ELECTRICAL STIMULATION OF SKELETAL MUSCLE BY DIRECTLY POWERED IMPLANTED R.F. RECEIVERS

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In the period of advanced progress of technics the number of disabled persons is increasing. This is the reason for development of Electrical Stimulation (ES). The surface method of ES has some disadvantages: placing and skin contact of electrodes, intermediate tissue influence, and connecting wires. In order to avoid these effects and to reduce current requirements we decided to implant the electrode in the muscle at the point where the best response to stimulation is obtained. We decided on intramuscular stimulation.

To avoid the connecting wires from external energy supply, R. F. energy transmission was applied. For this reason miniature receiver-stimulators were designed and implanted in the bodies of test animals. With the R. F. transmitter modulated in the rhythm of stimulating impulses, functional movements were achieved.

In certain cases the undamaged muscle cannot perform its function. The lesion is central or in the efferent pathway from the centre to the motor unit. In such paralyzed muscle external control can be applied if the mechanism of motor innervation is known. The nerve centre controls the muscle contraction by nerve impulses. When the nerve impulse reaches the motor-nerve termination acetylcholine is released preceding the muscle contraction. The same nerve impulse may be provked by a suitable electrical stimulus.

There is an »all or none« relationship between the stimulus and response. So the degree of muscle contraction depends only on the number of fibres activated and the frequency of stimuli and in the principle not on the amplitude of stimuli.

By our present stimulation technics described in this paper we cannot imitate this system of the contraction control. But we can make use of the geometry of the electrodes and muscle fibres. So with the amplitude of the stimuli we can control muscle contraction. To improve the plasticity of the contraction we are studying the realization of differential stimulation of separate fibre groups.

The Shape and Parameters of Stimulating Impulses

To get more information about intramuscular stimulation some preliminary experiments were performed. The skeletal muscle of the test animal was isolated and optimal conditions for ES at minimum energy consumption were determined. In the same conditions the stimulation with A. C. and D.C. impulses was compared. The amplitude of stimuli causing the same degree of muscle contraction was measured and we did not find any difference. We consider the A. C. stimulating pulses to be more convenient, because they avoid the polarisation effects. But for the sake of miniaturization and reduction of elements in implanted circuitry the receiver-stimulator was designed later to deliver in the first approximation D. C. rectangular pulses.

Then we studied the optimal parameters of stimulating pulses. At frequency constant we measured the amplitude producing tetanic contraction and pulse duration varied from 0.1 ms to 1 ms. The frequency range from 20 Hz to 1000 Hz was examined. The results are shown in the diagram (Fig. 1).

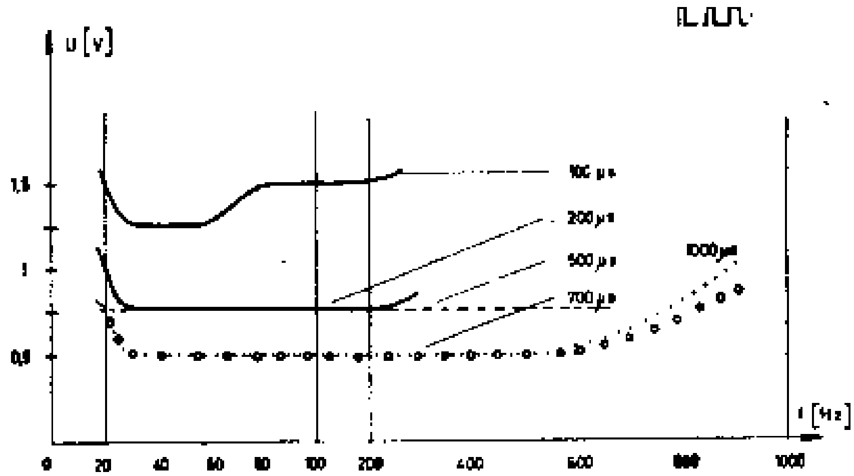

Figure 1.

At frequencies higher than 30 Hz the contraction occurs at the same amplitude and pulse duration constant. We decided to stay in a frequency range from 30—100 Hz. For frequencies under 30 Hz and higher than 200—300 Hz the amplitude is increased. The absolute value of the amplitude depends on the location of electrodes and is minimal when the negative electrode is placed at the motor point of the muscle. The current amplitude depends on unisolated surface (active surface) of the electrodes. We used the bipolar technics. At the measurements described the electrode distance was 30 mm. The electrodes were placed along the longitudinal axis of the muscle.

The influence of the change of the electrodes polarity was observed. If the negative electrode at the motor point was replaced by the positive one, the amplitude of the stimulus had to be increased by 30%.

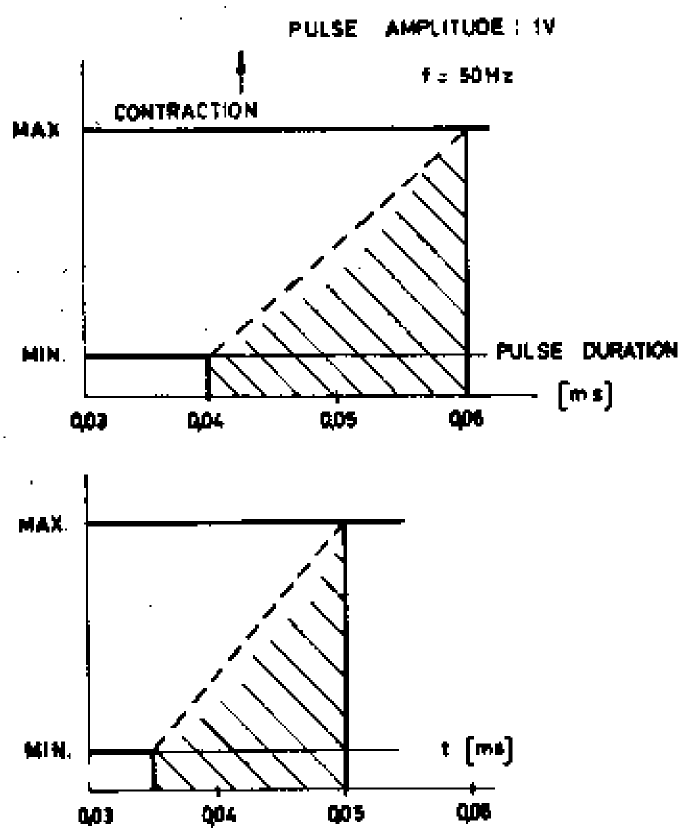

Figure 2.

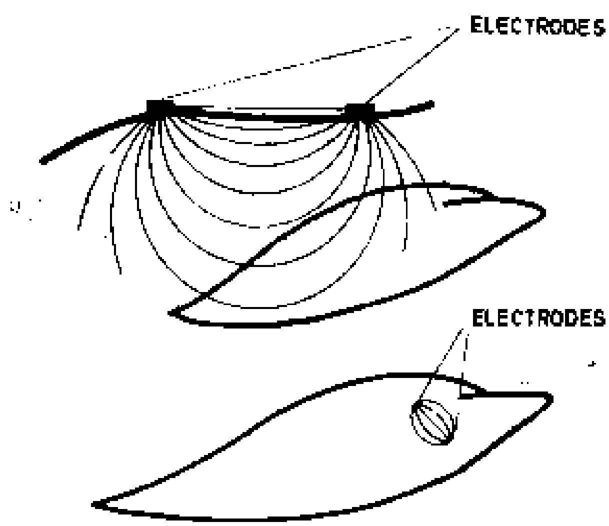

Figure 3.

In the experiment with dog No. 3 we succeeded in isolating the motor neuron. Maximal contraction was obtained with electrodes placed on the surface of the myelin sheath at 300 mV. Because the preparation of the neuron is very difficult, this method is not recommended for practical application. In experiment No. 15 we studied the possibility of regulation by means of control of amplitude and duration time of the stimuli at constant frequency. For certain location of

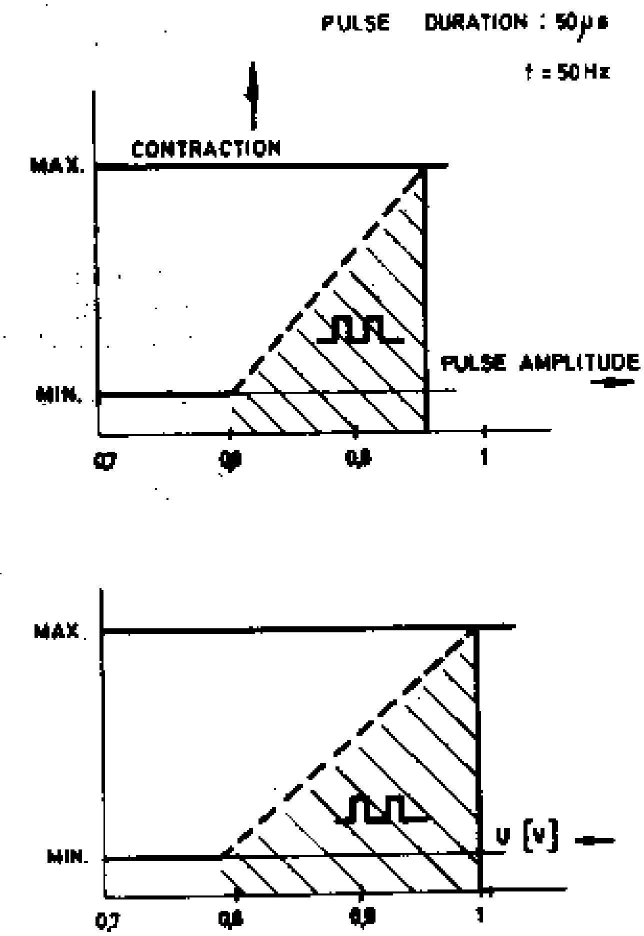

Figure 4.

electrodes and stimulating impulses of frequency 50 Hz and amplitude 1 V, we obtained the result shown in the diagram (Fig. 2). The regulation can occur in the range of width of 0.02 ms. For slight differences in location of electrodes the result is shown in the same diagram. The width of the range is 0.015 ms.

We can see that range of regulation is very small compared with surface stimulation. We explained this with different geometry of electrodes and muscle motor system in the surface and intramuscular electrodes. Figure 3 shows a very different shape of electric field in both cases. This is the origin of great differences in the range of regulation and amplitude in both cases.

We measured also the range of amplitude regulation. One of the results is shown in Figure 4. For pulse frequency 45 Hz and pulse duration 0.05 ms, the range of regulation was measured from observable to tetanic contraction. The width of the range is 0.2 V and for slightly changed location of electrodes 0.15.

Receiver

For the construction of the receiver the method of energy supply is of great importance. There are two basic types:

1. The receiver is R. F. powered from external source (Fig. 5).
2. a. The battery is part of the receiver (Fig. 6).
   b. The battery of the receiver can be R. F. recharged. The energy is transmitted as in 1.
   c. Chemical or mechanical internal conversion of energy.

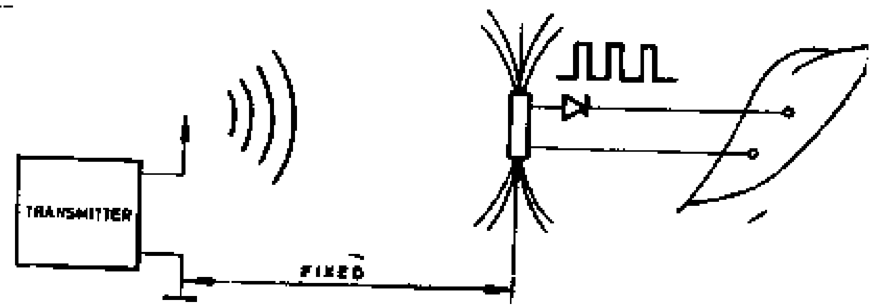

Figure 5.

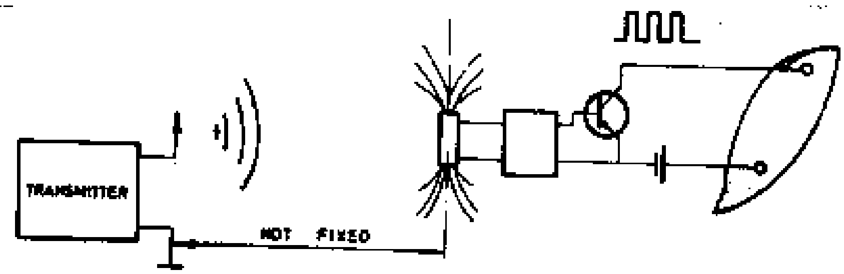

Figure 6.

We called type 1 direct R. F. stimulation. Each energy package is at the same time the stimulation impulse and energy is supplied in the rhythm of stimulating impulses.

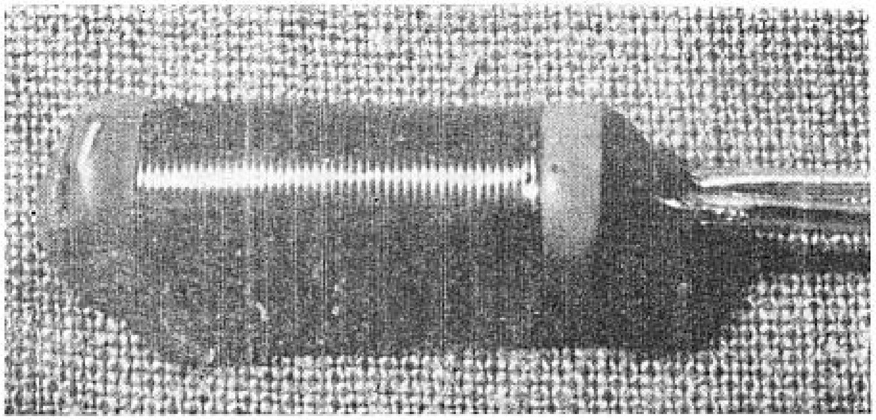

Figure 7.

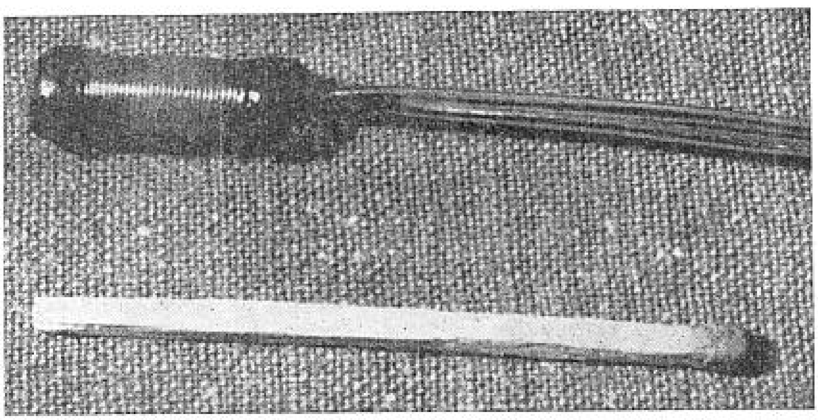

Figure 8.

The constructed receiver is shown in Figure 7 where an inductive coil on the ferrite tube can be seen. In the lumen of the tube the elements are mounted. The smallest receiver of this kind was cylindrical receiver 15 mm long and 4.4 mm in diameter (Fig. 8). The type 2 was designed to avoid the influence of the distance transmitter — receiver on the amplitude of stimuli. We wanted to control the stimulation using the same transmitter power at various distances and in a certain region independent of the distance to the transmitter. The control and power supply were separated in the case of type 2. We are constructing this stimulator in phototechnics which allows for satisfactory miniaturization.

In studying the materials for encapsulation we considered the electrical isolation, moisture protection, strength of the material, and biologic stability.

We tested the following materials: epoxy resins, silicone rubbers, teflon, and polyethylene.

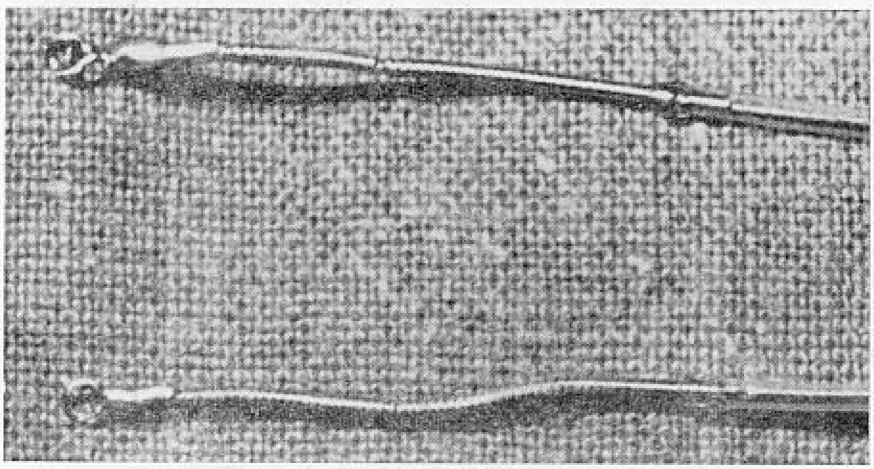

Figure 9.

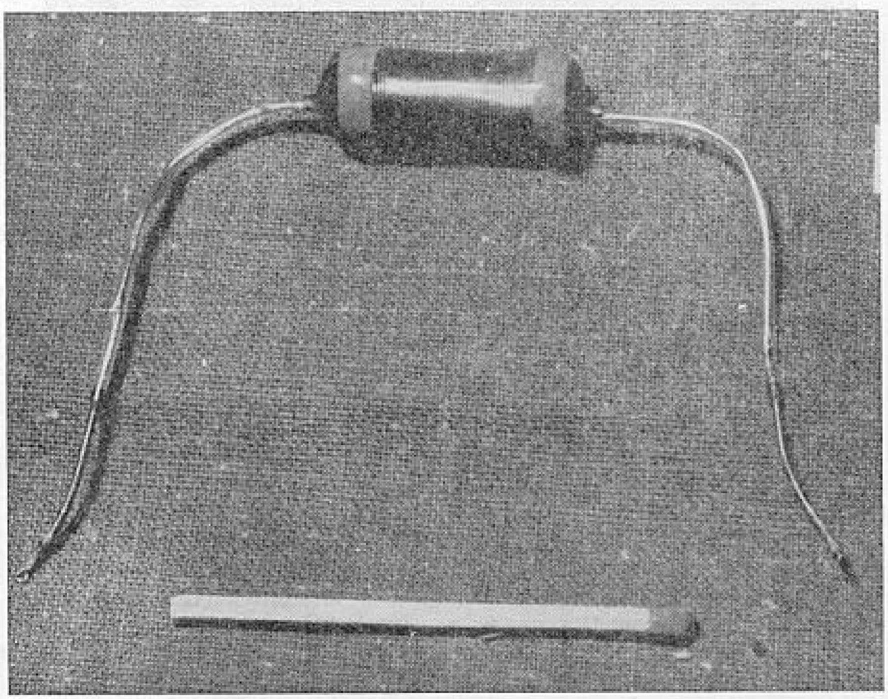

Figure 10.

Electrodes

The electrodes are exposed to constant mechanical stress and when choosing the suitable material its mechanical strength must be considered in the first place. The active surface and the insulation of the electrode should be biologically stable in the physiologic medium. The most frequently used materials are stainless steel and platinum-iridium.

Three types of electrodes were constructed and tested. They vary according to the construction of the active electrode surface and the method of fixation — Figures 9 and 10. For the application in patients we intend to use the Pt spiral wire with stainless-steel multistrand wire as a core. The electrode wires should be insulated by teflon tubes.

Transmitter

Several types of transmitters were designed. In the block diagram (Fig. 11), the principle of the transmitter construction is shown. In our experiments the transistorized circuit was employed as shown in Figure 12.

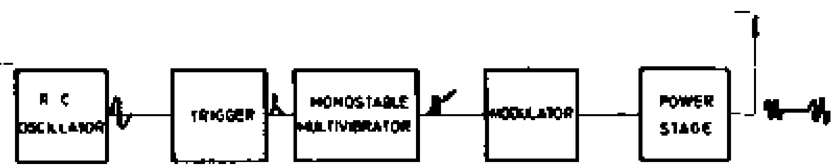

Figure 11.

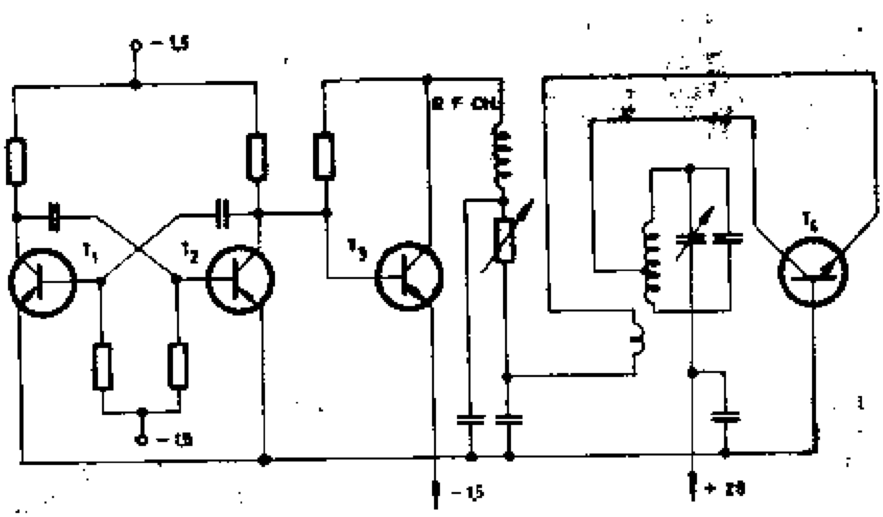

Figure 12.

The Implantation Techniques

Dogs of bigger sizes were used as test animals. Musculus quadriceps femoris of the hind legs of the dog was chosen because it can be easily approached during operation. It is an extensor muscle. No Curare or similar drugs were administered during anaesthesia.

A longitudinal skin incision was done above the upper part of the hind extermity. After incision of subcutaneous tissue and fascia the quadriceps muscle was exposed and bleeding was controlled. By means of special needles with an exactly defined active surface the motor point of the muscle was located. The negative electrode was placed into the cranial part of the muscle (Fig. 13). The negative and the positive electrodes of the receiver were sewn into the point previously determined with test electrodes.

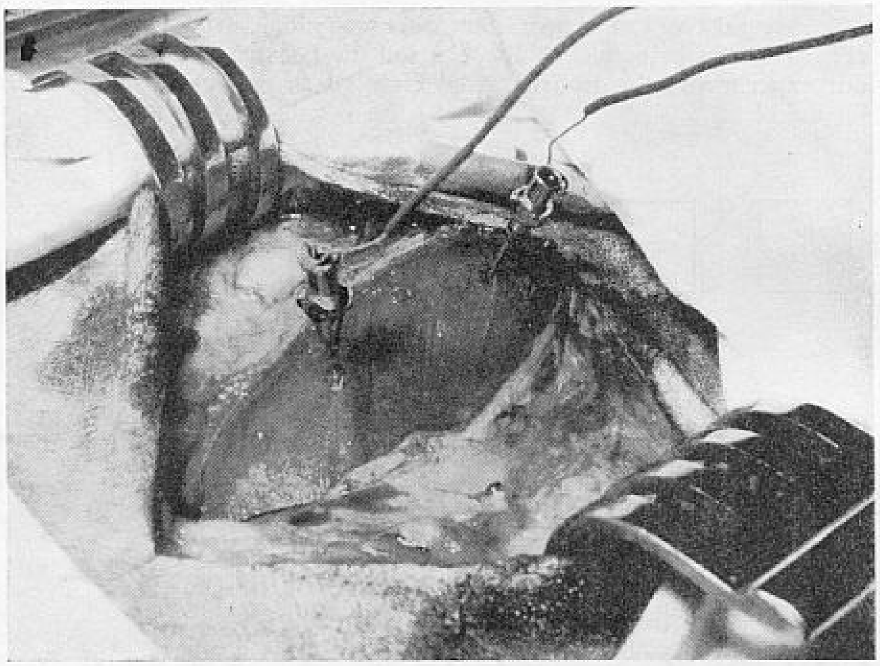

Figure 13.

The test of the receiver and the implanted electrodes was done with the transmitter (Fig. 14). Sutures of muscular fascia were followed by the implantation of the receiver into the subcutaneous tissue. Subcutaneous tissue and skin were sutured afterwards. Aseptic techniques were adhered to during the operative procedure. The receiver and the electrodes were sterilized by immersion into sterilizing solution for 24 hours.

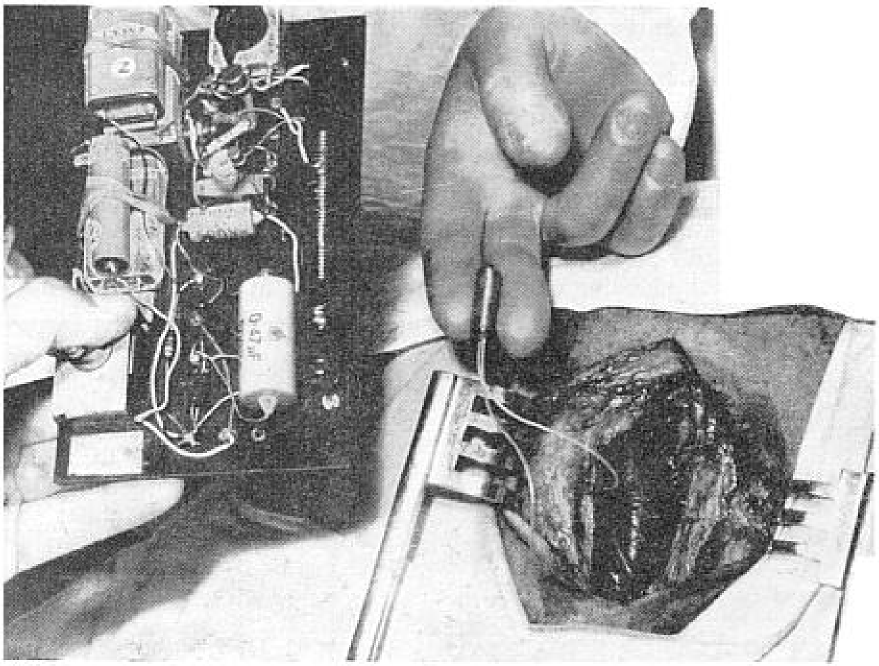

Figure 14.

Experimental Work

Fourteen receivers were implanted into 14 test animals. The experiments lasted for 15 months. The receivers varied regarding shape and construction. We also used the same type of the receiver for stimulation of smooth muscles. The longest period of observation of the receiver implanted in the body of the dog was about one year. In seven dogs autopsy was performed after euthanasia. The remaining seven dogs are still under observation. In one dog the receiver ceased to function after two months and in another dog four months after implantation. The autopsy revealed that the mistake was in both cases the same, occurring in the same place. The interruption of the electrode at the exit from the receiver occurred because of the mistake in the technologic process.

In all other animals the receiver and the electrodes were fibrously grown into the surrounding tissue and did not cause any clinical difficulties or changes, which was proved by macroscopic and microscopic examination of the tissue.

In Figure 15 we can see the receiver grown into the surrounding tissue. The membrane enveloping the receiver can also be seen. Histologic examination were performed.

On the ground of the final findings we decided to use in our further experiments the following encapsulating materials:

Araldite E, Ciba, with HY 956; The use of Erosil is still in the stage of investigation.

Teflon, Huth Asbest, München.

Medical Grade Elastomer 382, Dow Corning, Michigan.

The instructions of the manufacturer were considered in establishing the technological process of encapsulation. The functioning of the receiver was examined for the first time during the implantation and immediately after operation. The regular control stimulations were started after the healing of the operative wound at intervals of 10 days.

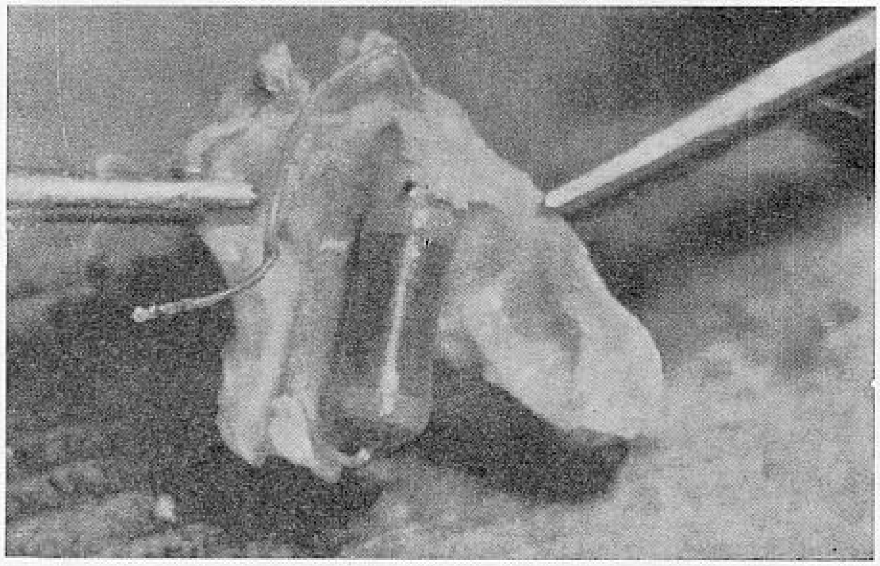

Figure 15.

Almost in all animals the receiver was placed subcutaneously. The degree of the contraction or intensity of the movement was controlled by the distance of the transmitter or amplitude modulation of the same. In both cases the signal to the input of the receiver was changed. This is possible in the laboratory experiment and not in practical use in eventual human experiment. The second method of the control was to fix the distance. Changing the frequency of the transmitter in the range of half the resonant curve of the receiver, the output was regulated from 0 to maximal value.

We concluded that for practical use a system should be designed where the stimulation control would be independent on the distance between transmitter and receiver. Adequate circuits were described in the chapter on the receiver. The devices are still evaluated.

The next step in the development of implanted R. F. stimulation should be the construction of the electrodes and an adequate receiver enabling the diferentiated stimulation of separate groups of motor units of the muscle with the adequate phase shifts to imitate the natural plasticity of the contraction. This is the object of further work of our research group. We implanted the miniaturized receivers in the bodies of test animals. Prolonged control of functioning was carried out. Various kinds of R. F. power-transmission muscle stimulation were tested. With this intramuscular method functional stimulation and simple movements were obtained. The problem of combined and complex movements is the object of special study and investigation. Improved implanted stimulation is expected to enable further progress in the investigation of this field.

Our work was performed with the aim of helping the disabled. The disabled muscle should regain its ability to exert movements.

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