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18 MONTH EXPERIENCE IN CLINIC APPLICATION OF IMPLANTABLE MULTICHANNEL STIMULATION DEVICES FOR PARAPLEGIC PATIENTS

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1. Abstract:

The basic idea of our research program entitled "learn to walk with fingers" was to control gait processes of paraplegic patients with implanted stimulators by means of the patients fingers and adequate control units. More than 100 in vitro and in vivo experiments on rats and sheep were done to test stimulation pulsforms and electrode materials or the physiological behaviour of the nerve-muscle complex. Since October 1982 two patients, and since November 1983 four patients are using our implantable multichannel stimulation device, which is performed in thin-filmhybrid technology. Energy- and information transfer from the control-unit to the implant is done by means of inductive coupeling (27 MHz). Several tests (e.g. long term test of the whole equipment) assures a reliable level for implantation in human. As result, half year after implantation the two patients were able to stand up and walk short distances with crutches. One year after the first implantation we had a failure and after further two month a failure of a second implant. The implants were changed in a small operation (like the change of a pacemaker) and a thorough failure analysis shows degradation because of moisture. All implants of the latest generation (the exchanged ones and those of the two last patients) are changed in design to avoid this failure. So the mean time to first failure (MTTFF) should increase.

2. Introduction

According to the concept of nerve stimulation of paraplegic patients, which was presented at the last symposium on external control of human extremities in 1981 /1/, we reached the level of human application and can describe more than one year experience in this field. Since October 1982 two paraplegic patients and since November 1983 two more patients are using our implantable 16-channel stimulation device for the functional movement of their lower extremities. The implants, to which the energy- and informationtransfer is done by transcutanous inductive coupling, are built in thinfilm-hybrid-technology. Each patient needs two implants in the size of a cardiac pacemaker to activate the left and right m. quadriceps and m. glutaeus via the inherent nerves. Each implant supplies 8 electrodes for two nerves - so a fatiquefree stimulation is guarranted /2/. The extracorporal control-unit is organized by a C-MOS microprozessor by the advantage of

small dimension and batterypowered use of the portable device.

3. Materials and methods

The complete stimulation device of the present generation consists for one patient of two implants, two transmission coils, the control-unit and the specially for the patient adapted switches to activate the muscles (see fig.1). The implant itself can be divided into following subgroups: the receiver coil, electronic supply, generation and management of the stimulation impulses and the 8 connection leads (two nerves) to the electrodes. All our in vitro studies and animal experiments have improved, that simple stainless steel electrodes are quite sufficient for all demands (no electrolytic effects, less injuring to the nerve, easyly reproduceable and cheap)/1/,/3/. These electrodes also offer the advantage to use the same material even as lead-in wire. So electrochemical processes are prevented. To obtain a high degree of resistance against material fatique the leads are circulary coiled and completely embedded in silicon rubber. The end is wound to a small loop (diameter 1 mm) which is fastened to the epineurium of the nerve using microsurgical methods with thin suture. Bending tests of the leads reached about 5 million 90° bending cycles. That suggests that an electrode has sustained this value without breakage the probability of a failure in its normal life is very low.

The implants itself of the present generation are built exclusively in thinfilm hybrid technology. Reason therefore was the desired smallness and the very low number of units to produce. Because of the very high technical resources in producing such hybrid circuits (photolithographic etching, ultrasonic preparation, die-bonding, wire-bonding, package welding etc.) most of these works are done at the Technical University of Vienna in the framework of a research project of implantable hybrid circuits /4/. Most of the testing- and screening methods to assure an acceptable quality level were done there and are corresponding to the respective american "MIL-Standards". These are for instance He-Leakage tests of the package to assure the resistivity against humidity or bond pull tests for proper mechanical fixing of the 25 µm Au-wires. Then a visual inspection of the ready equiped receiver print was performed by the aim to screen out units with poor solder joints or cracked glass feed-throughs or any damage resulting from handling and testing (visible evidence of corrosion, contaminations, breakage or leads which are not alligned in their normal location).

After sealing the implant-print in Hysol (pacemaker resin) it is connected to the electrode leads and the microplugs are luted with silicon rubber.

Generation and organisation of the supply and information which is transmitted transcutanously to the implant is done in the control unit by means of a C-MOS microprocessor (NSC 800) and it's family. The block diagram of the control unit

is shown in figure 2. So the battery powered and in all stimulation parameters free programmable control unit is reduced in size to 170x120x60 mm /5/,/6/.

4. First human application and trainings period

In October 1982 two 2x8 channel units were implanted in two paraplegic patiants, 41 and 25 years old. The trauma causing the spinal cord lesion occured 21 and 4 years previously. In both patients the complete spinal cord lesion is located between TH-9 and TH-12. The implants allow an activation of the m. gluteus and the m. quadriceps via the inherent nerves. Stimulation current necessary for desired activation is less than 3 mA for stretching knee and less than 5 mA for stretching the hip. Stimulation frequency is 30 Hz, and the stimulation pulse width is 0.6 ms. After a healing period of approximately 8 weeks the patients started a training program to strengthen atrophied muscles and to increase endurance. The periodic control visits were used to check all stimulation parameters. In sitting position with 90° bent knee-joint we measured the isometric muscle force of the m. quadriceps using a strain-gauged load cell. We noticed that muscle force depends on the switching mode of the electrodes' combinations. Desirable combinations are those for which only minimal stimulation current is necessary to result in a strong muscle contraction (see fig. 3). After nine month of training muscle force in the stimulated muscles increased to approximately 400% and the endurance was about 30 times higher (see fig. 4). After the last trainig periods which was focused on stand-up and walk exercises the patients are able to stand up with one hand on a mechanically fixed point, and using crutches with control switches they can walk a short distance (either swing-through gait or 4-point gait).

Supported by the experience of these two patients in November 1983 two more patients received our implants. Eight weeks postoperative we started the training, which is similar to that of the first patients. Also the progress and the results of both patients in this field are very satisfying.

5. Reliability and first failure

Though we did a lot of environmental tests to assure a high degree of quality (reducing the possibility of early failures and infant mortality to nearly zero), we had a inherent weakness failure exactly after one year after the implantation. During the production cycles of the implant it has been tested for hermiticity of the package of the hybrid-circuit, bond-pull tests, burn-in tests and other were performed.

After detection of the failure and its verification by means of myoelectric examinations the defect implant was exchanged by a newer one. This happens in a short operation which is comparable with the exchange of a cardiac pacemaker. A stepwise search for the failure mechanism shows small

cracks between the miniature-plugs and the sealingmaterial, through which humidity was diffused in. The reason for the cracks is the non-compoundability of sealing material (Hysol) and the plastic of the miniature-plugs (see fig. 5). When the implant was opened also small cavities between the plugs and the receiver print were detected in which a very good visible (see fig. 6) material migration betwenn the copper-bands of the print has taken place. This phenominas were located in the areas of DC-currents before decoupling the output by capacitors. So we had a "shunt" in the output-circuit, which at early times degrade and later would disable a functional stimulation current. Because of the fact, that this could not be the reason for the total failure of the implant, the hybrid package was opened. A few days later we found a loose bond in the area of the current generator. Because of the high packing density no bond-pull tests were performed at the first generation of hybrids. Two month later another implant failed by the same failure mode. Failure research is still going on, but moisture- or/and corrosionphenominas seem to be responsable for this intermittand failure.

For the implant of the last generation (see fig. 7) we can predict the absence of these phenominas, because the plug and its connections are completely embedded and no surface-leakage path could establish and all wire bond are bond pull tested to minimal 2,3g (MIL.STD.). Nevertheless we are conscious that the changeable connection (especially of eight) electrodes is the aim of further research.

6. Results and discussion

All four patients have accepted the disadvantage of the invasive method and the necessity to change an implant in case of failure.

The failures of the first generation of implants (MTTFF about one year) has proofed the effectiveness of careful testmethods to assure a reliability growth. This will be an important point for further research in the near future.

The advantages of nervestimulation by our system are:

- no limit in function, because all nerves can be connected
- fatique free stimulation due to multi electrode system
- fiber selective ... progressive force
- electrode redundancy
- implantable ... forgetable
- easy to apply and wear

The overall question of this new method is the practice. It is our experience that if we are not able to offer special features and possibilities during every day's practice the handicapped will persist in the wheel chair. Therefore we have to offer in the near future a stimulation device built in a belt with a check-up time less than half a minute and to define a list of duties necessary for every day's practice as e.g. check in busses, railways or aircrafts without any other personal help.

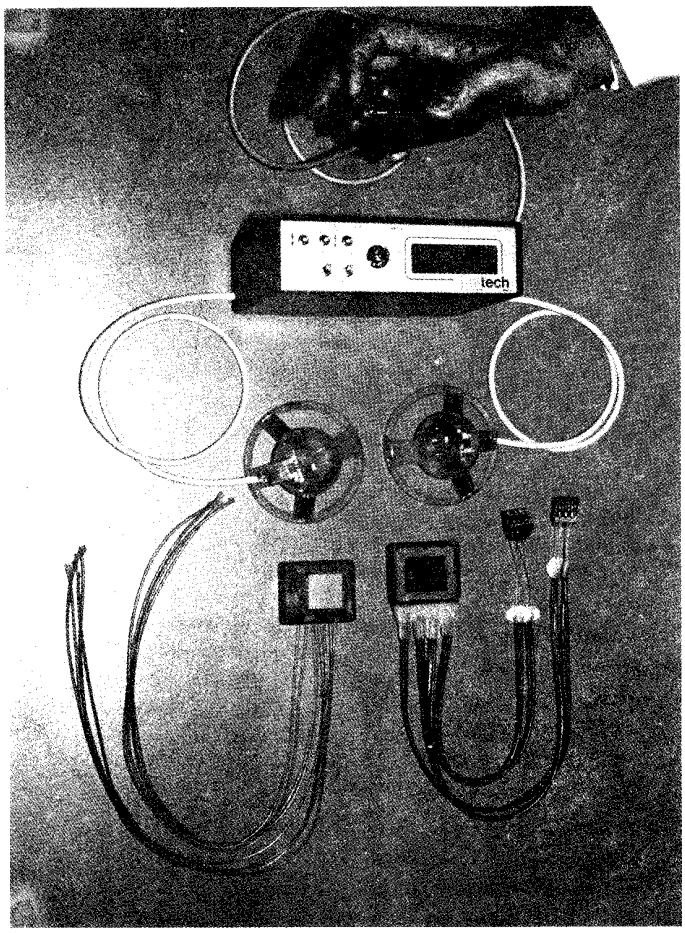

Figure 1: The stimulation device consists in:
Control stick (top), battery powered control unit with display and program-buttons, external transmission coil, implant with connected electrodes (left side: view on the hybrid-circuit, right side: view on the receiver coil)

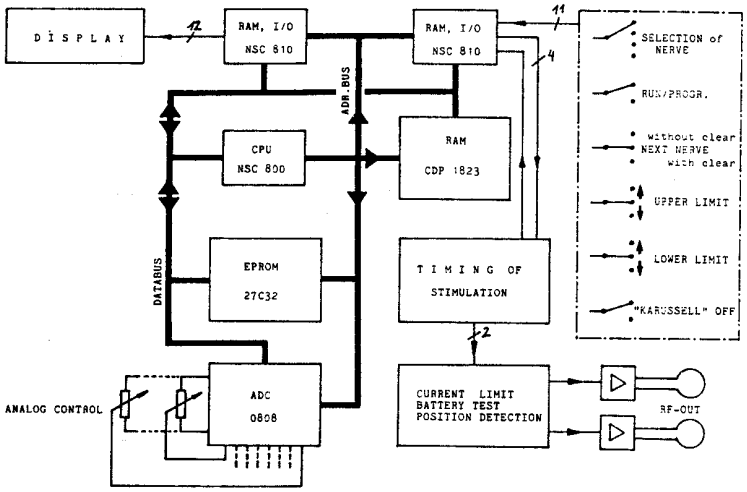

Figure 2: Electronic block diagram of the control unit using a C-MOS microprocessor family. The system is in all stimulation parameters free programmable and the RAM is powered up to save its contents

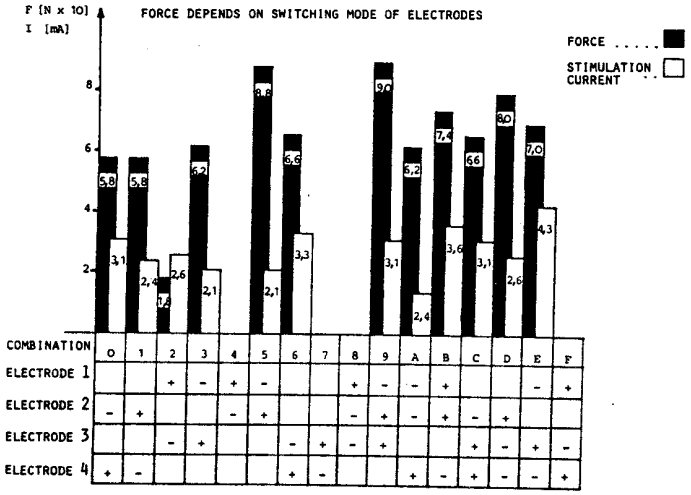

Figure 3: Fiber selective stimulation: The muscle force depends on the switching mode of the electrodes. Combinations with less force or additional effects (e.g. rotation) are switched off during automatic stepwise changing

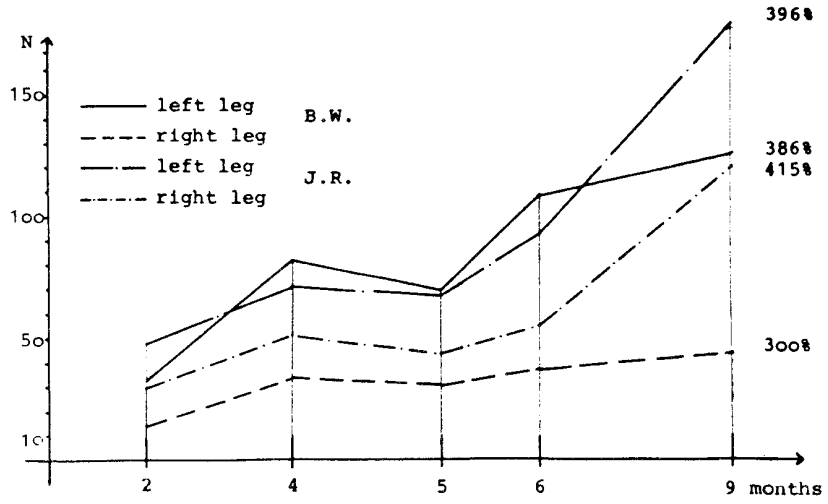

Figure 4: Developement of muscle force of the m.quadriceps for the first nine month postoperative

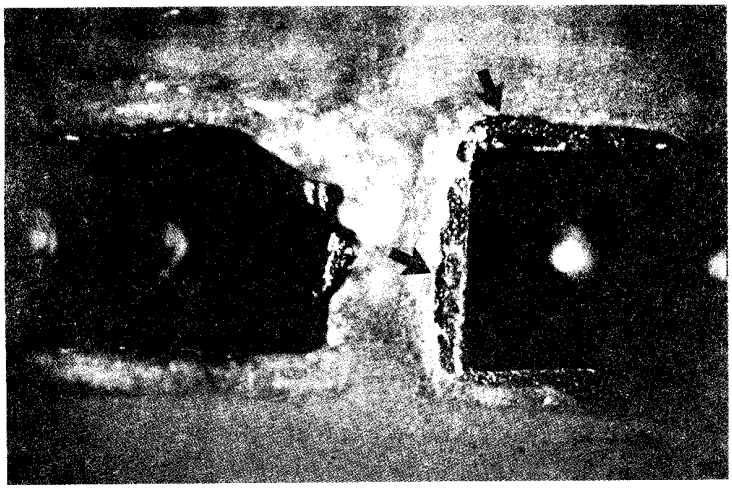

Figure 5: View onto the miniature plugs (magn. 15X) with cracks between Hysol and plastic material (arrow) which allows the moisture to diffuse in

Figure 6: View onto the basic print of the implant (magn. 20X) with cavities and copper migration because of humididty and DC-currents which shunts the output

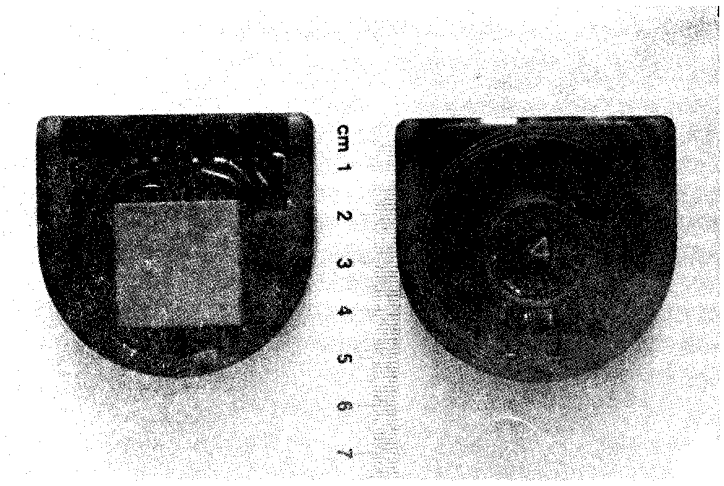

Figure 7: Implants of the last generation

7. References

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