IMPLANTABLE FUNCTIONAL ELECTRICAL STIMULATION AND SURGICAL PROBLEMS

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Summary

In certain cases there is a trend in functional electrical stimulation to move from the surface electrodes to the electrodes immersed under the skin. This involves medical and technical problems. These are anatomical, surgical, electronic, including energizing, encapsulation problems, foreign body rejection, and others.

The surgery should be as simple as possible but this depends on the miniaturization of the implant which again increases the technical requirements.

In the paper the main concepts in the design of implanted systems are discussed considering the anatomical conditions and surgery. The outpoint is the demand for differentiated excitation.

For an experienced surgeon the operative procedure during which the implant is located is a simple one with no special technique involved. In our work the emphasis was laid on preoperative examinations and preparation of the patients.

For our experiments only patients with central lesions and with the peripheral nerve pathways preserved were included. These are the patients with paretic extremities. The patients are selected under the same conditions as candidates for application of the functional electronic peroneal brace PO 8 (Rehab. Inst. Ljubljana). The additional restriction is that there is no improvement expected in the prognosis of the patient. Usualy these are the patients under application of surface stimulation for several months. Similar results as achieved with surface electrodes may be expected with the implant. The advantages and disadvantages of both systems were described elsewhere /1/. In the selection of the patient an interdisciplinary team consisting of a neurologist, psychologist, psychiatrist, physiatrist, surgeon, and implant engineer is involved.

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Patients who have used both systems prefer the implant because of much simpler application and improved cosmetics. There is no need for daily location and fixation of electrodes as well as for keeping them wet.

The main problem is concerned with the functional movement which has to be controlled by electrical stimulation. For that movement the corresponding muscle groups or only a portion of them /2/ have to be activated. The nerves innervating the selected muscle groups as well as their pathways from the ventral roots to the neuromuscular junction have to be known. Practically, the muscle function can be controlled by electrical excitation of innervating neurons on any level from ventral roots, along the nerve and in the muscle itself.

My basic criterion in determining the location of the implant has been by simple exposure and optimal functional response. Studies involving location at the exit of the nerve from the medularry canal was not investigated because it requires more extensive surgery. Under this criterion the highest priority received the location where the nerve is running very close to the skin surface, allowing simple exposure and a simple procedure.

The second criterion for location is that the configuration of the nerve trunk allows differentiated excitation of only selected muscle groups which have to be activated. At the same time the resultant action of the muscle groups activated should represent the movement which is desired. In the case of the drop foot it should be a combination of dorsal flexion and eversion and for radialis paresis dorsal flexion of the wrist and extension of the fingers. This criterion is achieved only if in the nerve trunk the fibers concerned for the desired movement are excitated and all others are not depolarized. This can be achieved with physical separation of the nerve fibers during the surgery /3/ a procedure which was developed at Rancho Los Amigos Hospital, California, by means of collar type electrodes that encircle the nerve.

In our clinic another method was developed based on two principles:

1. to avoid the electrodes which represent the potential risk of breakage and in some cases cause the compression of the nerve followed by lesion of the nerve;
2. to enable the differentiated excitation of nerve fibers.

In accordance with the first criterion, avoiding the electrode wires and decreasing the extent of the surgery, the implant stimula-

tor was developed with electrodes which are the integral part of the implant. The stimulator is cylindrical, its length is 15-20 mm and its diameter, 5-7.5 mm /1, 4/ (Fig. 1).

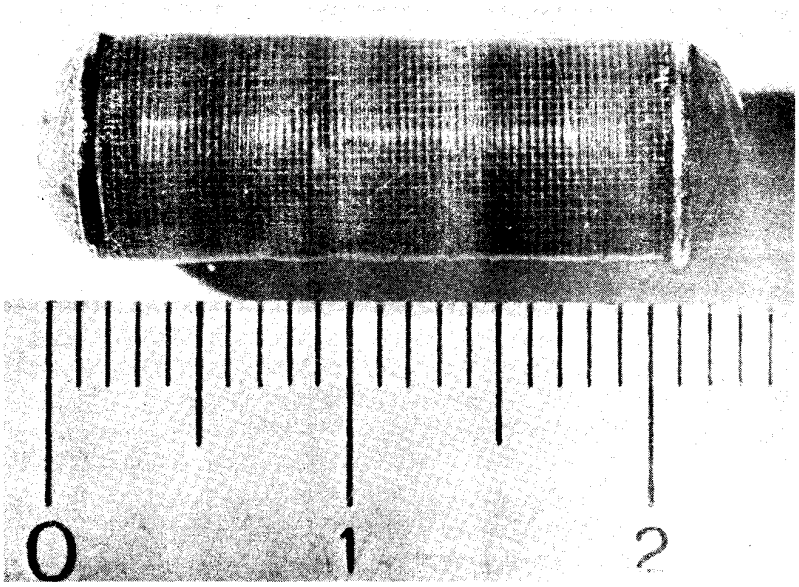

Fig. 1.

This implant was designed on the basis of the existing anatomical and geometrical configuration of distribution of the nerve branches in the nerve trunk. Geometrical distribution is changed along the nerve trunk as can be observed in repeated crossection of the nerve in small distances of some mm. This configuration enables the differentiated activation of nerve fibers by moving the stimulator axially along or circumferencially about the nerve trunk. Especially, the last technique requires very simple surgery and provides separate activation of corresponding muscle groups (Fig. 2).

For the sake of miniaturization of implant receivers two or more stimulators may be implanted very close to each other. In this manner control of different muscle groups is possible. This is the case in a two-channel implant control of ankle joint via corresponding agonistic and antagonistic muscle groups (Figs. 2 and 3) with location of implants in the region of the fossa poplitea.

The surgical procedure must be performed under strict aseptic conditions in local anasthesia. 1% Xilocain 40 ccm is administered and the patient need not be hospitalized. The implant is gas steri-

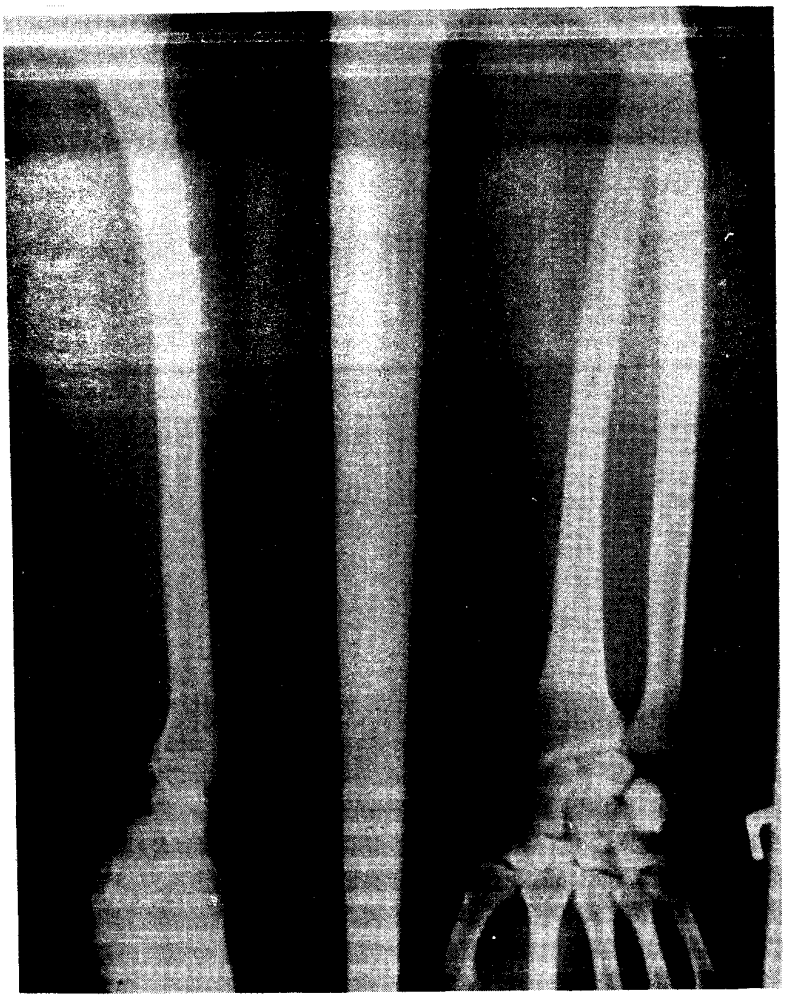

Fig. 2.

lized or by immersion in a detergicide solution. The position of implants was checked by X-rays in two projections, at various time intervals.

The functional testing of implants begins one to two weeks after surgery. Usually during the first days after implantation, an increase in excitability can be observed followed by a decrease during the next few weeks. These changes are estimated to be due to changes in the interface between the electrode and the surrounding tissue.

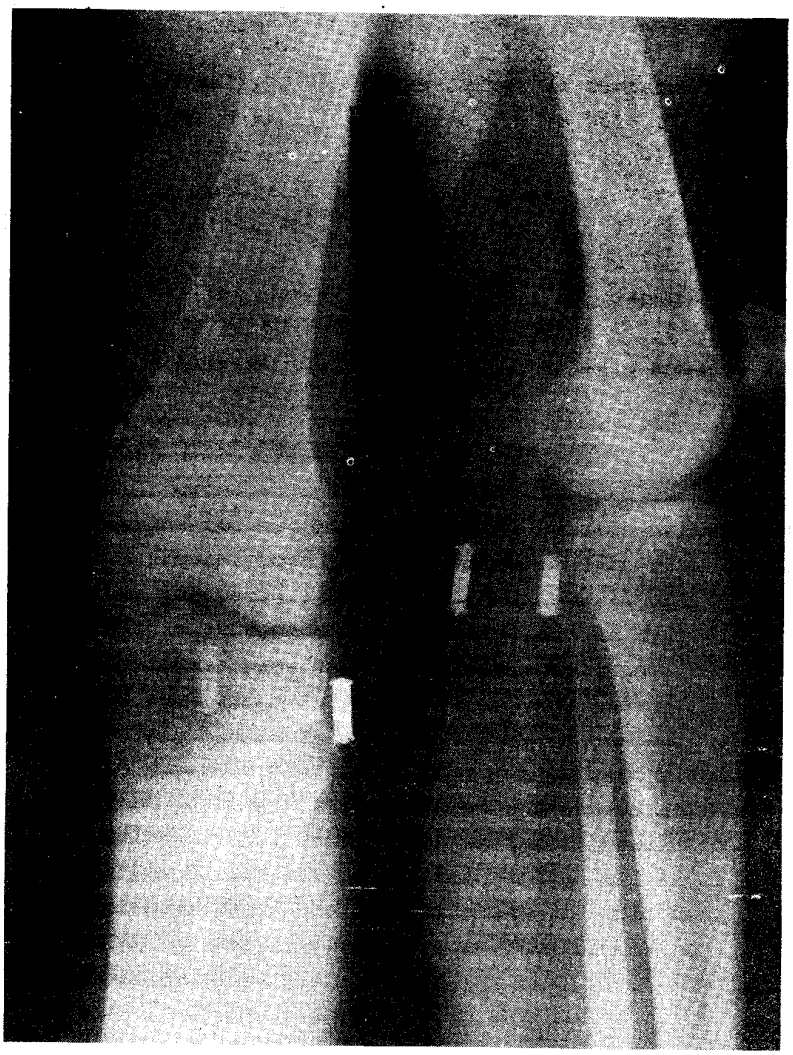

Fig. 3.

This implant type as described above was implanted the first time in man in May 1969. No changes in operation have been detected up to this time. Therefore we are sure of the quality of the encapsulating layer of epoxy resin /4/.

The mechanical response of the two-channel implant controlling the ankle joint (Figs. 2 and 3) is shown in Figure 4, as measured by

means of a special brace.

We can say that the success of the implant depends not only on the surgical procedure, but also on adequate control and evaluation of the system.

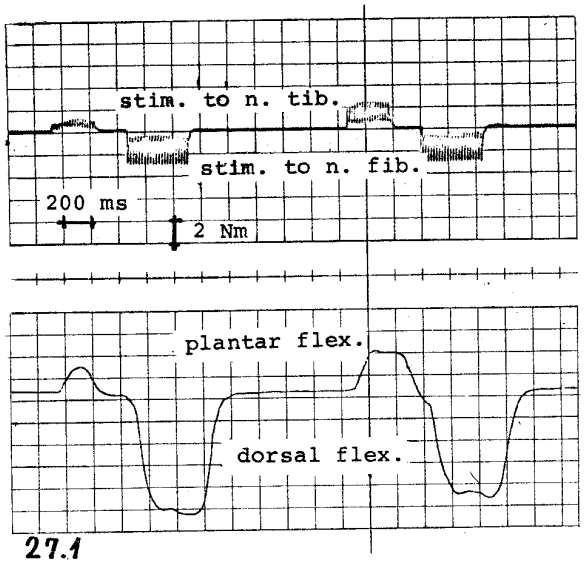

Fig. 4.

Conclusion

The method described above enables us to provide one, two, or more channel implants with only simple surgery being involved. Preoperative testing, preparation and selection of the patient, as well as postoperative control, evaluation, and education of the patient is of greatest importance. Evaluation of the first group of implant patients is still in course. The first two channel implant was performed in a normal subject, a volunteer. The implants in patients are planned after evaluation of results with the normal subject and a study of the physiological mechanisms involved.

References

/1/ Jeglič, A., Vavken, E., and Benedik, M., "Implantable Muscle or Nerve Stimulator as a Part of an Electronic Brace", *3rd Inter. Symp. on External Control of Human Extremities*, Dubrovnik, 1969.

/2/ Kralj, A., Doctor thesis, Faculty of Electrical Eng., Ljubljana, 1970.

/3/ McNeal, D.R., Wilemon, W.K., "Treatment of Spasticity Through Functional Electrical Stimulation", *Neuroelectric Conference*, February, San Francisco, 1969.

/4/ Jeglič, A., Vavken, E., Štrbenk, M., Benedik, M., "Electrical Stimulation of Skeletal Muscle by Directly Powered Implanted R.F. Receivers", *Proc. of the International Symposium on External Control of Human Extremities*, Dubrovnik, pp. 42-53, 1967.