NEW DEVELOPMENTS IN THE ELECTROTHERAPY OF SCOLIOSIS ONE YEAR EXPERIMENTS IN SHEEP [x)]

H. Stöhr*, M. Frey*, U. Losert*, F. Meznik**, G. Pflüger**
H. Thoma*
* IInd Surgical Clinic Vienna
** Orthopedic Clinic Vienna

Summary

Several implantable stimulation units for electrotherapy of scoliosis were developed and tested in animal experiments. So for instance an eight-channel-unit (originally developed for functional nerve stimulation) a miniature stimulation unit supplied by an extracorporal driving unit and a completely implantable and programmable battery-powered stimulation unit. Additionally a new screw electrode design was developed.

Introduction

A couple of years ago the almost only therapy in cases of idiopatic scoliosis of young patients was the treatment with the Milwaukee brace. Although this method is commonly used there are also critical opinions found in literature /1/. However there is no doubt, the Milwaukee brace is rather troublesome, restricting mobility and not satisfying completely. As an alternative treatment of scoliosis by means of electro-stimulation of paraspinal muscles is offered. Various reports of investigators engaged with this method give reason for optimism, although efficiency of electrotherapy is not completely proved yet as far as clinical applications are concerned. Altogether up to now probably 200 cases were treated with electrotherapy. With a view to statistics results seem to be comparable to those gained with the Milwaukee brace /2/. The stimulation system offered by industry consists of an implantable 2-channel receiver (without batteries) and a driving unit (battery supplied) outside the body. Stimulation energy is transmitted

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transcutanously by means of inductive coupling /3/.

Own experiments and developments

In 1979 our group also startet to test efficiency of electro-stimulation of scoliosis, using units produced in our own laboratories.

A first series of experiments was done with sheep with a weight between 29 and 37 kg and an age between 7 and 10 months. The age of the animals was chosen according to the age of treatment in human cases (8th to 15th year of life). The stimulation units we used were 8-channel-nerve-stimulators. These devices were originally developed for nerve stimulation for mobilisation after paraplegia /4/. For stimulation of the dorsal muscle only 2 channels were used. The advantage of this implantable stimulation unit is the possibility to adjust all parameters (amplitude, frequency, duration, polarity etc.) completely independent by means of the driving unit. Decoupling of electrodes is done by capacitors to prevent any DC-fraction of stimulation current to avoid electrolytical damage of electrodes. Transmission of information and energy is done at a frequency of 27 MHz. Stimulation is done in a constant current mode and is independent of an accurate positioning of the transmitter coil on the implanted receiver. Constant current stimulation offers the advantage that changes of the electrical resistance between electrode and muscle-tissue are not of importance.

In all 4 experiments in general anastesia three screw electrodes were positioned near the spine in a distance of 4-5 cm. Distance between electrodes was 7-8 cm. The stimulation unit (size comparable to a pacemaker) was positioned without any special fixing between muscle tissue and skin fascia. All screw electrodes were commercially available myocardelectrodes, produced by Medtronic. Fig. 1 shows the eight-channel-stimulation unit and the driving unit.

One week after implantation stimulation was started. Effects were supervisioned by X-ray examination. Stimulation currents necessary for visible contraction were rather different

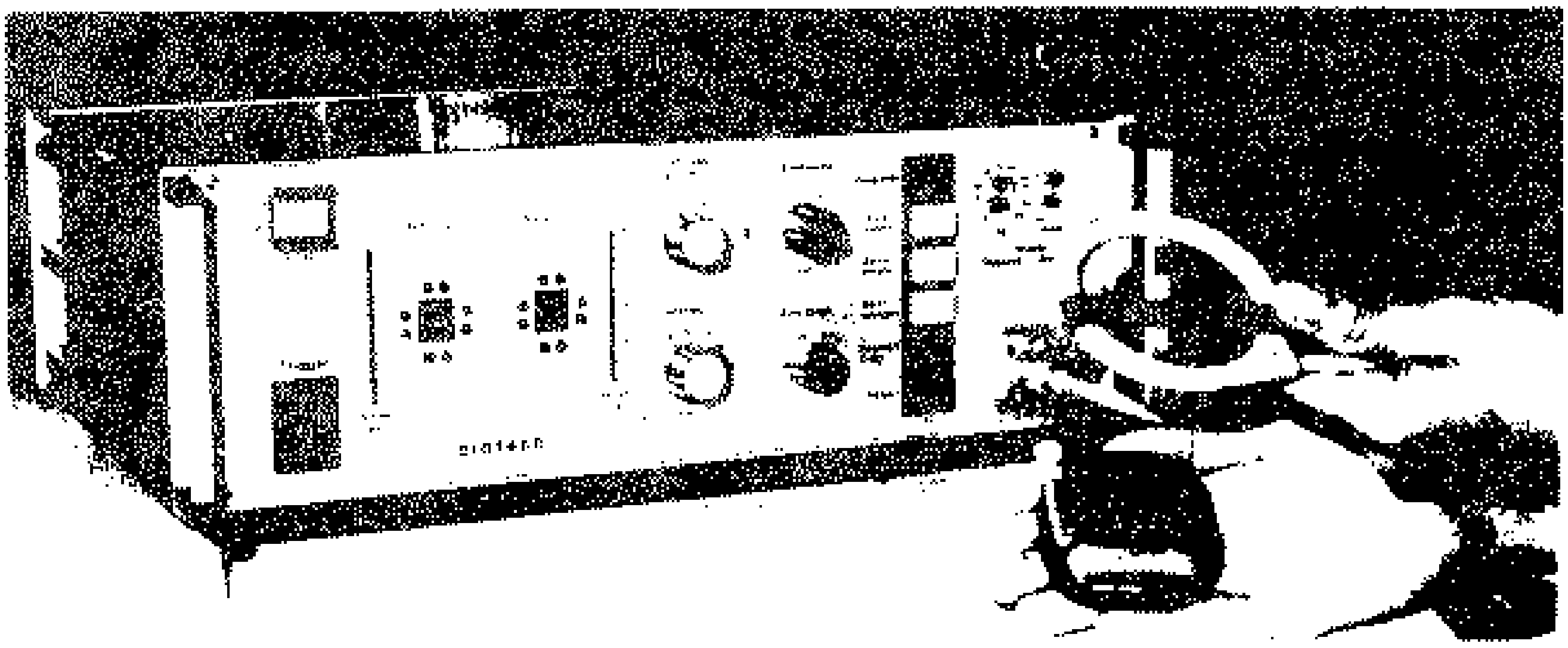

Fig. 1: Implantable 8-channel-stimulation-unit and driving unit

(1,5 mA - 11 mA). Stimulation was done with impulses, duration 1 ms, at a frequency of 40 Hz approx. Impulse train was switched on for 2 seconds, followed by an eight second break. All sheep were stimulated several hours a day (5 hours in an average). 50 days after stimulation start permanent bending of the spine was recordable even without stimulation, and was intensified when stimulation was switched on (approx. 13° when stimulating, 3° - 7° when switched off). To test our sealing technology stimulation units remained implanted for up to 8 months. No failure occured. A great disadvantage of the stimulation unit we used, was the connector cable necessary between the antenna coil and the driving unit. Because mobility of the test animals was rather restricted because of the cables, stimulation was only possible during attendance of superintending staff, limiting daily stimulation period. So we developed an implantable miniature stimulation unit which is supplied by a batters operated driving unit, which is strapped around the animal's body. The implanted receiver has a diameter of 22 mm, therewith being essentially smaller than units offered by industry. By means of a special electronic layout amplitude of stimulation impulses is largely independent of the distance between receiver and transmitter coil. The transmitter is grouped as a building block system. It consists of two separable parts: The very electronic system and a rechargeable battery-pack pluged to it. The battery pack can be adapted in size and capacity as circumstances may require. If necessary stimulation all the clock around is possible. Fig. 2 shows the implantable receiver as well as driving unit.

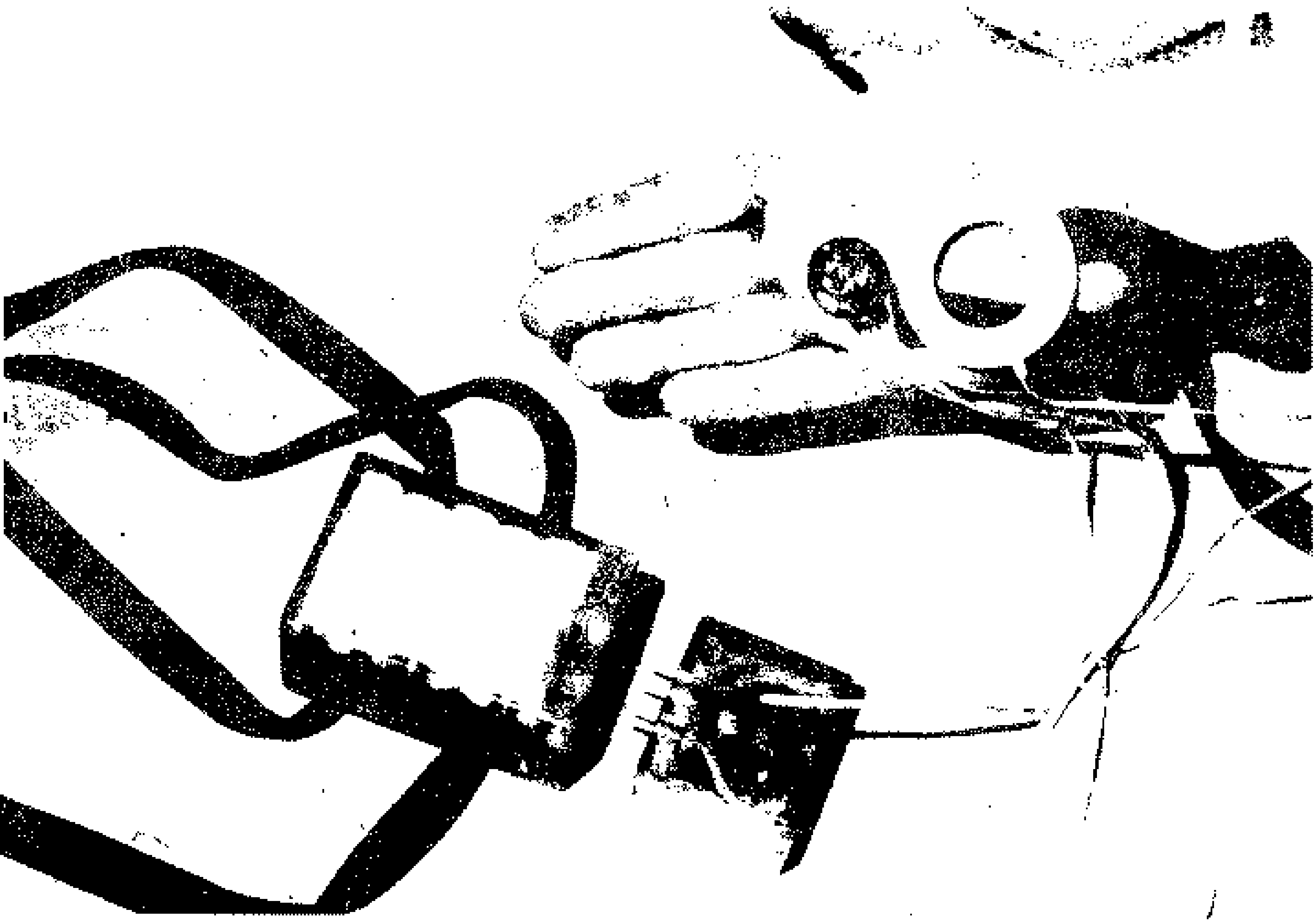

Fig. 2: Implantable miniature receiver and driving unit with separated battery pack

<u>Development of a completely implantable stimulation unit</u>

For clinical applications treatment with electrostimulation usually has to last for a rather long period. In such cases a "forgetable", automatically working and completely implantable system would be of great advantage. For the first time we developed a dorsal-muscle-stimulator which does not need any extracorporal driving or battery-unit. Fig. 3 shows the block

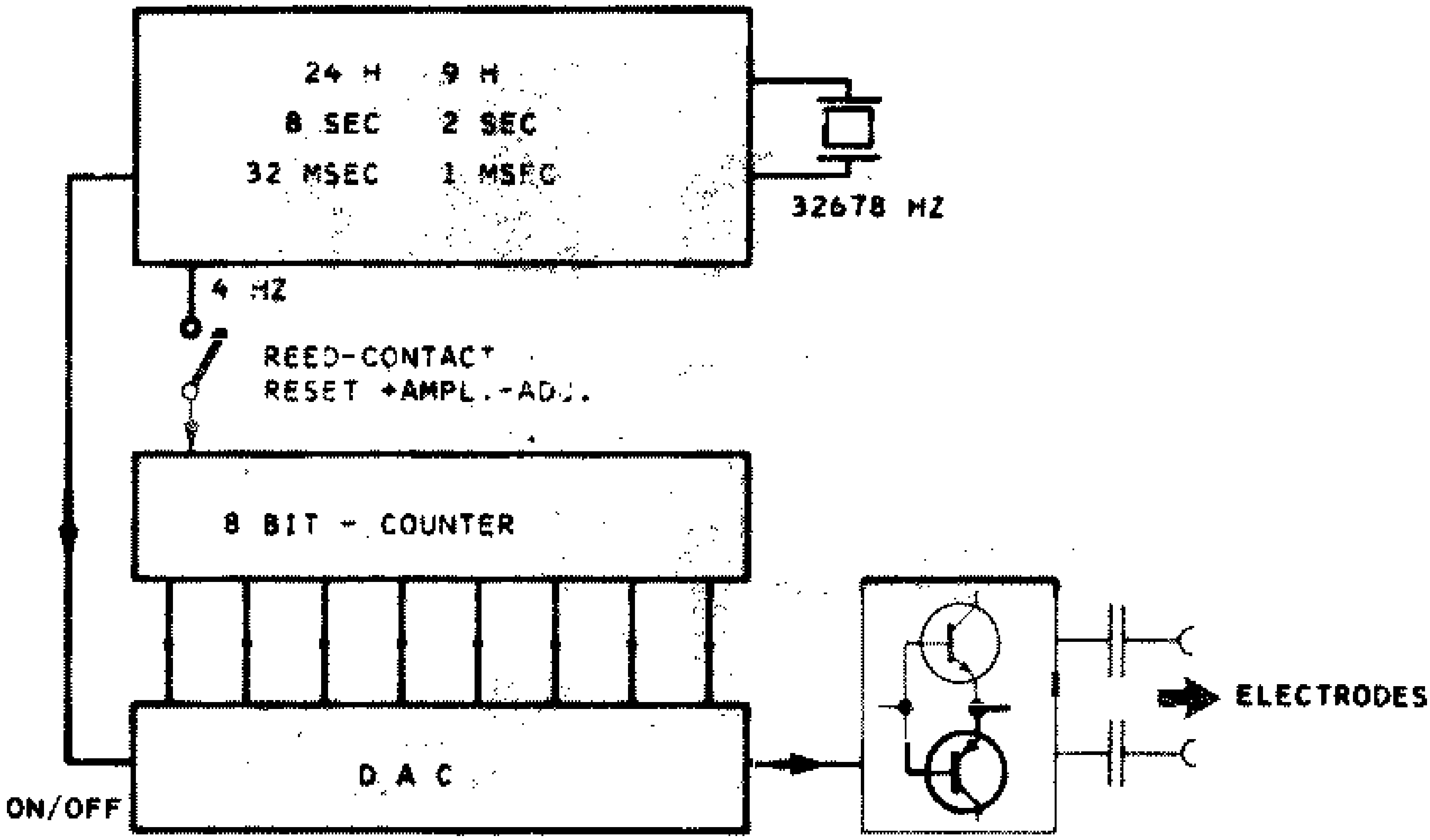

Fig. 3: Block diagram of the completely implantable stimulation unit

diagram. The stimulation unit has its own crystal controlled timer. Within 24 hours stimulation is switched on automatically for 9 hours. Stimulation is done with 1 millisecond impulses lasting for 2 seconds with 6 seconds break. Stimulation amplitude can be programmed in a range of Ø Volt (unit switched off) to 10 Volt. Programming is done by means of a small permanent magnet. When it is positioned on the implanted unit stimulation amplitude is increased continously. When maximum level is reached amplitude is decreased saw-tooth-like to zero volts, increasing again afterwards. After the magnet is removed the current amplitude remains stored. Also the 24 hours cycle is started again. Power supply is done by means of high density lithium batteries. Their capacity guarantees function for at least 6 months. Using low power C-MOS logic circuits power consumption could be extremely minimized, resulting in almost 97 % efficiency. Size of the

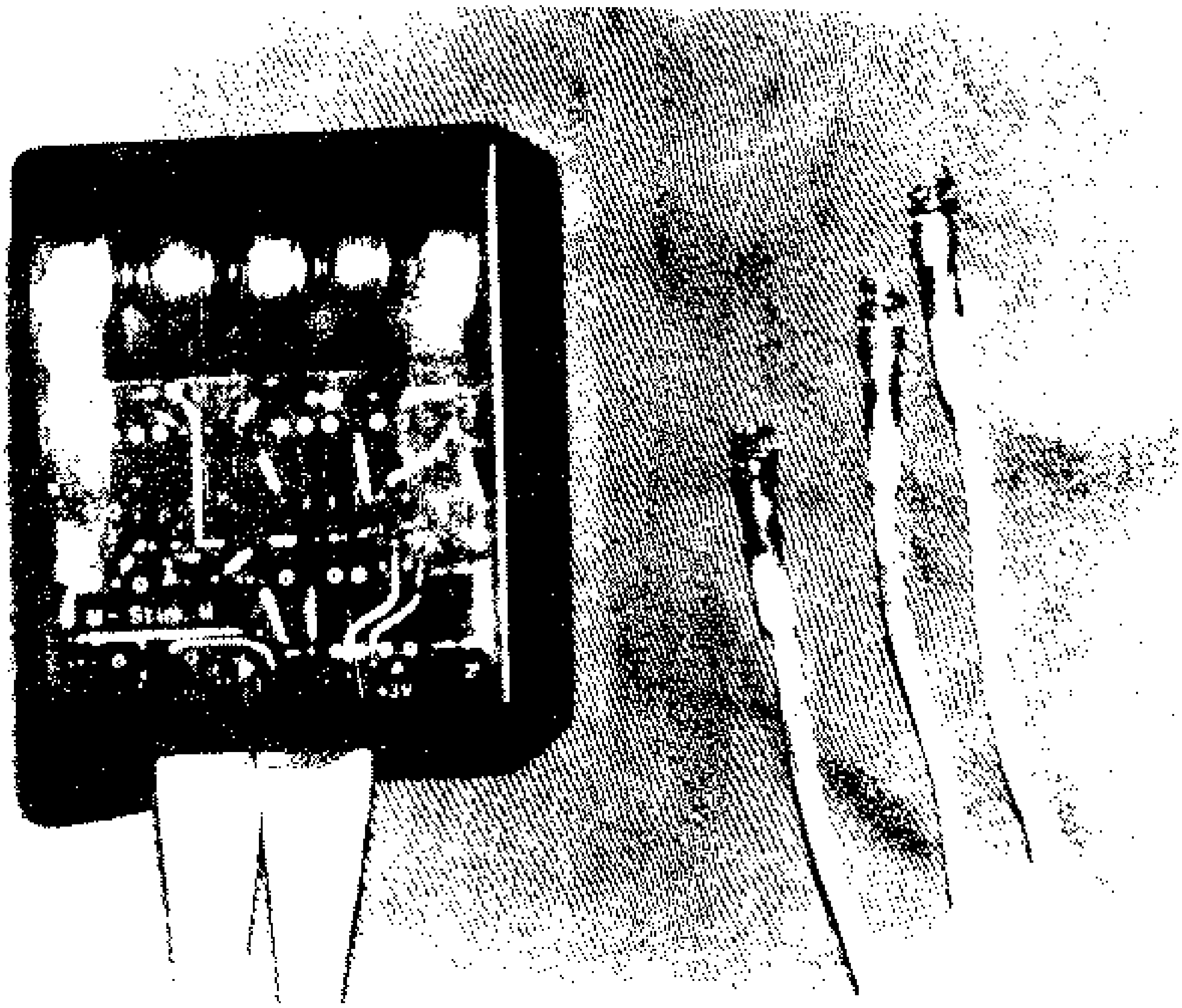

Fig. 4: Completely implantable stimulation unit with 3 screw electrodes

whole unit is 60 x 50 x 25 mm. As - according to some reports of literature - break of the helix of the usual screw electrodes can be possible we improved the electrode design with a central needle (fig. 5). Even if the helix is broken, stimulation can be continued allthough electrode resistance is slightly increased. Electrode materials is platinum-iridium. By means of three highly flexible leads of high grade steel, separately isolated, great reliability of the highly stressed electrode connection is given. Testing of the whole equipment is in progress at present. In future further reduction of size is planed using hybrid-technology.

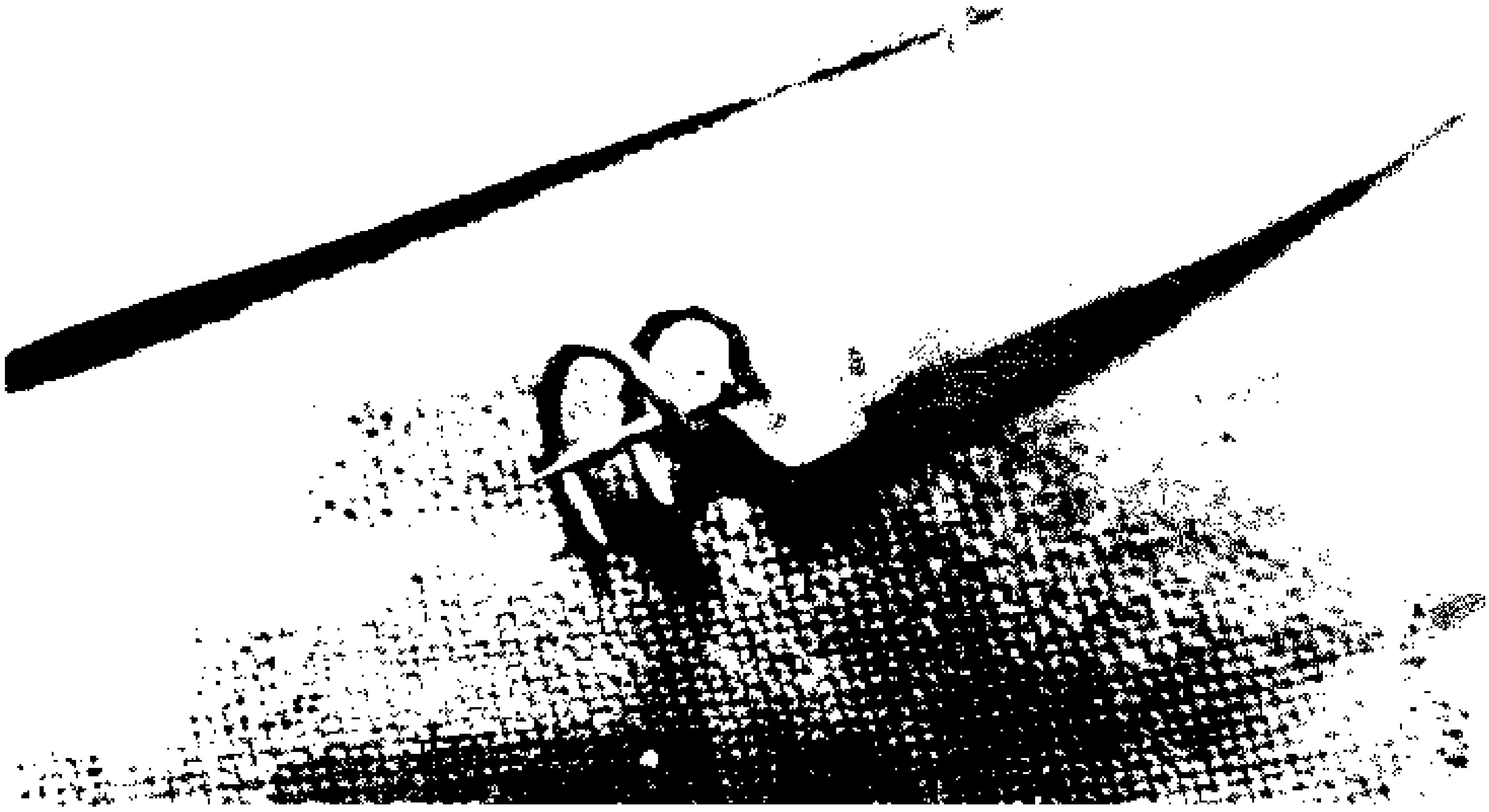

Fig. 5: New electrode design with middle needle

Discussion

Long-time muscle stimulation seams to be realizable in the technical point of view. It remains to further experimental examinations to prove efficiency of the method. In our experiments on sheep we had to learn that flexure of the spine decreased in course of the experiment. Nevertheless muscle contraction was still detectable. Similar experiences were made in first clinical applications (4 patients) after 6 months of stimulation. There are some theories trying to explain this phenomenon. It can be assumed that continous stimulation causes structural changes in the paravertebral muscle tissue and a loss of normal muscles. An other hypothesis is that growth of the test animal and the patients has already ceased according to the age reached.

/1/ "Skoliose - Ist das Korsett für die Katz?", Kongreßbericht, Medical Tribune, Jahrgang 13, Nr. 17

/2/ Bobechko, W.P., Herbert M.A., Friedman H.G., "Electrospinal Instrumentation for Scoliosis: Current Status", Symposium on Scoliosis and Related Spinal Disorders, Orthopedic Clinics of North America - Vol. 10, No.4, October 1979

/3/ "Medtronic Isomod, Electro-Spinal Instrumentation", Physician Manual, Medtronic, January 1981

/4/ Thoma, H., Holle, J., Moritz, E., Stöhr, H., "Walking after Paraplegia - a principle concept", 6. Intern. Symp. on External Control of Human Extremities, Dubrovnik, 1978