SOME PROBLEMS OF IMPLANT STIMULATION APPLIED TO GRASP MOVEMENTS

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Summary

The design of implant stimulators and implant techniques applied for assisting grasping movements are discussed.

Tetraplegia occurring in the case of spinal cord damage (or of spinal cord and nerve roots) causes decay of or impairs to a considerable degree the functions of human extremities. In such cases the invalid is confined to his bed or wheelchair, and cannot perform the simplest activities. Paraplegia of the upper extremities makes an invalid completely dependent on the help of other people.

The aim of this study is to make the invalid partly independent and train tetraplegic muscles so as to pervent decay. The application of implant stimulators for evoking purposeful movements of the upper extremities could make invalids feel more independent. It is most often advisable to implant stimulators in the vicinity of the medial and radial nerves.

Experiments with implant stimulators have so far been carried out on four invalids, using 6 stimulators. Those experiments enabled researchers to gather information about parameters of stimulation and stimulators, biological coatings, and on the reaction of the body to an alien object.

It was found that in the case of spastic tetraplegia of the upper extremity, direct stimulation causes contraction of the muscles, as well as uncontrolled contraction of other muscles belonging to the extremity. Stimulation of the nerve enables contraction of one chosen muscle.

The paper discusses some problems concerning the design of proper stimulators, and the implantation techniques. Elaboration of a control system, particularly in the case of tetraplegia, still presents basic problems.

Introduction

The knowledge we now have cannot help in providing restoration of morphological and physiological continuity of the structures within the central nervous system. However, replacement of certain functional defects by electronic circuits gains wider and wider application.

In respect to the people suffering from tetraplegia, the problem is of a most complex nature. Certain functions should be restored in a man who is able to move only his head and his upper limbs, and that to some extent. Another problem is spasticity, even more within the upper limbs; apart from central paralysis, lesions of a neurogenic nature can be found.

The solution should provide the choice of a few basic functions to be performed by the upper limbs, and the choice of an electronic control circuit. In case of spastic paralysis, excitation of the muscles should be obtained by nerve fibre stimulation in order to take advantage of afferent impluses (Dimitrijević, Gračanin). In injuries of the spinal column at cervical level, however, some nerves supplying the upper limb muscles develop inability to be excited. Direct stimulation of the muscle remains the only alternative in this case, but the nerves should also be stimulated in order to inhibit the antagonists by reciprocal innervation.

Classification of Spinal Cord Paralysis at Cervical Level

In cases of complete disruption of the spinal cord in the cervical section, three levels are of practical importance: the fifth, the sixth, and the seventh spinal segments. Complete disruption at C_4 is usually fatal, while lesions below C_7 usually spare the upper limb.

If lesion of the vertebral column is at C_5 level, the spine injury begins at the level of C_6, with concurrent lesion of the C_6 lower neuron.

The muscles of the upper girdle are not affected: the trapezius, deltoid, supraspinatus of the scapula, and flexors of the elbow joint - the biceps and coraco-brachial. The motor function of the following muscles is, however, lost: triceps, extensors of the **carpus** and fingers both teres muscles, the pectorals, and the coraco-brachialis.

The paralysis of two mentioned muscles can be of a neurogenic type (flaccid), or combined. The remaining muscles of the forearm and hand usually manifest spinal paralysis, although mixed lesions are found in some of them.

In cases of spinal cord injury at C_6, the above mentioned muscles of the upper girdle, and the elbow joint extensors remain active, or manifest fesion of lower motor neuron type with a trend towards improvement. The short muscles of the hand, the carpal and the finger flexors, develop spinal paralysis. Mixed lesion may be found in the remaining muscles.

If damage is at C_7, the motor function of the shoulder and of the elbow joint muscles is unimpaired. The extensors of the carpus and the fingers also remain active. The long flexors of the carpus and fingers manifest flaccid paralysis, while mixed lesion is found in the short muscles of the hand.

In cases of peripheral injuries (motor neurons - roots) or mixed injuries with predominance of the peripheral type, stimulation of the nerves is impossible, since the impulse conduction is lost. Direct stimulation of the muscles can be applied in this case. In lesions of "pure" spinal origin, stimulation of the nerve trunk might be useful.

It should be stressed that the classification of injuries presented here is of a general and schematic character. The nerve trunk innervating the muscles usually originates from two or three spinal segments and on individual differences in the nerve supply are no rarity.

Principles for Stimulator Implantation

It is beyond any doubt that functional stimulation in tetraplegic patients can be more successful if implanted stimulators are applied. They provide greater selectivity of excitation, painful sensations in the skin are avoided, and the required intensity of the impulse is not so great. It should be remembered, however, that introduction of an alien body into the human body is always followed by connective tissue response. This response is particularly marked during the 5 - 10 days period after the operation. The reaction does not increase later.

An evidence thereof was found during removal of the surgical material used for various anastomoses (removal of surgical anastomosing material occurred in various periods after the operation). For instance, steel springs used for stabilization of an injured or deformed vertebral column - removed three to four weeks after their setting up were surrounded by a connective tissue capsule isolating them from live body tissues. Similar changes were found in the patients who underwent repeated surgical procedures a few years after the introduction of the alloplastic material.

Tissue reactions must be taken into account in the case of implanted stimulators. Isolating an electrode from the nerve trunk will certainly affect conditions of the stimulation during the first few days following the implantation. A decrease in stimulation efficiency should be expected in this period.

Methods

The investigations we performed can be divided into two groups:

Group 1 - External Stimulation of the Nerve

Nerve stimulation with surface electrodes was performed in several dozen patients, suffering from a complete, or almost complete, disruption of the spinal cord in the cervical section. For the analysis of "pure" spinal lesions, an examination of the lower limbs was also carried out. This material was accumulated in preparation for implant stimulation in the cases of complete paresis and incomplete tetraplegia, performed in order to observe the effect of nerve stimulation on the muscles suppled by these nerves. The electrodes were applied over the tibial and the peroneal nerves in the popliteal fossa. In that way all the muscles of the tibia were excited.

In order to avoid mistakes, the nerves of the left lower limb were stimulated in every instance, while the right limb acted as the control one.

The nerves were stimulated, following Buchtal's advice, with a series of impulses of 1 msec. duration, and frequency of 50 cycles per second. Initially, we applied two-second series, with a pause of five seconds. Since a rapid fading of the motor effect was observed, the method was changed, as per recommendation of Koc and Chwialow, to a ten-second stimulation, and 50 sec. pause. Each nerve was stimulated for 10 minutes, twice a day. Stimulation was started in the first few days following the injury, and continued over a period whose duration depended upon the general condition of the patient, the time of hospitalization, and various other factors. The analysis of the collected data included patients who were observed for at least three weeks. The average period of observation was about 10 weeks. Before the beginning of the stimulation, and after termination of the treatment, an extensive clinical examination was carried out every 2 - 3 days, while measurements of the circumference of the stimulated and contralateral limbs were repeated every 2 - 4 weeks.

The average circumference values at corresponding levels of below and above the knee were recorded, and the average depletion of the muscular tissue was evaluated from these records. This type of studies covered 18 patients; in four of them incomplete disruption of the spinal cord was found upon admission. In the further course of the studies a special measuring stand was constructed (Fig. 1) which enabled continuous recording of the force produced by the stimulated muscle; a more accurate method of evaluation of the stimulation efficiency was thus obtained. These studies have covered six patients so far, and are being carried on.

Group 2 - Internal Inductive Stimulation

It included four patients, in whom the stimulators were implanted under the skin; two of them received one stimulator each, the other two two stimulators. These patients suffered from complete disruption of the spinal cord at C_5 - C_6 level. The terminal parts of electrodes were

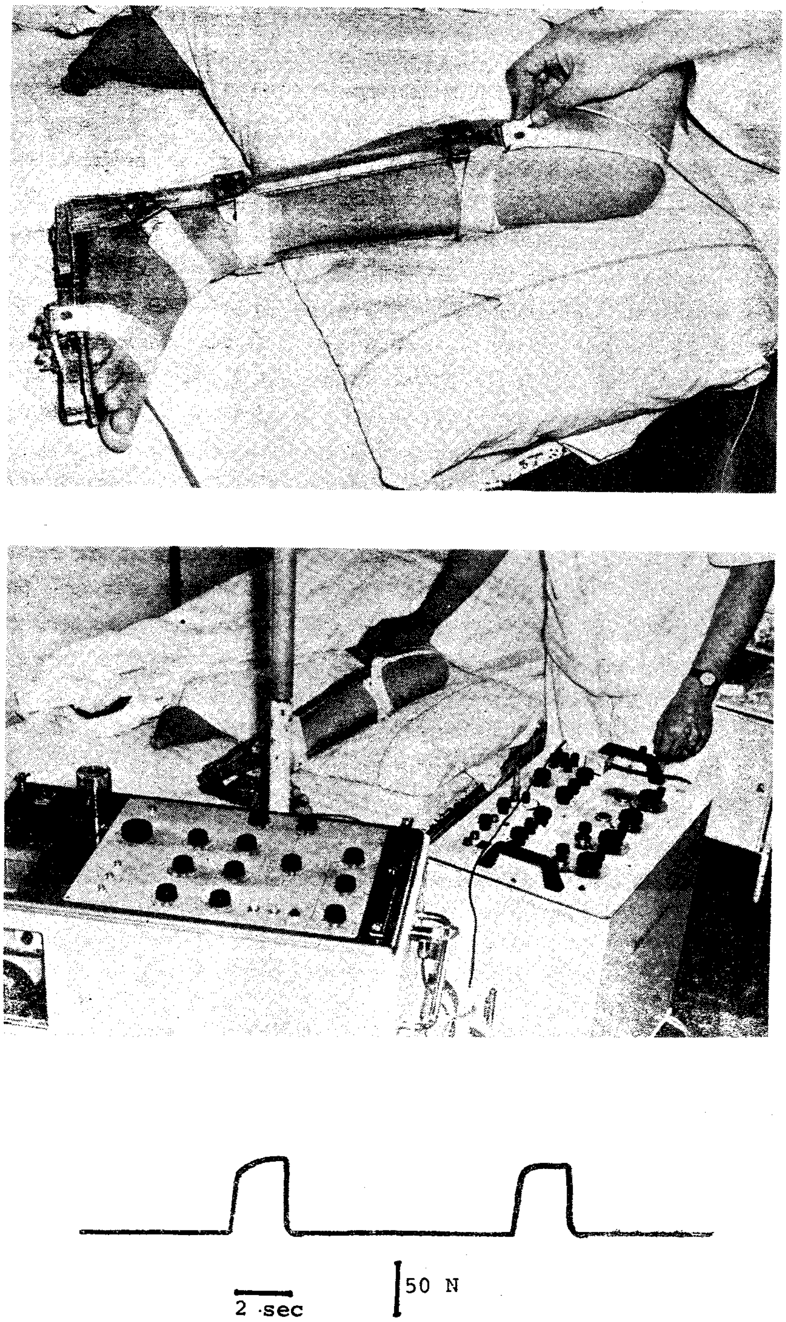
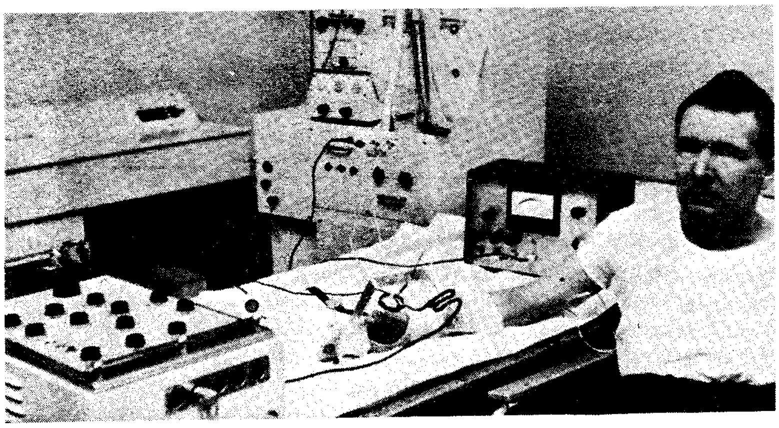


Fig. 1.

placed on the median nerve and, in one case, where direct stimulation of the muscle was necessary, on the biceps. When the operation wound healed, the stimulation was started by means of a programming device supplying impulses in five-minute series with a 55 minute pause. The duration of the impulse was one msec., of 45 cps. frequency. The series of impulses lasted for 10 sec., the pause, for 50 sec. Stimulation was obtained by application over the implanted stimulator of an external coil connected with a feeding circuit. By means of the measuring stand (Fig. 2), the following parameters were measured and recorded every two weeks: maximal value of the force, and its behaviour during a five sec. stimulation; the stimulation was prolonged to 20 seconds, and in some cases up to 30 seconds.



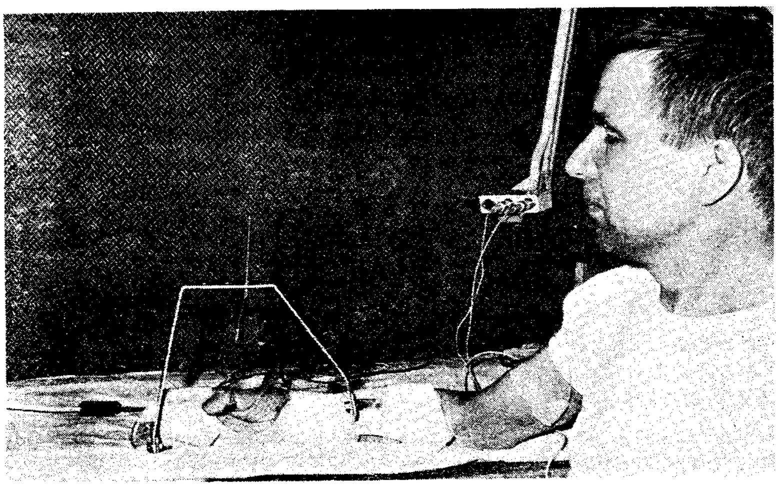


Fig. 2.

The Apparatus and the Implanted Stimulator Circuits

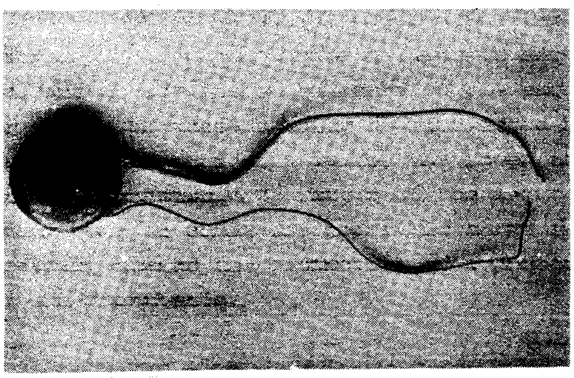
A universal stimulator (Tur Rs-8) was used for external stimulation, and sometimes the Multistim (Disa). In the second group, a special unit of implanted stimulator adapted to our needs was used; in one case a stimulator with voltage output (Fig. 3), and in the remaining cases - a stimulator with a Wattless implanted part (Fig. 4). Simultaneously, an implanted stimulator with current output was constructed and tested. Test results of all three basic units are presented in Table 1.*

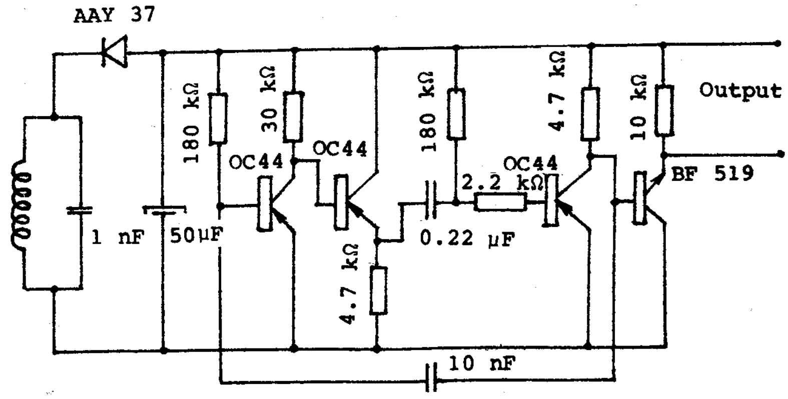
It might be assumed from this table that the current stimulator II provides the most suitable electric parameters. Despite the fact that its implanted sub-unit, in comparison with unit III, contains a greater number of parts, two of them active, the unit provides a wider range of stimulation possibilities. It provides stability of the stimulating current flowing through the body, thus making the effect of the stimulation independent on the tissue changes following implantation, and also on the processes occurring at the tissue-electrode junction. A mathematical analysis proved that the efficiency of energy transmission, with assumption of a maximal power release on the load of the implanted stimulation, cannot exceed 50 per cent. If we assume the efficiency of the external circuit to be 80 per cent, it may be concluded that the actual efficiency of 30 - 35 per cent is close to the maximal value. If there is no such assumption (that of maximal power), an 80 per cent efficiency could be obtained.

We took the latter situation into account, and our present studies aim at an increase in efficiency of the current stimulator, and also at a different technological design providing greater reliability. Some of our hopes for the future are connected with this new unit, since after an increase in the supply voltage of the impulses generator has been obtained, the permissible range of load changes with maximal output current could be increased, which is particularly important in direct stimulation of a muscle.

In the first stage, however, reliability of the implanted stimulator is of primary importance, since surgical and biochemical techniques are tested simultaneously. Not less important is a proper choice of the cases, the design of electrodes, the technique of their

*Implanted stimulator circuit means a transmitter-receiver unit, namely the implanted stimulator, and its external feeding circuit.




AAY 37
180 kΩ
30 kΩ
OC44
OC44
180 kΩ
OC44
2.2 kΩ
4.7 kΩ
10 kΩ
Output
BF 519
1 nF
50μF
4.7 kΩ
0.22 μF
10 nF

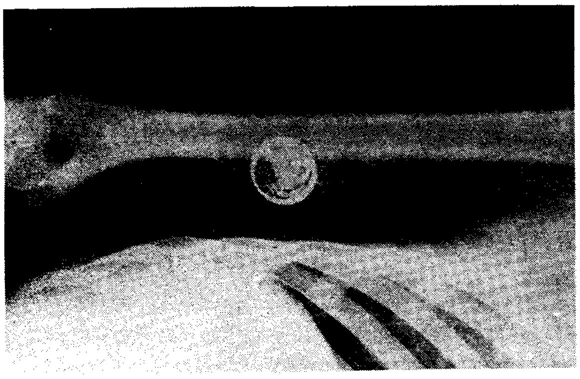


Fig. 3.

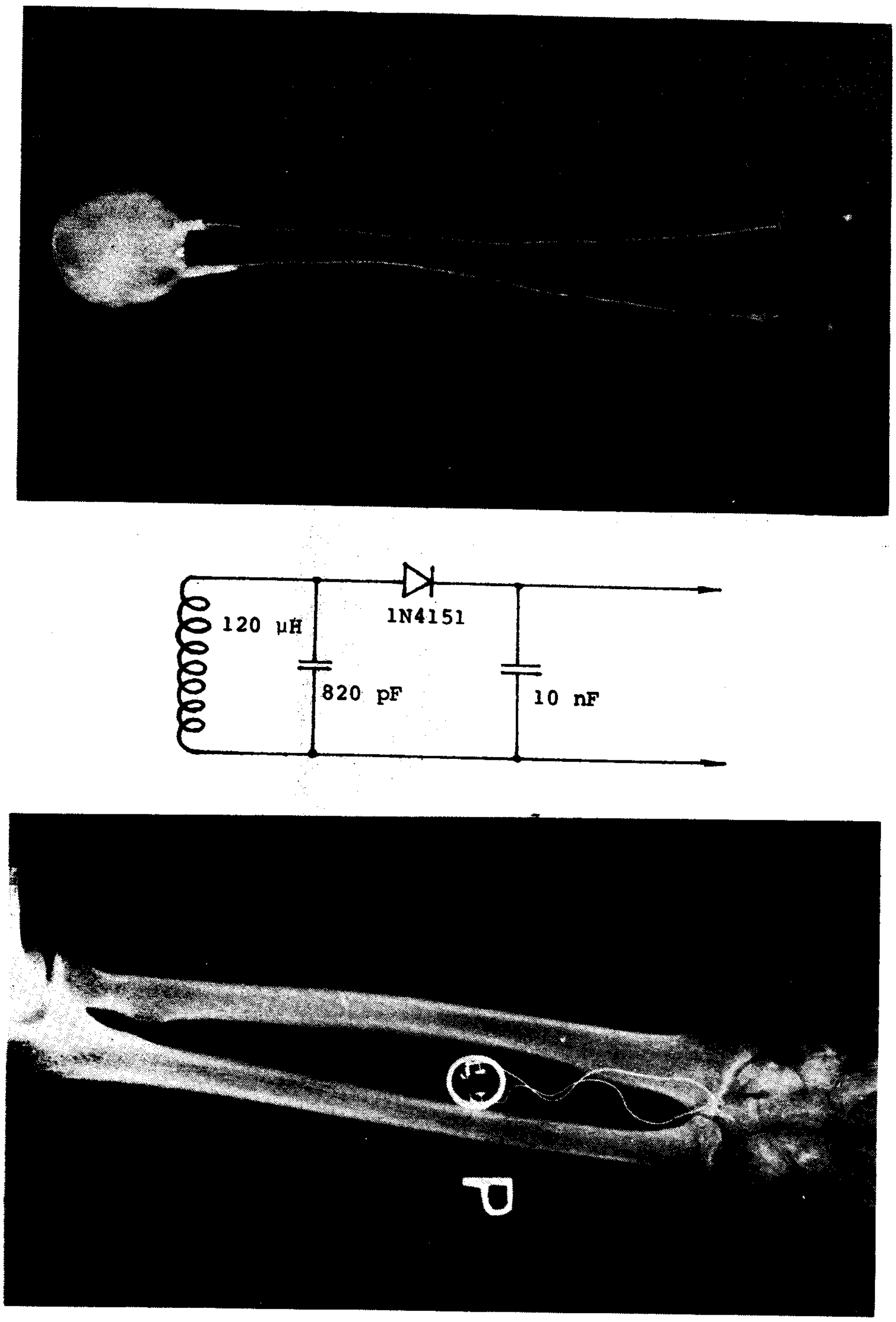


Fig. 4.

Table 1.

No.	parameter or criterion	I voltage stimulator	II current stimulator	III passive stimulator
1	Impulse duration	Constant	Adjustable 0.5-4m.sec.	Adjustable 0.2-3m.sec.
2	Impulse duration	Constant	Adjustable 20-70cps	Adjustable 20-80cps.
3	Amplitude of current impulse or voltage	3 - 30 V	5-30 mA and more	0 - 22 V not more
4	Maximal average current consump. from battery	ca 30 mA	ca 22 mA	ca 15 mA
5	Maximal power consumption	270 mW	200 mW	ca 3 W in imp average 140 mW
6	Maximal energy efficiency	25-30%	over 30%	ca 36%
7	Impulse lag	6%	5%	ca 4%
8	Voltage or current alterations with load resistance ±25 per cent	+4% -6%	±3%	+10% -12%
9	Current consump. from internal resonance circuit	ca 4.5 mA	2.3 mA	50 mA
10	Total number of elements	17	11	4
11	Number of active elements	4	2	0

implantation, and the choice of biological screening and isolating materials, neutral for the stimulator and its electrodes. Introduction of complicated and technologically difficult circuits would produce considerable difficulties for the accomplishment of the program of our studies. This is why unit III, namely the passive stimulating circuit, initially attracted the greatestattention.

A series of measurements performed on exposed muscles and nerves during surgical procedures confirmed the assumption that an approximate voltage of 20 V, and power of 1 Watt carried by the impulse on the electrode are sufficient to provide a regular stimulation effect, even in most unfavourable cases. Having in mind, however, the advantages of the implanted stimulator, we can anticipate its introduction in the tests, after problems of a technological nature have been put under control.

It was observed during laboratory investigations and clinical tests that if the accurate amplitude value of the stimulus is unknown, the interpretation of the effect is extremely difficult. It was found that determination of this parameter by an external measurement involves too big an error, while measurement of low values of output voltage of the stimulator (about 1 V) is practically impossible. Thus, a more accurate and simultaneously less complicated method of measurement has been worked out.

Following numerous trials, a telemetrically controlled implanted stimulator was designed and tested. A block diagram of the complete unit is represented in Figure 5. In Figure 6 - a detailed diagram of the implanted stimulator III (passive) with telemetric circuit can be seen. The operation principle is illustrated in the block diagram. The implanted stimulator operated by an external circuit was additionally fitted out with a frequency generator operating in ultra-high frequency (UHF) range. The generator is directly operated by impulses from the output of the implanted stimulator, to which the electrodes are connected. The impulses produce oscillations of the stimulating generator, thus an electromagnetic wave of 40 - 50 MHz frequency is propagated. The frequency of the UHF generator oscillations depends on the value of the supply voltage, namely on the amplitude of the stimulating impulse. The curve in Figure 7 presents correlation of the frequency to the impulse amplitude. It is nearly linear, within the range of 1 - 14 V, while a deviation of the curve appears for higher values.

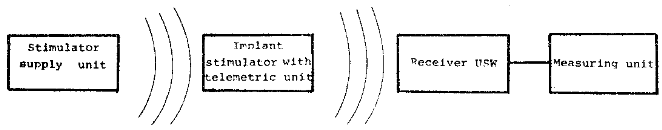


Fig. 5.

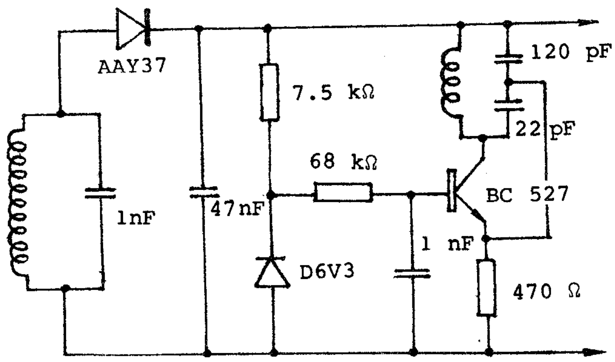


Fig. 6.

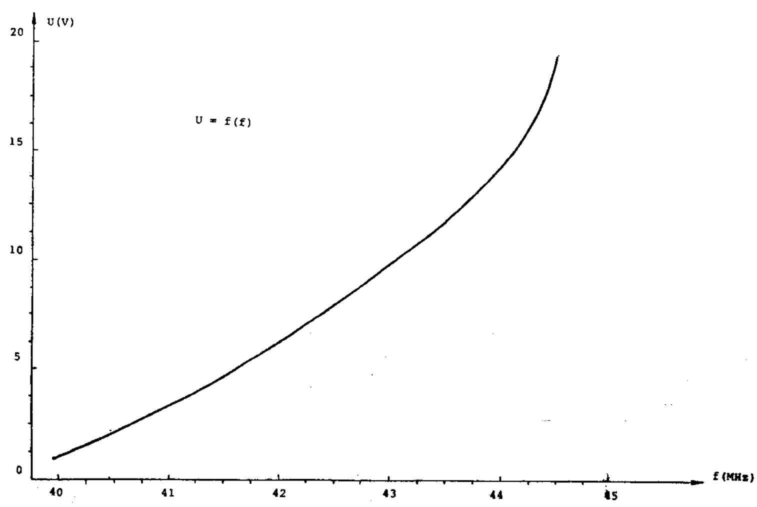


Fig. 7.

Results of Clinical Investigations

The performed studies aimed at evaluation of rapidity of muscular atrophy in patients with tetra- and paraplegia. Selective measurements at definite levels above and below the knee illustrate the progress of atrophy. Calculated values of the decrease under the circumference of the non-stimulated limbs (in cm.) at the above-mentioned levels are presented in Table 2.

Table 2.

Weeks after injury	2	4	6	8	10	12	16	22
Measurement (2 cm.)	1.4	3.2	5.0	6.8	6.9	7.0	7.1	6.8
Measurement (5 cm.)	1.5	2.1	3.6	4.8	4.8	5.3	5.3	4.8

It should be stressed that the evalation presented here considers neither the contralateral nor ipsilateral effect of stimulation of above-knee muscles, nor muscles of the contralateral limb; it is nevertheless evident that the progress of atrophy is dynamic, particularly in the first 8 weeks following the injury of the spinal cord. The further progress of atrophic changes is much slower, and after 16 weeks a small increase in the muscular tissue can be observed. This may be due to spasticity of muscles which appears in this period.

A comparison of average losses within the stimulated and opposite limbs, during various periods after the injury, proves that circumference differences above the knee are not significant, which suggest that the influence of ipsilateral exercises of the shin muscles on the thigh is negligible in these cases.

On the other hand, circumference differences below the knee are significant. In most of the cases the decrease was two- or threefold smaller in the stimulated limb.

The next problem that attracted our attention was the development of spasticity in stimulated patients. There prevails a widespread opinion that stimulation in the case of a central nervous system injury increases spasticity. This effect should considerably restrict application of stimulation. However, results of clinical observations and electromyographic tests permitted us to disagree with this opinion.

The effect of stimulation on the metabolic condition of the tissues also requires further investigation. Contraction of muscles following stimulation pumps out residual venous blood from the tissues, which facilitates removal of metabolic wastes. Thus, the condition of the tissues should be improved. Evaluation of atrophic changes, and preservation of the contractile force of muscles are the next problem to be considered.

Experiments on stimulation performed by Koc and Fidelus on healthy subjects support advisability of stimulation as a therapeutic measure, and this has been confirmed by our data. The first stimulator was implanted in a tetraplegic patient several months after spine damage at the C_6 - C_7 level, when spasticity was well developed. He could only move his head and, to a minimal extent, the shoulders and forearm (Fig. 8)

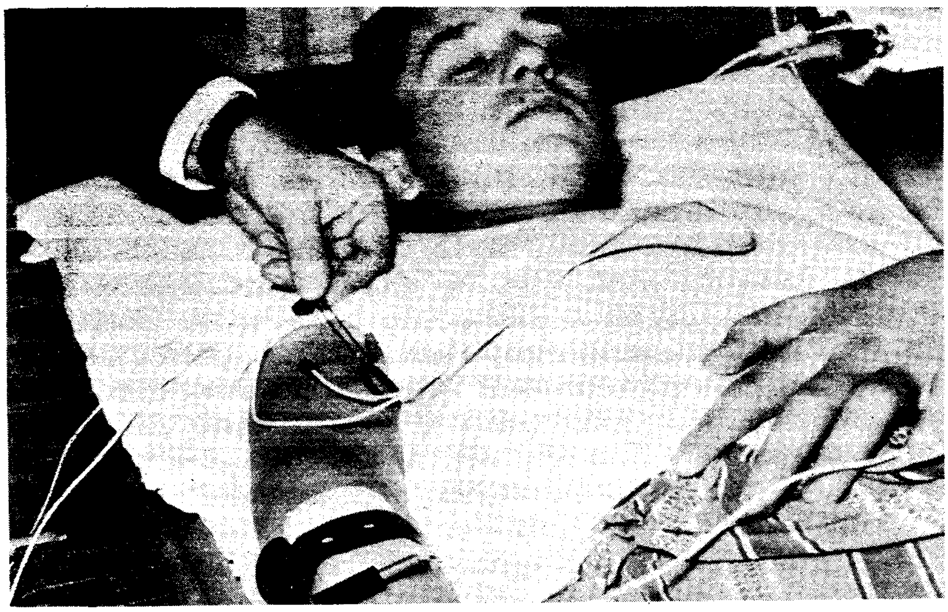


Fig. 8.

The stimulator was placed under the skin on the inner surface of the right arm. Electrodes were introduced into the biceps. During excitation of the stimulator from an external coil fed from a generator, a weak muscular contraction could be obtained. When the coil was moved around the stimulator muscular contraction was more pronounced, and it was accompanied by a minimal flexion in the elbow joint. These movements could be increased if the muscle was stimulated with surface electrodes, but this was followed immediately by a vigorous extension in the elbow. This might be assumed as being a component of a general spastic reaction from extensors in the upper limb, and reaction from flexors in the lower.

The results of this experiment prove that, in tetraplegic patient with central paralysis and developed spasticity, stimulation of muscles through the skin should not be recommended, as it precipitates a general spastic reaction.

The stimulator was removed after 4 months, as it was damaged in an attempt at increasing the stimulus amplitude obtain greater efficiency. Both the stimulator and the electrodes were surrounded by a thin, connective tissue capsule, confirmed by histological examination.

In later experiments electrodes were placed adjacent to the nerves (Fig. 9) in order to take advantage of reciprocal innervation. In this situation muscular contraction and movements do not produce any stretch reflex in the antagonists. When this stimulation technique was applied, a several-fold increase in muscular force was obtained in two cases, while loss of muscular tissue was minimal. Only small changes in the limb circumference were observed. In one of the patients the force of the opponens pollicis increased from 220 gr at the beginning of stimulation (two months after injury) up to 1260 gr, a six-fold increase after 6 months of training. The force of the opponens pollicis during a 5-sec. stimulation remains constant. When 20-second pauses between successive stimulations are introduced, even after dozen or so stimulations, the force changes only slightly with respect to the initial value. The values of the force during stimulation prolonged up to 30 sec. in the initial period were as follows: up to 10-11 sec. a slight drop is noticed; then, till the 18th second, an almost linear decrease; from the 18th to the 30th sec. - another slight drop, and in the 30th second the muscular force is 60 - 80 per cent of that in the first second (Fig. 10).

These phenomena were also found in several patients in whom the peroneal nerve was stimulated with surface electrodes. Similar variations of muscular strength could not be obtained at direct stimulation of the muscle. The conclusion is that, during continuous stimulation of the nerve, the stimulated fatigued motor units are exchanged for fresh ones. We plan to confirm this hypothesis in further experiments to be performed on a greater number of patients.

During an intermittent stimulation (1 swc. pause) it was observed that the final value of muscular force, after total stimulation time of 30 seconds, is 30 - 50 per cent of the initial value, in both implanted simulators and external stimulators. It may be assumed that static work leads to less fatigue of the muscle or nerve than a dynamic

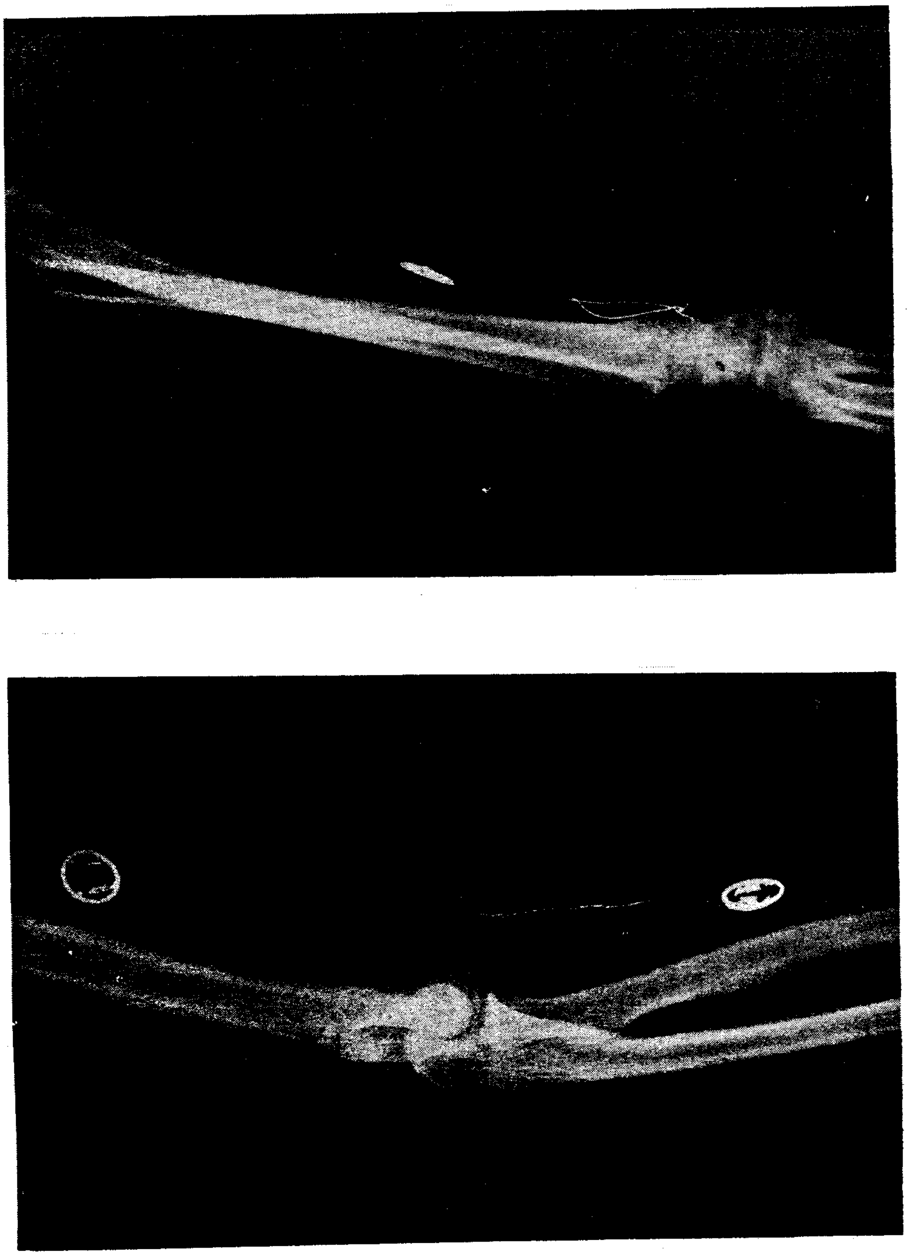


Fig. 9.

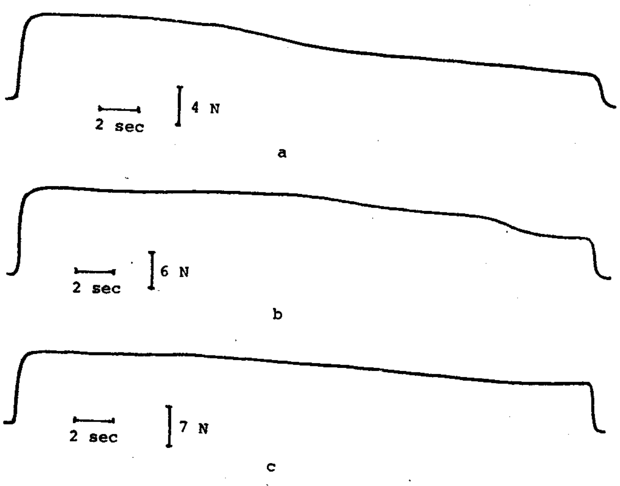


Fig. 10. The course of force at stimulation from an implanted stimulator (30 seconds' duration):
(a) in the early period of stimulation,
(b) after three months of stimulation,
(c) six months after starting stimulation.

one under the same nutritional conditions (Kozlowski). Our apprehension with respect to influence of the connective tissue reaction upon the stimulation conditions has been confirmed too. Even during the first week, a substantial increase in the force of the stimulus was necessary to obtain the same effect as at the beginning.

In the course of several weeks following the implantation, the conditions of stimulation do not deteriorate. On the contrary, a certain decrease of the threshold values can be observed. We are not in a position to explain this effect. It seems, however, that after investigations on the effect of the electrode size on the stimulus force have been completed, we will have a clearer picture of the matter.

Neither any tendency to stimulator rejection, nor any harmful body responses were observed in our patients. The longest period of observation of a patient with an implanted stimulator was nine months.

In another of our patients, in whom the stimulator had to be removed (because of electric disconnection) during the fifth month after implantation, histological examinations confirmed the presence of a connective tissue capsule around the stimulator.

Conclusions

Results of investigations performed in tetraplegic patients proved that:

1. Implanted stimulators remaining in situ over 9 months have not produced any abnormal reaction.
2. Implanted stimulators provide convenient conditions for stimulation, making painstaking exploration for excitation points unnecessary.
3. Stimulation can inhibit progress of atrophic changes in the muscular tissue and loss of its excitability.
4. Stimulation enables some voluntary movements of the limbs in tetraplegic patients.
5. Introduction of stimulation early after injury seems advantageous, since greater contractile force of the muscles can be obtained, together with smaller loss of muscular tissue compared with cases where stimulation was started several months after injury, with atrophic changes well developed.

We believe it is of great importance to ensure full proprioception to the damaged spinal cord. This can be achieved only by a full isometric muscular contraction.

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