation program is underway to study the efficacy of a system employing functional neuromuscular stimulation (FNS) of paralyzed muscles to restore active hand control. The system is intended for individuals who have sustained spinal cord injury at the C5 and C6 level. The initial phase of the program involved four Centers, in which chronically indwelling percutaneous electrodes were used. The second phase, presently underway, will involve the use of a surgically implanted multichannel receiver-stimulator at five clinical evaluation sites.

STATE OF THE ART

Electrical stimulation of paralyzed muscle has been shown to be effective in restoring active control of the hand in the individual with C5 and C6 level quadriplegia. In a retrospective study, Wijman /1/ showed significant improvement in performing activities of daily living when performing tasks when using the FNS system than without. This system has been transferred to patients at Centers in Downey, California (Rancho Los Amigos); Edmonton, Alberta (Univ. Alberta); Philadelphia, Pennsylvania (Shriners Hospital); and Toronto, Ontario (Hugh MacMillan) where systems have been successfully implemented with 15 users. More recently a surgically implanted system (described below) has been used in Cleveland with five patients, implanted for periods of approximately 6 years, 1 year, 1 year, 3 months, and 1 month /2/. We are presently preparing to transfer this system for evaluation to three VA Medical Centers (Baltimore, Palo Alto, and West Roxbury), and Shriners (Philadelphia).

MATERIALS AND METHODS

Two methods have been used for implementation of the FNS neuroprosthesis. They are identical with the exception of the electrode and stimulator used

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for delivery of electrical current. The first system utilized percutaneously implanted electrodes to activate the paralyzed muscles. The electrodes were placed intramuscularly near the motor point, with a single electrode used to activate each muscle. The user controlled the system with movement of the contralateral shoulder, with proportional control of two grasp configurations provided by shoulder protraction-retraction and lock function provided by a rapid shoulder elevation or depression. A chest mounted switch was used to select the grasp configuration. All control and stimulation electronic hardware was external and placed behind the user's wheelchair. More recently, a multichannel implantable receiver-stimulator unit has been employed /3/. The receiver is an eight channel passive device which is powered and controlled by radio frequency. Epimysial electrodes are sutured to the muscle near the motor point for nerve activation. The external system is identical, except that in the external electronics hardware an RF transmitter board replaced the multichannel stimulator board used in the percutaneous system.

Individual patients require different control and stimulator parameters to utilize the system. These are programmed for each individual user's shoulder movement (eg. range of movement, speed) and electrode placement (eg. muscle activated, recruitment gain). Versatility in the design of the external processor enables it to be programmed for virtually all control and stimulation values presented by individual patients, as well as be used with alternative command-control sources and experimentally in real-time feedback control.

RESULTS

The objective of an FNS system is to provide graded movement of the digits to supply both lateral and palmar prehension and release, so that the user will be able to independently perform activities of daily living. Control of both lateral and palmar prehension has been achieved in all patients except two (both in Cleveland). These two individuals were able to achieve only lateral prehension and release because finger contractures (one patient) and finger amputations (the other patient) limited hand opening and movement. All patients were able to perform activities of daily living with the FNS system in addition to those that they were able to perform without the system. In only one task with one patient was performance less with FNS than without.

All the individuals fitted with the neuroprostheses have used them outside of the laboratory. They use them in a variety of environments (home, work, entertainment), often on a daily basis. The longest continuous period of time for a percutaneous system is 15 years, and six years for the implanted system. The longest time for a patient outside of Cleveland is five years. The results, to be discussed more fully at the meeting, demonstrate the utility of the FNS system for the quadriplegic user in providing function of the upper extremity. Equivalent function is unachievable by any alternative means, and provides enhanced independence of the user.

DISCUSSION

Perhaps the most important aspect of the technology transfer program has been to define and develop the breadth of the components which must be provided to maximize successful deployment. First, Centers must have the appropriate personnel who are experienced and adequately committed to the

rehabilitation of the spinal injured patient in general, and the upper extremity explicitly. This involves primarily the rehabilitationist, the surgeon, and the therapist with support of the rehabilitation engineer. Adequate resources in terms of the facility must be provided to these individuals.

Second, appropriate and complete criteria must be available for selecting candidates for the program. These must be explicit and inviolate.

Third, the system that is to be used must be complete and fully documented. Since the system involves components that are both "patient portable" and "laboratory based" with many subcomponents, this is a substantial task. Interchangeability of components, in the event of malfunction or update, must be provided, necessitating careful engineering design. The importance of documentation cannot be overstated, as the satellite teams cannot be expected to have the same experience and proficiency as the primary site.

Fourth, means of evaluating the outcome must be established, agreed upon, and fully adhered to by each of the teams. Only then will the information across patient participants be fully comparable. Ideally this evaluation should measure a spectrum of outcomes involving both highly quantitative as well as quality of life measures. However, it must also recognize the limitations in the available time and resources of both the satellite team and the patient-users. The outcome measures should be carefully designed to lead to statistically quantifiable outcome analysis. The statistical measures must be defined before the outset of the study.

Fifth, all institutional and regulatory requirements must be followed to insure safety as well as efficacy in the study.

Sixth, careful monitoring of the study must be provided to insure that all investigators adhere to aspects of the study. It is the responsibility of the primary site to insure that this takes place, as failure to do so can result in suspension of the study.

These aspects of clinical study go far beyond the normal confines of the research laboratory. They involve aspects that are frequently foreign to researchers and are difficult to control. However, it is the premise of the primary author that only with commitment of effort and funding and facility resources toward these elements will advanced FNS systems reach daily use in the clinical environment.

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MODELLING NERVE FIBRE EXCITATION BY ELECTRIC FIELDS

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SUMMARY

Four membrane models are presented which can be used to predict the behaviour of warm-blooded axons, when excited by electric fields. These models, which describe the voltage – currrent relation of the neural membrane, are based on experiments in which the stimulating current is applied to the inside of the axon, whilst the current flow along the axon is suppressed. In this case, a positive current pulse produces increase of membrane voltage and finally an action potential. In the case of extracellular stimulation the inneraxonal current takes over the role of the inneraxonal electrode. The stimulation is caused by the different potentials along the fibre which are produced by the applied electric field. In a uniform fibre, the activating function f (which is the second derivative of the extracellular potential along the fibre) show the influence of the electric field: In regions with $f > 0$ the fibre is stimulated (polarized) and where $f < 0$ it is hyperpolarized. However, the question of propagation of spikes depends also on the gating dynamics of the ionic channels of the active membrane. A network consisting of a membrane model for every node will be of use to simulate the spatial effects of the mammalian neuron.

INTRODUCTION

The propagation of neural activity in a nerve fibre as well as the artificial excitability are consequences of the electrical properties of the axon membrane, which separates fluids of different ionic concentrations: the axoplasm and the extracellular fluid. However, without theoretical treatment, some of the experimental findings are hard to understand. For example, Fig. 1 shows surprising effects in an axon stimulated with increasing cathodic current pulses from a monopolar electrode. It is interesting to note that a sequence of stimulating pulses, which are gradually increased, produces alternating periods without and with firing:

i) NO PROPAGATION (subthreshold current)
ii) PROPAGATION
iii) NO PROPAGATION (cathodic block)
iv) PROPAGATION (break excitation) after switching off the impulse
v) NO PROPAGATION (suppression of break excitation) when the pulse is followed by a linear or exponentially falling phase.

This paper is concerned firstly with local models, i.e. the nonlinear membrane kinetics are examined whilest there is no current spread along the axon. Secondly, spatial models will be used in order to predict the reaction of a target fibre when an electric field is applied.

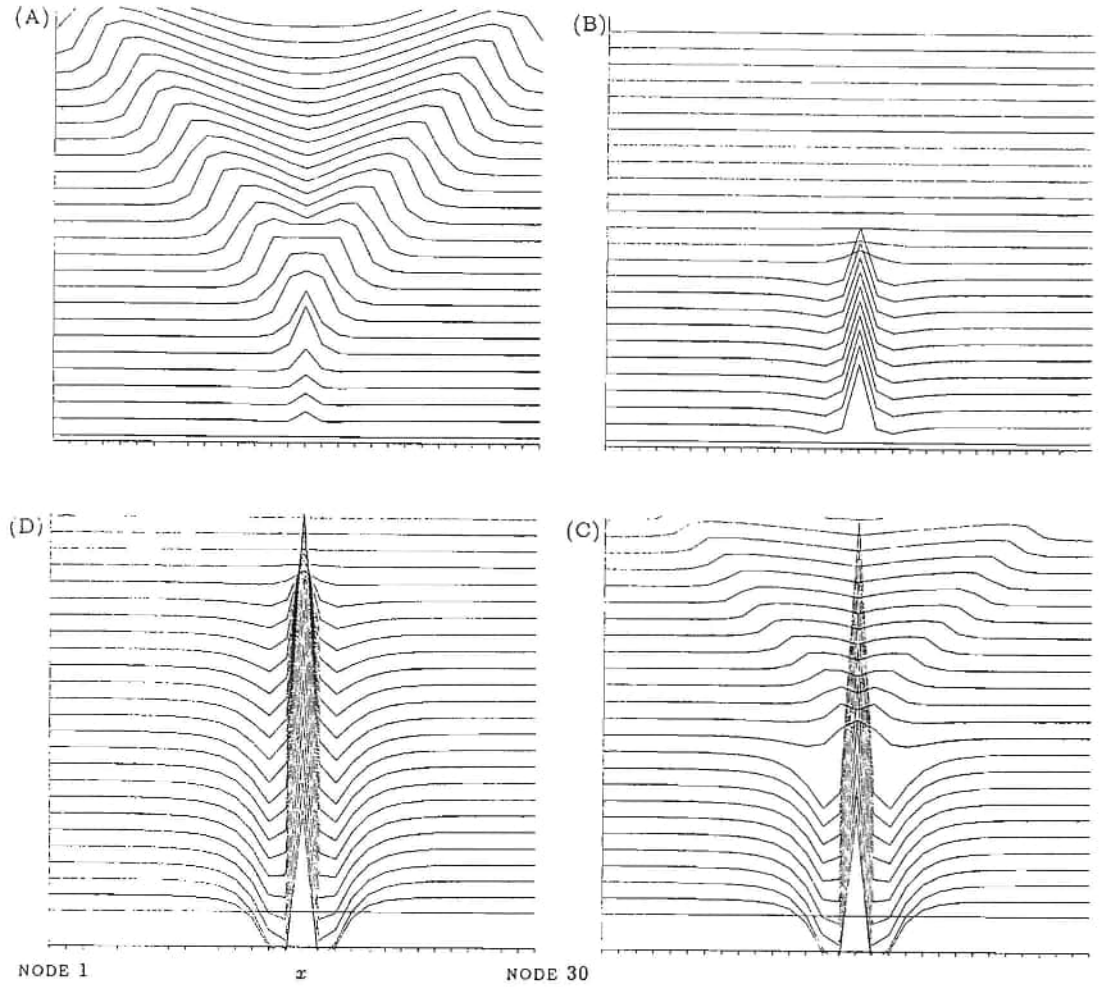
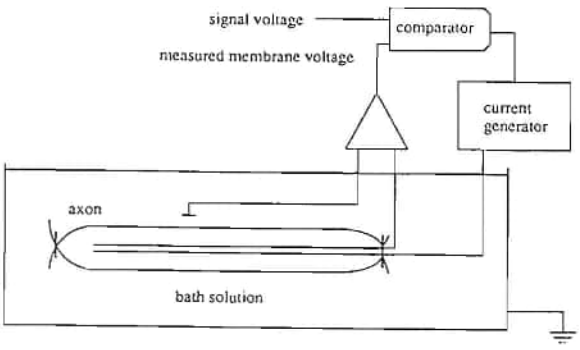


FIG. 1 REACTION OF A MYELINATED AXON TO CATHODIC $200\mu s$ PULSES WITH GRADUALLY INCREASED CURRENT. EVERY LINE SHOWS THE MEMBRANE VOLTAGES OF A 30 NODE AXON AT A FIXED TIME. SEPARATION OF LINES: $25ms$. (A) PROPAGATING SPIKE PRODUCED WITH AN ELECTRODE CURRENT OF $0.1mA$. (B) BLOCKADE AT $0.5mA$. (C) BREAK EXCITATION AT $10mA$. (D) BLOCKADE AT $10mA$ IS AGAIN OBTAINED BY LENGTHENING THE PULSE WITH A LINEAR FALLING PHASE OF $200\mu s$. NOTE THE HIGH SCALING IN (C) AND (D). THE ELECTRODE IS 0.5MM ABOVE A NODE OF A $10\mu m$ AXON. SIMULATION WITH THE CRRSS MODEL.

FIG. 2 VOLTAGE CLAMP EXPERIMENT ACCORDING TO HODGKIN AND HUXLEY (SIMPLIFIED). TWO LONG NONINSULATED WIRES ARE INSERTED ALONG THE AXON WHICH IS SEALED AT BOTH ENDS: ONE IS USED TO RECORD THE VOLTAGE ACROSS THE MEMBRANE, THE OTHER ELECTRODE INJECTS JUST ENOUGH CURRENT TO ALLOW THE RECORDED VOLTAGE TO FOLLOW THE SIGNAL VOLTAGE. THIS CURRENT IS MEASURED IN ORDER TO ANALYSE THE NONLINEAR CONDUCTING BEHAVIOR OF THE MEMBRANE.



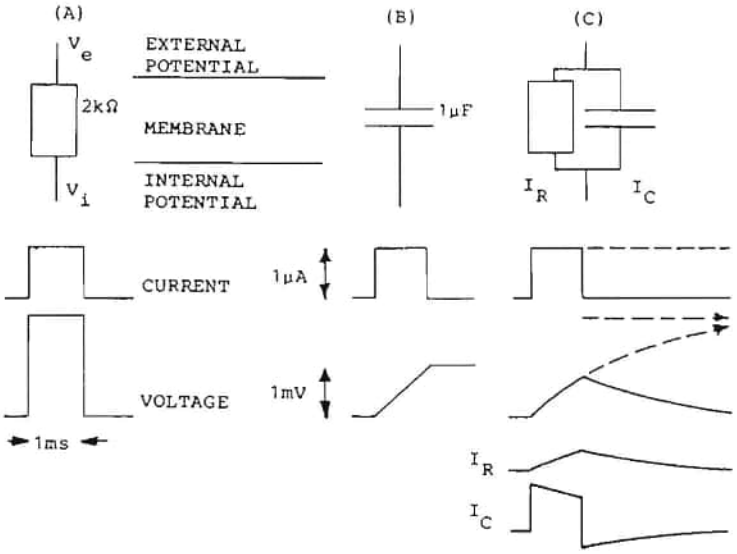


FIG. 3 SUBTHRESHOLD REACTIONS OF AXON MEMBRANES ARE DESCRIBED BY AN ELECTRIC CIRCUIT CONSISTING OF CONSTANT RESISTANCE AND CAPACITANCE. VOLTAGE CURRENT RELATIONS ARE SHOWN FOR $1cm^2$ MEMBRANE WITH $R = 2k\Omega$, $C = 1\mu F$ WHEN STIMULATED WITH A $1\mu A$ CURRENT PULSE OF $1ms$ SIMULATION BY RESISTANCE ONLY (A), CAPACITANCE (B) AND FOR BOTH (C). THE RELATIONS BETWEEN STIMULATING CURRENT AND VOLTAGE ARE

$$(A) \quad V = R.I \qquad (B) \quad I = I_C = \frac{dQ}{dt} = C \cdot \frac{dV}{dt} \qquad (C) \quad I = I_R + I_C = \frac{V}{R} + C \cdot \frac{dV}{dt}$$

THUS, IN THE GENERAL CASE (C) WE OBTAIN A DIFFERENTIAL EQUATION FOR V

$$\frac{dV}{dt} = -\frac{V}{RC} + \frac{I}{C} \qquad (C)$$

WITH $I = I_{max}$ IN THE INTERVAL $0 < t < t_{pulse}$ AND $V_{t=0} = 0$. THE RESULT OF THIS EQUATION IS $V = RI \cdot (1 - exp(-t/RC))$ FOR $0 < t < t_{pulse}$. THE VOLTAGE EXPONENTIALLY FOLLOWS THE VALUE WHICH IS DEFINED BY THE PURE OHMIC RESISTANCE OF CASE (A) (DASHED LINES IN CASE (C)). THE TIME CONSTANT OF THE MEMBRANE $\tau = R.C$ DEFINES HOW QUICKLY THE TRANSIENT BEHAVIOUR RETURNS TO THE STEADY STATE. FOR OUR EXAMPLE WE OBTAIN $RC = 2000\Omega.cm^2 \cdot 1\mu F/cm^2 = 2msec$; NOTE THAT RC HAS THE DIMENSION *sec* ! USING EQN. (C) WE SEE THAT, AT THE END OF THE PULSE, THE VOLTAGE IS DEFINED BY $exp(-t/RC) = exp(-0.5) = 0.6065$ WHICH MEANS THAT ONLY 40% OF THE FINAL VALUE (OF CASE (A)) IS REACHED. ($V_{(t=1ms)} = 0.787mV$). AFTER THE PULSE, THE VOLTAGE DROPS DOWN TO 0 WITH THE SAME EXPONENTIAL BEHAVIOUR. BY SPLITTING THE TOTAL CURRENT ACROSS THE MEMBRANE WE CALCULATE THE OHMIC PART WITH $I_R = V/R = I \cdot (1 - exp(-t/RC))$ (WITHIN THE PULSE INTERVAL), AND THE CAPACITIVE PART WITH $I_C = I \cdot exp(-t/RC)$. SEE THE LOWER TRACES OF CASE (C).

Action potential (AP) durations in mammalian nerve fibres are about 1ms or even less. The spikes propagate with velocities up to 100 m/s. This means that APs have a spatial length from some mm to some cm. Within this active length the neural membrane react differently at different locations and it is difficult to analyse the membrane properties when inneraxonal currents are active.

Squid giant axons with diameters up to 1 mm permit insertion of a stimulating electrode along the axis of the axon. In such a space clamp experiment (Fig. 2), which was introduced by HODGKIN and HUXLEY, there is no current flow along the axon and all parts of the membrane work under the same conditions. (There are 'isopotentials' at the inside, as well as at the outside.)

MEMBRANE MODELS

The electric properties of cell membranes are characterized by their resistances and capacitances. With $1 - 3\mu F/cm^2$ the capacitance of the membranes are relatively large because of the very thin sheets of the lipid bilayers. In contrast to their constant capacitance, the resistance of cell membranes depends to a large extent on the voltage sensitive gating mechanism of the ionic channels. Only in cases close to the steady state, we can approximate membrane resistances by constants of the order of $2000\Omega.cm^2$ (e.g. for lobster axons HODGKIN and RUSHTON, 1946). But variance is found from less than $1000\Omega.cm^2$ up to $50k\Omega.cm^2$ in membranes with relatively few channels. Fig 3. shows the dynamics of a RC circuit, which characterize the subthreshold membrane as well as the passive internode.

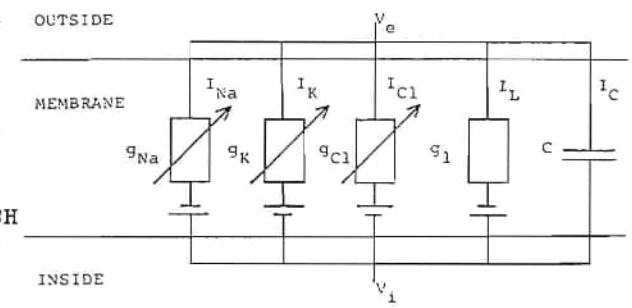


FIG. 4 MEMBRANES WITH ACTIVE GATING MECHANISMS HAVE CONDUCTANCES (g_{Na}, g_K ETC.) DEPENDING ON THE REDUCED VOLTAGE $V = V_i - V_e - V_{rest}$ ACROSS THE MEMBRANE (V_i IS THE INSIDE POTENTIAL, V_e THE EXTRACELLULAR POTENTIAL). THE ADDITIONAL VOLTAGE, RESULTING FROM THE DIFFERENCES IN THE IONIC CONCENTRATIONS ON BOTH SIDES OF THE MEMBRANE, IS SIMULATED BY BATTERIES DRAWN BELOW THE RESISTANCES. EACH IONIC CONDUCTANCE IS DIRECTLY RELATED TO THE NUMBER OF CORRESPONDING OPEN CHANNELS.

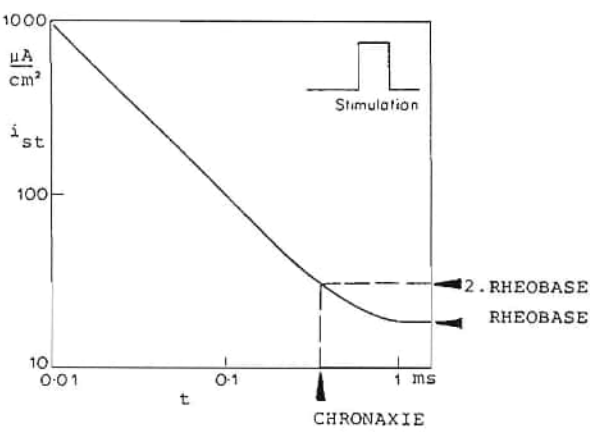


FIG. 5 STRENGTH DURATION CURVE FOR POSITIVE INJECTED CURRENT IMPULSES CALCULATED WITH HH STANDARD DATA BUT FOR $T = 29°C$. FOR SHORT TIMES, THE THRESHOLD STIMULUS CHARGE IS NEARLY CONSTANT AND THIS CAUSES THE STRAIGHT PART IN THE STRENGTH DURATION CURVE WHICH IS PLOTTED WITH LOGARITHMIC SCALES. IMPULSES LONGER THAN $1ms$ NEED ALMOST THE SAME THRESHOLD CURRENT OF $16\mu A/cm^2$, WHICH IS CALLED RHEOBASE. THE DASHED VERTICAL LINE MARKS CHRONAXIE, WHICH IS $340\mu s$ HERE. CHRONAXIE IS THE DURATION OF THAT IMPULSE WHICH NEEDS TWICE THE RHEOBASE CURRENT TO GENERATE AN AP.

The following four models have turned out to be useful to simulate suprathreshold reactions in mammalian axons: (See Box 1-4 for equations, Table II for constants and Fig. 6)

1952: The HODGKIN-HUXLEY (HH) MODEL describes the voltage current relation in an unmyelinated squid axon at $6.3°C$. It contains a thermal coefficient k which takes account of the quicker gating process at higher temperatures. Simulation with higher temperatures shows, in accordance with experiments, a reduction of spike amplitude, which leads to the 'heat block' at 31-33°C (RATTAY 1990, HODGKIN and KATZ 1949). However, HH data with $T = 29°C$ produces reaction times which are suited for simulation of the auditory nerve in respect to chronaxie (Fig. 5), AP duration and refractory behaviour. (See RATTAY 1990 for details.) Moreover, the HH model with a proper value k can be used to simulate the active parts in the electric stimulated dentritic tree.

TABLE I: SYMBOLS AND ABBREVIATIONS

AP	action potential
c	capacitance of cell membrane per cm^2
CRRSS	Chiu-Ritchie-Rogart-Stagg-Sweeney (model)
d	axon diameter
E	voltage, (V is also used for voltage)
f	activating function
FH	Frankenhaeuser-Huxley (model)
g_{Na}, g_K, g_L	maximum conductance of sodium, potassium and leakage per cm^2 of membrane
h	probability for an ionic membrane gating process
HH	Hodgkin-Huxley (model)
I, I_R, I_C	stimulus, ohmic and capacitive current
i	current density, i.e., current per cm^2
i_{ionic}	ionic current density passing through the membrane
i_{Na}, i_K, i_L, i_P	sodium, potassium, leakage and unspecific current densities
i_{st}	stimulating current density
$[Na]_i, [Na]_o$	sodium concentration, inside and outside of a fibre
$[K]_i, [K]_o$	potassium concentration, inside and outside of a fibre
k	temperature coefficient
L	nodal gap width
m	probability for an ionic membrane gating process
ms	millisecond
n	probability for an ionic membrane gating process
p	probability for an ionic membrane gating process
P_{Na}, P_K, P_P	ionic permeabilities
Q	charge
Q_{10}	acceleration factor for a temperature increase of 10^o
SE	Schwarz-Eikhof (model)
T, T_0	temperature, laboratory temperature
t	time
x	length coordinate of axons
Δx	segment length of fibre, for myelinated fibres Δx is equal to the internodal length
V, V_n	reduced voltage (of the nth segment) across the membrane, i.e., in the resting state $V=0$
V_e, V_i	extracellular potential, intracellular potential
V_{Na}, V_K, V_L	voltages across the membrane, caused by different (sodium, potassium, unspecific) ionic concentrations inside and outside of a fibre
V_{rest}	resting voltage across the membrane
$\alpha_m, \alpha_n, \alpha_h, \alpha_p$	coefficients in membrane models
$\beta_m, \beta_n, \beta_h, \beta_p$	coefficients in membrane models
ρ_i, ρ_e	intracellular and extracellular resistivity

1964: The FRANKENHAEUSER-HUXLEY (FH) MODEL for the node of frog motor neuron has a main equation, which models the ionic conductances in a more complex way compared to the HH model. It turns out that for repolarisation potassium current is not the only important

1 | HODGKIN-HUXLEY MODEL

$$\dot{V} = [-g_{Na}m^3h(V - V_{Na}) - g_K n^4(V - V_K) - g_L(V - V_L) + i_{st}]/c \quad \text{(HH-1)}$$

$$\dot{m} = [-(\alpha_m + \beta_m)\cdot m + \alpha_m]\cdot k \quad \text{(HH-2)}$$

$$\dot{n} = [-(\alpha_n + \beta_n)\cdot n + \alpha_n]\cdot k \quad \text{(HH-3)}$$

$$\dot{h} = [-(\alpha_h + \beta_h)\cdot h + \alpha_h]\cdot k \quad \text{(HH-4)}$$

with the coefficient k for temperature T (in ^oC)

$$k = 3^{0.1T-0.63} \quad \text{(HH-5)}$$

2 | FRANKENHAEUSER-HUXLEY MODEL

$$\dot{V} = [-i_{Na} - i_K - i_P - i_L + i_{st}]/c \quad \text{(FH-1)}$$

with the ionic currents

$$i_{Na} = P_{Na}m^2h\frac{EF^2}{RT}\frac{[Na]_o - [Na]_i e^{EF/RT}}{1 - e^{EF/RT}} \quad \text{(FH-2)}$$

$$i_K = P_K n^4 \frac{EF^2}{RT}\frac{[K]_o - [K]_i e^{EF/RT}}{1 - e^{EF/RT}} \quad \text{(FH-3)}$$

$$i_P = P_{Na}p^2\frac{EF^2}{RT}\frac{[Na]_o - [Na]_i e^{EF/RT}}{1 - e^{EF/RT}} \quad \text{(FH-4)}$$

$$i_L = g_L(V - V_L) \quad \text{(FH-5)}$$

with $E = V + V_{rest}$

$$\dot{m} = -(\alpha_m + \beta_m)\cdot m + \alpha_m \quad \text{(FH-6)}$$

$$\dot{n} = -(\alpha_n + \beta_n)\cdot n + \alpha_n \quad \text{(FH-7)}$$

$$\dot{h} = -(\alpha_h + \beta_h)\cdot h + \alpha_h \quad \text{(FH-8)}$$

$$\dot{p} = -(\alpha_p + \beta_p)\cdot p + \alpha_p \quad \text{(FH-9)}$$

3 | CRRSS MODEL

SWEENEY *et al.* (1987) transformed the original data of CHIU, RITCHIE, ROGERT & STAGG (1979) from experimental temperature of $T = 14^oC$ to $T = 37^oC$. We name the following equations after the investigators CRRSS model.

$$\dot{V} = [-g_{Na}m^2h(V - V_{Na}) - g_L(V - V_L) + i_{st}]/c \quad \text{(CRRSS-1)}$$

$$\dot{m} = -(\alpha_m + \beta_m)\cdot m + \alpha_m \quad \text{(CRRSS-2)}$$

$$\dot{h} = -(\alpha_h + \beta_h)\cdot h + \alpha_h \quad \text{(CRRSS-3)}$$

4 | SCHWARZ-EIKHOF MODEL

$$\dot{V} = [-i_{Na} - i_K - i_L + i_{st}]/c \quad \text{(SE-1)}$$

with the ionic currents

$$i_{Na} = P_{Na}m^3h\frac{EF^2}{RT}\frac{[Na]_o - [Na]_i e^{EF/RT}}{1 - e^{EF/RT}} \quad \text{(SE-2)}$$

$$i_K = P_K n^4 \frac{EF^2}{RT}\frac{[K]_o - [K]_i e^{EF/RT}}{1 - e^{EF/RT}} \quad \text{(SE-3)}$$

$$i_L = G_L(V - V_L) \quad \text{(SE-4)}$$

with $E = V + V_{rest}$

$$\dot{m} = -(\alpha_m + \beta_m)\cdot m + \alpha_m \quad \text{(SE-5)}$$

$$\dot{n} = -(\alpha_n + \beta_n)\cdot n + \alpha_n \quad \text{(SE-6)}$$

$$\dot{h} = -(\alpha_h + \beta_h)\cdot h + \alpha_h \quad \text{(SE-7)}$$

BOX 1-4 EQUATIONS FOR NEURAL MEMBRANE DYNAMICS. (USE ALSO TABLE I FOR THE MEANING OF THE SYMBOLS AND TABLE II FOR ADDIONAL INFORMATIONS ON THE EXPRESSIONS AND CONSTANTS OF THE MODELS.)

ALL THE MODELS USE THE MAIN EQUATIONS OF THE HH OR THE FH TYPE. THE CRRSS AND THE SE MODEL ARE DIRECTLY APPLICABLE FOR 37^oC. THE α'S AND β'S OF THE GATING PROCESSES DEPEND ON TEMPERATURE. Q_{10} IS THE ACCELERATION FACTOR FOR TEMPERATURE INCREASE OF 10^oC, E.G. FOR THE SQUID MEMBRANE $Q_{10} = 3$ IS VALID FOR ALL THE α'S AND β'S AND THEREFORE, THE INFLUENCE OF TEMPERATURE CAN BE CALCULATED BY EQN. HH-5 ($T_0 = 6.3^oC$). NOTE, THAT IN THE FH AND IN THE SE MODEL THE ABSOLUTE TEMPERATURE (IN ^oK) ENTERS EQNS. FH-2 - FH-4 AND SE-2, SE-3 AND, ADDITIONALLY, A TEMPERATURE DIFFERING FROM THE ORIGINAL EXPERIMENTS (20^oC FOR FH AND 37^oC FOR SE) DEMANDS FOR RECALCULATION OF THE α'S AND β'S ACCORDING TO TABLE II.

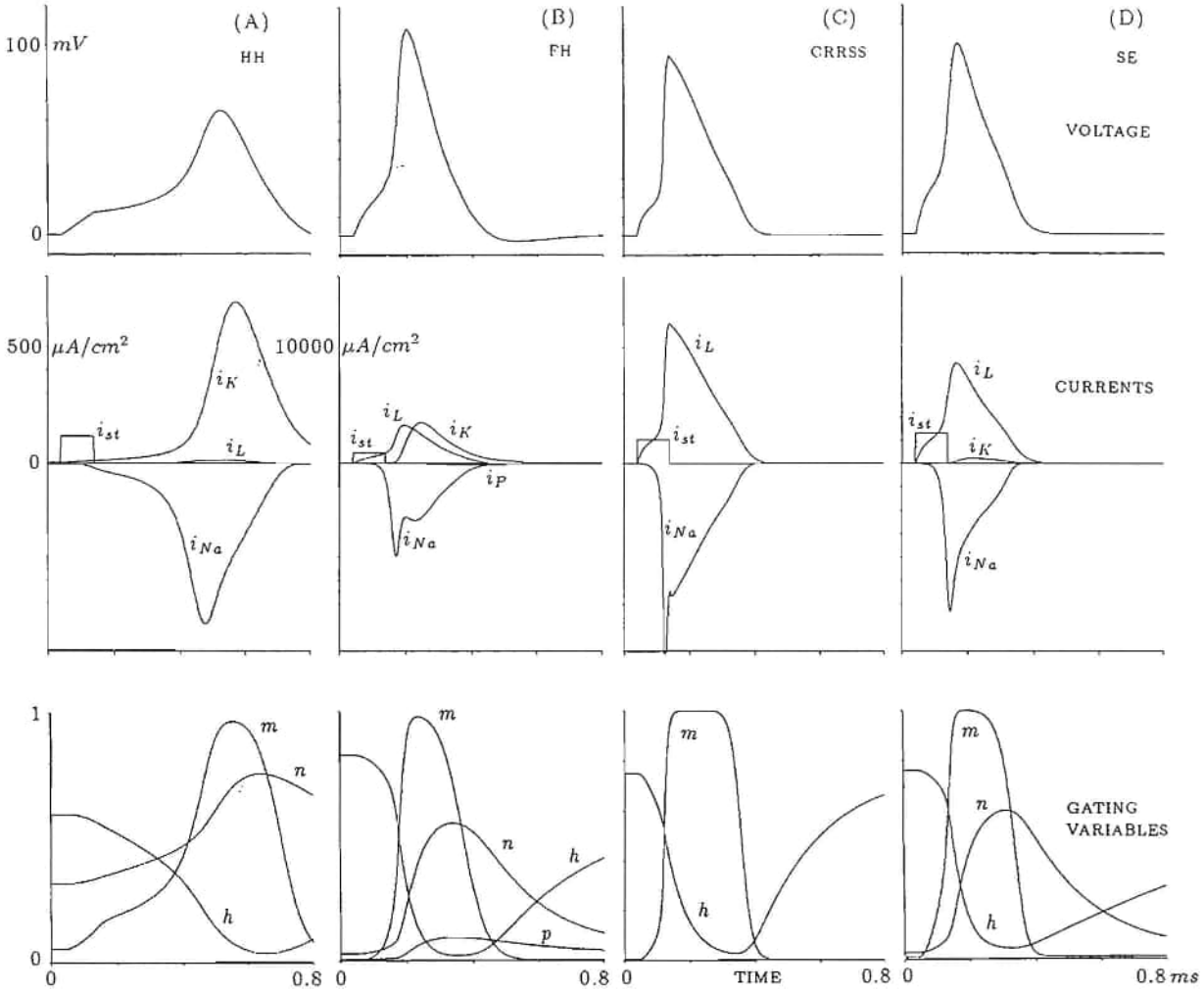


FIG. 6 LOCAL MODEL RESPONSES AT $37°C$. IN ALL CASES THE Q_{10}'S OF TABLE II ARE USED, BUT THE HH MODEL IS CALCULATED WITH k=12. NOTE IN THE CASE OF THE HH MODEL: THE DELAY OF THE AP AND THE SCALE FOR THE CURRENTS DIFFER FROM THE OTHER MODELS. STIMULATION WITH 100μs CURRENT PULSES 20 % ABOVE THRESHOLD (HH: 118$\mu A/cm^2$, FH: 890$\mu A/cm^2$, CRRSS: 2050$\mu A/cm^2$, SE: 2625$\mu A/cm^2$).

driving force, but that the process is also supported by the leakage current (compare Fig. 6 A and B). The laboratory temperature is 20 $°C$; application to higher temperatures needs fitting of α's and β's according to Table II.

1987: The CHIU-RITCHIE-ROGERT-STAGG-SWEENEY (CRRSS) MODEL for the node of a rabbit motor neuron shows that potassium current is not essential in the mammalian node. This model becomes now the most used one for FES-simulations.

1987: The SCHWARZ-EIKHOF (SE) MODEL for the node in a rat motor neuron is the only one which is based on $37°C$ experiments. It takes into account the minor influence of potassium current in the mammalian node.

An action potential is initiated by increase of the sodium conductance, i. e. sodium channels open up. This gating process can be described in a statistical manner by probability variables. HODGKIN and HUXLEY assumed, that a sodium ion has to pass 3 activation gates and one inactivation gate when crossing the membrane and therefore, they modelled the sodium current

TABLE II: EXPRESSIONS AND CONSTANTS FOR THE

	HH MODEL	FH MODEL	CRRSS MODEL	SE MODEL
α_m	$\frac{2.5-0.1V}{exp(2.5-0.1V)-1}$	$\frac{0.36\cdot(V-22)}{1-exp\left(\frac{22-V}{3}\right)}$	$\frac{97+0.363V}{1+exp\left(\frac{31-V}{5.3}\right)}$	$\frac{1.87\cdot(V-25.41)}{1-exp\left(\frac{25.41-V}{6.06}\right)}$
β_m	$4\cdot exp\left(-\frac{V}{18}\right)$	$\frac{0.4\cdot(13-V)}{1-exp\left(\frac{V-13}{20}\right)}$	$\frac{\alpha_m}{exp\left(\frac{V-23.8}{4.17}\right)}$	$\frac{3.97\cdot(21-V)}{1-exp\left(\frac{V-21}{9.41}\right)}$
α_n	$\frac{1-0.1V}{10.(exp(1-0.1V)-1)}$	$\frac{0.02\cdot(V-35)}{1-exp\left(\frac{35-V}{10}\right)}$		$\frac{0.13\cdot(V-35)}{1-exp\left(\frac{35-V}{10}\right)}$
β_n	$0.125\cdot exp\left(-\frac{V}{80}\right)$	$\frac{0.05\cdot(10-V)}{1-exp\left(\frac{V-10}{10}\right)}$		$\frac{0.32\cdot(10-V)}{1-exp\left(\frac{V-10}{10}\right)}$
α_h	$0.07\cdot exp\left(-\frac{V}{20}\right)$	$-\frac{0.1\cdot(V+10)}{1-exp\left(\frac{V+10}{6}\right)}$	$\frac{\beta_h}{exp\left(\frac{V-5.5}{5}\right)}$	$-\frac{0.55\cdot(V+27.74)}{1-exp\left(\frac{V+27.74}{9.06}\right)}$
β_h	$\frac{1}{exp(3-0.1V)+1}$	$\frac{4.5}{1+exp\left(\frac{45-V}{10}\right)}$	$\frac{15.6}{1+exp\left(\frac{24-V}{10}\right)}$	$\frac{22.6}{1+exp\left(\frac{56-V}{12.5}\right)}$
α_p		$\frac{0.006\cdot(V-40)}{1-exp\left(\frac{40-V}{10}\right)}$		
β_p		$-\frac{0.09\cdot(V+25)}{1-exp\left(\frac{V+25}{20}\right)}$		
V_{rest} $[mV]$	-70	-70	-80	-78
V_{Na} $[mV]$	115		115	
V_K $[mV]$	-12			
V_L $[mV]$	10.6	0.026	-0.01	0
g_{Na} $[k\Omega^{-1}cm^{-2}]$	120		1445	
g_K $[k\Omega^{-1}cm^{-2}]$	36			
g_L $[k\Omega^{-1}cm^{-2}]$	0.3	30.3	128	86
c $[\mu F/cm^2]$	1	2	2.5	2.8
$V(0)$ $[mV]$	0	0	0	0
$m(0)$	0.05	0.0005	0.003	0.0077
$n(0)$	0.32	0.0268		0.0267
$h(0)$	0.6	0.8249	0.75	0.76
$p(0)$		0.0049		
T_0	6.3^oC	293.15^oK=20^oC	37^oC	310.15^oK=37^oC
$Q_{10}(\alpha_m)$	3	1.8	3	2.2
$Q_{10}(\beta_m)$	3	1.7	3	2.2
$Q_{10}(\alpha_n)$	3	3.2	3	3
$Q_{10}(\beta_n)$	3	2.8	3	3
$Q_{10}(\alpha_h)$	3	2.8	3	2.9
$Q_{10}(\beta_h)$	3	2.9	3	2.9
P_{Na} $[cm/s]$		0.008		0.00328
P_K $[cm/s]$		0.0012		0.000134
P_P $[cm/s]$		0.00054		
$[Na]_o$ $[mmole/l]$		114.5		154
$[Na]_i$ $[mmole/l]$		13.7		8.71
$[K]_o$ $[mmole/l]$		2.5		5.9
$[K]_i$ $[mmole/l]$		120		155
Faraday constant F=96485 $[C/mole]$		gas constant R=8314.4$[mJ/K/mole]$		

by

$$i_{Na} = g_{Na} \cdot m^3 h \cdot (V - V_{Na})$$

The gating variables m and h as well as n for the potassium current are functions of voltage and time and can be described by differential equations.

It is convenient to use the reduced voltage $V = V_i - V_e - V_{rest}$ where V_i and V_e are the intracellular and extracellular potential respectively and V_{rest} is the resting voltage of the cell. Then in the steady state $V = 0$.

According to the voltage clamp experiment of Fig. 2, the relation between the injected current and the voltage across the membrane, depends on the active surface, i.e. on the diameter and the length of the fibre. In order to be independent of geometrical parameters we will calculate the currents passing through $1cm^2$ of the membrane. Thus, all currents become current densities and c the capacity per cm^2. By setting $\frac{dV}{dt} = \dot{V}$ and $i_{ionic} = i_{Na} + i_K + i_L$ we arrive at the complete description of the four membrane models. (Box 1-4)

Now, we assume that the fibre is at rest before stimulated with a current from an inneraxonal electrode. In all the membrane models, the first part of the stimulating signal will evoke a subthreshold response which can be predicted by a simple RC circuit with constant R. (Compare the first parts of the APs in Fig. 6 and Fig. 3C.) In order to reach threshold voltage we need a positive stimulus current, i. e. only a positive current can generate an AP. This is generally true for all four models with one exception: in fact, the special parameter configuration of the HH model also allows stronger negative signals to produce an AP. This is a 'swinging through' phenomenon similar (but stronger) to the hyperpolarization effect (negative afterpotential) at regular stimulation. Note, that the other membrane models don't show this effect. Nevertheless, we find a similar situation in Fig. 1C where switching off the strong stimulus impulse produces an AP (break excitation).

SOME RESULTS WITH SPATIAL MODELS

A milestone in computer simulation of neural reactions to electrical stimuli was reached in 1976 when McNeal introduced his spatial model which consists of a network of local models. Many investigators have used this, or sometimes more detailed, lumped circuit models. For example, Halter and Clark took different parts of internode into consideration: the periaxonal space, the area close to the node and the homogeneous part of the internode. Altman and Plonsey calculated the influence of a monopolar electrode to the electrical stimulated nerve bundle and they demonstrated that accumulated fibre activities of the whole stimulated bundle causes other potentials in the extracellular space as in the case when only a single fibre is embedded in a homogeneous fluid. Nevertheless, we obtain a good impression of the principles of electrical stimulation, if we neglect the capacity and membrane conductance of the internode as well as the change of the extracellular potential by fibres' own activity.

In the McNeal model the excitable fibre is parted into segments of the length Δx and every segment is represented by an electric circuit (Fig. 7). In order to find the fibre reaction, the extracellular voltages $V_{e,n}$, produced by the electrodes (or by magnetic coils), should be calculated first. Then, the reduced transmembrane voltage V_n of the nth segment ($V_n = V_{i,n} - V_{e,n} - V_{rest}$) can be computed from the current flow to the point marked as filled circle in Fig. 7. In the case of equal segments, and assuming that myelin has insignificant conductance and capacitance, we obtain the following equation.

$$\frac{dV_n}{dt} = \left[\frac{d\Delta x}{4\rho_i L}\left(\frac{V_{n-1} - 2V_n + V_{n+1}}{\Delta x^2} + \frac{V_{e,n-1} - 2V_{e,n} + V_{e,n+1}}{\Delta x^2}\right) - i_{ionic,n}\right]/c$$

For suprathreshold investigations the ionic currents $i_{ionic,n}$ must be calculated for every segment by using a separate (local) membrane model.

The influence of the artificial electrical field on each of the segments is given by the *activating function* f. For equal segments f is the second spatial difference quotient of the extracellular potential V_e along the fibre:

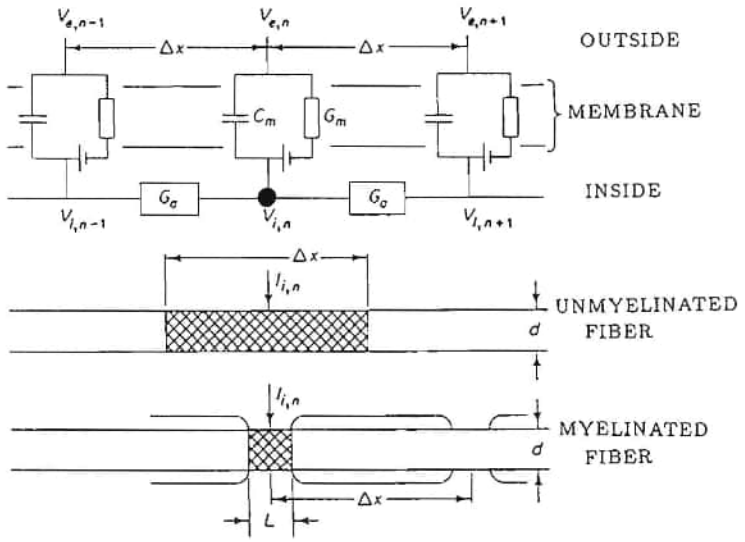


FIG. 7 ELECTRICAL NETWORK TO SIMULATE THE CURRENTS IN A FIBRE. UNMYELINATED AS WELL AS MYELINATED AXONS OF DIAMETER d ARE SEGMENTED INTO CYLINDERS OF THE LENGTH Δx. MYELINATED FIBRES HAVE ACTIVE MEMBRANE PARTS ONLY IN THE CROSS-HATCHED AREA AT THE NODES OF RANVIER. HERE, IONIC CURRENTS WILL ENTER ONLY AT THE NODAL GAP WIDTH L. THE MEMBRANE OF EVERY CYLINDER IS SIMULATED BY AN ELECTRIC CIRCUIT CONSISTING OF CAPACITANCE C_m, VOLTAGE SOURCE AND NONLINEAR RESISTANCE. $V_{e,n}$ AND $V_{i,n}$ ARE THE EXTERNAL AND THE INTERNAL POTENTIALS AT THE Nth SEGMENT. G_m SYMBOLIZES THE NONLINEAR MEMBRANE CONDUCTANCE AND G_a THE CONDUCTANCE OF AXOPLASM BETWEEN TWO SEGMENTS. $I_{i,n}$ IS THE IONIC CURRENT PASSING THE MEMBRANE OF THE Nth SEGMENT.

$$f = \frac{V_{e,n-1} - 2V_{e,n} + V_{e,n+1}}{\Delta x^2}$$

In the case of infinitely small segments, which can be used a.o. to describe the unmyelinated fibre the activating function becomes the second derivative of the extracellular potential. The author has shown in previous publications that several phenomena known from experiments are reflected by the activating function concept (RATTAY 1986, RATTAY 1989, RATTAY 1990).

The simplest problem which needs examination with lumped circuits is the simulation of an axon in a homogeneous medium when excited with a small spherical electrode. Fig. 8 shows the situation and f for the continuous case, which is directly applicable to unmyelinated fibres, but can also be used as an approach for myelinated fibres when the electrode distance is greater than the internodal distance. The activating function illustrates the following facts:

i) In general stimulation by anodic currents needs stronger impulses than by cathodic currents. Comparing Fig. 8B and Fig. 8C shows the differences in maximum values of f for both cases.

ii) Stimulation with strong cathodic signals can lead to a blockade of the action potential (cathodic block). The activating function predicts that strong cathodic signal produces strong hyperpolarized areas on both sides, which can block the spike from propagation (Fig. 2C; see also Fig. 8).

The activating function is of use to illustrate where excitation or blockade will start, but the question is how strong the influence of the nonlinear part of the system is, which results in the gating mechanism of the active membrane. The activating function predicts that the threshold with anodic signals is five times that of cathodic. However, Fig. 9 demonstrates that the anodic excitation

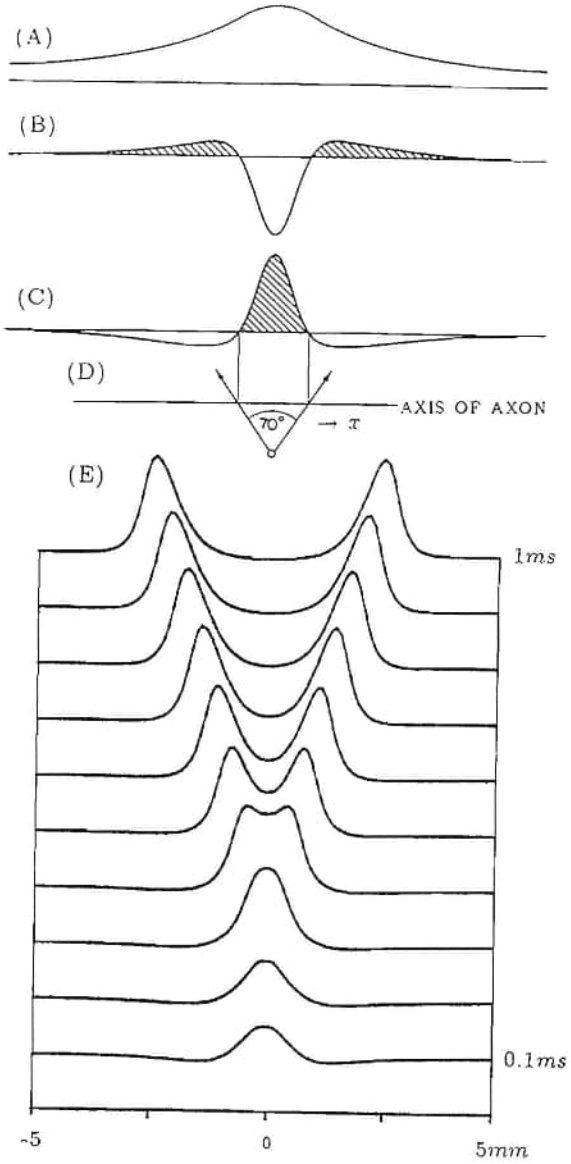


FIG. 8 INFLUENCE OF A SMALL STIMULATING ELECTRODE ALONG AN UNMYELINATED FIBRE. (A) SHOWS THE CHANGE OF THE EXTRACELLULAR POTENTIAL USING ANODIC STIMULATION. IN ADDITION THE ACTIVATING FUNCTION f IS SHOWN FOR ANODIC (B) AND CATHODIC (C) STIMULATION. THE HORIZONTAL AXIS CORRESPONDS TO THE X-AXIS, BEING THE AXIS OF THE FIBRE. THE PARTS ($f > 0$) WHERE THE FIBRE IS DEPOLARIZED ARE SHADED. (D) SHOWS THE POSITION OF THE ELECTRODE TO OBTAIN THE UPPER TRACES. THE BORDER BETWEEN THE DEPOLARIZING AND HYPERPOLARIZING REGIONS IS GIVEN BY AN ANGLE OF ABOUT 70°. THIS ANGLE DOES NOT DEPEND ON FIBRE PARAMETERS OR ON THE CONDUCTANCE OF THE EXTRACELLULAR MEDIUM AS LONG AS IT IS HOMOGENEOUS AND ISOTROPIC. (E) VOLTAGE ALONG THE AXON AS A RESPONSE TO AN EXTRACELLULAR CATHODIC STIMULUS SIGNAL. EVERY LINE SHOWS THE MEMBRANE VOLTAGE ALONG THE AXON AT A FIXED TIME. AT THE END OF A $100\mu s$ SQUARE PULSE, THE DISTRIBUTION OF THE VOLTAGE IS SIMILAR TO THE ACTIVATING FUNCTION AS A CONSEQUENCE OF THE NEARLY CONSTANT SUBTHRESHOLD MEMBRANE CONDUCTANCE. SIMULATION IS WITH STANDARD HH DATA, BUT FOR $k = 12$; THE AXON DIAMETER IS 10μ, ELECTRODE CURRENT $-1.5mA$, ELECTRODE DISTANCE $1mm$, EXTRACELLULAR RESISTIVITY $0.3k\Omega \cdot cm$.

factor also depends on pulse duration. (Due to logarithmic scales a constant relation between cathodic and anodic excitation thresholds would show parallel curves.) An even clearer example of the dynamics in the gating process can be seen in the relation between cathodic threshold and cathodic block (Fig. 9), which is of great interest for several applications, e.g. one side firing techniques to suppress unwanted firing by collision block. (UNGAR et al 1986)

DISCUSSION

The paradoxical relation between firing and stimulus strength which was introduced at the beginning of the article can be explained in the following way:

i) In contrast to the positive inneraxonal stimuli of the space clamp experiment a monopolar electrode will excite an axon (in accordance with the activating function) more easily by negative stimulating currents (compare Fig. 8B and 8C). Of course a weak signal will generate only subthreshold reactions.

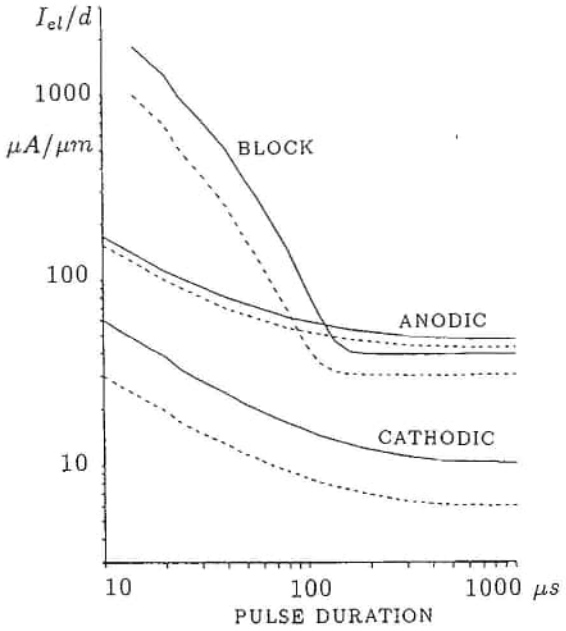


FIG. 9 EXCITATION AND BLOCKADE SIMULATED WITH THE FH MODEL FOR AN ELECTRODE DISTANCE EQUAL TO $\Delta x/2$. MAXIMUM CURRENT STRENGTHS ARE NECESSARY WHEN THE MONOPOLAR ELECTRODE IS CENTERED BETWEEN TWO NODES (FULL LINES), MINIMUM STRENGTHS ARE NEEDED WHEN THE ELECTRODES ARE JUST ABOVE A NODE (BROKEN LINES). $d=\Delta x/100$, $\rho_i=100\Omega{\cdot}cm$, $\rho_e=300$ $\Omega{\cdot}cm$, $L=2.5\mu m$, $T=310.15°K$ $(37°C)$; OTHER DATA FROM TABLE II.

ii) Threshold current depends on electrode distance, pulse length (Fig. 5 and Fig. 9), fibre diameter and, if the electrode is close to the fibre also on the distance to the nearest node (Fig. 9).

iii) Stronger currents produce strong hyperpolarized regions at both sides of the electrode according to the negative part of the activating function (Fig. 8C) which prevents the AP from passing – no propagation. Special electrode configurations (e.g. bipolar electrodes or cuff electrodes) will cause asymmetric activating functions with hyperpolarizing regions of different strengths at both sides and thus, they permit one side firing (see, e.g. MORTIMER et al 1988, RATTAY 1990).

iv) When very strong impulses are switched off (break excitation) the strong hyperpolarization produces a 'swinging through' effect similar to the inverse inside stimulation of the HH model mentioned above.

v) The break excitation disturbes the block effect which is of use for several applications. FANG and MORTIMER appended a long falling phase at the end of the stimulus signal to avoid break excitation, when they used the block technique to obtain natural recruitment order: By a slow falling phase the 'swinging through' effect can be avoided and thereby we are able to obtain block again (Fig. 1D).

In order to obtain anodic or cathodic threshold or block, and in spite of the fact, that the FH model shows other intensities of ionic current densities, we find that similar quantitative results for all three myelinated nerve models (as regards the relations between electrode current and pulse duration) can be achieved, provided that the node length is assumed as $L = 2.5\mu m$ at FH and $L = 1\mu m$ at CRRSS and SE.

The question remains: What is the use of the HH model in simulation of artificial neural excitation? Paradoxically this model is the only one which reflects the following effects known from experiments:

i) It mimics multiple spiking within a period of a $100Hz$ sinusoidal signal of high strength.

ii) It has a much higher range in response time between weak and strong stimuli. This is seen by

the relative long flat part before an AP is generated by signals just above threshold (compare Fig. 6A - 6D).

iii) The HH model with $k = 12$*) has a chronaxie of $340\mu s$ and this is exactly the measured one. The chronaxies of all other models are much shorter.

The method of segmentation of the nerve need not be restricted to the method shown in this article. Of course, we can use the same principle for complex forms of nerve geometry, taking into consideration change of diameter, branching, soma, dentritic tree and other irregularities as well as curvature, different end conditions etc. Moreover the same technique also allows for fine segmentations in order to investigate the influence of myelin or the complex geometric situation in and around the target fibre.

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*) This corresponds to $T = 29°C$ if the original $Q_{10} = 3$ is used. However with this k the refractory behavior is in accord with experiments.

MEASURING, ESTIMATING AND PRESERVING SKELETAL MUSCLE POWER FOR CARDIAC ASSISTANCE

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SUMMARY

The prospect of deriving cardiac assistance from a patient's own skeletal muscle offers new possibilities for the surgical treatment of chronic end-stage cardiac failure. Estimates based on experimental data suggest that the maximum continuous pumping work available from human latissimus dorsi muscle would be about 1.8 W, equivalent to an assist of about 8 l/min if the power could be harnessed efficiently. A feasible goal would be a continuous partial assist of 1–2 l/min, with flows of up to 8 l/min sustainable for limited periods. The acquisition of fatigue resistance appropriate to cardiac levels of work is not contingent on induction of myosin isoforms of the slow muscle type. In fact, conditioning régimes that preserved the fast muscle type of myosin would have the advantage of retaining more of the original contractile speed and power of the skeletal muscle. It remains to be seen whether this requirement can be reconciled with sustained pumping activity.

STATE OF THE ART

Grafts of skeletal muscle are now being used experimentally in a variety of configurations with a view to their potential for providing cardiac assistance in patients with heart failure. One such procedure—cardiomyoplasty—has already achieved clinical application in more than 200 patients worldwide. These new surgical approaches depend on 'conditioning' the skeletal muscle with long-term electrical stimulation so that it does not fatigue when called upon to perform its task continuously.

A muscle will be resistant to fatigue if it can supply, on a continuous basis, sufficient ATP to meet the prevailing energy costs of contraction. These costs derive mainly from the cyclic turnover of chemical bonds between actin and myosin and the transport of calcium between intracellular compartments. Skeletal muscle that has been conditioned by long-term electrical stimulation acquires more favourable bioenergetics for sustained contraction as a result of changes both in the isoforms of myosin and in the kinetics of the release and uptake of calcium. At the same time, sustained production of ATP becomes possible through a dramatic increase in the capacity of oxidative pathways, supported by increases in capillary blood supply and mitochondrial volume. As a result, the production of ATP can match even extreme increases in the utilization of ATP.

There is, however, a price to pay. Prolonged conditioning reduces the shortening velocity of the muscle to about 25% of control values, and this reduction in contractile speed, together with a loss of muscle bulk, is responsible for a substantial loss of power /9/. Moreover, the slowing of

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contraction and relaxation means that less shortening can take place within one or other phase of the cardiac cycle, and this limits the degree of assist that can be safely provided. Must we pay this price, or could we devise stimulation régimes that produce fatigue resistance and yet preserve mass and contractile speed?

In order to address this question, it is first necessary to recognise that "fatigue resistance" is not an absolute term. A muscle that is fatigue-resistant under one set of conditions may fatigue rapidly if challenged by conditions that impose a higher rate of working. So how much power does cardiac assistance require? And how does this compare with the power that a skeletal muscle can sustain after conditioning?

ESTIMATING THE POWER REQUIRED FOR CARDIAC ASSISTANCE

The power required for pumping is related to the flow and the mean pressure by the expression:

$$\text{Power} = \text{Flow} \times \text{Pressure}$$

For a normal 70 kg subject with a body surface area of 1.7 m^2, the mean flow at rest is about 6 l/min /3/. For an average systemic pressure of 100 mmHg, this corresponds to about 1.3 W. A capacity for at least 14 l/min should be available to support activities of daily living that impose a transiently higher demand: walking and climbing stairs, for example. This corresponds to a short-term power capability of at least 3 W. Of course, these are the levels needed to provide the entire systemic blood flow. In cases where the patient's heart is less severely impaired, lower levels may provide partial assistance that is sufficient to restore a reasonable quality of life while improving, or at least preventing further deterioration in, the condition of the patient's own heart. To what extent is it feasible to expect these levels of work from skeletal muscle?

MEASURING THE POWER AVAILABLE FROM SKELETAL MUSCLE

Isometric measurements provide no insight into the working capacity of a muscle, for a muscle must shorten in order to do work on an external load. We developed an apparatus that enabled us to measure the force developed by rabbit tibialis anterior (TA) muscles for a whole range of constant shortening velocities /5/. More recently, we have been using a powerful, fast servomotor under computer control to measure the shortening velocities corresponding to different constant loads. In either case, what emerges from the data is a curve describing the relationship between force and velocity. Since power = force x velocity, the same data can be presented in the form of a power–velocity curve. From this we can obtain the peak power and its corresponding velocity (V_{opt}).

For an unconditioned rabbit TA muscle, this peak power output is about 300 W/kg. After 10 weeks of continuous stimulation at a frequency of 10 Hz, the mass falls to 50% of control and V_{opt} to 25% of control values. The combined effect of these losses is a reduction in specific power output to about 10% of control values /7, 8/. In absolute terms, the maximal acute power output of such a muscle is 30–40 W/kg, close to the systolic power of the left ventricular myocardium. However, the power available for cardiac assistance must be less than this because:

a. In practice the muscle must spend at least as much time in relaxation as in contraction. Since work is available only during contraction the maximum power output would be about 20 W/kg.
b. The peak power outputs refer to the rate at which work is performed during a single contraction. We could not expect muscles to sustain such levels in repetitive use.

To examine the latter point, we have conducted fatigue tests on the same rabbit TA muscles under conditions in which they were loaded to perform at the peak of the power curve and stimulated to work at 10 W/kg. We were able to confirm that conditioned muscles could maintain this level of work for many hours. It is unlikely, however, that they could sustain levels much higher than this.

Even the figure of 10 W/kg overestimates the specific power available for clinical application, because the contractile characteristics of human muscle are slower than those of the rabbit /1/. The difference in power may be less obvious when the comparison is made between human and rabbit muscles that are fully conditioned for continuous use, but for purposes of estimation it would seem sensible to reduce this figure to 8 W/kg. The actual mass of muscle available for generating work will also be less than the starting mass, because:

a. Muscle that performs work continuously at this high level undergoes a loss of bulk which stabilizes at approximately 50% in the long term /6/. In the case of a muscle such as latissimus dorsi, which is the preferred choice of muscle for cardiac assist, this would reduce the working mass to about 300 g.
b. The grafting procedure is associated with a loss of mass. Experiments on orthotopic grafting of rabbit rectus femoris muscles suggest that a chronic reduction in mass of 25% would be anticipated as a result of tendon section alone /2/. This would bring about a further reduction to about 225 g.
c. Some (currently indeterminate) loss of muscle fibres must be anticipated as a result of ischaemic damage incurred by the grafting procedure.

Multiplying the specific tension (8 W/kg) by the mass (225 g) gives the maximum power available as 1.8 W. This amount of pumping power, if it were coupled directly into the systemic circulation, would be equivalent to about 8 l/min—more than enough to replace left ventricular function completely under resting conditions. A more realistic objective would be a partial assist of about 2 l/min, with a reserve of up to 8 l/min for transient, higher levels of exertion. If the patient's own heart were capable of providing 3–5 l/min, such an assist should restore a normal quality of life.

While these calculations support the feasibility of the skeletal muscle approach, there is no reason to feel satisfied with the *status quo*. If we could avoid some of the loss of power during conditioning, it would enable us to work with larger safety margins, and to tolerate some energy losses in harnessing the power of the skeletal muscle for pumping blood. Moreover, a fully conditioned muscle takes longer to contract and relax than cardiac muscle; this limits the shortening that can take place during the appropriate part of the cardiac cycle, and in some configurations could even interfere with normal filling and emptying of the left ventricle. Could the skeletal muscle be conditioned in such a way as to retain more of its original power and contractile speed?

PRESERVING THE POWER AVAILABLE FROM SKELETAL MUSCLE

As a first step towards answering this question, we have been comparing the effects of stimulation at 10 Hz and the lower frequency of 2.5 Hz /4/. Both the rate and extent of transformation were less when the muscles were stimulated at 2.5 Hz. Mechanical and biochemical data were consistent with transformation of the fast-glycolytic, 2B fibre type population of these muscles to the fast-oxidative, 2A type.

We can draw an important conclusion from this work: the transition to slow isoforms of myosin is neither *necessary* nor *desirable* for the development of fatigue resistance appropriate to cardiac levels of work. It is not *necessary* because the rabbit TA muscles stimulated at 2.5 Hz showed no evidence of induced synthesis of slow myosin isoforms, yet they proved as resistant to fatigue as the muscles that had been transformed fully to the slow type by stimulation at 10 Hz, when they were tested at the same working level. It is not *desirable* because the muscles stimulated at 2.5 Hz were significantly faster and more powerful than those stimulated at 10 Hz, and these are the characteristics best suited to configurations which require the skeletal muscle assist to be synchronised with the cardiac cycle.

Indeed, we recommend that people no longer speak of the need "to transform muscle into the slow, fatigue-resistant type", because it is now evident that slowness is not a prerequisite of fatigue resistance. Whether it is possible to have one without the other—in other words, whether it is possible to preserve the fast, fatigue-resistant properties stably in the long term, even at the working levels needed for cardiac assistance—is one of the questions that we will need future work to address.

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SIGNIFICANCE OF THE METHODIC OF FES FOR THE REHABILITATION OF PARALYSED PATIENTS

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INTRODUCTION

The main purpose of applying Functional Electrical Stimulation (FES) to paralysed handicapped is the reinstallation of lost motor functions in the limbs (Liberson, 4,). In the course of the development of the methodology a number of positive side effects of the stimulation have been observed in the paralysed areas as:

improvement in the
- muscle bulk and as a consequence of the upholstery
- local blood flow and the systemic circulation
- skin condition
- esthetic appearance

prevention of
- decubitus
- contractures

sometimes
- diminished spasticity
- repatterning of apparently lost movements.

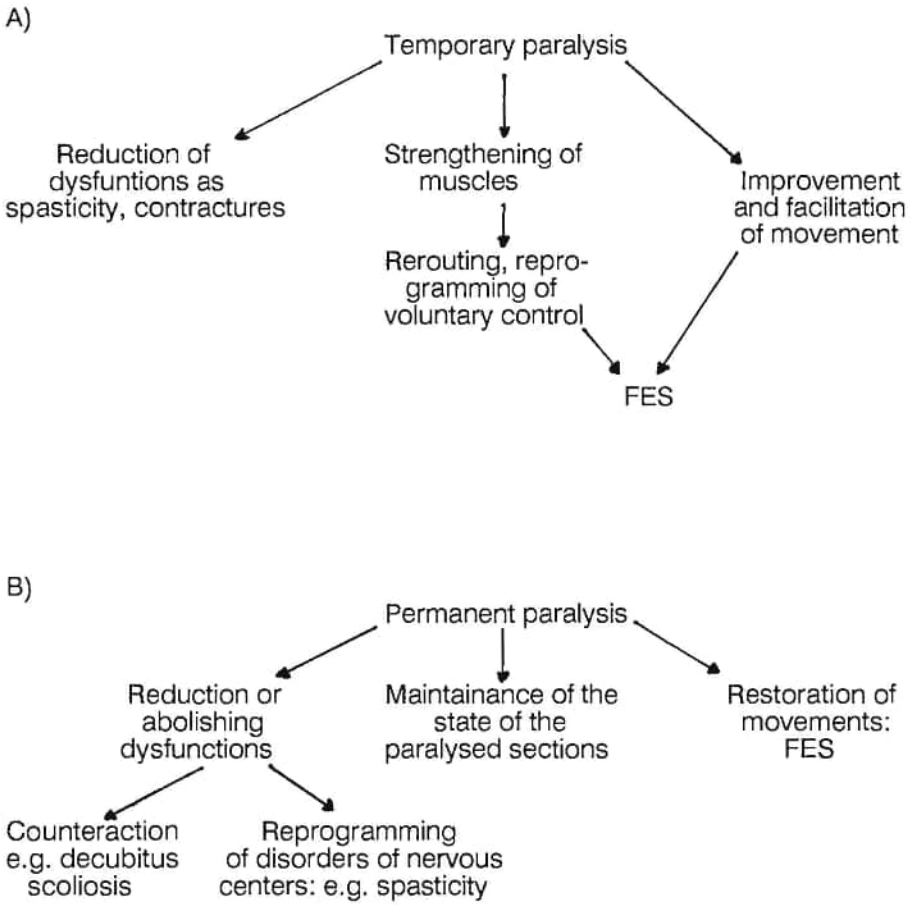
At this point we started, about 7 years ago, to transfer the method of FES to the daily clinical routine of the physically impaired, in most cases spinal cord injury patients. In this process the approach to the task in comparison to FES in a narrow sense was completely reversed. Now for each patient presented to us we had to answer the question what electrical stimulation, ES, amoung other procedures might contribute to the patient rehabilitation. We could no longer select a just few patients suited for FES out of a larger body of handicapped. In former times patients with severe spasticity, contractures, or decubitus would have been omitted.

Still the stimulation procedures developed in FES in a broader sense proved to be the most effective ones in order to achieve a controlled activation of specific muscles or muscles groups, individually or in combination one with another. The goal was still to build up the paralysed muscles, to make use of their function and/or to benefit the sensory feedback elicited by the contraction of the muscle.
Therefore, I propose to call this broader application FES, to differentiate it from Electrical Stimulation as routinely used in medical practice.
In the course of our clinical therapeutic work we were confronted with patients suffering from paralysis for various reasons, which will be mentioned later.
This work was conducted in collaboration with a number of hospitals comprising different specialities. We worked regularly at the Spinal Cord Section of the Rehabilitation Clinic Karlsbad-Langensteinbach, which is part of the Foundation for Rehabilitation Heidelberg (10).
Our prime goal as an Institute of Biomedical Engineering is to cover the application of FES in the broadest sense as it applies to the treatment of various forms of paraplegic and their presentations. This was to define the general clinical procedure and to determine the requirements for technical development. The development of a consistent study for the effective treatment of a specific disease is the task of the clinic.
All cases treated by FES have been evaluated by a physican, a physiotherapist and by us. The application of the stimulation and the routine check-ups that follow have all been conducted by our institute.

Normally we used skin electrodes but sometimes also implanted coire electrodes as introduced by Mortimer (5). Each patient was provided with an eight-channel, microprozessor controlled, battery operated, portable stimulator of the Co. Stratec, Birkenfeld 2.

CLINICAL APPLICATION OF FES

The clinical picture of paralysis may be divided in to two main parts and their subdivisions:



Application of the FES-routine

The application of the FES itself starts with a physical and psychological evaluation of the patient, his situation, his expectatance, and his goals. The degree and extent of his paralysis is determined. Thereafter a therapy plan is proposed to the patient and discussed with him. This includes the continuance of the treatment by the patient at home. The initial application of stimulation and the training of the patient in its use at home takes one to two weeks. At this time the patient preferrable stays at the clinic. The handicapped who are already well rehabilitated may also be trained as out-patients. Afterwards they must return for regular check-ups. At the beginning of each visit the patient himself has to execute the whole stimulation procedure in order to correct possible shortcomings. Then the results of the stimulation are reviewed and the stimulation sites and parameters are altered depending on the progress of the therapy.

From diagram 1 one sees that the two main domains, permanent and temporary paralysis, may both be subdivided into three subdomains:

- Dysfunctions
- Preserving the state of the paralysed areas
- FES in its narrower sense.

Each of these subdivisions posseses its independent value for the handicapped and in daily life it is chosen by them as their main goal according to their needs and individual objectives.

Dysfunctions

If a patient has severe dysfunctions, it is neccessary to treat these first in order to return the limb -or to a more or less larger extent the whole body - again into a managable state. This may also make him available again for physiotherapy and allow him to be incorporated into the other normal rehabilitation procedures including FES. On the other hand handicapped already well rehabilitated and leading normal lives, may lose their capabilities, more or less slowly developing dysfunction. In this case again it might be possible to restabilise the state of the handicapped by means of FES and to prevent him from an otherwise fatal outcome.

Spasticity

The most prominent dysfunction coming on with paralysis is *spasticity* (9). This topic was already dealt with at the 3rd Vienna Workshop. Therefore, only the most important points need to be replaced:
A successful stimulation set-up comprises a multiparametrical approach including the parameters of

pulse frequency, width and amplitude of the stimulus,
stimulation patterns,
stimulation sites and their combination,
duration of application per session,
repetition of sessions per day.

After the end of a session the degree and duration of the carry over effect has to be observed as a further indication of the impact the therapy has on the spastic process.
A very important precondition for successful treatment is the positioning of the patient in a way which prevents the excitation of spasticity as much as possible and avoids of any other stimuli. The stimulation has to be carried on for 30 to 60 min. If the muscles are tiring out earlier, they have to be trained at first, see also below.
So far we treated 39 patients for as long as neccessary to judge the results. The disorders have included Spinal Cord injuries (quadri- and paraplegic), brain damage, congenital cerebral palsy, stroke, virus infections of the CNS, multiple sclerosis and other degenerative diseases, spasticity of the vocal cord. All the patients presented to us showed no further improvement with any other therapy.

In all cases, but two, the spasticity could be decreased to such an extent, that it was not of further importance, and an extended function of the afflicted muscle groups was achieved. Two handicapped with a pronounced incomplete paralysis experienced a diminuition of the spasticity, but no pronounced functional improvement.
The large doses of antispastic drugs which are often used, with their pronounced side effects, could be reduced to zero in all cases. This often improved the general level of muscle strength, the voluntary control of movements and the state of the patient.
If the spasticity was assiociated with contractures of the joints, the threshold of spastic level could be lowered so far, that the contractures could be treated by the physiotherapist. This in consequence lowered again the tendency for spasticity.

In the course of the treatment the goal of the stimulation could be changed from that of diminishing of the spastic reaction to improving the functional use of the muscles. This also reduces the level of the spastic reaction thus leading to the reprogramming of the involved nervous structures. For example when treating on MS-patient, who has damages of the CNS due to the disease, with antispastic stimulation this patient, who could not even get up by

herself from her wheel chair and stand straight before stimulation, was able to stand up and walk without help in a parallel bar after 8 weeks of treatement.
If the reprogramming is successful within the framework of the patients capabilities, the final goal is reached, because then normal motor control has taken over.
If this goal is not reached, one may have to continue with the antispastic stimulation, but at a reduced rate. This seems, for instance, to be the case with spinal cord patients, who started out with FES on a limb and controlled their moderate - spasticity as a side effect - by the stimulation. After they ceased to apply FES for functional purposes, they continued to use the stimulation to control their spasticity and to maintain their physical state.

Stabilization of Spinal Cord

Especially quadriplegics may sooner or later develope a deviation of the spinal column such as scoliosis, kyphosis or lordosis, sometimes in conjunction with spasticity of the muscles of the back. In this case the spinal column may be stabilized very well by FES applied to the muscles in this area, especially the Mm. erector trunci and quadratus lumborum. If one wants to stabilize the lumbar region in particular, one may include the other muscle groups of the abdomen. In case of a deviation of the spinal cord it is important to start with the stimulation as early as possible, because it seems to be impossible to treat it beyond the point where the deviation is already fixed (1). We conducted this stabilization in 9 cases.

Dislocation of joints

If the muscle tonus around large joints decrease due to paralysis, the joints tend at least in the beginning to slaken. E.g. the humerus may slip out of its socket because of the constant pull of the arm while the patient is sitting. Also in the case of pronounced adductor spasticity of the leg the femur might be pulled out of its pelvic socket. By appropiate stimulation of the muscles controlling the joint, slackness might be diminished to such a degree, that the danger of permanent dislocation may be prevented, as we did in 4 cases.

Improvement of the skin condition

In general the skin condition improves together with the application of FES for other reasons as a side effect. Rather often handicapped develope a tendency for decubitus by sitting in a wheel chair. This might limit their working capability. This situation might be improved by a careful and extended stimulation of the muscles of this area, in our example of the gluteal region, or when stimulating the muscles of the back to stabilize the spinal column, the muscles might be very weak and difficult to stimulate in the beginning. The retraining of the muscles requires patience and time. It may take up to 6 month before the muscles develope good contractile force and up to 1 year before the situation is stable. We conducted this stabilization of the skin as a precondition along with other treatments in quite a number of cases.

MAINTAINANCE OF THE STATE

For permanently paralysed handicapped it is personally important to maintain their physical shape for two major reasons: One is the esthetical aspect, the keep their normal appearence, e.g. at the swimming pool. On the other hand, they want to stay prepared in case future developments allowing the restoration of motor functions by which means soever.
In case of a temporary paralysis the physican and the patient tend more and more to preserve the state of the muscles by ES - and in doing so to prevent the development of contractures - untill the innervation is restored in order to reduce the time of recovery and enhance the degree of improvement.
At the beginning of the stimulation procedure the muscle strength may already be reduced to a very large extent. If the paralysis last already for a longer time, the vascular supply of the muscles, the strength of the bones and the tendons, the condition of the joints and the connective tissue will be decreased. Initially one may observe just one to two muscle twitches as reaction to the stimuli, then the muscle is already tired out.

It is therefore important to execute the training rather cautiously and to discontinue it always when the muscles begins to tire, in order not to overwork and damage them. Overworked muscles tend to produce less muscle strength in the course of the training. If the muscles are weak, especially if they are paralysed already for a long time, we start out with continuous stimulation of a frequency of 2 Hz at lower amplitudes, and extend the time till the muscles last out for 20 minutes without tiring. Then the frequency is raised to 4 Hz and again kept till a 20 minutes period of stimulation may be conducted. This procedure is repeated in steps of 2 Hz. When a frequency of 8 or 10 Hz is attained the stimulation pattern is changed from a continuous to discontinuous trapezoid pattern, with an on-time of 5 sec. and ramps of 3 sec. duration. The intensity of the stimulus may be lifted up to a contraction strength below of the midle. This is continued till a frequency of 20 Hz is reached. Then the intensity of the stimulation might be reased up to 2/3 of the maximum force and the on-time extended up to 30 sec. The time of one session should be extended to 30 min. The stimulation should still be applied once or twice a day. Employing this rather conservative procedure, we want to allow the other tissues mentioned above to adjust adequately to the increasing load and we never observed an overstressing of the muscles. If the main goal of FES is the achievement of a function, e.g. standing of a paraplegic, this function is as soon as the state of the muscles allows intermittendly incorporated into the training routine. This produces a good functional execution of movements in adequate time and enhances the compliance of the handicapped. If the handicapped wants mainly to preserve the shape of the paralysed sections , the daily application of the stimulation may be reduced to 3- to 4-times week after their physical state is stable.

Reprogramming of voluntary motor control

After enforced immobility, temporary paralysis, and spasticity the patients often retains certain losses of motor control. This is especially the case with growing age. Liberson (4) recognized already, that stimulation of the lower leg because of drop foot increased the ability to lift the foot voluntarily after stimulation. This "carry over" effect has been observed again and again, equally, only with the inverted effect, when applying stimulation to reduce spasticity. The important point is, that this repattering of the normal control pathways might already be started by the use of low frequences, e.g. 2 Hz, which do not yet elicit the movement or increase the muscle strength. An example of congenital cerebral pals might illustrate this: A now 17 years old girl had still pronounced deficited in the motor control in conjunction with spastic lightness of her right leg because of this disease. The musculature of the right leg was clearly less developed and weaker than that of the right one, the Achilles tendon had been surgically lengthened. The walking movement was not completely executed, the joints were not properly loaded. The pronantion of the foot could not be performed, his stable control was missing. The M. soleus and the Peroneal muscle group were very weak, the M. extensor dig. longus could not be voluntarily contracted. A careful training by stimulation beginning with 2 Hz, as described above, started to improve the motor control of the foot, at once, extended at first the response time of the muscles, and then the muscle strength. After the muscle strength and the voluntary control of the foot had progressed enough, she could keep equilibrium when standing solely on the right foot for a short time (up to 1 min). Now a Physiotherapist is included in the therapy to improve the walking performance of the girl. Accompening all the muscles of the lower leg are stimulated to produce more strength because they are still not strong enough. The girl has now developed a stable control of her foot and her walking pattern is approaching normal.

FES IN ITS NARROW SENSE

Quite a number of contributions of this conference cover this topic as far as it is applied to permanent paralysis. Therefore I shall refer to them (see also 2, 3, 5, 6, 7). The attention should just be directed at one aspect, the sufficient stabilisation of all joints within the paralysed section and of the trunc (8). This point is often neglected. E.g. if FES is used routinely for walking of paraplegics over long periods of time, an insufficient active control or passive stabilization of the joints can lead to severe damages, which are irreversible.

Applying FES to a temporary paralysis the phase of training passes continuously into the stage of improving the movement patterns as demonstrated by the example in the previous

section. One part of the stimulation is aimed at strengthening the muscles still weakend and restoring the equilibrium of the (antagonistic) muscle forces. The other part is the continuation of the patterning of the movement. All of this may be achieved up to a certain level. From here on the treatment has to pass over to Physiotherapy and in addition employment of biofeedback has to be considered (11). Sooner or later the stimulation will fade out, because the final improvement can only be achieved by the patient himself through intensive practising.

CLOSING REMARKS

Electrical stimulation is used in the treatment of muscular diseases for quite a long time. The methodic which emerged in the course of the development of FES differs from the stimulation procedure commonly used in a number of points: In FES the treatment includes larger parts of the paralysed area, the application time per session is longer, the treatment sessions are more frequent, at least once a day; the stimulation sites, the shape of the stimulus and the stimulation pattern are carefully chosen, and, last not least, the patient himself is effectively incorporated into the treatment procedure.
When we had been asked to incorporate FES in its narrow sense into the normal routine of rehabilitation, soon it became obvious, that the restrictive criteria so far employed to select the candidates for FES had to be abandoned. In order to serve patients suffering from severe paralysis and its aftereffects electrical stimulation may be of much more extensive use as it was so far supposed. It is the only method to activate any individual muscle artificially controlled. But to apply the stimulation in the course of rehabilitation successfully the methodical strength developed in FES has to be observed. Therefore and because these aspects of the stimulation are later serving application of FES in its narrow sense, I should call it FES in a broader sense.
This paper dealt with the more general applications of FES in the daily routine, not with specific ones as stimulation of the phrenic nerve or the bladder. In the course of this study we treated so far 98 patients with spinal cord injuries and 34 with neurological diseases. 51 of the spinal cord injured ones were paraplegic, 12 of them proceeded to standing up, 7 to walking; 18 patients suffering from peripheral nerve leason, have been stimulated to keep the physical shape as much as possible; 47 of them were quadriplegic, in 33 we installed a gripp, 2 low level injured quadriplegic proceeded to standing up.

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COMPARISON OF FES UTILIZED ON PARAPLEGICS AND ON PATIENTS WITH CEREBRAL PALSY

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ABSTRACT

The objective of the studies was to investigate the potential of applying FES by surface electrodes to paraplegic patients to permit self locomotion and to patients with cerebral palsy to determine the immediate and long term effects on both locomotion and hand-arm function. The patients included several male patients, ages 20-30, with various degrees of paraplegia and several children, ages 8-12, in the CP studies under protocols approved by the OSU Human Subjects Committee. Patients were evaluated initially to determine base performance and at regular intervals throughout the studies through the gait analysis laboratory, Cybex machine, and various hand movement instruments including grip, pinch, angle, and general digit motion. Results were very positive, resulting in total self-locomotion under control of the paraplegic patient with velocities approaching 20% of normal. The CP results were even more dramatic, resulting in improvements of up to 1000% in locomotion and 200 to 300% improvement in upper digit motion. Tests are presently under way to determine the residual effects on the CP individual after termination of excitation. Detailed results comparing the two applications are presented.

BACKGROUND

Functional Electrical Stimulation (FES) has been applied to many human medical and rehabilitation problems. Some of the obvious areas include: ambulatory motion of paraplegic patients, upper limb and digital control of paraplegics and quadraplegics, upper and lower limb and digit function improvement in patients with cerebral palsy, pain suppression and control, bladder and colon control, respiration activation for quadraplegics, parastelsis activation, heart pacing, and many other applications involving the external stimulation of one or more muscles to carry out a function no longer feasible or handicapped in action.

The stimulation signals may be under the direct and exact control of the individual to totally automatic. The signals may be applied through electrodes applied to the skin surface, along wires through the skin to the muscles or motor neurons, or by surgically implanted remote electrodes controlled and given power either with their own batteries or by RF transfer of either or both control and power through the skin.

To suggest one application is good, another of no value, one method of application better than another, or the results of one technique of no value while some other is ideal based on how similar the results are to normallacy is inappropriate.

The basic concept of rehabilitation is to:

a) provide return of normal function if possible
b) provide a useful function, although different than normal
c) provide a substitute function when original function is not possible
d) improve the functional status of the handicapped individual to the extent possible.

The research to be discussed in this short paper relates to the application of FES through surface electrodes to the lower and upper body, ambulatory and digit function of paraplegic and quadraplegic patients, and to patients with cerebral palsy.

GENERAL CONSIDERATIONS

All cases of FES application referenced here are from specific research programs with patients carried out in the Biomedical Engineering Center Rehabilitation Facilities at The Ohio State University, see References. The works referenced relate only to research with patients in the areas of paraplegia, quadraplegia, and cerebral palsy. All stimulation is accomplished through the use of surface electrodes to provide greater experimental flexibility and minimal patient trauma.

The measure of success or improvement in function is generally related to the original functional capability, but may on occasion be relative to normal function as appropriate. Where possible, the measurements of improvement are quantitative, utilizing many diverse means of measurement from sophisticated gait lab analysis, Cybex evaluation, to the simplest form of stop-watch measurement of velocity, or simple function accomplishment — if you can or can't pick up a pencil. All are viable and realistic in the rehabilitation world.

UPPER AND LOWER FUNCTION IN PARAPLEGIA AND QUADRAPLEGIA

J.W. is a 46 year old male with complete spinal cord lesion at the T-6 level (3). He was involved in the rehab program for two years. The protocol called for IV phases including muscle conditioning, standing and walking in parallel bars, ambulation with reciprocal walker, and finally to home use of 1 and 2 canes. Six channels of simulation, under direct control of the patient were used. Balance, posture, and endurance increased steadily over the period to the point where the patient could walk up to nearly 200 feet, arm support reduced from 36% to 25% of body weight, and up to 20-35 Newton-meters of torque were produced at the knee joints with velocities of 30 degrees per second. All results remain positive and a home program should retain and improve the capability.

Patient C.C. sustained a C-7 level spinal cord lesion from a fall. While the leg control was lost, pelvis stabilizing capability remained intact (2). The right leg was completely paralyzed functionally, while the left leg retained some capability. Eight sessions were needed to initially train the patient to use the system and accept the arm crutches. Due to a degree of toe-in it was necessary to add a third channel of stimulation. Patient C.C. was able, in a year, to walk almost normally with one arm crutch, thus attaining a functional operation oscillating between 3-point static stable stance (2 leg and 1 crutch) and the 2-point dynamic stable stance of 1 leg and 1 crutch. Walking velocity was essentially normal although a degree of limp was retained. The final function was nearly normal walking with a single simple cane.

Other patients reached individual levels of attainment from essentially normal walk to dropping out of the program. In a few cases the limitation was spasacity, but more often individual commitment. The conclusion appears to be that it can be successful to a specific capability and that the FES becomes a permanent and constant part of the individual's capability.

Patient A.A. sustained a C4/C5 level injury and possessed only shoulder-shrug upper limb function (4). The protocol involved muscle training and reduction of joint calcification limitations, followed by training and regular sessions to learn the process and control techniques. The results were good. Elbow-flexion increased from zero to 18 degrees with stimulation initially to a final value of 35 to 42 degrees. Wrist flexion improved 38% over the project. The simple results in this case were both to actually provide controlled flexure of the wrist and elbow, as well as forearm pronation and supination, and to demonstrate an improvement due to learning, joint calcification reduction, and muscle strengthening. Again, the results are positive, show continued improvement toward a maximum, and will require continued use of FES.

UPPER AND LOWER FUNCTION IN PATIENTS WITH CEREBRAL PALSY

Patient B.B. is an eleven year old male with diplegic spastic cerebral palsy (6). Originally the patient ambulated in a crouched position with two forearm crutches for short distances, longer distances utilized a wheelchair. The protocol involved evaluation and optimizing the FES parameters to minimize pain and discomfort, but resulting in reasonable activation, initial strengthening of the muscles, followed by two 2-hour session per week to reduce spasticity, improve posture and range of motion, and improve gait cycle. In this case the following parameters proved optimum:

Biphasic pulse of 0.3 msec width
40 hertz repetition rate
Rise time of pulse train up to 0.5 seconds from 8 seconds
Amplitude from 42 ma to 60 ma over the 6 months.

Results included improvement of knee joint and ankle joint motion, distance to fatigue, and torque produced as measured by the Cybex. Plotting of these data show in most cases an improvement of voluntary motion asymptocially toward a maximum, with the stimulated motion roughly a constant magnitude greater than voluntary. It can be assumed that both may approach the same final asymptotic level limited physiologically. Studies presently involve the evaluation of what may happen to the obtained voluntary levels after periods of no stimulation. The opportunity to visually observe this patient over the period was particularly useful in seeing the bent over crouched stance straighten out and the walk approach normallacy. Again the results are positive. In this instance, a definite improvement is seen in voluntary capability without stimulation over the protocol. Whether or not this remains or is lost is yet to be seen.

Knee Joint Motion (degrees)

	Right			Left		
Date	Vol	Stim	Both	Vol	Stim	Both
10-17-88	115	125	126	127	132	135
12-05-88	126	135	138	135	138	140
01-05-89	128	138	140	135	139	140
01-19-89	133	150	152	139	145	148
02-13-89	155	160	160	155	173	173
03-09-89	158	163	163	160	170	172
04-06-89	155	159	159	162	167	169

Torque (foot-lbs)

	Right			Left		
Date	Vol	Stim	Both	Vol	Stim	Both
12-05-88	5	8	10	5	6	10
04-13-89	13	13	17	10	9	14

(Vol = voluntary; Stim = with stimulation)

Three cerebral palsy patients, aged 9, 12, and 15 were involved in the protocol for upper digit activation by FES (7). A detailed report is being presented at this conference by Mr. Kamper, so will only be mentioned here. Both range of motion and times for required motion improved. Again the differences between voluntary and stimulated function existed. The question of retention is yet to be determined.

CONCLUSION

As suggested in the beginning statements, all improvement of function or substitution of function are considered positive. There are no cases in which improvement was not seen if the patient remained in the program. This in itself is a very positive observation. Relative improvement or relative ability to carry out the function varied with many factors, for the most part limited as much by patient motivation and determination as technical feasibility. Specific properties are definite. Although proposed by some researchers as possible, we saw little or no development of parallel path signal processing in the paraplegic and quadraplegic. There was never any doubt that the FES source must be retained at all times, and while the individual demonstrated a pattern of learning in the utilization and synchronization of the signals, at no point did it appear that there was movement to eliminate the need of FES. The paraplegic and quadraplegic in every instance indicated a desire to retain control of rate, step, length of stride, start, stop, stand, stair climb, etc. However, some of the intricate phase control to carry out the process was seen as cumbersome. The future will need to address the method and extent of pre-programmed control, while retaining overall function independence. Robots are not seen as desirable.

The cerebral palsy patient in almost all instances demonstrated the typical original function ability and asymptotic improvement toward a final optimum with an essentially fixed or constant difference between the stimulated and non-stimulated capability over extended periods of time. If this level of asymptotic improvement can be retained at any particular level, then there is a useful residual to the application of FES. If the improvement decays with FES termination, then some or all of the improvement will be lost. This is yet to be determined for certain. However, the approach that FES is of no value to the cerebral palsy patient because it must continue is non-realistic. Like the paraplegic and quadraplegic, much is to be gained from the ongoing application even though it must be retained.

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TEN YEARS CLINICAL USE OF PERONEAL IMPLANTABLE SYSTEM

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SUMMARY

Since 1981-1991 19 out of 35 hemiplegic patients with previous implanted electrodes were evaluated, comparing different methods as clinical observation, gait parameters and M-waves of subcutaneously stimulated muscles before and after implantation. Results show that inspite of disadvantages (displacement subcutaneous electrodes excessive aversion of the foot in swing phase) implantable peroneal electrical stimulator from rehabilitation point of view as suitable orthosis was chosen. Because of high level of acceptance, stability of the response should be achieved, which requires in conclussion additional modification of the implant to get adequate electrode-nerve interface.

STATE OF THE ART

Various types of electrical stimulators (ES) have been used in daily practice for quite a number of years to detect advantages and disadvantages of them. Not so many versions remained routinely used orthotic devices but mostly applied for therapeutic procedures in rehabilitation units. (1). Comparative study of a functionality of the second generation of peroneal stimulators which were developed in Ljubljana implantable systems in 96 % of application as permanent orthoses have been accepted. (2)

MATERIAL AND METHODS

Selection of patients. Since 1981 - 1991 35 patients (stroke - 25, brain injury - 3, operated tumors - 4, high spinal cord lesion - 2, complete spinal cord lesion - 1, 21-63 years of age) have had a peroneal underknee ES for drop foot correction implanted in Ljubljana, (figure 1) The main indication was permanent use of device for the patients who had been using an electrical stimulator with surface electrodes.

Figure 1

The work was supported by Research Grant 23-P-59231/F from the National Institute of Disability and Rehabilitation Research, Department of Education, Washington, D.C., and by the Ministry of Science and Technology, Ljubljana, Republic of Slovenia.

Types of systems. The system consisting of the disc shape implant with platinium electrodes implanted close to the common peroneal nerve and fixed in epineurium and surrounding tissue on two or four points was RF powered by an external unit with transmitting antenna (figure 2) (2 different shapes). (3) The frequency of stimulating pulses was set at 20-30 Hz, the pulse width varied between 0,1-0,5 ms to adjust the intensity of stimulation with an amplitude from 1-5 V or 10 mA (depending of the type of implant) was adjusted to get optimal response. 35 patients with previous implanted electrodes were evaluated comparing different methods as clinical observation (assessment of motor functions, passive range of motion, kynesiological gait analyses), needle EMG conduction velocity of the peroneal nerve in order to observe possible noxious effect on the nerve fibres, angles in joints, vertical ground reaction forces before (with surface electrodes) and after operation.

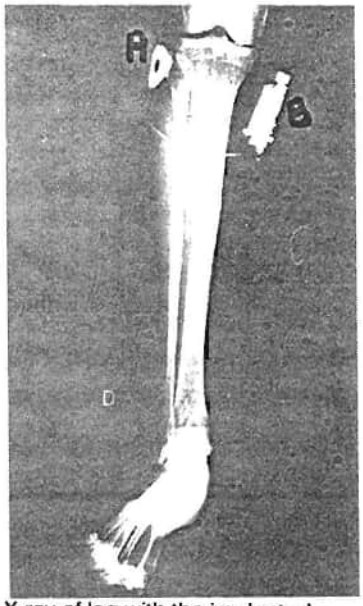

Fig.2: X-ray of leg with the implanted peron. ES IPPO
A - inner part, B - outer controlling device

Because clinical evaluation has shown that quality of the gait correction was not always satisfactory, 19 hemiplegic who had been daily using the stimulation out of 35 patients have been chosen for more detailed evaluation.

EMG responses (M-waves) of the tibialis anterior, peroneus longus and soleus muscles to the stimulation of peroneal nerve were recorded. Strong activation of the tibialis anterior, moderate one of the peroneus longus and only minor M-waves in the triceps surae indicated good electrode position, it means strong dorsiflexion (DF) and moderate aversion (m. EV) during the gait. **Gait dynamics** was determined by measuring vertical components of the ground reaction forces together with trajectories of the points of action (TPA) under soles of measuring shoes.(4) At the same time 3-dimension goniograms of the hip, knee and ankle joint were measured together with average stride length and velocity at freely chosen gait speed with and without stimulation. TPA had revealed to be rather sensitive and relevant for clinical assessment of gait (figure 3). Comparison between description of the stimulated ankle movement and gait dynamics could provide an information about the electrode nerve interface and functionality of gait control.

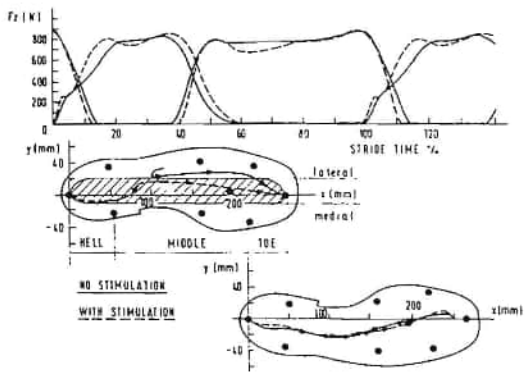

Figure 3

For example ankle response described as dorsal flexion and moderate aversion with strong activation of the tibialis anterior and moderate one of peroneus longus muscle by the stimulation and the desired heel - midfoot - toe TPA could be interpreted as a high correlation between the gait dynamics and stimulation. Excessive ankle aversion activation of only peroneus longus and heel - midfoot - toe is correlated poorly inspite of functionally stimulated gait.

RESULTS

Clinical outcomes. From the population of 35 patients three died within three years after the implantation, one had his leg amputated due to a cause unrelated to the implant, four implants were removed due to unpleasant sensations, three patients gave up the stimulation due to poor correction and one recovered his volitional control. Average life time of the remaining implants was 4,9 years (range 0,5-10 years). 19 who had been daily using the stimulation were analysed. 6 patients were implanted twice, two of them three times. (figure 4) Average life time of the second implants was 3,5 years, (range 1,2 - 5,2 years), were the third implants lasted 5,3 and 4,1 years. Prime reason for reimplantations was an inadequate response after a displacement of the electrodes due to fibrous capsule formation or muscle dynamics. Electrophysiological except by one patient and histological test showed not pathological changes of the stimulated nerve and surrounding tissue. With exception of one broken electrode, the removed implants were electrically intact.

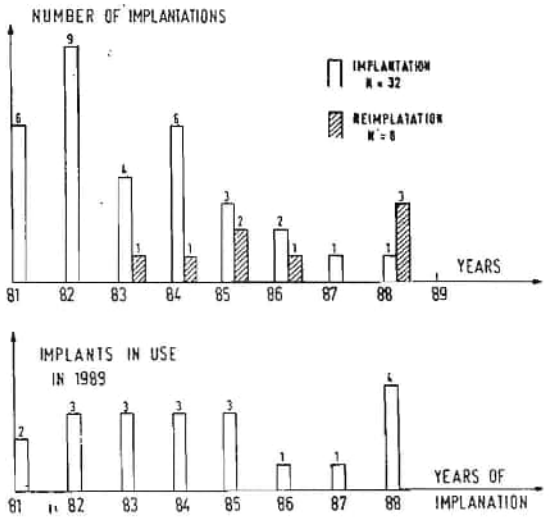

Figure 4: Number of implantations and reimplantations from 1981 to 1989

Analysing a **gait dynamics** of each patients separately has shown that 11 of 19 patients exhibited and excessive aversion of the ankle with even moderate plantar flexion in 1 patient. Various degrees of gait rection were reflected in TPA with the stimulation during the swing phase of gait. That in 8 patients a su cient ankle response has been achieved.

Variability of TPA as a function of stimulation presented in different time after implantation by two patients showed main changes after 14,5 months after implantation. Gate patterns of

the both sides were simetrically exchanged with respect to the surface stimulation. 28 months after the implantation TPA matched the normal gait pattern and difference between gait with and without stimulation disappeared (by one patient after second implantation). **Numerical analyses** of stimulated patients shows significant improvement of TPA for 72% ($P<0,005$), gait velocity increased for 20% ($P<0,005$), stride length for 14% ($P<0,005$) and stride time decreased for 7% ($P<0,01$). In two patients a good functional gait even without the stimulation was achieved and can be explained by a long term use of the subcutaneous stimulation over several years. (5) Similar effect were referred also by others (6). Lessening of tonic spastic component of triceps surae has been observed (7). No significant influence to other gait anomalies has been noticed. Follow-up of the M-waves, stimulated ankle movement and ground reaction force pattern over several years implied two characteristic groups: ten patients, who approached the normal patterns and nine patients, who after a period of stability exhibited a migration of the patterns to new undesirable ones, mostly due to excessive aversion. In these patients, the reimplantation was required after an average of 3,5 years of appropriate functioning.

DISCUSSION AND CONCLUSION

Optimal results can only be obtained by following some general principles developed in practice over the years. First, FES orthosis has to permit the patient to perform activities which would not be possible without it. Second, the device must serve a real need. Third, function which can not be achieved by bracing should be avoided. Fourth, acceptance of the patient remained the very important criterium for the application of devices. Inspite of disadvantages (in our case one or two reimplantations) patients have preferred to use implantable systems again. With careful positioning of the stimulated electrodes the subcutaneous stimulation may correct the impaired gait to a similar extend as the surface stimulation. Stability of the response depends on the electrode nerve interface, which requires additional modification of the implant, shape and fixation of the ecletrodes.

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DYNAMICS OF FES ASSISTED STANCE PHASE

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SUMMARY

Improved hand control module providing voluntary control over functional electrical stimulation (FES) restored walking pattern was developed. Specially designed two-step pushbuttons enable division of stride time into three distinct phases: midstance, push-off, and swing phase. During the midstance phase, electrical stimulation is delivered to both knee extensors. The push-off phase is enabled by stimulating the ankle plantar flexors of the trailing leg. The swing phase of walking is realized by provoking the flexion reflex in the swinging lower extremity. The dynamics of FES assisted stance phase was assessed by ultrasound motion monitoring system and two force plates. The measurements were performed in paraplegic person with complete T-7,8 thoracic lesion and tetraplegic subject with incomplete C-6,7 cervical spinal cord lesion.

INTRODUCTION

The feasibility of reciprocal walking in completely paralyzed paraplegic persons has been demonstrated by using only four-channels of FES [1]. This minimal gait pattern is voluntarily controlled by the patient pressing or releasing a hand pushbutton built into the handle of a walker or crutch. In this way the stride time is divided into two time intervals, first when the pushbutton is pressed and second when the pushbutton is released. First time interval corresponds to the swing phase which is realized through afferent FES provoking flexion reflex resulting in simultaneous flexion of hip and knee and ankle dorsiflexion and thus providing clearance of the foot from the ground. The second time interval belongs to the stance phase when knee extensors are stimulated bilaterally enabling sufficient support to the patient being helped also by walker or crutches.

The most crucial problem of simple four-channel FES walking is considerably longer double stance phase as compared to the one found in normal walking. It lasts 82% of the stride time which is in average 4.4s as assessed during crutch assisted walking and even 10.4s during walker assisted ambulation [1]. During this period of time the paralyzed person must bring his center of body forward. The four-channel FES does not assist this important walking event. Pushing the body forward must be performed by the help of arms supported by walker or crutches and by the use of preserved trunk muscles.

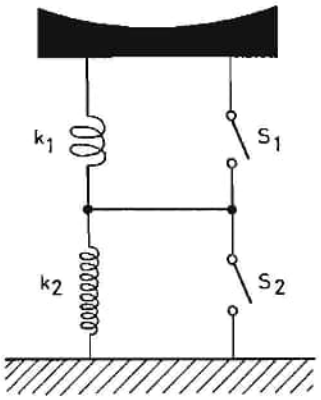

Fig. 1

It was our aim to upgrade the four-channel pattern by introducing more complex control of walking and by adding new stimulation channels.

In the same time it was our goal to preserve voluntary patient's control over all FES generated gait events. It is our opinion that walking must be under paraplegic subject's control [2] because of rough, uneven terrain present in natural environment and frequent obstacles encountered in man-made environment. In the present paper we are proposing improved control transducer providing division of the stride time into three distinct phases: midstance phase, push-off phase, and swing phase. The start and the end of each particular phase are determined by the walking subject. Each phase of walking is characterized by different pattern of multichannel FES.

INSTRUMENTATION

The division of the gait cycle into three different phases of walking is provided by the use of special two-step pushbutton which is schematically presented in Fig. 1. It consists from serial connection of two switches characterized by significantly different elasticities. When exerting low pressure by the thumb, the switch S_1 is only activated. This switch has lower elasticity k_1 as compared to the elasticity k_2. At stronger striking of the two-step pushbutton, both switches are closed. In this way two control events are obtained, first at the activation of the switch S_1 and second when the switch S_2 is closed. The two control events will be named SC1 and SC2 respectively. The third control event required occurs when the walking subject is depressing both switches. By removing the thumb from the two-step pushbutton both switches S_1 and S_2 are released resulting in the control event SO1. The three control events SC1, SC2, and SO1 are dividing the stride time into three distinct gait phases. Walking of completely and incompletely paralyzed subjects was assisted by two multichannel FES systems delivering electrical stimuli to the knee extensors, ankle plantar flexors and peroneal nerves of both extremities. The two stimulators were attached to the reciprocal walker. Each leg was stimulated by a separate stimulation unit. Each stimulator was controlled by a separate two-step pushbutton attached to the handle of the walker.

METHODS

The time course of the control switch function together with the corresponding division of the gait cycle is shown in Fig. 2. When neither of the switches is pressed, patient remains in the midstance phase of walking. Electrical stimulation is delivered to both knee extensors, providing sufficient support to the body. At a slight touch of the hand switch the first control event SC1 occurs starting the push-off phase. The control event SC1 is characterized by the unilateral electrical stimulation of ankle plantar flexors while the bilateral stimulation of knee extensors remains present. Electrical stimulation of plantar flexors of the trailing leg is prolonging the already extended extremity and, thus, providing forward and upward shifting of the center of body. At stronger pressing of the hand pushbutton both switches are activated resulting in the swing phase of the lower limb. Three changes

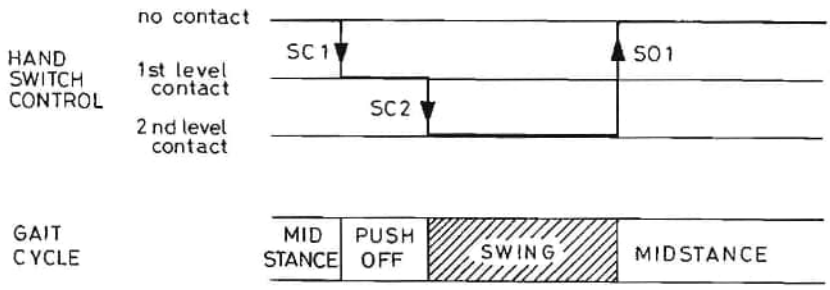

Fig. 2

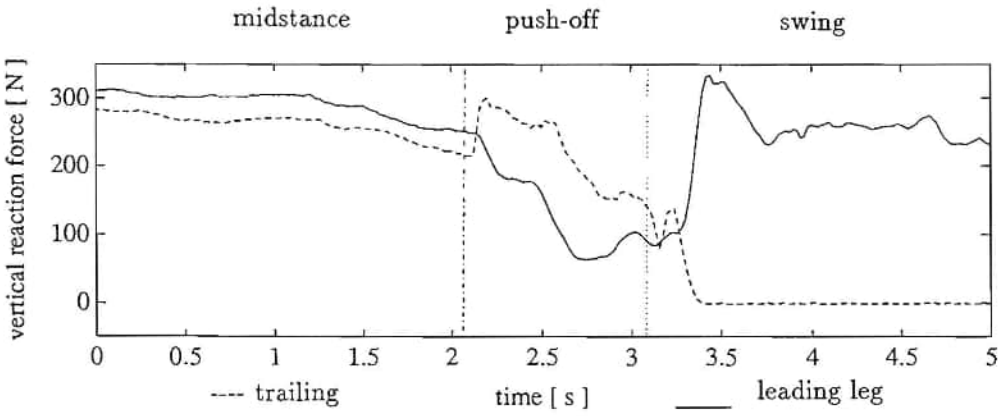

Fig. 3

in the stimulation channels occur at the control event SC2. Electrical stimulation is discontinued in the ipsilateral (with regard to the activated pushbutton) knee extensors and ankle plantar flexors. In the same time electrical stimulation is delivered to the ipsilateral peroneal nerve provoking flexion reflex of the lower extremity. The control event SO1 is returning the walking subject back into the midstance phase characterized by bilateral stimulation of knee extensors.

RESULTS

During the investigation the subject was initially standing on two AMTI force plates assessing the ground reaction forces under each foot. The position of both force plates corresponded to the position of the feet during the double stance phase. The motion performed during push-off and swing phase was measured by the use of contactless measuring system V-SCOPE. Small infrared ultrasound markers were attached to approximate ankle and hip joint center of rotation. Repeated measurements were performed in complete T-7,8 paraplegic and incomplete C-6,7 tetraplegic subject. Both patients were considered as experienced walkers when

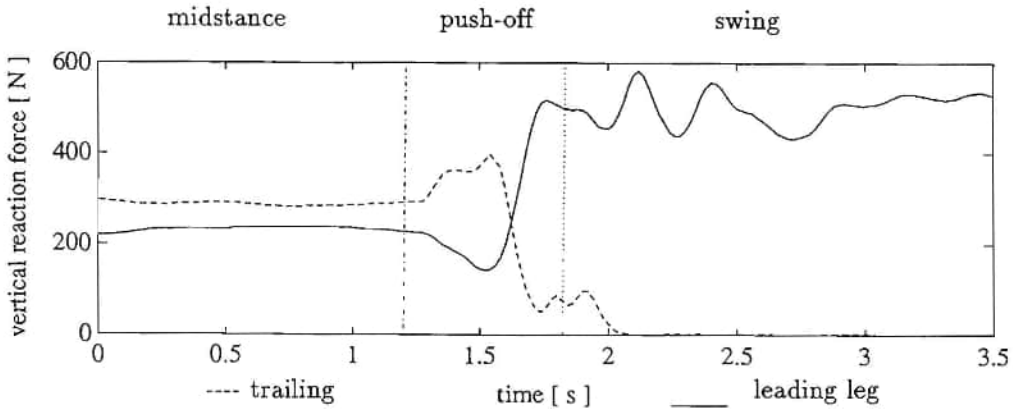

Fig. 4

assisted by FES. During the push-off phase the hip joint was shifted in the direction of walking for about 9cm in complete and for 4cm in incomplete SCI subject. This advancement can be considered significant when compared to the step length during FES assisted walking. Maximal vertical shift of the hip joint was rather low in both subjects and was not exceeding 2cm. When studying the double stance phase events, more interesting results are expected from dynamic than from kinematic assessments. Vertical reaction forces in midstance, push-off and swing phase belonging to the trailing and leading leg are presented in Fig. 3 for complete and in Fig. 4 for incomplete SCI person. During the midstance phase the body weight was almost equally distributed between both extremities. About 80% of the total body weight was supported by the lower extremities. The push-off phase was characterized by an approximate 35% increase of vertical reaction force in the trailing leg and corresponding decrease in the leading leg. During the swing phase the trailing leg was completely released. The leading leg supported in different trials only from 35% to 55% of the body weight in completely paralyzed person and around 80% in incomplete SCI subject.

DISCUSSION

In our early experiments [3], it was observed that bilateral FES of ankle plantar flexors can easily result in subject's lifting on the toes. Low fatiguing of stimulated paralyzed m. soleus and gastrocnemius was also noticed. When designing possible hybrid FES walking patterns [4], we found unilateral stimulation of ankle plantar flexors being sufficient to lift the body and, thus, providing smooth swinging of the contralateral leg. It was observed also by other authors [5] that walking approached a near normal appearance when adding FES of the extensors of the hip and the plantar flexors of the ankle. The stimulation of plantar flexors during double stance phase provides rotation of pelvis, forward shift of the center of body, and transfer of the body weight between the supporting legs. The flow of the proposed six-channel FES walking pattern is more continuous than rather interrupted four-channel gait and was well accepted by the SCI subjects. Improved loading of the leading leg during single stance phase can be achieved by introducing special exercise of FES standing, while the subject is supported by only one leg and both arms, and by adding sensory feedback providing information about excessive arm support. The two-step pushbutton was found specially useful in the early phase of gait training. Four switches, built into the handles of a walker or crutches, provide more control states than required in the described investigation. The unused control states can be found useful in later designs of FES orthotic devices introducing new channels of electrical stimulation.

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ULTRASOUND DISTANCE-VELOCITY MEASUREMENT INCORPORATED INTO FES REHABILITATIVE SYSTEM*

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SUMMARY

Continuous monitoring and evaluation of patient's gait is advantageous for efficient adaptive rehabilitation. The paper is discussing the principles and results obtained by using a simple ultrasound US distance-velocity measuring system being suitable to be included into the gait training functional electrical stimulator. The system needs to meet specific requirements such as low power consumption and robustness. Unlike other ultrasonic rangemeters, our system does not use the echo principle what improves its dynamic properties and expands its range of activity. It consists of two distinct units. The first one is mounted on patient's stimulator, while the second is standalone unit positioned in a fixed place at the start of a walkway. Distance is calculated from the time difference occurring between US and light passage when covering the same distance.

The results achieved with a prototype model indicate 24 Hz sampling rate, 3% accuracy in a 12 m range. Results are satisfactory and overall capabilities of the instrument are satisfactory and within expected limits. Several main sources of errors are pointed out and discussed for highlighting possible improvements.

STATE OF THE ART

In selected spinal cord injured patients the restoration of biped gait can be realized by means of functional electrical stimulation FES [1]. During the training process it is essential to monitor the patient's gait and adopt corrective training measures for achieving improved walking results. Important parameters in gait evaluation are velocity of the centre of body COB in correlation with different gait phases, like step length and overall distance covered. In FES rehabilitative process is important to estimate the efficiency and suitability of prescribed measures [2] which may result in faster gait or enlarged step length.

Quantitative evaluation of walking is in most cases performed with expensive motion analysis systems that are unpractical or even unavailable for daily routine work. Therefore, many different techniques were used so far for measuring the gait velocity and distance [5]. The most simple approach makes use of a string attached between the subject's COB and a wheel mounted on a shaft of a tachometer or optical encoder [3]. The main drawbacks are mechanical limitations such as oscillation of the string. Alternative distance measuring method can be based on accelerometers and inclinometer. However, calculating the distance or velocity is numerically intensive and therefore not very suitable for stimulator included measurements.

Our goal has been to develop a contactless distance/velocity measurement system that can be easily attached to any microprocessor controlled FES stimulator in order to integrate measurement and stimulating functions. In such a way simple and useful gait evaluation is performed by continuous recording of patient's performance. US was chosen as a suitable medium, because of its advantages proven in robotic applications [4] and mechanical engineering where it is utilized in proximity or obstacle detection/avoidance sensors.

There are two usual procedures for US based ranging. The first principle is sonar approach. The moving object emits US pulse bursts. The sound echoes from a fixed plane back to the emitter/receiver. The time elapsed between emission and detection of echo is directly proportional to the absolute distance between the emitter and the reflection plane. The sampling speed is twice lower than in our case since the sound has to sweep the same distance twice.

The second principle is suitable only for measuring the relative displacement between the initial and current position of an object and is also echo based. In this case emitter, placed on the moving object, is generating a continuous US signal. The displacement is obtained by integrating the Doppler difference between the source and the echoed signal. To obtain correct results the US signal cannot be interrupted what may not always be the case in everyday rehabilitation environment. The theoretical sensitivity of the method is half the

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wavelength, what is around 3 mm at 50 kHz US source.

Both methods require considerable energy from the stimulator power supply because both emitting and receiving units have to be powered from the stimulator. The emitted US power flux density should be 4 times greater to achieve the same signal/noise ratio of the echoed signal as it is in the proposed design.

MATERIAL AND METHODS

The measuring system is attached to and powered from stimulator and must therefore meet several requirements. These are: low power consumption, accuracy at least 0.5 cm, fixed sampling rate of at least 25 Hz, reliability, simplicity, compatibility with microprocessor buses or ports, usable in non-laboratory environment and with random environmental disturbances.

The principle utilized in the designed measuring system is combining infrared light IR and US as it is shown in figure 1. The system is divided into two physically separated units. The first unit contains both transmitters: LED diodes for IR and piezo loudspeakers for US respectively. The second unit includes both receivers and computer interface logic. Both transmitters are synchronously generating pulse bursts. When the IR receiver detects the presence of IR light, it resets and starts the counter. The US receiver, triggered by the US signal, stops the counter. The time counter is running during the time the US needs to travel from the transmitter to the receiver. By choosing adequate clock frequency it is possible to calibrate the system directly in cm or mm. The distance between the two units can be computed as:

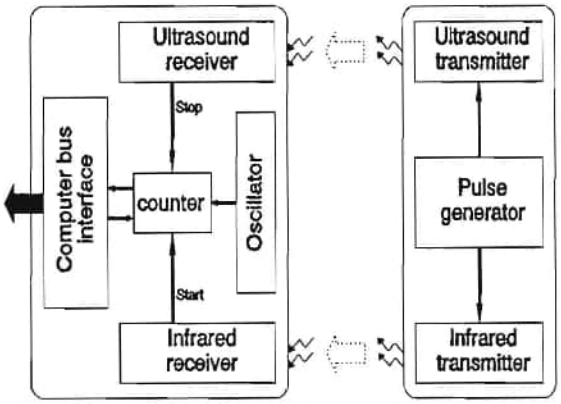

Figure 1: Principle of the measuring system

$$s = \frac{v_s \cdot t_s}{1 - \frac{v_s}{v_l}} \qquad (1)$$

Variables used in equation (1) are: s - distance measured, t_s - measured time of propagation of US over the distance s, v_s - speed of sound, v_l - speed of light. Since the speed of light is for several magnitudes higher than the speed of sound, the fraction in the denominator may be neglected. The derived formula becomes trivial and is hence implemented by the hardware. The mandatory velocity is derived by differentiating the two consequent distance recordings.

The proposed system has several advantages. Either transmitter or receiver unit can be placed on the moving object. Only one unit is powered from stimulator thus expanding batteries lifetime. The second unit can be mains powered. Transmitters need to emit less power as compared to the usual methods, since the travelling distance of US signals is equal to the distance measured.

In real applications the receiving box with the interface logic, which is less power demanding compared to the transmitting box, is placed approximately in patient's COB. In this way the distance-velocity measuring system is an addition to the microprocessor based multichannel electrical stimulator which also serves as a control and storage unit for gait measurement data. The gait phase detection is performed by stimulator logic while scanning the signals from foot-switches and lightweight goniometers attached to patient's knees [2]. Results are kept in stimulator's memory and can be later transmitted through serial line to remote computer for possible further storage and additional evaluation.

For the prototype used, we have because of flexibility and experimental reasons positioned the transmitter on the patient to avoid additional cabling. This set-up does not influence the system overall functionality. The prototype uses IBM/PC as a host computer instead of stimulator microprocessor. Receiving unit also includes a 4-digit numerical display and outputs BCD coded data. Instrument outputs are connected to a digital ports on PC's data acquisition board. Interface logic is compatible with 16 bit data bus with an interrupt requesting capability.

RESULTS

Results shown in this paragraph were obtained using the prototype system. To emphasize the dynamic capabilities of the system only information gathered from distance/velocity measuring system are shown, neglecting any other sensory information.

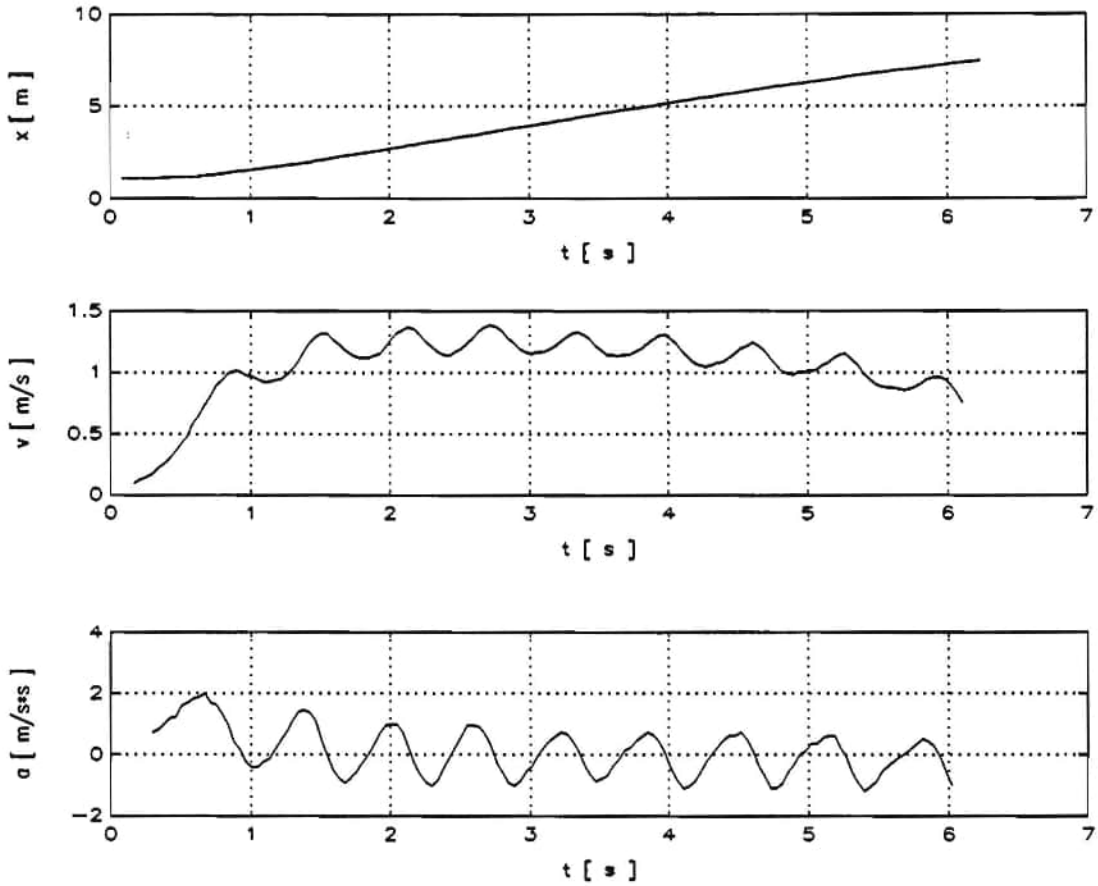

Figure 2: Distance, velocity and acceleration assessed in a healthy person

Figure 2 shows typical records for a healthy person. The curves presented are distance, velocity and acceleration of the COB versus time. The person was asked to walk along the walkway in free gait. The gait velocity was derived by differentiating two consequent distance recordings. The gait acceleration is derived from current velocity in the same way. As differentiation is numerically ill conditioned operation the fifth order moving average filter was employed after each differentiation to smooth the data. The error in acceleration signal introduced by filtering is under 4%.

The results assessed in a complete T-12 paraplegic subject are shown in figure 3. The patient was using 4-channel FES [1]. Swing phase was realized through afferent FES provoking flexion reflex resulting in simultaneous flexion of hip and knee and ankle dorsiflexion and thus providing clearance of the foot from the ground. Stance phase was achieved by stimulating bilaterally knee extensors enabling sufficient support to the patient utilizing crutches for balance and partial support. The patient was considered as experienced FES walker. The velocity and acceleration curves significantly differ from those measured in healthy subject and hence demonstrate the energy inefficiency of the executed FES assisted gait.

The sharp peaks noticeable in both acceleration curves are due to the noise of quantization which is impossible to filter out completely. The prototype system was designed with a 4-digit counter enabling the resolution of 1 cm. This will be improved in the final design to ensure $\pm$ 2 mm resolution. The sensitivity is better that 1 mm and accuracy achieved is just under 3% in laboratory environment within 12 m range. Accuracy of the system was tested manually under static conditions. The sampling rate achieved was 24 Hz.

DISCUSSION

The prototype measuring system showed to be reliable and fulfilling most of the requirements. However the final version will be minimized by using SMD technology. The computer bus interface will be improved to increase its resolution.

Occasionally the measurement process was malfunctioning because of rather small radiation angles of the transmitters. When the transmitter on the patient was rolled for more than approximately 30°, it didn't emit

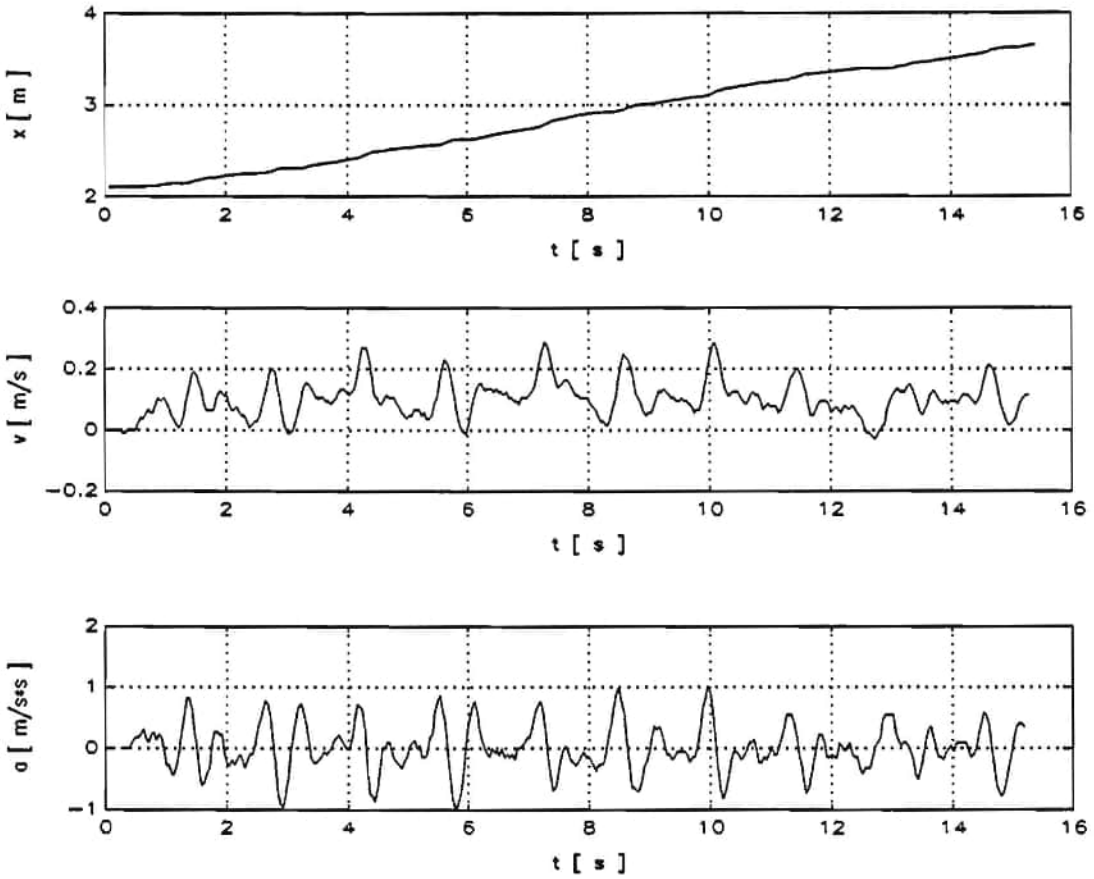

Figure 3 Distance, velocity and acceleration assessed in a T-12 paraplegic subject

enough energy in the direction of the receiver, thus disabling proper signal detection. It was shown that this error may be overcome by placing the receivers on the patient and using transducers with wider receiving angles.

The systematic errors resulting in inaccuracy of the measuring system are mainly originating from atmospheric conditions with notable influence on speed of sound, e.g. temperature. It is our opinion that accuracy can be significantly improved through temperature compensated design. Rotation of transducers around the roll and pitch angles is also introducing errors as the transducers characteristic properties heavily depend on reception/transmission angles. Doppler phenomena also becomes important at speeds higher then the one achieved in human gait. The above mentioned errors can be compensated either through hardware or software.

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EFFECT OF FUNCTIONAL ELECTRICAL STIMULATION (FES) ON STANCE SYMMETRY AND WEIGHTSHIFTING IN HEMIPARETIC PATIENTS

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SUMMARY

FES was applied to hip abductors/extensors and knee extensors/flexors of 8 hemiparetic patients to improve stance symmetry and weight shifting abilities. Ground reaction forces and center of pressure (COP) displacement were measured from the patients standing on two triaxial Kistler force plates. With FES posture and body alignment was improved. Positive aftereffects of stimulation indicate that a simple FES device can be used temporarily in addition to physiotherapy to assist the rehabilitation process for posture control.

STATE OF THE ART

After cerebral vascular accident most patients suffer from loss of movement control of one body side. As a consequence these patients mainly load their healthy leg, with bent knee and retracted hip on the paretic side. This is stressful for the healthy leg and causes contractures at the hip and knee on the impaired side which in turn reduces mobility in the long run. Therefore it is beneficial for the hemiparetic patient to learn to load both legs symmetrically while standing, to align the body weight properly and to be able to shift the body weight from one leg to the other as early as possible.

In rehabilitation physical therapists guide the patients by active support to stand symmetrical and shift their weight to the paretic leg. To support the learning process we applied FES to hip and knee extensors. The idea was to make the patient feel safe by active muscle contraction and thus giving the motor system - the muscle fibres which might be left intact - an additional chance to recover and build up a motor pattern which then can be used for better motor control.

The PURPOSE of the present study was to check if FES can improve stance symmetry and weight-shifting abilities in hemiparetic patients.

METHODS

8 hemiparetic patients - 4 - 60 months after stroke - were involved in the study. They were not able to stand upright without any support for more than one minute and could not walk more than a few steps without support.

For stimulation a commercially available open loop stimulation device (Stratec, 8 channel) (20 Hz, 200 µs pulses) was used.
Three pairs of surface electrodes (10 x 3 cm flexible metal plates) in water soaked pads were attached to:

1. Mm. vastus medialis and lateralis of the quadriceps group
2. M. biceps femoris
3. Mm. gluteus medius and maximus

Ground reaction forces and center of pressure (COP) as given by two triaxial Kistler force plates were evaluated. The data were processed by a commercially available data analyzing system.

The TEST PROTOCOL was:

Any sequence included standing (STA) on two force plates and weight shifting (WS) to the paretic leg as far as possible.

1. STA - WS - no stimulation
2. STA - WS - stimulation (starting with 30 mA)
3. STA - WS - no stimulation

For the stimulation trials weight shifting was repeated with increasing current strength. Between trials the current was increased by 10 mA each until the patient signalled discomfort. After this the patient was asked to do one more trial for standing and one for weight shifting without stimulation (3.).

RESULTS

1. In application of FES for hemiparetic patients it has to be taken into account that other than paraplegics, who suffer from loss or impairment of sensation, these patients are sensitive to pain. Therefore the strength of the current applied is limited by the patients tolerance. Some patients signalled pain already with low current strength (30-40 mA) and obviously did not feel safe with stimulation. Others had no discomfort with low current strengths. With 70-80 mA often knee and sometimes hip extension was visible. Current strength above 100 mA caused discomfort or pain to most patients.

2. Vertical ground reaction forces show better stance symmetry (39.9 vs 36.0 % body weight on the paretic leg), faster weight transfer (36.0 vs 22.4 %bw/s) and more maximum weight accepted on the paretic leg (81.6 vs 78.7 %bw) with stimulation (fig. 1).

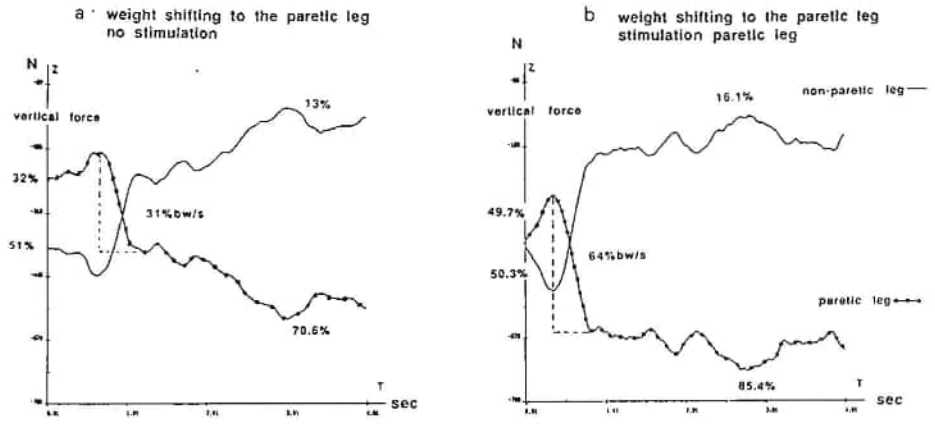

Fig.1: Vertical ground reaction forces during weight shifting
a: no stimulation b: with stimulation

3. Anterior-posterior ground reaction forces are not influenced much by stimulation, the variability increases slightly.
Medio-lateral ground reaction forces sometimes show a pronounced force peak to shift the weight to the paretic leg. With stimulation this force peak is less pronounced while the general variability is increased.

4. While in a healthy person during weight shifting the center of pressure (COP) of the pushing leg moves synchronously with the vertical ground reaction forces forward and lateral this can only rarely be seen in hemiparetic patients. Their COP often starts to move after weight transfer, moves only slightly forward and medial. After the weight transfer is finished great oscillations of the COP can be seen in the patients. There is only very little movement of the COP of the paretic leg.

5. The amount of movement of the COP (oscillation in either direction) is markedly reduced during stimulation.

6. In some patients spasticity in arm and hand muscles was reduced during and after stimulation.

7. The improved values for weight shifting with stimulation are preserved in the non stimulation trial after the stimulation series (table 1).

Table 1: Results: Weight Shifting with FES

		no stimulation (before)	stimulation	no stimulation (after)
Vertical Force: (% bw)	initial	32.2	49.7	38.4
	maximum	70.6	85.4	78.3
	rate	49.7	80.6	53.9
COP	eff. footlength	10.79	3.68	7,45

DISCUSSION

Stance data with a distribution of 36% (affected) vs. 64 % (uneffected leg) distribution of weight are in agreement with the literature (Bohannon, Dettman). Weight shifting data have not yet been reported. Our data suggest that from the starting point in stance three phases can be separated: Preparatory movement, transition, and stabilization phase. Difficulties in weight acceptance on the paretic leg are reflected in less maximum weight accepted, reduced transition rate, and oscillations in the stabilization phase, and COP movements mainly of the pushing leg

The weight shifting technique in hemiparetic patients has to be controlled carefully, because often patients move their upper body over the paretic leg instead of shifting the center of gravity (pelvis). This behavior ist not helpful for posture control and has to be corrected.

Immediate effects of FES are due to activation of paretic muscles and a more physiological posture with the affected knee and hips extended and the trunk in upright position.

The results in general show a positive effect of Functional Electrical Stimulation on stance symmetry and weight shifting abilities for hemiparetic patients. But looking at the results in more detail reveals a great variability between subjects as well as within subjects. Even in those patients, who tolerate current application well, there is no linear relationship between current strength and improvement in weight shifting. Each patient seems to have his individual optimum current strength under which he feels well and performs best.

Each patient needs some time to adapt to the feeling and the effect of stimulation. Proper information helps to improve this process. After this adaptation process most patients feel safe with stimulation. Their movements are relaxed and spasticity is sometimes reduced.

These positive effects are preserved in weight shifting trials after stimulation is removed. This means there is an aftereffect of stimulation which can be used for learning. It might be that during stimulation some rudimentary patterns can be activated which than can be preserved for non stimulation trials.

CONCLUSION

The study shows that functional electrical stimulation (FES) can be used temporarily to assist physiotherapy of hemiparetic patients to improve stance symmetry and weight transfer to the impaired body side.

Further investigation has to be done to find criteria for selection of those patients who benefit most from this kind of therapy, why some patients tolerate current application better than others do and what is the appropriate current strength.

A clinical study with daily stimulation over a longer period of time is planned.

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Fatigue of Intermittently Stimulated Quadriceps during Imposed Cyclical Lower Leg Movements

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SUMMARY

During prolonged experiments the influence of knee angular velocity, and stimulation parameters (interpulse interval (IPI), duty cycle (DC), number of pulses per cycle (NP)) on fatigue-induced torque decline of paralyzed human quadriceps was studied. Identification of torque-angle and -angular velocity was also performed. The overall loss of maximum torque (MT) and torque-time integral (TTI) per cycle during sustained intermittent stimulation during isokinetic movement had a typical exponential decay reaching asymptotic values. Larger knee velocities resulted in a significantly faster and relative larger decay of MT and TTI. The rate and relative magnitude of fatigue during concentric contractions are in direct relation to NP. The results may be valuable in the design of optimal control systems for FES which pursue minimization of muscle fatigue.

STATE OF THE ART

A major issue in the control of functional electrical stimulation (FES) of paralysed muscles is the decay of muscle force as a result of fatigue under sustained (continuous and intermittent) stimulation [1-3, (2: in press)]. Stimulated paralyzed human quadriceps fatigue under isometric condition can be described by an exponential decay [2,3]. In this study the torque of intermittently stimulated paralysed human knee extensors during imposed (isokinetic) cyclical lower leg movements has been investigated.

MATERIALS AND METHODS

I. Subjects

The subjects who participated in this study were complete T5-T6 level spinal cord injured patients. All had normal excitable quadriceps muscle and had been enrolled in the FES training program of the rehabilitation center *'t Roessingh* (Enschede, The Netherlands).

II. Protocol

A protocol of 7 fatigue trials (FT) was designed to compare overall loss of tetanic torque at the knee joint during sustained intermittent stimulation at different isokinetic velocities. The quadriceps of the strongest leg was stimulated using adhesive sruface cathode and anode (Pals, Axelgaard Manufacturing Co, Ltd, Fallbrook, CA, USA, 5x9 cm) over the motor points of the rectus femoris/vastis lateralis and vastus medialis respectively. The electrodes remained on the sites during the entire day. The knee angle and velocity ranges were limited by the anatomical restrictions of the lower leg, the restrictions imposed by the dynamometer bench and the desire to maintain a constant cycle time (2 s.), comparable to a walking cycle. The experimental set-up is shown in fig. 1. The influence of IPI (20 and 40 ms), DC ([ontime/cycle time]: 16 and 32 %) and NP ([ontime/IPI]: 16 and 32), at isokinetic joint movement, was investigated. Pulsewidth (PW=300 μs) and stimulation amplitude (SA=100 mA) were set to obtain maximal recruitment. Three muscle identification trials, determining the torque-angle (isometric measurement) and torque-angular velocity (isokinetically measured at 50 deg.) relations, were performed. Force, knee angular position, and velocity were sampled at 100 Hz. These signals and stimulus data were stored on disk for off-line analysis.

III. Off-line data analysis

From the active torque, the maximum torque (MT) and torque-time integral per swing (TTI) are calculated. "Fatigue parameters", describing the decay of the MT and TTI as a function of time (one sample per cycle), were derived by curve-fitting the following equation to the data:

$$\xi(t) = \xi_{max} \cdot [(1-\xi_o) \cdot \exp(-t/\tau_\xi) + \xi_o] \qquad (1)$$

where ξ is either MT or TTI, t is time, ξ_{max} is the maximum achieved in the considered trial, τ_ξ is the time constant of decay in ξ due to fatigue, and ξ_o is the relative asymptotic value to which $\xi(t)$ descends. The first part of the data (approximately 10 samples) which increases to ξ_{max} has been ignored. Equation (1) is fitted iteratively by minimizing the resulting RMS deviation from the experimental data (see also [2]).

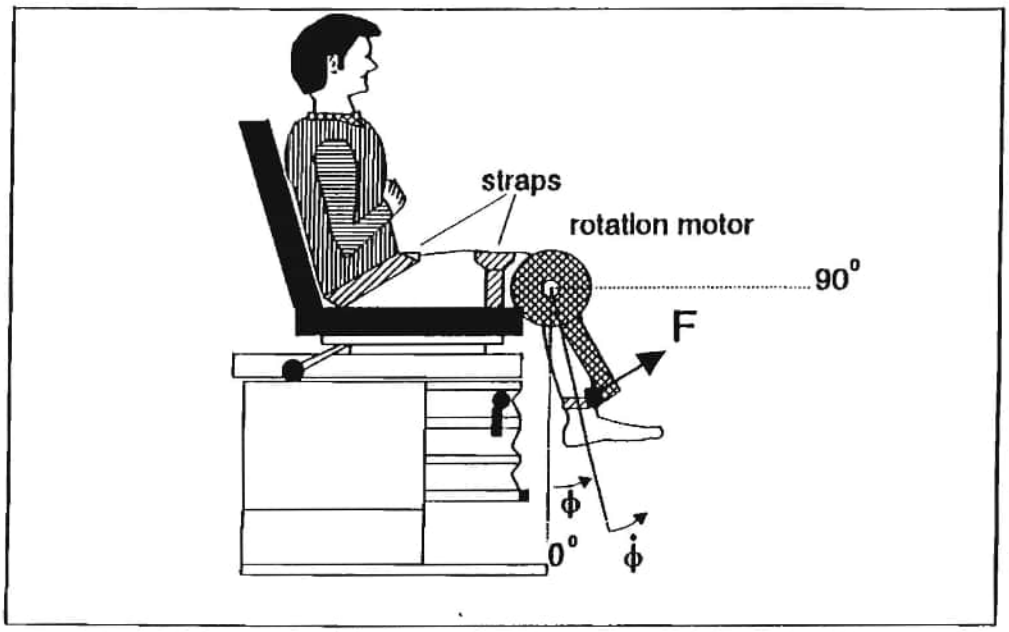

Fig. 1. *Schematic of experimental set-up. The angular position and velocity, measured at the motor axis, are defined positive in extension motion with zero as indicated. The patient is strapped at the hip and knee to measure knee torque (at the tibia) only and to ensure static position of the body.*

RESULTS

I. Measured and estimated signals

Fig. 2 displays a typical registration of measured and estimated signals for one cycle. The active, generated by the quadriceps, is estimated by subtracting the passive torque (ie. without stimulation) from the total torque.

II. Fatigue parameters

Fig. 3 depicts the fatigue parameters estimated from the decay in TTI. TTI_{max} displays a Hill type dependence on velocity, indicating comparable muscle condition for each trial. The graphs for τ_{TTI} and TTI_o show that higher velocities result in a significantly larger and faster decay of TTI ($\alpha < 0.05$). Variations in stimulation parameters indicated that the rate and magnitude of fatigue for concentric contractions are in direct relation to NP. The fatigue parameters for MT are similar.

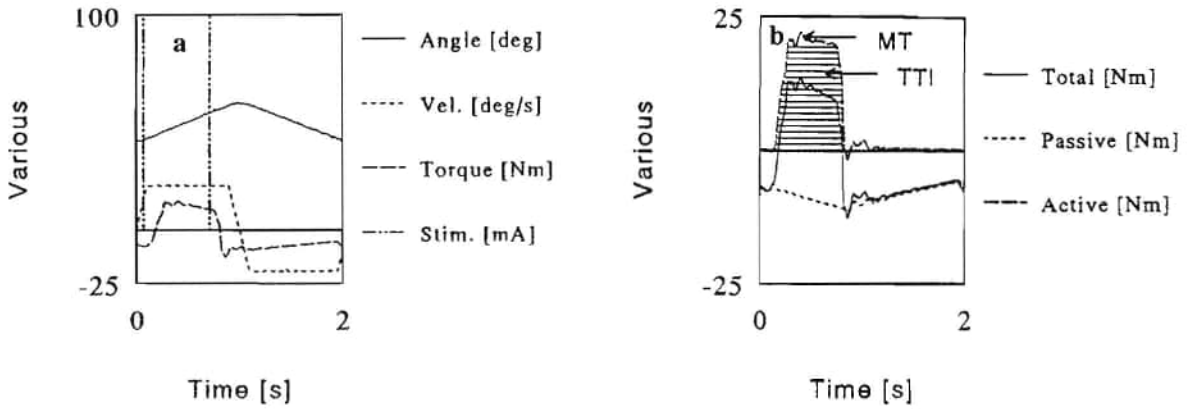

Fig. 2. a: *Total knee torque, angular position and velocity, and the applied stimulation burst, for one cycle with concentric contraction.* **b:** *Total, passive and active knee torque. Estimated parameters TTI [Nms] and MT [Nm].*

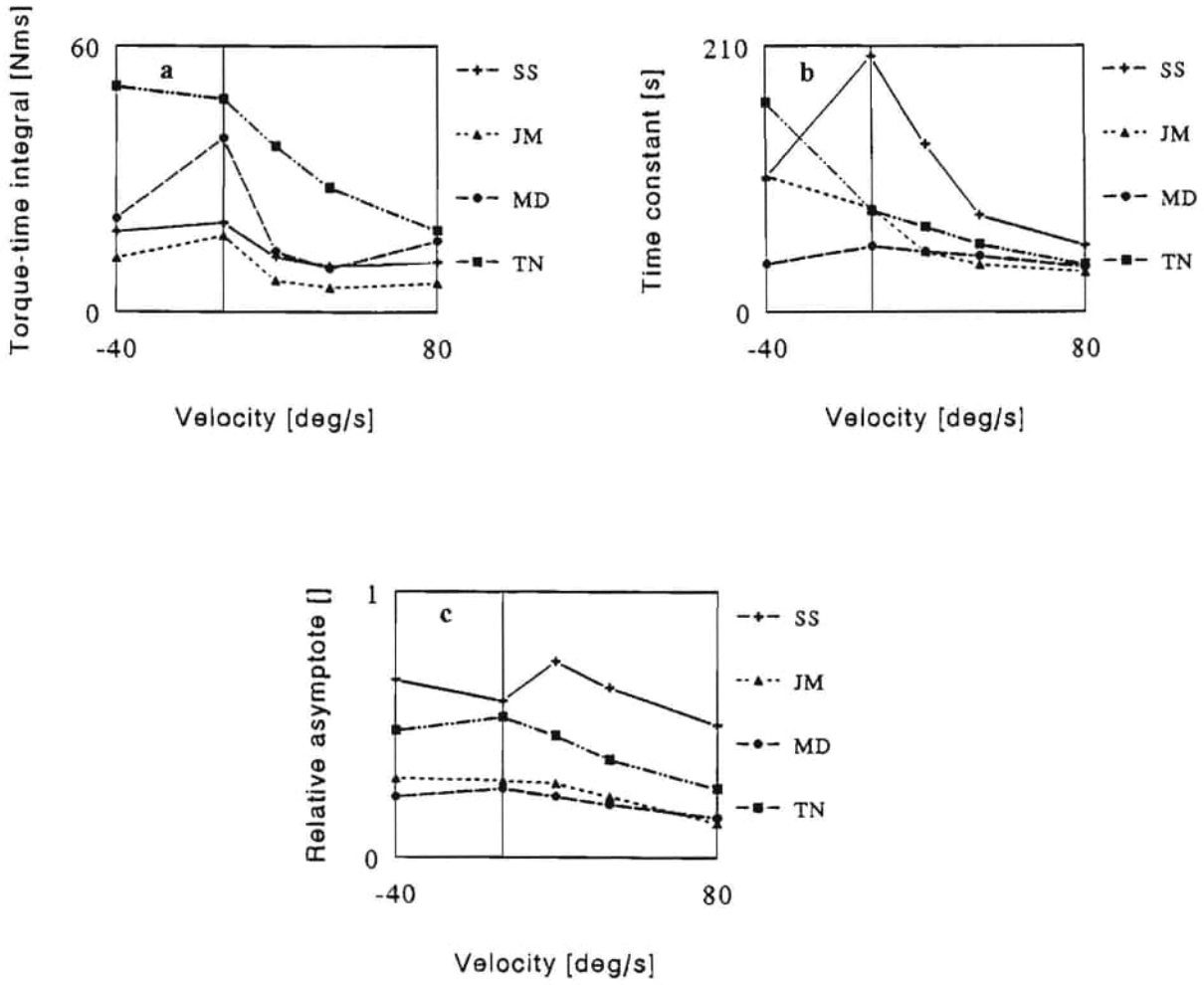

Fig. 3. *Different velocities refer to seperate fatigue trials with identical parameters. (Subjects: SS, JM, MD, TN)* **a:** TTI_{max}, **b:** τ_{TTI}, **c:** TTI_{o}.

III. Muscle dynamics.

A typical Gaussian-type dependence of the isometrically generated torque on the angle was found (fig. 4a). The measured torque-angular velocity relations supports the Hill equation. The relations alter due to fatigue. The decline in torque output due to fatigue is larger at higher velocities (see also fig. 3c).

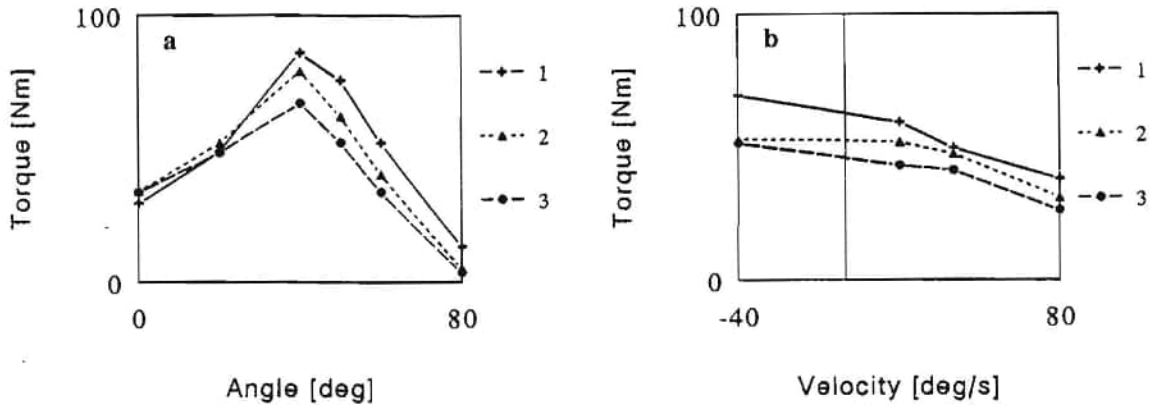

Fig. 4. *Identification results of subject TN. (1): prior to FT 1; (2): after FT 3, (3): after FT 7. (IPI = 20 ms)* **a:** *Torque-angle relation.* **b:** *Torque-angular velocity relation.*

DISCUSSION

The apparent dependence of the quadriceps fatigue curve on the isokinetic knee joint velocity has not been reported before. The dependence might be explained by lower metabolic efficiency (shortage in ATP or high IMP concentrations) of the total muscle or by complete exhaustion of fast twitch fibers, which are more susceptible to FES than slow twitch fibers. Concerning stimulation parameters, the results indicate that, within the boundary conditions for a given task, NP should be minimized to postpone fatigue. This can be accomplished by minimization of DC and/or 1/IPI. The results may contribute to the derivation of an optimization criterion, describing muscle fatigue as a function of both joint movement and stimulation parameters.

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Synthesis of swing-through crutch-aided locomotion in paraplegics using electrical stimulation

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SUMMARY

We proposed that electrical stimulation can be used to synthesise crutch aided locomotion in paraplegics by providing active hip and knee flexion during the swing phase of the gait. Three subjects could perform this mode of gait for distances in excess of 40m without rest. The kinematic parameters of the gait were measured. We have demonstrated that induction techniques can used to produce rules for the FES finite state controllers.

STATE OF THE ART

Although swing-through gait is fast it has generally been used only by low-level paraplegics with braced knees. FES has been used to synthesise swing-to gait patterns [1] and in these applications electrical stimulation was used to brace the knees simulating the action of KAFOs. In this mode FES induced quadriceps muscle fatigue limited the duration of the gait. Also, by bracing the knees the upper limbs are required to lift the centre of gravity of the body to obtain ground clearance. We proposed that flexing the knees during the swing phase of gait will reduce quadriceps fatigue and upper limb effort [3]. We demonstrated the feasibility of synthesising this mode of gait using a rollator [4] and using crutches [2] as the support device. The control of this gait used finite state machines with intuitive rules to determine the state transitions [4]. It has been demonstrated that using machine learning can enable the automatic induction of state transition rules [5] and was proposed that this technique could be used for FES-assisted swing-through gait [4].

In this study we have investigated the kinematic parameters of crutch-aided FES-assisted-swing through gait using crutches of our improved FES controllers.

MATERIALS AND METHODS

Five normal volunteers were trained in swing-through gait. An adjustable KAFO was developed that could fit all subjects and had the ability to lock and unlock the knee joints. EMG surface electrodes were placed over the major muscle groups of the lower limb. Swing-through gait of these volunteers was characterised using the *VICON* motion analysis system together with Kistler force plates. From the kinematic and kinetic data the sensors were simulated. Rules were then induced, using on/off muscle characteristics (from the envelope of the EMG signals), for the state transitions using the simulated sensors.

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A mobile overhead safety harness system was constructed. This was to allow paraplegics to perform swing-through gait using crutches whilst providing a means of arresting a fall.

Paraplegics underwent a gait training programme [3, 4]. Gait was synthesised using the Strathclyde programmable stimulator with surface electrodes. Gait control software was developed based on the use of the finite state technique, in which the gait is divided into discrete states. Progress to the next state in the gait cycle was governed by a set of rules triggered by the set of sensors. Stimulation was applied to the quadriceps, hamstrings, glutei, erector spinae, peroneal nerve, and gastrocnemius. A Floor Reaction Orthosis (FRO) control system was incorporated allowing a reduction in the quadriceps stimulation duty cycle and hence reducing fatigue. Gait parameters were derived from the analysis of the video recordings. The controller was then modified in an attempt to optimise the gait. This iterative process for each patient was continued for 4-8 months. Sensors that were used for the transition rules included: tilt switches placed on the crutches, strain gauged crutches and hand switches. On completion of the project three subjects could perform FES-assisted swing-through gait using crutches in the overhead safety harness system.

Distance trials The gait trials took place at Philipshill Hospital, Glasgow. The subjects walked until they reported fatigue. The optimum FES finite state controller and sensor set were used. Heart rate was monitored during the trial using a PE3000 Sports tester. Average speed of progression, average step length and maximum distance were recorded.

Kinematic parameters Basic kinematic parameters of speed, stride length and cadence were determined throughout the project by use of the video gait analysis system. This permitted a relatively quick evaluation of different gait strategies.

When the subjects had been trained for a period of three to four months with their optimum swing-through gait strategy the kinematic and kinetic gait parameters of a number of different trials were determined using the *VICON* motion analysis system. FES swing-through gait was compared with KAFO swing-through gait when possible. Using KAFOs subject B was unable to perform swing-through gait due to insufficient trunk stability and was only able to perform swing-to gait.

RESULTS

The data from normal subjects was used to indicate the occurrence of signals from the simulated sensors. For the initiation of stance either crutch force alone or heel switch alone gave the best performance. For the initiation of swing crutch inclination gave the best performance.

The maximum range, overall speed, average stride time and average stride length for each subject are given in table 1. At the end of each gait trial the hip extensor muscles had become fatigued to the extent that the subjects had difficulty in preventing jackknifing. The parameters, derived from a detailed stride by stride analysis of the gait using the *VICON* motion analysis system, are presented in table 2. There was no loading transmitted to the overhead safety support system during these swing-through gait trials.

DISCUSSION

The parameters of speed, stride length and cadence of FES-assisted swing-through gait are significantly greater than those of reciprocal gait. However the speed does not yet approach that of reciprocal or swing-through gait of normal individuals [2]. This is a reflection of relatively low cadence which could be improved by a refinement of the controllers. Subject A (performing swing-through gait both with

KAFOs and FES) had a similar stride length for both gait modes, but a longer stride time (and hence lower speed) for KAFO gait. There were similar times in both gaits for body-swing, crutch-swing and double support after leg swing. The slower time for the KAFO gait cycle was due to more time being spent in the double support phase after crutch swing, that is a longer time spent in preparing for the body swing phase. This was due to the hip extensors being stimulated during FES gait. Subject B (performing swing-through gait with FES and swing-to gait with KAFOs) had a higher speed for FES gait due to a longer stride length.

Subject	Swing-through gait				Reciprocal gait
	Maximum distance (m)	Average speed (m/s)	Average cadence (steps/s)	Average step length (statures)	Average speed (m/s)
A Female 28yrs (T11)	55.5	0.40	0.32	1.26	0.12
B Male 23 yrs (T6)	43.3	0.30	0.27	1.08	0.08
C Male 27 yrs (T11)	50.6	0.38	0.34	1.13	-

Table 1 Comparison of parameters of maximum distance trials using the optimum strategy for FES assisted swing-through gait. Average step length is presented as a multiple of the subjects height. Speeds for FES-assisted 4-point reciprocal gait are given as a comparison.

Subject and gait type	Mean stride time (s)	Mean body swing time (s)	Mean crutch swing time (s)	Mean body swing time (s)	Mean 1st double support time (s)	Mean 2nd double support time (s)	Double stance ratio (percent)	Mean distance beyond crutches (m)
A (FES-STh)	1.19 ±0.07 (1.24)	2.75 ±0.33 (2.28)	0.74 ±0.07 (0.72)	0.64 ±0.06 (0.58)	0.93 ±0.19	0.43 ±0.17 (0.32)	49.7% (43.0%)	0.51 ±0.05 (0.57)
A (KAFO-STh)	1.17 ±0.08 (1.17)	3.63 ±0.93 (2.62)	0.77 ±0.12 (0.88)	0.68 ±0.22 (0.74)	1.76 ±0.80 (0.90)	0.43 ±0.23 (0.10)	60.2% (38.2%)	0.48 ±0.03 (0.49)
B (FES-STh)	1.13 ±0.05 (1.11)	3.24 ±0.69 (2.48)	0.71 ±0.15 (0.68)	0.49 ±0.12 (0.64)	1.22 ±0.59 (0.76)	0.82 ±0.36 (0.40)	63.0% (46.8%)	0.25 ±0.07 (0.24)
B (KAFO-ST)	0.52 ±0.10 (0.69)	1.94 ±0.39 (1.78)	0.34 ±0.03 (0.36)	0.40 ±0.04 (0.46)	0.57 ±0.13 (0.56)	0.63 ±0.28 (0.40)	61.8% (53.9%)	N/A
F (AFO-STh)	1.76 ±0.05 (1.82)	1.64 ±0.06 (1.62)	0.70 ±0.06 (0.64)	0.67 ±0.02 (0.66)	0.18 ±0.03 (0.22)	0.09 ±0.01 (0.10)	16.5% (19.8%)	0.87 ±0.03 (0.92)
F (KAFO-STh)	1.60 ±0.06 (1.66)	1.67 ±0.08 (1.62)	0.72 ±0.07 (0.66)	0.67 ±0.03 (0.68)	0.19 ±0.01 (0.18)	0.09 ±0.02 (0.10)	16.8% (17.3%)	0.77 ±0.08 (0.76)

Table 2 Temporal and distance parameters of FES swing-through gait (FES-STh), KAFO swing-through gait (KAFO-STh), KAFO swing-to gait (KAFO-ST) and AFO swing-through gait (AFO-STh). Details for subjects A and B are as in table 1 and subject F is unimpaired. Standard deviations are shown (±). Figures in brackets are for the single fastest stride.

Quadriceps fatigue did not occur in any of the prolonged gait trials due to a) the effective training regime and b) the use of the FRO controller. However hip extension, produced by stimulation of adductor magnus and gluteus maximus proved to be the limiting factor. Although effective strong hip extension could be produced it fatigued relatively quickly. Even after a recovery period in excess of 30 minutes, the period for which the hip extensors produce a functional contraction was considerably reduced. As yet no effective training regime has been devised for hip extensors. Hip extensor stimulation time was reduced by adaptations to the controllers but we had no controller which is as effective as our closed-loop FRO controller for quadriceps. Rest periods during stance, although relieving quadriceps fatigue, did not solve the problem of hip extensor fatigue.

This study has examined an alternative FES gait mode and has demonstrated that for the subjects tested FES-assisted swing-through is a viable alternative to reciprocal gait for covering long straight distances. FES-assisted swing-through gait and FES-assisted reciprocal gait can be viewed as complementary gait modes, with the latter being used in confined areas.

CONCLUSIONS

- Inductive learning techniques, combined with study of normals performing a movement, provide a means of automatically determining the transition rules for FES finite state controllers. Crutch forces and inclination detectors are effective sensors in the identification of the state transitions in swing-through gait.
- FES-assisted crutch aided swing-through gait using free knees is feasible in paraplegics. There are highly significant improvements in the kinematic parameters of this form of gait when using crutches as compared with 4-point reciprocal gait and swing-through gait using KAFOs (see tables 2 and 3).
- It is possible for mid-thoracic paraplegics to perform this gait using FES whereas it is not possible with only KAFOs.

It is recommended that additional bracing to prevent bilateral hip flexion during stance and periods of standing should be investigated to reduce hip extensor fatigue.

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STIMULATION OF PARASPINAL MUSCLES IN PATIENTS WITH SPASTIC TETRAPARESIS

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SUMMARY

Ambulatory spinal cord injury patients walk with associated irregular motor activity, spasticity and weakness. Their locomotor patterns can be externally modified by the afferent stimulation of cutaneous and spinal nerves or by the efferent activation of movements. Cutaneous electrical stimulation of the paraspinal muscles combines these approaches. Seven patients, 5 with cervical lesions (C3 to7), 1 with hereditary paraparesis and 1 after barotrauma, were included in the study. Up to 50mA and 25Hz stimulation train of 0.5ms biphasic current pulses was applied to the paraspinal muscles in the lumbar and lower end of thoracic region during gait. Force shoes and 3D goniometric system were used for the assessment of forces, curves of their points of action under both feet and joint angles in all three planes together with time, length and velocity parameters. The gait was assessed without and with the stimulation. The forces and angles showed less expressed changes, while the stride time, length and velocity improved considerably by the stimulation. The improvement built up gradually during the trials and showed a prolonged effect. The results were confirmed by subjective opinion of the patients.

STATE OF THE ART

Spinal cord injury patients, who regain their ability of independent ambulation, walk with associated irregular motor activity, spasticity and weakness. Their locomotor patterns can be externally modified by the afferent stimulation of cutaneous and spinal nerves or by the efferent activation of movements. Cutaneous electrical stimulation of the paraspinal muscles, combining all these approaches, was considered as an asset to the impaired suprasegmental control.

MATERIALS AND METHODS

Seven ambulatory spinal cord injury patients, 5 with cervical lesions (C3 to7), 1 with hereditary paraparesis and 1 after barotrauma, were included in the study. Continuous 25Hz stimulation train of biphasic constant current pulses was applied to the paraspinal muscles during gait. With large 5x13cm self-adhering electrodes over the erector spinae muscles in the lumbar and lower end of thoracic region, 0.5ms pulses were raised up to 50mA for a good muscular contraction.

Force shoes with 9 sensors each /1/ and TRIAX™ 3D goniometric system were used for the assessment of gait. Forces, curves of their points of action under both feet and joint angles in all three planes were averaged together with time, length and velocity parameters for 10 to 12 consecutive trials on a 10m walkway. After free gait, the assessment was repeated with the stimulation.

RESULTS

The forces and angles showed moderate changes, while the stride time, length and velocity improved considerably by the stimulation. The improvement built up gradually during the trials and showed a prolonged effect. The results were confirmed by subjective opinion of the patients. They also reported a relief by the stimulation during the laborious measurements.

Average stride time and length during the trials of the patient 6 are presented in Figs. 1 and 2.

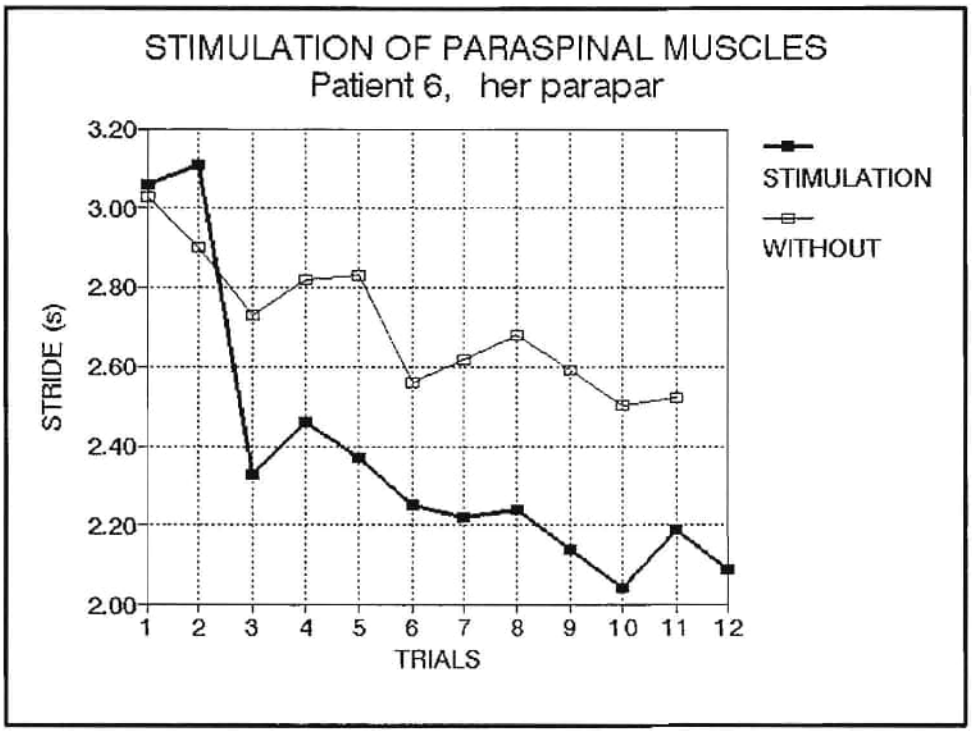


Figure 1.

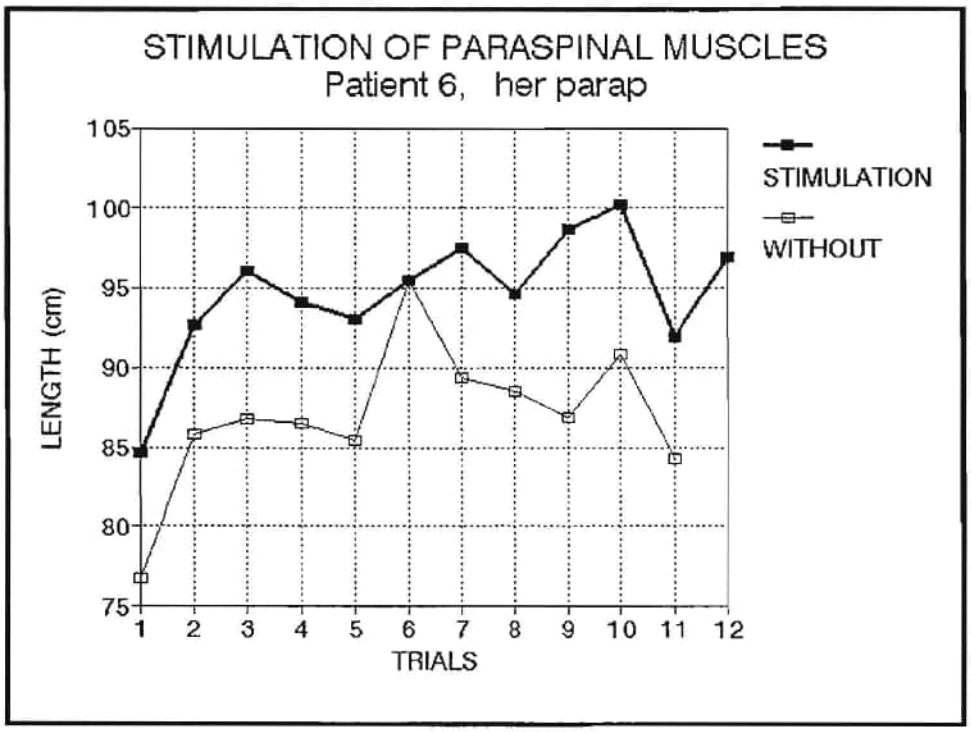
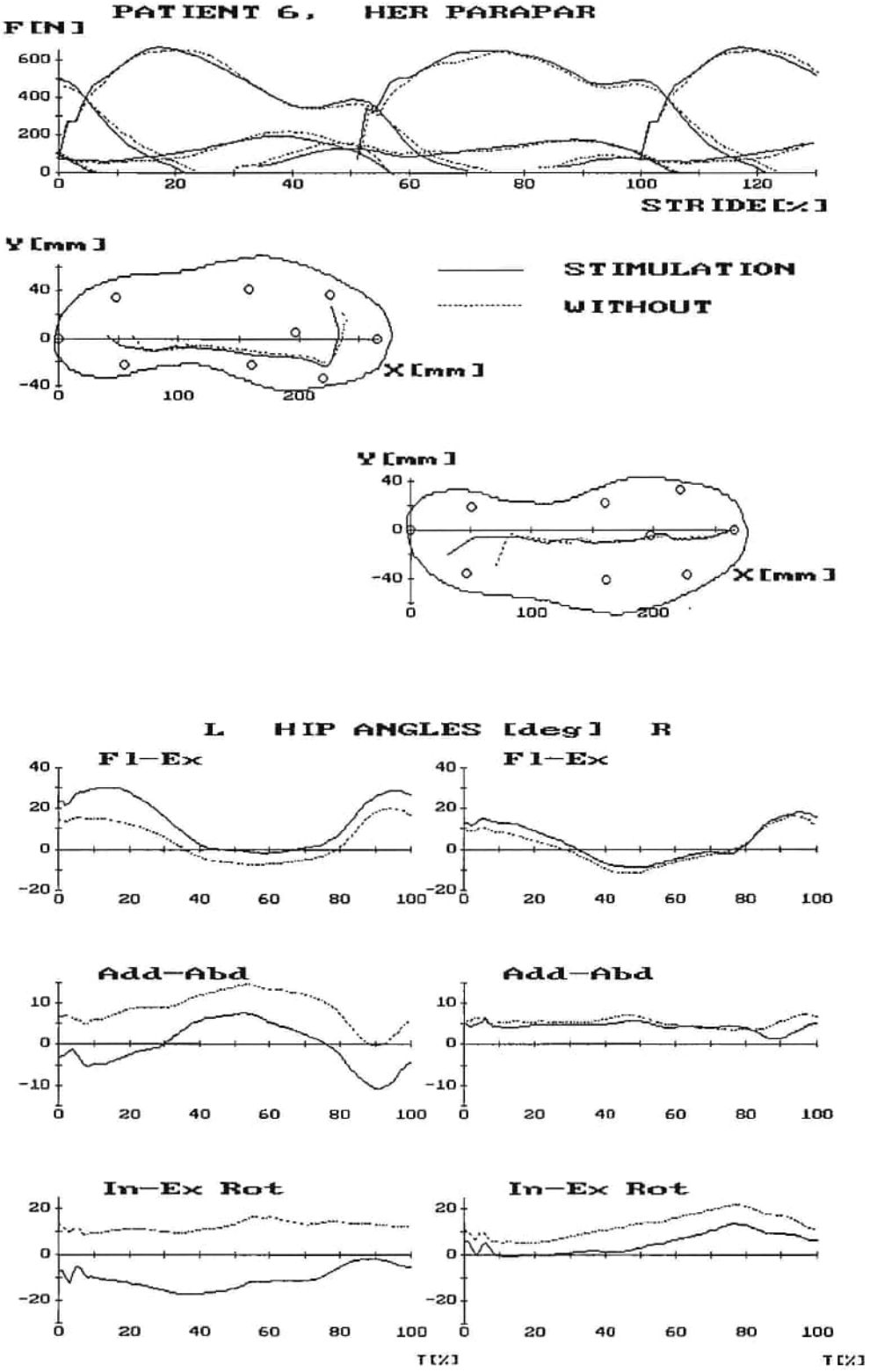


Figure 2.


PATIENT 6, HER PARAPAR
F [N]
STRIDE [%]
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STIMULATION
WITHOUT
L HIP ANGLES [deg] R
Fl-Ex
Add-Abd
In-Ex Rot
T [%]

Figure 3.

In Fig. 3 ground reaction forces under both feet and crutches (upper diagram) are presented for the same patient together with curves of their distribution (next two diagrams). On the lower part of Fig. 3, hip angles in all three planes are shown. The stride durations and lengths in Figs.2 and 3 were better with the stimulation and were improving during the whole set of trials. The forces in Fig. 3 showed moderately improved swing to stance ratio, lesser crutch loading and improved loading of the heels. The goniograms from the same figure displayed 8-15° higher flexion, 15-20° better abduction and 20° higher external rotation of the left hip during the stimulation. It also enabled 10° higher external rotation during the whole stride and 5° better flexion in the initial stance phase of the right hip. Angles in the knee and ankle joints did not change to such an extent during the stimulation.

Similar results were obtained in all 7 patients, with exceptions of patient 4 (tetraparesis, C3-4), who did not improve his stride time and length with the stimulation, and patient 5 (tetraparesis, C5), who showed a considerable fatigue in the last couple of 12 consecutive trials with and without the stimulation.

DISCUSSION

Role of central nervous system mechanisms in the motor control of human gait has not been fully established so far. Spinal generators of gait were postulated following the experiments in spinal cat /2/. At least partly preserved ventral pathways of the spinal cord were required in primates to perform stepping movements suspended over a moving treadmill /3/, demonstrating so a necessity of supraspinal generators in the control of biped gait. Centrally preprogrammed control, suprasegmental and segmental stretch reflexes were studied in healthy persons /4, 5, 6/ and their alterations screened in motor disabled patients /7, 8/. In the light of these studies it might be expected, that a combined, rather strong afferent and efferent transcutaneous electrical stimulation of the paraspinal muscles could facilitate both the supraspinal and spinal control of gait in the observed incomplete spinal cord injury patients.

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PARAPLEGICS LOCOMOTION WITH FES: WHAT IS THE REAL OBJECTIVE?!

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It is possible for paraplegics to walk with the aid of several types of FES or Hybrid Systems. Although walking by itself has many medical and psychological benefits, it is still a question if such walking systems are of any use in daily, occupational and social functions. Participation in many such activities requires standing, walking, good balance and independent activities of the arms.

Occupational, social and daily activities that are possible to perform by mid-thoracic paraplegics using the LSU-FES powered reciprocating gait orthosis (RGO) were evaluated. Paraplegics could independently prepare food in kitchen, barbecue in backyard, play ball with children, shoot rifle/pistol, work in a machine shop, do office work, package parcels for shipment and check the motor of their automobile.

Limitations are also present. It is impossible to bend down to pick-up objects that fall on the floor or to reach low shelves below the thigh level. Going up-down stairs is slow and carrying large objects in hand during locomotion is not possible.

The first signs indicating that paraplegics can do some work and participate in social activities are present and partially fulfill the objective of reversing their position from tax burden into tax-payers, which is the ultimate objective of rehabilitation.

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ASSESSMENT OF PROPULSIVE PROPERTIES OF HIP MUSCLE STIMULATION METHODS IN HYBRID SYSTEMS

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SUMMARY

The propulsive properties of different hybrid systems incorporating the Steeper's Advanced Reciprocating Gait Orthosis (ARGO) were assessed. Four system configurations: (1) walking with the ARGO alone, (2) with electrical stimulation of the flexion withdrawal reflex, (3) the gluteal muscles and (4) efferent stimulation of hip flexors were compared.
The study involved measurement of propulsive components of ground reaction forces, ground reaction force distribution between foot and crutches, and hip joint kinematics.
Results of the first single subject trial indicate that the main differences appear in the calculated vertical and horizontal impulses. The distribution of impulses between foot and crutches seems to be most favourable for the patient when gluteal stimulation is incorporated. The distribution differences seem to have little effect on walking speed.

STATE OF THE ART

Our current FES research programme is directed towards the development of a hybrid walking system for SCI patients incorporating free knee joints during the swing phase of gait. A prerequisite to walking with free knees is sufficient propulsion at the hip.
Several methods of transcutaneous hip muscle activation have been incorporated in hybrid systems for this purpose. Most commonly used are electrical elicitation of the flexion withdrawal reflex at the swing leg /1/ and stimulation of gluteal muscles or hamstrings of the stance leg /2/. An alternative for the flexion withdrawal reflex may be efferent stimulation of hip flexors, though generally its feasibility is doubted.
This study was carried out to compare propulsive properties of these hip muscle activation methods, with the prospective of incorporating the best in our hybrid system.

MATERIALS AND METHODS

Subject
The study was carried out on one 31 years old, T8 complete, female subject, who is an experienced hybrid system walker.

Electrical stimulation
Prior to the experiments, the subject underwent specific training of incorporated muscles during a period of 6 weeks. Electrical stimulation of gluteus maximus was applied by two large self-adhesive electrodes placed over the muscle belly. Hip flexors electrodes were placed in the groin

medially and laterally from the femoralis nerve. The flexion withdrawal reflex was elicited at the common peroneal nerve by electrodes in the fossa poplitea and under the knee.
During measurements, electrical stimulation was controlled by computer in order to obtain a reproducible activation pattern. Foot switches, placed under the ball of the foot, were used to trigger the stimulation signal (ipsilateral gluteus maximus activation, contralateral flexion withdrawal reflex and hip flexors activation). The delay between foot contact and stimulation onset, burst duration and amplitude were set before measurements to values that produced comfortable and safe activation patterns. Pulse width and frequency corresponded to the training settings. All parameters were kept constant between trials.

Measurement set-up and protocol
Measurements were carried out with a Vicon 3-D video gait analysis system and two AMTI force platforms. Three retro-reflective markers were placed unilaterally on the subject's shoulder, hip joint and ankle of the orthosis. A flexible electrogoniometer was attached to the hip joint. Video signals were acquired at 50 Hz, analog data of force platforms and goniometer at 200 Hz.
The experiments comprised a total of 40 trials, in which the four hybrid system configurations were randomly alternated (10 trials each) in order to avoid systematic trends. In each trial, the subject walked over the force platforms once; one foot contact and one crutch contact were measured.

Data management and analysis
The measured horizontal position of the hip joint marker was first linearly interpolated to a 200 Hz signal, smoothed using moving average filtering (approx. 20 ms) and differentiated in order to calculate the peak and average walking speed. From the goniometer signal the angular acceleration of the hip, as measure of the hip moment, was calculated in a similar way.
Horizontal and vertical impulse (force-time integral) of foot and crutch were calculated from the force platforms data.

RESULTS

The measurements were performed with stimulation parameters set to the values of table 1.

Table 1 Stimulation parameters settings

Stimulation method	Amplitude	Pulse width	Frequency	Delay	On time
Gluteus maximus	65 mA	300 μs	50 Hz	300 ms	800 ms
Hip flexors	65 mA	300 μs	50 Hz	300 ms	800 ms
Flexion withdrawal reflex	40 mA	300 μs	20 Hz	0 ms	800 ms

From the 40 performed trials, 26 provided valid data for the calculation of average and peak walking speed. From the results in table 2 it can be seen that no clear differences between methods occur in the average walking spéed. The peak walking speed tends to be highest during walking with stimulation of gluteal muscles. From the standard deviations it can be noted that the subject is used to walking with stimulation of flexion withdrawal reflex and walking with ARGO alone.
Calculation of hip angular acceleration did not yield any useful results. Moving average filtering techniques are propably unsuitable for the video signal type.

Table 2 Averaged measurement results - Gait parameters

( ) = standard deviation		ARGO alone (n = 4)	Gluteus maximus (n = 8)	Hip flexors (n = 8)	FWR (n = 6)
Peak walking speed	(m/s)	0.45 (0.04)	0.56 (0.07)	0.48 (0.12)	0.47 (0.07)
Average walking speed	(m/s)	0.21 (0.01)	0.19 (0.05)	0.15 (0.05)	0.17 (0.02)

Only a small number of the trials provided useful ground reaction force measurements. Major problem was the difficulty the subject had in placing one foot and one crutch on seperate force platforms without interference of the other foot or crutch. Eventually 19 valid measurements of a crutch contact and only 2 valid foot contact measurements resulted. Examples of foot and crutch contact measurements are shown in figure 1.

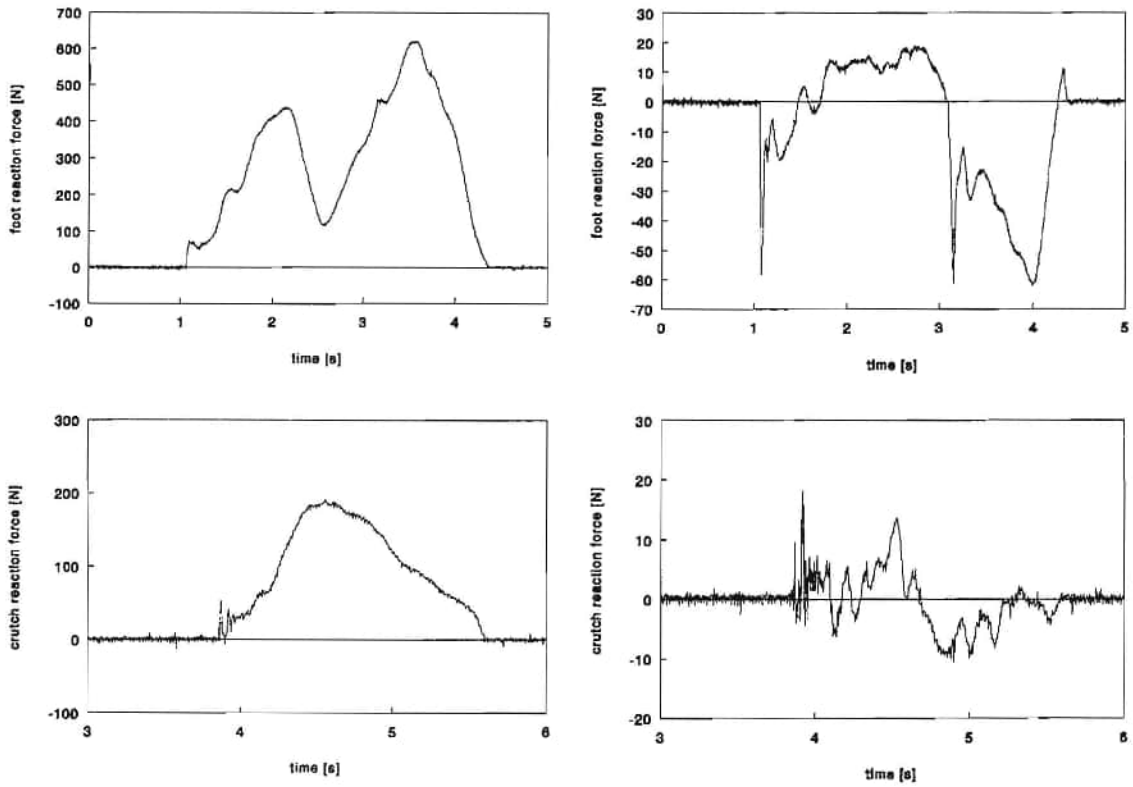

Figure 1 Examples of foot (upper graphs) and crutch (lower graphs) contact measurements (seperate measurements). Gravitational components (left) and components in walking direction (right) of ground reaction forces are shown. Force peaks during first foot and crutch contact can be clearly seen. The horizontal components clearly show a deceleration stage (positive reaction force) and a stage of acceleration (negative reaction force).

The foot ground reaction force shows a bimodal vertical component. Its similarity to normal gait is misleading since gait with locked knees and ankles and crutches is very different from normal gait. Probably in the case of hybrid system walking the two force peaks result from weight shift to the crutches, more than deceleration or acceleration. The crutch vertical reaction force component increases during deceleration and decreases during acceleration.
Vertical and horizontal impulses were calculated by integration of the measured ground reaction force components. The combined results are reproduced in table 3.

Table 3 Averaged measurement results - Ground reaction force parameters

( ) = standard deviation n.m. = not measured	ARGO alone (n = 5)	Gluteus maximus (n = 4)	Hip flexors (n = 5)	FWR (n = 5)
Horizontal impulse of foot (Ns)	n.m.	5734.72 (n=2)	n.m.	n.m.
Horizontal impulse of crutch (Ns)	133.72 (629.47)	158.05 (822.95)	846.08 (2153.97)	18.96 (654.78)
Vertical impulse of foot (Ns)	n.m.	592428.65 (n=2)	n.m.	n.m.
Vertical impulse of crutch (Ns)	67376.82 (11043.45)	61292.16 (2622.75)	66606.01 (17495.7)	65683.3 (14271.15)

It can be seen that the horizontal components of crutch reaction forces have a very low reproducibility. Therefore interpretation of the seemingly strongly varying impulses is difficult. What can be seen is that the major contribution to propulsion originates from the foot.
The vertical impulse of the crutch appears to be lowest for gluteal muscles stimulation. The vertical impulse seems to originate mainly from the foot.

DISCUSSION

Interpretation of results of a single subject study is always hazardous. Extending the study to a larger subject group will be necessary. However, from this first study it can be concluded that the main differences between assistive methods in hybrid systems appear in the calculated horizontal and vertical impulses of foot and crutch. Firstly the asolute impulse values differ between methods. Secondly it can be expected from the results that a shift in impulse distribution between crutches and legs will be seen between methods, indicating the method's efficiency. From this point of view stimulation of gluteal muscles appears to yield highest efficiency. No clear differences in walking speed seem to result from the forementioned differences.

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NEW HYBRID TECHNOLOGY FOR WALKING PARAPLEGICS

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SUMMARY

In this new hybrid technology for walking paraplegics we welcome the methodology of Yugoslavian workers but are proposing to add motorized leg braces for activating hip joints as described in this paper.

STATE OF THE ART

Stimulation of paralyzed lower extremities using functional electrical stimulation introduced by Liberson, et al in 1960 by direct stimulation; and in 1973 by Liberson in reflex stimulation, has been recently masterly described by Kralj. Yet very few paraplegics are walking in hospitals and in homes. We believe the main reason is the difficulty in mobilizing their hip joints by surface stimulation. We propose to integrate into the Yugoslavian system a double motorized hip joint brace. While the advancing leg on one side is moved forward by the motor, the standing leg and torso are pushed backward by another motor. The action changes sides at each new step.

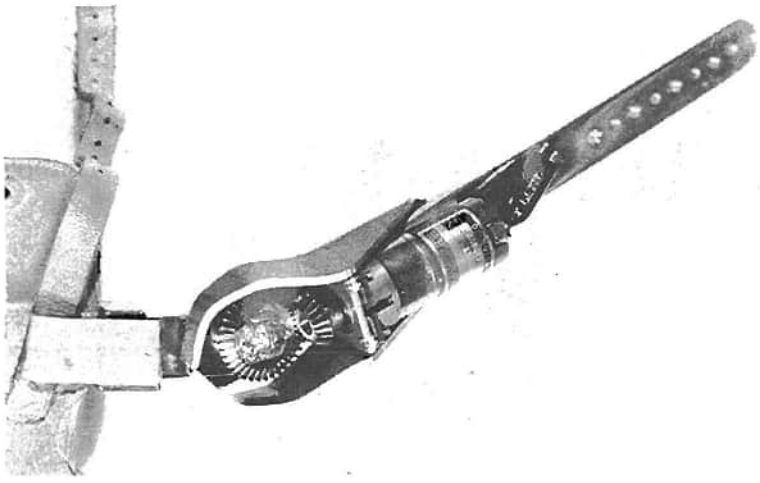
MATERIAL AND METHODS

We use a relatively small DC motor with enough power to assure a comfortable gait at 27 volts but offering slow rates with lower voltages.

The motor is mounted on both sides of the brace. The upper portion of the brace is tightly fixed on the thorax. The lower portion is just as tightly fixed over the thigh. The rotating joint is precisely centered over the hip joint. In order to limit the movement of the leg forward, a mercury switch is appropriately adjusted to interrupt the current when a desired angle is achieved.

Programming is achieved by the switches held by the patient in each hand, attached to a walker. The motor circuit is treated in the same way as an appropriate stimulator. Fig 1 shows the motor.

Fig. 1



RESULTS

The greatest difficulty in using the brace is the friction of the advanced foot against the floor or ground. Inasmuch as the Yugoslavian methodology involves the use of the walker permitting the patient to shift his weight over the standing leg reinforced by the brace and the stimulated quadriceps, the patient by inclining his body laterally and extending his arms, permits him to avoid the friction and his leg freely moves ahead by the motor, while his quadriceps and his dorsiflexors are stimulated.

DISCUSSION

Adding the motor for mobilizing the hip solves the main deficiency of transcutaneous methodology. We hope that those using Yugoslavian or analogous techniques will try our "robotic" addition.

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SKELETAL MUSCLE MORPHOLOGY IN PARAPLEGICS AFTER PARAWALKER ORTHOTIC TRAINING

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SUMMARY

Four adult paraplegics with recent spinal cord traumatic lesion (neurological level between T5-T11) have been evaluated after use of the gait orthosis (HGO,ORLAU Parawalker),the period after supply ranging from 5-6 months.Eight untrained paraplegics had a 6 months physiokinesiologicaltherapy and served as control group.After a needle skeletal muscle biopsy,morphological studies on fibre type composition and diameter and on intramuscular capillaries were performed.In paraplegic untrained subjects there was a remarkable fibre atrophy with preferential type 1 fibre involvement and reduction of the capillary bed.A number of type 2B and 2C fibres suggested that spasticity developed plastic muscular changes with transformation of type 1 into type 2A fibres through intermediate fibre types.After orthotic walking training, there was a discrete preservation of the fibre diameter, and a less number of type 2B and 2C fibres.The mean number of capillaries per fibre and surrounding a single fibre was less reduced in comparison to untrained patients.

INTRODUCTION

The main experimental researchs on functional recovery of paraplegic walking are now performed on two directions:the electric functional stimulation (FES)and the bio-mecha nic orthoses.The mechanical principle of hip guidance articulations were used to develop the hip guidance orthoses for childrens with congenital paraplegia/1/.After this experience,interesting results were obtained with the ORLAU Parawalker,an hip guidance orthosis composed by knee,ankle and foot (KAFO)and a pelvic belt,with possible inclusion of the hip (HKAFO).The success of this mechanic lies in the fact that it mantain intrinsic rigidity with possible walking with energy costs 2-3 times lower that other orthoses/2/.Previous studies on skeletal muscle biopsies from paraplegics with traumatic cord transection showed ingravescent muscle atrophy with degenerative changes,changes in fibre type distribution probably induced by spasticity and a significant reduction of the capillary bed/3,4,5/.The present study was carried out to determine the morphologic and enzyme-histochemical modifications in the rectus femoris muscle of adult paraplegic trained Parawalker users,the period after supply ranging 5-6 months.

PATIENTS AND METHODS

So far 12 paraplegic patients have parteciped to this study.All subjects were male aged between 20-29 years with spastic paraplegia after recent complete traumatic cord transection with neurological levels between T5-T11.The patients were divided into two groups on the basis of the type of the rehabilitative therapy . Eight untrained patients had a rehabilitative physiokinesiological theraphy for the control of the muscular hypertone and the avoidance of the pressure sores.Four paraplegic patients received the same physiokinesiological treatment and were also trained with Parawalker mechanic orthosis (ORLAU Parawalker HGO),the period after supply ranging from 5-6

months.Needle biopsies from the rectus femoris muscle were performed under local anaesthesia after patient's informed consent.Muscle specimens were frozen in liquid nitrogen and serial cryostat sections were stained with routine histological staining and treated with ATPase pH 9.6,4.6 and 4.3 for fibre type differentiation.Quantitative evaluation of fibre types,diameter and percentage was made with an Automatic Interactive Image Analysis System (IBAS I and II,Kontron).Overall capillary measures were performed on transverse semithin sections of epoxy-resin embedded material stained with Toluidine blue and with Gomori' silver impregnation.The following values were determined for each biopsy: capillaries per fibre (C/F);Capillaries surrounding a single fibre (CAF) and the capillary density per square millimeter (CD).The analysis of variance was used to test mean differences between biopsies from untrained and Parawalker trained paraplegic patients.

RESULTS

The results of the present study are reported in Table I and II.The results of a morphometric analysis of muscle fibre types and diameter,and of capillaries in normal healthy subjects derived from previously published studies/6,7/.

Table I. Overall capillary and muscle fibre morphometry in rectus femoris muscle from untrained and Parawalker trained paraplegics and from normal adults(mean+SEM

	Fibre diameter µm	Type 1 fibre %	C/F	CD	CAF
Untrained paraplegics	26.0±4.2	47.0±4.0	1.10±0.1	340+8	2.70±0.1
Trained Parawalker users	33.0±5.4	50.0±5.6	1.46±0.6°	300+8	3.60±0.4°
Normal adults	53.3±7.4	52.0±4.2	1.80±0.1	280+18	4.00±0.2

P<0.001. Untreated paraplegic patients versus trained Parawalker users.

Table II. Fibre type composition of rectus femoris muscle from trained and Parawalker trained paraplegic patients and from normal adult subjects(mean +SEM).

	Muscle fibre types (%)			
	1	2A	2B	2C
Untrained paraplegics	47±0.4	20±3.2	33±0.4	6.4±4.0
Trained Parawalker users	50±5.6	26±4.0	24±3.2°	2.0±0.2°
Normal adults	52±4.2	30±4.2	18±2.0	---

P<0.001. Untreated patients versus Parawalker trained users.

Morphological studies of biopsies from paraplegic untrained patients showed variability in the fibre size with presence of groups of atrophic fibres.The diameter of type 1 and 2 fibres was markedly reduced if compared with normal healthy subjects.After fibre type differentiation by ATPase pH 4.6 and 4.3,the muscle fibres were categorised as type 1 (ST),type 2A (SR),type 2B (FF) and type 2C (regenerating fibres). In 5 months paraplegic patients there was marked atrophy and reduction of type 1 fibres.In this stage a significant number of type 2B and some type 2C fibres were seen near a lot of type 2A fibres.The mean number of capillaries per fibre(C/F) was reduced as well as

the number of capillaries surrounding a single fibre.For most patients the C/F and CAF values decreased as mean fibre diameter decreased.A variable number of capillaries and arterioles showed thikening and reduplication af the basement membrane.
Morphological analysis of biopsies from trained Parawalker users showed variability in the fibre size and scattered degenerative changes.The fibre diameter was less reduced than the fibre diameter in paraplegic untrained patients.The fibre percentage of type 1 was similar to those seen in untrained paraplegics but a less number of type 2B and type 2C fibres was seen.The mean number of capillaries per fibre and the number of capillaries surrounding a single fibre was less reduced in comparison to untrained paraplegics.Interspersed capillaries and arterioles showed thikening of the basement membrane width; most of them showed only an increase of micropynocytosis phoenomena.

DISCUSSION

In the past numerous orthotic methods of walking were performed for the rehabilitation of adult paraplegic patients.Studies on energy requirements of paraplegic locomotion with different orthoses indicated that during deambulation the subjects utilized up to 6 times their basalenergy levels and were unable to sustain this high energy demand for long periods/8/.The Parawalker(name given to the hip guidance orthosis in the routine clinical supply)has been in use for adult paraplegics for about nine years and the energy cost in the Parawalker users was one of the lowest(up to 3 times their basal energy)/9/.The object of the present study was to compare the muscle fibre morphology and composition, and the intramuscular capillary supply in paraplegics with 5-6 months Parawalker training versus paraplegics after 5-6 months of clinical physiokinesiological rehabilitative treatment.Longitudinal studies on short and long term paraplegia showed in the flaccid period a predominant type 2A atrophy.In long term paraplegia,atrophy and reduction of type 1 fibres was seen with predominance of type 2B fibres; in this stage the consistence of type 2A and the appearance of some type 2C regenerating fibres seems to indicate the initial stage of a mechanism of fibre transformation reflecting the adaptative capacity of the paretic muscle to spasticity/3,4,5/
In these patients a significant reduction of the capillary percentage and thikening of the arteriolar and capillary walls have been described/5/as well as in numerous neuromuscular diseases associated to progressive muscle atrophy/7/.After 5-6 months Parawalker training the muscle fibre diameter and the type 2A fibre percentage increased and a lesser number of type 2B and 2C fibres was seen in comparison to untrained paraplegics.The number of capillaries was higher in respect to untrained patients.
The present results are in agreement with those described in experimental spinal cord lesions performed in animals/10,11/.Exercice-induced changes in biochemical and contractile properties of muscle,with recovery of muscular weights and increase of myofibrillar ATPase activity and of type 2 fibres have been described in cordotomized animals/12/.At last it can be said that 5-6 months of systematic training with the mechanical orthosis allowed a discrete preservation of muscle fibre diameter with reduction of the plastic reorganisation of fibre types and a more efficient vascular supply.
Studies on new bio-mechanic integrated systems for walking rehabilitation with significant reduction of energy requirements will be useful in the preservation of skeletal muscle in paraplegics.

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THE VIENNA PHRENIC PACEMAKER CLINICAL EXPERIENCE 1983 - 1992

W.Girsch

15 quadruplegic patients (age: 9-58 years), suffering from total ventilatory insufficiency due to high cervical cord lesion (C0-C2), were treated with the Vienna Phrenic Pacemaker. In 14 cases synchronous stimulation of both hemidiaphragms provides sufficient ventilation (p02: 92±5.6mmHg, pC02: 28±2.3mmHg). Chronical stimulation is performed in 11 patients since 37±24 months. Tracheotomy could be closed finally in 7 patients. 11 patients are living permanently at home. 4 patients died. 4 other patients, demanding full time mechanical ventilation due to various reasons also were treated with a Vienna Phrenic Pacemaker. The results for all patients will be presented in detail and discussed.

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Rehabilitation of Quadruplegic Patients with Electrophrenic Ventilation - two Case Reports

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Electrophrenic ventilation may be part of the rehabilitation for high quadruplegic patients - but not its replacement.
As an example, we present two cases of continuous 24 h-stimulation; one of our first patients, a now 30 years old man, was implanted nearly seven years ago and whose tracheostomy was closed after chronic stimulation, and our last patient, a 13 years old boy. Both live at home.
These case histories demonstrate the encreasing knowledge, typical complications and how they may be avoided as well as the gain of quality in life which was achieved using phrenic stimulation and appropriate additional rehabilitation utensils.

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Case 1:

Initials: J.S., male. Date of birth:	05.06.62
Date of accident (car driver):	28.08.85
Injuries: Polytrauma (fracture dislocation C 1 with bony fragment within foramen magnum, multiple fractures of three limbs)	
Neurological diagnosis:	
Compl. motoric lesion C 1	
Compl. sensoric lesion C 3	
Date of admission:	17.10.85
Implantation of phrenic nerve stimulator:	13.01.86
24 - h - stimulation since	19.06.86
Decanulation	7/86
Discharge at home:	03.12.86
Complications:	
Chronic constipation with raised diaphragm leading to basal pneumonia (12 h mechanical ventilation)	1/87
Recurrence without mechanical ventilation	2/87
Deep vein thrombosis	5/87
Pressure sore left foot	1/88
Recurrence	1/90
Obesity (30 kg plus) requiring encrease of high frequency power	2/90
Sudden failure of implant and electrodes requiring complete exchange	05.09.91
Retracheotomy	08.09.91
24-h-stimulation	06.10.91
Dismission with closed tracheostomy	16.12.91
ever since: 24-h-stimulation without complications	

Case 2:

Initials: K.B., male. Date of birth:	08.11.78
Date of accident (fall from height of 2,5o m):	20.10.90
Injuries: Dens fracture	
Neurological diagnosis:	
Compl. motoric lesion C 1	
Compl. sensoric lesion C 3	
Date of admission:	07.02.91
Implantation of phrenic nerve stimulator:	05.09.91
Start of stimulation:	17.11.91
24-h-stimulation since	06.01.92
Ever since: tape-closed phonation canula	
No complications	
Discharge at home:	15.04.92

A STUDY IN COCHLEAR IMPLANT PITCH CODING STRATEGIES

J.J. Hanekom

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SUMMARY

Pitch (also referred to as *timbre*) is the subjective frequency that a listener ascribes to a sound and which enables him to tonotopically arrange sound from high to low /1/. Pitch carries aesthetic information (emotional value) as well as semantic information (a *question* is distinguished from a *statement* by the rise in pitch). Because of the electrical stimulation used in a cochlear implant to create a sensation of sound, sounds are always voiced (if the electrodes are stimulated in a specific order). It is important to have control over the pitch sensation caused by the electrical stimulation, so that random values of pitch are not created which could undermine the understanding of speech. The provision of pitch information provides the deaf person with clues about whether the speech is unvoiced or voiced, and can aid him in attaining much better lipreading abilities /5/. We set out with the question: How should pitch be encoded as an electrical stimulation pattern in the cochlea, in order for the subject to be able to use this information? In this paper, we describe two of the experiments that we implemented, using synthesized vowel sounds to evaluate possible strategies for the coding of pitch in cochlear implants. In one experiment a position coding scheme for the coding of pitch is tested, and the other, periodicity coding is tested. It was found that periodicity coding of pitch is an effective way of coding pitch. A pitch extraction algorithm was incorporated into the existing speech processing algorithm of the South African cochlear implant. Results with the MAC tests were encouraging and indicated that periodicity coding is an appropriate and sufficient mechanism for the coding of pitch in the cochlear implant.

STATE OF THE ART

The exact processes by which the pitch of a sound is established, are not clear. Various models describe possible processes and they are aimed at fitting subjective data to physiological processes in the cochlea /1/. Two mechanisms are usually proposed for the coding of pitch in the cochlea: (i) position of maximum neural activity and (ii) the phase-locking of cochlear firing patterns to the stimulation waveform. These two mechanisms are referred to as position coding and temporal coding (or periodicity coding), respectively. Some researchers prefer to think that one or the other of these mechanisms is exclusively responsible for the perception of pitch, dependant on the pitch frequency /1/, but more probably these mechanisms operate in parallel /5/. One research group /6/ has used the presence or absence of a stimulation pulse on one of the electrodes to encode the presence or absence of voicing. The same group also uses a stimulation frequency equal to the fundamental, for a certain ranges of fundamental frequencies. With the electrical stimulation of the cochlea, the temporal and positional stimulation can be varied independently /7/, and in the research on which this paper is based, the viability of both methods is explored.

MATERIAL AND METHODS

Subject and instrumentation

The experiments described were performed with the help of a volunteer, P.B., who has been bilaterally deaf since 1974. In 1987 six active electrodes and an earth electrode was implanted in the cochlea of his right ear. Biphasic current pulses are used for electrical stimulation. As convention, the electrodes are numbered from 1 to 6, with electrode 6 ranking tonotopically the highest and electrode 1 the lowest. The locally developed test station /2/ was used in all experiments.

Position coding

Position coding of pitch presents the following problem: How many channels will be necessary to encode the possible range of pitch frequencies (70 Hz to 500 Hz)? Electrode 1 covers this entire range (because of the distribution of current in the cochlea), so how can the pitch perception be varied by stimulating on one channel only? A possible approach might be to modulate the amplitude of the electrode 1 stimulation with the pitch, and this approach has been implemented in the experiment described below. With a higher stimulation amplitude on electrode 1, it might

be expected that the tonal quality of the whole sound will become deeper. When electrode 1 stimulation is low, the tonal balance will shift towards the higher frequency side and the perceived pitch should be higher. It is, however, conceivable that a varying F_0 component in the spectral pattern might be confusing as to the identity of the sound. Our locally developed cochlear implant test station /2/ was programmed to make different synthetic vowel sounds With the push of a button, one of these sounds is applied directly to the implanted electrodes by way of an electrical stimulation pattern, for a time length of about 500 ms. The amplitude of the stimulation on electrode 1 was user-variable by means of a manual potentiometer.

Periodicity coding

It seems realistic to assume that, if periodicity is a mechanism for pitch perception, this pattern of periodicity, or standing wave pattern, must appear across the whole length of the basilar membrane, as most cochlear models suggest /1/. In the normal cochlea, the acoustical wave is conducted along the length of the cochlea. Higher frequency components are filtered out by the properties of the basilar membrane, while the lower pitch frequencies remain in the signal, until they are filtered out further down the membrane towards the apex. Periodic signals will cause successive periodic peaks in the cochlea, with a pitch-dependent distance between these peaks. Also, at a single point within the cochlea, peaks will pass this point with a pitch-dependant time lapse. Most probably, the brain does correlation in time as well as distance on the cochlea to discover the exact patterns that have been formed on the basilar membrane. Thus, the cochlea is not simply an instantaneous Fourier transform device! (This is why it is not adequate to use a simple vocoder strategy in a cochlear implant). To simulate this mechanism, the periodicity of stimulation was varied along the whole length of the cochlea in synchronism with the pitch in the periodicity coding tests.

We would also like to establish the effect on the pitch of translating the complete spectral pattern of the vowel sound up or down on the electrode set. The information content of the vowels is in the relative frequency positions of the formants as well as in the relative formant amplitudes, and not necessarily in the absolute positions on the frequency scale. Also, in the cochlear implant, the spectrum is already translated to unknown positions on the frequency scale, simply because the absolute tonotopical positions of the electrodes are not known. It is conceivable that the character of the vowel will take on a deeper quality when the spectral pattern is translated downward on the electrode set. If true, this technique could be considered for the position coding of pitch. That is, the spectral pattern is translated one channel up or down. Two possible problems may arise with this method: (i) spectral information is lost from the highest or the lowest ends of the spectrum (because of the small number of electrodes), depending on which way the spectrum is shifted and (ii) only relatively large pitch variations can be encoded this way because of the relatively small number of electrodes (and therefore the limited possibilities for spectral translation).

In previous experiments it was found that, with stimulation on a single channel, higher frequencies of stimulation gave the sound a smoother quality, without affecting the relative position on the tonotopical scale. Included in the current experiment, sounds are synthesized with the spectral pattern of a specific vowel sound, presented with a pulse repetition frequency of 110 Hz or 260 Hz. In this test, one of two effects is expected: Either the vowel will sound clearer because non-spectral buzz has been removed, or the vowel will have a higher pitch, because the periodical pattern is applied across the whole length of the cochlea.

A simulated statement/question comparison experiment was also set up. For the statement, the normal vowel spectral pattern (for a specific vowel) was applied across the electrode set with a 110 Hz pulse repetition frequency. For the question, the same spectral pattern was applied, but with a rising periodicity towards the end of the sound.

The four sounds described, as well as a reference vowel sound with pulse repetition frequency of 110 Hz, was available as synthetic sounds (an electrical stimulation pattern on the electrodes) with the simple push of a button. These five sounds were available for a few of the vowels, but in our further description is concentrated on results with specifically the vowel "a". Periodicity coding was used in all these sounds. The amplitude of each stimulus could be varied with a potentiometer which amplified or attenuated the complete stimulation pattern in 8 discrete steps. The time span of each stimulus was in the order of 400 to 600 ms. For each keypress, the chosen sound was presented once as a stimulation pattern on the electrode set. Pulse width was kept constant on all the electrodes. Vowels could be presented on their own or in a consonant-vowel-consonant context.

These sounds were used in a set of paired comparison tests, the detail of which is not described here. The five sounds are described for the "a" sound below, but could be repeated for other vowels. The five synthesized sounds were:

Sound 1: An "a" sound, synthesized by using the spectral pattern of an "a" to establish the stimulation values for the electrodes, with pulse repetition frequency of 110 Hz.

Sound 2: An "a" sound, synthesized as above, with stimulation frequency increasing from 110 Hz to 260 Hz

from the start to the end of the sound.

Sound 3: An "a" sound with the same spectral amplitudes as sound 1, but shifted one electrode higher on the relative pitch scale.

Sound 4: An "a" sound with only the first three formants used for stimulation, and the other spectral values suppressed to zero.

Sound 5: An "a" sound, synthesized in the same way as sound 1, with stimulation frequency 260 Hz.

RESULTS

Position coding

It was suspected that the perceived pitch might change when varying the electrode 1 amplitude of stimulation. However, from the results and the descriptions of the subject it was clear that this was not the case. The perceived pitch showed almost no correlation with the sounds that we were trying to achieve, resulting in very low scores for question/statement tests. With electrode 1 stimulated with a low amplitude, the sound was described as being muffled, "almost as if someone is talking into a telephone with a handkerchief folded over it". This almost gave the impression that the sound might have sounded voiceless. As the amplitude of stimulation on electrode 1 is increased a specific amplitude is found at which the sound is at its clearest. When the amplitude is made still larger, the "a" sound is flooded by whistling sounds.

Periodicity coding

Sound 1 is the reference sound, and was described as a recognizable "a" sound. Sound 4 sounded very unnatural, and was described as a metallic voice saying an "a" sound. By suppressing the non-formant stimuli, the effect is the same as putting zeros in the spectrum at these frequencies. For the normal-hearing listener, zeros in the spectrum is recognized as echoes. The description of a hollow metallic sounding voice is understandable. Sound 3, on the other hand, did sound like an "a", but also metallic and unnatural. It seems that the shifted spectral pattern is even farther away from the natural pattern than sound 1. Sounds 3 and 4 had more or less the same subjective pitch, although their formants are stimulated at different sites in the cochlea. The "a" sound with pulse repetition frequency of 260 Hz was described as a wailing sound. The subjectively observed pitch was high and the sound was not a natural sounding "a" in the vowel-only context.

From the results described, it seems that the coding of pitch with periodicity of the electrical stimulation should be an appropriate technique, and the two question/statement tests served as a control for this statement. The subject achieved full marks without hesitation on both these tests and the question-sound was clearly distinguished from the statement-sound. The question-sound was immediately recognized as being a question.

DISCUSSION

Position coding

Position coding does not seem appropriate for pitch coding in the cochlear implant, especially since it is our aim to create a natural-sounding cochlear implant, and therefore this technique disqualifies itself. Thus, we are not implying that this technique has no merit at all for the coding of pitch, but it is not suitable for a natural sounding cochlear implant. It is also noteworthy that quite recognizable vowels became non-speech sounds when we tampered with the spectrum. The brain might have interpreted the extra stimulation pulse on the low-frequency electrode, as an extra formant. Not being able to recognize the sound with the strange formant pattern, the sound was crystallized into a number of simultaneous whistling sounds.

Periodicity coding

The fact that sounds 3 and 4 had the same subjective pitch, leads to two possible conclusions: (i) Translation in the spectral pattern is probably not of value for the coding of pitch and (ii) relative formant amplitudes and frequency positions are important for the recognition of a vowel, more than the absolute values. It may be added that sound 3 did sound subjectively somewhat higher than sound 1, but that it was not regarded as being a good "a" sound. It seems that the most natural vowels are created by stimulating with the complete speech spectrum - it does not seem necessary to suppress the non-formant frequencies in the context of this experiment.

Two conclusions can be made from the subjective effect of sound 5: The increase in periodicity on the stimulating pattern as a whole has a different subjective effect than when only one electrode was stimulated. In the stimulation pattern where the periodicity is varied on all the electrodes, the effect is rather that, for a higher frequency of

stimulation, this is perceived as a higher pitch. In previous experiments, it was found that periodicity is not ideal for the coding of higher frequencies, because, on a single electrode, the subjective pitch stayed the same, while the character of the sound changed.

It seems that with single electrode stimulation, higher periodicity cannot be interpreted as pitch by the brain. With the stimulation of a complete pattern over all the electrodes (for example the "a" sound) the brain recognizes the spectral pattern and the increase in periodicity is recognized as a higher pitch. It is as if the brain does not recognize unknown patterns as speech, but rather "spells" it out as whistling sounds, in exactly the same way that some text to speech synthesizers would do with unknown words.

The results from the question/statement test were really encouraging. The question-sound was immediately recognized as being a question. Coding of pitch by varying the pulse repetition frequency of a spectral pattern seems to be an effective strategy for the coding of pitch for the cochlear prosthesis. Positional coding can then be reserved for the coding of the spectral pattern of the speech.

Implementation

Based on these experiments, a pitch extraction algorithm was incorporated into the current South African cochlear implant. The new strategy was evaluated using tests from the MAC ("Minimal Auditory Capabilities") battery /4/. The MAC battery includes two useful tests for determining the quality of pitch perception: the question/statement test and the man/woman voice discrimination test.

The subject P.B. scored extremely well on both these tests, 85 % on the first and 96 % on the second. The reference subject, M.J., wears a commercial cochlear implant in which no pitch extraction is done. He had been wearing his cochlear implant for at least a year at the time of the MAC tests. He scored worse on both tests, 70% and 57 % respectively. It is seen that M.J. has learned the ability to observe the change in pitch (therefore a reasonable score of 70 % in the question/statement test) but that he cannot determine absolute pitch (a score of 57 % is just above the guess score of 50 % in the man/woman voice discrimination test).

This clearly demonstrates the need for a pitch extraction algorithm in the speech processing strategy, as well as the effectiveness of periodicity coding of pitch. Furthermore, it demonstrates that temporal coding is a real and also a sufficient mechanism for pitch coding in the hearing system.

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THE BTE-SPEECH PROCESSOR FOR THE VIENNA COCHLEAR IMPLANT

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SUMMARY

The Vienna Cochlear Implant is available with both a pocket- and a BTE-speech processor, which in size is adequate to a conventional hearing aid. Less weight, size and no disturbing and rubbing noises because of the short cable distance were observed as an advantage by all patients. A comparative study in 6 patients with the old and the new processor demonstrated a significantly improved speech-perception with the BTE-processor. The better wearing comfort and the cosmetic picture increase the daily wearing periods significantly.

MATERIAL AND METHODS

Our new processor has the size of a conventional behind-the-ear-hearing aid (Fig.1,2). There are some minor technical differences between both in the realizetime, compression-ratio and supply voltage which is much lower but the analog coding strategy is the same as in the conventional body-worn processor.

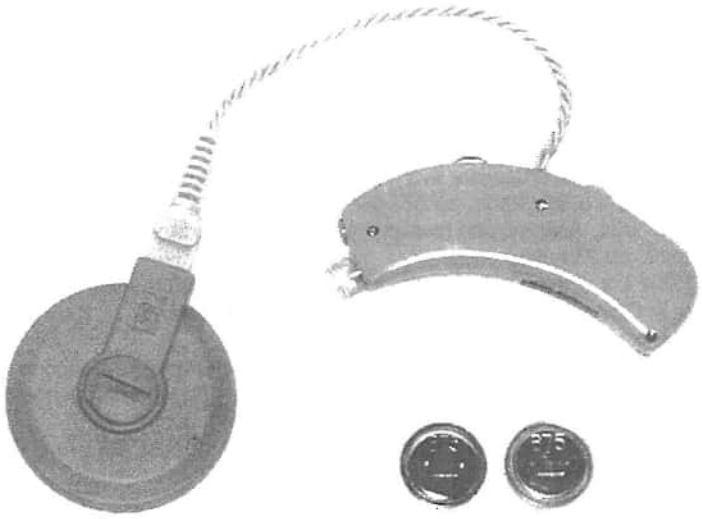

Fig. 1 BTE-Speech Processor for the Vienna Cochlear Implant

Our first experiences result from 6 adult postlingually deafened patients who were supplied with the new processor. The patients were tested with the old processor using the Auditory Testbattery, a vocal and consonant matrix and a speech tracking test. All patients were then asked to use the new device in the same manner as the conventional one and after one week the test procedure was once repeated in the same way as with the old processor.

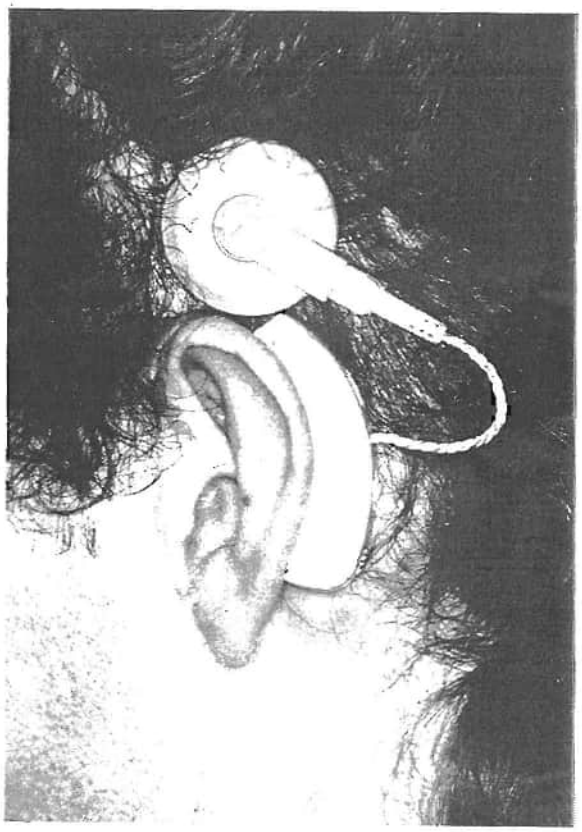

Fig.2 BTE-Speech Processor worn by a patient

RESULTS

In general the performance remains the same from the speech tracking test. Only in one subtest of the Auditory Testbattery, a test of open set recognition did the decrease of performance became apparent in 3 patients. The majority of the patients reported that the new processor sounded clearer and more natural. 3 patients found their voice to sound nearer. Regarding the results of the speech tracking test, we could not find any difference between the two processors.

DISCUSSION

With the group of recipients of the BTE-processor it was found that the speech understanding and the results in the speech tracking test is nearly the same to that one which resulted with the body-worn-processor. All patients were highly attracted by the smallness of the device and most of the patients reported of the lack of the friction noise due to the short cabel. The increased comfort in wearing the device results in a increase in the duration of daily use.

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IMPLANTABLE STIMULATION SYSTEM FOR FUNCTIONAL ELECTRICAL STIMULATION

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SUMMARY

An electrical stimulation system is being developed for experimental and clinical research in the restoration of movement and other body functions with Functional Electrical Stimulation techniques. The main component of the system is an implantable, radio-frequency powered, digitally-controlled current pulse generator with 16 outputs. This device is able to generate both conventional and alternative stimulus waveforms for different stimulation applications. A telemetry function is incorporated into the device to transmit signals from implanted sensors to the external control unit. The external control unit is designed to power and command up to three implants simultaneously, totaling 48 outputs for demanding applications such as walking restoration in spinal cord injury patients.

INTRODUCTION

Functional Electrical Stimulation (FES) has reached the stage of multi-center clinical trails after thirty-year basic research and clinical exploration. As an example, researchers at Case Western Reserve University and Cleveland VA Medical Center of the United States have used FES technology to restore hand grasp and leg movement in spinal cord injury patients /1,2/. An eight-channel implantable stimulator has been developed and implanted into several patients by the same group of researchers /3/. To further facilitate FES clinical application, a program for next-generation FES device development was initiated in 1991 under the support of the Department of Veterans Affairs and National Aeronautics and Space Administration of the U.S. government. The devices developed by this program will serve as a standardized device for clinical researchers, and will be made available to many medical centers. Providing these devices to the researchers will enable them to focus their efforts on the medical implementation issues, as opposed to focusing on hardware development, and allow objective comparison of results achieved by various investigators. The program has just finished its engineering feasibility phase and is proceeding into prototype development phase.

SYSTEM CONFIGURATION

The stimulation system is designed according to the specifications originally defined by Cleveland FES researchers and recently expanded through a collaborative effort between the system design team and VA/NASA technical representatives. The basic system requirements include 16 output channels for each implantable stimulator and the capacity of simultaneously controlling three implants for the external control unit. The stimulator circuitry is encapsulated in a hermetic enclosure. The power and command is transmitted from the external unit to the implanted stimulator through a radio-frequency link. A multi-contact connector is installed between the stimulator package and the electrode leads. A single-contact in-line connector is inserted between each proximal and distal lead. The additional features extend to the

provision of alternative stimulus waveforms to implement selective activation of small nerve fibers or collision blockage of neuronal activities /4,5,6/, and to the provision of implantable sensor support to acquire and transmit feedback or command signal to the external control unit /7/. The configuration of a complete stimulation system is shown in Figure 1.

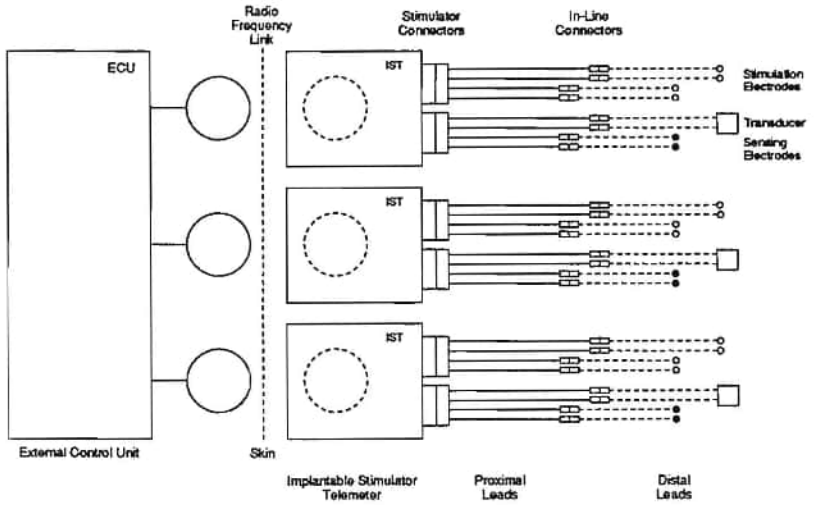


Figure 1 System Configuration

IMPLANTABLE STIMULATOR-TELEMETER

The implantable stimulator-telemeter consists of three functional components: stimulus waveform generator/driver, sensor signal processor/encoder and command-parameter decoder/controller, as shown in Figure 2. The circuit design adopts a modular approach and takes advantage of some features suitable for custom integrated circuit implementation.

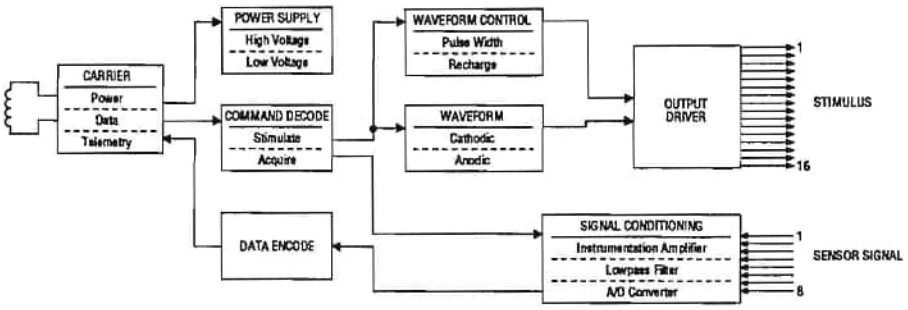
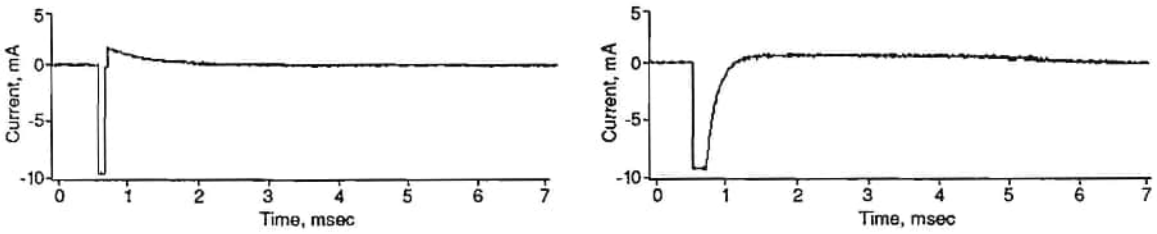


Figure 2 Block Diagram of Implantable Stimulator-Telemeter

The basic form of stimulus pulses includes a rectangular cathodic phase, an inter-phase delay, and an exponentially-decaying anodic phase (Figure 3a). The alternative form of stimulus pulses consists of a wider cathodic pulse with an exponentially-decaying tail which extends into the anodic phase of a low level plateau and an exponential tail (Figure 3b). The parameters for both basic and alternative waveforms are shown in Table 1. The stimulus waveform generator/driver circuitry is designed to maximize the parameter programmability.



(a) Basic waveform (b) Alternative waveform

Figure 3 Stimulus Pulse Waveforms

PARAMETER	RANGE	
	Basic	Alternative
Cathodic Current	0.1-20 mA	0.1-10 mA
Pulse Width	1-255 µsec	2-500 µsec
Time Constant	–	100, 200, 300 µsec
Delay	50 µsec	–
Anodic Current	Load-limited	50-400 µA, Limited
Frequency	1-50 Hz	1-50 Hz

Table 1 Stimulus Pulse Specifications

The sensor support circuitry provides sensor powering, signal conditioning, data encoding and telemetry for signal acquiring from implanted transducers and electrodes. The specifications for this part of the circuitry is shown in Table 2. Pulse powering and passive telemetry techniques are employed to minimize power consumption.

PARAMETER	RANGE
Number of Channels	8
Gain	10 or 100
Bandwidth	0-100 Hz
A/D Converter Resolution	10 bit
Sampling Rate	0-1 kHz, total
Acquisition Delay	<1 msec
External Powering	5V, 5mA, pulsed

Table 2 Sensor Signal Processing Specifications

The controller-implant communication protocol is configured to accommodate a synch burst, a command for either stimulation or acquisition, up to three parameter bytes, and a period for either sending pulse width or acquiring data (Figure 4). The design of the command-parameter decoder/controller ensures

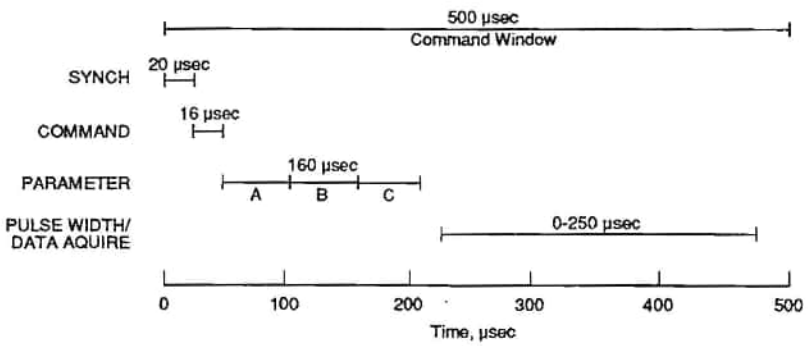


Figure 4 Controller-Implant Communication Protocol

maximum information transfer rate for pulse-to-pulse parameter control and bidirectional data transfer capability.

EXTERNAL CONTROL UNIT

The external control unit processes patient inputs, and schedules stimulation and acquisition events accordingly. The event commands are directed and formatted into serial data streams for radio-frequency transmission into one of the three implanted stimulators, as shown in Figure 5. The unit is designed to maximize hardware integration of function while minimizing its power consumption. Stimulus waveform programmability is attained by defining a waveform parameter array that provides independent control of each of the 48 stimulus outputs. The maximum command rate is 1 kHz to each implant, and the unit is able to initiate a stimulus from each of the 48 channels within 16 msec.

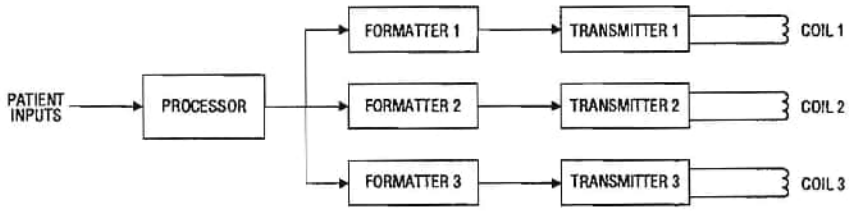


Figure 5 Block Diagram of External Control Unit

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MULTIELECTRODE SPIRAL CUFF FOR ORDERED AND REVERSED ACTIVATION OF NERVE FIBRES

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Abstract

The purpose of this paper is to represent the modelling, design, and experimental testing of a forty-five-electrode spiral nerve cuff system. It is intended for ordered and reversed activation of fibres within different superficial regions of the peripheral motor nerve. The spiral system with 45 electrodes was manufactured taking into consideration the results of modelling selective stimulation of superficial regions and activation of thin nerve fibres prior to thick ones in the same regions within the sciatic nerve of the dog.

Introduction

Neuromuscular control by artificial electrical stimulation of the nervous system often requires the development of multielectrode system which would be able to activate selectively a certain population of nerve fibers within different compartments in a peripheral nerve trunk (3,6). Moreover, selective stimulation of small groups of fibers within the motor nerve in the physiological order of recruitment is a desirable and important advantage in Functional Electrical Stimulation (1,2,5). It was demonstrated by Fang et al. (1991) (2) and others, that larger α axons could be blocked at lower current levels than γ fibers. Besides, it was demonstrated that slow twitch, fatigue-resistant muscle units in a heterogeneous muscle could be activated before fast-twitch, fatigable units by the specially shaped stimulating pulses (2). Namely, the type of inverse recruitment order obtainable by the conventional stimulation scheme, as opposed to the physiological recruitment order during natural activation, results is poor force gradation and rapid muscle fatigue (1,2,5,7).

Methods

Modelling of the electric field generated in the superficial region of the nerve by a certain group of electrodes was based on the geometrical model of dog sciatic nerve, dissected through the longitudinal axis and selected group of three electrodes, taking into consideration the conductivities of different tissue compartments appearing in the proposed dissection. The cross-sectional geometry of the sciatic nerve of the dog used in modeling of the electric field in its superficial regions is presented in Fig. 1.

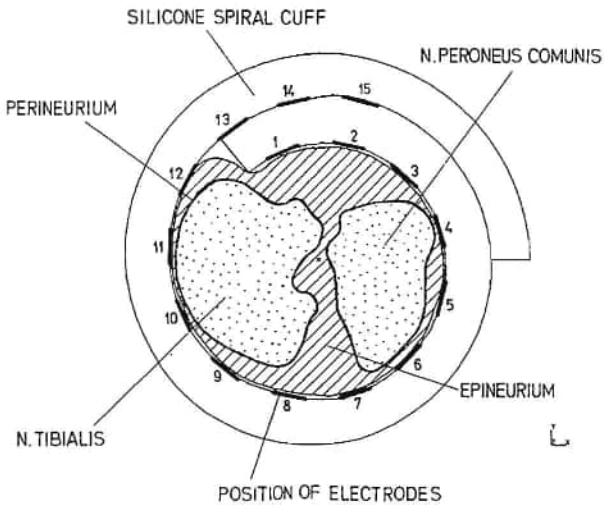

Fig. 1. The cross-section geometry of the sciatic nerve of the dog used in modeling of the electric field

Preliminary animal testing of the nerve cuff was performed on the sciatic nerve of a Bigley female dog weighing 15kg. A sterile technique was used to expose the sciatic nerve in the left leg from the mid-thigh to the poplitea fossa. The level of bifurcation into tibial and peroneal branch was hard to identify so the multielectrode system was installed with the central band of electrodes positioned at a level of one third of the thigh.

A train of 350μs (2) quasitrapezoidal biphasic pulses was delivered at a frequency of 20Hz for a duration of 3s on the specific group of tripolar electrodes situated close to the region of the sciatic nerve innervating gastrocnemius muscle. The current amplitude was adjusted so that the tetanic force of about 10% below the maximum tetanic force was obtained. A 10s resting period was introduced between two tetanic contractions. The entire test was repeated using 200μs rectangular cathodic first biphasic current pulses delivered monopolarly on the electrode acting as cathode and situated in the middle between the two outer electrodes of the tripolar group with the same position as described above. A needle with a large geometric surface used as a common neutral electrode was inserted in the leg distally to the multielectrode system. Measurement of force was performed using a specially designed electronic brace which was capable of measuring isometric torque elicited in the ankle joint by the gastrocnemius muscle. In both experiments an isometric torque in the ankle joint elicited by the gastrocnemius muscle was measured and compared.

Results

The manufactured multielectrode system consists of 45 platinum electrodes embedded within a self-curling spiral silicone sheet organised in fifteen longitudinal groups consisting of three electrodes spaced equidistantly around the circumference of the cuff as presented in Fig. 2.

Electrodes in the center band acted as stimulating cathodes while the two electrodes of the same group in the two outer bands were connected together and corresponded to the position of a particular cathode, serving as anodes to block the nascent action potentials by membrane hyperpolarization. The interpolar distance was 6mm on both sides, resulting in a total cuff length of about 20mm. The cuff was constructed in a diameter of 3.0mm to fit the size of the dog sciatic nerve.

A distribution of isopotential lines of the electric field within the superficial region of the dog sciatic nerve generated by electrode group No. 10 is presented in Fig. 3. It was shown that tripolar activation with quasitrapezoidal stimulation pulses elicited an isometric torque with a peak value of 0.83Nm in 65ms after onset of delivering stimulating pulses in comparison to the monopolar activation with rectangular biphasic pulses where the peak of the same value was observed in 45ms after onset as presented in Fig.4.

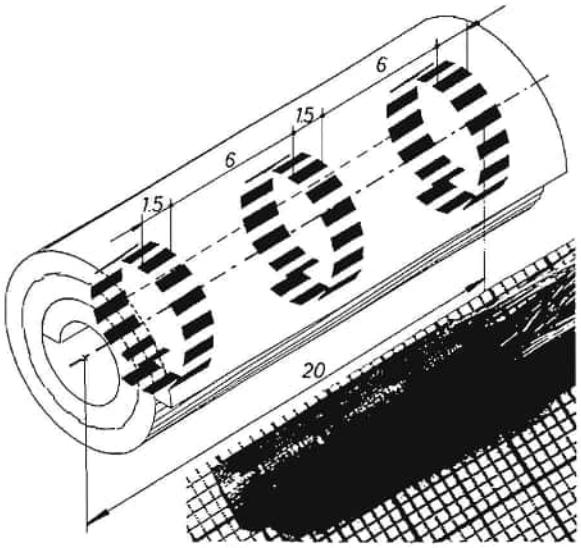

Fig. 2. 45 electrode spiral cuff system for selective stimulation of superficial regions and thin nerve fibres prior to thick ones in peripheral motor nerves

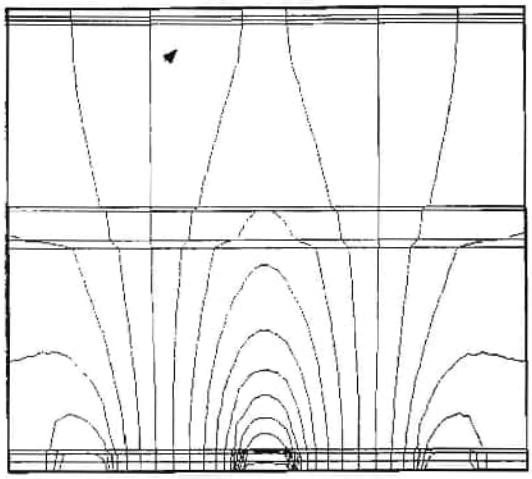

Fig. 3. A distribution of isopotential lines of the electric field within the superficial region generated by electrode group No. 10

Discussion

It was shown through animal experiments that monopolar stimulation using rectangular biphasic current pulses and an electrode in the middle of the tripolar group elicited steep isometric contraction of the gastrocnemius muscle. However, tripolar stimulation using biphasic quasitrapezoidal stimulation pulses and tripolar electrodes close to the mentioned region elicited less steep isometric muscle contraction, indicating that small motor units were recruited before big ones. Thus, it was evident that recruitment of muscle fibres was more physiological when elicited tripolarly using quasitrapezoidal biphasic pulses than when elicited monopolarly using rectangular biphasic pulses.Thus, the multipolar cuff stimulating monopolarly provided an effective means to selectively activate motor axons within the gastrocnemius muscle fascicle while, more physiological recruitment of the muscle fibres was evident when stimulating tripolarly.

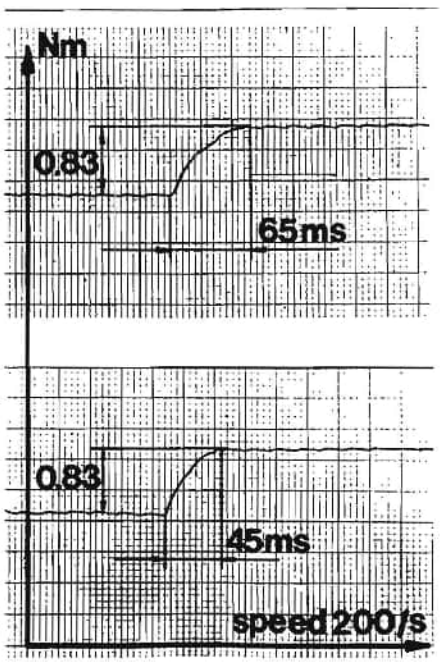

Fig. 4. Isometric torque generated in the ankle joint by the gastrocnemius muscle stimulated with quasitrapezoidal stimulation pulses (a) and with rectangular biphasic stimulation pulses (b)

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MULTICHANNEL FES STIMULATOR WITH DISTRIBUTED IMPLANTABLE MODULES

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SUMMARY

A novel multichannel Functional Electrical Stimulator (FES) has been developed. Instead of one centralized unit with multiple electrode leads, this device uses multiple distributed stimulation modules. Up to 256 implanted modules can be addressed, powered and activated from one external transmitter/controller. Current amplitude and pulse-width can be programmed for each individual stimulation pulse. Stimulation modules have the form of a cylinder made of biocompatible glass tubing with an electrode on each end. One electrode is made of activated iridium, the other is a slug of anodized sintered tantalum and serves both as a power storage and charge balance capacitor. Modules are powered via a high efficiency E-class transmitter. A modulated 2 MHz carrier powers and transfers stimulation data.

STATE OF THE ART

Development of multichannel implantable stimulators started as utilization of multiple single channel implanted devices and multiple external devices. Both the Medtronic NeuroMuscular Assist Device /1,2/ and the Ljubljana Implant /3,4/ were used in dual channel applications /5,6/. Later the development of actual multichannel implants began.

A conventional multichannel implantable stimulator approach today consists of one transmitting antenna and one receiver/ stimulator with multiple electrode leads channelled to stimulation sites. Another approach to multichannel stimulation is the utilization of multiple addressable stimulators, each one implanted directly at the stimulation site. An outstanding example of the latter was presented by Hildebrandt /7/. In clinical practice, however, centralized implantable stimulators have been more common. Two separate designs of the centralized approach have been successfully used in paralyzed hand control in Cleveland /8/ and in paraplegic gait assistance in Vienna /9/.

MATERIALS AND METHODS

The purpose of this project was to develop an inductively powered multichannel FES system applying the principle of distributed stimulation modules. The design included both the external high efficiency transmitter and multiple, microminiature, single-channel modules with integral electrodes that could be implanted or injected in or near muscles and nerves. The main electrical requirement was a charge-balanced monophasic stimulus pulse of 10 mA amplitude, with adjustable duration up to 200 μsec in 1 μsec steps, and with stimulation frequency up to 50 Hz. The main physical constraints were that the overall dimensions of the

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modules were set to 2 mm diameter and 10 mm length and that the modules had to be inductively powered from an external coil antenna, 20 cm long and 9 cm in diameter, and should work anywhere within that coil.

Description of the system

The entire electronic circuitry for the implanted modules consists of a self resonating receiving coil and a custom designed chip. A modulated, continuous 2MHz carrier provides the energy for stimulation and for the internal electronic circuitry. Two supply voltages are provided: 2,5 V for the logic circuitry and 8 V for stimulation. The 2MHz carrier is conditioned into a 2MHz clock which is reduced to 1 MHz and 125 kHz clocks. A data decoder, address detector, 15 bit RAM, and 8 bit counter are used to decode the demodulated signal, identify the module, store stimulation information and synchronize events. A mode control circuit defines four states of the implant: waiting for the beginning of data stream, receiving and evaluating the data stream, executing the stimulation pulse, and providing a 1 ms refractory period after the generation of a pulse. An output driver generates a stimulation pulse with a controlled pulse length, current amplitude and shape by controlling the discharge of the tantalum capacitor through the tissue.

The overall implant module dimensions dictate a tiny receiving coil resulting in a very small coupling coefficient to the external coil. Only a small amount of energy (Approx 240 μA at 20 Vpp) can be continuously provided to a single device. To obtain the electrical charge required for a stimulation pulse, this energy has to be accumulated between pulses.

A capacitor electrode /10/ is utilized as the energy storage device, stimulation electrode, and as a electrical charge balancing capacitor. It consists of an anodized slug of sintered tantalum. When in a conductive fluid medium, such as body fluids, an electrolytic capacitor is formed between the sintered mass and the fluids with tantalum pentoxide as dielectric and the fluid as the electrolyte. The capacitor is charged by the rectified RF carrier through the receiving coil and the tissue with a controlled low current. During stimulation the charge is released in a controlled manner back through the tissue to form a stimulation pulse. Thus charge balance is maintained. Such electrodes, anodized to 15 V and having a capacitance of 10 μF have leakage currents as low as 13 nA.

The use of a custom chip was an obvious solution to several aspects of the microstimulator requirements, including the small size and shape constraints on the die, relatively high operating voltage for stimulus compliance, and combination of low-power digital and high-current analog circuits on a single chip with no external components except a coil. Three micron, double poly P-well CMOS was selected as the most suitable technology. Seventeen different chip masks were made on one wafer to generate seventeen different chip addresses.

A communications protocol consisting of a 36-bit data string contains the information necessary to identify and activate a single device to produce a single stimulus pulse. Up to 256 modules can be addressed from the same external antenna. This protocol includes two different forms of parity to avoid erroneous activation and several different modes of operation added as optional features, including two levels of recharge current, two pulse shapes, and two ranges of stimulus current each consisting of 15 selectable levels. A variant of Manchester encoding is used to assure reliable data reception by equalizing the lengths of "high" and "low" modulation amplitudes. A special, E-class, high efficiency transmitter was designed and developed for the purpose of powering the implants with minimal losses.

Mechanical Assembly

The implant module has the form of a cylinder, made of biocompatible glass tubing that contains the chip and the receiving coil. The receiving coil is wound on a ferrite core. It consists of 200 turns of 25 micron copper wire and is self resonant at 2MHz. The lower portion of the ferrite core is extended to form a shelf which supports the electronic chip. Using gold wire bonds and conductive epoxy, electrical connections are made between the chip, the coil and the electrodes. The electrodes are positioned at each end of the tube and are hermetically sealed to the glass.

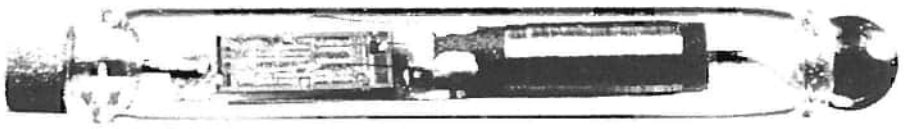

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Fig.1 Microstimulator module. Left to right: tantalum electrode, chip, coil, and iridium electrode

RESULTS

Twenty electrically functional devices, ten of them hermetically sealed, have been fabricated. In addition, working breadboard controllers efficiently power the microstimulators and format and transmit digital commands to them. Since the main energy-storing capacitor exists only when the device is immersed in saline it cannot be directly probed without damaging the electrochemically prepared surfaces of the electrode contacts. Therefore, a set of saline-filled test wells had to be built in order to test the microstimulators. A pair of non-contacting electrodes detecting the potential gradient produced by current from the microstimulator was used for the purpose.

The present construction method allows two types of electrodes. Instead of the tantalum electrode, another iridium electrode can be used together with an internal energy storage capacitor. The advantage is a sturdier construction, however the device becomes longer. Several units have been successfully built with iridium electrodes.

Present construction and assembly techniques still require some improvement. A larger series of microstimulator units will have to be manufactured and extensive in vitro and in vivo tests will have to be performed before the device is ready for human use.

TABLE I: Stimulator module parameters

a: Electrical

Voltage	7.5 V
Pulse Width	3.5 μs - 257,5 μs in 256 steps
Current(Ver.1)	0.2mA -30 mA
Current(Ver.2)	0.4 mA -60 mA
Recharge	20 μA or 200 μA
Tail	50 μs
Max Pulse Rate per unit	637 Hz
Max Pulse Rate per Coil	3462 Hz

b:Mechanical

Diameter	2.0 mm
Length	<15 mm
Weight	<0,2 g

c:Materials:

Body	soda-lime glass
Positive electrode	Tantalum Oxide
Negative electrode	Activated Ir Oxide

DISCUSSION

The choice as to which of the two approaches, centralized or distributed, is optimal for an application depends mostly upon the particularities of the application. Stimulation of deep structures almost inevitably requires electrode leads. On the other hand, stimulation of the forearm muscles to control a paretic hand seems to be an ideal application for a miniature, distributed, multichannel stimulator, powered and controlled by a sleeve-like antenna covering the forearm.

Other advantages of distributed FES system are discretional number of stimulation channels, easy replacement of defective channels and addition of new ones, absence of electrode leads and connectors, cost directly related to number of channels required, a relatively minor surgical procedure, and reduced risk of infection.

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A battery powered, programmable, implantable stimulator for multichannel nerve stimulation

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Summary

Since 1982 we are developing implantable multichannel implants for functional electrostimulation. The Implants are used for tetraplegic patients in order to stimulate the diaphragm through the N.phrenici and for the stimulation of the lower extremities of paraplegic patients. In order to avoid an early fatigue of the muscle four or more electrodes are being placed directly at the epineurium of the nerve. By changing the combination of electrodes and adjusting a submaximal amplitude, a selective stimulation of different areas of the muscle is possible and fatigue can be reduced ("round-about" stimulation)
The implant has been developed for its use as an ECG triggered 8 channel nerve stimulator in order to activate a muscle (specially the m.lattisimus dorsi) as an mechanical support of the heart and the circulation (cardiomyoplasty/2/)

Material and methods

The implant works as an independent vital function supervising circuit in the human body by reacting on the output of a built in measurement system with given algorithms. This was possible by using a freely programmable microprocessor for process evaluation an process controlling.
In the following paragraphs the use of the implant as an ECG triggered eight channel stimulator for the cardiomyoplasty is described.

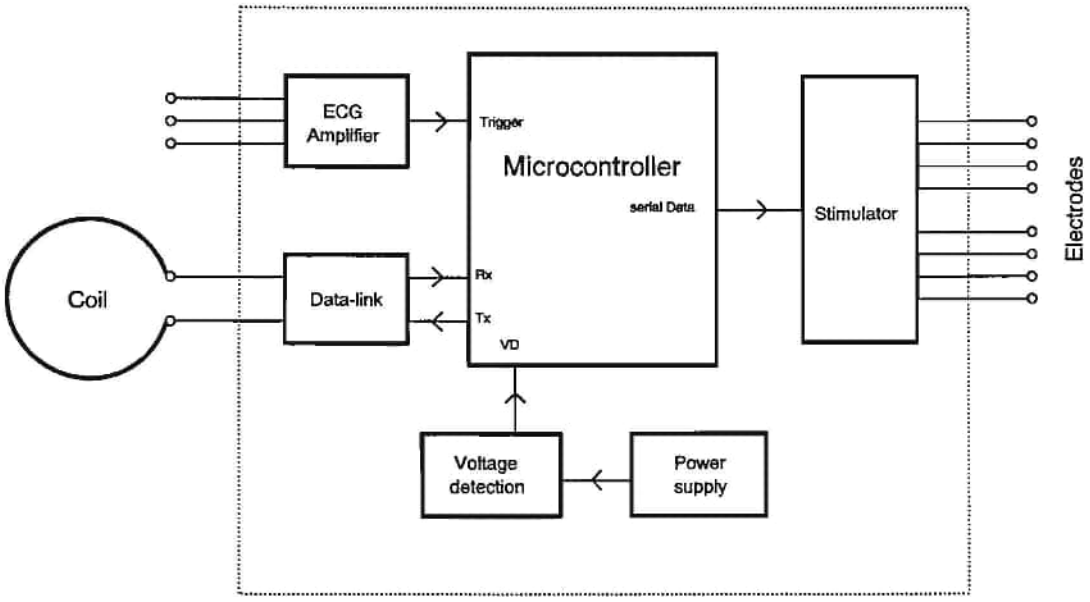

Fig.1 Block diagram of the implant

The heart contraction is registered by an ECG amplifier which passes a trigger signal to the microcontroller. After a given time delay the mc activates the stimulator and produces a series of stimulation impulses to contract the two m. latissimus dorsi.
To avoid a rapid fatigue of the two muscles the stimulation is paused for a given number of heart contractions and during the stimulation periods the "round about" stimulation is used.

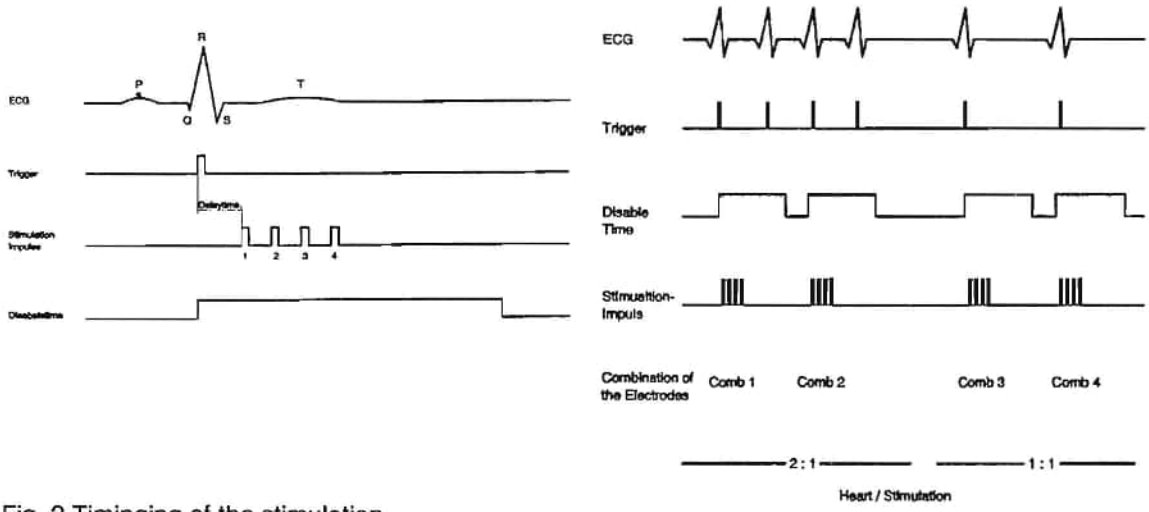

Fig. 2 Timinging of the stimulation

One major design problem was to reach a sufficient operating time based on an embedded battery.
For a stimulation based on the "round - bout" principle constant current pulses with a 8 - bit resolution of the amplitude have to be generated. The impedance of the tissue varies between 200 and 2000 ohms and thus requires step up conversion of the battery voltage.
The following features were implemented in order to increase the efficiency of the implant:
- the Stimulator itself multiplies its supply voltage only at the moment of activity
- the multiplication of the voltage is been controled by the mc in function of the stimulation current and the impedance of the electrodes
- a high efficiency charge pump performs this step-up conversion.

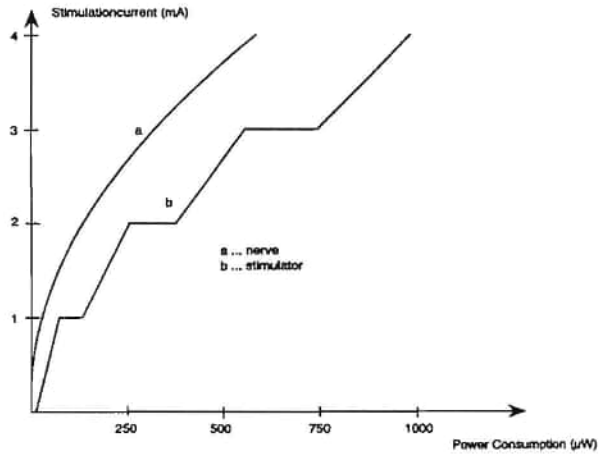

Fig. 3 power efficiency of the stimulator

Figure 3 compares the power consumption of the stimulator with the actual power input into the nerve. By the means of the above features the power efficiency of the stimulator (power to the nerve compared to the input power from the battery) is above 40 percent.
Data to and from the implant are sent with a loosely coupled system of two coils operating at the same resonance frequency of 13.5 mc/s. To minimize the required circuit for data decoding in the implant, data is sent pulse code modulated with a modulation index of 100 percent.
Data from the implant is sent passively by detuning the resonance frequency by approx. 10 percent. This can be detected as a phase modulation in the transmitter circuit. Demodulation is done via the detection of changes in the impedance of the transmitter resonance circuit.

Results and Discussion

The implant developed permitts an uninterrupted heart-synchronous stimulation of two mucles (e.g. the m.latissimus dorsi) according to the principle of the round about stimulation. An external programming device and an emitter provide the possibility to adjust freely and change on a large scale the timing and the measurement and stimulation parameters of the implant.

The use of a personal computer for programing offers the following advantages:

-The using is supported by a selfexplaining program and gives the doctor the possibility to operate on patients datas directly
- all changes of the parameters of the implant are automatically saved and permit the extrapolation of the durability of the implant
- in case of technical problems datas can be transmitted by a telephonmodem to our institute and analysed here
- the medical histories of all patients can be documented and administrated in a central way

Technical datas of the implant

ECG amplifier

Input Sensitivity 0,1 - 5,0 mV
Adjustment 16 steps
Interval + 30%

Stimulator

Number of channels 8
Stimulation mode constant current
Selection of the electrode combination any
Amplitude max. 4 mA (20µA)
Impulse duration 0,2 - 1ms (0,1ms)
Frequency 1 nerve 1 - 66 Hz (1Hz)
2 nerves 1 - 33 Hz (1Hz)
Number of impulses 0 - 255

Additional Functions

Delaytime after trigger 5-3250ms (1ms)
Disabletime 0,1-6s (1ms)
Durability
Max. stimulation (worst case) 1 year
Average stimulation 2,3 years

( ) Resolution of this parameter

The first version of the implant is being tested now by animal experiments and offers good results.
For its human implantation more steps will be necessary in order to increase its durability and reliability. After the end of the tests the implant is due to be used as a diaphragm peacemaker and for the cardiomyoplasty.

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AFFERENT SIGNALS IN PALMAR DIGITAL NERVES

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SUMMARY

Semi-chronic afferent recordings in palmar digital nerves in human volunteers are presented in this paper. Volunteers were recruited among able-bodied humans who suffered a hand injury and that required open hand surgery. A combined anaesthesia was used to allow subjects to recover from motor paralysis while the sensory paths were still under analgesic. Cuff electrodes with a slit were implanted onto the digital nerves. Subjects grasped test objects (pinch and lateral grasp) and visual feedback was provided to them from a instrumented test object. The amplified, rectified and integrated signals were sampled at 20 kHz, and an averaged record was stored every 20 ms into a RAM of the portable recorder. The largest neural activity was when the grasping force changed, i.e. a contact, slippage, increase or decrease of the force happened. We registered many artifacts resulting from touching and rubbing fingers against one another, different timing of the contact with the testing device and the like, but we were still able to detect most of phenomena of interest.

INTRODUCTION

Multi-channel implantable FES systems for grasping include at this point only visual feedback and there is no force feedback control. Closed-loop control can enhance grasping, but it requires reliable and reproducible sensory feedback. Experience in using artificial sensors for grasping has proven to be very complex and many problems have been registered: mounting, accuracy, reproducibility, robustness, energy consumption, size, weight, etc.

The use of natural sensors for control of assistive devices has been suggested a number of years ago. Myoelectric hands and legs were designed and used with variable success [3]. Published results [8,15] and unpublished observations [Thomas, personal communication] showed that many cutaneous sensory receptors in the palm are preserved in spinal cord injured human who suffer a cervical spinal cord injury (complete lesions at C_5 and C_6), and that afferent information from these receptors is in peripheral nerves and can be used as a tactile feedback.

Nerve cuff electrodes [13,14] are safe and reliable for chronic recording from whole nerves as shown in animal models [6]. To obtain maximal signal amplitudes of the nerve electrical activity a nerve cuff should tightly fit the size of the nerve and be approximately as long as the wave length of the action potential. Good signals can be recorded if the length of the electrode is several times bigger compared to the diameter of the nerve (internal diameter of the cuff).

Dr. Hoffer and his collaborators [4,5,6,11] proved that it is possible to correlate neural activity with external perturbations such as touch, sliding, change of the force in extended experiments in cat and humans. Dr. Hoffer succeeded in using biological sensor in a closed-loop control system for control of the cat's hind limb [6].

In another animal model, [9], cuff electrodes implanted on a tibial and a superficial peroneal nerve have been used for recording during the gait cycle of an intact chronic cat. These records have been processed in real time and a rule based control system triggered the stimulation of cat's hind limb ankle flexors and extensors.

Gardner et al. [2] also demonstrated in experiments with macaque monkeys the ability to determine spatio-temporal changes through afferent recordings. They suggested two mechanisms: 1) a rate intensity code in which spacing of surface features is encoded by the average frequency of firing of individual sensory afferents, and 2) an isomorphic representation of shape in which variations in the firing patterns of individual afferents reflect a spatio-temporal profile of skin indentation.

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Dr Popović is on sabbatical with the Miami Project to Cure Paralysis, University of Miami, Miami, Florida on leave from the Faculty of Electrical Engineering, Belgrade.

There are no studies,that we found, on afferent activity in complete digital nerves. Most of the work we analyzed is dedicated to monitoring the activity of median nerve, which we believe is not good enough to detect slip, contact and force reliably.

In semi-chronic experiments, presented in this paper, we showed that afferent recordings in palmar digital nerves can be processed in real time and used for detection of contact, slip, and change of grasping force.

METHODS AND RESULTS

Cadaver work. We looked mostly at the hand and only partially the forearm. We found that digital nerves can be instrumented with small cuff-electrodes, and that these sites (Fig 1) are safe and reliable places for implantation. They are protected well enough with the soft tissue of the palm and the relative motion of the cuffed nerve is small which reduces the chance of eventual injury of the nerve. There is a little bending of the instrumented portion of a digital nerve meaning that the cuff needs to be flexible.

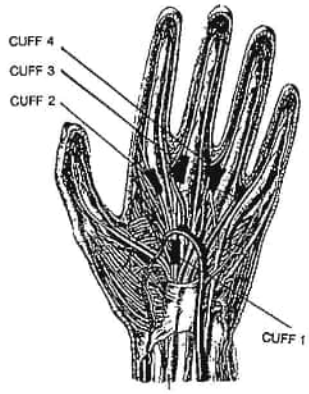

Fig 1. The sites of implanted cuff electrodes in digital palmar nerves. Three silastic triphasic cuff have been used for recordings.

Our anatomic dissections agree with results presented by Siverhus et al. [10]. The branching of the median nerve is very consistent and variations found in digital nerves of the fingers are expected to be functionally equivalent and anatomically almost identical. These findings were confirmed in another study by Hobbs et al. [7] where they looked at anatomical differences of digital nerves in reference to the fixed anatomical lines of the palm and wrist. Their results show even less variation of palmar digital nerves in comparison to Siverhus' results.

The digital nerves from 20 adult hands were studied histologically [1]. The number of fascicles increases from the proximal to the distal portion of the finger. The number of myelinated fibers was nearly the same in the nerves of the thumb, index, long and ring fingers. The mean diameter of the fascicles was of the order of 210 μm. There were many variations in the number of fascicles in the same nerve of different subjects. We could not find a site for the thumb nerve, because it moves and flexes while grasping and there is no good protection of the surrounding tissue.

Experimental work - implantation. Volunteers were recruited among able-bodied humans who suffered a hand injury requiring open hand surgery. These volunteers were informed about the possible risk of semi-chronic implantation of cuff electrodes and they signed the consent form that they accepted a temporary implantation of up to four cuff electrodes on their palmar digital nerves. Prilocaine 1% (supraclavicular brachial plexus block) and discrete nerve block at the elbow with 0.5% bupivacaine without adrenaline was used for anaesthesia. This combined anaesthesia was used to allow the patient to recover from motor paralysis while the sensory paths are still under analgesia. This combination was suggested by Smith et al., [12]. They showed a significantly shorter duration of unwanted postoperative motor blockade and a significantly longer duration of postoperative analgesia ($p < 0.005$).

Cuff electrodes (Medical grade Dow Corning silastic cuff electrodes with a slit) were implanted. The electrodes were 10 mm long, with 0.9 to 1.1 mm internal diameter and 0.6 mm wall thickness. Medical $Pt_{90}Ir_{10}$ multistranded wires were used for recording. Teflon insulated $Pt_{90}Ir_{10}$ wires were positioned along the digital nerves and fed out just below the wrist along the median nerve. The palm was temporarily closed, after the implantation, and subjects recovered from a motor block.

Once subjects recovered from anaesthesia, but still had decreased motor abilities (35 minutes after the initial surgery was finished), we started behavioral tests. Subjects were asked to grasp sterile test objects (pinch grasp with four, three or two fingers and lateral grasp). Testing objects had a smooth, non-slippery surface contacting the hand to eliminate any possible injury on the temporarily very sensitive site of implantation and slippage of the object. Test devices were instrumented with strain gauges to measure the force exerted while grasping.

The experiments were done in three subjects. The residual effects of anesthesia caused limited dexterity and control over grasp force, but still allowed us to accomplish our experiments and prove our hypothesis. A custom designed pre-amplifier and portable recorder have been used allowing three neural recording channels and one channel recording from the force transducer. The data were transferred to a host PC computer, via a RS-232 as a binary file for further processing. The portable recorder initially processes neural signals (instrumentation amplifier, with a 4^{th} order band-pass

filter (from 1 kHz to 10 kHz), full-wave precision rectifier and integrator. Analog data are connected to the digital board, sampled at 20 kHz, averaged for every 10 ms and stored into the RAM memory. This period of 10 ms sampling has been chosen for use of a device to suppress artifacts in the presence of stimulation. This custom designed artifacts suppression circuit gates the output of the preamplifier output, i.e. shortening of the output of the preamplifier to the ground 3 μs before the stimulation, and opening the gate after an arbitrary selected period shorter than 10 ms. This circuitry was developed for future use in closed-loop FES systems.

RESULTS

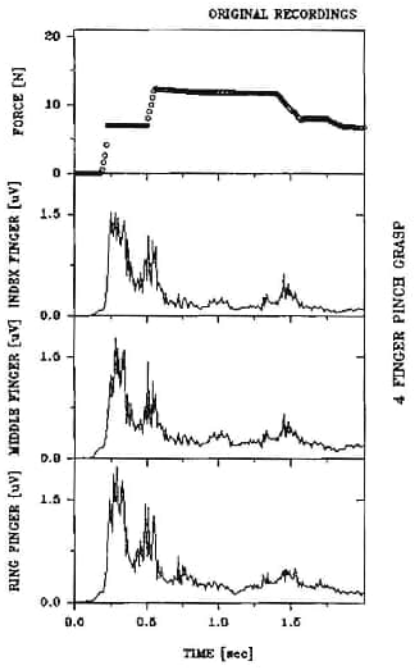

Fig 2. BIN integrated, rectified and amplified recordings from index, middle and ring finger digital nerves in semi-chronic able-bodied volunteers while grasping.

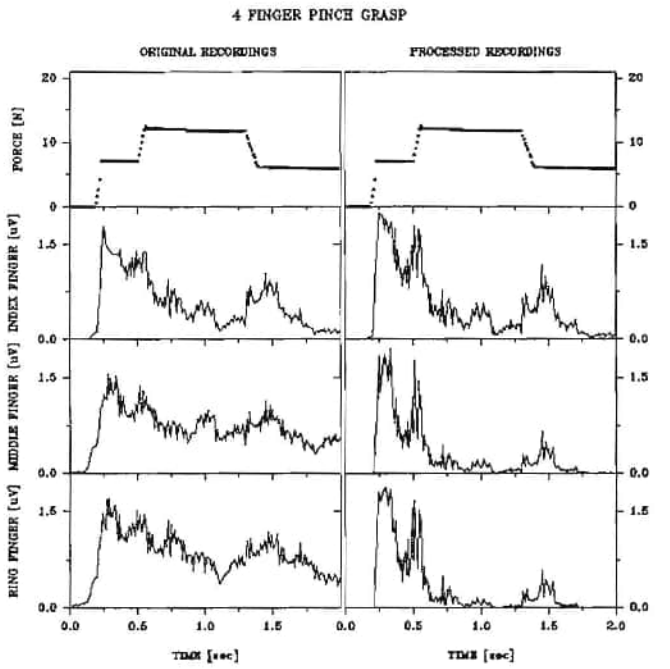

Fig 3. Neural recordings from digital nerves when subject volitionally contaminated signals by rubbing fingers among them (left), these signals after processing (right).

Recordings from one subject pinching the test object are in Figure 2. The neural activity was largest when the change of force occurred (increase of the force, sliding, decrease of the force). A exponential decrease of activity was found when a constant force was exerted. These recordings match very well with recordings from our own cat experiments [9] and results presented by Hoffer [6], as well as recording from human nerves [11].

However, relative motion of fingers and scrubbing one to the other while grasping shows similar activity, because a number of receptors lateral and medial on index, middle and ring fingers are innervating the digital palmar nerve. Neural recordings, somewhat different from the one presented in Fig 2, comes from very similar grasping patterns and similar forces exerted by fingers. These signals are "contaminated" with neural activity resulting from relative scrubbing of fingers, after the contact and after an increase of the force while holding the test device (Fig 3).

We asked our study subjects to rub fingers, without touching the test object, and bursts of activity were recorded. We learned that there is one major difference between rubbing of fingers and touching the force transducer which can be used to eliminate rubbing effects when detecting the slip, contact and change of the force. The grasping events can be recognized as multi nerve patterns, and was very difficult through analysis of individual neural recording except in special cases (Fig 3).

We passively changed the position of fingers and wrist and we are very confident that there is almost no muscle spindle afferent activity in nerve cuff recordings at the position presented in Fig 1.

We stimulated several hand muscles (Flexor digitorum profundus m., First, second, third and fourth lumbrical m., Extensor digitorum m., Abductor pollicis longus m., Extensor pollicis longus m., Flexor pollicis longus m., Adductor Pollicis m., Abductor pollicis brevis m.) using intramuscular electrodes (Cooner wire AS 631, bared wire length 4 mm) positioned closely to the motor point of the muscle, with monophasic, compensated, constant current pulses. Stimulation parameters were fixed, I = 6 mA, f = 16 Hz, T = 30 μs and we were only interested how big are stimulation artifacts and is it possible to detect same changes in neural recordings which occurred when there was no stimulation. The current was limited to 6 mA and pulse width to 30 μs to avoid pain and uncontrolled movements during grasping tests. Recordings from digital nerves, when Adductor pollicis m. was stimulated are presented in Fig 4. The second trace shows actual stimulation applied to the muscle, while the three bottom traces show processed neural recordings from digital palmar nerves. The upper trace shows the grasping force, which a subject produced voluntarily.

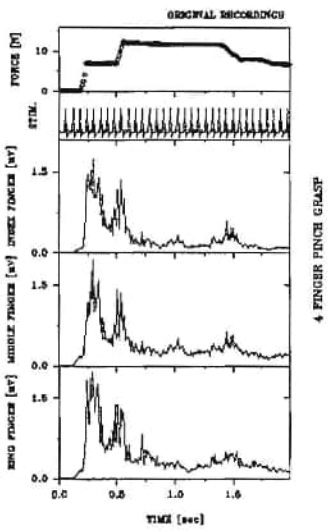

Fig 4. Recordings from digital nerves when surrounding muscles are electrically stimulated (trace 2) and a custom designed blanking circuit applied. Parameters of stimulation are in the text.

The recording in three subjects showed good coincidence for pinch grasp and lateral grasp. No complication or other nerve injury was found as a result of our procedure. We followed our volunteer subjects and functions, which were the reason for the open-hand surgery, have been developing according to our expectations over a twelve month period since the surgery. All graphs present mean values for all three subjects that we tested, normalized to the mean maximal recording at the index finger.

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AN EVALUATION OF ACOUSTIC MYOGRAPHY DURING ELECTRICALLY STIMULATED CONTRACTIONS.

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SUMMARY

Active skeletal muscles generate low frequency sounds which can be recorded with a microphone or accelerometer placed on the skin surface over the muscle belly. The acoustic myogram recorded this way has some similarities to the more familiar electromyogram and can be processed in the same way. The origins of muscle sounds are not yet known, but they may be related to mechanical events early in the contraction process. If so, they might provide a signal directly related to force development and free from electrical artefacts, which could be used in the control of electrically stimulated contractions.
We have recorded the acoustic myograms from human and rabbit muscles during voluntary and electrically stimulated contractions to study the effects of muscle length changes, stimulation frequency and fatigue on muscle sound production.

STATE OF THE ART

Fatigue is a major problem in controlling electrically induced contractions. In many circumstances force cannot be measured directly and open loop control strategies have great difficulty in coping with the changing force output of muscle. The M wave of the electromyogram cannot be used to indicate force because it does not bear a constant relationship to force development and the proximity of stimulating and recording electrodes generally leads to large artefacts which make it difficult to follow any changes in the waveform. The origins of muscle sounds may be related to mechanical events early in the contraction process and so could be more directly related to force development. In addition they are free from electrical artefacts. This has led to the use of AMG as a control signal for powered prostheses (Barry *et al* (1986))
The first reports of muscle sounds are surprisingly old (Grimaldi 1665) and much had been inferred about their low frequency content (Wollaston (1810) before the first modern recordings were made using microphones (Gordon & Holbourn (1948). There has been a substantial increase in interest in the study of muscle sounds since Oster's review article in 1984. Several groups have investigated the acoustic myogram (AMG) during voluntary isometric contractions (Barry *et al* (1985,89), Orizio *et al* (1988a,b), Goldenberg *et al* (1991), Stokes *et al* (1990,91)) and the general opinion is that AMG intensity increases with increasing force up to about 80% of maximum voluntary contraction (MVC). Beyond this force Orizio et al reported a reduction in AMG even though force continues to rise. One source of difficulty in comparing work in different laboratories is the use of a variety of devices for recording AMGs. Microphones are commonly used though they generally have a poor sensitivity in the frequency range where muscle sounds occur (0.5-50Hz). An exception here is the Hewlett-Packard 21050A microphone which has an appropriate frequency response and sensitivity. However, it is bulky and sensitive to displacement as well as to vibration. The use of accelerometers is becoming more common (Barry *et al* (1985,86,89)) these perform well but are expensive and fragile.

Supported by S.E.R.C.

MATERIALS AND METHODS

Experiments were performed in healthy adult volunteers. The experimental protocol was reviewed and approved by the local ethics committee.
Transcutaneous electrical stimuli were delivered to the muscles via large pad electrodes from a Devices 3072 isolated stimulator (Digitimer Ltd, UK). Electromyograms were recorded from prepared skin using Littman electrodes (2325VP 3M Ltd) filtered and amplified using Neurolog NL 125 and 106 modules (Digitimer UK). Acoustic myograms were recorded using a Hewlett-Packard 21050A heart sounds microphones, Tandy 270-090 electret condenser microphones or an Entran EGAX-F-100 accelerometer. These signals were filtered (0.5-100Hz) and where necessary amplified using NL106, 125 modules. Force was recorded using a strain gauge (RS 645-811, Radio Spares UK.). Data was stored on magnetic tape or analysed on line using a Cambridge Electronic Design 1401 interface and Spike 2 software.
Similar experiments were performed in deeply anaesthetised New Zealand white rabbits under project licence 60/01063 issued by the UK Home Office. In rabbits, the motor nerve supplying the tibialis anterior muscle was exposed and stimulated directly to confine the contraction to only that muscle. The limb was rigidly clamped and the tendon cut and securely fixed to a strain gauge. The AMG was recorded by stitching the accelerometer to the skin over the muscle or directly to the muscle belly after the skin had been removed. The signals were stored and processed in a similar manner to those described above.

RESULTS

Transducer Evaluation

Figure 1 shows the rectified integrated AMG recorded during voluntary isometric contractions. The transducers were placed at the same position over quadriceps during successive non fatiguing contractions. The Entran and HP 21050A transducers gave the most linear responses. The Entran transducer was preferred because of its smaller size and the greater ease with which it could be attached to skin.

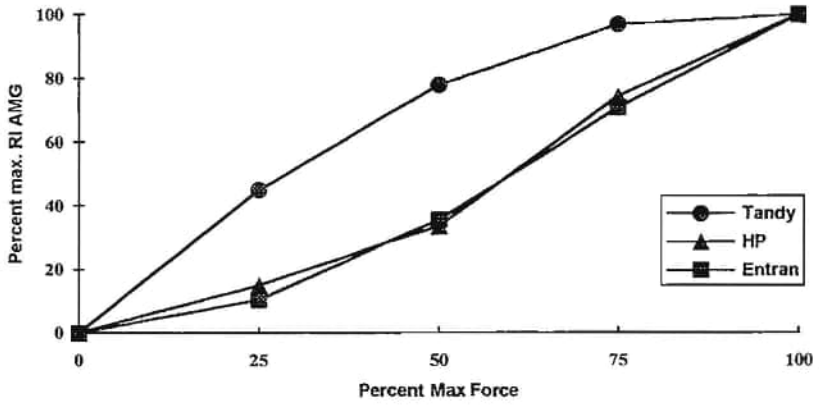

Figure 1.: Full wave rectified, integrated AMG, (τ = 0.5sec)during voluntary quadriceps contractions. Each contraction lasted 3 to 5 sec. the RI value was the average for the last second.

Effect of muscle length.

AMG, EMG and force were recorded simultaneously during a series of maximal isometric twitches from rabbit tibialis anterior muscles at a range of muscle lengths. Data from one such experiment are plotted in figure 2.

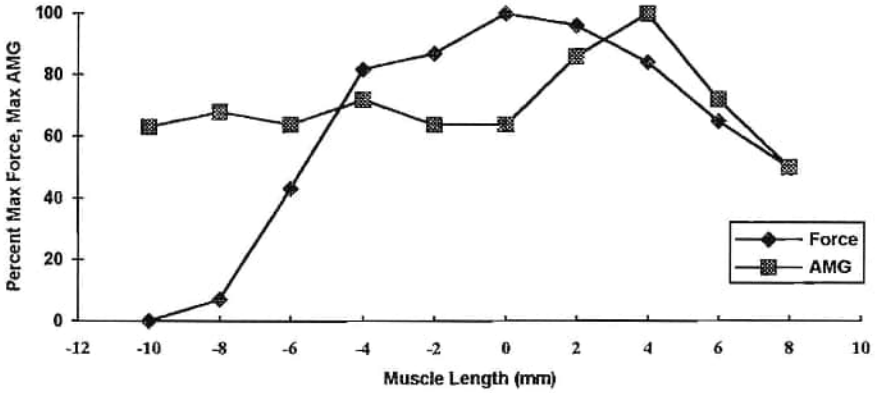

Figure 2. Changes in peak to peak amplitude of AMG and twitch amplitude at a series of muscle lengths.

AMG signals were still strong at muscle lengths so short that no external force was developed. The largest AMG waves were recorded close to L_O, and at longer lengths both force and AMG declined. The M wave amplitude changed by less than 10% over length changes of 20mm. Similar results were observed when experiments were repeated using unfused tetanic stimulation at frequencies between 20 and 40Hz.

Effect of Stimulation Frequency.

With the length set at L_O, the muscle was stimulated with 1 second bursts at frequencies between 10 and 200Hz. Data from these experiments is plotted in figure 3. As the tetanus becomes more fully fused the amplitude of the AMG wave falls. In each train of stimuli the first few shocks generate AMG waves which decline in amplitude progressively.

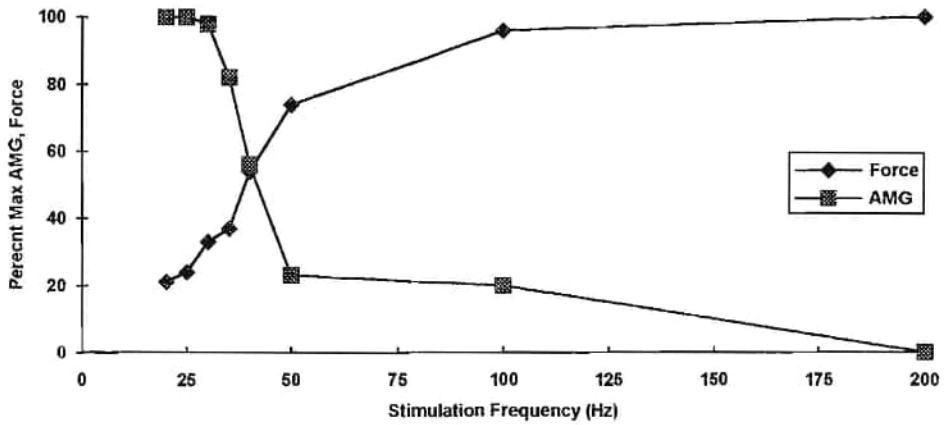

Figure 3. Force and AMG (p-p) recorded from rabbit tibialis anterior during stimulation at a range of frequencies. Each period of stimulation lasted 1 second. Data plotted were measured during the last 10 stimuli in each burst.

Fatiguing Stimulation.
In some experiments, muscles were stimulated continuously for periods of 1-2 minutes. Initially at a frequency too low to fuse the contraction fully initially (15-40Hz). After 15-30 seconds as the muscle fibre contraction slowed, the tetanus fused more completely and the mean force increased. During this period the AMG amplitude also increased. As the contraction continued the force developed fell and this was reflected in a decline in AMG amplitude. The M wave amplitude declined progressively as the force fell.

DISCUSSION

The performance of all three types of transducer investigated was surprisingly similar given the variation is price and specification. The lower sensitivity of the Tandy microphone could be offset by using rather greater amplification than was needed with the other devices. The main problems encountered with using the HP microphone were 1. its physical bulk made it difficult to mount on the skin and 2. its displacement sensitivity caused a large artefacts at the start and finish of contractions as the contour of the muscle caused the central core of the device to rise and fall.
The AMG signal recorded during twitches was relatively independent of changes in muscle length over the range of $L_O \pm 10\%$ ie the range of lengths likely to be used normally. The process of tenotomy allowed a wider range than this to be examined and particularly at very short lengths the AMG and force were unrelated. During tetanic stimulation the AMG signal is often similar to the derivative of the force record. At all frequencies the onset of stimulation causes a large AMG signal which declines over the next few stimuli. When the muscle is fully tetanised no AMG signal can be detected, presumably because there is no movement within the muscle.
In conclusion, AMG signals offer the prospect of some applications in force regulation of electrically stimulated contractions. Since such contractions are isometric for the greater part and at sub tetanic frequencies there should no difficulty in obtaining AMG signals. During sustained periods of stimulation the AMG record bears a closer similarity to the force record than does the M wave of the electromyogram.

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A NOVEL EEG-BASED CONTROLLER FOR THE SEVERELY HANDICAPPED

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SUMMARY

A system has been developed to provide a C2-quadriplegic who has minimal physical capability and no voice with the ability to access an environmental controller and a wordprocessor via a computer. The handicapped person is presented with a number of flashing light emitting diodes (LED's), each associated with an option on a menu. By merely looking at the appropriate LED, the person can activate one of the options on the menu. This is accomplished by an analysis of the visually evoked EEG potential (VEP) elicited by the flashing lights.

STATE OF THE ART

The EEG of a person looking at a light which is flashing at a rate of 8 to 12 Hz contains a clearly distinguishable visual evoked potential (VEP). The spectrum of the VEP contains a fundamental frequency component at the flicker frequency and has a peak response at 10Hz /1,2,3/. See Figures 1 and 2.

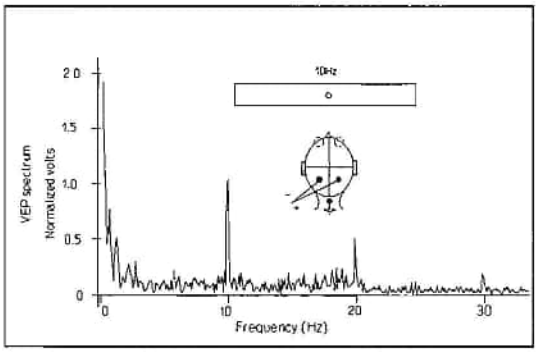

Figure 1 Spectrum of the VEP of a person looking at a LED flickering at 10Hz. The spectrum was calculated by FFT from a 10 sec recording of the EEG. The electrodes were mounted at EEG-recording positions O_1 and O_2.

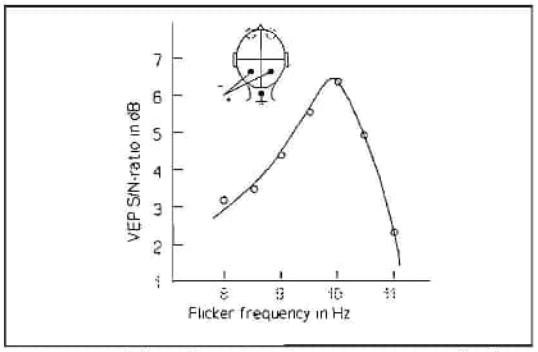

Figure 2 The low-frequency VEP window /2/. Each data point corresponds to the spectral peak at the flicker frequency. The source was a HI-SUPER BRIGHT LED (2000 mcd) viewed against a dark background from a distance of 30 cm.

MATERIALS AND METHODS

In order to implement the VEP to detect which controller choice the handicapped person wishes to activate, it was necessary to determine whether the VEP-spectrum has a distinguishable peak at the frequency of the LED at which the subject is looking, even when

This work is supported by a research grant from the South African Medical Research Council.

there are other flickering LED's in his field of vision. For this study electrodes were attached to the scalp of an able bodied individual at points O_1 and O_2 near the inion. The sources were three HI-SUPER BRIGHT LED's (2000 mcd), spaced 8 cm apart on a black background and flickering at 8, 10 and 12Hz. The subject viewed the LED's from a distance of 30 cm. The VEP was recorded with a custom built EEG-amplifier. The VEP spectrum was obtained by a FFT calculated offline from a 3 sec recording of the VEP during which time the subject was looking at each of the lights in turn. The noise level was determined by shielding the flickering LED from the subject's eyes. We determined that the peak at the flicker frequency of the LED at which the subject was looking can be detected despite the presence of other LED's flickering at other frequencies. See Figure 3. However, this approach is slow because it requires a VEP sample of at least 3 sec (measured while the subject is fixating on one of the sources) to give a S/N-ratio of 3 after calculation of the FFT.

In order to speed up the system, improve the S/N-ratio, and facilitate an on-line detection of the subject's choice, we exploited the observation that the low-frequency VEP-region peaks at about 10Hz. We presume that the peak response at 10Hz could be caused by the entraining of the phase of the alpha-region EEG by near-threshold stimuli. Such a phenomenon was observed by Sayers and Beagley in auditory EP's /4/. We are now using four LED's modulated in phase quadrature (QPSK) at 10Hz. The success of the QPSK modulation scheme depends on the shift-invariance of the VEP. This was verified experimentally with a setup similar to that used for the multi-frequency tests. See Figure 4.

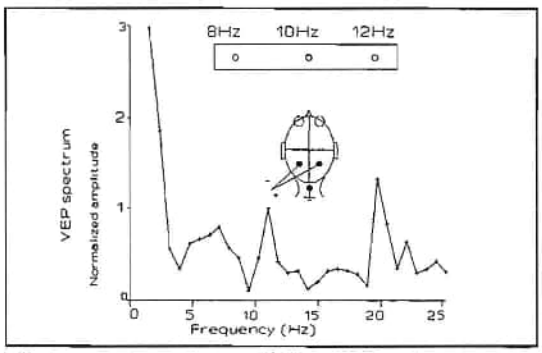

Figure 3 Spectrum of the VEP of a person looking at a LED flickering at 10Hz while two other LED's in the visual field are flickering at 8 and 12 Hz. The spectrum was calculated by FFT from a 3 sec recording of the EEG.

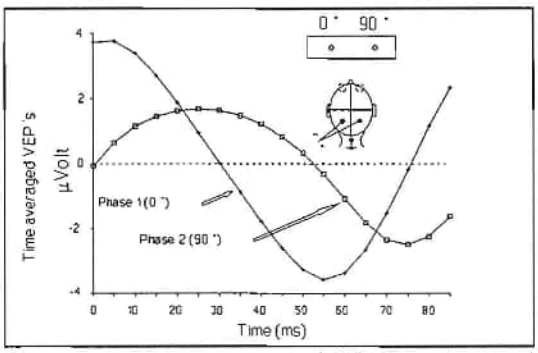

Figure 4. Time averaged VEP's obtained with two LED's spaced 8cm apart, sinusoidally modulated at 10 Hz with 90° phase shift while the subject fixates on the each LED in turn. VEP spectrum derived by FFT from a 5 sec time recording.

With the QPSK system we derive the subject's choice by means of an on-line matched filtering technique. The correlation between the phase of the VEP and that of each of the four phase shifted stimuli is determined by multiplying each data sample with the corresponding sample of a set of templates obtained from the steady state VEP during a learning phase. The value of the correlation is determined and accumulated at the end of each period (i.e. 10 times per second) for each source. When the value in the accumulator exceeds a threshold, the appropriate menu choice is activated. This permits an identification of the choice in less than a second. The templates are obtained from a time-average VEP measured during the learning phase while the subject fixates for 5 seconds on each of the four stimuli.

RESULTS

Figure 3 shows the results of an off-line determination of the VEP-spectrum obtained from a

3 sec recording of the VEP while the subject was looking at the LED flickering at 10Hz, during which time two other LED's in his visual field were flickering at 8Hz and 12Hz respectively. The peak at 10Hz and its harmonics is clearly distinguishable. Figure 4 shows the results of the on-line determination of the average VEP during the learning phase with the QPSK system. The two LED's used in this experiment were sinusoidally modulated with a phase difference of 90 degrees. The subject looked at each source in turn for a period of 5 seconds.

DISCUSSION

The feasibility of using the VEP for an environmental controller for a physically handicapped person has been demonstrated. The proposed system will use four options as direction controls for a pointer on the computer monitor, thus permitting the subject to steer the cursor as with a computer mouse. Button clicks are implemented with eye-blink switches. We have developed software for using the VEP-based interface to drive an environmental controller with which the subject can control an alarm, lights, a radio, a TV and other devices as well as a dedicated wordprocessor.

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SENSORY FEEDBACK IN VOLUNTARY CONTROLLED FES ASSISTED WALKING [x]

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SUMMARY

Paraplegic person can walk by the help of voluntary control over a minimum of four channels of functional electrical stimulation (FES), crutch support and visual feedback providing necessary information for taking appropriate control actions. Patient's preserved rudimentary sensing capabilities can be improved by introducing sensory feedback, by means of delivering adequate sensory information stimuli to the upper nonparalyzed body. Feedback information is related to two important decisions: direct the continuation into the next walking phase after successfully accomplishing the previous movement of the lower limb (reward) and warning for prevention of person from falling (warning).

The sensory feedback system developed consists of lower limb transducers with processing devices providing appropriate input signals for personal computer and four channel hand-switch controlled stimulator. Patient's gait is recorded by lightweight strain gauge goniometers attached to the knees and foot-switches positioned under the toes and heels. Computer output is coupled to a two channel sensory stimulator providing electrotactile stimulation signal of 5 Hz (warning) or 50 Hz (reward). The lower limb sensory feedback was tested in three completely paralyzed spinal cord injured subjects.

STATE OF THE ART

The lower-extremity FES orthosis itself is usually open loop /1/ with only visual feedback. A computer controlled walking was presented by Petrofsky and Phillips /2/ with closed loop controller using the sensory signals measured from knee, hip and ankle potentiometers, toe and heel sensors and ultrasonic sensor on the person's shoe. "The total neural prosthesis" was presented as the next step in biofeedback systems development and it consisted from closed loop controlled FES prosthesis, appropriate sensor transducers, cognitive feedback system and reciprocating gait orthosis. Mayagotia and Andrews /3/ researched simple FES supported walking using hybrid floor reaction orthosis and sensory system. Standing-up, sitting-down and standing was controlled by computer program based on goniometer signals and the preliminary biomechanical data.

The aim of this contribution is to provide sensory information from the paralyzed lower limb of a spinal cord injured subject while walking assisted by the help of FES. Artificial sensory signals are instead to the stimulator delivered directly to the patient via electrical stimulation of skin areas in nonparalyzed upper body. Fatiguing, being a serious problem in daily use of FES rehabilitative aids, is specially evident in knee extensors during the stance phase of walking. When applying a closed loop FES controller, satisfactory knee extension can only be obtained for a given short time. The problem of insufficient knee extension can be solved by preventing overloading and hence of wasting FES muscle power. For this purpose information about successfully accomplished movement and about inappropriate knee extension is provided to the patient. Such role of sensory feedback may result in faster and more energy efficient walking.

MATERIAL AND METHODS

During gait initiation state patient is supported by both legs and both crutches. The knees are locked in a fully extended position by the help of bilateral stimulation of knee extensors. Pressing of the hand control switch in the handle of a crutch or walker brings the walking subject in the state characterized by ipsilateral peroneal nerve stimulation provoking flexion reflex in the lower extremity resulting in hip and knee flexion and ankle dorsiflexion. The foot is lifted from the ground. As the subject is slightly leaned forward the stimulated leg swings forward in the sagittal plane. The contralateral extremity remains in fully extended position. When the walking subject depresses the hand switch, the controlled leg makes full contact with the ground while both knees are again in extended position. Crutch transfer is considered as the final state of a walking cycle.

The described states of FES assisted walking can be assessed by bilateral strain-gauge knee goniometers and foot-switches. The selected sensors can provide the information about the following biomechanical variables:

ϕ_k ... knee angle (180^o belongs to fully extended lower limb)
SH... binary heel switch function (SH=0, heel is in the contact with the ground, SH=1 heel is lifted from the ground)
ST... binary toes and metatarsals switch function (ST=0 toes are in the contact with the ground, ST=1 toes are lifted from the ground)

The sensory stimulation is delivered to the patient through two pairs of electrodes positioned over the skin of patients upper arm. Within the leg in the stance phase the adequateness of the knee extension is tested by the help of knee goniometer. In the case of inadequate knee extension, the sensory signal is delivered to ipsilateral sensory stimulation electrodes. The signal

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remains present as long as patient is not correcting the state by unloading the limb in the stance phase or increasing the stimulation amplitude. The sensory stimulation of 5Hz is used /4/. The sensory signal at the side of the swinging leg represents the information that the planned movement was satisfactorily accomplished and that new gait event can be started by the patient. The signal occurs immediately when the desired state is achieved, lasts for a predetermined time duration (0.1 s) and can be generated only once in each gait phase. The signal at the side of the swinging leg is characterized by high stimulation frequency (50 Hz) so that patient can distinguish between warning (5Hz) and reward (50Hz).

Control decisions depend on the state of both hand switches and measured sensory signals. The control rules are described only for the swinging leg, while in the contralateral leg appropriate knee extension is tested all the time. The state occurring after pressing the hand switch is assessed by all sensors of the controlled leg. The goniometric signal is compared to the predetermined knee flexion (ϕ_{1k}):

$\phi_k > \phi_{1k}$.

The foot must be lifted from the ground, yielding:

SH=1 and ST=1.

After depressing the hand control switch person finds himself in foot-contact phase. The patient's state is again estimated by goniometers and heel switches. The knee joint must be fully extended:

$\phi_k < \phi_{0k}$,

where ϕ_{0k} represents maximal allowed knee flexion during the stance phase. Foot-contact phase is recognized when at least heel is on the ground:

SH=0 and ST=1 or ST=0.

In the swing and foot-contact phase the "reward" signal is generated in the ipsilateral sensory electrodes, while inappropriate lower limb position is tested in the contralateral leg. In the double stance phase only inappropriate knee extension is tested. The most important is the initialization phase of the control algorithm, when appropriate constants ϕ_{0k} and ϕ_{1k} are defined for both extremities. All four parameters are first set manually and then automatically adjusted with respect to the first two steps measured.

THE PROTOTYPE SYSTEM

The prototype biofeedback system runs on a personal computer containing Intel 80386 microprocessor and Burr Brown data acquisition module PCI-20000. The PC board operates as an input analog interface for the bilateral goniometer, foot-switch and hand switch signals. Two digital channels produce control signals for the stimulator delivering sensory feedback information to the patient.

An adequate solution of measuring the knee angles was found by applying Penny & Giles® goniometers. They are easy to attach to the joints and cause only small errors due to movements of the skin. By the help of instrumentation amplifier ICL 7605 reliable output signal with accuracy of 5 degrees is produced. Foot-switches are made of printed board and have considerable resistance so the output signals require further computer processing. They are attached to the toes and heels of both feet. Hand switches are fixed in handles of walker or crutches and are used to control voluntarily the simple four-channel FES walking pattern. Another module attached to the patient's waist contains also the two-channel stimulator delivering sensory stimulation to the electrodes positioned over the patient's arm. Two electrodes are placed to the left and the other two to the right upper arm. Both stimulation channels produce output voltage up to 50 V with the frequencies 5 Hz or 50 Hz. In the first experiments, it was found suitable for the operator and the walking individual also to provide an auditory feedback signal.

RESULTS

The investigation was preformed in three completely paralyzed paraplegic persons during five days, three runs a day with each person. While measured, the signals from transducers were not only used in control algorithm, they were also recorded as a useful information for estimating patient's walking.

Figure 1 represents both hand-switch signals, basograms, goniograms and sensory stimulation signals such as resulting from feedback system during four-channel FES assisted walking. Sensory information appears in three different forms represented as levels on vertical axis:

4 - sensory stimulation occurring after predetermined right knee flexion and foot-switch states were accomplished,

5 - sensory stimulation representing reward signal delivered to the left sensory electrodes,

1 - sensory stimulation representing warning caused by excessive knee flexion when patient was in midstance phase.

There can be generated two more types of warning by sensory feedback system caused only by right or left knee flexion. In single gait cycle two reward signals can be generated on each side providing patient with the information that:

- appropriate knee flexion occurs, while leg is lifted from the ground,
- the extended leg contacts the ground, after the swing phase.

In Fig. 1 it is interesting to note that heel-switch goes into off position at the activation of the contralateral hand-switch. The reason may be in the occurrence of the extension reflex when the body weight is transferred to single limb. It can be further noticed that after each reward a short warning signal occurs. The reason is in the leg duration of the polysynaptic flexion reflex. The knee joint remains flexed after the walking subject released the ipsilateral hand-switch.

Our preliminary task was to find the difference in patient's walking after daily use of sensory feedback system. Patient was first extensively trained by the physiotherapist without using the sensory feedback, so his FES aided walking was considered as quite stable. After four-days training period with sensory feedback the patient was measured while walking with and without sensory feedback in order to find the difference in gait pattern. He walked for about 5% faster when using the sensory feedback system. The measuring protocol was found inadequate, so it was changed in the following investigations. The next two patients were measured without sensory feedback during the first day and then trained with the sensory feedback system. Some promising results can be observed from Fig. 2, where right knee goniograms and the diagram demonstrating gait

cadence improvement during the learning period are presented. The upper record represents the goniogram measured during the first day, when sensory feedback was not applied. The lower goniogram belongs to the last day measurement showing that the patient walked faster then during the first day. In the third diagram (cadence-days) the improvement as assessed in the third patient during the training period is presented.

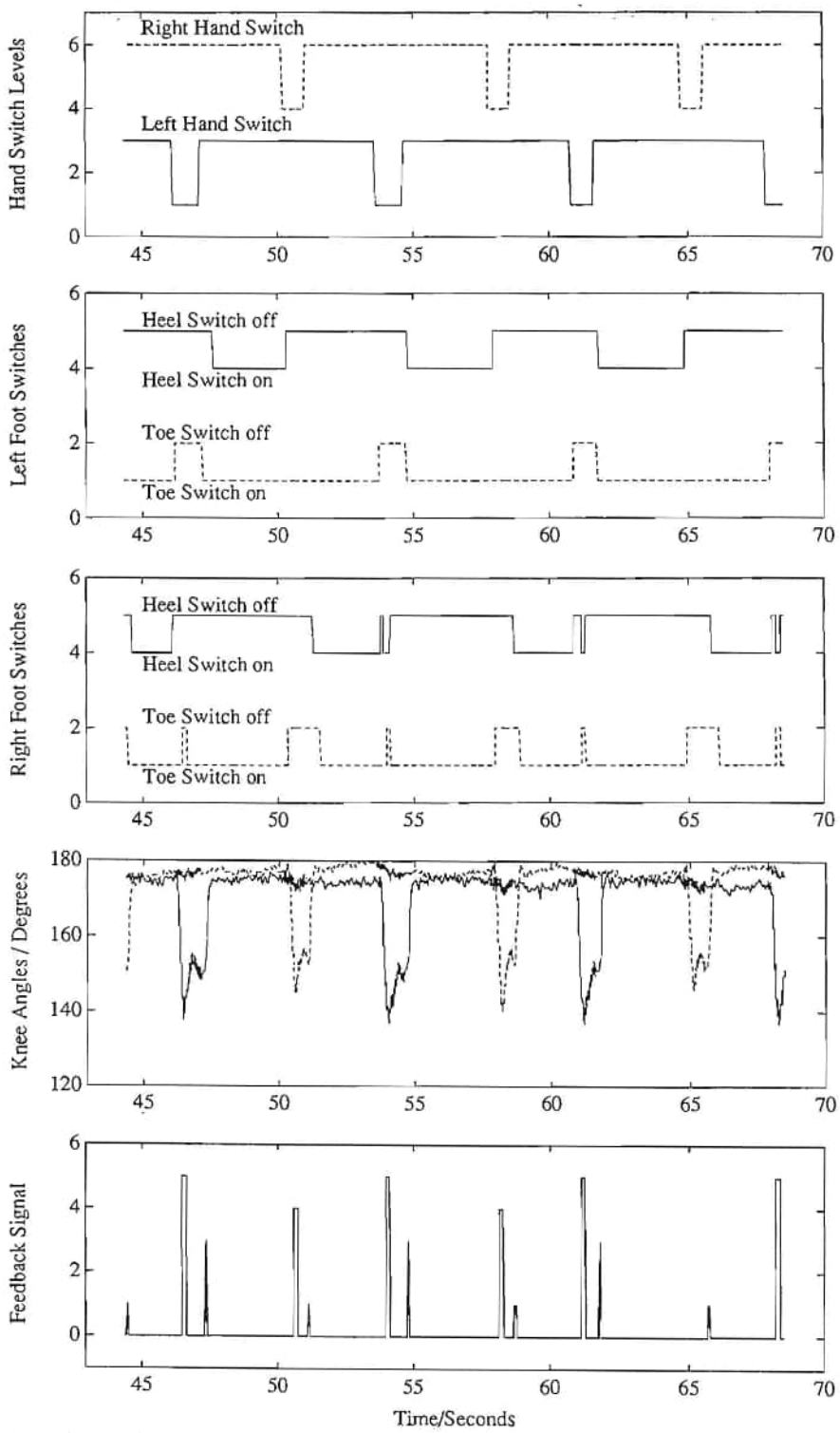

Fig. 1: Hand switch signals, basograms, goniograms, and sensory stimulation signal as measured during walking

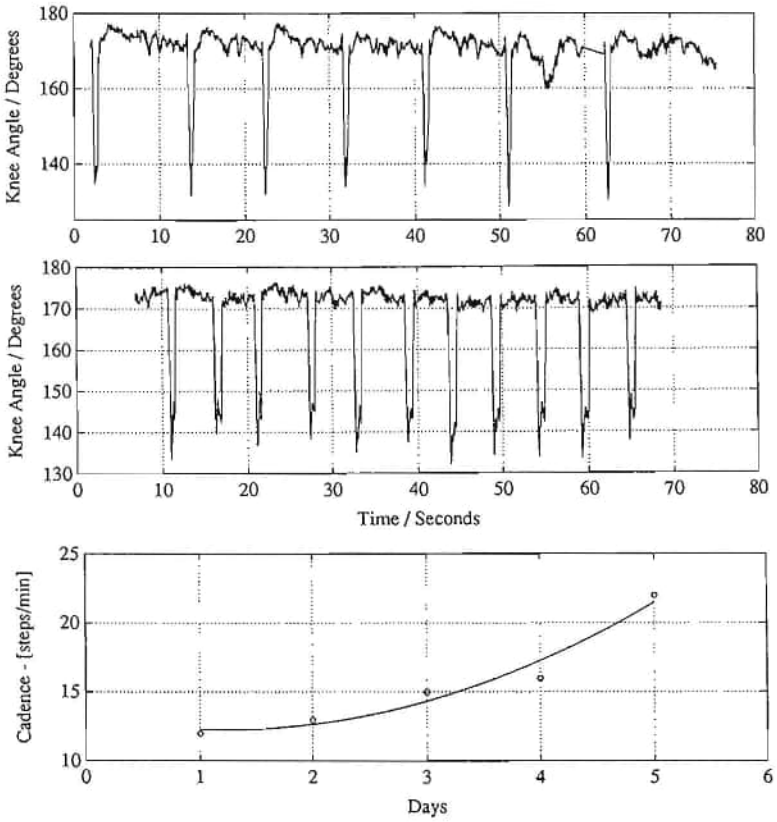

Fig. 2: Improvement in gait speed during patient's learning period of 5 days

DISCUSSION

The proposed type of sensory biofeedback system can be functionally separated into two important tasks:
"reward" - suggesting to proceed in to the next phase, after successfully accomplished movement,
"warning" - preventing a person from falling.
Using sensory feedback system during five-day training period, patient's gait speed was increased and his safety feeling was improved. According to our preliminary experiences, warning function appears to be more relevant and useful in FES assisted walking than reward and will be further investigated. It was observed that patient is loading his arms excessively during the swing phase /5/, so it will be useful to provide feedback information about loading of upper extremities. There were already reported some systems using upper limb load detection /6/ which will be considered in our future investigations.

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FUNCTIONAL ELECTRICAL STIMULATION AND RESTORATIVE SURGERY FOR PATIENTS WITH FACIAL PALSY (x)

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SUMMARY

Functional stimulation of muscles introduced by Liberson et al in 1960 may prove to be useful in restorative surgery for patients with facial nerve palsy. While this idea appears perfectly feasible, as we show in this paper, we are proposing in the meantime a technique which may substitute functional stimulation of the skin to that of the muscle itself at the price of a delay of a fraction of a second.

STATE OF THE ART

Treatment of a severe risidual facial nerve palsy of any etiology, either post surgical or not has been recently revolutionized by the use of either an anastomosis between a portion of the hypoglossal nerve and the distal end of the facial nerve or a graft (usually of the sural nerve) between a portion of the facial nerve over the normal side and the distal end of the paralyzed nerve (crossfacial graft). In children this kind of surgery is successful in most patients and is also true in adults with one frequent annoying complication. Most adult patients learn how to use their paralyzed facial muscles voluntarily after surgery and rehabilitation treatment. However in some, while voluntary smiling on the involved hemiface is present, an emotional non-voluntary smile may be more difficult to restore. Thus if such a patient hears a joke he/she may smile only on the normal side, thus betraying the original condition. It is easy to pick up by an EMG electrode the activation of the facial muscle on the normal side. Using this signal we may close a switch that we developed for this purpose. This switch may of course close a circuit of the stimulator which in turn instanteneously stimulates the muscles of the smile on the involved side. Therefore, this is bound to correct the difficulty. The idea came to us however that we might avoid the functional stimulation of the involved muscle at the price of a delay of a fraction of a second.

MATERIAL AND METHODS

In the proposed methodology we pick up the myoelectric signal in the way described above, but our myoelectric switch, instead of closing the circuit of the stimulator, closes that of a miniscule DC motor that we attach to the skin of the patient at any desired place. If this is not sufficient for some patients, the switch may activate the stimulator with electrodes applied to the skin instead of the facial muscles. Each time the patient smiles for any reason on the non-involved side, the motor vibrates the skin and the patient then voluntarily smiles on

the involved side. The result is a practically imperceptable delay of 1/3 of a second between the hemifaces.

RESULTS

Our myoelectric switch is depicted in Fig. 1. It has a sensitivity adjustment. It is energized by two 9 volt batteries and is free of any problems. It can be tested on anyone!

Fig. 1

DISCUSSION

The main difficulty related to an emotional smile can therefore be solved. It is noteworthy to mention that our myoelectric switch can be used in any case of automatic signal and bilateral coordination deficiency, possibly in balance deficiency. It can also be used for biofeedback exercises all day long, invisible to others!!!

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(x) Technical assistance of Paul Fried is gratefully acknowledged.

MAN-MACHINE CONTROL SYSTEMS FOR RESTORING MOVEMENT TO THE PARALYSED LIMBS

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SUMMARY

Multichannel Neuromuscular Electrical Stimulation (NMES) based locomotor strategies have been designed, aiming at restoring or augmenting movement to complete paraplegics and tetraplegics. Aiming at the control of muscle groups under electrical stimulation, a multichannel microcomputer controlled neuromuscular stimulator is used. Triggering of the "n" stimulation channels, in the case of paraplegics, can be performed either automatically or through the use of switches and sensors (eg. above lesion electromyographic signals), based upon gait parameters. In the case of the paralysed upper extremity, a voice controlled system using neural networks is used. The system is composed of several modules which are responsible for the filtering and sampling of voice, digital signal processing, pattern recognition (using a neural network paradigm) and neuromuscular stimulation. Arm movements can therefore be achieved by the patient through voice commanding.

STATE OF THE ART

This paper refers to feasibility studies being performed in our Rehabilitation Engineering Laboratory, aiming at designing suitable means for controlling NMES induced movements. Surface NMES can allow the restoration of gait or upper limb function to spinal cord injured subjects /1/, /2/, /3/. Nevertheless, its use outside the research lab as well as its efficiency will definitely depend upon well elaborated control strategies. Control Techniques have been applied in such direction but we are still to see paraplegics or tetraplegics performing daily activities, with the use of NMES, in an ordinary environment. Some developments in the field are presented along this paper.

MATERIAL AND METHODS

Microcomputer Controlled Stimulator

In order to restore ambulation to complete paraplegics and tetraplegics, the stimulator developed applies low intensity stimuli to the paralysed limbs, thus generating the necessary muscle contraction for the intended movements. The microcomputer system allows for the synchronisation of 08 channels of stimulation. Each channel has 04 phases: (i) standing up; (ii) double stance; (iii) walking and (iv) sitting down. Each phase has a maximum time duration which can be subdivided into several minimum periods of stimulation, depending upon the patients needs, i.e., data input.

The required software was implemented in "C" language, using a microcomputer type PC-XT/AT IBM compatible and is presented through a 3 options "menu". The first option is the data input through which the phase sequences are defined together with the maximum and minimum periods. The second refers to data processing whereby the several stimulation sequences are shown on the screen. The third is the actual stimulation with interrupts being awaited (triggered by the keyboard): once the stimulation has started, the phases occur in a repetitive way, until an interrupt signal is received.

Electromyographic Signals

Monitoring of electromyographic signals (emg) above the level of injury seems to be useful in detecting the patients' intention to performing a step. Simple threshold detection has been tried with doubtful results /4/. Digital analysis of electromyographic signals can permit more reliable control strategies.

The system is composed of an amplifier, low-pass filter (500 Hz), rejecting 60 Hz (mains); the conditioned signal is then applied to an A/D converter (1 KHz), which is connected to a microcomputer for numerically processing the digitised signal.

The software used to acquiring and selecting the relevant portions of the emg signal was written in turbo C whilst emg processing was made through the use of a MATLAB environment. Fast Fourier Transform (FFT), variance and Autoregressive models (AR) were chosen as algorythms.

Voice Controlled Stimulation for Tetraplegics

Complete tetraplegics show extra difficulties in the selection of hand-wrist, arm and forearm movements, since the way to triggering the stimulation will depend on the patient's remained physical abilities. The latter aspect leads to a specific data input system for a particular patient. Taking into accout that most of these patients have their voices preserved, a voice controlled stimulator can become a modular and functional rehabilitation system. Neural networks were used because the voice commanding input must be reliable and able to easily adapt to different sound patterns inherent to diferent subjects (new users), i.e. without the need for a complex training for each individual.

The system is composed of five modules which are responsible for filtering and sampling sonorous signals, signal processing, pattern recognition and neuromuscular stimulation. A low pass filter (1 KHz) was used for the spectral analysis. The sampling made use of an A/D converter (2 KHz), yielding a vector with 1024 time signal samples. A FFT module generated an 1 KHz normalised spectrum. This spectrum was subdivided into 10 equal bands, each with 100 Hz, from which higher energy frequencies were selected.

Training a network consists in determining the synaptic connections in such a way that once a learned pattern is presented at the input, the network yields the desired values at the outputs. The training was performed using three patterns (phonemes) one for each neuromuscular group were taken to be activated: /a/, /e/ and /i/ were used and 5 samples of 3 male patients. The samples were taken in different days, increasing the variability to the patterns and therefore making sure

that the network would be less susceptible to noise due to changes in the sound patterns.

RESULTS

The microcomputer controlled stimulation /5/ is under use (figure 1) in the Rehabilitation Engineering Laboratory being an essential tool for the implementation of several locomotor strategies through the appropriate matching, for instance, between mechanical orthoses (that provide stability), and neuromuscular stimulation patterns (that permit the swing phases).

Preliminary tests with emg detection/recognition were done with an incomplete tetraplegic subject walking with NMES and aided by crutches (the muscle chosen was the right "biceps brachi"). Pattern recognition was checked through a neural network: 12 data examples enclosing signals acquired during the subjects' intention to performing a step as well as other gait data with AR parameters (order 3) have led to a rapid convergence of the network with an extremely low error rate! There is therefore a pattern for the use implementation an emg control system with NMES. Further tests are still needed (figure 2).

The voice-neural network stimulator was implemented in an IBM-PC microcomputer, being tested on an incomplete C6 tetraplegic. With phonemes from male patients, the network showed an index of success of about 70%; with female voices (5 subjects), this rate was bellow 20%, yielding output values different from the expected ones. The prototype was tested (figure 3) and a good acceptance of the system by the patient was noticed. Further clinical tests are being done in order to optimize the system.

DISCUSSION

The approaches used to optimize NMES based systems, i.e. microcomputer based, emg analysis and neural-network voice controlling strategies do work well. A further aspect now being implemented is the overall integration of strain-gauged transducers that measure A/P bending moments (which can be related to the gait phases) on the handles to the existing systems, in order to have a more "involuntary" control system. Proprioception (Artificial) is also under investigation.

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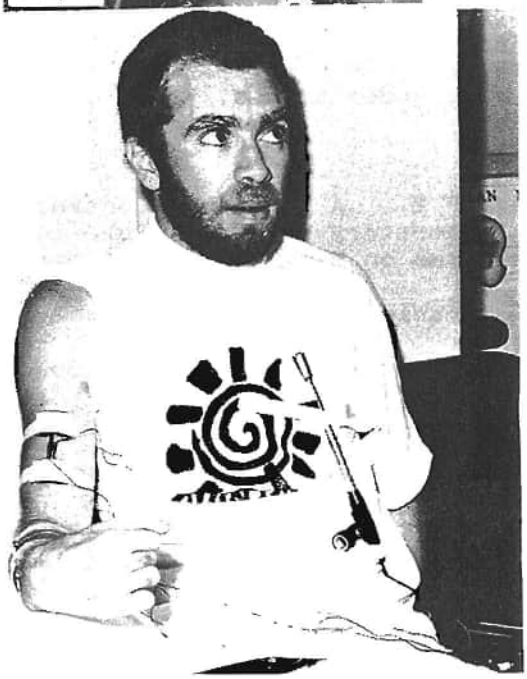
Fig.2



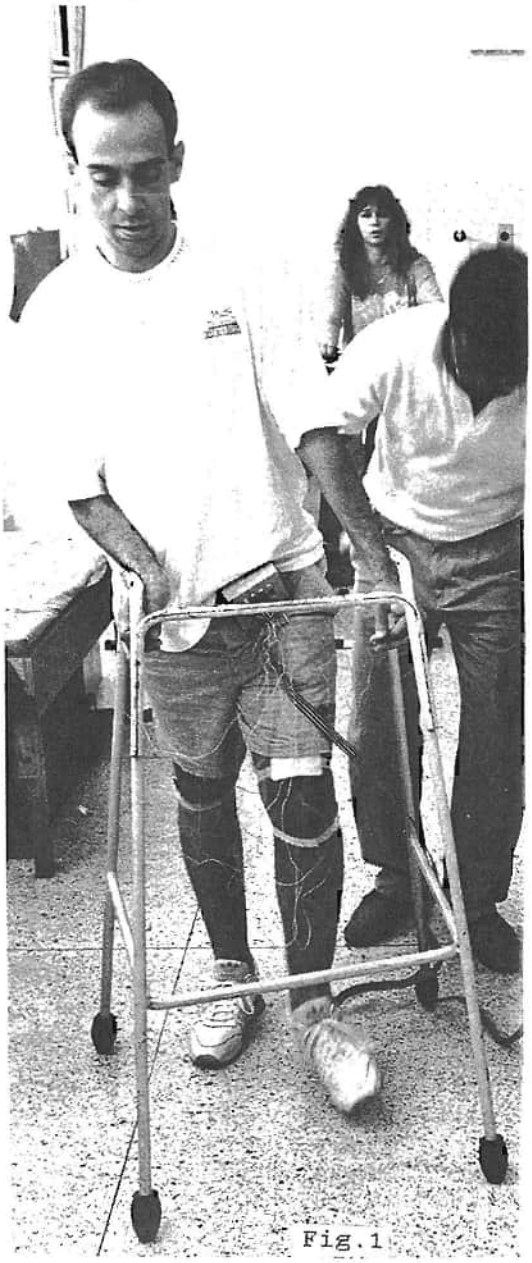


Fig.1

FES-CONTROL OF SHOULDER MOTION IN HEMIPLEGIC AND QUADRIPLEGIC PATIENT

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SUMMARY

On the basis of averaged EMG data during shoulder motion in normal volunteers, spatio-temporal patterns of stimulation were created in order to restore motor functions of the paralyzed or paretic shoulder in the stroke and cervical cord injury patients. Percutaneous intramuscular electrodes were implanted to twelve muscles relating to shoulder motion. By using stimulation data, flexion, abduction and horizontal adduction/abduction of the shoulder joint were restored in three hemiplegic and a C4 quadriplegic patients.

INTRODUCTION

Stroke or high cervical cord injury (CCI) patients often shows paralysis of musculatures not only in the upper limb but also in its girdle. If the neuromuscular system of the girdle is excitable to electrical stimulation, restoration of shoulder function by FES is possible in principle. However, since the shoulder movements involve the clavicle scapula and upper arm, it is well recognized that kinetics of the shoulder is the most complicated one and many problems remains undissolved. Therefore, no systematic investigation on the shoulder control by FES has reported.

We have utilized averaged EMGs during motion obtained from normal subjects in order to create the stimulation data for FES control of the upper extremity. Thus, the motor functions of the elbow, wrist and hand in C4 quadriplegics has been successfully restored by utilizing the stimulation data of FES. Hence, we have performed EMG analysis of the shoulder motion and created spatio-temporal patterns of stimulation for controlling shoulder muscles.

This paper describes FES control of shoulder movements in the stroke and CCI patients by using these stimulation data which were applied through percutaneous electrodes.

METHODS

Muscle activities of the shoulder girdle during shoulder flexion, abduction and horizontal abduction/adduction in thirteen volunteers were picked up by bipolar intramuscular wire electrodes and averaged. The stimulation data for controlling the shoulder motions by FES were obtained from statistically analyzed data of the averaged EMG and were applied to four hemiplegic and one C4 quadriplegic patients through a portable FES system which we developed. The shoulder motions restored by FES were ana-

lyzed by a motion analyzer (Quick MAG).

RESULTS AND DISCUSSION

Out of shoulder muscles which we examined, twelve muscles were selected for restoring shoulder motions by FES from stastically analyzed EMG data during shoulder motion. Fig. 1 shows tonic muscle activities during 90 degrees of shoulder flexion. Activities of prime movers such as the anterior part of the deltoid and the coracobrachialis were significantly high. The muscles from the axial skeleton to the scapula, the serratus anterior, the upper and lower part of the trapezius, also showed higher values for providing upward rotation of the scapula. Among the rotator cuff muscles, the infraspinatus and supraspinatus showed high activities during flexion of the shoulder joint.

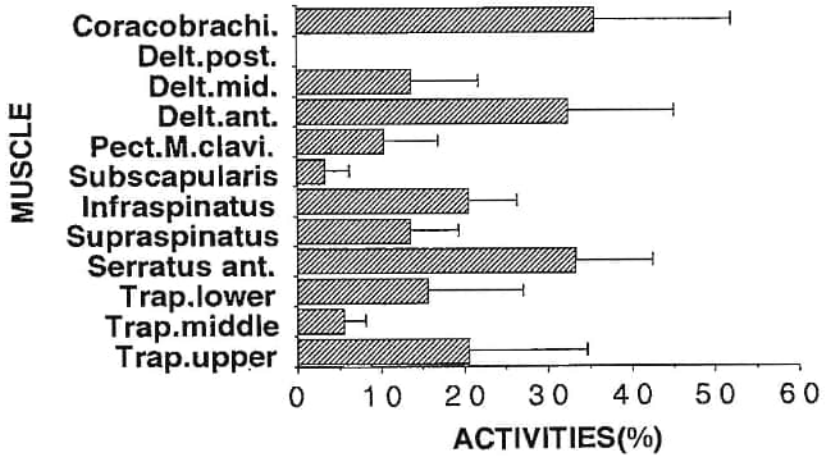

Fig. 1 Muscle activities at the tonic state of shoulder flexion

Fig. 2 shows the standard stimulation data for sequential control of shoulder flexion and horizontal abduction which were created from the statistical EMG data of shoulder motions. The stimulation data for individual patients were automatically made by measuring thresholds and maximum stimulation voltages of the muscles to be controlled with a stimulation data creating system and were transferred to RAM of a portable FES system.

Fig. 3 shows shoulder movement controlled by the portable FES system in a hemiplegic patient. Although almost no active movement of his shoulder was observed, FES application to twelve shoulder muscles through percutaneous intramuscular electrodes provided shoulder flexion and abduction sequentially. However, the shoulder movements were restored by the automatic control mode (cyclic stimulation mode) of the portable FES system. A controller for volitional control of the paralyzed upper extremity including the shoulder is required.

It is likely that the shoulder control is essential for the restoration of the totally impaired upper extremities in the hemiplegic and quadriplegic patients. However, well coordinated control of every joints in the upper extremity is required in order to realize its functional movements for activities of daily living. Further investigations is needed for practical application of the shoulder FES.

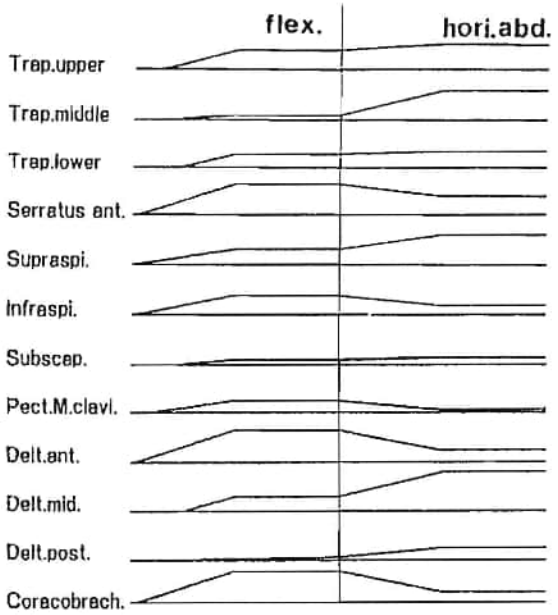

Fig. 2 Stimulation data for sequential control of shoulder flexion and horizontal abduction

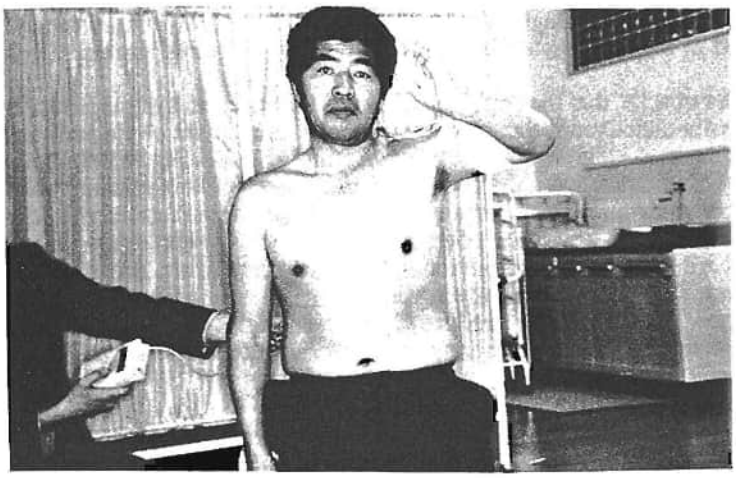

Fig. 3 Shoulder flexion of a hemiplegic patient by FES

FORCE INFORMATION IN WHOLE HUMAN SENSORY NERVE RECORDINGS

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SUMMARY

It has previously been suggested, and shown in an animal model, that it may be possible to use the whole nerve electroneurogram (ENG) recorded from a sensory nerve as a source of feedback signals for a closed-loop system for functional electrical stimulation (FES). The present study was aimed at verifying that signals of similar quality and with similar features can be obtained from human sensory nerves. During a standard nerve graft procedure, four patients were acutely instrumented with a nerve recording cuff electrode on the sural nerve, and the nerve responses to different mechanical stimuli of the skin were recorded. Also, a hemiplegic patient with a drop-foot was chronically implanted with a cuff on the sural nerve, and recordings were made regularly. The results showed that the human sural nerve responded in a similar way to pushes and slips applied on the skin as did the tibial nerve in cats, which indicates that previous experimental systems for closed-loop FES are possible to adapt to humans. Using a model that relates the applied force on the skin to the neural signal, it was possible to describe the neural recordings as a sum of the properties of slow and fast adapting mechanoreceptors in the skin.

STATE OF THE ART

It has been possible to study the cutaneous mechanoreceptive innervation using the microneurography technique developed by Vallbo and Hagbarth /1/. During restricted motor tasks the technique is able to provide a detailed picture of single afferent fibers in the peripheral nerves of human subjects /2,3/.

This technique has the drawbacks, that the population of units that one can sample is relatively small and the recording electrode is easily dislodged if there is any significant movement of the surrounding tissue. These limitations can be circumvented when using whole nerve cuff electrodes /4/. Whole-nerve recordings with cuff electrodes provide information from the activity of many nerve fibers that represent various sensory modalities and arise from widespread skin areas. The whole nerve cuff gives a more global picture of neural activity than the microelectrode. On the other hand, nerve cuff signals feature considerable spatial and temporal averaging and are therefore far smoother and less sensitive to the specific location and detailed pattern of the skin input, than signals recorded from single mechanoreceptors /5/. Unless a nerve is damaged as a consequence of the surgical procedure /6/, the recorded signals are stable for many weeks and months /8,9/, and reproducible for matched testing conditions /9/, because nerve cuff electrodes record from a fixed population of neurons.

It has been a general view that nerve cuff electrodes not are applicable in studies with human subjects due to ethical problems. But during a standard neurosurgical nerve grafting procedure, where a healthy nerve (very often the sural nerve) is explanted and used to recover a damaged nerve, a nerve cuff electrode can be implanted on the healthy nerve just prior to the explantation, and the cutaneous mechanoreceptive innervation can be explored. The nerve cuff is again removed after the receptive field has been explored.

Four types of mechanoreceptive units have previously been identified based on single unit recordings in human /1,2/ according to their rate of adaptation and size of receptive field. Fast Adapting units (type FA I and FA II) respond to changes in the force on and/or indentation of the skin but do not respond to any lasting stimulus, while Slow Adating units (SA I and SA II) respond to a lasting mechanical stimulus by continuously sending action potentials to the central nervous system with a frequency that relates to the intensity of the stimulus. Type I units have a small, well defined receptive field, whereas the type II units have a larger, vaguely defined receptive field. Since the nerve cuff sums the responses from many receptors into one signal, the spatial resolution is lost, as long as the stimulus is within the innervation area of the fibers within the cuff. The nerve cuff recording electrode records the nerve activity as a weighted sum of all the active axons within the cuff at any time. The amplitude an action potential in a single fiber gives rise to in the compund ENG depends on the axon diameter and conduction velocity, as well as the position of the fiber within the cuff /4/. To be able to extract information about the different types of receptors from the

compound signal, a physiologically based model relating the compound ENG to the perpendicular force has been developed for animal experiments /9/.

The aim of the present study was twofold. Firstly we wanted to adopt the nerve cuff electrode recording technique as a tool to investigate the cutaneous mechanoreceptive innervation in humans and to explore the quality of a physiologically based model on human sensory nerve recordings. Secondly, since the electroneurogram recorded from peripheral nerves in cats has demonstrated that relevant and reliable information is present in natural sensor for feedback regulation of Functional Electrical Stimulation (FES) systems /9,10/, we also wanted to demonstrate that this technique is a feasible option for feedback regulation of implanted FES systems, suitable to restore hand function, gait and stance in motor impaired subjects. The present paper describes the whole nerve signals response to different mechanical stimuli of the skin while comparing it to similar recordings from cats and relating it to single unit recordings, and an accompagnying paper /11/ desribes how the signal can be used in a practical FES system.

MATERIALS AND METHODS

The nerve cuff recording electrode

The cuff electrode was designed as reviewed by Hoffer /5/, consisting of a length of silicone tubing (Dow Corning) with an inner diameter at least 30% larger than the diameter of the sural nerve. On the inside of the cuff there were three circumferential electrodes, one in the center and one in either end of the cuff. The electrodes were the deinsulated ends of Teflon coated, multistrand stainless steel wires (Cooner Wire, AS634, with 40 strands), that were also used to connect to the external amplifier. The length of the cuffs used in this study was 30 mm, (similar to cuffs used in previous studies in cats /9/, and the diameters were 2.0-2.5 mm depending on the nerve size. Impedances (at 1 kHz) to an external ground electrode placed around the thigh was approximately 1 kOhm for the end electrodes and 1.5 kOhm for the center electrode.

Implantation procedure

Two series of experiments were performed: One where cuffs were implanted acutely during a normal surgical nerve graft procedure on four subjects, and signals were recorded for about half an hour whereafter the electrode was removed. The other was a chronical implant of a cuff on the sural nerve performed under local anaesthesia, the patient now wearing the cuff for the 7'th week.

The acute experiments were performed on patients who went through a nerve graft procedure. During the surgery, after it was verified that a nerve graft would be performed, an opening was made 3-4 cm posterior and 7-8 cm proximal to the lateral malleol of the ankle joint, and a cuff with a suitable inner diameter was implanted on the sural nerve. While making sure the cuff contained no airbubbles, the wound was covered with saline-soaked gauze, and about half an hour was spent doing the experiments as described below. When the recordings were finished, the sural nerve was cut, the cuff removed and the nerve taken out for grafting.

The chronic implant was carried out during local anaesthesia. The three wires from the cuff electrode were put through the skin approximately 25 cm above the lateral malleol. The nerve cuff was placed so that the nerve was neither pulled nor torqued by the wires. This makes the long-term prognosis of a nerve preparation excellent /7/.

All subjects gave their consent, and the study was approved by the local ethical committee.

Experiments

The following experiments were performed:

- The innervation area of the sural nerve was investigated by touching the skin lightly at different places on the foot and ankle, while listening to the nerve response.
- A hand-held force probe equipped to measure forces in the axial and lateral direction, was used to apply a range of different force profiles to the skin of the lateral part of the foot, while the subject remained passive. The perpendicular and lateral skin contact forces and the neural signal were recorded.

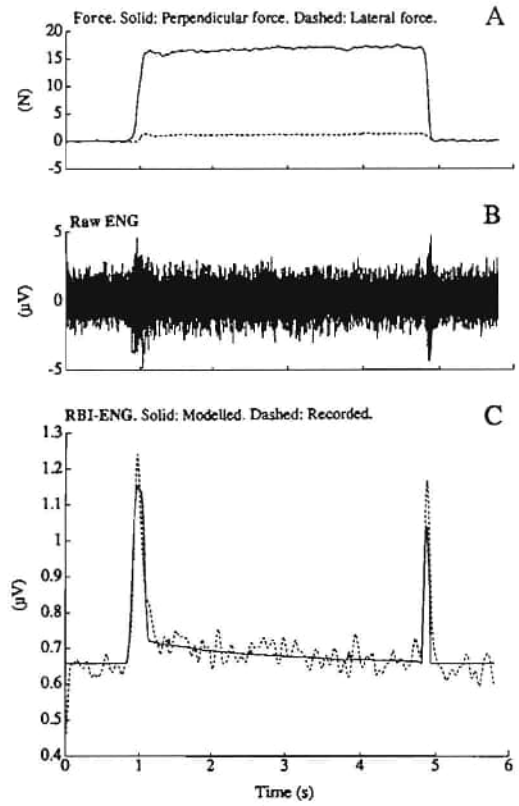
Signal analysis

The signal from the cuff was amplified using a custom made amplifier (based on an AMP-01 integrated instrumentation amplifier from PMI) with a gain of 70000 and bandwidth 80 Hz to 10 kHz. The amplified signal was then sampled into a digital signal processor (sampling frequency = 20 kHz), where it was rectified and bin-integrated in bins of 10 ms duration. The signal processor (DSP) was a TMS 320C25 placed in a '386 computer (PC). When a whole bin was sampled, the DSP interrupted the PC (i.e. every 10 ms, i.e. with a frequency of 100 Hz) that saved the integrated value as one sample. The result of the

rectification and bin-integration was a signal that represented the overall activity in the nerve, as has earlier been described for cat experiments /9/. Other signals, such as perpendicular and lateral forces, were sampled in the same manner, but without rectification, and all raw signals were saved on tape for backup.

RESULTS

An example of the signals recorded from the cuff when a step-like perpendicular force was applied on the lateral part of the foot, is shown in the figure below. Before any force was applied, the noise from the amplifier etc. caused the rectified, integrated signal to have a DC level of about 0.6 μV. When the force was applied, the nerve responded with a brief peak of activity, returning to a level only very little above the level before onset of the force. When the force was removed, another brief peak of activity appeared. These findings were in close resemblance to what has previously been seen in recordings from the tibial nerve in the cat when applying a force on the central footpad, although the human sural nerve seemed to have a smaller tonic response to a constant force. The rectified and integrated nerve signal modulated between 0.6 μV and 1.3 μV, which was a somewhat smaller modulation than the signals previously obtained from cat tibial nerve. The difference was attributed to two things: One, the inner diameter of the cuff was larger in the human (chronic) experiment compared to the nerve diameter than it was in the previous cat experiments. Two, the part of the innervation area on the skin that was mechanically stimulated was smaller in the human experiment when related to the total area than it was in the cat experiments.



Data from chronic experiment. A: Perpendicular (solid) and lateral (dashed) skin contact force applied manually on the lateral part of the foot. B: Raw ENG. C(dashed): Rectified and bin-integrated ENG. C(solid): Modelled RBI-ENG.

A model between the force applied perpendicularly on the skin and the resulting nerve signal previously developed for the cat tibial nerve /9/ was adapted with a single change. The cat model contained three groups of receptors: fast, medium and slow adaptation. It may be argued whether this reflected three different receptive units present in the paw of the cat or if it was a consequence of the mechanical properties of the paw. Based on the microneurographic recordings in human, the group of receptors with medium adaptation was removed from the model when adapting it to the human data. When optimizing the model parameters to the experimental data using an iterative technique, a model performance could be obtained that was comparable to the cat studies.

DISCUSSION

The results of this study shows that the sensory nerve activity recorded from a cutaneous nerve with a whole nerve cuff is comparable to similar recordings from a cat. This is of great importance for the development of FES systems that use natural sensory information as a source of feedback signals, since previous studies with a cat model of such a system have given encouraging results.The whole nerve cuff recordings presented in this study behaved as could be expected from the large body of data from single sensory units obtained in other studies. Single-unit recordings from human have been found to be very important for precision grip in persons with normal sensory-motor function, encouraging further attempts to use natural neural feedback in FES systems.

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THE USE OF NATURAL SENSORY NERVE SIGNALS AS AN ADVANCED HEEL-SWITCH IN DROP-FOOT PATIENTS

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SUMMARY

The aim of the present study was to demonstrate the possibility of using natural tactile sensory information in humans to control a Functional Electrical Stimulation (FES). The sural nerve in a hemiplegic patient with a drop-foot was instrumented with a tripolar cuff electrode. During walking, the recorded nerve signal was strongly modulated and gave a clearly detectable response at foot-contact and a silent period when the foot was in the air through the swing phase of the walking cycle. The nerve signal reflected a clear "heel-switch" signal and information about the changes in the force applied to the skin. The foot-contact information, which was extracted reliably from the sural nerve signal, controlled a drop-foot stimulator which could be applied during walking.

STATE OF THE ART

If natural sensors are to provide a suitable feedback signal for the control of FES systems in paralysed subjects, it must be possible to extract reliable and relevant information from the nerve innervating the sensors. An experimental animal model has demonstrated that the tactile sensory information, recorded from a whole nerve cuff electrode, contains reproducible information about changes in forces applied perpendicularly on the skin /1/. Analogously to the human precision grip, for which updating of the motor program during a small slip is based on the phasic activity triggered in glabrous skin mechanoreceptors, an event-driven FES system automatically corrects the "motor" output to the controlled muscles, whenever an object starts to slip /2/. Recently, it has been demonstrated that tactile sensory information can be recorded from whole nerve cuff electrodes implanted on cutaneous human nerves /3,4/. Such findings have led to the suggestion that the tactile sensory information, recorded from whole nerve cuff electrodes, implanted on cutaneous nerves of the hands or feet of para- or tetraplegics, will render a feedback signal closely related to skin contact force, suitable for closed-loop control of FES /5,2/.

For the first time, in this paper, we demonstrate that sensory feedback, derived from a sural nerve cuff recording, can be used to control the activation of paralysed dorsiflexors in a drop-foot patient.

Electrical stimulation of the peroneal nerve, used for correction of the gait of a hemiplegic patient, has become an established therapeutic and functional method /6/. The stimulation is applied during the swing phase of the affected leg and prevents drop-foot, so the patient walks faster and more securely. The stimulator is often located distally to the knee on the lateral part of the tibia. The stimulator can be either external or partly implantable /7/. In both situations, the stimulator is triggered by an external heel-switch that is linked to the stimulator through a wire running from the switch under the heel up to the stimulator.

We "replaced" the heel-switch by a single sural nerve cuff that monitored whether or not the affected foot was supporting weight. The use of the natural tactile information from the foot made it possible for the patient to walk without wires running from heel to stimulator.

MATERIALS AND METHODS

The sural nerve in a 35 year old hemiplegic spastic male subject with a drop-foot was instrumented with a tripolar whole nerve cuff electrode approximately 7 cm proximal and 3 cm posterior of the lateral malleol of the right ankle joint. The subject gave his consent and the study was approved by the Local Ethical Committee. A clinical examination has revealed that the patient has an Achilles tendon contracture and tremor around the ankle joint.

Surgical procedure
The surgery was performed during local anaesthesia. To prevent compression-neuropathy associated with post-surgical oedema, we ensured that the inner diameter of the cuff was more than 30% larger than the nerve diameter. The three Cooner™ wires from the cuff electrode were put through the skin approximately 25 cm above the lateral malleol. The nerve cuff was placed so that the nerve was neither pulled nor torqued by the wires. This makes the long-term prognosis of a nerve preparation excellent /8/.

Nerve cuff electrode configuration
The nerve cuff recording electrode consisted of an insulating cuff (silicone tubing) containing three circumferential metal electrodes (flexible 40-strand stainless steel wire, Teflon-coated), placed around part of the sural nerve. The design, fabrication and surgical implantation of nerve cuff recording electrodes have been reviewed in detail elsewhere /8/. The insulating cuff serves to resolve the small action currents generated by nerve fibres, by constraining the current flow within a long, narrow resistive path. The cuff was 3 cm long and had an inner diameter of 2.5 mm.

Neural amplification and stimulation
The leads from the implanted nerve cuff electrode were connected to a differential ENG amplifier with a high common mode rejection. The amplified (Gain = 70.000) nerve signal was fed to a computer together with an external heel-sensor. The heel-sensor was adhered under the heel in the area where it has impact with the ground during walking. The location was outside the innervation-area of the sural nerve. Based on the processed sural nerve signal, a trigger-pulse was delivered to an external drop-foot stimulator (KDC 2000A). The transcutaneous stimulation was made by means of a reference electrode above the tibialis anterior muscle and an active electrode above the common peroneal nerve just distal to the branching off of the superficial peroneal nerve. In this position, it is possible to recruit a major fraction of the deep peroneal nerve which dorsiflexes the foot.
The neural amplifier was battery-supplied and optically isolated from the mains to increase the common mode rejection and to reduce the risk of electrocuting the subject. To further reduce noise pick-ups, an external reference electrode was placed between the stimulation electrodes and the nerve cuff electrode. The neural signal was fourth-order band pass filtered from 0.7 to 10 kHz (Kron-Hite, model 3750). This would reduce remaining pick-ups of 50 Hz from the mains, if any, and the EMG from neighbouring muscles to a negligible level. The bandwidth of the recorded neural signal ranged from 0.2 to 3.0 kHz.

Signal analysis
The computer calculated the rectified and bin-integrated sural nerve signal (RBI-ENG, time constant = 10 ms). This signal was then digitally high-pass-filtered (1 Hz, 2nd order Butterworth) and rectified (HP-filtered RBI-ENG).

Day-to-day stability and reproducibility of recorded signals
Using a bipolar stimulation electrode, a compound action potential (CAP) was elicited in the cuff-electrode by stimulating the skin at a fixed position within the innervation area of the sural nerve. The amplitude of the CAP signal increased during the first two days after implantation. Thereafter, the CAP signal became stable on a day-to-day recording and was reproducible under matched testing conditions. The unchanged CAP suggests that no nerve damage had taken place. The increase in the CAP during the first two days after the implantation probably reflected a post-surgical trauma to the sural nerve, which it recovered from.

Experimental protocol
The patient walked in a 30 m long hallway at his preferred walking speed (about 1.2 km/h) during four conditions: 1) barefoot without stimulation, 2) barefoot with stimulation, controlled by the recorded neural signal, 3) with shoes without stimulation, and 4) with shoes with stimulation. The computer was connected with cables fastened at the waist of the patient to the external force-device under the heel, the stimulator and the neural amplifier.

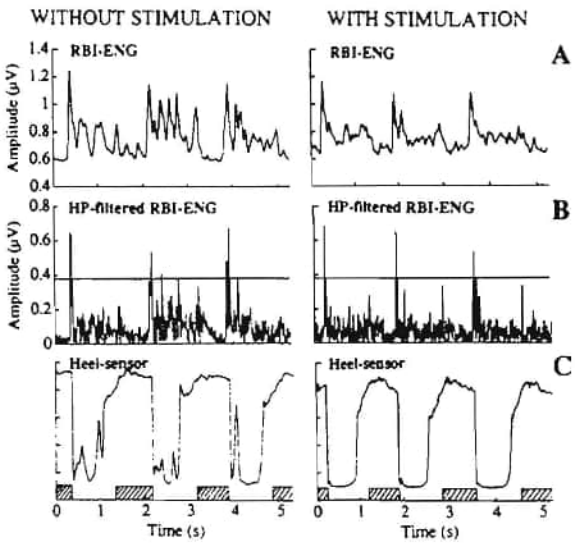
RESULTS

The recorded sural nerve signal arises from sensory axons that innervate mainly low-threshold skin mechanoreceptors from the dorsal and lateral part of the foot. In this patient, the lateral border of innervation ran along the lateral part of the foot that just touched the floor while the patient was

standing. We defined the innervation area, using a hand-held pen with a narrow nib. The nib was slid along the skin from outside to within the innvervation area, and at the location where we detected a response in the raw electroneurogram, the border of the innervation area was defined. The applied force of the pen did not give rise to any visually detectable skin deflection. Mechanical stresses of the skin inside as well as outside the innervation area made the receptors fire. This was recorded as an increase in the amplitude of the rectified and bin-integrated electroneurogram.

Typical data recorded from three barefoot steps without and with stimulation of the ankle dorsiflexors are shown in the figure below. During a step, the electroneurogram modulated between 0.6 and 1.2 μV with a distinct peak at heel-contact (Fig. A, top). In the swing phase, where the foot was in the air, the neural activity decreased to the baggrund noise level of 0.6 μV (Fig. A). The swing phase between the first and second step was from 1.5 to 2.0 s, whereas the heel had no ground contact from 1 to 2 s (Fig. C). The distinct peak at heel-contact (Fig. A and C) was extracted and the background noise suppressed by high pass filtering the RBI-ENG (Fig. B). When the high pass filtered neural signal rose above a threshold of 0.38 μV the stimulation was turned off. This is illustrated by the termination of the hatched bars in Fig. C. The stimulation was turned on again after 1 s, which corresponded to the stance phase. The stimulation continued until the next foot-contact was detected or until the occurrence of a time-out of 1.5 sec.

When walking without stimulation (left panel in the figure) the peak in the RBI-ENG was followed by a series of smaller distinct bursts in the stance phase of the step (2 broader bursts in the first step and 3 more narrow bursts in the second step), that coincided with fluctuations in the heel-contact (Fig. C, left). We attribute the bursts to the reduced weight bearing on the drop-foot. When the neural signal was used to control the stimulator (right panel in figure), again a distinct neural peak was detected at heel-contact (Fig. A and C, right) but less fluctuations were seen during the stance-phase. This was also reflected in the heel-sensor signal (Fig. C, left). The bursts in the neural activity before foot-lift at 1.5 s and 3.2 s (Fig. A, left) was probably caused by a slip of the lateral fore-foot against the floor. Since this burst was not very distinct during stimulation it can be attributed to a well-functioning stimulator that started to dorsiflex the foot at the transition from stance to swing phase.



Typical data from barefoot walking without (left panel) and with stimulation (right panel) of the ankle dorsiflexors. From top to bottom is shown (A) rectified and bin-integrated sural nerve activity (RBI-ENG), (B) rectified high pass filtered bin integrated sural nerve activity (HP-filtered RBI-ENG). (C) heel-sensor signal and control signal to stimulator. The heel-sensor is high during heel-off and low during heel-contact. The control signal to the stimulator (hatched bars in (C)) was decided on the basis of the threshold of 0.38 μV in (B).

In order to make the sural nerve signal applicable for the control of the drop-foot stimulator, it was necessary to eliminate the electrical artifacts that were elicited by the stimulation and picked up by the nerve cuff recording electrode. Artifact-free nerve cuff electrode recordings were achieved by detecting the stimulation pick-up in the neural signal and then cutting the signal within the stimulation artifact time periode.

When the patient was wearing socks and shoes, the neural signal became more noisy. This was probably because the shoe moved around the foot, but still the computer correctly detected a trigger-pulse to the stimulator from the neural signal in all steps during a continues 2 min. of walking.

DISCUSSION

This is the first human study to demonstrate a functional use of cutaneous mechanoreceptors recorded by an implantable whole nerve cuff recording electrode. Using the distinct peak in the neural signal at heel-contact, we were able to control a drop-foot stimulator during walking. We attribute the distinct neural peaks to stretches of the skin mechanoreceptors that is innervated by the sural nerve.

Although heel-contact information can be obtained with external pressure sensors placed inside shoes, inherent problems of calibration, mechanical and electrical drift, lead breakage, and sensitivity to environmental factors are known to affect external transducers /6/. Achilles tendon contractures in some spastic patients also makes a heel-switch useless, because the supporting weight on the heel is too low to activate the heel-switch properly. Nor can problems with excessive inversion or eversion of the foot during dorsiflexion be corrected from a simple heel-switch. The above problems may be avoided if tactile information, recorded from the sural nerve and/or tibial nerve, was used to control a dual-channel stimulator. One stimulator might activate the muscles that dorsiflex and invert the foot and the other the muscles that dorsiflex and evert the foot /7/.

The simple and reliable neurosurgical procedure, and the consistency in the recordings makes this technique a feasible option for feedback regulation of implanted FNS systems, suitable to restore hand function, gait and stance in motor impaired subjects.

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DOES FES DAMAGE THE JOINTS: PART II CO-CONTRACTION IN DAILY FUNCTIONS

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In the last workshop we presented a cadeveric study which show that static contractions of agonist muscle alone at most points of the knee's range of motion can cause significant displacement in the joint. It was also shown that low level co-contraction in the antagonist muscle prevents the risk to the joint. It was questioned if coactivation is present in dynamic movements in activities of daily living such as standing, walking, going up and down stairs etc...
We studied the EMG of the quadriceps and hamstrings of normal subjects and found the following results: EMG co-contraction was present in the antagonist during standing-up (peak 15% MVC@ 90^{o}) sitting-down (17% MVC@ 90^{o}), going up-stairs (32% MVC@ 90^{o}), going down-stairs (11% MVC@ 90^{o}) walking (14% MVC@ 90^{o}) and disturbance to balance by sudden push (7-14% MVC@ 90^{o}) depending on the direction and intensity of the push. Quiet standing varies from subject to subject and occasionally in the same subject doing several trials.
It was concluded that co-contraction is present in every common activity of the legs relevent to FES rehabilitation of paraplegia. The co-activation varies from 5% to 50%, depending on the function performed, and must be duplicated by FES systems in order to prevent joint damage due to long term use.

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ISOMETRIC AND ISOTONIC LENGTH-FORCE RELATIONSHIPS OF NINE SKELETAL MUSCLES

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SUMMARY

The length-force relations of nine muscles in the cat's hindlimb were studied by a standard isometric method and a new isotonic technique. It was found that isotonic length-force relations are similar to isometric length force relations, with slight shift in optimal length and slight decrease of maximal active force. It was also found that the Tibialis Anterior, Medial Gastrocnemius and Extensor Digitorum Longus exhibit bicompartmental fiber populations, with differing internal architecture and optimal lengths. Modeling the behavior could enhance the success of tendon transfers and predict the occurrence of muscle -tendon tears.

INTRODUCTION

The length-force relation of muscle is its most fundamental functional property. It reflects the architecture of each muscle, and plays an important role in the readaptation of tendons which have been transferred, by determining the strength and effective elongation range of the transferred muscle. In transfer and lengthening procedures, the length-tension relation of muscle dictates the slack length of the muscle-tendon complex, and the passive and active tensions through the range of motion.

The aims of this study were to determine if the length force relation held under load moving conditions, and to develop a model for the behavior of active force in muscles that showed distinct morphological subgroups of fibers, with differing architecture. This model may then be used to predict the functional result of tendon transfers or lengthening procedures according to muscle architecture.

METHODS AND RESULTS

Adult cats, anesthetized with chloralose were used. The isometric length-force relationships were obtained by isolating muscles in the hindlimb from their distal insertion, fixing them to a force transducer which was mounted on a sliding mechanism. The muscle was set a a fixed length, whereupon it was stimulated supramaximally. The force before and at the peak of contraction were defined as passive and total force. Active force was determined as the difference between total and passive force. Tests were performed at 2.5 mm intervals to obtain a full range isometric length force relation.

Isotonic length force relations were determined by applying various load weights to the muscle, and measuring its length with a potentiometer in a pulley system. Its length prior to stimulation was defined as passive length. Supramaximal stimulation was applied, and after the muscle shortened its length was defined as active length from a series of which the total force curve was drawn. Based upon models by Otten /1/ and Kaufman /2/ the

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following model was developed for muscles with multiple compartments:

$$F=\sum_{1=1}^{n} K_i \exp\left[-\left(\frac{(\epsilon_i+1)^{B_i}-1}{Wi}\right)^2\right]$$

where F is muscle force, ϵ_i is compartment strain, β is compartment skewness factor, Wi is the compartment width factor, and Ki is the maximal force by the fibers in the compartment, n is the number of compartments. The Flexor Digitorum Longus (FDL), Lateral Gastcromemius (LG), Peroneus Brevius (PB), Peroneus Longus (PL), Soleus (SOL), and Tibialis Posterior (TP) were fitted in both isometric and isotonic conditions with single compartment models (n=1). The Tibialis Anterior (TA) and Medial Gasctrocnemus (MG) by virtue of their complex architecture were fitted with bicompartment models (n=2). The Extensor Digitorum Longus (EDL) showed bicompartmental behavior in isotonic conditions but not in isometric.

DISCUSSION

The architecture of the muscles tested is represented in the length force models which show that the compartmentalization of muscle fibers may have functional significance by extending the range of motion through which a muscle may effectively exert force. The morphology of each muscle is then tailored to its function, making more critical the selection of a muscle to transfer in surgical procedures.

The length force relation holds in isotonic condition even if some differences exist between isometric and isotonic curves. In general, shifts of optimal lengths may be observed between both conditions, and a slight loss of maximal active force is seen in isotonic conditions. It is important, then to use load moving measurements when trying to predict the dynamic behavior of muscle.

The multiple compartment model could also be used for muscles which are clearly of multiple nature (quadriceps, biceps and triceps brachii, etc.).

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FORCE-VELOCITY RELATIONSHIPS OF NINE SKELETAL MUSCLES

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SUMMARY

The force-velocity relationships of nine skeletal muscles in the cat's hindlimb were obtained and modeled using a least squares estimation of Hill's Model. Large variations were found between the models of the different muscles tested. It was found that muscle architecture and fiber composition are the most important contributors to each muscle's force-velocity model.

INTRODUCTION

The force-velocity relationship of skeletal muscle is one of its most fundamental dynamic properties. The first investigation and modeling of this relationship was by Hill /1/, who derived a model of the following form:

$$(V + a)(F + b) = K$$

One common procedure in Hill's experiments was to stretch the muscle to an arbitrary length, then stimulate it and record the velocity at some given points.

During a naturally occuring contraction, it is seldom that a limb is restrained and released. Therefore a technique to study muscle dynamics has been designed in which a muscle load is allowed to equilibrate with a muscle in its passive and active conditions. This results in a more natural condition of contraction, where velocities are generated by the active element of muscle with little influence of transient passive tissue recoil. It is therefore the objectives of this work to obtain the force-velocity relationships of nine skeletal muscles in the cat's hind limb and to discern the major factors that affect the relationship amongst the nine muscles.

METHODS

Sixteen adult cats were anesthetized with chloralose. Their hind limbs were prepared by placing an electrode on the sciatic nerve through a posterior thigh incision, disarticulating the ankle joint and dissecting the insertion of 2 or 3 muscles which were not in mechanical contact. A pin placed through the femoral condyles and a pelvic clamp held the preparation rigidly. A load system consisting of a cable, pulley and load weight was attached to one muscle through a tendon holding device. Tests on other selected muscles were performed subsequently.

Loads starting at 100 g were applied to the muscle under test, until its passive force equilibrated with the load. A tetanic supramaximal stimulus pulse train was applied, which resulted in muscle contraction and load movement until the active force equilibrated with the load. During the contraction, displacement was recorded, and its time derivative ob-

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tained, yielding the velocity. Loads were increased until each muscle was unable to attain more than 1 mm displacement. Maximum velocity in each trial was plotted against load. Four preparations of each muscle were pooled and used to fit a Hill model by the least squares method.

RESULTS AND DISCUSSION

Fig. 1 and 2 shows an example of T.A. and Soleus pooled Hill's Model respectively with its unloaded velocity (Vo), maximum isometric force (Po), and dynamic constents a and b. Insets also contain the correlation coefficient (R) and standard error (SE). Table 1 summarises the results of modeling on all muscles.

Statistical analysis shows a significent correlation between muscle mass /2/ and maximum isometric force (Po). Significant two dimensional correlation is found between the maximum velocity (Vo) and the length-tension relation's elongation range combined with fiber composition /3/.

These findings show that muscle architecture, both in terms of its fiber pennation pattern and its fiber population is the central determinant of the force velocity relationship. The pennation pattern, which is directly responsible for the length of the elongation range thus plays a role in the force velocity relation also. Parallel fibered muscles attain higher velocities than do highly pennate muscles. As expected, the Soleus, which is a purely slow twitch muscle, attains much less velocity than its other triceps surae agonists with similar range of motion.

These findings point to the need of a comprehensive model based on the fundamental properties of muscle in order to obtain a more complete view of its dynamic behavior.

TABLE 1

Muscle	Vo (cm/s)	Po N	a g	b (cm/s)
EDL	24.1	4155	280	1.6
FDL	8.7	3137	560	1.6
LG	14.8	6736	1050	2.3
MG	11.2	5560	1440	2.9
PB	5.6	2687	420	.95
PL	11.3	3096	210	.76
SOL	5.8	3149	2920	5.82
TA	28.4	5851	720	3.5
TP	4.2	3937	360	.38

Results for all model fits:

EDL = Extensor Digitorum Longus, FDL = Flexor Digitorum Longus, LG = Lateral Gastrocnemius, MG = Medial Gastrocnemius, PB = Peroneus Brevis, PL = Peroneus Longus, SOL = Soleus, TA = Tibialis Anterior, TP = Tibialis Posterior

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Fig. 1: TIBIALIS ANTERIOR

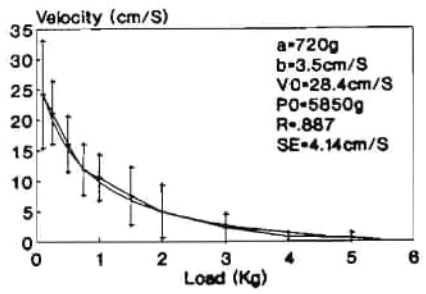
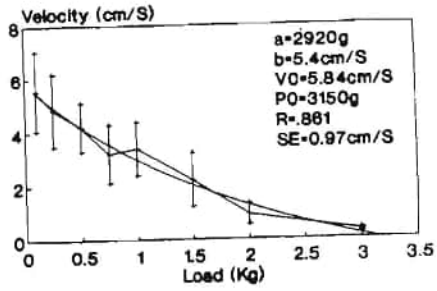


Fig 2. SOLEUS



MUSCULAR ACTIVITY CALCULATION BY MUSCULO-TENDINO-SKELETAL MODEL INCLUDING MINIMAL BONE BENDING

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SUMMARY

The key element of the developed model is represented by muscle activation criteria based on minimization of bending loading along the femur and tibia bones. Such minimization function reflects in coordinated muscle action and synergistically distributed load between several muscles which, could be further displayed in lower muscle fatigue and prolonged FES activity. Musculotendon model consist of first order activation dynamics and first order musculotendon dynamics and is with minor differences similar to those used in other biomechanical studies. Tendon is assumed to be elastic and linear, considered is also muscle pennation, muscle fiber composition, nonlinear parallel elasticity (PE), force-length and Hill velocity-force relation of contractile element (CE).

INTRODUCTION

Improved knowledge in the fields of medicine and biomechanics and new technological achievements in the last decade enable clinical implementation and home use of FES systems for paraplegic standing and walking /1/. Unfortunately, the restored functions, while compared to the normal activity, are in most cases poor, inefficient, energy costly and slow. Control schemes and stimulation sequences applied to multiple surface electrodes are simple. Widely used four channel FES walking pattern remains unchanged except for few attempts when additional channels were used such as m. soleus for posture switching in standing, or addition of m. gluteus for hip stabilization. For FES control purposes most frequently there is implemented the measured EMG muscle activity /2/. This method is not adequate because of two weaknesses: (i) because of high EMG to muscle force nonlinearity, higher EMG amplitude does not necessary show larger muscle (tendon) force while compared to another muscle (EMG channel), (ii) recorded and replayed EMG control signals result in automatic, preprogrammed locomotor behavior. Furthermore, with inadequate use of FES, which is poor imitation of normal human activity, the possibility of joint and bone chronic damages is risen.

As was explained by Pauwels /3/, muscle action not only provide moment equilibrium in joints, but also minimizes high bending moments in long bones of lower extremity. The stresses in bone material produced by bending moments exceed for several decades compression and shear stresses, therefore, they are most dangerous and deserve special attention. These criteria should be, together with other biomechanical constraints of musculo-tendino-skeletal model, included in a reasonably complicated model with acceptable computer time complexity.

Different optimization functions were used until now by several authors. Dul /4/ as first minimized the muscle fatigue. Minimization of metabolic energy was used by Hatze /5/, Khang&Zajac /6/ and Pandy et al /7, 8/. Other authors have widely implemented criterion of optimal output tracking /9, 10, 11/. Hatze /5, 12/ also used time optimal or speed criteria, specially for jumping studies. Metabolic energy expenditure is also frequently optimized /12/.

MODEL

Model construction: Bending moment optimization method is based on compensation of ground reaction (M_{GR}) and gravitational (M_G) bending moments along femur and tibia bones with optimized muscle activity. Bending moments produced by Coriolis and centripetal forces are neglected with little error introduced according to findings of Bresler&Frankel /13/. The measuring methods of partial inertial moments for shank and thigh segments on the tested subjects would considerably complicate this work. The optimization flow is sequential, procedure is the same for each step and occurs in equal time intervals. First, M_{GR}, M_G and raw muscle profiles are calculated (Figure 1). The muscle profiles for all 19 muscles included in the study are then combined in least square error sense (Sample of muscle bending profiles is shown in Figure

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2). The bending moment compensation would be very good if any force value, including negative, would be allowed. However, biomechanics of human body allows only selected muscle force values. The lower $\bar{F}_{min}$ and upper $\bar{F}_{max}$ muscle force constraints are determined according to the musculotendon dynamics for neural excitation u=0 and u=1. With tendon/muscle forces known, muscle activation and neural excitation can be backward determined with musculotendon model.

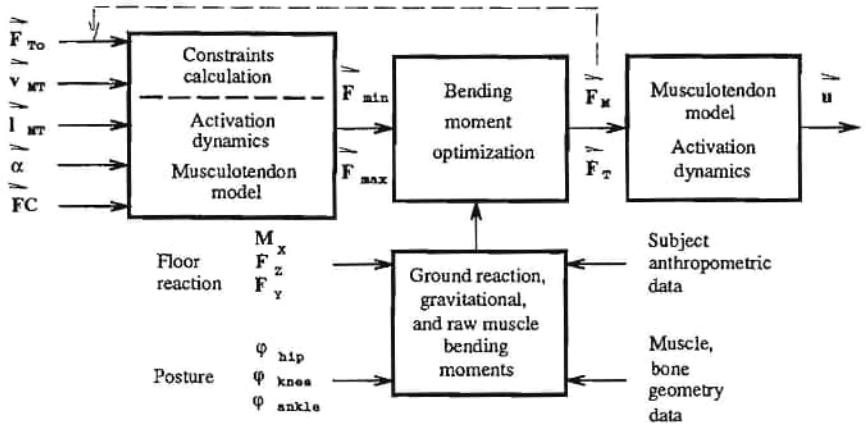


Figure 1

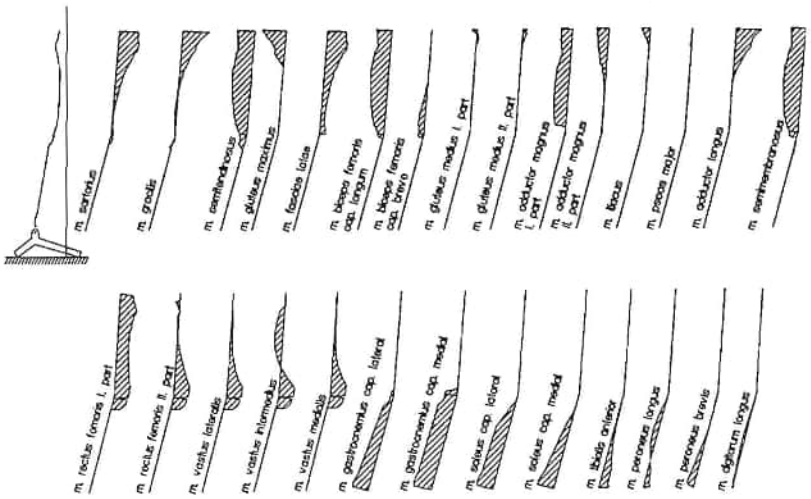


Figure 2

Ground reaction, gravitational and raw muscle bending moments: Anthropometric data including: segment lengths of foot, thigh, shank and body height and weight are needed. Posture of subject (hip, knee and ankle joint angles), floor reaction forces (anterior-posterior force F_y, vertical force F_z, and moment M_x) could be measured with different optical techniques and force plate. Muscle attachment coordinates together with femur and tibia bone geometry were measured on cadaver and were later scaled according to the measured person. The details of calculation technique for bending moments could be found in /14/. We should stress that here are calculated muscle bending moment levers (muscle bending profiles) together with M_{GR} and M_G.

Hill musculotendon model is shown in Figure 3 and 4. It is used for $\bar{F}_{min}$ and $\bar{F}_{max}$ calculation. Important definitions used in model are noted below, others are introduced later in text:

- $u(t)$ ... neural excitation
- $a(t)$ ... muscle activation
- α ... muscle pennation angle
- F_o ... maximum isometric active muscle force
- l_{Mo} ... muscle length at which F_o is developed
- l_s ... tendon slack length
- v_{max} ... maximum shortening velocity of CE
- FC ... percentage of muscle fast fiber
- $\tilde{F}_i=F_i/F_o$ ... normalized force in i-th element;

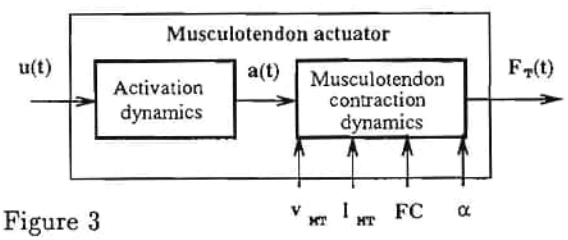
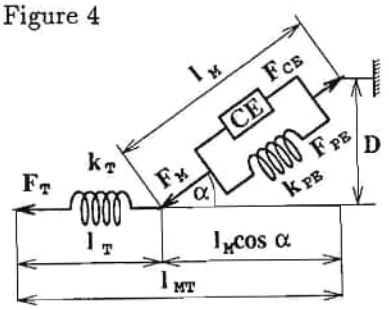


Figure 3

Figure 4



$\tilde{l}_i = l_i / l_{Mo}$ ... normalized i-th element length
$\tilde{v}_i = d\tilde{l}_i/dt = v_i / v_{max}$ ... dimensionless i-th element velocity
i = M, PE, CE
$\tilde{k}_{PE} = d\tilde{F}_{PE}/d\tilde{l}_{PE}$ ... normalized PE element stiffness
r_{ij} ... muscle levers in (i=hip, knee, ankle), j=muscle
F_{Tj} ... j-th tendon force
M_{Li} ... ligament moments in joints (i=hip, knee, ankle)
M_{Gi} ... sum of gravitational and ground reaction moments in (i=hip, knee, ankle)
$\mathbf{R}$ ... matrix (28 × 200) of muscle bending levers for 28 muscles, 100 femur and 100 tibia points
$\vec{M}_g$ ... sum of ground reaction and gravitational bending moments along femur and tibia bones

Central neural system excitation $u(t)$ acts through first order activation dynamics, generating internal muscle state called muscle activation $a(t)$. The Ca^{++} concentration presented by activation $a(t)$, triggers muscle cross-bridges through contraction dynamics and muscle force is developed. Activation dynamics is modeled as muscle-independent, single-input single-output (SISO) model /15/ with activation time constant 20 ms and deactivation time constant 200 ms.

The dimensionless musculotendon contraction dynamics includes properties of tendon, contractile element and passive element. Serial elasticity is neglected with little error according to /15/ in non-highly dynamic applications. All absolute parameters in model are scaled according to the l_M, v_{max} and F_o. Force-length relation $\tilde{F}_{CEa}(\tilde{l}_M, a)$ of CE with belly shape is modeled after /5/. Force-velocity is standard Hill relation, whose shape and v_{max} varies with muscle fiber composition. Hill relation itself is defined elsewhere /10/. Parallel elasticity greatly influences model output force and is defined as in /16/. Tendon is assumed to be elastic and linear with tendon strain $\epsilon_o = 0.033$ at $F_T = F_o$ (stress equal 32 MPa)/15/. With the following equations recognized from Figure 4:

$$\tilde{v}_{MT} = \tilde{v}_T + \tilde{v}_M \cos\alpha, \quad \tilde{l}_{PE} = \tilde{l}_M, \quad \tilde{F}_M = \tilde{F}_{CE} + \tilde{F}_{PE}, \quad \tilde{F}_T = \tilde{F}_M \cos\alpha \tag{1}$$

and

$$\frac{d\tilde{F}_{CE}}{dt} = \frac{d\tilde{F}_{CE}}{d\tilde{l}_M} \cdot \frac{d\tilde{l}_M}{dt} = \frac{d\tilde{F}_{CE}}{d\tilde{l}_M} \tilde{v}_{CE} \tag{2}$$

it can be found by combining equations (1), (2) that the contraction dynamics shown in Figure 4 becomes:

$$\frac{d\tilde{F}_T}{dt} = [\tilde{v}_{MT} + (\frac{d\tilde{F}_{CE}}{dl_M} \tilde{v}_{CE}) \frac{\cos\alpha}{\tilde{k}_{PE}}] \frac{\tilde{k}_T \tilde{k}_{PE}}{(\tilde{k}_{PE} + \tilde{k}_T \cos\alpha)} \tag{3}$$

This equation can be also written as:

$$\frac{d\tilde{F}_T}{dt} = f(\tilde{F}_T, \tilde{l}_{MT}, \tilde{v}_{MT}, a, \alpha, FC) \tag{4}$$

since

$$\tilde{k}_{PE} = f(\tilde{l}_M) = f_1(\tilde{F}_T, \tilde{l}_{MT}, \alpha), \qquad \tilde{k}_T = 1/(\epsilon_o \tilde{l}_s) \tag{5}$$

$$\tilde{v}_{CE} = f[\tilde{F}_{CE}/(\tilde{F}_{CEa}(\tilde{l}_M, a)), FC] = f_2(\tilde{F}_T, \tilde{l}_{MT}, a, \alpha, FC)$$

With minor differences this model is simplified version of more sophisticated models /5/ and similar to the more simple solutions /10, 15/.

Bending moment minimization procedure: The stress in the bone should be minimal, therefore, the solution of the model is optimal, when minimal value of norm:

$$\min \left\| \mathbf{R}\vec{F}_T - \vec{M}_g \right\| \tag{6}$$

is found, with additional constraints considered:

$$\vec{F}_{min} \le \vec{F}_T \le \vec{F}_{max} \tag{7}$$

$\vec{F}_{min} = f(\tilde{F}_T, \tilde{l}_{MT}, v_{MT}, a=0, \alpha, FC)$ lower margin calculated with musculotendon model
$\vec{F}_{max} = f(\tilde{F}_T, \tilde{l}_{MT}, v_{MT}, a=1, \alpha, FC)$ upper margin calculated with musculotendon model

$\vec{F}_{min}$ is frequently approximated with 0, which could at $l_M > l_{Mo}$ act as error source because of F_{PE}. In eq. (6) muscle action $\mathbf{R}\vec{F}_T$ compensates for ground reaction and gravitational moments $\vec{M}_g$. As some muscles are divided into two separate independent parts, the number of inequalities is doubled (to 56) according to the muscle number. Also, the following three additional equations (i = hip, knee, ankle) should be included:

$$\sum_{j=1}^{28} r_{ij} F_{Tj} + M_{Li} + M_{Gi} = 0 \qquad (8)$$

Muscle levers r_{ij} are determined according to the subject posture. The ligament moments in joints M_{Li} are most important in extreme joints positions and are calculated according to the published literature /5/. Least square error method with Kuhn-Tucker conditions /17/ is used for finding optimal constrained solution with all mentioned constraints and conditions included.

DISCUSSION

The optimization process with musculotendon model, described in this paper, can be used for determination of muscle activity during support phases of human locomotor activity. It is important also as possible generator of FES control sequences. The process is based on functional, natural and evolution criteria. Also the muscle synergism is prerequisite for minimal bone bending moment and optimal muscle force activity. For model realization there are needed numerical data about muscle properties, muscle attachments, femur and tibia bone geometry. Body posture and kinetic floor reactions should be measured for each selected posture. Included are nineteen lower extremity muscles relevant mainly for motion in the sagittal plane. Musculotendon model is divided into two separate parts: SISO first-order activation dynamics and musculotendon contraction dynamics. Because of simplicity the activation dynamics is muscle independent even if activation and deactivation time constants differ among muscles. Musculotendon contraction model has five scaling parameters: tendon slack length l_s, optimal muscle fiber length l_{Mo} and muscle force F_o (which do not appear in in the dimensionless dynamics) and two another: pennation α and muscle fast fiber composition FC which are passed to the dynamics.

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CONTROL PROPERTIES OF HUMAN LOWER LEG DYNAMIC SYSTEM

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SUMMARY

Spatial and temporal recruitment mechanisms are involved in muscle activity function generation, but their quantitative relations are still uncertain. The aim of the study was to determine the relationship between the frequency of motor units activation on the segment joint force output. N.femoralis was stimulated in 5 healthy children.The trains of supramaximal electrical pulses with controlled frequency had been applied (0.5-30 Hz). The knee joint isometric force at the ankle joint level was measured and expressed as a certain percentage of MVC. The force output understood as a result of quantum of stiffness composition was divided into constant (CF) and the variable (VF) part. Up to 3-4 Hz CF did not appear and the amplitude of VF was 20-30 % MVC.At the range of 3-25 Hz the CF was increasing and the amplitude of VF was decreasing. Above 25-30 Hz the saturation of CF (65-120 % MVC) was obtained and VF disappeared The range of frequencies which can be recommended in isometric task with controllable output is 15-25 Hz. In ballistic tasks the short lasting 30 Hz antagonistic bursts of activity can be used.

STATE OF THE ART

In voluntary activity the central nervous system regulates the muscles output by changing the number of motor units recruited (spatial recruitment)and by varying the individual motoneurones frequency of firing (temporal recruitment). It was shown that during increase in voluntary activity the frequency of motoneuron's firing increase in line with the number of motor units recruited (Milner-Brown H.S. et.al. 1973, Kukulka C.G. et.al. 1981). The other studies are confirming that the frequency mechanism is involved in the muscle strength gradation (Person R.S. et al. 1972). The quantitative relation between spatial and temporal recruitment order mechanisms are different in different muscles and it was hypothesised by Bigland B. et.al. 1954, Burke 1981 that the slower the muscle the lower is its tetanic fusion frequency. For the m.biceps brachii and m.adductor pollicis the value of this frequency is 30 Hz, and for m.soleus muscle 10.7 Hz (Bellemare F. et al. 1983) so the rules governing those features seem to be still unclear. The poor amplitude controllability of nerve electrical stimuli had led to the choice of muscle stimulation rather than the nerve. Especially that the linear-like dependence of the force output on the stimuli intensity has been demonstrated (e.g. Levy M.,et.al 1990). The aim of the study was to experimentally determine what is the role of temporal recruitment in the human lower leg segment force output generation .

MATERIAL AND METHOD

The stimulation electrodes were applied (with a force) manually over the stimulus point of nerve femoralis at inguinal fossa and the trains of square wave (0.2 ms width) at frequency range 0.5-30 Hz were applied. The lower leg in the pendulum position was attached to the strain-gauge beam (stiffness C of the beam was 790 N/m) at the ankle joint. The force signal was transformed in strain-gauge full bridge configuration CMT-83, amplified (Tektronix AM502) and fed to the after preamplifier input of the electromyograph Disa-1500. Monopolar, surface electrodes were attached over a skin projections of mm.vastus lateralis . The

EMG signal was fed to the Disa-1500 another channel to control the supramaximal value of stimuli. The maximal voluntary extension force (MVC) was measured and the force lower leg responses on electrical pulses were expressed as a certain percentage of MVC. The muscle force output in biological lever system was defined as a composite of force quantum in which above the certain level of frequency (fusion frequency) the constant composite of force (CF) and the variable composite of force (VF) may be separated. The quantum of force is defined as the average force reaction obtained with single supramaximal stimuli of nerve supplying the muscle in isometric condition (Ekiel J. et.al. 1983). The amplitudes of constant (CF) and variable (VF) force components were measured and plotted as a function of stimuli frequency in five healthy children aged 8 to 18 years.

RESULTS

The fusion frequency changes from 3.5 to 4.5 Hz and the tetanic fusion frequency changes from 25 to 30 Hz. Up 3.5 to 4.5 Hz (fusion frequency) constant force (CF) did not appear and the amplitude of variable force (force quantum) (VF) was 20-30 % MVC.The time of force quantum duration changes from 0.17 to 0.33 s. At the range of 3-25 Hz the CF was increasing and the amplitude of VF was decreasing. Above 25-30 Hz (tetanic fusion frequency) the saturation of CF (65-120 % MVC) was obtained and VF disappeared (Fig.1, Fig.2).

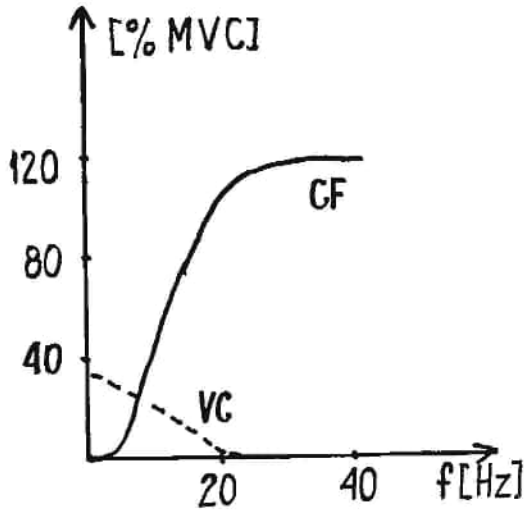

Fig. 1 The force output of m. vastus lateralis (% MVC) on different stimuli frequency (f)

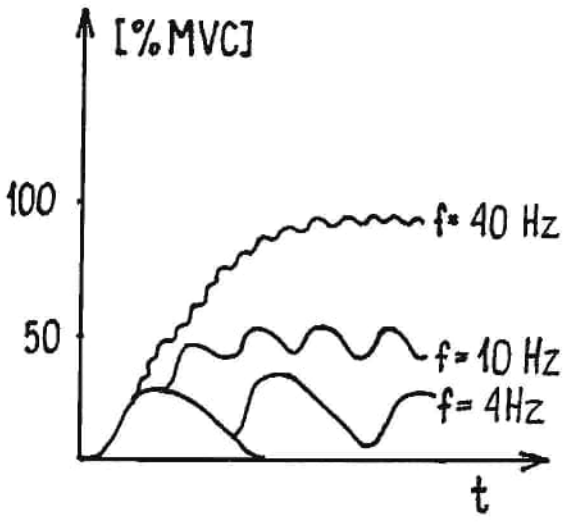

Fig. 2. The amplitude of constant (CF) and variable (VF) force composites as a function of stimuli frequency (f)

The amplitude of the constant force composite (CF) and variable force composite (VF) is determined by the frequency of stimulation (Table 1).

Frequency of stimulation [Hz]	CF [% MVC]	Vf [% MVC]
< 3.5 – 4 Hz	0	20 -30 f
from 3.5 Hz to 25 – 30 Hz	(4 f – 20)	(–2/3 f + 30)
> 25 – 30 Hz	60 – 120 %	< 1 %

Table 1. Sependence of force amplitude (% MVC) on frequency (F) of stimuli CF – constant force composite VF – variable force composite.

DISCUSSION

The fusion frequency obtained for m.vastus lateralis (3-5 Hz) is the frequency at which the fusion begins and it is similar to the values obtained for the m.adductor pollicis (3.8 Hz Ekiel J.et.al. 1983). The frequency of tetanic fusion (25-30 Hz) is in agree with values found for the m.biceps brachii and m.adductor pollicis (Bellemare F. et al. 1983, Ekiel J. et.al. 1983).That range of frequencies is usually used in FES (e.g. Levy M. et.al. 1990).

The relationship between the fusion, tetanic fusion frequency and the time duration of force quantum was found, but larger data sample is necessary to evaluate its statistical significance. The time of quantum duration does not seem to change in relation to child's stature.Its shape depends on the biomechanical properties of the segment,which are invariant properties of human growth (Lebiedowska 1990). There is no need to change the range of the stimulation parameters during human body growth.

At the range of frequencies 4.5 to 25-30 Hz the close to linear increase of constant force can be achieved with the presence of force variability. The linear-like dependence of the force output on the amplitude ,stimuli intensity has been also demonstrated (e.g. Levy M.et.al. 1990). Variability of force output obtained with frequency stimulation may be disadvantage in postural tasks ,but it is meaningless in changing position tasks. It seems that the utilization of amplitude and frequency combined stimulation should be investigated . Transition from one limb position to another can be better controlled with frequency than with the amplitude, but in the postural tasks the amplitude control seems to be better.To avoid fatigue in long lasting tasks different electrodes configuration might be applied. The volume of the active motor units could be change with the help of configuration variability. In ballistic tasks the antagonistic, short lasting trains of tetanic frequency stimuli should be used with amplitude scaling of velocity of movement.

The detailed understanding of physiology of neuronal recruitment across motor pools in the synergistic and the antagonistic activity is necessary to improve the supplementary neural control. The inhibition techniques should be developed in line with improving of stimulation techniques. The frequency stimulation is rarely used in the functional applications of stimulation although it seems that its influence on the output segment pattern is more important.

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PLASTICITY IN DENERVATED RAT EXTENSOR DIGITORUM LONGUS MUSCLE AFTER DIRECT LOW FREQUENCY ELECTRO STIMULATION

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Introduction:

It is well known that slow - twitching muscles become faster after high frequency stimulation. In this study we stimulated denervated fast - twitching extensor digitorum longus muscles (EDL) in the rat with a low frequency stimulation pattern. After denervation the EDL muscles were stimulated directly from 6 to 120 days. We used a 20 Hz stimulation pattern with 10 seconds bursts and 20 seconds rest. This pattern resembles the motor unit activity in the normal rat soleus muscle (Hennig and Lomo, 1985).

After stimulation time the EDL muscles were removed and snap frozen. Then serial cryo - sections were made. Fibre typing was carried out by incubating the serial cross sections with antibodies against myosin heavy chains obtained by courtesy of Prof. Schiaffino. For detecting degenerating and regenerating fibres we used an antibody against embryonic myosin provided by Prof. Schiaffino.

The morphological analysys was made with an computer assisted image analysing system (IBM PS2/80; SYSGRAPH). Finally for all of the muscles absolute counts of the number of muscle fibres were ascertained.

We detected a significant increase of oxidative metabolism even in fast - twitching glycolytic fibres within the first ten days of stimulation. After seven to nine weeks the transformation of the 2B fibres seemed to be complete because of the absence of positive fibres incubated with the antibody against type 2B myosin heavy chains (MHC). A lot of fibres containing two or three types of MHCs could be detected. After 93 days of stimulation the muscle contained 87% type 1 fibres, 1.5% type 2C fibres and 11.5 % type 2A fibres.

The number of degenerating fibres - detected by their content of embryonic myosin and centralisation of their nuclei - was always quite low (50 to 100 fibres) in the stimulated as well as in the denervated control muscles.

Materials and methods:

In 31 male rats the right EDL muscles were denervated and stimulation electrodes attached for direct muscle stimulation. The stimulation pattern was 20 Hz with 10 seconds bursts and 20 seconds rest according to the physiological motor unit activity in normal rat soleus muscles.

The stimulation was finished after 7, 10, 14, 20, 43, 50, 55, 62, 67, 79 and 93 days. The stimulated muscles were carefully removed and snap frozen in isopentane at -80^{o}C. Then serial cross - sections were made. Fibre typing was carried out by incubation with the following antibodies obtained by courtesy of Prof. Schiaffino:

BA-D5 for type 1 myosin
BA-71 for type 2A myosin

BF-35 staining all isomyosins instead of type 2X
BF-F3 for type 2B myosin
BA-G6 for embryonic myosin

Also the following staining techniques were used:

Hematoxilin/Eosin
NADH-TR representating the activity of oxidative enzymes
ATPase (pH 4,3)
ATPase (pH 10,4)
PAS for demonstration of glycogencontent in the muscle fibres
Van Gieson for assessment of the connective tissue

The cross sections were photographed and the single fibres compared with each other. Prior to fibre typing the absolute number of muscle fibres was ascertained.

Subsequently morphological analysys was performed with the aid of a computer assisted image analysing system (IBM PS2/SYSGRAPH).

Results:

Normal EDL muscles:

In average, the untreated EDLs consisted of 2.8% type 1, 23.3% type 2A, 29.1% type 2X and 44.8% type 2B fibres. A decrease in the relative amount of 2B fibres could be observed in the older rats, which is consistant with observations made by Prof. Schiaffino concerning the aging of muscles. The absolute number of muscle fibres varied much less extensively in the denervated and stimulated muscles. Probably, the standardized experimental treatment of these muscles inhibited a higher degree of heterogenety, wheras the innervated muscles more readily responded to the physical activity and condition of the rats.

Stimulated EDL muscles:

Within the first week to 10 days of stimulation all fibres - even the 2B fibres- became more reactive for NADH-TR. That means a multiplied attachment of mitochondria and a significant increase of oxidative metabolism even in glycolytic fibres. The 2X fibres start to produce 2A mysin (2AX - fibres). The 2B fibres selectively displayed a reduced diameter.

In the second week the average amount of 2A fibres increases from 22.8% to 73.1%. The number of 2B and 2X fibres was considerably reduced and 2A myosin could be detected in 2B fibres . The NADH-TR showed a uniformly staining.

In the third week only a few fibres contained solely 2B (8.02%) or 2X myosin (6.51%). In the sixth to nineth week the transformation of the 2B fibres was completed, the 2X fibres seemed significantly reduced (6.51%). Many fibres containing two or even three isomysins could be detected. There was also a significant increase in 2A fibres (up to 81.6%) and type 1 containing fibres (19.4%).

After more than eleven weeks of stimulation a massive shifting into type 1 fibres started. After 93 days of stimulation the stimulated EDL contained 87.05% type1, 1.48% type 2C and 11.47% type 2A fibres.

Denervated EDL muscles:

As a consequence of dedifferantiation fibres synthesizing more than one type of myosin (2C, 2AX) could be detected. Very likely, also type 2BX fibres occured, but they were difficult to identify with the applied techniques. The most remarkable increase particularly in the third week of denervation concerned the type 2A and 2AX fibres.

After two weeks of denervation a conspicious loss of 2B fibres started although this fibre type never vanished completely (7.7% after 124 days of denervation). Since the total amount of muscle fibres did not decrease significantly many 2B fibres suggestively started to produce another isomyosin, supposedly 2X and 2A. Despite the fact that the course of atrophy of 2B fibres was more pronounced in the first three weeks the mean diameter of the remaining 2B fibres in the long-time denervated muscles was still larger than the one of the 2AX fibres.

Mostly resistant to atrophy were the type 1 and type 2C fibres. There was a slight increase of fibres producing type 1 myosin.

Course of percentages of fibre types during denervation.

Degeneration and regeneration:

The number of regenerating fibres - detected by their content of embryonic myosin or/and centralisation of their nuclei - is always quite low (50 to 100 per muscle) in the stimulated as well as in the denervated muscles. In two stimulated muscles (WN08Dx and WN10DX) an area close to the surface which showed signs of inflammation, such as increase in nuclei and myophagia, contained some G6 positive fibres. The majotity of these fibres were also reactive fot type 1 myosin and some, particularly the larger ones, exhibited type 2B myosin. Hence, fibres containing three kinds of myosin (type 1, 2B and embryonic) could be detected. Since these triple reactive fibres are confined to a small and circumscribed area of the muscle cross sections cross reactivity of the antibodies, which would show a more scattered pattern of polyreactive fibres, hardly seems responsible for this phenomenon.

Some very small fibres in long-time denervated muscles exhibited a weak reactivity for embryonic myosin.

Conclusion:

Our results indicate that low frequncy high amount direct electro stimulation evoked full plasticity in 2B fibres. This hypothesis becomes likely because there is no significant loss in fibre counts in the stimulated EDLs. The majority of formerly 2B myosin expressing fibres remain, apart from a decrease of their diameters, unimpaired in the long - time stimulated muscles. Furthermore, the existence of 2B myosin does not nessessarily imply that this isomyosin is still expressed in the tonically stimulated muscle fibres. More likely these fibres started to produce another myosin type, while the degradation of the 2B myosin is still in progress. The selective 2B fibre atrophy as well as the absence of BF-F3 positive fibres after 6 to 7 weeks of stimulation also favour the degradation hypothesis. All myosin types, except for 2X, could be ascertained in BF-F3 reactive fibres.

According to the scheme of Dr. Gorza fibre transformation seems to be a step by step process, where the route 2B - 2X - 2A - 1 appears prevailingly in the conversion process.

Maybe some 2B fibres - see triple reactivity of fibres in WN10ED - might undergo dedifferentiation, as indicated by the production of embryonic myosin, and then start expressing immediately type 1 myosin in the course of redifferentiation.

The fact, that after 93 days of stimulation the EDL contains 87% type 1 fibres by lack of loss in fibre counts, we assume that it is possible to convert 2B into type 1 fibres by using a long - time, low frequency high amount direct electro stimulation.

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DYNAMIC PROPERTIES OF SKELETAL MUSCLES

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SUMMARY

Muscle dynamics were measured by means of two measurement systems. The first system is based on a mechanical brace constructed to record the isometric joint torque [1] and the second system is based on the detection of radial globulisation of the muscle belly due to muscle contraction [2]. Both measurements were done on the tibialis anterior muscle and simultaneously on the ankle joint. The same methods were also applied in measurements of the isometric hip extension that was realized by a strain gauge sensor and in globulisation of the muscle gluteus maximus with the help of magnetic displacement sensor. The results show significant differences in dynamic responses between healthy individuals and patients with an amputated side. A significant difference in the slope of the response was also obtained between records of patients with progressive muscular dystrophy and healthy people. For both muscle groups twelve healthy subjects were considered in order to establish the statistical patterns. These results are useful primarily as a reference for the selective evaluation of the changes of muscle characteristics due to various pathology [3,4].

The aim of the present study was to find a simple method for measuring the relative force and dynamic properties of musculus gluteus maximus. Musculus gluteus maximus is not important in normal walking but in above-knee amputees it remains the only uninterrupted hip extensor. It is also important for control of prosthesis [5].

MATERIAL AND METHOD

The method, which is widely used for measurement of muscle force is mechanical brace [4]. However, this method is restricted to measurement of moment produced by action of all muscles acting upon the joint in selected direction. Because we were interested only in the action of a single muscle the new method has been developed. This method is based upon measurement of radial displacement of muscle belly or muscle tendon. Displacement is measured with a magnetic sensor. The method is highly selective. The action of a single muscle within a given muscle group might be detected.

Experimental work

The study has two parts. In the first part the optimal position of the magnetic sensor on m. glut. max. was searched for. Seven points on the greatest gluteal muscle have been compared. The points were determined on the basis of their anatomical position. Fig. 1.

[1]ACKNOWLEDGMENT: The work was supported by the Ministry of Science and Technology of the Republic of Slovenia

Subject lies prone on the table and has been fixed with straps over the lower back and the measured thigh. Two elliptical self adhesive electrodes have been placed over the muscle belly.
The displacement of muscle belly has been measured at every point five times maximal voluntary contraction and five times at electrical stimulation with 3 seconds train of 0.2ms width electrical impulses at 30 Hz. The amplitudes were adjusted to 80 - 110V. At point No 1 the dynamic response of the muscle has also been measured. Twitch stimuli (1 ms) were applied in order to elicit twitch contraction and twitch responses were recorded by an analog recorder.

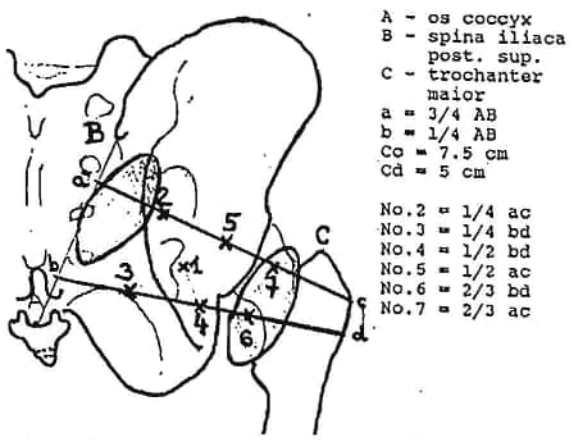

Figure 1: Anatomical positions of the measurement points and position of the electrodes.

From the records two time intervals and slope of record during the onset of contraction and maximal response were measured. The first time interval t_1 is the time from the twitch occurrence to the beginning of contraction. It is a delay of contraction. The second time interval t_2 is defined as the time between start and 90% of the maximal response occurrence, assigned as a peack occurence. The same measurement procedure was applied in the pretibial muscle group during the previous experiments [1].

The measurement was performed on left side of twelve healthy men age from 21 to 42, and on both sides of seven above-knee amputees. In comparing with healthy subjects on both sides of above-knee amputees statistically significantly smaller radial displacements of muscle belly - muscle contractions were observed.

RESULTS

According to the findings of the first part of the study, the point No. 2 in all further experiments was chosen.

In the second part of the study the relationship between radial displacement of the great gluteal muscle and isometric hip extension moment was observed. Both sides of 12 healthy men and three above-knee amputees were measured. Subject again lies prone but his legs has been in 20 degree of flexion in hip joints. Over the lower back he has been fixed with strap. The tight of person was fixed with plate which was connected by strain gauge sensors for measurement of extension moment. In healthy men it was positioned in the middle third of the tight and in amputees as distal on the stump as possible and on the symmetrical place on the healthy side. Radial displacement of muscle belly was measured in point No 2, Fig 1. The knee of the measured leg was flexed in 90 degrees.

Five maximal voluntary contraction and twice slowly rising voluntary contraction were measured. The dynamic properties of the great gluteal muscle was also observed.

The results show statistically significant difference in the time intervals t_1, t_2 and slope between healthy men and patients' amputated side. A significant difference is stated also with respect to the second time interval t_2 and slope between both sides of the amputees (healthy and amputated side), Fig. f3.

The greatest differences were in slope, which is the steepest for the healthy men and the least steep

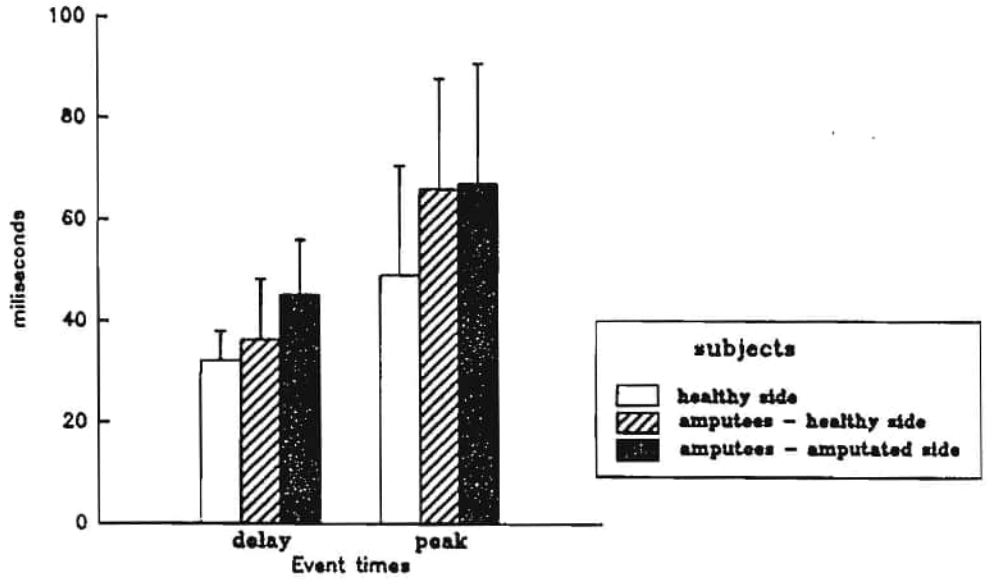

Figure 2: Dynamic characteristics of the skeletal muscles in healthy subjects and above-knee amputees were measured as a response on twitch stimuli (1 ms, 80-130 V). Two dynamic parameters were considered. The first is delay of the response and the second is the slope time interval of a record during the onset of the muscle contraction and 90% of the maximal response. Statistically significant differences between patterns are evident.

on the amputated side of the patients, what mean that the healthy muscle is the quickest and the muscle of the amputated side is the most slow.

In the second part of the study the linear relationship between isometric torque and radial displacement has been analyzed for both legs. The regression and confidence interval lines for both side are shown in Fig. 3. The confidence interval lines are 0.99% and the regression line of the left side is

$$T_l = 0.84\ d_l - 0.015.$$

The regression line of the right side is

$$T_r = 0.74\ d_r + 0.080,$$

where T_l, T_r are normalized torques and d_l, d_r are normalized displacement. The variability of the measurements is obtained due to anatomical and biomechanical differences between individuals.

Also statistically significant differences between dynamic properties of the muscle on right and left side were not observed.

DISCUSSION

The new method is simple, selective and suitable for following the state of muscles. The measurement system has been designed in order to objectify a muscle test. The disadvantage of the proposed method is that a muscle force can be approximately calculate from the statistically estimated regression lines. In contrary, the displacement method is useful for the measurement of a dynamic muscle properties, following their changes and evaluating the effects of various therapeutic methods.

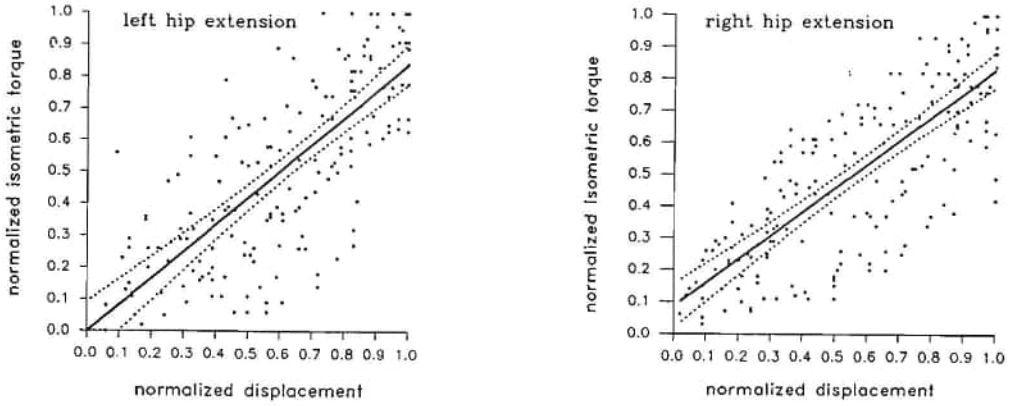

Figure 3: The regression and confidence interval lines of linear relationship between normalized isometric torque and normalized radial globulisation (displacement) of gluteus maxsimus in twelve healthy subjects.

The displacement method has not been tested on deeper laying skeletal muscles. In this particular case the method might be applicable if the sensor point is possible to position on a superficial laying tendon [1]. Recently, the whole measurement system has been extensively used in research projects for studies of above-knee amputation and patients with various plegias.

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THERAPEUTIC POTENTIAL OF FES IN IMPROVING HAND FUNCTION IN CHILDREN WITH CEREBRAL PALSY (1)

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SUMMARY

The research focused on employing functional electrical stimulation therapy to treat cerebral palsy in the distal, upper extremities. Three boys, aged 9, 12, and 15, participated in FES programs tailored to their individual needs for 14, 32, and 16 weeks, respectively. All three exhibited spastic hemiplegia, while one also showed signs of dystonia. Muscles targeted for stimulation with surface electrodes included the extensor carpi ulnaris, extensor pollicis longus and brevis, abductor pollicis brevis, and the digitorum superficialis and profundus. Periodic measurements of voluntary range of motion of the wrist and thumb, grip and lateral and palmer pinch strengths, and timed completions of dexterity tests developed for this research were made. An increase of over 35° in range of motion was seen in all three subjects. Two of the subjects developed the ability to produce a palmer pinching motion correctly. Times required to perform the dexterity tests fell over the course of the study by values ranging from 24% - 80%. Amelioration in the strengths assessed was contingent on the initial level of hand control. Overall improvement led to noticeably better everyday hand usage in two of the subjects. All three participants chose to continue to use FES, and favorable results are still being observed.

STATE OF THE ART

Promise of relief of spasticity and of effects which carry over after the removal of the stimulation seemingly point to a great potential for FES in treating cerebral palsy, a neuromotor deficiency manifesting itself in severe spasticity in a number of cases, as well as in difficulty with posture and voluntary movement. Yet, the number of studies conducted in this area is not large, and the conclusions drawn from the studies that have been performed are often quite conflicting.

The medical personnel in Ljubljana, Yugoslavia have applied FES to a considerable number of children with cerebral palsy. Already in 1974 Gracanin described the use of FES to improve gait in cerebral palsied children /1/. By 1981 peroneal and tibial nerve stimulation had been tried on approximately 250 children with improvement in gait observed in 200 cases /2/. However, researchers involved in some other studies have concluded that FES produces no effects in gait that carry over once the stimulation is turned off /3/. Previous work regarding the effects of neuromuscular stimulation on the upper extremities of cerebral palsy patients is scarce. The forerunner to this work was a case study conducted at OSU in which the subject's voluntary wrist extension increased by over 70° after 18 weeks of electrical excitation of the wrist extensors /4/.

1) Aided by a grant from the United Cerebral Palsy Associations

MATERIAL AND METHODS

Subjects

The original protocol for the clinical portion of this research called for a single case study of a boy with cerebral palsy. It was expanded to three case studies when two more cerebral palsy subjects became available four months after the first, ongoing subject had begun the FES program for this research. All three boys, M.E., D.S., and C.R., aged 9, 12, and 15, respectively, when they began participation, exhibited spastic hemiplegia. C.R. was also dystonic. Each attended his local, public school and was in the grade considered normal for his age.

FES Programs

Electrical stimulation was employed for 30-60 minutes per session and sessions were held on 5 days of every week. The electrical charge was provided by Respond II® stimulators from Medtronics and passed to the body via surface, carbon-rubber electrodes. The output waveform of the Respond II® is a monophasic, rectangular pulse of 300 μsec duration. Experimentation led to the selection of a 53 Hz pulse frequency. The treatment was conducted in the boys' homes under parental supervision. The participants were instructed to aid the FES in working specific muscle groups against applied resistances. D.S. underwent electrical excitation targeted for the extensors pollicis longus and brevis for 8 months and for the abductor pollicis brevis for 7 months in an effort to increase thumb function. Prior to the start of this study he had received FES of the wrist extensors for 18 weeks /3/; this therapy was continued for another 20 weeks as part of this research. C.R. experienced stimulation intended for his wrist extensors for 4 months, for his thumb extensors and abductors for 2.5 months, and for his flexor digitorum profundus and superficialis for 1.5 months in order to try to improve grasping and pinching motions. M.E. already had reasonable control of his thumb and fingers before beginning the program; the primary goal was to increase wrist extension. Thus, his extensor carpi ulnaris muscle was targeted for FES during the 3.5 months he received treatment.

Measurements

Measurements were taken once every two to three weeks. Only entirely voluntary performance was tested. The measurements were performed 3 - 24 hours after the stimulation therapy. Range of motion of the wrist and thumb were assessed with a goniometer. Grip strength was evaluated with a hand dynamometer and pinch strength was measured with a pinch gauge.

Tasks were developed as a basis for quantifying changes in hand dexterity. Multiple, timed trials were run for each task with both hands on every examination date. Performance of the tests required basic grasping and pinching motions: lifting cans, turning over playing cards, and picking up pens, coins, and balls.

Results

During the course of their programs all three subjects exhibited some amelioration as defined by improvement in some of the measurements described previously. D.S.'s voluntary range of thumb extension increased by 35° while the range of thumb abduction showed no improvement. His peak wrist extension in his involved limb increased until actually surpassing that of his uninvolved wrist. The advances in

thumb extension enabled D.S. to properly perform the palmer pinch. Figure 1 captures the gains D.S. made in control of thumb movement and pinch. Table 1 shows the decrease between the average time of the first two testing dates and that of the last two for the dexterity tests. Percent decreases with the involved hand were considerably greater than those with the uninvolved hand for 5 of the 6 tasks.
C.R.'s voluntary wrist extension increased by 89°. Grip strength of the involved hand rose 1000% due to the attainment of the abilities to extend his wrist to a more mechanically advantageous position and to curl his fingers when the wrist was extended. Lateral pinch force climbed from 3 to 7 lb. while palmer pinch strength rose from 2 to 7 lb. before falling back to 5 lb. Progress in manual dexterity enabled C.R. to switch from pinching with his first two fingers to pinching with his thumb and first two fingers. Improved dexterity resulted in the decreases in time to task completion as summarized in table 1. C.R. improved from not being able to pick up any of the coins in testing done early in the study to being able to retrieve all four coins in examinations conducted near the end of the study

M.E. was involved in the research for 3.5 months, during which he received FES of the extensor carpi ulnaris. Voluntary wrist extension increased 51° from 15° to 66°, as shown in figure 2. His supination seemed to improve as well; this greatly helped him in the test involving lifting the pens out of a box and into a cup.

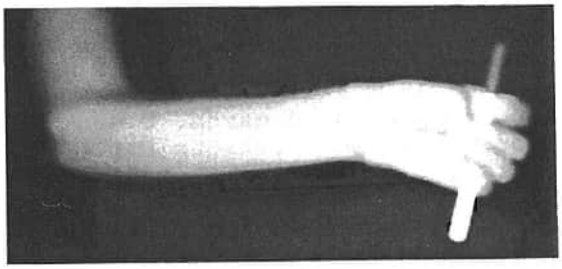
a)  b) 

Figure 1 D.S. picking up a pen a) 6/7 and b) 2/11

Table 1 % decrease in time to complete a task between the scores at the beginning and end of the study

Subject	Task	Involved Hand	Uninvolved Hand
D.S.	Pick up pens	53%	19%
	Pick up coins	80%	42%
	Lift lighter can	28%	42%
	Lift heavier can	55%	22%
	Turn over cards	45%	22%
	Pick up balls	31%	13%
C.R.	Pick up pens	30%	20%
	Pick up balls	43%	23%
M.E.	Pick up pens	70%	10%
	Pick up balls	27%	29%
	Pick up coins	24%	19%

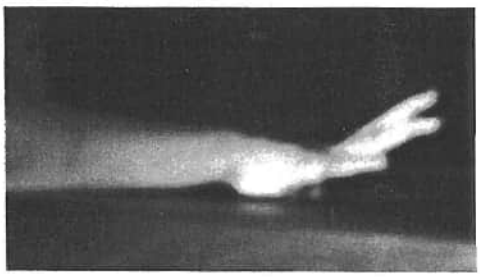
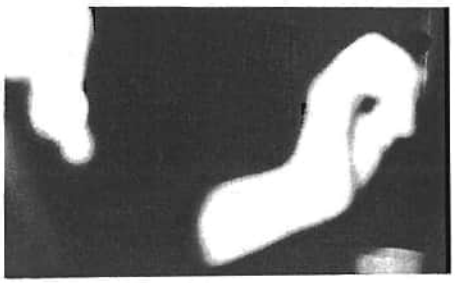
a)  b) 

Figure 2 M.E. peak wrist extension a)10/6 and b)2/1

DISCUSSION

Considerable improvement in volitional function in the upper extremity affected by CP was quantified in all three subjects during the course of their FES programs. Due to the encouraging results all three boys chose to continue their stimulation therapy beyond the end of this study.

Of course, amelioration in test performance may have resulted from the practice associated with repeating the tests over time. Advances may also have been due simply to renewed attention being paid to the affected limb. Yet, the boys' greater use and functionality of their involved hands in everyday life suggest actual physiological change.

It is difficult to determine exactly what physical changes led to the improvement in the three subjects. Hypertrophy of the muscles agonistic to a desired motion, reduction in the degree of spasticity of the muscles antagonistic to the movement, or better neural innervation of the agonist muscles may have facilitated voluntary function. This research did not differentiate the individual contributions of these three possibilities.

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SACRAL ROOT STIMULATION FOR BLADDER CONTROL; A STUDY BY COMPUTER MODELLING[1]

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SUMMARY

The sensitivity of excitation and blocking thresholds of nerve fibres within a sacral root to geometric and electric parameters in stimulating using a cuff electrode, have been simulated by a computer model. The model predicts that an asymmetrical tripolar cuff can generate unidirectional action potentials whilst blocking the large fibres bidirectionally. This shows that selective stimulation of the detrusor muscle may be possible without activating the urethral closure mechanism.

STATE OF THE ART

Functional electrical stimulation of the bladder can be used to restore its function in patients with serious neuropathic voiding disorders. Sacral root stimulation by implanted electrodes /1, 2/ has been most successful in bladder evacuation and is commonly used in case of intact efferent innervation of the detrusor muscle. We have morphologically investigated the sacral roots and they consist, among others, of small (~4μm) diameter fibres which innervate the detrusor and larger (~12μm) fibres innervating the urethral closure mechanism (external sphincter). This is confirmed by Schalow /3/. Since large fibres need a smaller stimulus for their excitation than small fibres, activation of the small fibres (detrusor) is preceded by activation of the larger ones (sphincter). Therefore bladder emptying by sacral root stimulation is always hindered by simultaneous contraction of the closure mechanism.

The solution to this is selective activation of the small fibres without involvement of the large ones by using an anodal block /4/. To achieve both excitation and blocking a tripolar cuff electrode can be used. The design of a cuff electrode however, still mainly relies on rules-of-thumb and improvements by animal testing. Few attempts (eg. /5/) have been made to analyze the behaviour of nerve fibres in a cuff and the influence of geometric and electrical parameters by modelling.

We developed a model to calculate the electric field generated by a tripolar cuff electrode and the responses of myelinated nerve fibres to this field. The effect of various geometric and electrical parameters which influence the behaviour was simulated. The optimal parameters to be used for sacral root stimulation, considering requirements as minimal dimensions and minimal current, were determined.

MATERIALS AND METHODS

Volume conductor

The model used to simulate the behaviour of nerve fibres in a cuff consists of two parts, a

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[1]This work was supported by the Dutch Kidney Foundation C90.1032

volume conductor and a model of a myelinated nerve fibre. The electric field generated by a cuff electrode was determined using a volume conductor, representing the geometry and electrical conductivity of a nerve root surrounded by cerebrospinal fluid and a cuff. The electric potential in the volume can be described by the Poisson equation. The volume conductor is rotation symmetric with the axis of the cuff electrode and nerve being equal to the symmetry axis of the model. Therefore Poisson's equation can be expressed in cylindrical coordinates (1). The right hand site of (1) expresses the current sources and resembles N infinitely thin ring contacts with current I_n and radius R_n.

$$\frac{\partial}{\partial r}\left(\sigma_r \frac{\partial u}{\partial r}\right) + \frac{\sigma_r}{r}\frac{\partial u}{\partial r} + \frac{\partial}{\partial z}\left(\sigma_z \frac{\partial u}{\partial z}\right) = -\sum_{n=1}^{N} \frac{I_n}{2\pi R_n}\delta(r-R_n, z-z_n) \qquad (1)$$

A numerical solution of (1) was found using the finite difference technique in a grid with variable spacing. The resulting set of linear equations has been solved using the (iterative) successive relaxation method.

Nerve fibre model

The nerve fibre model was adopted from McNeal /6/. McNeal modelled a myelinated frog nerve, but because the properties of myelinated mammalian nerve fibres differ from these of a frog we adapted the equations of the membrane kinetics according to Chiu /7/. With this model the responses of a 4μm fibre, representing the parasympathetic fibres (bladder wall) and a 12μm fibre representing the somatic fibres (sphincter) /3/, have been calculated.

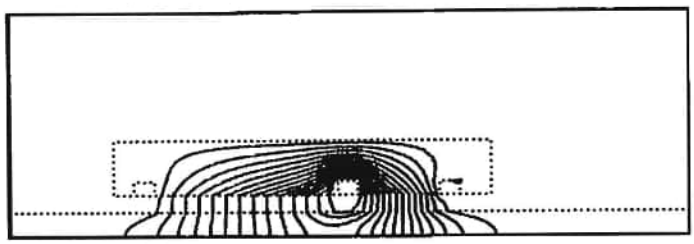

Figure 1: Isopotential lines computed in the volume conductor.

RESULTS

An example of the potential distribution generated by a modelled asymmetrical cuff electrode is shown in figure 1. At the lower boundary of the model (the axis) the isopotential lines are normal to this boundary, which means that no current crosses the symmetry axis of the model. Figure 2 shows the response of a 4μm fibre at the axis of the nerve bundle to the field shown in figure 1. It shows the deviation of membrane potential from its resting value at each node of Ranvier at several moments, after the initiation of a rectangular stimulus pulse (300μs). On top of the figure, the cuff with contact positions relatively to the nodes is shown. At increasing time there is successive depolarisation of nodes at the distal, but not at the proximal side, indicating a unidirectional propagating action potential. The hyperpolarization at the proximal anode is strong enough to arrest propagation, known as an anodal block.

With the model we simulated the influence of inner cuff diameter, contact separation, contact width, pulse duration and fibre position on the excitation and block thresholds. Only the infuence of contact spacing and inner cuffdiameter is presented below.

Relation between contact spacing and blocking threshold

The relation between blocking threshold and contact separation was calculated in a symmetrical cuff with a zero contact width. The response of a 4μm and a 12μm fibre was simulated at two positions, the axis and the border of the nerve bundle. A node of Ranvier was in the plane of

the blocking anode (symmetrical configuration so at both anodes the same behaviour will occur). The pulse duration was 700μs, being long enough to achieve a minimal block threshold. The results show that, with decreasing contact separation, the threshold of fibres at the axis of the bundle (fig. 3 b,d) does not change till approx. 3.5mm contact separation is reached. At smaller contact separations the thresholds increase sharply. The thresholds of fibres at the border of the bundle (fig. 3 a,b) do not change much if the contact separation decreases till 2mm. Also is shown that the threshold of a fibre with a given diameter is higher at the axis of the bundle than at its border. Further is shown the possibility to block all 12μm fibres without blocking any 4μm fibre when contact separation is beyond 2.1mm.

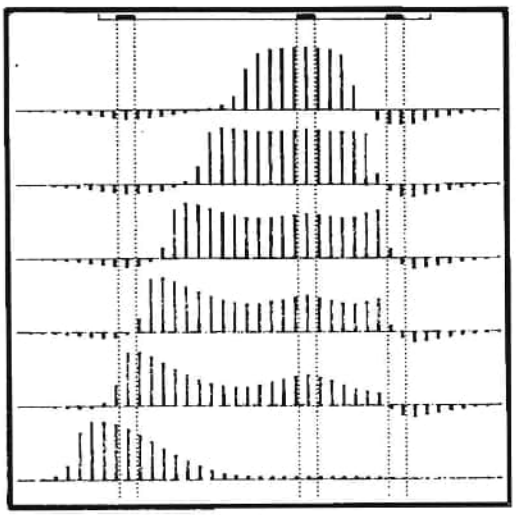

Figure 2: Response of 4μm fibre to field shown in fig. 1. With increasing time there is successive depolarisation of node to the left but not to the right.

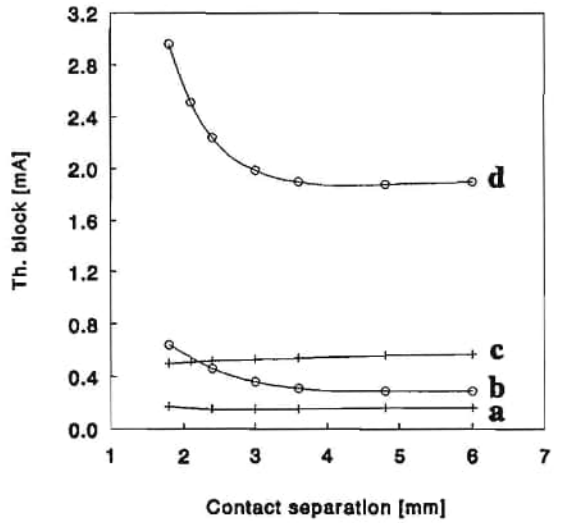

*Figure 3: Block threshold as a function of contact separation. Zero contact width, inner cuff diameter: 2mm, sacral root diameter: 1.4mm. **a**: 12μm fibre at border of nerve bundle, **b**: 12μm fibre at axis of nerve bundle, **c**: 4μm fibre at border of nerve bundle, **d**: 4μm fibre at axis of nerve bundle.*

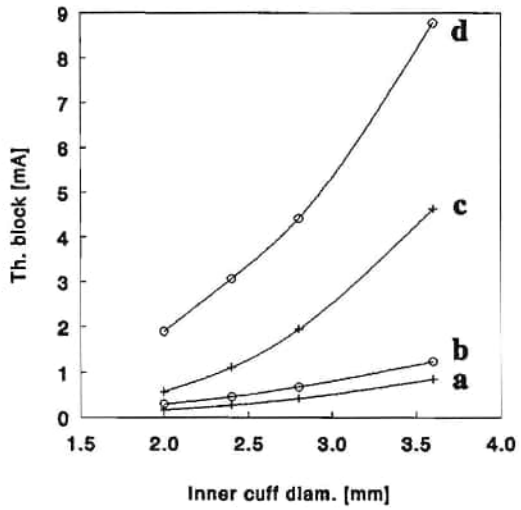

*Figure 4: Block threshold of function of inner cuff diameter. Zero contact width, contact separation: 6mm, sacral root diameter: 1.4mm. **a-d**: fibre positions, see fig. 3.*

Relation between inner cuff diameter and blocking threshold

The influence of inner cuff diameter on blocking threshold has been calculated for a fixed contact separation of 6mm. Figure 4 shows that thresholds increase with increasing inner cuff diameter. Over the whole range of diameters it is possible to block all 12μm fibres without

blocking any 4μm fibre. The selectivity ratio (Thresh. 4μm fibre at nerve border / Thresh. 12μm fibre at nerve axis) increases from 1.97 to 3.69 if the inner diameter increases from 2.0 to 3.6 mm.

DISCUSSION

The aim of this study was to determine the optimal geometric parameters for an tripolar cuff electrode to be used for sacral root stimulation. Therefore threshold currents for blocking of a 4μm and 12μm fibre were calculated. The found relation between threshold and contact spacing can be explained with the aid of activation functions. At a relative large contact spacing, the contacts can be considered as monopoles without interaction. At decreasing contact separation the activation functions start to overlap. The negative central lobe of the anode overlaps with the negative sidelobe of the cathode which enlarges the resulting peak and decreases the threshold. At a smaller separation the positive central lobe of the cathode overlaps with the central lobe of the anode which decreases the resulting peak and thus increases the block threshold. This overlapping of activation functions occurs for a fibre close to the contacts at smaller contact separation than for a fibre further away.

The model predicts that an asymmetrical tripolar cuff electrode can generate unidirectional action potentials in small nerve fibres whilst blocking the large fibres bidirectionally. This can be used for selective activation of the bladder wall without activating the closure mechanism. The results are tested in acute experiments on dog (see accompanying paper). When applying this new technique in patients, bladder emptying by sacral root stimulation will be improved because simultaneous contraction of the urethral closure mechanism will be reduced.

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SACRAL ROOT STIMULATION FOR BLADDER CONTROL; ACUTE EXPERIMENTS ON DOG[1]

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SUMMARY

In acute experiments on dogs, sacral roots have been stimulated using tripolar cuff electrodes. Recordings of bladder and urethral pressure have been made. Using 200μs wide rectangular pulses, contraction of bladder and urethral sphincter could be elicited. The threshold for initial sphincter contraction was 0.1mA. The threshold for initial bladder contraction varied between 0.3 and 0.6mA. Using 800μs wide rectangular pulses the thresholds for sphincter and bladder contraction were about the same but beyond the threshold for anodal blocking (0.4 - 1mA), a reduction in urethral pressure occurred. Blocking could be achieved with rectangular pulses, anodal break excitation did never occur.

STATE OF THE ART

Sacral ventral root stimulation, in combination with a dorsal rhizotomy, is used to regain control over the bladder in paraplegic patients /1/. However, stimulation of the ventral roots causes a simultaneous activation of the bladder and urethral sphincter /2/ which prohibits voiding. Several attempts have been made to overcome this problem.

The post-stimulus voiding technique /3/ takes advantage of differences in biomechanical characteristics of smooth and striated muscle. The contraction and relaxation timeconstants of the striated muscle of the sphincter are shorter than the smooth muscle of the detrusor. When stimulating by pulse trains this leads to a bladder pressure which is usually high enough to achieve voiding between the pulse trains. But this artificial micturition pattern often results in voiding in spurts and supranormal bladder pressures, possibly threatening the kidneys.

Another technique is to fatigue the sphincter by high frequency pulse trains above the threshold for somatic fibres (sphincter) but below the threshold for parasympathetic fibres (bladder) /4/. After this fatiguing burst, a stronger stimulus is given to activate the bladder. However, the exhaustion does not cause sphincter relaxation at or below prestimulus tone as is the case in physiological voiding so the problem of supranormal bladder pressures still exists.

Other techniques to reduce the outlet resistance involve a rhizotomy /5/ or an electric block /6/ of pudendal nerves which innervate the sphincter. The draw-back of these methods is the involvement of irreversible surgery or extra electrodes.

Because the sacral roots consist, among others, of small fibres which innervate the bladder wall and larger fibres innervating the urethral sphincter, the ultimate solution to get rid of the simultaneous sphincter contraction would be selective activation of the small fibres (bladder) in the sacral roots. Selective activation of small fibres has recently shown to be possible in peripheral nerves /7/.

With a computer model /8/ we determined the optimal parameters for a cuff electrode to be

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[1]This work was supported by the Dutch Kidney Foundation C90.1032

used for sacral root stimulation. Based on these modelling results, tripolar cuff electrodes have been developed and tested in acute experiments on dog.

MATERIALS AND METHODS

Ten female nonspinalized dogs (beagle) were given pentobarbital anestesia. A sacral laminectomy was performed, allowing for an exposure of the conus medularis. Individual nerves were identified using a bipolar hook electrode and cuff electrodes were placed around a complete sacral root (left and right) with good bladder response. Bladder and urethral pressure as well rectal pressure were recorded using microtip pressure sensors. In addition EMG was recorded with wire electrodes in a muscle of the tail and external urethral sphincter.

A cuff electrode (fig. 1) consists of an insulating silicone rubber tube. Inside the tube 3 ringshaped contacts made of nickel foil have been mounted. The presented preliminary results have been achieved using a symmetrical tripolar cuff electrode (inner cuff diameter: 1.5mm, contact separations: 5mm, contact width: 1mm). Stimulus parameters as current, pulsewidth and pulse frequency were all adjustable, using a special designed computer controlled stimulator which consisted of two independent current sources.

Monophasic current pulses without any charge balancing have been used to avoid the possibility of nerve excitation at the anodes during the reverse pulse.

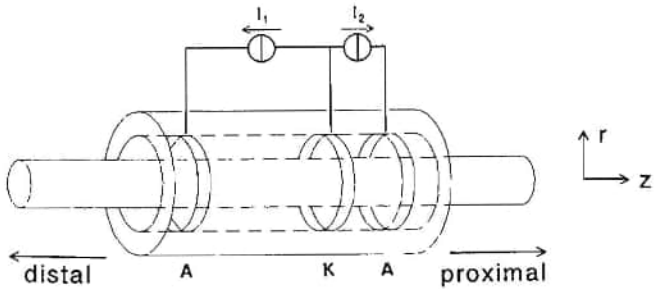

Figure 1: Tripolar cuff electrode connected to two independent current sources. ***A:*** *Anode,* ***K:*** *Cathode. Excitation of nerve fibres occurs at the cathode while blocking occurs at the anodes.*

RESULTS

Test stimulations with the hook electrode showed that in most dogs stimulation of S2 roots caused the best bladder response with simultaneous sphincter contraction. Occasionally separated innervation of bladder and sphincter was found with S2 and S3 innervating the bladder and sphincter respectively.

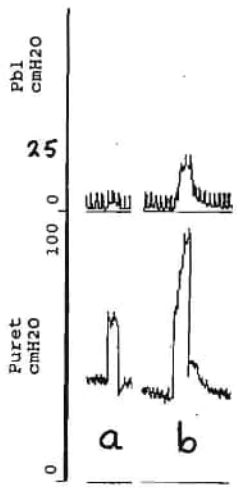

Figure 2: Pressure response of bladder and urethra to stimulation of sacral root S2-left. Stimulus frequence: 30Hz, pulswidth: 200μs, Cathodal current: ***a:*** *0.35mA,* ***b:*** *0.8mA. (4/6/92)*

Stimulation of sacral roots

Using rectangular pulses (pulsewidth: 200μs) contraction bladder and sphincter could be elicited. Figure 2 shows a typical stimulation induced pressure response of bladder and urethra. The stimulus threshold for sphincter contraction was 0.1mA while the threshold for an initial bladder contraction varied between 0.3 and 0.6mA. Beyond the threshold the response increases as more nerve fibres are recruited till a maximum pressure response is reached. Simultaneous with sphincter contraction, contraction of muscles in the hind leg and tail muscles occurred.

Blocking of large fibres

Selective activation of the small fibres has been achieved using 800μs wide rectangular pulses. When increasing the stimulus current the following events appear (fig. 3). First the urethral pressure rises when the threshold for somatic fibres is reached. At a higher current bladder contraction appears if the current exceeds the threshold for small parasympathetic fibres. With a further increase of the current, urethral pressure decreases when the current at the distal anode reaches the threshold for anodal block. When stimulating with 800μs pulses, thresholds for initial sphincter and bladder response are comparable with 200μs pulses.

The EMG-signals of tail muscles and urethral sphincter show the same behaviour. With increasing stimulus above the threshold for the motor fibres a increase in EMG amplitude was recorded as more motorunits are recruited. Above the threshold for anodal block, EMG amplitude decreases till it completely vanishes.

Threshold for blocking varied among the experiments between 0.4 and 1mA.

DISCUSSION

If stimulation takes place right after placing of the electrode, excitation of the nerve fibres can usually be performed without any problems. This is however not the case for blocking. We could never get any blocking effects immediate after the electrode placing. Even not if the cuffs were placed with great care and the fibres were excitable with low thresholds. Usually one or two hours after placement of the cuff's the blocking appears. The absence of blocking effects right after the electrode placing is probable due to nerve damage such as streching of the nerves. The intradural part of the sacral roots, from spinal cord to their exit through the dura, is approximately 2cm in dogs while the cuff electrodes had a lenght of 1.2cm. Therefore extreme caution is needed to place the electrodes with out inducing any mechanical damage.

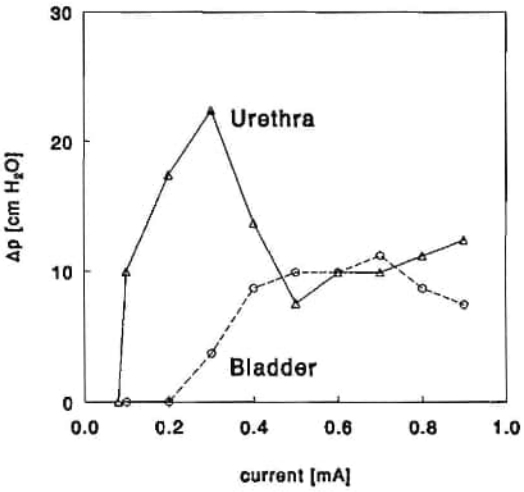

Figure 3: Pressure response of bladder and urethra as function of stimulus current. Pulswidth: 800μs, f: 30Hz (S2R, 7/5/92).

Anodal break excitation at the end of the rectangular pulses did not occur in our experiments. This is in contradiction with the literature concerning blocking of peripheral nerves (e.g. /9/) which stresses the necessity of a slow current decrease at the end of the pulse (0.2-1ms) to suppress anodal break. Only Brindley /10/ reports the occasional absence of anodal break when blocking the sacral roots. Since sacral roots have nearly no perineurium, this supports the idea that the perineurium connective tissue plays a key role in the generation of anodal

break /6/.

Measurements of EMG of the tail muscles and external urethral sphincter confirmed the absence of any muscle activity during the block. The urethral pressure during the block however is, although significant lower compared with ordinary stimulation, higher compared with the prestimulus pressure. This is caused partly by contraction of smooth muscle tissue of the urethra and partly by pressure transmission from the bladder.

The results show that urethral pressure can be reduced without affecting the bladder pressure by selective stimulation of the small fibres of the sacral roots. When applying this new technique in patients, bladder emptying by sacral root stimulation will be improved because the outlet resistance is largely reduced.

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AN IMPLANTABLE BLADDER MICROSTIMULATOR; PRELIMINARY RESULTS IN DOGS X)

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ABSTRACT

The purpose of this study is the design of a flexible neural stimulator which is intended to restore normal bladder functions to patients with neural disorders, especially spinal-cord injuries. The device consists of a hand-held controller which communicates data and energy transdermally via an inductive coupling stage to an implantable multichannel microstimulator.

The microstimulator is a fully programmable implant using a CMOS gate-array integrated circuit controlling 8 monopolar (or 4 bipolar) stimulation channels. In the experimental phase, we present the operative technique that enabled us to investigate the effect of early electrical stimulation of the bladder during the spinal shock phase in paraplegic dogs. In addition, using this stimulator we localized the save parameters of stimulation that give the best results in terms of effective bladder pressure and voiding a high volume of urine.

STATE OF THE ART

Urinary dysfunctions generally fall into one of two categories (or both): incontinence or retention. These dysfunctions may result from any neurological disorder or spinal-cord injury at the T12 level or higher /1, 3 /. Despite technological advances, progress up to now has not been satisfactory in either the electrostimulation domain or in surgical techniques. On the medical side, the exact mechanism of urinary control has still not been clearly identified, and, on the technical side, the majority of existing stimulators still present significant restrictions (insufficient output channels, too few programmable parameters, too small variety of stimuli and restricted external control of stimulation). We present a complete stimulation system with the following advantages: generation of a wide variety of stimuli, a high displacement tolerance of the radiofrequency-coupled device and an implantable prosthesis generating stimuli by 8 monopolar (or 4 bipolar) channels and monophasic (and/or biphasic) independent current pulses simultaneously /2/. The intensity, format and timing of the current pulses available at different channel outputs are fully programmable. These parameters are received transdermally by the implanted device via a simple binary signal modulating a 20 MHz carrier.

MATERIAL AND METHODS

The experimental miniaturized system described in this paper includes (Fig. 1):

• **A hand-held microcontroller (PEPU):** it has been developed to miniaturize the available controller based on an IBM-PC /2/. Its main characteristic is its low power consumption. In order to create a user-friendly stimulator, this pocket-sized external device is based on the MC68HC805C4 Motorola microcontroller, which contains a special full-custom integrated circuit (SHCOM) that is used to produce Manchester-coded words. This VLSI chip is composed of 24-bit data register and a 24-bit shift register to perform a serial data conversion. The Manchester code consists of 24-bit command words modulated onto the synchronization clock. PEPU is composed of a 20-key keyboard, a 16-character LCD, an RS232 line printer and a radiofrequency-coupled device. This controller is restricted to use by a physician who can fully program the implant.

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The PEPU also has two utility interfaces: a piezoelectric buzzer and a low-battery detector which is achieved by a voltage regulator. Another interesting feature included in this regulator is its capacity to shut down the output voltage of 11 volts when it is not required.

• **An implantable prosthesis:** it receives commands transdermally from the external controller. It is located on a circular, thick hybrid circuit, 2.2 cm in diameter, and includes the following main elements:

- An AM demodulator designed to recover the transmitted signal and communicate information to the chip.
- A voltage converter and regulator which uses the received carrier to power-on the whole hybrid.
- A CMOS 4-micron gate-array chip, which works as a microprocessor executing 24-bit command words at a transmission rate of 300 kbits per second. It contains a Manchester decoder which extracts the data and clock from the received digital signal. A 24-bit shift register receives the command word serially. A 21-bit data register keeps the command word for immediate processing. The command decoder transmits the valid data to the control units. The timer synchronizes the data flow among all the circuits. The output stage consists of a 6-bit digital-to-analog converter, a selector, a multiplexer, eight control units and eight current sources /2/.

• **A radiofrequency-coupled interface:** it is used to transmit an electromagnetic signal to the implant by inductive coupling. It encloses a 20 MHz AM modulator that produces a carrier, the amplitude of which is modulated by the incoming coded data (Manchester code). The resulting modulated carrier is then presented to a class D amplifier, the output of which is controlled by a power regulator to compensate for the variations in the coupling factor brought about by the displacement between the transmitting and receiving coils /2/.

• **A versatile software:** it is interactive and consists of a multifunction program, which allows the user to communicate the necessary information to the implant. It requires about 3.5 kbytes of assembler code and 150 bytes of RAM. The program must supply, in real time, the opcodes required to generate a fixed-amplitude train waveform, with adjustable duty cycle for both frequencies. The operator enters the various stimulation parameters via the keyboard with 10 basic functions, and can visualize the data with LCD. Also, the user has the capability to print the parameters via an RS232 line driver.

EXPERIMENTATION

In the experimental phase, in the Urology Research Laboratory at the Royal Victoria Hospital /1, 2/, 17 dogs have received implants. We have studied the effect of early electrical stimulation of the bladder during the spinal shock phase on the return of the detrusor activities. In order to investigate the model of spinal cord injuries, a dorsal laminactomy is performed at the T10 level (Fig. 2), where a spinal section renders the dog paraplegic. The animals are kept in specially designed bins. The implantation procedure is composed of the following steps /1/: a sacral laminactomy exposes the cauda equina with the upper sacral roots. In this region of the spinal canal, each sacral root nerve is identified and individually stimulated. The changes in the bladder and urethral pressures are observed during the stimulation of each root. The roots that give the highest intravesical pressure with (sometimes) the lowest intraurethral pressure are identified. The electrodes are wrapped around the selected nerves and connected to the implant which is located in a subcutaneous pouch on the animal's flank . In this case, the electrical stimulation was carried out at least twice a day, even during weekends and holidays. Immediately following the stimulation, the residual urine was measured by intermittent catheterisation.

RESULTS

The parameters of generated stimulus by the implant are highly correlated with the

theoretical data entered to the PEPU using the keyboard. The PEPU gave good results for frequencies in the 2 to 256 Hz range. Most of implanted stimulators are composed of two bipolar channels and all the stimulus consist of a train wave.

On the experimental side, prototypes were implanted many times in animals (dogs). After spinal section, the bladder capacity increased to reach at least twice as much as the normal capacity. The stimulation was done from the first post-operative day. This stimulation produced a maximum intravesical pressure ranged between 50 and 70 cmH_2O. After the first few weeks, the stimulation was carried out only twice a day, since the residual amounts were negligible. Many favorable results are obtained by stimulating the animals for 10-60 sec. Better voiding is obtained at a high-frequency signal of 60-200 Hz modulated by a low frequency of 1-2 Hz and a 0-3 mA current level. The detrusor activities, defined as spontaneous detrusor contraction, were demonstrated on the CMG, which was done within a mean of 1.3 +- 0.5 weeks. Most of the implanted prototypes remained in place for 7-10 months, were then removed and the animal was sacrificed. The electrode-tissue interface was extracted to examine the stimulation effect. Post-operative stimulation necessitated large amounts of charge which involved tail and legs movement. Five weeks after implantation, the charge quantity was reduced and the stimulation was completely tolerated by the animals.

DISCUSSION

The modalities of bladder stimulation can be divided into direct and indirect stimulation. Direct stimulation includes detrusor, transurethral, transrectal and transvaginal stimulation. The indirect modality included spinal cord, sacral nerves and pelvic nerves stimulation. Neurostimulation using electrodes implanted in the spinal cord did not cause complete evacuation. The results of direct detrusor muscle stimulation were not favorable because of tissue damage, fibrosis production and electrode movement during voiding. The indirect modality (or neural stimulation) has recently provided a method for managing the neurogenic bladder. The complexity of evacuation is due to the overlap between the detrusor and sphincter segmental neural representation. The stimulation of the ventral sacral roots (parasympathetic), accompanied by dorsal rhizotomy and somatic neurotomy, produced effective evacuation of the bladder /3 /. In our experiments, the stimulation of S1 resulted in an increase of urethral pressure and no change in bladder pressure. S2 stimulation increased bladder pressure of 50-70 cmH2O and not urethral pressure. Occasionally, individual stimulation of S3 produced effective bladder contraction /1/. The ongoing research of our team is geared to finding a means for fatiguing the sphincter following S2 stimulation for evacuation. This fatigue will be achieved by stimulating S1 roots and/or the pudendal nerves.

The data from the urodynamic studies has shown that early electric stimulation of the bladder shortened the time required for the recovery of detrusor activity during the spinal shock phase, less residual urine, decreased bladder capacity and complete voiding with neurostimulation. We have described a new urological miniaturized electrical stimulator. It is considered that this device with only minor modifications could be used in other neurostimulation applications. A much simpler external unit will be made available for use in patients . This unit, which is based on a read only memory (ROM), will be used to send preprogrammed commands to the implant.

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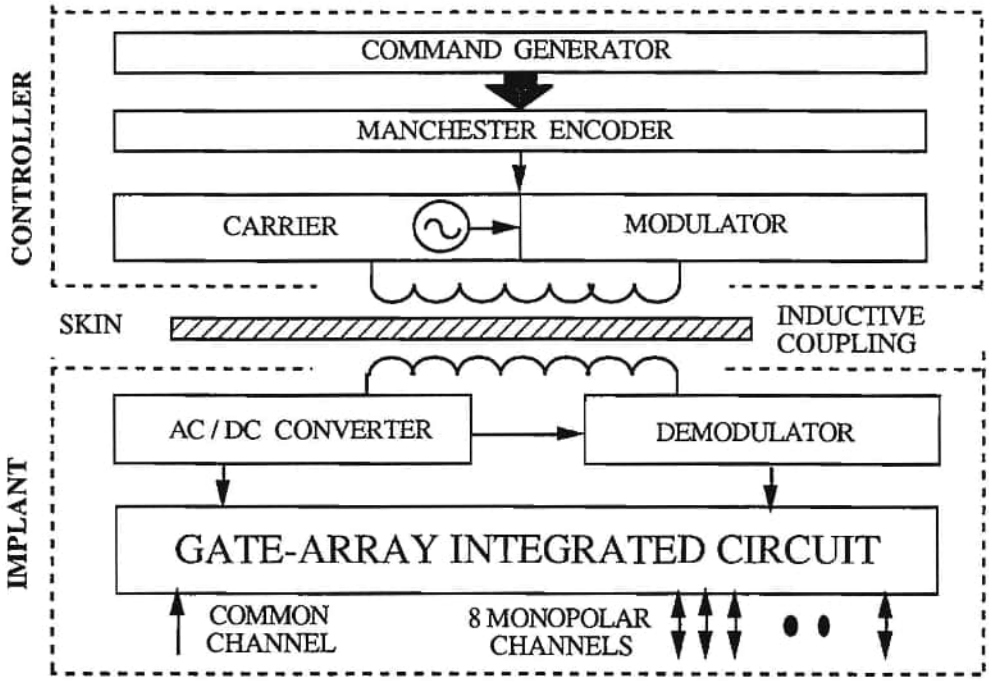

Figure 1: Physical arrangement of the bladder stimulator.

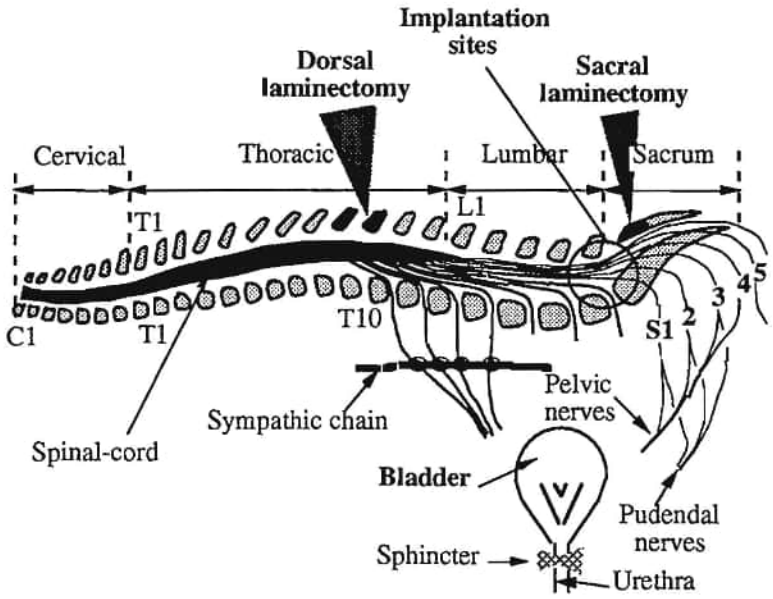

Figure 2: The Operative technique.

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BLADDER STIMULATION IN THE CANINE

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SUMMARY

A totally implantable Cordis stimulator was used to excite the neural vascular bundle of the gracilis muscle with an electrode which was sewn under the nerve at the muscle entry. Excellent contractions where noted at a pulse duration of 320 micro seconds with a current up to 10 milliamperes at a rate of 50 pulses per second. A surgical pedicle was designed to encircle the neck of the bladder. The muscle was appropriately trimmed and passed under the inguinal ligament and sutured in place. A fluid coupled Bard pediatric catheter was inserted into the bladder to determine urethral pressure as a function of applied current. Pressures up to approximately 100 centimeters of water were measured in contrast to pressures of approximately zero with the current turned off. The magnitude of pressure was also a function of fluid volume. Histologic specimens were taken of the muscle fibers which showed a mixture of slow-twitch, Type I and fast-twitch, Type II fibers. Contractions were observed up to four months following implantation.

STATE OF THE ART

Neurogenic bladder dysfunction is a major unresolved clinical problem. It may arise secondary to spinal cord injury, pelvic nerve damage, or due to trauma or surgery. Results can be excessive bladder distension resulting from outlet obstruction and metabolic disease such as diabetes mellitus. Detrusor arreflexia, a form of neurogenic bladder dysfunction is characterized by the inability of the detrusor muscle to generate a significant voiding contraction. Other groups of patients are those with external urinary sphincter dysfunction usually due to neurogenic spinal cord pathology trauma or atriogenic surgical etiologies. This problem is routinely characterized secondary to the inability to maintain incontinence. The patient often leaks either continuously or with various maneuvers. Because of these problems, considerable effort has been focused to the development of methods to electrically control micturation /2-4,6,8-11,25-29/. Although stimulation of the spinal cord is non-specific and often leads to undesirable responses /1,5,30/. Some variable clinical results have been reported /7,12-14,19-24,31/. Methods involved selective ablation of sacral nerve roots to prevent simultaneous activation of external urethral sphincter. Various electrical simulation has been advanced for intravaginal and intra-anal electrical stimulation /18/. Other nerve cuff systems are available for peripheral nerve stimulation /17/. Various electrode systems have also been used to stimulate the spinal cord directly /15,16/. Recent success has been reported with the use of the gracilis muscle for sphincter construction after abdominal peroneal resection /12/.

This study was directed to study the effects of stimulation of the gracilis muscle upon the neck of the bladder to ameliorate incontinence.

This research was supported in part by C.R. Bard Corporation, Atlanta, Georgia, the Department of Veterans Affairs Medical Center, and the Medical College of Wisconsin, Milwaukee, Wisconsin, U.S.A.

METHODS

Four mongrel canines were used in the study. All animals were anesthetized at surgical levels and mono-polar stimulation at a rate of 50 pulses per second with current level of 1 to 10 milliamperes was applied at a duration of 320 microseconds. A platinum disk electrode with silastic backing 5 mm in diameter was sutured over the neural vascular bundle of the gracilis muscle. The case of the implated stimulator provided a ground. A one cm diameter reference electrode was sutured at a distant point. A surgical pedicle was prepared and trimmed to encircle the neck of the bladder. The muscle was passed under the inguinal ligament and sutured in place. Histological samples of the muscle were taken. Approximately ten days later the animal was anesthetized and a Bard fluid-coupled catheter was inserted into the bladder to measure intraurethral pressures.

RESULTS

Stimulation with the totally implantable Cordis system provided palpable contractions of the gracilis muscle which were capable of markedly altering the urethral profile within the canine's bladder. Figures 1 and 2 show typical bladder profiles as a function of the applied currents approximately two to three weeks following implantation. The gracilis muscle appears to be the one of choice since it has the advantage of being sufficiently long for wrapping around the bladder neck with enough bulk to provide the force required for relief of incontinence. Several previous attempts in our laboratory utilizing the sartorius muscle were unsuccessful since the pedicle lacked the robustness of the gracilis muscle. Histologic studies in the laboratory have indicated conversion of muscle fibers from fast to slow after a continued period of stimulation of several weeks. Various electrodes such as straight wire intramuscular electrodes were difficult to implement and resulted in mechanical damage to the muscle and often were found to loosen from their implanted positions. Epimycel electrodes were also used, however, fluid build-up was observed and electrodes which wrapped around the nerves were also used, however, those were not successful. The greatest success was with the monopolar type platinum electrodes which were sewn onto the muscle in the region of the neural vascular bundle. Furthermore, the pedicle can be easily preserved. Also, two gracilis muscles can be used if required.

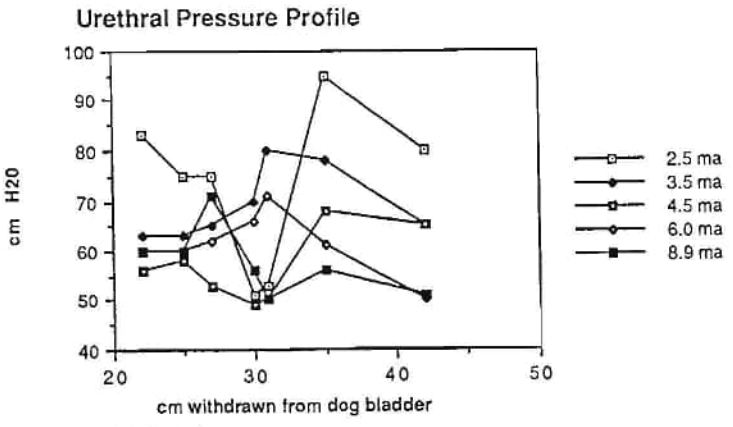

Figure 1.

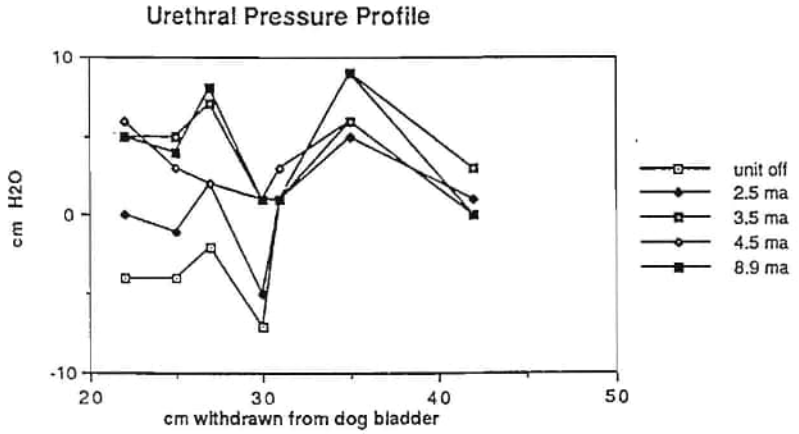

Figure 2.

DISCUSSION

In summary, these preliminary results suggest that a totally implantable stimulator can be used in the experimental animal for the management of urinary incontinence. Conversion of muscle fibers was observed. While an increase in urethral pressure was observed with this system, the long-term clinical affects have yet to be determined.

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TREATMENT OF URETHRAL AND DETRUSOR INSTABILITY WITH FUNCTIONAL ELECTRICAL STIMULATION

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SUMMARY

Electrical stimulation of the pelvic floor muscles in the form of acute maximal functional electrical stimulation (AMFES) is a very efficient method for treating micturition disturbances caused by detrusor or urethral instability.

AMFES is applied on the pelvic floor muscles with either vaginal or rectal electrode 20 minutes daily for 5 consecutive days. The intensity of the applied current should be 65 mA or more with a vaginal application, and 40 mA with a rectal one.

By using this method 86.4% of patients treated for urge incontinence were either completely cured or had essentially improved signs of urge incontinence or urgency.

79.5% of patients treated with AMFES for micturition disturbances due to urethral instability were completely cured or improved.

The method not having negative side effects is especially applicable in the treatment of elderly patients with micturition disturbances due to detrusor or urethral instability. Recurrency of micturition disturbances, found in 23% of patients, is efficiently treated with repeated AMFES application.

STATE OF THE ART

Urge incontinence and urgency are frequent micturition disturbances in females. From 14% to 30% of female population are estimated to experience these problems. The most frequent cause for urge incontinence and urgency is the instable bladder (detrusor). With regard to its origin the instable bladder is classified either as neurogenic, found in the patients with affected and injured central nervous system, and idiopathic (non neurogenic). The cause for the occurrence of the latter is unknown.

Urethral instability is in urodynamics defined by the International Continence Society as involuntary drop of intraurethral pressure at simultaneous absence of detrusor activity resulting in involuntary leaking of urine. In urodynamics urethral instability is referred to as oscillation of maximal pressure in the urethra, which is not synchronous with a heartbeat or respiration and is not related to the changes of intravesical pressure exceeding 15 cm H_2O. The defined critical limit of intraurethral oscillations, determining urethral instability, is 15 cm H_2O (1).

Micturition disturbances found in the patients with urethral instability are the following: mixed incontinence (stress and urge incontinence; 61.5%), urge incontinence and urgency (15.4%), frequency (10.3%), and genuine stress incontinence (12.8%) (2).

Dysuria, suprapubic pain and pain on catheterization are frequently observed in patients with urethral instability. The cause of urethral instability is a disturbance in the activity of smooth and striated urethral muscles. Urethral instability can be found in patients with meatal stenosis, and in patients with neurologic injuries of the central nervous system, demonstrated as vesico-urethral dyssinergia. Instable urethra with unclear etiology is classified as idiopathic.

Both disturbances, detrusor and urethral instability can be diagnosed and proved only urodynamically.

There exist numerous modes for treating idiopathic urge incontinence, urgency, and idiopathic urethral instability. Patients with urge incontinence and urgency are treated with re-education of the bladder (exercises, biofeedback, psychotherapy), with drug therapy, with functional electrical stimulation (FES), with dilatation of the bladder and with surgical methods.

In the treatment of micturition disturbances, caused by urethral instability, dilatation of the urethra, local application of estrogens and FES are used (4).

MATERIAL AND METHODS

In order to define the value of FES applied on the pelvic floor muscles 44 patients with urge incontinence and/or urgency, due to detrusor instability, were treated with FES.

FES was also applied in 39 patients with micturition disturbances due to urethral instability.

The tests for objectivization of urinary incontinence, i.e. tests for stress and urge incontinence, were performed in all the patients included in the study. All the patients underwent multi- channel urodynamic investigations enabling us to include only the patients with urodynamic parameters characteristic of detrusor or urethral instability. In the study were included the patients with urge incontinence and/or urgency who showed signs of motor urge incontinence. In these patients cystometry showed either spontaneous signs of the instable detrusor, or the signs of instable detrusor, which occurred during provocative tests on cystometry (listening to running water, putting hands in cold water, changing the position). The group of patients with motor urge incontinence consisted of 17 patients with clinical signs of urge incontinence and with the established urodynamic parameters of the spontaneous detrusor instability, and of 27 patients with the signs of detrusor instability occurring only on provocative tests. The group of patients with urethral instability consisted of 39 patients with micturition disturbances and urodynamic signs of urethral instability.

All the enrolled patients were treated with FES applied on the pelvic floor muscles.

The mode of action of functional electrical stimulation (FES) applied on the pelvic floor muscles

In previous studies we have already proved FES, applied on the pelvic floor muscles either vaginally or rectally, with the current of 35 mA, to stimulate only the contractions of the pelvic floor muscles. On the other hand, FES, applied on the pelvic floor muscles (vaginally or rectally), with the current of 65 mA or more, performs a double function, namely contractions of the pelvic floor muscles and relaxation (inhibition) of the detrusor. The current of 65 mA and more can be achieved by the application of a vaginal electrode. The same effect can be achieved with the application of a rectal electrode with the current of 40 mA (current over 40 mA applied rectally is painful). The treatment involves a single-channel application of a vaginal or rectal electrode. Simultaneous application of both electrodes is rare. In the majority of cases the changes of cystometric curve occur already during the FES application. Our latest findings clearly show that the changes of cystometric curve during the FES application do not necessarily ensure the successful outcome of treatment and its lasting effect. It has also been established that although in some patients the complete discontinuation or at least the reduction of detrusor's spasms does not occur during the stimulation itself, we cannot conclude that the outcome of treatment will be unsuccessful. In the patients not responding during the FES applications the successful outcome has frequently been observed only after the completed five FES applications. In these patients a long-lasting effect has often been observed.

Treatment with functional electrical stimulation (FES) performed at our Department

We use acute maximal functional electrical stimulation (AMFES) in the treatment of idiopathic urge incontinence and micturition disturbances due to urethral instability. For this kind of stimulation we use special stimulators that reach maximal current of 100 mA, applied through a vaginal or rectal electrode, on the pelvic floor muscles. The current is usually applied through one channel (vaginally or rectally). Its intensity is being increased gradually to achieve the limit of pain in 2-3 minutes. In cases where this limit is with a vaginally applied electrode under 65 mA, we achieve it in the following 2-3 minutes. The applied intensity (65 mA) is then maintained for 20 minutes. New stimulators maintain the set intensity automatically for 20 minutes, and also automatically regulate the intensity when the tissue resistance changes. In this way, by maintaining the same intensity of the current during the application, we have achieved markedly improved results. After 20 minutes of stimulation it is automatically disconnected. Such a stimulation is applied for five consecutive days.

Stimulation parameters:

stimulus: rectangular and biphasic, frequency: 20 Hz,
duration of impulse: 1 msec, current: over 65 mA,
stimulation duration: 20 minutes

RESULTS

Forty-four patients with urge incontinence, urodynamically proved as motor urge incontinence were treated with FES applied on the pelvic floor muscles. The patients had urodynamic signs of spontaneous detrusor instability or the signs of detrusor instability occurring only after provocation.

Table 1: Our results of treating idiopathic motor urge incontinence with AMFES

	Number of patients	%	
Cured	32	72.8	= 86.4
Improved	6	13.6	
Unchanged	6	13.6	
Total	44	100.0	

The patients were considered cured when no clinical signs of urge incontinence and/or urgency were encountered after treatment, with normal urodynamic parameters.

The group of improved patients after AMFES consisted of the patients without subjective or objective signs of urge incontinence and/or urgency, while the signs of spontaneous or provoked detrusor instability remained.

Table 2: Our results of treating micturition disturbances due to urethral instability with AMFES

	Number of patients	%	
Cured	22	56.4	= 79.5
Improved	9	23.1	
Unchanged	8	20.5	
Total	39	100.0	

The patients were considered cured, if after the fivefold FES application no clinical signs of micturition disturbances were found present, and urodynamic investigations showed normal urethral activity (no signs of urethral instability present). The patients were after treatment considered improved, if they did not experience micturition disturbances, while urodynamic investigations showed individual signs of urethral instability.

After the fivefold AMFES stimulation recurrency was notified in 23% of patients. The patients with detrusor and urethral instability were treated at a urodynamic laboratory. The treatment lasted 20 minutes daily (5 consecutive days). The essential characteristic of this treatment is the use of a stimulator that continuously maintains the set intensity regardless of the changes in tissue resistance. The patients with recurrency or even with frequently occurring recurrencies of idiopathic urge incontinence, and the patients with recurrent micturition disturbances related to urethral instability take their treatment (five days per week for 20 minutes a day) at home with smaller and less automatic stimulators. A two-day pause is recommended after the fifth day of stimulation. This kind of stimulation can arbitrarily be repeated.

DISCUSSION

Treatment with acute maximal functional stimulation (AMFES), applied on the pelvic floor muscles is simple and very efficient. Drug treatment of idiopathic urge incontinence is generally estimated to be successful in 60% of the treated patients. After the drug treatment has been terminated recurrency is established in almost 80%. Drug therapy has numerous contraindications due to the effects of the drugs used on the vegetative nervous system. These contraindications should be considered with a greater care in the treatment of elderly women. This fact is all the more important, since the incidence of urge incontinence increases with age and is most frequently found in women older than 70 years (2/3 of all incontinent women).

Micturition disturbances related to urethral instability are above all treated etiologically as the urethral syndrome, taking the cause of the urethral syndrome into account. The treatment involves dilatation of the urethra, massage of the urethra and periurethral glands, application of estrogens, and FES.

We consider only the patients with micturition disturbances and with proved urethral instability to have genuine urethral syndrome, most efficiently treated with FES. Schmidt (3) stimulates directly the sacral roots S3-S4 through foramina sacralia. Under the local anesthesia of subcutaneous tissue

he stabs the needle through foramina sacralia S3-S4, and with the needle stimulates the appropriate roots. When urodynamic changes or relaxation of the pelvic floor muscles are observed, he applies a wire-shaped electrode on the site. A patient can thereafter perform the stimulation herself for more days even at home. The results of this treatment of urethral instability are good.

At the University Department of Obstetrics and Gynecology in Ljubljana the patients with urethral instability are treated with FES applied on the pelvic floor muscles. The obtained results are better than the results of the drug therapy (parasympathicolytics or relaxants of the pelvic floor muscles). For the simplicity of the treatment with FES, and for its unharmful application in elderly patients, we consider FES the method of choice in the treatment of micturition disturbances having their pathophysiologic origin in either detrusor or urethral instability. No negative side effects have been encountered in electrical stimulation. AMFES is, however, not applied during menstruation and in pregnant women. The use of AMFES is contraindicated only in the patients with a pace-maker.

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COMPARISON OF ANAL MAXIMAL ELECTRICAL STIMULATION WITH ANAL PLUG INSERTION IN ENURETIC CHILDREN

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SUMMARY

Anal maximal electrical stimulation (MES) causes the clinical and urodynamic statistically significant improvement in the different types of enuresis comparing with the anal plug insertion itself.

STATE OF THE ART

Enuresis is one of the most common and harassing conditions in childhood. A variety of treatments has been used in the management of enuresis in children, including the enuresis alarm, tricyclic antidepressants, psychological treatment and vasopressin analogue.
MES turned out to be a successful method in treating urinary incontinence by activation of the closing musculature of the urethra and inhibition of premature bladder contractions /1/. The promising results were also obtained by MES in enuretic children /2,3/. Some authors, on the contrary believe that the improvement of incontinence after perineal MES would be the result of placebo effect /4/.
The aim of this study was to compare clinical and urodynamic effects of anal MES with anal plug insertion without stimulator in children with different types of enuresis.

PATIENTS AND METHODS

77 girls, average age 9,7 years (5 - 17 years), with persistent enuresis (39 nocturnal, 7 diurnal, 27 mixed nocturnal-diurnal enuresis) were treated with anal MES.
21 girls (6 - 14 years), average age 9,3 years used only anal plug without battery for one month. 8 girls had nocturnal enuresis, 1 diurnal and 12 mixed enuresis. They served as a control group.
Before treatment, a detailed history was obtained, a clinical examination made and a specimen of urine examined to exclude urinary infection. An organic cause for the enuresis was excluded with ultrasound of the urinary tract, micturition cystography and cystoscopy. Urodynamic measurements (cystometry) were performed before and after treatment.
77 girls were stimulated with electrical stimulator 20 minutes a day for one month. Anal plug electrodes were used for stimulation. Intensity of stimulation was being increased up to the level of tolerable discomfort, that was at the current ranging from 15 to 60 mA (average 30,5 mA). Electrical stimulator generated monophasic square current pulses of 1 ms duration and frequency of 20 Hz.
After the end of the treatment the children were controlled from 1 to 36 months (average 4,5 months).
The statistical method employed was the nonparametric Wilcoxon's matched pairs test and the statistical data package STATGRAPHICS STSC was used for data processing.
Methods, definitions and units conform to the standards recommended by the ICS /5/.

RESULTS

Out of the electrically stimulated group 23 girls were cured, 32 were improved by 50% or more and 18 enuretics noticed no improvement.
Out of the control group none of 21 girls were cured, 3 were improved and 18 didn't notice any changes.
The difference of subjective clinical improvement of enuresis between the stimulated and control group was therefore statistically significant ($p < 0,01$).
After anal MES the average number of nocturnal enuresis per month decreased from 14 to 6,5 ($p < 0,001$) and diurnal from 3 to 0 ($p < 0,001$).
In the control group no difference could be established in the number of nocturnal and diurnal enuresis after the use of anal plug.
After anal MES the statistically significant changes were established also in urodynamic parameters. The average maximal cystometric capacity of 73 enuretics increased from 250 to 288 ml ($p < 0,0001$), compliance increased from 11 to 19 ($p < 0,0001$), and the volume of the first contraction of detrusor from 180 to 235 ml ($p < 0,01$). The average number of uninhibited contractions of detrusor decreased from 2 to 0 ($p < 0,001$).
In the control group no significant changes in cystometry could be found.

DISCUSSION

From the results of our study it is possible to conclude that the improvement of enuresis after anal MES couldn't be the result of placebo effect of electrical stimulation.
The differences between subjective and objective clinical results of anal MES and anal plug are statistically significant.
The clinical improvement of enuresis after anal MES could be explained by the statistically significant urodynamic improvement of the lower urinary tract.
Our findings agree with the opinion of other authors that the increase of functional bladder capacity and improvement of cystometric curve are necessary for successful treatment of enuresis /2,6,7/.
Anal plug doesn't cause any significant changes of urodynamic parameters in enuretic children.
It is concluded that the anal MES is a valuable method of treatment in enuretics.

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ELECTROSTIMULATION OF ANORECTAL MUSCLE LAYERS

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SUMMARY

Main indication for electrostimulation of anorectal muscle layers are anorectal anomalies of the supralevator type. The indication is dependend on anorectal pressure studies, especially sector manometry, even in children younger than 1 year of age. Electrostimulation of the puborectalis sling is performed in children under the age of 4 years by bipolar microelectrodes connected to a pace maker. It is performed twice or three times a day. In children elder than 4 years of age a voluntary sphincter training is combined with electrostimulation by anal plaques individually adapted to the anal canal. This provides an increased contractility of the levator- and puborectalis muscles. In children under the age of 4 years in whom voluntary sphincter training is difficult, electrostimulation is an important way to improve muscle contractility. In elder children with partial continence endoultrasound of the rectum is combined with anorectal manometry in order to investigate the perirectal tissue. In case of perirectal scarformations an operative procedure is indicated to release the muscle layers. If muscle layers are present, but too weak, a combined active muscle training and an electrostimulation are indicated.
Sphincter training improves in the course of time partial incontinence significantly in children between the age of 10 - 15 years from 28,7% to 49,8% in children at the age of 15 years (12 children out of a series of 312. Electrostimulation is an important additional help. Since 1 year we have started with electrostimulation immediately after operation in newborns (n = 5) connecting the muscle layers intraoperatively with an electrostimulating ano-rectal pace maker being brought out of the abdominal skin for electrostimulation.

STATE OF THE ART

A survey of 464 children treated in our hospital and together with Mr. Nixon (GOS London) with anorectal anomalies demonstrated, that among 27 different types of anorectal anomalies the supralevator types have deficiencies of the perirectal muscle layers in approximately 55%. This concerns the levator muscle, the puborectalis muscle, the internal and the external sphincter.
These datas are the main indication for a sphincter training.
The sphincter in children can be devided in an active sphincter training and in a passive sphincter training. We have exercised an active sphincter training since 1972 in 349 children. Passive sphincter training using electrostimulation is an additional help, especially in small children, for an early sphincter training of perirectal muscle layers.

MATERIAL AND METHODS

Before sphincter training in all cases a very accurate continence grading is performed by the following methods: anorectal manometry, especially sector-manometry. This investigation is a very accurate information on the contractility of the puborectalis/levator sling, the external and intranal muscle layers and the reflex mechanism of the bowel. Functional endoscopy of the levator sling is a further important investigation to visualize the contractility of the perirectal muscle layers devided in a complete and incomplete closure of the rectum. The endoultrasound furthermore gives an important information of the localization of the perirectal muscle layers, the quantity and is an important information concerning scarformations being located around or inside the muscle tissue.

Having performed these routine functional tests of the anorectum the indication for a passive and active sphincter training is based on these investigations. If muscle elements are present sphincter training is indicated. Active sphincter training is performed by a volontary squeeze training three times a day over a period of 5 minutes. The active training of the perirectal muscle layers can be improved using anal tampons. These tampons are placed inside the rectum being distended by the elasticity of the anal tampon itself. The anal tampon consists of polyvenyl, being extremely compatible with the mucosa of the rectum and the anal canal. The spongy tampon is during active sphincter training, compressed by voluntary sphincter training. This sort of training, however, is difficult to be performed in children under the age of 4 years. In those children we have used the so called passive sphincter training. This sort of sphincter training enables contractility of muscle layers by electrostimulation of perirectal muscle layers. This training can be performed either by so called anal plaques individually adapted to the anal canal and being inserted inside the rectum like a hegar dilatator. This device is produced by IT System 100. This training is performed three times a day for 5 minutes. In newborn babies we have implanted bipolar microelectrodes from Med Tech (Art.Nr. 46002, LOT Nr. 210492/H0023/000) for electrostimulation (n = 5). In these children we have implanted immediately at the end of the perirectal reconstruction for anorectal anomalies these bipolar electrodes exactly at a puborectalis/levator sling being brought out at the lateral side of the abdomen for this sort of a electrostimulation.

RESULTS

Sphinctertraining has been performed in 349 children by active sphinctertraining over an 18 months interval of time, in 12 children over a 5 years interval of time, in 16 children with the endoanal plaque over a one year interval of time and in 5 children with electrostimulation in the newborn period after reconstruction of the anorectum for supralevator anorectal anomalies.

In the first group of 349 children contractility of the puborectalis and the levator sling have been improved from partial incontinence to the continence side in 76% after 18 months of active muscle training. The squeeze pressure in this group improved from 25mm to 220mHg. In 24% of these children an operation had to be performed because of scarformation around the rectum. The sphinctertrainng was combined with a toilet training and a sensory training of the anorectum.

In a group of 111 children at the age of 10 years having been operated for anorectal anomalies the continence rate from 28.7% improved by this training within 5 years to 49.8% (n=12 children).

In a group of 14 children who underwent the passive muscle training by endoanal plaques and electrostimulation within 12 months an improvement of muscle contractility checked by anorectal manometry could be documented by a 75% increase of muscle contractility. The group of the 5 newborn children undergoing electrostimulation immediately after operation is demonstrated by anorectal pressure studies performed in the first year of life.

DISCUSSION

Electrostimulation is an important help in the therapy of anal incontinence. Electrostimulation can be performed either in the neonatal period in order to activate weak muscle layers as early as possible for functional reasons or to stimulate muscle layers by endoanal plaques. This therapy has to be performed over a period of 3-5 years depending on the primary weakness of the muscle layers. An important additional help, however, is the active sphinctertraining (squeeze pressure training) three times using a day over 5 minutes anal tampons.

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IN SITU CONDITIONING OF THE LATISSIMUS DORSI MUSCLE FOR CARDIOMYOPLASTY BY MULTICHANNEL STIMULATION

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INTRODUCTION

Since its first successful clinical application in 1985 cardiomyoplasty has proved to be a useful procedure in the surgical treatment of chronic heart failure. In spite of an improvement in the patient's subjective state, the objective recording of improved physiological parameters has always been difficult. Data about the real effect of the chronically conditioned latissimus dorsi muscle in the whole procedure do not exist so far. The present study was done in order to develop an optimal protocol for the transformation of the sheep latissimus dorsi muscle into a fatigue resistant one by the means of chronic multichannel stimulation. Thus an in-situ model was designed to survey the changes in force and fatigue of the latissimus dorsi muscle during and after conditioning.

MATERIALS AND METHODS

Implanting procedure

In sheep the left latissimus dorsi muscle was dissected from the thoracic wall. A silicone balloon connected to a pressure transducing system was implanted between the thoracic wall and the muscle (Fig. 1). Four ring shaped stainless steel electrodes were sutured to the epineurium of the left thoracodorsal nerve. A silicone tube connected to the balloon for pressure monitoring and the electrode wires were led out percutaneously.

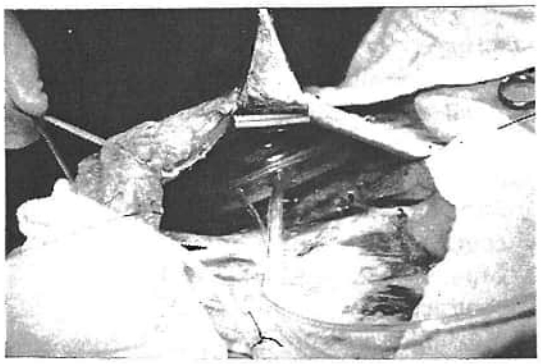

Figure 1

Muscle conditioning

Two weeks after implantation the conditioning programme was started. Muscle conditioning was performed by multichannel ("carrousel") burst stimulation of the thoracodorsal nerve using at least 6 combinations of electrodes. Stimulation parameters were: Burst stimulation, burst duration 330 ms, burst frequency 28,8 Hz, single impulse duration 540 μs. Stimulation thresholds (mA) were determined. The stimulation current was adapted to the respective thresholds.

We used the following stimulation protocol for conditioning of the muscle :

Phase 1: Carrousel-Stimulation with 10 contraction per minute starting with 10 min/hour work and 50 min/hour break. The periods of activity were adapted to the fatigue resistance of the muscle until 10 contractions per minute could be performed during 24 hours.

Phase 2: The frequency of contractions was increased from 10/min to 70/min adding each week 10 contractions per minute.

Phase 3: Stimulation was stopped for two weeks in order to simulate the break after a cardiomyoplasty procedure.

Phase 4: According to the fatigue resistance of the muscle, the frequency of contractions was once again inreased to 70/min for 24 hours per day.

Monitoring

While the conditioning programme was performed the silicone chamber was used to measure the following parameters every 2 weeks in the anaesthetized sheep:

- Stimulation threshold of different combinations of electrodes.
- Frequency of fusion into a tetanic contraction.
- Maximum pressure of different combinations produced in the ballon during supramaximal stimulation.
- Using the "strongest" combination the maximum tetanic pressure was determined for preloads between 15 and 90 mm Hg.
- A test of muscle fatigue using "Caroussell-Stimulation" was performed.

Final experiments

When the conditioning programme was finished electrodes were sutured to the contralateral, right thoracodorsal nerve, too. Both tendons of the latissimus dorsi muscle were fixed in a force transducing system. The following parameters were determined bilaterally:

- Maximum force of different combinations of electrodes during supramaximal stimulation.
- Using the "strongest" combination the maximum tetanic force was determined varying the preload between 0 and 50 Newton.
- Using the "strongest" combination of electrodes muscle fatigue after 2 minutes of single channel stimulation with 50 contractions/min was determined.
- Muscle fatigue after 15 minutes of multichannel (carrousel) stimulation performing 50 contractions/min was determined.

RESULTS

The maximal pressures which we observed in the balloon during burst stimulation at the time of the implanting procedure (preload 60 mm Hg) amounted to 121,3 mm Hg on the average. This value decreased to 110,5 mm Hg at the end of the programme, which means 9 % loss of pressure during the conditioning programme ($p=0,34$). **Figure 2** is representing a synopsis of muscle force in relation to the progress in muscle conditioning.

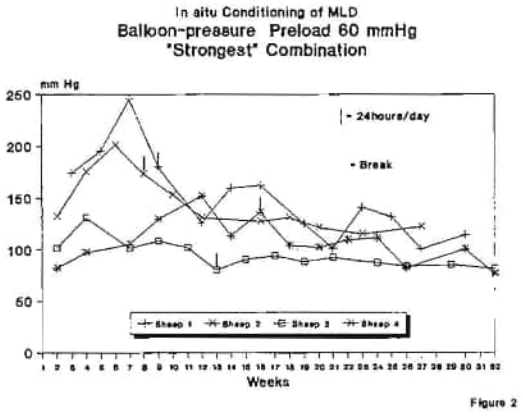

Figure 2

During the initial measurements 2 weeks after the implantation procedure muscle fa-

tigue occurred after 10 minutes of 10 contractions per minute. Thus the conditioning programme was started with 10 minutes "on" and 50 minutes "off" per hour.
The total duration of the programme was varied between 27 and 39 weeks. Within this range force and fatigue in different sheep did not depend markedly upon the duration of the conditioning programme.
Figure 3 is presenting an overview about the exact stimulation protocol in each animal. <*Abscissa:* Time period after balloon implantation in weeks. *Ordinate:* Progress in muscle conditioning. e.g.: 10/60=10 minutes "on" and 50 minutes "off" per hour, 10 contractions/minute. 70/min=70 contractions per minute during 24 hours.>

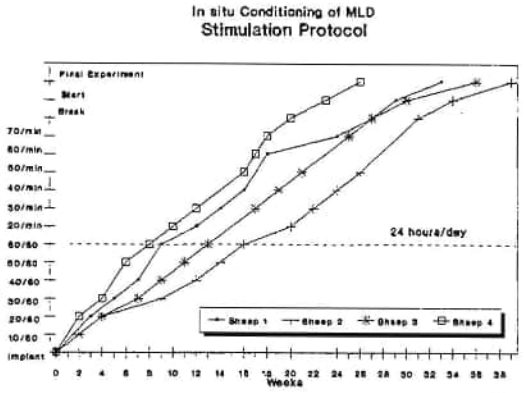

Figure 3

The average burst frequency, at which fusion into a tetanic contraction occurred, decreased during the conditioning programme from 48,8 Hz to 15,8 Hz.

Final experiments

Force
With a preload of 20 N using the "strongest" combination of electrodes the maximal tetanic tension at supramaximal stimulation amounted to 104,8 N on the average in the conditioned latissimus dorsi muscle. In the contralateral unconditioned muscle the corresponding value was 140,5 N on the average. (p=0,18). Thus the loss of strength caused by muscle conditioning was 25 %.

Fatigue
Marked differences between the unconditioned and the conditioned latissimus muscle concerning the muscle fatigue index during 2 minutes of *single channel* stimulation (50/min) were observed. In sheep 1 the maximum tetanic force of the conditioned muscle decreased to 84% after 2 minutes, in the unconditioned one we found a decrease to 40 % of the initial force.
During 15 minutes of *carrousel stimulation* performing 50 contractions per minute no significant decrease in force was observed in the conditioned left latissimus dorsi muscle, whereas in the unconditined right muscle distinct differences were found. In the right latissimus dorsi muscle of sheep 1 the maximal force decreased to 50 % after 1 min. 20 sec. and was 24 % of the initial one after 15 minutes of stimulation. Figure 4 summarizes the test of muscle fatigue during carrousel-stimulation in sheep 1.

DISCUSSION

The present study was successful in providing data about the changes, which are taking place in an electrically conditioned skeletal muscle. Our conditionig programme using multichannel "carrousel" stimulation was able to create a skeletal muscle which could contract 70 times per minute with complete fatigue resistance. Like the other research groups we found a decrease in force which amounted to 25% in our experiments. Nevertheless this decrease was lower than described for the application of some of the other conditioning programmes.
The monitoring of the progress in fatigue resistance by the silicone chamber prevented an overwork of the latissimus dorsi muscle. A period of 20 to 30 weeks may seem rather long for a useful conditioning programme. We believe, however, that a reduction of this time period will result in a pronounced loss of muscle force.
Even in the conditioned muscle we found a difference in fatigue resistance between

single- and multi-channel stimulation. Thus carrousel-stimulation has once again proved to be a very important factor for reducing muscle fatigue.

Although the final outcome of cardiomyoplasty depends on a lot of different factors like optimal positioning of the muscle around the heart by the surgeon, the conditioning programme proposed in the present study can be of great help in optimizing the results of this surgical technique.

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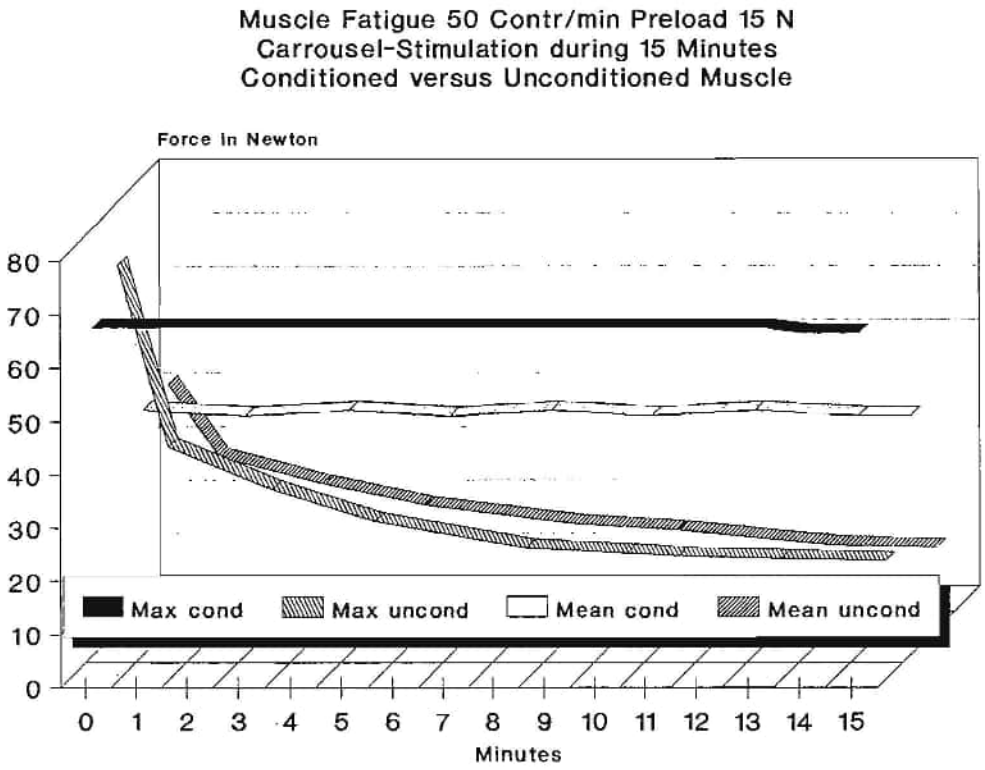

Sheep 1 Figure 4

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LOW FREQUENCY ELECTROSTIMULATION TO ALLOW EARLY POST-OPERATIVE LATISSIMUS DORSI CARDIAC SUPPORT

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SUMMARY

In our laboratory we evaluated the possibility to adopt a new stimulation protocol following Dynamic Cardiomyoplasty (DC). In order to avoid potential muscle damage as well as displacement from the wrapping position a low pacing frequency was performed from day 1 after surgery. The effects of this new stimulation pattern were observed in short and long-term studies. No wrapped Latissimus Dorsi (LD) muscle damage occurred. Original wrapping location was maintained and effective LD cardiac support was documented. Therefore we conclude that using a prudent stimulation protocol early post-op LD conditioning and related cardiac assistance is feasible.

STATE OF THE ART

Because of collateral vessel severance during LD mobilization a two-week rest period is currently adopted following DC before starting wrapped muscle conditioning. This time allows, moreover, adhesion formation occurrence at the intermuscular level. Mannion and co-workers previously showed the importance of such a recovery period since an eraly stimulation would cause muscle ischemia and eventually muscle necrosis (1). Anyhow no study was performed in an attempt to test an early post-op LD stimulation using a low pacing frequency in order to prevent muscle dislocation and damage, concomitantly aiming at slight cardiac support soon after surgery.

MATERIAL AND METHODS

Twelve goats were submitted to a new stimulation protocol following DC. The surgical procedure entailed a counterclockwise wrapping technique.
Seven goats (group A) underwent a short-term evaluation (2 weeks) in order to timely detect any wrapped muscle graft damage or displacement. The LD electrostimulation was started from day 1 after surgery. The stimulation patterns included a pacing frequency of 10 Hz (2 pulses per burst), a pulse amplitude of 5 Vs, a burst duration of 185 msec, and a heart/LD contraction ratio of 2:1 or 3:1 according to the heart rate.
Five animals (group B) were submitted to chronic assessment (4 - 6 months). DC procedure was the same as in group A and the post-op LD pacing was started always on day 1 following the surgical intervention. The stimulation protocol entailed a 10 Hz pacing frequency for the first 2 weeks, 15 HZ for the 3rd and the 4th weeks and 30 Hz (5 - 6 pulses) thereafter achieving a fully transformed left LD.
Both groups underwent extensive hemodynamic, macroscopic and histological evaluation. At sacrifice left ventricular pressure and dP/dt were recorded by a Millar catheter positioned through the right carotid artery. The aortic pressure was obtained by placing a pressure catheter juat above the aortic valve plane from a femoral artery. The right ventricular pressure data were obtained from a catheter introduced from the ri-

ght internal jugular vein. In both groups all the registered data were obtained at normal heart function.
Following hemodynamic recording all the animals were carefully analysed after sacrifice to observe macroscopically whether any sign of muscle damage were present. Attention was paid at the LD wrapping position to document any dislocation, even if partial.
Histological evaluation was carried out to assess muscle fiber transformation, muscle structure after early stimulation and intermuscular fixation.

RESULTS

Group A animals, after 2 weeks, did not show any wrapped muscle damage nor displacement despite early post-op LD stimulation.
At hemodynamic evaluation a slight cardiac assistance was furthermore observed (Right ventricular pressure increased from 26±6 mmHg to 30±8 mmHg -p=0.014) despite the very low pacing frequency and the related negligible muscle force produced.
At gross evaluation all the wrapped LD muscle grafts were still well positioned and no major evidences of muscle derangement or necrosis induced by early pacing were detected.
Group B animals confirmed hemodynamic improvent due to LD contraction (LVP improved from 111±21 mmHg to 119±18 mmHg - p=0.013 - RVP from 33±7 mmHg to 39±9 mmHg - p=0.043 - and AoP from 116±16 mmHg to 123±15 mmHg - p=0.003). Even in this group no wrapped muscle dislocation nor necrosis were found. Histology documented some degree of fatty tissue infiltration and complete muscle fiber transformation (type I fibers). Optimal intermuscular adhesion was observed in all animals.

DISCUSSION

The current post-op conditioning protocol allows the mobilized LD to rest from the surgical stress and to enhance collateral vessel re-growth (2). In this period needed intermuscolar adhesions would form to get proper LD/heart contact and related optimal functional relationship. Any how the uncontractile state of the wrapped LD may induce some adverse effects. The muscle structure may be deranged because of muscle immobility. The already unstable heart may be furthermore impaired by such an uncontractile burden leading to dangerous hemodynamic deterioration. Therefore an anticipated post-op LD stimulation would be desirable, taking into consideration to prevent muscle displacement and to avoid muscle graft ischemia.
These preliminaries let us test a new stimulation protocol respective of the potential damage to the mobilized muscle but aiming at an early cardiac support.
A low pacing frequency was then adopted and a short-term study was carried out in order to document whether this new stimulation pattern were not harmful to the wrapped LD.
No major muscle damage was reported and optimal wrapping position was retained.
These results prompt us to use the same early post-op LD stimulation at long-term achieving a fully trained muscle graft. Even the chronic evaluation confirmed early stimulation feasibility. Effective cardiac support was documented and perfectly viable muscles were found confirming the safety of such a new stimulation protocol.
Further studies are required to compare hemodynamic and histological results obtained with such a pacing pattern with the traditional stimulation protocol.

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SKELETAL MUSCLE VENTRICLE: MUSCLE-POWERED COUNTERPULSATOR PLACED INTRATHORACICALLY AND CONNECTED TO THE SYSTEMIC CIRCULATION USING A VALVED GRAFT

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SUMMARY

In considering the future application of skeletal muscle ventricles (SMVs) for use in humans, we developed a new configuration for SMVs in circulation, where the SMV was placed intrathoracically and connected to the descending aorta using a non-valved afferent and a valved efferent conduit. A dog with this configuration of the SMV survived for seven months, and the SMV pumped blood effectively. When compared with our previous extrathoracic SMV configurations, this study suggests that this new configuration has advantages in chronic hemodynamic and histological findings.

STATE OF THE ART

We have reported the effectiveness of SMV diastolic counterpulsators in circulation from several weeks to more than two years.[1-4] In these canine models, SMVs were positioned extrathoracically and connected to the descending aorta using non-valved conduits. If SMVs were to be used in humans with our previous configuration, the SMV would be placed on the left antero-lateral chest wall subcutaneously. However, this position would not only be unsightly, but would also increase the risk of compression or trauma to the SMV. Additionally, our previous work suggested that SMV filling occurs from both the proximal and distal aorta which results in a decreased degree of pre-systolic unloading and efficiency in the distal arteries.[1] Therefore, when considering the possible clinical use of SMVs, this configuration was changed, placing the SMV intrathoracically and connecting it to the descending aorta using a non-valved afferent conduit and a valved efferent conduit to prevent reversal of flow in the distal aorta during SMV filling. A dog that had this SMV configuration lived for seven months and its SMV pumped blood effectively in the circulation during that time. This report describes this new configuration, and the hemodynamic effects and histological findings of the SMV in that animal.

MATERIALS AND METHODS

An adult beagle weighing 10.5 kg was operated upon. Through a left flank incision, the left latissimus dorsi muscle was mobilized from the chest wall on its neurovascular pedicle. A bipolar cuff electrode (model 4080, Medtronic) was placed around the left thoracodorsal nerve. The muscle was then wrapped around a cone-shaped mandrel with a volume of 30 ml. The SMV was placed intra-thoracically, following partial resection of the left third rib. A pulse generator (model 7420, Medtronic) was connected to the nerve electrode and placed under the rectus abdominis muscle. The wound was closed in layers.

After a three-week vascular delay period, the pulse generator was activated to deliver 2 Hz continuous stimulation of 210 μsec pulse duration and 1.5 V amplitude. This was continued for six weeks.

Following the period of conditioning, a left thoracotomy was performed. The base of the SMV was exposed to allow removal of the mandrel. The afferent conduit, a 14 mm PTFE vascular graft (Gore-

Tex, WL Gore & Associates) was anastomosed between the descending aorta immediately distal to the left subclavian artery and the SMV. The efferent conduit was a canine ascending aorta homograft with the aortic valve. It was connected between the SMV and the more distal portion of the descending aorta. The homograft was obtained from a mongrel dog before the second operation and stored in saline with cefazolin at 4°C. Two sensing leads (model 6917A-35T, Medtronic) were placed on the left ventricle. The pulse generator was replaced with a rate-responsive synchronized pulse train stimulator (model 6100, Prometheus™, Medtronic) and this was connected to the nerve lead and cardiac sensing leads (Fig. 1).

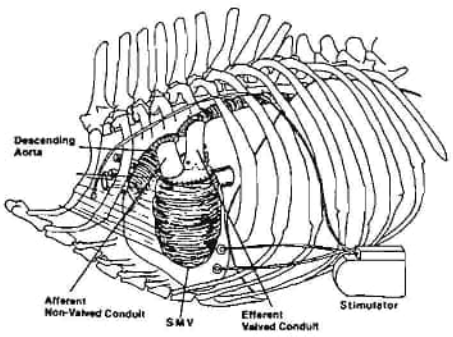

Fig. 1 Diagram of skeletal muscle ventricle, paced intrathoracically and connected to the descending aorta using a valved efferent and a non-valved efferent conduits.

After completion of all anastomoses, the stimulator was activated and SMV contraction was begun. The aorta was ligated between the afferent and efferent conduits to obligate blood flow through the SMV. The stimulator was programmed to deliver a 33 Hz burst frequency at 50 % R-R delay, 35 % R-R duration and 2.5 V amplitude, using a 1:2 diastolic synchronization mode. The thoracotomy was closed after hemodynamic measurements. After the second operation, the dog was given aspirin (75 mg/day) as an anticoagulant. Repeat measurements were performed at post-operative 8 days, 21 days, 78 days, 151 days and 216 days.

Tension time index (TTI) and diastolic pressure time index (DPTI) were calculated as integration of the area under the systolic portion of the carotid artery pressure trace and that under the diastolic portion of it, respectively. Endocardial viability ratio (EVR) was calculated as DPTI/TTI. Diastolic augmentation was determined as the difference between the DPTI with and without SMV stimulation.

RESULTS

The dog tolerated both operations well and was fully ambulatory without apparent discomfort. The animal was tether free in that no tubes or wires crossed the skin.

The SMV contraction produced significant diastolic argumentation (Fig. 2). The percentage diastolic argumentation was 5.3 % at operation, and decreased to 2.5 % at POD 8, but improved to 9.2 % at POD 21. This improvement continued throughout the postoperative period (POD 78, 11.4; POD 151, 9.7; POD 216, 9.9 %). The SMV contraction also produced pre-systolic unloading at the second operation because of the SMV filling, and resulted in a 19.9 % decrease in TTI and a 32.4 % increase in EVR. In the chronic phase, the pre-systolic unloading was not uniform and depended on the hemodynamic state at each measurement. When the systemic arterial systolic pressure was over 100 mmHg, the decrease in TTI and the increase in EVR were attenuated. A pressure gradient between the carotid and femoral arteries at end-diastole, due to closure of the valve in the efferent conduit, was observed at the operation (8.8 mmHg). However, the pressure gradient had disappeared by POD 8.

After POD 210, the hematocrit decreased to 22 %. We suspected impending rupture of the SMV, and a median sternotomy was performed. The SMV contracted well and no apparent evidence of rupture was found. The SMV adhered to the chest wall strongly, and moderately to the left lung. The outside of the SMV was covered with well-vascularized, fibrous tissue. 70 % of the SMV wall muscle appeared well preserved and the thickness of the muscle layer was 6 mm. The inner wall of this portion was lined by thin compact fibrous tissue layer (1 mm). The remaining 30 %, consisting of the lateral aspect adjacent to the chest wall and apex was atrophic (1 mm) and replaced by fatty and fibrous tissues (4 mm), and the inner wall was lined with a thin compact fibrous layer. The surface of the

inner fibrous layer was smooth and had no laminated thrombus. The cusps of the homograft aortic valve maintained their appearance but lost flexibility. However, the lateral aspect of the homograft myocardium which was sewn to the SMV showed pseudoaneurysm formation (50 × 25 mm), contained by the fibrous tissue between the SMV wall and chest wall. The inside of the pseudoaneurysm was filled with a thick, calcified layer (3 mm) and organized thrombus, which occupied approximately 10 % of the SMV cavity. This pseudoaneurysm was covered by the muscles of the chest wall.

Microscopic examination of the portion where the muscle layer was well preserved showed the outer layer to be composed of mature adipose tissue and capillaries; almost all muscle fibers were uniform and well preserved in the middle layer. The inner layer showed fibrosis and foci of lymphocytic infiltration and calcification. In the other portion of the SMV, the muscle was atrophic with extensive fatty infiltration. At the aneurysm wall where calcification was greatest, the middle layer showed much fibrosis, fibroblastic proliferation and hemosiderin deposition, and the inner layer showed calcification, osteoid deposition and marked fibrosis.

The upper lobe of the left lung adjacent to the SMV was partially collapsed, and marked thickening of the visceral pleura was shown microscopically. Gross and microscopic examination of kidney, liver, spleen, pancreas, and spinal cord demonstrated normal appearance and no evidence of embolism.

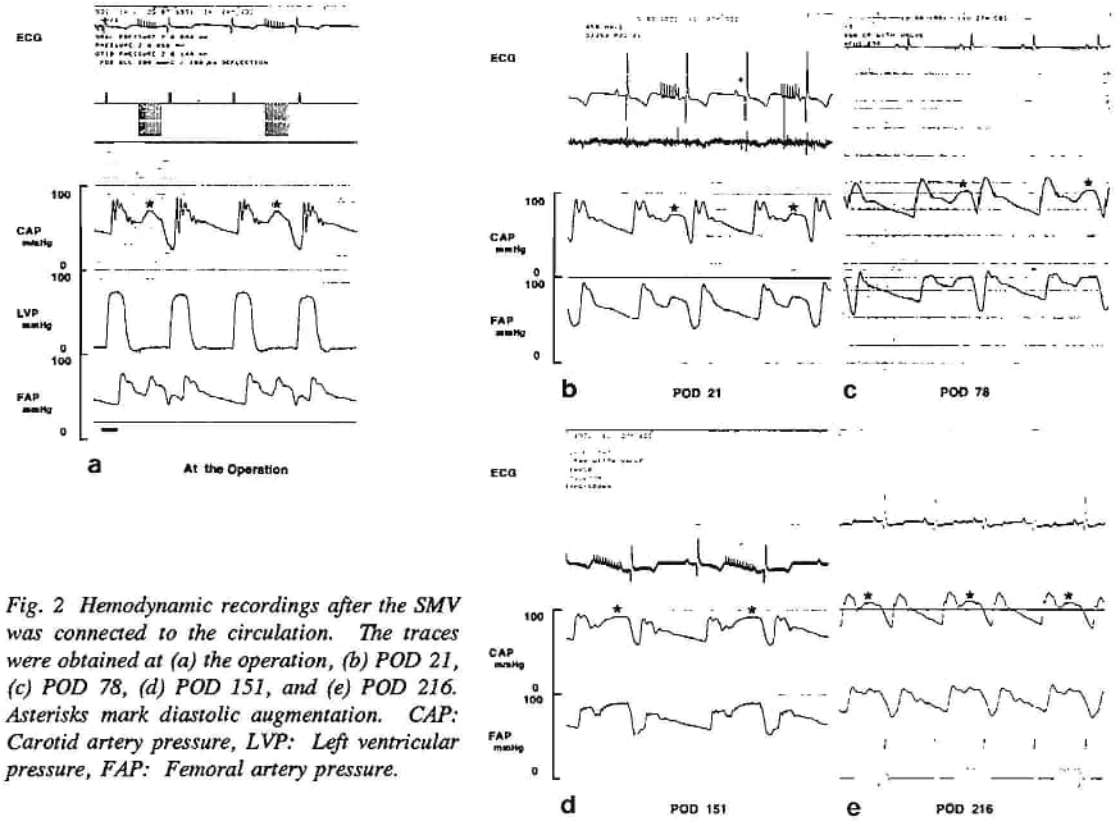

Fig. 2 Hemodynamic recordings after the SMV was connected to the circulation. The traces were obtained at (a) the operation, (b) POD 21, (c) POD 78, (d) POD 151, and (e) POD 216. Asterisks mark diastolic augmentation. CAP: Carotid artery pressure, LVP: Left ventricular pressure, FAP: Femoral artery pressure.

DISCUSSION

SMV contraction in this model produced aortic diastolic augmentation throughout the postoperative period (%diastolic augmentation approximately 10 %) except POD 8. This value is compatible with our previous configuration of SMVs.[3] At POD 8, temporary decline of the percentage diastolic

augmentation was shown. This decline may have resulted from dissection of adipose tissue around the SMV at the operation; improvement may have occurred as the collateral blood flow of the SMV recovered.[1, 3]

The outer surface where the muscle layer was well preserved was covered by vascularly rich fibrous tissues and the mobility of the muscle was maintained. In the portion adjacent to the chest wall, strong adhesions between the chest wall and the SMV were observed, and the muscle layer was replaced by fibrous and fatty tissue. One could speculate that the adhesions within the chest wall restrained the movement of the muscle and caused muscle atrophy, and then, finally, the muscle was replaced by fibrous tissues.

We used an aortic valve homograft as the efferent conduit of the SMV, because it was appropriately sized. The valve was no longer functioning at POD 8. Additionally, the myocardium, attached to the homograft aortic root, showed the evidence of pseudoaneurysm formation. The pseudoaneurysm was possibly to be formed within the early postoperative period, because it was filled with the organized thrombus accompanied with calcification. Fortunately, the muscles of the chest wall covered this aneurysm and protected against further dilatation and rupture. These may be related to the method of storage of the homograft valve after harvest.

When comparing intrathoracic and extrathoracic SMVs, one might expect the intrathoracic SMV to be better than the extrathoracic one hemodynamically, because the efferent and afferent grafts of the intrathoracic SMV are much shorter than the extrathoracic ones, and this could decrease the inflow and outflow resistance of the SMV. Another advantage of the intrathoracic SMV was noted in the histological findings; there were less adhesions with non-mobile tissues which could restrain the wall movement of the SMV. Furthermore, the intrathoracic SMV has a positional advantage, namely protection from compression and trauma. On the other hand, the intrathoracic SMV compressed the left lung and was adherent to it. In this study, histological findings demonstrated marked pleural thickening and partial atelectasis suggesting that the intrathoracic SMV may cause pulmonary complications. However, in spite of this, we feel that the intrathoracic position may be better for eventual clinical application.

In conclusion, this report shows that SMVs in this new configuration are capable of pumping blood in the circulation for over 7 months. This study suggests that the intrathoracic SMV has less adhesions with non-mobile tissue; this may decrease fibrosis of the muscle layers and result in improved SMV function in the chronic phase when compared to the extrathoracic SMV.

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DYNAMIC TRAINING OF SKELETAL MUSCLE VENTRICLES - A METHOD TO CREATE HIGH PERFORMANCE FOR MUSCLE POWERED CARDIAC ASSIST

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SUMMARY

In nine Jersey-calves intrathoracic skeletal muscle ventricles (SMVs) were constructed from the M. latissimus dorsi (LDM), electrically conditioned and dynamically trained on a training-device called 'FROG'. This experimental model of a dynamic training makes it possible to create SMVs with high performance. After optimal dynamic training over several weeks SMVs developed systolic pressures higher than 200 mmHg and a performance of more than 10 Watt, which is three to four times as high as that of a healthy left ventricle.

STATE OF THE ART

As recently reported SMVs constructed from a canine latissimus dorsi muscle have been tested for both the pulmonary and systemic circulation. As aortic counterpulsators an output of the SMV of 20% of the total systemic blood flow was generated over eight hours. In one dog a SMV has functioned in circulation for 27.5 months without evidence of thromboembolism. SMVs also pumped effectively in an atrio-aortic and apico-aortic configuration for several hours under resting conditions /1/.
The aim of this experimental study is to develop SMVs, which are able to support failing hearts effectively, by training them dynamically in order to obtain high performance even under working conditions. This method of dynamic training is to be developed in a manner that such an experimental model is transferable to clinical use.

MATERIAL AND METHODS

In nine Jersey-calves with a weight between 61 and 107 Kg intrathoracic double layered SMVs from the LDM were constructed.
The experimental setup for electric conditioning and dynamic training of these SMVs included a myostimulator with electrodes, a specially designed training device for windkessel training (FROG) with an integrated pressure transducer and a PC. The FROG consists of a central pumping chamber and two side bladders made of silicon and filled with a fluid (Fig.2).
Under insufflation anaesthesia the left LDM was dissected and wrapped in a double layer around the central chamber of the FROG /2/. For intrathoracic placement the left ribs II-IV had to be resected (Fig.1). The tip-catheter containing the pressure transducer was passed through the only transcutaneous passage.

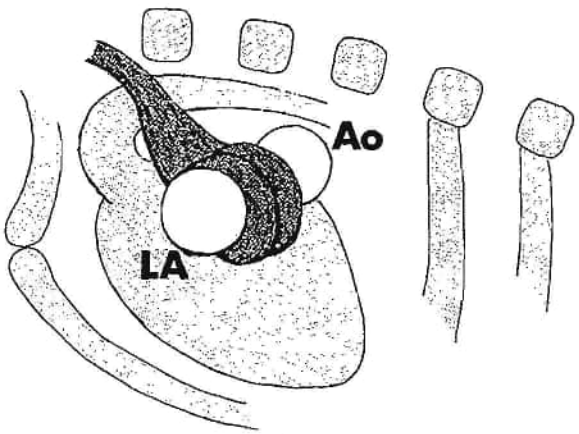


Fig.1

Pressure measurements in the FROG during a contraction of the SMV and the registration of definite characteristic curves allowed a calculation of the shifted volume from the central pumping chamber into the elastic side bladders /3, 4/. From the recorded pressure wave of a SMV contraction, with a contraction time -t_{dyn}- and a peakpressure -P_m-, the applied power and energy can also be calculated at each moment during the training period (Fig.3).

During the dynamic training over several weeks we started with a low preload/low afterload training while increasing the contraction rate and, subsequently, continued with an increasing afterload training by filling gradually more fluid into the FROG (Fig.4).

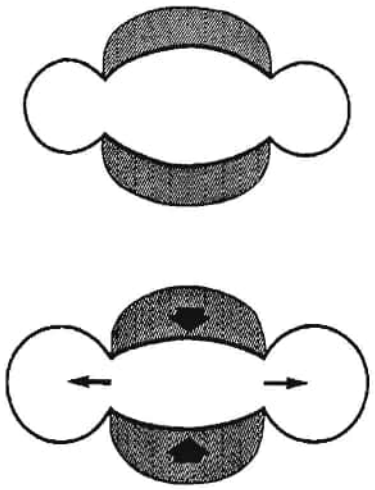


Fig.2

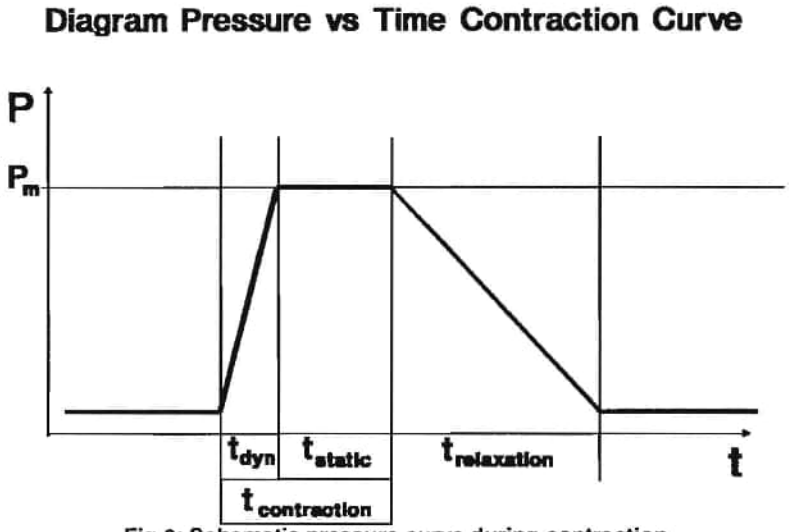
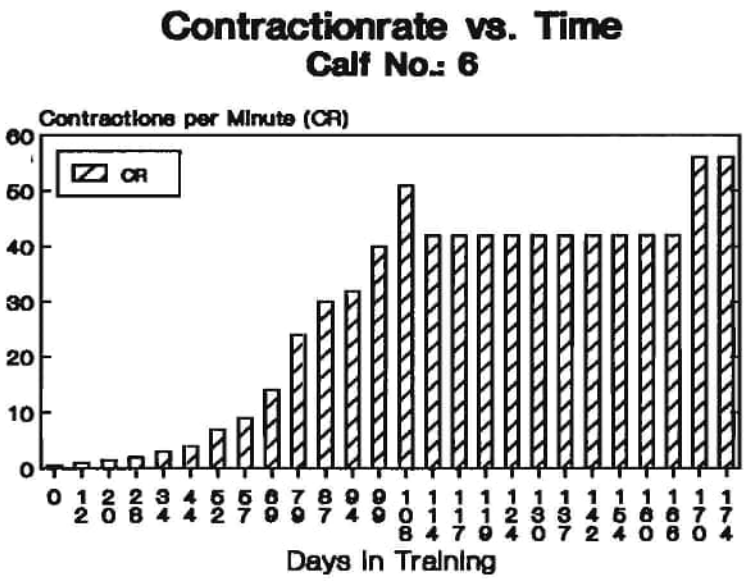


Fig.3: Schematic pressure curve during contraction

RESULTS

All nine calves tolerated the surgical operation of constructing the SMVs well.
On the first two SMVs a vascular delay was applied; they both failed. The remaining other SMVs were stimulated immediately after constructing and worked well.
On the 48th day of training the FROG device in calf Nr.7 failed; this occured one day after systolic pressures of 342 mmHg were measured.
Fig.4 demonstrates the development of diastolic and systolic pressure and performance after starting with low and continuing with high afterload training. Contraction rate was mainly increased during low afterload training. Tab.1 shows the end stage data after completing dynamic training.
Up to now only four SMVs were integrated into circulation, one atrio-aortic and three aorto-aortic. The atrio-aortic integrated SMV showed a sphincterlike contraction due to the fact that left atrial blood pressure was not high enough to bring the SMV back to its position before contraction (i.e. relaxation position) and therefore showed no effective pumping action. In this configuration an elastic inlay with adequate rebound force is mandatory.
The first aorto-aortic integrated SMV ruptured on the 16th postoperative day, due to the absence of a prosthetic inlay. For this reason the other two SMVs were supported by an inlay. One of them continued pumping for a period of more than twelve months.



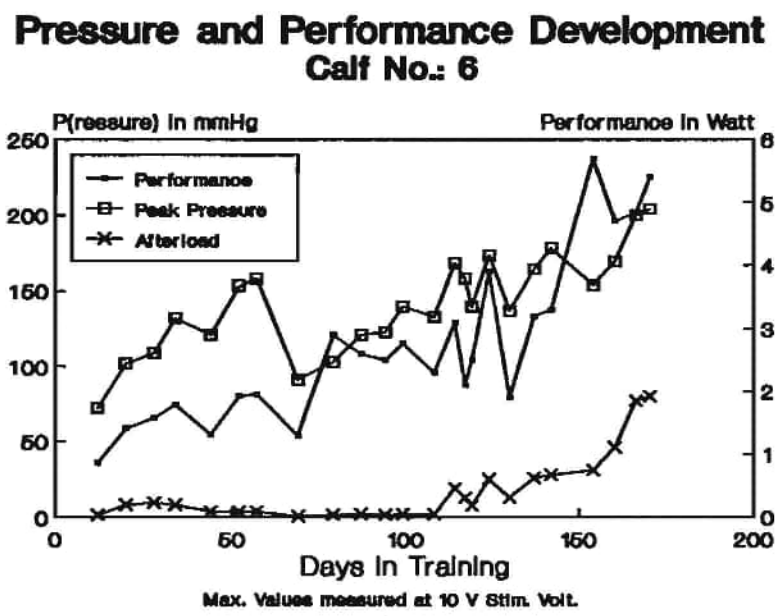


Fig.4

DISCUSSION

By constructing a SMV around the FROG, it is possible to develop high contraction velocity and force in windkessel training with low resistance (i.e. low afterload). This phenomenon can be explained by the power-velocity relation as described by Salmons and Jarvis /5/.
As we already were able to establish with help of an implantable extrathoracic mock circulation system, it was demonstrated again, now by using the FROG training system, that SMVs trained with low preload can develop systemic pressures /2, 6/.
Low preload/low afterload training with increasing contraction rate offers an adequate training method before integrating a SMV between left atrium and aorta.
Additionally, before integrating a SMV in a aorto-aortic configuration as a counterpulsator, an increasing afterload training as shown in Fig.4 is indispensable in order to cover future requirements in circulation.

Although a performance of more than 10 Watt after a dynamic training is three to four times higher than that of a healthy left ventricle at rest, it should be taken into account that this represents an end stage training performance; the question to what degree this energy is transferred to the circulating blood (effectiveness of pumping action in circulation)) is still subjected to further investigations.
However, preliminary results from current experiments seem to indicate that it may be very well possible to further increase the performance of a SMV undergoing this training. In this way the loss of performance due to the process of integration into circulation (effectiveness) may be compensated.

The differences in performances developed comparing the third to the ninth calf might have three explanations:
1. learning curve effects.

Endstage Training Data								
Calf No:	3	4	5	6	7	8*	9*	Human Left Ventricle
Maximal Performance (Watt):	2.1	1.85	5.3	7.1	13.2	1.1*	4.3*	3
Days in Training:	28	124	133	174	48	93*	80*	
P_{peak} / $P_{afterload}$ (mmHg)	115/5	128/38	165/47	204/80	342/46	130/16*	206/5*	
Max. Stimulation Rate. (Contractions/Min)	40**	24**	42**	56.5**	13.3	30*	24*	
* : Calves No. 8 and No. 9 are still in training. **: immediately before integration into circulation								

Table 1.

2. the side bladders of the last three FROGs were much more compliant than those used earlier.
3. the distances from the electrodes to the nerves were shorter in the last three experiments.
Current experiments may help to give a more definite answer as to the question how the described effects can be explained.

Stephenson reports that SMVs, used as aortic counterpulsatores in an acute experiment over 8 hours, generated an output of approximately 20% of the total systemic blood flow. The same data were reported for an atrio-aortic configuration in an acute study; during apico-aortic in-circulation experiments about 40% of the total systemic blood flow was pumped by the SMV./1/.
Although results of acute and chronic studies can hardly be compared, the haemodynamic effects of untrained SMVs in acute studies can give an indication of the possibilities using dynamically trained SMVs.

Dynamic training during electric conditioning is essential for a powerful cardiac assist by means of SMVs: Performance achieved with this dynamic training may be sufficient enough to support an endstaged failing heart under working conditions.
Furthermore, the procedure of a dynamic training using the implantable training device (FROG) may be transferable to humans.

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Development of an Athrombogenic Inner Surface with High Stability for Skeletal Muscle Ventricles as Cardiac Assist

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As part of a research programme investigating the feasability of cardiac assist by the use of autologous, intrathoracal skeletal muscle ventricles (SMVs), the morphology and thrombogenic properties (in vitro as well as in vivo) of the inner lining of 6 extrathoracal and 10 intrathoracal skeletal muscle ventricles (SMVs) which were constructed from the M. Latissimus dorsi (LDM), were examined in an experimental setup.

Between the silicon bladder of an implantable mock circulation device that has to prepare the SMVs for posterior integration into the circulation and the muscle, a tissue layer developes during the training period. The morphologically most outstanding feature is the presence of an inner stratified layer of polyhedric mesothelial cells, in which we were able to prove the presence of endothelial markers. In a test set-up the surface thrombogenicity of this mesothelial layer appeared as nearly identical with the value of the normal calf aorta. Integration of SMV into the circulation proved that this presumption based on the in vitro experiments was correct for an in vivo setup, as we had no thrombo-embolic complications during the period of testing without using any anti-coagulants.

Although this biological inner lining of the SMV appears to offer a solution for the problem of surface thrombogenicity when switched in an atrio-aortic order, integrating the SMV in an aorta-aortic or apico-aortic order requires a mechanical reinforcement of the SMV through the use of Dacron (vascular-prosthesis) material.

However, we are examining whether the advantages of the Dacron material (mechanical stability) can be combined with the advantages of the biological inner lining (non-thrombogenic) by developing a special ventricular prosthetic inlay.

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THE IMPORTANCE OF LATISSIMUS DORSI ACTIVATION TIME IN CARDIOMYOPLASTY OUTCOME

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SUMMARY

In our Center echo-doppler assessment following Dynamic Cardiomyoplasty (DC) procedure deserves a crucial role. As a matter of fact, uncorrect management of the muscle stimulation parameters may lead to a suboptimal Latissimus Dorsi (LD) contraction during cardiac cycle and to an unproper cardiac support.
Since the very beginning of our DC clinical program we carefully evaluated the effects of different LD activation times in DC outcome. Echo-doppler was performed in every pt submitted to DC at 4-6 months after surgery. Hemodynamic responses and LD cardiac support were recorded varying the LD activation time from sensed QRS complex. The results obtained by such a protocol showed that unproper LD contraction timing may lead not only to a suboptimal cardiac assistance but even to a deterioration of the myocardial performance.
Therefore we conclude that careful post-op echo assessment of LD activation time is mandatory in order to optimize wrapped muscle/heart relationship and avoid potential negative effects.

STATE OF THE ART

Molteni and co-workers did already point out the importance of LD activation time in DC management (1). Anyhow they stated that a correct setting should be between 100 and 150 msec. Furthermore they were adopting a LD stimulation protocol with a single pulse pacing instead of a burst stimulation, analysing the different effects of LD activation time starting from 75 msec from sensed QRS.
Currently adopted protocol entails to program LD contraction to begin just at the mitral valve closure time.
No precise evaluation was performed in an attempt to correctly document the actual DC outcome varying the LD activation time.

MATERIAL AND METHODS

In May 1991 a DC clinical program was started in our Center. From that time 9 pts have been submitted to such a procedure. Patient age varied from 51 yrs to 61 yrs. Preoperative hemodynamic data showed an Ejection Fraction (EF) ranging from 14% to 28% (by MUGA evaluation) and a Left Ventricular End Diastolic Diameter (LVEDD) ranging from 61 mm to 86 mm. All pts were contraindicated for heart transplant because of medical or social reasons.
All pts underwent DC procedure according to the technique described by Carpentier and Chachques (clockwise left LD wrapping procedure).
There was no operative mortality. There was one early death (one month from surgery) because of a deterioration of a severe peripheral vascular disease.

One late death occurred at 7 months following DC (sudden death) despite significant functional and hemodynamic improvements.
Seven pts completed the post-op LD training program, leading to a fully transformed muscle graft, and were submitted to hemodynamic evaluation by means of echo-doppler assessment. Echo study was performed from 4 to 6 months after surgery.
Basal hemodynamic data (unassisted cardiac performance) were recorded switching off the cardiomyostimulator (Medtronic SP 1005 A) blocking, in so doing, the LD contractions permanently. Assisted values were obtained varying the time between the sensed QRS complex and the LD contraction (4, 25, 50, 75, 100, 125 msec). Heart/LD contraction ratio ranged from 2:1 to 3:1 according to the heart rate. Ejection Fraction, Velocity Time Integral (VTI) and Stroke Volume (SV) were analysed with and without LD cardiac support.

RESULTS

All pts showed a clear beneficial LD support. At the best LD activation time setting EF improved from 19.5± 7.4% to 32.8±12.1% -p=0.007-, VTI from 12.5±3.1 to 15.1±3.2 -p =0.002-, and SV from 53.2±18.9 ml to 64.2±21.4 ml -p=0.003-.
Anyhow these significant improvements were achieved at different interval from sensed QRS from pt to pt. In some cases negative effects related to uncorrect LD contraction timing were observed, leading to a marked deterioration of the cardiac performance. Furthermore unproper LD contraction during cardiac systole led to a suboptimal LD cardiac assistance. In our series mitral valve closure time ranged from 70 to 75 msec from sensed QRS whereby the best LD activation setting varied from 25 to 75 msec. Mitral regurgitation appearance or deterioration furtherly occurred at uncorrect settings.

DISCUSSION

Dynamic Cardiomyoplasty is currently a source of debate because of the sometime lacking evidence of clear myocardial benefit from LD support.
Uncorrect pt selection was indicated as the crucial factor in DC outcome. Nevertheless other aspects might be relevant in surgical results. The importance of LD contraction timing during cardiac cycle was not sufficiently investigated despite previous evidences (1). Current procedure entails to set the LD contraction to begin just at the mitral valve closure time (2).
Since the very beginning of our clinical experience we investigated this aspect of the DC management. A careful analysis of the hemodynamic responses related to different LD activation times was performed.
Our preliminary data are showing that wrapped muscle contraction timing plays a cru - cial role not only in terms of myocardial contractile improvement but even being pote ntially deleterious.
Adopting a post-op evaluation by a carefulecho-doppler study and concomitantly varying the LD activation time an adjusted heart/LD performance may be achieved optimizing the DC outcome.
Echo-doppler assessment moreover displays the LD contraction influence on both cardiac systole and diastole.
Notorious changes in muscle contraction and relaxation times should be costantly checked during the pt follow-up since the best setting observed at 6 months from surgery may change.

Proper LD activation time is a determinant of DC result since may deteriorate an al - ready present mitral regurgitation or deteriorate it.
In our experience currently adopted LD contraction protocol is uncorrect since mitral valve closure time did not correspond to the best LD activation time in terms of cardiac support.
Finally we have to realize that even a small detail might be crucial in DC outcome altering a potential myocardial improvement to a negative LD contribution.
Further studies are required to investigate the exact role of LD contraction in cardiac cycle.

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Clinical measurement of cardiac impedance in post-transplant patients: Initial results with conventional pacemaker electrodes x)

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SUMMARY

Impedance measurement is used to detect structural changes in biological tissue. This method may have the potential to avoid endomyocardial biopsies by noninvasive rejection monitoring in heart transplant recipients /4,7/. In this study standard pacemaker electrodes Medtronic 6500 were placed into the myocardium of the right ventricle and impedance was measured using a sinusodial current of 20μA at a frequency of 15kHz.
Up to now 35 patients were monitored. In one group n=5 two pairs of electrodes were implanted and showed good correlation between three impedance traces derived from the four electrodes. Initial results in patients with normal recovery revealed a rapid drop in impedance to about 70% of the initial value within the first 48 hours and then a stable course for the next weeks. The sole rejection episode observed so far, induced an increase of impedance to 85% of the initial value and biopsy proved an allograft rejection ISHLT Deg. II.

INTRODUCTION

Many authors showed applications of impedance measurement for the detection of ischemic stress in organs and other structural alterations in tissue /1,2,3,5,6/. Structural alterations caused by allograft rejection are predominantly at cell membranes in the subendomyocardial layer and therefore changes in the intercellular impedance can be expected /4/. Highest sensitivity for the detection of phase angle and good specifity for the measurement of intercellular impedance occurs at β-dispersion of muscle tissue and so a test frequency of 15kHz was chosen /6/. In this frequency range polarization phenomenons and electrode impedance can be neglected /2,5/ which allows the use of only two electrodes (instead of four electrodes necessary at lower frequencies). Furthermore, the choice of this rather high frequency instead of low frequency or DC is advantageous in respect of the critical excitation level of ventricular fibrillation and avoids synchronization with the electrical heart activity (ECG) /4/. Of course, rapid transients during current onset at the beginning of measurement current should be prevented.

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MATERIALS AND METHODS

Temporary pacing leads (Medtronic 6500) were implanted in the myocardial wall of the right ventricle with a distance of approximately 2 cm. These electrodes with cylindric shape (diameter 0.8 mm, length 3 mm) are smallish compared to the distance of the location and have a surface area of 17 mm^2. With the applied measuring current of 20 μA a mean current density of 1.2 $\mu A/mm^2$ results. In case of conductor fracture or excessive voltage at the electrodes an immediate cessation of the measuring current is provoked.
The incoming voltage signal passes amplifiers and band passfilters (Fig. 1) before it is fed to the DA converters of the microcontroller. The amount of impedance is calculated from the voltage drop whereas time difference between voltage drop and current gives the phase angle and further the dielectric loss factor. Signal proportions below 50Hz contain intracardial ECG signals that were monitored during measurement. Status of the device, mean values of impedance and phase angle are displayed on the device itself whereas actual values of impedance, phase angle and intracardial ECG are transmitted to a notebook computer via fiber cable for aquisitation /7/.

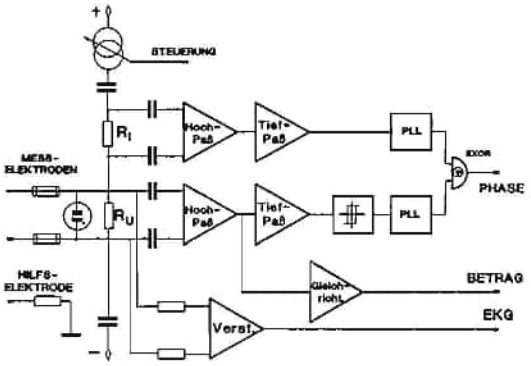

Fig 1: AC-Coupling and overvoltage protection for the input amplifiers, analog signal processing

RESULTS

In a first series of patients two electrodes were located in the myocardial wall of each ventricle to do rejection monitoring in different tissue areas. Furthermore electrode impedance and sensitivity of location could be observed by recording the impedance traces of both ventricles and the "transmyocardial" impedance (Fig 2). The maximum deviation that occurred between the shapes of the three impedances never exceeded 5%.
In case of normal recovery mean impedance decreased from 600 +- 50 Ω to 75% +- 5% of this initial value within 2 to 4 days after implantation. The next two to three weeks showed a stable course for impedance and nearly constant values of phase angle (Fig. 3). Impedance patterns were pulsatile corresponding to contraction of the heart and superimposed by ventilation. A quite similar trend was observed in further 28 patients using only right ventricular impedance.

The sole rejection episode observed so far, showed an increase of impedance to 85% of the initial value for the duration of allograft rejection and then a decrease to again 75% of the initial value.

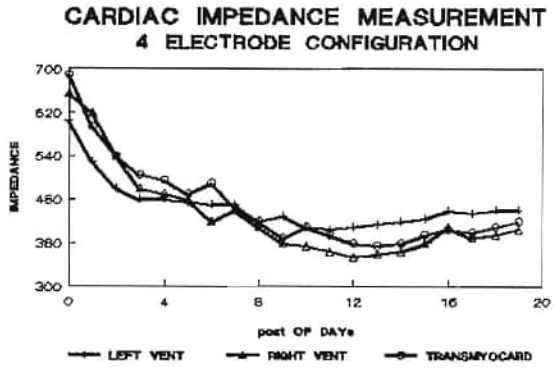

Fig. 2

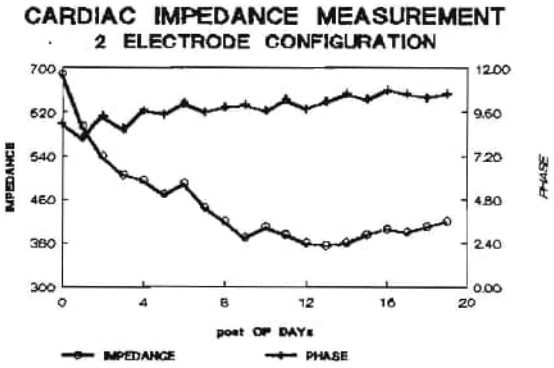

Fig. 3

Fig. 2 : Impedance traces of left ventricle, right ventricle and transmyocardial impedance

Fig. 3: Impedance and phase angle in case of normal recovery

DISCUSSION

With this setup the sensitivity and stability of a 2 electrode configuration at relatively high frequencies could be examined. Steady-going impedance traces and neglectable deviations between the curve shapes of ventricular and transmyocardial impedance suggest the qualification of the selected electrodes for this application. No major electric changes occurred and impedance developed a stable course independent of particular location.
Problems could arise by shunting the tissue impedance by blood whose specific resistance is up to ten times lower than the impedance of muscle tissue. To avoid that problem it was important to locate the electrodes completely in the myocardium near as possible to the subendomyocardial layer. The so observed continuous decrease of impedance during the first two days represents the well known intramuscular healing process and confirms the absence of shunting by blood. This course may be used as an index for proper electrode positioning.
These preliminary results show, that intramyocardial tissue impedance can be measured with rather simple electrodes and that the impedance measured at the frequency of 15 kHz may be an appropriate indicator to detect allograft rejection.

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A MICROPULSE STIMULATOR (x)

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SUMMARY

Since using pulses of a few microseconds duration is less capable of stimulating slow pain fibres, our new micropulse stimulator permits one to effectively use pulse durations from 5 to 50 microseconds, the voltage being of about 300 volts for any pulse duration.

STATE OF THE ART

Stimulation of paralyzed muscles was introduced by Liberson et al in 1960. While in paraplegics stimulation is not perceived in patients, it is perceived in hemiplegics in whom stimulation of the extensor mass of the forearm inhibits spasticity. Also functional electrical stimulation of the deltoid permits restoration of the subluxed shoulder joint and stimulation of the first dorsal interosseous permits a grasping movement in a number of patients. Also stimulation of the quadriceps in hemiplegics who are unable to walk, first restores the muscle contractibility and decreases the fatigability. Stimulation of the dorsiflexors corrects "foot drop". It is believed that one of the important reasons for under-utilization of functional electrical stimulation is the intolerance of certain patients to the electrical stimulation. With the decrease of pulse duration the number of such patients is bound to decrease. Such a stimulator may be better tolerated in other cases of therapeutic electrical stimulation: stimulation for disuse atrophy, pain, painful spasms, etc..

MATERIAL AND METHODS

We have used this stimulator in our private practice for the past year on scores of patients with multiple sclerosis, hemiplegia, back, neck and shoulder pain, etc.. The stimulator eliciting pulses of 0-50 microseconds duration, with 20-40 c/s frequency can be used either continuously or intermittently. Intermittent stimulation can be 5 sec on and 5 sec off. It also permits all day or all night stimulation with 10 sec on and 50 sec off. Fig 1 shows the stimulator and Fig 2 the shape of the pulse of 20 microseconds.

Fig. 1

General view of Stimulator

Fig. 2

Tracing of 20 microsec. pulse

Because of the use of higher voltage than the usual commercial stimulator, an additional safety device was introduced. The stimulator is activated by a 9 volt alkaline battery.

RESULTS

The following observations have been made:

1. Practically all the patients tolerated effective stimulation of the neck, shoulder, back and upper extremity muscles, using stimuli generally around 10 microseconds duration and always below 20 microseconds. Patients report in most cases "vibrations". When pain is perceived the patient is usually adapted to it within less than ten minutes.

2. In cases of the lower extremities, the observation is the same for the muscles and nerves at the knee and below, with rare exceptions concerning the gastrocnemius. In cases of quadriceps stimulation only about 50% of non-paralyzed patients tolerate a total contraction of the muscle and this only when one uses very large electrodes. The same situation prevails for the hamstrings. In only about 10% of patients did we succeed in stimulating transcutaneously the gluteus maximus.

It is noteworthy that stimulation under the positive electrode elicits contractions almost simultaneously with those under the negative electrode, because of the brevity of pulse duration. Although contractions under the positive electrode are somewhat weaker than under the cathode, both can be equalized by using a smaller electrode under the anode and stimulating there a more excitable tissue. However, invariably with each electrode over the quadriceps on the left and right sides, both muscles contract in most patients.

DISCUSSION

Our results are therefore most encouraging and we believe that the next time around, using a voltage twice as high, further progress will be achieved.

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COMPARATIVE RELIABILITY OF COCHLEAR IMPLANTS

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More than 7000 cochlear implants of various designs have been implanted worldwide. To date, there is more than 9 years of clinical experience available with some devices and comparisons on the reliability of the different designs are possible. Device failures can be classified in those which can be solved through programming and those which need a revision surgery. We have analyzed data on 1000 3M/House devices and more than 4500 Nucleus implants in terms of their probability to survive a certain lifetime. These data indicate that hermetically sealing can improve the probability to survive by more than 10 fold. Most of the 3M/House epoxy packed devices can be expected to fail prematurely. The comparative survival rate data for the Nucleus Standard and the Mini implant show how continuous improvements in the design and the manufacturing process improve the reliability of the device.

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