



**Austrian Society for Artificial Organs
Biomaterials and Medical Replacement Devices**

International Society for Artificial Organs



**2nd VIENNA INTERNATIONAL WORKSHOP
ON**

**FUNCTIONAL ELECTROSTIMULATION
BASICS, TECHNOLOGY AND APPLICATION**

VIENNA (AUSTRIA), SEPTEMBER 21 – 24, 1986

PROCEEDINGS

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2nd SURGICAL CLINIC, UNIVERSITY OF VIENNA**



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ON FUNCTIONAL ELECTROSTIMULATION**

Sunday 21st — Wednesday 24th September, 1986, in the
PARKHOTEL SCHÖNBRUNN, Hietzinger Hauptstraße 10 — 14,
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THE FUNDAMENTAL LAW OF ELECTROSTIMULATION

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SUMMARY

Around the turn of the last century, there was an intensive discussion among physiologists as to whether there is a law describing the phenomena of electrostimulation and which formula may best approximate it mathematically. J.L. Hoorweg found that the voltage to which a capacitor must be charged to elicit an excitation, was a function of the capacitance in an inverse correlation. G. Weiss reported in 1901 that according to his investigations a linear relationship existed between the duration of a pulse and the corresponding quantity of electricity applied to reach threshold level. He was the first to call this linear function "formule fondamentale". In 1909 Louis Lapicque accepted it as a convenient approximation and used it in its hyperbolic form introducing the terms "rheobase" and "chronaxie".

We are now able to give the "fundamental formula" a physical interpretation which yields as result that it is the electric field produced by the electrode acting on the excitable membrane which changes the permeability. The electric field in the extracellular space is transformed by the cell geometry ratio: cell diameter to membrane thickness yielding a high transmembrane field capable of reducing the inherent electric field to its threshold level. The consequences drawn from this hypothesis are remarkable and (should) have an influence on all applications of electrostimulation including the discussion on accidents caused by electricity.

It is not the current to stimulate or endanger humans but the electrical field which needs, of course, current or voltage or energy to be built up.

1. INTRODUCTION

Electrostimulation is already known since antiquity. However, it was investigated systematically only within the last 220 years. At that time the famous Leyden jar was invented which was the prerequisite of quantitative electrostimulation.

The results of innumerable investigators have formed a picture of electrostimulation which is part of the electrophysiology of every textbook of physiology. Although this knowledge appears to be complete and well established, we have to note critically that physiology books do not offer a basis on which engineers can establish design parameters when constructing or optimizing electrostimulation systems. A fundamental law of electrostimulation which comprises all physiological and physical properties of the phenomena has not yet been published. This would be of immense importance now and in the future as modern technology will probably allow establishment of new forms of electrotherapy which were either too expensive or impossible in the past.

Current knowledge of electrostimulation is decisively determined by the conceptions of the past. They have entered literature long ago and are to some degree above discussion or criticism. For example, Pflüger's Law of Stimulation describing the effects of cathodal and anodal closure or break of currents is based upon the hypothesis of Du Bois-Reymond and, if valid at all, is no longer relevant for modern electrostimulation procedures.

It is the intention of this paper to briefly sketch the historical evolution of electrostimulation knowledge and to develop a theory of electroexcitation which makes the engineering access to electrostimulation more feasible.

2. HISTORICAL EVOLUTION OF ELECTROSTIMULATION

Electrostimulation is far older than the knowledge of electricity. The torpedo fish (*torpedo marmorata*) offering electric shocks of up to 200V is already mentioned in the scripts of Plato (427-347 a.D.) for the treatment of pain, specifically for headache and gout (12). Exploration of electrostimulation in the following 24 centuries was accompanied by the discovery of electrical phenomena which fertilized much more physics than medicine. The invention of Muschenbroek's "Leyden Jar" -the first capacitor of up to 10nF for storage of up to 1J electrical energy- or of the "Volta Column" are convincing examples. Both were necessary to study electrostimulation on a reproducible basis. It is interesting to note that Volta published his column to disprove Galvani's theory of "animal electricity" and ironically called it "Galvanic element".

The search for more profound knowledge of electrostimulation and electricity was hampered by the fact that there was no measuring procedure to quantify the electrical parameters necessary for electrostimulation which, at that time, was called "Galvanism". It is, therefore, not surprising that the first apparatus sufficiently sensible for current measurements, invented by Leopoldo Nobili in 1825, was called "Galvanometer". His principle for current measurement was based on a method induced by Schweigger to which he added a trick by which the influence of the magnetic field of the earth was cancelled. We would say he applied the principle of "common mode rejection" for the first time.

Electrotherapy or "medicina electrica" was applied in a large number of indications reaching from resuscitation to treatment of impotence, from seriosity to scharlatanism (16). The broad range of applications may be explained by the fact that electric current can induce either electrolyte disturbance or excitation of nerves and muscles.

Whether electrostimulation was effective as excitation or as excitability was not yet distinguishable. The current applied was of a few second duration and direct coupled (galvanic) or of (unknown) short duration and biphasic (faradic) (13).

3. THE SEARCH FOR THE QUANTITATIVE DESCRIPTION OF ELECTROSTIMULATION

The list of investigators in the field of electrotherapy is long and contains famous names such as A.v. Humboldt, Du Bois-Reymond, Pflüger, Duchenne de Boulogne, Fick, d'Arsonval, Hermann, Hoorweg, Weiss, Lapicque, Nernst amongst others. The latter four tried to find a stimulation law expressed as a mathematical formula and based on experiments in which the duration of the electricity applied was varied. They laid the foundation on which our knowledge of electrostimulation is still based. They all postulated that electrostimulation is in principle similar for all sorts of nerves and muscles, a thesis which was refused by d'Arsonval.

3.1 HOORWEG'S LAW

Hoorweg, a physicist at the university of Utrecht, the Netherlands, carried out his investigations on electrostimulation with simple appliances but high accuracy. In 1882 he found that the voltage to which a capacitor was charged in order to elicit an excitation, was a function of the capacitance of the capacitor in an inverse correlation of the form (2):

$$(1) \quad V = a R + \frac{b}{C}$$

where:

- V = voltage to which the capacitor was charged,
- R = resistance of the discharge circuit,
- C = capacitance,
- a and b = coefficients given by the specimen.

He believed his detected relationship to be fundamental, though his wave had a very specific shape and he did not prove that other waveforms would yield the same results. From his various experiments with different nerves and muscles he calculated that there always exists one specific capacitor for which the threshold energy is minimal. He also found that the charge needed to reach threshold was a linear function with positive slope intersecting the y-axis above zero (see Figure 1).

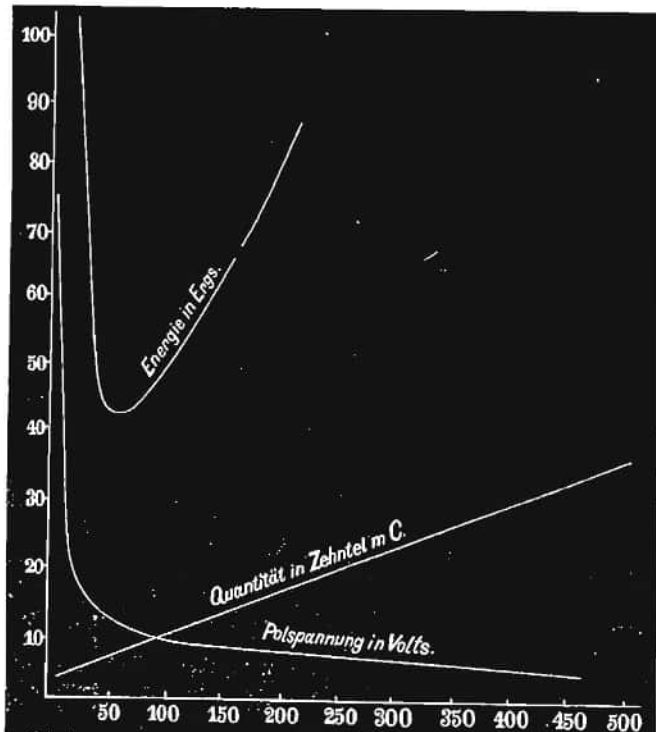


Figure 1:
Reproduction of Hoorweg's original diagram (2) of energy (curve on top) measured in Ergs = $0.1 \mu J$, of charge (straight line) measured in μC , and of voltage (hyperbola) measured in V, necessary to reach excitation threshold with discharge of a capacitor. The abscissa is scaled in nF.

The importance of his investigations were twofold:

1. He disproved the law of excitation of Du Bois-Reymond who had postulated that the threshold of excitation is not correlated to the magnitude of the applied electricity but to its change with time.
2. He firstly investigated electrostimulation with simple means (voltage source, galvanometer and various low leakage capacitors), high accuracy, and excellent reproducibility.

3.2 WEISS' LAW

The physicist and physician Weiss from Paris published a paper in 1901 in which he tried to make comparable the different methods of electrostimulation (17). Being one of the very first appointed as professor of medical physics, he was well aware of the work previously done by Hoorweg. He generalized the law of Hoorweg by finding a linear relationship between the charge needed to reach stimulation threshold and the duration of current flow and called it "formule fondamentale". He pointed out -and this makes his investigation so important for engineers- that the threshold energy varies with varying wave shape whereas the quantity of electricity remains always constant. We have to state the limitations of this statement later on. He personally showed that his formula

$$(2) \quad Q = a + bt$$

where:

- Q = charge at threshold,
- t = duration of current flow,
- a and b = coefficients given by the specimen,

is formally similar to what was found by Hoorweg, if equation (2) is rewritten and if t is substituted for the K fold of the time constant RC:

$$(3) \quad Q = a + b \cdot K \cdot RC = a + AC$$

We now know and can explain that the experiments of Weiss and Hoorweg applied to the same specimen will yield different straight lines with different slopes if the one is expressed in time constant the other in duration of current flow. We therefore disagree with Lapicque's interpretation that Hoorweg and Weiss have found an identical law but expressed it differently (Hoorweg-Weiss-Law (11)).

The importance of the Weiss investigations are twofold for us today:

- 1) If thresholds are expressed as quantity of electricity (charge or voltage-time-product), then they are comparable even if measured with different wave shapes.
- 2) He investigated the "quantity-duration-curves" in a range (0.23ms to 3ms) which is quite modern for instance for cardiac stimulation, whereas the investigators before him mainly explored a range of some milliseconds to 0.1s. This is of importance insofar as the mathematical formulation is only a good approximation for a limited range.

One may ask how Weiss could measure times down to 0.2ms without an oscilloscope or equivalent instrument. His experimental setup is fascinating and proves his experimental genius. The stimulation circuit was connected via a wet and thereby conducting paper to the voltage source. Another wet paper in parallel to the stimulation circuit formed a short circuit reducing the voltage practically to zero. With proper arrangement of the two wet strips in a defined distance he could firstly remove the short circuit and secondly interrupt current flow by destroying the strips by a shot of an air-gun bullet of known velocity.

3.3 LAPICQUE'S INTERPRETATION OF THE EXCITATION LAWS

The Parisian Lapicque performed numerous experiments on electrostimulation himself and knew very well the results of Hoorweg and Weiss. Two problems seemed him to exist when describing electrostimulation by mathematical formulae:

- 1) The Weiss formula did not correctly represent the experimental results over more than one decade. He found that the charge-duration relationship was a right bended (convex) curve especially in the ms-range which needed approximation by at least two straight lines (see Figure 2).
- 2) He thought it to be disappointing that the Hoorweg and Weiss equations were merely empirically justified and not by physiologic or physical argumentation.

Therefore, he tried another approach taking into account polarization phenomena around the membrane as they were proposed by Helmholtz, Nernst and Ostwald. Assuming the membrane as a leaking structure which could be substituted by a parallel circuit of a capacitor and a resistor, he obtained the following equation (4) published in 1907 (9):

$$(4) \quad V = \frac{\alpha}{1 - e^{-t/\beta}}$$

Though this approach seems to have a physical justification he had to admit that the approximation was still worse as compared to the Weiss

equation as it expresses a left bended (concave) curve which is still more inaccurate in the short duration range (see Figure 2). This was the reason why he rejected this formula as an insufficient approximation. It is more surprising that the formula entered physiology books up to the present without reflecting the scruples of Lapicque. By the way, formula (4) was reinvented by Pearce and coworkers in 1983 (15):

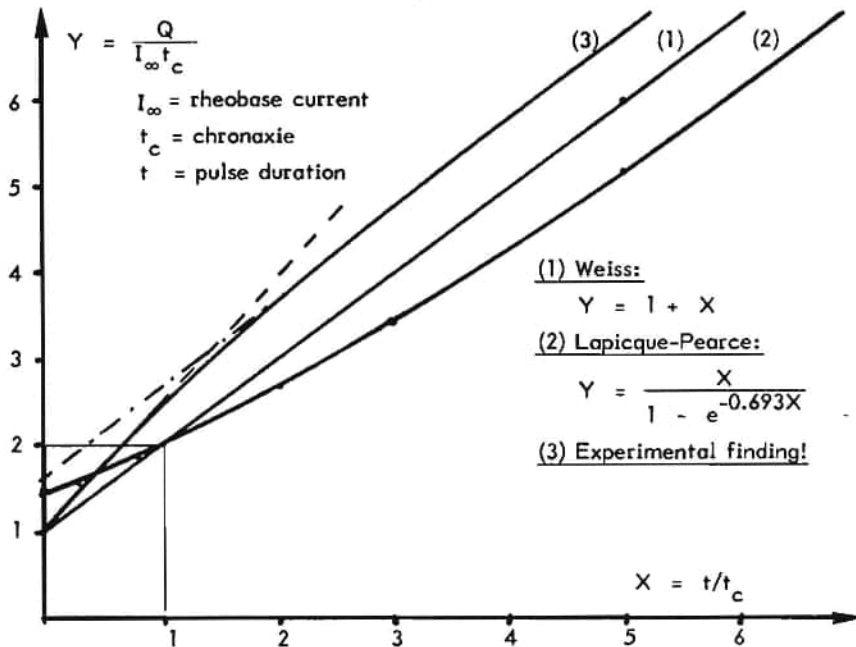


Figure 2:

Comparison between Weiss' formula (1), Lapicque's exponential formula (2), and experimentally found current threshold (3). The charge is normalized to the rheobase-chronaxie product (minimum charge capable of stimulation) and to the chronaxie.

The bended experimental curve can be approximated by two straight lines for the small and large pulse duration ranges.

During the annual conference of the Society of Biology in 1909, Lapicque proposed to give the coefficients of the Weiss formula a physiological meaning (10). Considering the Weiss formula in its hyperbolic form:

$$(5) \quad i = \frac{a}{t} + b$$

where:

i = intensity to reach excitation,
 t = duration of electricity applied.

he argued that for long durations the value b is asymptotically reached which he called "rheobase". He recognized that even with indefinitely long durations there is a "fundamental threshold" which must be reached or exceeded in order to initiate excitation. This minimal threshold should characterize the type of excitable tissue and the surface of the active electrode in contact with the tissue (10). Rearranging equation (5) in the following way:

$$(6) \quad i = b \left(1 + \frac{a}{b} \cdot \frac{1}{t} \right),$$

he found that the ratio a/b is a sort of time constant which characterizes the excitable tissue (10). It was called by him "chronaxie". He was already aware that a stimulation duration equal to the chronaxie reaches excitation with the lowest amount of energy. All other durations shorter or longer than the chronaxie must have a higher energy level.

The chronaxie can simply be determined from the intensity-duration-curve in that the rheobase value is doubled. Its intersection with the hyperbola yields the chronaxie value.

Though Lapicque has not found a new law of electrostimulation, his influence in electrophysiology was important for understanding and characterizing phenomena of electrostimulation.

3.4 NERNST' LAW

Nernst, Professor of physical chemistry in Berlin, the founder of physical chemistry and Nobel Award winner for chemistry in 1920, was engaged in electrostimulation too. He developed a model of ion concentration alterations in which ions had to be moved by the stimulation current. His differential equation system yielded as result an equation which he called "square root law" which was published in 1908 (14):

$$(7) \quad i \sqrt{t} = \text{const.}$$

where:

i = current at threshold,

t = duration of the applied current.

If we square equation (7) and multiply both sides with the resistance R of the stimulation circuit, we get

$$(8) \quad R i^2 \cdot t = \text{Const},$$

which means:

- 1) the threshold expressed as energy should be constant for all durations,
- 2) with the duration t approaching to infinity the current should go to zero, and
- 3) if both sides of equation (7) are multiplied by $\sqrt{t}$ we obtain the stimulation charge which is, according to Nernst, zero when t goes to zero.

All consequences are not in agreement with what Lapicque has worked out very clearly on the basis of his own, Weiss's and Hoorweg's results. It is somewhat amusing to read how Nernst defended his concept of constant energy in that he rejected measurements of others in the 1ms-range as inaccurate whereas deviations in the 100ms-range were characterized as being influenced by "accomodation" phenomena.

Though we know for sure that the Nernst concept of constant energy must be refused as unphysiologic, it is surprising that this idea has still its thoughtless repeaters today. There is one pacemaker manufacturer claiming as advantageous that his models have constant energy output when battery voltage decreases. On the other hand, defibrillation dosis is always given as energy dosis as if defibrillation obeys other rules than normal electrostimulation.

4. DEVELOPMENT OF A STIMULATION MODEL

From electrophysiology it is known that excitation of a nerve or muscle cell is initiated when the permeability of the membrane with respect to sodium (Na) is greatly increased, resulting in a breakdown of the potential profile across the membrane. This can be thought to be established by a force acting on obstacles within the pores of the membrane (Figure 3). It is assumed that the obstacles are not neutral electrically but either ionized or polarized (8,5). Any force in an electrolytic environment can be explained by an electric field or by a diffusion gradient. Electrostimulation, therefore, may be interpreted as the application of an exogenic field to an excitable tissue so that a change in permeability with respect to sodium occurs, resulting in a continuing excitation. The electric field seems to us to be the primary parameter. All other electric parameters, such as current or voltage, (both only measurable outside the body) are derived from it in accordance with Maxwell's law.

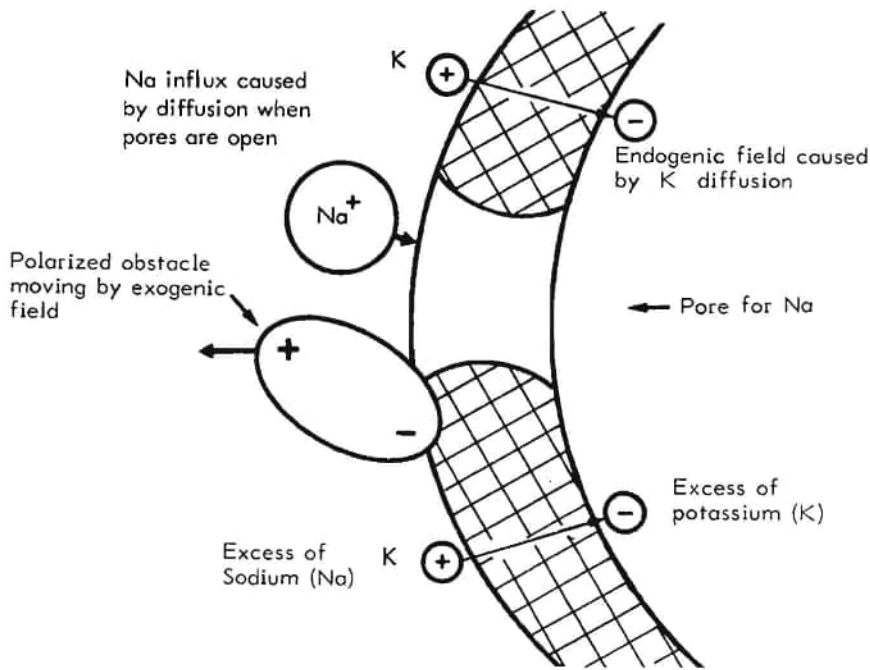


Figure 3:

Model of a pore barrier to Na-ions: The positive dipole charge is attracted by the endogenic electric field. The application of an exogenic field turns the dipole thus opening the channel for Na-ions.

Left side = extracellular space,
right side = intracellular space.

An experiment of Cole (1) is very informative under the aspect of stimulation mechanism. When simultaneously registering the potential difference across the membrane and its conductivity, it is obvious, that the change in voltage corresponding to a change in electric field within the membrane precedes the change in conductivity. Apparently the change of the electric field needs a certain time to effect a change of the permeability. In electrostimulation the exogenic force F_{exogen} has to be greater than that which fixes the obstacles within the membrane F_{stat} . The idea can be formulated mathematically (4,3):

$$(9) \quad \int_0^{\tau} (F_{\text{exogenic}} - F_{\text{static}}) dt \geq I_{\text{min}}$$

where:

F_{exogenic} = exogenic force applied from outside the cell,
 F_{static} = force fixing the obstacles during the unexcited state,
 τ = time during which the exogenic force acts on the obstacles called pulse duration,
 I_{min} = minimal impulse necessary to remove the obstacle to open the sodium channels.

As we assumed the obstacles not to be neutral electrically, we can substitute the exogenic force by an exogenic electric field by the well-known equation:

$$(10) \quad F_{\text{exogenic}} = q_0 \cdot E_{\text{exogenic}}$$

where:

q_0 = charge of the ion or dipole forming an obstacle for sodium on or in the membrane,
 E_{exogenic} = electric field applied by a stimulating electrode.

Inserting equation (10) in (9) and expressing $F_{\text{static}} : q_0$ by E_{static} , we get by rearranging:

$$(11) \quad \int_0^{\tau} E_{\text{exogenic}} dt \geq \frac{I_{\text{min}}}{q_0} + E_{\text{static}} \cdot \tau$$

Dividing both sides by τ , the mathematical formulation of our hypothesis reaches the form of a hyperbola which is well-known in electrophysiology:

$$(12) \quad \frac{1}{\tau} \int_0^{\tau} \vec{E}_{\text{exogenic}} dt \geq \vec{E}_{\text{static}} + \frac{I_{\min}}{q_0} \cdot \frac{1}{\tau}$$

Equation (12) can further be simplified, if we only consider the components of $\vec{E}_{\text{static}}$ and $I_{\min}$ in parallel to $\vec{E}_{\text{exogenic}}$ (this is the case, if the exogenic field is perpendicular to the cell membrane surface), the vector equation, then, is a simple algebraic equation:

$$(13) \quad \frac{1}{\tau} \int_0^{\tau} E_{\text{exogenic}} dt \geq E_{\text{static}} + \frac{I_{\min}}{q_0} \cdot \frac{1}{\tau}$$

With the terms of "chronaxie" and "rheobase", introduced by Lapicque, we can rewrite equation (13):

$$(14) \quad \frac{1}{\tau} \int_0^{\tau} E_{\text{exogenic}} dt \geq E_{\text{rheobase}} \left(1 + \frac{t_{\text{chr}}}{\tau} \right)$$

where: $E_{\text{rheobase}} = E_{\text{static}}$,

$t_{\text{chr}} = \text{chronaxie time defined by}$

$$\frac{I_{\min}}{q_0 \cdot E_{\text{static}}} = \frac{I_{\min}}{F_{\text{static}}}$$

The interpretation of equation (14) reads:

The mean value of the exogenic electric field applied to an excitable membrane during the pulse duration τ must be equal to or larger than a minimal field strength, called "rheobase field strength" times a hyperbolic expression of the duration τ to reach excitation.

Introducing the Lapicque terms into equation (11), the result is similarly structured as the linear "formule fondamentale" found by Weiss (17) in 1903 based on experiments made in the milliseconds region:

$$(15) \quad \int_0^{\tau} E_{\text{exogenic}} dt \geq E_{\text{rheobase}} (\tau + t_{\text{chr}})$$

Equation (14) and (15) are both identical, if, and only if the amplitude of the electric field in equation (14) is given as mean value. Equation (15) can be interpreted as follows:

The quantity of the electric field (the field strength time product) applied to an excitable membrane must be equal to or higher than the rheobase field strength times a linear expression of the pulse duration to reach excitation. The sign of equality in equations (14) and (15) defines the threshold of excitation.

Both equations (14) and (15) indicate that the shape of the electric field pulse plays no role, as long as E_{exogenic} exceeds E_{rheobase} .

A declining exponential pulse, as it is given with a capacitor discharge in the Hooweg experiments, will not be governed by this characteristic, if it is not truncated above E_{rheobase} . We can formulate this consideration by:

$$(16) \quad \int_0^{\tau - \Delta\tau} E_{\text{exogenic}} dt \gg \int_0^{\Delta\tau} E_{\text{exogenic}} (\leq E_{\text{rheo}}) dt$$

where:

$\Delta\tau = \text{time duration during which } E_{\text{exogenic}} \text{ is equal to or smaller than } E_{\text{rheobase}}.$

As long as inequality (16) is fulfilled, the effect of an exogenic electric field pulse is independent of its shape ($\ll$ means: some percent).

An electric field within excitable tissue can normally only be established by at least one electrode adjacent to it which is connected to a current or a voltage source. Though the electrode-tissue interface is normally non-linear and, therefore, there is no proportionality between electric field inside the tissue and the applied voltage or current, we can assume as an approximation that the threshold definitions in terms of voltage or current obey a similar law as that of equation (15). Thus, we can define the voltage - time integral threshold as:

$$(17) \quad \int_0^{\tau} U(t) dt = U_{\text{rheobase}} (\tau + t_{\text{chr}} \cdot U)$$

where:

$U(t)$ = voltage applied to a stimulation system
which may be a function of time,
 U_{rheobase} = rheobase voltage, in analogy to equation (14),
 $t_{\text{chr}} \cdot U$ = voltage chronaxie, in analogy to equation (14).

The voltage time integral necessary to reach stimulation threshold is a linear function of the pulse duration as was experienced by Weiss (17)

By dividing equation (17) by τ , we get the well-known hyperbola describing the strength-duration curve:

$$(18) \quad \frac{1}{\tau} \int_0^{\tau} U(t) dt = U_{\text{rheobase}} \left(1 + \frac{t_{\text{chr}} \cdot U}{\tau} \right)$$

The mean value of the voltage necessary to reach stimulation threshold is a hyperbolic function of the pulse duration τ determined by the same two constants U_{rheobase} and $t_{\text{chr}} \cdot U$ as in equation (17). Equation (17) and (18) are mathematically and physically identical.

Similarly we can approximate the charge threshold in analogy to equation (15):

$$(19) \quad \int_0^{\tau} I(t) dt = Q = I_{\text{rheobase}} (\tau + t_{\text{chr}} \cdot I)$$

where:

$I(t)$ = current applied to a stimulation system
which may be a function of time,
 Q = charge which is identical with the current
time integral,
 I_{rheobase} = rheobase current, in analogy to equation (14),
 $t_{\text{chr}} \cdot I$ = current chronaxie, in analogy to equation (14).

The charge necessary to reach stimulation threshold should be a linear function of the pulse duration.

If the field strength hypothesis expressed with equation (14) is applied to a spherical electrode, assuming a medium with homogenous ohmic conductivity, the influence of the size of the electrodes on the stimulation threshold can be estimated (3,4). We will spare ourselves a repetition of this calculation. But the results were in full agreement with experimental findings (3,5).

We experienced in an animal experiment using differently shaped electrodes of different size that the voltage-time-product was really nicely a linear function, over a wide range of pulse durations (10 μ s to 4ms) as predicted by equation (17). The corresponding charge curves, however, were right ben-

ded (concave) in the smaller pulse duration range, as was stated already by Lapicque (9,11). It is our belief that discussions in the literature sometimes with incredible personal defamation, have their origin in the fact that those investigators experimenting with current sources did not realize that experiments with voltage sources may yield different results. The majority of investigators have used and use current. Hoorweg and Weiss, however, employed low ohmic sources (Hoorweg capacitors, Weiss galvanic elements). Obviously Ohm's Law is not applicable to electrophysiological experiments. Moreover, the chronaxie times for voltage and for current thresholds are different. The voltage chronaxie is nearly half that of the current chronaxie (6).

One question needs special consideration. How is it possible to influence the electric field within the membrane of about 10^5 V/m by an exogenic electric field of about 10^2 V/m (4)? The answer shows the importance of thinking in terms of electric field when discussing electrostimulation.

A non-excited cell may be regarded as a cylinder within the extracellular space which possesses a much lower conductivity due to its insulating membrane. An exogenic electric field, then, is distorted in the vicinity of the cell in a known way. If we assume a homogenous electric field E_{exogenic} to be produced by large electrodes (large with respect to the diameter of the cell), the voltage drop across the cell is given by the electric field strength and the diameter D of the cell by:

$$(20) \quad \Delta V_{\text{cell}} = E_{\text{exogenic}} \cdot D$$

where:

$$\begin{aligned} \Delta V_{\text{cell}} &= \text{voltage drop across a cell in an exogenic electric field,} \\ E_{\text{exogenic}} &= \text{exogenic electric field,} \\ D &= \text{diameter of the cell.} \end{aligned}$$

Now, the potential within the cell must be uniform, since the conductivity of the intracellular space is similarly high as that of the extracellular space. For reasons of symmetry, it must lie in the middle of the potentials of the outside lines just touching the cell. This means that half the potential difference calculated with equation (20) drops across the membrane yielding a membrane field strength due to the exogenic field strength of:

$$(21) \quad E_{\text{Mem.b.ex}} = \frac{1}{2} \frac{\Delta V_{\text{cell}}}{d} = \frac{1}{2} E_{\text{exogenic}} \cdot \frac{D}{d}$$

where:

$$\begin{aligned} E_{\text{Mem.b.ex}} &= \text{electric field within the membrane due to the exogenic electric field } E_{\text{exogenic}}, \\ d &= \text{thickness of the excitable membrane.} \end{aligned}$$

The typical structure of the excitable cell with its high-ohmic membrane insulating intracellular from extracellular space gives rise to a transformation of membrane field strength which is determined by the ratio of cell diameter to membrane thickness. More accurate calculations (18) disclose that the transformation of the membrane field strength is twice that which we had calculated with equation (21)

The same consideration can be expanded by the question: Which effect is produced by the cathode or the anode of a stimulation system? The answer is very simple for an homogenous electric field as was assumed above: exactly the same. The cathode hypopolarizes the membrane nearest to it, whereas the anode hypopolarizes the membrane opposite to it. Pflüger's Law no longer applies in this case. With decreasing electrode size the electric field is more radial which will reduce the field strength with dis-

tance. In this case the anodic threshold is higher than the cathodic one. In cardiac stimulation we found an up to nearly three-fold increase with very small electrodes (1mm diameter).

The key for understanding and discussing stimulation phenomena, in our opinion, is the transformation of the exogenic electric field to a much larger field strength within the membrane due to the cells diameter to membrane thickness ratio. For instance, large fibers must have thick membranes otherwise their stimulation threshold would be very low. Or, if drugs alter the stimulation threshold, a swelling or shrivelling could be discussed as the mechanism according to the above mentioned ratio.

One word should briefly be devoted to the danger caused by 50 or 60Hz electricity. Typically the term "electricity" is simply replaced by "current" which, according to our preceeding reflections, cannot be accepted as jeopardizing humans unless it produces a sufficiently high electric field within the myocardium. According to our calculations (7) the minimum dangerous field strength is approximately 25V/m. Discussions devoted to electric shock and the protection against it would probably be more effective if this view could be taken into consideration.

5. FINAL REMARKS

The work done by the investigators around the turn of this century was admirable. Their results are the more remarkable since they only had an inert galvanometer which was unable to measure pulses in the ms-range. This fact has to some extent prejudiced their thinking and that of their successors. Even though current and voltage could be measured with their galvanometers experimenters mostly investigated the current as the source of stimulation. It is surprising that this superficial quantity has so much dominated thinking in electrophysiology. Some theories in physiology books are the best proof thereof.

We are convinced that our model of electrostimulation, which has so far been confirmed in its practical implications (3,5), will prepare the foundation on which a better understanding of electrostimulation will be advanced. It is the electric field of the extracellular space and its transformation due to the cell geometry which we believe to be responsible for electrostimulation. Though this view is a step deeper into the secret of stimulation, the last step still needs to be taken: How is the change of membrane permeability established? As long as this question remains unanswered, we cannot claim to have found the fundamental law of electrostimulation.

It may sound like a provokation if we state that it is not the current to simulate or endanger humans but the electric field. Of course, any production of electric field in a conductive medium is accompanied by a current as well as by a voltage and both together form the energy needed. But engineering considerations should focus on the question of how the necessary electric field can be produced by suitable electrodes in order to make the stimulator work with lowest energy consumption (or how jeopardizing fields can be avoided).

Such engineering considerations have probably found broadest application in pacemaker therapy. Other disciplines similarly interested in low energy stimulation, should try to activate for themselves the substantial amount of experience and knowledge which is already available to pacemaker therapy.

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ELECTRODE AND NERVE MEMBRANE PROCESSES DURING STIMULATION

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The long-term utility of a neural prosthesis will, in general, depend on the maintained viability of both the stimulating electrode and the cells that are activated by the electrode when a pulsed current is applied. If the electrode is damaged by corrosion and/or the cells damaged by the products of the electrochemical processes occurring during stimulation the neural prosthesis will fail to function. Failure of a neural prosthesis or fear of its failure through these mechanisms is a common problem impeding their development.

The purpose of this communication is to heighten your awareness of processes that are involved in electrically activating nervous tissue. The approach to the topic will be to establish a base by presenting three findings regarding membrane excitation, electrode processes and tissue damage. These three topics are strongly interrelated and it is more efficient to talk about electrode processes in the context of membrane excitation and tissue damage.

BACKGROUND CONSIDERATIONS

The following three facts provide a base for the succeeding discussion:

- the amount of charge required to excite nerve membrane decreases as the stimulus pulse width decreases,
- the electrode processes occurring on the surface of the stimulating electrode can alter the ionic composition of the tissue medium in the vicinity of the electrode,
- a greater excitatory stimulus can be applied to an electrode without the risk of cell damage if a biphasic stimulus is used rather than a monophasic stimulus.

Action potentials propagate along axons by way of a potential gradient established between nodes. Electrically initiated action potentials can be created in a similar way by the application of a pulsed current applied between two electrodes, with one electrode usually closer to the nerve membrane than the other. The phenomenon has been extensively studied and the relationship between the pulse duration and the stimulus magnitude can be described by the well known strength-duration relationship; larger stimulus strengths are required for shorter pulse durations. Transforming this relationship into one that relates charge injection to pulse duration one finds that less charge is required for threshold excitation when shorter pulse durations are used (Mortimer, 1981).

Current flow is supported in the electrode medium by electron migration and in the tissue medium by ion migration. At the electrode-tissue interface some process or processes must occur to support the conversion of the charge carrier (Loeb et al., 1982). These processes almost always produce a change in the composition of the chemical species in the immediate vicinity of the stimulating electrode. Changes in the chemical composition of the tissue medium may directly or indirectly damage the electrically activated cells.

Lilly et al. (1952, 1955) found that biphasic stimulus pulses provided "stable" thresholds for protracted periods of stimulation and that monophasic stimulus pulses resulted in rising threshold over protracted periods of electrical stimulation. Mortimer et al. (1970) and Pudenz et al. (1975) observed more extensive damage to brain tissue when monophasic stimuli were applied to the surface of the brain than when biphasic stimuli were applied. Mortimer et al. (1980) found that muscle tissue could tolerate monophasic stimulation with average current densities less than 10 $\mu\text{A}/\text{mm}^2$ and that greater excitation currents could be applied if biphasic stimuli were used compared with what could be tolerated safely by muscle cells with monophasic stimuli.

MEMBRANE PROPERTIES

Models of excitable membrane have been developed that provide very good insight into the properties of an electrically activated nerve. We have used the myelinated nerve model developed by McNeal (1976) extensively in our own studies. The ability to visualize the model parameters that control the ionic permeability of the membrane has been particularly helpful in understanding how the anodic and cathodic pulse of a biphasic stimulus influence membrane excitability. The ordering of the positive and negative pulse, the duration of each phase and the timing between the application of each phase can either raise or lower (relative to a monophasic stimulus) the required stimulus for threshold excitation (van den Honert et al. 1979).

Threshold excitation is a function of fiber diameter because the node spacing on an axon is a function of fiber diameter. This property is pulse duration dependent and waveform dependent. At short pulse durations thresholds of different size fibers are more widely separated. The separation increases with the use of biphasic pulses (Gorman et al., 1983) These properties offer opportunities to grade a stimulus response by controlling the order in which fibers are activated.

ELECTRODE PROCESSES

In general, the electrochemical requirements for stimulation without damage to the cells in the vicinity of the electrode oppose those for the avoidance of corrosion of the electrode itself. It is therefore crucial to understand the interfacial processes that occur at the electrode in order to determine the appropriate operating conditions for any given electrode material. In practice, small electrodes and high charge densities are desirable.

The data available now clearly mandate the use of biphasic stimuli. Most applications employ a negative pulse to activate the neuron. However, a negative pulse alone produces chemical changes in the immediate neighborhood of the electrode that can cause tissue damage at all but relatively low levels of charge injection. For most electrodes currently used, the major cathodic processes occurring during a

negative pulse are double-layer charging, oxide reduction and reduction of the aqueous medium (hydrogen evolution reaction). Double-layer charging, which does not produce chemical changes, has not been found to support sufficient charge injection to effect cell activation at any practical level. The other two processes generate hydroxyl ions. Therefore negative pulses alone result in a local increase in pH near the electrode, and this must be suspected as a major factor in the observed cases of tissue damage.

At very high levels of cathodic charge injection it is possible to exceed the local supersaturation limits for dissolved hydrogen and in this case gas bubbles will be generated which may be capable of mechanically damaging cells. Even if bubbles are not formed the hydrogen generated by reduction of water may dissolve into the electrode itself (particularly in some high strength metal alloys) and cause hydrogen embrittlement which can degrade the fatigue resistance of the electrode material. For these reasons, very high levels of cathodic charge injection should be avoided, but the exact levels will depend upon the electrode materials and the specific application.

Riphasic pulses are designed to minimize overall chemical changes caused by reversible processes. Ideally in the positive pulse which immediately follows the initial negative pulse the products of the cathodic processes, primarily hydroxyl ions, are consumed by anodic reactions before they can diffuse away from the electrode. For most of the electrodes currently in use, the major anodic processes are double-layer charging, hydrogen oxidation, formation of anodic films (particularly oxides), anodic metal dissolution, and, at very positive potentials, oxidation of the aqueous medium. Double-layer charging does not appear to play any significant role. Hydrogen oxidation and oxide formation produce hydrogen ions or consume hydroxyl ions, and thus counteract the pH changes induced in the negative pulse. However, dissolution processes, either directly of the metal, or indirectly of the anodic film, result in a net loss of material, i.e., corrosion, and will eventually lead to electrode failure. Corrosion may be general or localized, usually depending on the electrode material. For example, pitting is usually the initial form of corrosion seen for high strength alloy electrodes. Oxidation of the medium may involve the oxygen evolution reaction, which produces protons and tends to counteract pH increases resulting for the negative pulse, but can also result in the oxidation of chloride ion to chlorine which could cause severe tissue damage. However, this has not been found to be a problem for platinum electrodes and may not be a problem for other materials (Donaldson et al. 1986).

While a biphasic pulse is desirable to minimize the chemical changes that cause tissue damage, the potential excursion during the positive pulse must be carefully limited to avoid either corrosion or oxidation of the medium. The anodic potential constraint will usually be more severe than the cathodic, and for this reason a symmetric biphasic pulse may not be desirable. In general, it will be necessary to keep the potential below some limiting positive value. This may require that the ratio anodic charge to cathodic charge be less than one. This tends to increase the amount of cathodic products lost by diffusion away from the electrode.

In order to determine the positive limit for a given electrode, and hence the optimum waveform for stimulation, it is important to consider kinetics as well as thermodynamics. In the very short periods (of the order of a hundred microseconds) of most neurostimulation pulses, the electrode processes cannot reach steady state, and it can be expected that processes involving the most mobile species will be favored. For example, it has been found for stainless steel electrodes that the positive potential limit above which corrosion is induced is considerably more positive under stimulation conditions than would be predicted from steady state measurements because the kinetics of the pit initiation process are too slow for surface breakdown to occur in the time of a pulse.

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STATE-OF-THE-ART OF CUSTOM DESIGNED INTEGRATED CIRCUITS WITH RESPECT
TO IMPLANTABLE STIMULATION DEVICES

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SUMMARY

Custom-designed integrated circuits are not restricted to commercial use and mass production any longer. Relatively easy development in reasonable periods as well as acceptable costs offer the advantage of optimal reduction of circuit space and power requirements combined with increased reliability and make them ideally suited for electronic implants. A short survey of various semi-custom design techniques is given as well as a description of the latest IC-development for own implants for multi-electrode nerve stimulation.

INTRODUCTION

A general view of own experiences as well as of results of internationally renowned researchers show, that progress in implantable substitution devices is lower than expected some years ago. We had to learn that "things are not so easy" and that despite of huge biological and technological findings too much optimism had to be revised. This had to be excepted in various fields of bioengineering, e.g. artificial organs, biosensors and problems concerned with functional electro stimulation too.

What are the consequences to be drawn? Because generally "things are not so easy", they should be simplified and reduced wherever it is possible. I.e. solutions should be as straight-lined as possible. Of course it's easier to demand than to fulfill. Nevertheless progress in the technological development of microelectronics was immense in the past. So at least in this field optimism can be justified. According to a saying by Saint-Exupery "technical science grows from primitiveness to complexity and further to simplicity". A tool to achieve the latter might be full- or semi-custom designed integrated circuits. This sounds paradox because up to now in research custom designed ICs are rather unusual probably because of their complexity. But careful consideration of pros and cons of custom designed ICs can show their competence.

FUNDAMENTAL CLASSIFICATION OF INTEGRATED CIRCUITS

Usually designers use standard integrated circuits in more or less complicated electronic circuits. But this proceeding might imply a lot of disadvantages if special requirements on high functional density, superior performance, lowest power-consumption and overall dimensions and a maximum of reliability are demanded. Intentionally the factor "manufacturing costs" is not drawn into consideration because in the domain of medical research it is of minor significance. Custom designed ICs allow to concentrate a maximum of components of an electronic layout into one chip, so overcoming the disadvantages listed above. There is a broad spectrum of solutions of custom designed ICs.

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Conventional full-custom design shrink circuit size to the absolute minimum. The design can be optimized with respect to all parameters because the IC is developed completely anew meeting exactly the premises of the circuit to be integrated. It is evident that circuit design using such a technique is extremely complicated and therefore restricted. Usually full-custom design is done in mass production and is not a metier for rather small quantities in research; expenditure of development time and risk would not be worthwhile.

An alternative is semi-custom design. This technology closes the gap between standard ICs and full-custom ICs. Using pre-manufactured parts the designer can determine the final functional properties within a single additional working process. Corresponding to the practicability and the universality various types of semi-custom design can be distinguished. Without claim to completeness the following technologies can be listed:

- * PROMs, EPROMs, EAROMs, etc. (various types of programmable read-only-memories),
- * PALs (programmable array logic),
- * Gate-array design and
- * Standard cell design.

Most of the solutions mentioned above are digital ICs, but linear circuits are available too (standard cells and gate arrays). Also bipolar (TTL and ECL) as well as MOS (mainly CMOS) technologies are offered. Which type suits best a certain circuit integration depends on diverse conditions. For electronic circuits in implants usually low power-consumption is most important, while frequency behavior is often restricted to less than 1 MHz. This allows the conclusion that CMOS is preferred in most cases. Additionally CMOS has a broad range of possible supply-voltage range (<3Volts - >15Volts) and excellent noise-immunity. Types of ROMs can be considered as well-known and are only mentioned because they are custom-programmed too.

Using PALs, a logic function of small complexity which can be reduced to an AND-OR configuration, can be implemented easily.

Usually PALs are used for replacement of some standard small scale integrated circuits. PALs gained importance for implants since they are available in CMOS and also can be reprogrammed (like an EPROM) which is important for development. Some restriction might be, that they are only offered compatible to HCMOS (high speed) allowing a maximum supply voltage of only 7Volts.

PROMs as well as PALs can be programmed by the circuit designer himself. Hardware requirements are just proper programmer devices and to facilitate development of code of PAL-contents a special software (PAL-assembler).

Opposite to user-programmable parts function of gate-arrays is fixed during production of the chip. Structure of gate-arrays consists of arrays of transistors (N- and P-channel MOS-transistors) which are arranged on the surface of the chip. The transistors are connected by a single metal mask which determines functional properties of the chip, digital as well as analog functions are possible. So for instance appropriate connection of four transistors result in a NOR- or a NAND-function. Such gates also define the complexity of the gate-array. Usual complexity range from 10 to 5000 gates. Of course adequate combinations of array transistors allow to construct all kinds of logic elements.

Design of gate-arrays is done in several steps. Transfer of an electronic circuit into a gate-array first demands check of principle feasibility of integration. This is done by "logic-conversion" of the circuit into elements available on the chip. Additionally time critical paths have to be analyzed and number of pads for in- and outputs must be estimated. It is advantageous to test a bread board design of the converted circuit to prevent any failures, redesign of the metal mask

can be very expensive. Additional simulation programs decrease risks and perhaps suggest some reductions or simplifications of the circuit. Development of the layout of the metal mask can either be done by the circuit designer himself or by the company producing the chip. Computer support is possible but can be omitted without essential disadvantages. If the circuit is not too complex, manual layout usually is more effective and allows better utilization of the chip.

An alternative of gate-arrays is standard-cell design. While maximum complexity as well as number of connection pads is fixed when a gate-array chip is used standard cells offer additional degrees of freedom. "Macrocells" representing elements of medium integration size are stored in a software library and can be composed to a dense layout. So there are no restrictions concerning chip size, complexity and number of pads. Of course production of standard-cell-ICs is more expensive compared to gate-array chips because all essential steps of chip-production have to be done individually.

Housing of chips can almost be arbitrary. Plain chips for use in thin- or thickfilm circuits, SMD-packages as well as standard DIL-packages are possible.

Although financial aspects are of less importance some hints at development costs might be valuable. Of course costs vary between companies, but for example development of mask layout and production of prototypes of a medium size gate-array chip (450 gates) is charged with \$ 15.000.- approx. Development time of the mask layout and production of prototypes is reported to be 7 weeks approx. /1/. Considering that such a chip replaces 20-50 standard IC, so perhaps allowing to put a circuit in an implant, might justify the expenditures.

CUSTOM-DESIGNED INTEGRATED CIRCUITS USED IN IMPLANTABLE DEVICES

Literature search reveals that there are some few applications of custom-designed ICs in electronic circuits for stimulation implants. Of course main utilization is in commercially produced pacemakers but also in research /2/. Other application refer to cochlear implants /3/ and to neural stimulators /4/. Beside this there are applications in biotelemetry /5/, /6/ and sensor technology /7/, /8/.

EXAMPLE OF A GATE-ARRAY DESIGN: DEVELOPMENT OF AN UNIVERSAL STIMULATION IC FOR IMPLANTABLE NERVE STIMULATORS

Multi-channel implantable nerve stimulation devices used by the Vienna group are rather complicated because of the principle of the "round-about-electrode". For stimulation of one function four or five electrodes are used and activated in a periodically varying way. 8-channel implants were produced in thin-film hybrid technology using standard CMOS-ICs. To expand the number of nerves to be stimulated the principle of a master-slave implant system was developed. To simplify circuit design a semi-custom designed gate-array IC is used. Technical data of the 8 channel implant and the gate-array is given in /9/ and /10/.

At present the gate-array-IC is used in a 20-channel implant for simultaneous stimulation of four nerves via five electrodes. Disadvantageous is the fact that additional electronic parts used with the gate-arrays consume more than 70 percent of space. So a second gate-array-IC was developed with special emphasis on universality. There are several modes of operation. The chip can be used either as a

- * single chip 10-channel stimulator for stand-alone applications,
- * single chip 10-channel stimulator in multi-master applications consisting of up to eight stimulators,
- * master implant with up to eight slave implants and
- * slave implant with 10 outputs.

Activation of one of the four modes is done by mode-control inputs.

Additional electronic parts necessary for the implants are limited to some resistors, capacitors and a current source supplying the stimulation current. The latter is controlled using an 8-bit R-2R-network. Beside the choice of the operational mode also some output parameters can be selected. It is possible to use

- * true mono-phasic stimulation impulses,
- * bi-phasic stimulation impulses,
- * chopping of output impulses,
- * inversion of output impulses and
- * either tri-state or grounded output condition between successive stimulation impulses.

Input information into the chip is either directly derived from a demodulation circuit of the receiving coil of the implant or can be supplied by an additionally provided microprocessor using on-chip level converters.

The gate-array is produced by CROSSMOS using a CM840 CMOS-chip consisting of 840 N- and P-channel MOS-transistors /1/. Supply voltage range is 3 to more than 18 Volts. Output stages can drive more than 6mA.

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CONTROL OF FES BY DETERMINISTIC CONCEPTS
AND STATISTICAL SEARCH PROCEDURES

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SUMMARY

At the present time paralyzed handicapped may regain some functional moveability by use of FES. But the extent and the applicability in daily use of these movements is still limited. To extend the possibilities of FES sophisticated feed back control has to be incorporated, requiring sufficient observability and controllability as prerequisites. This altogether requires the installation of numerous sensors, electrodes electrodes and computing power. In addition the FES-Systems have to be customized to the individual needs of each handicapped. The paper gives an overview of the principles the developer has to observe.

By now research in FES is carried through continuously for more than 20 years (1, 2). So far the basic foundations for applying FES have been laid, as: The physiology of the stimulation of the centrally paralyzed muscle including the stimulus parameters, the training for the paralyzed muscle, and the selection and combination of different muscles to perform simple functional tasks as a handgrip or show steplike movements with the support of crutches. But besides all the progress having been achieved FES is still waiting to pass the boundary of general acceptance by the handicapped to be included in the routine of his daily life on a broader scale. Three major shortcomings have still to be overcome to give the handicapped a sufficient command and smoothness of movement to make FES serviceable for everyday use:

- Mounting of the stimulation equipment and setting of the stimulation parameters
- Easiness of operation and variability of guidance of the limb movement by the handicapped
- Artificial control of the movements with sufficient degrees of freedom.

In order to envisage the magnitude of the problem one may briefly recall the chain of control man uses to execute normal movements and its anatomical and physiological basis. Each limb has more than 40 degrees of freedom which are controlled by roughly the same number of muscles (a few more). Between the muscles often exists crosscoupling, quite a number of muscles serve more than one joint, and the function of some muscles changes depending upon the position of the limb. To contract the muscle of the body appropriately they are subdivided all together into about 100.000 motor units controlled by the motoric centers of the nervous system enclosing billions of nerve cells. The chain of control itself, for instance to pick up an object, may be subdivided into the following functions:

- Location of the object
- Computation of the trajectory of the movement

- Determination of the stimulation patterns of the muscles
- Issuing the command for the movement
- Control of the muscle contractions itself
- Measuring, evaluating and correcting the position and force vectors of the limb.

In this chain the "Location of the object" and "Issuing the command for the movement" has always to be executed by the handicapped. The other functions have to be more or less transferred into the technical domain and substituted by technical means depending upon the level of injury. Staying with the example of an injury of the spinal cord at a high level, a tetraplegic, the loss of voluntary functions may include more or less A) only the hand-function, or B) the elbow joint, or C) the whole arm with the shoulder joint. For all of these three cases the controlled element is the limb or parts of it, the actuators to be activated artificially are the paralyzed muscles, feedback has to be established by technical sensors. A precondition for applying FES is up to now, that the injury resulted in a central paralysis, interrupting the connection between the brain and the spinal cord, whereas the motor neurons with the nerve connections to the muscles are still unhurt. At the level of injury of the spinal cord this precondition is always more or less not given with the result, that not all of the muscles needed for a specific function might be available for the stimulation.

Starting with the most simple case A) shoulder and elbow joint may still be controlled by the handicapped, the hand function has to be restored artificially. The hand with the fingers has about 30 degrees of freedom which makes it such a marvellous tool. It is at once obvious that it is impossible, at least right now, to make use of all of these degrees of freedom. They have to be restricted to a limited number of functional grips. Today this are mainly the, the key grip and a pointed grip of the first three fingers. The goal is always to grasp object, a cup, a fork, or a pencil and use it. During stimulation the hand with the fingers is fixed, the variability of the executed movements is achieved by the voluntary control of the shoulder and elbow joint. At a first glance the stimulation pattern seems to be rather simple - and it often is. Two or more muscles or muscle groups have to contract themselves at a short range, the grip has to be firm. What is needed is an on-off-control after the initial setting of the parameters. But in quite a number of cases this is incorrect.

To begin with the activation of each stimulation channel requires the control of one degree of freedom. A tetraplegic may control voluntarily but only one degree of freedom, two degrees at the most.

- Besides the activation has to be executed with the appropriate timing, e.g. at first to open the hand, than to close it.
- When closing the fingers, they have to be moved in parallel with correct timing in order to adjust at the endposition wanted.

Using a few stimulation channels, this might be achieved by a linear time-slope matrix. To combine a larger number of channels and/or if severe crosscoupling between the channels exists, than a more complex programming procedure might be applied (19). This procedure divides the total movement in a number of steps. At each step the parameters of every channel is set, thus modelling the nonlinearities of the system piecewise. By means of a speech recognition system the movement might be programmed by the handicapped himself (3, 11). Regardless which method one uses the result is a preprogrammed movement, of which only the onset, inbetween stops, the end, and the selection of different movement patterns might be controlled by the handicapped. The sensor system are the eyes. The method seems to be rather rigid, but true improvements usable

during the daily routine are difficult to gain. One might think of at least force and slip sensors to give a secure but not too strong grip, also to reduce fatigue. Adding position sensors would provide the possibility to adjust the fingers automatically to the shape of the object, and to store the result. The price of adding sensors at this level is loading the hand with additional elements and wires, which requires a lot of effort and time by the handicapped. Besides the main problem of the handicapped would persist: how to pattern the handmovements on-line to different situations and control it during the course of movement, so to say naturally without requiring too much effort. At this level of FES therefore a model with fixed parameters, heuristic programming and feed-forward control seems to be appropriate for the time being.

The next stage B) includes the control of the elbow joint. In controlling the movement of large joints the need for feed back is more obvious, because the stimulus - contraction - relation is often not constant. The elbow joint has basically one degree of freedom. The M. biceps and M. triceps must be sufficiently stimuable to control the fore-arm. The angle position has to be set voluntarily by the handicapped because he has to determine the position of the hand in space. The necessary variability of the hand position may be achieved through the shoulder joint, which allows a good range of adjustment. - We have been able to activate hand and fore-arm movement in one handicapped with good success. - To secure the position of the elbow joint- or the knee joint - one might use feedback with a simple PID-controller as Chizek et. al. (7) did, assuming a plant with fixed parameters.

True control problems will arise when one proceeds to C) including the movement of the shoulder and/or a large number of stimulation channels. The problems are similar with the lower extremity. In these cases relatively large masses have to be guided over wider ranges. Some of the muscles moving the shoulder or the hip joint are short and difficult to stimulate. In addition with the increasing number of stimulation channels the degrees of freedom to be controlled do the same. The amount of severe nonlinearities to be taken into account grows. To build an unique deterministic model of the whole limb takes great effort and its validity is very limited because of the nonlinearities. Crago et al. (8) found already in the simple situation of the force control of the contracting muscle, that the controller has to be at least adaptive. Nguyen et. al. (10 ,19) conducted a more extensive analysis of the control problem and came to the conclusion, that even for a simple antagonistic pair of muscles the nonlinearities in time and space are this severe, that only a fast repetitive real-time identification routine of a deterministic model of second to third order results in a control-loop of sufficient properties. This means in essence, that the control-surface of the muscle contraction is a multidimensional nonlinear surface and the deterministic model incorporated in the identification routine is nothing but a substitute being guided in a heuristic way along this surface. Petrofsky (21) tried to model the leg dynamics deterministically and presented a system with 63 parameters. To cope with the requirements of real walking through FES, he used a stepwise mode of operation for the different phases of the step (22).

These experiences rule out the use of a deterministic model of the whole limb. Three principal procedures may be used in this situation:

- a) A stepwise algorithmic control of the different phases of the movement, switching between modes of operation at certain repeating breakpoints;
- b) a division of the control into subloops for each joint and a master controller guiding the movement along the trajectory; a) and b) might be combined, Chizek et. al. (7);

- c) a statistical search procedure as controller assuming that any overall knowledge of the actual system properties of a paralyzed limb and the ability to stimulate its muscles is heuristic.

In order to evaluate the applicability of search procedures Nürnberg et al. (4) conducted a basic theoretical and experimental study. The control concept has the advantages to avoid the modelling of the plant completely and to take into account and combine parameters, variables and boundary conditions of different nature. In order to do so the controller of a conventional deterministic control loop is replaced by a heuristic search algorithm.

The goal of this algorithm is to vary the vector of the actuator outputs in such a manner that the distance between the limb position and the target becomes (close to) zero. By this the actuator outputs are not computed due to the knowledge of the deterministic properties of the system but due to a general procedure - control strategy - . The final and the actual quantities of the vectors Ω_f and Ω_a are most often repre-

sented by angles and moments of n components each, the degrees of freedom. The actuator signals are the currents stimulating nerve and muscle. They are combined to the m -dimensional actuator vector, with $m \geq n$.

The balance of the vectors Ω_f and Ω_a is used as a criterion of

performance, i.e. by using its absolute value $P_C = \sum_{k=1}^n |\Omega_{f_k} - \Omega_{a_k}|$

or its square $P_C = \sum_{k=1}^n (\Omega_{f_k} - \Omega_{a_k})^2$. The target is reached by the

limb for $P_C = 0$. The connection between the vector of the actual

values of the parameters of the limb and the vector of the actuator signals is given by the unknown stimulus-contraction characteristics of the muscles. Therefore the control strategy might be formulated generally:

"Search a vector of the actuator signal in such a way, that the performance criterion P_C becomes zero".

This procedure has the advantage, that also complex systems, which are not identifiable, might be controlled by it, provided the search algorithm converges sufficiently.

As search procedure the Evolution Strategy introduced by Rechenberg (13) has been chosen, because it works especially well with difficult boundary conditions.

The method intends to copy some of the rules the evolution procedure of Nature by applying the mutation - selection - principle. The object to be mutated is in our case the actuator vector. The offspring is a new actuator vector, generated by adding a vector at random with Gaussian distributed components to the former one. The stepsize of the mutation is determined by the standard deviation S of the distribution. Is the quantity of the old performance criterion larger than the new one, the new vector is varied again. Is it the other way around, the old actuator is varied. A good convergence of the algorithm is obtained if S is chosen such that 2 out of 10 trials are successful.

In order to prove the applicability of the Evolution Strategy on the control of FES experimental and model studies have been conducted. The position in space of the hand and the elbow joint in the upper limb was measured and the hand could be moved to a given target by means of this control strategy. Even if the hand was thrown out of place more severely by an unforeseen muscle contraction, the strategy brought the hand back towards the target at once.

Model calculations showed that the strategy should be applicable to the control of FES for systems with at least 8 actuator - stimulation - channels, taking into account the computational speed of today's microcomputers

The control procedure has the advantage, that boundary conditions and the successful stimulus parameter combinations might be worked into the performance criterion expanding it to a learning system. By this the application of FES will be divided into a learning phase and an execution phase. The computing time needed by the execution phase will be much shorter than the learning phase. In addition even during the execution phase the system is improving its performance and adjusting changes of the situation of the limb.

Regardless which procedure will be chosen to control the movement of the limb at first one has to prove, that conditions of observability and controllability are fulfilled. To illustrate these prerequisites, one has to care that every degree of freedom of the movement might be measured precise by enough over a sufficient wide range and that the muscles being stimulated develop their force not only strong enough to support the body weight but also sufficient fast to keep the upright balance. Looking at today's effort to let a paraplegic stand and walk these conditions seem by far not given. Especially the loss of the counterbalancing capabilities of the more or less paralyzed body has so far not been touched. For instance has a tetraplegic often has to use his one arm to fix the body to the wheelchair when executing a movement with the other arm thus being limited in his range of reach.

At least when controlling the movement of an entire limb the trajectory along which the movement has to be guided must be established. In FES supported walking this trajectory is better or worse given by the limited number of degrees of freedom and the control via the eyes, which try to adjust the body in such a position that a forward step results. But this puts again a lot of effort on the handicapped. To free him of this an efficient system computing the trajectory and its boundary conditions after he has pointed out his goal of movement would be necessary. This pointing and scanning device might be ultrasound or laser based and has to have sufficient computing power to fulfill its task adequately.

As a consequence of this evaluation it might be concluded in general: At every stage of applying FES on a paralyzed limb heuristic components of installing a control, feedforward or feedback, are included. These methods to match the heuristic components might be more or less of the trial and error type, using the available preknowledge, or sophisticated from a stepwise programming procedure to a systematic search procedure. Especially if certain shapes, positions, forms, or trajectories exist or if the number of parameters becomes larger search procedures might be applied with benefit. This holds also true if one wants to obtain only the transfer properties of a plant, e.g. a limb.

Deterministic control procedures are useful only if one may assume constant relations between the variables with unimportant nonlinearities. Within limited sections and applications this is the case. But for the

majority of applications non deterministic control strategies will provide an easier access and more comprehensive solution of the problem, especially because FES has to individual customtailored according to the situation of every handicapped.

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SELECTING THE STANDING-UP STRATEGY IN SCI PATIENTS UTILIZING FES*

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SUMMARY

The feasibility of functional electrical stimulation (FES) for restoration of locomotion in spinal cord injured (SCI) patients has been demonstrated. FES is now entering the phase of clinical utilization. In this paper, attention is focused on the problems of optimizing each patient's individual performance by selecting the best FES sequence and providing adequate training to make use of all the patient's preserved capabilities. To do this, some of the biomechanical principles of standing-up in normals and in SCI patients using FES are highlighted. This knowledge can be utilized for the development of rules and standing-up strategies for patients. Consequently standing-up trajectories which require lower effort and allow more effective standing-up can be selected. In this respect the patient's physical therapy (PT) training is adjusted and the required learning time is shortened.

MATERIAL AND METHODS

Walking is performed in an upright position. Therefore a prerequisite for gait is the ability to rise from a sitting position, maintain upright stance, and return to sitting, safely and by minimal effort. The minimal requirement for standing by means of FES is bilateral activation of the quadriceps muscle for providing the locking of the knee joints. /1,2,4/ The SCI patient uses his hands for assisting and balancing during standing-up. Once the upright position is achieved, the hip joint is locked in hyperextension by ligaments while the hands provide stabilizing forces for maintaining the well known "C" posture. This standing is similar to standing with KAFO. The FES provides knee locking so that the ankle remains free and the hands must be used for balancing. For this study, well rehabilitated SCI patients using FES were selected and their standing-up and sitting performance while using FES were biomechanically recorded. A force plate provided ground reaction forces, torques and supportive vector coordinates while electrogoniometers recorded joint angles. Light markers and photography were used for later calibration and verification of

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the electrogoniometers. The standing-up and sitting performance of patients using different seat heights and hand placement in parallel bars was recorded and compared to records obtained during comparable movements in normals. For each standing/sitting test at least three runs were recorded. A/D conversion was performed by a 50 Hz sampling rate. The coordinate frame used for data recording was: z-coordinate-vertical, y-coordinate antero posterior direction and x-coordinate medial/lateral direction. Eight channels of data were recorded: M_x torque, F_z and F_y forces, Φ_h -hip, Φ_k -knee and Φ_a -ankle angles, and seat contact. In normals at least two EMG channels were used (M. Quadriceps and hip extensors and/or ankle plantarflexors). Three patients and five normals were measured. The data was stored on a disk for later evaluation. The stored data was plotted out as functions of time, angle/angle diagrams, vertical/horizontal displacement and displacement versus time curves. From the trunk, hip and knee marker displacement versus time curves, computer graphics stick figure drawings were constructed. The angle/angle diagrams for displaying the data are selected according to the posture space definition proposed by Nashner et-al. /2/ The Φ_k represents the vertical-suspensory movement axis, the Φ_h the horizontal x-axis and Φ_a the horizontal y-axis. We elaborate, supposing symmetrical left/right performance the sagittal plane display of Φ_h versus Φ_k and Φ_a versus Φ_k presents the "suspensory" trajectory projections while the Φ_h versus Φ_a projection is a measure of ankle/hip joint coordination since it is a prerequisite for balance. Here the presentation will be focused on the trajectories' use. The influence of seat height was also studied and how the speed of the stand/sit movement influences the data. The origin of posture space is perfectly upright standing, theoretically requiring no muscle effort since the ground reaction vector passes through all three joints. Normals tend to select an end point for standing near this origin.

RESULTS

The records-projections of the stand/sit trajectory show a rather smooth curve in normal subjects, particularly where the Φ_k -suspensory axes is involved. The sit curve nearly follows the stand-up curve. Also the vertical displacement versus time curves for the z-coordinate of trunk, hip and knee (z_t , z_h , z_k) are smooth and nearly parallel. The Φ_h/Φ_a projection of the stand/sit trajectories are less smooth, have very similar slopes and can be farther apart. In Figure 1.a,b,c and d the stand/sit projections are shown together with the vertical displacement curves for a normal 30 year old male. In Figure 2 the same plots as in Figure 1 are displayed, this time for a T-7 complete injured paraplegic patient sitting down. The M. Quadriceps FES provides partly suspensory assistance, while the majority of standing-up propulsion (sitting down braking) is performed by the hands. Therefore the more vertical (horizontal) character of Figure 2b and c is preferential. Similar records have been obtained from normals using hands to assist standing-up. The lower U-shaped part of curve depends on the velocity of movement and distance between leg placement and chair center line, and is a measure of required/produced antero/posterior shear force. The appropriate leg placement for stand/sit by FES of Quadriceps alone is close to the weight line of the sitting person resulting

in a near vertical Φ_a/Φ_k and horizontal Φ_h/Φ_a plot ensuring the shortest and most effective standing-up trajectory. Any "looping" or "arching" with irregularities indicate poor patient performance and excessive energy use. We also note that proper leg placement results in nearly no vertical displacement of the knee (Fig 1d and 2d.) Accordingly, the hip and trunk centers have large displacements, therefore the knee extensors and hip versus trunk extensors are providing the antigravity lifting work. We conclude that adding of FES to hip extensors, hamstrings and adductor magnus are indicated and that this may result in standing-up with minimal use of the hands. During standing, the hands are used mainly for aiding balance and safety.

The standing-up maneuver in normals lasts approximately 0.5 - 1s. During that time, the amplitude of FES should be ramping to a sufficiently high level, after which, reaching standing the amplitude may be reduced to a level being sufficient for safe joint locking. The stand/sit time in our patients is 0.7 - 2.0 s. The good performers have shorter time indicating that PT training shall concentrate on achieving stand/sit times of about 1 s.

DISCUSSION

The presented results indicate that initial leg placement and timing for M. Quadriceps FES standing up is important. Improper leg placement and sitting height with posture lead to drastic increase of patient effort. In general smooth trajectories indicate effective stand/sit performance. Adding FES of hip extensors with part of hamstrings and adductor magnus might enable stand/sit maneuvers with minimal weight bearing by the hands.

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Figure 1

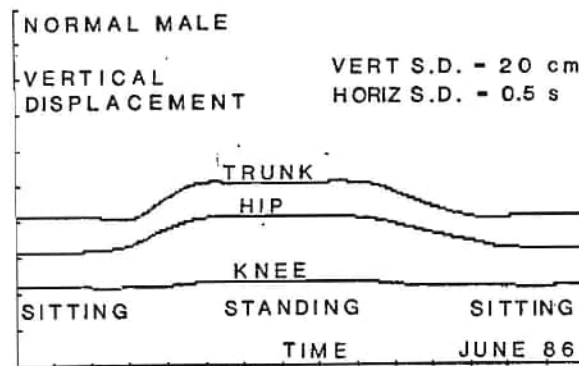
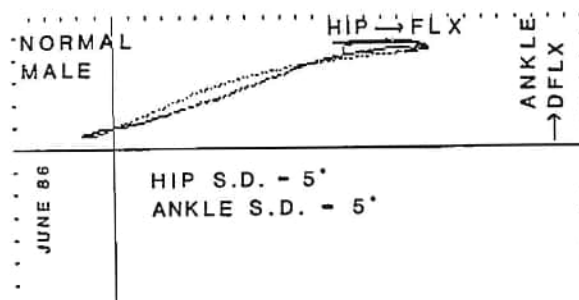
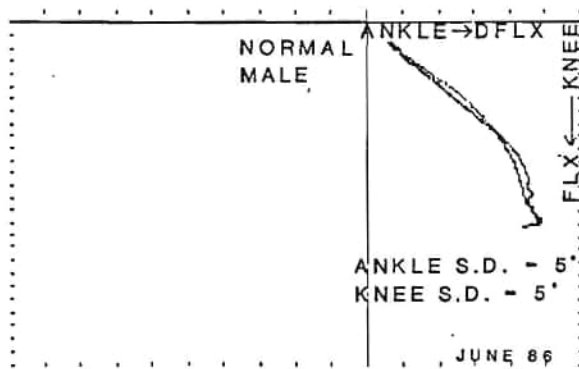
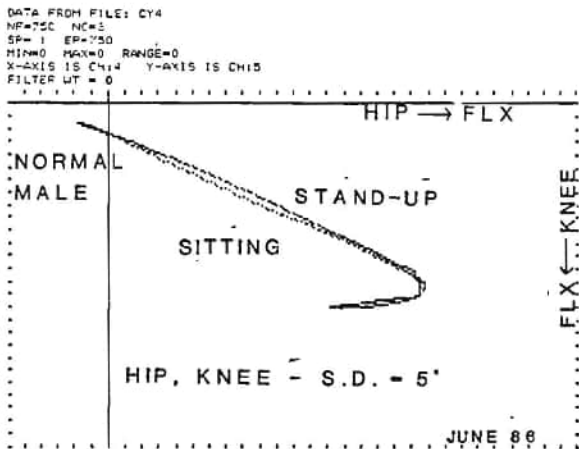
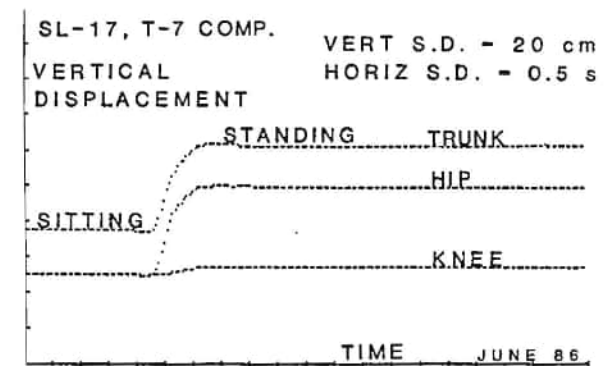
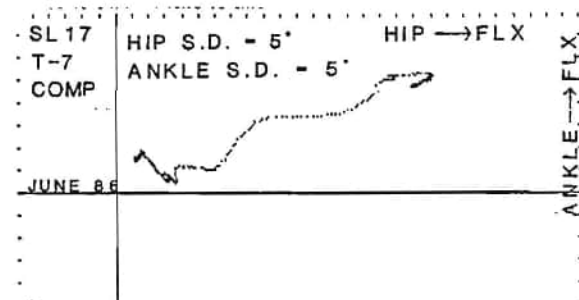
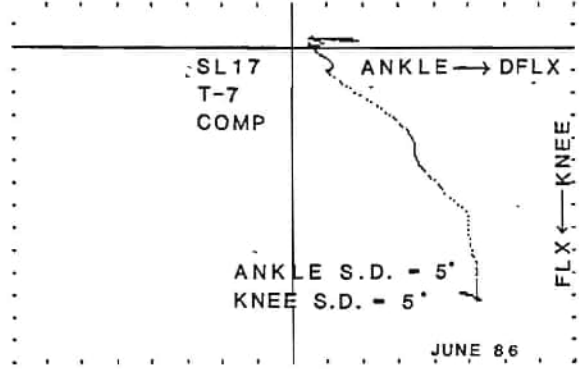
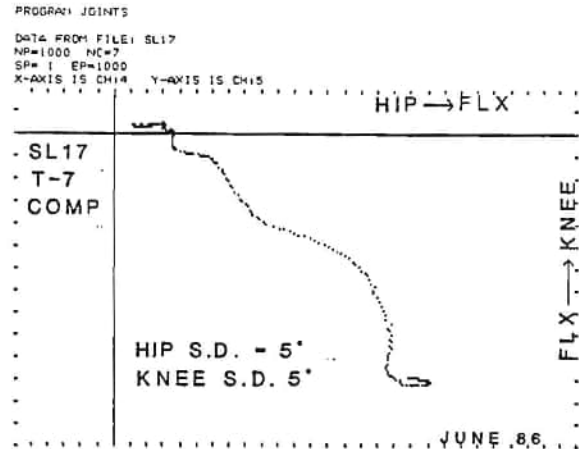


Figure 2



SOME EXPERIENCES AS A RESULT OF USING PERSONAL FES EXERCISE UNITS

* H.W. Grenfell

Enablement Technology

SUMMARY

Since 1982 over two hundred patients have exercised using personal exercise units mostly at home but also at eighteen hospitals and rehabilitation centres. Over seventy of these patients are now standing and many are using their own exercise equipment for learning to walk.

A large amount of experience has been built up as a result of this work and this paper outlines some of the more important findings.

Quadriplegics and paraplegics have been treated, complete and incomplete; upper and lower limbs have been exercised using electrostimulation as well as postural muscles.

MATERIALS AND METHODS

Since starting electrostimulation in 1982, (Ref 1.) we have studied most of the other work that is going on in the subject and realised that virtually all the work is being done under stringent selection of patients and also laboratory based. For example, all lesions had to be complete; they had to be within certain limits, i.e. T5 to T9; the subjects had to respond well enough to electrostimulation and they had to be exercised to a rigid protocol. This approach seemed to be more than adequately covered so we decided on a totally different approach.

1. Where possible the person would have their own exercise equipment at home.
2. If money was available, anyone was accepted for the programme though priority was given to those who fitted into particular lines of research.
3. All levels of lesion including brain damage was tried.
4. Upper and lower limbs as well as posture muscles were exercised.
5. Each patient had to obtain approval from his medical adviser.

Because of the wide acceptance of patients a large number of people were used who would otherwise have to wait sometime before the research came out of the laboratories. In all over two hundred people are using the exercise equipment and about one third are already standing on paralysed muscles.

To establish the initial state of the patients, Muscle Strength/Duration Curves are plotted using an Orthotron mark 6 Controlled Current Stimulator to the method outlined in Ref 2. which allows a curve to be plotted of muscle reaction from 300 to 0.1 milliseconds. The patient is assessed by our physiotherapists using the equipment as well as a complete assessment of muscle function and sensation. A programme of exercise is then suggested to the patient using electrostimulation and conventional exercise. The patient then goes and carries out the exercise before returning for review at a recommended time interval, usually two months. The exercise period is built up from fifteen minutes to one hour over the first month and the recommended regime is a minimum of three times a week.

Four types of stimulator are in use; the first is a ten channel stimulator that can be set up in an exercise mode with an auto timer and a real time counter to show remaining time; the second is a four channel stimulator with an exercise and standing programme; the third is a two channel stimulator for exercise and standing; finally a four channel stimulator which can be worn on the waist and contains an ambulation programme.

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The patients are arranged in groups according to the research programme they are taking part in as follows:-

1. Those with reasonable balance and posture control for the ambulation and electrically assisted transfer programme.
2. Those with cervical lesions for arm exercises and hand control.
3. Those with flexor spasm, ankle inversion or adductor spasm which needs special exercise programmes.
4. Those with special problems such as decubiti or contractures.
5. Those with lower motor neurone lesions and flaccid muscles.
6. Those with significant return of function after electrostimulation for EMG, evoked potential and special pulse tests.
7. Cardiovascular fitness and homeostasis programme.

Electrically Assisted Transfer (EAT)

The Electrically Assisted Transfer and the ambulation programme is split into two parts. The first part is to produce a very simple device that is easy and cheap to produce. To do this the approach has been to arrive at a consensus between patients of the minimum number of muscle groups necessary to produce reasonable ambulation and simple switching devices for the control of steps. It also involved the design of a simple walking frame.

Cervical Lesions

The work that is being carried out on cervical lesions is as follows:-

1. The triceps are stimulated to strengthen them for assistance with transfer. This involves research into electrode placement and design as well as looking at the effect of different pulse shapes for producing improved function. It is quite often complicated by overflow into the biceps, some sensation and lower motor neurone damage.
2. Stimulation of the wrist flexors and extensors and finger flexors and extensors to produce useful hand functions.
3. Sitting posture for quadriplegics is usually very bad and so considerable work is being done to improve the posture and all muscles from the deltoids down are being stimulated depending on the particular problems of the patient.
4. The leg muscles of these patients are also being stimulated according to an athletics training programme to improve cardiovascular fitness, produce a normal homeostasis, improve blood circulation and skin nutrition. This programme is akin to 'wheelchair jogging'.

Problematic Reactions

Some patients suffer from patterns of spasm which are detrimental to producing useful function by electrostimulation. This usually takes the form of flexor spasm in legs when we are trying to produce extension. This is usually overcome by careful electrode placement and design and exercising very gradually so that the agonist muscle is strengthened with respect to the antagonist, spastic muscle.

Lower Motor Neurone Lesions

A large number of patients have lumbar lesions with cauda equina damage. These muscles become denervated and atrophied and the Strength/Duration Curve shows that they cannot normally be stimulated at 50 ma below a pulse length of at least 10 ms and sometimes 30 ms. A considerable amount of work has been done over the past two years experimenting with different pulses and exercise programmes in an attempt to build up muscle strength. There are spinal injuries and brachial plexus lesions on a research programme which consists of experimenting with electrode design and pulse shapes.

Return of Function

A totally unexpected side benefit of electrostimulation has been that some patients experience some return of function. This has prompted a whole new research investigation to attempt to answer the following questions:-

1. What injury is likely to result in return of function?
2. How long since commencement of stimulation can different types of return be expected?

3. What are the likely mechanisms of return?
4. Can even more return be achieved?

The method of approaching this research is to physically examine each patient before electrostimulation. This is done by our physiotherapists and charts produced for sensation and mobility according to the Oxford Scale. Any signs of function below the lesions means that the patient becomes a candidate for the return of function research programme, though everyone is continually monitored for signs of return.

Particular tests are being designed to initially assess and continually monitor patients mostly involving the use of a Medelec Mystro EMG Machine and involves such things as somato-sensory evoked potentials and late responses.

Finally a graphic waveform generator has been designed and linked to the Mystro so that the response above the lesion to any pulse shape or combination of stimulation can be recorded.

DISCUSSION

Arm and Hand Control

Particular priorities have arisen as a result of the experiences derived from seeing a large number of patients. Top of the list must be obtaining an improvement in the function of arms and hands for quadriplegic patients. The difficulties arising have only hardened the endeavour to find solutions.

A particular theory arising out of the work is that spinal injury is rarely confined to upper motor neurone damage but it is suspected that it is usually accompanied by lower motor neurone damage in the area of the lesion. This has been arrived at purely from the difficulty in stimulating certain limb muscles in quadriplegics. The two muscle groups which are usually involved in this problem are the triceps and the wrist extensors. This is usually accompanied by some spasticity in the opposing biceps and wrist flexors. It might be complicated by some sensation or even hypersensitivity, so that the pulse usually needed for stimulation in the case of lower motor neurone lesions is out of the question. Techniques are therefore being developed to produce pulses which can produce the desired responses without too much discomfort and to combine these with the electrode design and placement to improve function. The unusual aspect of this work appears to be those very muscles that are susceptible to the apparent lower motor neurone damage, are also those that tend to get return of some voluntary function. Since this cannot be predicted at present, it is therefore important to continue with the stimulation even though the response is minimal.

Cardiovascular Fitness

A further important consideration is cardiovascular fitness and chemical imbalance caused by large volumes of muscles being paralysed. The 'wheelchair jogging' aspect of the electrostimulation programme is therefore of paramount importance since it really makes the body function as though muscles are not paralysed.

Almost every patient reports improvements in general health and well being, feeling exhilarated after electrostimulation exercise. One patient a C6/7 lesion of long standing was receiving electrostimulation of her quadriceps throughout the whole of her pregnancy on the advice of her gynaecologist since it heightened her blood pressure to a more acceptable level and he felt that the baby would benefit from possible improved blood circulation. She finally delivered a 2½ Kg baby girl by Caesarean section but the doctors believed she could have had a normal delivery which would have been the first at this level of lesion.

Ambulation and Electrically Assisted Transfer

The EAT programme is certainly considered of lower priority than that of either arm and hand function for quadriplegics or the 'wheelchair jogging' programme for cardiovascular fitness.

About eighty people are standing using electrostimulation up to mid-1986 and over twenty are learning to ambulate.

The production of a simple four channel ambulation device is complete and these units are now being used by patients at home for everyday living. They are reasonably small and light and can be worn on the waist. Electrodes are fitted into a harness which can be put on in the morning, worn all day and taken off at night and ensures that the electrodes are in the correct position. Electrode gel has been formulated which lasts all day without drying or crystalising. No calipers or braces are necessary except occasionally some sort of ankle support for those who have a tendency to plantarflex and invert the foot. All patients at present are using a specially designed reciprocating walking frame though there is no doubt that some of the more skillful will eventually use elbow crutches since some have already taken a few steps using them. Control of the equipment is by means of hand switches which are mounted on the walking frame. There are four switches in all; two to switch the power on for standing, two further switches, one for each hand,

initiates the step for each leg when the person is ready. So the speed is completely under the persons control and depends on the degree of skill acquired in shifting weight and balance.

The first model of the more sophisticated device has undergone trials and includes stimulation of posture muscles as well as lower limbs. It has allowed one subject to climb a step, to take a step backwards and to balance for a short period without holding on to anything. Because of the limited trials to date it cannot yet be said that this was due to the equipment rather than the skill of the subject.

Return of Function

Return of sensation and voluntary contractions of muscles is one aspect of electrostimulation which has been totally unexpected. It has highlighted the possibility that present methods of assessing completeness of lesions are totally inadequate. There are certain facts emerging from the stimulation programme concerning return of function.

Some people get return of function very soon after the electrostimulation programme has started. It would be difficult to argue that these people were not going to get that return anyway. Disregarding this first group the first signs of return of function are seen after five months. This usually takes the form of return of some sensation. The most likely areas for this return is immediately under the stimulation electrodes, or in the feet. The next thing to return is some proprioception or return of sensation a few levels down from the lesion. Return of the motor function is very limited though quadriplegics seem to get return of their triceps and finger flexors. Posture muscles certainly improve quite frequently and occasionally hip flexors. In lumbar lesions return of the quadriceps function has occurred, usually only partially in individual muscles, though in some it has resulted in them standing and starting to walk.

If a limb is partially spastic and the spasm can be reduced, it is sometimes found that there is some voluntary function in that limb. As far as when, if at all, this return will stop it is still difficult to say. The person who has undergone stimulation on our research for the longest period of time is a C6/7 lesion. She had a steady return of function from the fifth month of stimulation and we started fourteen years after her injury when her condition had remained unchanged for twelve years. It is very difficult to explain why she had return of her intercostal muscles after three and a half years of stimulation and after almost four years of stimulation she had return of her ability to perspire under her arms.

CONCLUSIONS

A large number of paralysed people develop contrary conditions as a result of living in a wheelchair. Many of these unfortunate troubles could be avoided with correct electrostimulation and life expectancy improved. The general cardiovascular fitness must help with the respiratory infections to which these people are prone as well as problems associated with poor circulation such as oedema and decubiti. If electrostimulation is applied as soon as possible after spinal injury then we might see a totally different pattern emerging from spinal units. Since it is so difficult to predict return of function in spinal injury there must be a need to apply electrostimulation where possible. In the meantime there is a great need of more accurate assessments of the neural damage in such cases. Such ambulation is already available for paraplegics using transcutaneous electrostimulation alone, with no external braces. A more sophisticated device is well on the way which will allow posture muscles to be stimulated as well as lower limbs, and it is hoped that this will allow people to climb steps.

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Preliminary results of studies on functional electrostimulation of paraplegics.

The post-traumatic injury to the spine is most often found in the thoraco-lumbar segment. This part of the spine is particularly injury-prone, as it is the junction between the quite stable and compact thoracic spine and the physiologically mobile lumbar segment. The stability of the thoracic spine is due not only to the junction with the chest, as is generally thought, but also to its very anatomical structure: the intervertebral discs are not high and the articular facets are in frontal plane. In the lumbar segment the anatomical situation is different - the intervertebral discs are high and the distances between particular discs are great, while the intervertebral articular facets are in nearly sagittal plane, hence permitting a wide range of mobility in this direction. Therefore it is not surprising that sometimes the force of injury acting much above the thoraco-lumbar segment leads to the disconfiguration of the vertebrae at this border site of the two segments of the spine characterized by different biomechanical properties. In such cases of spinal injuries, the spinal cord is, as a rule, severely damaged what subsequently leads to the paralysis of lower extremities and buttocks. Under such circumstances the simplest solution is to adapt the patient to a wheel-chair way of life. With a view to psychological problems and practical aspects concerning the numerous architectural barriers encountered by a wheel-chair person, however, we try to teach paraplegics to walk.

The conventional process of locomotive rehabilitation provides the patients with lower limbs paralysis with braces

stabilizing knee and ankle joints and this enables them to ambulate on the principle of rotative movements of pelvis and trunk, or like a physical pendulum. The most common equipment for paraplegics, nevertheless, is still a wheel-chair pushed by hands. Such orthotic locomotion aids will obviously be in use for a long time, and although they will be improved and perfected, still will not create optimistic perspectives for paraplegics.

Another approach to this problem is the creation of circumstances for regeneration of impaired nervous structures controlling locomotion or the replacement of their function by external control of activity of paralyzed muscle groups. In the present state of knowledge it seems that the only method which can meet the requirements is functional electrical stimulation by means of multichannel stimulator controlled by a programator or microprocessor.

Good results of studies carried out in this field by various centres in the world made us take up clinical experiments on the application of FES methods to restore the upright position of paraplegics at first and then their locomotion. Our studies started in the beginning of the 80-ties. At first we carried out a series of tests to assess the influence of electrical stimulation on gluteal muscle, quadriceps and peroneal muscles in 6 paraplegics in different periods after spinal cord lesion. 6-channel standard stimulator equipment with surface electrodes was used in these investigations. The 15 minute stimulations were carried out once a day subsequently exciting 6 muscle groups of both limbs. The time duration of one contraction was set on 4sec. so the time interval for muscle resting was 20sec. During the measurements of the effectiveness of electrostimulation we observed improvement of the force developed by stimulated muscles and an increase in their resistance to fatigue. Simultaneously it turned out that the use of a standard stimulator with non-isolated outputs with bipolar surface electrodes caused the transfer of excitation to other muscle groups, not the stimulated ones. Hence a necessity arose

to construct a multi-channel stimulator with all outputs galvanically isolated. Having constructed such a device we resumed clinical investigations in 1985, aiming at utilization of FES methods to enable paraplegics to change position from sitting to standing. Nowadays the stimulation program is being applied to 3 patients in order to magnify the strength and resistance to fatigue of the muscles.

Before the stimulation training was begun, measurements were made for each patient to assess the maximal force developed by the dorsal flexors of the foot and extensors of the knee by means of peroneal and femoral nerve stimulation, resp.

Fig. 1. and 2. present the graphic recordings of the force developed during the stimulation of the two muscle groups by one of the examined patients. The recordings show that the initial values are relatively high, so it can be expected that systematic stimulation training of the paralyzed muscles will lead to an increase of the maximal values of the forces developed by the patients and thus will render it possible to try to achieve verticalization of the patient by means of stimulation.

The stimulation training was carried out over the period of 3-4 weeks. Stimulation was applied to 2 or 4 muscle groups in one or both lower limbs. 10 min. stimulation series were applied once a day to excite each muscle group. After 7-9 days of the stimulation training control measurements were carried out to record both the values of the force developed by the stimulated muscles and the duration of maximum torque to assess the resistance to fatigue.

Our preliminary investigations were a failure. It turned out that in two of our patients there was a partial /and in one a complete/ loss of excitability of the femoral and peroneal nerves and no muscle excitation was possible in this way. Only traceable contraction was noted, whereas direct stimulation of the muscles elicited normal force response. This phenomenon is probably a consequence of the progressive degeneration of nerve fibers coming from the spinal centers /L2, L3/ located

at the site of injury or in the adjacent region. In such cases it became indispensable to apply direct stimulation to the main muscles participating in the locomotion function /gluteal, quadriceps and peroneal muscle groups/.

In our further investigations we intend to make attempts at the stimulation of femoral and peroneal nerves, and in case of failure - the mixed stimulation of nerves and muscles or muscles only. It may be possible to stimulate the nerves in cases of higher spinal cord injury levels when the centers of the above mentioned nerves are located below the site of injury.

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Knee extensors of the right limb / U.S. /

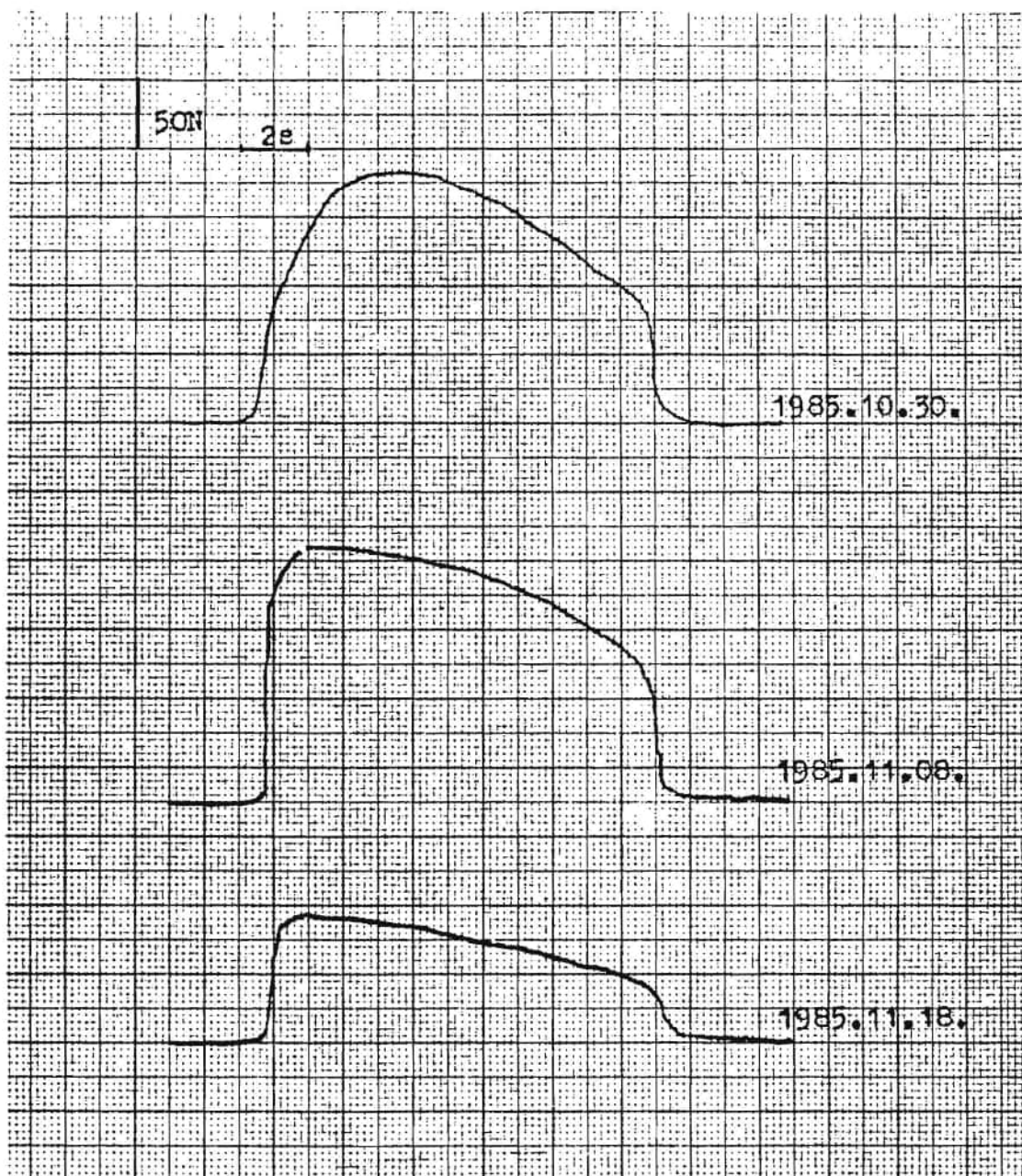


Fig. 1. Recordings of the maximal values of force developed by the extensors of the knee elicited by femoral stimulation: before, during and at the end of the stimulation training.

Dorsal flexors of the right limb / G.J. /

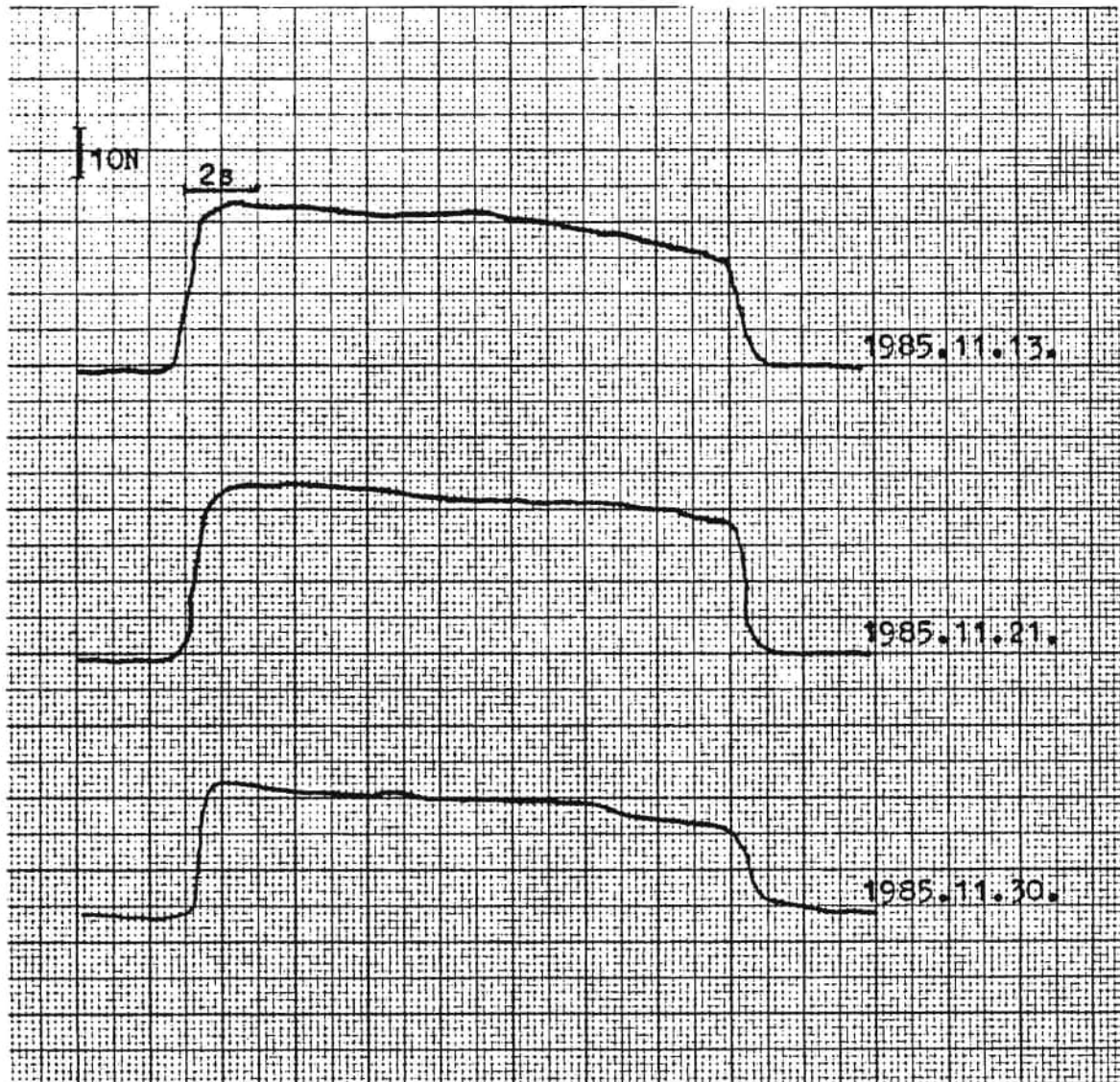


Fig. 2. Courses of the maximal values of force developed by the dorsal flexors of the foot excited by peroneal stimulation: before, during and at the end of stimulation training.

ASSESSMENT OF KINEMATIC FEEDBACK INFORMATION WITH ACCELEROMETERS FOR FES.

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ABSTRACT.

We study the assessment of feedback parameters with accelerometers for functional electrostimulation of the lower extremities. Especially the calculation of the angle is troubled by offset in the angular velocity causing drift after integration. We therefore developed a theory for the assessment of the angle, without integration, for 2-dimensional rotations using accelerometers. This theory was validated by measurements on a pendulum and has also been applied to angle measurements of semi 2-dimensional movements of the lower extremities during stance phase. The study demonstrates the feasibility of assessing feedback parameters with accelerometers although further improvements are needed.

INTRODUCTION.

Functional Electrical Stimulation (FES) to restore locomotion for paraplegics needs the development of feedback control mechanisms. The assessment of kinematic parameters (angle, angular velocity and acceleration of leg segments) is one of the related problems. Because of the potential acceleration transducers offer for implantation we investigated the assessment of kinematic parameters with these transducers. In static situations, the signal from accelerometers is a direct measure for the angle between sensor and gravitational field so using a number of sensors attached to the leg segments it can easily be detected whether one is lying, sitting or standing. Angular velocity and angular acceleration of the leg segments can be calculated using accelerometers [1,2]. The angle is calculated by integration of the angular velocity. Drift problems associated with this integration [3] are either solved by restricting the measuring time [4,5] or by comparing the calculated angle at the begin and end of a walking cycle [6]. Marking of a cycle is performed off line. Considering the accuracy needed for feedback and the fact that data has to be available in real-time this technique is not suitable for FES. Therefore we developed a new method to calculate the angle without integration for 2-dimensional rotations using accelerometers.

THEORETICAL DEVELOPMENT.

We can think of the leg as two rods with ideal rotational axes. For two dimensional movements we place an inertial reference system xy with origin O at the ankle joint and a body-fixed system uv with origin q at the knee joint. The distance O to q is R (Fig 1). At p we connect an accelerometer at the lower leg with sensitive axes in the radial and tangential direction. For a piezoresistive strain gage accelerometer we can give the forces working on its seismic mass (Fig 1B). With g being the gravitational acceleration we get using Newtons laws:

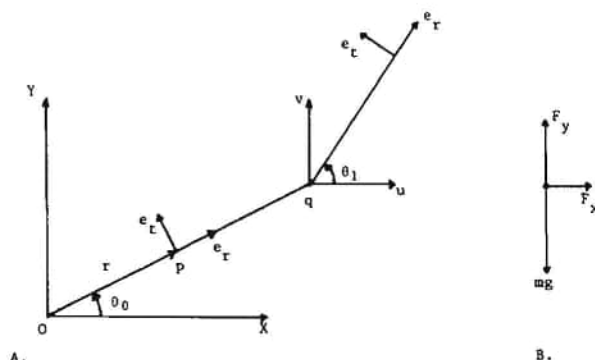


Fig. 1 A: Inertial and body-fixed reference systems. e_t and e_r are unity vectors in tangential and radial direction. B: Forces working on the accelerometer.

$$F_x(p) = m \ddot{x}_p \quad (1)$$

$$F_y(p) - mg = m \ddot{y}_p \quad (2)$$

$$\text{So } F_y(p) = m(g + \ddot{y}_p) \quad (3)$$

With sensitive axes of the accelerometer in the radial and tangential direction we can calculate a radial (a_r) and tangential (a_t) "acceleration".

$$a_r(p) \equiv F_r/m = \ddot{x}_p \cos \theta_0 + (g + \ddot{y}_p) \sin \theta_0 \quad (4)$$

$$a_t(p) \equiv F_t/m = -\ddot{x}_p \sin \theta_0 + (g + \ddot{y}_p) \cos \theta_0 \quad (5)$$

With $x_p = x_0 + r \cos \theta_0$ and $y_p = y_0 + r \sin \theta_0$ we get:

$$a_r(p) = \ddot{x}_0 \cos \theta_0 + (g + \ddot{y}_0) \sin \theta_0 - r \dot{\theta}_0^2 \quad (6)$$

$$a_t(p) = -\ddot{x}_0 \sin \theta_0 + (g + \ddot{y}_0) \cos \theta_0 + r \ddot{\theta}_0 \quad (7)$$

Attaching accelerometers on the lower leg at distances r_a and r_b from 0 we can solve equations (6) and (7) for the angular velocity and angular acceleration.

$$\dot{\theta}_0^2 = \frac{a_r(r_a) - a_r(r_b)}{r_b - r_a} \quad (8) \quad \text{and} \quad \ddot{\theta}_0 = \frac{a_t(r_a) - a_t(r_b)}{r_a - r_b} \quad (9)$$

Normally θ_0 is calculated by integrating (8) or (9). Now we will show our method. During stance the ankle joint is considered to be an ideal non-moving axis so $\ddot{x}_0 = \ddot{y}_0 = 0$. Now we can solve (6) and (7) for $\sin \theta_0$ and $\cos \theta_0$.

$$g \sin \theta_0 = \frac{r_b a_r(r_a) - r_a a_r(r_b)}{r_b - r_a} \quad (10) \quad g \cos \theta_0 = \frac{r_b a_t(r_a) - r_a a_t(r_b)}{r_b - r_a} \quad (11)$$

So for two-dimensional rotations, assuming that the axis is not accelerating itself, we are able to calculate the angle of the lower leg segment without integration. Accelerometers can be used also to calculate the kinematic parameters of the upper leg segment. Placing accelerometers at distances r_c and r_d from q, equations (8) and (9), being independent of the movement of the rotational axis, can be converted to calculate the angular velocity and angular acceleration of the upper leg segment. To calculate the angle of the upper leg segment we convert equations 6 and 7.

$$a_r(q) = \ddot{x}_q \cos \theta_1 + (g + \ddot{y}_q) \sin \theta_1 = \frac{r_d a_r(r_c) - r_c a_r(r_d)}{r_d - r_c} \quad (12)$$

$$a_t(q) = -\ddot{x}_q \sin \theta_1 + (g + \ddot{y}_q) \cos \theta_1 = \frac{r_d a_t(r_c) - r_c a_t(r_d)}{r_d - r_c} \quad (13)$$

We see from equations (12) and (13) that we can calculate the "acceleration" of the axis q with accelerometers at r_c and r_d . Solving for $\sin \theta_1$ and $\cos \theta_1$ we find:

$$\sin \theta_1 = \frac{(g + \ddot{y}_q) a_r(q) - \ddot{x}_q a_t(q)}{(g + \ddot{y}_q)^2 + (\ddot{x}_q)^2} \quad (14) \quad \cos \theta_1 = \frac{(g + \ddot{y}_q) a_t(q) + \ddot{x}_q a_r(q)}{(g + \ddot{y}_q)^2 + (\ddot{x}_q)^2} \quad (15)$$

$$\text{Where } \ddot{x}_q = -R \cos \theta_0 \dot{\theta}_0^2 - R \sin \theta_0 \ddot{\theta}_0 \quad (16) \quad \text{and} \quad \ddot{y}_q = -R \sin \theta_0 \dot{\theta}_0^2 + R \cos \theta_0 \ddot{\theta}_0 \quad (17)$$

The angles are calculated successively without integration. This means that during stance we can calculate the angles directly. During swing phase we have to integrate the angular velocity to obtain the angle. Because the swing phase is short drift problems will be limited.

EXPERIMENTAL PROCEDURE.

Measurements to validate our theory were performed on a single axis pendulum. Two 1-dimensional sensitive accelerometers (Kyowa AS-5GA) were attached to the pendulum at various distances in either the radial or tangential direction. The angle calculated from the accelerometer data was compared with the angle measured with a rotary potentiometer (MCB PP-27C). Calibration of both accelerometers and potentiometer was performed at 0 and 90 degrees. By attaching an extra mass to the pendulum its voluntary oscillation frequency was changed from 1.4 Hz to 1.8 Hz. For measurements on the lower leg two accelerometers were mounted on an aluminum bracket which was attached to the leg with 2 VELCRO straps. Again a potentiometer was used for comparison. For measurements on the pendulum as well as on the lower leg light-weight cables were used to connect the sensors to an amplifier. After amplification all signals were low-pass filtered by a second order Butterworth filter (cut-off frequency 20 Hz). Special care was taken to avoid phase shift between the various signals. The data were sampled on a DEC LSI 11/23 computer using a 12-bit ADC board (AXV11-C) at a rate of 100 Hz during 10s intervals.

RESULTS.

We used the pendulum to validate our technique. An indication of the accuracy can be obtained from 2 typical histograms of the difference in the angle calculated from accelerometer data and as measured by the potentiometer. (Fig 2.) (Sensitive axis of the accelerometer in the tangential direction.) The resolution of these histograms is 1 mrad. Offset and gain errors by calibration

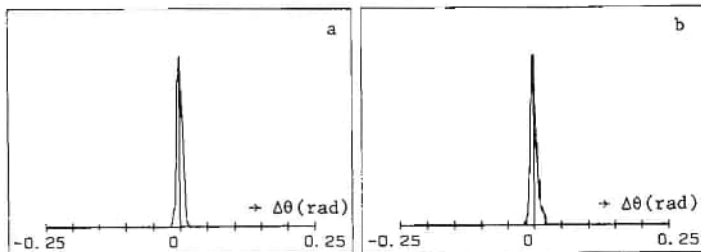


Figure 2.
Measurements on the pendulum.

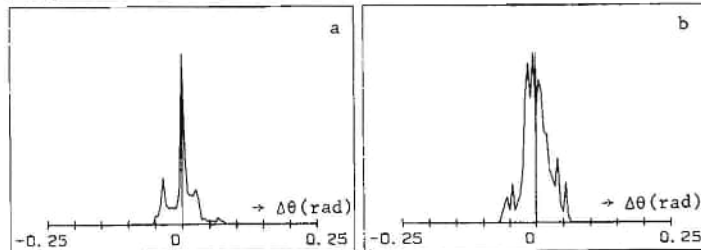


Figure 3.
Measurements on the lower leg.

Normalized histograms for the difference in the angle as calculated from accelerometer data and as measured with the potentiometer. (in rad.)

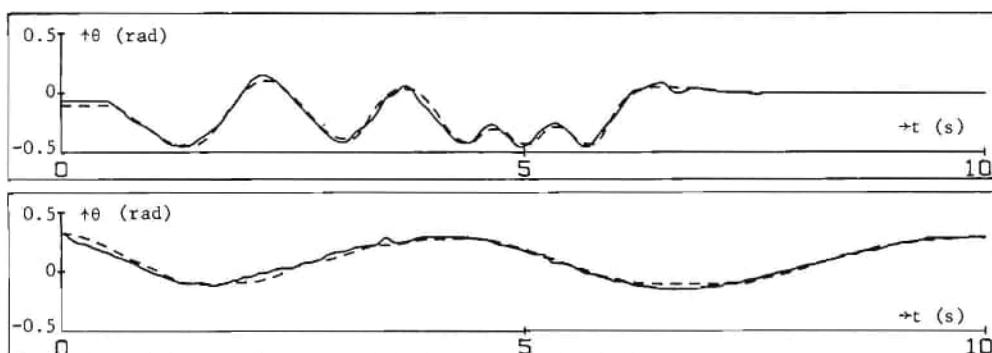


Fig 4. Lower leg angle after LSF correction.
Solid line : accelerometer data.
Broken line: potentiometer data.

were compensated using a least square fitting (LSF) technique. Gain error was 1% for the 1.4 Hz oscillation and 2% for the 1.8 Hz frequency. Offset ranged from -2 mrad to 8 mrad. Maximum errors (Δ) and the standard deviation (S.D.) after correcting the potentiometer data are 0.02 and 0.01 rad respectively. With sensitive axes of the accelerometers in the radial direction Δ and S.D. are 0.1 rad and 0.02 rad respectively.

The measurements on the lower leg were performed with sensitive axes of the accelerometers in the tangential direction. Gain and offset errors were again compensated for by a least square fitting technique. Fig. 4 shows 2 plots for the lower leg angle as calculated from accelerometer data and as measured with the potentiometer. Figure 3 shows the associated error histograms. Errors are generally within ± 0.05 rad. S.D. is below 0.03 rad.

DISCUSSION.

The measurements on the pendulum show the necessity of a mathematical procedure for the calibration of accelerometers and potentiometer in order to minimize errors. Calibration is no problem as long as its parameters do not change with time. This was not tested but considering that the pendulum needs to be improved and that the exact alignment of the accelerometers is troublesome the results obtained are remarkable.

The comparison of the lower leg angle calculated from accelerometer data and measured with the potentiometer shows that errors are within ± 0.05 rad. Although the accuracy needed for the control of the ankle is not known exactly the accuracy obtained so far might suffice [7]. The accuracy of the calculated knee angle depends on the ankle angle so further improvements are necessary. Calculation of the knee angle might be complicated further by the complex geometry of the knee joint so it may be necessary to combine the accelerometers with some other type of knee angle sensor e.g. one based on the Hall effect [8].

Further measurements need to be performed before we can tell whether the remaining errors are caused by the accelerometers, the potentiometers or both. Also, true 3-dimensional measurements are necessary to see how movements deviate from two-dimensional movements and how this effects the results. None the less, the results obtained so far are very encouraging and further improvements seem possible.

We feel that using accelerometers for shank and thigh a fully implantable system for the assessment of feedback parameters may be achievable.

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A NATURAL "FORCE SENSOR" SUITABLE FOR CLOSED-LOOP CONTROL
OF FUNCTIONAL NEUROMUSCULAR STIMULATION*

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SUMMARY

In spinal cord-injured persons, partial restoration of motor function can be achieved using functional electrical stimulation (FES) of paralyzed muscles in both upper and lower limbs (1,4,7,10). In present clinical implementations, however, users must visually monitor performance and make frequent corrective adjustments because the force produced by FES tends to vary markedly with limb position or changes in load. In experiments, the force produced by FES can be regulated in closed-loop mode using feedback from sensors (2,3,7). A prime objective in the field of FES is to provide injured persons with automatic control of force using feedback (2,3,7,11,13). In order to implement closed-loop control of FES, a suitable force sensor needs to be developed. We demonstrate here that a close correlate of muscle tendon force and skin contact force is obtained from the electroneurogram (ENG) recorded from a cutaneous nerve using a nerve cuff recording electrode. Cuff electrodes implanted in animals have been shown to provide stable neural signals indefinitely (5,6). We propose that, on both practical and cosmetic grounds, a fully implantable nerve cuff "force sensor" is likely to be well-accepted by users.

MATERIALS AND METHODS

The cat footpads served as our model of human glabrous skin. We implanted a 30 mm-long Silastic cuff (2.5 mm I.D.) with three circumferential stainless steel recording electrodes (Cooner Wire AS 631) on the left tibial nerve just proximal to the ankle joint (5). The two end electrodes were shorted to each other and served as reference for differential recording at a gain of 20,000 and 1-10 kHz bandpass. The "tripolar" recording configuration and bandpass were selected to reduce the pickup of unwanted EMG signals generated by surrounding muscles (5,6). Electrode impedances were about 5 kOhm. The viability of the tibial nerve was verified periodically from compound action potentials recorded from a second cuff placed more proximally on the sciatic nerve (5). Compound action potentials and recorded neurograms were stable over the entire duration of the experiment (several weeks).

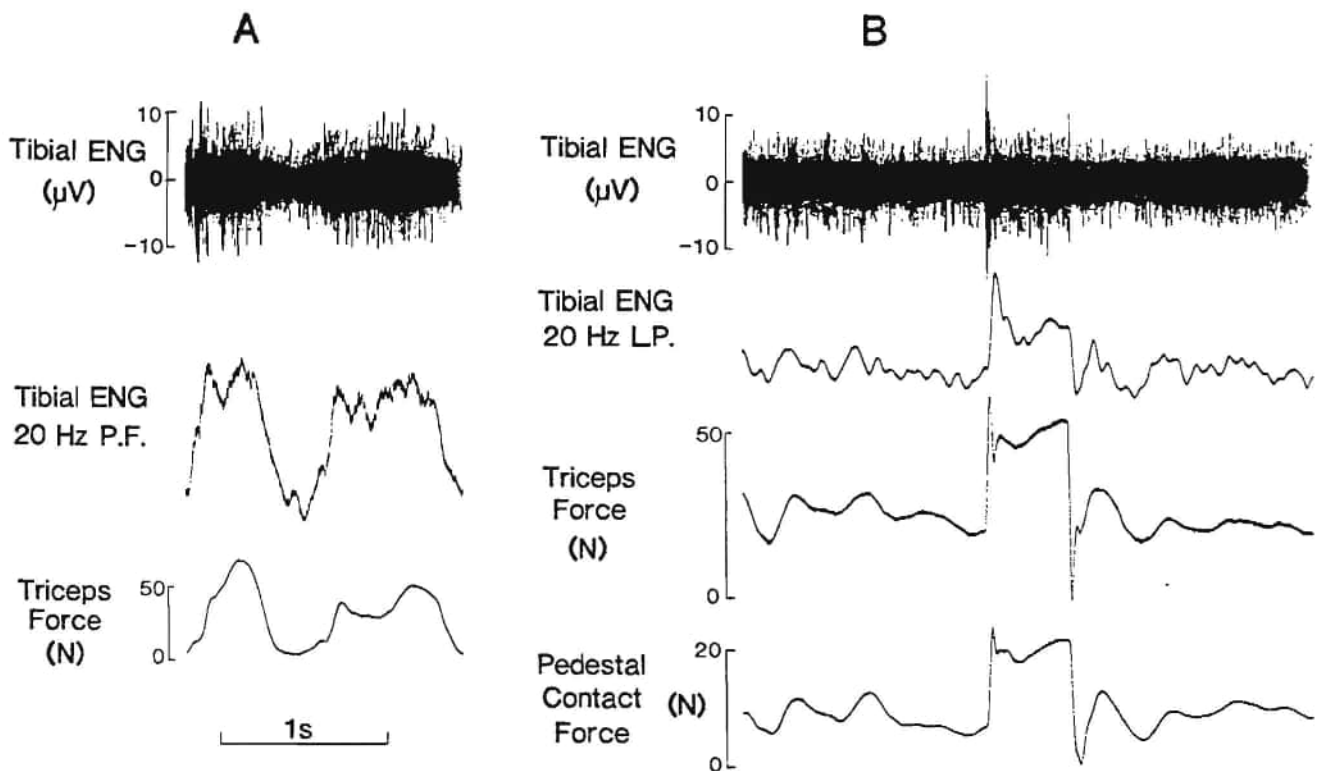
In walking cats, at least 75% of the neural traffic recorded from the tibial nerve arises from sensory axons (6) that innervate mainly low-threshold skin mechanoreceptors from the plantar pads and hair afferents. Since we were primarily interested in the contribution of glabrous skin mechanoreceptors, we applied depilatory cream to the foot to reduce neural activity contributed by hairs. In addition, we transiently eliminated the motor traffic recorded by the tibial nerve cuff by infusing lidocaine (2%) via a catheter connected to a 10 mm-long blocking cuff placed between the tibial and sciatic nerve recording cuffs (8,9). The completeness of the nerve conduction block was demonstrated by the disappearance of the sciatic cuff compound action potential (8,9).

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The EMG, force, length and temperature of triceps surae muscles were monitored with implanted transducers (8,9). The relations between triceps tendon force and tibial nerve ENG (with and without motor traffic) were assessed as cats walked on a treadmill. Relations between ENG, tendon force and ground contact force were further assessed as cats stood unaided on four pedestals. One pedestal contained a vertical force sensor (Revere FT 50). Its position was controlled and could be unexpectedly changed by a computer (14).

RESULTS

Typical data recorded from a cat walking on a motorized treadmill are shown in Fig. A. The electroneurogram recorded from the tibial nerve during walking modulated between ± 5 and ± 10 μ V (Fig. A, top trace). For the purpose of comparison with force, the ENG was rectified and Paynter-filtered (6) at 20 Hz (middle trace). The filtered tibial ENG closely resembled the triceps tendon force simultaneously recorded during walking (bottom trace). During the brief hesitation apparent midway through the second step, the filtered ENG accurately reflected the transient decline in the force recorded from the triceps tendon.



An example of a rapid postural adjustment in response to an unexpected upward movement of the pedestal supporting the left hindlimb is shown in Fig. B. The filtered tibial neurogram (20 Hz low-pass cutoff), triceps force and vertical contact force recorded from the pedestal accurately followed each other. The rapid changes at onset of the perturbation and subsequent slower oscillations in force are clearly reflected in the tibial ENG.

During walking, the filtered tibial ENG showed a somewhat faster rise time than the force (Fig. A). This effect can be attributed to the dynamic properties of both the rapidly adapting and the slowly adapting skin mechanoreceptors (10). During rapid postural adjustments the rate of rise in the response at the onset of the perturbation was slower in the filtered ENG than in either the triceps

tendon force or the pedestal contact force (Fig. B). This was caused by the filter time constant selected (20 Hz). Using a higher cutoff value (30 or 50 Hz) the transient force changes were more accurately reflected in the tibial ENG, but at the expense of having a noisier signal.

We compared the tibial nerve activity patterns during walking, with and without a proximal block to eliminate motor traffic. We found a small decline in the amplitude of modulation but no noticeable differences in the features of the modulated activity, as expected from the mainly sensory nature of this nerve.

To verify that the tibial nerve cuff recordings did not pick up significant EMG activity generated by surrounding muscles (5,6) we transected the tibial nerve above and below the recording cuff. Under this condition, recordings during walking did not show modulations even though typical EMG patterns were still recorded from surrounding muscles. Spectral analysis also indicated that the frequency components of the intact tibial ENG and ankle extensor muscle EMG were essentially non-overlapping.

It remains likely that some of the sensory activity recorded from the tibial nerve was generated by proprioceptive afferents from the foot muscles. We did not determine the relative proportion of sensory activity contributed by muscle and cutaneous afferents contained in the tibial nerve.

DISCUSSION

The performance of clinically implemented open-loop FES systems is currently limited by the highly nonlinear relationship between stimulus parameters and muscle force and position and by the time delay between muscle activation and force production (3,12). At present the user must compensate for errors by visually monitoring the performance of the limb and making corrective adjustments of the command signal. Feedback control could automatically correct for time-varying properties and regulate the input-output behavior of the stimulated limb musculature (1,3,4,7). Thus far, efforts at providing a force feedback signal have employed external sensors (3,11,13). External sensors are typically difficult to calibrate, require frequent recalibration, are sensitive to environmental factors like moisture and temperature, have lead breakage problems and are bulky and unsightly and thus cosmetically undesirable.

Recently, fully implanted telemetered multichannel FES units have begun to be used in the spinal cord injured (1; Peckham, personal communication; Brindley and Donaldson, personal communication). The advent of fully implanted open-loop stimulation devices makes it possible to also consider providing closed-loop control once a reliable, implantable force sensor is developed.

On the basis of our evidence from glabrous skin nerve recordings in cats, we propose that nerve cuff recording electrodes, implanted on cutaneous nerves of the hands or feet of para- or tetraplegics, will render a feedback signal proportional to skin contact force, suitable for closed-loop control of FES. Most glabrous skin mechanoreceptors remain functional because spinal cord injuries generally do not affect the integrity of afferent neurons with cell bodies in dorsal root ganglia at levels above or below the lesion. Electrode longevity and the stability of peripheral nerve signals recorded with cuff electrodes have been demonstrated in animal research (5,6). For these as well as for cosmetic reasons, a fully implantable nerve cuff "force sensor" is likely to be well accepted by users.

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MYOSIN HEAVY CHAIN ANALYSES AS A TOOL FOR THE STUDY OF ELECTROSTIMULATED MUSCLE.

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SUMMARY

Myosin is a multi-subunit protein consisting of two heavy chains and four light chains, which exist in polymorphic form. Developmental and physiological transitions of myosin isoforms involve the expression either of different gene products or of a pool of genes in different proportions, so that a definite myosin light chain can be associated to different myosin heavy chains.

Immunological, peptide mapping, and aminoacid sequence analyses have demonstrated the existence of closely related but distinct isoforms of myosin heavy chain /1/. More recently, by the use of complementary DNA and genomic DNA clones, it was demonstrated that multiple genes encode these MHC isoforms.

The myosin heavy chain genes presently known to be expressed in skeletal muscles are those characteristic of fast IIA, fast IIB, embryonic, neonatal and slow muscle fibers.

Polyacrylamide gel electrophoresis in the presence of sodium dodecyl sulfate (SDS-PAGE) is a sensitive method that separates nanograms or micrograms of heavy chain isoforms in a complex mixture of myosins. This is now an accepted technique that separates most of the isoforms of the MHC of skeletal muscles. The myosin heavy chain isoforms which comigrate in SDS PAGE can be distinguished by Orthogonal Peptide Mapping in SDS PAGE (SDS OPM). The small amount of protein needed allows the characterization of myosin heavy chains from few cryostat sections of muscles /2, 3/.

MATERIALS AND METHODS

Purification of myosin markers, one-dimensional analysis (SDS PAGE) and orthogonal peptide mapping (SDS OPM) of myosin heavy chains (MHC) from cryostat sections of experimental and normal rat muscles were as described in Carraro et al. /3/. Cryostat sections of muscle were processed either immediately or after drying and storage at room temperature.

RESULTS

The Figure 1 shows the SDS PAGE of myosin heavy chains extracted from cryostat sections of rat muscle. Contractile proteins were solubilized from cryostat sections of EDL and soleus muscles either after storage at room temperature or without storage. In the soleus sample two bands appear, the predominant band MHC-S (slow type myosin heavy chain) and as a minor component the fast type MHC-IIA. In the EDL samples the predominant, ahead-migrating band is MHC-IIB, followed by MHC-IIA. By visual inspection, the drying and storage of the cryostat sections seem to reduce the total amount of solubilized proteins, but the proportion of the different isoforms of the myosin heavy chains seems to be unchanged.

The work was supported by institutional funds from the Consiglio Nazionale delle Ricerche, Unit for Muscle Biology and Physiopathology, Padova, and by grants of the Ministero della Pubblica Istruzione, Fondi 60% to Prof. U. Carraro.

The Figure 2 shows a SDS PAGE of myosin heavy chains from soleus muscles of rat, mouse and sheep. The slow type myosin heavy chains of these three mammals comigrate in 6% polyacrylamide gels. In keeping with the fiber typing the myosin from the mouse soleus shows an high proportion of fast type myosin heavy chains /4/. The Figure 3 shows the orthogonal peptide mapping of myosin heavy chains electrophoretically purified from myosin of soleus muscle of rat and sheep. The peptide patterns of the sheep slow myosin heavy chains is very similar to that of rat, as confirmed by the co-digestion analysis.

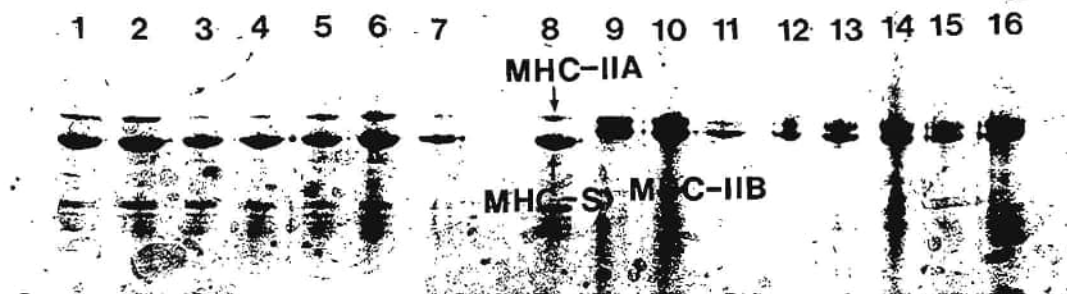


Figure 1. SDS PAGE of Myosin Heavy Chains extracted from cryostat sections of EDL and soleus rat muscles: effect of storage of the sections at room temperature. Myosin heavy chains from cryostat sections of : 1-8 soleus, 9-16 EDL. 1-2, 9-10: 2 and 4 microl. of sample immediately solubilized from frozen cryostat sections. 3-4, 5-6, 7-8, 11-12, 13-14, 15-16: two and four microl. of samples solubilized from cryostat sections stored one day at room temperature.

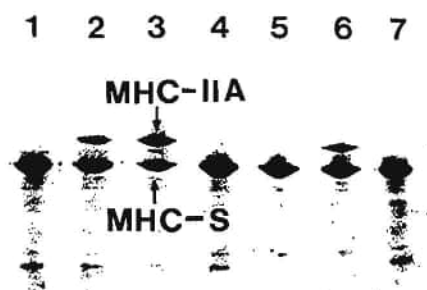


Figure 2. SDS PAGE of Myosin Heavy Chains from soleus muscles of rat, mouse and sheep. Heavy chains of myosin from: 1, rat; 2, 1+3; 3, mouse; 4, 1+5; 5, sheep; 6, 3+5; 7, rat.



Figure 3. SDS OPM of Myosin Heavy Chains from rat and sheep soleus muscles. Peptide mapping of: 1, rat; 2, sheep; 3, rat and sheep co-digestion; 4, rat.

DISCUSSION

The fibers of a muscle unit, that is, those supplied by a single motoneuron have identical characteristics. On the other hand, motoneurons have different frequencies of activation: those innervating slow muscle fibers are frequently recruited and discharge for prolonged periods, but their firing rate is lower and the frequency range is narrower than those of fast motoneurons. It is well known that the nerve reaching a muscle determines its characteristic responses. Cross-reinnervation produces a reciprocal transformation of the muscles properties, including the type of myosin isoenzymes synthesized. The preferential distribution of fast and slow myosin subunits into different fiber types characteristic of normal adult muscles is no longer evident following denervation. However an agreement has not been reached on the mechanism, either chemotrophic or impulse-mediated, by which the nerve influences gene expression in the muscle /5/. The muscle regeneration in permanently denervated muscle or the lack of innervation itself, and during development and in adulthood, can lead to the expression of fast myosin, but it prevents the accumulation of slow myosin. We have unambiguously tested the activity hypothesis by investigating the possibility of switching the synthesis of myosin from fast to slow forms in the fibers of the denervated rat EDL, a fast muscle, by low-frequency electrostimulation. Our results show that after several weeks, unlike sham-operated muscles, the denervated electrostimulated EDL shows a dramatic increase in the content of slow myosin light and heavy subunits /6/.

We have here presented comparative studies on the slow myosin heavy chain. The results confirm that SDS PAGE and orthogonal peptide mapping can be used to characterize the isomyosin composition of sheep and mouse skeletal muscles. The analyses can be performed on contractile proteins solubilized from cryostat sections of normal and experimental muscles, so that biochemical and morphological analyses can be performed on serial sections. By combining biochemistry and morphology the effects of electrical stimulation of different skeletal muscles in different mammalian species can be better understood.

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EFFERENT MOTOR NERVE STIMULATION OF SKELETAL MUSCLE IN ISCHEMIA

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SUMMARY

The degree of damage sustained in skeletal muscle due to a reduction in the perfusion, even to the point of total ischemia, appears to be relatively independent on the duration of "malperfusion". In literature, there is more and more coming up the opinion that specific or non-specific damages actually occur in the reperfusion phase after starting again the muscle perfusion. The specific damages are caused mainly by the resulting hypoxia. This hypoxia causes, for example, an increase in the redox-potential, a lowering of pH and a lactate acidosis. Non-specific damages are characterized as the results of inflammatory processes, increased free oxygen radical production or increased vascular permeability.

Ischemia in skeletal muscle (1,2,3) may be considered as being a local intramuscular hypoxia. There is often seen a redistribution of the capillary bed (4), often occurring edema. There are intramitochondrial damages (5) with lactate acidosis resulting from anaerobic glycolysis (5,6); the release of potassium and myoglobin is also increased (7,8).

MATERIALS AND METHODS

The experiment was carried out on the gracilis muscle of 10 mongrel dogs (18+/-3kg bodyweight). Suffering from muscle ischemia, one part was activated by electrostimulation of the gracilis muscle (parameters: 0,1ms; 20Hz; 20V) and perfused with hydroxyethyl stark (HAES-steril (R), 10%). The other part was performed without electrostimulation. The ischemic phase was followed by the reperfusion period. The following parameters were measured directly in the muscle tissue: pH (micro-electrode type 83334, Ingold Company, Frankfurt/Main, reference electrode, filled with 20% NaCl, type 126387, Ingold Company, Frankfurt/Main, pH-meter type 742, Knick Company, Berlin), redox sum potentials (electrode type PT 4804 M6, Ingold Company, Frankfurt/Main) and temperature (digital sound type Tastotherm D 700, Impac Company). The free oxygen radicals were determined from the venous effluat of the gracilis muscle. One pre-ischemic measurement and four post-ischemic ones (i. e. during the reperfusion) were made by using the chemiluminescence technique (counter for chemiluminescence: Berthold Biolumat LB 9500 T, graphic recording of emission by a Servogor writer, calculator: Hewlett-Packard 97 S I/O).

Controlled measurements were also performed of the intravascular concentrations of the electrolytes (sodium, potassium, calcium, chloride) and from several other relevant chemical parameters

Finally, the oxygen partial pressure was analysed on the muscle surface by using a multi-wire oxygen electrode by Kessler and Lübbers.

A two-channel anapulse stimulator (type 302-T, WPI-Instruments, Hamden, Connecticut, USA) with stimulation modulator and trigger (type T 912, Tektronix Company) was employed for the efferent electrical stimulation of the skeletal muscle. On an oscilloscope, a continuous monitoring of the electrode resistance (visible as stimulations voltage) was maintained and the strength of stimulation was kept at a constant level.

RESULTS

Depicted in figures 1 and 2 are the direct physical and electrochemical parameters obtained during ischemia in comparison to the control phase. The pH, however, remained at the low niveau of 6,6 (fig. 1, left side of the picture). The integration of the oxydation and reduction processes in the muscle cells, especially the mitochondrial respiratory chain, is represented by the redox sum potential which ranged from -40mV to -90mV (fig. 2, left side of the picture). The muscle temperature decreased during the phase of reduced perfusion and the oxygen partial pressure lowered, as expected, proportionally to the decrease of blood perfusion.

Comparing the two groups of stimulated and non-stimulated gracilis muscle, no distinct differences in the ischemic phase could be verified. Single measurements of the extracellular oxygen radicals revealed quite wide ranges. We therefore did not carry out any measurements during the phase of ischemia. The parameters mentioned above were also analysed during ischemia under efferent stimulation comparing the resulting values to the already specified ones: Figure 1 (right side of the picture) clearly shows that the pH decreased to 6,2, while the redox sum potential (fig. 2, right side of the picture) increased to -130mV averagely.

In the reperfusion phase, i. e. after the restoration of the blood perfusion, a delayed restitution of the non-stimulated muscle to initial control values can be observed (fig. 1 and 2, left side of the picture). In stimulated muscles a quick recovery of the redox sum potential was followed by a drastic increase in pH to control niveau (fig. 1 and 2, right side of the picture). The temperature normalized and the oxygen partial pressure in the superficial muscle tissue already showed normal values in the early phase of reperfusion. As for the extracellular electrolyte concentrations in the post-ischemic period, only potassium showed a significant increase in the late reperfusion period of the stimulated muscle, whereas a decent calcium decrease can be noticed in both - stimulated and non-stimulated - muscle preparations. However, indirect indications of early inflammation, i. e. free oxygen radicals, were significantly increased after a period of five minutes (fig. 3, right side of the picture) when compared to the inactivated muscle emissions (fig. 3, left side of the picture).

M. gracilis	with stimulation				without stimulation			
	Na	K	Ca	Cl	Na	K	Ca	Cl
I	152	4.35	2.48	120	148	4.50	2.23	117
II	153	5.05	2.41	122	147	4.60	2.18	118
III	153	4.35	2.45	121	148	4.55	2.14	118
IV	153	4.75	2.39	123	147	5.35	2.07	121
V	152	6.10	2.38	125	149	5.05	2.09	125

(all references in mmol/l)

This information is compatible with the ischemia-caused loss of the energy rich phosphates. Evidently, a simultaneous calcium inflow induces a protease-dependant transformation of xanthine-dehydrogenase to xanthine-oxydase. This then catalyses in the reperfusion phase, i. e. the phase of increased oxygen supply, the reaction of hypoxanthine to oxygen radicals. The importance of the increase in free oxygen radicals has been previously indicated in literature as the cause for elevated vascular permeability and edema (3,9,10).

DISCUSSION

It was the purpose of this experiment to see through the additional indirect electrostimulation of ischemic muscle to what extent perfusion (i. e. energy) situation was influenced in the phase of reperfusion. Experimentation proved that the efferent-motor electrostimulation of ischemic skeletal muscle is qualified as an accurate model to use in the analysis of post-ischemic inflammatory processes.

fig. 1

pH-value

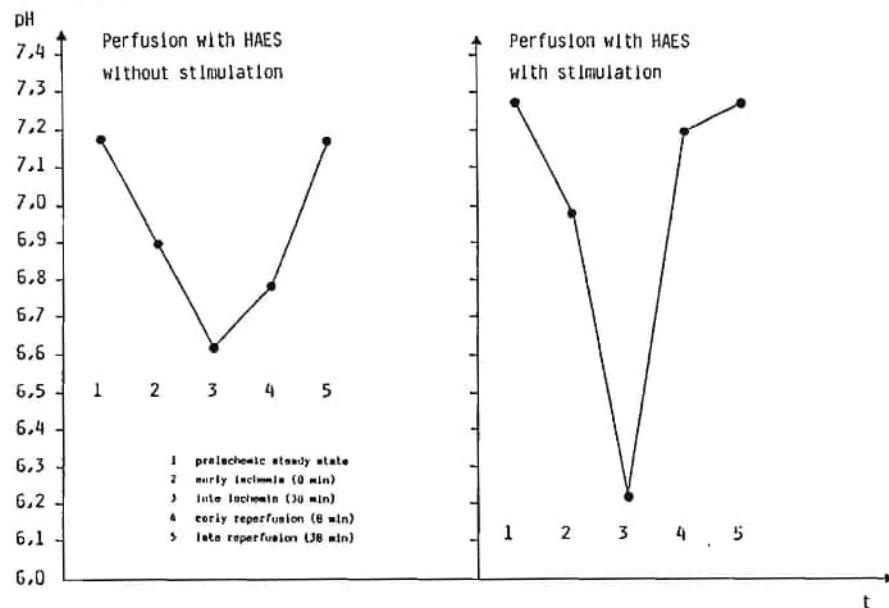


fig. 2

Redox - Potential

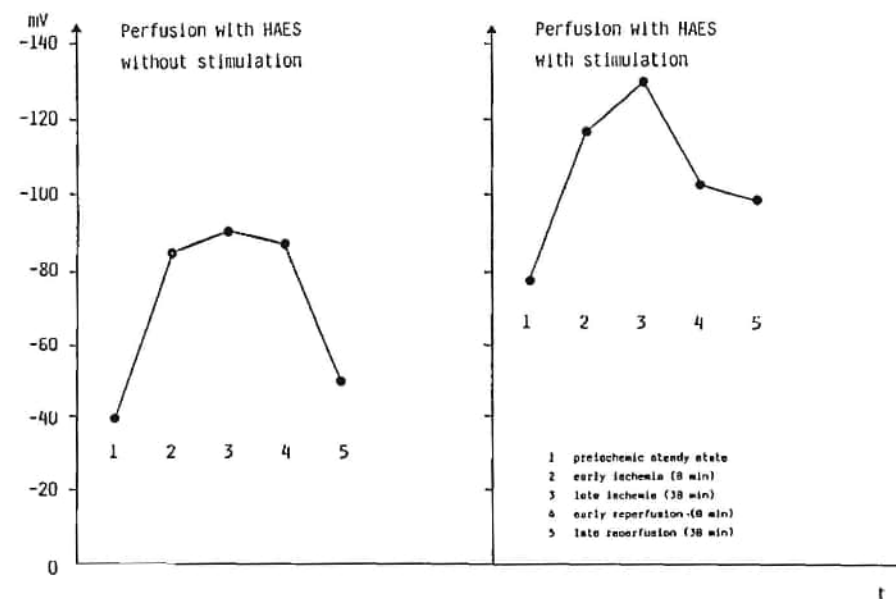
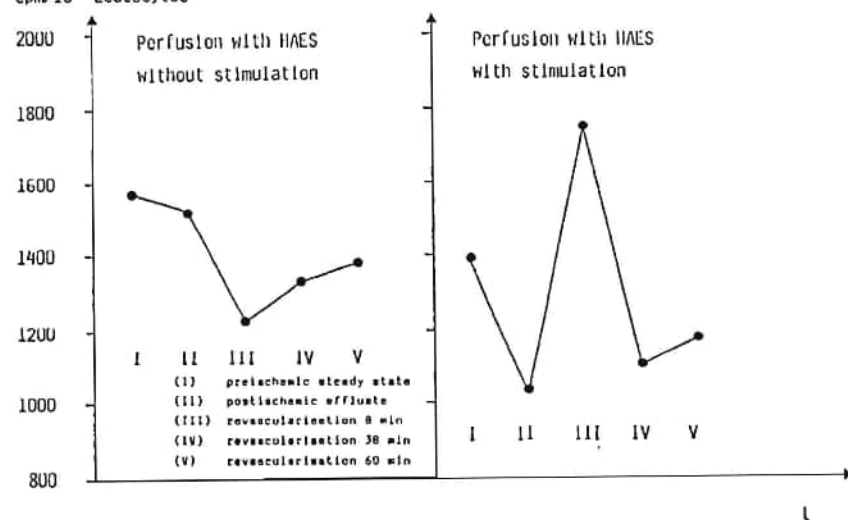


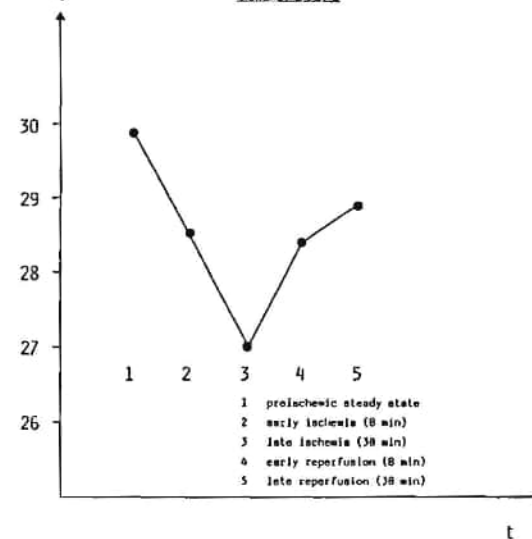
fig. 3

Specific Chemiluminescence

cpm/10³ Leucocytes

°C

Temperature



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VALIDATION OF F.E.S. THERAPY WITH MAGNETIC RESONANCE IMAGING - A PILOT STUDY

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SUMMARY

A pilot program to determine feasibility of utilizing magnetic resonance imaging (MRI) for early detection of changes induced by F.E.S. was conducted. Increase in muscle mass of four subjects who received F.E.S. treatments was clearly observed in both axial and sagittal MRI images. F.E.S. was self-administered twenty minutes per day, three to six times per week, by paraplegic individuals. Muscle mass increase appeared to be correlateable to treatment time but unrelated to years post-injury. This approach may prove useful in determining F.E.S. treatment parameters, motivating paralyzed patients and demonstrating progress to third-party payors.

MATERIALS AND METHODS

The objectives were (1) detect and quantify (approximate) any changes in muscle mass induced by F.E.S. therapy, (2) observe any changes in subcutaneous fat, (3) observe any changes in the femur and (4) observe possible changes in vasculature.

Participating patients were evaluated and determined to be appropriate F.E.S. candidates by a registered physical therapist who specializes in F.E.S. therapy. Each participant was provided with a Myocare Plus Model 6810 Stimulator which was preprogrammed as follows:

Treatment Time	20 minutes
Pulse Rate	35 Pulses per second
Pulse Duration	249 microseconds
Amplitude	100 milliamperes (maximum pulse current)
Ramp Up	1.0 second
Hold Time	15 seconds
Ramp Down	1.0 second
Off time	50 seconds

The physical therapist instructed the participants in proper placement of 2"x2" flexible electrodes over the quadriceps muscles and operation and care of the stimulators. The patients assumed responsibility for adhering to the established treatment protocol.

A Picker 0.5 Tesla superconductive MRI system was used for acquiring images prior to the initial F.E.S. treatment and approximately three months after treatments began. Imaging system parameters were as follows:

Axial	TR-2000	TE-30/60	T2W
Sagittal	TR-550	TE-20	T1W
Coronal	TR-550	TE-20	T1W

Muscle mass was approximated by assuming a circular geometry of the quadriceps at the point of reference which was chosen near mid-thigh. The pre-treatment and post-treatment diameters were measured from the ventral surface of the femur to the muscle-subcutaneous fat interface at 90°. Character or density of the muscle was ignored for this calculation. A unit length was assumed so that percentage of change in mass equalled percentage of change in volume, $\Delta V\%$, as follows:

$$\Delta V\% = \frac{V_2 - V_1}{V_1} = \frac{\frac{d_2^2}{4} - \frac{d_1^2}{4}}{\frac{d_1^2}{4}} \times 100$$

where diameters d_1 and d_2 equalled measured muscle thicknesses. See Figure 1.

Changes in the volume of fat was approximated in a similar manner except that pre-treatment and post-treatment volumes were calculated for cross sections described by annular rings. See Figure 1.

Six paraplegic patients participated in the program and data for four of these were analyzed.

RESULTS

MRI images acquired pre-treatment and post-treatment with F.E.S. clearly indicated that muscle mass increased for all four of the subjects that were studied. Sample MRI image data are shown in Figure 2 and Figure 3. From these images the following relative muscle thicknesses were measured for the right leg of subject E.C.:

Pre-treatment axial - 5.5 mm
Post-treatment axial - 6.5 mm

Pre-treatment sagittal - 4.2 mm
Post-treatment sagittal - 6.0 mm

Using the method and assumptions described above, it was determined that muscle mass increased approximately 60% in this subject.

— Assumed Geometry for Approximating Muscle Mass

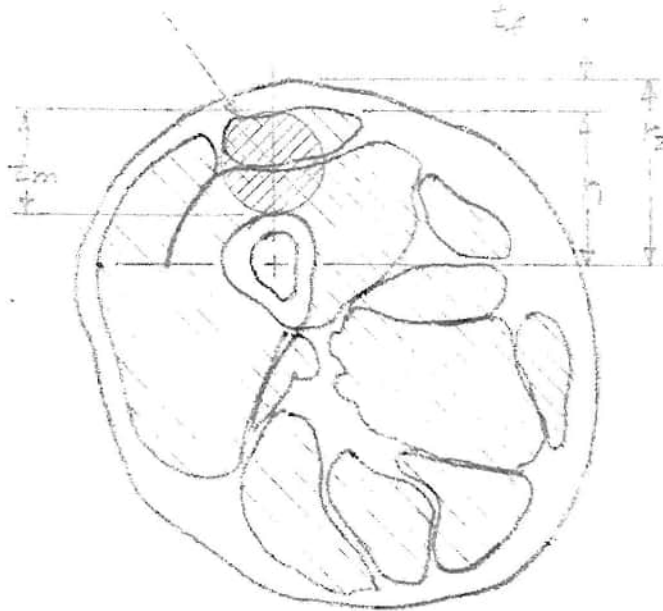


Figure 1. Cross Section Thigh
tm = thickness of muscle
tf = thickness of subcutaneous fat



Figure 2. Thigh of Subject E.C.
MRI Axial View
Pre-F.E.S. Treatment
January 21, 1986
tm - 4.2 mm Left

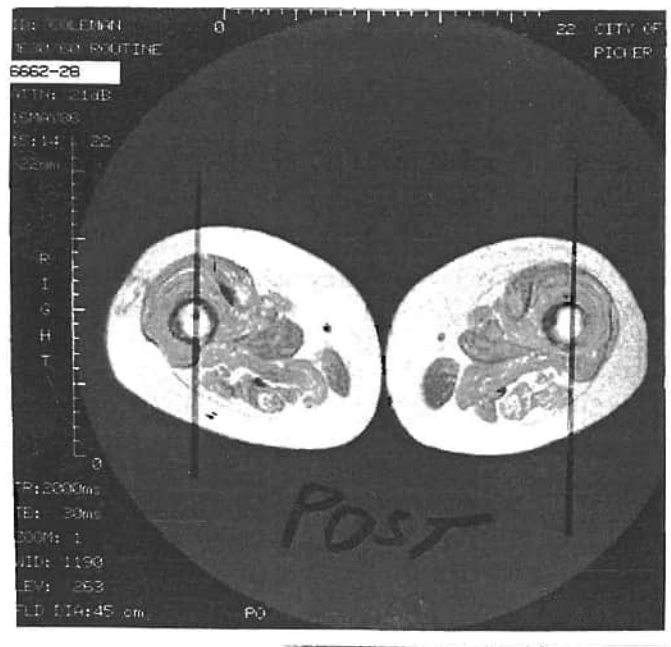


Figure 3. Thigh of Subject E.C.
MRI Axial View
Post-F.E.S. Treatment
May 16, 1986
tm = 6.0 Left

Note in Figure 4, that muscle mass increased in both legs of all four participants. It appears that muscle mass increase is related to number and frequency of F.E.S. treatments. It also appears that muscle mass increase is independent of level and onset on injury. Additional data must be acquired to verify these preliminary observations.

Subject Level Age Disabled	% Muscle Mass Increase		Treatment Weeks Frequency Time
	Right Leg	Left Leg	
L.L. T 4/5 50 yrs 22.5 yrs	79% - -	85% - -	14 Weeks 6 x/Week 20 Minutes
E.C. T-4 48 yrs 3.7 yrs	60% - -	38% - -	17 Weeks 6 x/Week 20 Minutes
M.B. T-11 30 yrs 5.4 yrs	63% - -	30% - -	15 Weeks 5 x/Week 20 Minutes
R.G. T-10 31 yrs 6.8 yrs	23% - -	4% - -	13 Weeks 3 x/Week 20 Minutes

Figure 4. Muscle Mass Increase vs Treatment

DISCUSSION

Results of a pilot study with four subjects suggest that MRI may prove to be an effective means for early assessment of the effects of treatment of muscles with functional electrical stimulation. Measurement of changes in muscle thickness, which implies muscle mass, is a simple procedure. Accurate determination of muscle mass may demand additional attention.

Measurement of changes in thickness of subcutaneous fat at selected sites is simple but accurate determination of mass will demand additional work if this proves to be important.

Assessments of changes in bone is extremely important. Although clear changes were exhibited by only one of the subjects, examination of a significant number of paraplegics deserves consideration.

No changes in vasculature were observed. Perhaps such changes will occur later if F.E.S. therapy is continued and intensity of stimulation is increased.

ACKNOWLEDGEMENTS

F.E.S. evaluations and therapies were provided to the participating paraplegics by Kaiser Rehabilitation Center. This work was supported by Sarkeys Foundation, Tulsa Royalties Company and Cities Service Foundation. Continuing effort is presently funded by the Franklin and Grace Bernsen Foundation.

City of Faith Medical and Research Center provided MRI facilities for acquisition of images and interpretation of the records at no charge.

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THREE YEAR CLINICAL EXPERIENCE WITH THE LOCOMOTION PACEMAKER IN HUMAN

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SUMMARY

Summarizing our 3-years experience with the locomotion pacemakers in paraplegic patients,we want to point out the principle possibility to walk by means of FES of the femoral and infra-gluteal nerve.The nerval and muscular tissue seems to be resistant to the electrical current up to 4 mA without any histological signs of damage.Great personal motivation of the patients and individual training are necessary for successful use of the pacemaker-system.Up to now walking with FES is still tiring and the patients do not feel safe enough to use it during daily life.For climbing a staircase aktive bending of the hip is necessary,which should be realized in our future concepts. The way of gait has to be improved functionally and esthetically to be accepted by the patients.

MATERIAL AND METHODS

Since 1970 our group has been interested in functional elektrostimulation of peripheral nerves and has published our first experimental results in 1971.The rapid development of micro-electronic techniques during the last 10 years changed the applicability of functional electrostimulation markedly. With these new technical achievements electrophrenic respiration could be developed for clinical application and mobilizing of paraplegic patients by means of functional electrostimulation came into the range of clinical realization. Before the development of a FES-device for clinical use a lot of questions had to be investigated in animal experiments. The technique of implantable devices,wireless transmission through the skin,a programmable external equipment and electrodes being in close contact with nerves had to be developed.The reaction of nerve and muscle systems to the electrodes and the electrical current had to be examined.

According to these experimental investigations stainless steel electrodes were developed being resistant to corrosion and mechanical stress. These electrodes consist of 12 monofiles with a diameter of 0.05 mm and are twisted in a silicone envelope. A device for multichannel electrostimulation was constructed. The device consists of an external control system, 2 inductive coils, 2 implants with receiving coils, and 4 electrodes for each implant. In October 1982 the device was implanted in two female patients 25 and 41 years old, with posttraumatic spinal cord lesion at the level of D9 and D12. The femoral and infragluteal nerves of both legs were connected with 4 electrodes each, using microsurgical technique. Postoperatively the patients were told to train their paralyzed muscles to increase the muscle force which increased up to 400% during the following 6 months. 3 months after the operation they were taken to a rehabilitation center to learn how to stand up and walk with the aid of crutches, first in a swinging through and later in a four-point-gait.

The patients were able to stabilize the knee and hip joints by stimulating the quadriceps and gluteus maximus muscles, but were not able to bend their hips. The trunk muscles play an important role to perform the four point gait. With the latissimus dorsi muscle one hip is elevated, while the other leg is stabilized and with the elevated hip the leg can be brought forward. Now the second leg is stabilized and the opposite hip is elevated with the opposite latissimus dorsi muscle.

It is possible to perform a four point gait by moving the crutches forward and changing the weight.

In November 1983 two other patients with similar symptoms and results were operated.

Several complications had to be dealt with: First the dislocation of the electrodes at their connection site to the nerves could be recognized, but because of the possibility to exchange the electric current between 4 electrodes at each nerve no functional loss was observed.

In one patient the implant and the electrodes had to be removed on one side because of infection. This patient died because of cerebral bleeding several months later.

The electrode-nerve -connections were removed and histologically examined .Neither proximal nor distal of the connection site any severe changes on the cross sections of the femoral or infragluteal nerves could be observed and the axon count showed no difference between the stimulated and not stimulated nerves.

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SIMULATION OF NERVE RESPONSES BY EXTRACELLULAR ELECTROSTIMULATION

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SUMMARY

Implanted electrodes are used to excite nerve or muscle fibers. A model is presented to examine the influence of arbitrary electrode configurations on excitable fibers. Excitation, propagation and blocking phenomena can be studied by computer simulation of this model. The model is appropriate for myelinated as well as for unmyelinated fibers and for stimulation with single or multiple electrodes.

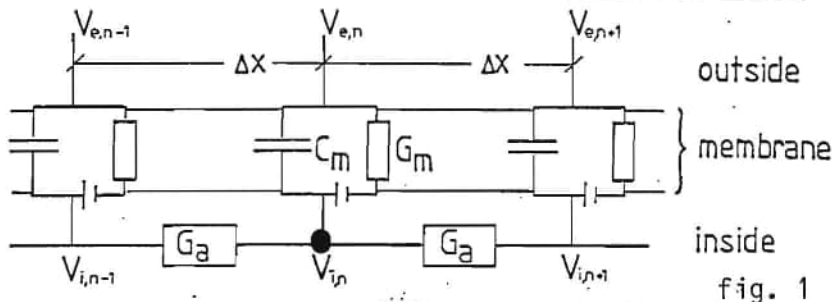
INTRODUCTION

Ionic currents are responsible for the activity of axons. For different ions the conductance of the membrane depends on the voltage between the inside and the outside of the fiber but it is also a function of the time. To find out the quantitative dependence Hodgkin, Huxley and Katz introduced the space clamped experiment /1/. The stimulating electrode is inserted along the axis of an axon and thus every part of the membrane works under the same conditions. Of course, no propagation of fiber's activity is possible in this experiment but the excitation process (starting with the sodium inward current and stopped by potassium outward current) can be observed and modelled. The famous model of Hodgkin and Huxley for the giant squid axon was modified in many ways. Firstly it was modified to make it adequate for special fibers and secondly to find simpler equations for analyzing and computing /2/.

Since the points of membrane have a similar behaviour at a small piece of a stimulated fiber we can simulate it by a local model derived from the space clamped experiment. In this way several local models are used successfully for different applications without considering spatial influences /2/.

Muscle fibers can be simulated in the same manner as nerve fibers.

SPATIAL MODELS



The behaviour of an electrostimulated axon can be described by an electrical network consisting of (cf. fig 1 and ref 3)
current source caused by different ionic concentrations
resistance resulting from several ionic conductances and capacity.

Every circuit describes the behaviour of a small disk of length Δx of the fiber. For myelinated fibers the discretization length is given by the internodal length whereas for unmyelinated fibers Δx is determined by computational accuracy.

The current flow at the marked point ● of fig. 1 reads

$$C_m \cdot d(V_{i,n} - V_{e,n})/dt + I_{i,n} + G_a (V_{i,n} - V_{i,n-1}) + G_a (V_{i,n} - V_{i,n+1}) = 0 \quad (1)$$

and by introducing the reduced voltages

$$V_n = V_{i,n} - V_{e,n} + V_{\text{resting}} \quad (2)$$

we find the basic equation for the n-th circuit of fig. 1 /3/

$$\dot{V}_n = (G_a \cdot (V_{n-1} - 2V_n + V_{n+1} + V_{e,n-1} - 2V_{e,n} + V_{e,n+1}) - I_{i,n}) / C_m \quad (3)$$

The ionic current flow $I_{i,n}$ depends on V_n and t and is given by a suited local model usually described by a system of n differential equations. /2,4/

The values of the membran's conductance G_a and capacity C_m and those of the ionic currents $I_{i,n}$ depend on the discretization length Δx . By inserting $G_a = 1/r_s \Delta x$ and $C_m = \pi \cdot d \cdot \Delta x \cdot c_m$ into (3) we obtain

$$\dot{V}_n = \left(\frac{1}{r_s d \pi} \cdot \left(\frac{V_{n-1} - 2V_n + V_{n+1}}{\Delta x^2} + \frac{V_{e,n-1} - 2V_{e,n} + V_{e,n+1}}{\Delta x^2} - i_{i,n} \right) \right) / c_m \quad (4)$$

	Symbols	and	[units]
C_m	capacity of membrane		[μF]
G_a	conductance of axoplasm		[kohm]
$V_{i,n}$	internal potential		[mV]
$V_{e,n}$	external potential		[mV]
V_n	reduced voltage (equ. 3)		[mV]
$I_{i,n}$	total ionic current		[μA]
Δx	discretization length of axon		[cm]
r_s	inner resistance of axon/cm		[kohm/cm]
c_m	capacitance of membrane/cm ²		[$\mu F/cm^2$]
d	axon's diameter		[cm]
i_i	total ionic current density		[$\mu A/cm^2$]
ρ_e	extracellular resistivity		[kohm.cm]
I_{el}	electrode current		[μA]
z	distance of electrode to axon		[cm]
r	distance to electrode		[cm]
t	time		[msec]

If we let $\Delta x \rightarrow 0$ (4) takes the following form

$$c_m \cdot \frac{\partial V}{\partial t} = \frac{1}{r_s d \pi} \cdot \left(\frac{\partial^2 V}{\Delta x^2} + \frac{\partial^2 V_e}{\Delta x^2} \right) - i_i \quad (5)$$

The term $S = \partial^2 V / \Delta x^2$ in (5) demonstrates a novel modelling of the axon. We call S the activating function for extracellular stimulation. The activating function is the second derivative of the extracellular potential along the axon.

When an axon is firing, the reduced voltage between the inside and the outside is about 100 mV, but the change of the inside potential is about 30 times greater than that of the outside /5/. On the other hand, to stimulate an axon the threshold voltage is in the order of 30 mV and therefore we have to change the extracellular potential by external stimulation much more as it is done by the fiber's own activity. This allows a simplification of the simulation: We calculate the activating function S for all the points of interest without considering the activity of the axon.

This means S is determined by the current flow of the electrodes.

The simplest case to simulate extracellular stimulation occurs when the current comes from a monopolar spherical electrode which is imbedded in an isotropic medium. The electrode produces the extracellular potential V_e at a distance r

$$V_e = \rho_e \cdot I_{el} / 4\pi r \quad (6)$$

Measuring Δx along the axon according to fig 2 we find

$$V_e = \frac{\rho_e}{4\pi \sqrt{x^2 + z^2}} \cdot I_{el}(t) \quad (7)$$

and

$$S = \partial^2 V_e / \partial x^2 = \frac{\rho_e}{4\pi} \cdot (x^2 + z^2)^{-5/2} \cdot (2x^2 - z^2) \cdot I_{el}(t) \quad (8)$$

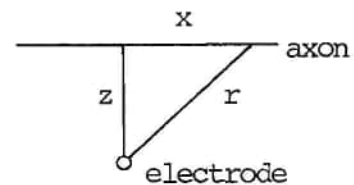
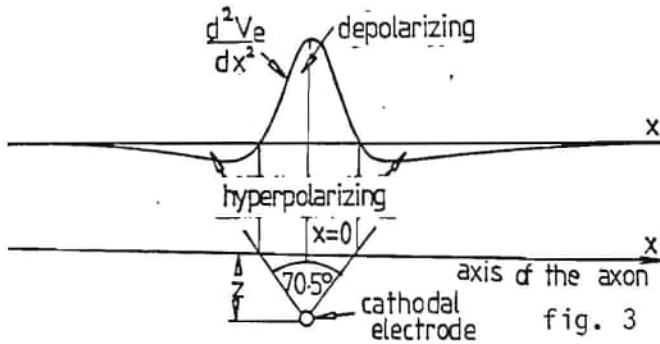
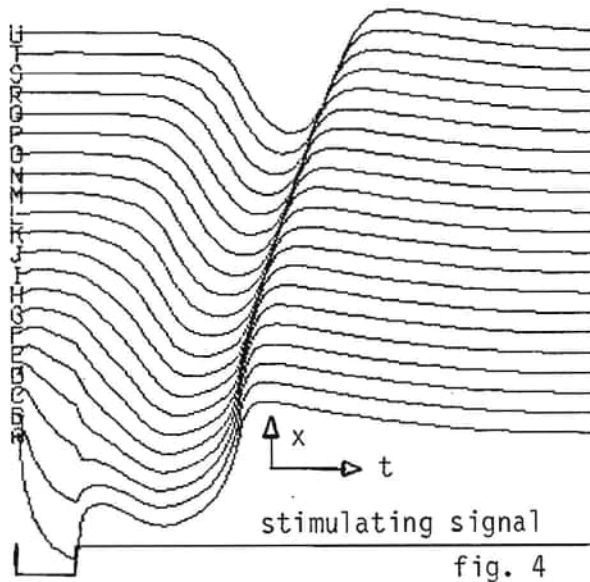


fig. 2



Starting from the resting state at $V=0$ of (5), $\partial V/\partial t$ has to be positive in order to reach the threshold voltage at the most excitable location $x=0$. Therefore S has to be positive at $x=0$ and this requires $I_{el} < 0$ in (8).

Fig. 3 shows the influence of cathodal stimulation. The depolarizing region depends on the distance of the electrode to the axon and is given by an angle of 70.5° resulting from $S > 0$ in (8). On both sides the electrode hyperpolarize the axon in the outside regions where $S < 0$. If $I_{el}(t)$ is positive S changes the sign and the outside regions get depolarizing. Firing occurs here for strong anodal stimulation. In every case the reaction of the fiber is symmetrical to both sides. In fig. 4 we have plotted the propagation of an action potential in the region $x > 0$ for an axon stimulated by a negative current pulse. Before simulation starts the axon is at rest. Line A ($x=0$) and line B ($x=1\text{mm}$) start with a polarizing phase whereas in the lines C-O we find a weak hyperpolarization in the starting phase caused by the activating functioning in accordance with fig. 3

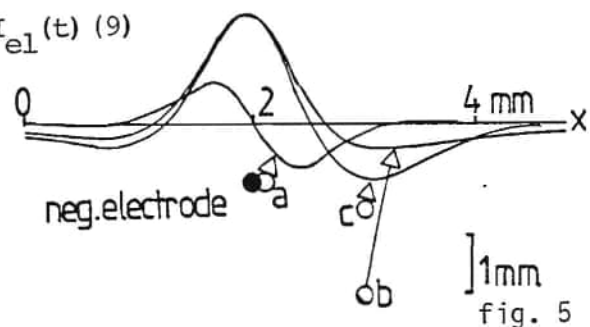


BIPOLAR- AND MULTICHANNEL ELECTRODES

We find the activating function of multichannel electrodes which consists of several dipoles by superposing the influences of monopolar electrodes. Now we note the shortest distance of the i -th electrode to the axon by z_i and the corresponding point of the length coordinate of the axon by x_i . We get from (8) the activating function by summing up the single influences:

$$S = \frac{\rho_e}{4\pi} \sum_{i=1}^n ((x-x_i)^2 + z_i^2)^{-5/2} \cdot (2(x-x_i)^2 - z_i^2) \cdot I_{el}(t) \quad (9)$$

At first, we consider bipolar electrodes with $I_{el,2} = -I_{el,1}$. We assume that the negative electrode is at a fixed position (marked with a full circle in fig. 5) and that the positions of the positive electrode takes one of the places a)-c). For this three cases the activating functions are displayed for constant I_{el} . In case b) one pole is relative far away from the axon which is situated on the x -axis



in fig 5 and the activating function is similar to that of the monopolar case with symmetrical reactions. If the distances of both electrodes to the axon are similar the activating function has one dominant depolarizing and one dominant hyperpolarizing part. The hyperpolarizing part is strong enough to allow an action potential to propagate only in one direction. If the dipole is supplied with alternating superthreshold current the axon is firing only to one side at the maxima of $I_{el,1}$ and to the other side at the minima. Different distances of the electrode to the fiber cause different thresholds

and therefore the fiber can fire only to one side or it can fire with different frequencies at both sides. The firing rates depend on electrode position and the intensity and frequency of current signal.

The behaviour of an axon is more complicated when it is stimulated by multichannel electrodes. This may be shown by simulation results which we get from two dipoles: In the following example we set $I_{el,1} = -I_{el,2} = a_1 \sin 2\pi f_1 t$ and $I_{el,3} = -I_{el,4} = a_2 \sin 2\pi f_2 t$. We assume that the electrodes of every dipole have the same distances to the fiber: $z_1 = z_2 = 2\text{mm}$ and $z_3 = z_4 = 3\text{mm}$. $x_1 = 0, x_2 = 2\text{mm}, x_3 = 12\text{mm}, x_4 = 15\text{mm}$ and $f_1 = 900\text{Hz}, f_2 = 600\text{Hz}$. Now we normalize the amplitudes so that $a_1 = 1$ is the threshold value in the case that only the first dipole is active. We fix now $a_1 = 2.66$ and look at firing rates of the fiber for varied a_2 . For $a_2 \leq 0.2$ the fiber will fire with frequency $f_1/2 = 450\text{Hz}$ at both sides, but at one side the spikes occur at the maxima of the stimulating signal and at the other side at the minima. Higher intensities of a_2 show differences in the rates at both ends of the axon. The rate depends also on the phase differences of the stimulating signals and this leads to branching of the firing rates. If $a_2 > 2$ the right end answers with $f_2/2$ or no response, depending on the phase difference of the stimulating signals. It is interesting that for this configuration even for strong a_2 it is not possible to get firing according to f_2 on the left side of the axon for $a_1 = 2.66$.

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MICROPROZESSORCONTROLLED 8-CHANNEL STIMULATOR
WITH SURFACE ELECTRODES FOR FES OF GATE

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SUMMARY

Krajl et al. described the first portable 6-channel stimulator system for walking of hemiplegic patients in a laboratory environment. Since then a number of other groups published portable stimulator systems with voltage controlled stimulation outputs. To support our studies on walking of paraplegic patients by means of FES microprocessor controlled 8-channel stimulator has been developed. The stimulator unit has LCD-display and is menu operated to enable the user to choose the movement procedure wanted himself and set the appropriate parameters. The current controlled output is charge balanced, therefore the stimulator might also be used with implanted electrodes. Safeguard procedures control the electrode impedances and switch the system to a safety state.

Introduction

To free paraplegic handicapped from the compulsion to use a wheelchair whenever they want to move is quite a testing challenge. Especially any stairlike elevation stops the wheelchair user and makes him dependent on the help of others. The group in Ljubljana published already in 1971 (3) a portable 6-channel stimulator to assist hemiplegic patients in walking with crutches in a laboratory environment. From this evolved a 4-channel portable stimulator which allows a paraplegic handicapped to move freely about with crutches within a limited range and sometimes even to climb stairs (1,2,8). Although this possibility has been available for quite a time, the handicapped themselves did not pay much attention to it. Only recently the situation seems to change. The work of the Vienna group using an implantable stimulator (7) and of the Dayton Group using surface electrodes together with a gait orthosis (5,6) caught a lot of public attention and rose hope with the handicapped that they may walk again soon. Also a group in Cleveland around Marsolais (4,9) concentrated on applying FES to the lower limb in a rather sophisticated way using up to 30 implanted electrodes in one leg. This work promises a good insight in the possibilities which might be achieved through FES, but it is still bound to the laboratory.

The group in Karlsruhe being involved in FES since 1976 directs now also part of their activities more continuously to the stimulation of the lower limb to meet the demand by the handicapped. To have an appropriate research tool to gather more experience in the field we developed a microcontrolled 8-channel stimulator which encloses the experiences collected by now.

Hardware of the stimulator unit

The stimulator has to serve so to say two motors: it shall be carried by a handicapped and therefore be small and of light weight and shall on the other hand have a larger potential in control and stimulation power to be adequate as a research tool. The outcome is a compromise in weight and energy consumption, both might be reduced for the final application. The stimulator channels themselves are current controlled and load balanced. The maximum stimulation current is ≥ 100 mA to be used with surface electrodes. The load compensation allows also the application of transcutaneous implanted electrodes. The pulse duration might be varied between 10 and 500 μ sec, the frequency between 0,5 and 50 Hz. For stimulation normally the pulse duration and the frequency are set at 300 μ sec and 20 Hz. - Unlike Petrowsky we have made the experience, as the group in Ljubljana, that a frequency of about 20 Hz gives a good continuous tetanic contraction and reduces tiring greatly. The use of higher frequencies is more disadvantageous. - During FES only the current amplitude is varied. The stimulation channels are decoupled. The impedance of the electrodes is controlled. If it rises high a light and sound signal is switched on and both Mm. quadriceps are stimulated to prevent falling. (If the electrode supply of one M. quadriceps fails at least the other one is activated.) 8-channels need 200 mA of current supply.

As controller serves a Z 80 with 32 k of memory. To allow the use of feedback sensors eight A/D converters are included. The communication with the computer goes via few specialized keys and a LCD-Display. All components are in CMOS-Technology besides the powerstage. The microcomputer circuits use 120 mA.

The operating software

The software is divided in programs for the setting of the parameters (learning programs) and for the stimulation procedure (movement programs). The display present in addition the state of the system and the following program procedures. It serves together with the operating keys as a dialog system. Right now the following movement procedures are included, they might be learned and called upon:

1. Training
2. Stand up
3. Standing
4. Walking
5. Stairs up
6. Stairs down
7. Sit down

During the learning cycle the following parameters have to be set:

- a) Maximum stimulus amplitude
- b) Starting time of the stimulus
- c) Slope of the rising stimulus
- d) Slope of the falling stimulus

After the learning cycle the movement procedure might be called by a special "Function key". The parameters may also be changed during the movement procedure to adjust them appropriately.

Ongoing application

At the moment the stimulation procedures are being tested. Besides the stimulation of the m. quadriceps and the reflex arch for lifting the leg the muscles controlling the hip are included. While stimulating the reflex arch we try to position the electrode close to the M. tibialis anterior to obtain concomitantly a straight forward lift of the foot. The possibility to stimulate the M. gastrocnemius to support the step forward movement and the Mm. biceps group to counterbalance the M. quadriceps and avoid overstretching of the knee are also looked into.

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THE DURATION OF ISOMETRIC CONTRACTION WHILE USING FES WITH STIMULI OF DIFFERENT PARAMETERS*

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INTRODUCTION

The feasibility of standing and reciprocate walking of paraplegics by functional electrical stimulation (FES) has been demonstrated in a number of studies carried out in recent years in various research centers. In terms of ease of application and avoiding complications, the noninvasive surface electrodes have been preferred as means for muscle stimulation^{1,2}. Of the muscles being stimulated, the quadriceps muscles are especially significant, since their activation is responsible for extending the knees, the latter being essential during weight-bearing on the legs. Other main functions include stimulation of the peroneal nerve to induce the flexion reflex, and the gluteus maximus muscles for controlling the body posture.

To evaluate the effect of stimulation and of the various stimulus parameters on the patients being activated and their performances, biomechanical³ and physiological^{4,5}, parameters were developed by our group. These parameters were incorporated in setting criteria for optimization of performance during the training and follow up procedures.

In previous studies the effects of stimulus parameters on muscle activation by FES were investigated during isometric⁶, or isotonic^{1,2} contractions, to determine the optimal stimulus parameters. In the present study search for optimal stimulation was conducted by measuring the duration of isometric contraction of activated muscles while using FES with stimuli of different parameters. Two positions of full extension of the knees of the patients were studied: the sitting and the supported standing positions.

PATIENTS, METHODS, TRAINING AND TESTING PROCEDURES

Five patients with details given in Table 1, took part in this study. The patients' prerequisite for inclusion in this program are: paraplegics below 55 years of age with upper motor neuron lesion, due to spinal cord injury between level D6-D12; no pressure sores; without any orthopaedic insufficiencies, such as unhealed fractures, joint contractures and unstable joints; equally divided spasticity of the lower limbs; general good state of health; good motivation and willingness to cooperate. The training program is divided into three main stages: the first stage is dedicated to: (a) search after the motor points of the quadriceps and gluteus muscles and the triggering points on the leg, which serve to provoke the flexion response, and, (b)

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strengthening of the patients' muscles. Isotonic contractions of the quadriceps muscles are achieved by using FES when the subject is in the sitting position. The flexion response of the lower extremity is achieved by giving electrical stimulation to the trigger points on the shank.

In the second stage, patients learn to stand up and to maintain the standing position. This is achieved by applying continuous FES to the quadriceps muscles of both legs, and, in some patients, to the gluteus muscles as well. Further strengthening of the quadriceps is being achieved in the standing stage, while the patient is gradually increasing his weight-bearing on his legs and decreasing the support on his arms.

The third stage is devoted to ambulation training, while the subject is supporting himself with a suitable device according to his ability. FES is given at first by the trainer and subsequently by the patient himself. For the stance phase, the quadriceps are stimulated and for the swing phase, stimulation is given to the shank to elicit the flexion reflex.

Stimulation was given via external rubber electrodes, with karaya gum as a medium. The electrodes were attached to the skin by micropore adhesive tape. An adjustable electrical stimulator was used to provide electrical monophasic impulses in the following ranges: frequency of 18-30Hz and pulse-width of 0.1-0.3ms. The current intensity used was the minimal required to obtain full extension of the knees. It was readjusted whenever the knee joint started to show any signs of fatigue by beginning to flex. The procedure of readjustment was carried out until the maximum allowable intensity, corresponding to 200mA, was reached. Tests were done in the sitting and the standing positions. The tests consisted of extending both knee joints until the knees started to flex after reaching the maximal current intensity. The time of extension of the knee till maximal fatigue was taken. All tests were made after the patient had been trained for a period of approximately 3 months. As reported earlier³, after this training period of muscle strengthening and exercise, the patient reaches a reasonable stable functional capability when activated by FES.

All tests were made prior to any other routine FES activity; only one test was done per day per patient. Altogether 9 combinations of frequency and pulse-width were covered and each of them was repeated 3 times. Patient JR was tested in the standing position and patients RH and AM in the sitting position. In addition to the abovementioned measured time, the heart rate was measured by telemetry for a period of 15 s at rest before FES, as well as during activation, for patients JR, BM and AS. The combinations tested in the heart rate measurements were of pulse-width of 0.1, 0.2 and 0.3 ms at frequency of 24Hz.

Table 1: Patients taking part in this study

Patient	Age	Sex	Level of Injury	Spasticity
AS	52	M	D5-6	severe
JR	37	M	D5-6	severe
BM	30	M	D4-5	moderate
RH	35	F	C6-7	severe
AM	21	M	D5	moderate

RESULTS AND DISCUSSION

The times of extension of the knees till maximal fatigue for the various pulse combinations are shown in Table 2. It can be clearly seen that the maximal time was obtained at stimulus frequency of 18Hz and pulse width of 0.3ms.

Table 2: Maximal extension duration for different impulse parameters

Frequency (Hz)	Pulse-width (ms)	Patients (time in min)		
		AM (sitting)	RH (sitting)	JR (standing)
18	0.1	2.15	2.52	6.33
	0.2	15.52	8.01	6.66
	0.3	20.45	11.51	8.35
24	0.1	1.95	1.85	4.1
	0.2	11.50	2.10	4.52
	0.3	5.10	2.10	4.54
30	0.1	1.40	1.50	2.43
	0.2	1.51	2.01	2.55
	0.3	1.62	1.75	2.35

The heart-rate increase during FES for the various pulse combinations is shown in Table 3. In this Table, the percentage increase as referred to the resting position is shown for various FES activities: sitting, standing and supported walking. It appears that pulse-width of 0.1 ms gives the least heart rate increase during FES activity.

Table 3: Percentage increase of heart rate (referred to resting) during FES with different stimulus pulse widths at frequency 24Hz

Patient	Pulse width (ms)	Sitting	Standing	Walking	
				parallels	walker
JR	0.3	18.6	30.1	46.5	63.0
	0.2	7.0	11.0	25.5	33.0
	0.1	9.0	11.2	29.0	34.0
BM	0.3	4.7	19.0		
	0.2	10.6	22.1	-	-
	0.1	11.2	16.2		
AS	0.3	20.3	41.3	79.2	
	0.2	16.6	52.6	122.3	-
	0.1	9.2	36.2	70.6	

As previously mentioned, attempts at optimizing the stimulus parameters are reported in the literature. Among the studies using surface electrodes, different evaluating methods were applied for the optimization of stimulus parameters. Isometric force measurements were made on the tibialis anterior, gastrocnemius and quadriceps muscles of normal subjects to produce strong tetanic contractions with minimal fatigue⁸. The optimal parameters in this case were frequency 50Hz and pulse width of 0.2 ms. In other studies, joint torques were evaluated revealing optimal parameters of 20Hz, 0.3 ms for the knee joint^{1,9}, and 30Hz, 0.3 ms for the ankle in hemiparetic patients¹⁰. Isometric voluntary moment of the ankle before and after peroneal FES was also evaluated in patients with central spastic paresis¹¹, with stimulation parameters of 30Hz, 0.3 ms. Dorsiflexion angle of the foot was used¹² for evaluating optimal stimulus, revealing parameters of 15Hz and pulse width as high as 20 ms.

In this study, the parameters used for optimization of FES were directly related to fatigue: maximal endurance time and heart rate, both during weight bearing, either in the sitting or in the vertical standing and walking positions. The consistency of the results obtained indicate that 20Hz is the best of the tested frequencies and it should be combined with the optimal pulse width of 0.3 ms. However, as indicated in Table 3, a pulse width of 0.3 ms involves a higher heart rate increase as compared to lower pulse widths.

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AN ASSESSMENT OF THE PARAWALKER HYBRID ORTHOSIS

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SUMMARY

Functional gluteal electrical stimulation has been shown to reduce the work load on the shoulder girdle muscles of adult complete paraplegics using a hybrid orthosis. The total energy cost of walking using the ParaWalker orthosis with and without FES still remains to be estimated. In practice electrode problems remain the main obstacle and will need careful appraisal.

INTRODUCTION

Rose outlined the mechanical principles of Hip Guidance articulations (3). These fundamental principles were used to develop the Hip Guidance Orthosis, initially for children with congenital paraplegia. Applying the knowledge and detailed principles established from the experience gained with these patients, the first adult paraplegic was fitted with this orthosis (now known as the ParaWalker) in December 1981. Since then a total of 20 adult paraplegics have been fitted with the ParaWalker and 17 of those patients are still regular users. None of the adults walked as well as children with this orthosis. Analysis of adult patients showed that deformation of the orthosis at the orthotic hip joint was the major reason.

Whilst it is theoretically possible to increase stiffness of the ParaWalker structure, this would render it unacceptably heavy. Consequently consideration has been given to the use of Functional Electrical Stimulation (FES) of paralysed muscles to improve the walking performance of adult traumatic lesion patients. A combination of Functional Electrical Stimulation and mechanical bracing to achieve ambulation seems to be the best compromise at present. (1). The 'Hybrid' system of FES and the ORLAU adult hip guidance orthosis allows complete paraplegics to achieve reciprocal gait with low energy demands. (2).

The present study is being conducted to assess the viability of the laboratory technique for paraplegics in their everyday life.

SUBJECTS AND METHOD

So far seven subjects have participated in this study. All subjects are adult traumatic paraplegics ages ranging from 22 years to 33 years with mid thoracic lesion between T4 and T9. All are experienced ParaWalker hip guidance orthosis users.

Our exercise regime consists of electrical stimulation of gluteal muscles incrementally to a maximum of 1 hour daily by the end of the 3rd week. The training period was for 3 months then "hybrid walking" was commenced using functional electrical stimulation (FES) of

gluteii added to the ParaWalker mechanism.

FES parameters used were	Peak Voltage	80 Volts
	Pulse Width	400 us (less than)
	Frequency	25 hz

The preliminary exercise regime and functional use parameters were the same but exercise stimulators had an automatic duty cycle of 4 sec. on and 4 sec. off. Functional stimulators had external control with switches fitted to the crutches operated by patients during the appropriate phase of the gait cycle.

In our Gait Laboratory subjects were asked to walk along a 20 ft. walkway in their natural rhythm, first without stimulation and then with gluteal stimulation: single crutch strike forces were recorded from a Kistler force platform. The data, using a computer, was presented in a graphical or absolute value form.

Three different types of electrodes were tried: Myocare, BMR rubber electrodes with Karaya gum discs (Karadiscs) and Carbon impregnated rubber discs with conductive gel smear.

RESULTS

One subject out of seven experienced severe spasm of the abdominal wall muscles each time when the gluteal muscles were stimulated during walking and was unable to continue with functional electrical stimulation of gluteal muscles and hence has been excluded from the results. He did not experience these spasms during the training period. Five out of six patients who continued to participate in the programme reported that reduced effort was required to swing the leg forward. They all requested a greater orthotic hip flexion angle so that their step length could be increased.

Table I shows the effect of FES on walking speed of the subjects.

TABLE I
EFFECT OF FES ON WALKING SPEED

FEET PER MINUTE			
SUBJECT	WITHOUT FES	WITH FES	% CHANGE
AE	62.1	73.8	18.8%
JMcK	56.7	63.9	12.7%
DL	35.9	44.2	23.1%
JM	66.24	72.48	9.4%
MS	87.72	93.97	7.1%
DR	114.72	102.96	↓10.3%

Five subjects experienced an increase in walking speed from 7.1% to 23.1% and one of the subjects reduced his walking speed by 10.3%.

Reduction in total crutch impulse was seen in five out of six subjects ranging from 7.8% to 35.9% (Table II).

TABLE II

TOTAL IMPULSE

SUBJECT	WITHOUT FES	WITH FES	% CHANGE
AE	369.99	236.94	35.9%
DL	458.61	330.43	27.9%
JMCK	345.12	280.47	18.7%
DR	268.8	281.59	↑ 4.7%
JM	142.15	131.16	7.8%
MS	227.3	167.11	26.5%

One of the subjects felt more exhausted generally though there was no fatigue of the muscles as such after his walks with gluteal stimulation. He could walk the same distance without FES with no tiring effects felt.

Three subjects encountered difficulties in keeping the self adhesive type of electrodes in position. They all had excessive sweating and the interaction between their sweat and adhesive material appeared to jellify this material and the electrodes became loose, increasing the impedance and loss of position thereby reducing the force of contraction

DISCUSSION

The success of the ParaWalker lies in the fact that it maintains intrinsic rigidity. During single leg stance the centre of the body mass tends to travel downwards to produce the adduction moment about the stance hip. This moment is counteracted by the downward thrust of the opposite crutch. This is (always) inadequate and results in an outward bowing of the orthosis on the stance side. This causes difficulty in leg clearance on the swing side. Stance side gluteal stimulation will to a certain extent prevent the bowing of the orthosis by keeping the opposite hemipelvis and leg elevated and thus allowing it to swing, also adduction around the stance hip is lessened, reducing deformation in the orthosis.

Although we see a reduction in the crutch impulse overall total energy expenditure is not necessarily decreased as more (paralysed) muscle is being made to contract; more metabolites will be collected and that could be the reason for the general exhaustion one of our

subjects experienced. Increased usage and training may improve the capability of prolonged ambulation.

Abdominal wall muscle spasm was severe in one subject and three other subjects also experienced it in varying degrees. Spasm tended to cause flexion of the trunk defeating the object of maintaining extension and abduction of the hip joints through gluteal action. The cause of these spasms remains obscure. We hypothesise that retropropagation of the gluteal stimulus to the cord, then through intact interneurons to abdominal efferents causes them to contract.

Interestingly, the subject with T9 lesion did not experience these spasms.

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FNS AUGMENTATION OF RECIPROCATING HKAFO AND KAFO BRACES
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INTRODUCTION

Two orthotic approaches exist that aim to assist locomotion in the spinal cord injured subject. The traditional orthotic approach that utilises passive external mechanical bracing to facilitate standing and reciprocal walking by means of upper limb mediated posture shifting and gravitational actions; the second approach utilises active movements induced by means of functional neuromuscular stimulation (FNS). FNS synthesised walking is more aesthetic than locked knee gait using KAFO's and may require less upper limb effort. However, maintaining upright support of body weight can present a limitation in the presently used schemes. For example, a continuous activation of quadriceps to stabilise the leg in stance induces muscle fatigue with a consequent loss of function. A combination of the two approaches, whereby external mechanical bracing provides body weight support whilst electrical stimulation, applied in short bursts, helps ambulation, may lead to a more effective orthotic result than when the two techniques are applied individually. Such combined devices are often referred to as "Hybrid Orthoses" (1). A further advantage of this "Hybrid" approach is that the mechanical bracing may be designed to provide a backup, although less efficient, "get back home" system should the FES component fail.

An outline is given of hardware related aspects of three devices, presently being developed, based on knee ankle foot (KAFO) and hip knee ankle foot (HKAFO) reciprocating mechanical braces -another hybrid, based on an AFO brace, is also presented at this meeting (6). These hybrids avoid the requirement for continued stimulation of the antigravity musculature during standing and provide an independent backup mechanical system to the FNS component. In each case the ankle joints are fixed and the knee joints remain mechanically locked during reciprocal ambulation, thus ensuring good upright stability. Devices (A) and (B) provide mechanical stabilisation of the trunk and are suited to higher thoracic lesions. Device (B) provides additional antero/postero stabilisation of the trunk because the hip joints flex and extend reciprocally and bilateral flexion is prevented. This is particularly useful during standing when the trunk is stabilised primarily by the brace and not the upper limbs. Device (C) does not include any mechanical components encompassing the hip and trunk.

MATERIALS AND METHODS

The electrical stimulus used was a monophasic, rectangular pulse train with a PRF of 20Hz, PW 0.3ms and voltage output adjustable between 0-150volts. The surface electrodes used were the self adhesive type (Myocare 3M Ltd.).

Hybrid HKAFO (A)

This hybrid is based on the Oswestry Parawalker HKAFO (5). The hip joint allows for flexion and extension and incorporates a mechanism that allows either free or restricted motion. When sitting, the mechanism is disengaged and the joint is free. When upright and walking the mechanism is engaged to limit the range of motion to suit the stride length of the user. Crutch aided reciprocal ambulation can be achieved in both the adult and child user even for higher thoracic level spinal lesions.

Standing up and sitting down in the device presents problems for many adult users. This may be assisted using bilateral stimulation of the quadriceps as described in (2). When sitting, the knee and hip joints are free. The subject moves himself to the edge of his seat with both feet positioned on the ground. He then presses the STAND control on the stimulator and prepares for the manoeuvre by holding onto a supporting frame. After a delay of a few seconds the stimulus is applied bilaterally to the quadriceps and rapidly increases to maximal intensity. The subject may regulate his rate of ascent by taking more or

less body weight through his upper limbs. Once upright the knee joints lock out automatically when fully extended. If the ground reaction force vector passes anteriorly to the knee joint axis then a knee extending force action will be applied at the level of the patella tendon strap. This is helpful in assisting to lock out the knee joints. The hip joint mechanism is then engaged and the quadriceps stimulus removed. To sit down, quadriceps stimulus is applied to unload the knee joints, the joints are then manually unlocked, the hip joint mechanism released and the SIT control pressed. After a short delay to allow the user to prepare for the manoeuvre, the stimulus intensity to quadriceps is gradually reduced. The user may control his rate of descent by taking more or less body weight through his arms.

During walking the swing leg is cleared from the ground by the action of the user tilting laterally towards the stance leg side. However, deformation of the lateral brace upright occurs on the stance side during single support and may cause the swinging leg to catch the ground and disturb the gait pattern. This is more evident with the larger adult user. To compensate, he must tilt excessively to the stance side at the cost of increased upper limb effort. It was found that stimulation of the hip abductors on the stance side during single support could reduce the deformation in the brace and eliminate the need for compensatory over tilting. Without stimulation the swing leg swings through by the action of gravity in a pendular manner. However, it was observed that stimulation of the hip extensors on the stance side provided a rapid hyper-extension of the hip thrusting the pelvis forward, which in turn, propelled the swing leg through more positively. Stimulation of both gluteus medius and maximus can be effected using at least one pair of surface electrodes. Figure 1 shows the three electrodes used for stimulation of the gluteal and quadriceps muscles. Since these muscles are not active together, a single stimulus channel may be used with the active output switched between the active electrodes (a) and (c). For the smaller adult user, deformation of the lateral upright is not so evident. In this case, hip flexion on the swing side was found to be useful in propelling the swing leg through to increase step length and cadence. Hip flexion may be obtained reflexively by stimulating an afferent nerve such as the common peroneal nerve. The electrode configuration used is shown in figure 2., electrode (b) serves as the common indifferent and (a) & (c) the active electrodes for quadriceps and common peroneal nerve respectively. Hip flexion is often difficult to achieve by direct stimulation because the musculature lies deep and is often covered by a thick layer of fatty skin tissue. The stimulation may be controlled manually using switches mounted on the crutch handgrips. Alternatively, the stimulus may be delivered automatically using pressure sensitive switches mounted onto the footplates of the Parawalker. In this mode, the stimulus is applied when the subject tilts to one side and unloads the swing leg causing the footplate switch to change state. The stimulus is maintained throughout the swing phase until the subject leans back over again causing the swing leg to contact the floor and change the state of the footplate switch. This automatic mode was preferred for level ground walking since it relieved the user from the tedium of controlling each step. Gait laboratory tests were conducted to assess the effect of gluteal stimulus. The results, presented in (4), show reductions in both physiological cost and upper limb effort, as well as an increase in cadence when stimulation was used.

HYBRID HKAFO (B)

This device was based on the LSU RGO HKAFO described in (5). The fitted knee joints were similar to those used on the Oswestry Parawalker. Standing can be assisted using bilateral stimulation of quadriceps in a manner similar to that described above for the Parawalker orthosis. It was observed that the step length and cadence could be improved by reflexively stimulating the hip flexors on the swing leg side. The electrode configuration was the same as that shown in figure 2. The stimulus may be applied automatically to the common peroneal nerve when the swing leg is unloaded and removed again on foot contact using a shoe

insole switch. Deformation of the brace occurs on the stance side in a similar manner to that described above for the Parawalker. In one of our larger subjects (S.M., age 24yrs, mass 73Kg, height 1.78m T9 complete) it was found that the swing leg dropped medially to the extent that the uprights caught up and prevented walking. This may be compensated for in a similar manner to that described above for device (A) by stimulation of the hip abductors on the stance side. In addition, stimulation of the hip extensors, on the stance side, assists the reciprocation of the brace. The electrode configuration used to give this extension/abduction on the stance side and hip flexion on the swing side is shown in figure 3. In this case electrodes (a, active) and (b) were used to stimulate gluteus medius and maximus, electrode pair (c, active) and (b) were used to stimulate quadriceps and the pair (d, active) and (c) to stimulate the common peroneal nerve. Only one channel being active at any one time. Alternatively, a mechanical joint was used linking the proximal ends of the medial thigh uprights of the KAFO sections similar to that shown in figure 4. This joint allowed flexion/extension but restricted adduction/abduction. This was found to significantly increase the rigidity of the brace and eliminate the need for gluteal stimulation.

HYBRID KAFO (C)

This device was fabricated in high density polypropylene comprising two KAFO sections in which the medial uprights were linked proximally as shown in figure 4. This linkage allows for flexion/extension of the hips but prevents abduction/adduction. The AFO section is rigid with the ankle set in approximately the neutral position. The rigid footplates extend to the metatarsal heads and fit inside the users shoes. A restraining padded strap passes over the patella tendon and is attached to the rigid AFO section. The AFO connects with the thermoformed posterior thigh cuff by a single medial upright fitted with a bale lock type knee joint. Again stimulation of quadriceps applied bilaterally was used to assist standing in a similar manner to that described for device (A); the knee joints automatically locking out once the subject is upright and leaning slightly forward. In order to clear the swing leg from the floor the subject tilts laterally towards the stance side. Reciprocal walking using a rollator was possible without stimulation as shown in figure 4. (Subject D.T., age 38yrs, mass 74Kg, height 1.75m, T6 complete). However, reflexively induced hip flexion applied during the swing phase to the swing leg was found to be helpful in increasing the step length and cadence. The electrode configuration being the same as that shown in figure 2.

COMMENTS

With the surface electrodes used (Myocare, 3M Ltd) gluteal stimulation proved to be inconvenient in some cases because: (i) electrodes tended to be scuffed off by the clothing, (ii) electrodes were difficult to apply and remove by subject, (iii) electrode adhesion was sometimes impaired by sweating and (iv) the presence of a thick fatty layer in some cases made it difficult to obtain a sufficiently strong contraction. Further work remains to be done to assess the practicality and to determine the relative advantages/disadvantages of these devices.

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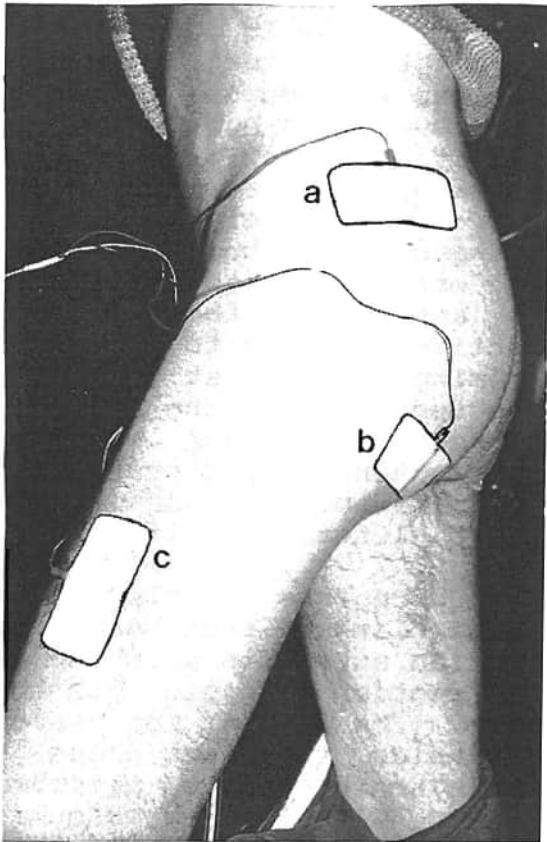


Fig. 1. ELECTRODE LAYOUT (1)

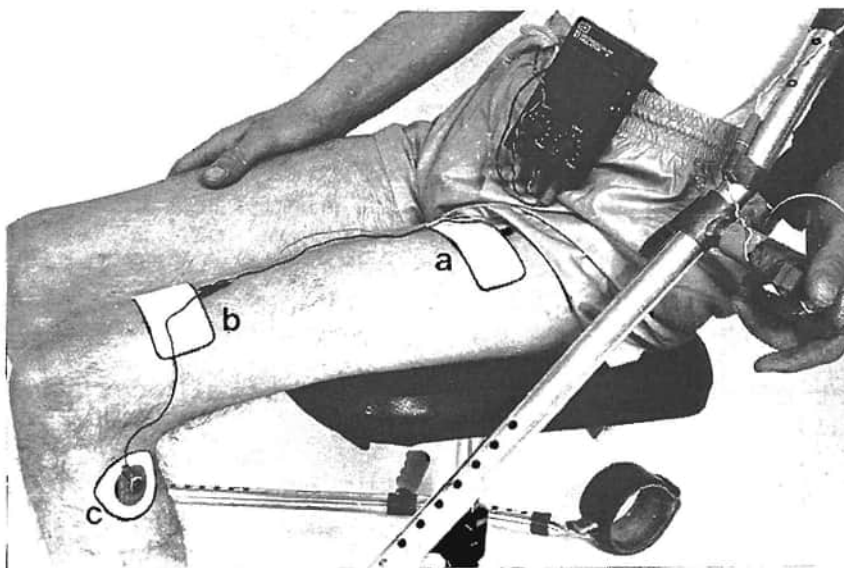


Fig. 2. ELECTRODE LAYOUT (2)

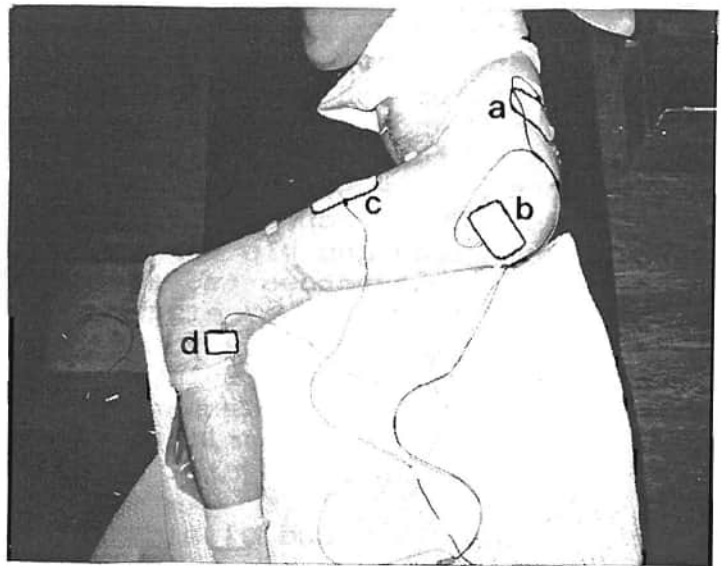


Fig. 3. ELECTRODE LAYOUT (3)

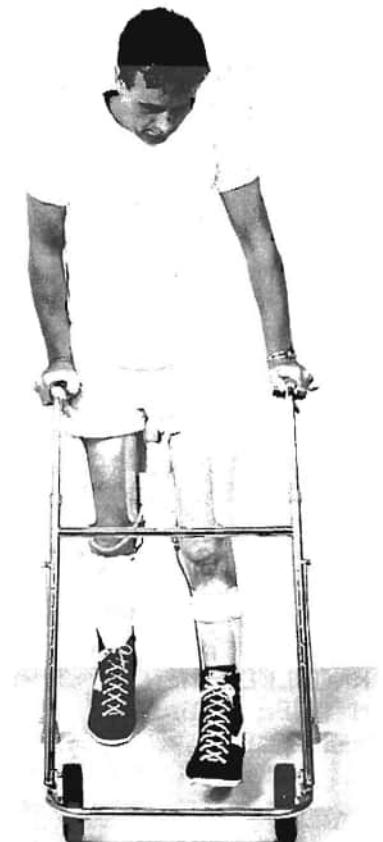


Fig. 4. LINKED KAPO

STRATEGIES FOR OVERCOMING MUSCLE FATIGUE CAUSED BY FUNCTIONAL ELECTRICAL STIMULATION

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SUMMARY

Skeletal muscle must be prepared to receive functional electrical stimulation (FES) in order to minimise fatigue and damage. Fatigue is assessed by examining the contractile properties of muscle. Conditioning and strengthening stimulation are performed in preparation for an FES treatment programme. The pattern of stimulation for FES may be guided by examining the fibre type composition, muscle chemistry and fatigability.

INTRODUCTION

Muscle fatigue is well recognised as a limiting factor with the use of FES in patients following spinal cord injury (1,2). Fatigue is the failure to maintain a given force or power output during sustained or repeated contractions and can occur at high or low frequencies of stimulation (see Table I and (3)).

Table 1. PHYSIOLOGICAL CLASSIFICATION OF PERIPHERAL MUSCLE FATIGUE

Fatigue	Characteristics	Mechanisms
High Frequency	Selective loss of force at high stimulation frequencies	Impaired neuromuscular transmission and/or sarcolemmal excitation
Low Frequency	Selective loss of force at low stimulation frequencies	Impaired excitation-contraction coupling

This paper describes methods of assessing muscle fatigue during the preparatory phase for using FES and also for monitoring its effects during a programme of treatment.

PHYSIOLOGICAL ASSESSMENT OF MUSCLE FUNCTION

Percutaneous Muscle Biopsy

Samples of muscle are obtained from quadriceps for histology and chemistry using the needle biopsy technique (4) or the conchotome technique (5). In paraplegic patients, the quadriceps consists predominantly or exclusively of type II fibres (6). The initial biopsy is useful for assessing the mitochondrial enzyme activity of the muscle which is low in the absence of type I fibres.

Analysis of Contractile Properties of Fresh Muscle

The force:frequency and relaxation characteristics of quadriceps are examined by percutaneous supramaximal stimulation via motor end nerves using pad electrodes and isometric force is measured by strain gauge dynamometry (Fig 1).

Stimulation is delivered in a set pattern of frequencies and the force record produced is termed the "programmed stimulation myogram" or "PSM" (Fig 2a). When a muscle is fatigued, force loss can occur at different frequencies (Fig 2b). Maximal relaxation rate is also reduced in fatigued muscle (7). Maximum force can only be achieved by supramaximal stimulation of the femoral nerve but this can be dangerous (the patella can dislocate or, in paraplegics, bones may fracture due to osteoporosis). With the use of pad electrodes only part of the muscle is stimulated supramaximally. Tests are repeatable when frequency:force relationship, fatigue or relaxation rate are determined since these are all proportional and not absolute measurements.

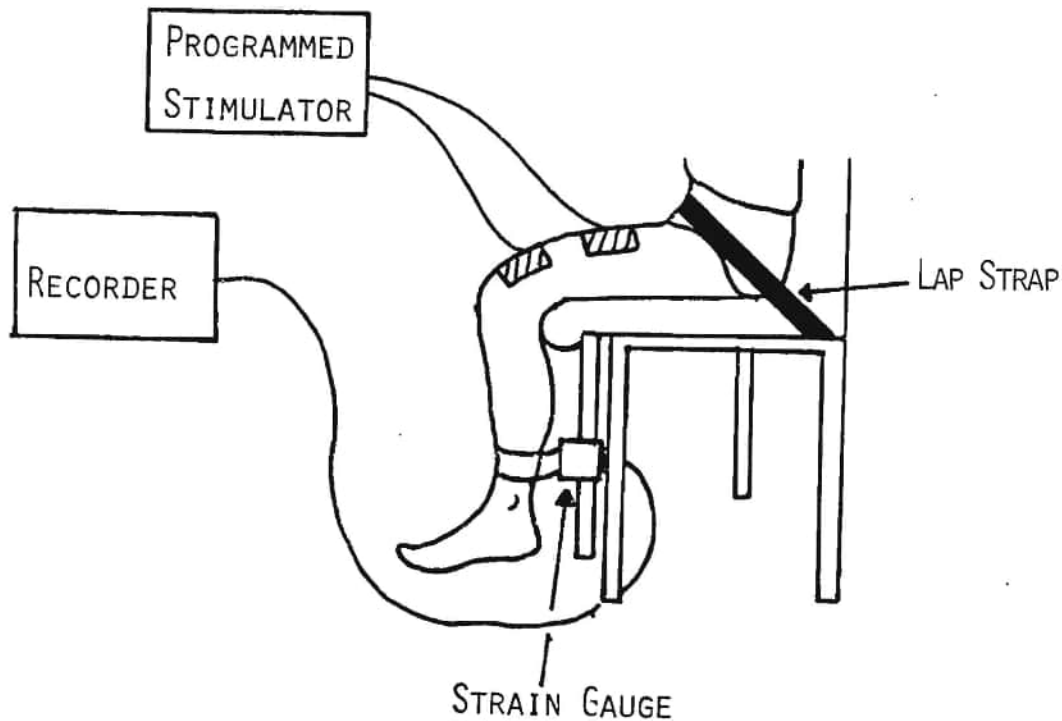


Fig 1. Stimulation of the quadriceps produces knee extension. The force exerted at the ankle is recorded by a strain gauge and the signal is displayed on an oscillograph.

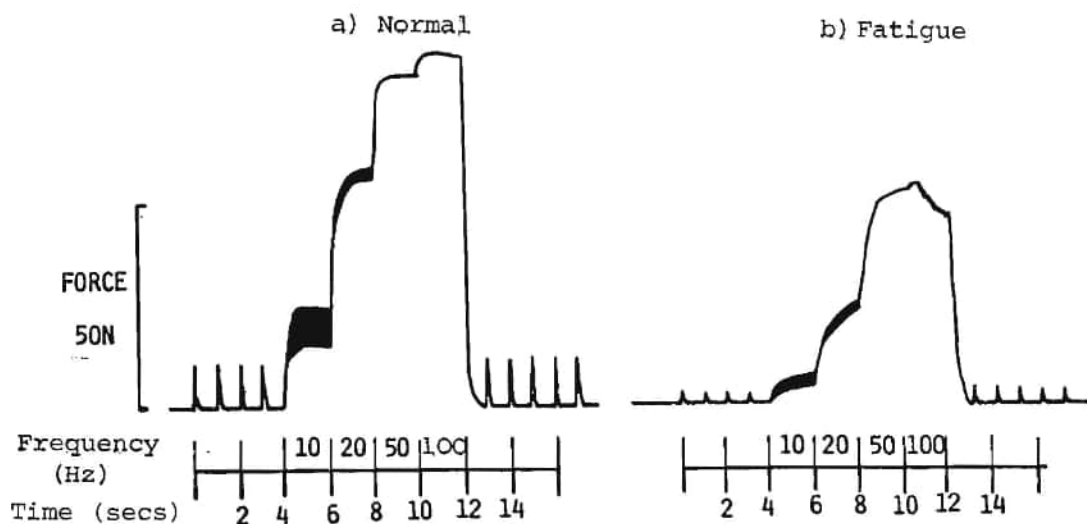


Fig 2. a) Forces generation in normal fresh muscle during stimulation at different frequencies.

b) Force loss at low and high frequencies of stimulation in fatigued muscle.

Analysis of Fatigability of Active Muscle

As well as establishing whether fatigue is present on static testing, it is also important to know the rate and extent of fatigue during sustained electrical stimulation. An example of a fatigability test is stimulation at 30Hz for 30s (8,9). The effect of the test run on the PSM (which is expected to show that low frequency fatigue is greater and longer lasting than high frequency fatigue) is also examined (see Fig 2b and (10)). Test runs can be performed at intervals during a treatment programme to monitor the effects of chronic FES.

PREPARATION OF TISSUES TO ACCEPT FES

Bone

In paraplegia it is important to strengthen osteoporotic bones in preparation for weight-bearing.

Muscle

Following the period of inactivity after spinal injury the muscles must be prepared for receiving stimulation before they can safely respond to FES. Firstly, the fatigability of the muscle must be reduced and this can be achieved by chronic low-frequency stimulation (i.e. conditioning stimulation) which has been shown to increase mitochondrial enzyme activity (11). Muscle strength must then be increased to prepare for weight-bearing. Kralj et al. (2) found that stimulated isotonic contractions were more effective than isometric contractions for strengthening. Changes in the contractile properties with the use of FES can be monitored by looking for changes in the force:frequency curve (Fig 3).

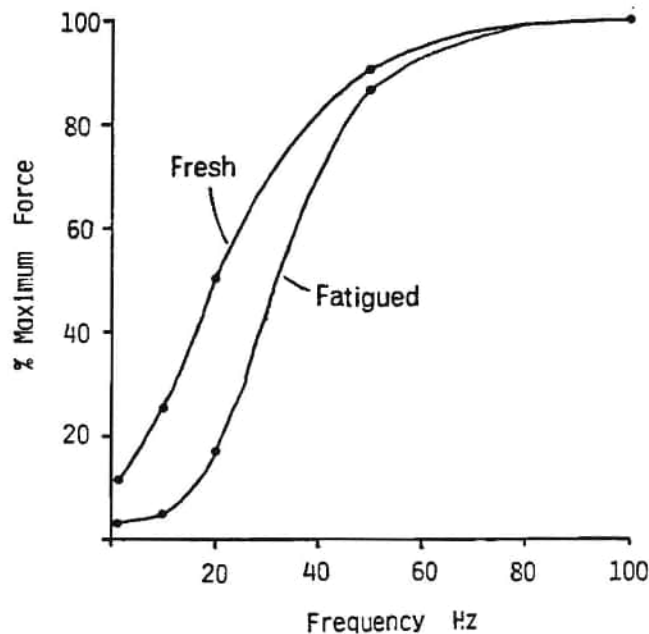


Fig 3. During fatigue the force:frequency curve shifts to the right indicating that a lower force is achieved at a given frequency.

Weight reduction is of vital importance during this period of preparation because body weight is the main determinant of force per unit fibre area of muscle (see below). Excessive loading can cause muscle damage, particularly during eccentric contractions (12).

OPTIMUM STIMULATION PATTERN FOR SUSTAINING ACTIVITY

The appropriate pattern of stimulation for each patient will depend of the muscle fibre type composition and the results of the fatigue tests (see above). The fatiguing effect of an FES "treatment" run can be tested by PSMs before and after treatment. One of our patients said that her life would be dramatically altered if FES could allow her to transfer independently. This would involve standing up and walking a few steps. Bearing this in mind, particular care is needed when designing FES systems which allow a patient to sit down. The control of sitting down involves eccentric contractions of quadriceps which cause both greater fatigue and force generation per fibre, thus increasing the likelihood of damage (13). In order to minimise these effects, a large proportion of muscle must be stimulated to reduce the force per unit fibre area.

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A PERSONAL COMPUTER BASED FNS CONTROLLER x)

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SUMMARY

A Functional Neuromuscular Stimulation control system (FNS-controller) based on a standard IBM Personal Computer is described. The FNS controller is tailored for use with a stationary cycling device (Paracycle), for training of the lower extremities of paraplegic subjects. Similar cycling devices and control systems have been described in the literature /1/,/2/. These authors have clearly shown the benefits of FNS induced cycling on the properties of paralyzed muscles and the well-being of the subjects.

The system was made as flexible as possible, in order to cope with all the variations in stimulation parameters. It is possible to program stimulation parameters such as pulse waveform, amplitude, width and frequency independently for each channel and also as a function of certain system input variables. The stimulation waveforms are generated by digitally programmable modules which operate independently from the Personal Computer's processor. This frees the computer from the time consuming task of generating the stimulation waveforms, and allows the use of a high level language to coordinate the stimulation process.

To accomodate paralyzed subjects with a high degree of muscle atrophy, a motor was provided to assist the cycling motion in defined parts of the crank cycle. The same motor can be used to impose a programmable load on the subject.

Variables controlling the stimulation on the Paracycle are the position of the crank and the positions of controls operated by the subject and the system operator.

A software package, written in TURBO PASCAL, controls the setting of stimulation parameters and the sequences which are entered as a function of crank position. The entered data sets can be edited on the graphics screen between stimulation sessions and be stored on floppy disk for later reference.

METHODS AND EQUIPMENT DESIGN

THE FNS CONTROLLER SYSTEM

The FNS controller can be defined as a complex system which has to perform various input, output and internal or control operations :

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I. Output Operations :

- a.) Mono- or bi-phasic pulsatile waveforms with pulse currents of up to 100 mA into a 1500 Ohms load are required /3/,/4/,/5/.
- b.) The pulse waveform, its frequency, amplitude and width must be individually adjustable for each channel.
- c.) The system must support the use of a motor, either to assist the motion or to act as a resistive brake.
- d.) Information for estimating the efficiency of stimulation must be available to the system operator.
- e.) Individual stimulation sequences need to be stored, preferably on floppy disk, to simplify system operation.

II. Input operations :

- a.) The definition of stimulation parameters and sequences;
- b.) The acquisition of variables which coordinate the stimulation.
- c.) Provisions for collecting additional positional or force information for closed loop controlled FNS must be made.

III. Control functions :

- a.) The information relating to stimulation parameters and sequences must be processed to allow real time control.
- b.) Facilities for stimulation data storage and retrieval management must be provided.
- c.) A user friendly working environment must be provided;

THE FNS CONTROLLER HARDWARE DESIGN

The above design criteria precluded the implementation of a purely hardware programmable stimulation system, and thus a multipurpose FNS controller was developed. Similar approaches have been followed using a minicomputer /6/ and using a multiprocessor system /7/. The design of the FNS controller was based on an IBM Personal Computer (see Figure 1).

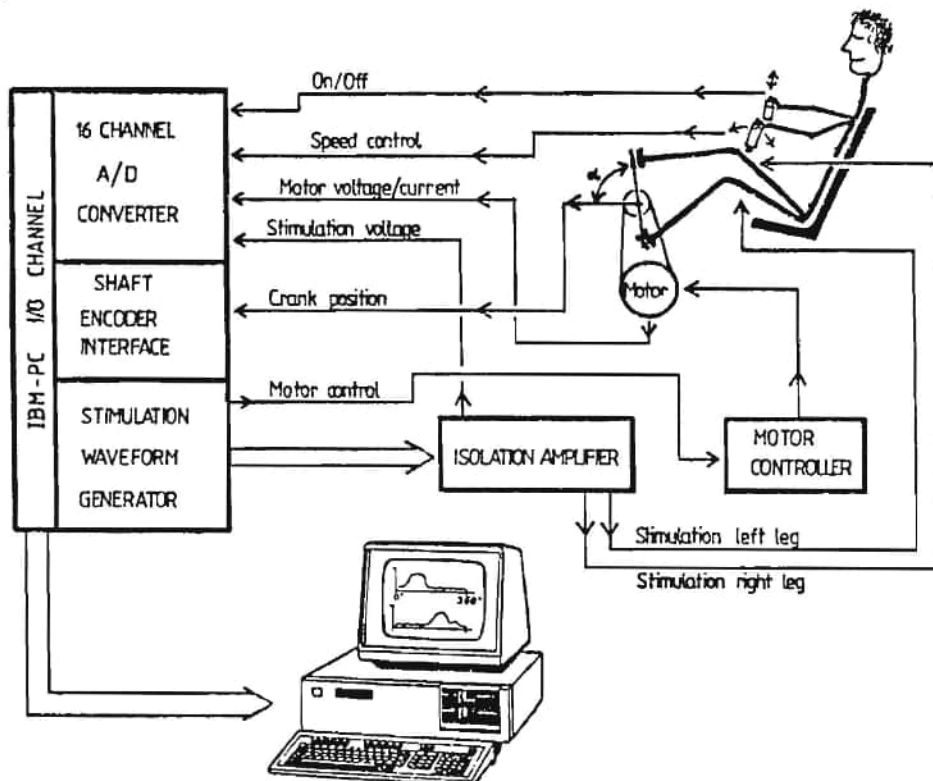


Figure 1 Block diagram of the FNS controller and Paracycle

The following five customized modules are interfaced to the computer.

1. THE STIMULATION WAVEFORM GENERATOR houses six intelligent output modules which can be individually programmed. In each channel, 3 programmable timers and 2 D/A converters control the generation of biphasic or monophasic waveforms. The FNS-controller can easily be expanded to 12 channels by the addition of another stimulation generator board.
2. A FAST 16 CHANNEL 12-BIT A/D CONVERTER allows the measurement of electrode impedance, motor current and voltage and the input of other analogue control signals.
3. THE SHAFT ENCODER INTERFACE allows measurement of the position and speed of the Paracycle's crank using a Hewlett Packard shaft encoder. In addition, an eight bit parallel I/O port is provided on this expansion board for sensing switch positions, for example.
4. THE MOTOR CONTROLLER uses a programmable pulse width modulator (PWM) to control a 24 V DC motor which either assists or loads the patient during cycling.
5. THE ISOLATION AMPLIFIER converts the signals from the waveform generation module to a level suitable for stimulation via surface electrodes. The outputs are current controlled and isolated via pulse transformers. The output voltage of each channel can be measured via opto-coupler circuitry.

THE FNS CONTROLLER SOFTWARE

An extensive software package for the FNS controller enables the user to define individual stimulation parameters and sequences for each subject. The stimulation patterns and patient data can be stored on floppy disk. The real time stimulation process measures the crank position of the Paracycle and according to the position of the controls operated by the subject, coordinates the stimulation. The entire software package, including all real time stimulation procedures, is written in TURBO PASCAL. Thus future changes dealing with the control of all stimulation parameters and the implementation of closed loop algorithms is made relatively easy. Despite the use of a high level language, the existing real time software updates the stimulation hardware and the screen displays every 11.6 ms. Without screen displays, the update interval can be reduced to about 5 ms.

DISCUSSION

The FNS-controller/Paracycle system was tested in a clinical case study with two paraplegic subjects (complete T3 and T6 lesions of recent origin). Electrode locations and torque versus stimulation parameter characteristics were determined in each subject for three muscle groups, namely Quadriceps, Hamstrings and Gastrocnemius. The initial intention was to base the stimulation sequences necessary to produce a cycling movement on EMG studies of each muscle group. The EMG studies were carried out on four non-paralyzed subjects on the Paracycle. However, the stimulation sequences thus obtained proved not capable of producing the desired cycling movement.

On the basis of these results, the stimulation sequences were determined by analysis of the biomechanical characteristics of the Paracycle and the known actions of the muscle groups in question. The stimulation sequences and individual stimulation parameters were stored in the FNS-controller. Initially the subject was assisted through the 'dead spots' of the crank cycle by the motor. During the first sessions, both subjects were able to cycle with partial motor assist for 2 minutes at 30 rpm at a load of approximately 5 watts. During the subsequent training program, the stimulation sequences

were adapted to the subject's improving response to FNS. After six weeks both subjects were able to cycle for 5 minutes at 30 rpm without motor assist against a load of 20 watts and 12 watts, respectively.

The FNS-controller offers easy programmability of stimulation parameters, a feature only offered by few other systems described in the literature. The combination of a standard IBM compatible Personal Computer with customized expansion boards and a software package written in TURBO PASCAL could prove to be highly advantageous for future expansions of the system. This is mostly due to the fact that the waveform generation is performed by dedicated output modules, which frees the Personal Computer to acquire and process data for the real time control of the stimulation. The execution speed of TURBO PASCAL allowed even the real time control routines to be written in this high level language. This could simplify the implementation of more complex control algorithms in the future.

The possibility to assist the paralyzed subject in the early stages of the training program on the Paracycle in order to overcome 'dead spots' in the crank cycle, proved to be a very valuable feature, leading to a smooth cycling movement. In addition, it was possible to drive the subject's legs passively during periods of rest in order to increase joint mobility and circulation in the extremities. If the subject's muscle torques improved, the motor could be used as a programmable load.

Finally, the FNS-controller could be used for applications other than cycling. Thus with an additional software package, the FNS-controller was used for the assessment of patient response to different FNS waveforms and the measurement of muscle torques produced by FNS.

In order to use the Paracycle as a mobile cycling device, a portable microprocessor controlled stimulator is currently being developed. Customized stimulation sequences will be loaded from the FNS controller into this unit in order to optimize stimulation.

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FES EXERCISE EQUIPMENT FOR THE LOWER EXTREMITIES

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SUMMARY

Before applying functional electrical stimulation to paraplegics to let them stand and walk, it is necessary to train their atrophied muscles intensively. Therefore we developed an exercise bicycle and a Quadriceps exerciser, both for use with surface electrodes. The exercise systems are based on a computer controlled 4 channel research stimulator for surface electrodes previously developed at our centre.

This paper describes the research stimulator and its first clinical application: the exercise bicycle.

INTRODUCTION

Since 1984 an extensive co-operation exists in research on functional electrical stimulation between the Twente University of Technology and our centre.

The long term goal of the research is focussed on the development of a multichannel closed-loop stimulation system to enable paraplegics to stand and walk.

Part of the research at our centre is now directed to the development of FES exercise equipment to train the atrophied muscles in an optimal way. Our philosophy is to develop this exercise equipment first with a special research stimulator in which all parameters and pulse shapes can be used. In this way the method of exercising can be optimised in an easy way. When the optimal parameters are found, these are transferred to a low cost user friendly stimulator system.

When surface electrodes are used in stimulation, a complicating factor is formed by the time dependence of the relation between stimulation current and motor unit recruitment. During contraction this relation depends on fatigue and the changes in muscle shape, which directly effect the current density through the muscle. Therefore a stimulation system that has to control movement over a long period will have to adapt it's parameters repeatedly [1].

To work on this and other problems we developed a computer controlled stimulator system called the research stimulator which could potentially accomplish the required tasks.

In training of paraplegics muscle strengthening by weight lifting is one aspect, another important aspect is building up fatigue resistance. A well known form of physical therapy to train for muscle endurance is cycling [2]. This enables the training of muscles at relatively low loads and high rates. It also provides a dynamic exercise of knee and hip joints.

Although in paraplegics cardiovascular response to FES induced exercising is less then that induced in voluntary exercise, cycling can also improve the cardiac condition of patients as a preparation to standing and walking [3].

This paper describes our research stimulator and the application of it to develop the bicycle exerciser.

MATERIAL AND METHODS

The research stimulator

The system consists of an Apple IIe microcomputer to control the actual stimulation, and a 4 channel microprocessor controlled stimulator.

In a master/slave set-up the stimulation patterns are generated with the Apple computer and passed to the dedicated stimulation computer, which takes care of the actual pulse generation. The pulse shape as well as the stimulation parameters can be adjusted over a wide range of values, and can be independently choosen for each pulse and each channel. Therefore the stimulator is receiving a specified stimulation instruction from the control computer each time a stimulation pulse should be generated on any of the 4 channels. Each instruction consists of four 8-bit words and contains information about channel number, pulse shape, pulse duration, pulse amplitude and polarity. Data is send from the Apple computer to the

stimulator through an optically coupled serial data link. At the stimulator the pulse information is decoded and processed by a 6502 microprocessor and 6522 peripheral interface. Specially developed hardware finally controls the current end-stage of the stimulator. A ROM memory contains information about 8 different pulse shapes, which all may be generated mono- or biphasic. Frequency is controlled using the clock interrupt facilities of the Apple computer.

This set-up of the system enables us to reduce the tasks of the control computer to timing, control and security.

A special control program was developed for research on stimulation parameters. In this program all stimulation parameters can be changed on-line from the computers keyboard.

The exercise bicycle

The mechanical part of the exercise bicycle was realized using a modified standard bicycle ergometer and a modified dentist chair (Figure 1). The dentist chair replaces the ergometers seat. Equipped with a four-point seat belt and leg support, the chair provides a safe, easy serviceable seat, adjustable over a wide range in height and position of seat and back seat. Arm layers and seat belt enable the patient to maintain good balance.



Figure 1:
Patient sitting on the bicycle ergometer.

To detect the angle of the pedals the ergometer is equipped with a contactless goniometer mounted on the cranks. The patients feet are secured to the pedals by velcro soles for optimal fastening during pedaling and easy loosening in case of spasticity. The ankles are protected by under-leg orthosis with a fixed ankle joint, and a centrally positioned upper-leg support to avoid hip ab-/adduction.

To control the stimulation we use our 4 channel research stimulator operated by the Apple IIe computer. For this purpose the Apple is equipped with a special interface to determine the crank angle from the goniometer signal.

During cycling the stimulation amplitude and speed of rotation are controlled by measuring the crank angle $\phi(t)$ and passing it closed-loop to the stimulator (Figure 2).

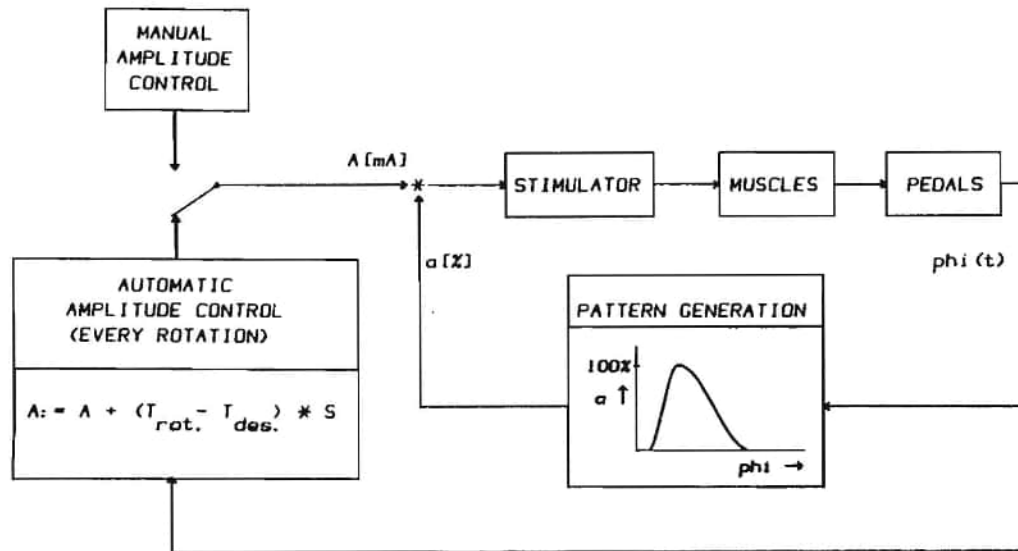


Figure 2: Simplified blockdiagram of the bicycle ergometer system.
Refer to the text for details.

Cycling is started by a manual start-up procedure. During the start-up the stimulation amplitude is controlled by hand from the computers keyboard. After reaching a desired speed of rotation, automatic speed control is enabled. This provides automatic compensation of fatigue and load changes within specified ranges.

Automatic control is done by measuring the pedal rotation-time (T_{rot}) every rotation. When the rotation time mismatches it's initial value (T_{des}) the stimulation amplitude (A) is changed according to the steepness (S) of the muscles' recruitment curve.

Not included in the blockdiagram of figure 2 is a special software security module providing the stimulation to stop immediately in case of spasticity. This is detected from sudden changes in the speed of rotation.

The envelope of the stimulation pattern for each channel can be given any particular shape to adjust it to sitting position, knee angle range and speed of rotation. The patterns can be saved to disk for later use.

RESULTS AND DISCUSSION

The research stimulator has proved to be useful in both research on stimulation parameters and as a tool in developing exercise equipment.

Some results concerning the first item are presented in our paper 'Research on electrical stimulation with surface electrodes' included in these proceedings. In this paper fatigue resistance is examined in relation with electrode configurations.

As a first spin-off a 4 channel Quadriceps exerciser is commercially available now for combined standing/switch controlled walking and automatic practising.

At this moment our exercise bicycle is ready for clinical application. Until now our research concerned especially the development of suitable stimulation patterns.

To determine the correct stimulation patterns we investigated the muscle activation patterns in healthy subjects while they were pedaling the bicycle. This was done using dynamic real-time averaged EMG measurements. Using Quadriceps and Hamstrings for stimulation in cycling, the mean activation patterns of these muscles were measured for different sitting positions and speed of rotation.

Figure 3 shows the mean integrated EMG over seven rotations for one person pedaling at 60 rpm in a sitting position at a 110 W load.

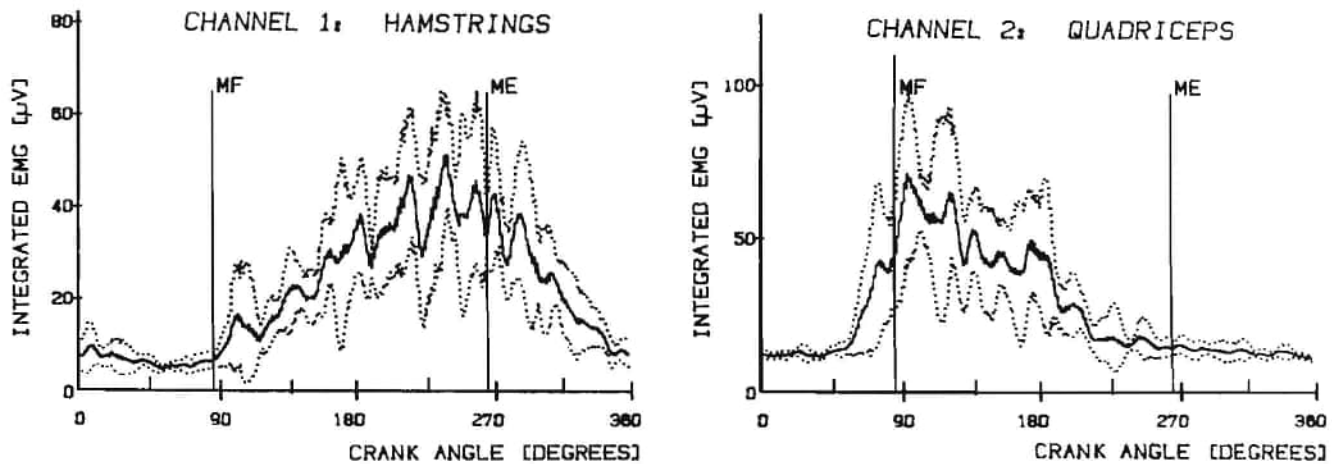


Figure 3: Integrated EMG of Quadriceps and Hamstrings for a healthy subject during cycling.
 Solid line: mean integrated EMG over 7 rotations
 Dotted line: one time standard deviation
 MF: point of maximum flexion
 ME: point of maximum extension

For the Quadriceps we see how muscle activity reaches it's optimum around the point of maximum flexion, then decreases. For the Hamstrings the activity increases until the point of maximum extension then rapidly decreases.

Until now in patients only the Quadriceps have been stimulated. This has resulted in good pedaling, in which timing appeared to be the most critical factor.

Besides computer controlled cycling the bicycle ergometer is used with a switch controlled stimulator. In this way the patient, who controls the stimulation by hand, can get a good visual hand-to-leg coordination which is important as a preparation for walking.

The exercise bicycle offered us a first experience with closed-loop stimulation systems. Although the control system is relatively simple, it has shown to work in a stable way during cycling.

Never the less it has become clear that, as far as direct control of leg position is concerned, more sophisticated closed-loop systems will be needed e.g. for automatic adaptation to changing muscle characteristics.

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GAIT ASSESSMENT USING SURFACE F.N.S. ON S.C.I. SUBJECTS WITH INCOMPLETE LESIONS: PRELIMINARY RESULTS.

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SUMMARY

Gait tests were performed with four subjects who had incomplete spinal cord lesions and had achieved aided walking using FNS. Physically, each subject has sufficient voluntary control and strength in one leg to be able to remain standing for short periods of time aided only by forearm crutches. Initially all subjects underwent a muscle conditioning program. During the tests a microcomputer controlled stimulator was used to synthesise movement of the paralysed leg.

The kinematics of the subjects gait was measured using goniometers and foot contact switches. Data was acquired for level walking using the subjects previously prescribed mechanical braces as well as with the FNS. The preliminary results indicate that all four subjects were able to walk with improved symmetry and efficiency using FNS than braces.

MATERIALS AND METHODS

Initially the criteria for the subject selection were: 1) Type of spinal injury, 2) Good cooperation 3) No emotional and physiological disturbances preventing the application of FNS 4) Sufficient passive range of movement in all joints of the lower limbs 5) No excessive spasticity of the paralysed legs 6) Were able to ambulate using previously prescribed mechanical braces. Following the muscle conditioning phase, the additional selection criteria were applied: 7) Have responded positively to the muscle conditioning exercises 8) Able to remain standing for short periods (up to 3 min) without the support of braces or FNS 9) Able to ambulate themselves with FNS using a walking aid.

TABLE 1

PATIENT	A		B		C		D	
LESION	C3/C4		C6		C5		C6	
MUSCLE GROUP	MUSCLE GRADE (Oxford scale 0 to 5)							
	R	L	R	L	R	L	R	L
GLT.MAX.	4	4+	3-	1	3+	4	3-	2
HIP.FLEX.	2+	4	4-	2-	4+	5-	3-	2
QUADS	4	4	4-	1	4	4+	4-	3+
HAMS.	2-	3+	2	1	3+	4	3	2
GASTRO.	3+	4+	3	0	4	4	5-	3+
HIP ABD.	2	3	3-	1	3-	5-	3+	2
HIP ADD.	4	4	3+	3+	4+	4	4	3
DORSIFL.	3	1	3+	0	0	0	3	0

The incomplete level of spinal injury for each subject tested can be found in Table 1. Initially each subject's walking was classified according to the Hoffer scale: : Patient A used a short leg ankle-foot calliper and was able to perform limited community walking. Patient B used a full length calliper with crutches and was able to perform limited household walking. Patients C and D were physiological walkers only using full length KAFO callipers.

The FNS program began with muscle conditioning exercises lasting approximately one month. During this period, the knee extensors were strengthened using cycled stimulus applied to both legs 1 hour/day. After the first month, gait training was started. Initially, parallel bars were used but eventually three of the subjects were able to perform crutch assisted walking; subject D still required a Zimmer type

walking frame. All four subjects were able to stand and walk with unilateral stimulation of the knee extensors during the stance phase and the common peroneal nerve to elicit the flexion withdrawal response during the swing phase as described in (1). This could be controlled by the subject using a hand switch connected to the stimulator. The stimulation was delivered through surface electrodes (Myocare 3M Ltd.) and was controlled by a BBC microcomputer. The operator can set up the stimulus sequences for locomotion using an interactive program as described in (2). The gait cycle is divided into three phases: double support, right swing and left swing. During the swing phase of the paralysed leg, the common peroneal nerve was stimulated to elicit the flexion withdrawal reflex. When the hand switch was not pressed, stimulus was delivered to the knee extensors. The knee extensors were stimulated throughout the double support and the single support phases. The swing phase was initiated by the subject first transferring his body weight to the supporting leg and then pressing the hand switch; the swing duration was controlled by holding the switch pressed. When the hand switch was released the knee extensors were again stimulated to extend the knee prior to foot contact. During the investigation, a three electrode configuration was used as shown in figure 2. Two active electrodes were used: one to stimulate the knee extensors (a) and one the common peroneal nerve (c). The common indifferent electrode (b) was positioned on the anterior area of the thigh approximately 5cm above the patella with the knee fully extended.

Prior to the gait test each subject underwent a muscular evaluation test of the lower limbs using the Oxford scale (0 to 5). The results for each subject are listed in Table 1. During the gait tests, kinematic data was collected using six electrogoniometers and four foot switches. In order to measure the spatial parameters of the gait, the subject walked on paper with inked foot markers mounted on the shoes. The electrogoniometers and foot switches were connected to a second BBC microcomputer and both systems were placed on a trolley that was wheeled behind the subject.

RESULTS

Two sets of kinematic gait data were collected and analysed for each subject: (1) walking with FNS orthosis (2) with the subject's previously prescribed calliper. The following gait parameters were derived for each leg: Hip, knee and ankle joint angles as well as foot contact times. The data collection time for each subject lasted approximately 30 s. By analysing the temporal data, it was possible to derive the following gait parameters: Right/Left cycle times and Right/Left single support times. The parameters derived using the spatial foot contact markers were: step length, foot angle, step width, Right-heel Left-heel (HRHL) and Left-heel Right-heel (HLHR) lengths.

The mean and standard deviation for each gait parameter was calculated based on the data for 8 consecutive steps. The HRHL and HLHR lengths as well as the single support times are presented as percentages of the mean step lengths and the cycle times. Also the mean value of right and left joint angles and their standard deviations at every 1% of the mean right and left cycle respectively were calculated and the results are plotted against the percentage of the corresponding cycle. All data, except the joint angles, are presented in Table 2 in the form: mean and one standard deviation.

CONCLUSIONS

In all four cases the swing through of the paralysed leg was quicker and the step length longer when using stimulation than when using a brace. Specifically, this is shown by the single support time, heel to heel distance and hip angle. The single support time of the

TABLE 2

Patient: A (Incompte)		Paralysed leg: Right		Aid: Crutches	
GAIT PARAMETERS		with stimulation		with brace(AFO)	
	Right	Left	Right	Left	
Foot Angle (deg)	32.2+2.56	15.1+5.80	23.6+11.03	12.5+2.25	
Step Width (cm)	13.6+2.64	13.6+3.81	14.0+2.11	14.2+6.24	
Cycle time (sec)	3.4+0.58	3.6+0.13	2.8+0.18	2.9+0.23	
S.Support (%)	23.6	18.3	28.7	34.8	
Step Length(cm)	80.6+4.35	80.3+4.47	85.3+1.97	84.6+3.17	
*HLHR,HRHL (%)	46.9	53.1	42.9	57.1	
Av. Speed (cm/s)	23.7		29.5		
Hip Ext(Hyp) (deg)	20(16)	13(18)	10(22)	10(10)	

Patient: B (Incompte)		Paralysed leg: Left		Aid: Crutches	
GAIT PARAMETERS		with stimulation		with brace(KAFO)	
	Right	Left	Right	Left	
Foot Angle (deg)	11.5+5.79	7.8+2.67	21.8+3.49	6.2+3.34	
Step Width (cm)	13.1+2.52	13.2+4.64	17.9+1.36	18.1+3.5	
Cycle time (sec)	2.5+0.15	2.6+0.10	2.5+0.07	2.6+0.06	
S.Support (%)	26	30	69.7	35	
Step Length(cm)	106.4+3.46	105.4+3.98	99.3+2.80	99.5+5.6	
HLHR,HRHL (%)	49.5	50.8	48.6	51.17	
Av. Speed (cm/s)	41.2		40.3		
Hip Ext(Hyp) (deg)	10(16)	20(2)	12(21)	14(22)	

Patient: C (Incompte)		Paralysed leg: Right		Aid: Crutches	
GAIT PARAMETERS		with stimulation		with brace(KAFO)	
	Right	Left	Right	Left	
Foot Angle (deg)	5.2+11.43	5.5+3.86	-5.2+1.42	9.6+2.97	
Step Width (cm)	32.4+2.82	32.8+4.73	34.6+1.21	34.8+2.31	
Cycle time (sec)	3.5+0.32	3.4+0.18	3.2+0.31	3.2+0.26	
S.Support (%)	11.5	35	18.5	39.2	
Step Length(cm)	81.9+4.31	77.4+11.78	76.5+12.15	79.8+3.81	
HLHR,HRHL (%)	50.3	52.4	45.9	51.7	
Av. Speed (cm/s)	23.1		24.1		
Hip Ext(Hyp) (deg)	40(8)	30(2)	10(18)	30(3)	

Patient: D (Incompte)		Paralysed leg: Left		Aid: Zimmer	
GAIT PARAMETERS		with stimulation		with brace(KAFO)	
	Right	Left	Right	Left	
Foot Angle (deg)	12.5+10.8	1.9+5.76	6.1+2.81	0.8+2.01	
Step Width (cm)	31.3+1.70	31.5+4.98	33.4+1.04	33.2+1.81	
Cycle time (sec)	5.7+0.23	5.6+0.23	2.7+1.30	4.5+0.92	
S.Support (%)	16.8	16.7	25	17	
Step Length(cm)	55.6+4.81	54.3+6.10	58.4+3.94	57.9+2.33	
HLHR,HRHL (%)	32.3	69	47.1	53.3	
Av. Speed (cm/s)	9.7		11.1		
Hip Ext(Hyp) (deg)	25(12)	20(2)	20(0)	8(4)	

L_L, L_R = L, R Step Length.

CT_L, CT_R = L, R Step Time.

ϕ_L, ϕ_R = L, R Foot Angle.

HRHL = % of Left S.Length.

HLHR = % of Right " " "

$b_L + b_R$ = Step Width(Left).

$b_L + b_R$ = Step Width(Right).

MP = Mid Point of M to H line

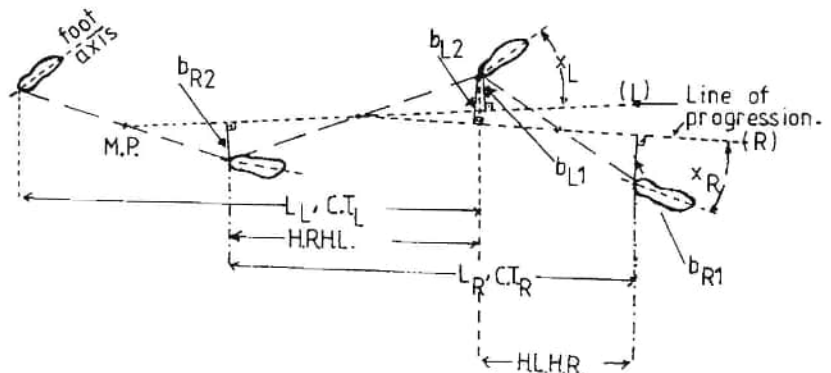


Fig.1 Geometrical definition of foot gait parameters.

supporting leg was significantly reduced when the subject walked with FNS compared to the braces. The HRHL & HLHR values show that when the subject walked with stimulation, the stride length of the swinging paralysed leg was longer than when using a brace. It was also observed that when the subjects walked using their braces, hyperextension of the hip joint in the supporting leg was greater than when stimulation was used. Also, the degree of reflex hip flexion of the paralysed leg was greater and this further helps the swing. The degree of hip flexion was controlled by regulating the intensity of the stimulus to the common peroneal nerve.

In order for the subject to proceed from double support to swing phase with the paralysed leg, he must, first, reposition the walking aid and transfer body weight to the supporting leg before operating the hand switch to initiate the flexion reflex. Therefore, although the single support time is reduced, the period of double support is increased and the overall cycle time shows a slight increase.

These results show that each subject tested walked at approximately the same cadance with stimulation as with their previously described braces but with better degree of symmetry.

ACKNOWLEDGEMENTS

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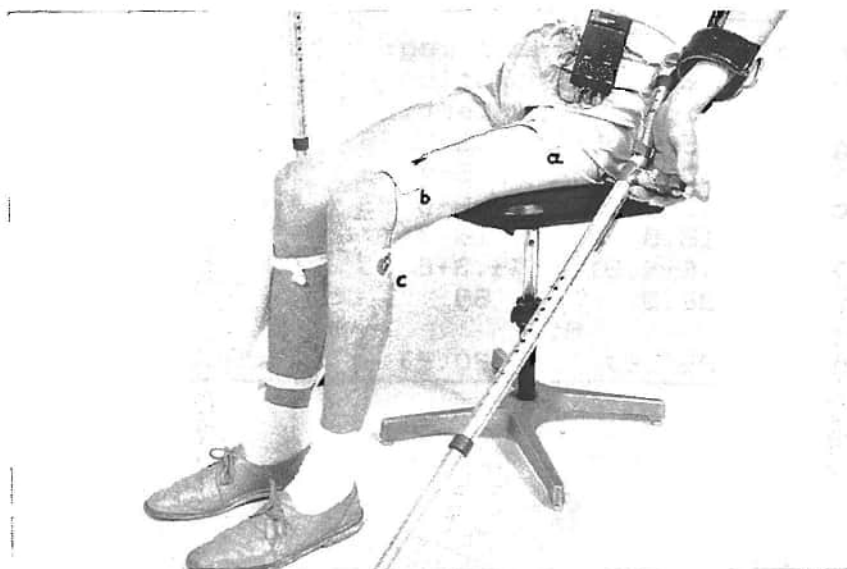


Fig. 2 Typical 3 electrode configuration used in tests.

Titel: Metabolic Changes in Hypoxic and
Anoxic Skeletal Muscle

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E. Brug

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Skeletal muscle fatigue, hypoxia and ischaemia have been of interest to scientists. With the advance of new technologies a more detailed analysis of the metabolic changes in impaired circulation and lack of oxygen became available.

WISTAR rat hindlimb muscle was used in an experimental model to investigate skeletal muscle hypoxia and ischaemia. In arterial occlusion experiments pH was measured epifascially. A non linear time dependent change was observed. A pH below 6.0 did not allow recovery of the myofibrillar function. In perfusion experiments the electrolyte and enzyme wash out was measured, it showed correlation to the available oxygen. Myoglobin was detectable early in hypoxic muscle.

³¹P NMR spectroscopy was used to assess the early changes in hypoxia and anoxia. A depletion of high energy phosphates was observed in the immediate period after the onset of arterial occlusion. The shift in inorganic phosphate was used for non invasive determination of intracellular pH and compared with electrode measurements. A good correlation of both methods was obtained.

NMR spectroscopy offers a powerful new tool in non invasive assessment of muscular metabolism in fatigue, hypoxia and anoxia.

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MORPHOLOGIC AND ENZYMATIC CHANGES OF THE MUSCLES
OF PARAPLEGICS CAUSED BY ELECTRICAL STIMULATION

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INTRODUCTION

Functional electrostimulation with surface electrodes for the therapy of paralysed muscles is nowadays intensively researched in several centers all over the world.

By stimulating spastic and denervated muscles with surface electrodes we differentiate among the following aims:

- Active walking and standing
- Four point gait walking and swing through walking
- Training of paralysed muscles
- Increasing of blood-flow and improvement of trophism
- Preservation of denervated muscles
- Decubitus-prophylaxis

MATERIAL AND METHODS

We carried out a controlled study, in order to document the effect of electrostimulation with surface electrodes in spastic and denervated muscles.

For that purpose 9 patients (5 with spastic and 4 with denervated muscles) have been subjected to a controlled training program. Each patient received a device for homotherapy and surface electrodes in order to stimulate their muscles regularly. They started to exercise each muscle once a day for 10 minutes and then extended their program on to twice a day for 15 up to 20 minutes.

At the beginning respectively after 4 - 6 months the following examinations from the m.quadriceps femoris of the paraplegic patients were made:

- IR-Thermography
- Xenon-clearance
- Thalliumscintigraphy
- Computertomography
- Checking of stimulation parameters
- Muscular strength measurement
- Muscle biopsy for histological and enzymatic observation

RESULTS

In order to objectivate the extent of the increase of blood-flow and its position concerning the improvement of trophism and decubitus prophylaxis, we carried out an intra-, subcutaneous and intramuscular blood-flow measurement with Xenon 133 and Thallium 201 as well as a thermographic course control of the blood supply of the skin.

Thermography:

The thermographic examination showed that at the reactive hyperemia after relief of the back, that should be carried out by paraplegic patients several times a day, there occurs an increase of temperature of 3.5 degrees C. in the 3rd minute and reaches five times the level of the blood-flow at rest. This increase of blood-flow decreases relatively fast until the 30th minute.

The hyperemia caused by a 10 minute electrostimulation is not only 30% higher in quantity but also lasts for over 2 hours after end of stimulation.

Xenon- Thalliumscintigraphy:

In order to determine the quantity of both the skin and muscle blood flow, measurements with Xenon- and Thalliumscintigraphy were carried out. The skin blood-flow showed an increase of 5.1 ml/100g tissue and minute. The muscular blood-flow increased to 8.7 +/- 2.7 ml/100 g tissue and minute.

Computertomography:

The interpretation of the computertomography of the upper leg muscles shows a planimetric increase of the sectional area of those muscle tissues of about 48 % with spastic muscles and about 10% with denervated muscles after a 4-month electrically induced kinesy therapy.

Electrostimulation:

The regular examination of the stimulation parameters resulted in maximal muscle contraction for spastic muscles at 0.4 msec biphasic pulses and a frequency of 15 to 17 cps. Only after a longer period of training a tetanic muscle contraction was also reachable with this low stimulation frequency. At the isometric strength measurement of the m.quadriceps values of 60-70 Nm were obtained.

With denervated muscles we started with single twitches caused by biphasic pulses of 150 - 200 msec pulswidth and 600 msec pause. Due to training we could obtain a reduction of the pulswidth so that tetanic muscle contraction could be released at all patients with denervated muscles. Biphasic single pulses (25 - 30 msec duration and 20 - 30 msec pause equivalent to a stimulation frequency of 15 or 20 cps) were used.

Light- and Electromicroscopy:

The biopsies withdrawn from defined positions of the m. quadriceps femoris before stimulation show light- and electromicroscopic changes that correlate with the symptoms. Spastic paralysis are a matter of small morphologic changes. In the relatively well preserved muscles there are only a small amount of strongly atrophied fibers. Considering the histochemic colouring the muscles of spastic patients do not appear in the same way: In some cases the type I fibers are struck more intensively in others the type II fibers.

With the electromicroscopy certain changes such as swelling and degeneration of mitochondria, fibrilolysis in the peripheral areas of the muscle fibers and z-streaming can be observed.

The changes in denervated muscles are more complex. The typical lightmicroscopical signs of denervation are:

Small and large group atrophy, sever differences in the cross-section of muscle fibers, fiber necrosis and myophagia. Atrophy strikes the type II fibers more evidently with the usual reinforcement in the NADH-TR colouring. The interstitial tissues occurs strongly increased in opposition to spastic patients. Therefore the electromicroscopical changes are to be found more complex and in all muscle fibers which show distinctive difference in size. As a sign of atrophy in the cytoplasm of muscle fibers we find fibrillary desorganisation, fibrilolysis, swelling and disintegration of mitochondria.

After 6 months of stimulation the general condition of spastic muscles may be called normal. There are hardly any extensions of endomysial tissue areas. Sporadically there are fat cells to be found. There is an obviously strong predominance of the type II fibers in the ATP-ase colouring. Central nuclei as a sign of regeneration are no longer to be found. In denervated muscles there are sometimes areas with small group atrophy in which small basophile fibers with numerous big nuclei are to be found which may be called regenerating muscle fibers. In the ATP-ase colouring the fiber types with a marked predominance of the type II fibers are easy to distinguish. It can be said that short time stimulation leads the muscle to a generally good condition and a state of regeneration.

DISCUSSION

The gained stimulation parameters illustrate that paralysed muscles can be trained with functional electrostimulation with surface electrodes. Spastic muscles as well as denervated muscles can be led to strong tetanic contractions by chronical electrostimulation. The thermographically examined hyperemia effect obtained by electrostimulation proves to be more effective than the one obtained by relief of the back.

Furthermore an essential improvement of trophism and therewith a contribution to decubitus prophylaxis is achieved in the denervated muscles due to intra-, subcutaneous and intramuscular increase of blood flow (8 - 15 times increase).

In comparison to the biopsy 6 months before the muscles have obviously reached a still better condition by electrostimulation. The high predominance of type II fibers seems to result from intensive short time stimulation whereas long time stimulation is considered to result in type I fibers.

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ELECTROSTIMULATION OF THE UPPER LIMB: PROGRAMMED HAND FUNCTION

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ABSTRACT

Neuroelectrical stimulation of nine individual muscles of the forearm and hand by surface electrodes has generated three modes of gripping in quadriplegic patients, plus active physiotherapy regimes. A microcomputer interfaced with a multichannel stimulator generated the programmed modes in open and closed loop.

INTRODUCTION

Functional electrostimulation of the upper limb, although still in its research phase, has in the last few years been applied clinically in several centers over the world. Peckham et al /1/ have used electrodes implanted into the muscle body to generate hand function. Comprehensive clinical work has been carried out by Waters et al /2/. Morecki et al /3/ has reported the development of a hybrid system utilizing direct nerve stimulation with finger position and contact force transducers providing feedback. Rebersek et al /4/, Vossius /5/ and Girbardt /6/ have also been engaged in clinical work on stimulation of the upper limb.

Research in Beer Sheva /7/ has concentrated on isolating individual muscles of the forearm using high resolution surface electrodes, and subsequently the generation of coordinated movements of the hand and fingers using a technique of discrete configuration programming. This work reports results on one quadriplegic subject. The research has been carried out over the previous six months at the Spinal Rehabilitation Department of Tel Hashomer Hospital in Tel Aviv. Over this period a clinical research laboratory has been established and clinical procedures and apparatus developed. Pilot work has been carried out in biweekly sessions on one quadriplegic subject. Further potential subject are now being screened and selected for treatment in a first group.

THE STIMULATION SYSTEM

Figure 1 shows the system components. An Apple 2e microcomputer with voice input communicates through an A/D,D/A converter with a 24 channel stimulator. A square wave double pulse is generated by the stimulator; pulse width, frequency and current level are programmable variables. Stimulation current parameter information during manual control is feedback to the computer. Conductive rubber electrodes are positioned on the forearm surface and on the hand. The electrodes are placed over the respective muscle such that the response is maximal and isolated, i.e., no overflow carries to other muscles.

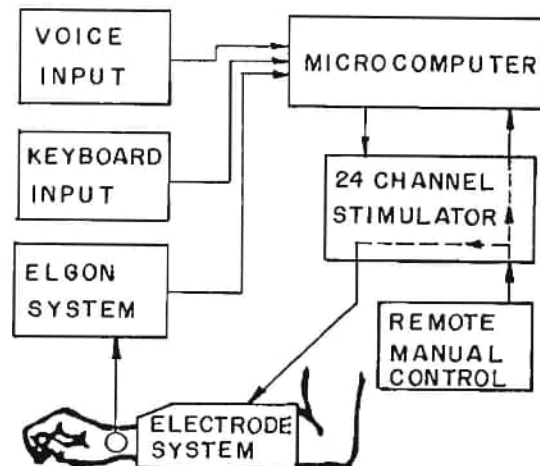


Fig.1: The Stimulation System

An electrogoniometer measuring flexion-extension and ulnar abduction-radial adduction can be used to supply feedback of the wrist joint angle to the computer, although it was not used in the work reported here due to the weakness of the wrist extensors of the test subject. The arm of the test subject was suspended by two straps, one proximal to the elbow, and the other around the palm of the hand.

The Test subject. Quadriplegic as a result of a C-4 spinal cord lesion sustained in a road accident in 1983. The subject has no voluntary upper limb movements apart from trace movements of the shoulder elevators. No spasticity and moderate atrophy is present. Exteroception is absent from the forearm and hand. Some degree of denervation is present in the upper arm and shoulder muscles, and possibly also in certain muscles of the forearm.

The Voice Input System. During the research stages the clinical work is slow and difficult. The voice input system is programmed with the vocal commands necessary to operate the computer; at this stage simple descriptive vocal replacements for keyboard inputs. The quadriplegic subject now can operate the computer and becomes an active member of the research team.

THE MOTION PROGRAM

Recording

A manually operated remote control unit of the stimulator is used to control the current level and the pulse frequency of each channel of stimulation. A first set of readings of the current threshold for each muscle is taken by raising each stimulation channel current level to its maximum sub-contraction level. The set of parameters are input to the computer automatically, and may be stored on discette. Discrete hand configurations are now generated by manual adjustment of the stimulation parameters in each channel. Each type of grip has its characteristic sequence of discrete hand configurations. Generally, the hand is firstly opened for receiving the object, then closed in stages in a specific sequence of movements. When closed on the object an increased gripping or squeezing force may be applied. The final phase in the sequence is a repeat of hand opening to release the object.

The stimulation parameters for each discrete configuration of the gripping motion are stored in the system memory. Intermediate positions can be generated to increase the accuracy of the motion; or to increase the length of the corresponding phase of the gripping. The recording of an entire gripping sequence can be carried out and stored on discette in the space of a few minutes only.

Playback

The programmed sequence can be played back split into phases for a single gripping motion. The phases are as follows:

- (i) Raise currents to sub-threshold levels
- (ii) Hand opening
- (iii) Hand closing and gripping
- (iv) Hand opening

Phase (i) is to check the current thresholds at the start of each session. Each subsequent phase is triggered by single keyed or vocal input to the computer. The entire sequence may also be run as a continuous loop. The speed can be adjusted from a maximum of five parameter sets per second. Slower speeds are achieved by dividing the current increment in each channel between subsequent parameter sets into equal channel between subsequent parameter sets into equal steps according to the speed requested. At the slowest speed the computer inserts five additional intermediate steps between each parameter set

or discrete hand position, and the speed of the motion is effectively reduced to one-sixth.

During playback the current parameters in all or in individual channels may be increased or decreased without stopping the motion. The motion may be put in "HOLD" or the current levels may be zeroed. Finally, any changes to the parameter values may be automatically stored on discette.

Musculature

The following muscles are used for the three gripping modes. It should be noted that the choice of muscles is determined by the medical condition of this subject; and muscles which we were unable to activate are not listed here.

(a) Wrist Extensors 1. Extensor carpi ulnaris, ECU. 2. Extensor carpi radialis longus, ECRL.

(b) Finger and Thumb Extensors 3. Extensor digitorum, ED. (Extensor Indicis, EI). 4. Extensor pollicis brevis, EPB.

(c) Finger and Thumb Flexors 5. Flexor digitorum superficialis, FDS. 6. Flexor digitorum profundus, FDP. 7. Flexor pollicis longus, FPL. 8. Abductor pollicis brevis/Flexor pollicis brevis, APB/FPB.

(d) Abduction of Index Finger 9. 1st Dorsal interosseus, DI.

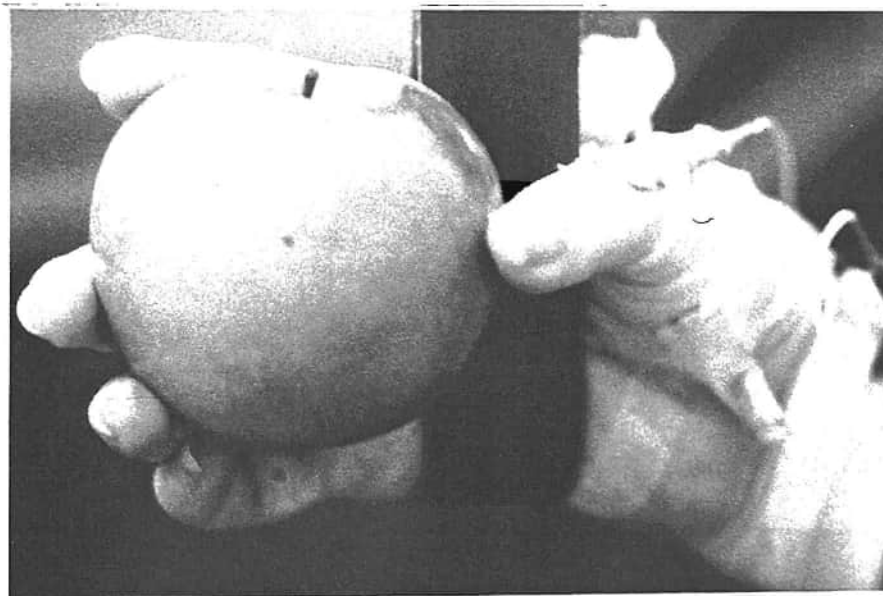


Fig. 2: The grasp

Generation of Gripping

(a) The Grasp Used to grip spherical and cylindrical objects, the grasp is shown in figure 2. The sequential hand articulations during a single grasp movement are shown in figure 5(a). The three gripping motions shown in figure 5 are each photographed consecutively during a single motion. The camera was operated manually, and consequently the sequence was run at the slowest speed, taking approximately 5 seconds to complete each grip. There is no constant time increment between consecutive positions. The gripping sequence is as follows:

(i) Hand opening (EPB, ED, APB/FPB). More thumb flexion to bring it into opposition with the index finger would have been desirable here.
(ii) The metacarpophalangeal (MP) and interphalangeal (IP) joints of the fingers and thumb are flexed simultaneously (FDS, FDP, APB/FPB). The wrist joint is stabilized by the wrist extensors (ECU, ECRL).

(b) The Pinch Grip The pinch between the thumb and index finger is used for gripping and manipulating small objects, as shown in figure 3. Figure 5(b) shows the motion sequence of this grip.

(i) The hand is opened by thumb extension only (EPB). This could be augmented by extension of the index finger, (EI).

(ii) The thumb is moved across the plane of the palm of the hand into opposition with the face of the index finger, (EPB, APB/FPB).

(iii) The MP joint of the index finger is fully abducted then flexed. The IP joints remain fully extended (DI). Some abduction of the first carpometacarpal (CM) joint also occurs, closing the thumb against the index finger.

(iv) The strength of the pinch is now augmented by flexion of the IP joints of the index finger (FDS).



Fig. 3: The pinch grip

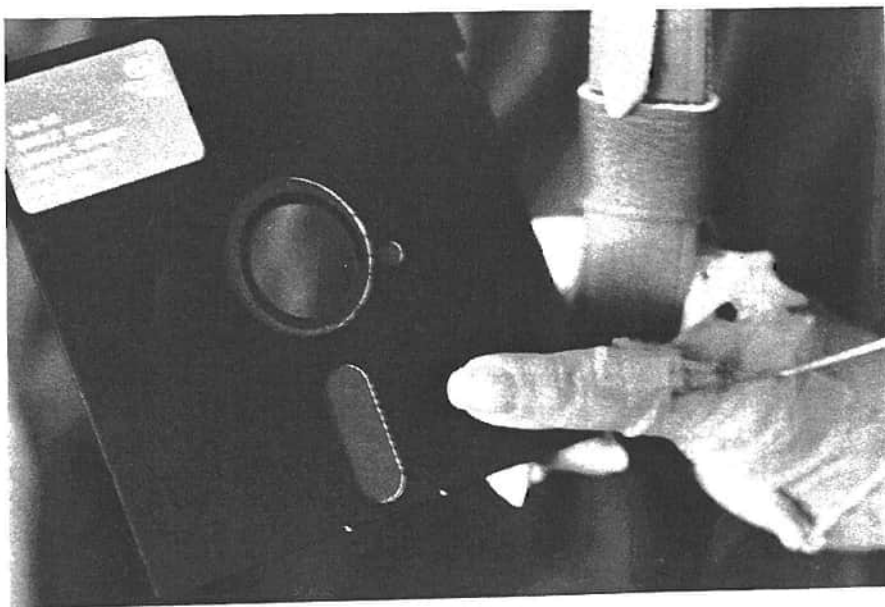


Fig. 4: The key grip

(c) The Key Grip A more powerful and stable grip than the pinch, the key grip is used for small or flat objects as shown in figure 4. Figure 5(c) shows the motion sequence of the grip.

(i) Extension of the CM and MP joints of the thumb, (EPB), to move it out of the way of the flexing index finger.

(ii) Flexion of the MP and IP joints of the four fingers with low level wrist stabilization by the wrist extensors, (EPB, FDS, FDP, ECU, ECRL).

(iii) Flexion of the CM and MP joints of the thumb, (APB/FPB), bringing the distal segment into contact with the lateral surface of the index finger. The index finger itself is stabilized laterally against the other fingers.

(iv) The strength of the grip is now augmented by flexion of the IP joint of the thumb, (FPL), increasing the pressure of the distal thumb segment against the side of the finger.

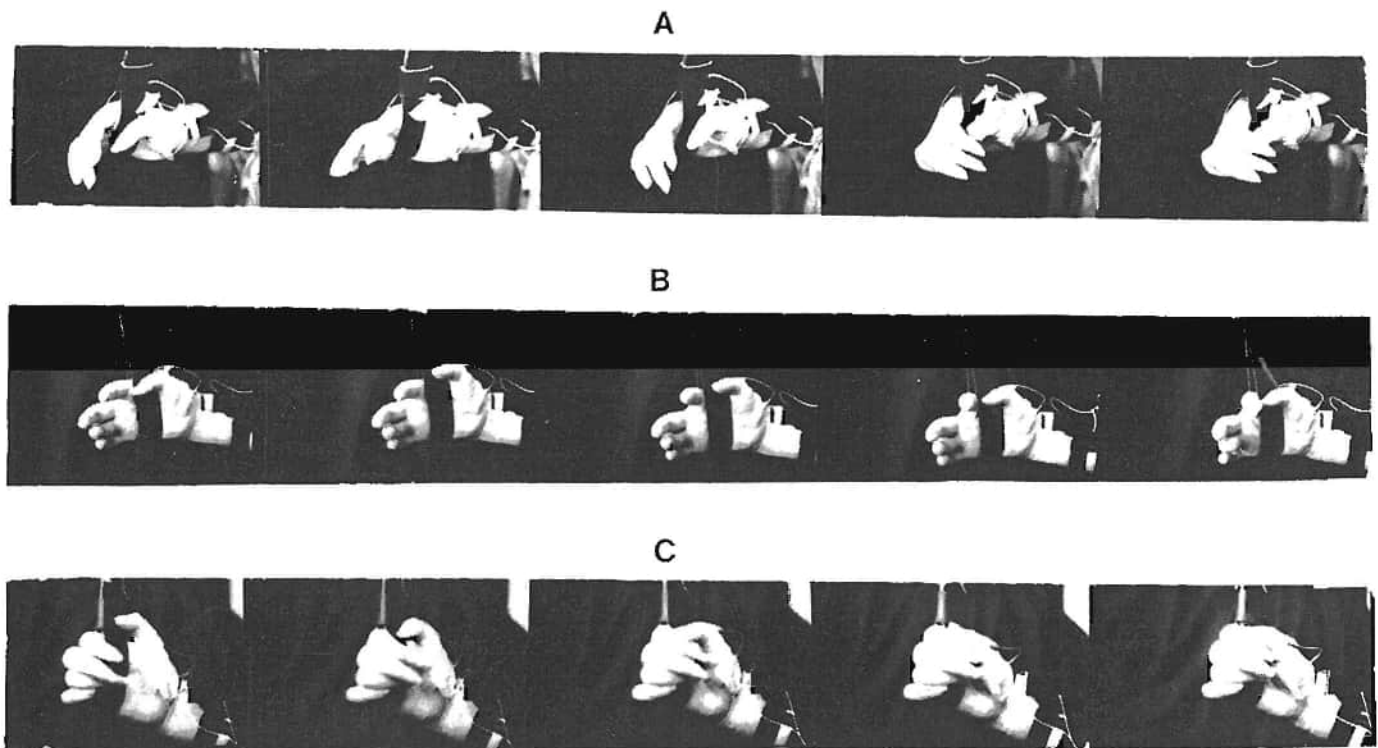


Fig. 5: Gripping Sequences (a) Grasp, (b) Pinch grip, (c) Key grip

Active Physiotherapy of the Hand

Active physiotherapy in its most effective form combines maximum muscular activity together with maximal joint excursions, whereas gripping involves more the stabilization of joints.

In physiotherapy of the forearm and hand, all muscles associated with extension of the wrist and finger joints are activated together as synergists; while the flexors are activated at a lower level as antagonists, providing a controlled resistance to the motion. The roles are then reversed: the flexors acting as synergists and the extensors as antagonists. The result is flexion-extension excursions of the hand and finger joints, with graded resistance provided by the muscles themselves. The stimulation currents to the two muscle groups can be adjusted while the program is running.

DISCUSSION

The essence of generation of controlled gripping modes lies in both spatial and temporal coordination of the fingers and the thumb together with separate control of the proximal and distal phalanges. Discrete hand configurations are generated by manual adjustment of the stimulation parameters and the parameters are automatically input to the computer. Playback of these parameters has been found to generate good temporal coordination of the appropriate grip as physiological parameters have negligible effect on the speed and length of the phases of the gripping motion. Temporal coordination is controlled primarily from the computer program. Good spatial coordination on the other hand depends on the repeatability of the kinematic response of the muscles to sets of stimulation parameters. The physiological condition of the muscles, plus electrode placement both affect this response.

The physiological condition of the muscles undergoes both short, medium and long term changes. In the short term, the dominant change is a slow reduction in the force generating capability of the muscles due to fatigue; although using low stimulation pulse frequencies, the muscles have been found to respond well for up to three hours. Significant fatigue is generally exhibited by muscles stimulated at high intensity for relatively long periods. In gripping, the FDS and EPB muscles were most affected.

In twice weekly sessions fairly significant unpredictable changes were found in the medium term from session to session in the response as a whole of the arm muscles. Long term changes showed over a six month period as a general and very significant improvement in the response of the muscles to stimulation. Variations in electrode placement and any subsequent movement of the skin overlying the muscle can also affect the response of the muscles. Certain muscles have been found to be far more sensitive to this phenomenon than others due to a relatively small surface region available for stimulation, and high sensitivity of adjacent muscles. This is, of course, of greater significance when activation of an adjacent muscle generates a specifically unwanted movement. The ECRL muscle, for example, used as a stabilizer during gripping can overflow to the ED causing unwanted finger extension. A check is carried out on the threshold and maximum current levels of each muscle at the start of each session, and any necessary changes of the stimulation parameters are made accordingly. Spatial coordination is of particular importance with regard to the spatial relationship between the thumb and index finger. Each grip can be said to be largely characterized by this spatial relationship. Correct positioning of the thumb in opposition prior to gripping is essential; and voluntary control by the quadriplegic subject of thumb positioning may eventually be necessary. Control of the rest of the gripping configuration is less critical and less subject to variations, and may be preprogrammed in open loop.

Control of the Wrist Joint

The long flexor muscles of the fingers and thumb tend to generate unwanted flexion motion of the wrist joint, which in turn reduces the effectiveness of the finger flexion. In fact, gripping is carried out ideally with the wrist joint slightly extended. Control of the wrist joint angle would be carried out in closed loop using a monitoring elgon. However, the radial extensors of the wrist joint (ECRL, ECRB) were insufficiently powerful to achieve this wrist extension before the stimulation overflowed to the neighboring muscles (ED or EPB). We were unable to activate the ECRB alone. Although we were at first unable to activate the ECRL alone, we repeatedly stimulated this

muscle over many sessions, and eventually not only succeeded in activating this muscle on its own, but to date have even generated a trace of radial extension in the joint. The extensor carpi ulnaris also improved considerably during the duration of the work. At first weak contractions only were obtained. Today, after six months strong movements against resistance are obtainable. Together the wrist extensors provide minimal stabilization of the wrist joint.

The different grips require different levels of wrist joint stabilization. The pinch grip required little. During the keygrip finger flexion is a free movement and not resisted, thus low levels of stabilization only are required. The grasp requires a large stabilizing extension moment at the wrist joint and figures 2 and 5(a) show the wrist to be flexed during gripping.

Picking up objects has not yet been possible; gripped objects are "hand fed" to the subject. Duration of the grip depends on many factors. Generally, where the object is gripped by friction, gripping can only be of short duration, while objects supported by normal forces can be gripped indefinitely.

Fatigue was noticeable particularly in two muscles: the FDS muscle, resulting in reduced index finger flexion in the key grip and grasp; and in the EPB muscle, resulting in reduced thumb extension on hand opening.

CONCLUSION

Stimulation of isolated muscles and a semi-automated learning mode has been developed and used effectively in generating discrete configurations of the hand; and thereafter a continuous gripping sequence.

Three gripping configurations have been generated with fairly good repeatability by one quadriplegic subject, and a variety of objects have been held in the hand.

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COMPARISON OF FES OF THE UPPER EXTREMITIES BY
MEANS OF SURFACE AND OF IMPLANTED ELECTRODES

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SUMMARY

The advantages of implanted (transcutaneous) electrodes are the specificity of the stimulation locus, low stimulation energy, fixed position, large number of electrodes applicable, no stimulation of pain. Their disadvantages are long training for good placement, unpredictable life time, positive electrode has to be positioned on skin, limitation of energy current, cover and care for skin feed through, change of position difficult, method is invasive. The advantages of surface electrodes are easy mounting easy change of position, serving also larger muscle areas, method is none invasive, easy to be attended. Their disadvantages are less specific, often to be changed, deep muscles not to stimulate, high stimulation currents needed, possibility of stimulation of pain receptors. The paper discussed these advantages and disadvantages of both electrode types and the special situations for their application in more detail.

The upper limb has more than 40 degrees of freedom, the hand with the fingers about 30. To make use of this capacity a sophisticated system of muscles with fine differentiated muscle innervation is provided. This muscle system does not only move the fingers to execute very fine, variable, and precise work but also stabilizes that part of the limb not needed for the movement itself. An injury of the spinal cord at high level leaving the patient as a tetraplegic strips him off these functions to a more or less degree. Did the injury interrupt only the nervous pathways from the brain to the spinal cord but leaves the motor neurons and the nerve connection to the muscle intact it is called a central paralysis. In the case of such an injury some of the lost motorfunctions may be restored by FES. The situation is especially suited for applying FES, if not the entire limb is paralyzed, but if the shoulder and elbow joint may be controlled voluntarily. In this case the hand function or parts of it have to be restored whereas the handicapped is still able to guide the hand in space voluntarily. Very often an injury of this type has a more or less prominent shortcoming: At the level of injury also the motor neurons will be destroyed to a smaller or larger extension. As a result the appertaining motor units will perish, a peripheral paralysis, and not be available for stimulation. This might be the case for an entire muscle or parts of a muscle, leaving it with less excitable force.

Surface electrodes and transcutaneous implanted electrodes

Surface electrodes may consist of a fabric pad soaked with sodium chloride solution, a carbon donated rubber or silicon pad or a special metal buffered with an electrode jell to transmit the current. Transcutaneously implanted electrodes consist mostly of very thin coiled stainless steel wire (3, 4) which moves due to the coilny with the muscles and the other

tissues thus avoiding breakage. The implanted electrodes may only be used as negative ones, because they would otherwise corrode electrolytically. The positive electrode has to be positioned outside as a common surface electrode. The implanted electrodes are normally positioned within the muscle close to the motor point, allowing the stimulation of specific muscles this way.

FES for Handfunctions

To restore the handfunction the hand has to be stabilized at the wrist, the finger have to be opened and than closed to perform different types of grips according to the task to be executed. Are all muscles controlling the hand and fingers centrally and not peripherally paralyzed this task is not this difficult. Of course the variety of grips an unhurt person owns may not be achieved. Basically one may elicit three types of grips by FES: The first, the key grip, and a pointed grip of the first three fingers with some variation. All of these grips might be elicited by using surface elctrodes or transcutaneous electrodes. With transcutaneous electrodes the movements of the fingers are stimulated more precisely, but for practical use the difference is not this prominent. Although the electric field origing from the surface electrodes is spreading more widely within the limb, the size of the electrodes might be kept small enough to stimulate single muscles located next to the skin, e.g. the M. extensor carpi radialis, very specifically. In addition the hand, yet paralyzed, has still some of the property left to adjust according to the shape of the object with its muscles stimulated.

Preferred use of surface or implanted electrodes

The decision to give preference to one or the other type of electrodes depends on special conditions.

The use of implanted electrodes will be of advantage, if

- a muscle is partically denervated. In this the stimulation and the training of the muscle might be difficult. Other muscles close to the stimulated one might be exited earlier and impede thus the proper stimulation. These side effects are avoidable with implanted electrodes.
- deep muscles have to be stimulated. Using surface electrodes most of the current, flow along the skin, deep muscles are, if at all, difficult to stimulate with surface electrodes.
- the handicapped has pronounced pain sensation. The implanted electrodes are fed through the skin, circumventing the painreceptors this way.
- complex movements requiring a larger number of electrodes should be evoked. To apply a larger number of surface electrodes, about more than six, is because of the limited the space available and the repetitive time for positioning practically not feasible.

Surface electrodes might be preferred,

- if one starts rather early after the injury with the stimulation. specially during the first phase after injury the extent of the paralysis might change, requiring relocation of the electrodes more often.
- during the training period of the muscles. Being trained the muscle volume might increase drastically, and the muscle might be stimulated over a wider range including more motor points. New combinations of muscles to be stimulated might evolve, requiring equal combinations of

stimulating electrodes. In general with surface electrodes larger areas might be covered, easing the task of training.

- if the patient has developed more extended spasticity, resulting in improper positions of the hand. By stimulating preferable antagonistic skin areas and muscles the reflectoric spasticity might be reduced, the antagonistic muscles are being built up to create a better balance of force. From there on one might begin with FES.
- for evoking simple movements requiring only few electrodes with easy positioning.

In conclusion the answer to the question surface or implanted electrodes is not yes or no, one or the other might be the better choice, depending upon the type and degree of paralysis and its concomitant conditions.

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POTENTIALS OF PLATINUM ELECTRODES
VERSUS A Ag/AgCl REFERENCE ELECTRODE

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SUMMARY

Safe stimulation of the nervous system implies the avoidance of chemically irreversible Faradaic reactions such as water electrolysis, saline oxidation, and metal dissolution. As these reactions depend mostly on the values of the potential of the platinum stimulating electrodes, the polarisation properties of platinum electrodes in physiological saline (0.9 % NaCl) were studied. The purpose of this work was to measure the potentials of platinum electrodes of bipolar and monopolar versions of implants versus a Ag/AgCl reference electrode where the geometric areas of the electrodes were different. Monophasic and biphasic waveforms were both examined; biphasic pulses were of exponential decay type. In the case when monophasic stimulation pulses were used, anodic and cathodic potentials were above the potential limits for O_2 and H_2 evolution. The best results were obtained in the monopolar version of the implant where a current output stage was added. The nerve electrode served as the platinum cathode, while the common platinum electrode with greater surface acted as the anode.

MATERIAL AND METHODS

The IPPO system (Fig.1) is an electronic device for correction of footdrop by electrical stimulation of the peroneal nerve. The device consists of three main parts: (1) An external stimulator and antenna that generate and transmit radio-frequency signals through the skin, (2) a heel switch which triggers the stimulator and (3) a surgically implanted passive receiver which receives the signal and converts it to a train of electrical pulses with a frequency of 30Hz and a pulse width of 0.05 to 0.5ms delivered to the peroneal nerve by platinum stimulating electrodes.

A. The direct-coupled stimulating electrodes

In the past four years 35 implants with monophasic voltage stimulation pulses and direct-coupled stimulating electrodes (Fig.2,A) were implanted; five of them have been subsequently replaced. The implant shown in Fig.2,A was a 5mm thick epoxy resin disc with a diameter of 17mm. The electrodes were made from platinum wire (99.99 % purity), diameter 0.7mm. Anode and cathode were of equal shape and had a geometric area of $37mm^2$.

B,C. Capacitor-coupled stimulating electrodes

In the case B and C (Fig.2,B,C), a capacitor was connected in series with the cathode of the same bipolar platinum stimulating electrodes with the aim of ensuring no, or almost no, net transfer of charge by employing a simple pulse and using passive charge balancing. To achieve an appropriate, passive, balanced current stimulating waveform, switching of the output resistance to obtain very rapid exhaustion was utilized.

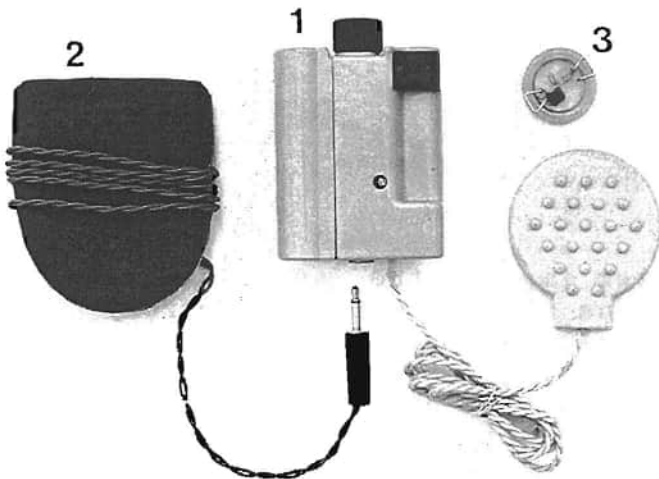


Fig.1

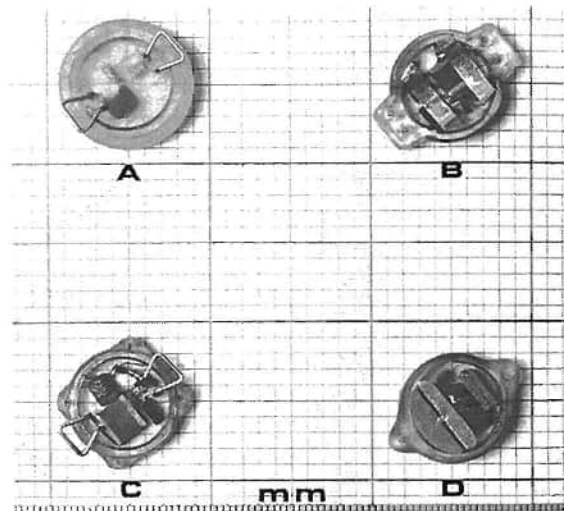


Fig.2

The implants shown in Fig.2,B and C were of the same dimensions as described in case A, but the shape and surface of the stimulating electrodes were different. In both cases anode and cathode were of equal shape and had a geometric area of 30mm^2 (Pt tape) in case B and 37mm^2 (Pt wire) in case C. The distance between the electrodes in the case B was 5mm.

D. Capacitor-coupled stimulating cathode

In the last case (Fig.2,D), a capacitor was connected in series with the cathode for the same reason described in the previous two cases. The nerve electrode served as the platinum cathode with a geometric surface of 15mm^2 , while the common platinum electrode with greater geometric surface (70mm^2) was the anode. The dimensions were the same as described in the first case. Beside the capacitor and switching of the output resistance to achieve the appropriate current waveform, a current output stage was added to the electronic circuitry. Since the electrochemical reactions depend mostly on the range of electrode-electrolyte voltage over which the electrode cycles from pulse to pulse, the potentials of electrodes during pulsing and the value of the potential for an electrode passing no current (merely left to come into equilibrium with its surrounding) were measured. Dummy platinum electrodes with the same shape and surface as the real electrodes of the implants were connected to the corresponding receiver circuitry and immersed in 0.9 % NaCl solution. The above mentioned potentials versus a Ag/AgCl reference electrode were measured using a high impedance digital voltmeter, type HP 3456A. Separation between receiver and transmitter antenna, frequency of pulses and pulse widths were equal in all measurements and were 1cm, 30Hz and 0.2ms.

RESULTS

The observed range of anodic and cathodic potentials, measured in 0.9 % NaCl solution are shown in Table 1. It is evident that the potential of the anode as well as of the cathode was the highest in case A where the electrodes were directly-coupled in the receiver circuitry. In such a system, unwanted side reactions cannot be excluded. Some of them accelerate the corrosion of the electrode material, others lead to degradation of proteins and deposition of heavy soluble products on the electrode (12). According to Donaldson (8) a 2V swing (Table 1, A) implies a cyclic local pH variation from nearly 0 at O₂ evolution (+1230mV NHE - normal hydrogen electrode) to 14 at H₂ evolution (-830mV NHE). The potentials measured in cases B, C and D were considerably lower than the potential limits for O₂ and H₂ evolution. Most of the charge is injected by redox and hydrogen plating and stripping reactions which are bound to the surface of the metal. In the last three cases the amount of charge injected in the secondary anodic pulse was equal in magnitude but opposite in sign to the amount of charge injected in the primary cathodic pulse.

IMPLANT		A	B	C	D
Geometric surface of anode	mm ²	37	30	37	70
Geometric surface of cathode	mm ²	37	30	37	15
Ea	mV	+1310	+256	+425	+360
Ec	mV	-954	+486	+573	+386
Eoa	mV	+208	+322	+470	+384
Eoc	mV	+130	+343	+538	+384
Charge density	μCb/mm ²	0.03	0.033	0.027	0.047

Ea, Ec - anodic and cathodic potentials during pulsing.

Eoa, Eoc - anodic and cathodic potentials after the electrodes have been quiescent for 3 minutes.

Table 1

DISCUSSION

In chloride-containing solutions, a platinum electrode exhibits a definite potential, in accordance with its position in the electrochemical series. As the application of an external potential on the platinum electrodes results in their polarisation (7,10,11) the potential of the anode and cathode is shifted in the anodic and cathodic direction, respectively. The potential of anode and cathode can be set at some potential between E_{max} and E_{min} over periods typical of the duration of the stimulation waveforms and will remain there. During the application of the electrical pulse, the potential limits at which a significant amount of oxygen (at E_{max} = +1230mV NHE) and hydrogen (at E_{min} = -830mV NHE) are formed should not be exceeded (1,2,3,4,5,9). Although it is thermodynamically possible for platinum to form Pt (at +1200mV, in fact platinum group metals

do not form simple ions in aqueous solution (8). It must be emphasized that the prolonged evolution of chlorine gas or other oxidative species allows complex ions to form (formation of soluble $PtCl_4^{2-}$ and $PtCl_6^{4-}$ at potentials 730mV and 720mV NHE respectively) and leads to electrode damage (8,10). In the presence of an electrolyte of more complex composition (extracellular fluid), a number of cations and anions are present which are more easily oxidized or reduced and the corresponding actual potentials of implanted electrodes are less anodic and cathodic.

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EFFECT OF ELECTRICAL STIMULATION IN PATIENTS WITH ISCHIATIC NERVE LESION

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SUMMARY

Two groups of patients with complete peripheral lesion of peroneal portion of ischiatic nerve (axonothmesis) were selected. In four patients denervated muscles were electrically stimulated, in the other four patients electrical stimulation was not applied.

The ninth patient had complete bilateral lesion of ischiatic nerve trunks in the thigh, which was reconstructed by microsurgical technique. In this patient the denervated muscles of the left lower extremity were electrically stimulated, but not also of the right lower extremity.

Comparing the results of different treatment in our patients three years and more after injury the therapeutic value of traditional electrical stimulation of completely denervated muscles has been shown as practically unimportant for the end function of reinnervated muscles.

INTRODUCTION

In the domain of rehabilitation of patients with disability of locomotor system we daily deal with a multitude of patients with lower motoneurone lesions, the resulting paralyses and pareses of muscles and thereby reduced rough muscle force and disturbed functional state of extremities. Lower motoneurone lesions represent a difficult and sometimes insoluble problem with respect to the restoration of motor activity and proper functional recovery.

In anticipating reinnervation - if all conditions indispensable thereto do exist - various methods of physical therapy are applied to maintain as good a trophic state of denervated muscles as possible. This, however, does not always take a satisfactory course. One of the most widely applied methods for preventing atrophy of denervated muscles is electrical stimulation. Electric pulses of a relatively long duration and great intensity are applied via surface electrodes onto denervated muscles. However, opinions on the value and efficiency of electrical stimulation with respect to peripheral nerve lesions are contradictory (1,2,3). Not so long ago it was a generally accepted belief that daily electrical stimulation of a denervated muscle could prevent atrophy to a certain extent, though, as well known, it cannot exert an influence upon the specific changes in the muscle itself (4). Due to the fact that electrical stimulation is still widely applied in the treatment of denervated muscles, the effects of this therapy should be closely examined and evaluated as to their true value.

MATERIALS AND METHODS

A relatively homogenous group of 8 patients, 6 men and 2 women, with ages ranging from 18 to 42 years old, were selected. All patients had lesions of the ischiatic nerve at the height of the hip, appearing because of compression, either due to pressure of the head of the thigh bone in luxation or during surgery as a result of manipulation in the hip region. The basic purpose in choosing the patients was to obtain as homogenous as possible a group of patients with axonothmesis of the ischiatic

nerve at the height of the hip and the resulting denervation of the musculature associated with the peroneal portion of this nerve. Where these lesions are located fairly proximately in the area of the nerve trunk they require long term rehabilitation and make it possible for us to follow fairly systematically the development of muscular atrophy and EMG changes in the denervated muscle.

Four patients were chosen for study; the members of this group had electrical stimulation applied to the denervated muscles. The other four patients who did not have electrical stimulation applied to them formed the control group. Besides, all patients performed conventional physical therapy (active and passive exercises, hydrogymnastics, gait training by means of passive peroneal braces and crutches).

The ninth patient, P.B., male, 40 years old, had complete bilateral lesion of the ischiatic nerve trunks in the thighs, which were reconstructed by microsurgical technique. In this patient, in addition to other methods of physical therapy, the denervated muscles of left lower extremity were electrically stimulated, but not also those of the right lower extremity.

The patients in the study group performed electrical stimulation regularly each day until electromyographic test showed the first initial signs of reinnervation (nascent potentials) in the particular muscle. Then electrical stimulation therapy was stopped. The electrical stimulation applied to the denervated musculature was routine electrical stimulation with monophasic electrical pulses of rectangular shape. Pulse width was set at 200 ms, with a frequency of 0,5 Hz, the intensity of stimulation being set individually so that the most powerful contraction of the muscle not felt by the patient as painful was obtained (for the majority approximately 30 mA). One muscle or muscle group under sponge electrodes with a rectangular surface, moistened with water (dimensions 5 cm x 10 cm) was stimulated for up to 10 minutes twice daily (in four patients from study group two muscle groups, in patient P.B. three muscle groups).

In the main two principal goals of the research were investigated:

- the speed of regeneration in terms of the first signs of reinnervation noted in individual muscles
- the muscle strength achieved or the final functioning, when this state could be regarded as final or near final.

All patients were followed up systematically by examinations every 3 months when besides an exact checking of the patient's history and clinical status the following measurements and tests were repeated:

- muscular status of the affected extremities as a whole
- determination of electrostatus (the rheobase, chronaxy, accomodability and IT curve) of the affected muscles
- electromyographic examination (with special emphasis on the determination of fibrillation potentials and nascent potentials of the motor units; a typical test site was detected for a particular muscle and observed over an area with a radius of 1 cm from the typical point.
- determination of evoked M waves
- measurement of the circumference of the affected extremities
- measurement of the isometric moment of muscle contraction for dorsal flexion in the ankle.

Immediately upon observing the first signs of reinnervation in each single muscle (nascent potentials), the electrical stimulation of that muscle was interrupted at once.

RESULTS AND DISCUSSION

The first reliable signs of reinnervation became apparent in the pretibial muscles of the control group from 1 year 3 weeks to 1 year 8 months and in the study group from 10 months and 3 weeks to 1 year 3 months and 3 weeks after the appearance of the lesion.

More homogenous results were obtained in the measurement of the gross muscle strength achieved by measuring the isometric moment of dorsal flexion of the ankle.

The patients in the study group by the time of measurement three years and more after injury had achieved values of from 1 to 4 Nm (mean value 2,5 Nm), while the patients in the control group had values of 5 Nm to 11 Nm (mean value 9,5 Nm).

In patient P.B. electromyographically detected reinnervation appeared in about a year and a half to two years in several muscles and soon after that also a clinically poor recovery in already slightly fibrotic changed muscles set in. Five years and six months after the injury the measurements of isometric moment of dorsal flexion and plantar flexion in ankle joints have shown the following results: left side (stimulated): dorsal flexion 0 Nm, plantar flexion 8 Nm; right side (non stimulated): dorsal flexion 1 Nm, plantar flexion 15Nm. Five years after the injury his clinical state, electromyographic examination and a computer tomography of both affected extremities have shown no essential difference between the functional state of the left and the right lower extremity.

In establishing the onset of reinnervation the methods of classical electrodiagnostics (electrostatus) proved, as expected, to be less reliable and lagged behind by a period of weeks or months the reliable evidence of reinnervation found by electromyography. In the first months after the onset of reinnervation the electrical responsiveness of the regenerated motor units also did not reach such a stage that it was possible to register and evaluate M waves in the affected muscles, and hence this method in our study also did not prove to be especially useful.

Measurement of the maximum circumference of the lower extremities with the intention of evaluating the atrophy and making a comparison between the affected and unaffected sides also proved to be fairly unreliable. The affected leg was often very oedematous, while the swelling differed greatly from control to control according to the patient's previous weight-bearing. No measurement of the circumference of the leg is a suitable method for the evaluation of the volume of the muscles, in this respect only computer tomography of the circumference of the leg coming into consideration. This technique was used with the ninth patient P.B. in whom a slightly greater atrophy of the calf on the left than on the right side was shown.

The number of patients and thus the data at our disposal is unfortunately insufficient for statistical analysis. This applies both to data analysis in terms of the period from the start of the injury to the first signs of axon reinnervation in particular muscles and also in terms of the value of the gross muscle strength attained in the reinnervated muscle groups.

Since it is necessary to bear in mind that the speed of regeneration depends also on the age of the patient and the length of the nerve, or the distance from the site of the lesion to the denervated muscle, these relationships should also be taken into consideration in evaluation of the effects of therapy. However a considerable spread in the data was discovered which is in the accordance with the finding that the amount of reliable results is relatively small.

Regardless of this it is evident that the patients in the study group several years after the appearance of the lesion and several years after the appearance of the regeneration achieved fundamentally lower values of gross muscle strength than the patients in the control group. Regarding the already mentioned deficiencies of the

study, relating mainly to the relatively small number of patients, it is nevertheless necessary to stress that it is very difficult to bring together for the purpose of study a more numerous suitably homogenous group of patients and it is not possible to conclude, in spite of the low values of gross muscle strength achieved by the study group, that electrical stimulation as used by us is harmful. It would be easier to maintain that using it the desired or expected effects were not achieved. This applies both to the attainment of gross muscle strength, or rather the prevention of muscular atrophy and maintenance of a better trophic state of the muscle, which is otherwise predominantly dependent on the influences from higher nervous centers and which would finally contribute to less loss of muscle strength after the final phase of regeneration.

It is evident that electrical stimulation as described is ineffective and has more of a psychological than any other effect. It is necessary therefore to find other more effective forms of therapy, as well as other methods of electrotherapy, with which it would be possible to accelerate the regeneration process of the damaged axons and in this way achieve a better final functioning of the affected muscles after recovery.

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THE USE AND FUNCTION OF THE PERONEAL NERVE STIMULATOR IN DAILY LIFE

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SUMMARY

The use of the peroneal nerve stimulator in daily life after rehabilitation, is investigated by means of a questionnaire. Out of the 50 questionnaires, 42 (84%) were received back fully completed. It appeared that 64% of the patients (27 out of 42) still uses the stimulator. Of the 15 patients (36%) that do not use the stimulator anymore, only 6 (14%) gave up using the stimulator because it was really inadequate as an orthosis for them. In general, the stimulator is used nearly every day, for more than two hours, both indoors and outdoors. All the patients who still use the stimulator indicated that walking had become easier, and 24 patients (88%) noted a considerable increase in walking distance. Seven patients also use other walking aids, especially for short walking distances, because the application time for the stimulator is relatively long compared to the time needed to apply the alternative walking aids. Patients suffering from a hemiparesis left score relatively high at so called "subjective assessments", in contrast with hemiparesis right patients.

INTRODUCTION

Since Liberson introduced the peroneal nerve stimulator (PNS) in 1961 (3) many papers have been published on this matter. Most of these papers present results of laboratory investigations (e.g. 2,5). Although these investigations are of importance, it will finally be the user who determines whether or not peroneal nerve stimulation is successful in daily life, independently of the success in laboratory situations. In order to get a better insight in the long-term effects of the stimulator, we investigated the use of the stimulator after rehabilitation by means of a standardized questionnaire.

MATERIAL AND METHODS

In the treatment of functional disturbances of the lower leg due to a lesion in the central motor neuron, the seriousness of the paresis on the one hand and the extent of the spasticity on the other, are important factors. The choice of lower leg orthosis is determined by a combination of these two factors. Slight or manifest paresis with no or slight spasticity is an indication for the stimulator. In patients with manifest spasticity one may reduce the degree of spasticity by phenolization of the calf musculature. This may result in an indication for the stimulator. Furthermore the patients have to satisfy the following conditions in order to consider the use of the stimulator.

1. Intact peripheral nervous system.
2. Absence of significant communication problems.
3. Absence of significant emotional or mental disturbances.
4. Absence of tactile and sensibility disturbances of the skin.
5. Complete passive mobility of the joints of the lower extremity.
6. Capacity to stand and walk with limited help or no help at all.

The group of patients that was investigated consisted of 50 patients with a central motor lesion who had been prescribed a stimulator in "Het Roessingh" between 1981 and 1984. In all the cases the objective of the prescription was an improvement of the walking pattern. All the patients were sent a standardized questionnaire aimed at the following components: diagnosis, still using or not using the stimulator, use in daily life, other walking aids and "subjective assessments".

RESULTS AND DISCUSSION

Out of the 50 questionnaires, 42 (84%) were received back fully completed. For an investigation of this kind, this is a very high response percentage and one which increases the reliability of the results. The 42 patients who answered the questionnaire, were divided into the following diagnoses groups.

Diagnosis groups	PNS prescribed	% of total	still in use	% of PNS prescribed
- Hemiparesis right (HPR) as a result of a cerebrovascular accident (CVA).	12	29%	7	58%
- Hemiparesis left (HPL) as a result of a CVA.	13	31%	9	69%
- Multiple sclerosis (MS).	6	14%	3	50%
- Patients with various diagnosis such as partial transverse lesion and pyramidal syndrome (VAR).	11	26%	8	72%
Table 1	total	42 100%	27	64%

The second and third column in table 1 give the number (absolute and relative to the total number of 42) of stimulators prescribed for the different diagnosis groups. The fourth and fifth column show the number of patients that is still using the stimulator at the moment (absolute and relative to number in the second column). From this we can conclude that the percentage of patients still using the stimulator is high (64%). Statistically, the 'still in use' percentages of the different diagnosis groups do not differ from the percentage of the total group (chi-square test, $p > 0.5$). The various reasons for terminating the use of the stimulator of the remaining 36% of the patients, are listed in table 2.

Reason of termination	number
PNS no longer necessary (improved condition).	4
Total deterioration of condition.	5
Sensitivity to the stimulation current.	2
Too many defects of the stimulator.	1
Preference for another walking aid.	3
Table 2	total 15

The patients in the first group no longer need the peroneal nerve stimulator because of an improved overall condition. Whether or not this improvement is due to the use of the stimulator in the early stage after the rehabilitation, cannot be proved. The second group does not use the peroneal nerve stimulator because these patients, for various reasons, don't walk anymore. Only the last three groups (14% of the total of 42 patients) stopped using the stimulator because to them, the stimulator appeared to be inadequate as an orthosis.

Most of the patients (18) said to use the stimulator every day. Only 1 said to use it for about 4 days a week and 2 for about 2 days a week. The remaining 6 patients use the stimulator especially for long distance walking. The major part (24) uses the stimulator for more than 2 hours a day. Only 3 patients use it for less than 1 hour. The stimulator is used inside as well as outside the house by 16 patients, whereas 10 patients said to use it only outdoors and 1 patient only indoors. All the patients who are still using the stimulator (27) indicated that walking had become easier, and 24 of them noted a considerable increase in the walking distance. Summarized: on the average the stimulator is used frequently, for long consecutive periods, inside as well as outside the house, and it increases the mobility of the patient.

Six patients said to use the stimulator especially for long distance walking. This can be explained by the fact that without using walking aids, these patients are only able to walk short distances because of early fatigue in the dorsal flexors. Using the stimulator, fatigue occurrence is delayed and as a result, walking distance can be increased. Another explanation can be found in the time the patient needs to apply the stimulator (see below). The shorter the walking distance gets, the larger is the relative effort to apply the stimulator.

The question whether or not these patients are also using other walking aids besides the peroneal nerve stimulator, is answered with yes by 7 patients (2 are using a light brace, 4 orthopedic shoes and 1 a double bar brace). Most of the patients wear these walking aids during work and indoors because, as they said, the application is easier and faster. This can also be concluded from the fact that 22 patients need about 10 minutes to apply the stimulator (which is relatively long), 3 patients need between 10 and 20 minutes and 2 patients need more than 20 minutes (The last 2 patients are both suffering from a hemiparesis right with slight communication problems).

Subjective assessments most often mentioned by the patients are:

Subjective assessments	total	HPL	HPR	MS	VAR.
1. A warmer feeling in the leg.	7	4 (57%)	0	0	3
2. After stimulation the leg is less thick.	3	1 (33%)	0	1	1
3. Less tension in the affected arm (4).	2	2 (100%)	0	0	0
4. After using the stimulator raising the foot is easier	13	6 (46%)	0	2	5

Table 3

Remarkable in the results of table 3, is the fact that in three of the four items the share of patients suffering from a hemiparesis left is higher (chi-square test, $p < 0.2$) than the share of these patients in

the total group of 27 (33%, see table 1, column 4). In contrast with this is the share of patients with a hemiparesis right. Although in many investigations concerning peroneal nerve stimulation, the patients suffering from a hemiparesis left and right are pooled in one group (CVA patients), we here have evidence that, at least with respect to subjective assessments, these patients should be seen as different diagnosis groups. This is in better agreement with general insights in the functional effects of CVA presented in recent literature (1).

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EMG MONITORING OF ELECTRODE POSITION IN IMPLANTABLE PERONEAL STIMULATION

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SUMMARY

Subcutaneous stimulating electrodes must be carefully positioned to obtain a functional movement. Observed ankle dorsal flexion during the surgical insertion with a laying patient could result in excessive eversion or coactivation of plantar flexors during gait. In order to find a correct electrode position, EMG responses to single stimulation pulses were monitored in tibialis anterior, peroneus longus and triceps surae muscles. Strong response in tibialis anterior with moderate activation of peroneus longus was determined by surface electrodes. Triceps surae was monitored to exclude the unwanted plantar flexion. Responses to the surface stimulation during optimal movement in a standing position were used as a guideline when monitoring the responses to implantable stimulation during surgery. The method, tested on 2 healthy adults and 14 patients, rendered a reliable positioning of the subcutaneous stimulating electrodes and later examination of possible stimulation malfunctions.

INTRODUCTION

The long term electrical stimulation of the peroneal nerve implies the use of implantable devices in several motor disabled patients. Implanted stimulating electrodes and a radiofrequency receiver, powered by an external control unit via a transmitting antenna, help the patient to functionally lift the foot during gait /2,4,7/. The electrodes are attached to the nerve during a minor surgical procedure, which eliminates the need of daily repositioning. Since they are applied permanently, the choice of their position is of critical importance for the quality of stimulated movement.

The implantation is performed under local anesthesia with the patient lying on the hip and the involved leg supported by the opposite one SSC. The electrode position is selected by moving the implant along the exposed common peroneal nerve close to the lateral head of the fibula under the knee. Clinical observation of the stimulated ankle movement during surgery did not prove to be a satisfactory criterion for position selection. In several patients, posture and other factors, to mention only the different influence of foot weight during standing and lying on the hip, altered the intended dorsal flexion during gait. An excessive eversion was the frequent result.

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In order to improve the positioning of the implant and to allow a more objective assessment of stimulated movement, an EMG monitoring method with surface electrodes on the ankle muscles was introduced. It can be used both during the surgical procedure and during later examinations of patients.

METHODS

Two healthy males aged 38 and 42 and 13 patients, 4 females and 9 males with a mean age of 46 and on average 6 years after onset, were included in the study. There were 4 right and 6 left hemiplegics: 8 after cerebrovascular insult, 1 after head trauma and 1 after tumour in the temporal lobe. In addition, there were 3 spinal cord injury patients: 2 incomplete at the C7 and Th7 levels, and 1 clinically complete at the Th5 level. The 2 healthy adults and 1 patient were tested with surface electrodes, while 11 patients, who had been using the implanted stimulators for 6 years on average /1/, were studied with their subcutaneous electrodes. In 1 patient, who was implanted during the study, both stimulation modes were applied.

Responses to single pulse stimulation of the common peroneal nerve were monitored in the ankle dorsal flexors, evertors and plantar flexors, with the patients in the standing and lying position. EMG electrodes were placed over the tibialis anterior, peroneus longus and soleus muscles. Before the implantation, the functional lifting of the foot was found by surface stimulation in a standing patient. With good ankle movement a strong EMG response in the tibialis anterior and a moderate one in the peroneus longus was observed. The triceps surae was monitored to exclude the unwanted plantar flexion. The responses were then recorded with the patient lying on one side, as required for the surgical procedure. These records were used during the surgery as a guideline, when the implant position was determined by monitoring the activation with the same technique. The responses were tested again after the wound was covered, to check accidental displacements, and after the sutures were removed.

Recording was achieved by three pairs of In Vivo Metric Ag-AgCl surface EMG electrodes, placed 2.5 cm apart over the muscle bellies, and a wraparound earthing electrode between the stimulation and detection sites. EMG signals were amplified by three Tektronix AM502 differential amplifiers (gain 1000, bandwidth 1-1000 Hz), displayed on Tektronix 7633 oscilloscope and recorded by a Tektronix C-5C oscilloscope camera and two synchronized Gould 2200S dual channel stripchart recorders. The oscilloscope was externally triggered by the stimulation pulses.

Surface stimulation was provided by a constant current stimulator with amplitudes of rectangular monophasic pulses from 0 to 50 mA /3/. Monopolar wet felt pad electrodes with the neutral 10 by 5 cm rectangular anode in the fossa poplitea and the active 2.5 cm round cathode at the lateral head of fibula were used. At preset 1 Hz and 0.2 ms, the amplitude was selected for the desired response.

Subcutaneous stimulation was achieved by an implantable receiver with bipolar platinum electrodes at the nerve close to the head of fibula /4/. The receiver was powered by an external unit with a carrier frequency of 2 MHz. The implant provided modulated packages of rectified carrier frequency voltage. The frequency of these stimulation pulses ranged from 0.8 to 50 Hz and the duration from 0.05 to 0.5 ms. The amplitude could reach 15 V at 200 Ohm load and 1 cm distance between the transmitting and receiving coil. It was individually adjusted on a reference receiver according to the orthotic stimulator used by each patient. With a preset frequency of 1 Hz and an adjusted amplitude, the modulated pulse duration was selected for the desired response.

In order to check the ankle movement, single pulses and a 30 Hz train of pulses with the same amplitude, duration and electrode position were applied during all tests.

RESULTS

During 18 tests in 15 subjects, different combinations of M waves in the tibialis anterior, peroneus longus, and to a smaller extent in the soleus, were recorded together with slight H reflexes in some cases. The responses sometimes changed considerably depending whether the patient was standing or lying on the flank. When compared to sustained tetanic contractions, the combination of M waves in the observed muscles correlated fairly with the direction of ankle movement.

The desired strong dorsal flexion with moderate eversion was achieved in 2 healthy adults and 2 patients during all 4 tests with surface stimulation. In the left hemiplegic patient, good responses were found only with the help of this method. The 11 already implanted patients displayed strong dorsal flexion with moderate eversion in 3 cases. In two more patients, a similar response was achieved when the implant was pressed against the nerve. The other 6 patients displayed various stages of excessive eversion with or without dorsal flexion and even with a plantar flexion in one case.

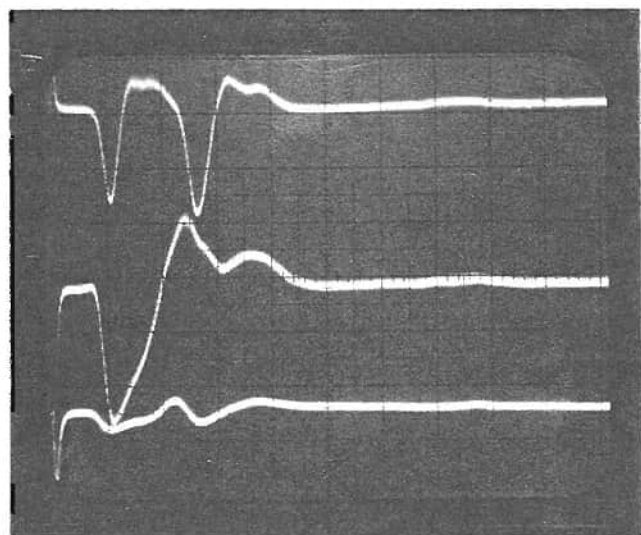


Fig. 1.

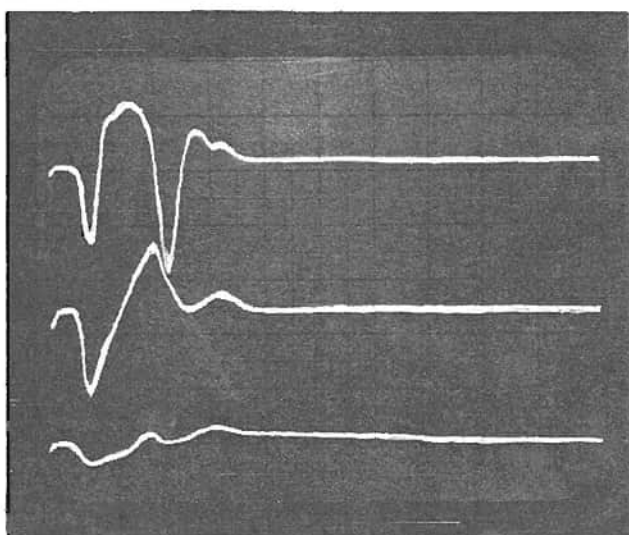


Fig. 2.

In the clinically complete spinal cord injury patient, whose responses to the surface stimulation before the implantation are shown in Fig. 1, strong dorsal flexion with moderate eversion was combined with the withdrawal flexor reflex, when a higher stimulation amplitude was applied. With the implant, the same movements were achieved, as before the surgical procedure, together with practically equal EMG responses to the ones before the implantation, as shown in Fig. 2.

DISCUSSION

Peroneal stimulation displayed mostly direct M wave responses in the 15 tested subjects. They also appeared with a lower amplitude in the soleus muscle of the examined population in spite of the stimulating electrodes on the peroneal nerve. M waves were changing during sitting, lying or standing, which also resulted in different ankle movements. The problems of different movements in the lying position during surgery were solved by comparing the previous EMG responses of desired stimulation during lying with the monitored responses. The change due to xylocain did not prevent equal responses to the surface and subcutaneous

stimulation in the implanted patient.

The method presented promoted viable monitoring during the selection of electrode position for surface and subcutaneous stimulation. In addition, four successive tests in the same patient before, during and twice after the implantation showed good predictability of its outcome on the basis of the initial responses to surface stimulation.

Two patients with implanted electrodes lost functional movement after 2 and 3.5 years. Contractions could be achieved by pressing the antenna against the electrode area. The present but changed EMG responses showed correct electrical characteristics of the implants. The function was lost due to a loose fixation of electrodes close to the nerve. Besides monitoring during surgery, the method described also proved suitable for the examination of cases of stimulation malfunction.

It is quite possible to achieve good dorsal flexion without excessive eversion by the surface stimulation of the peroneal nerve. However, it might be more problematic with implanted electrodes. During a follow up of 28 patients with implanted electrodes, excessive eversion was encountered in 4 cases /6/. In 1 patient a surgical release of the peroneus longus tendon was accomplished. In general a difficulty in obtaining balanced dorsal flexion was reported. The authors proposed a dual channel stimulation of the motor innervation to the anterior tibial muscle and the nerve supply to the peroneal muscles.

In this study, excessive eversion was found in 6 of the 11 patients with previously implanted electrodes. The method presented may solve the problem of correct electrode placement without a change in the easily accessible stimulation site and convenient position during surgery, or an increase in the number of stimulating channels.

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COMPARISON OF PHYSIOLOGICAL PARAMETERS
FOR THE CONTROL OF RATE RESPONSIVE PACEMAKERS

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SUMMARY

In the present work results are discussed of simultaneous measurements of physiological parameters and their behaviour under different levels of work load to determine their suitability as control parameters for pacemakers.

Venous oxygen saturation, temperature, right ventricular impedance and ECG were all measured with an intracardiac catheter while the subject performed on a bicycle ergometer at different work loads.

Results were obtained from 7 healthy volunteers. Oxygen saturation level was found to have a high negative correlation ($r=-0,89$) to load with a decrease sensitivity with load. Temperature has high correlation ($r=0.92$) with an increase sensitivity with load. With the existing measurement technique impedance showed very poor correlation to load.

The time constants and time delays of the system parameters to changes in loads were estimated. The results of parameter behavior are discussed, including influence on the suitability of the parameters to be used as pacemaker controller.

MATERIALS AND METHODS

In 7 human, healthy volunteers, mean age 28 years, an intracardiac catheter was introduced and placed in the right ventricle. The catheter was a normal bipolar stimulating catheter with an oxygen and temperature sensor integrated at 8 cm from the tip [1,2]. Relative venous oxygen saturation (SO₂) and intracardiac temperature (T) were measured with the above catheter. Impedance measurements were carried out between the tip of the stimulating catheter and the ring, which is placed 4 cm from the tip. A constant 50 μ A square wave current with a frequency of 6.25 kHz was applied between the tip and the ring of the catheter [3]. The same electrodes were used, by proper filtering, to monitor intracardiac ECG. Surface ECG was monitored for control.

Volunteers were asked to perform work on a bicycle ergometer. Work load was increased from 0 to 200 Watts in 50 Watt steps. Each step of work load lasted for 5 minutes with a 5 minutes rest period between loads.

Data processing

During the experiments data was recorded on an analog FM tape recorder. The data was processed off-line using a microcomputer. Each channel was sampled at 20 Hz. To reduce the effects of artefacts in SO₂ measurement, the minimum value was recorded for each cycle and averaged over 8 cycles. This moving averaged result was taken as the relative value of SO₂. The temperature reading was also averaged over 8 cycles.

A chopper amplifier was used to reconstruct the impedance envelope measured. The amplitude variations thus obtained were used to estimate the relative changes in stroke volume (SV) [3]. To filter out

spurious signals like breathing, the impedance signal was then high pass filtered at 0.66 Hz and averaged over 8 cycles.

All parameters amplitude variations from rest were normalized to the maximum change in the individual parameters for each subject, i.e. for heart rate (HR) its normalized value is defined as

$$HR_n = \frac{HR - HR_{rest}}{HR_{max} - HR_{rest}} * 100\%,$$

which is 100%, attained by the subject during the experiment at 200 W or zero at rest.

The relationship between the normalized value of the various parameters and work load was estimated using linear and non-linear regression techniques. The time course of parameter changes with the application of load can determine the time constant of the given parameter. Time constants were estimated from the 10% value above rest value to 90% of its maximum response to a given load. Time delay is calculated from the application of load till the parameter exceeds by 10% its rest value.

The sensitivity (S) of the parameters to variation in load, which is an important factor for the selection of a pacemaker controller parameter, is calculated as the ratio of changes in the normalized parameter value to changes in load, i.e. sensitivity of HR_n is defined as $S = \frac{dHR_n}{dP}$,

where P is the applied load in watts and S for all parameters is given in % per W. Heart rate was calculated from the recorded ECG signal and was also averaged over 8 cycles.

RESULTS

Steady state

The least square regression curve for the heart rate yield:

$$HR_n = 0.5 * P - 6.4 \text{ with a correlation coefficient } r=0.98.$$

Oxygen saturation:

$$SO_{2n} = -100 + 102.5 * \exp(-(0.013*P))$$

and $r = -0.89$

Temperature:

$$T_n = 32.3 * (P/50 + \exp(-(P/50))) - 29.5$$

and $r = 0.92$

Stroke volume:

$$SV_n = 0.017 * P + 50.7$$

and $r = 0.02$

where P is in watts.

Sensitivity

The sensitivities calculated from the above results are (all in %/W):

$$S (HR) = 0.5$$

$$S (SO_2) = 1.33 * \exp(-(0.013*P))$$

$$S (T) = 0.64 * (1 - \exp(-(P/50)))$$

$$S (SV) = 0.017$$

Dynamic behaviour

In figure 1 the results of the measurement of the various time constants are shown.

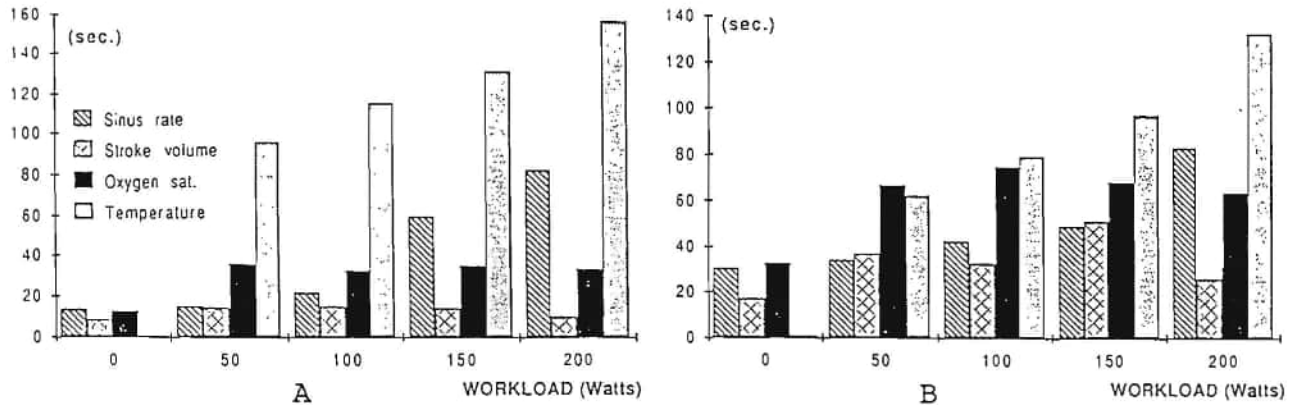


Fig. 1. Mean time constants of physiological parameters as a function of workload for A) exercise and B) recovery.

In figure 2 mean time delays of the measured physiological parameters are shown.

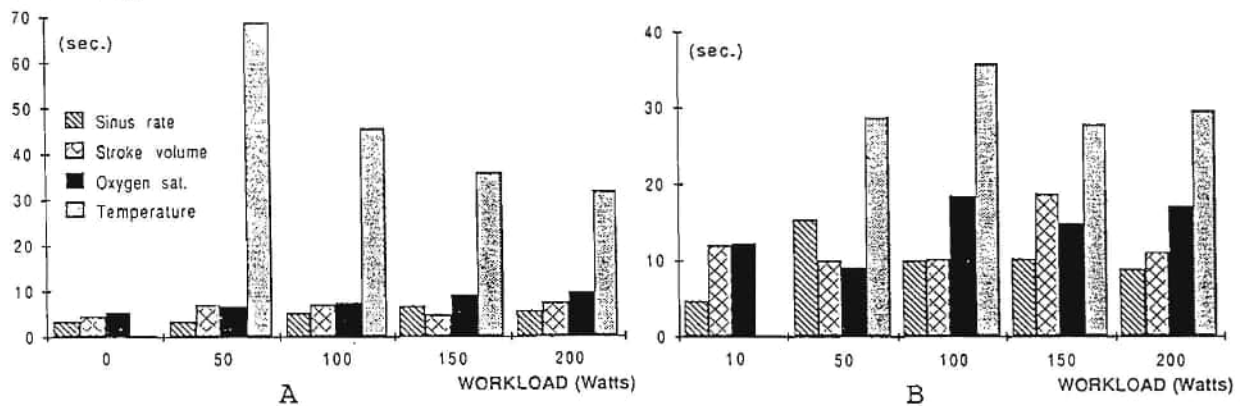


Fig. 2. Mean time delays of physiological parameters as a function of work load for A) exercise and B) recovery.

Time delays, for step increase in load, of heart rate, oxygen saturation and impedance are about 10 seconds and for step decrease in load about 15 seconds. Time delay of temperature, for step increase in load, is about 70 seconds for loads under 50 W decreasing to 30 seconds for 200 W loads. The time delay of temperature for step decrease in load is constant at about 30 seconds.

Time constants of SO_2 and stroke volume are smaller than 40 sec. and independent of load. Time constant of temperature increases with load from 80 sec. at 50 W to 160 sec. at 200 W. Time constant of heart rate shows an exponential relation to work load.

DISCUSSION

SO_2 level follows exponentially the values of work load with a very good negative correlation. In addition the SO_2 parameter has relatively short time constants and delays. The sensitivity of SO_2 goes down with increasing load. The relative SO_2 parameter therefore, is an excellent parameter to control pacemakers especially at low level of exercise.

The temperature level follows exponentially the values of work load with a very good positive correlation. However the time constants and delays of this parameter are larger and more extensive than those of SO_2 . At low level of exercise temperature falls in value in response to work which has been observed before [2,4]. For that reason temperature seems to be an inferior parameter to control pacemakers as compared with SO_2 . Only at high level of exercise the temperature parameter has the advantage of having a higher sensitivity than SO_2 . It is therefore possible to combine these two parameters in order to achieve high sensitivity throughout the dynamic range of work loads.

The impedance measurements used to estimate stroke volume were contaminated by catheter movements due to exercise and respiration. Stroke volume measurement was taken at the highest level after the application of each step in load. The impedance variations tend to resettle to the rest level after the initial transient. These results are in contradiction to results obtained by others [3]. This method therefore requires further and more elaborate experimentation before further conclusions can be drawn. The present results indicated very small correlation with work load. However, the response of the measurement had very small time constants and delays. It should be pointed out that stroke volume measurement is very important in the control of pacemakers, since when multiplied by the heart rate, it yields the cardiac output. Cardiac output is an important measure of the efficiency of pacing and oxygen supply, in addition it can supply the controller with information about the optimal heart rate. When stroke volume measurement is at hand, a combination of all of the above parameters can provide the ultimate information necessary for an exercise controlled pacemaker.

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Abstract

Title: NON-INVASIVE ASSESSMENT OF CARDIAC
FUNCTION FROM RATE AND RHYTHM CHANGES
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Variations in electrical stimulation of the heart result in hemodynamic changes. Assessing the relative state of cardiac function and the capacity of cardiac reserve is virtually impossible except by continual invasive monitoring. Cardiac function is a complex interaction of pre load, after load, filling pressure, ejection fraction, and myocardial function and integrity. Changes in the amplitude, slope, and volume of the systolic ejection wave can be used to assess functional variation. With the non-invasive utilization of ophthalmic artery plethysmography we have been able to evaluate the changes in the amplitude, time of activation of systolic ejection, and interval between electrical stimulation and the onset of systolic ejection. These results have been easily reproduced and confirm that normally functioning electrical depolarization results in the most effective rapid systolic ejection phase. Intrinsic or artificial variation of the electrical stimulating system produce effects with variations clinically represented by symptom complex of congestive heart failure or cerebral hypoperfusion. We are able to document what changes produce these symptoms and what alterations correct the induced abnormalities.

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ASSESSMENT OF ATRIAL REPOLARISATION FROM SURFACE ELECTROCARDIOGRAM.

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SUMMARY

Compared with the QRS complex the electrocardiographic deflection due to atrial depolarisation is relatively small. Atrial repolarisation is usually hidden by the ensuing QRS complex. As noted previously by others, (1, 2, 3) AV block may be used as a model to study atrial depolarisation and repolarisation.

In this paper we report on our technique of recording the electrocardiographic atrial activity and the extension of this model to the determination of the effects of heart rate on the atrial surface electrocardiogram.

PATIENTS AND METHOD

The patient group consisted of 21 patients (12 males) aged from 32 to 85 years. Each had either 2:1 or complete AV block, spontaneous in origin in 14 whilst 7 others were studied following therapeutic catheter ablation of AV conduction.

All patients had atrial and ventricular pacing electrodes. None of the patients were taking any antiarrhythmic drugs and none had abnormal P waves, as defined by Lepeschkin (4). There was no ischaemic pathology.

Standard bipolar leads I, II and III of the conventional surface electrocardiogram were recorded directly onto half inch FM magnetic tape using a Racal store 7 recorder. The amplification through a Biodata low noise physiological amplifier ranged from 1,000 to 10,000. Extraneous noise was reduced by collecting the signals over a narrow frequency band of 0.16 to 30 hertz (3 dB points). For analysis, the signals were transferred to computer memory via a twelve bit analogue to digital converter (A-DC) at a sampling rate of 256 samples per second. Once in computer memory, good quality low noise recordings could be displayed directly on a Tektronix 4010 graphics terminal. In more difficult cases, if necessary, signals could be subjected to further amplification (up to a factor of 4) and/or further digital filtration. Measurements were made from the displayed complexes by means of movable high resolution cross hair cursor provided on the computer interactive screen.

The total duration of the atrial electrocardiographic event, the PTa interval, was measured from the beginning of the P wave (atrial depolarisation) to the end of the Ta wave (atrial repolarisation). The end of the P wave (and the beginning of the Ta) was arbitrarily defined as the point at which the electrocardiographic trace crossed the isoelectric line.

For each value, five unencumbered PTa complexes were measured from the lead with the clearest PTa complex recorded in each patient. The average and standard deviation were calculated in each instance

allowing determination of the coefficient of variation (CV) of the method. The intraobserver variation was determined by measuring blindly the same recordings (50 complexes) on two different occasions. The interobserver variation, by 8 different observers, was assessed by measuring 50 complexes.

The effect of atrial pacing at rates varying between 80 and 150 bpm was determined. The PTa and Ta intervals and the P wave durations were correlated with the paced PP intervals and the correlation coefficient (r) was calculated for each pair of variables.

Simple linear regression equations were derived to predict the effect on PTa, P and Ta of changes in PP interval.

RESULTS

The coefficient of variation of the method was <7%. The intraobserver CV was <2%, (PTa= 388 msec, PP interval= 694 msec); the interobserver CV was <5% (PTa= 448 msec, PP= 722msec).

There was a good linear correlation between both the PTa interval and the Ta duration and the PP interval with a slope of 0.29 for PTa and of 0.25 for Ta and an intercept of 202 msec for PTa and of 108 msec for Ta (n=109). The regression coefficient was 0.72 for the PTa interval and 0.68 for the Ta interval with a p value of <0.001 for both.

There was no obvious relationship between the P wave duration and the atrial rate (coefficient correlation = 0.22, NS, n=109, slope=3.59, intercept= 92 msec).

From this linear regression was derived a correction equation for the PTa interval accounting for the effect of atrial rate : $PTa_c = 290 + PTa - (CL \times 0.29)$.

DISCUSSION

Leads I, II and III were preferred to X, Y and Z (3) because better recordings were obtained. This is confirmed by the low coefficient of variation using these leads. Determination of the P wave duration and Ta interval was easier and more reproducible from the standard leads, particularly leads II and I where, as expected (4), the P wave is positive and the repolarisation is negative. The use of standard leads also allows comparison with the P wave in the clinical ECG.

Recording the ECG signals on paper, for example using approximately 20X ECG gain on an Elema Mingograf would allow adequate measurement of some recordings. But in order to standardise the method of measurement, the computer interactive screen was used.

The measurements were made openly for obvious practical reasons. This was judged satisfactory considering good intraoperator and interoperators coefficients of variation obtained in a blind manner.

This study was conducted to determine the effect of pacing rate on the duration of depolarisation and repolarisation of the normal atrium. Patients with abnormal atrial depolarisation and repolarisation, as defined by the interval durations: $P > 120$ msec, $Ta > 345$ msec, $PTa > 460$ msec, and by their morphology: depolarisation and repolarisation in

opposite direction (3), were excluded. None had ischaemic heart disease. However the subjects were patients with spontaneous AV block or AV block post Hiss bundle ablation. These patients could have underlying atrial disease, as higher incidence of sinus node dysfunction is well documented in AV block; others may have atrial damage due to the Hiss bundle ablation method. Some Hiss bundle ablations were performed in patients with preexisting atrial pathology.

Increasing atrial pacing rate decreases the P_{Ta} interval mainly by reducing the repolarisation interval. The P wave duration is little affected by rate.

Olson (5) found a good linear correlation between atrial monophasic action potential duration (at 90%) and the pacing interval in a group of 12 patients on no drug treatment. The relationship is similar to ours with a slope of 0.16 and an intercept of 138 msec.

Denes et al (6) also reported a decreasing atrial effective refractory period with decreased pacing cycle lengths.

Comparing the atrial surface ECG, the P_{Ta} interval, to the ventricular QT interval, although Bazett's QT correction formula is hyperbolic using subjects before and on exercise (7), Warrington (8) has reported a linear correlation between QT and RR interval in normal volunteers on different doses of atropine.

In conclusion, assessment of atrial repolarisation is practical in patients with second or third degree AV block. The effect of different paced rates on atrial depolarisation and repolarisation permits derivation of a rate correction formula which should allow future investigation of the intrinsic effect of chronotropic drugs on the atrial depolarisation and repolarisation.

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VOLATILE ANESTHETICS AND VENTRICULAR FIBRILLATION THRESHOLD IN MINIPIGS

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SUMMARY

Ventricular fibrillation technique serves as a useful general indicator for drugs with potential antiarrhythmic properties. This study was performed to investigate the influence of volatile anesthetics (halothane and enflurane) on electrically induced ventricular fibrillation. Halothane and enflurane demonstrated a significantly increased antifibrillatory effect as compared to opioid anesthesia. The clinical relevance and pathophysiological mechanism of this effect is not yet clear but may help to prevent ventricular fibrillation caused by R on T phenomenon in pacemaker patients intraoperatively.

MATERIAL AND METHODS

The experiments were performed in 15 minipigs (weight range 17 - 29 kg) divided into three groups. After premedication with diazepam the halothane group was anesthetized with 1 MAC halothane, the enflurane group with 1 MAC enflurane and as reference the opioid group was anesthetized with fentanyl (0,03 mg/kg/h) and pancuronium (0,6 mg/kg/h). After tracheostomy controlled ventilation was initiated with 50 % oxygen and 50 % nitrous oxide to maintain the PCO_2 between 35 and 45 torr in all animals. After median sternotomy the pericardium was opened and the screw-in pacemaker electrodes were placed on the base and on the apex of the heart. During the experiments heart rate, ECG, arterial pressure, body temperature, endexpiratory CO_2 and halothane concentration were recorded continuously. Hematocrit, serum electrolytes, blood gases and acid base balance were determined intermittently. Before measurement of ventricular fibrillation threshold (VFT), the enddiastolic ventricular stimulation threshold was evaluated to assess and exclude electrode-specific artefacts. Ventricular fibrillation threshold was determined by using square wave pulse currents of 2 ms duration delivered at 3 ms intervals for a total time of 140 ms. The impulses were triggered by the R wave of the ECG so that they fell into the vulnerable period of every ninth heart cycle. The stimulus intensity was increased by steps of about 1 mA until ventricular fibrillation occurred. Immediately after ventricular fibrillation started, defibrillation was induced by a DC countershock with 12,5 Joule. So this procedure permitted reproducible determination of VFT every 15 minutes. Statistical analyses were performed using Multiple Comparison by Wilcoxon and Wilcox, H-Test by Kruskal and Wallis and Multiple Comparisons by Nemenyi.

RESULTS

There were no statistical differences in weight, heart rate, body temperature and laboratory data between the three groups. Evaluation of enddiastolic ventricular stimulation threshold yielded similar results (Fig. 1).

In halothane anesthesia ($11,5 \pm 0,49$ mA) and enflurane anesthesia ($11,0 \pm 0,49$ mA) significantly higher ventricular fibrillation thresholds were found than in opioid anesthesia ($9,07 \pm 0,49$ mA) (Fig. 2).

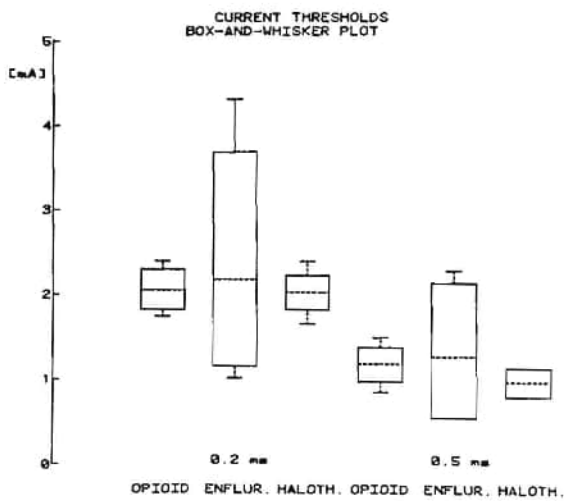


Fig. 1: Enddiastolic ventricular stimulation thresholds with impulse durations of 0,2 ms and 0,5 ms

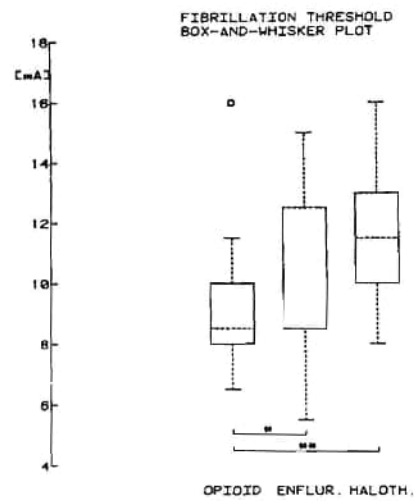


Fig. 2: Ventricular fibrillation threshold (* $p < 0,05$, ** $p < 0,01$)

DISCUSSION

The ventricular fibrillation threshold technique was used in many studies as a useful general indicator for the arrhythmic properties of drugs (6). This experimental technique of passing current during the vulnerable period serves to artificially increase the amount of inhomogeneity between adjacent ventricular fibers. If sufficient inhomogeneity and dispersion in recovery is produced, ventricular fibrillation develops. The results of this study demonstrate an antifibrillatory effect of halothane and enflurane. These data are in agreement with other experimental studies (1). A decreased mortality after coronary ligation because of a decreased incidence of irreversible ventricular fibrillation was found under halothane and enflurane anesthesia. These experiments relied upon spontaneously occurring ventricular fibrillation.

Kroll, using electrical stimuli, found similar results when determining the influence of halothane on ventricular multiple response threshold which is correlating with ventricular fibrillation threshold (2). Speck et al. investigated effects of volatile anesthetics on defibrillation threshold in dogs and found significantly increased values (7).

The clinical relevance and pathophysiological mechanism of this antifibrillatory effect is not yet clear and somewhat surprising in view of the well known arrhythmogenic actions, especially of halothane.

One possible explanation is the ability of halothane and enflurane to depress the mechanisms of Ca^{++} membrane transport similar to calcium entry blockers (4,5). The antidysrhythmic effects of calcium entry blockers may be due to blockade of depressed action potentials or prevention of myocardial cellular calcium overload or both. On the other hand volatile anesthetics may also cause complex alterations of intracellular calcium control by the sarcoplasmic reticulum and other membrane systems of the myocardial tissue (3).

In conclusion this protective antifibrillatory effect of halothane and enflurane may help to prevent ventricular fibrillation in pacemaker patients caused by R on T phenomenon.

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Abstract

Title:	FIRST RESULTS WITH THE AICD (AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)
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Treatment of ventricular tachyarrhythmias (ventricular tachycardia - VT, ventricular fibrillation - VF) refractory to medical treatment is possible by different surgical approaches. Besides EP-mapping guided endocardial resection the AICD is a new method to treat this type of arrhythmias. At the 2. Surgical University Dept. Vienna 6 AICD were implanted in 5 patients, 4 of them had documented VF (1-5) 1 had recurrent VT. Despite serial antiarrhythmic drug testing VF or VT were inducible during electrostimulation. Left ventricular function was markedly reduced in all cases (16-33%).
1 patient died postoperatively from mediastinitis, another died 3 months later from congestive heart failure. The other patients (3) are still alive and spontaneous as well as induced arrhythmias were promptly terminated by the device. Clinical condition is satisfactory (NYHA II).

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APPLICATION OF CMOS-VLSI CIRCUITS IN ADVANCED CARDIAC PACEMAKERS

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1. Introduction

The age of electronic computing machines started in 1946, when the first such machine, the ENIAC, was taken into operation. It consisted of 18.000 electronic tubes, weighted 30 tons and consumed about 150 kilowatts of power [fig.1]. It was not very reliable and rather complicated to program. Due to dramatic progress in microelectronics, microprocessors consisting of 20.000 to 400.000 transistors on a single integrated circuit, which consume only microwatts rather than kilowatts can be built at reasonable costs [fig. 2] and are used almost everywhere today. Thus it is a quite natural step to make use of these devices in advanced pacemaker architectures as well.

Software controlled pacemakers have been on the market for several years now, but only in the last two years microprocessors have begun to be utilized in this field. The goal of this paper is to discuss the advantages and limitations of microprocessor controlled pacemakers.

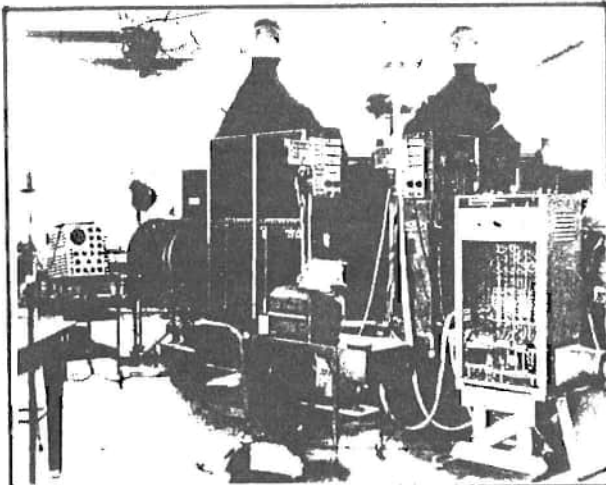


Fig.1: ENIAC-Computer: 30 tons, 18000 tubes, 150 kW, scale: $\longleftrightarrow$ = 1 meter

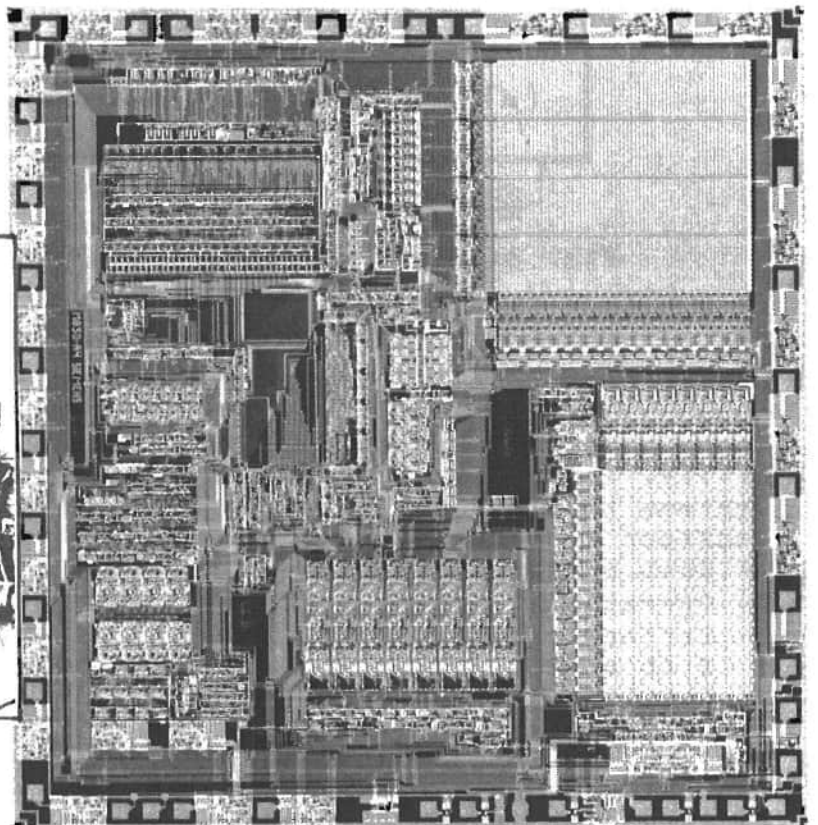


Fig. 2: SIEMENS Pacemaker up: 28 mm², 25000 transistors, Power level μ Watts, scale: $\longleftrightarrow$ = 1 millimeter

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2. Advantages of Microprocessor Controlled Pacemakers:

Until now modern pacemakers consisted of one or several complex, large scale integrated circuits (LSI). All the features of the pacemaker were implemented in these LSI chips. As they took several years to develop the situation was rather inflexible. The smallest detail of the specification had to be decided long before the actual testing began.

Microprocessor (uP) based pacemakers can be designed to be more flexible. The characteristics of the pacemaker may be stored either in a ROM (non alterable memory), in an RAM (alterable memory), or a combination of both can be used [fig.3]. This leads to systems, which can virtually be "redesigned", even after implantation by loading a new program code. This flexibility of a uP based pacemaker gives it great value in research, development, and implementation of new clinical methods. The same hardware can be used for completely different pacing situations as bradycardias and tachycardias. Furthermore the uP is a must for monitoring the patient between two follow up examinations. Pacemarkers responding to changes in different physiological parameters also require the use of a uP, which enables the treatment of the individual patient to improve dramatically. Other diagnostic features available today are monitoring of the battery state, electrode impedance, intracardiac ECG, temperature etc.

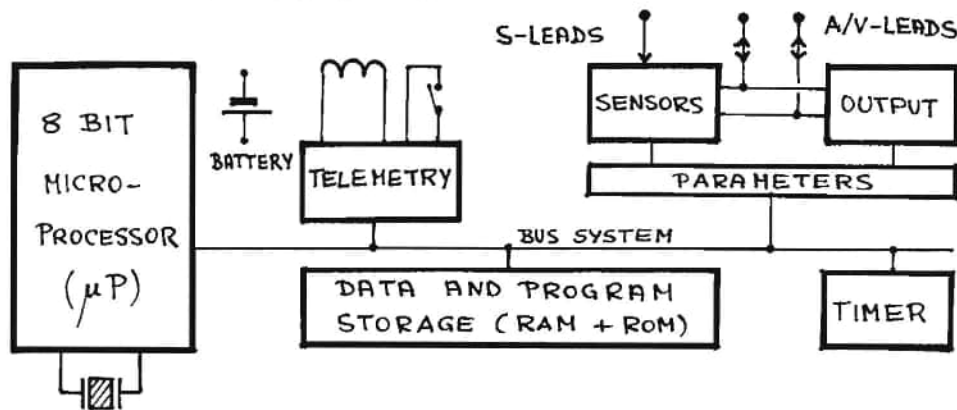


Fig. 3: Block Diagram of a μ P Based Programmable Pacemaker

3. Requirements for VLSI-Circuits in Pacemakers:

Design Constraints - Power Consumption

Every pacemaker has to meet strict requirements concerning reliability, longevity, performance and cost. The major limitation in systems that use uPs is power consumption, which impacts longevity. Consider a system with

- Dual chamber operation
- Operational life 8 years
- Battery capacity 6 Wh, i.e. 2 Ah at 3 V
- Complex functions, requiring extensive computing power.

The restrictions on service life and battery capacity lead to a maximum power drain of about 90 μ W, which can be divided as follows:

- Atrial stimulation 30 μ W
- Ventricular stimulation 30 μ W
- Pacemaker electronics 30 μ W (at 100% stimul.; 70bpm; 5V-500 Ω)

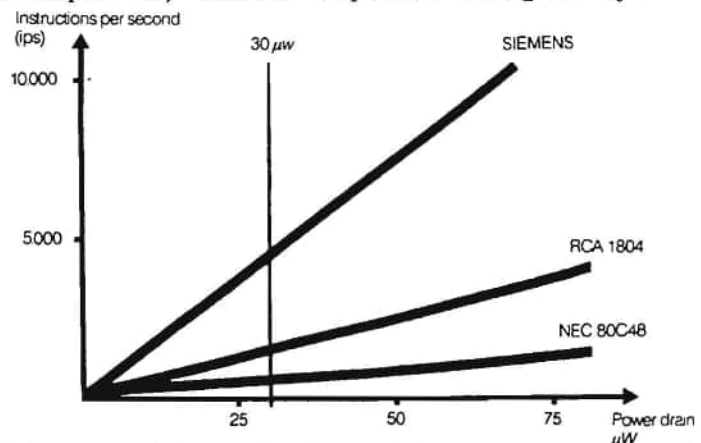


Fig. 4: IPS (Instructions per Second) vs. Power Consumption

Technological Aspects

The complex functions available in a μ P controlled pacemaker require a modern CMOS technology for the fabrication of the VLSI circuits. This technology allows the combination of analog and complex digital functions on a single chip. Given the state of the art only a few chips are needed to implement the whole system. These circuits operate under very difficult conditions: The overall average power drain must be less than 30 μ W and the battery voltage may change from 3.2 V to 1.6 V during its life cycle. To ensure proper operation under these conditions extensive precautions have to be taken. A special process was developed in order to ensure low voltage / low leakage devices with a close match between each other. Measures for circuit design include restrictions on the minimum gate length, a careful choice of the proper operating frequency for the μ P, and the temporary shutdown of certain circuit blocks whenever they are not needed.

Reliability

VLSI circuits for implantable electronics have to be extremely reliable, because their failures are likely to cause life threatening situations. During the design of the circuit precautions are taken to ensure easy and complete testability. All interfaces and communication paths are designed using redundant codes. Special circuits provide a multilevel backup and recovery system, which gets enabled in case of any malfunction. The system may e.g. switch from an erroneous RAM-based to a ROM-based program or even just provide pacing at a constant amplitude and frequency as an ultimate backup. Finally an advanced packaging and mounting technique (surface mount technology; SMT) is used.

To assure extreme high quality, extensive life span tests have to be carried out. These tests are done at high temperature using static and dynamic electrical, temperature and humidity stresses. Performance characteristics are monitored after 0, 168, 500, 1000 and 2000 hours. These include stability of threshold voltage and current constants, oxide leakage currents (local electrical fields as high as 10^8 V/m!) and the observation of electromigration (current densities in aluminium lines up to 10^6 A/cm²!). From these data, the so called "bath tub curve" is gathered, which then can be transformed into a curve for the life span under normal operating conditions. To increase reliability all circuits used in pacemakers are subjected to a "Burn-In Procedure" (Operating at high temperature). During this time all the early failures (fig. 5) can be eliminated and high quality circuits can be guaranteed.

Microprocessor-Performance

Given a system like the one depicted on fig. 4 it can be demonstrated that the μ P must at least execute 2000 instructions per second (ips) for a simple DDD-function. For a more complex system with sensors and diagnostics about 5000 ips have to be provided by the μ P. At 2000 ips commercially available μ Ps already consume 30 μ W (fig. 5), thus leaving no processing power for any additional functions. The reason is that standard μ Ps are optimized for speed rather than power. Consequently a specially designed processor is required in this application, where minimum power is essential.

4. Hardware Design:

The most feasible hardware configuration consists of a special microprocessor in conjunction with dedicated integrated circuits. The pacemaker pulse output stages e.g. must handle currents several orders of magnitude higher than the signals within the processor and also need

reliable protection networks against defibrillator currents, which otherwise may damage the circuits.

The system uses two clock generators: a slower one for the timing of pacing functions and a faster one for the processor itself. To minimize power drain the latter one is switched off when computations are not needed. Certain functions as battery check or telemetry are seldomly used, they may draw more current without affecting battery longevity too much.

The resulting configuration implements detection and timing functions in custom VLSI-circuits. This external hardware also acts as a rudimentary pacemaker in case of a μP failure.

5. Software Design:

It is not difficult to program a μP so that it performs the basic pacemaker functions. However, the situation is rather complex, when all aspects of modern pacemakers are taken into account (self test, bradycardia / tachycardia treatment, telemetry etc). To provide the designer with a better overview of what is happening and to ease programming, Siemens has developed a Pacemaker Multitasking Real Time Operating System and a special programming language called Graphic Pacemaker Language. These tools partition complex functions into simple subfunctions, provide flow charts, and generate code in the machine language of the μP .

6. Conclusion:

Modern CMOS - VLSI devices including microprocessors as well as custom analog and digital circuits will have a major impact on cardiac pacemakers. They will lead to very complex and highly adaptive systems that can improve the treatment of the individual patient by responding to several relevant physiological parameters. Although these pacemakers are software-controlled, many functions still must be placed in custom VLSI chips outside the microprocessor in order to minimize power drain and program complexity and to provide special interfaces and communication channels. The development of software controlled "intelligent" pacemakers requires specially designed microprocessors and special high level languages.

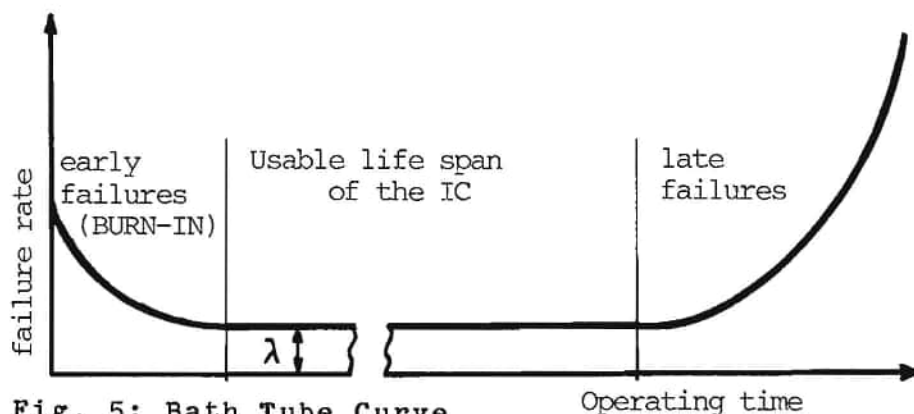


Fig. 5: Bath Tube Curve

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HIGH QUADRIPLÉGIA ACCOMPANIED BY NEUROGENIC RESPIRATORY INSUFFICIENCY,
POTENTIALITIES, LIMITS AND OUTLOOK

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Respiratory insufficiency by para- or quadriplegia is caused on the one hand by neurogenic loss of respiratory muscles, on the other hand by concomitant disturbances of pulmonary function. When, according to the level of a transverse motoric lesion, a sudden failure of abdominal and intercostal muscles occurs, all symptoms of respiratory insufficiency may develop to the full extent particularly if obstructive or ventilatory disorders have been preexistent. Problems increase with each higher spinal segments. At C 4 we arrive at a type of sonic barrier.

Since the beginning of the phrenic nerves are the spinal segments C 3, 4 and 5, a functionally sufficient diaphragmatic respiration may be expected in cases of quadriplegia below C 4. Provided no severe pulmonary complications exist, intubation should be avoided when the level lies below C 4. This is due to the high rate of later difficulties and complications later on during the transitional period between mechanical and spontaneous respiration. We also feel, that keeping up the ability of articulation is of eminent importance during the early stage of spinal cord injury. In order to subtain spontaneous breathing, active breathing physiotherapy must start at once in regular day- and night rythm. Generally this can only be guaranteed only in spinal cord injury centers or in hospitals with special units because of the need for a considerable amount of trained staff. Another reason for immediate hospitalization in a specialized unit with comprehensive care.

Respiratory insufficiency by transverse lesions between C 4 and T 6 is caused by incapability of expectoration more so than by the reduction of minute volume.. Inadequate expectoration leads to congestion in the respiratory tract, further restriction of ventilation leading to the development of atelectasis. Therefore, respiratory therapy has to accomplish:

1. Conscious expectoration by supporting manual, rhythmical compression and decompression of the chest, in accordance with the patients own efforts.
2. Support of patients breathing during deep inhalation and exhalation to compensate the neurogenic loss of intercostal muscles.
3. Stimulation of conscious diaphragmatic and auxiliary respiration.

Further essential supportive treatments are humidifiers, secretolytic drugs, regular postional changes of the patient, standing training - even while in the intensive care ward, vibratory massage, manual percussion and the devices for augmentation of dead-space. Other supportive apparatus such as Monoghan, Bird and other trigger machines (with C-PAP-respiration) can also help to avoid the intubation.

In the case of additional pulmonary disorders of traumatic or non-traumatic nature, a temporary mechanical positive pressure breathing (PEEP) may be required. Indicative are the parameters of pulmonary function.

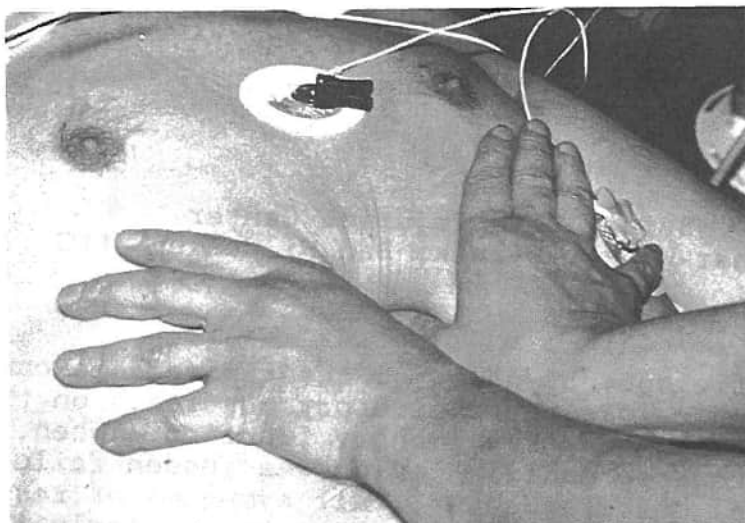


Fig. 1: By stretching the diaphragm

We believe that with sufficient physiotherapy the following limit values for an adult quadriplegic can be tolerated:

Tidal volume	300 ml
Vital capacity	800 ml
PO_2	> 60 mm Hg
PCO_2	< 60 mm Hg

We favour nasotracheal intubation to the oral tube, as it simplifies oral hygiene, maintains the patients verbal communication by lip language and in most cases allows normal food intake over a time of prolonged mechanical respiration from two, at the most three weeks.

Tracheotomy by quadriplegia below C 4 is an exception and is justified only by severe additional complications when artificial respiration for more than 14 days is to be expected.

Weaning from the respirator by neurogenic respiratory insufficiency is exceedingly strenuous for the patient and the therapeutic team. Weaning should start as soon as possible, if no contraindication exists. The duration of artificial respiration increases the difficulties of weaning. The stepwise process, often troublesome, begins with single spontaneous breathing actions by which the patient (under controlled mechanical respiration) surmounts a trigger threshold by relative negative pressure or minimal inspiratory flow, so that the machine responds by an additional volume. A number of modern respirators offer further technical devices which intermittently support spontaneous breathing and facilitate the patients inspiratory efforts. At this stage medical data must be controlled frequently. Renal function as well as regular voiding of the bladder for reasons of neurogenic bladder disfunction have to be observed. Regular defaecation is also important, as flatulence and constipation may obstruct respiration considerably in this early and unstable period.

When sufficient spontaneous breathing has been achieved, whether in hospital or at home, in order to improve pulmonary function, we use more and more breathing equipment - the so called C-PAP-breathing - so that there is a continuous airways pressure to minimize the tendency of alveolar collapse, the prevention of atelectasis, and to improve an maintain a better ventilation.

Up to September 1985 46 quadriplegics with respiratory insufficiencies had to be mechanically ventilated. From these patients 10 died, 3 by accompanying illnesses, 2 by cardiac problems, 1 by a pulmonary

embolus and another by a massive tracheal hemorrhage, 3 had a severe pulmonary infection. From 36 patients it was possible to wean 30 (80 %) from the ventilator.

Distinctive problems may arise with paralyzed patients who suffer from a partial or total loss of diaphragmatic function. Here a mechanical respiratory support must be considered for long periods, sometimes for constant use. Through modern emergency organization and rescue teams, also by helicopter transfer, it has been possible to admit a greater number of patients with total paralysis of the diaphragm to a medical unit. It is thus that the problems have been relayed from the place of accident into the clinic, where these problems are sometimes thought to be unsolvable.

The common problems that occur in high quadriplegia tend to be multiplied and to be complicated by respiratory insufficiency. Close teamwork between the different medical departments is essential to obtain the desired results. In 1982 we installed a respiratory unit with 5 beds for long term ventilation in high quadriplegia. This unit is operated with the cooperation of the departments for anaesthesiology and intensive medicine together with the department of orthopedic surgery and rehabilitation medicine. These few beds are not designed for nursing-care to death under permanent artificial ventilation. This expensive unit is only justified when the outlook for the treatment such as the independence from the mechanical respirator and the ability to leave the intensive care ward is high.

Without doubt, in specialized centers under optimal conditions, many more paralyzed patients with a lesion above C 4 can achieve spontaneous respiration than people presume nowadays. We have treated 22 quadriplegics with transverse lesions at C 3/4 and above with neurogenic respiratory insufficiency, and have been able to achieve an independence from the mechanical ventilator in 13 of these cases. In patients with transverse lesions in C 3/4 and above, we see three different ways for alienating:

1. Spontaneous breathing with the auxiliary inspiratory muscles permanently.
2. Conscious breathing with the auxiliary inspiratory muscles for a few hours, and additional provision of transportable breathing apparatus, which enables the discharge from hospital - also as a temporary compromise.
3. Pace-maker for the diaphragm.

A conscious breathing with cervical musculature is also possible when the lungs have not been damaged and the function of the accessory nerve remains. The work of breathing is taken over by the auxiliary inspiratory muscles. They must be trained through intensive physiotherapy of each individual muscle group. In use are the muscles of the neck, innervated by the upper cervical segments, especially in the region supplied by the accessory nerve, the hypoglossal muscles, the intact scalenus and above all the sternocleidomastoid. They can elevate the chest, while at the same time the head and neck are fixed by the pre- and paravertebral muscles.

The conscious use of the neck muscles can be trained. Tipping the head backwards supports the elevation of the chest and strengthens the force of contraction of these muscles. Depending on the elasticity of the thorax and its own weight, the first conscious breaths are taken while sitting or lying down.

It is a long process from the first reaction, to self inspiration for minutes, later hours, which takes over a year, and is a great strain both mentally and physically on the patients and the staff. If spontaneous breathing has been achieved over a period of hours, the



Fig. 2: Physiotherapy for strengthening the auxiliary muscles

quality of life is greatly improved. It is possible to insert an artificial larynx, the patient is able to leave the intensive care ward in a chin-steered electrical wheelchair to start occupational training at a mouth operated worktable. In cases such as young children and craniocerebral traumatics in spite of good muscles these aims sometimes are unachievable due to the low mental capacity. While sleeping problems arise because the auxiliary respiratory muscles are not stimulated from the respiratory center. The patient then "oversleeps" this breathing. In some cases this problem can be solved through a long training course. Before reaching the stage where spontaneous respiration is achieved also in the sleeping phase, we use an iron lung transitionally. In some cases it may be permanently necessary, in others a chest bell may be sufficient. The development in micro electronics has opened a new possibility of functional stimulations of the diaphragmatic muscles through the phrenic nerve.

Experiences of over 10 years has been gathered in the USA in the practical use of electronic stimulation of the phrenic nerves. For this method enough motory anterior horn cells must be left intact. Before the implantation of such a pacemaker a trial with a transcutaneous or open stimulus of the phrenic nerve is necessary. In the system used in the USA, both phrenic nerves and diaphragm halves were stimulated for 12 hours separately. After a time a certain amount of tiredness was noticed, which was traced back to the non-physiological stimulation of the nerve diameter through one electrode. A much improved pacemaker technique was developed by Thoma, Vienna. 4 electrodes applied to each nerve and steered by a processor, stimulate the nerves in constant "carousel switch". The constant change in steering of the different nerve sections enables an extended recovery phase, and a possibility to stimulate the phrenic nerves spontaneously over a period of 24 hours.

Two of our patients have been treated by this method. In one of these patients data of the stimulation has been recorded for more than 2 years. This now 23-year old man was discharged home from hospital, and is only temporarily for a check-up and to review the function of the system hospitalized. In the spring of 1985 a subcutaneous re-implantation of the receiver was necessary and occurred without problems. One disadvantage of this impressive technical possibility is limited indication. A successful implantation of this method can only be promised when the anterior horn-levels of the spinal cords C 3 - C 5 is intact.

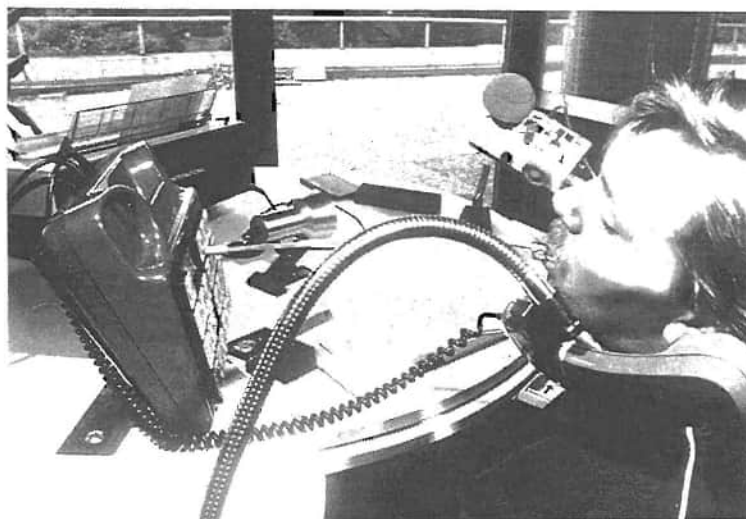


Fig. 3: Patient with electrophrenic respiration in OT

Patients with insufficient functions of the auxiliary inspiratory muscles, and a phrenic nerve which cannot be stimulated, a temporary or permanent mechanical respiration is unavoidable. Today this means in most cases a permanent stay in the intensive care unit, either in a spinal injuries center or in another clinic.

Following dutch experiences we are singularly trying to arrange a "home-care" unit for these patients, where it is possible to obtain a mechanical ventilation for overnight. Here we see a possibility to free the paralysed patient from the dependancy of the hospital.

SUMMARY

With this technique and at this time very expensive, overall personnelintensive therapy, patients with neurogenic respiratory insufficiency in high spinal cord injuries, are now able to survive longer than one expects. We cannot judge today the expectation of life, and the perspective of living in these high quadriplegic patients with a diaphragmatic paralysis.

However, we maintain the point of view that these methods of treatment today have passed the experimental stage, and have given rise to improvement in the freedom and quality of live in those patients who are intensively striving to maintain their lives.

ACCEPTABLE QUALITY LEVEL (AQL) IN UNIVERSITY RESEARCH - A CASE STUDY IN IMPLANTABLE NEUROSTIMULATION DEVICES x)

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Institute for Biomedical Engineering & Physics

SUMMARY

The acceptable quality level (AQL) is defined as a quality standard associated with a given producer's risk, which is prescribed by the "customer" or design engineer for the products on order, usually expressed in percent defective per hundred units. In the case of medical electronics research and development on universities the patient in the role of a customer has a right to have satisfactorily functioning devices.

In our experience, the success of the treatment (better substitution) of lost body functions with FES devices has found limits which correlate to structures of university research. Dealing since more than 8 years with electronic implants to restore the locomotion of paraplegics or enable breathing for tetraplegics the experience is that the maintenance of implants and control units claim more efforts, time and money than the development does. A detailed description of the features of the stimulation system and the medical and rehabilitation data of the project can be found in /1,5,6/.

PATIENT INITIALS	LEFT/RIGHT	NO. OF CHANNELS		1982			1983					1984					1985					1986				
		PHRENIC PACEMAKER	LEG PACEMAKER	OCTOBER	NOVEMBER	DECEMBER	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	
B. W.	L		8	1																						
	R		8	1																						
J. R.	L		8	1																						
	R		8	1																						
M. S.	L		8																							
	R		8																							
R. K.	L		8																							
	R		8																							
U. D.	L	4																								
	R	4																								
C. M.	L	4																								
	R	4																								

Fig.1.: Time schedule of implants; 1-implantation, 2-failure, 3-change of the implant, 4-dislocation of electrodes, 5-change to external device, 6-infection and replantation, 7-ad mortem, 8-demotivated, training aborted.

x) Supported by the Austrian Research Foundation

The equipment manufactured in our laboratories since the first implantation in human in 1982 is:

17 implants (design change 3x)
 23 control units (design change 1x)
 25 transmission coils (no design change)
 20 charge units (design change 2x)

The longest time an implant was working satisfactorily was 25 months. The shortest time to a reimplantation was 7 months. Compared with similar implants (e.g. cardiac pacemaker) produced by special industries, where the Mean Time to First Failure (MTTF) is between 7 and 12 years the long term stability seems to be rather poor. On the other hand the efforts which are undertaken for quality assurance in industries are sometimes up to 60% of the annual budget /4/.

So to have properly designed high quality implants and appertaining peripheral devices is not only a question of ethic responsibility to the patient, but to enable a transfer of technology and know-how to industries on the basis of satisfying and reliable results in the pre-clinical and clinical studies of a new device.

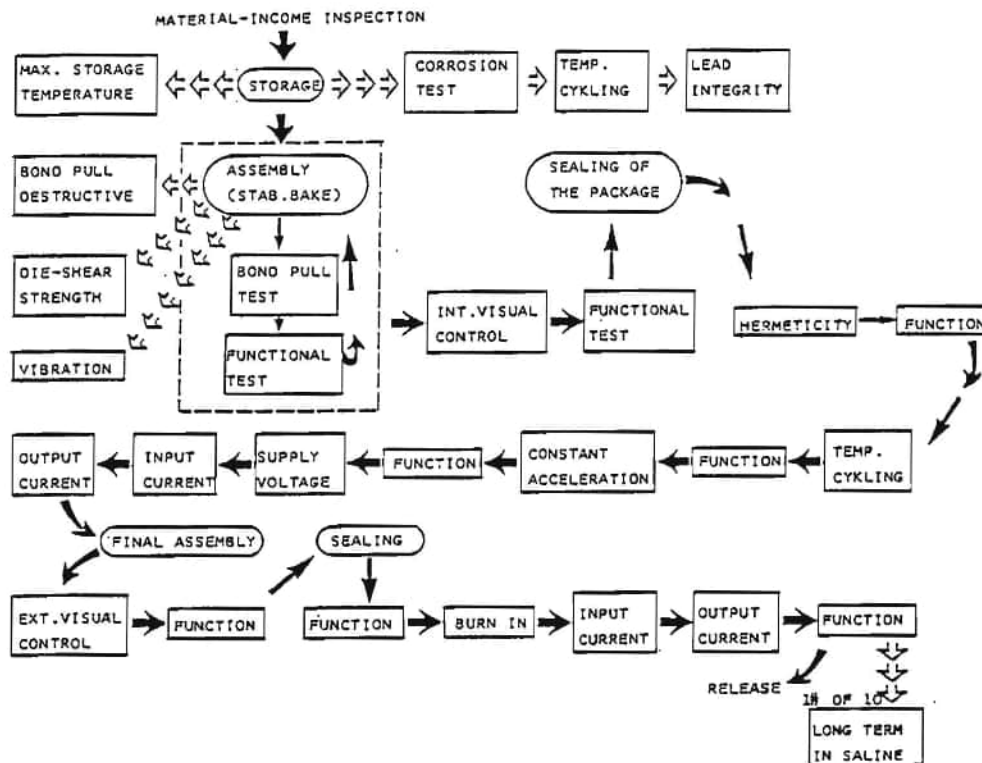


Fig.2.: Flow chart of the accompanying quality control

MATERIAL AND METHODS

The methods used for quality assurance on universities should be nearly the same as those comparable manufacturers are using, although staff, money, time, etc. are drastically reduced compared with industries. Startingpoint after the establishing of a systems design (no occurrence of design inherent failures) will be the material income inspection. One had to give up the idea, that one device has the same behavior to an other with the same manufacturers specifications. An example is the use of special capacitors in the receiving circuit of our implantable

system. PE-coated styroflex capacitors with excellent RF-features are going to be changed to glass-encapsulated ones, because of its drift in capacitance values after six months in the tissue environment. The next step are test procedures related to preassembly, assembly and post-assembly, which are described detailed in /2,3/ and are here only shown in the flow chart in fig. 2. In the following the changes of parts and system components due to the occurrence of problems in vivo or in the accompanying quality assurance program are listed.

RESULTS

The first essential result was the change from a printed circuit board inside the implant to free structure connections between devices like the hybrid circuit, decoupling capacitors, and limiter diodes or other. The reason has been copper migration on the printed circuit board due to moisture and therefore ion transport inside the encapsulation.

A second success has been a series of tests with the conductive epoxy to check the correct workmanship, performed because of loose or nonconductive capacitors on the glass substrate inside the hybrid. The result shows that the glass transission temperature of 180° C should not be exceeded in more than three cycles (stabilization bake etc.). So we had to change the timing of the assembly to avoid this kind of stressing of the conductive epoxy.

The change of a filter capacitor due to problems with it's conductive surface, which was not designed for die bonding to glass substrates. This failure occurred during constant acceleration tests. We changed to gold or silver palladium coated surfaces instead of tin coated. In that kind of failure mechanism die shear tests have been the right tool to quantify the improvement.

To the problem workmanship we have seen in one case the need for very correct visual inspection. A glassivated diode inside the implant had had obviously too long or too hot soldering and so a small crack allowed moisture to disable it's function after half a year. It was inside a phrenic nerve stimulation implant and could be changed within 4 days, so that there was no need to "reconnect" the patient to the respirator.

But not only problems with the implants are influencing the quality. If you use the system for phrenic nerve stimulation as respiratory aid the control units have to guarantee adequate function. In that cases we had troubles with the rechargeable Ni-Cd accumulators because the guaranteed 200 charging cycles could not be obtained. These patients use the device 24 h/day and after 50 - 70 cycles the capacity was drastically reduced. So we had to change the distributors or/and to perform life/characterization tests.

So in that way the process of further improvement never is finished and each small change at the occurrence of problems will help to reach a better quality level for the patient.

DISCUSSION

These and other standardized methods of quality control establish uniform methods and procedures for testing implants and control devices with the final aim to reach an acceptable outgoing level of quality.

The necessity of efforts in quality control for manufacturing prototypes on university is in our opinion not disputable. Advantages can be seen in the patient's confidence in medical electronics, less efforts in maintenance, and a better chance to perform a knowledge transfer to industries.

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SIMULATION OF THE FUNCTIONING OF ELECTROSTIMULATION PROSTHESIS FOR THE PROFOUNDLY DEAF

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SUMMARY

Results of computer simulation of the excitation of nerve signals by stimulation according to various physiological models are presented. They are discussed in relation to the problems of prosthesis for the profoundly deaf.

INTRODUCTION

During the last three years we have studied models for the action of electrostimulation signals on acoustic nerves and dendrites, with the aim of understanding successes and difficulties with prosthesis for the profoundly deaf. /1-3/

Three models were examined in detail, the Bonhoeffer-Van der Pol-Fitzhugh (BVF), the Hodgkin-Huxley (HH) and the Frankenhaeuser-Huxley (FH) model. The first one has the advantage of giving mathematical insight into phenomena; it is also computationally easier to handle than the other two, which have however the great advantage of being strongly supported by physiological experiments.

The models furnish the pulse sequences generated in the nerve by the stimulating electrode. They allow the comparison of the information transmitted to the nerve with that contained in the signal. Our work reaches certain tentative conclusions concerning the functioning of single-channel stimulation, the difficulties encountered with multi-channel stimulation due to channel interference, and the limitations of methods involving modulated high-frequency signals. We shall report on confirmation by experiments of some of our theoretical predictions.

SINUSOIDAL SIGNALS

The following features are common to the three models considered. There is a threshold below which no action potential (AP) is generated. Above it, every depolarizing amplitude maximum leads to an approximately synchronous AP, but, as the frequency is increased beyond appr. 700 Hz the firing becomes intermittent. At a low frequency of about 100 Hz, when the half period of the wave is longer than the refractory interval of the nerve, double firing during the half period occurs in the case of the HH model but not in the case of the FH model.

In order to model sub-threshold activity of the nerve, we have added a noise signal low enough to lead only rarely, by itself, to AP production. This noise signal, added to a weak sinusoidal signal helps it to reach threshold, so that a firing rate increasing with signal amplitude is found until saturation sets in at a high amplitude.

Theoretical period histograms and interval histograms were computed and agreement with animal experiments by Hartmann et al./4/ was found when noise was added to the signal. In these experiments the response of single fibers to sinusoidal electrostimulation was tested. They showed the double firing phenomena mentioned above confirming the HH model and not the FH model.

In the case of patients with implants, the information is conveyed to the CNS by a multiplicity of fibers. The amplitude range from threshold to saturation may be due to the range of distances from the stimulating electrodes to the different fibers. Weak signals may be carried only by proximal fibers and strong signals also by distant ones. It may also, in the presence of subthreshold fluctuations, be augmented

by the extension of the range due to noise as mentioned above. The amplitude range observed with patience is of the same order as that found from our model when noise is included./2/ A clear discrimination between the two alternative explanations is not possible. It seems likely that both mechanisms operate.

VOWEL RECOGNITION

Vowels of the German language may be characterized by their first and second formant. A table for the eight vowels /a:/, /ε:/, /o:/, /ø:/, /e:/, /u:/, /y:/ and /i:/ is shown below. It is seen that the formants for /e:/ and /i:/ are not very different. The amplitude ratios for equal loudness (supplied to us by E.L. Wallenberg) are also shown in the table.

vowel	first formant		second formant	
	frequ.	ampl.	freq.	ampl.
a:	780	4.5	1100	4
ε:	480	5	1780	0.8
o:	320	8	550	5.5
ø:	320	4	1300	1.5
e:	310	2.5	2000	0.4
u:	300	5	600	2.2
y:	300	2.2	1500	1.8
i:	270	1	2000	0.4

It has been shown experimentally that the frequency of discrimination of implanted patients is rather limited. Some authors speak of an upper limit of 300 Hz, others of 800 Hz. At any rate 2000 Hz are far beyond the limit. Yet, a fair measure of success with vowel recognition has been reported. The Hochmair group reports up to 80% correct responses and 40 to 60 % have been achieved by several patients.

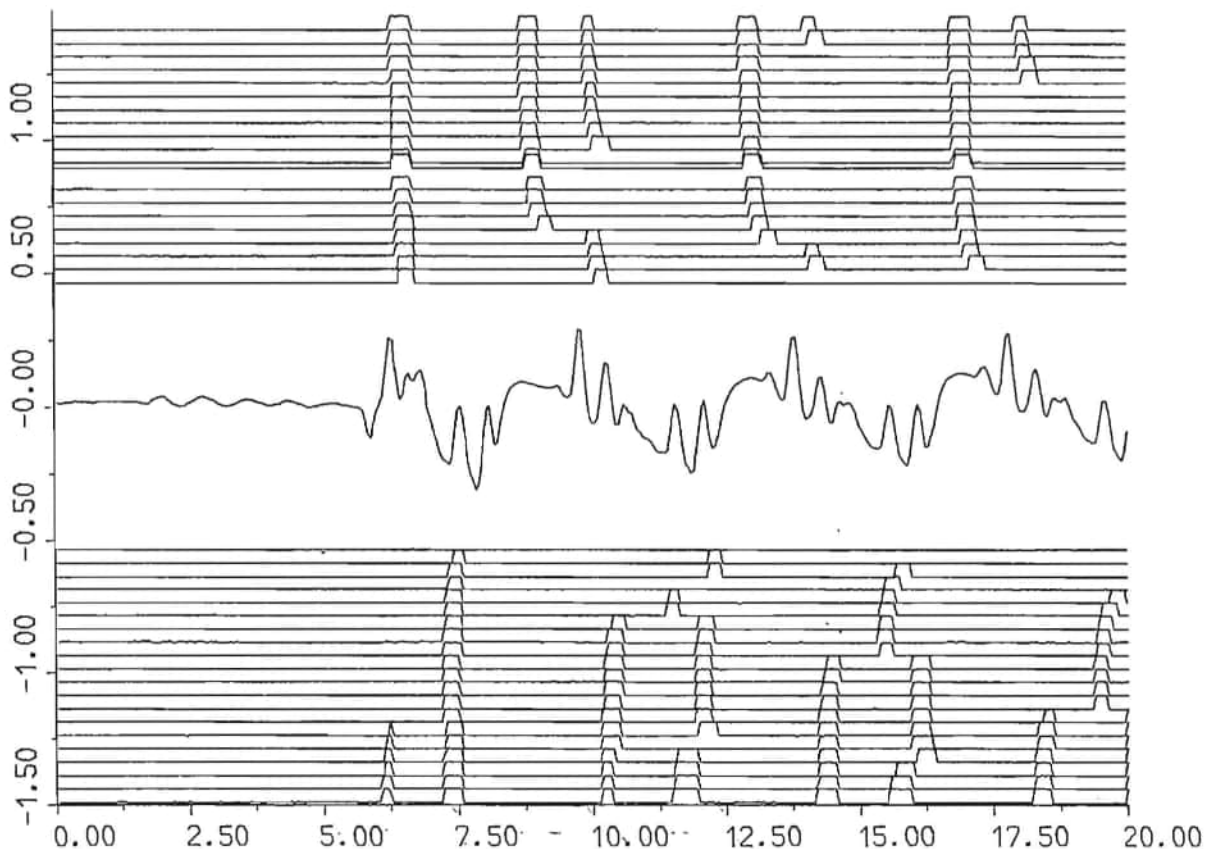


fig.1

We believe that the explanation is given by the 'Volley Theorie' of Wever /5/ for normal hearing, which we modify for the case of electrostimulation. According to this theory frequency information is carried to the CNS by a multiplicity of fibers. In the absence of an intact cochlea with its hair-cells, implanted patients still have a multiplicity of acoustic fibers which can carry information. The nature of this information will be illustrated below.

Our model produces a pulse sequence as the nerve response to a speech signal. The AP's are synchronized with depolarizing amplitudes maxima of the speech signal. It has been shown experimentally by E.L. Wallenberg that inversion of the polarity of the signal sometimes leads to different percepts. This is understandable since the positive and the negative parts of the signal are not necessarily the same. In the example shown in fig.1, the signal for /y:/ is not symmetrical with respect to the horizontal axis. We have recorded nerve responses for both polarities.

The computer produces an AP whenever threshold is exceeded and records a rectangular pulse as shown in fig.1. The horizontal lines are drawn for different signal amplitudes. At the lowest amplitude few AP's appear, and more and more are recorded as the amplitude increases. Note the asymmetry of the signal and the delays up to 0.4 msec, appearing for low amplitudes. This delay appears because at low amplitudes the time for build-up to threshold is longer. When noise is added more AP's are brought into play and the synchronization at low amplitude is improved because the attainment of the threshold is helped by the noise.

To apply the volley theory we interpret the amplitude scale as a measure of fiber distance, the more distant fibers corresponding to the lowest amplitudes. It is seen that in the combined signal, the volley, small time differences between AP's carried by different fibers appear, and it must be assumed that they can be recognized by the CNS.

It is seen from fig.1 that the signal maxima separated by time intervals shorter than the refractory interval, which is in the order of a msec, interact. Sometimes the higher, sometimes the lower amplitude maximum leads to an AP. The reason for this is that the build-up time of an AP depends in a complicated way on the signal shape. It is possible to follow this behaviour computationally and we have done this in connection with an experiment proposed by us and carried out by N. Dillier./3/

In this experiment a large rectangular signal pulse of short, i.e. 100 μ sec duration, is followed after a 100 μ sec interval by another pulse of lower amplitude and the same duration, as illustrated in fig 2a. During the first pulse the fiber response shows a linear rise, followed by a flat portion after the end of the first pulse. In the case of fig. 2a the first pulse is not strong enough to produce an AP, but a second weaker pulse completes the process leading to an AP. Without a second pulse no AP is produced and the response decays (fig 2c). Fig. 2b shows a stronger pulse leading to an AP. The time difference between the maxima of the AP's of fig 2a and fig. 2b is appr. the same as the time difference between the two pulses. The detailed behaviour depends on the strength and duration of the two pulses and explains much of what is seen in fig. 1. Thus time intervals short compared to the recovery time of the nerve may appear in the combined output of a fiber bundle. We believe that it is possible to develop a new pulse strategy on the basis of these findings which may lead to an improvement of performance.

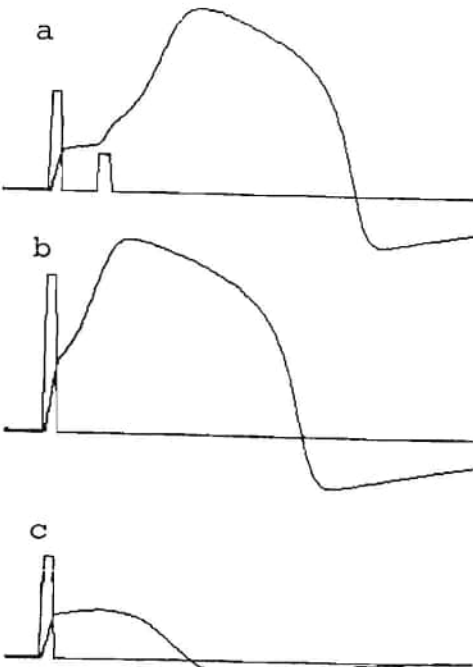


fig.2

PROPAGATION OF HIGH FREQUENCY AND MULTI-CHANNEL SIGNALS

For the purpose of the forgoing analysis it was sufficient to deal with the local excitation. The investigation of high frequency and multi-channel response must take account of the propagation of the response along the nerve, which we have studied in detail.

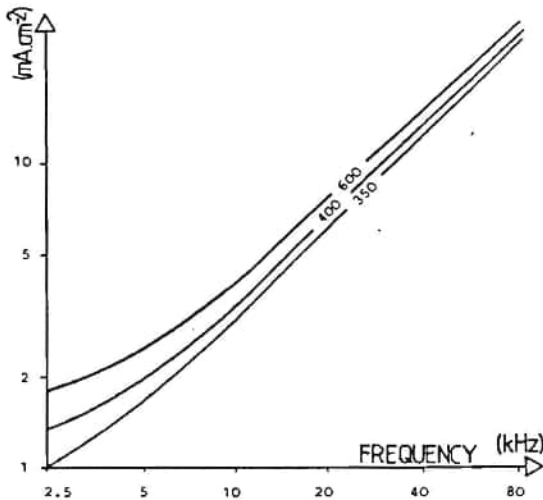


fig.3

To round off the report of our researches, we wish to mention some conclusions from a detailed study of nerve response to sinusoidal signals up to 70 kHz motivated by the House-Urban system of electrostimulation /6/, and the effects of modulation of such signals used as carrier frequencies. We find a local nerve response at high frequency but only a fraction of the peaks propagates along the nerve. Moreover the frequency of the propagated pulses varies as a function of amplitude. Fig. 3 shows how the firing rate varies as function of the carrier frequency signal and its amplitude from 350 to 600 Hz between a lower and an upper amplitude limit. Thus the volley principle cannot work because the frequencies excited on different fibers do not bear a clear relationship to those of the signal. These and other observations lead us to the conclusion that speech understanding cannot be achieved with this system.

The salient feature important for multi-channel stimulation is the interference of the responses produced by two spatially separated electrodes on one and the same fiber. The firing rate due to one electrode is influenced by that due to the other in a manner depending on the relative amplitude, thus leading to confusion.

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THE VIENNA COCHLEAR IMPLANT PROGRAM

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The attempt to help deafened people by electrostimulation of the acoustic nerve has proved effective during the last nine years. In 1975, the first steps of research and development aimed towards a cochlear prosthesis which in its present state enables 60 per cent of the postlingually deafened patients implanted in Vienna to achieve limited open-set speech comprehension without lipreading. It has been demonstrated that the method may convey usable information to the nerve and thereby to man which is far beyond simple eliciting hearing sensations by application of electrical current to the ear, a phenomenon observed long before. Looking at the result from a theoretical point of view it seems remarkable, how far the normal function of the ear can be replaced by that means.

The external speech processor employs a coding scheme based on the rate pitch principle. It may be combined with all Vienna implant systems featuring either an extracochlear electrode for fixation in the round window niche, a 6 mm intracochlear electrode or a 4 channel intracochlear electrode.

Experience with 63 patients implanted in Vienna and more than 110 world wide using systems based on the Vienna design provided with an analog broad-band signal for single site stimulation confirm that cochlear implants are finally emerging from being experimental devices. 3M already offers the extracochlear and the 6 mm intracochlear device and in Europe 7 centers have started their program with more than 20 patients.

The program was supported by the Austrian Research Council and conducted in cooperation between the Department of Electrical Engineering, Technical University Vienna and 2.ENT Department of the University of Vienna.

LARGE STIMULATION AREA COCHLEAR ELECTRODE*

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SUMMARY

The fabrication of a flexible microelectrode array suitable for use in a cochlear prosthesis is described. The conductors are made of platinum on a polyimide substrate. Photolithographic techniques are used to fabricate the electrode array on a planar film of polyimide. The film is subsequently rolled into a cylinder of 0.75 mm diameter and about 10 cm long. The platinum stimulation pads then form rings around the cylinder. This structure results in a large electrode area for stimulation and hence low current density. In vitro and in vivo tests so far give good results.

MATERIAL AND METHODS

Electrode Properties

The physical dimensions of the electrode are dictated by the size of the tympanic canal. Measurements taken from cadaver cochlear show that a diameter of 1 mm is the maximum that can be accommodated. To avoid physical trauma to the cochlear and to simplify the insertion of the electrode a diameter of 0.75 mm was considered desirable.

To optimize the intelligibility of speech, the electrode must be in contact with the area of the cochlear which approximately corresponds to 300 Hz to 3k Hz. It has been determined that the electrode must penetrate a distance of about 25 mm from the round window. This requirement determines the length of the electrode.

In order to successfully implant the electrode in the spirally shaped cochlear, the electrode must combine the correct flexibility and stiffness so that it will follow the shape of the tympanic canal without tearing the delicate membranes in the cochlear.

The number of single electrodes in the array is limited by the physical dimension of the Scala Tympani and the minimum diameter of the conductors in the array. Studies have shown that a good practical number is 8 to 12.

It is of the utmost importance that the electrode be inert in the perilymph which fills the Scala Tympani, that is, the electrode materials must be biocompatible. The insulating material must not absorb the perilymph nor should it leach out any foreign matter. The conductor chosen must maintain its integrity when subjected to electrical excitation in the harsh chemical environment. It is very important that the "active" area of the electrode be small enough to limit the spread of electrical stimulation to a confined area of the cochlear and yet large enough to keep the current density to a safe level.

The Art of Electrode Manufacture

The first recorded use of an electrode was by Volta who placed the electrode on his eardrum and applied a voltage to it. He subsequently likened his sensation to one of being "hit on the head". More recent electrodes can be classified into two broad groups. The first group is designed to go into the cochlear and therefore must be flexible. The second is designed to go directly into the auditory nerve and it must be stiff. The cochlear electrodes can be further classified according to the method of manufacture - those that are hand-made [1,3,4,5,6] as opposed to those that employ the photolithographic techniques developed in the semiconductor industry. [7,8,9,12].

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In terms of cost and reliability the electrodes made by the photolithographic method are superior. However, those that have been made have shown a number of severe drawbacks. They have tended to delaminate or have been toxic to tissue mainly because of the chemical etching methods that are part of the microcircuit production process. The result is that all the existing cochlear prostheses use hand-made electrodes for delivering the necessary current to the auditory nerve.

This paper is concerned with the development of an electrode that is flexible, non-toxic, reliable and which can be mass-produced and hence is inexpensive.

Electrode Design

The photolithographic process is a planar process so that it can produce an electrode in which all the single elements of the array are in the same plane. In order to accommodate the stimulation pads and features, within the 0.75 mm width, the electrode was designed as shown in Fig. 1(a) and (b). It is evident that the width of the electrode pads have to be severely restricted if all the feedlines are to pass by them. Since the surface area of the pad is an important parameter in terms of the maximum current density [10] it is necessary to make the pad as long as possible. However, it is undesirable to have electrode pads that overlap since each pad must stimulate only a specific region of the cochlear. It became evident that changing the orientation of the electrode pads from longitudinal to transversal would increase the distances between the pads but would aggravate the width problem. The width problem can be overcome if the planar electrode can be rolled to form a cylinder. This step has the added advantage that when it is placed in the cochlear, no particular measures need be taken to ensure that the electrode pads are as close as possible to the Basilar membrane. The electrode pad design was changed to that shown in Fig. 2. The problem of rolling the planar electrode into a cylinder is discussed later.

FABRICATION PROCESS [12]

A 10 cm silicon wafer is cleaned and about 1 μm of aluminum is deposited on it. A layer of polyimide 7 μm thick is now spun onto the aluminum. The viscosity of the polyimide and rpm can be varied to achieve this. The polyimide is cured and 400 Å of Titanium followed by 5000 Å of Platinum is deposited by sputtering. Positive photoresist is used to expose the areas of platinum not required (Fig. 2 shows the mask) and these are removed by sputter etch. A second layer of 7 μm of polyimide is spun onto the structure and after curing the polyimide covering the stimulating and contact pads is removed by sputter etching. The wafer is dipped into dilute HCL which dissolves the aluminum, thus separating the silicon wafer from the electrode array. The electrode array is cut and rolled into a cylinder.

Rolling the Planar Electrode into a Cylindrical Form

A special die is used to form the flat electrode into a cylinder. The die is shown in Fig. 3. It consists of a funnel leading to a circular hole of diameter 0.75 mm. The width of the polyimide substrate is $0.75 \times \pi$ mm so that as it is pushed into the hole, it folds over and the ends meet. The space inside the cylinder is then filled with medical grade silicone rubber. When the silicone rubber is fully cured, the electrode can be withdrawn. Fig. 4 shows the finished electrode with the transversal bands of platinum now taking the form of rings around the cylindrical structure.

RESULTS

The flexibility of the electrode can be controlled by changing the thickness of the polyimide film. A thickness of about 7 μm was found to give the appropriate mechanical properties for easy insertion into a plastic "cochlear" whose dimensions were taken from a cadaver.

The cylindrical electrode array has not yet been tested for toxicity. However, a planar electrode made of the same materials using the same process [12] is currently

being tested in chinchillas. Some samples have been implanted for over a period of 6 months and so far no adverse effects have been noted.

The electrode is currently undergoing in-vitro testing. During the last 6 months, a bipolar current density of 100 mA/cm^2 with a repetition rate of 300 Hz and pulse width of 0.3 mSecs has been applied. The electrode is removed and photographed every 2 weeks. So far no deterioration of the platinum pads has been detected, and the platinum/polyimide interface has maintained its integrity and the impedance between the electrodes in air is greater than $100 \text{ M}\Omega$.

Mechanical deformation tests in which the electrode array is curled into a spiral and then straightened have been carried out over a hundred cycles on one sample. No damage resulted. These tests are to continue with more samples.

Comparison with other Electrodes

	Hochmaier	Nucleus	Cylindrical
Pad Area mm^2	0.06	0.5	1.2
No. in array	16	22	9
Impedance at 1 kHz ($\text{k}\Omega$)	3.5	-	1.0

DISCUSSION

A flexible scala tympani electrode has been developed using standard photolithographic procedures. Platinum is used as the conductor material and it is deposited and etched by radio frequency sputtering. The substrate material is a polyimide film which is deposited in liquid form by spinning, followed by a high temperature cure. The masks used for defining the electrode configuration are generated by a standard computer software package; the masks have the appropriate dimensions for use without further reduction. Thus the electrode shape and dimensions can be very easily changed if this is deemed desirable. Except for the use of dilute HCl, (which is present in perilymph) the manufacturing process avoids the use of strong etchants which may be toxic to living tissue.

The mechanical deformation properties of the electrode array can be adjusted by varying the thickness of the polyimide film. So far bending and curling the electrode several hundred times have not produced any failures.

In electrical tests, currents well beyond expected stimulation requirements have been passed through the electrode but no deterioration of the platinum or the polyimide has been noticed. The impedance of the electrode at 1 k Hz is about 1 k ohm which means that a low voltage CMOS circuitry can be used in conjunction with it.

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Fig. 1(a) Stimulation pads and feedlines of the planar electrode. The pad dimensions are 0.965 mm x 0.05 mm. The line width is 0.05 mm.

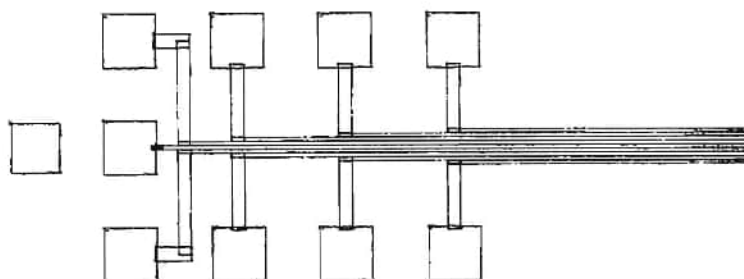


Fig. 1(b) Connection pads and feedlines of the planar electrode.

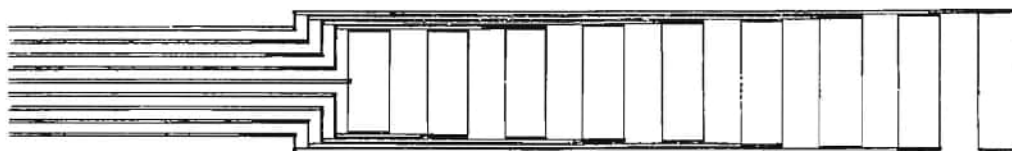


Fig. 2 Stimulation pads and feedlines of the cylindrical electrode before it is formed into a cylinder. The dimension of the stimulation pads are: Minimum - 0.89 mm x 1.37 mm. Maximum - 0.89 mm x 2.18 mm. Feedline width: 0.05 mm.

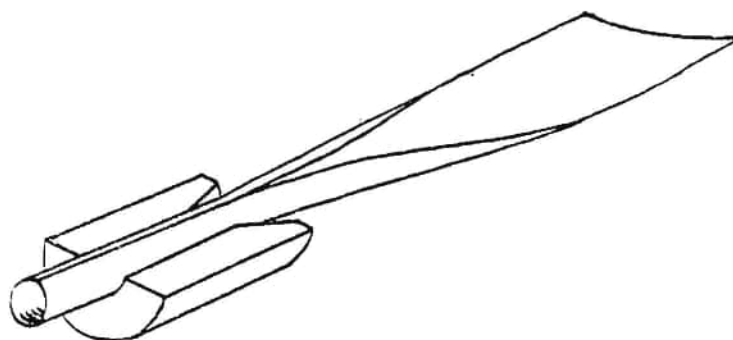


Fig. 3 Partial view of the die used in the formation of the cylindrical electrode.



Fig. 4 Photograph of the finished electrode. The stimulation pads are now transversal bands of platinum.

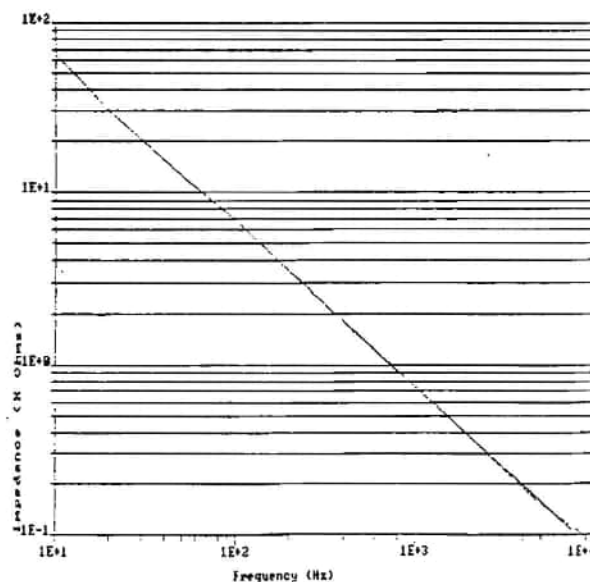


Fig. 5 Electrode impedance in artificial perilymph at 100 mA/cm^2 .

SINGLE FIBRE RESPONSES FROM CAT'S AUDITORY NERVE DURING ELECTRICAL STIMULATION WITH DIFFERENT TYPES OF MULTICHANNEL ELECTRODES.

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Implantation of cochlear prostheses in cats led to an increase of the acoustic threshold and affected the acoustically evoked discharges of primary afferents. The tested three multichannel devices show a clear but poor channel separation. The channel separation was higher with bipolar than with monopolar intracochlear stimulation.

The variation of thresholds for individual neurones using one stimulation channel was in the same or higher range than channel separation.

Such a strong channel interaction during multichannel stimulation suggests that although it is possible to evoke different discharge patterns near different electrode pairs a much higher degree of channel separation would probably be needed for speech coding systems.

For sensorineurally deaf patients several types of cochlear implants have been developed. In contrast to monopolar devices, multichannel systems should utilize frequency-place (place pitch) in addition to time structure (periodicity pitch) coding of speech signals. This paper examines how 3 different types of intracochlear multichannel electrodes code pitch in animal experiments.

13 adult cats (body weight between 1.6 and 3.6 kg) were premedicated with 0.25 mg atropine and anaesthetized with pentobarbital (32 mg/kg i.p.). During the experiments end-tidal CO₂, blood pressure and body temperature were controlled /1/.

A silver wire ball electrode was placed near the round window (RW) to record compound action potential frequency threshold curves (CAP FTC) for monitoring the condition of the cochlea. The large indifferent electrode was inside the ipsilateral middle ear at the bulla wall.

Single fibre recordings from the VIIIth nerve were performed via a posterior fossa approach. Glass microelectrodes ($Z > 20$ megOhm) were inserted under visual control in the region of the internal auditory meatus. Care was taken to record only from primary auditory fibres.

The stimulating devices were either a 4-channel cat (4-ch c; /2/), a 8-channel human (8-ch h; /3/) or a 22-channel human (22-ch h; /4/) electrode. The electrode was inserted via the opened RW in the scala tympani (ST). Priority was given to implant the electrode without damaging the cochlea rather than to insert the entire array.

Both the 4-ch c (tip diameter $\varnothing = 0.7$ mm; distance of individual electrode pairs: 1.2 mm) and the 8-ch h device ($\varnothing = 0.45$ -0.8 mm; intraelectrode distance = 1.5 mm) have mushroom/ball like knobs as stimulating electrodes whereas the 22-ch h electrode ($\varnothing = 0.5$ mm; intraelectrode distance = 0.75 mm) has rings. The knobs are arranged in such a way that after implantation one knob of a stimulating pair lies under the basilar membrane whereas the other of the pair lies adjacent the spiral lamina beneath the spiral ganglion. In case of monopolar stimulation the individual knobs or rings were stimulated against the indifferent middle ear electrode. With bipolar stimulation every neighbouring knob or ring made a stimulating pair.

The characteristic frequency (CF) of each recorded neurone was determined by acoustic stimulation in a closed sound system (earphones: Bruel & Kjaer 4145 1-inch microphone). With known CF it is possible to determine the place of origin of the fibres inside the cochlea. Stimuli were computer controlled shaped 50 ms (5 ms rise-fall time) or 5 ms (1 ms rise-fall time; only for CAP FTCs) tone bursts. Electrical stimulation was performed with an optically coupled constant current source (< 2 mA rms). The current was measured as voltage drop across a serial 10-ohm resistor, using a high impedance differential amplifier. Electric stimuli

were 100 Hz continuous sinusoids.

Details on stimulus artifact reduction have been published elsewhere [1;5/.

Neural discharges were evaluated on-line (PDP 11-34).

Implantation of all three devices led to an increase in acoustical threshold and distorted acoustic response pattern.

Fig.1 shows CAP FTCs of one animal before implantation, after removing of the RW-membrane and after implantation of the 22-ch h device. Removing of the RW-membrane led to decreases in the acoustic threshold of 12 dB below 1 kHz and 5.8 dB between 1 and 10 kHz. Above 20 kHz, the threshold increased by 5.8 dB. Although the 22-ch h array was only inserted to a depth of 5.5 mm in the ST in this experiment the threshold of CAP FTC increased of about 5.6-17 dB below 8 kHz and 30.4 dB in the high frequency range.

Only fibres with $Cf < 2$ kHz showed normal acoustical response pattern. Above $Cf = 2$ kHz as tuning curves and iso-intensity impulse rate functions of the neurones showed them to be tuned to more than one acoustic stimulation frequency.

The disturbance of acoustically evoked responses was higher for 4-ch c and 8-ch h than for 22-ch h electrode. The post implantation hearing loss increased with time.

Fig.2 shows 4 types of typical threshold (20 impulses/s above spontaneous activity) curves with 100 Hz bipolar electrical stimulation for 3 electrodes tested. In most experiments there was a clear dependence of threshold currents on the depth of the implanted electrode channels inside the ST. Threshold were lowest for the apical channel and showed a continuous increase as stimulation was applied to more basal channels. A second type of flat or L-shaped threshold curve was found. In this cases, the threshold was relatively independent of the stimulation channel. Rarely type 3 threshold curves were seen, with lower threshold at the basal channel (4-ch h: 11%; 8-ch h: 14%; 22-ch h: 0 %). A 4th type, the V-shaped threshold curve, was seen only with bipolar electrical stimulation with the 22-ch h electrode (21%). In one experiment with the 8-ch h electrode using monopolar electrical stimulation a V-shaped threshold curve was found. In this example channel 4 had lower threshold currents than the more apical channels 2 and 3 (Fig.3, P44).

The other examples in Fig.3 show a clear apical to basal order of the rate-level functions with both monopolar and bipolar 100 Hz electrical stimulation. The thresholds for monopolar stimulation were lower than for bipolar stimulation (Fig.3).

The mean threshold currents of the apical channel 1 (I) with 100 Hz electrical monopolar stimulation were 28 dB for 4-ch c (P35), 24 dB 8-ch h (P44) and 25 dB for 22-ch h (P37) electrode; with electrical bipolar stimulation 39.6 dB for 4-ch c (P35), 30 dB 8-ch h (P44) and 39 dB for 22-ch h (P37).

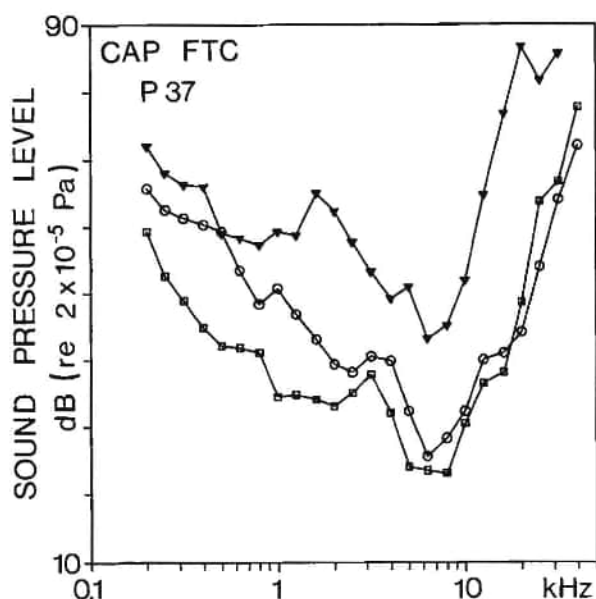


Fig. 1: Compound action potential frequency threshold curves (CAP FTC) from one animal (P37). Sound pressure level in dB as function of stimulus frequency.

○ - before opening the cochlea
□ - after removing of the RW-membrane
▽ - after implantation of the 22-ch h electrode

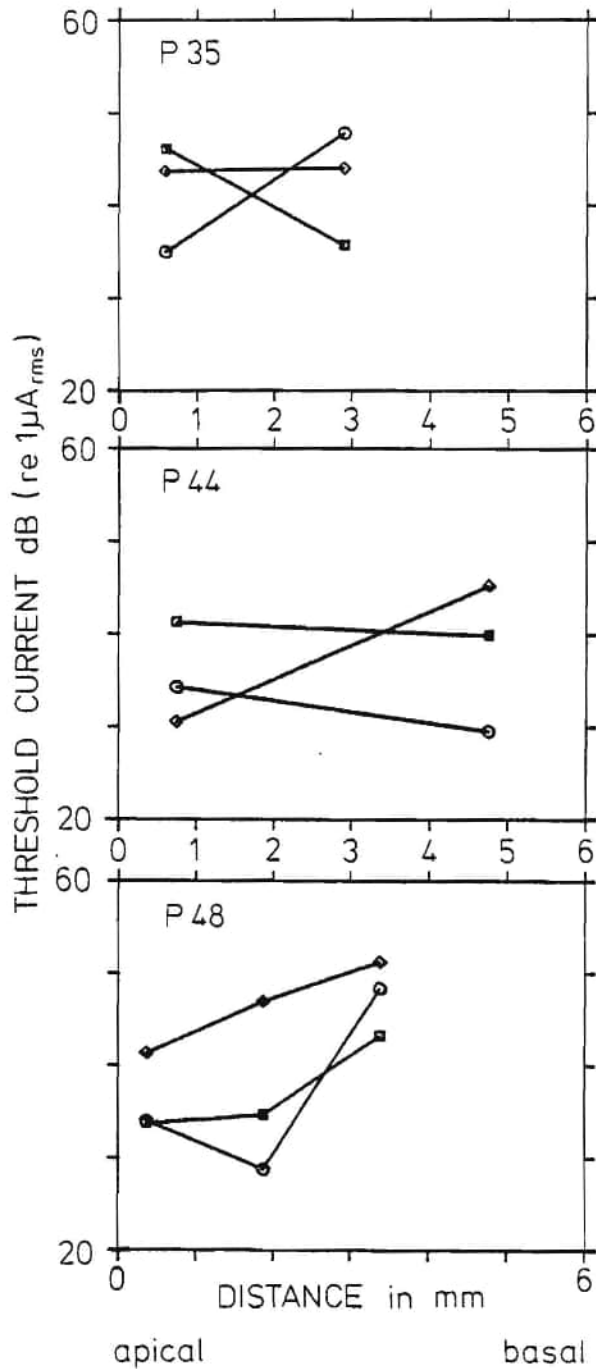


Fig.2: Neuronal responses to 100 Hz bipolar electrical stimulation. Threshold as function of distance of the most apical electrode in mm. Apical electrode ring/knobs equal 0.
P35: 4-ch c; P44: 8-ch h; P48: 22-ch h.
For each device 3 typical threshold curves are shown.

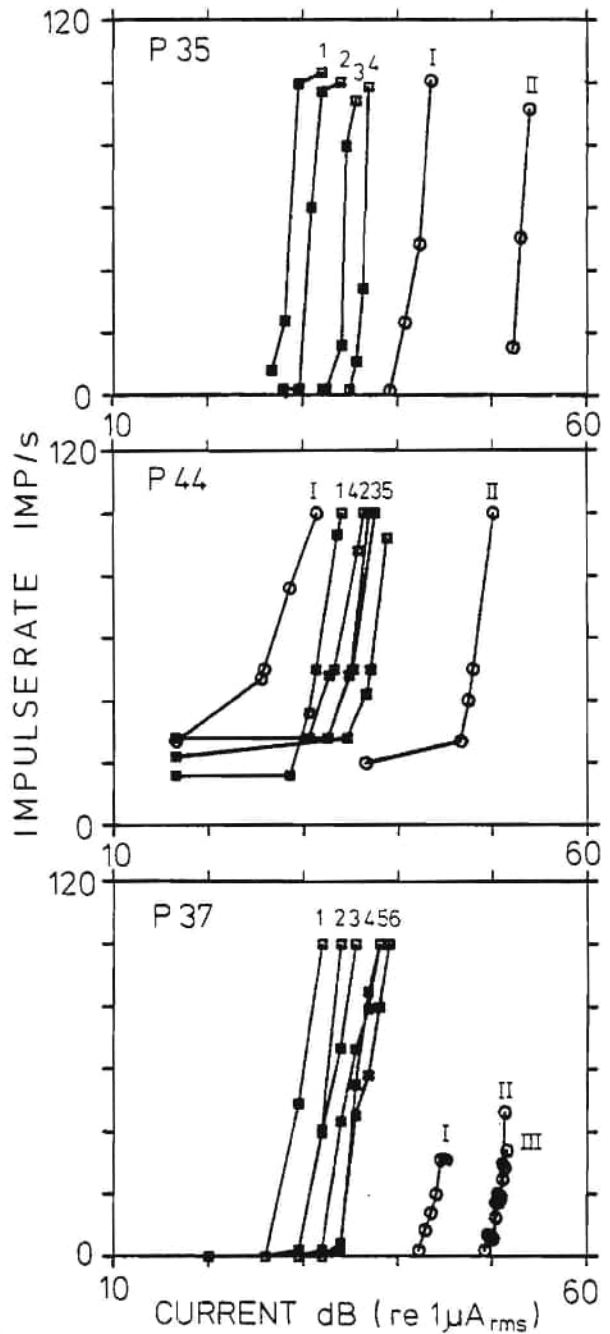


Fig.3: Comparison of rate-level functions with monopolar (arabic numbers; square symbols) and bipolar (roman numbers, circle symbols) 100 Hz electrical stimulation. Mean discharge rate of one neurone as function of stimulation current.
P35: 4-ch c, P44: 8-ch h; P37: 22-ch h.
The numbers are arranged in such a way that the apical stimulation channel is number 1 (I) with increasing numbers for the more basal channels.

The channel separation for bipolar 100 Hz stimulation determined from the steepest slopes of the averaged threshold-place functions for type 1 of the threshold curves were 2.5 dB/mm for 4-ch c, 1.95 dB/mm for 8-ch h and 7.4 dB/mm for 22-ch h electrode. The V-shaped type of threshold curve had slopes of 4.3 dB/mm (apical) and 13 dB/mm (basal).

In our experiments implantation of all devices led to an increase of acoustical thresholds and to acoustical response pattern abnormalities which increased with time to finally produce total deafness. However, one must consider that the 8-ch h and the 22-ch h electrode were human devices and that the size and the length of the cochlea in the cat are considerably smaller. Therefore best channel separation was found with the smallest diameter electrode, the 22-ch h electrode.

Because of the abnormal acoustical response pattern it was not possible to determine the CF of fibres with $CFs > 2$ kHz, and therefore we could not estimate the place of origin of the neurones inside the cochlea. For middle and high frequency fibres correlation between place of stimulation and place of activated fibre was unknown.

Hence it is difficult to interpret the different types of threshold curves. Type 1 showed a similar course of threshold curves as we got from $CF < 2$ kHz fibres, so we suggest that this might be fibres whose place of origin in the cochlea is basal from the stimulation electrode position. In cases where V-shaped curves were seen, we believe that the implantation depth of the electrode was close to the place of origin of these fibres.

Channel separation for all tested implants was better for bipolar than for monopolar stimulation. Interfibre threshold differences at a given electrical channel were similar or higher than interchannel threshold differences (4-ch c: 5.2 dB; 8-ch h: 36.4 dB; 22-ch h: 9 dB). Our preliminary results show however that channel separation can be improved by applying inhibitory stimulation patterns to adjacent electrode pairs.

The average threshold at 100 Hz stimulation was lowest for the 8-ch h electrode (30 dB). The intraelectrode distance between the bipolar electrode pairs were highest (1.5 mm) for this type of prosthesis. For the 22-ch h electrode we could show that the threshold decreases with increasing intra-electrode distance by 5.7 dB/mm.

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Abstract

Title:	PARAMETERS FOR DIRECT STIMULATION OF THE DENERVATED POSTERIOR CRICOARYTENOID MUSCLE
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As a means of determining the stimulation parameters useful for a laryngeal pacer, electrodes were implanted in innervated, curarized, and denervated posterior cricoarytenoid muscle (PCA) and vocal cord excursion assessed. Pulse duration and amplitude, intramuscular vs. superficial electrode placement, and bipolar vs. monopolar stimulation modes were manipulated in the eight dogs studied. Vocal cord excursion could be increased by augmenting either stimulus amplitude or pulse duration, these parameters exhibiting a hyperbolic relationship when assessed for a given vocal cord excursion. Denervated PCA required about 90x more charge per pulse in order to achieve a vocal cord excursion equivalent to that in a dog with innervated PCA. With denervated PCA, the charge per pulse necessary to achieve a given excursion was lowest at stimulus duration of .5msec and amplitude of 20mA, representing the values of peak efficiency of current utilization. Neither stimulation mode nor site of electrode placement significantly affected excursion for a given set of stimulus parameters. With a bipolar stimulation mode, however, pulse duration could be increased to 100x that applied in a unipolar mode before excessive current spread would activate surrounding muscles.

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FUNCTIONAL ELECTRICAL STIMULATION IN BILATERAL RECURRENT NERVE
PALSY in SHEEP: FUNCTIONAL AND BIOCHEMICAL RESULTS: x)

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SUMMARY

Bilateral recurrent nerve palsy is most frequently caused by thyroid gland operations. The paralysis of the glottis opening muscles (M. postici) causes a severe narrowing of the glottis. Due to this, shortness of breath occurs, which often makes a tracheotomy necessary as primary treatment.

The multitude of treatments of bilateral recurrent nerve palsy shows that a therapy of choice does not exist. Several different laterofixation techniques as well as glottiswidening techniques by means of vocalcord resection, may better respiratory function but have the disadvantage of voice degeneration, are mostly irreversible and mutilating.

With the goal of achieving a breath correlated glottis opening, this study group is engaged in direct electrical stimulation of the paralysed posticus muscle of experimental animals.

MATERIAL AND METHODS

A one sided recurrent nerve palsy was set by resecting a nerve piece of approximately 2 cm length. Bipolar electrodes were implanted into the ipsilateral posticus muscle. The denervation time varied in each of the five animals (Tab. 2) upon which a intermittent, chronic, direct electrical stimulation was begun over an external stimulation unit.

The following stimulation parameters were used:

Biphase exponential current

Amplitude: 7mA

Frequency: 10 Hz

Impulseduration: 30 msec

Stimulation / Pause : 1,5 sec / 2 sec

The duration of stimulation per day started with 12 hours and was increased upto 24 hours (Tab. 1) whereby a intermittent current was used. The outcome of stimulation was documented with a direct microlaryngoscopic videorecording of the vocal cord abduction. The degree of the vocalcord abduction angle was used as the parameter (Tab. 2).

After termination of the test, the denervated and stimulated muscles were removed and examined histochemically. In two animals (S23, S24) biochemical examinations were also performed.

X)Supported by the Austrian Research Foundation, P5183

The determination of the myosin-heavy-chain isomeres was done by one dimensional gel electrophoresis on cryostat sections. Quantitative analysis was made by densitometric scanning.

	S20	S21	S23	S24	S25
Stim. /d					
12h	23d	23d	14d	14d	13d
15h	7d	7d	12d	12d	18d
18h	20d	20d	28d	28d	14d
20h	5d	5d	7d	7d	-
22h	4d	4d	7d	7d	-
24h	41d	-	9d	9d	100d

Tab. 1: Stimulationprogram of 5 sheep
Stim.: Stimulation; d: days.

RESULTS

Table 2 shows that all animals achieved a vocalcord abduction sufficient for respiration throughout the test. In one animal it was possible to hold up a vocalcord abduction angle of 27° over a 100 day time period using a chronic, 24-hour cyclic, direct electrical stimulation (Tab. 2; S25). Correlated to the average angle of the sheeps' thyroid cartilage laminae, this degree of one sided glottis opening means maximal abduction. In all cases, the termination of the experiment was due to the corrosion of the stimulation electrodes.

The intact posticus muscle of sheep S23 had a slow myosin-heavy-chain percentage of 57, in S24 it amounted to 50%. After quantitative analysis the stimulated muscle of the same animals showed a slow myosin-heavy-chain percentage of 85% for sheep S23 and 94% for sheep S24.

	S20	S21	S23	S24	S25
Denerv.	91d	75d	15d	15d	13d
AA/12h	10°	15°	14°	16°	-
AA/15h	17°	16°	23°	18°	28°
AA/18h	18°	32°	25°	17°	24°
AA/20h	18°	32°	-	-	-
AA/22h	18°	18°	-	-	-
AA/24h	17°	-	25°	17°	27°

Tab. 2: Denervation time before chronic stimulation and the vocalcord abduction angle at the end of a stimulation interval.<5 Sheep>.
Denerv.: Denervation time; d: days; AA: Abduction angle.

DISCUSSION

The vocalcord abduction angles show that the denervated posticus muscle of sheep can be kept irritable by means of direct electrical stimulation over a long period of time (weeks). The tendency of the opening angle to decline towards the end of the experiment is not due to muscle tiring or damage as macroscopic and microscopic results prove. Moreover, the corrosion of the stimulation electrode as well as the formation of granulation tissue around the electrode seem to be the cause.

The biochemical results of the myosin-heavy-chain analysis add to and confirm the results found histochemically. These show that a denervated posticus muscle converts into a muscle consisting of slow muscle fibers by means of direct electrical stimulation. The biochemical results are also in conformity with literature, where it is stated that slow myosins accumulate in denervated muscles after low frequency direct electrical stimulation. The amount of the myosin-heavy-chains can, nevertheless not be directly correlated with the fiber type pattern since slow and fast myosin can also be differentiated in types of light chains.

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Functional Electrical Stimulation in Bilateral Recurrent Nerve Palsy in Sheep: Morphological Results.

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This paper offers an overview over the morphological changes observed in posterior cricoarytaenoid (PCA) muscles of sheep which were denervated and afterwards chronically stimulated (see Table 1). For further information about the experimental setup and the functional results refer to the paper of Dr. Zrunek in this volume and References 1 and 2. In this paper only the main experimental effects are reported concerning morphological alterations caused by:

1. mechanical irritation due to the implantation of the electrodes,
2. the longest continuous denervation periods (see Table 1) and
3. chronical electrical stimulation.

Their morphological effects were analyzed by using histological, histochemical and planimetric methods at the end of the experiments, when the pair of PCA muscles was totally excised. The untreated contralateral muscle of each animal was used for control.

Histological analysis reveals formation of scar tissue accompanied by large group atrophy of muscle fibres at the site of the implanted electrodes. Furthermore, the abnormal variability of fibre sizes (see Table 3) observed in the whole cross section of stimulated muscles was more pronounced in the vicinity of the scar.

Apart from signs of fibre degeneration caused by mechanical irritation other marks of degeneration, such as small group atrophy with angulated fibres and scattered myolysis, typical for denervation (3), occurred in the experimentally treated muscle tissue. The degree of these alterations depended on the duration of the longest continuous denervation period.

In electrically stimulated PCA muscles numerous highly active and centrally situated myonuclei are observed, which indicates increased muscle fibre metabolism (3). Obviously these signs of regeneration are caused by chronical electrical stimulation, since similarly configured myonuclei are absent in merely denervated muscles.

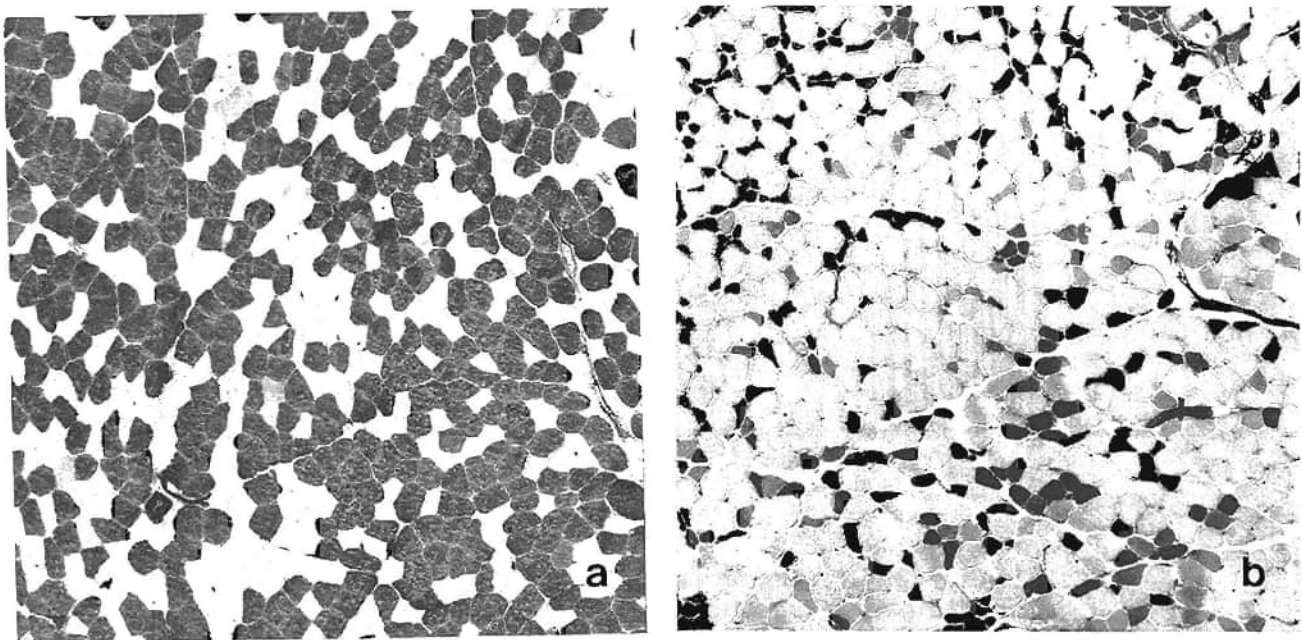


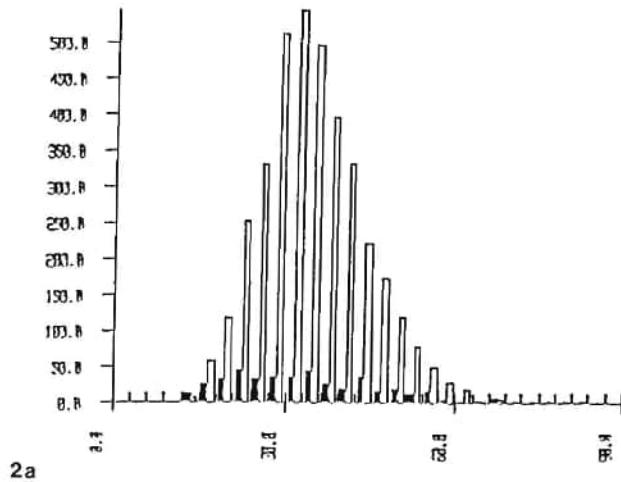
figure 1a,b: Routine ATPase staining of a untreated control (a) and a stimulated (b) muscle. (Magn.: 80)

Further histological alterations in experimentally treated muscle tissue are the proliferation of connective tissue and an increase in the number of fat cells. Table 2 shows the higher percentage of endomysial area determined by planimetical means. Perivascular infiltration and myophagia, characteristic for massive myonecrosis (3) and visible in merely denervated muscles, could not be observed either.

The NADH stain of muscle fibre cross sections shows uniformly increased activity of oxydative enzymes in stimulated muscles. This observation confirms the higher metabolism in an overwhelming majority of the fibres.

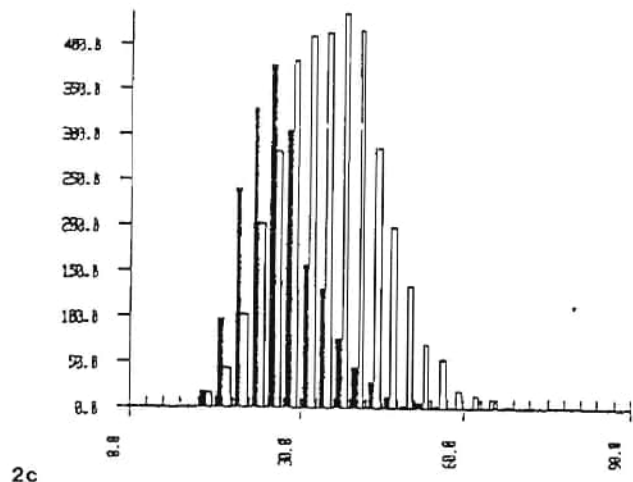
The routine ATPase staining (Ref. 4 and Fig. 1a and b) discloses a relative increase of type I fibres due to transformation of type II fibres into type I fibres in the stimulated muscles. The staining intensity of all type I fibres in stimulated muscles in any case is higher than that of the untreated control muscles. This observation implies that the stimulated type I fibres show higher ATPase activity.

S-SEP 24 POSTICUS dm. 15d; stm. 77d; brk. 70d; sta. 62d: fibertyp1:hlu;2:sld



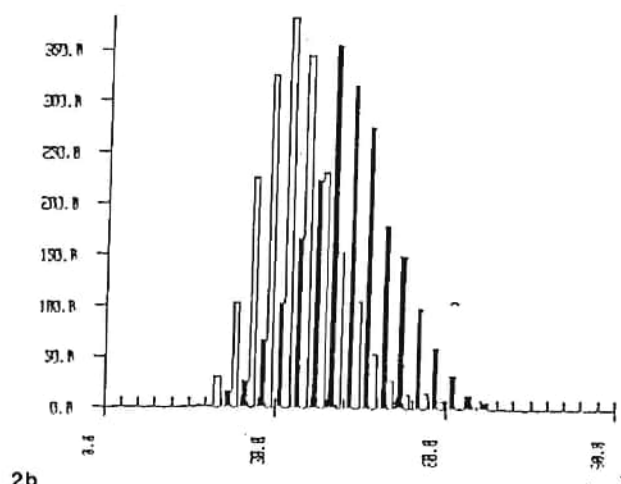
2a

S-SEP 23 POSTICUS dm. 14d; stm. 68d; brk. 63d; sta. 41d: fibertyp1:hlu;2:sld



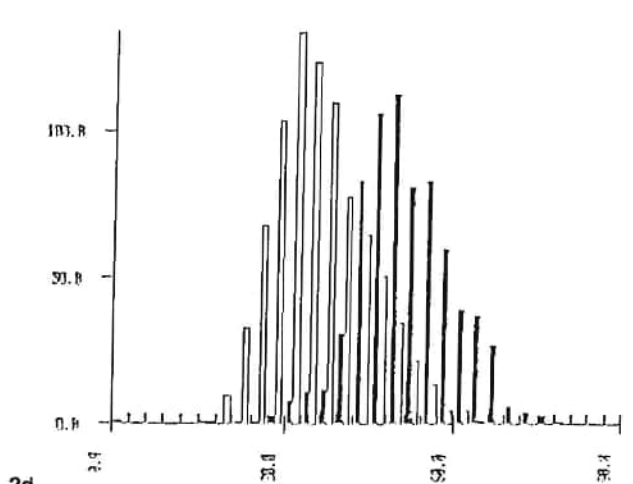
2c

S-SEP 24 CONTROL POSTICUS MUSCLE: fibertyp1:hlu;2:sld



2b

S-SEP 23 CONTROL POSTICUS MUSCLE: fibertyp1:hlu;2:sld



2d

figure 2a-d: Histograms showing the distribution of fibretypes using their diameter as the parameter of classification.

Type I fibres represented by hollow columns, type II fibres by solid ones.

- (a) long term stimulated muscle
- (b) control muscle of (a)
- (c) short term stimulated muscle
- (d) control muscle of (b)

Sheep	Denervation Period (d)	Stimulation Period (d)
20	90	111
21	75	73
23	97(83*)	121(41**)
24	93(78*)	139(62**)

* longest continuous denervation period

** final stimulation period

table1: periods of denervation and functional electrical stimulation; stimulation parameters: 10Hz, +7mA bipol. exp. pulses, pulsewidth: 30ms, duration: 12-24h per day(d).

Functional stimulation of sheep 23 and 24 had to be interrupted for technical reasons. The periods effecting the alteration of the fibre pattern most significantly are shown in brackets.

Sheep	Type I Fibre(A%)	Type II Fibre(A%)	Connective Tissue(A%)
CTL	10,7	35,0	55,3
20 STM	26,6	5,9	67,5
CTL	15,6	47,3	37,0
21 STM	42,0	9,9	48,1
CTL	19,7	33,4	46,8
23 STM	25,1	7,5	67,5
CTL	22,0	37,8	40,2
24 STM	33,4	3,8	62,8

table2: percental area distribution (A%) of type I and II fibres and the connective tissue of PCA muscle cross sections.

Sheep	Type I Fibres			Type II Fibres		
	MD (um)	VC	n%	MD (um)	VC	n%
CTL	20,4	0,32	45,3	33,6	0,23	54,7
20 STM	26,1	0,29	71,7	19,6	0,30	28,3
CTL	28,1	0,26	40,9	40,7	0,18	59,1
21 STM	36,7	0,27	65,3	24,4	0,30	34,7
CTL	36,0	0,24	54,7	51,5	0,18	45,3
23 STM	35,5	0,26	65,7	26,8	0,26	34,3
CTL	33,4	0,22	49,3	43,2	0,19	50,7
24 STM	34,5	0,27	89,7	34,0	0,39	10,3

legenda: MD...mean-diameter (in um) CTL...control muscle
VC...variability-coefficient STM...stimulated muscle
n%...relative frequency

table3: comparison of the MD, VC, n% of type I and II fibres between the stimulated and the contralateral control PCA muscles.

The VC corresponds to the variability of fibre sizes. The type II fibres particularly tend to have a higher variability in stimulated muscles.

Additionally, routine ATPase staining reveals a selective type II fibre atrophy. This phenomenon is caused by the higher sensitivity of type II fibres to denervation (5) on the one hand, on the other hand chronical stimulation favours type I fibres, as mentioned earlier.

The qualitative results described above are quantified by histograms (Fig. 2 a to d) documenting the results of the planimetric analysis. Figures 2 a to d show that the transformation of fibres is more conspicuous in long-term stimulated muscles- it amounts to nearly 90 per cent of type I fibres in a cross section (Table 3)- whereas selective type II fibre atrophy expressed by the shift of the solid columns towards the left side in the histograms is typical for short-term stimulated muscles. The percental area (see Table 2) of muscle fibres, calculating the fibre sizes as well as their relative frequency, was evaluated to confirm the increase of type I fibres. This change of the fibre pattern was observed in all four animal experiments. The degree in which it depends on the duration of the stimulation periods is non-linear, since transformation of type II fibres slows down. The modus of dependency is already described by more elaborate studies on chronical electrical stimulation of skeletal muscles (6, 7).

Finally, it should be mentioned that the results of these studies, despite the shorter or even absent denervation period, were very similar to our findings. It is planned to increase the rather limited number of samples in order to evaluate enough data for proper statistical analysis.

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REHABILITATION OF MICTURITION IN PATIENTS WITH INCOMPLETE SPINAL CORD LESIONS BY TRANSURETHRAL ELECTROSTIMULATION OF THE BLADDER

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SUMMARY

This report presents the results with transurethral electrostimulation according to Katona (1975) in patients with neurogenic bladder dysfunction due to an incomplete spinal cord lesion during 1978 and 1985. According to our findings this method is helpful in the restoration of micturitions in patients with incomplete spinal cord lesions in regards to the development or improvement of bladder sensation, development or improvement of bladder contractions, induction or improvement of conscious bladder control and efficiency of micturition as shown by the decrease of residual urine.

METHOD AND MATERIAL

The stimulation technique involves direct intraluminal monopolar electrical stimulation via a special catheter equipped with a silver tipped electrode, which is connected by a thin wire through the catheter to the stimulator. The active electrode is placed in the bladder, the neutral one preferably is located on a skin area with normal sensation. Stimulation is carried-out by impulse packages. Their duration, the intervals in between and their rise-time can be varied from 1 to 10 s; each package is built up by impulses with a current variable between 1 and 10 mA, with an impulse duration between 6 and 8 ms and a frequency of 70-100 Hz. Thus, individual stimulation can be applied according to the response of the bladder during stimulation monitored by continuous urodynamic control. Therefore during the stimulation the intravesical and intrarectal pressure are recorded continuously.

The scheduled treatment comprises 5 stimulations weekly, with a daily stimulation time of about 90 min.. The course is terminated if no bladder sensation or changes in the pattern of bladder contractility occur during the first 15 stimulations, otherwise it is continued until maximum improvement is achieved.

The basis for this treatment is as following: in incomplete lesions at least some nerve fibres between the bladder and the central nervous system are preserved. During the first phase of intravesical electrostimulation receptors are thought to be activated or reactivated, in a further phase a sensor-motor-reaction occurs during the stimulation-periods, resulting in bladder-sensation, detrusor contraction and an increasing degree of voluntary inhibition. The basic principle therefore is a receptor-stimulation. It was already proved by Katona, that the above mentioned effects of transurethral electrostimulation are abolished by intravesical application of Xylocaine.

Between 1978 and 1985 138 patients, 105 males and 33 females with incomplete spinal cord lesion underwent transurethral electrostimulation because of neurogenic bladder dysfunction suffering initially mainly

from an areflexia or a hypocontractility of the detrusor.

RESULTS

27 patients received more than 30 TES, 11 with an excellent result, 25 with partial success and 41 without clinically relevant response; 61 patients received less than 30 TES, in 39 the result was excellent, in 12 a partial success was achieved, whereas in 10 TES was without clinically relevant effect.

In regards to bladder contractility from those with areflexia or hypocontractility of the detrusor 67 % achieved a normocontractile detrusor, 26 % remained either a- or hyporeflexic, and in the remaining patients there was some improvement. About 50 % of the patients with no or minimal sensation of the bladder at the beginning gained perfect bladder sensation. From those patients, who could not void at all at the beginning or had significant residual urine (over 50 cc) about 60 % voided with none or minimal residual urine (up to 50 cc), 23 % showed some improvement and had a residual urine between 50 and 100 cc, whereas in 23 % no effect could be observed with transurethral electrostimulation.

62 % showed a significant improvement of conscious urinary control, 1/3 of them with normal control of micturition, in 38 % no relevant improvement was seen.

DISCUSSION

Discussing the results in patients with incomplete lesions one can always argue as to what would have happened if no stimulation had been undertaken. To overcome these difficulties at least to some extent, we have compared the urological improvement with the overall neurological progress in these patients using Frankel's scale. This comparison shows that in fact 2/3 of the patients during their stay in the Rehab.Center also showed a neurological improvement, but nevertheless 1/3 of the patient showed urological improvement only. Moreover, there is no control group treated without stimulation to compare with. In regards to such a control group one can argue, that it seems to be rather difficult to form two comparable groups of patients with incomplete lesions as each of these patients shows a specific pattern with an individual capacity of recovery.

However, which are the facts, leading us to believe, that it is really the stimulation and not the time going by which brings the results?

Firstly there is a close, time related correlation between recovery of detrusor function, and the transurethral electrostimulation-programme.

Secondly, this progress in the recovery of bladder function and bladder control does not correlate with the recovery of somatic function in about 30 % of the patients. Thirdly, about 20 % of the patients who had been stimulated, ask for restimulation, because of weakening of the stimulation effect after 6-12 months.

There are definite advantages of transurethral electrostimulation: it is a non-invasive technique, that can be performed without interfering with other rehabilitative measurements and it can be repeated if the therapeutic effect is becoming weak. Disadvantages however are that the method is time consuming, that at least one well trained nurse doing this as a fulltime job is necessary and, moreover, up to now we have no test, by which we can really predict whether the patient will respond to electrostimulation or not.

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A 24-OUTPUT IMPLANTABLE STIMULATOR FOR FES

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SUMMARY

During the last eight years, a 24-output stimulator has been developed for FES and several have been implanted in patients. The device uses a solder-sealed hermetic package, a silicone rubber encapsulant, no blocking capacitors, and two r.f. inductive links. Lessons from this work are summarised.

HISTORY

- 1978 Design of custom PMOS multiplexing chip/1/.
- 1979 Design of hybrid circuit.
- 1979-80 Trial hermetic seals, coil connections and moulds.
- 1979-81 Made 9 "dummy" implants for in vitro tests.
- 1981 Two "Mk I" devices implanted in paraplegics (failed after 7 and 6 months respectively).
- 1982 Improved electrical and mechanical design.
- 1983-86 Four Mk IIs implanted. One removed because of infection. In June 1986, the others have been working for 2yr 9mo, 2yr 2mo and 6mo respectively.

Mk I

Figure 1 shows a cross section through the Mk I. An alumina package, containing the hybrid circuit, is in the middle, attached to the base plate disk, also made of alumina, which supports the two coils, one circular and one 8-shaped /2/. On the right, there is a gold post, to the bottom of which a coil is terminated by soldering (Sn-Pb), while a wire bridges between the top of the post and one of the package feedthroughs pins. Figure 2 shows an assembly before introducing it to

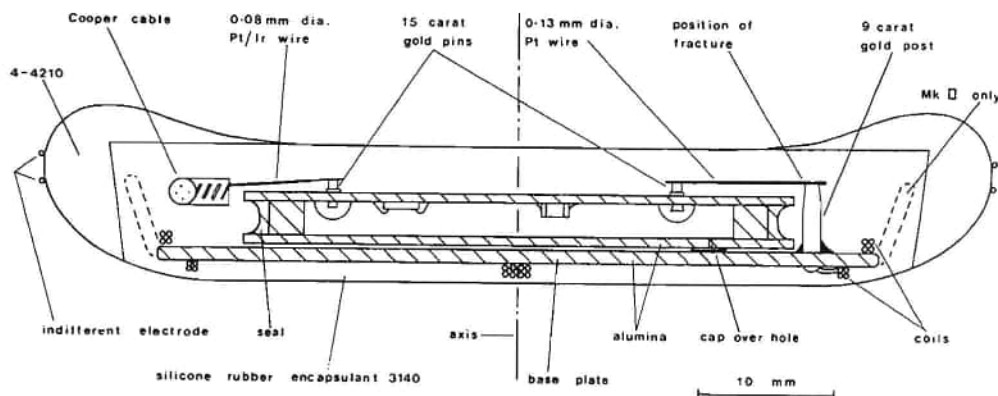


Fig. 1

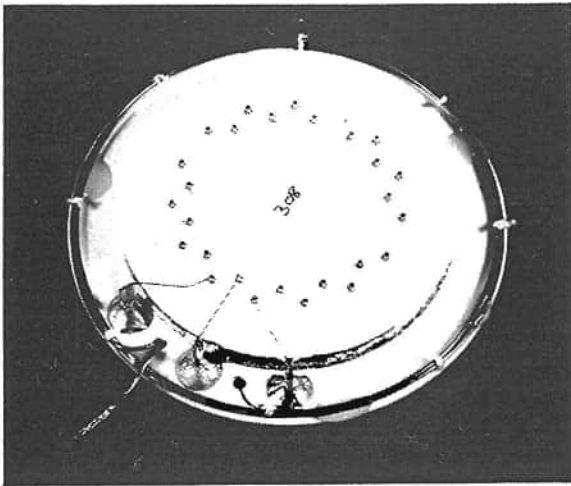


Fig. 2

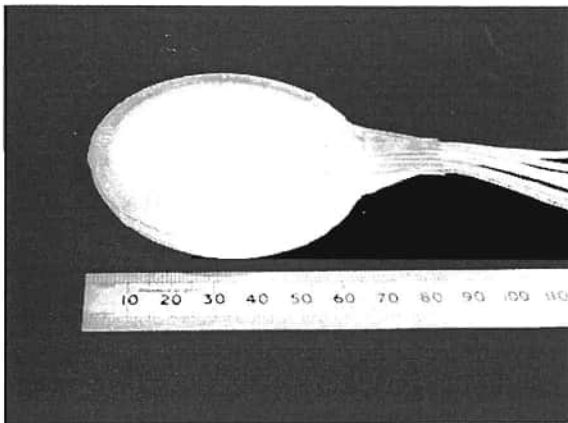


Fig. 3

the jig which holds the Cooper cables /3/ in place, ready for welding to the 24 output pins. Adhesive silicone rubber (Dow Corning 3140) is cast round the whole and it is finished by a second moulding in medical grade 4-4210 which leaves a more comfortable rounded edge. Both the two Mk I devices failed due to fatigue fracture of a bridging wire near a weld, at the point shown in figure 1. As I have described /4/ the soft platinum wire was replaced by springy gold alloy clips with a much better fatigue life. Since, presumably, the Pt wire had been frequently stressed by movement of the surrounding soft rubber when the implant was squeezed, the Mk II was also improved by having an alumina dish made (shown dashed in fig. 1), instead of the disc-shaped base plate, to support the rubber round the rim of the implant, and shield the 27 vital connections to the feedthrough pins from the radial forces to which the device is subjected. Figure 3 shows a completed Mk II. The platinum indifferent electrode wires can be seen on the perimeter; also the four Cooper cables, each with four output wires.

INTEGRAL-SUBSTRATE PACKAGE

The thick-film hybrid circuit is shown in figure 4 before the lid attachment. Here is an outline of the construction:

1. The alumina is cut and drilled by laser.
2. The thick-film circuit (including resistors) is printed on the substrate. The lid is also metallised.
3. Gold pins, for the feedthroughs, are rivetted through the substrate.
4. The pins are sealed by solder (Sn-Ag) and the chip capacitors are soldered on.
5. The substrate is cleaned.
6. The alumina ring and the semiconductor chips are glued in place with epoxies.
7. Semiconductor wire bonding.
8. The circuit is covered with junction coating resin (Dow Corning R-6103).
9. After placing a copper ring over the wall, the lid is attached with epoxy. This is cured and the circuit baked at 150 deg C.
10. The package is evacuated, back-filled with helium through a small hole in the lid, and a small cap is soldered over the hole; all without cooling the package.
11. The epoxy seals are helium-leak tested.

12. A solder seal (Sn-Pb) is formed round the perimeter of the package between the copper ring and the metallisations on the lid and substrate.
13. The solder seal is helium leak tested.

This double seal allows the circuit, after baking dry, to be sealed without contamination by flux. For a successful seal, the time constant of water vapour entering the cavity, based on measurements of the rate that helium leaks out, is over 1000 years.

IN VITRO TESTS

The dummy implants, tested in Tyrode's solution at 37 deg C, were made like this except that the first six had no solder seal. Of these "non-hermetic" devices, three have catastrophically failed (at 1yr 7mo, 5yr 1mo, & 6yr 6mo), one due to corrosion outside the package (at a copper-to-gold weld which was never repeated), and two due to moisture inside the packages, causing dendrite growth between

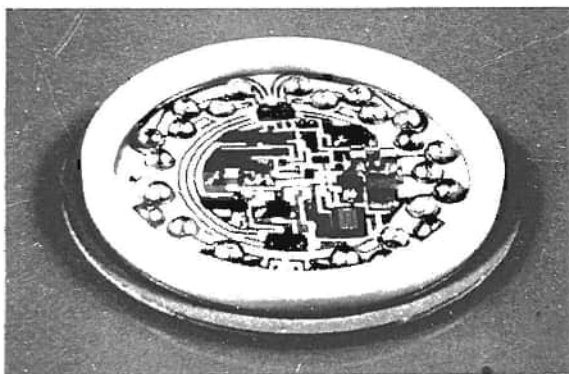


Fig. 4

conductors, mostly under the junction coating resin but close to, or in contact with, epoxy. These "non-hermetics" sometimes showed, by occasional malfunction, that water had got in before - sometimes years before - catastrophic failure. The remaining epoxy-sealed packages have survived six and a half years. None of the three solder-sealed packages has failed catastrophically; two are running faultlessly after five and a half years in vitro; one was retired after five years and

examined. So far, the conclusions from these tests are:

1. That liquid tracks up the cables to the feedthrough pins on the package but it does not cause corrosion there,
2. Nor does the adhesion of the encapsulant to the alumina, in between the pins, fail. (Which would permit ionic leakage currents.)
3. The encapsulant adheres well to the solder seal and prevents it corroding.
4. With careful encapsulation, galvanic corrosion can be prevented where solder meets noble metal.
5. If water enters a package, the places where epoxy is used are likely to be the sites of failure. However, the use of epoxies is acceptable in an adequately hermetic package.

COMMENTS ON THE MK II

The circuit neither actively balances the stimulus charge, nor does it have blocking capacitors, which would be too bulky. There are 10 kilohm resistors, diffused on the multiplexing chips, to allow the electrodes' self-capacitance to discharge (passively balanced). Our reasons for believing that this is adequate have recently been presented /5,6,7/ and there is no evidence of tissue damage, from stimulation, in any of the patients.

The chief deficiency of these devices is now the poor tolerance to

misplacement of the transmitters. Lateral movement in the least favourable direction, for a typical patient, of no more than 15 mm is possible before the stimulator cuts off. This is far too little. It is important, though, that there is a definite cut-off so that no spurious stimulation can occur as the transmitter moves away: this improvement was introduced after the Mk I. Better position tolerance could be achieved if only one inductive link were used instead of two.

Although the technology is satisfactory, this design is rather thick and the construction requires more skilled manual work than is suitable for a manufacturer. These matters and the transmitter position tolerance should be improved in the Mk III. Even so, our patients are using Mk IIs and we expect to implant several more.

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THE ANTERIOR SACRAL ROOT STIMULATOR - OWN EXPERIENCE WITH REMARKS TO THE INDICATION

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SUMMARY

Between July 1985 and February 1986 an anterior sacral root stimulator according to Brindley was implanted in 4 women with neurogenic bladder dysfunction. All 4 patients so far void by electromicturition with none or minimal residual urine and 3 remain completely dry inbetween, one leaks occasionally. The indication for the operation in general as well as the benefits, disadvantages and indications for cutting the posterior sacral roots together with the implantation are discussed.

MATERIAL AND METHODS

In 1973 and 1977 Brindley reported the development and animal testing of an implant for emptying the bladder by stimulating sacral ventral roots, in 1982 the results of implanting stimulators of this type in a series of 11 patients with traumatic lesions of the spinal cord, and in 1984 in a series of 40 patients were published.

The implant consists of 3 main parts, the electrode "books" (1), in which the sacral roots are trapped intradurally and the cables, coated with silicon rubber, the radioreceiver block (2), which is implanted subcutaneously over the left low ribs and costal cartilages, and the external stimulating apparatus (3). During the operations the roots are stimulated electrically and the result is controlled urodynamically by monitoring the intravesical and intrarectal pressure, in order to find the relevant roots for electromicturition (as well as for electrodefecation and electroerection).

Between June 1985 and February 1986 an anterior sacral root stimulator was implanted in the Rehab.Center of Bad Häring in 4 women with neurogenic bladder dysfunction:

Pat. 1 W.K., 17 a, with a traumatic paraplegia sub D1/D2 (1982) suffered from a hyperactive, hypercontractile reflex bladder combined with a severe detrusor-external sphincter-dyssynergia; emptying of the bladder was achieved by anal stretch, 3-4 hourly, but the girl remained wet inbetween.

Pat. 2 R.M., 45 a, suffers from a intramedullary lesion of the spinal cord below C7 (1983) most probably due to a cervical disc prolapse (which was operated elsewhere), with an almost complete tetraplegia with a hypoactive, hypocontractile detrusor with detrusor-sphincter-dyssynergia; bladder emptying had to be managed by intermittent catheterization by the nursing staff; preoperative testing showed that she would be able to manage the external stimulator by herself.

Pat. 3 E.B., 20 a, suffers from a traumatic paraplegia sub C8 (1984), resulting in a noncompensated reflex bladder with reflex urinary incontinence. Therefore the bladder was made hyporeflexic by Oxybutynin (Ditropan^R) and bladder emptying was achieved by intermittent catheteri-

zation (by the mother). The young woman wanted to be independent from intermittent catheterization, which she could not perform by herself and was therefore also in this regards dependent from other persons. Moreover occasional wetting could not be avoided.

Pat. 4 F.B., 18 a, with a traumatic paraplegia (1983) showed a non-compensated reflex bladder with a detrusor-external sphincter dys-synergia and with reflex urinary incontinence; with the help of Oxybutynin a hypocontractile, but still low compliance bladder was induced, micturition was achieved by intermittent catheterization (by the mother) but reflex urinary incontinence although improved, could not be eliminated.

RESULTS

All 4 patients so far void by electrostimulation with none or minimal residual urine, 3 remain perfectly dry inbetween; 1 (Pat.No.4) has to stimulate every two hours, otherwise urinary leakage can occur due to still existing spontaneous reflex contractions; two patients (No.3 and No.4) had sterile urine at all regular controls, pat.No.2 so far had two unsterile episodes during one year, pat. No.1 had recurrent urinary tract infections during the first 3 months, but became sterile thereafter probably due to the gradual decrease of the residual urine. So far the upper urinary tract is stable, no secondary vesico-uretero-renal reflux occurred in all 4 patients.

DISCUSSION

In all 4 patients bladder emptying is achieved by electromicturition with physiologic detrusor pressures and with the typical voiding in spurts due to the stimulation in bursts. In most patients the external sphincter is activated during detrusor stimulation, as they are innervated through the same roots. To overcome this difficulty stimulation is performed in bursts: such bursts will activate the external sphincter intermittently, but if the intervals are not too long the detrusor will contract continuously (Brindley, 1977), so that micturition occurs between the bursts.

To assure continence cutting of the relevant posterior sacral roots is mandatory to eliminate spontaneous reflex contractions, except in patients with detrusorhypocontractility. Cutting of the relevant posterior sacral roots results in loss of reflex erections and is an important disadvantage, as electro-erection can only be achieved in about 50 %. In females this procedure results in loss of vaginal lubrication as a minor disadvantage. In pat.No.4 intraoperative testing showed that the main nervous supply to the bladder was accomplished by S4. Unfortunately due to anatomical reasons the separation between posterior and anterior roots was not possible in this patient. Therefore spontaneous reflex contractions are still present causing urinary incontinence unless electromicturition is performed every 2 hours, before such spontaneous contractions do occur.

Therefore the ideal patient for this type of stimulator is firstly a women with a complete suprasacral lesion suffering from a noncompensated reflex bladder and from reflex incontinence, which we can not be managed otherwise and with a bladder innervation mainly through S3 or/and S2 in order to be able to separate and cut the posterior roots, and secondly a male patient, again with a complete suprasacral lesion, with a hypocontractile reflex bladder combined with external sphincter dyssynergia, without involuntary loss of urine so that the posterior roots can be saved and reflex erections preserved.

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ADVANTAGES OF USING PULSES OF SHORT DURATION IN ELECTRICAL STIMULATION FOR THE TREATMENT OF URINARY INCONTINENCE x)

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SUMMARY

Intravaginal electrical stimulation was performed in patients for the investigation of the sensitivity to pulse duration and in cats for the investigation of bladder inhibition.

During the stimulations pulses of alternating polarity and 10 Hz frequency were used. The pulse durations were 0.1, 0.2, 0.5 and 5 ms. In patients the stimulation voltage levels required at threshold of sensitivity and/or at sensations close to pain were regarded.

The amplitudes required at threshold of sensitivity, normalized to that of the 5 ms pulse, were for the 0.1 ms, the 0.2 ms and the 0.5 ms pulses 2.3, 1.9 and 1.5 respectively. Almost identical normalized values were attained at sensations close to pain. For bladder inhibition the relative amplitudes for the 0.1, the 0.2 and the 0.5 ms pulses were 1.9, 1.6 and 1.3 /1/. The power ratio for the 0.1 and the 5 ms pulses is about 1:10 at equal clinical efficiency /1/.

MATERIAL AND METHODS

Eight women were selected for the mapping of sensitivity to different pulse durations of alternating pulses during intravaginal electrical stimulation.

The experiments were carried out in 16 adult female cats /1/ which were supplied with intravaginal electrode carriers. Their bladders were filled until basal intravesical pressures of 10-20 cm H₂O were reached. Small abortive bladder contractions were regularly registered, whose suppressions were used as measures of the effects of the stimulation for bladder inhibition.

The pulse patterns consisted of alternating, constant voltage pulses, i.e. pulses of consecutively varying polarity of equal and constant magnitude. The pulse width, i.e. the time between the leading and the trailing edge of a pulse, was 0.1, 0.2, 0.5 or 5.0 ms. The pulse repetition rate for the alternating pulses was selected to 10 Hz due to its efficiency for bladder inhibition /2, 3/.

The stimulation amplitude was increased until the patient reported the first sensation of stimulation. This voltage level was defined as the sensation threshold level for that specific pulse constitution. The voltage level was thereafter decreased to zero. Two minutes later the procedure was repeated with the use of any of the remaining pulse types. When all types of pulses had been used in threshold stimulations the voltage levels at sensations close to pain were regarded. The voltage was slowly increased to a level where the subject reported considerable unpleasantness. (During these stimulations the sensation threshold levels were confirmed.) The required voltage level for the cause of similar extent of discomfort was regarded for each pulse type. The power dissipation

x) Magnus Fall and Solveig Frankenberg at the Urodynamic Laboratory, Department of Urology, Sahlgren Hospital, Göteborg, have made this study possible.

for each pulse type was calculated /1/.

RESULTS

The voltage amplitudes required at equal sensations of stimulation at different pulsewidths are recorded in Table 1.

Table 1. Voltages at threshold/ discomfort for sensation of intravaginal electrical stimulation with 10 Hz alternating pulses with different pulsewidths.

Patient	Pulsewidths			
	0.1	0.2	0.5	5.0
F1909	16.0/	14.0/	10.0/	6.3/
F1919	18.0/23.0	15.0/20.0	12.0/18.0	7.5/10.0
F1924	14.0/21.0	13.0/17.0	10.0/14.0	6.3/ 8.0
F1924HI	13.0/18.0	10.5/15.0	9.0/12.0	5.8/ 8.0
F1926	14.5/20.0	13.0/17.0	10.0/13.0	6.3/ 9.0
F1928	/22.0	/17.0	/15.0	/ 9.0
F1931	14.0/18.0	10.8/14.0	7.3/11.0	5.0/ 7.0
F1948	15.0/20.0	13.3/16.5	13.0/15.0	8.3/ 9.5

Mean values for treshold voltage were for the pulses from the left to the right in the above presentation 14.9 V, 12.8 V, 10.2 V and 6.5 V respectively. Relative voltage amplitudes, as normalized to that of the 5 ms pulse, were for the 0.1, 0.2 and 0.5 ms pulses at mean 2.3, 1.9 and 1.5 respectively. The voltages at sensations close to pain were for the above pulses, from the left to the right in Table 1, at mean 20.3 V, 16.6 V, 14.0 V and 8.6 V respectively. Normalized voltage amplitudes were for the 0.1, 0.2 and 0.5 ms pulses 2.4, 2 and 1.6 respectively.

In the cat, corresponding relative voltage amplitudes for bladder inhibition were for the 0.1, the 0.2 and the 0.5 ms pulses at mean 1.9, 1.6 and 1.3 respectively /1/.

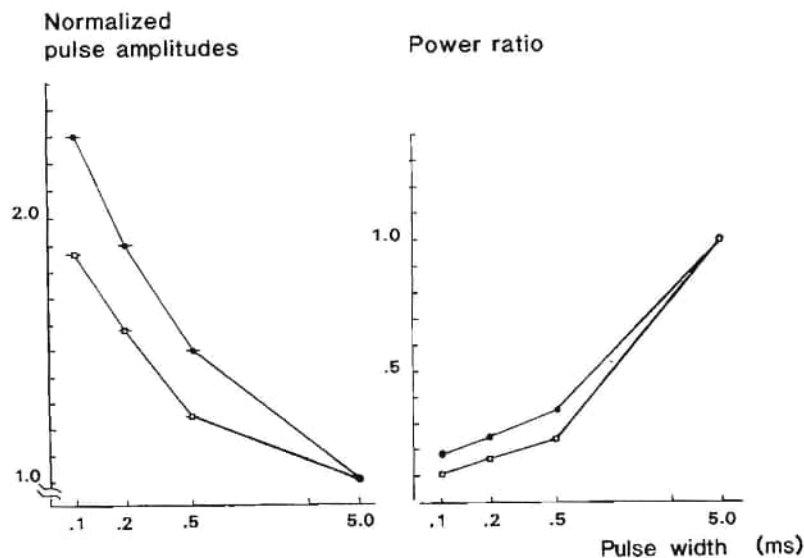


Fig. 1. Normalized voltage amplitudes for threshold of sensitivity and bladder inhibition in strength-duration curves (left) and relative power dissipation for each pulse type (right).

The left part of Fig. 1 shows the stimulation voltage amplitudes normalized to that of the 5 ms pulse in compared stimulations of bladder inhibition (lower trace) and sensitivity in intravaginal electrical stimulation (upper trace). The continuous lines join the mean values of the required stimulation voltage amplitudes.

The right part of Fig. 1 shows the power ratio for each pulse width, normalized to the power dissipation for the 5 ms pulse. The upper curve shows the power ratios at equal sensitivity for the different pulse types, and the lower curve shows the power ratios at equal bladder inhibition.

DISCUSSION

In the design of an intravaginal electric device the power consumption and the voltage requirements are important /1, 4, 5/. Most of the weight of such a device comes from the batteries. This implies that the number of battery cells should be kept low, which in turn limits the voltage available. Such considerations point to drawbacks of very short pulses, requiring relatively high stimulus amplitudes. It was shown that a 0.1 ms pulse required a voltage amplitude 1.9 times that of a 5 ms pulse for an equal inhibition of bladder contractions /1/. This would correspond to impractically high voltages for an integrated intravaginal device. It was suggested in the same study that a 0.5 ms pulse could offer a good compromise between voltage requirements and power consumption as concerns the bladder inhibition. A 0.5 ms pulse requires a 25 per cent increase in pulse amplitude as compared to the 5.0 ms pulse for an equal inhibition of bladder contractions. This implies that the 0.5 ms pulse dissipates only 20 per cent of the energy required for the 5 ms pulse.

The result obtained in this study points to further advantages with the 0.5 ms pulse, requiring up to 1.6 times the voltage level of the 5 ms pulse for the cause of equal sensations of stimulation. This indicates that at equal inhibitions of bladder contractions, the stimulation with 0.5 ms pulses is less uncomfortable. Furthermore, the 0.5 ms pulses are most probable to reach functional suprathereshold levels at equal sensations of stimulation. These qualities are advantageous for both laboratory and long-term electrical stimulation.

In long-term stimulation, patients are stimulated at voltage levels so low that stimulation is acceptable for several hours. Laboratory electrical stimulation is performed at higher voltage amplitudes aimed to be tolerable for twenty minutes /7/. In both applications of electrical stimulation it is fundamental to optimize the stimulation parameters. Obviously the 0.1 ms pulse requires an amplitude that is too high in long-term applications due to a large amount of batteries. In maximal electrical stimulation, however, the 0.1 ms pulse could offer a most appropriate alternative, since the voltage and current required are at hand. The power dissipation in human tissue is hereby also considerably lowered.

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INTRA-VAGINAL FUNCTIONAL ELECTROSTIMULATION
FOR THE TREATMENT OF POST-PARTUM INCONTINENCE

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Post-partum urinary incontinence is more frequent than we usually think. We found it following as much as 30 % of the deliveries. We indicated the determining role of the first delivery and that of the beneficial effect of post-partum reeducation. We report here the result of the functional electrostimulation in 90 patients having urinary stress incontinence in the post-partum period.

MATERIAL AND METHODS

We studied 90 cases of urinary stress incontinence which were completely explored e.g. who had complete clinical as well as urodynamic static and dynamic profile before and after perineal electrostimulation.

All patients had electrostimulation, either by the use of an out-patient Urogyn apparatus, or at home by the Microgyn. The characteristics of the system were :

- Electrical frequency of 50 Hz ; Execution time of 1 second ; Resting period of 2 seconds ; The intensity of the current was always below the pain threshold ; Stimulation time was between 15 and 20 minutes ; Total number of sittings was at least 10.

In all the 90 patients the program was undertaken between the 7th week and the 6th month post-partum. The age-distribution of the patients is shown in Table I :

		Incontinent	Control serie	
< 20 years	0		0,5 %	
20 - 24	3	3,3 %	18 %	xxx
25 - 29	20	22,2 %	43,5 %	xxx
30 - 34	41	45,6 %	27 %	xxx
35 - 39	22	24,4 %	7,5 %	xxx
> 40	4	4,4 %	3,5 %	N S

The incontinent population was older than the control group, all having deliveries in our unit. The study of the parity shows that primiparas have a high rate of incontinence as compared to the age-matched control, which confirms the importance of the first vaginal delivery in the genesis of incontinence.

				Control serie
TABLE II :	I PARE	48	53,3 %	43,5 % xx
	II PARE	29	32,2 %	35 %
	III PARE	11	12,2 %	12,5 %
	IV P. - V PARE	2	2,2 %	9 %

Urodynamic studies permitted us to classify the patients into 4 groups :

- Isolated insufficiency of the uretral closing pressure (S.I.)- 6 cases
- Isolated defect of transmission (D.T.) - 49 cases
- Association of the above 2 (S.I. + D.T.) - 33 cases
- Normal findings - 2 cases

Clinical examination had always discovered a frank stress incontinence and was associated to utero-vaginal prolapse in 8 cases (9 %).

Testing of the Levator ani muscle showed that most of the patients had scores below 2 : TABLE III

- | | |
|--------------------|--------|
| - Testing à 0 : 11 | } 70 % |
| - Testing à 1 : 52 | |
| - Testing à 2 : 19 | |
| - Testing à 3 : 6 | |
| - Testing à 4 : 1 | |
| - Testing à 5 : 1 | |

RESULTS

We present the results in the form of clinical and urodynamic findings :

CLINICALLY :

a - Objectively we appreciated the results by the number and type of absorbing pads patients had to use daily.

- 16 patients did not use pad at all even before reeducation
- 61 used one a several thin absorbing pads and after treatment only 7 were still using pads (89 % were improved)
- 10 patients had to use several thick pads per day of which 6 did not have to use any pad at all and 4 used only thin pads.

b - Subjectively :

- The cure was defined as the total absence of urinary leakage in all conditions.

- Improvement was defined as the absence of leakage in day to day normal efforts but having some during stressful activities such as sneezing and coughing bouts. We obtained :

- 26 cures (29 %)
- 54 improvements (60 %)
- 10 failures (11 %)

c - Clinical results of the muscular strength of the levator ani muscle :

In presence of weak muscles the average improvements was an average of 2 points on the testing of the levator ani.

URODYNAMIC RESULTS :

a - Uretral closing pressure (U.C.P.)

The average UCP was 70.5 cm H₂O before treatment and 76 cm H₂O after ($p < 0.005$)

b - We singled out an incontinent population of 39 whose UCP was abnormally low. The UCP was 51.4 before and 61.6 after treatment ($p < 0.001$).

We conclude that lower the UCP, better are the improvements following stimulation.

c - Results of the pressure transmission from bladder to urethra :

We calculated the transmission of pressure in the cervical as well as in the sphincteric zones.

Results are given in Table IV :

	Transmission cervical Zone		Transmission sphincteric Zone	
	BEFORE	AFTER	BEFORE	AFTER
TOTAL POPULATION (90)	71 $p < 0.001$	86 $p < 0.001$	68 $p < 0.001$	83 $p < 0.001$
LOW U.C.P. (39)	72 $p < 0.001$	83 $p < 0.001$	66 $p < 0.001$	81 $p < 0.001$

CONCLUSION

Intra vaginal fonctionnal electrostimulation is the treatment of choice for post-partum urinary incontinence. After an out-patient training, use of miniaturized apparatus enables the patients to treat themselves at home, rendering this method practical and acceptable.

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OPTIMIZATION OF VAGINAL AND ANAL ELECTRIC STIMULATION FOR URINARY INCONTINENCE

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SUMMARY

Vaginal or anal electrical stimulation is used clinically to improve the symptoms of urinary incontinence by enhancing the activity of weakened urethral mechanism and/or by inhibition of overactive detrusor. This is most probably due to the excitation of pudendal nerve fibres which are within the electric field generated by vaginal or anal electrodes.

In this study, the optimal pulse duration of electric stimuli has been determined by measuring the strength/duration curves during vaginal or anal sensory threshold study and during pudendal motor threshold study. Pulse duration of 0.2 ms proved to be optimal.

The requirements for the stimulator output stage design were also determined on the basis of measurements of electric impedance of vagina and anal canal during treatment with electric stimulation. Thus, the minimum supply voltage of the constant current output stage was defined.

THE CURRENT/PULSE DURATION RELATION

Sensory threshold study

In 20 incontinent cases (stress incontinence, urge incontinence, enuretic children) which were in the course of treatment with short term electric stimulation /1/, the sensory threshold currents were determined at different pulse durations in the range from 0.1 to 1.5 ms, at frequency of 20 Hz. The laboratory battery powered stimulator was used generating constant current rectangular charge balanced pulses. Vaginal (11 patients) and anal (9 patients) electric stimulation was performed using specially constructed plugs with ring electrodes. The intensity of stimulation was gradually increased at different values of fixed pulse duration and the current at the patient's first sensation noted. A characteristic plot of the results obtained is shown in Fig. 1a. The range of pulse durations which provided minimal charge per pulse were 0.1 - 0.3 ms.

Motor threshold study

In two patients with an unstable bladder but preserved peripheral innervation of perineal muscles the pudendal nerve was stimulated with teflon-coated bare tip needle electrodes and the direct muscle response was recorded with a concentric needle electrode. A similar current intensity/pulse duration curve for the motor threshold was obtained as in the sensory threshold study (Fig. 1.b).

Conclusions

Vaginal or anal electric stimulation produces closure of the urethra and inhibition of the bladder /1/. This is most probably due to the excitation of pudendal nerve fibres which are within the electric field

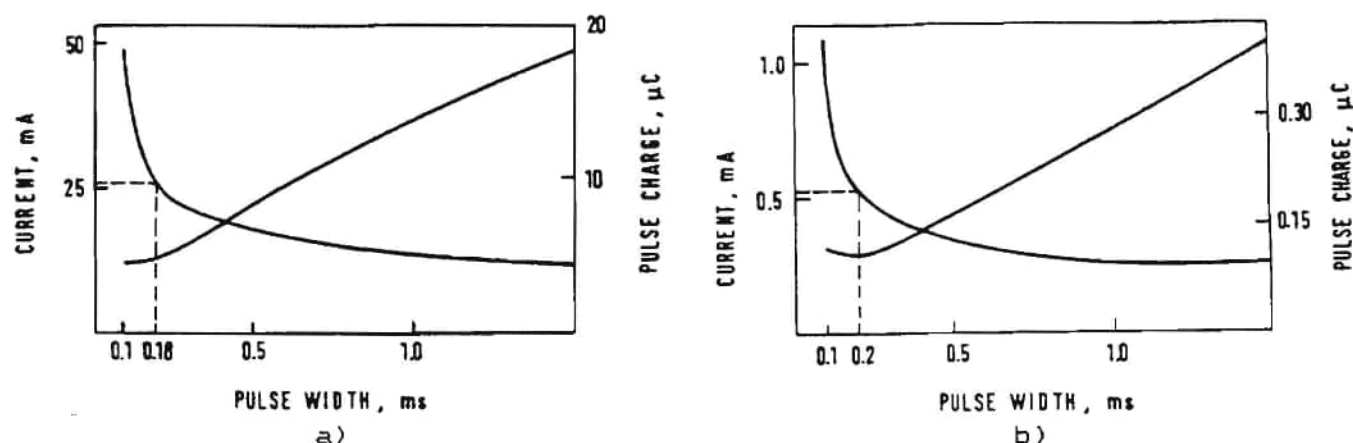


Fig.1 Current intensity/pulse duration and pulse charge/pulse duration curves for sensory (a) and motor (b) fibres of pudendal nerve

generated by vaginal or anal stimulating electrodes.

The optimum pulse durations obtained in our study are much shorter than the so far used pulse duration of 1 ms. Considering that the pulse charge at 1 ms duration is approximately three times greater than the charge at 0.2 ms duration, this finding represents an important guideline as regards to the pulse parameters selection in the future electrical stimulation studies. The clinical efficiency of the optimized pulse duration and correspondingly smaller charge needs to be tested in further studies.

REQUIREMENTS FOR THE STIMULATOR OUTPUT STAGE DESIGN

Current and voltage measurement

Current and voltage of the electric pulse was measured during regular vaginal (35 patients) and (anal 34 patients) short term stimulation sessions, using Tektronix 5111 oscilloscope. The values were noted at each 10 mA increase of current. The values of current at first sensation as well as the maximum bearable currents were determined. Maximum current was limited to 100 mA. Constant current laboratory stimulator was used producing charge balanced pulses (of 1 ms duration and 20 Hz frequency) in the range of output resistance from 0 to 3 kOhms. Specially constructed vaginal and anal plug ring electrodes were used for stimulation having geometric electrode area of 580 mm² and 240 mm², respectively.

Maximum current

The mean maximum bearable current measured was 60.4 mA, sd 23.2 and the range from 15 to 95 mA. To obtain the good effects of treatment, it is desirable to excite all relevant neuromuscular structures within the electric field of stimulating electrodes. Since it is difficult to design the experiment which would actually show at what particular current intensity all the structures are stimulated, the estimation of the maximum bearable but safe current intensity seems to be the most we can do at the moment towards optimizing this aspect of the problem. The value of 75 mA which was selected as the maximum current of the pulse (at 1 ms duration) still fulfills the safety requirements regarding the charge and current densities according to the AAMI standards and the international standards for patient security.

The threshold of vaginal and anal sensation which have been also noted were mean 14.9 mA, sd 4.3 and range 5 - 35 mA. The results are similar to those of Kiesswetter and Flamm /2/ as regards to the wide range of the values obtained.

Vaginal and anal impedance

The impedance of the vagina as well as anus showed gradual decrease as the current was gradually increased during stimulation (Fig. 2). One of

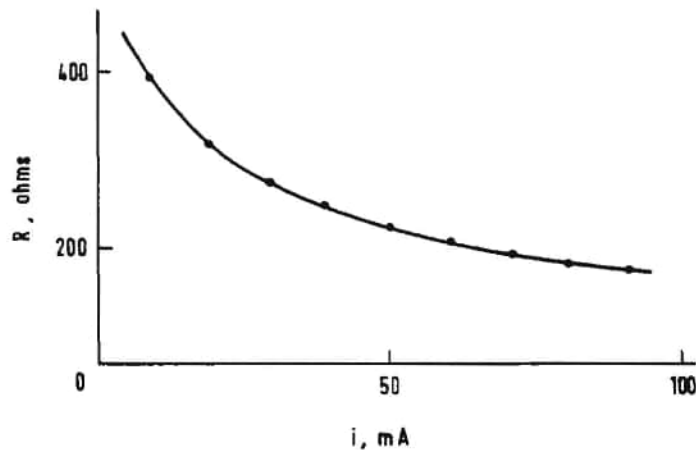


Fig.2 Case 5 - R/i relation during the course of vaginal stimulation

the possible explanation might be the establishing the better contact as the pelvic floor muscles contract during stimulation.

Vaginal impedance	mean 311 Ohms, sd 109, range 160-500 Ohms (start)
	mean 180 Ohms, sd 57, range 110-350 Ohms (end)
Anal impedance	mean 409 Ohms, sd 127, range 180-950 Ohms (start)
	mean 264 Ohms, sd 90, range 150-550 Ohms (end)

On the basis of these results, the impedance of 500 Ohms was selected to represents the upper limit and the corresponding supply voltage of 38 volts defined.

Conclusions

The requirements for the output stage design of the electric stimulator for short term stimulation were defined. Current controlled charge balanced pulse of maximum intensity of 75 mA (1 ms duration) and supply voltage of 38 volts selected. The selected values might still not be optimal as regards to the pulse width and corresponding charge, but this is dealt with elsewhere /3/.

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MAXIMAL ELECTROSTIMULATION IN WOMEN WITH DETRUSOR INSTABILITY

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SUMMARY

In 1983 a research program was started at the Dep. of Ob. & Gyn. in collaboration with the Electronics Research Laboratory, University of Trondheim, in order to evaluate the therapeutic effect of maximal electrical stimulation of the pelvic floor in female motor urge incontinence. An electronic device (Maxicon) was constructed and was applied on 45 women with urge incontinence caused by an over-active detrusor. The results indicate that about 50% are cured after the therapy and 25% significantly improved. Positive effect was confirmed by urodynamic examination. No serious side effects have been observed.

MATERIAL AND METHODS

The study group consisted of 45 women with detrusor instability verified by medium-fill water cystometry of the bladder. Before treatment, a gynecological and urological examination was performed including a mid-specimen culture, urodynamic examination and urethra-cystoscopy. A neurological examination of the perineal region was done to exclude peripheral denervation of the pelvic floor. The age range of the patients was 15-79 years (mean 54,6 years). 67% were postmenopausal.

The maximal stimulation therapy was applied using anal and vaginal plugs simultaneously. Biphasic, intermittent, square pulses of 1 msec duration were applied with a frequency sweeping between 5 and 10 Hz in 2 sec. The current intensity was gradually increased to the pain threshold and kept there for 20 minutes. The stimulation was repeated once a week until the patients reported complete normalization of the bladder dysfunction. If no effect was observed after 5 sessions, the treatment was stopped. If some improvement was registered, it was continued until cure was achieved or no further improvement was registered.

RESULTS

On average, 7 stimulations were given to each patient (range 2-16). The mean total current delivered to the patient on both electrodes was 85 mA. After the treatment frequency, urgency and nocturia were significantly reduced. The therapeutic effect was confirmed by control cystometry showing a significant increase in volume at first desire to void and at maximum cystometric bladder capacity. About 50% of the patients had a stable bladder with normal capacity after the treatment. In about 25% of the cases the detrusor contractions appeared at a higher volume and could partly be suppressed by the

patient without leakage. We found a good correlation between clinical effect and changes in the urodynamic parameters.

DISCUSSION

Acute maximal stimulation of the pelvic floor has been successful in various kinds of urinary incontinence /1,2,3/. There is a good correlation between our results and those of Plevnik and Janez, who reported bladder inhibition in 79% of temporarily recovered or improved patients after maximal stimulation for urinary incontinence. We found great individual variation concerning tolerance of the current intensity, reflecting variation in tissue impedance and sensibility. In patients with low pain threshold and unsuccessful therapy, the stimulation should probably be given under general anesthesia in order to increase stimulation intensity sufficiently to give therapeutic effect.

We experienced some unexpected positive "side effects" after the electrostimulation therapy. Long-standing suprapubic pain was relieved in one patient, chronic pelvic pain without known etiology was relieved in two, chronic obstipation disappeared in one and slight stress incontinence was cured in one. These findings need to be confirmed in extended studies.

The stimulation device is easy to operate, technically reliable and is now commercially available (Medicon A/S, Trondheim).

In women with motor urge incontinence, maximal electrical stimulation of the pelvic floor is a safe and simple method to regain normal bladder function.

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Abstract

Title: **SHORT-TERM STRONG ELECTRIC PELVIC
FLOOR STIMULATION FOR URINARY INCONTINENCE**

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Short-term strong electric pelvic floor stimulation was applied in 26 patients with lower motor neuron lesion who suffered from total or severe urinary incontinence. The causes of lower motor neuron lesion were myelomeningocele (7) discus hernia (10), traumatic spinal cord lesion (6), radical hysterectomy and amputation of rectum (3). The stimulation which lasted 20 minutes daily one month with the intensity of 90-100 mA was applied via anal (males) or vaginal (females) plug electrodes. Cure or improved continence was noticed in 18 patients (69 %). In the majority of patients the effect of stimulation was long lasting while in four patients repeated stimulations were necessary to maintain the effect (observation period one to three years). Urodynamic investigations (urethral pressure profile cystometry, residual urine) and EMG of pelvic floor muscles were done before and after stimulation. No harmful side effects were noticed. For that reason and because of good results we recommend electric pelvic floor stimulation for the treatment of this type of urinary incontinence.

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Abstract

The Electrical sphincter stimulation in the treat-
ment of detrusor hyperreflexia of paraplegics

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Strong anal stimulation at the onset of the vesical pressure increase during an uninhibited bladder contraction prevented further bladder pressure increase and urine loss in 11 out of 15 paraplegics; 5 Hz, 10 Hz and 20 Hz stimuli were equally effective. This effect is probably a spinal reflex. In the acute experiments, stimulation of the peroneal or anterior tibial nerve was without effect on bladder pressure.

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TREATMENT OF DETRUSOR DYSFUNCTION WITH FUNCTIONAL ELECTRICAL STIMULATION (FES)

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SUMMARY

Results of the treatment of detrusor dysfunctions using functional electrical stimulation (FES) are described. These dysfunctions are divided into three groups, i.e. hyperactivity, an atonic detrusor as well as vesico-urethral dyssynergia. Characteristics belonging to each of the changes are given. AMFES (acute maximum functional electrical stimulation) is applied to treat dysfunctions of the detrusor muscle. In the last few years the AMFES method has been slightly modified. However, the stimulation parameters have remained unchanged: the impulse is rectangular and monophasic, stimulus duration is 1 msec, frequency 20 Hz, and current of above 65 mA.

168 females with urge incontinence were treated. The treatment was successful in 61,3% while an improvement was observed in 25,6% of the patients. In other words the treatment could be considered successful in 85,9% of the cases. Recurrent dysfunctioning was observed in 23% of the females.

In the group of the patients with frequency 42 were treated of whom 71,4% were completely cured, and in 16,7% of the cases an improvement was achieved.

The authors consider that the AMFES method is quite successful and reliable for the treatment of detrusor dysfunctions and that it has no negative side effects and can be used in all periods of life.

MATERIAL AND METHODS

Bladder detrusor dysfunctions can be divided into three groups:

- a) a hyperactive (uninhibited) detrusor
- b) an atonic detrusor (urinary bladder)
- c) detrusor dysfunctions due to vesico-urethral dyssynergia.

The most frequent kinds of bladder detrusor dysfunctions are described in the literature as an unstable bladder (Bater, Whiteside and Turner-Warwick, 1970), uninhibited detrusor dysfunction (Torrens and Griffiths, 1974) or as hyperreflexic detrusor dysfunction (Bradley and Timm, 1976). These dysfunctions of the bladder detrusor can be found in 30 - 50% of females with urinary incontinence (Torrens and Griffiths, 1974).

Detrusor instability is frequent in females with an injury of the central nervous system (the upper motor neuron) due to a systemic disease (multiple sclerosis, less frequently in cases of diabetes mellitus), brain tumor or mechanical injuries of the spinal cord. In the majority of cases the reason for detrusor instability is unknown, so we speak of idiopathic, primary or non-neuropathic detrusor instability.

An atonic type as well as vesico-urethral dyssynergia as bladder detrusor dysfunction is generally found in a neurogenic bladder. It results from the upper motor neuron lesion and sometimes also from lesions of the peripheral nerves.

A special lesion of bladder detrusor functioning is observed following radical hysterectomy (Wertheim's operation) because of carcinoma colli or corporis uteri. After the above surgical approach dysfunctions of the bladder detrusor is observed in one third of the patients. It is mainly manifested either as a hyperactivity (an increasing type of the cystometric curve) or an atonic type (an atonic type of the cystometric curve).

In an unstable detrusor dysfunctions are clinically manifested by urgency (80%), frequency (79%), night frequency (69%) (Cardozo, 1984), and urge incontinence. In one third of female with stress incontinence mixed incontinence can be found, i.e. combination of both stress and urge incontinence. In each patient signs of either urge or stress incontinence could prevail.

An atonic detrusor is clinically manifested as dysfunctioning of the urinary bladder voiding. This dysfunction is determined by establishing the quantity of urine remaining in the bladder following micturition.

Vesico-urethral dyssynergia is clinicall manifested as a disorder in micturition.

All these changes of detrusor functioning can be clinically determined only in part, but they will only be confirmed and proved by means of uradynamic analyses, particularly by means of cystometry. An unstable detrusor cannot be proved by any other method except cystometry, so it is a matter of cystometry and/or urodynamics.

There are several ways of treating bladder detrusor dysfunctions: an approach to the nerves innervating the urinary bladder (vaginal denervation, cystocystoplasty, sacral neurectomy), enlarging of the urethra, training of the urinary bladder, drug therapy and treatment with functional electrical stimulation (FES). The last two methods have proved successful in the treatment of detrusor dysfunctions.

It is widely known that FES applied to the pelvic floor achieves contraction of the pelvic floor muscles and at the same time relaxation (inhibition) of the bladder detrusor. This double effect of FES can only be obtained if a current of over 65 mA is applied. Usual stimulators of the pelvic floor muscles with current up to 35 mA will mainly achieve contraction of the pelvic floor muscles while inhibition of the detrusor is smaller.

When treating urinary bladder dysfunctions we apply FES to the pelvic floor muscles in the form of AMFES (acute maximum functional electrical stimulation). The following parameters of stimulation are used: a rectangular and monophasic stimulus, stimulus frequency of 20 Hz, stimulus duration of 1 msec, current above 65 mA (usually 80 mA). The power is determined for each patient individually and is increase up to the limit of the sensation of pain. Duration of stimulation: 20 minutes for 5 days consecutively.

RESULTS

According to the above described AMFES method 168 females with urgency and urge incontinence due to an unstable bladder were treated. Results of the treatment are shown in Table 1.

Table 1	Urge incontinence: cured 193 patients or	61,3%
	urgency improved condition in 43 patients or	25,6%
	failure in 22 patients or	13,1%
Total 168 patients or		100,0%

Results of the treatment of females with frequency using AMFES is illustrated in Table 2.

Table 2	Frequency:	cured 30 patients or	71,4%
		improved condition in 7 patients or	16,7%
		failure in 5 patients or	11,9%
	Total 42 patients or		100,0%

Results of the treatment of females with detrusor dysfunctions following radical hysterectomy are given in Table 3.

Table 3	cured 2 patients
	improved condition 5 patients
	failure 7 patients
	Total 14 patients

AMFES was also applied to 5 females with an atonic bladder (atonic detrusor). Improvement was observed in only 2 patients. It was manifested by a decrease or urinary retention.

DISCUSSION

Drug therapy seems to be most frequently used in the world for the treatment of detrusor dysfunctions. A number of various means have been applied such as ganglion blocker, anticholinergic preparations, musclatropic agents, beta-adrenergic stimulants, etc. However, their effects is only temporary, it only lasts during the treatment. Besides, drug therapy effectiveness is relatively low. It is considered to be successful only in 60% of the patients. Moreover, drugs have numerous side-effects and as such they involve many contraindications for use. Bladder detrusor dysfunctions tend to increase with age - they are more frequent in older than in younger female population. Since systemic diseases such as diseases of the cardiovascular system and similar diseases connected with the vegetative nervous system tend to increase, the use of drug therapy is limited with age. Drugs have an effect on the vegetative nervous system, this one being connected with the bladder detrusor. All these problems are not involved in the use of FES and/or AMFES and this therapy has no limitations of use connected with groups of age.

Results of the treatment of detrusor dysfunctions with AMFES are better than the ones with drug therapy. AMFES does not involve any negative side-effects and there are practically no contraindications for its use.

AMFES that we started to use in 1974 has been modified in the last few years. At the beginning we used a three-channel stimulation, and now we use one-channel, either vaginal or anal stimulation. Initially used needle electrodes have also been omitted as they couldn't increase the current applied and because their application was somewhat painful and unpleasant.

Duration of application was 20 minutes. Stimulation was applied once only. Results of the treatment of urge incontinence were rather favourable (81,9%) with recurrent incontinence in 26% of the females treated. As current was applied to the pelvic floor with full power (65 mA and more) all at once, the application was rather painful in the first moments. A usual two-channel stimulation with a complicated pulse generator required a clinical and laboratory use. By increasing current power gradually up to the maximum values we succeeded in diminishing pain involved in the application of AMFES. The maximum value of current is determined individually and should not get beyond the limits of pain.

In order to get a still more simplified AMFES, commercially available stimulators of the pelvic floor have been modified. Now they generate intensity of stimulation of 65 mA and/or 80 mA. These stimulators can be used by female patients at home once a day for 20 minutes.

What has been changed in AMFES used for the treatment of detrusor dysfunctions?

- 1) Stimulation parameters have remained unchanged,
- 2) One-channel stimulation (either vaginal or rectal) has been applied,
- 3) Stimulators for the eplvic floor muscles have been simplified so that female patients can use them at home,
- 4) In order to prevent recurrence AMFES should be applied 20 minutes for five days consecutively,
- 5) Current power should not be applied all at once but gradually increased in order to prevent pain.

Despite the above modified application of AMFES and five consecutive applications we haven't succeeded in diminishing the number of recurrences following the therapy (26% : 23%).

AMFES applied to the pelvic floor does not have any sufficient effect on the contraction of the atonic detrusor. In 5 females with this pathology improvement was observed twice only. In spite of that AMFES has provided a reliable and successful therapy for the treatment of troubles with miction caused by bladder detrusor dysfunctions.

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MECHANICAL RESPONSE TO ELECTRICAL STIMULATION OF
INTESTINAL LOOPS AND POUCHES

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SUMMARY

Electrical currents applied to the intestinal wall may have inhibitory or excitatory effects on the spontaneous motility of the gut (1,2). The effects of transmural currents have not previously been systematically studied in the intact animal. We present a preliminary report on our evolving experience.

Applied currents influence the inhibitory (2,3,4) as well as the excitatory (1) intrinsic nervous system and may directly depolarize the smooth muscle layers (1,2). Because the thresholds for each of these functional units depend on a number of variables such as food intake, temperature, the trauma of laparotomy and anesthesia, the state of the spontaneous motility and even the phase of the slow wave cycle, we faced a great variety of responses. Five dogs were studied in acute experiments to gain basic information about the effect of varying electrode configurations and sizes as well as combinations of pulse width and frequency.

MATERIAL AND METHODS

Five mongrel dogs weighing 17 - 20 Kg were used. They were anesthetized with Surital (1 mg / Kg) intubated and maintained on Surital throughout surgery. For stimulation we used a constant current stimulator with variable pulse width, frequency and current. It provided rectangular stimulating pulses that were followed by an inverted recharge pulse. In the first experiment we used bipolar stimulating electrodes similar to those described by Akwary et al.(5). One pair was attached to the serosa of the jejunum 15 cm from the duodenojejunal flexure so that the electrodes faced each other in the same cross section. A second pair was placed 5 cm distally. To recruit a larger part of the intestinal wall than that between both prongs of one electrode one bipolar electrode always served either as a cathode or an anode. A high frequency 200 usec, 1,67 kHz, 25 mA current and single stimuli with a long pulse duration (500 msec) were applied.

For all further experiments the electrodes were made of 12 x 3 mm 0.001 inch thick stainless steel sheets. They were attached to an insulating suturing cuff made of silastic soaked Dacron velour. Two pairs of electrodes were used and spaced 5 cm apart. The electrodes of each pair were sutured to the serosa perpendicular to the long axis of the jejunum on either side of the mesentery. In the first experiment of this kind thresholds for single pulses (110, 50, 6, 1, and 0.5 msec) were evaluated. In the second we tested excitatory high frequency pulse trains (200 usec 1,67 kHz, 500 usec 910 Hz and 1 msec 330 Hz) and an inhibitory combination (1 msec 10 Hz). In the last two acute dogs we constructed an U-shaped jejunal pouch. Four pairs of stimulating electrodes were spaced evenly along with pressure catheters and EMG recording electrodes. The same excitatory pulse trains were used as mentioned above. EMG electrodes were made from 3 mm diameter stainless steel discs fixed to an insulating

suturing cuff. Intraluminal pressures were measured via continuously perfused 1.67 mm ID polyethylene tubes. Permanent tracings were recorded with a Hewlett Packard 7758-3 eight channel chart recorder.

RESULTS

When both pins of a bipolar electrode were used as anode or cathode respectively in an instrumented loop of jejunum the peak pressure change for 500 msec pulses with at a frequency of 0.2 Hz with 20 mA current flow was 22 mm Hg (Fig 1). For high frequency stimulation the peak pressure change during stimulation was 20 mm Hg with an 'off response' of 30 mm Hg starting 4 seconds after termination of the pulse train.

The thresholds for single constant current pulses for creating a visible contraction ranged from 3 mA for horizontal stimulation (i.e. across a cross section of the bowel) at 110 msec to 30 mA at 1 msec pulse duration. For longitudinal stimulation over a 5 cm distance these were 8.5 mA for 110 msec and 25 mA for 6 msec. Shorter pulse durations were not accompanied by any visible contraction. Intraluminal pressure changes were noticeable just for the 110 msec pulses at threshold currents.

High frequency stimulation with 1 msec 330 Hz 20 mA trains caused a pressure increase up to 62 mm Hg and an "off response" of 38 mm Hg for horizontal stimulation (Fig 3). Longitudinal stimulation with 500 usec 910 Hz 30 mA pulse trains evoked a 25 to 30 mm Hg pressure increase over the length of the stimulated segment. An inhibitory train of 10 Hz 1 msec 25 mA for horizontal stimulation caused first a pressure decrease of 5 mm Hg then a gradual pressure increase during stimulation and finally a pressure increase of 50 mm Hg after termination of the stimulus (Fig 2).

The results in the U-shaped pouch were promising in the acute experiments. Stimuli of 200 usec at 1.67 kHz 20 mA increased the pouch pressure up to 50 mm Hg while 500 usec 910 Hz at 25 mA current gained 80 mm Hg pressure increase for horizontal stimulation and 55 mm Hg in the whole pouch for longitudinal current flow (Fig 4). When the frequency for a certain pulse width was lowered under the maximal possible rate, the mechanical response was decreased (e.g. 200 usec at 910 Hz). Rectangular pulses without recharge pulse caused visible electrolysis with bubble formation under the given conditions.

DISCUSSION

Both extremes of the effects of electrical currents on the small intestinal motility, excitation and inhibition may be useful in treating various clinical entities. Retrograde pacing of the slow wave with the goal of reversing the propagation of peristalsis is under investigation (6,7). Yet despite being unable to entrain the slow wave in some cases using pacing pulses of 50 msec duration at a frequency of 18 per minute the propagation of intestinal content decreased. Interestingly, Bennett and other authors reported in 1966 (1,3,4) an inhibitory effect of low frequency pulses for isolated intestinal wall preparations. This effect is caused by stimulating the inhibitory fibers of the intrinsic nervous system. The range of inhibitory frequencies is wide and the best effects were observed at 10 Hz. By using this frequency in the intact bowel we observed an initial relaxation similar to the type 3 reaction described by Campbell (1). By increasing the frequency to the maximal possible rate for a certain pulse width the effect on the excitatory part of the intrinsic nervous system exceeds the inhibitory effect. Still the "off response" a rebound phenomenon that is atropine resistant in the in vitro condition and thus not initiated by the excitatory nerve fibers is to be observed. Our experiments showed best results for 500 usec and 1 msec pulse trains. However the 1 msec 330 Hz combination

was usually followed by a stimulation of the striated muscles of the abdominal wall and the feasibility of using this combination has to be tested in chronic experiments. A further way of influencing bowel motility is by directly depolarizing the smooth muscle layers by stimuli with a long pulse duration (2,4,8). Because only the susceptibility or the threshold change for depolarization is propagated along the bowel with the slow wave activity and not the action potentials themselves (9), a great amount of smooth muscle fibers have to be depolarized directly by the stimulating current to gain considerable mechanical response. The smooth muscle fibers themselves need relatively high currents to be depolarized. Direct depolarization thus needs high current densities within the bowel wall. A future perspective might also be to phase link the stimulating pulses with the slow wave activity - migrating phase of decreased threshold - to resemble the natural way of depolarization where the action potentials exclusively occur in a certain phase of the slow wave cycle (10). The response to low frequency long lasting pulses occurred immediately and was not followed by an "off response". In chronic experiments the response to stimulating currents has to be evaluated with respect to the different phases of the spontaneous motility. Further the tolerance of conscious animals to intraabdominal currents and the tissue tolerance to the applied energy has to be studied.

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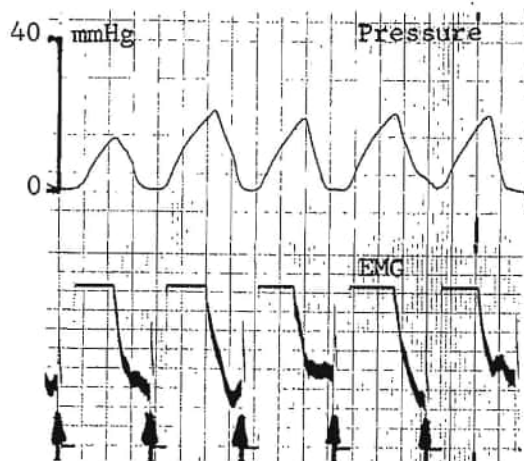


Fig 1: Jejunum loop stimulation
500 msec, 0.2 Hz, horizontal
current flow 20 mA.

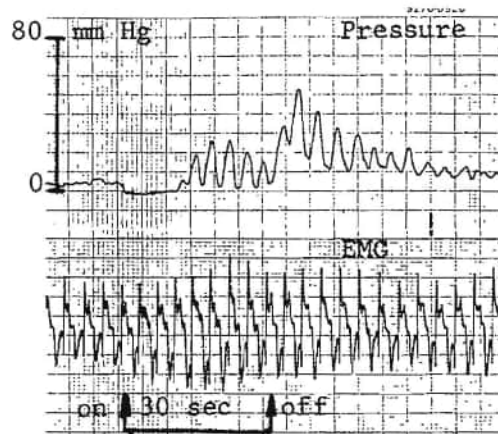


Fig 2: Jejunum loop stimulation
1 msec, 10 Hz, 25 mA horizontal
current flow.

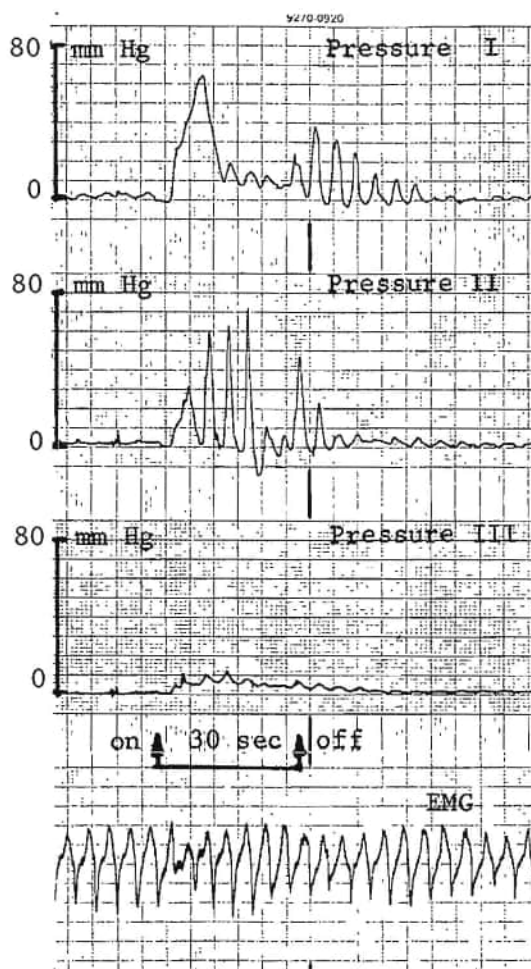


Fig 3: Jejunum loop stimulation
1 msec, 330 Hz, 20 mA horizontal
current flow. Pressure I at elec-
trode site, all others distal.

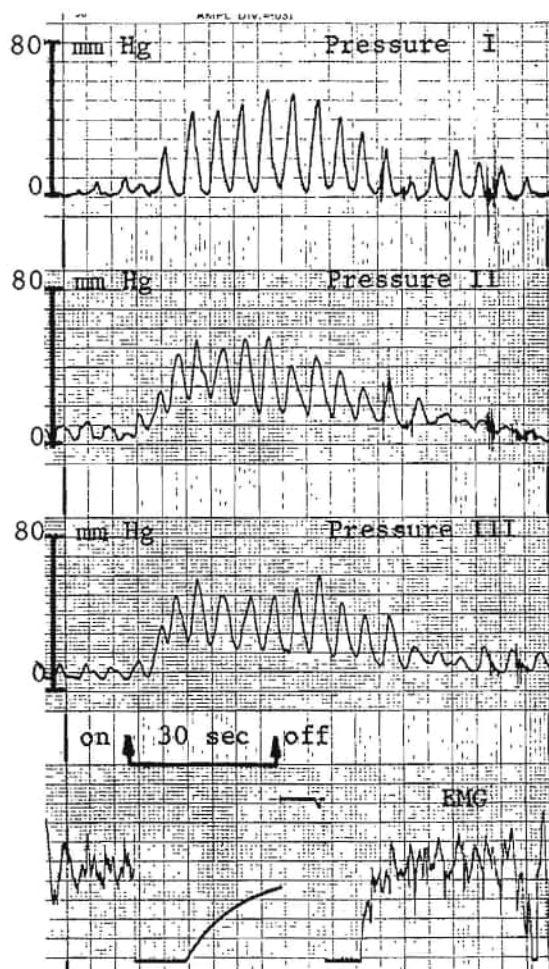


Fig 4: Jejunum pouch stimulation
500 usec, 910 Hz, 25 mA longitudinal
current flow. Pressures I to III are
within the pouch.

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CONTRACTION CONTROL OF A MECHANICALLY LOADED MUSCLE DURING ARTIFICIAL NERVE STIMULATION (EXPERIMENTAL SETUP AND PRELIMINARY RESULTS)

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SUMMARY

In rat experiments, length and force signals of artificially stimulated muscles connected to a defined second order mechanical load were investigated. A concept for open-loop muscle length control by graded contraction of artificially stimulated muscle is presented and some preliminary experimental results are discussed. Extension to closed-loop control is introduced.

INTRODUCTION

A paralysed muscle that is electrically stimulated to evoke functional movements is part of a muscle-skeleton-load system (Nguyen [1]). For example this is the case when a joint angle has to be controlled by graded contraction of the stimulated muscle. The objective is then to control muscle length. Figure 1 describes this situation schematically. We constructed a system in which the stimulated muscle is attached to a mechanical load, of which the characteristics can be adjusted flexibly.

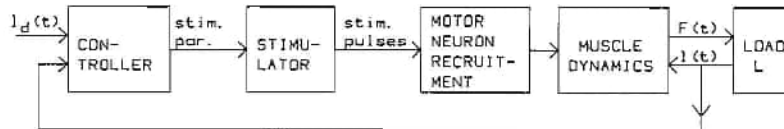


Figure 1. Schematic representation of a circuit for controlling muscle length by graded contraction of a stimulated muscle that is connected to a mechanical load.

MATERIALS AND METHODS

Experiments were performed on rats (Wiston, male, 3-4 months old, 0.30-0.35 kg) that were anaesthetized intraperitoneally with pentobarbital sodium. The initial dose was 70 mg/kg. On the average 15 mg/kg was given in addition every half hour. Atropine was given subcutaneously. In the right hind limb the Peroneus Communis Nerve was stimulated. No spinal reflexes were observed during stimulation. The Tibialis Anterior muscle was connected to a servo controlled linear motor system via a force transducer based on a strain gauge bridge. Monopolar cathodic stimulation was performed, using monophasic constant current pulses. The tip of a 200 μ m diameter stainless steel wire electrode was used for extraneural nerve stimulation. An indifferent electrode was placed in between muscles outside the stimulation region. Muscle contraction was modulated by motor neuron recruitment regulation realized by variation of stimulation pulse amplitude. Stimulation frequency and pulse width remained constant during stimulation (respectively 30 Hz and 60 μ s).

A mechanical load was realized by using the servo controlled linear motor to impose muscle length and the strain gauge bridge for measuring muscle force. A programmable processor, incorporating a 6502 μ -processor and an AM9511 floating point arithmetic coprocessor, was used to compute a desired length signal from the measured force signal via a mathematical simulation model of the mechanical load. This model can be downloaded from an LSI 11/23 computer

which controls the experiments. The mechanical load system is schematically illustrated in figure 2.

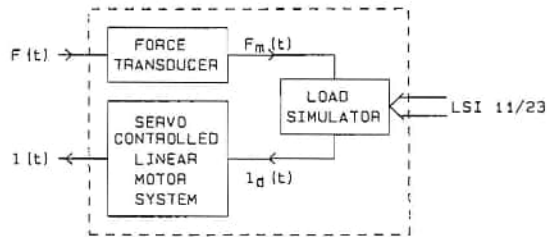


Figure 2. Realization of a mechanical load connected to a stimulated muscle.

$F(t)$: muscle force
 $F_m(t)$: measured muscle force
 $l_d(t)$: desired muscle length
 $l(t)$: imposed muscle length

Firstly some experiments were performed to investigate the influence of various mechanical loads on the muscle contraction. This was done for a second order linear load model:

$$F = M \cdot \ddot{l} + D \cdot \dot{l} + C \cdot l \quad (1)$$

The model parameters are M (mass), D (damping) and C (compliance). During the experiments muscle contraction was investigated for a number of parameter combinations, while stimulating the muscle supra-maximally (all motor units recruited) during about 2 s.

We first studied open loop length control, because it enables us to obtain a model of every functional block of the control system (see figure 1), especially the recruitment characteristics and muscle dynamics, which is necessary when designing a control system. A closed loop control system can later be obtained by adding a controller that minimizes the difference between desired and actual muscle length. Wilhere [2] evaluated such a closed loop controller for regulation of muscle force under isometric condition.

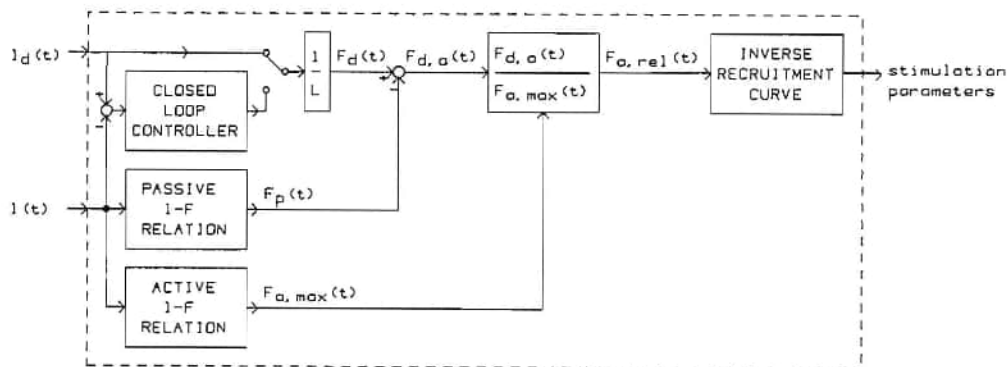


Figure 3. Concept of an open and closed loop controller for control of muscle length. The stimulation pulse amplitude or width is modulated.

$l_d(t)$: desired muscle length
 $l(t)$: actual muscle length
 $F_d(t)$: desired muscle force
 $F_{d,a}(t)$: desired active muscle force
 $F_{a,max}(t)$: maximal mean muscle force at stimulation frequency used
 $F_{a,rel}(t)$: desired active muscle force, relative to $F_{a,max}$

A concept for an open-loop controller for muscle length control is shown in figure 3. Extension to closed-loop control can be achieved by adding a closed loop controller as indicated in the figure. Currently this concept is investigated. Some initial experimental results on open loop-control will be discussed. The muscle is considered to be a force generator. The desired muscle force is computed from the desired length signal using the inverse of the known mechanical load model. The desired active muscle force is obtained by subtracting the passive muscle force from the desired muscle force. This passive muscle force depends on muscle length [3]. This relation can be measured easily. The maximal mean active force also depends on muscle length

[3] (active length-force relation). When the desired active force is divided by the time average of the maximal active force at the stimulation frequency that is used, a relative desired active force is obtained. This yields a stimulation pulse amplitude via the inverse of the recruitment curve, which is the relation between stimulation pulse amplitude and relative muscle force. The active length-force relation and the recruitment curve can also be measured. The time characteristics of the muscle dynamics, which can be modeled as a second-order linear system as described by Wilhere [2], can be incorporated in the open loop controller (not shown in figure 3). To assess the usefulness of the open loop length control concept described above, the passive and active length-force relations and the recruitment curve were measured. Also, a simplified version of this control system was tried out in a length range for which the passive muscle force was near zero and the maximum mean active force was nearly constant.

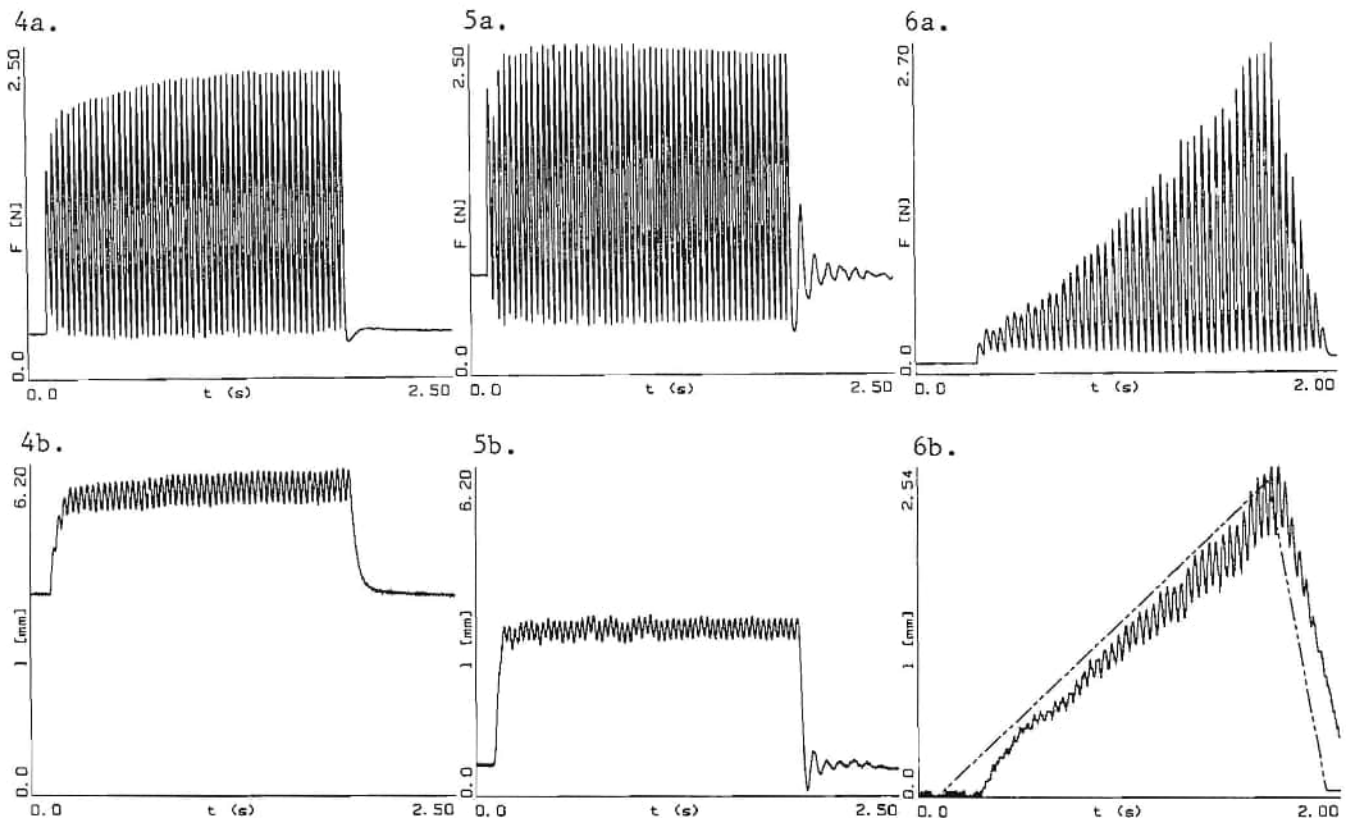


Figure 4: $m = 0.12$ kg
 $D = 32.6$ Ns/m
 $C = 463$ N/m

Figure 5: $m = 0.41$ kg
 $D = 13.0$ Ns/m
 $C = 260$ N/m

Figure 6: $m = 0.12$ kg
 $D = 32.6$ Ns/m
 $C = 463$ N/m

Figure 4,5. Force (a) and length (b) signals for two parameter combinations of the second order load model of expression (1) during 2 s supramaximal stimulation at 30 Hz. Both registrations are from the same experiment. Zero length is taken arbitrarily, but is the same for both figures; l increases for shortening muscle. The rest length, when the muscle is not contracting, differs for both figures.

Figure 6. Muscle length control for a triangular desired length function. Only the recruitment curve and the compliance of the load were taken into account (other experiment than figures 4 and 5). Force (a), length (solid line b) and desired length (dashed line b).

RESULTS

Figure 4 and 5 show length and force signals when stimulating during about 2 seconds supramaximally at 30 Hz for two parameter combinations of the second order load model (1). The resonance frequency of the load for zero damping was 9.9 Hz in figure 4 and 4.0 Hz in figure 5, which results in a larger ripple in the length signal in figure 4b compared to figure 5b. The rest length, when the muscle is not contracting, differs for both figures. The load model of figure 4 is damped super critically, while the load of figure 5 is subcritically damped. It is apparent from the results that the effective load characteristics of the load connected to a muscle are different from the

imposed load. This is caused by the mechanical characteristics of the muscle, especially its compliance. The effective compliance is greater than the load compliance, which results in a higher resonance frequency and a higher resonance peak in the modulus characteristics of the effective transfer function. Examples of the non-linear muscle characteristics that must be compensated for in the open loop length control system are given in figure 7. For both passive and active length-force characteristics hysteresis was observed depending on lengthening or shortening velocity. A simplified version of the open loop controller of figure 3 was tried out in a length range of near zero passive muscle force. The passive force was taken zero and the maximal mean active force was taken as constant. Only the recruitment curve was compensated and only the compliance of the load was taken into account in the load model within the controller (L in figure 3). Figure 6 shows the result for a triangular desired length signal.

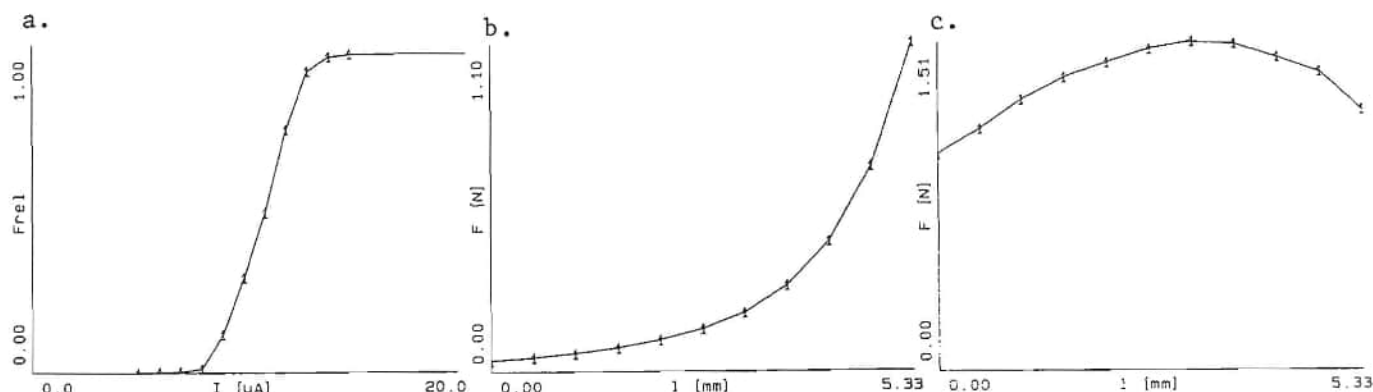


Figure 7. Non-linear muscle characteristics that have to be compensated for in the open loop length control system (the points 1 are measurement points):
a. measured recruitment curve.
b. measured passive length-force relation
c. measured active length-force relation
Shown are twitch amplitudes measured under isometric condition.

DISCUSSION

Further research is needed for testing the open loop control concept of figure 3, also in length ranges of non-zero passive force. The two length-force relations show a hysteresis. A question is whether compensating the mean length-force relation is sufficient. In future a closed loop length control system is needed for more accurate control of muscle length, especially to compensate time dependent characteristics, e.g. because of fatigue, and errors because of non-linearities that are not compensated for, e.g. hysteresis. This can probably be performed by adding a PID closed loop controller as shown in the block diagram of figure 3. Furthermore, muscle length control must be investigated for other loads, e.g. including a simulated antagonistic muscle.

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FUNCTIONALLY STIMULATED PSOAS MUSCLE AS A POWER SOURCE
FOR IMPLANTED SYSTEMS - IN VITRO MODELING

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SUMMARY

The underlying program deals with intracorporal generation of electrical energy. The source of energy is the chronically stimulated psoas muscle /1,2/.

Up to now a series of animal experiments has shown the behavior of the psoas muscle during long term chronical electrical stimulation concerning problems of mechanical response and of histological and histochemical changes /3,4,5/.

As a tool for development and optimization of a useful implantable energy-converter we have developed an electromechanical device for simulation of the mechanical behavior /6,7/ of an electrically stimulated skeletal muscle. It consists of an electronic control unit and a mechanical frame construction with a DC-motor, a transmission to tractive force, a strain gauge cell and a rectilinear potentiometer. The active and the passive force characteristic and the stimulation input characteristic are processed in an analog computer and can be adapted to measured ones. The device is also prepared to measure isometric force and isotonic length curves using additional operation modes.

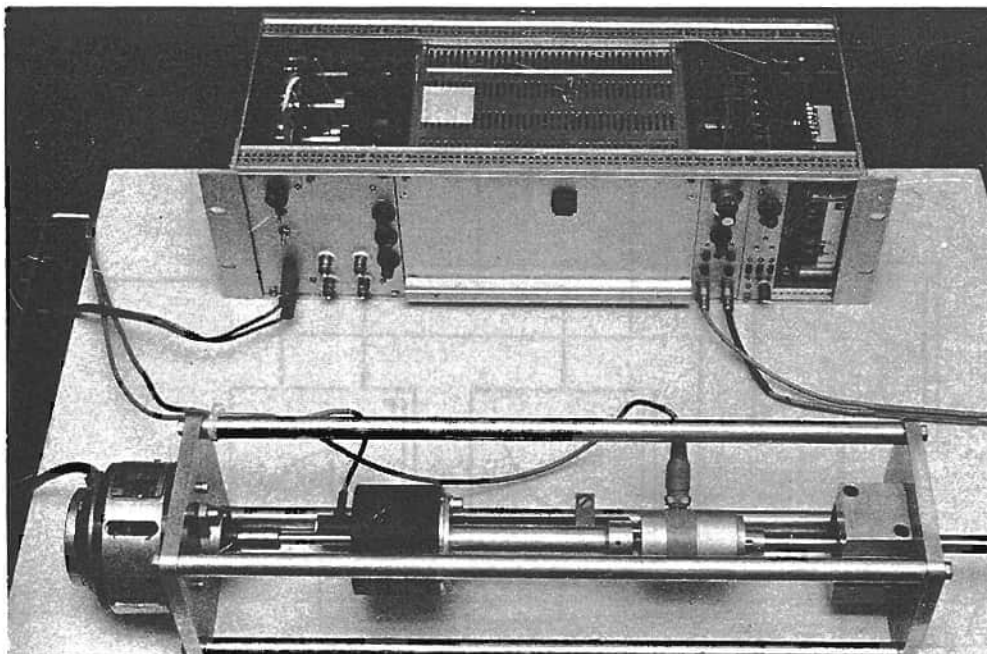


Fig.1: Simulation and measurement system

MATERIAL AND METHODES

The developed electromechanical system (Fig.1) has been designed for three different applications:

- Muscle simulation
- Isometric force measurement
- Isotonic length measurement

The dynamic requirements led to the use of a DC-motor with an ironless disc rotor. The torque is transformed to tractive force with a friction trolley head fixed to a connecting rod. The rod guided by a linear ball bearing set carries the isometric force transducer and a lever to the length transducer. The rectilinear potentiometer itself as well as the motor and the bearings are rigidly mounted on a solid aluminium frame. All moved parts are light weight components to reduce the inertia of the system.

The electronic unit controls the armature current depending on length, force and stimulation input signal and the selected operation mode.

For all three modes forces up to 200N and length changes up to 10cm can be processed.

Muscle simulation:

The mechanical behavior of an electrically stimulated skeletal muscle is simulated. Fig.2 shows a schematic diagram of this application.

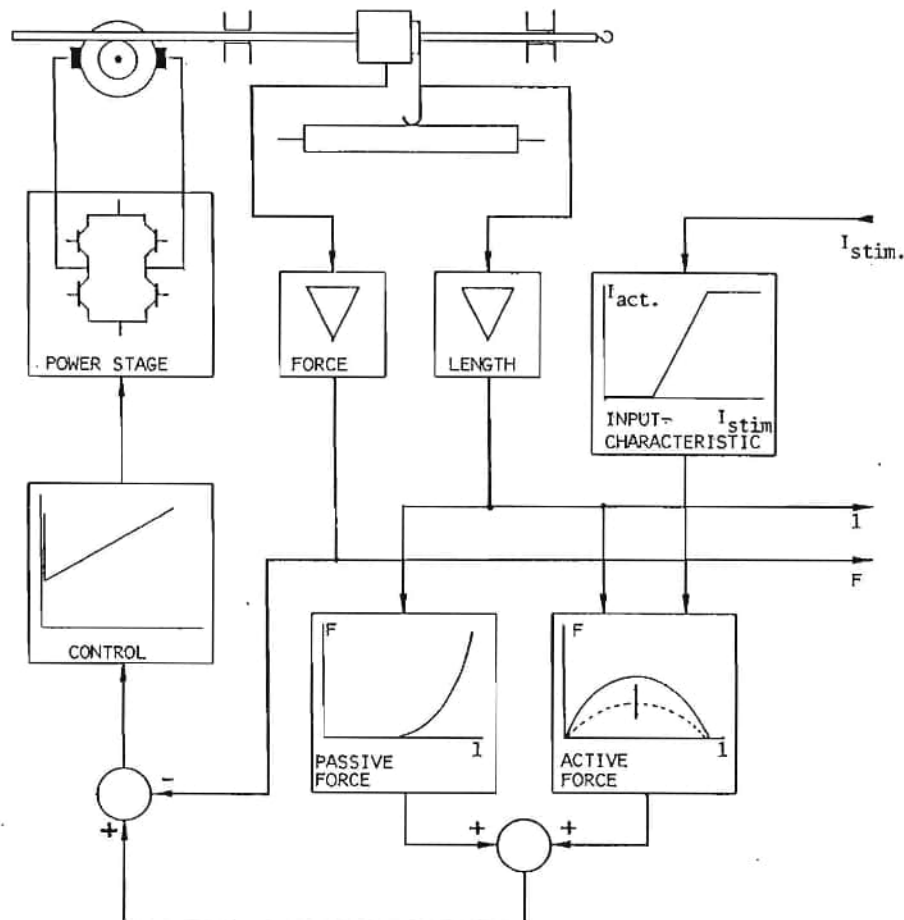


Fig.2: Muscle simulation

The input variable - a stimulation amplitude aequivalent - is trans-

formed to an action magnitude defined by threshold, amplification und saturation. This signal, the position signal and the active force characteristic determine one component of the nominal force; the second component is the length dependend passive tension. All involved characteristics can be adapted to measured ones. The difference between nominal and measured force is passing a PID-controller. A chopper amplifier supplies the DC-motor.

Isometric force measurement:

For this mode(Fig.3) a position signal is the input variable. It can be adjusted using a scale potentiometer or an external reference. The control of the armature current ensures the nominal position without dependence on external forces. Gradual measuring of isometric force curves can be performed.

Isotonic length measurement:

This operation mode(Fig.4) is done quite similarly. The input variable is a certain force level that is executed by the control system.

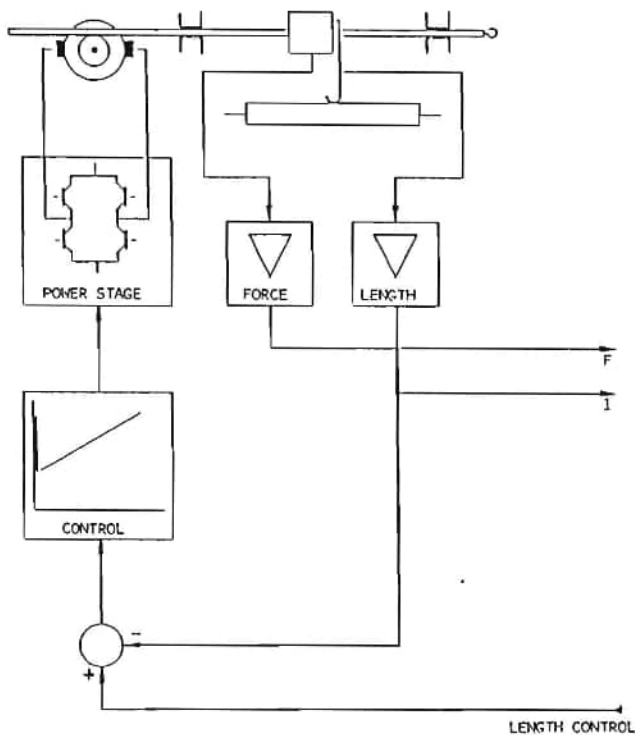


Fig.3:
Isometric force measurement

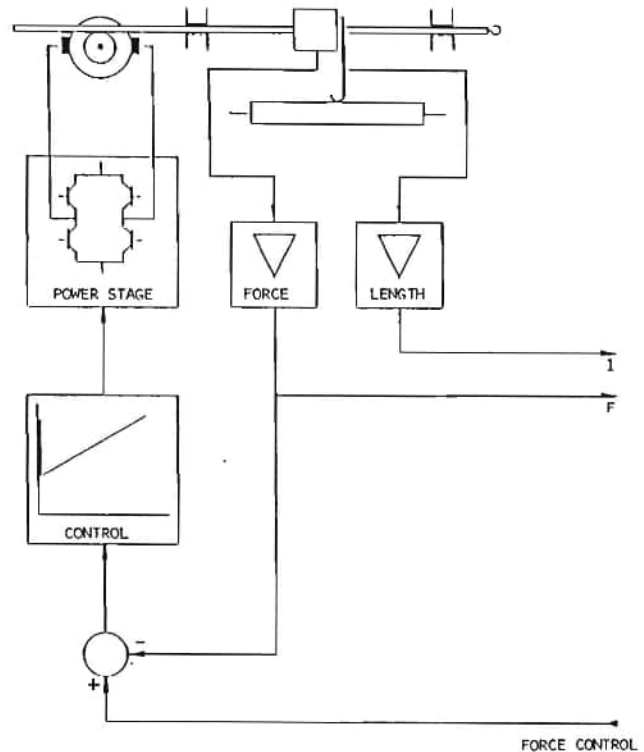


Fig.4:
Isotonic length measurement

RESULTS

Initial tests have shown a sufficient approximation of the mechanical muscle behavior. The shortest rise time to a 100N tetanic contraction is 200ms at the present optimization level; the maximum deviation of the position at 200N isometric force measurement is 5%.

DISCUSSION

The simulation device used as an "artificial psoas muscle" should help us to develop the implantable energy-converter und the appropriate control system avoiding many animal experiments. As weight and physical dimensions of the converter have to be kept small, a high level of reliabi-

lity and protection against humidity has to be achieved and a muscle's release of energy is extremely discontinuous (contraction-/relaxation-time approx. 1/2) a high efficiency generator will require a lot of development work. We plan to perform most of the testing in vitro.

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Abstract

Title: Skeletal Muscle for Cardiac Assist:
Effects of Electrical Stimulation

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We have shown canine skeletal muscle (pectoralis, latissimus, diaphragm, rectus) can be made fatigue resistant by continuous electrical stimulation (6 wks) at the dog's natural heart rate (120/min). We constructed ventricles from this fatigue resistant skeletal muscle (SMV) and connected them to the canine systemic circulation. SMVs generate 20% of the cardiac output for many hours; chronically SMVs are capable of significant continuous pressures and flows for many weeks.

This experiment examines (1) longterm effects of continuous electrical stimulation on muscle, (2) effects of continuous electrical bursts of the type needed to actuate SMV to do meaningful work. Diaphragm stimulated continuously at 120/min for one year appeared healthy and contracted vigorously. Histochemical, immunohistochemical, and biochemical analysis revealed the muscle was 100% transformed to fatigue resistant type I fibers. Similar analysis of latissimus stimulated continuously with burst patterns for 8 weeks revealed complete transformation to fatigue resistant muscle. No evidence of muscle damage occurred in either study.

Thus skeletal muscle can be stimulated for prolonged periods and burst patterns can be used for actuation of continuous contractions without causing muscle damage. Muscle stimulated as above develops and maintains slow-twitch fatigue resistant characteristics needed for long term cardiac assistance.

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RECONSTRUCTIVE CARDIAC SURGERY USING AN AUTOLOGOUS SKELETAL MUSCLE.

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SUMMARY

Neuromuscular electrical stimulation has been investigated for use as a means to provide cardiac assistance in cases of heart muscle failure. In previous experimental and clinical experiences we showed that electrically activated skeletal muscles can produce chronically repeated and sustained work without significant fatigue. This long-term biocompatible skeletal muscle stimulation, has become possible in our laboratory as a result of the development of specially designed electrodes and the use of progressive, sequential stimulation protocol to adapt the skeletal muscle to a cardiac support function. In this work, we attempted the substitution of part of the ventricular wall, rather than only its reinforcement, by an electrostimulated Latissimus Dorsi muscle flap. Reconstructive cardiac surgery with autologous skeletal muscles seems to be a valid alternative in addition to current methods of treatment for irreversible myocardial failure.

MATERIAL AND METHODS

To overcome fatigue in long-term stimulation of a Latissimus Dorsi muscle (LDM) flap used as a myocardial substitute, we have trained the LDM preliminary to its transposition over the heart, with a progressive and sequential stimulation protocol. Ten goats were implanted with original intramuscular electrodes and an Itrel stimulator for in situ stimulation of the LDM, with pulse trains composed of 210 μ sec balanced charge cathodic pulses occurring at a frequency of 30 Hz, with a duty cycle of $(T(\text{on})/T(\text{on}) + T(\text{off})) = 25\%$. The number of bursts per minute was gradually increased from 30 to 80 every two weeks. After 3 months of training histochemical and electrophysiological studies of conditioned LDM were performed. Subsequently the cardiac walls of the 10 goats were substituted with the stimulated LDM flaps. A partial resection of the right (5 goats) and left (5 goats) ventricles was performed, under cardiopulmonary by-pass. In order to have an hemocompatible new cardiac wall, an autologous pericardium patch, intraoperatively treated with glutaraldehyde (0.62%, 10 minutes) was placed as an interface between blood and the skeletal muscle, and covered by the LDM flap, stimulated in synchrony with the heart contractions after 10 days of the operation. The 10 minutes contact of pericardium with glutaraldehyde is necessary to allow a sufficiently high degree of collagen cross-linking to insure long-term pericardium stability. The postoperative cardiac output was measured by thermodilution technique using a Cardiac Output Computer (American Edwards model 9520 A) coupled to a Swan-Ganz catheter (6 months follow-up). New histochemical, histological and electrophysiological studies were performed over the muscle flaps transferred to this heterotopic position.

RESULTS

Electrophysiological measurements showed that conditioned muscles were slower than their contralaterals. Burst stimulation at increasing frequencies demonstrated that the fusion frequency was consequently lower for conditioned muscles. Fusion was investigated by measuring the relative force ripple at different burst frequencies.

Burst conditioned muscles exhibited lower fusion frequency (12 ± 3 Hz) than their contralateral controls (24 ± 4 Hz).

The fatigue resistance characteristics were estimated by measuring the relative evoked force decrease after 15 minutes of cyclic stimulation. Force decrease was lower with conditioned muscles ($-22 \pm 4\%$) than with unconditioned contralateral muscles ($-50 \pm 6\%$).

Histochemical studies showed that in stimulated LDM flaps, the percentage of slow-twitch oxidative, fatigue resistant fibers ($99 \pm 1\%$) was greater than in contralateral muscle controls ($46 \pm 5\%$).

Pyrophosphate gel electrophoresis performed over muscle fibers to identify myosin isozymes showed that the fast isozymes had disappeared and were replaced by slow isozymes, in all electroconditioned muscles.

A normal cardiac output was preserved with this technique, for periods exceeding 6 months: control animals 3.72 ± 0.25 l/min; right ventricle replacement 3.67 ± 0.18 l/min; left ventricle replacement 3.61 ± 0.28 l/min.

DISCUSSION

This study was designed to determine the satisfactory operation, safety of the cardiac assist system (electronics and leads) as well as the effectiveness of the "cardiomyoplasty" procedure for improving chronic low cardiac output.

This surgical technique has been called cardiomyoplasty in our laboratory, because it involves the reconstruction of the heart with the help of a skeletal muscle. It could perhaps be more appropriately named "electro or dynamic cardiomyoplasty", since the skeletal muscle is electrically stimulated. (3)

The experiments have demonstrated the feasibility of this technique and the long-term adaptability and adequate electrophysiological properties of the Latissimus Dorsi flap transferred to an heterotopic position over the heart.

Autologous pericardium treated with glutaraldehyde was found to be a suitable material to close the ventricular cavity, and showed good hemocompatible characteristics: no thrombogenic.

This biological cardiac assist system, designed to augment cardiac output by pacing a skeletal muscle wrapped around a deficient heart, in synchrony with the heart contractions, is intended for use in patients with chronic low cardiac output e.g. resulting from cardiomyopathy, ischemic heart diseases, aneurysm, congenital disease, tumoral outgrowth, etc. (2)

Beneficial cardiac effects of dynamic cardiomyoplasty has been documented in patients (1, 4). Our successful clinical application in cases involving the resection of a large cardiac tumor (20 months of follow-up) and a left ventricular ischemic aneurysms repair (6 months follow-up) showed that cardiomyoplasty with an autogenous electrostimulated skeletal muscle will be considered a valid alternative in addition to current methods of treatment for irreversible myocardial failure.

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MYSCLE POWERED EXTRA-AORTIC BALLOON FOR CARDIAC ASSIST

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An emerging technology of Cardiac Assist Systems (CAS) is being developed in which the work energy is harnessed from a suitably located endogenous muscle pedicle. Since the skeletal muscle has to contract in prescribed synchrony with the natural heart, a muscle electrical stimulator of the pacemaker type is developed as a system component for total implantation. As an intermediate to both the total mechanical or artificial heart approach on the one hand, and the total biological or heart transplant on the other hand, the new biomechanical approach will combine the best features of both, while attempting to reject their drawbacks.

Three interrelated muscle activated cardiac assist systems are being investigated (Figure 1). In the first, a strip of diaphragmatic muscle is utilized to perform cardiomyoplasty of either ventricle.¹ In the second, a specially designed balloon is wrapped with skeletal muscle to pump blood between the heart apex and the descending aorta.² The third system which will be described in this paper involves an extra aortic balloon counter-pulsation device to reduce cardiac afterload and increase coronary perfusion pressure. The advantages and limitations of these systems and their sub-systems will be discussed.

Muscle electrical stimulation parameters were optimized to produce muscle contractions of sufficient duration and strength to produce diastolic augmentation. Various protocols were devised to address the problem of muscle fatigue. Conversion of muscle fast twitch, type II fibers to slow, fatigue-resistant, type I fibers by prolonged muscle stimulation at low frequency provide one successful approach. Another approach involves a change in muscle stimulation protocol to keep it relaxed during systole where the major blood supply is available and make it contract only during diastole or end systolic stages. Finally, a change of pacing ratios can be adopted in conjunction with the above procedures to circumvent the fatigue problem.

Materials and Methods

Mongrel dogs, 17 kg to 35 kg in weight, were anesthetized with sodium pentobarbital and ventilated with 100% oxygen. Arterial blood gases and blood glucose were monitored and kept within the normal range. Extra-aortic balloon pumps (EABP)³ were built by Medtronic with 30 cc and 100 cc volume capacity from Biomer. In the acute canine experiments to be reported, a T tube was inserted between the transected aorta and the tube outlet of the EABP and held by snares. The EABP was connected directly to the divided left subclavian artery distal to the thoracodorsal and thoracoacromial branches. The pumping chamber was wrapped by the latissimus dorsi pedicle. The muscle was stimulated directly by two electrodes placed 3 cm apart on the muscle. The stimulator (with stimulation parameters described in Figure 2) was triggered from the Electrocardiogram (ECG) or from the pressure tracing. Parameters monitored included stimulator output, aortic arch pressure, LV pressure and its dP/dt, and the ECG. The subendocardial viability index (DPTI/TTI) was derived from superimposed tracing of aortic arch and LV pressures.⁴

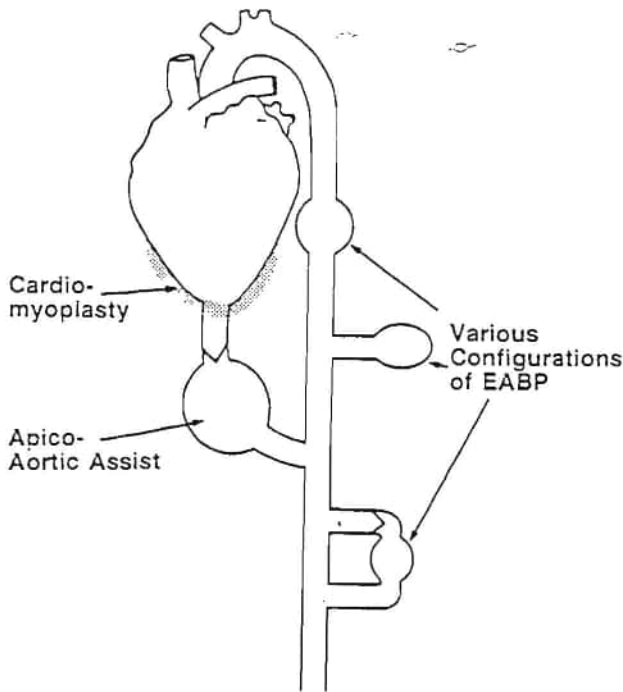
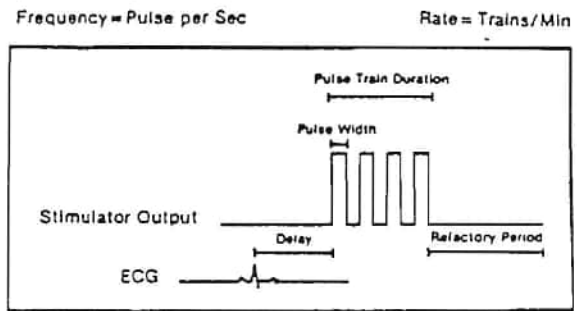


FIGURE 1 Left ventricular assist device configurations: LV apico-aortic valved conduit, aortic-aortic valved conduit, extra-aortic balloon pump and aortic in-continuity chamber.



Programmable Stimulator
 Delay.....30-475 msec
 Frequency.....4-155 cps
 Pulse Width.....130-500 μ sec
 Pulse Train Duration...30-475 msec
 Current.....0-50 ramp in 15 steps

FIGURE 2 Definitions and ranges of programmable stimulation parameters.

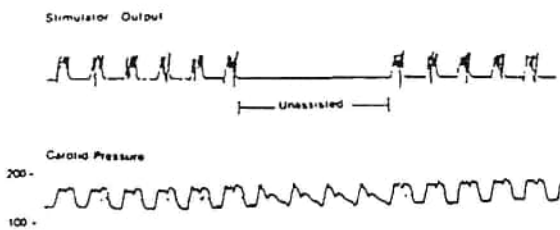


FIGURE 3 Synchronous diastolic assistance by extra-aortic balloon pump powered by latissimus dorsi pedicle with 1:1 pacing ratio.

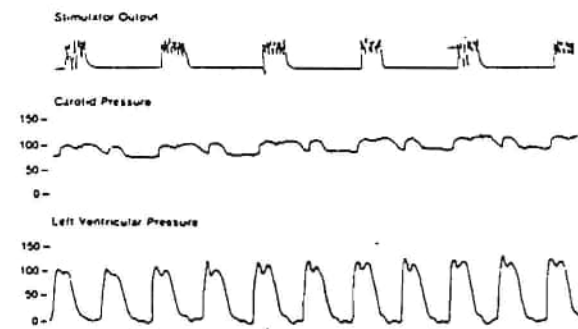


FIGURE 4 Synchronous diastolic assistance by extra-aortic balloon pump powered by pectoralis major pouch with 2:1 pacing ratio.

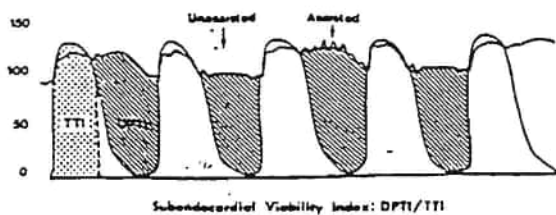


FIGURE 5 Subendocardial viability ratio (DPTI/TTI) defined by superimposed aortic arch and LV pressure tracings.

TABLE I
 Subendocardial viability index (DPTI/TTI)

Experiment	Unassisted	Assisted	% Increase
1	0.82	1.08	32
2	1.27	1.45	14
3	0.88	1.03	17
4	1.09	1.25	15

The increase is statistically significant ($p < 0.05$, paired t-test)

Results

Counterpulsation by EABP was achieved at a pacing ratio of one-to-one for over two hours and a pacing ratio of two-to-one and three-to-one for over 3 and 7.5 hours, respectively. The increase in DPTI/TTI was significant and consistent.

Conclusion

The value of counterpulsation is well known and must be taken in consideration in the selection of the device configuration. The EABP is more effective than the intra-aortic balloon pump when adapted for right heart assistance, due to its greater stroke volume. It is also advantageous to use a skeletal muscle power source for diastolic rather than systolic assist. This allows the muscle to relax during systole, maximizing muscle perfusion. Secondly, variable pacing ratios are possible and allow for more complete filling of the pumping chamber. Finally and most importantly, systolic filling of the chamber provides adequate resting stretch to the skeletal muscle fibers. This allows greater contraction pressure to be generated by the length-tension relationship.

In conclusion, a prototype synchronous pulse train stimulator has been developed and the optimal stimulation parameters characterized. This stimulator has been used to stimulate skeletal muscle and drive an EABP for up to 12 hours in acute experiments in dogs.

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NERVE STIMULATION WITH A ROUND-ABOUT ELECTRODE: SENSITIVITY AND FORCE ADDITION

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SUMMARY

A four-electrode round-about configuration was used to stimulate the nerve of rat. The sensitivity was higher using longitudinal current flow using an indifferent electrode than for transverse current flow between two electrodes of the round-about configuration.

Based on isometric force registrations it was concluded that the short-term stability of the motor unit recruitment is poor. The force addition using two electrodes simultaneously was also poor.

INTRODUCTION

Progress in the application of functional electrical stimulation (FES) for for instance the restoration of locomotion in paraplegics is expected from the use of dedicated implantable systems. When using the direct stimulation of peripheral motor nerves, muscle force can be modulated by varying the number of active motor units and their activation frequency. Multi-channel extraneural electrodes may be used to stimulate different groups of motoneurons within the nerve bundle. Then by simultaneous activation of motoneurons by stimulating them alternately their firing rate may be kept low, while obtaining smooth muscle contractions. Alternating the group of active motor units is in addition helping to achieve long-term fatigue-free contractions. We studied the sensitivity of a four electrode round-about configuration in rat and also the short-term reproducibility of the motor unit recruitment. By stimulation on two electrodes simultaneously the force summation was studied.

MATERIALS AND METHODS

Twelve rats (wiston, male, 3-4 months, 0.30-0.35 kg) were anaesthetized intraperitoneally with pentobarbital sodium (initial dose: 70 mg/kg plus every half hour 15 mg/kg in addition). Atropine was given subcutaneously. The Peroneus Communis Nerve of the right hind limb was stimulated while the isometric force of the Tibialis Anterior muscle was measured.

Four stainless steel electrodes with a diameter of 200 μm and spaced in one plane were put around the nerve as shown in figure 1. This round-about electrode configuration was used with monophasic current pulses having a width of 60 μs . The current level was kept constant during the stimulation pulse.

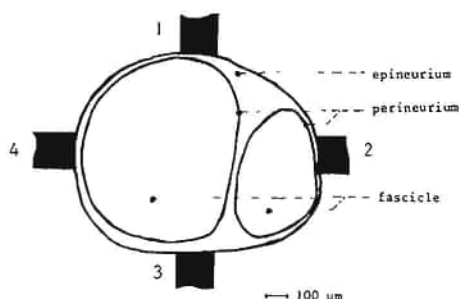


Figure 1:
Impression of the round-about electrode configuration and the stimulated nerve, both drawn to scale. The four stainless steel electrodes have a diameter of 200 μm . The numbering of the electrodes is according to that used in the text. The nerve is drawn from a photograph of the cross-section of the N. Peroneus Communis of the rat.

The sensitivity of this round-about electrode configuration was investigated by stimulating:

- bipolar between two electrodes of the round-about configuration.
- between one round-about electrode and a Au ring electrode around the nerve at a few mm distance.
- monopolar between round-about electrodes and a large indifferent Ag/AgCl electrode between some muscles outside the stimulation region.

Short term stability of the recruitment of motor units was investigated by stimulation at a low frequency (0.5 or 1.0 Hz) on single electrodes. The current amplitude was chosen low, so only a few motor units were recruited. In this way the recruitment properties can be compared with those of intrafascicular electrodes as described by Veltink, 1986.

The stability of the obtained twitch force levels at a specific stimulation amplitude gives an indication of the recruitment stability.

The uniqueness of the group of motor units activated by each electrode was investigated by studying the force addition properties when stimulating monopolar at more than one round-about electrode simultaneously. Therefore near tetanic force levels were evoked during about 0.5 s by stimulation at a frequency of 70 Hz at each electrode separately and in combinations. At near tetanic force levels the non-linear compliance of the serie elastic component of the activated muscle fibers is small. So the shortening velocity of the contractile elements is minimized and also its influence on the force level achieved. Interference of the electric fields resulting from the stimulation pulses at the various electrodes was prevented by using the same stimulation frequency while maximizing the phase lag between the pulses. The extend of force addition by stimulation at more than one electrode provides a measure for the extend in overlap of the recruited groups of motor units. The electrode configuration was studied at stimulation amplitudes resulting in small force levels, corresponding to the activation of a few motor units and up to force levels corresponding to a quarter of the maximum achievable with one electrode.

RESULTS

During stimulation of the Peroneus Communis Nerve no spinal reflexes were observed.

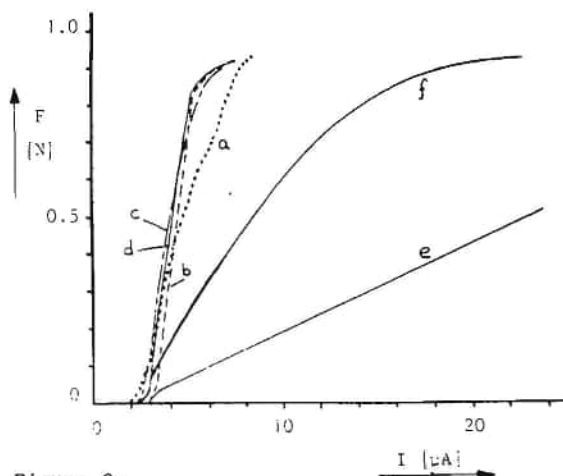


Figure 2:
Typical relation between maximum twitch force and stimulation current pulse amplitude. Pulse width is 60 μ s.

- round-about electrode 1 as cathode and indifferent electrode between muscles at distance.
- the same as a but electrode 1 as anode.
- the same as a but electrode 3 as cathode.
- the same as a but electrode 3 as anode.
- electrode 1 of the round-about electrode used as cathode and electrode 3 as anode.
- electrode 1 anode and electrode 3 cathode.

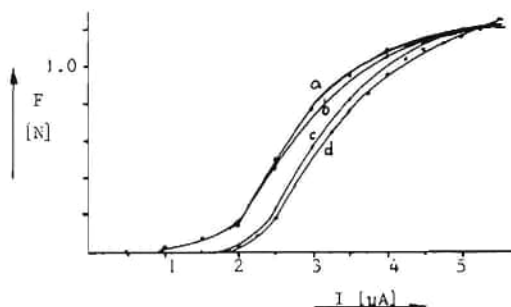


Figure 3:
Typical maximum twitch force when using one electrode of the round-about configuration as cathode against two different indifferent electrodes. These are an Au ring around the nerve about 8 mm proximal or a large Ag-AgCl electrode between the muscles at distance.

- electrode 1 against Ag-AgCl electrode.
- electrode 4 against Ag-AgCl electrode.
- electrode 1 against Au ring electrode.
- electrode 4 against Au ring electrode.

The relations between the stimulation current amplitude and the resulting twitch force amplitude using several stimulation electrode combinations are given in the figures 2 and 3. Typical results show the anodic stimulation to be less sensitive than the cathodic stimulation. Stimulation between two of the electrodes of the round-about configuration is much less sensitive than stimulation against an indifferent electrode.

The following results concern stimulation on one or more electrodes of the round-about electrode using an indifferent Ag/AgCl electrode at distance. Stimulation at low frequency (0.5 and 1.0 Hz) and for low force (less than a quarter of maximum) showed discrete levels of maximum force, corresponding to the sum of the discrete motor unit contributions. A typical example of the twitch amplitudes obtained with one electrode of the round-about configuration at several small stimulation amplitudes is presented in figure 4. As shown at a specific stimulation amplitude the resulting force amplitude varies in a wide range. The number of force levels is great, and the differences between these levels is small, which indicates a great variety in the combinations of recruited motor units. So apparently not only a few large motoneurons are activated, but a wide range of motoneurons seems to be involved.

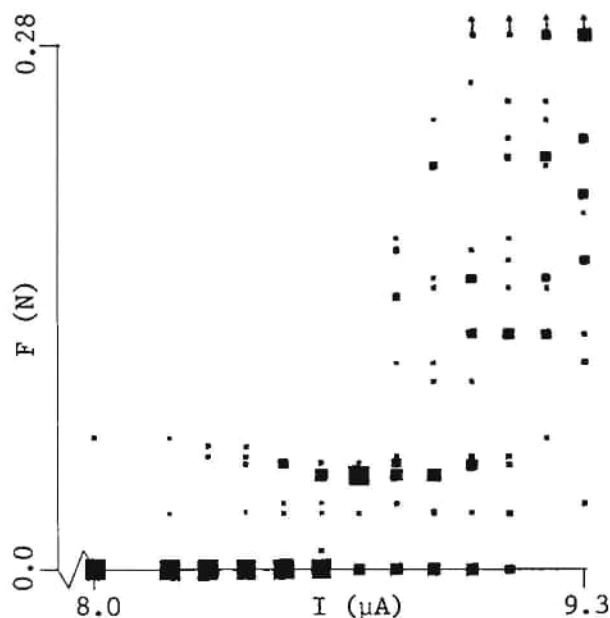


Figure 4:
Typical example of twitch amplitudes at several stimulation pulse amplitudes, using one of the extraneural electrodes of the round-about configuration. The area of the squares indicate the relative contribution of the twitch amplitude at the specific pulse amplitude. Pulse width was 60 μ s.

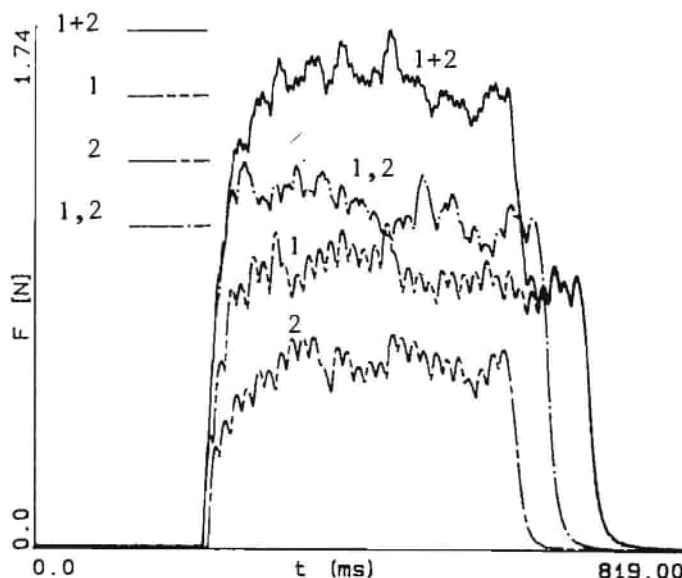


Figure 5:
Typical example of near tetanic force registrations at 70 Hz stimulation frequency.
1. registration of electrode 1.
2. registration of electrode 2.
1,2. registration for combined stimulation, at same current amplitudes as in 1 and 2, on both electrodes (stimulation was done alternately).
1+2. summation of registrations 1 and 2.

Figure 5 shows a typical example of a near tetanic force registration. Here also lack of recruitment stability can be observed, which was also the case in all our experiments using this method. From figure 5 and all our other experiments like those presented in table 1, it was observed that summation of force, when stimulating on two electrodes simultaneously was never complete. Mostly the summation was reasonable for the first 50 ms but often about a quarter lower than the mathematical sum of the individual electrode force responses. Then the two electrode force response decreases soon. No systematic differences were observed in force summation for all possible combinations of two extraneural electrodes.

DISCUSSION

Recruitment of motoneurons appeared at lower current levels when stimulating against an indifferent electrode than when stimulating between two electrodes of the round-about electrode. This may be explained by the larger gradient in

electrodes used	force [N]	force deficit [N]	force [N]	force deficit [N]	force [N]	force deficit [N]
1	0.14		0.50		1.35	
1,2	0.23	0.07	0.95	0.35	2.6	0.75
2	0.16		0.80		2.0	
2,3	0.32	0.12	1.25	0.60	2.8	1.4
3	0.28		1.05		2.2	
3,4	0.29	0.07	1.25	0.50	3.5	1.15
4	0.08		0.70		2.45	
4,1	0.18	0.06	1.05	0.20	2.9	1.15
1	0.16		0.55		1.6	
1,3	0.36	0.16	1.20	0.35	3.1	0.7
3	0.36		1.10		2.2	
2	0.30		1.00		2.2	
2,4	0.33	0.05	1.25	0.45	>3.8	<1.4
4	0.08		0.70		3.0	

Table 1. Near tetanic force maximum during the first 150 ms of stimulation at 70 Hz. Stimulation on single electrodes or combinations of two electrodes of the round-about configuration at the same current amplitude and frequency. The columns with "force deficit" show the difference between the summation of the individual electrode force responses and the combined stimulation response.

the electric potential along the nerve fibers at the same stimulation current when using a "far away" indifferent electrode. When stimulating between two electrodes of the round-about electrode the greatest electric potential gradient is perpendicular to the nerve fibers (see also McNeal 1976). Stimulation in a cross section of the nerve could be used to achieve a lower slope of the stimulus amplitude versus force recruitment curve. Talonen, 1985 investigated a 4-electrode cuff-electrode and showed that using specific electrode and stimulation parameters combination could result in selective stimulation of motor neurons of two muscles connected to the ischiatic nerve of the cat for force twitches. Our results show that this becomes doubtful when evoking near tetanic contractions. Good summation of near tetanic force levels for combined stimulation on two electrodes was not observed, this is in contradiction to the results obtained using intrafascicular electrodes (Veltink, 1986). So this is not caused by muscle properties but probably by the mutual influencing of activated neurons within the nerve. This could result in lack of recruitment stability. Overlap in the recruited populations of motor units is often indicated by a decrease in force summation after an initial better force summation. As a consequence it is concluded that the stimulation of disjunct groups of motor units was not stable enough to use combinations of these groups to obtain reliable force gradation.

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INTRANEURAL ELECTRODES FOR FUNCTIONAL ELECTRICAL STIMULATION*

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SUMMARY

Functional electrical stimulation has great potential for increasing the function and autonomy of those with spinal cord injuries or other central nervous system lesions. It is unlikely, however, that current techniques will be routinely applied because of present limitations in the interface between the individual and the computer-controlled stimulator apparatus, i.e., the stimulating electrodes. Lack of specificity, versatility, and/or durability of the electrode system severely limit this application. The intent of our current efforts is to develop an indwelling, intraneural, multipolar stimulation system that allows selective activation of peripheral motor nerve fibers. The immediate goal is to determine the tolerance of peripheral nerve to chronic implants.

Teflon-coated Pt-Ir wire was implanted for up to eighteen months in sciatic nerves of frogs. Mean leaping forces before and after implantation were statistically indistinguishable. Axons were neither destroyed nor injured; they were merely displaced by implants. Tissue response to Teflon was mild whereas that to metal was more reactive, although this abated over time. Silicon and stainless steel chips implanted in tibial nerves of rabbits caused no discernible changes in locomotion. These results demonstrate that peripheral nerve will tolerate chronic intraneural implants and corroborate the work of others in suggesting that intraneural electrodes may well be feasible.

MATERIALS AND METHODS

Sciatic nerves of 20 frogs (*Rana catesbiana*) were penetrated with a 30 gauge cannula, which was used to guide a trocar into intraneural tissues. In each anesthetized frog, one sciatic was implanted with platinum-iridium (90:10) wire (O.D. 0.114 mm, L. 1.0 mm) and the other penetrated but not implanted. Implants were coated with Teflon except at cut ends. Skin over thighs of ten control frogs was opened and sutured. Peak leaping forces in X, Y, and Z planes were determined before, at one month, and at three months postsurgery using a multicomponent force platform. ANOVA was used to compare pre- and postsurgical total leaping forces of implanted and control animals. Eighteen sciatic nerves were removed from anesthetized animals and immediately fixed in Millonig's 10% neutral buffered formalin. Impaled and implanted nerves were processed through a series of graded ethyl alcohols, infiltrated with glycol methacrylate monomer, embedded transversely in activated glycol methacrylate polymer, and allowed to polymerize. Blocks were serially sectioned at 4-7 microns on a Sorval JB4-A retracting microtome and stained with either Gill's hematoxylin and eosin (1), Palmgren's silver stain (2), or 0.5% toluidine blue in 1% sodium borate. Extent and nature of neural damage was examined with a compound microscope. Two specimens for TEM were fixed in 3% glutaraldehyde in 0.1M sodium cacodylic buffer containing 0.1% tannic acid, then post-fixed in 0.5% osmium tetroxide. Enblock staining in 2% uranyl

acetate was used to enhance contrast. Tissues were dehydrated through acetone, infiltrated and embedded in Spurr low-viscosity resin (3). Transverse ultrathin sections were cut using a diamond knife on a LKB Ultratome II, and stained with 1.5% alcoholic uranyl acetate (4) followed by lead citrate (5). These were viewed and photographed using a JEOL JEM 100 CX II transmission electron microscope at 80 KV. Silicon and stainless steel chips 1 x 2 mm x 10 microns were implanted in tibial nerves of eight anesthetized rabbits.

RESULTS

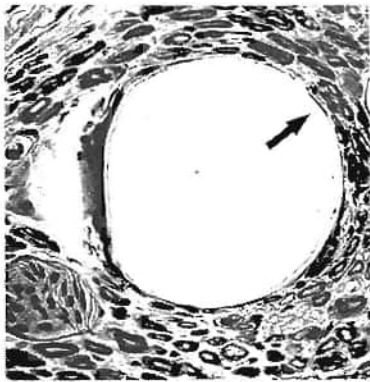
Mean maximal leaping forces one and three months postsurgery were not significantly different from those of controls. Fourteen implanted nerves were suitable for examination by light microscopy and two more by transmission electron microscopy to evaluate implant biocompatibility. Stained impaled and implanted segments were examined for evidence of demyelination, axon destruction or deterioration, scar tissue, and overall tissue response to implantation and/or surgical procedure. Segments of sciatics were examined just proximal, through, and just distal to implants or impaling sites. These demonstrated normal wound healing and declining inflammatory reaction over time. Teflon elicited formation of thin-walled capsules (1-5 cells thick) composed of fibroblasts, myofibroblasts, collagen fibers, mast cells, macrophages, and eosinophils. Axons adjacent to capsules were intact but compressed and displaced laterally. Thickenings in epi- and perineuria and increased vascularity adjacent to implant or puncture sites subsided to normal by three months. Eosinophils were obvious in areas where Teflon had been nicked or abraded; epithelial-like cells with round, dark, dense nuclei and dark pink cytoplasm were found between Teflon and metal at such sites. Tissue response at metal-tissue interfaces varied among animals and over time. The most pronounced response consisted of nodular collections of granulomatous cells at distal and proximal ends of implants exhibiting large, round, diffuse nuclei with pale pink cytoplasm along with collagen fibers (Fig. 1). At three months post-implantation these areas also included eosinophils and increased numbers of RBC's. Initially, granulomas extended about 20 microns proximal and distal to ends of implants, but decreased in size over time, sometimes to extinction. One nerve implanted for one year developed a dense capsule that contained bits of the implant. The margin of that implant was scalloped. The one sciatic implanted for eighteen months had a well developed capsule and showed a predominance of mast cells at its metal-tissue interface along with abundant collagen fibers, eosinophils and macrophages (Figs. 2 & 3).

DISCUSSION

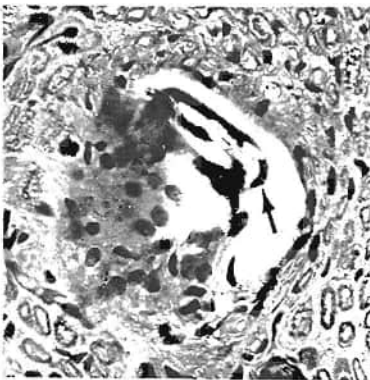
Free-standing intraneural electrodes offer a number of potential advantages for chronic electrical stimulation. The current required for nerve stimulation is only a fraction of that needed for cuff electrodes (6) and even a smaller fraction of that necessary for intramuscular or cutaneous electrodes (7). Low current requirements make telemetry feasible, reduce tissue damage, and increase longevity of electrodes (8). Multiple electrodes within a motor fascicle may permit much finer control of muscles from a minimum number of implant sites and sequential phasing of motor units to reduce fatigue. Once encapsulated, movement of intraneural electrodes relative to target axons should be minimal so responses should remain uniform over longer periods. Elimination of connecting leads will preclude stress fractures in leads, tension on electrodes, irritation at entry sites and reduce the mass to be implanted. Trauma caused by the implant and the implantation procedure should therefore be less.

Chronic implantation of sophisticated radiopowered electrode arrays within cochlear nerve has shown that nerve is capable of withstanding fairly drastic insult while maintaining function, and that distinct populations of neurons within a nerve can be addressed (9). Work by Bowman and Erickson (8) and Rabischong et al. (10) suggests that peripheral nerve will tolerate chronic implants with little or no loss of function. Our work corroborates those findings. Frogs with segments of Teflon-coated Pt-Ir wire implanted for up to eighteen months within their sciatic nerves showed no

Fig. 1. Frog sciatic nerve one month post-implantation.



A. Teflon-tissue interface with implant removed. Note thin capsule (at arrow), smooth luminal surface, and axons adjacent to capsule.



B. Metal-tissue reaction. Granulomatous cells, indicative of chronic inflammation in response to a foreign body, are just distal (<5 microns) to Pt-Ir implant. A small fragment of Teflon is seen at arrow.

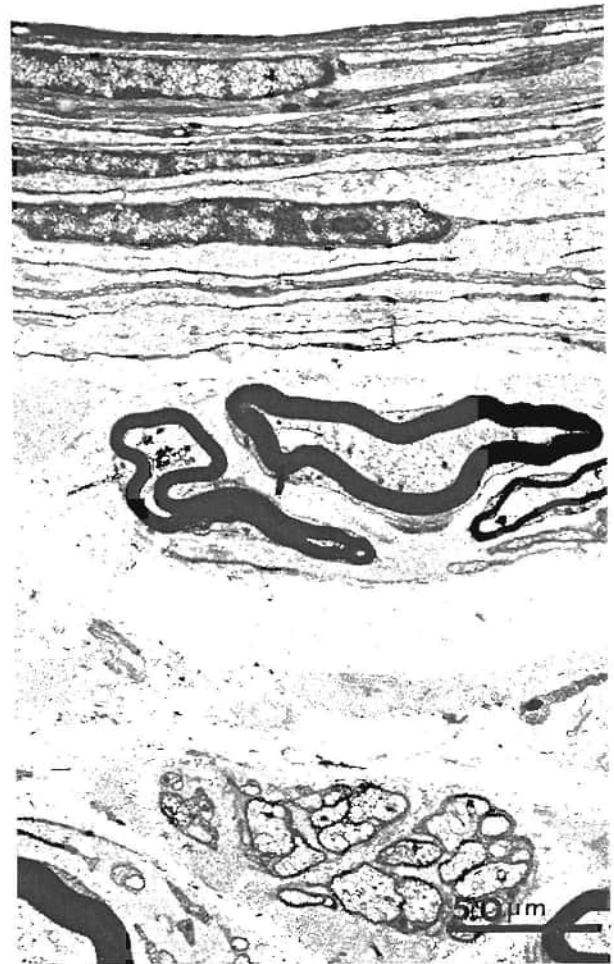


Fig. 2. Electron micrograph through capsule of a section of frog sciatic nerve implanted for 18 months. Implant crypt is at the top. The capsule is composed primarily of fibroblasts with thin cytoplasmic processes and collagen. Myelinated axons bordering the capsule appear compressed, but intact with no indication of pathology.

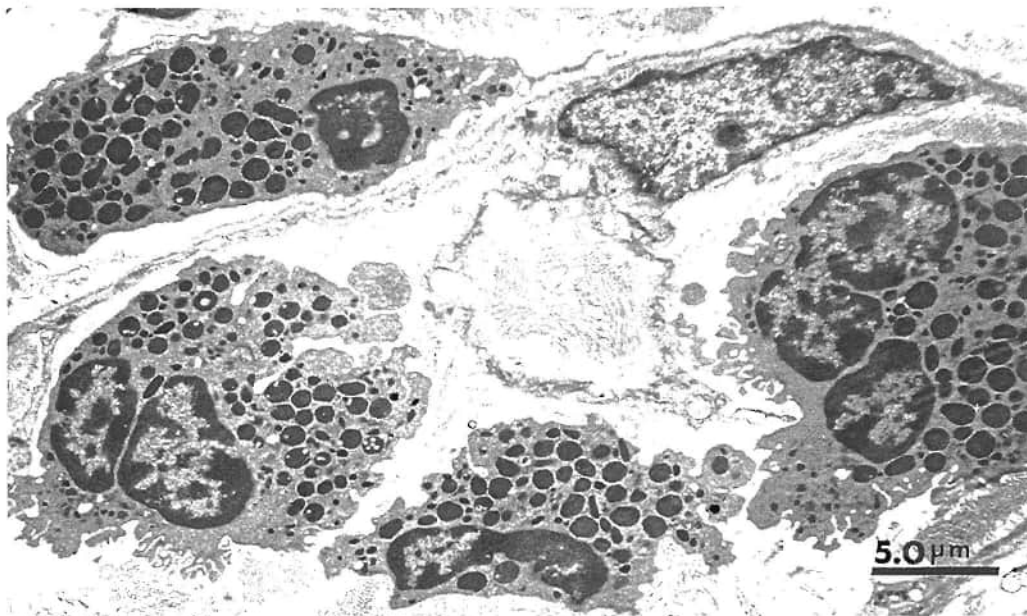


Fig. 3. Electron micrograph from same specimen shown in figure 2 through tissue just distal to implant. Shown are mast cells with numerous cytoplasmic granules, abundant collagen fibers, a fibroblast nucleus and cytoplasmic process.

loss of leaping force compared to controls or to preoperative conditions. Implants were surrounded by cells indicative of wound healing and chronic inflammation. Tissue response to Teflon was less reactive than to metal where mast cells and eosinophils were common suggesting mild, but chronic irritation. Capsules of fibroblasts, myofibroblasts and collagen remained thin with smooth luminal surfaces. Exceptions were seen when Teflon was abraded and in one animal implanted for one year, which demonstrated a thick-walled capsule. This severe reaction may have been caused by corrosion of the implant, fragments of which were seen within the lumen of the capsule. Corrosion may have been due to the biochemistry of the individual frog or a defect in the implant material. All implants, however, were made from the same stock. Irritation at metal-tissue interfaces, seen in all specimens but to a marked degree in at least one animal, suggests that Pt-Ir is not completely inert. No demyelination or axon destruction was observed; axons seemed only to have been displaced by implants. Scar tissue along implant entry routes and that formed in nerves that were simply impaled persisted for less than three months.

We have not yet completed histologic examination of rabbit tibial nerves implanted for six months with either silicon or stainless steel chips so tissue response to these materials is not yet known. However, locomotor behavior of these animals is indistinguishable from that of normals with no indication of atrophy or weakness in the implanted limbs.

These results and those of others suggest strongly that peripheral nerve will tolerate chronic implantation of a variety of electrode materials. Caution must be exercised, but indications are that intraneural electrodes are feasible.

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INTRAFASCICULAR NERVE STIMULATION USING A MULTI-ELECTRODE

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SUMMARY

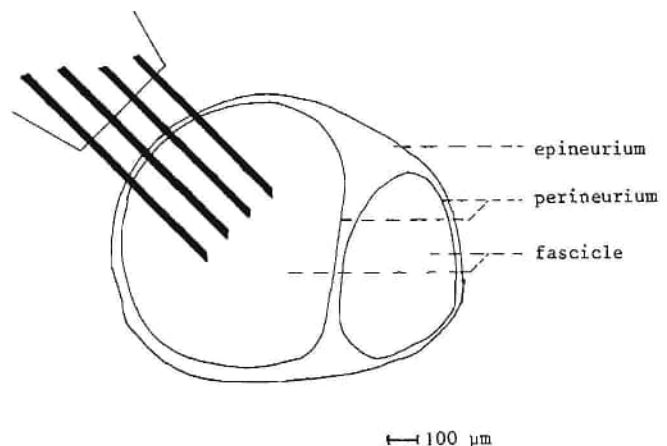
Short term motor neuron recruitment stability and recruitment overlap were investigated for a four wire intrafascicular electrode configuration. Reasonable short term recruitment stability was found in about half of the measurements, and disjunct recruited groups were seen in about half of the cases when recruitment was stable.

INTRODUCTION

Artificial nerve stimulation can be used to obtain graded muscle contractions for generating functional movements. The motor units of the stimulated muscle should contract alternately in order to reduce fatigue. Furthermore, nerve stimulation should be selective for a specific muscle and recruitment of motor units should be stable in time.

Alternating contractions of motor units may be achieved by using a multi-electrode configuration for stimulation. The groups of motor neurons stimulated by different electrodes must be non-overlapping and the composition of each group should remain unchanged when stimulation parameters are not changed. When motor neurons belonging to different muscles lie in the same fascicle, selectivity for a specific muscle may be achieved when each intrafascicular electrode only stimulates a small number of motor neurons in a reproducible way.

Figure 1: Impression of the intrafascicular electrode configuration and the stimulated nerve (drawn to scale). The electrode configuration consists of four 25 μm diameter stainless steel wires placed 100 μm apart. The wires were insulated upto the tip. The nerve is drawn from a photograph of the cross-section of the N. Peroneus Communis of the rat. Diameters of the nerve fibers are about 10 μm .



MATERIALS AND METHODS

In this study short-term recruitment stability and recruitment overlap were investigated for an intrafascicular electrode configuration consisting of four 25 μm diameter stainless steel wire electrodes, placed 100 μm apart (figure 1). The wires were insulated upto the tip.

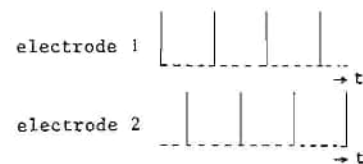
Experiments were carried out on rats (Wiston, male, 3-4 months old, 0.30-0.35

kg) that were anaesthetized intraperitoneally with pentobarbital sodium. The initial dose was 70 mg/kg. On the average 15 mg/kg was given in addition every half hour. Atropine was given subcutaneously. In the right hind limb the Peroneus Communis Nerve was stimulated and the force of the Tibialis Anterior muscle was measured under isometric condition. During stimulation of the Peroneus Communis Nerve spinal reflexes were not observed.

Stimulation was performed monopolar, using monophasic constant current pulses having a width of 60 μ s. An indifferent electrode was placed in between muscles outside the stimulation region. The four electrodes were placed in one fascicle cross-section of a nerve. Insertion of the electrodes was either done by piercing the electrode through epi- and perineurium into a fascicle, making an incision in the epineurium first and then piercing the perineurium, or making an incision in both epi- and perineurium.

During the experiments on intrafascicular stimulation low cathodic pulse amplitudes were used for which only a small number of motor units were recruited per electrode. Two kinds of stimulation experiments were performed. First, short term stability of recruitment was investigated by stimulating on each single electrode at a low frequency (0.5 to 1.0 Hz) and investigating the short term reproducibility of twitch amplitudes. Secondly, we investigated overlap in recruited motor unit groups by studying force addition resulting from stimulation on two different electrodes at near tetanic force levels. Near tetanic contractions were generated during about 0.5 s by stimulating at a frequency of 70 Hz. This was done for each electrode and alternating stimulation was performed for combinations of two electrodes, as illustrated in figure 2. The electrical fields resulting from stimulation pulses on both electrodes and the stimulated active nerve fibers influenced each other as little as possible. Near tetanic force levels were used because the non-linear compliance of series elastic components in the activated muscle fibers is minimal for a tetanic contraction. In this way shortening velocity of contractile components in the muscle is minimized, so it does not influence the force level (Hill's force-velocity relation [1,2]). The extend of force addition provided a measure for the the extend of overlap in recruited motor unit groups. Furthermore, the stability of the force levels gave an indication of the recruitment stability.

Figure 2: Illustration of the stimulation sequence on two electrodes with stimulation on both electrodes. The pulses give the stimulation moments. The pulse frequency per electrode was 70 Hz. The phase lag between the two stimulation sequences was 180°.



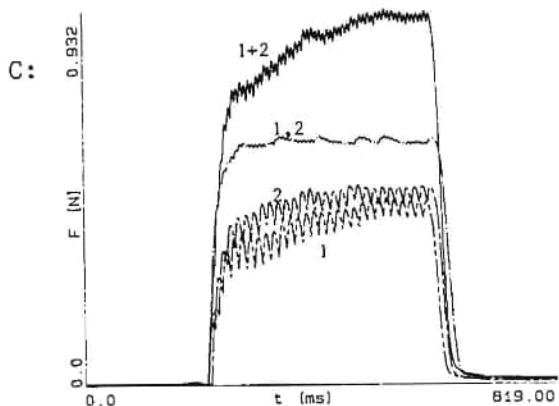
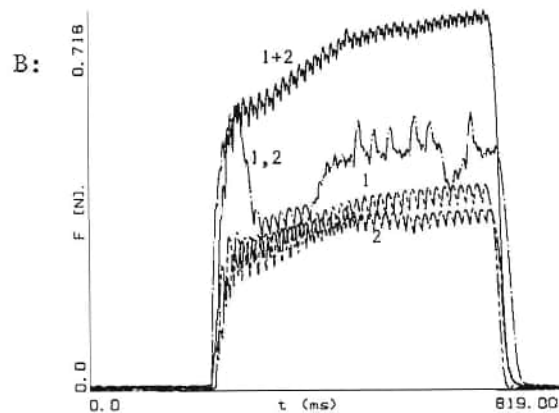
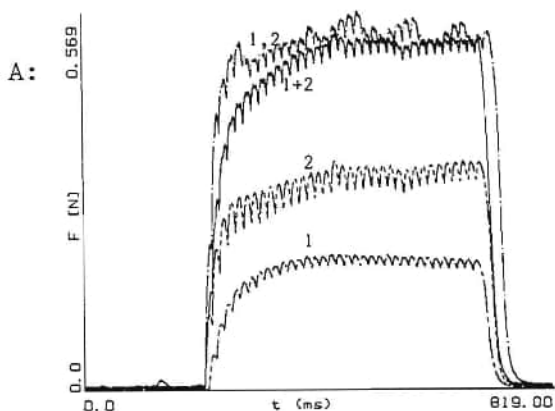
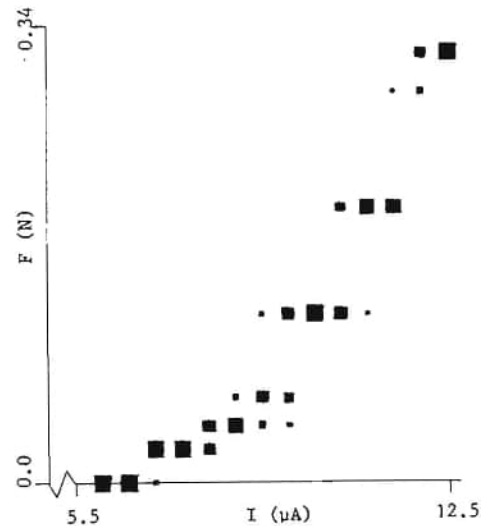
RESULTS

Short term stability of recruitment at 0.5 or 1.0 Hz stimulation was investigated in 6 rat experiments. Discrete force levels were obtained for the low force levels investigated. Figure 3 shows a typical example of the twitch amplitudes at several stimulation pulse amplitudes. No large overlap of force levels was observed. It can be concluded that stimulation by intrafascicular electrodes is reasonably stable.

Force addition for near-tetanic contraction was investigated in 5 rat experiments. Often stable near tetanic force levels were obtained (figure 4). Not always the force remained stable at one level, but changed between a few force levels. In about half of the experiments no stable force registrations were obtained. We expect the condition of the fascicle to be of importance. Especially when an incision was made in the perineurium the condition of the fascicle was bad. In that case the intrafascicular substance bulged out and stable near tetanic contractions were harder to obtain. Insertion of the

electrodes in a fascicle appeared to be easier when an incision was made in the epineurium than without this incision. When a stable near tetanic contraction on one or a few force levels was obtained, good summation was observed in about half of the cases. Figure 4A and 4B show examples. In 4B summation occurs in the beginning, but falls back to a few lower force levels. Figure 4C shows an example of a stable near tetanic contraction without good summation. Apparently non-overlapping motor unit groups were not always recruited. For all combinations of two electrodes no systematic differences were observed in these results.

Figure 3: Typical example of a twitch amplitude distribution for an intra-fascicular electrode at various stimulation pulse amplitudes. The area of the squares give the relative contribution of the twitch amplitude considered. Pulse width was constant at 60 μ s.



- 1 : registration on the first electrode.
- 2 : registration on the second electrode.
- 1,2: registration for combined stimulation on both electrodes, as shown in figure 2.
- 1+2: summation of registrations 1 and 2.

figure 4: Example of near tetanic force registrations. Stimulation frequency was 70 Hz.

- A: a non-overlapping and stable registration for two adjacent intrafascicular electrodes at low force level.
- B: a registration for which a few force levels occur during combined stimulation.
- C: a stable registration with a large overlap in recruited motor units.

DISCUSSION

Reasonably stable recruitment for intrafascicular electrodes was probably caused by a large gradient in the electrical potential in the neighborhood of the electrodes (see also [3]). The method of inserting the electrode wires in the fascicle appears to be important for the recruitment stability obtained. The method should be improved in order to increase the chance of a stable recruitment.

Summation of near tetanic force levels for combined stimulation on two electrodes indicates stimulation of disjunct groups of motor units for both electrodes. If it would be possible to use many intrafascicular stimulation electrodes, all with stable stimulation of small disjunct groups of motor units, muscle force regulation could be performed by variation of the number of recruited motor unit groups and their stimulation frequency. The stimulation pulse amplitude and width could be kept constant for each electrode. Fatigue can be reduced by alternately stimulating with various electrodes. Selectivity of stimulation for a specific muscle could be obtained by making the stimulation frequency on each electrode dependent on the distribution of motor units belonging to that muscle over the motor unit groups that are recruited by the different electrodes. This concept has to be further investigated, especially selectivity for a specific muscle must be tested.

Long term intrafascicular stimulation has not been considered in this study, but is of importance for use in functional electrical stimulation applications. Bowman and Erickson [4] investigated long term operation of intraneural electrodes for 18 rabbits upto 9 weeks and performed histological examinations of the nerve afterwards. They used 50 μm diameter stainless steel wires twisted in a 280 μm diameter helix form. No severe defects were seen in the nerve stimulated intrafascicularly.

Currently we are investigating the use of an electrode array made on a silicon substrate using chip technology for multichannel intrafascicular stimulation [5]. This could be an adequate technology for inserting many intrafascicular electrodes, but it has to be investigated whether insertion of such an electrode array does not damage the fascicle too much for obtaining stable motor unit recruitment.

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Abstract

Title: SINGLE- AND MULTI-CHANNEL NERVE STIMULATION.
A PRELIMINARY REPORT ON MUSCLE FATIGUE.

Name: W. Happak, H. Gruber, J. Holle, H. Janousek,
W. Mayr, G. Schwanda, H. Thoma

Institution: Institut of Anatomie and Second Surgical
University Clinic, Vienna, Austria

Experimental approach: In adult sheep single-channel nerve stimulation was compared with multi-channel nerve stimulation (roundabout electrode). The N. femoris and the M. rectus femoris proved to be an appropriate model. A stimulation cuff, fitting exactly to the surface of the nerve, contained 4 ring shaped wire electrodes with a diameter of 0,5 mm, was used. The cuff was sutured near the Plexus lumbalis to the nerve, 18 cm proximal to the muscle. The nerve was stimulated by a 8-channel stimulator, at which the electrical field could be changed after every impulse to another combination of the electrodes. Force and fatigue index at maximal tetanic tension were determined according to Burke & al. (1973) for the whole muscle. Fatigue indexes also were determined at several submaximal levels by reducing the stimulation amplitude. At these levels the nerve was stimulated with both methods. The preliminary results of these experiments are discussed.

Notes

Address

Street

City

Postal code

Abstract

Title: SURGICAL ASPECTS OF EPINEURAL
ELECTRODE IMPLANTATION FOR FES.

Name: M. FREY, J. HOLLE, M. DEUTINGER,
H. GRUBER, H. THOMA
2nd Surg. Univ. Clinic of Vienna
Institute of Anatomy of the Univ. Vienna

Indirect stimulation of the skeletal muscle requires electrodes as small as possible on the one hand and a careful microsurgical treatment of the nerves on the other hand.

The results of some experimental studies concerning the electrode-nerve contact are concluded to underline these important factors.

Details of the surgical procedure of electrode implantation in paraplegics will be shown.

Special attention will be paid to the two main complications of electrode implantation: electrode dislocation and infection of the implant bed.

Experimental attempts to overcome the problem of infection by coverage of the silastic surface of the electrode lines with bacteriostatic metals is summarized.

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TENS IN CHRONIC FACIAL PAIN TREATMENT

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SUMMARY

In 24 patients with chronic facial pain TENS was applied. To diminish pain the patients were previously cured with analgetics, local infiltrations, acupuncture, and some were treated surgically. The effect of all applied therapies was not lasting. To assess the pain a modified questionnaire by Picazza, Ray and Shealy was used. Controls were performed on the 10th, 20th and 30th day of application. The patients were educated to use TENS at home 1-4 hours daily. A significant decrease of drug intake was gained in 15 patients /62.5%/. The results show that in a certain number of chronic facial pain patients TENS represents a successful alternative to pharmacotherapy.

There are various methods in physical medicine and rehabilitation for chronic pain control or modification. Those methods have to irritate or activate afferent nerve fibers. Of the various techniques developed, transcutaneous nerve stimulation /TENS/ has been used since the early 1970s as very effective in chronic pain treatment. Our experiences with using TENS in chronic facial pain treatment are shown in this paper. Facial pain includes typical trigeminal neuralgia /i.e. neuralgic pain attacks lasting less than two minutes/, atypical trigeminal neuralgia /i.e. attacks lasting more than two minutes, sometimes with recurrent pain/ and atypical facial pain /i.e. persisting pain or paroxysms lasting more than one hour/ [1,2].

METHOD AND SUBJECTS

In 24 patients /19 women and 5 men/ during 1984 and 1985, TENS was applied in trigeminal nerve area. 17 patients had typical trigeminal neuralgia, and the remaining had atypical trigeminal neuralgia and atypical facial pain. Their symptoms lasted 1 to 18 years. A modified questionnaire was used with three major criteria for assessing the pain: /a/ intensity of pain; /b/ the duration of the pain each day, in percentage; and /c/ the use of drugs [3]. Before entering the study group all patients were treated with analgetics, local nerve infiltrations, 10 patients were treated with acupuncture and 4 patients were treated surgically without a lasting effect. All patients were treated with "FEBA-PO 25" /"Soča", Ljubljana/ electronic stimulator for personal use, a simple, single-channel model. The device has a pair of transcutaneous electrodes, rectangular monophasic impulses, 0.1 - 0.4 ms duration, 10 - 120 Hz frequency and 30-40 mA intensity. The anode was placed above the place where pterygo-palatine fossa can be reached with a needle and the katode was above maxillar or mental foramen [4]. The first treatment lasted 30 to 40 minutes and after that the patients were instructed to use the stimu-

lator at home for several hours daily /average 1-4 hours/. Controls were performed on the 10th, 20th and 30th day.

RESULTS

After the first control, i.e. on the 10th day, all patients felt better. The intensity of pain was reduced during stimulation and during 24 hours. Neuralgic pain attacks were reduced too. After 30 days the presence of pain was found in 9 patients /37.5%/ the same as before application, but with minimal subjective improvement. 5 patients /20.8%/ felt the same as after the first control. The pain intensity was reduced /25% to 50% of time/. In 10 patients /41.6%/ there was a satisfactory improvement. Drug intake was significantly reduced in 15 patients /62.5%/. 10 of them were not on the drugs and 9 took the same dose discontinuously.

DISCUSSION

In the past 15 years a lot of papers have been dealing with the success or failure of TENS. A lot of questions about the mechanism of pain control still remain unanswered. The concept of and approach to pain management has been revolutionized after Melzack and Wall's introduction of the "gate" theory of pain and after the discovery of opiate-like enkephalins and endorphins. Brief periods of intense stimulation or longer periods of lower-intensity stimulation have both been shown to be more effective than placebo treatment.

From the viewpoint of selection, it is desirable that the patient is motivated to obtain pain reduction. He must be prepared to reduce medication against pain and capable of using the stimulator by himself [5]. Previous experiences have shown that TENS is more effective in patients with neurogenic pain. Our results show that in 62.5% of 24 patients with chronic facial pain TENS was effective. In patients with atypical trigeminal neuralgia and atypical facial pain better results were obtained in cases with persistent or recurrent pain. This fact confirms that TENS can be applied in a certain number of patients as an alternative to medication. The efficacy is similar, there are fewer contraindications and no side-effects.

CONCLUSION

A trial of TENS in a group of 24 patients with chronic facial pain showed improvement in 62.5% subjects. The results suggest that TENS represents a successful alternative to medication especially in conditions where it can be either ineffective or undesirable. Except for an implanted cardiac pacemaker and pregnancy, there are no specific contraindications to TENS and accompanying negative effects are exceptionally rare and minimal.

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INTERFERENTIAL CURRENTS IN RELIEF OF BACK PAIN

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SUMMARY

From 1974 the Rehabilitation Department of Poznań Medical Academy applies interferential currents in treatment of patients with back pain. On the basis of our several - year experience marked and best analgetic and spasmolytic effect is being achieved when applying interferential current of constant frequency 90-100 Hz.

MATERIAL AND METHODS

Electrotherapeutic procedures as a stimulating factor have a defined influence on human organism. The action of a given stimulus depends, to a great extent on the way of its application. All biological reactions take place in the range of low frequencies. The maximum of physiological effect is being obtained in frequency range of 0-100 Hz. The difficulty in applying currents of low frequency lays in skin resistance which decreases when frequency is higher. Introduction of electronic equipment in medicine allows for obtaining and application of very low frequency currents. An apparatus for therapy with interferential currents of low frequency /according to Nemeca/ like Nemecrodyn, Interdyn i.t.c. is such an apparatus. It is equipped in 2 medium frequency current generators of 4000 and 3900 Hz. Due to simultaneous application of both above mentioned medium frequency currents, by using 4 electrodes, in the crossing point of these two current circuits, low frequency interferential current of 0-100 Hz modulation range occurs in the deep tissue. /Fig.1/

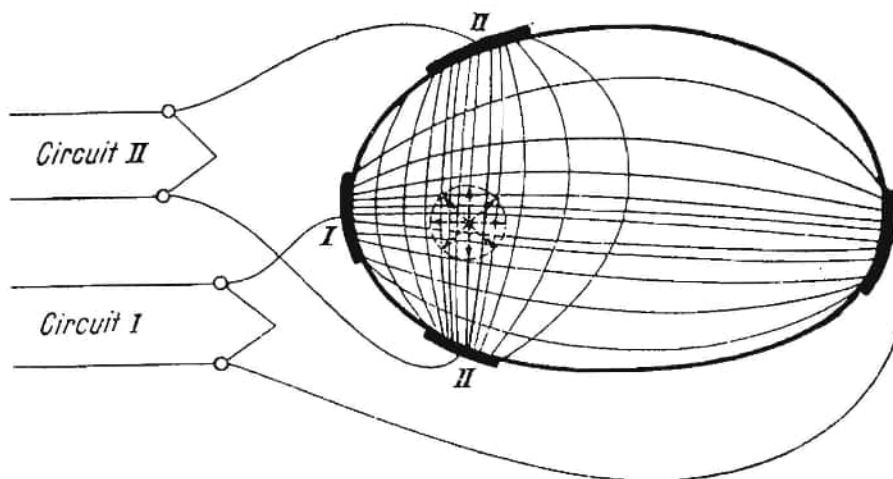


Fig. 1. Scheme of overlapping and crossing of two medium frequency current circuits, the result of what is formation of low frequency interferential current /place surrounded by a circle/.

The main feature of Nemeca interferential currents is indeed their localized action in deep tissue. The direction of current is not linear here; the resulting vector of electric stimulus crosses the place to be treated a few thousand times per second and it can be compared to radar rays which penetrate and discover the indicated place. This apparatus produces interferential currents, changed automatically in the range of following frequencies: 1-10 Hz, 10-100 Hz, 90-100 Hz, 0-100 Hz.

From 1974 the Rehabilitation Department of Poznań Medical Academy applies interferential currents in treatment of patients with back pain. On the basis of our several - year experience marked and best analgetic and spasmolytic effect is being achieved when applying interferential current of constant frequency 90-100 Hz. This kind of current, due to its influence on vegetative nervous system, decreases the tension of sympathetic system acting on vasomotor nerves mainly, what is manifested by disappearance of painful hypertension of back muscles. Besides, due to afferent sensory nerves stimulation, these currents decrease sensation of pain - we obtain the raise of pain threshold. The effectivity of procedures depends on: a/ The correct choice of electrodes and place of their application, b/ current intensity, c/ duration of procedure, d/ number of procedures. The 4 electrodes are applied to the patient's body in such a way that currents flowing in one circuit cross with currents of the second circuit in the focus of pathologic changes and pain. Current intensity must be equal in both circuits; we obtained satisfactory effect when applying current of low and medium intensity, i.e. the patient must feel strong but still pleasant vibrations. In new apparatuses like Interdyn ID 79, automatic change of circuits current intensity into the function of interferential frequency changes is applied. The higher interferential frequency the bigger currents flow in both circuits. The duration of such procedures was graded from 8-15 min. Usually, 10-20 procedures were applied.

RESULTS AND DISCUSSION

Until December 1985, Nemeca interferential currents were applied in 816 patients with back pain syndrome. Only 14 patients did not tolerate them being allergic to all electric procedures. In the remaining patients we achieved marked and positive results namely: in acute back pain - disappearance of painful hypertension of back muscles, removal of radiating pain along spinal nerves. Marked decrease of pain was obtained after 2-4 procedures what allowed for earlier introduction of basic treatment i.e. traction, mobilization, graduated exercises that restore and develop good functional efficiency of spine with strong muscle gorset. In patients with chronic pain syndromes, that were usually connected with spinal degenerative changes and localized pain, we obtained pain disappearance after 10-15 procedures, what allowed for more intensive rehabilitating treatment of the patients and for increase of their spine functional efficiency.

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DIRECT NERVE STIMULATION FOR PAINFUL PERIPHERAL NEUROPATHIES

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Although peripheral nerve stimulation has been used since 1965, only a few follow up studies have been published up to now.

The variety of pain conditions, for which this method was applied is so large, that a final evaluation of its effectiveness can not be concluded from these reports.

We are describing the results in a consecutive group of 24 patients suffering from intractable pain due to a peripheral neuropathy. They correspond to 25 % of a total of 96 patients referred to us during this period.

CLINICAL MATERIAL

There were 13 women and 18 men with a mean age of 49 ranging from 38 to 73 years.

14 patients had lesions of the lower extremities nerves.

There were four etiological factors involved, a lesion following a surgical intervention in the hip or knee area, being the most common. Before the patients were referred to us, they received already all the standard conservative treatment measures and all but two underwent a neurolysis one to three times before they reached our clinic.

Pain modality was not characteristic for any etiological group, with dragging, drilling and cutting being the most common. Only two patients have a burning pain, one femoral and one sciatic lesion.

1.) Patient selection

- Electrophysiological studies:
Either E.M.G. for motor or mixed nerves or S.S.E.P. for sensory nerves had to show clear pathology for the patients to be included in this group.
- Selective nerve blocks:
These blocks are performed always proximally to the injured area. For the patient to be included in the series, he had to be completely pain free for at least the duration of the anaesthesia.
- Percutaneous electrical stimulation:
If the patient is rendered pain free with the block a P.E.S. is performed with a needle inserted proximal to the lesion, using stimuli sufficient to procedure paresthesias in the painful area. During this trial the patient has to be relieved of this pain for more than 50 %.

2.) Surgical technique

We used a nerve stimulator with a four electrode cuff. The operation was performed in two sessions. The first session was done under general, spinal anaesthesia or a plexus block, varying with the nerve involved.

The nerve is exposed at least up to 10 cm proximally to the injury. No neurolysis of the involved area is performed. The cable coming from the cuff is buried subcutaneously, the plugs are pulled out and connected to the transmitter system. When the position is found with which the paraesthesias are felt exactly in the pain area, the receiver is implanted.

3.) Stimulation technique

The same day, an external transmitter connected to an antenna is taped to the area where the receiver is implanted. The pulse width, rate and voltage that obtain the best response are then selected. The device is used, for the first day each second hour and the patient fills an hourly chart with percentage pain relieve during stimulation and inbetween.

4.) Psychosocial work up and evaluation

Patients with major psychopathology were excluded from this series.

5.) Complications

In two patients there was a skin breakdown at the place of the receiver implantation, one of them with a skin necrosis over the cables. There was one infection that required implant removal.

RESULTS

Follow up time ranges between 8 and 41 months with a mean of 17,5 months.

Our evaluation criteria were as follows:

- 1) Very good: Complete pain relief with stimulation.
- 2) Good: More than 50 % subjective estimate of relief with abstinence from analgesic medication.
- 3) Poor: Less than 50 % subjective improvement.

Of the 24 patients, fourteen were classified as very good, six as good and four as failures.

The etiological factors or the nerve involved did not influence the result. From the four cases rated as failures one had what was retrospectively diagnosed as a centrally fixed pain; another got infected; an elderly lady with a sciatic lesion was relieved from her pain for six months, but suffered from an endogenic depression and pain recurred once her psychiatric condition worsened again.

The fourth failure with a peroneal nerve lesion following a knee arthrodesis, had the electrode cuff implanted very close to the lesion. Preoperatively she was only pain relieved by peroneal nerve block but pain free with a sciatic nerve block.

From the six partial successes three involved the leg nerves beyond the knee region, twice the posterior tibial nerve and one peroneal nerve. Although implanted proximally to the lesions, the electrodes cuff should have been implanted on the sciatic nerve. The two patients with burning pain were classified as good and poor respectively.

The painfree patients had to use the stimulation up to 4 times a day for two hours each time. The partially successful cases had to stimulate every second hour for one hour.

DISCUSSION

From the reports published up to now it becomes evident that the best clinical results are to be expected from the use of peripheral nerve stimulation in peripheral painful neuropathies. In our series 83 % of the patients were clearly pain relieved, whereas 58 % were completely pain free for a period of up to 41 months.

A burning pain does not improve and should be a contraindication for this type of treatment. Neuropathies of both nerves of the leg are better controlled by sciatic nerve implantation, as could be shown in one patient rendered pain free with a neuropathy of the peroneal nerve following total knee replacement, and on the other hand the partial success or failure in two peroneal nerve and two tibial nerve neuropathies implanted close to the lesion.

Although we assume that ectopic firing lies in the background of peripheral painful neuropathies the mechanism by which peripheral nerve stimulation relieves pain is by large unknown.

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INFLUENCE OF ELECTRICAL STIMULATION ON SPASTICITY IN SPINAL CORD INJURED PATIENTS

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SUMMARY

The efficacy of three electrical stimulation modalities on muscle spasticity was tested in SCI patients: cyclic agonist stimulation, cyclic antagonist stimulation and continuous dermatome stimulation. In the investigation the muscle groups governing the knee joint movement were treated. The degree of spasticity was assessed by the help of pendulum testing. It was shown that cyclic agonist and antagonist stimulation treatments do not increase the level of spasticity so that they can be safely used for therapeutic exercises or functional activities. The degree of spasticity was reduced to a noticeable extent while applying the dermatome stimulation. It was further demonstrated that transcutaneous electrical stimulation delivered to the dermatomes, corresponding to the same spinal segmental level as the spastic muscle group under consideration, produces the greatest reduction of spasticity.

MATERIAL AND METHODS

Simple and convenient approach to the measurement and evaluation of spasticity is represented by eliciting the abnormal stretch reflexes with passive swing manoeuvres of a limb. Such an approach is called a pendulum test. Spasticity of the knee extensor muscles was tested by placing the patient on a tilt table in supine position with both legs bent over the edge hanging free at the knee. The examiner grasped the foot and brought one leg to a horizontal position. The limb was allowed to fall freely while recording knee angle with an electrogoniometer. The level of spasticity was evaluated from the first minimum of the knee goniogram. This corresponds to the angle at which spasticity stops the natural backward swing. As a quantitative measure of spasticity relaxation index was defined being a ratio of the amplitude of the first backward swing normalized by the difference in angles between the resting and starting position of the limb /1/. The relaxation indices greater or equal to one would signify a nonspastic limb whereas values lesser than one would quantify various degrees of spasticity. Special importance was assigned to this parameter because it belongs to the first "burst" of spastic activity which is the most cumbersome to paraplegic patients while performing daily activities such as dressing, transfers from the wheelchair etc.

RESULTS

The effect of cyclic electrical stimulation of the knee extensors on the spasticity of the same muscle group was tested in ten spinal cord injured patients. The measurements were performed in the morning before other physical therapy exercises. No stimulation was applied to the patients during the first three days when only one pendulum testing was performed. Two measurements were performed on the fourth day, the first

before and the second after 30 minutes of stimulation therapy. Cyclic surface electrical stimulation of knee extensors with 6 seconds of stimulation followed by 12 seconds of rest was applied. Stimulation frequency was 33 Hz and the duration of rectangular pulses was 0.3 ms. The electrical stimulation exercise was isotonic /2/. In Fig.1 the results are shown from ten patients where knee extensors were stimulated and spasticity tested in the same muscle group. The white columns represent the average of four spasticity measurements performed on four different days. The standard deviations show the fluctuations of spasticity from day to day. The black columns belong to the level of relaxation after the application of electrical stimulation on the fourth day. In three patients (A.O., E.R., and R.S.) spasticity was significantly decreased. In four other patients (R.S., L.D., M.H., and T.T.) the spastic activity demonstrated by the pendulum test was only slightly lessened. In the rest of the patients, the differences after the stimulation were smaller than the natural fluctuations of spasticity, showing in one patient (D.D.) tendency to increase of spasticity after stimulation therapy.

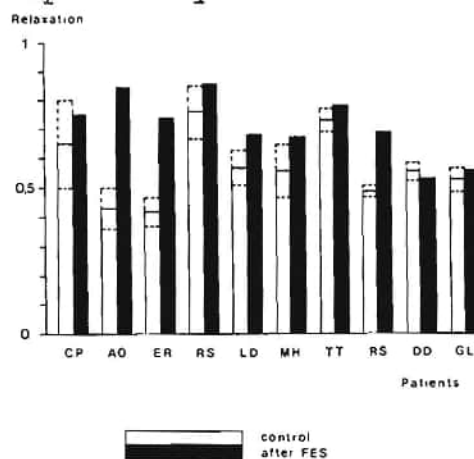


Fig. 1. Influence of electrical stimulation on spasticity of stimulated muscle

Five spinal cord injured patients participated in the investigation of the effects of cyclic neuromuscular stimulation of knee extensors on the spasticity of the flexors. The same measuring method and electrical stimulation treatment protocol as described earlier were applied. Here, in three patients (V.S., M.G., and T.M.) spasticity was decreased while no significant changes were recorded in two other patients (Fig. 2).

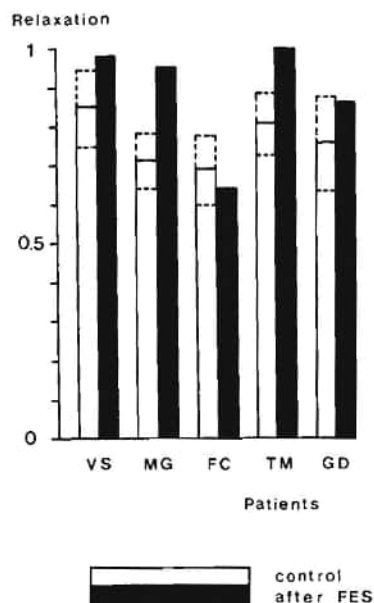


Fig. 2. Influence of electrical stimulation on spasticity of antagonistic muscle

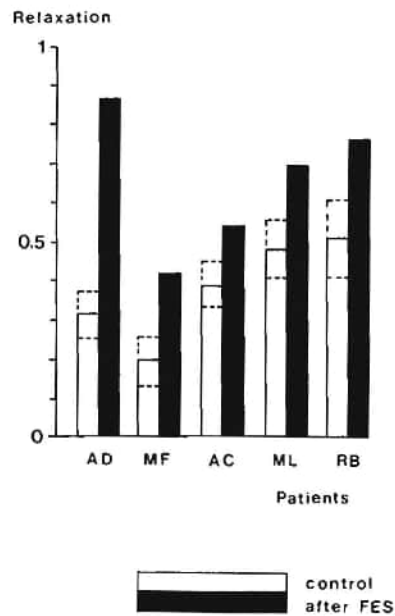


Fig. 3. Influence of transcutaneous electrical stimulation of the dermatomes on spasticity in the muscle innervated from the same spinal level as the corresponding dermatome

The pendulum test is generating extensor pattern of spasticity in the quadriceps muscle group, whose motoneurons lie in the L-3,4 segments of the spinal cord. It was therefore hypothesized that transcutaneous electrical stimulation applied to the L-3,4 dermatomes, corresponding to the same spinal segmental level as the spastic muscle group under consideration, will produce the greatest reduction of spasticity /3/. Dermatomes L-3,4 were excited by electrodes placed on the lateral aspect of the leg just above the knee and on the medial aspect just below the knee. A monophasic rectangular stimulus waveform was used with a pulse repetition frequency of 50 Hz, pulse duration of 0.3 ms and current pulse amplitudes up to 50 mA. Stimulation did not produce muscle contraction as the electrodes were not positioned over a single muscle. Such a stimulation waveform was applied continuously for 20 minutes. The results obtained from a group of five spinal cord injured patients having severe extension spasticity are presented in Fig. 3. The white columns represent the average of eight spasticity measurements performed on eight different days. It can be observed that the degree of spasticity was reduced to a noticeable extent in all subjects tested /4/.

DISCUSSION

Although the population studied was limited in numbers, it was shown that cyclic agonist and antagonist stimulation is not increasing spasticity in SCI patients so that it can be safely used for therapeutic exercises or functional activities. The trend, however, was toward a reduction of spasticity following electrical stimulation.

Because of evident beneficial effects of dermatome stimulation on skeletal muscles spasticity the patients were supplied with inexpensive two-channel stimulators. It is hoped that after using electrical stimulation regularly the patients will be less dependent on the antispastic drugs. It was suggested to the patients that they apply the stimulator three times daily for twenty minutes. A stronger decrease of spasticity can be achieved by more permanent use of cutaneous electrical stimulation.

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MODIFICATION OF SPASTICITY WITH ELECTRICAL STIMULATION

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SUMMARY

Four different studies of influence of electrical stimulation on spasticity are presented. Both, afferent and efferent stimulation were applied to hemiparetic and spinal cord injured patients. The main interest of all studies was devoted towards effectiveness of electrical stimulation in spasticity reduction. Furthermore some additional insight regarding differences or analogies between hemiplegic and paraplegic spasticity has been expected as well. According to the data obtained in different studies it seems that in approximately half of patients a reasonable decrease of spasticity occurs which lasts for hours. There is also an important difference between hemiplegic and paraplegic spasticity. The dermatome stimulation has proved as most effective in paraplegic patients, but without any effect in hemiplegics. Besides, the pattern of EMG activity before and after stimulation shows that stimulation decreases only the tonic activity, while the phasic one is left unchanged or even increased.

MATERIAL AND METHODS

About 200 patients of various pathologies i.e. tetraplegia, paraplegia, hemiplegia, multiple sclerosis and Parkinsonism were electrically stimulated with the aim to reduce spasticity and rigidity in different programs of the Ljubljana Rehabilitation Engineering Center. Only some specific experiments will be described in this paper, showing our attempts to find the most successful therapeutic procedure for separate group of patients. Two different approaches were implemented for this goal. The first one was based on mostly efferent stimulation of spastic muscle and their antagonists while the second one aimed at an exclusively afferent stimulation technique without any contraction response of spastic muscles. In these kinds of experiments different dermatome were stimulated.

Two types of measurement techniques (neurophysiological and biomechanical) are at present in use for quantitative evaluation of spasticity. Only biomechanical tests were used in our studies. The basic input stimulus in biomechanical testing is stretching of spastic muscles, which can be performed by means of imposed movement of the limb or a force acting against resistance of the limb. As such a force, gravity can also be used. Especially for the testing of the knee joint muscles the gravity driven testing is very suitable (1). In all our experiments dealing with the spasticity of knee muscles this test was used. According to (1) spasticity is evaluated through a relaxation index R_T , which is defined as the ratio between the amplitude of the first swing and the difference between the starting and the resting angle, divided by 1.6. Since pendulousness cannot be applied at the ankle joint, we estimated the spasticity status through resistive torque measurement procedure. In these measurements the stretching of spastic muscles is

achieved with a controlled external device, which is able to provide power for rotational movement of the limb (2). As an integral measure of spasticity, the magnitude of a vector of resistance to passive movements R was used. Its components were average peak-to-peak values of resistive torques at four different frequencies of rotational joint movements. Together with resistance the EMG signals of both agonistic and antagonistic muscles were also recorded.

EXPERIMENTS AND RESULTS

A. Efferent Stimulation of Spastic Ankle Joint Muscles in Hemiplegic Patients

Ten hemiparetic patients with increased resistance to passive movements (but no contractures) in the ankle joint were included in this program. A set of tests included measurements for ten periods of passive movements at frequencies 0.5, 1, 1.5 and 2 Hz. Tests were performed on four consecutive days. The first and the second tests were performed in order to obtain a control level of the patient's spasticity. On the third day first the test was performed. Thereafter the patient was cyclically stimulated for 15 minutes with tetanizing currents (pulse width 0.3 ms, frequency 40 Hz) applied to the triceps surae and tibialis anterior. The frequency of the cycling was 0.5 Hz. After 15 minutes of each stimulation the spasticity was tested. The patient was then asked to remain in relaxed inactivity for another 20 minutes when he was again tested. The same test was repeated the following day and after two more days in order to detect some possible long-term effects. In most of the patients the tonic and the phasic components of spasticity could be observed. However, all patients exhibited predominantly only one type of spasticity. It was observed that only tonic activity decreased after 15 min of electrical stimulation. In patients without this activity the phasic one remained the same or even increased after such stimulation. In Fig. 1 a cumulative picture for one "tonic" and one "phasic" type of patient is presented. According to decreased or increased reflex activity the changes in passive resistance are evident from Fig. 1a and b.

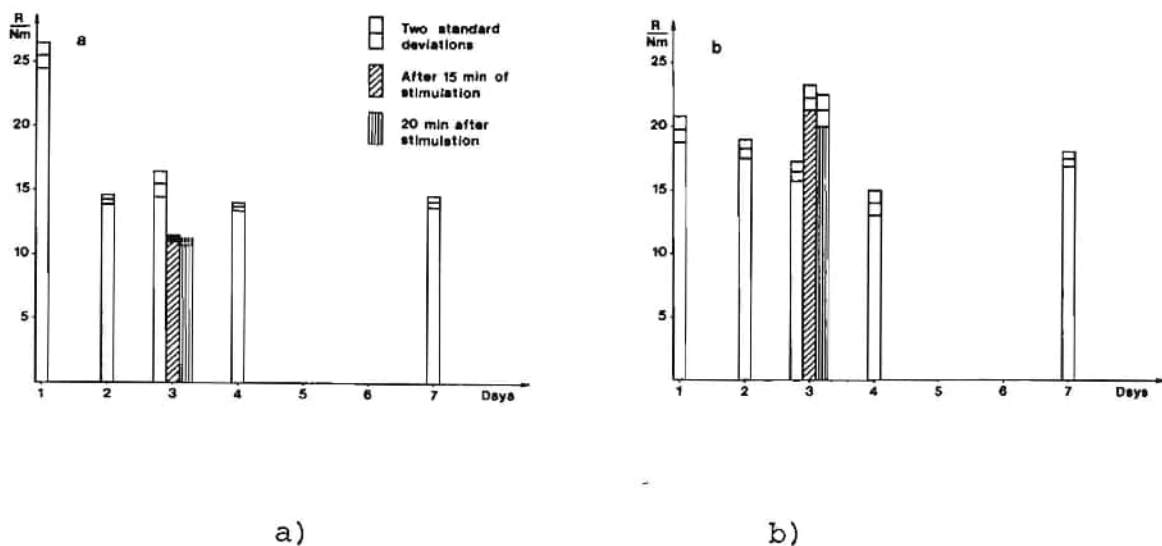


Fig. 1 Cumulative results of resistance to passive movements for two patients: a) patient with tonic activity in stretch reflex, b) patient with phasic activity in stretch reflex.

B. Efferent Stimulation of Spastic Knee Joint Muscles in Spinal Cord Injured Patients

Seven spinal cord injured (SCI) patients were included in a particular study (3). Four channels of cyclic stimulation have been applied to the flexors and extensors of both knee joints. During the first half period of activity (5 sec) stimulation activated the flexor of one leg and the extensor of the other leg. In the second half period the remaining two extensors and flexors were activated. It was postulated that such a stimulation sequence would produce reciprocal movements similar to the ones in gait and might favourably influence the neural reorganization at the spinal cord. The stimulation parameters included compensated monophasic square pulses at a rate of 30 pulses per second with a 300 μ s pulse duration. The current amplitude was set to approximate 100 mA with the rise time of the pulse train set to 2 sec. A typical experiment for each patient lasted five days and was always performed in the afternoon. On the first day only two control measurements with time delay of 20 minutes has been done in order to obtain a general idea about the level of patients spasticity. As a measure of spasticity a pendulum test was used (1). On the next three consecutive days after the second control test the described stimulation was applied for 30 minutes. Immediately after stimulation the pendulum test was performed and 20 minutes later ones more. On the last day of the experiment the patient was not stimulated anymore but only tested for any possible long-term (carry over) effects of the treatment. The results of electrical stimulation in these seven randomly selected SCI patients show that in some patients the spasticity can be noticeable decreased, while in others it remains unchanged. One such result is presented in Fig. 2.

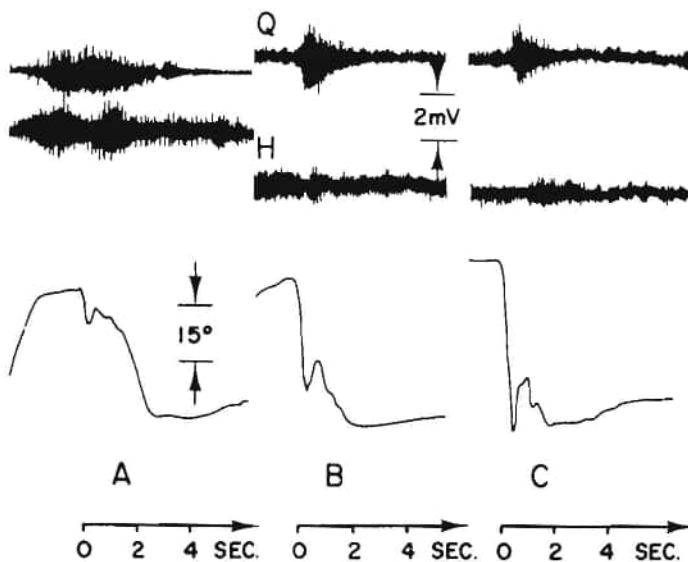


Fig. 2

- (A) Prestimulation spasticity
- (B) Spasticity after 30 min of stimulation
- (C) Spasticity after 20 min of rest, lowest trace displays joint movements

C. Afferent Stimulation of Spastic Knee Joint Muscles in Spinal Cord Injured Patients

Six SCI patients were randomly selected for a study of dermatome stimulation. They included those with clinically incomplete lesions who had retained some voluntary movements of their lower extremities and those with lesions resulting in completely paralyzed lower limbs. All showed at least moderate spasticity on manual testing of passive resistance about the knee joint. In this study $L_{3,4}$ dermatomes were stimulated with pulse currents up to 50 mA (pulse duration 0.3 ms and frequency 100 Hz). Such a stimulation pattern was applied continuously for 20 min.

Spasticity was tested with the pendulum test (1). A series of ten tests were performed for each estimation of relaxation index (1). The first series of pendulum tests were performed prior to the application of electrical stimulation, the second one immediately after the treatment, while the third was made two hours thereafter. The results for all patients are presented as average relaxation index in Fig. 3.

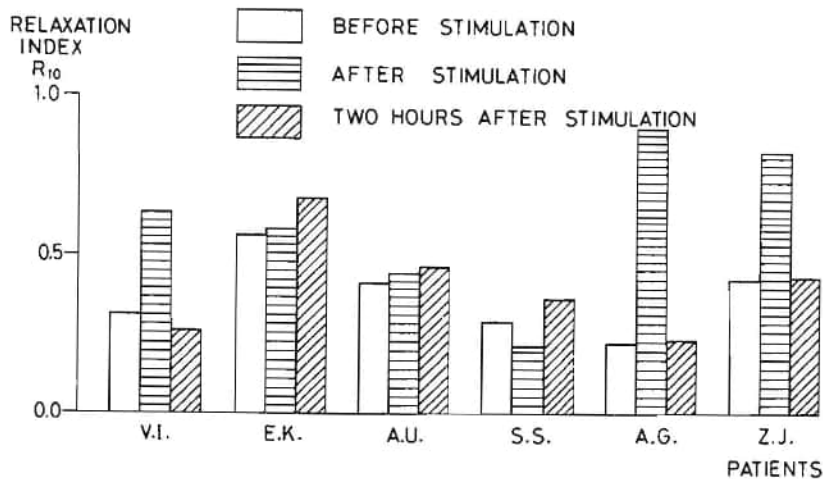


Fig. 3. Relaxation before and after application of L_{3,4} dermatome stimulation

D. Efferent Stimulation of Dorsal Flexors with Implantable Stimulator

Eight patients have been included until now in a study, which attempts to provide quantitative data regarding the influence of chronic functional electrical stimulation (FES) on spasticity of the ankle joint muscles in hemiplegic patients. In these patients peroneal stimulator has been implanted for improving dorsal flexion during gait. All these patients use their stimulators regularly during daily walking. In each patient the measurements of ankle joint resistance, as a measure of spasticity level, are being performed in certain time intervals: before implantation, one month after implantation, six months after implantation and every six months thereafter.

Integral data for all patients are presented in Fig. 4. In patient without exaggerated reflex activity before implantation (C.A.), usage of electrical stimulation did not change the degree of resistance to passive movement. The obtained resistance was also a year after stimulation <12 Nm, as it is for the healthy subjects. The use of FES as an orthotic device in patient in whom longer period of time after injury elapsed (> 1 year), as was patient P.M., can lead to decrease of spasticity in ankle joint muscles.

In patients with implanted stimulator few months after the injury (J.R., S.A., M.S., and G.J.) the resistance was increased one month after implantation. Six months after implantation the resistance was lower than before implantation for three of them. The EMG records (not shown herein) show that noticeable changes of reflex pattern occurred during observed time period, which resulted in increased phasic activity of triceps surae muscles and coactivation of muscle tibialis anterior.

DISCUSSION

Of the various possible mechanisms of spasticity discussed in the past decades it seems at present, that reduced presynaptic inhibition and

hyperexcitability of the motoneuron are the most plausible ones. Considering these two mechanisms the results of all four studies can be partially elucidated. Assume that phasic spasticity results as a lack of presynaptic inhibition whereas tonic one appears due to hyperexcitability of the motoneuron.

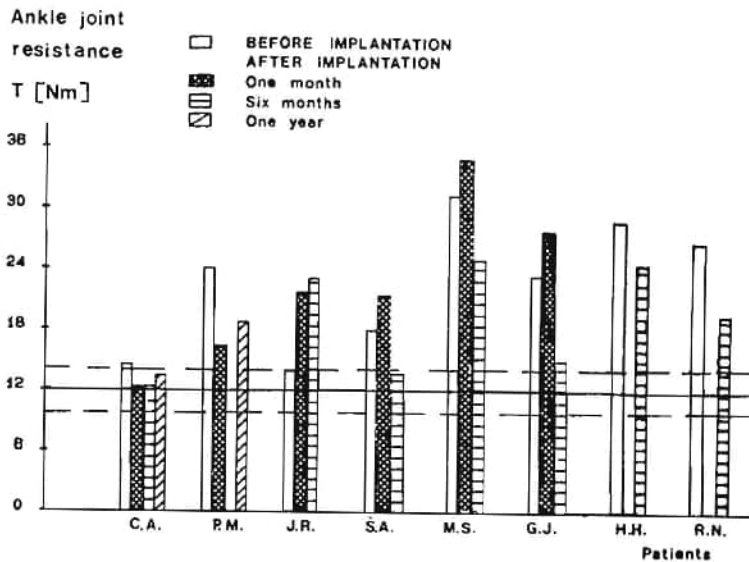


Fig. 4. Values of joint resistance obtained before implantation, one month, six months, and for the patients C.A. and P.M. one year after implantation.

In two different studies (A. and D.) we found that electrical stimulation can increase phasic activity of stretch reflex. Since these responses are monosynaptic they may have been enhanced due to posttetanic potentiation. It is also very interesting that tonic activity which was decreased in patients of study A did not appear in any patients of study D. Since the results of study D have been obtained on the basis of chronic stimulation it can be concluded that regular electrical stimulation can prevent spontaneous appearance of tonic activity, especially if we take into account that implantation in all spastic patients was made early after the outset of the lesion - less than 11 months. The most plausible mechanism for decrease of tonic activity is again posttetanic potentiation mediated now through reciprocal inhibition of antagonist Ia fibers. The third phenomena also appeared in both studies, i.e. phasic response in antagonist during the stretching of agonist could also be elucidated with posttetanic potentiation. The same phenomena were observed by Gotlieb et al. (5), where they suggest abnormal spinal cord circuitry in CP children, while our experiments suggest that lack of presynaptic inhibition at antagonist should be responsible for it.

Before we try to discuss the results of studies B and C we might assume that spasticity in spinal cord injured patients is different in many aspects from those in hemiplegic patients. In a very rough approximation such difference is a consequence of released spinal mechanisms due to absence of supraspinal control. As a pattern spinal spasticity usually displays much stronger tonic activity, therefore the phasic one cannot be differentiated from it. In such a disconnected spinal cord many unpredictable ways can be facilitated according to the specific peripheral input, thus the great variability of spasticity testing is to be expected. Although the same mechanism of reciprocal inhibition could be responsible for reduction of tonic activity in SCI patients it seems that additional possibility exists in these particular patients. This mechanism is based on a "balance hypothesis". In a normal neuromuscular system the generalized excitation and inhibition are in equilibrium, and both types of synapses operate close to their maximal activity. In spinal spasticity and perhaps in some other pathologies

the activity of inhibitory synapses is reduced while the activity of the excitatory ones remains close to normal. Electrical stimulation applied at the periphery as in our experiments or centrally in the spinal cord or cerebellum excites diffusely excitatory and inhibitory nerve fibers. Due to the lack of spinal and supraspinal control the excitation triggered by electrical or other stimulation can easily reach the spinal circuitry. However, excitatory synapses are operating already close to their saturation activity and additional signal due to stimulation do not change their activity very much. On the other hand, inhibitory synapses have been inactive and are easily excited by the additional signals. Therefore inhibition increases and a state closer to balance is established. The results of study B and particularly of study C therefore strongly support the hypothesis that many "ways" are open in SCI patients at their spinal circuitry throughout which the abnormal reflex activity can be dramatically changed in many patients.

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LOW FREQUENCY PULSED ELECTROMAGNETIC FIELDS AND HUMAN LYMPHOCYTE PROLIFERATION x)

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SUMMARY

The basic idea of this study was to investigate if pulsed extremely low-frequency, low-intensity electromagnetic fields (PEMFs) could affect "in vitro" cell proliferation. The biological system used was the human peripheral lymphocytes stimulated by a mitogen such as phytohemagglutinin (PHA).

Peripheral blood lymphocytes appear to be a suitable model in order to understand the mechanisms of PEMF action, owing to the large amount of data concerning the proliferative mechanisms and the growth factors of such cells.

Moreover, the "in vitro" lymphocyte activation by means of plant lectins allows an analysis of the effects of PEMFs on the mechanism of external signal transduction at the cell membrane level. At present, few studies have employed this promising cell system, suggesting that both stimulatory and inhibitory effects can be obtained, depending on the different culture conditions and on the PEMF physical characteristics.

In our conditions, PEMFs were not mitogenic by themselves; in PHA-stimulated lymphocyte cultures an increased ^3H -thymidine (^3H -TdR) incorporation was observed when exposed to PEMFs, but it was statistically significant only at optimal and supraoptimal mitogen doses.

Preliminary data suggest that the effects of PEMFs depend on the characteristics of the fields, the geometry of the microculture system, the dose of the mitogen employed, the age of the lymphocytes donors and possibly the immune status of subjects. The hypothesis that PEMFs may affect lymphocyte proliferation by decreasing cell membrane fluidity is suggested.

MATERIALS AND METHODS

Subjects

A group of 14 healthy donors of both sexes, aged from 22 to 46 years (mean age 27), was studied.

Some preliminary experiments were made with far aged subjects (more than 85 years) and patients with immunological disorders.

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Lymphocyte Purification

Lymphocytes were separated from peripheral blood. 20 ml of heparinized venous blood were obtained, and the lymphocytes were separated by density gradient centrifugation through Ficoll-Hypaque, as described by Boyum et al. [1].

PHA-Stimulated Cultures

Cultures stimulated with PHA were performed in quadruplicate, using a microplate well system, following a method previously described [2]. Such micromethod is very useful because it allows the analysis of a large amount of samples in the same experimental conditions.

Five doses of mitogen (0; 0.1; 1; 5; 10 μ l/ml) were used.

Cultures were incubated in a humidified atmosphere of 5% CO₂ and 95% air for 72 hours. Six hours before the termination of the incubation period, 0.5 μ Ci of ³H-thymidine (³H-TdR, the Radiochemical Center, Amersham, Bucks, U.K., sp. act. 5 Ci/mmol) was added to each culture well. At the end of the culture period, the cells were harvested and washed on glass-fiber filters by a multiple-cell harvester (Skatron, Norway). ³H-TdR incorporation (cpm) was measured by scintillation counting as described elsewhere [2].

Characteristics of PEMFs and Culture Exposure to the Fields

The samples were placed between a pair of Helmholtz aiding coils that were powered by a pulse generator (Igea stimulator). The coils were maintained parallel to the microtiter plates. The pulse shape is shown in Figure 1, where the upper part of figure represents the magnetic field and the lower part the derivative of the magnetic field, which is proportional to the induced electric field in the sample, both as a function of time. The pulse duration (T_1) was about 2 ms and the repetition rate ($1/T$) was 50 Hz (yielding a duty cycle of 1/10). The maximum

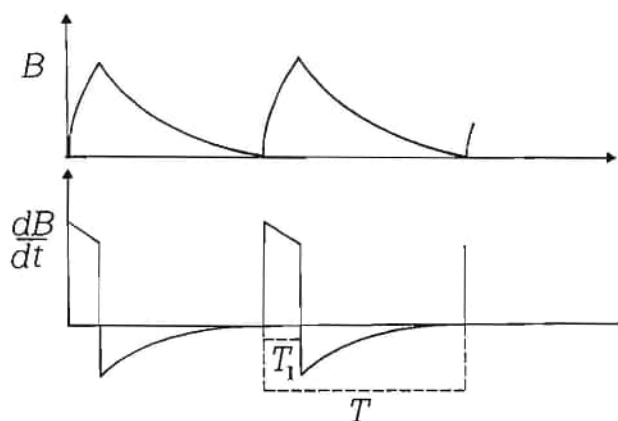


Figure 1

intensity of the magnetic field was about 2.5 mT. The induced voltage, as detected with a coil probe made up of 50 turns (diam. 0.5 cm), was about 2 mV. Taking into account the size of each well and its position with respect to the magnetic flux lines, the induced electric field inside each well was lying in the plane parallel to the microtiter plate surface, and its maximum intensity was estimated about 0.02 mV/cm[3].

The experimental cultures were exposed for the entire period of the culture of 72 hours. The control cultures were maintained in the same incubator at a distance where no electromagnetic field was detectable using the coil described above.

Data Presentation and Statistical Analysis

The effects of the exposure of PHA-stimulated cells to PEMFs was evaluated as a stimulation index (S.I.), calculated as follows:

S.I. = cpm of experimental cultures (with PHA and PEMFs) /cpm of control cultures

(with PHA and without PEMFs). Statistical analysis was performed using Student's *t* test and paired Student's *t* test [4].

RESULTS

PEMFs alone did not increase cell proliferation and in many cases they provoked a small decrease in ^3H -TdR incorporation in the unstimulated cultures. When lymphocytes were stimulated with an optimal dose of PHA, in a majority of subjects the exposure to PEMFs caused an increase in ^3H -TdR incorporation in comparison with the unexposed cultures. On the whole, this increase was small but statistically significant.

The effect of PEMFs is represented in Figure 2 as stimulation index (S.I.). Such effects was more pronounced where optimal and supraoptimal doses were used.

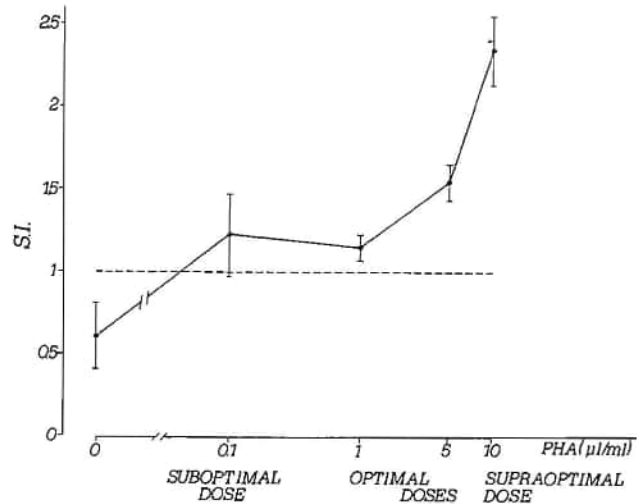


Figure 2

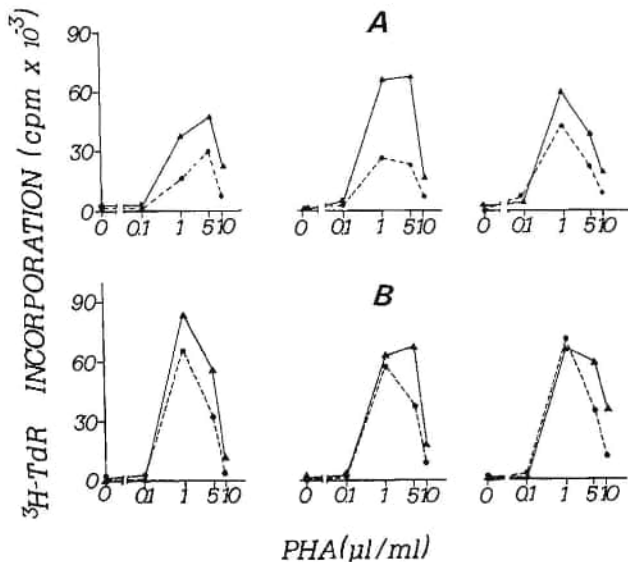


Figure 3

Some preliminary data have shown that an higher increase of cell proliferation (measured by ^3H -TdR incorporation) may be observed in lymphocyte cultures from far aged donors, and from subjects with severe immune disorders (data not shown).

As an example, Figure 3, shows three cases of ^3H -TdR incorporation in cultures of lymphocytes stimulated by four different doses of mitogen, exposed (continuous line) or not (dashed line) to the PEMFs, from aged donors (A), in comparison with three cases of cultures from young subjects (B).

DISCUSSION

From the data above reported the following conclusions can be drawn:

- 1) PEMFs were not mitogenic by themselves, in accord with previous observations [5], [6], [7]. A slight decrease of ^3H -TdR incorporation was found in unstimulated cultures.
 - 2) When the lymphocytes were stimulated with optimal and supraoptimal doses of PHA, exposure to PEMFs caused a statistically significant increase of ^3H -TdR incorporation in comparison with the unexposed cultures [8].
 - 3) Preliminary results seem to indicate that the increase of cell proliferation is markedly pronounced in lymphocytes from far advanced age donors.
- Our results are in agreement with those by other investigators, [6]. The apparent conflict with other authors who observed inhibitory effects on lectin-induced human

lymphocyte proliferation, is probably due to differences in the electromagnetic fields employed [5]. In fact, either inhibitory or stimulatory effects may be obtained with different field characteristics (frequency, intensity etc.), as suggested by some preliminary results [9]. This probably implies the existence of "window effects" which deserves further investigation.

As far as the mechanisms of PEMF action is concerned experiments are in progress, particularly focusing cell membrane modifications and lymphocyte growth factors production and utilization. Some preliminary observations with a fluorescent probe showed that membrane fluidity decreases under PEMF action, suggesting a correlation between cell membrane physical status and cell proliferation.

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FIELD EFFECTS ON NEURON DERIVED CELLS IN CULTURE.

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SUMMARY

This report presents preliminary results of investigations to examine the possibility of non thermal interaction of electromagnetic fields with neuronal growth, differentiation and maturation.

RF stimulation of connective tissue cells in earlier investigations resulted in increased protein synthesis. Our preliminary data from analogous experiments with neuron type cells suggest that similar effects occur. In comparison to unexposed cultures, 45% of the exposed cells form an increased number of neurites, which have diameters similar to the control cells but are 1.5 to 2.5 times longer.

MATERIALS AND METHODS

The cell line we are employing to study RF-effects on neurons is derived from the line NG 108CC15. The initial material, donated to us by the Dept. of Pharmacology, Hammersmith Hospital, London, consisted of a cell population with widely varying morphological and neurophysiological properties. Subcloning on semiliquid agar (double strength medium, 20% fetal calf serum) enabled us to preselect clones that express neurophysiological properties, such as excitability and the synthesis of neurotransmitters.

For functional selection we developed a procedure which enables us to clone only those cells that differentiate upon treatment with dB-cAMP or in serum depleted medium. The presence of catecholamines in the synaptic endings has been confirmed by fluorescence methods based on the work of Falck and Hillarp, and Koenig [1,2].

McGee et al. and McDermott et al. have reported, that a proportion of the the NG 108CC15 hybridoma cells store and release acetylcholine (ACh) [3,4]. Both cell types are said to have corresponding functional receptors. We used immunological techniques to investigate whether this applied to our clones. An anti ACh-receptor monoclonal antibody, labelled with fluorescein isothiocyanate, was allowed to attach to functional receptors of the cells, and the receptors could be easily identified in vivo with fluoroscopic techniques [5].

For the experiments 3x5 dishes with neurone derived cells were plated

at an average density of 10^5 per ml in 60mm polystyrene Petri dishes containing 10ml of Dulbecco modified Eagle's minimum essential medium supplemented with HAT and foetal calf serum (group 1-3). Group 1 cultures served as untreated controls, group 2 cultures were treated with 0.5mM dibutyryl cAMP to induce morphological differentiation, and the group 3 cultures were exposed to fields. Parameters being examined included morphology, the length of neurites, and synapse formation. Exposed and control groups were cultured in the same incubator at 37°C, gassed with a mixture of 95% air and 5% carbon dioxide.

The exposure conditions employed for earlier investigations were also applied to the differentiated neurone derived cells [6]. After a period of evaluation the cells were exposed to sinusoidal, continuous RF fields of 10 MHz with a constant field intensity of 0.645×10^{-4} T.

For exposure a computer controllable radio frequency stimulator has been developed to study the significance of waveform and frequency for stimulation. The stimulator operates over the frequency range 1.6 MHz to 35 MHz. The design principles permit an expansion up to 144 MHz. The output power was measured by a RF-power meter capable of monitoring the forward and reflected power (VSWR). The exposure coils were of 90mm inside diameter and mounted in a Helmholtz configuration. This arrangement produced a uniform vertical magnetic field in the region of interest, an area of 10 x 10 mm, around the axis of symmetry of the coils.

RESULTS

In the initial clones about 65% of the cells extended processes upon treatment with dB-cAMP (1mM). By cloning we could increase this percentage to about 90%. The resulting clones NG 108CC15-ST9 and NG 108CC15-ST10 differentiate well under the prescribed conditions. Both cell types express neuronal characteristics such as excitability, neurotransmitter synthesis and release and the formation of functional synapses. Preliminary electrophysiological data confirm these results. The presence of catecholamines in the synaptic endings has been demonstrated by fluorescence methods based on the work of Falck and Hillarp.

In the exposure experiments no noticeable differences were observable during the first 12 hours. In all cultures the cells were growing in a similar fashion. Upon examination after 24 hours the controls of group 1 contained poorly differentiated cells similar to those in routine cultures. In contrast, the cultures of group 2 (0.5mM dB-cAMP) appeared different. As was to be expected, the cells had partially ceased mitosis and showed various stages of morphological differentiation. The exposed group 3 neurons appeared similar to the cells in group 2.

Clearly noticeable differences existed after after 36 hours. The cells in group 1 still had the appearance of routine cultures whereas the group 2 neurons showed various stages of differentiation. Some cells had detached from the substrate and were floating in the medium. The

group 3 neurons which were exposed to the field appeared similar to group 2 cells but appeared to possess longer neurites. Upon reexamination after 48 hours, the differences between the 3 groups were even more pronounced. In group 1 the cultures had entered the exponential growth phase. A few neurons were differentiated and had short, mostly straight neurites. A medium pH of 7.3 indicated that neither the nutrient supply nor the buffer capacity of the medium were exhausted. The neurons in group 2 which appeared morphologically differentiated had a cell body diameter of about 33 μ m. The mean length of the neurites (45 measurements) was 144 μ m. The medium pH was identical to that in group 1 cultures, indicating also adequate growth conditions for the group 2 neurons.

In contrast, the medium pH in group 3 cultures had dropped from pH 7.3 to pH 7.1 although the cell density was similar to the group 2 cultures. In addition the group 3 neurons had a larger cell body (mean diameter 59 μ m) and considerably longer neurites (327 μ m $\pm$ 1.5 μ m, 45 measurements). The morphological changes were accompanied by an increase of acetylcholinesterase and tyrosine hydroxylase activity which indicated cell maturation. Since the lowered medium pH indicated that the growth conditions were suboptimal the experiment was then terminated.

DISCUSSION

Our experimental results relating to connective tissue cells confirmed that non thermal influences on cell physiology are possible. The observed increase in the mitotic rate of exposed cells is consistent with the results of Liboff et al. who demonstrated an increase in 3H-thymidine uptake [6,7]. The observed cluster formation indicated a change in cell adhesion which could be caused by influences on the protein synthesis. Because of the altered cell adhesion, the plasma membrane and membrane bound receptors or other specific proteins which promote cell adhesion would have had to be involved. However, any change in the protein metabolism could have only occurred as a consequence of a change in RNA transcription.

The observations indicated an increase in the rate of DNA synthesis. This hypothesis is supported by the time dependence of the events. Liboff reports a maximum effect 20 hours after the onset of irradiation [7]. In experiments we have estimated the cycle time of human fibroblasts of being approximately 40 hours. This suggests that Liboff observed a peak effect during the synthesis phase. Since DNA is replicated during this part of the cell cycle, the observations suggest that the exposure of some specimens may lead to an increase in either the DNA synthesis or alter earlier transcriptional events which may change the characteristics of the plasma membrane.

The latter mechanisms could explain the morphological changes of the neuron derived cells. When activated by extracellular ligands, most cell surface receptor proteins generate intracellular signals by altering the activity of membrane bound enzymes. The involvement of

second messenger pathways could have led in the exposed neurons to an increase of intracellular mediators like cAMP. Elevated cAMP levels induce morphological changes in both connective tissue cells and neurons [8]. The events are time dependent and are accompanied by an inhibition in mitotic activity. The involvement of protein synthesis is also suggested by the functional changes in the exposed neurons and by the increased length of the neurites. It is therefore possible that an altered receptor function and a resulting intracellular accumulation of cAMP caused the differentiation and maturation of the exposed neurons.

Our results indicate further that the field exposure caused possibly an increase in the metabolic rate via the elevated cAMP levels. This increase could explain the increase in nutrient consumption in comparison to the controls. The same event would have to lead to an increase in CO₂ production via the citric acid cycle which may be an explanation of the insufficient buffer capacity in group 3 cultures after 48 hours.

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Abstract

Title: FUNCTIONAL BEHAVIOR AND PERFORMANCES OF ELECTRO-
CHEMICALLY DRIVEN "MUSCLE-LIKE" ACTUATORS.

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Experiments have been recently reported, focused on contractile phenomena in polyelectrolyte gels activated by electric fields. Devices based on this principle may have important application in the fields of prosthetics and artificial organs. The research reported here is focused at two complementary aspects. First, the origin of the observed electromechanochemical (EMC) effects has been experimentally investigated and a conclusion has been reached which ascribes the observed contractile response primarily to spatio-temporal pH gradients created by electrochemical reactions at the electrodes. To provide a phenomenological characterization of linear polymeric actuators in view of their possible use as motor units, isometric experiments have been performed on a specific EMC system to obtain force-velocity curves at various potential differences at the electrodes. Isotonic measurements allowed determining the maximum available contractile force and to obtain a relationship between sample initial length and maximum isometric tension generated under electric field. By extrapolating the experimental data to a different sample geometry, it can be inferred that a gel contractile element 1 μm thick and 1 cm long can contract under electrical stimulus (2.5 V) with a velocity of the order of 5-10 cm/sec, exerting a contractile tension of the order 1-3 Kg/cm². These contractile performances come quite close to those typical of natural muscles.

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TREATMENT OF IDIOPATHIC SCOLIOSIS WITH FULLY IMPLANTABLE STIMULATORS OF THE PARAVERTEBRAL MUSCLES.

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Previous studies have demonstrated that, in children with idiopathic scoliosis, periodic stimulation of the paravertebral muscles may stabilise the vertebral curvature increase during puberty (1) (2) (3). Our studies in this area in the last ten years have been directed towards constructing a fully implantable stimulator, and thus avoiding the disadvantages of daily fixation of the stimulating device to the patient's back and the discomfort it can cause during the night. Four years ago a prototype stimulator was built and implanted in a dog for a period of two and a half years. A frequency modulation device was used for percutaneous programming of the stimulator, which was programmed to operate for periods of six to eight hours a day. The following parameters could be programmed: output voltage, stimulation frequency, burst duration, first and last pulse width of each burst, percentage of the burst duration which had a regularly increasing pulse width, and the resting period between each burst. The animal experiment, which produced encouraging results, was ended after two and a half years. Finally, during the last twelve months we implanted stimulators in five scoliotic children.

MATERIAL AND METHODS

Three girls and two boys, aged between nine and thirteen years, underwent surgery. The following clinical criteria were taken into account before the implantation was decided on: idiopathic character of the scoliosis, unique curvature, dorsal or dorsolumbar topography, curvature angle less than 40 degrees, rapid evolution determined by measuring the curvature angle three times in six months, Risser's test less than two, reducibility more than 40%, absence of previous treatment, absence of hollow back, easy post operative follow-up. The operation was done under general anesthesia. Each child was settled on the operating table, flat on its stomach, with hips and knees bent at right angles. Before any incision was made, needle electrodes were placed on the upper and lower part of the vertebral convexity and pushed into the deep paravertebral muscles. A strain gauge microtransducer was attached to the back, equidistant to the needle electrodes which were themselves connected to an external stimulator. Simultaneously the transducer was connected to an amplifier and a graphic recorder.

Brief pulse bursts were released through the two electrodes and the contraction strength was recorded. The upper electrode was then repositioned several times, moving it a small distances each time, and the contraction strength was remeasured after each repositioning in order to determine the optimal point of fixation of the permanent electrodes. In addition, the relationship between muscular strength, stimulation intensity and pulse duration was established in order to ensure effective muscular contraction with a minimum of current consumption (4). The relationship between stimulation frequency and muscular strength was then established so that the rapid decrease of muscular strength at higher stimulation frequencies could be taken into account in programming the optimal frequency (4).

Finally, an intermuscular pocket was made in the lumbar region after a vertical cutaneous incision was made a few centimetres above the iliac crest. The stimulation electrodes (Tektronics) were then connected to the implantable stimulator and then tunnelled subcutaneously to the optimal points of muscular fixation as previously determined using the needle electrodes. At these two precise points small cutaneous incisions were made which permitted fixation of the permanent electrodes. These electrodes have a spiral steel conductor with silicone rubber insulation. The stimulating electrode, which is in direct contact with the muscle, has a Nylon thread and a curved needle attached to it. The needle is passed through the muscle and used to pull the stimulating electrode into the muscle and thus obtain optimal positioning. This type of electrode was chosen from five different types, following analysis of their electrical properties, geometric form, and fixation procedures.

After the electrode had been positioned the stimulator was programmed using a programmer head (Vitatron PH 1) connected to a micro computer (Hewlett Packard HP 85). The stimulator was then inserted into the pocket and its functioning was checked, whereby particular attention was paid to uniform muscular contraction without affecting adjacent muscles. Finally the skin was sutured.

The children were discharged from hospital about five days after the operation and their status was reevaluated after the first month of follow-up, and then again every three months. On each occasion clinical and radiographical examinations were carried out and the stimulator function was subsequently verified by transcutaneous telemetry.

RESULTS

The post operative period in our five patients has now varied from three to thirteen months. In four patients a stabilisation of the vertebral curvature was noted. In the fifth patient the linear evolution of the vertebral curvature had the same slope as before implantation of the stimulator. This had clinical course, which was noted 10 months after the operation corresponded with the absence of visible periodic muscular contractions while the stimulator was operating. Telemetered data from the stimulator did not reveal any abnormality in the stimulation parameters, and neither did radiographic analysis show fracture of the electrode conductor. For all patients the output voltage was programmed to 7 V, the burst duration to 2 seconds, the resting period between bursts to between 10 and 15 seconds, and the pulse frequency between 30 and 37 Hz. For each burst the width of the first pulse was programmed to 0.1 sec., and that of the last to either 0.3 or 0.4 sec, and the duration of the pulse width increment to between 50 and 53% of the total burst duration. Each day the stimulator is automatically switched on at 11 p.m. and switched off at 7 a.m. Pain was never felt during stimulation.

DISCUSSION

The preliminary results of stimulation of the paravertebral muscles have been reported in this study. Preliminary results show a stabilisation of the scoliotic curvature angle in four out of five cases. It seems that our stimulator has two advantages: the implanted electrodes allow for stimulation of the deep paravertebral muscles at a point where the strength of the small muscles wards off vertebral bending (5). Furthermore, the use of a fully implantable stimulator, which has a complete range of programmable parameters and a long life power source, relieves the patient of the daily discomfort of an external device and reduces the risk of mistakes.

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ELECTRICAL MUSCLE STIMULATION
AS AN ADJUNCT TO HEALING OF LONG BONE FRACTURES IN THE RAT*

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SUMMARY

Chronic, repetitive electrical muscle stimulation (EMS) might be expected to hasten fracture healing in the same way as functional weight bearing. This thesis was investigated in a rat model utilizing intramedullary (IM) rodded closed transverse femoral fractures. Tetanic stimulation was applied by external electrodes in two signal patterns: 2 s on/15 s rest (EMS 2/15) or 2 s on/80 s rest (EMS 2/80) for 16-18 hrs/day. The stimulation signal was a 50 Hz square wave with a nominal current of 7-10 ma. Control animals were immobilized, as were the stimulated animals, in a splint, with electrodes, but did not receive stimulation. Animals were sacrificed at times up to 12 weeks post-fracture and the results were evaluated by measurement of bending stiffness of femurs after rod removal as well as by radiographic and histological criteria.

The EMS 2/80 signal produced a 36% increase in stiffness ($p < 0.05$, over controls) by 3 weeks but no significant differences at later times. However, EMS 2/15 did not produce increased stiffness over controls at any time. Some biceps femoris muscle atrophy was seen in all animals, control and stimulated, but EMS 2/15 produced significant muscle atrophy at 4 weeks ($p < 0.05$ vs. controls). A group stimulated for 5 weeks (EMS 2/80) and then sacrificed 7 weeks later showed normal progression to full healing.

These results suggest that carefully selected EMS might be a useful form of adjunctive therapy for stabilized long bone fractures in patients.

MATERIALS AND METHODS

Male Sprague-Dawley rats (Charles River), with initial weights of 275-325 g were used. They were housed singly, given water and standard laboratory rat rations, ad libidum, and maintained on a 13/11 hour light/dark cycle.

The fracture model is a modification of one which has been previously reported [1,2] and involves the production of a closed fracture after surgical placement of a loosely fitting IM rod. The rods (0.9 mm 316L SS (Zimmer-USA)) were inserted with sterile procedure after anesthesia (Ketalar (Parke-Davis)) one week before fracture. The fracture was produced, after re-anesthesia, by three-point bending in a hydraulic universal testing machine (MTS, Inc.). The fracture parameters were: 17 mm support separation, preload force of 11.8 N, reduced to 4.9 N before fracture and fracture produced by a 4 mm excursion (lateral to medial) of a central wedge at 15 cm/sec. Peak forces of 100-120 N were obtained and a sharp crack was heard in most cases.

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Radiographic screening eliminated animals with incomplete, angulated and/or comminuted fractures or excessive cortical angulation or displacement (20% of animals were eliminated). The vast majority of animals were weight bearing on the day after fracture; any with limps which persisted more than 18 hours after fracture were also eliminated.

Selected animals were randomly assigned to treatment or control groups and to sacrifice-time cohorts (2,3,4,5 or 12 weeks). After re-anesthesia, each animal was supplied with a modified Thomas splint with custom fitted mesh polyimide body jacket (JET Enterprises), a polyethylene neck collar and two 12 x 18 mm carbon impregnated rubber electrodes (Stao-dynamics, Inc) were applied to the lateral thigh. The electrodes were moistened with a lubricating jelly and secured with velcro fasteners to the splint frame.

Electrical muscle stimulation was produced by a monophasic signal (frequency = 50 Hz, pulse width = 250 us, peak current = 7 - 10 ma). This produced a readily visible but apparently painless tetanic contraction of the leg musculature and tail extensor mechanism on the electrode equipped side. The signal was provided by a battery operated power supply (Stao-dynamics, Inc) placed external to the rat cages and connected with two flexible wire coil enclosed leads. Control animals wore the same apparatus but without a power supply attached.

Two stimulation patterns were used in the first study, with both applied for 16-18 hours/day, 5 days/week. The first pattern (Group A) alternated a 2 second stimulation period with a 15 second rest period (EMS 2/15). This stimulation pattern was abandoned in the second study, since independent studies in our laboratory suggested that 15 seconds is too short a time to permit full recovery of muscle high-energy phosphate stores [3]. The second pattern (Group B), which was used in both studies, alternated the same 2 second stimulation period with an 80 second rest period (EMS 2/80). Finally, the 12 week stimulated animals in the second study were only stimulated for the first 5 weeks followed by a 7 week recovery period without splints and electrodes.

Animals were sacrificed by barbiturate overdose (IP) and both right and left femurs and biceps femoris muscles were removed. The fully wet muscles were weighed to determine the effect of EMS on muscle mass. The intramedullary pins were removed from the left femurs, both bones were radiographed and then mechanically tested. Stiffness was determined by bending in a 15 mm three point bending jig in a universal testing machine (Instron) until the load-deformation curve entered a linear region. The bones were positioned so that the callus was centered under the central point and the posterior surface was placed in tension. After testing, the bones were fixed in 10% phosphate buffered formalin, decalcified, embedded and sectioned longitudinally for histological study.

The radiographs and histological sections were evaluated with graded scoring systems and the scores analysed by either Student's "t"-test or Yates Chi-square test. The mechanical results were analysed by Student's "t"-test.

RESULTS

In the first study, 104 animals were rodged, 72 were randomized to the experiment, 8 were later excluded (for previously undiscovered experimental model defects) and 11 died during the course of the experiment, for a final total of 53 available for analysis (overall morbidity and mortality, 26%). In the second study, 60 were randomized to the experiment, but only 9 survived the 12 week study period (substudy morbidity and mortality, 55%; overall morbidity and mortality, 22%).

Radiographic and histological results will be reported in detail elsewhere [4]. EMS 2/80 produced significantly ($p < 0.05$) more callus than controls by radiographic score at 3 weeks. EMS 2/80 was also associated with a pattern of earlier maturation of the fracture (as compared to controls) seen as soon as 2 weeks, while EMS 2/15 showed a pattern of delayed callus maturation, which was particularly evident at 4 and 5 weeks. All experimental groups showed muscle atrophy (secondary to immobilization) at all time points with EMS 2/15 showing a significantly ($p < 0.05$) increased atrophy (compared to controls) at 4 weeks.

The table below reports the mechanical results for both studies. These are expressed as left (fractured, stimulated or control) divided by right (intact) stiffnesses, to normalize animal to animal size variations. EMS 2/80 treated fractures had a significantly greater (36% ($p < 0.05$)) L/R stiffness ratio than controls at 3 weeks and were stiffer at 4 and 5 weeks (study 2) (not significant).

Fracture Stiffness Ratio (L/R +/- 95% CI)

Study 1:	Control	Group A(EMS 2/15)	Group B(EMS 2/80)
Time:			
2 weeks:	0.396 ± 0.19		0.266 ± 0.11
N:	7		6
3 weeks:	0.618 ± 0.14	0.613 ± 0.29	0.840 ± 0.21*
N:	10	5	6
4 weeks:	0.802 ± 0.26	0.632 ± 0.68	
N:	6	4	
5 weeks:	0.921 ± 0.12	0.936 ± 0.55	
N:	5	4	
Study 2:	Control		Group B(EMS 2/80)
Time:			
4 weeks:	0.495 ± 0.15		0.592 ± 0.13
N:	10		10
5 weeks:	0.818 ± 0.19		0.941 ± 0.14
N:	10		8
12 weeks:	0.972 ± 0.09		0.950 ± 0.35**
N:	6		3

* significantly greater than control, $p < 0.05$

** 5 weeks stimulation, 7 weeks recovery

DISCUSSION

The clinical efficacy of early functional weight bearing in the healing of stable fractures is well recognized [5] and has been demonstrated in a controlled animal model [2]. Using a similar animal model, we have demonstrated that EMS can provide early beneficial effects similar to functional weight bearing, when applied in a nonweight bearing situation. Normal fracture maturation was seen, with EMS 2/80 producing acceleration of maturation and, in particular, an earlier transition to the condensed or small callus stage. This stage of callus maturation, the initiation of White et al. [6] Stage II and III behavior, is associated with a hard tissue type of failure on refracture and stiffness near to that of intact bones, permitting normal but guarded use of the involved limb. However, this beneficial effect is only seen with a

signal (EMS 2/80) sufficient to permit continuous recovery and maintenance of muscle energy stores [3]. The early beneficial effect of EMS 2/80 is not lost at longer healing times, as demonstrated in the second study reported here. The shorter rest period associated with the other signal used in the first study (EMS 2/15) produces increased muscle atrophy and delayed callus maturation, perhaps secondary to muscle exhaustion. Furthermore, in this disuse model, there was no evidence that EMS treatment provided protection against the expected muscle atrophy of disuse.

The origin of the beneficial effect of EMS seen in these studies is unknown. It may be due to strain related production of current within the fracture, increased regional blood flow or increased local or central metabolic activity. In any case, these studies suggest that the cautious use of the appropriate EMS signal in stable, well splinted long bone fractures might provide a similar beneficial effect on bony healing in patients. Thus it appears to be appropriate to consider EMS as an adjunctive therapy in the clinical treatment of fractures.

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PROGRAMMING SYSTEM FOR NERVES, MUSCLES AND BONES STIMULATION x/

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SUMMARY

A research project called "Multifunctional apparatus for electrostimulation of nerves, pain and bones" was carried out in the period of 1981-1985 in the frame of the Key-Problem "Medical Technic", under sponsorship of the Medical Center of Technology, Ministry of Metallurgy and Machine Building.

The main goal of this project was to design and testing in clinical conditions an universal system for rehabilitation and training purposes, specially for tetraplegia patients.

In this paper some results concerning the engineering part of this programme are presented.

MATERIAL AND METHODS

Functional Electrostimulation

Electrostimulation of the tissues and organs become now not only a standard method for rehabilitation, after the nerve-muscles diseases, but also an efficient factor for supporting of the lost functions after motorical disorganization.

Based on the present knowledge about motorical activity and influence of the programming electrostimulation of the CNS we concluded that FES can be applied for

- supporting of the less effective functions and acceleration of the rehabilitation process to restore the lost functions of the paralyzed extremities,
- restoration and reorganization of the basic motorical mechanisms, primarily on the spinal cord level,
- renovation of the lost motorical functions, which were lost after CNS destroying,
- supporting of the regeneration process of the motorical activity in children with the brain stroke,
- prevention or correction of deformation of the locomotor system caused by the inefficiency of the posture mechanism or others senso-motorical mechanisms on different levels of the CNS.

FES influences on the reorganization of the motorical activity and of the repeating of the series of the impulses, which act on motorical output of the nerves centres. The influence of the electrical impulses on the nerves system can be also used as a method of pain elimination or its decreasing. Clinical experiences shows that this method is more efficient and less danger for the patients as traditional one.

A good results are obtained with the surface electrodes as well as with implanted electrodes on the peripheral nerves, spinal cord even the brain.

In the last period the surface electrodes for the pain elimination

x/ Supported by the Key-Problem 0.6.5.

are used temporarily before the implantation.

If the results after some days are negative the electrodes are taken out. In the positive case the implanted electrodes are applied. It is expected that this method will be used not only for the spinal cord stimulation in the cases of chronic pain but will also be applied for the cancer problems.

The electrostimulation method becomes also effective for the surgical treatment in the case of bone fracture. Based on the clinical experience we considered that electrostimulation in the case of the complicated fracture healing and spurious joints influence positively on the restoration process of the bone, mainly through increasing of the vessel restoration during the process of the fracture healing.

By using the electrostimulation method we obtain a faster rehabilitation and a shorter period of the immobility of the extremity. In the congenital cases and after injuries of the spurious joints, by using the combination of the traditional medical treatment with electrostimulation method in majority of the patients we obtain the fracture healing of the bones/after Bassett and others in 70% of the cases/.

In the last four years a multipurpose system for electrostimulation was designed and tested by the Team from the Warsaw University of Technology in cooperation with the Team from the Metropolitan Center of the Rehabilitation, Konstancin near Warsaw.

This system permits the application of different kinds of the electrostimulation methods and techniques.

RESULTS

The mentioned above system was built in a panel form with different changeable panels and can be used for motorical, pain elimination and fracture healing purposes.

Because of the similarity of the form and electrical parameters of the impulses used for the motorical and pain elimination stimulation, these two kinds of panels were designed as a one unit. The possibility to regulate the parameters and switching the series of impulses, makes possible to use this unit both for motorical and pain elimination stimulation. This unit can be used for the patients with paralyzed extremities/upper and lower one/ after CNS injuries on the different levels for forcing or supporting the lost activity of the muscles, supporting of the respiration process by control of the diaphragm activity and for the patients with the lingering acute pain. This unit can be used also for the electrostimulation of the peripheral nerves or muscles, spinal cord even the brain. It can be also used for the excitation of internal organs like bladder or intestines. The surface or implanted electrodes can be used. The two kinds of the stimulation impulses can be used namely, the current output for the surface electrodes and the voltage output for the implanted electrodes. The unit can work as a continuous system according to the adjusted programme in the programming system connected with the amplifier or can be released at stated time by the regulator from an external source of the release.

Each unit output is galvanically isolated from each other to eliminate the influence during the stimulation process using different methods for the same parameters. The parameters of the unit are as follows: rectangular impulses with the exponential increasing and decreasing slopes. The output resistance for the surface electrodes is 4.7 k Ω , for the implanted electrodes 430 k Ω . The output current amplitude for the surface electrodes is 0-30 mA, for implanted electrodes 0-25 V. The frequency of the stimulation is 1-10 Hz or 10-100 Hz. Duration of the time is 0.2 to 1 ms. The time of the increasing of the series of the impulses is 0.1-0.7 s. The duration of the series of the impulses is 0.6-3.5 s. The unit for the fracture healing of the bone works under the voltage signal. There is a sinus wave 3 kHz with the modulated amplitude by the sinus, triangle or rectangle signals. The

main parameters of this unit are as follows: voltage signal 3 kHz, the amplitude is 0-120 V_{pp}, depth of the modulation is 0-80%, the envelope is of the sinus form, triangle or rectangle and the frequency of the modulation envelope is 50-200 Hz. There exists the possibility of automatic filling of the envelope/in the full range of the frequency/ and programming or continuous kinds of work.

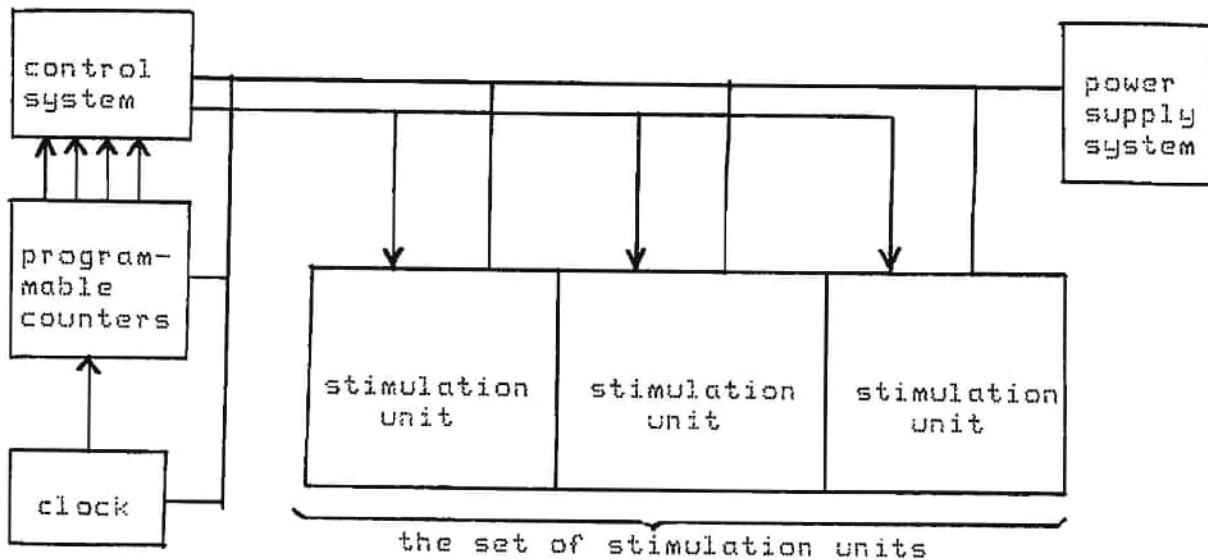


Fig.1 The block diagram of the multipurpose apparatus for the electrostimulation method

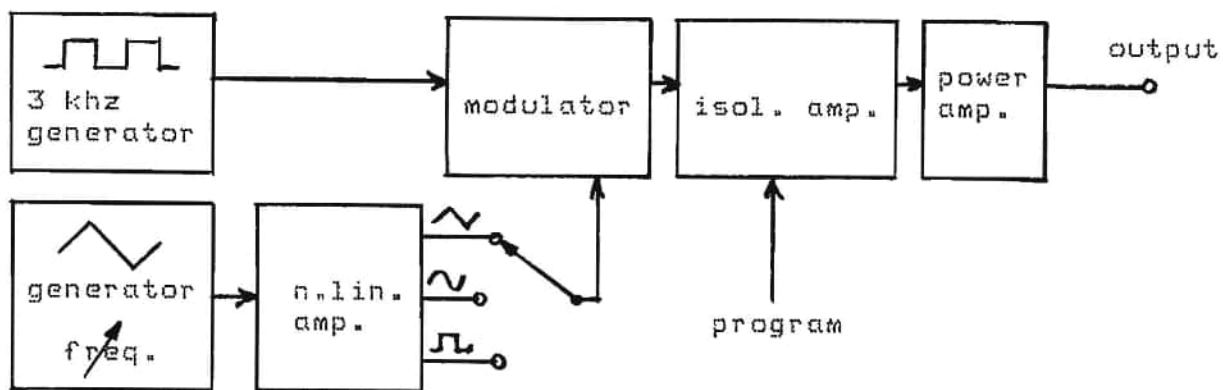


Fig.2 Block diagram of the fracture healing unit

On the figure one the block diagram of the whole system is shown. It consists from the control system, programmable counters, clock and the power supply system connected with the set of the changable stimulation units. The main parameters of this system are as follows: supply voltage 220 V/50 Hz or 12 DC. It can work with one, two or three units connected in the different compositions, for example: two motorical and pain elimination units together with one fracture healing unit.

The system is able to work as programming or continuous one. The beginning of the stimulation cycle is announced by the acoustic

signal.

The dimensions of the system are as follows: 440x220x380 mm and the mass is 11 kg.

DISCUSSION

After the testing in the laboratory conditions the prototype of the system was improved and tested again in the two independent laboratories, which belong to the Medical Centres of Technology in Warsaw. Next the system was tested in the clinical conditions in the Metropolitan Center of Rehabilitation. The first obtained results were positive. Now this system is under investigations in the other clinic of rehabilitation in Poland.

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REGENERATION OF ULCERATED TISSUE BY ELECTRICAL STIMULATION x)

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SUMMARY

With recent advances in medicine and engineering the opportunity for a spinal cord injured person to return to a normal, functioning role in society after rehabilitation has become widely accessible. As a result, paraplegic and quadriplegic patients are spending many hours in the wheelchair to participate in daily activities. Along with the progress wheelchair users have made towards independent living however, a problem of decubitus has developed into one of the foremost obstacles in rehabilitation. Population affected by pressure sores are also patients confined to bed, and those who are inactive and have medical problems such as circulation and trophic disturbances.

Electrical stimulation appears as a promising method in prevention and treating of pressure sores /1,2/. In our preliminary study electrical currents were applied to spinal cord injured patients with decubitus ulcers, to postamputation wounds and to ulcers cruris. In more than 40 patients included in the preliminary study, encouraging results were obtained.

This study presents the results of application of electrical stimulation in seven spinal cord injured patients with nine decubitus ulcers. The patients have developed these wounds over few weeks to several months. The size of all wounds decreased after electrical stimulation. The rate of healing depends on the initial wound surface, the duration of existence of wound before stimulation, as well as on the location of the wound.

Once weekly photographed wounds were analysed by the astereological method. CAD program was used to calculate wound surface. Seven wounds decreased exponentially, while two others linearly. Initial healing rate - for wounds which decreased exponentially - is $0.42 \text{ cm}^2/\text{day}$. The average healing rate for all wounds is $0.07 \text{ cm}^2/\text{day}$.

MATERIAL AND METHOD

Electrical stimulation was delivered from a dual channel stimulator. Tetanizing currents were applied through four electrodes across the wound. The frequency of biphasic current stimuli was 40 Hz and the pulse width 250 μs . The stimulation sequences are 3.5 s on and 4.5 s off. The amplitude (up to 50 mA) was adjusted to achieve minimal muscle contraction when feasible. Stimulation was applied twice for 20 min daily.

Wound surface was photographed once weekly. The data of the surface were stored by means of a digitizing tablet after projection of slides. CAD program was used for entering the shape and calculation of the skin area.

Seven spinal cord injured patients with nine decubitus ulcers were included in the study. Three ulcers were located in the sacral area, three over the left trochanter major, two over the right trochanter major and one above the scapula. The patients have developed these wounds over several weeks (from 2 to 19 weeks) and electrical stimulation was started one week after admission to the Rehabilitation Institute.

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Surface/cm²

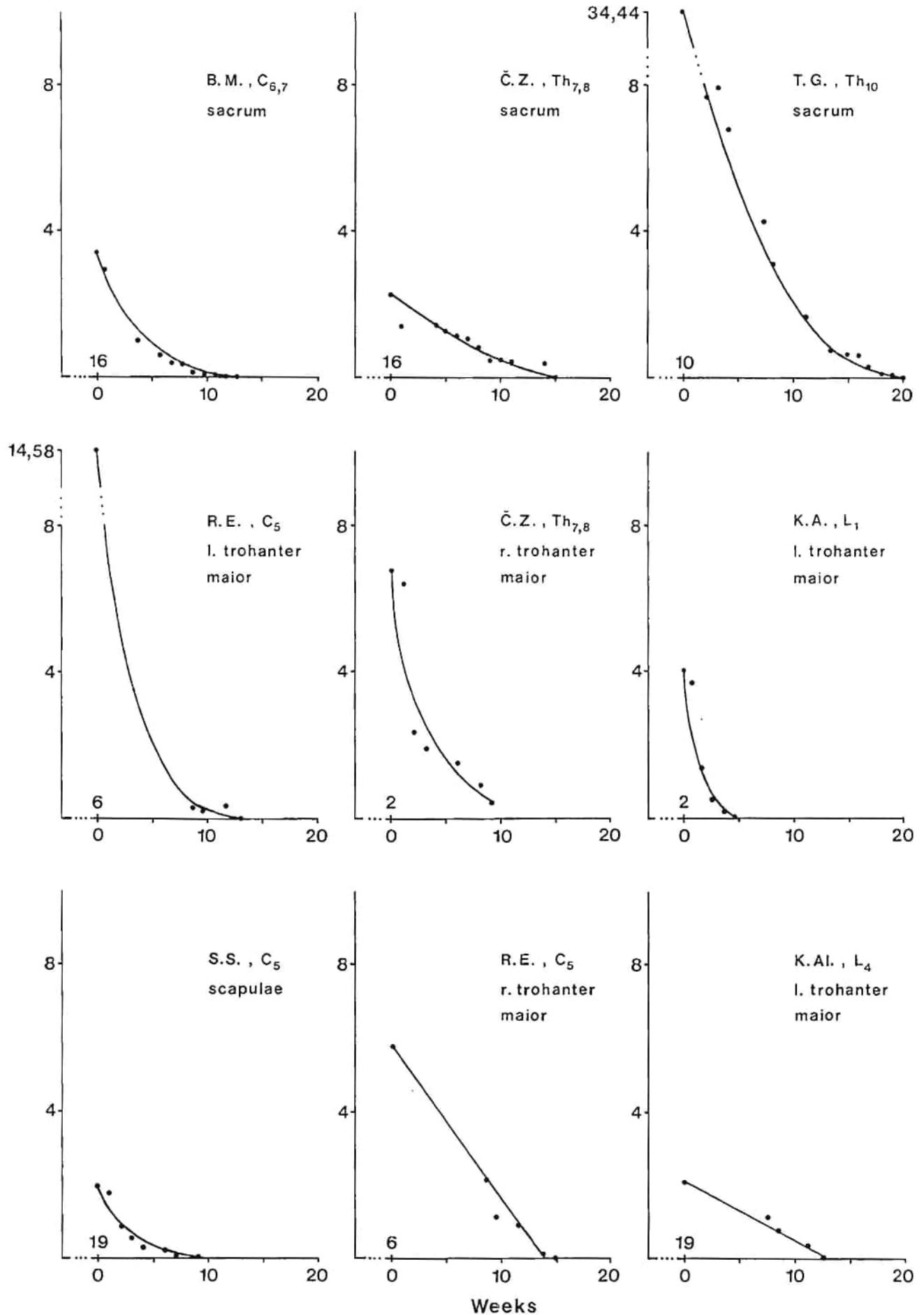


Fig. 1.: Changes in wound surface due to electrical stimulation. Upper values on the horizontal axis represent the duration of ulcer before treatment by electrical stimulation. Lower values - time of treatment.

RESULTS

Improved regenerative processes by electrical stimulation resulted in healing of eight out of nine ulcers. The surface area of one wound is decreased by 93.5% after nine weeks of electrical stimulation. The time courses of calculated surface for all wounds are presented in Fig. 1. Fig. 2. shows the changes in shape of the sacral wound in patient B.M. due to treatment of electrical stimulation. The rate of healing depends on the initial wound surface, the duration of existence of wound before stimulation, as well as on the location of the wound. The data of decreasing of seven wound surfaces

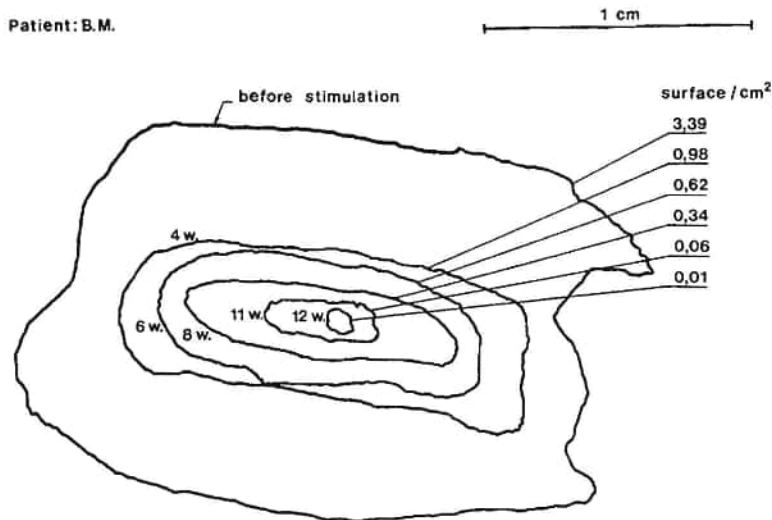


Fig. 2.:

Sacral wound decreasing after application of electrical stimulation.

could be fitted by exponential function. Thus, the initial healing rate is greater than average healing rate - $0.42 \text{ cm}^2/\text{day}$ per 1 cm^2 initial wound surface. The average healing rate for all wounds (either exponentially or linearly decreased) is $0.07 \text{ cm}^2/\text{day}$.

DISCUSSION

Electrical stimulation increases the rate of healing of ulcerated tissue. Possible mechanisms which increased the level of regeneration are:

- effects of generated fields in the damaged tissue, and
- improved blood circulation.

Electrical field might represent a contact net which helps fibroblast division as well as its growth into the scar. Also, electrical field can possibly draw already synthesized collagen in scar formation. Since Ca^{++} has an important role in regeneration, one may assume possible influence on increasing free cytoplasmatic calcium. Improved blood flow increases oxygen concentration, which in turn improves collagen synthesis.

However, in this study, analysis of the scar tissue did not show significant collagenase activity. For such analysis biopsy specimen are obvious, but not ethically acceptable in a clinical study. Thus, animal experiments, or experiments on tissue cultures might probably offer some more information about the mechanisms of regeneration influenced by electrical stimulation.

Bacterial analyses made in some wounds treated in this study, showed no correlation between the rate of healing and the presence or the type of bacteria.

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A SHORT LEG HYBRID FES ORTHOSIS FOR ASSISTING LOCOMOTION IN SCI SUBJECTS

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INTRODUCTION

A "Hybrid Orthosis" (HO) combines the techniques of mechanical bracing and Functional Electrical Stimulation (FES). By combining these techniques a better orthotic solution can often be obtained than that achieved by using either technique alone (1,2).

This paper and video recording presents a novel HO based on a modified short leg floor reaction orthosis (FRO) (3,4) and a FES control system. The use of this HO minimises the amount of quadriceps stimulation required to stabilise the leg and thereby avoids fatigue of these muscles. The FRO also provides stabilisation of the ankle and subtalar joints and substitutes for the lack of active push off during late stance.

THE FLOOR REACTION HYBRID ORTHOSIS (FRHO)

The FRO was fabricated using a high density polypropylene thermoformed on to a positive plaster of paris model of the subject's leg. The ankle joint was set in approximately 5 degrees of plantar flexion. A number of workers have reported application of the FRO in some paraparetic subjects having weak knee extensors and preserved hip flexion (3,4). The FRO has the cosmetic advantage of a thermoplastic ankle foot orthosis. It is lightweight (approximately 0.3kg) and it inserts into standard footwear and is easily donned and doffed. The FRO has the functional advantage of being able to stabilise the leg without requiring muscular activity or limiting free knee movement, provided that the ground reaction vector passes anterior to the knee joint axis. The FRO cannot stabilise the leg whenever the ground reaction vector (GRV) passes through or behind the knee joint axis. For example, in standing/sitting, early stance phase of walking, when negotiating steps or uneven ground and whilst performing swing through type gait patterns. In order to extend the application of the FRO in SCI subjects having extensive paralysis of the leg(s), additional means must be provided to deal with the above destabilising situations, and to provide flexion of the leg during the swing phase of gait. The FES control system was designed to react appropriately to such destabilising events and to provide a means of flexion to initiate swing phase.

The FRHO is shown schematically in figure 1 comprising a rigid FRO, three surface electrodes and a two channel stimulator for each leg. Electrode (b) acts as a common, indifferent electrode for both channels. Monophasic, rectangular pulses were used having a duration of 0.3ms, a pulse repetition frequency of 20Hz and an amplitude adjustable up to 120 volts (measured with a 1kohm load). Stimulation of the knee extensors electrodes was delivered through two 41mm x 88mm self-adhesive electrodes (Myocare, 3M Ltd.), labelled (a) and (b) in figure 1. Stimulus was delivered to the common peroneal nerve using the indifferent electrode (b) and a smaller active electrode (c) positioned behind the head of fibula. The quadriceps were activated in response to the changing direction of the GRV. This is illustrated in figure 1. As shown, the GRV passes anteriorly to the knee joint axis. In this case, an anticlockwise moment is generated by the floor reaction force (R). This moment is balanced by a limb orthosis reaction force (F) due to the pressure applied in the region of the patella tendon by the restraining strap. In this posture the FRO locks the knee in extension without the need of continued quadriceps stimulation. The force (F) is related to the magnitude and line of action of the FRV

relative to the knee joint axis and can be inferred from the tension generated in the restraining strap. The strap tension will increase as the GRV moves forward away from the knee axis and the leg will be stable. However, if the strap tension is zero, this indicates that either the limb is unloaded or else that the direction of the GRV passes through or behind the knee axis. In this case the leg is potentially unstable. In order to prevent the subject collapsing an appropriate action would be to activate the knee extensors. A simple artificial extension reflex (ER) was implemented, by maximally stimulating the knee extensors whenever the strap tension drops below a preset threshold level. The subject may cause the stimulation to be switched off again by leaning forward slightly, thus bringing the GRV in front of the knee axis causing the strap tension to exceed the threshold. In order to make this postural change the subject must be aware of the stimulus. Many SCI patients have preserved sufficient sensation to be aware of the applied stimulus. For others this feedback may be provided either by stimulating a sensitive area of skin or else by using an appropriate audio visual cue. In the prototype FRHO the strap tension was used to compress a spring affixed to the FRO upright. The threshold tension was set by adjusting the displacement of the spring required to turn off an electrical switch labelled (s) in figure 1. This switch controlled the stimulator output to quadriceps. Thus, when the ER was enabled the quadriceps were stimulated only when the strap tension fell below threshold in response to a destabilising influence.

STANDING AND SITTING

In order to stand up, the subject first moves to the edge of the seat with both feet positioned on the floor. In this position the strap tension is below threshold. The STAND control on the stimulator is pressed and the subject prepares for the manoeuvre by holding the supporting frame or crutches. After a delay of 5s, the ER is enabled and the quadriceps are activated. The subject assists the manoeuvre with his upper limbs. Once upright, he leans forward slightly to bring the GRV in front of the knee joint axis and the stimulus switches off. To sit down again, the subject presses the SIT control on the stimulator and, when ready, leans backwards. Maximal stimulus is applied in response to the reduced strap tension. This stimulus then decays to zero in approximately 5s enabling the subject to return to his seat. His rate of descent being controlled by him dependent upon the amount of body weight taken through his upper limbs.

During quiet standing only a minimum of upper limb effort was found to be required to maintain stability. This is because the ankle joint was effectively immobilised. In one patient (G.D.) quiet standing was possible without any assistance of the upper limbs.

RECIPROCAL WALKING

It has been determined that a minimum of four channels of electrical stimulation are required to synthesise a simple reciprocal gait pattern in paraplegics with complete motoric lesions (5). During the stance phase the leg was stabilised by stimulating the knee extensor muscles. A forward step was achieved by first transferring body weight through the opposite leg, then eliciting a flexion withdrawal response followed by knee extension prior to foot contact. A similar approach was used for the FRHO described here.

From the patient's control point of view, the gait cycle was divided into stance and swing phases. For each leg the transition from one phase into another was achieved by pressing a corresponding hand switch. These hand switches were mounted onto the handgrips of the forearm crutches or walking frame or rollator. When a switch was not pressed the ER was enabled. In order to take a step forward, the subject first transfers his body weight onto the opposite leg and then presses the ipsilateral hand switch. Whilst the switch was pressed, the

ipsilateral ER was disabled and the common peroneal nerve stimulated. Stimulation of this mixed nerve elicits a flexion withdrawal response producing dorsiflexion and eversion of the foot, flexion of the knee and flexion with slight external rotation at the hip. The amount of flexion was dependent upon the preset stimulus intensity. In order to terminate the swing phase, prior to foot contact, the hand switch was released and the ER re-enabled. This resulted in the immediate stimulation of quadriceps, causing the knee to extend prior to foot contact. The duration of the swing phase was regulated by the time of pressing the switch. The quadriceps stimulus was maintained until shortly after foot contact when the patella strap tension again exceeded the threshold. Thus the quadriceps were inactive for most of the stance phase. In contrast to normal walking the stance phase may be extended by up to 75% of the stride cycle for some paraplegics. This is largely due to the extended period of double support required by the subject to transfer body weight from one limb to the other and to push the rollator walker forward. Flexion may, optionally, be triggered using a shoe insole switch, with the active element positioned in the region of the metatarsal heads. When the subject transfers his body weight onto the stance leg, this will cause the swing leg insole switch to change state. This change of state causes the quadriceps stimulus to be inhibited and the peroneal stimulus to be applied for a preset time interval. This preset interval is adjustable to suit the subjects cadence. In order to prevent false triggering of flexion, it was necessary to build in the condition that the metatarsal switch be unloaded for an uninterrupted period of 0.1s before triggering flexion.

PATIENT TRIALS

Two patients with spinal cord lesions have so far been included in the trials of the FRHO. In both cases the quadriceps muscles were conditioned by a course of cyclical electrical stimulation exercises similar to those described in (5).

The first subject (K.D, male age 34 yrs, mass 88kg, height 1.88m, lesion T5/6 complete, 4yrs post injury) used the FRHO bilaterally using the handgrip mounted switches to control flexion when walking with a rollator. The second subject (G.D, male, aged 22yrs, mass 70kg, height 1.8m, incompletely lesioned at the level C6, 3yrs post injury) has one leg that is completely paralysed. The other, has after the conditioning phase, sufficient voluntary controlled function to enable him to remain standing for a short time using forearm crutches without stimulation. He had previously used a 2 channel FES device described in (6). This subject used the FRHO unilaterally for standing and walking in forearm crutches fitted with handgrip switches for flexion control. This patient preferred the option of automatic triggering of flexion when walking on level ground. He used manual control, as he did with his 2 channel FES device (6), when negotiating uneven ground, slopes and steps.

The following refinements of the FRHO have been developed. When negotiating uneven terrain or stepping over obstacles a greater degree of flexion is often required than that for level ground walking. The degree of flexion may be increased by increasing any of the parameters of the stimulus (frequency, amplitude or pulse width). In the present system the pulse amplitude was increased. The handgrip switch referred to above was implemented using a force transducer. In the manual mode a small force applied by finger to this transducer produced the changeover of stimulus to the common peroneal nerve to initiate the flexion response. The degree of flexion was initially preset for level ground walking by a potentiometer on the belt worn stimulator. The force transducer provides an additional control input to the voltage controlled stimulator. Whenever a greater degree of flexion was required then the subject pressed proportionally harder on the force transducer. In the automatic flexion triggering mode the force transducer input may be used to boost flexion. Additional pelvis/hip stability can be provided by adding gluteal stimulation in the ER. Hip

extension and abduction may be useful following foot contact. This may be implemented using a gluteal location for the proximal electrode (a) and repositioning (b) more proximally. Simultaneous activation of gluteus maximus, gluteus medius, tensor, rectus femoris and the external vastus may then be effected.

DISCUSSION

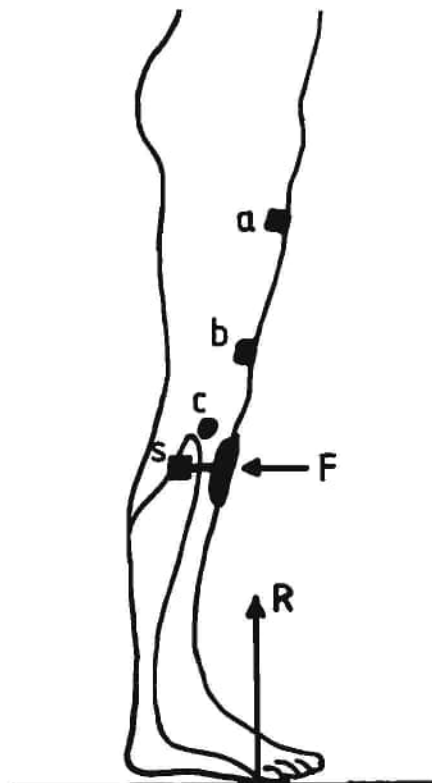
These preliminary trials indicate that the application of the FRO may be extended to cases where the leg musculature is paralysed but electrically excitable and where the flexion withdrawal reflex may also be elicited. The duty cycle of stimulation delivered to the quadriceps was found to be greatly reduced during standing and walking. This avoided fatigue and prolonged the time for which the device could be used. The quadriceps were stimulated in an all or none manner thus eliminating the need for periodic adjustment of stimulus intensity. The combined FRO and simple three electrode configuration was found to be cosmetically attractive and convenient to don and doff. Walking in the FRO was found to be more aesthetic to both subject and observer than locked knee gait using conventional knee ankle foot orthoses (KAFO). The FRO provides mediolateral stability of the ankle and subtalar joint. The FES assisted walking was preferred by both subjects and may require less energy than KAFO walking because no hip hiking was necessary with active flexion. The FRO is significantly lighter than conventional KAFO's (0.3kg vs 2.2kg approx.). A number of important therapeutic benefits may be gained from regular mobilisation using FES based orthoses. These may include prevention of pressure sores, prevention of joint contractures, prevention of muscle and bone atrophy, improved urinary drainage and relief of spasticity.

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LONGTERM ELECTRICAL STIMULATION OF A MOTOR NERVE BY A TOTAL
IMPLANTABLE STIMULATOR IN AN ANIMAL EXPERIMENT.

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With the ever-increasing use of the functional electrical stimulation by surface electrodes in many patients, the need for a system with implanted electrodes increased also. To study the long term effects of electrical stimulation with a total implantable system, an animal experiment was set up. Special attention was given to the histological aspects of nerve and muscle before and after stimulation. Twelve adult cats received a bipolar electrode made of platinum, placed around the femoral nerve in one leg. A radiogrequency powered stimulator connected with the electrode was implanted in the muscles of the back. The electrode lead ran subcutaneous to the stimulator. A special constructed cage, with a built-in antenna in its wall, permitted the delivery of radiosignals to the animal anywhere in that cage. A transmitter outside the cage had the ability to adjust the time, intensity and frequency of the stimulation pulse and the interval of the stimulus. The animals were stimulated during one hour a day. The intensity of the pulse was two times the threshold value with a pulsetime of 0,20 milliseconds. This intensity varied from animal to animal between 200 and 400 microamperes. The pulse frequency was 30 c/s. The stimulus was on for 2 seconds with an interval of 28 seconds.

Before and during the experiment threshold value was measured and contraction-strength was registered by strain gauges. Muscle biopsies were taken before and after the experiment, as a control of the eventual changes of fiber-composition. Finally nerve samples were taken to study the histologic changes in the stimulated nerve.

Stimulation took place during 3 - 16 months. In three cases stimulation ceased to give a response after 5, 6 and 11 months. At re-operation the electrodes appeared to be dislocated with respect to the nerve in two cases. In the remaining animal the electrode had its normal position, but histologic examination of the nerve showed a considerable degeneration and signs of chronic infection, probably due to mechanical irritation or compression of the nerve in the electrode.

The threshold value of the nerve initially increased just after implantation but stayed then on its level till about 6 months.

After that period a slight increase could be seen again.

Contraction strength of every individual animal displayed great variability, but the progress in time was the same in all cases:

initially an increase of about 25% of the original strength. After 6 months however there was a decrease in strength till the original level

An explanation for this phenomenon could be that the increase initially is to be seen as an effect of muscle training and the decrease later on as a consequence of the increasing threshold-value of the nerve.

Histological examination of the nerve showed an abnormality in only 2 animals. As above mentioned in one case stimulation was not possible anymore after a sudden increase of threshold value over 500 microamperes. This nerve showed severe degeneration on histologic examination.

The other animal showed in its nerve sample moderate degeneration, although there had been no diminishing response to stimulation.

The only difference with a normal nerve in the other cases, was the amount of collagen in the endoneurium and signs of some chronic irritation in the epineurium.

In muscle biopsies taken from the upperleg muscle before and after stimulation muscle fiber composition was studied by histochemical staining methods.

The size of all fibers did not change in the stimulated muscle. Also no change was found in the distribution of the fast-twitch and slow-twitch fibers.

Some investigators found in their experiments a shift in fiber composition induced by the kind of electrical stimulation. We however, in our experiment, found the period of electrical stimulation to short to influence the excitation rate of the motorunits. Also our animals kept their normal gait and movements, when not stimulated, because of their normal central and peripheral nervous system.

The conclusion of this experiment is that electrical stimulation with the described method on the normal nerve and muscle, will give no disfunctioning and will not change the contraction pattern of the muscle so that this kind of stimulation can be continued for a long period.

Encouraged by these results we started implantation of a

peroneal stimulation in patients (Yougoslavian model of implantatable stimulator).

However it is too early to discuss all the results. We think that this kind of functional electrical stimulation by means of an implantable stimulator will be of great advantage for a numerous group of patients.

The Electromyogram as a control signal for FNS.

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The successful application of Functional Electrical Stimulation to the muscles of paraplegics depends to a large extent on the adequate provision of a means by which the subject can exercise control over the resulting movement.

The use of above-lesion electromyographic signals as a solution to the control problem is considered. To achieve this aim, the suitability of time series analysis as a means of processing electromyographic signals is investigated. The signals are represented by a fourth order autoregressive model, the parameters of which are used to achieve signature discrimination. The success of this method is dependent on the choice of electrode location. Various experiments to determine such an electrode location are described.

As a result of the above investigations, it is concluded that electromyographic signals can be used to control Functional Electrical Stimulation. In this light, a number of recommendations relating to the practical application of a suitable control system are made.

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RESEARCH ON ELECTRICAL STIMULATION WITH SURFACE ELECTRODES

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SUMMARY

In order to develop control systems for stimulation of muscles it is necessary to investigate the relation between stimulation current and force (the recruitment curve) in different situations. This applies especially to the use of surface electrodes. Several experiments were carried out, using a 4-channel computer controlled stimulator which was developed at our center. We investigated the influence of the knee angle on the recruitment curve of quadriceps muscle with different electrode placements. Although the curve was steeper with a small electrode on the motorpoint of the rectus femoris muscle reproducibility and smoothness of the curve was far better compared with the electrodes placed over the whole quadriceps. We developed a standardized method to compare the influence of stimulation frequency and electrode placement on fatigue of the quadriceps muscle. With this method we also investigated the effect of using three electrodes in alternating pairs on the occurrence of fatigue.

INTRODUCTION

Since 1984 an extensive co-operation exists in research on functional electrical stimulation between the Twente University of Technology and our centre. The long-term goal of the research is focussed on the development of a multichannel closed-loop stimulation system to enable paraplegics to stand and ambulate. In order to be able to develop optimal control systems for stimulation, it is necessary to investigate the relation between stimulation parameters and the generated force under different circumstances. This applies especially to the relation between stimulation current and force: the recruitment curve. Additionally the recruitment curve will change with the occurrence of fatigue of the stimulated muscle. The relatively fast occurrence of fatigue due to the synchronised contractions limits successful application of electrical stimulation. Various investigators have tried to overcome this problem, e.g. by using multiple electrodes in alternating pairs (Petrofsky, 1983), so the stimulation frequency of each electrode pair may be lowered. Because in literature there is little quantitative information about the above mentioned aspects we started to investigate it. In this paper results will be presented concerning the influence of the electrode placements on the recruitment curve and on fatigue of the stimulated muscles.

METHODS

All experiments were carried out by using our 4-channel computer controlled research stimulator. This system consists of an Apple IIe computer and a 4-channel dedicated computer stimulator in a master/slave set-up. With the Apple computer all the stimulation parameters as well as the pulse shape can be controlled. More details are shown in our paper 'FES exercise equipment for the lower extremities' also in this proceedings. In these experiments we applied monophasic current pulses with a duration of 300 μ s. Carbon rubber electrodes were used with a conductive gel. All the

experiments were carried out with the same 8 healthy subjects. During the experiments with which we studied the fatigue phenomenon, the stimulation was switched on and off every 5 seconds. In the first second the stimulation current was ramped up. The force was measured with strain gauges and a carrier frequency bridge. The mean force was determined over the period between the second and fourth second. Before the experiment started, the stimulation current was chosen for each subject individually to correspond to a standard force level and remained the same in each experiment.

RESULTS

The influence of knee angle and electrode placement on the recruitment curve.

The recruitment curve was measured with two different electrode placements. First with the electrodes placed proximal and distal of the quadriceps and secondly with one electrode placed on the motor point of the rectus femoris muscle and the other electrode placed nearby the knee. The recruitment curve was measured with both electrode placements at 10, 30, 60 and 90 degrees flexion of the knee.

From the data and our experiences during the experiment it can be concluded that:

- The recruitment curve is steeper and the reproducibility is better when the active electrode is placed on the motor point of the rectus femoris muscle.
- The dependence of the recruitment curve on the knee angle is less than the reproducibility of the measurements.
- With the electrodes placed over the quadriceps muscle sometimes oscillations in the muscle occur.

The influence of the stimulation frequency on fatigue.

During this experiment the active electrode was placed on the motor point of the rectus femoris muscle and the other electrode was placed nearby the knee. The goal of these experiments was not just to determine the influence of the stimulation frequency on fatigue of the rectus femoris muscle. It was also meant to develop a standardized way to investigate fatigue and to get mean normal values for healthy subjects.

From figure 1 it can be seen that with a stimulation frequency of 15 and 20 Hz maximum force first tends to raise before decreasing due to fatigue.

Remarkable is the rapid decrease of force when the muscle is stimulated with a frequency of 30 Hz.

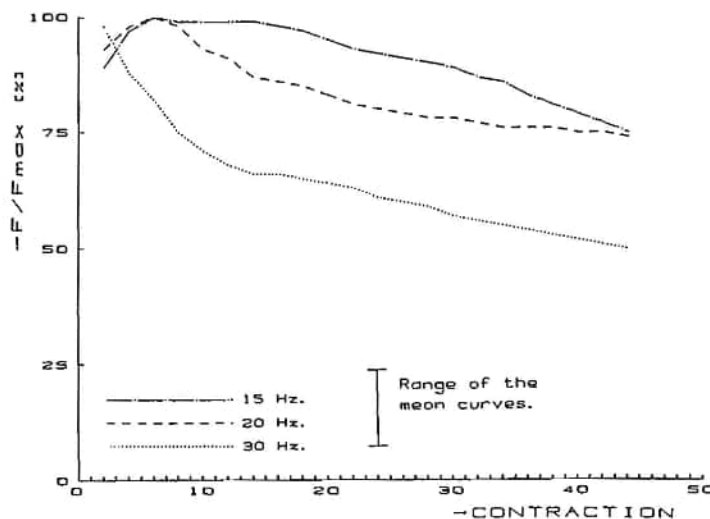


Fig.1. The influence of different stimulation frequencies on the course of the force at repetative stimulation, with normal subjects.

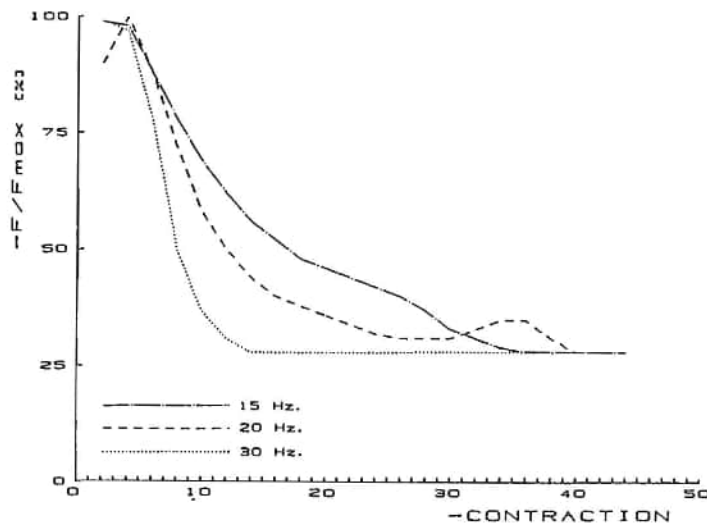


Fig.2. The influence of different stimulation frequencies on the course of the force at repetitive stimulation, with a spinal cord injured subject.

In figure 2 the results are shown with a spinal cord injured subject after 4 months of exercise. The differences compared to the normal values are very distinct: fatigue occurs much faster and the decline of force is larger.

The effect of using three electrodes in alternating pairs on the occurrence of fatigue.

In order to compare the influence of the use of alternating pairs of electrodes with the use of a single electrode pair two experiments were carried out. These experiments were carried out under the same conditions and with the same 8 subjects as before, in order to compare the results.

In the first experiment three electrodes were placed equally over the quadriceps from proximal to distal. In the second experiment the middle electrode was positioned carefully on the motorpoint of the rectus femoris muscle.

The proximal and distal two electrodes were used in alternating pairs with a summed stimulation frequency of 30 Hz. The results are shown in figure 3.

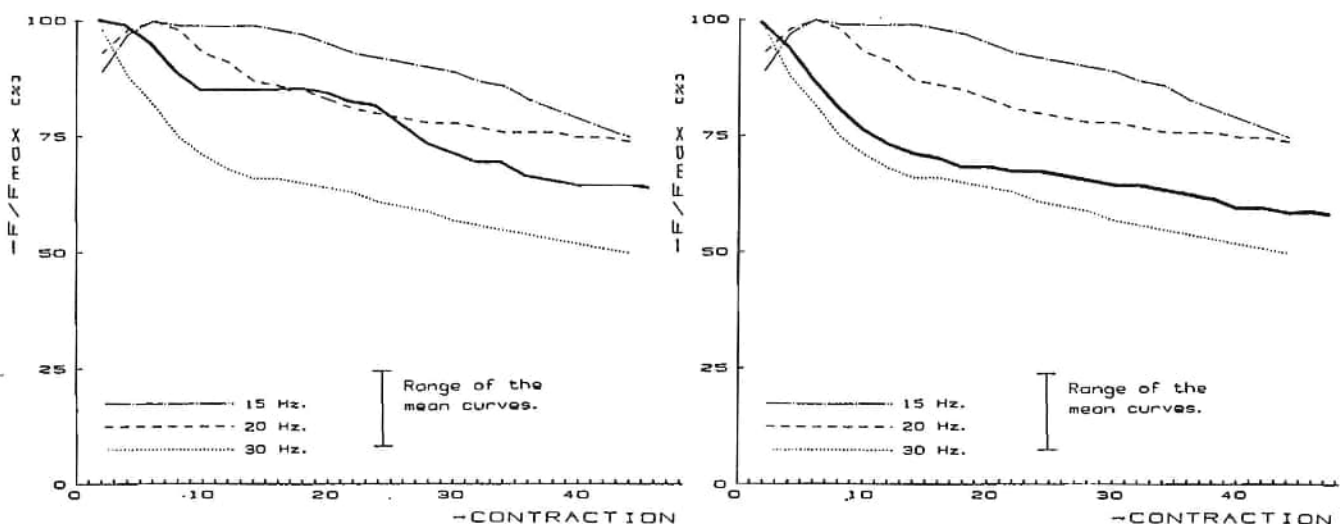


Fig.3. The course of the force when using three electrodes in alternating pairs compared with the use of two electrodes with different frequencies.

A: active electrode halfway the quadriceps

B: active electrode on the motor point of the rectus femoris

From this figure and our experiences it may be concluded that:

- Placing the electrodes equally over the whole quadriceps gives some improvement compared to the curve at 30 Hz of the single electrode pair.
- Placing the middle electrode on the motor point of the rectus femoris gives no significant improvement.

However the curves shown in figure 3 are group mean curves obtained by smoothing the individual curves with a moving average window. If we calculate the root mean square error between the unfiltered data and the filtered data of each subject it appears that this error is approximately three times larger in the first experiment (fig.3B) compared with the second experiment (fig.3B). This means that during the first experiment the force varies much more when the muscle is stimulated with the same current.

DISCUSSION

The recruitment curves measured with surface electrodes are very steep and non-continuously. This is probably because relatively large nerve fibres are stimulated in the muscle, with small differences in excitation threshold levels. The changes in the muscle geometry due to the stimulation will also contribute to these findings and may also cause oscillations of the muscle. From our experiments it may be concluded that for a better reproducibility the active electrode needs to be placed on the motor point of the muscle to be stimulated. The standardized method to investigate the changes in force output during stimulation, provides a good starting point to investigate fatigue. For example to evaluate the effect of training and to compare this with normal muscles. With this method it is also possible to estimate to what extent the same parts of a muscle are stimulated when multiple electrodes are used.

From our results it may be concluded that stimulating one muscle with three surface electrodes in alternating pairs gives no delay in the occurrence of fatigue. Stimulating the whole quadriceps, like Petrofsky does, gives some improvement but the reproducibility of this method is rather low. In order to delay the occurrence of fatigue in a reproducible way, one probably needs to stimulate different muscles alternately at their motor points. This method will be investigated on its applicability and its efficiency.

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IMPLEMENTATION AND MARKETING F.E.S. THERAPY

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SUMMARY

The purposes of this program were to, (1) identify those F.E.S. services that are sufficiently developed for clinical use and, (2) to implement and incorporate them as routine, augmentative, income-producing services in the Department of Physical Therapy. Methods for applying electrical stimulation and criteria for selecting and accepting spinal cord injured patients for treatment were implemented. Six paraplegic individuals participated in an intensive muscle strengthening program utilizing portable preprogrammed electrical stimulator units. They also participated in standing programs and sessions of pedalling a stationary exerciser bicycle. Additional patients participated utilizing portable F.E.S. units at home. One participant was fitted with reciprocating leg braces which he will use in F.E.S.-assisted walking in the near future.

While good and beneficial results were achieved with patients in the demonstration program, little success was achieved in marketing F.E.S. as a "primary" therapy. However, the numbers and types of disabilities treated with F.E.S., and the number of physical therapists who used this augmentative procedure, increased dramatically. Physical Therapists at Kaiser Rehabilitation Center benefited from demonstrations, instruction and equipment provided by this program, but they integrated F.E.S. therapy into their repertoires primarily by their own volition!

MATERIALS AND METHODS

A. Assessment of F.E.S. Services

The primary purpose of this program was to identify and implement those F.E.S. services that have been sufficiently developed for clinical use. Prior personal knowledge and utilization of existing technical information were augmented by visits

to other rehabilitation centers and consultation with other therapists, physicians, engineers and equipment vendors. During these visits vital information regarding patient selection and screening, therapy methods and technical equipment was acquired. Little useful information was acquired regarding marketing.

B. Patient Selection and Treatment

Criteria developed at the rehabilitation center in Ljubljana, Yugoslavia and at the Rancho Los Amigos Hospital were utilized.

Accepted individuals were placed on a muscle strengthening program utilizing the Myocare Plus electrical muscle stimulator. They were instructed to use the stimulator at home two times per day, five days per week. The quadriceps muscle group (vastus medialis and lateralis) on each leg was stimulated. The stimulator was programmed at the rehabilitation center.

Participants were placed on a progressive, resistive exercise program with electrical stimulation. When they were able to perform ten repetitions of knee extensions, they were progressed to one pound weight which was attached at the ankle. Their program included standing in a standing frame for thirty minutes, three times per week. Individuals who could not come to the rehabilitation center on a regular basis were advised to acquire their own standing frame. The participants were directed to perform self range-of-motion on their lower extremities and to work independently on upper extremity strengthening.

Each individual was progressed to a custom-designed stationary, F.E.S. equipped, exercise bicycle, when he/she could perform ten repetitions

of knee extensions with a two pound weight, and after participating in a standing program for three months. See Figure 1.

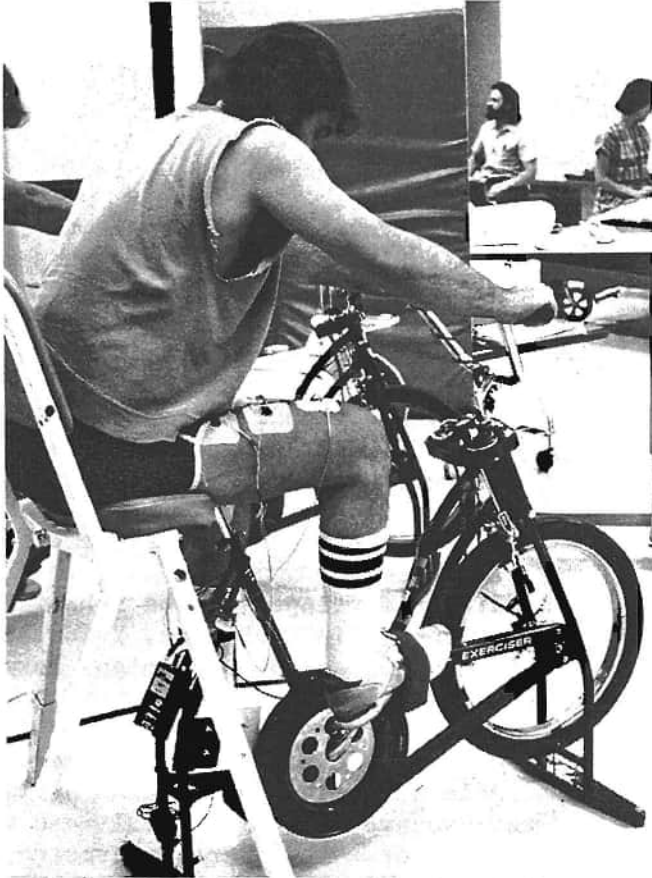


Figure 1. Custom-Designed F.E.S. Exerciser Bicycle with Special Seat

C. Planning for Collection of Fees

The initial plan was to charge \$25.00 for an F.E.S. evaluation and \$16.00 for each therapy session.

D. Planning for Marketing

An intensive marketing program was initially planned. But due to funding constraints alternate strategies were adopted as follows: (1) announce implementation of the F.E.S. program and the services available to paralyzed patients in local media, (2) present a one-day seminar on F.E.S. and invite disabled individuals, insurance company representatives, vocational rehabilitation counselors, special facilities and program administrators and special educators, and (3) direct contact with disabled patients. It was anticipated that these modest efforts would attract 30 to 60 outpatients and that more than half of these would be able to pay the scheduled fees.

E. Selection of Electrical Stimulation Equipment

The Myocare Plus Model 6810 Stimulator, a product of 3M, was selected for clinical and home use. This system includes a programmer which permits the therapist to conveniently set operational parameters and prevents the patient from manipulating vital controls. Two Respond Quadriflex stimulator units, products of Medtronic, Inc., were acquired for use with stationary bicycles and mobile tricycles.

F. Development of F.E.S. Exerciser Equipment

One of the goals of this program was to investigate means for developing inexpensive F.E.S.-related equipment for home and clinical use. Accordingly, a simple novel, inexpensive synchronizer switching mechanism was conceived, designed, fabricated and used for about nine months. A special seating system was designed and fabricated for the stationary bicycle.¹

G. Instructional Program for Physical Therapists

Almost all of the physical therapists at Kaiser Rehabilitation Center had some prior knowledge and experience with F.E.S. But the formal implementation program provided, (1) one-on-one instructional sessions by a key physical therapist knowledgeable in latest F.E.S. techniques, (2) access to various stimulator equipment, and (3) observation of patients in the intensive F.E.S. treatment program described above.

H. Market Survey

Facilities engaged in research and development programs had little interest in marketing F.E.S. services.

Manufacturers of F.E.S. equipment are, obviously interested in marketing of F.E.S. services. Medtronic-Neuro has an active marketing plan which includes interaction with private insurance companies and public programs such as Medicare. Medtronic Neuro reports inconsistent success of patients in acquiring F.E.S.

stimulators through Medicare but good success with private carriers - when the prescription argument is properly presented.

Therapeutic Technologies, Inc., which manufactures sophisticated F.E.S. rotary exerciser equipment, has a creative marketing program. This includes interaction with third-party payors and a very attractive revenue-sharing plan which enables rehabilitation centers to "test the market" at virtually no risk. Therapeutic Technologies reports that many insurance companies are willing to pay as much as \$100 per therapy session with their equipment and that some insurance companies have purchased their \$8,000 home units for individual patients. Nevertheless, Kaiser Rehabilitation Center elected not to acquire this equipment because the number of "paying" spinal cord injured clients in this region will not justify its presence, particularly when acquisition of an \$8,000 home unit by each patient is a requirement.

RESULTS

A. Evaluation and Selection of Patients

Fourteen individuals were accepted into the program in accordance with the established criteria. These individuals were regarded as candidates for the Core Demonstration Program. Twelve others who did not meet the criteria were, nevertheless, treated with varying degrees of success. Some individuals in both groups were removed from the program because they did not demonstrate sufficient interest.

B. Core Demonstration Program

Salient steps in treatment of patients were as follows:

1. F.E.S. evaluation - patient selection.
2. Initial muscle strengthening with F.E.S. - at home and in the Center.
3. Muscle strengthening with F.E.S. using one-pound weight at ankle.
4. Muscle strengthening with F.E.S. using two-pound weight at ankle.
5. Standing with F.E.S. assistance in standing frame.

6. Standing without F.E.S. - if feasible.
7. Riding stationary bicycle with F.E.S. assist - in appropriate cases.
8. Riding mobile three-wheeler - with F.E.S. assist.
9. Walking with reciprocating leg braces with F.E.S. assistance - in critically selected cases.

Five participants progressed to Step 7 - riding stationary bicycle with F.E.S. assist. Two individuals discontinued after 2-3 months due to pneumonia and skin breakdown from riding the stationary bicycle.

The remaining three participants have consistently ridden the bicycle three times per week, 30 minutes per session, for 6-7 months. The quadriceps muscles are stimulated to assist in pedalling. The bikers ride the equivalent of 3-6 miles each session. The participants increase their heart rates to 140-150 beats per minute. In each case the following has been observed.

1. Increased muscle mass.
2. Increased aerobic capacity.
3. Decreased spasms - temporarily.
4. Maintenance of flexibility.
5. Increased self-esteem.

One exceptional patient gained sufficient strength and function to warrant trial of reciprocating leg braces with F.E.S. assisted walking in the near future.

C. Treatment of Other Patients

Seventeen additional candidates who did not meet the criteria for the Core Demonstration Program were treated within the framework of the F.E.S. Implementation Program. Included were traumatic quadriplegics, brain injured, stroke and cerebral palsied individuals. This provided significant service to the patients and served as demonstration and learning experience for the staff.

An indeterminate number of others were treated with F.E.S. by other physical therapists at KRC. These treatments were recorded in a general category of "Electrical Stimulation" but the records do not permit

accurate analysis. It is clear, however, that a substantial increase in use of F.E.S. occurred as a direct result of the F.E.S. Implementation Program.

D. Use of F.E.S. Stimulators in Home Programs

Twenty participants used electrical stimulation in home programs. Fourteen are paraplegics and two are quadriplegics. Four others suffered from cardiovascular accidents (CVA), brain injury or cerebral palsy. In the group of paraplegics, one person used an F.E.S. unit for one month. Three participants used a unit for 3-4 months and three others used one for six months. Three individuals participated in home treatment for a year or longer. Ten of these people purchased their own stimulator units. Of the six participants in a MRI study, only one purchased a home muscle stimulator. Four of the remaining five would purchase units if they could afford them.

E. Collection of Fees

Initially, fees were collected from those on the program who could afford to pay. This caused dissension among the participants so collection of fees was discontinued. Those who received F.E.S. treatment outside the formal program, however, were billed.

F. Integration of F.E.S. Services

A visible "self-sustaining" or "primary" income producing F.E.S. service did not clearly emerge as a result of the F.E.S. Services Implementation Program. Something even better happened. Physical therapists, of their own volition, made judgments and properly incorporated F.E.S. therapy as an adjunctive tool in the excellent professional services that they routinely provide! F.E.S. therapy has been truly integrated as a routine, augmentative procedure within the Department of Physical Therapy of Kaiser Rehabilitation Center.

DISCUSSION

Primary activities and considerations for implementing F.E.S. services in an established rehabilitation center are as follows:

1. Plan to integrate F.E.S. services as adjunct methods and avoid attempts to establish F.E.S. as a "primary" or "stand-alone" service.
2. Assign a key physical therapist to the F.E.S. program and provide opportunities to study, visit other rehabilitation centers and teach other therapists.
3. Implement and conduct an F.E.S. demonstration program. This will engender confidence and acceptance by staff members.
4. Study and select appropriate equipment for use in both the center and at home.
5. Study the current status of the marketing issue. Consult local and regional third party payors.
6. Establish a records keeping system that will permit valid determination of the financial impact of F.E.S. services.

Probably the most important consideration is to give ample opportunity for therapists to determine efficacy of F.E.S. for themselves. Implementation of a successful program will thus be assured.

ACKNOWLEDGEMENTS

This work was supported by Sarkeys Foundation, Tulsa Royalties Company and Cities Service Foundation. Continuing effort is presently funded by the Franklin and Grace Bernsen Foundation.

We thank Dr. Alojz Kralj and his colleagues from Yugoslavia who visited Kaiser Rehabilitation Center to demonstrate functional electrical stimulation in 1984.

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INEXPENSIVE F.E.S. SYNCHRONIZER FOR LEG-POWERED ROTARY DEVICES

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SUMMARY

Widespread acceptance and use of F.E.S. therapy for muscle strengthening and preparation for functional applications, is predicated upon the availability of low-cost equipment. Commercially available leg-powered rotary devices for this purpose are prohibitively expensive. One costly component is the device that synchronizes applied electrical stimulation with position of the pedal arms. This paper describes a simple, reliable and inexpensive F.E.S. Synchronizer Switch, (FESSS) based upon magnetic reed switches mounted in semicircular arrays in a plane parallel to that described by motion of the pedal arm.

MATERIAL AND METHODS

A. Criteria for Bicycle Pedalling

It is imperative that the pedal arms be about 15 degrees past or over "top-dead-center" when pressure is applied to the pedal. It is also essential that pressure be removed when the pedal is about 15 degrees above "bottom-dead-center". It is also essential that the alternate pedal be similarly synchronized. These conditions hold whether or not the rider is disabled. (NOTE: Racing enthusiasts apply force in both the downstroke and upstroke while the casual rider ordinarily does not.)

B. Switch Assembly Construction

The switch assembly is made by preparing a circuit board as shown in Figure 1 and Figure 2 and installing magnetic reed switches in pairs of holes described by radii of 1.3" and 2.0". Magnetic reed switches are deleted from positions of $0^\circ \pm 15^\circ$ and $180^\circ \pm 15^\circ$ to assure onset of stimulation and removal of stimulation at 15° past top-dead-center and bottom-dead-center respectively.

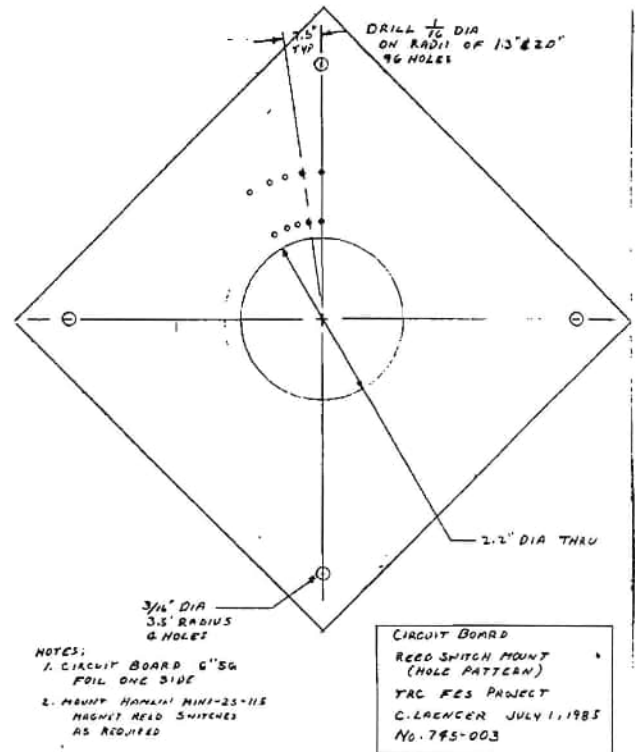


Figure 1

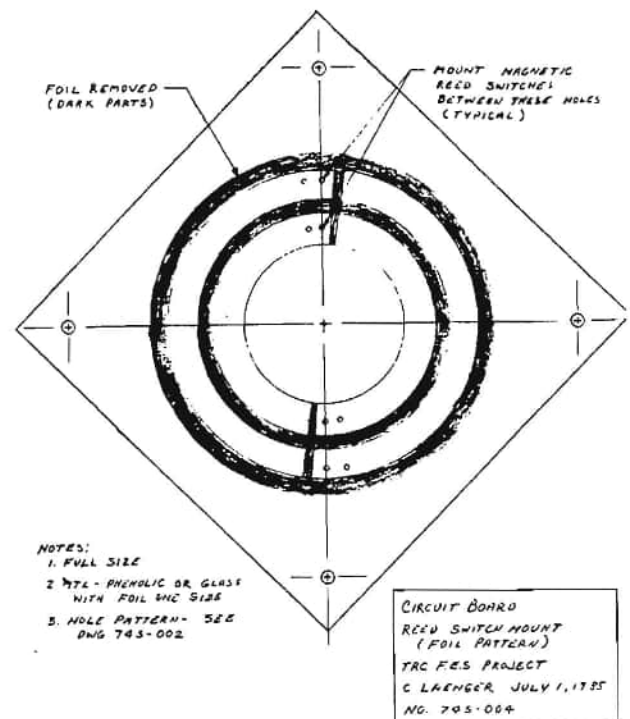


Figure 2

The activating permanent bar magnet is attached to the pedal arm so that its motion describes a circle whose radius is about 1.65". This places the bar magnet at the center of the magnetic reed switches where they are most sensitive.

Mechanical details of the switch mount are shown in Figure 3. A photograph of the assembly mounted on a bicycle is shown in Figure 4.

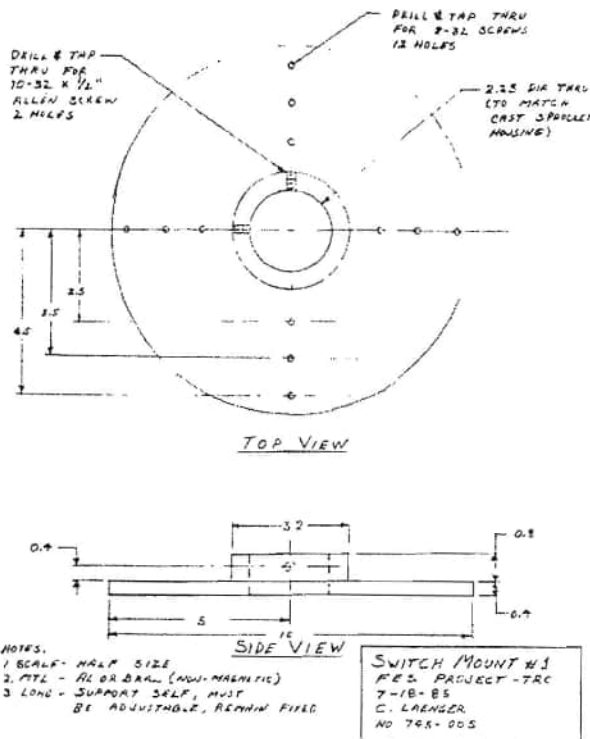


Figure 3

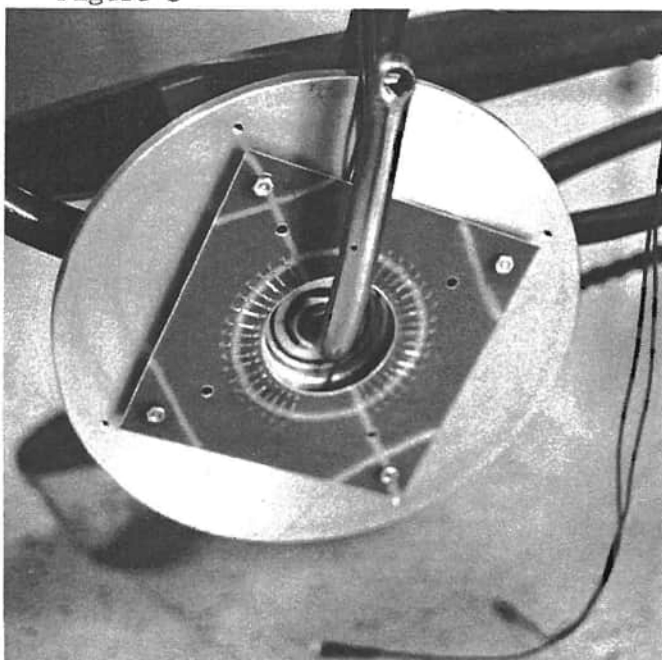


Figure 4. FESS Installed on exerciser bicycle.

C. System Circuit Diagram

The system circuit diagram is shown in Figure 5. The novel parts are designated "Sync Switch #1 and "Sync Switch #2. Sync Switch #1 and Sync Switch #2 are composed of twenty individual magnetic reed switches all wired in parallel. It is important to note that these switches can be mounted in various configurations if desired.

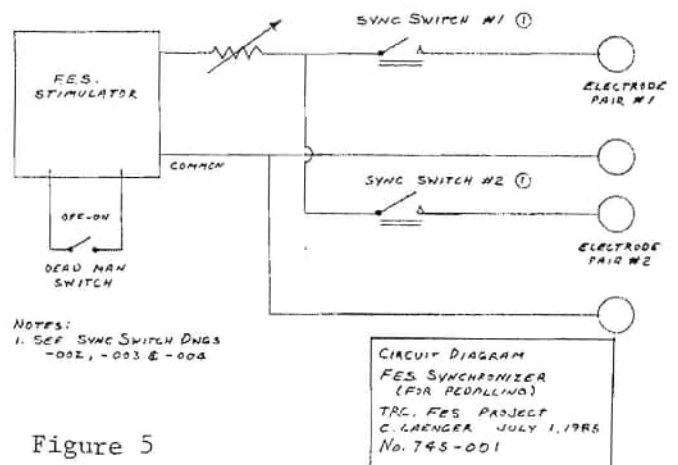


Figure 5

D. System Operation

Assume that the rider, whose legs are paralyzed, is in place and is ready to begin. When the pedals are at top-dead-center and bottom-dead-center, none of the magnetic reed switches are activated and no external electrical stimulation is applied. Therefore, no muscle contractions are present and no force occurs on the pedals. But when the pedals and pedal arms are rotated to point 15° past top-dead-center, the first magnetic reed switch (MRS #1) is closed and electrical stimulation is applied to the corresponding leg. As the pedal arm rotates, MRS #1 opens and MRS #2 comes under the influence of the magnetic field provided by the bar magnet and it closes. This action continues until the pedal arm reaches a point about 15° above bottom-dead-center. Then all MRS's are open and electrical stimulation is removed. The muscle relaxes and force to that pedal is removed.

Inertia drives the alternate pedal past top-dead-center and a similar sequence involving the other leg occurs. This results in smooth pedalling action.

E. Novel Features

Other functional electrical stimulation synchronizer systems use position sensors and computers to synchronize electrical stimulation. The FESSS system described herein, inherently provides accurate timing and is independent of pedal rotational velocity. That is, onset of stimulation always begins at 15° past top-dead-center.

This system is simple and inexpensive and it can easily be modified to facilitate "ramping" which is gradual increase or decrease of electrical stimulation. The system can also be expanded or modified to accommodate additional pairs of electrodes to stimulate additional muscle groups.

RESULTS

The FESSS was used on a stationary bicycle for eight months. See Figure G.



Figure G. Stationary FESSS Bicycle and Paraplegic Rider

Five paraplegic patients used this system in scheduled sessions three times per week. Approximately three hundred hours of use in therapy sessions and demonstrations were accumulated. Most "down-time" has been attributable to lead failure and breakage of the magnetic switches. Installation of a protective plastic cover eliminated this problem.

Another synchronizer switch device that operates on a light reflection-reception principle was fabricated by students at the University of Tulsa. This system will be compared with the magnetic switch system on functional and cost bases.

DISCUSSION

A reliable, flexible and inexpensive FES synchronizer switch was designed, fabricated and demonstrated. This system is applicable to both stationary and mobile muscle-powered, rotary devices. Additional engineering effort to minimize costs and improve convenience of installation is warranted.

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This work was supported by Sarkeys Foundation, Tulsa Royalties Company and Cities Service Foundation. Continuing effort is presently funded by the Franklin and Grace Bernsen Foundation.

The Mechanical Engineering Department at the University of Tulsa designed and fabricated various components and instrumentation devices for this project.

NEW DEVELOPMENTS IN NEUROMUSCULAR STIMULATION [1]

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INTRODUCTION

Neuromuscular stimulation is finding increased use in correcting motor dysfunction: [2,3,4] whenever the lower motor neuron is intact and a modicum of innervation is extant, function may be restored by stimulation. Transcutaneous stimulation may also be envisaged as a means for providing long-term, sustained and intensive exercise to preserve and correct the trophic state of muscles and to gradually provide a measure of neural control to the affected part.

Novel technological advances have made it possible to provide neuromuscular stimulation in a manner more effective than heretofore.

MICROPROCESSOR-CONTROLLED REGIMENS

A properly administered regimen of electrostimulation requires a careful selection of the stimulation parameters. The amplitude and the duration of the current pulse must be determined, as well as the frequency.

These parameters will naturally vary from patient to patient and it may also be advantageous to vary them in the course of a single patient's therapy.

Stimulation, therefore, is preferably done by means of a portable device worn by the patient to allow mobility and for convenience, controlled by means of microprocessors and digital techniques.

Figure 1 illustrates a typical clinical device for the clinicians's office. It allows the clinician to concentrate on the patient while selecting the parameters of the two output channels and easily controlling the timing and relationship between them. For example, a very gradually increasing succession of pulses over a period of many seconds, leading to a smooth contraction of a given muscle, may be followed by a swift contraction of the antagonist muscle applied through the second channel. This routine (or any other) will then be stored in the device's memory and repeated indefinitely. Furthermore, the routine may be transferred to the patient's personal unit for continuous use away from the clinic (See figure 2). The routine can also be stored (See figure 3) in a memory module, for prompt retrieval at a later time.

Since the number of variables that can be stored in the device is limited only by the size of the program memory, the use of ever larger memories will allow programming progressive routines that may change automatically over time, as the condition of the patient requires it, thus providing progressive therapy without direct intervention by the clinician.

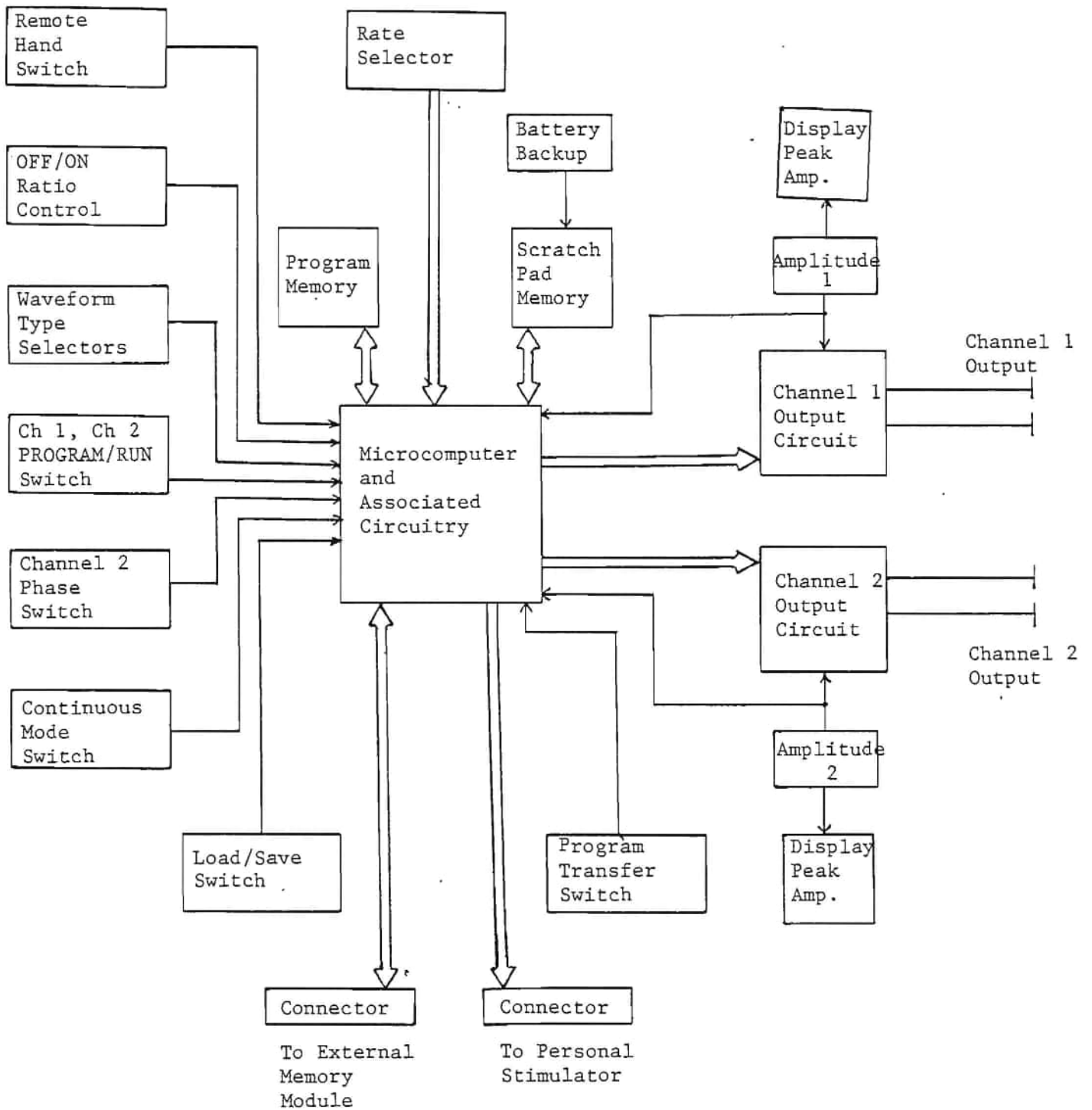


Fig 1. CLINICAL DEVICE

Fig 2. PERSONAL STIMULATOR

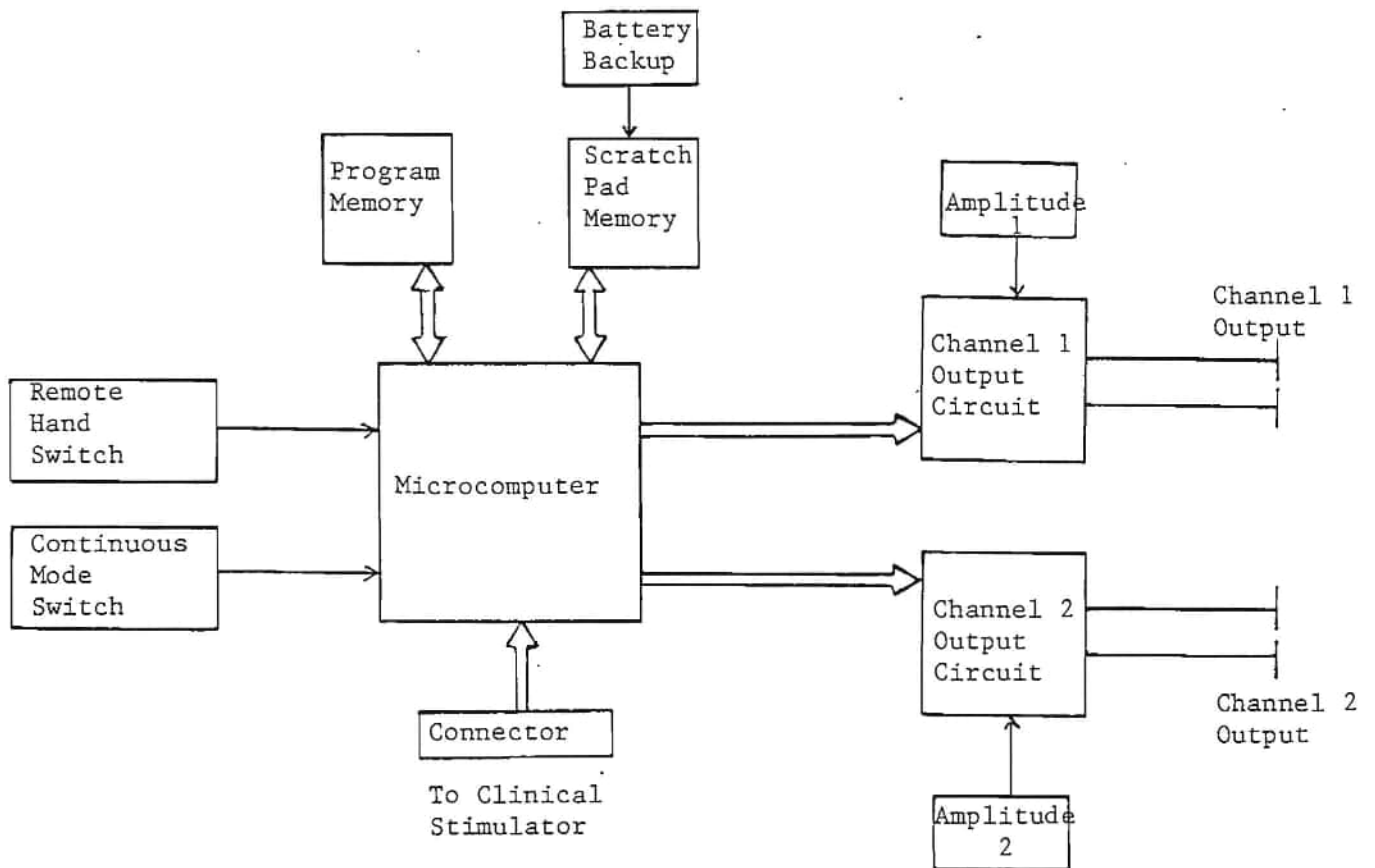
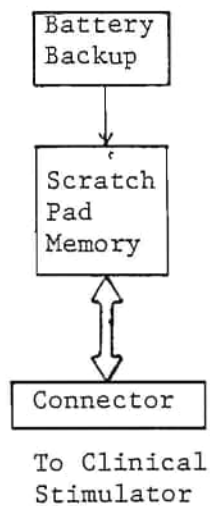


Fig 3. MEMORY MODULE



Another possibility of microprocessor-controlled devices is the pursuit of stimulation regimens that cause "physiologically correct" muscular contractions. Results of animal experiments [5,6] point to the possibility of applying a blocking stimulus followed and superimposed by an activating stimulus. The result is a contraction that is modeled closely after a voluntary contraction and also involves a reduced exchange of metabolites. Thus, this contraction is less conducive to fatigue. The result of such routines is the advantage of achieving therapeutic regimens of sustained and intensive contractions.

CLOSED-LOOP STIMULATION REGIMENS

Clinical applications of neuromuscular stimulation, be they function augmentative or therapeutic have one characteristic goal in common: the reversal of extremity paresis. Pure weakness without accompanying postural dysfunction is rare in cases of upper motor neuron disorder. Imbalances of muscle tone accompany the weakness, and those imbalances in tone are identified in a neurologic sense as conditions of rigidity or spasticity.

In normal function, the local neural control loops contribute a check and balance to the volitional, cortically driven fine extremity movements. [7] Position and force are tonically modulated to resist variances in the intrinsic and extrinsic loads of the system. In physiologic terms, these control loops can be subdivided into transducers of length, velocity and tension (muscle spindle and Golgi tendon organs), afferent transmission links (Ia, IIb fibers), feedback gain set point controllers (γ neurons), and controllers of motor tension (α neurons). In more abstract analytical terms, the extremity can be likened to a position servo loop with position and tension sensors, motor elements and some local data processing. Central neural elements (cortex, cerebellum) provide the adjustment for the gain of local control loops, specifically the ratio of loop-gain between agonist and antagonist muscles (See figure 4). Postural dysfunction can be interpreted as gain imbalances of the local control loops, imposed by a disordered central set point input. Thus, on first inspection, spasticity is the unilateral enhancement of the stretch reflex resulting in the directional loss of joint elasticity, clinically manifest by the clasp-knife resistance. The hypertonia of Parkinsonian type rigidity is a bilateral enhancement of stretch reflexes, causing a position-independent loss of joint elasticity, clinically described as a "lead-pipe" resistance. [8]

For controlled, complex movements about a joint, muscle stimulation must be viewed in superposition to the existing local motor control loops. The relative simplicity of driving a muscle with electrical stimulation under conditions of central nervous system dysfunction and local loop imbalance rapidly becomes quite an intricate undertaking. In order to meet the changes in the local control environment, external control loops must be instituted in an analogous manner to those constructed of neurons and muscle. Stable and practical input signals relating extremity force and position must be secured to serve as currency for the external feedback loops. Position information may be obtained from an external potentiometer reference. Force information may be harvested from processed surface electromyographic signals. From these informational materials, a servo regulated force-length ratio may be constructed analogous to the stretch reflex model of Nichols and Houk. [9] The gain of these external systems must then be matched to the gain of the internal loops and the sign of the input inverted. Thus, the dysfunctional fraction of a positive feedback

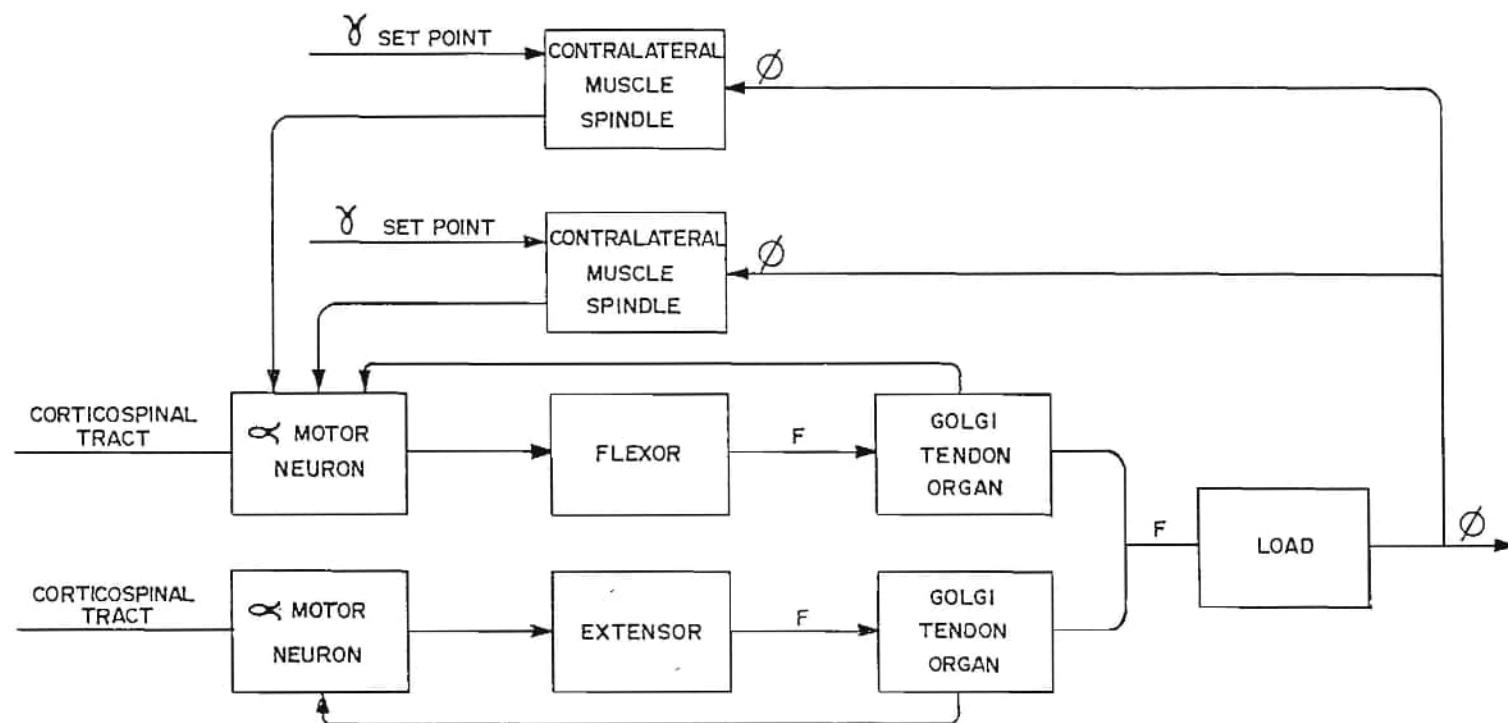


FIGURE 4
LOCAL REFLEX ENVIRONMENT DESCRIBED AS A FORCE-DISPLACEMENT REGULATED SERVO

loop is paired with an external negative feedback loop of equal gain. With local control dysfunction thus countered, a volitional signal may then control desired functional movement in a larger, cortically closed loop.

Tailoring external control loops to an environment of dysfunctional local control requires attention to quantitative parameters. Such methodology is described by servo-analytic theory. [10] It is necessary to transpose the traditional neuro-anatomical functional description to one utilizing force and position transfer functions and indices of loop gain ratios. Once the mechanism of the local control loops is specified using externally accessible parameters, the process of creating augmentative and corrective servo loops external to the nervous system becomes possible.

CONCLUSION

The advent of microprocessor-controlled stimulators, either used in the traditional open-loop manner (where the clinicians's observation provides the necessary parameter settings and progressive changes) or applied in a closed-loop fashion as outlined above, signals the advent of a new era in the therapy of motor dysfunction. Rather than being limited by the versatility of digital techniques, the implementation of such devices requires the careful design of human interfaces that must make their operation effective, safe and reliable.

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DESIGN OF A CYCLING DEVICE FOR
USE WITH FNS

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The purpose of this study was to develop a cycling device that, with functional electrical stimulation (FNS), provided both exercise and locomotion for paraplegics. The device, which we have called the Paracycle, has four wheels, an adjustable seat, and foot pedals. An onboard electric motor (with electronic speed control) passively rotates the legs so as to reduce joint stiffness. The motor can also assist in accelerating the vehicle from rest, thereby reducing the force output that the occupant needs to provide. Measurements of motor current are made to quantify pedal force, and reduce muscle stimulation if necessary. A goniometer on the cranks provides position feedback to the stimulator. Preliminary trials are being conducted on 10 paraplegic subjects to investigate musculoskeletal, psychological and general fitness changes during stationary exercise. Initial results seem encouraging.

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PROLONGED EPIDURAL STIMULATION OF A SHEEP'S
CEREBELLUM WITH PLATINUM ELECTRODES

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SUMMARY

Results of an "in vivo" experiment which was performed with the main goal of studying the effect of prolonged monophasic electrical stimulation of a sheep's cerebellum on the surface of the bipolar stimulating platinum electrodes and of neural damage, after 20 months application of daily stimulation. Microscopic observations of anodic and cathodic surfaces by means of scanning electron microscopy (SEM) and histological evaluations of cerebellum tissue by means of light microscopy are described. Various anomalies on the surface of the electrodes which can be attributed to electrochemical reactions were identified. With electrical stimulation at the applied charge density and of monophasic waveform, histologically demonstrable neural damage was observed.

MATERIAL AND METHODS

The implant shown in Fig.1 was a 3.2 mm thick epoxy-resin disc with a diameter of 12 mm. The electrodes were made from platinum wire (99.99 per cent purity), diameter 0.7 mm. The unpolished anode and cathode were of equal shape and had a geometric area of 28.5 mm². An external

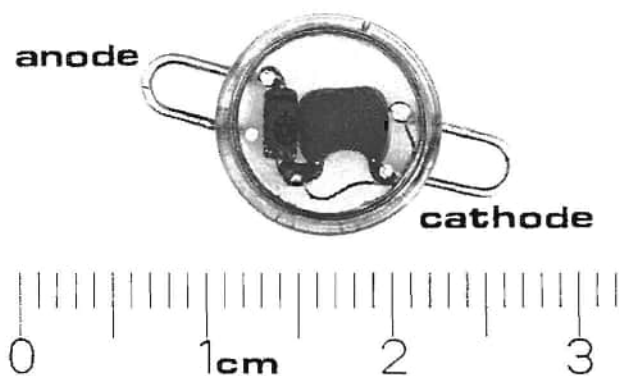


Fig.1

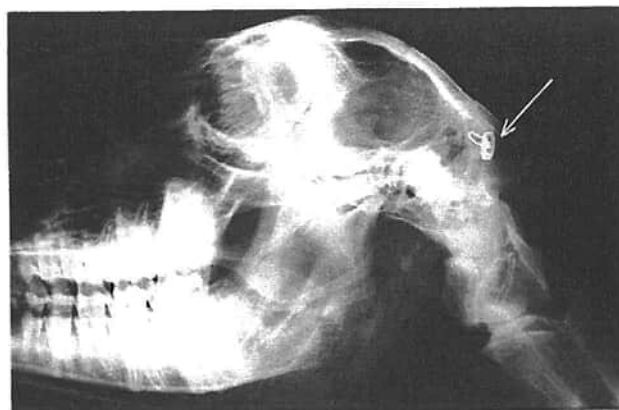


Fig.2

stimulator and antenna generate and transmit a radio-frequency signal through the skin to the surgically implanted passive receiver. Stimulation was bipolar monophasic with a pulse duration of 0.6 ms, frequency of 25 Hz and a charge density of $0.283 \mu\text{Cb}/\text{mm}^2$ (geometric) and approximately of $0.14 \mu\text{Cb}/\text{mm}^2$ (real) in accordance with the work of Brummer (3). The electrodes were implanted in the space between the dura and the skull bone above a sheep's cerebellum (Fig.2) for 18 months, during which we estimate they actually in use for a total of about 3200 hours (one stimulating session per day, each of 8 hours).

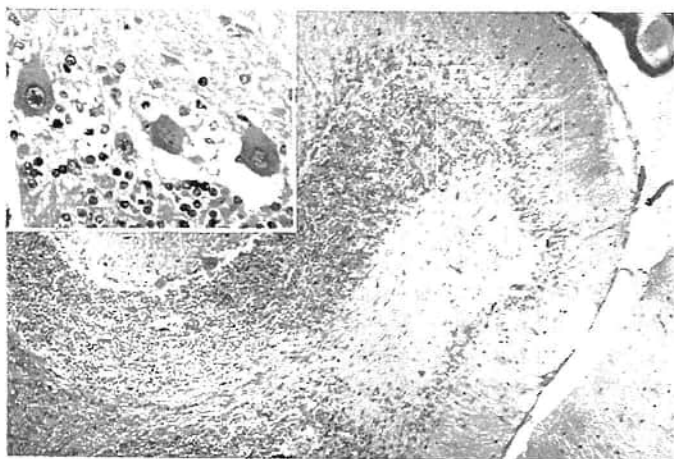


Fig.3

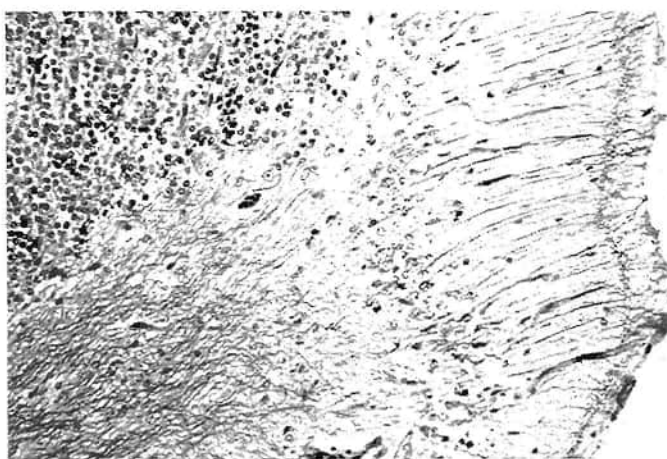


Fig.4

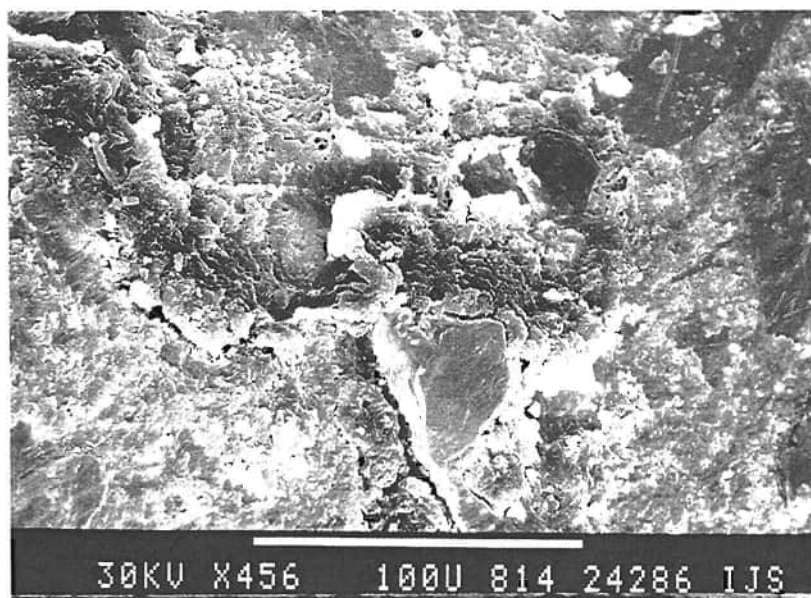


Fig.5

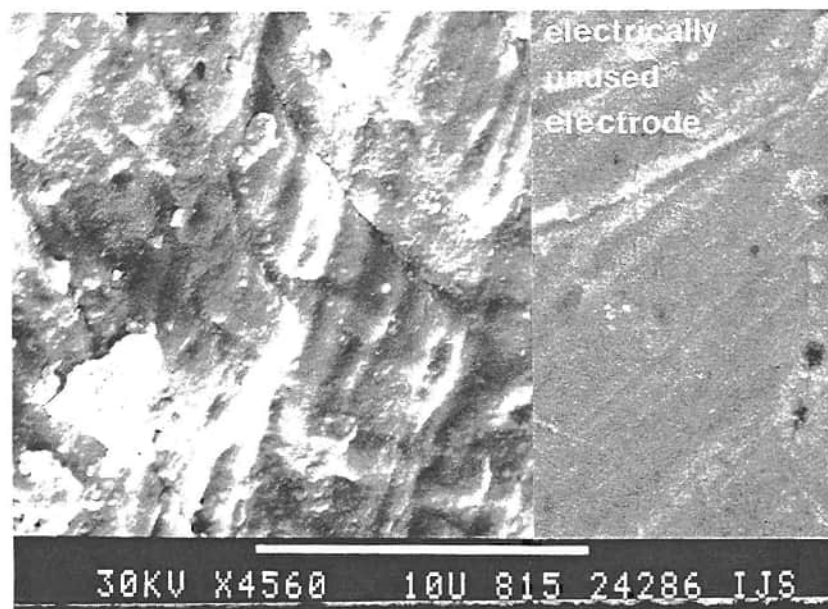


Fig.6

RESULTS

By visual examination, the only noticeable observation on the surface of the cerebellum was compression by the implant body. There was no consistent difference in the pattern of neural damage in the vicinity of anode or cathode. Control tissue taken from two different regions appeared normal. The most notable changes in the stimulated tissue (when compared to control tissue) were the disappearance of Purkinje cells in some locations (Fig.3) with atrophy of the granular layer and gliosis of molecular and granular layers of the cerebellum (Fig.4). A SEM of the cathode is shown in Fig.5. The surface of the anomaly is crystalline and bright in appearance, indicating appreciable metal removal. Such anomalies were observed in different regions of the surface of the cathode. Fig.6 shows part of the corresponding anode where appreciable erosion of anode can be seen. In comparison, the surface of an identical but new, electrically unused electrode is shown at the same magnification on the right side of the same picture.

DISCUSSION

Changes on the surface of platinum electrodes removed after 18 months application of daily stimulation as observed by SEM can be attributed to corrosion, passivation etc., as a consequence of irreversible electrochemical reactions due to monophasic stimulation pulses (1,2,3, 4). Direct coupled, monophasic pulses induced a large increase in pH at the tissue surface near the negative electrode and a decrease in pH near the positive electrode (5, 6). Specifically this study indicates that neural damage is correlated with charge density and with the shape of stimulation pulses (7, 8, 9). These findings have implications both for the

design of electrodes intended for stimulation of the central nervous system and for the shape of the actual stimulus parameters.

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EFFECTS OF ELECTRICAL NERVE STIMULATION ON SKELETAL MUSCLE IN MYELOTOMIZED RABBITS

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SUMMARY

The effects of 6-weeks continuous electrical stimulation of sciatic nerve at 10 Hz on fast (EDL) and slow (soleus) muscles of myelotomized rabbits were studied using morphological methods. Electrotherapy was found to antagonize the reduction of fiber diameters induced by myelotomy in soleus muscle. In EDL muscle it increased the type 1 fiber percentage and caused reduction of type 2b fiber diameter. Moreover the stimulation caused structural alterations of muscle fibers, mainly in EDL muscle and increased the number of central mitochondria.

MATERIAL AND METHODS

Four adult female New Zealand rabbits received a transverse complete myelotomy on middle dorsal spinal cord segment (T2-T3). Two normal rabbits were used as control.

Electrical stimulation

The electrodes of an electronic stimulator were positioned near the left sciatic nerve. The right limb is used as unstimulated control. The stimulation begins 1 day after surgery, with a continuously pulsating current field (10 Hz, 0.25 ms pulses). After a 40 days period of stimulation the rabbits were sacrificed.

Morphology and morphometry

Right unstimulated and left stimulated soleus and extensor digitorum longus (EDL) muscles were processed for histology, enzyme histochemistry (mATPase pH 9.6, 4.5 and 4.3; DPNH-TR) and electron microscopy. The muscle fibers were studied using an IBAS Zeiss imaging analyzer. Fiber type classification was according to Brooke et al (1) for rabbit skeletal muscle using reactions for ATP-ase and DPNH-TR activities. The diameters of type 1 (slow oxidative), type 2a (fast oxidative) and 2b (fast glycolytic) fibers were measured on micrographs at the final magnification of 400 X. The percentage of fiber types and of central mitochondria for fiber area (μ^2) was calculated. The results are expressed as means $\pm$ SD and the variance analysis F-test was used for statistical evaluation between unstimulated and contralateral stimulated muscles (2).

We thank Mr. Vittorio Necchi for technical assistance.

RESULTS

The consequences of myelotomy on skeletal muscle were generalised reduction of fiber diameters, with changes of degeneration of single fibers. Such alterations in fiber type distribution may be a consequence of muscle immobilisation.

The effects of electrical stimulation on muscle of myelotomized rabbits, in comparison with unstimulated muscle following myelotomy are summarized in Table 1.

Table 1. Fiber types. Mean $\pm$ SD from normal, myelotomized-unstimulated and myelotomized-stimulated soleus and EDL.

	Normal rabbits		Myelotomized rabbits			
	soleus	EDL	soleus unstimulated	EDL unstimulated	soleus stimulated	EDL stimulated
Type distribution (%)						
Type 1	70 $\pm$ 9	12 $\pm$ 8	58 $\pm$ 9	20 $\pm$ 8	66 $\pm$ 11	$^{\circ}$ 40 $\pm$ 6
2a	30 $\pm$ 6	46 $\pm$ 6	42 $\pm$ 7	62 $\pm$ 8	34 $\pm$ 8	46 $\pm$ 10
2b		42 $\pm$ 6		18 $\pm$ 8		14 $\pm$ 8
Mean diameter (μ m)						
Type 1	66 $\pm$ 12	50 $\pm$ 6	44 $\pm$ 7	38 $\pm$ 8	$^{\circ}$ 54 $\pm$ 8	42 $\pm$ 12
2a	63 $\pm$ 10	56 $\pm$ 8	46 $\pm$ 8	44 $\pm$ 6	$^{\circ}$ 58 $\pm$ 10	36 $\pm$ 10
2b		60 $\pm$ 4		50 $\pm$ 10		$^{\circ}$ 34 $\pm$ 8

Ultrastructural studies revealed in both soleus and EDL muscle a great deal of alterations, as myofibrillar disorganisation and fragmentation; in stimulated muscles these alterations were increased and were associated to mitochondrial changes. The percentage of central mitochondria for fiber area was significantly increased in the stimulated muscles (Table 2).

Table 2. % of central mitochondria for fiber area (μ^2) in myelotomized rabbits $^{\circ}$ P<0.001

Right unstimulated leg		Left stimulated leg	
Soleus	EDL	Soleus	EDL
3.6 $\pm$ 0.6	1.8 $\pm$ 0.4	$^{\circ}$ 6.8 $\pm$ 1.0	$^{\circ}$ 2.8 $\pm$ 0.4

DISCUSSION

In the present study the 6-weeks continuous electrical stimulation of sciatic nerve of myelotomized rabbits had such an effect on studied muscles. There was significant preser=

vation of type 2 fibers in the slow muscle; by contrast there was a reduction of type 2b fiber diameters in the fast muscle. Statistical evaluation of the fiber type distribution showed increase of type 1 slow-twitch fibers in EDL muscle, in comparison with contralateral unstimulated one. This pattern may be considered the result of a transformation of fast into slow muscle fibers, as described in normal rabbits by chronic electrical stimulation of the motor nerve (3-8-9).

A positive response to electrical stimulation was the increase in mitochondrial volume occurring in both studied muscles. This change occurred also in muscle of normal stimulated animals (3-9) and it is considered the morphological counterpart to the increase in the activity of enzyme oxidative activities described in stimulated muscles (5). In the present experimental conditions, the muscles of the stimulated side showed fiber degeneration and changes of mitochondria, particularly in EDL muscle. These alterations indicate that fast muscle of some animals as the rabbit and the rat may be unable to sustain continuous low frequency electrical stimulation without some fiber degeneration (10).

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THE INFLUENCE OF A PROTEINASE INHIBITOR ON THE ELECTROCHEMICAL ISCHEMIC REACTION OF
AN ISOLATED NEUROSTIMULATED SKELETAL MUSCLE

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SUMMARY

Skeletal muscle is one of the most sensitive tissues in regards to its ischemic tolerancy. NMR-studies concerning the critical phase of ischemia have shown that a critical borderline to irreversible cellular damage in skeletal muscle is reacted far earlier than previously postulated (1). The limited ischemic tolerancy of skeletal muscle is approximately 2.5 hours. Such a short tolerance period may be the cause of the failure of a performed operation, i. e. as in reconstructive plastic surgery (2). Additionally, the tourniquet-induced stop of local perfusion, the ischemic phase of an amputation stump (carrying the to-be-transplanted muscle), as well as the free microvascular muscle transfer used for the purpose of the reconstruction are all extremely sensible in this phase. It is therefore of importance to reduce those 15-20% of the cases where an insufficiency in the microvascular anastomosis or muscle necrosis (following an hemorrhagic or ischemic infarction) occurs. The above mentioned mechanisms are responsible for a cascade enzyme reaction, for the eventual release of myoglobin which is systemically dangerous due to its nephrotoxicity (3).

Since it is known that anastomosis insufficiency and muscle necrosis can be caused by postoperative edema, it is of major interest to learn more about causative mechanisms. In the postoperative reperfusion phase the concentration of free oxygen radicals increases significantly indicating inflammatory events concomitant with edema (4). The series of events is initiated by leucocyte proteases, i. e. by Kathepsin G (6).

Based on these results in order to avoid or at least minimize, i. e. inflammation, edema, or trans- or replantation of muscle tissue, it appears plausible to assume a reduction in protease release through a proteinase inhibitor such as Trasylol (R)). The inhibitory action of the protease Kathepsin G is based on α -1-Antichymotrypsin induction. The α -1-Antichymotrypsin inactivates α -1-Chymotrypsin resulting in the prevention of the activity of a muscle damaging enzyme. For this reason the research animals received postischemically and systemically applied Trasylol (R).

MATERIAL AND METHODS

Studies were performed on either the gracilis muscle or the latissimus dorsi muscle of 8 mongrel dogs (18 $\pm$ 3 kg bodyweight). One group received preischemically a dosage of 1 mio. i. u. of Trasylol (R) per infusion. Once a steady state of the electrochemical parameters was reached, the measurements were taken under ischemic conditions during indirect electrical neurostimulation (parameters: 0.1ms stimulation duration, 0.5Hz, 10V). A control group received stimulation without proteinase inhibitors.

During the following reperfusion phase, the skeletal muscle was perfused with the arterial blood of the corresponding animal via its own nutritive vessels. The electrochemical parameters were followed by direct measurement of the pH and the redox potential (pH: microelectrode type 83334, Ingold Company, Frankfurt/Main, referency electrode, filled with 20% NaCl, type 126387, Ingold Company, Frankfurt/Main, pH-meter type 742, Knick Company, Berlin; redox potential: electrode

type PT 4804 M6, Ingold Company, Frankfurt/Main). A two-channel anapulse stimulator (type 302-T, WPI-Instruments, Hamden, Connecticut, USA) with a stimulation modulator, trigger (type T 912, Tektronix Company) and a 10MHz oscilloscope were used for the efferent-motor electrostimulation of the skeletal muscle. The electrode resistance of the nerve was visible on the oscilloscope as stimulation voltage and was kept constant by variation of the degree of stimulation strength.

RESULTS

It is of interest to note that during the efferent stimulation, the electrochemical parameters such as pH and redox potential decreased unexpectedly little during the early ischemic phase when compared to the non-stimulated ischemic skeletal muscle (5). Further, the standardized isolated skeletal muscle (latissimus dorsi muscle or gracilis muscle) in complete ischemia reached exhaustion after a neurostimulation with 0.5Hz for an average of 75 minutes.

After preischemic application of a proteinase inhibitor (Trasylol (R)), two major aspects were observed: (1) an increase in the stimulation capable phase of ischemia from 20 to 40 minutes, and (2) the electrochemical parameters decreased at a much less accelerated rate with significantly flatter running slopes. pH-values reached an average of 6.8 instead of 6.2 (table 2). The redox potential, relating the mitochondrial buffer balance, was limited to an average of -100mV (table 1). When no pharmacon (for example a proteinase inhibitor) was administered, the values ranged between -120 to -150mV.

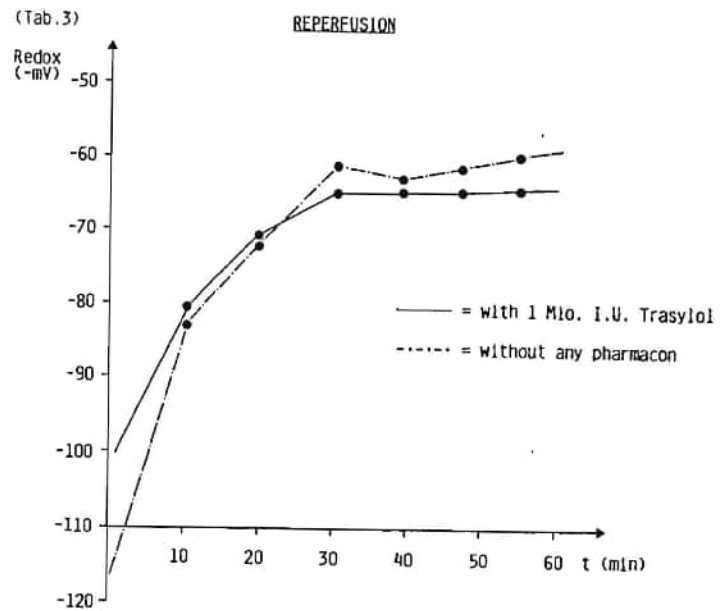
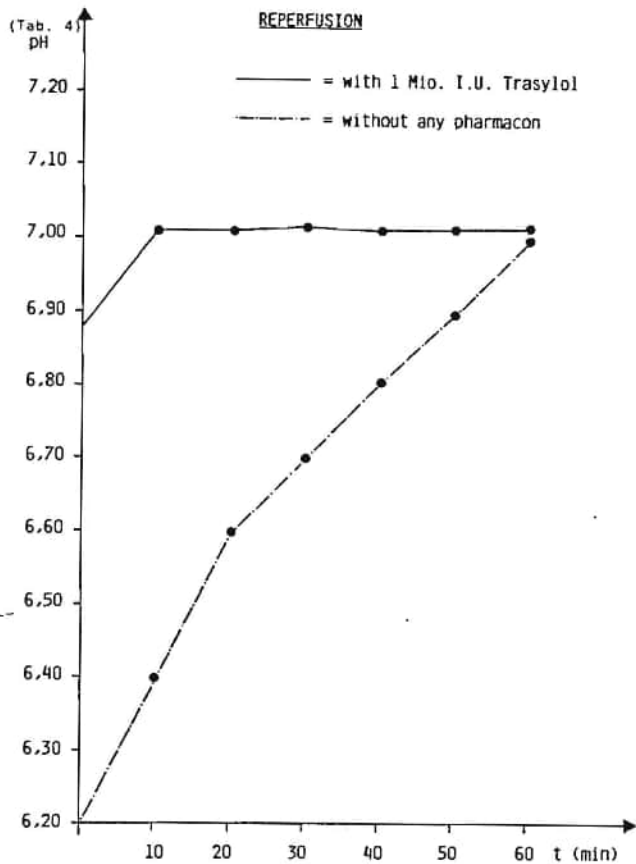
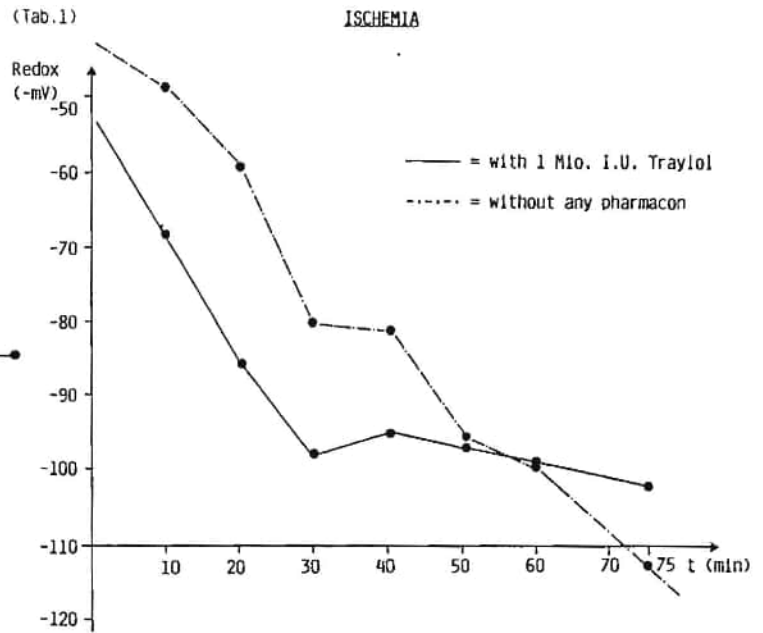
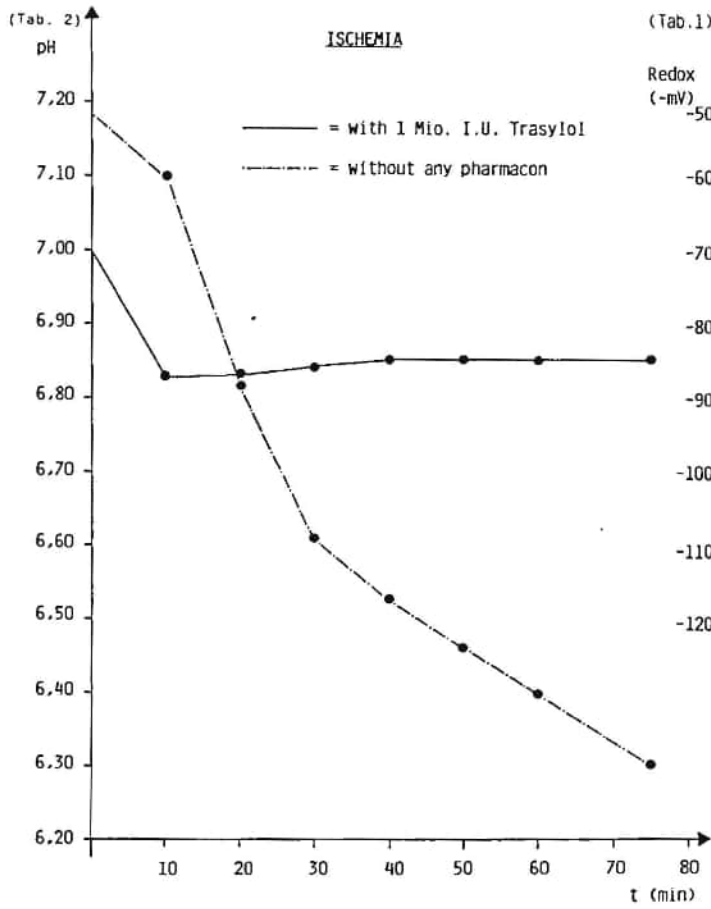
The prolongation of ischemia in any of the groups did not lead to any further measurable electrochemical changes.

During the reperfusion phase the pH and the redox potential increased spontaneously. Already after 15 minutes the pH had reached its control niveau, with even a small overshoot (table 4). The redox potential, however, reached only -65mV and not the original full control level (table 3).

DISCUSSION

The mode of operation is still so far unexplainable. One postulation is that the proteinase inhibitors provide protection for the skeletal muscle in ischemia. It has been found that the enzyme activities of leucocyte collagenase are regulated by the cellular redox potential (6). It is possible that Trasylol (R) reduces the mitochondrial activity during ischemia, which would support the fact that the redox potential does not further increase in ischemia (as if being evidence of a cell protecting action).

Another possible consideration is that through minimization of the leucocyte enzymatic activities, an additional muscle protecting effect in ischemia occurs. Much fewer free oxygen radicals are released when the enzyme activity is inhibited. The free oxygen radicals are responsible for the inflammatory edematous effects in connective tissue and for increased fluctuations in the electrochemical parameters. An interruption of this vicious circle at the point of origin through the use of proteinase inhibitors would represent interesting therapeutic progress in connective tissue surgery.



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Abstract

Title: ELECTROPHYSIOLOGIC DIAGNOSTICS
AND THERAPY OF PERIPHERAL FACIAL
Name: PARESIS
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In the first week of peripheral facial paresis, EMG testing is applied, and from amplitude ratio, prognosis, important for rehabilitation programming, is expressed.

In all cases except in complete block, EMG biofeedback training with EMG control for 3 weeks (denervation and convalescence degree) is applied.

Electrostimulation is applied only in case of activity insufficiency for EMG biofeedback, and in case of previous synkinesis occurrence obligatory interrupted, when under audiovisual control, relaxation exercise of undamaged musculature, because of aesthetic effect, are applied.

According to our experience, functional recovery is more significant, if the possibility of EMG biofeedback training application is immediate.

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REHABILITATION TRAINING AND TEST EQUIPMENT FOR FES IN PARAPLEGICS

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SUMMARY

Testing and training paraplegic patients using functional electrical stimulation can be supported by special equipment. We realized a sit-to-stance exerciser for gradually increasing the leg load; a bicycle ergometer for endurance and coordination training; an arm ergometer for testing the cardiopulmonary condition.

INTRODUCTION

Two years ago the Roessingh Rehabilitation Center and the Twente University of Technology joined in a research project on the restoration of walking in paraplegics. One of the findings was that testing and active training of paralyzed muscles using functional electrical stimulation (FES) needs an approach which sometimes differs from conventional rehabilitation therapy. Therefore it is important that equipment and procedures are developed that enable physiotherapists to test and train patients with paralysis, in order to achieve functional rehabilitation. Currently we are developing and evaluating the clinical use of exercise equipment for the testing and physical conditioning of spinal cord injured patients. Part of these developments are the protocols describing the optimal use for the individual patient. The accent of the research is towards the restoration of walking.

The training for strength of leg muscles, needed for the sit-to-stance transfer is performed by specially designed equipment which is usable for a patient in a supine position. So it can already be used when the patient is still in bed.

The training for muscle endurance is performed on a bicycle ergometer, in which the stimulation patterns are synchronized with the position of the pedals.

Testing of the cardiopulmonary condition of the patient is performed using an arm ergometer. The exercise may be combined with leg exercise induced by electrical stimulation.

MATERIALS AND METHODS

Sit-to-stance exerciser

The sit-to-stance transfer is the first step in the restoration of walking in paraplegics. It is an "all or nothing" movement and cannot be executed partially. It is therefore important for patients to train this exercise gradually without at once the load of their full body weight. We developed equipment by which the sit-to-stance transfer can be trained while the legs exercise against a resistance which is adjustable from zero load up to full body weight. The patient is in supine position on a bench or bed. In the start position the feet rest against a foot board while the hip and knees are in flexion. The angles between the back and the legs is according to those of people sitting on a chair and leaning forward with their trunk in order to put their center of gravity above their feet.

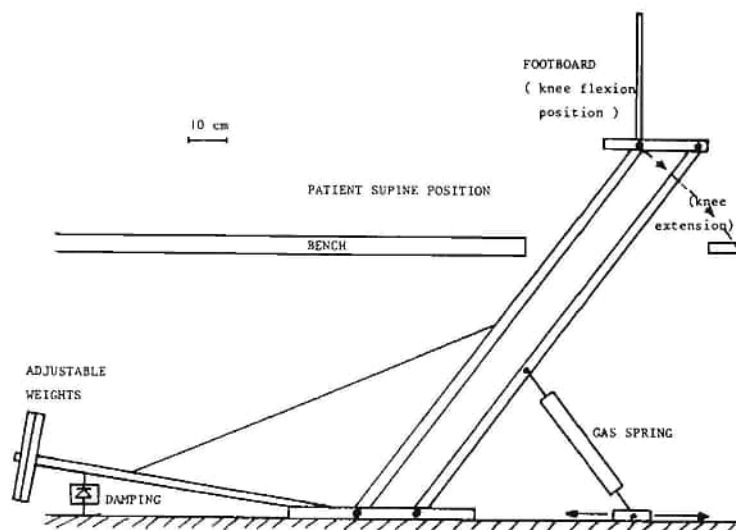


Figure 1. Sit-to-stance exerciser for training for strength of the muscles involved in the sit-to-stance transfer. The supine subject places his feet against the footboard with hip and knees in flexion. When the legs are stretched an adjustable reaction force must be met. The equipment is developed for the training of standing-up induced by electrical stimulation from low up to full body weight loads.

During stretching of the legs the feet follow a trajectory which can be described as a part of a circle (radius = 1.20 m), and which is more or less similar as during standing up. The footboard is kept in vertical position using a parallelogram construction. Backstrike of the footboard is prevented with a damper which is active only in the backstrike direction. The resistance force is realized by combination of gas-springs and a momentum adjustable with weights. See figure 1.

The resistance force consists of two components:

- an almost constant force which represents the body mass. This force is adjustable from a few kg up to 80 kg.
- a varying force needed to compensate for the increasing force due to the weight of the legs while stretching them.

Bicycle ergometer

Leg muscle endurance can be trained on a bicycle ergometer. The energetic load of the ergometer is adjustable. For FES it is important that the stimulation patterns are well synchronized with the rotation angle of the pedals. For training coordination, patients can be asked to start the individual muscle contractions with hand switches.

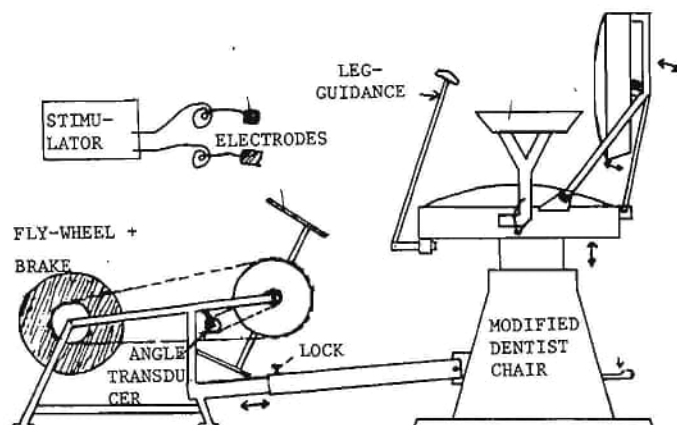


Figure 2. Bicycle ergometer with a crank-angle transducer. It can be used for training leg muscle endurance when the electrical stimulation patterns are closed loop controlled using the crank-angle, the angle velocity and acceleration as feedback parameters. It can be used for coordination training when the stimulation sequences are controlled manually by the cycling subject.

The bicycle ergometer, the stimulator and the closed loop control of the stimulation timing and intensity is described by Mulder et al. 1986.

Arm ergometer

The cardiopulmonary condition can be estimated from the heart rate response to graded exercise testing. We developed an arm ergometer (see figure 3) for leg amputees in which the seated patient turns two handles in the same phase against an adjustable torque. The electrocardiogram can be analyzed on-line using a special developed system (Van Alsté, 1985). Graded exercise on this arm ergometer can be executed by spinal cord injured patients, secured to the chair with seat belts.

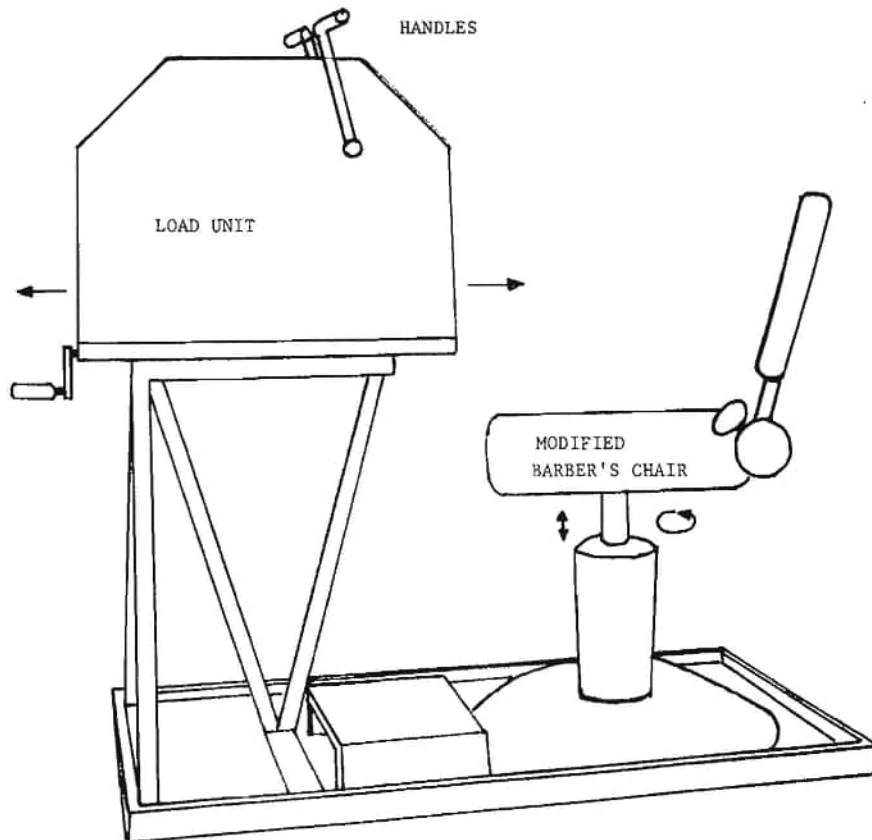


Figure 3. The arm ergometer. The ergometer is easily accessible for spinal cord injured patients. The chair with a seated patient can rotate and its height is adjustable. The external load is in a wide range independent of the rotational speed.

RESULTS

The application to spinal cord injured patients of the equipment is still under development. The sit-to-stance exerciser is improved for the development of suitable control strategies using transcutaneous stimulation of the upper leg muscles.

Preliminary results of the bicycle ergometer are described by Mulder et al. 1986. Preliminary results of the arm ergometer concern the heart rate response of male spinal cord injured patient. The heart rate was recorded during FES induced exercise with one leg, during arm ergometry and during both arm ergometry and leg exercise. The results are presented in figure 4. Accordingly to the measurements of Glaser, 1985, we did not see an increase in heart rate resulting from the work of the paralyzed leg which was induced by electrostimulation. It was not verified if the cardiac output was maybe increased by an increasing stroke volume.

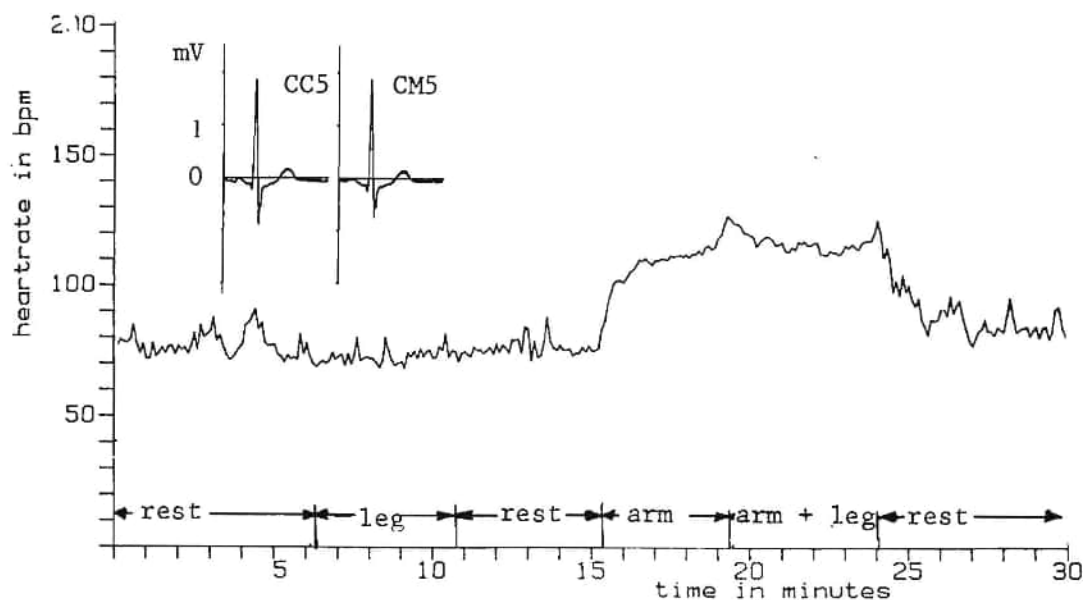


Figure 4. The heart rate response of a spinal cord injured patient to FES induced leg exercise and arm exercise using the arm ergometer shown in figure 3.

The protocol used was:

- a) rest during 6 min.,
- b) 5 min. leg exercise with 4 kg extra mass attached to the foot.
The leg is fully extended 10 times per min.,
- c) 5 min. rest,
- d) arm exercise with a load of 50 W,
- e) continuing the arm exercise of d) with additional leg exercise as specified in b),
- f) rest.

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