Proceedings of the Eighth International Symposium on ECHE, 1984, Dubrovnik

K.Fr. Eichhorn, W. Schubert
Lehrstuhl fuer Elektrische Energieversorgung
Direktor: o.Prof. Dr.-Ing. G. Hosemann

E. David
Institut fuer Physiologie und Biokybernetik
Direktor: o.Prof. Dr. med. W. Keidel

Universitaet Erlangen-Nuernberg

SPECIAL PROBLEMS IN THE STIMULATION OF DENERVATED MUSCLES

Abstract

In the case of cerebral paralyses electrical stimulation will not only maintain the muscles but will also enable a functional use. In flaccid paralyses, however, the conventional therapy with exponential currents produces rather unsatisfactory results. Only when applying bidirectional currents, we were successful in producing tetanic contractions all by avoiding fatigue. At present some 30 children suffering from different diseases, such as spina bifida, Erb's palsy or a tumor of the cord, perform a daily domiciliary treatment with especially constructed home stimulators.
Measurements prove distinct improvements of blood circulation, phosphoric metabolism and of the condition of the affected extremities.
Daily treatment requires either implanted stimulators or special home devices. The different aspects will be discussed with regard to the required current densities, by attributing considerable importance to the dimensioning of electrodes and to the degree of inhomogeneity in the current fields.
A home stimulator must certainly exclude any possible dangers, ranging from skin damages up to heart fibrillation. Handling must be easy for laymen without restricting the range of therapeutic application.

Contents

K.Fr. Eichhorn, W. Schubert, E. David
Universität Erlangen - Nürnberg, FRG

SPECIAL PROBLEMS IN THE STIMULATION OF DENERVATED MUSCLES

1. Electro-therapeutic treatment of flaccid paralyses

If a muscle is denervated, the loss of function is accompanied by secondary damages, such as progressing atrophy, insufficient blood circulation, bad condition of skin and a restricted growth of the affected bones in children. The electrotherapeutic treatment is disputed in literature and among therapists /1/ and is thus exclusively limited to such cases where a re-innervation is expected.

The conventional therapy with triangular or exponential currents, according to figure 1 a, can only retard the degeneration of the affected muscles but cannot prevent it. The slow increase of the pulses enables, at least within certain limits, a selective stimulation of the affected muscles, as the other muscles and nerves evade the stimulating effect by means of accomodation. This advantage is opposed by the considerable disadvantage of muscle fatigue rising after few twitches only, in spite of the pause duration indicated in fig. 1 a /2/. Reasons for this are to be seen in the unphysiologically long pulse durations which certainly shift the ionic environment in the membrane area. The muscle membranes are no more capable to spread action potentials,which usually start the local emission of calcium ions then releasing the sliding together of the actin-myosin-filiaments. A contraction of the whole muscle can therefore only be obtained if the same is stimulated with bipolar electrodes creating a current flow all over the whole length of the muscle (see fig. 2).
In one direction of current only part of the muscle can be activated as these reactions depend on the mutual orientation of membrane and current density. Applying alternating pulses we did not only succeed in reducing fatigue but also in training the muscles to such a degree that muscles could be maintained and even regenerated.
With a minimum daily training of one minute per muscle pulse duration can successively be shortened down to 20-30 ms. The initial single twitches will then turn over to considerably more powerful tetanic contractions. Since an accomodation to the intact environment can only be realized by a very slow increase of the pulses, bidirectional, rectangular pulses (see fig. 1 b) should be applied /3/.
The necessary current intensity cannot be reduced by the daily training; it depends, according to our experience, on the cross-section of the muscle and on the time-lag between appearance of the damage and the beginning of therapy.

Non-invasive investigations by means of NMR-spectroscopy show that a daily stimulation training builds up muscles of the red type. This is confirmed by other investigations /5,6/ on animals, which proved by means of electrophoresis that innervated and denervated muscles are transformed by stimulation from the mixed type to the red type. As there exist no action potentials we suppose that the calcium ions, which are indispensable for producing contractions, are directly released by the electrical field. The latency period between electrical stimulus and mechanical contraction comes up to about 50 ms and is thus significantly longer than the usual 2 -3 ms. It seems to be more probable, that the lengthened latency period points at ions permeating a membrane, like it is in smooth muscles, than at ions released from cisterns /3/.

Figure 3 shows the blood circulation of a paralysed leg after 2 minutes of stimulation. On stimulating twice or three times a day blood circulation can be maintained on the higher level.
For reasons of costs and time such a therapy can only be performed with home devices by instructed laymen. Other working groups try to approach this target with implanted stimulators or electrodes /7,8/, which were advantageous in treatment of spastic paralyses /9,10/.
We want to discuss some of the problems from this complex and present possible solutions.

2. Surface electrodes and implanted electrodes

Electrodes are of major importance as transition point between muscle and stimulator where conductance is transferred from electrons to ions.Even in inert electrodes made of carbon or platinum this process includes an increase of the ph-value.
If surface electrodes are applied, the phase boundary can be separated from the surface of skin by an inset soaked with salt water in order to eliminate acid burns. This is not possible with implants.
Figure 2 contains several current lines to demonstrate the current density. Current density attains its maximum under the electrodes and its minimum in the middle between the electrodes. Since the current density releases the contractions in the muscle, its minimum value must be larger than the limiting value given by the condition of the muscle. This will only be obtained by adapting the size of the electrodes to the cross-section of the muscle. The current density at the electrodes can amount up to o,2 mA/mm^2.
Implanted electrodes are for instance constructed as ring electrodes (fig. 4) or as needle electrodes. Due to their smaller dimensions the necessary current density must rate at a higher grade. This causes certainly a damage to the tissue in the environment of the electrodes. The stronger divergence of current density may even require a higher current, compared to that necessary for the application of surface electrodes. As a consequence the advantage of implanted electrodes, as it is known from indirect stimulation, saying that sensitive complaints are reduced, is abolished.

We are therefore convinced that an electro-therapeutic therapy for flaccid paralyses in human patients can only be performed with home stimulators under transcutaneous application of currents.

3. Requirements to a home stimulator

A home stimulator must satisfy many and partly ambivalent requirements, such as:

- easy and clear handling for the patient
- a large range of setting possibilities for the physician for diagnosis and therapy
- protection from defective device and operation errors and elimination of any dangers to the patient, from skin damages up to heart fibrillation
- reasonable purchase price and operation costs.

Figure 5 shows the general construction of a home stimulator. Setting and monitoring is done by module (1). The chosen signals are produced in module (2) and magnified in the power amplifier (3). The control system (4) supervises the other modules and connects the amplifier (3) with the electrodes via the output relais (5).

The amplifier may either be equipped with a voltage-constant or a current-constant output, with the first meaning no additional encumbering to the skin,if the electrodes are in a bad position or if they are taken off. Figure 6 a shows the increase of current under stimulation, because the resistance of the corneum stratum (fig. 6 b) is slowly shunted. We therefore apply amplifiers with current-constant outputs including an additional control of voltage. ith the current peaks being suppressed, the sensible burdens are inferior to those in voltage-constant outputs.
The insulated supply system (6) provides the voltages, for instance ± 15 V and ± 100 V and together with the amplifier (3) it limits the output current. A supply with batteries could be built up easier, but proved to be unsuitable and too expensive for continuous working. The supervision of all functions is very extensive and can only be effected with parallel modules and comparison of the outputs. Nevertheless it may happen that multiple faults are not detected. Instead of this supervision is reasonably graduated according to various principles which are partially overlapping.

Modules being more probable to become defective, such as voltage regulators and power amplifier are under permanent control. The output currents are also permanently controlled under the aspect of endangering the patient. Futhermore the stimulator is cleared if the user does not pay attention to pressing the operation key once a minute (dead man's feature). Use and operating are thus restricted to prevent to an utmost degree the switching on in case of danger and to guarantee a riskless switch-off at any moment. Any possible dangers must therefore be identified by means of electrical measurements without too much complicating the handling. Large steady components and too short pauses between the pulses may cause acid burns to skin. Steady components and duty cycles can be measured easily.
If unbalanced currents, for example monodirectional pulses, are applied for therapy, we recommend to demand a duty cycle exceeding two, instead of the two criterions.
If the maximum value $\hat{I}$ of the current is limited to 70 mA - this value being still necessary for flaccid paralyses /3/ - by an adequate dimensioning of main supply and power amplifier, heart fibrillation will certainly be eliminated /13/. Under these conditions burnings may be avoided by choosing a suitable size of electrodes. Apart from this current intensity should be limited depending on the pulse duration, as per figure 7.

Treatment can only start if the electrodes are fixed, i.e. the circuit is closed and the output current is at its minimum value. This prevents that electrodes are unwillingly touched after voltage is applied. Moreover voltage can be turned off still below dangerous current intensities in the case of a wrong position of the electrodes.
A sensitive earth fault protection breaker connected with the main supply clears if leakage currents flow back from supply via the electronic device into the body. In the circuit patient - stimulator it may also switch off leakage currents rising from a faulty connection of box to electronic device and thus flowing back to the electronic device, as is shown in figure 8.

In some settings of the stimulator, depending on frequency and amplitude,even highly sensitive earth fault protection breakers will not clear. That is why a device with medium-frequency magnetic polarisaiton has been developped for measuring the impedance of the faulty loop /12/.

The medium-frequency current will in no case cause damages to the patient and will above all not initiate heart fibrillation /13/.

In well-trained and experienced users it might be reasonable to renounce at certain functions, such as the repeated turning on of the operating key after every minute or after every change of the electrodes' position, in order to cut down the large amount of time spent on therapy.

Suitable home stimulators can be realised by using a microprocessor, which would then take over several duties /14/. By joining an additional logical circuit a sufficient redundance of control will be obtained.This kind of realisation offers new possibilities for operation. The device possesses two modes of operation. In the patient mode therapy programs can be set via ten keys. These keys are preset in a way to comply with all necessary requirements. The patient has only to adjust the current intensity with a potentiometer.
With a special key word you can enter the second operation mode, the mode for physicians. The double function of the keys enables the selection of 32 wave forms and of a vast range of parameters to be allied to the keys and be saved for therapy.

4. Application

The positive results of therapy in 20 children have been reported in /3/. Application will however be limited if current pains in sensitive patients prevent to use the necessary current intensity. We try to overcome this by using additional medium-frequency currents proximally applied from the stimulation area and blocking the afferent nerve /15/.Figure 9 gives a first impression of sensation measured by evoked potentials, with and without medium-frequency stimulation. We hope that by means of suitable parameters we will succeed in further increasing the admissible current intensity und thus open this therapy to a larger circle of patients. The force development in trained muscles can quite easily be controlled via current intensity or pulse duration. This offers good chances for a strengthening of the denervated extremities in the course of a functional training, thus preparing a functional use /4/.

As there is no tonic setting in most cases, motion chains can only be closed by the parallel stimulation of several muscles. The great electrical power which will then be necessary requires the development of portable stimulators with highly efficient output stages being able to produce long-lasting bidirectional pulses /15/.

References

/ 1/ Pinelli, P.: Workshop on The Electrotherapy on Denervated Muscles; Riv.Pat.Nerv.Ment., 99 (1978), 87-96

/ 2/ Edel, H.: Fibel der Elektrodiagnostik und Elektrotherapie, Verlag Müller u. Steinicke, München 1983

/ 3/ Eichhorn, K.-Fr., et al.: Reizstromtherapie bei schlaffen Lähmungen; Biomedizinische Technik 28 (1983) 48-58

/ 4/ Eichhorn, K.-Fr.; Schubert, W.; David, E.: Maintenance, Training and Functional Use of Denervated Muscles, Journal of Biomedical Engineering, London, accepted

/ 5/ Pette, D.: Transformation of Skeletal Muscle by Chronic Nerve Stimulation; Proceeding 1st Vienna International Workshop on Functional Electrostimulation, Vienna 1983

/ 6/ Carroro, U.; Catani, C.: Isomyosin Changes in Direct Electrical Stimulation of Denervated Rat EDL; Proceeding 1st Vienna International Workshop on Functional Electrostimulation, Vienna, 1983

/ 7/ Nix, W.; Seidenfaden; Seibert, W.: Zur Wirkung niederfrequenter isotonischer Elektrostimulation auf den denervierten EDL des Kaninchens; Fortschritte der Myologie (Band VI), Mainz 1980

/ 8/ Vossius, G.; Hildebrandt, J.; Gusek, W.; May, H.-U.; Finken, S.: Verträglichkeit und Lagestabilität von implantierbaren Stimulatoren zur drahtlosen Reizübertragung; Biomedizinische Technik 25, Ergänzungsband (1980), 319-321

/ 9/ Vodovnik, L.; Bajd, T.; Kralj, A.; Gracanin, F.; Strojnik, P.: Functional Electrical Stimulation for Control of Locomotion Systems; CRC-Critical Reviews in Bioengineering (1981) 63-123

/10/ Thoma, H.; Benzer, H.; Holle, J.; Moritz, E.; Panzer, G.: Methodik und und klinische Anwendung der funktionellen Elektrostimulation; Biomedizinische Technik 24 (1979) , 4-10

/11/ von Moxtel, A.: Skin resitance during square-wave electrical pulses of 1 to 10 mA; Med.&Biol.Eng.&Comput.,19 (1977), 679-687

/12/ Eichhorn, K.-Fr.: Fehlerschutzeinrichtung mit mittelfrequenter Schleifenüberwachung; etz 104 (1983), 1196-1199

/13/ Jacobsen,J., et al.: Experimentelle Untersuchungen an Schweinen zur Frage der Mortalität durch sinusförmige phasengeschnittene sowie gleichgerichtete elektrische Ströme; Biomedizinische Technik 20 (1975), 99-107

/14/ Eichhorn, K.-Fr.; Schubert, W.: Heimgeräte für die Elektrostimulation - Schutz gegen Bedienungs- und Gerätefehler; Biomedizinische Technik 28 (1983)

/15/ Jenker, F.L.: Transdermale Elektrostimulation; Z.f.Phys.Med. 10 (1981), 25-29

/16/ Eichhorn, K.-Fr.; Schubert, W.: Mehrkanalige Reizstromgeräte mit Wandlerendstufen; Biomedizinische Technik (in Vorbereitung)

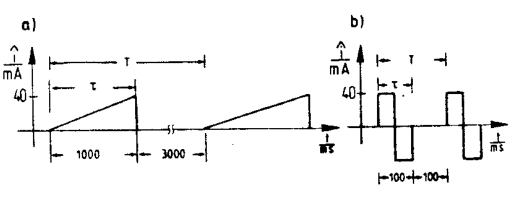

Figure 1 Stimulation for the treatment of flaccid muscles
a) Triangular or Exponential b) Bidirectional

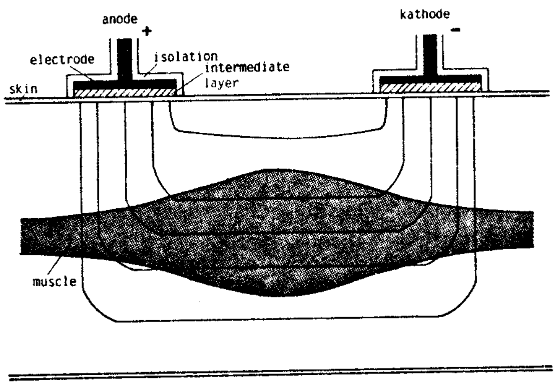

Figure 2 Quasi homogeneous current density under large surface electrodes

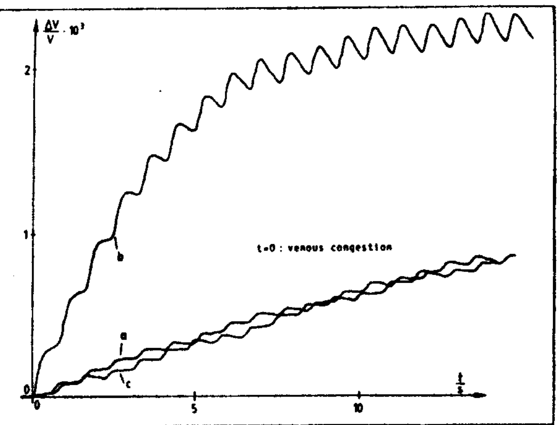

Figure 3 Blood circulation of lower leg before and after stimulation (plethysmography)
a) without stimulation b) after bidirectional stimulation
c) after stimulation with middle-frequency currents

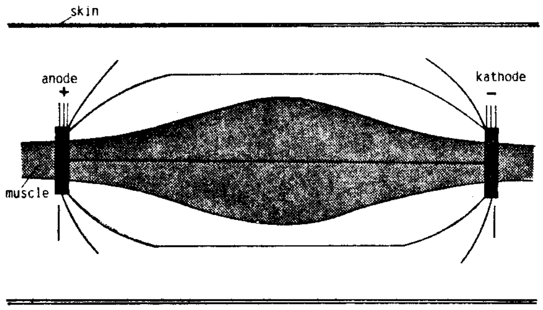

Figure 4 Inhomogenous current density between implanted toroidal electrodes

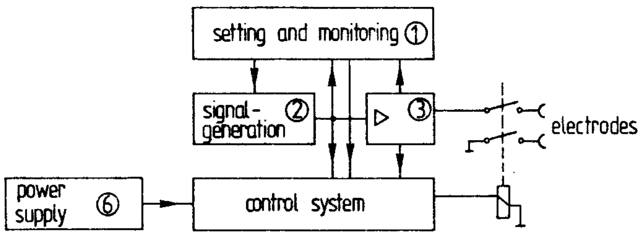

Figure 5 Scheme of a homestimulator

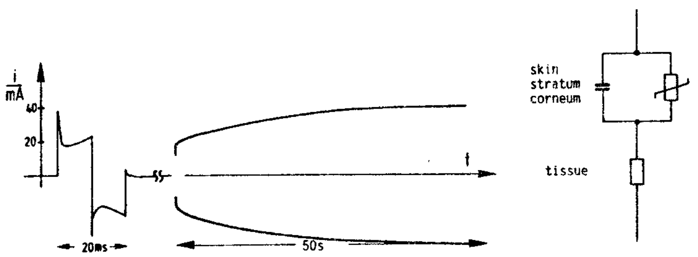

Figure 6 Influence of skin

a) current pulse induced by a voltage pulse according to Figure 1

b) envelope caused by a tetanic stimulation with a constant voltage output τ = 10 ms, T/τ = 2, f = 25 Hz $\hat{U}$ = 40 V

c) equivalent circuit for skin and tissue from /11/

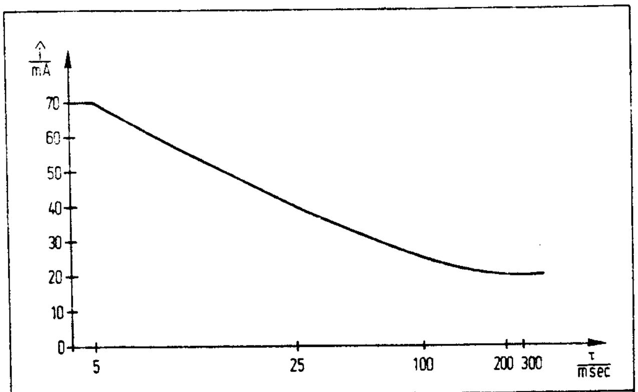

Figure 7 Safe maximum current intensity dependent on pulse duration τ

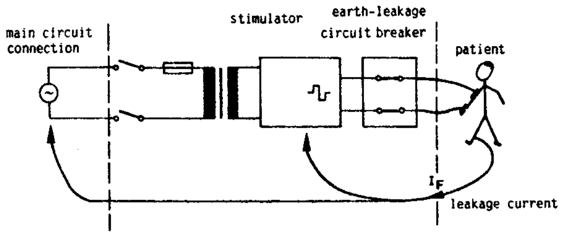

Figure 8 Connection of an earth-leakage circuit breaker and a home-stimulator

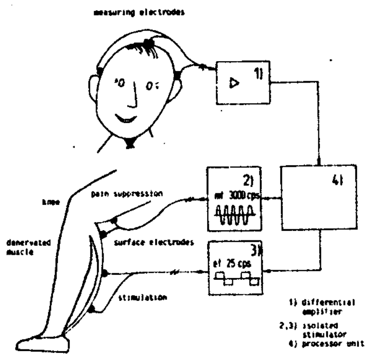

Figure 9 Pain suppresion with mf-currents by means of nerve blockade
a) measurement equipement

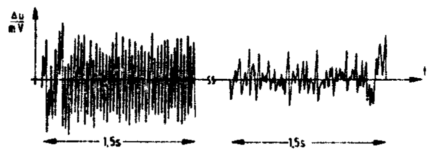

Figure 9 b) without mf-stimulation c) with mf-stimulation
The measured decrease of the amplitudes is combined subjectively reduced pain
proband: healthy subject; average of 50 measurements