

CONSIDERATIONS FOR USING THE NERVE SIGNALAS A CONTROL SOURCE FOR ABOVE-ELBOW PROSTHESES

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ABSTRACT

This paper presents arguments and experimental observations to support the concept of employing nerve signals for controlling electrically driven prostheses. Direct neural control would enable the prostheses to perform more "natural" functions in accordance with the volitional commands of an amputee.

An electrode for recording nerve signals was designed and tested. Several electrodes have been implanted around severed peroneal nerves of rabbits. Results show that when appropriate design considerations are taken into account, the enclosed nerve suffers minimal damage and that the electrode can record electrically stimulated compound action potentials for periods up to 244 days (the longest implant tested to date). A modified version of the electrode was built to correct some of the shortcomings of the original electrode. Specific consideration was given to eliminating the recording of the concurrent EMG signal. Two of the modified versions have been implanted thus far and the preliminary results are encouraging. They indicate the possibility of chronically recording and isolating nerve signals from the unwanted EMG signals.

### INTRODUCTION

The problem of providing a suitable method of controlling prostheses, especially upper-limb prostheses, has been germane to their development. In order to overcome some of the shortcomings of conventional mechanically operated prostheses, various approaches have been employed. In the case of upper-limb prostheses, one of the most promising approaches has been the use of the electromyographic (EMG) signal to control an electrically driven device. The first such device used EMG signals to effect the movement of a prosthesis in an "on-off" manner. However, there were two major physiological disadvantages of this system. Firstly, the EMG signal used to control the movement was recorded from surrogate muscles not ordinarily involved in the activity to be duplicated. Secondly, the patient was not able to modulate the output (position, force or velocity) of the terminal device. Hence, the effective control of the prosthesis required an attentive, conscious effort on the part of the amputee. Such systems have met with limited success.

A different conceptual approach was proposed by a Harvard-M.I.T. - Liberty Mutual Insurance Co. team of investigators. They proposed that EMG signals used to control the motion in prostheses be derived from muscles that normally performed the required function in the intact extremity. The motion in a prosthesis actuated in such a manner would be "volitional" in the sense that, theoretically, the patient would merely desire a particular motion in order to spontaneously set off a chain of events beginning in the pre-central gyrus in the cortex and ending with the contraction of the appropriate muscle(s). Since the extent of the muscle contraction and the EMG signal would be a function of the volitional demand of the patient, the output of the prosthesis could be continuously modulated by the demand of the amputee. This approach has the advantage of reducing the muscle function retraining required for effective prostheses control. In addition, it enables the amputee to perform the motions in the same natural, essentially reflexive manner that he normally performed them in the intact extremity. As a result of the above considerations, an above-elbow prosthesis was developed which was capable of proportional elbow flexion and extension by the command of the EMG signals generated from the biceps and triceps muscles respectively. Further description of this prosthesis, now known as the "Boston Arm", can be found in the literature (1,2,3).

From anatomical considerations it is obvious that the Boston Arm approach severely limits the motions and degrees of freedom possible in an above-elbow prosthesis since the muscles controlling the hand and forearm motion have been ablated. Thus, in order to obtain volitional, non-mechanical control of additional degrees of freedom, it is necessary to harness other "signals" or "information" from the amputee.

Recently, pattern recognition approaches have been used to associate the EMG signal from the remaining muscles on a limb or shoulder girdle with a functionally distinct movement of the limb (4,5,6). This appears to be a worthwhile approach, but has some practical disadvantages. It will require a relatively large number of recording electrodes whose individual impedance must be maintained constant with respect to that of the other electrodes. The muscles and particular EMG signal pattern used will depend on the type of amputation, resulting in a detailed prosthesis fitting procedure. If the function to be duplicated is sufficiently removed from the surrogate control muscles, the EMG signals will not be related to the movement. For example, the EMG signals from the muscles in the shoulder girdle cannot easily be related to the movements of the hand with respect to the forearm. The muscles controlling the movements of the hand and the muscles in the shoulder girdle are supplied by separate nerves and the hand can be moved with respect to the forearm without generating any appreciable moments about the shoulder.

In the case of above-elbow prostheses which ideally require several degrees of freedom an alternative control approach may be possible - that is, direct neural control. Although the muscles normally controlling the desired functions may no longer be present, the peripheral nerves that contain the motor neurons to these muscles are accessible in the remaining part of the arm. If it were possible to record the nerve signals on a chronic basis, the viability of this approach could be tested.

#### APPROACHES

Three essential functions of the upper limb are flexion-extension of the forearm, pronation-supination of the forearm, and opening-closing of the hand. Flexion of the forearm is governed by the musculocutaneous nerve and extension by the radial nerve. Pronation of the forearm is governed by the median nerve and supination by the radial and musculocutaneous nerves. Opening of the hand is governed by the radial nerve and closing of the hand by the median and ulnar nerves. Three nerves, the musculocutaneous, median and radial supply sufficient information relating to the three essential functions. At least six functionally distinct nerve signals are required to supply an adequate control scheme. Therefore, two or more functionally distinct nerve signals must be recorded from one or more of the nerves. Lichtenberg (7) has shown that under experimental conditions functionally distinct signals can be recorded from the surface of the sciatic nerve in rabbits. A paper describing the technique and results of the experiment for recording functionally distinct signals is in preparation.

The concept of interfacing a nerve with an electrode for the purpose of recording nerve signals has been considered before. In 1964, the Harvard-M.I.T. Liberty Mutual Insurance Co. team of investigators attempted to record volitional motor nerve signals in a below-elbow amputee (Alter (8) ). The median, ulnar and radial nerves were exposed at the end of the amputation stump. Platinum wire loops were placed over each of the dissected and isolated nerves. The patient was instructed to think about performing hand and finger motions normally controlled by the exposed nerves in the ablated forearm. Signals were recorded in phase with the volitional intent. However, the investigators encountered technical and physiological restrictions that prevented them from reliably isolating nerve signals.

A Liberty Mutual Insurance Co. - Harvard Medical School team then attempted another approach utilizing the tibial nerve in the hind limb of rabbits. The distal end of the tibial nerve was divided into four or five fiber bundles by cutting the epineurium and delicately teasing the fiber bundles. Tubes of Teflon<sup>®</sup> and Silastic<sup>®</sup> were located over the individual bundles. All these attempts resulted in nerve damage and/or necrosis; probably as a result of interference with the nutrition to the nerve. However, it is possible that this approach may yield positive results if a sophisticated microdissection technique is employed to divide the nerve.

More recently, Marks (9) and Mannard *et al.* (10) working with amphibians have developed a nerve regeneration electrode. Marks (9) induced cut nerve fibers to regenerate into a multiple microelectrode consisting of a Teflon structure having small metal-lined holes. Mannard *et al.* (10) advanced the design of the regeneration electrode unit. They constructed an electrode that consisted of a thin epoxy plate pierced by several holes whose surfaces were coated with a metal. The pierced plate was secured in a notch cut into a nerve. They have shown that in amphibians the nerve fibers will regenerate and pass through the holes, thus establishing an interface with the electrode. The regeneration unit approach has the advantage of supplying a large nerve signal-to-noise ratio due to the fact that the recording element is very close to the individual axons. However, the technique for installing the unit requires a relatively delicate

surgical procedure that may not be convenient during an amputation. In addition, this electrode would by its nature be highly selective in recording action potential trains of individual motoneurons. In general, several channels of information would be necessary to associate the nerve signal with the resulting muscle contraction which is modulated by motoneuron recruitment as well as firing rate.

In this article, a new approach for developing an electrode capable of recording functionally distinct nerve signals for prolonged periods of time will be described. The electrode satisfies the following requirements:

- (1) It should be possible to place the electrode on severed nerves during amputation.
- (2) The implant procedure should be relatively simple.
- (3) The electrode should have the capability of recording functionally distinct nerve signals from the nerve.

#### BASIC ELECTRODE DESIGN AND IMPLANTATION PROCEDURE

A suitable electrode should have the following characteristics: (1) a good mechanical connection with the nerve trunk, to minimize the relative movement of the electrode and nerve; (2) a good signal-to-noise ratio; and (3) the capability to disregard the concurring EMG signals from adjacent muscles. The design of an electrode to achieve the above presents two basic problems: (1) the electrode must be placed close to the nerve with minimal physical damage and few physiological restrictions to the nerve; and (2) all the materials used to construct the electrode must be biocompatible.

The construction of the electrode can be divided into two parts. The first is the structural component that provides the mechanical connection to the nerve trunk. The second consists of the recording elements of the electrodes that provide the electrical connection.

The structural component consists of a tube fabricated from a sheet of Dacron<sup>®</sup> or Teflon knitted cloth with the borders glued together with Silastic rubber. The tube has an inside diameter of 2.5 mm and a length of 1.5 cm. The recording elements consist of two wires (90% platinum-10% iridium) with a diameter of 75 $\mu$ m covered with a Teflon coating. The wires are woven into the cloth and terminate with an inter-wire spacing of 0.5 cm. At the terminal point the wires are curved perpendicularly to the cloth towards the inside of the tube. The wires are cemented in this position and the terminal ends are cut flush with the cloth. The portion of the wires protruding from the tube is placed inside a Silastic tube that is affixed to the cloth. A 6-0 silk suture is tied to the distal end of the cloth tube. Figure 1 shows an electrode ready to be implanted.

New Zealand white rabbits (3½-4 kg) were used as the experimental animals. The rabbits were anesthetized. Their hind parts were shaved and surgically prepared with the Betadyne solution. An incision was made in the popliteal fossa and the peroneal nerve (a branch of the sciatic nerve) was exposed. The nerve was severed as distally as possible near its insertion into the peroneus muscle. (The severing of the nerve duplicated the amputation trauma.) A 6-0 braided silk suture was passed through the epineurium at the distal end of the nerve. The suture and nerve were pulled through the tube until the tube was located over the distal part of the nerve. The suture on the nerve was tied to the suture on the distal part of the tube, thus securing the unit to the nerve. The implanted unit was comfortably arranged in the popliteal fossa and the incision was sutured. A total of 22 electrodes were implanted.

(Figure 1 near here)

#### BIOLOGICAL COMPATIBILITY

The histological appearance of the nerve and surrounding tissue, and the nerve signal characteristics of the electrode-nerve unit were studied for implantation periods ranging from 3 to 244 days. No serious biocompatibility problem was observed in the nerve and surrounding tissue. In some cases the enclosed nerve experienced severe degeneration. The information presently available is not definitive; it is very likely that the denervation was a result of some anatomical damage that occurred accidentally during the implantation procedure.

A capsule of connective tissue develops around the tube. This external capsule is continuous with the adjacent fascia and the connective tissue around the nerve proximal to the electrode. Figure 2 shows a typical fusion of the electrode tube to the terminal end of the peroneal nerve. (The nerve-electrode unit has been isolated from the surrounding tissue by a cotton swab for visual clarification.) The space between the enclosed nerve and the inside wall of the tube is also invaded by connective tissue that is well bound to the enclosed nerve. The internal and external connective tissues communicate through the interstitial spaces of the knitted cloth providing a good mechanical bond between the nerve and electrode. Figure 3 shows a cross-sectional view of the electrode tube and enclosed nerve.

The presence of the Dacron and Teflon tubes induces a slight inflammatory reaction in the adjacent connective tissue. Foreign body giant cells were present in the connective tissue but they decrease in number with increasing implantation time. Also, the internal connective tissue undergoes a reorganization with increasing implantation time. The cellular component diminishes and the remaining cells occupy the space adjacent to the tube wall. The space between the epineurium and the cellular component is filled with collagen fibers and fatty tissue. This connective tissue reorganization may be important in explaining the signal levels recorded from the electrodes.

(Figures 2 & 3 near here)

#### PARAMETERS EFFECTING THE RECORDED SIGNAL

The implanted electrodes were tested by maximally stimulating the sciatic nerve proximal to the origin of the peroneal nerve. Tubocurarine chloride was administered to the rabbit to eliminate the concurring EMG signal. Most of the electrodes could successfully record the electrically-stimulated compound action potential. The few failures were due to problems unique to particular experiments and not basic to the electrode design.

The recorded compound action potentials had an amplitude that ranged from 40 to 300  $\mu$ V and a time duration of 0.9 to 1.5 msec. The amplitude of the compound action potentials recorded from electrodes implanted less than 17 days had a mean and standard deviation of  $150 \pm 101 \mu$ V; whereas that recorded between 25 and 244 days was  $79 \pm 46 \mu$ V. The coefficient of variation is 0.67 for the former group and 0.58 for the latter. This indicates that the relative amplitude of the recorded signal is as apt to vary by almost similar amounts regardless of implantation time. A detailed discussion on the histology and signal properties of the nerve-electrode unit will be presented by De Luca et al. (11).

The decrease in the absolute value of the amplitude of the recorded signal is, in all probability, caused by physiological and physical properties within the implant, rather than the structural properties of the electrode unit. A decrease in the signal amplitude can result from the following developments: (1) the nerve degenerates; (2) the impedance of the internal connective tissue increases; and (3) the metal-electrolyte interface of the recording electrode changes. As stated previously, the light microscopy analysis revealed that with increasing implantation time, the connective tissue between the enclosed nerve and the inside wall of the tube becomes reorganized. It appears that the increasing deposits of collagen fibers and decreasing cellular component in the connective tissue impede the conduction of compound action potentials from the nerve to the electrode. The compaction of the collagen fiber matrix surrounding the nerve could induce nerve degeneration by directly invading the space occupied by the nerve fibers or by occluding the nutrients required by the nerve. Fortunately, if it is found to be necessary, the amount of connective tissue formation can be regulated by pharmacological agents such as proline and lysine analog (12).

There are several possibilities that can account for the large standard deviation of the recorded signal amplitude. One prominent source for the amplitude irregularity is the lack of concentricity between the nerve and surrounding electrode as seen in the majority of the histological cross-sections. Thus, the exposed area of the wires would not be at a consistent distance from the surface of each nerve. Detailed measurements have shown that in a normal saline medium, the amplitude of a compound action potential is approximately inversely proportional to the radial distance from the surface of the nerve. The amplitude decreases by approximately 45% in the first millimeter from the nerve. Another possible explanation for the large standard deviation is the variation in the diameter of the rabbit peroneal nerves. All the implanted electrodes were constructed with a fixed inside diameter of 2.5 mm. An attempt was made at using rabbits of approximately the same weight (3½-4 kg), however, it was not possible to accurately measure the diameter of the severed end of the peroneal nerve during the operation. Hence, it is inevitable that the recording wires in some implants are closer to the nerve than in other implants.

The sharp decrease in the compound action potential as a function of radial distance requires that the wires in the electrode be placed as close as possible to the nerve, so that larger signals may be recorded. With the current design this requirement is satisfied by decreasing the inside diameter of the tube. Several electrodes of varying tube diameter to nerve diameter ratio have been implanted. The analysis on this series of experiments is not yet complete. Preliminary data indicates that a tube diameter to nerve diameter ratio greater than 1.4 does not cause serious damage to the enclosed nerve. However, experiments are in progress to document the effects of a smaller diameter ratio. This investigation is considered important because minimization of the diameter ratio is the simplest method for increasing the effective signal-to-noise ratio.

It is also possible to obtain a greater signal-to-noise ratio by changing the configuration of the recording wires, i.e., by increasing the area of the exposed wire and by increasing the inter-wire spacing. The larger recording area would decrease the impedance of the electrodes and the increased inter-wire spacing would increase the differential signal recorded by the electrode. However, the increase in these two parameters also yields an electrode that would record the average signal from a larger surface area of the nerve trunk. This could have the result that the electrode might no longer be able to record functionally distinct signals localized on the nerve surface.

### ELIMINATION OF CONCURRENT EMG SIGNAL

It is an inevitable fact that an electrode capable of recording signals from the surface of a nerve has the capability of recording the much larger concurrent EMG signals from adjacent muscles. In the limbs the proximity of muscles to nerves is unavoidable. Two approaches have been considered for eliminating or reducing the unwanted EMG signal.

The first approach consists of surrounding the knitted-cloth tube of the electrode with a thin Silastic rubber tube that is sealed at the distal end. The Silastic tube acts as an insulator that partially isolates the recording elements of the electrode from the EMG signals. Several units of this type have been implanted. Two problems arise: 1) it is difficult to permanently affix the Silastic tube to the electrode. In several implants the Silastic tube managed to detach itself from the electrode after an implantation period of less than two months. 2) the presence of the Silastic tube appears to have a detrimental effect on some of the enclosed nerves. The reason for this latter result is not yet clear. In any case, the Silastic tube in the present form cannot yield a totally effective solution because it is open on the proximal end. Hence, the EMG signal has a leakage path. This arrangement reduces the recorded amplitude of the EMG signal, but does not eliminate the EMG signal.

The second approach employs a double differential recording technique. The electrode unit is modified by weaving an additional pair of Teflon coated (90% platinum-10% iridium) wires in the tube. The exposed terminal ends are oriented towards the outside of the tube. Each of the two new wires is located on the opposite side of the tube to the corresponding internally located wires. With this arrangement, the internal pair of wires is closer to the nerve, hence, they will record a larger nerve signal than the external pair (in the first millimeter from the nerve surface, the amplitude of the signal decreases by approximately 45%). However, the EMG signal will have a source that will be approximately equidistant from both electrode pairs and the amplitude of the EMG signal recorded from both pairs will be approximately equal. By subtracting the two signals from the two recording pairs, it should be possible to eliminate the EMG signal and retain most of the nerve signal.

### AN ELECTRODE FOR RECORDING VOLUNTARILY ELICITED SIGNALS

The basic electrode described in a previous section required a terminal experiment to be performed on the animal to evaluate its usefulness thus precluding the possibility of recording voluntarily elicited signals. A chronically implantable version of the basic electrode has been designed. This version allows the continuous monitoring of the bioelectric signals. The design incorporates both of the above mentioned techniques for eliminating the EMG signals.

The new electrode is an improvement of the previous version. The previous version is supplemented with an additional pair of wires woven into the knitted-cloth tube and originating on the external surface of the tube. The four wires that leave the tube continue as a helical-coil cable wound around a strain-relieving element. The cable is enclosed in a Silastic tube. The wires terminate on connectors that are located in a vitreous-carbon transcutaneous button (13). This electrode is implanted around the peroneal nerve in the same fashion as its predecessor. When the electrode has been secured to the nerve, a Silastic tube is placed over the nerve-electrode unit. Figure 4 presents a complete electrode ready to be implanted.

To date, only two of the new electrodes have been implanted. Additional implants are planned. Preliminary results of the quality of voluntarily elicited

signals that have been recorded can be seen in Figure 5. The top trace represents the signals recorded from the internal wire pair and the bottom trace those recorded from the external pair. For every pulse in the top trace there is a corresponding pulse in the bottom trace. This indicates that both wire pairs record similar signals to some extent. However, the relatively large pulses in the top trace have a corresponding low amplitude pulse in the lower trace and vice versa. It is tempting to identify the relatively large amplitude pulses in the top trace as the nerve signal and the relatively large amplitude pulses in the bottom trace as the EMG signal. If such is shown to be the case, it would require a relatively simple processing scheme to isolate the nerve signal.

The signals obtained from the new electrode will require extensive analysis to certify the distinction between EMG signals and nerve signals. Detailed stimulation and recording techniques are being devised to identify the properties of the motor unit action potentials from the adjacent muscles and the nerve action potentials from the enclosed nerve.

Additional implants are planned to study the effect of connective tissue ingrowth and reorganization on the recorded signals.

(Figures 4 & 5 near here)

#### CONCLUSION

The current information available from experiments designed to record nerve signals from severed nerves for prolonged periods of time suggests that the proposed recording technique may be viable. Electrodes constructed with suitable materials can be located around the distal end of the severed nerve by proper surgical techniques without causing serious damage to the nerve and the surrounding tissue. Electrically stimulated compound action potentials have been recorded from electrodes implanted around the peroneal nerves of rabbits for periods up to 244 days. There is some evidence that voluntarily elicited nerve signals may be recorded after prolonged periods of implantation and may be separated from the concurring EMG signal. However, this last point requires more investigation.

The possibility of obtaining prolonged recordings of voluntarily elicited nerve signals from severed nerves coupled with the fact that functionally distinct nerve signals have been acutely recorded from the surface of the sciatic nerves in rabbits (7) advances the likelihood of direct neural control for prostheses.

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CAPTIONS

Figure 1. The basic electrode implanted to study biocompatibility response and nerve signal characteristics. The measurement units are in centimeters.

Figure 2. The nerve-electrode interface. The peroneal nerve proceeds from the top left hand corner and enters the electrode tube that has been isolated and placed in front of a cotton swab for visual contrast.

Figure 3. The cross-section of an electrode unit that had been implanted for 20 days. Note the connective tissue that occupies the space between the nerve and the threads of the tube. The internal connective tissue is continuous with the external connective tissue through the tube interstitial spaces.

Figure 4. The latest version of the chronically implantable electrode. The Silastic tube shown separate from the unit is sutured to the Dacron tube during the implantation procedure.

Figure 5. Signals recorded from a chronically implantable electrode. The top trace represents the signals recorded from the inner wire pair and the bottom trace the signals from the external wire pair. The amplitude scale is 50 $\mu$ V/div. and the time scale is 10 msec/div.

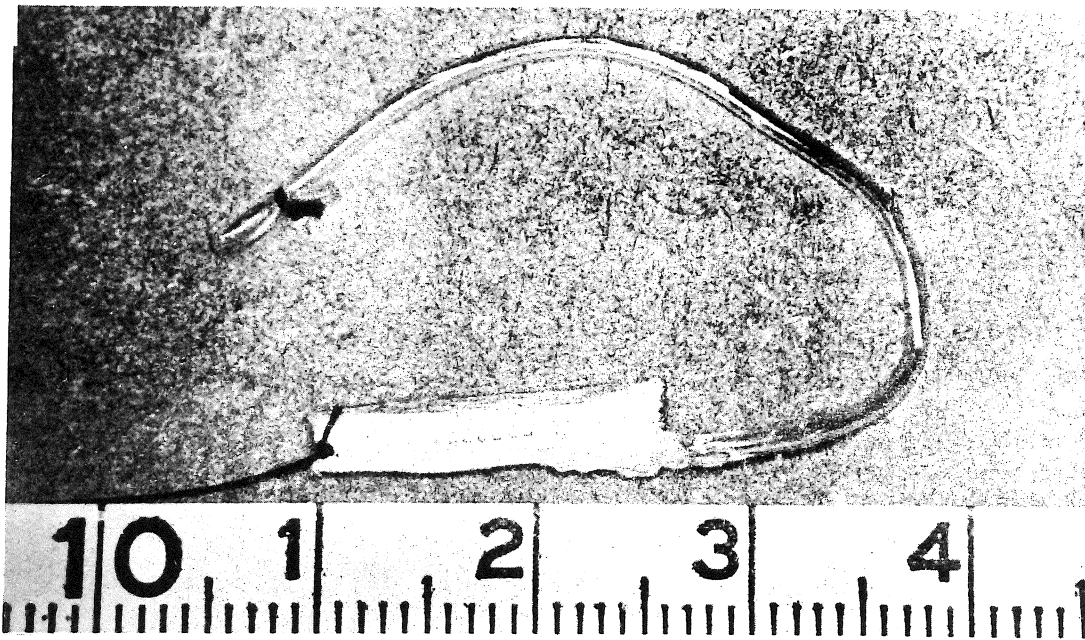


Fig. 1.

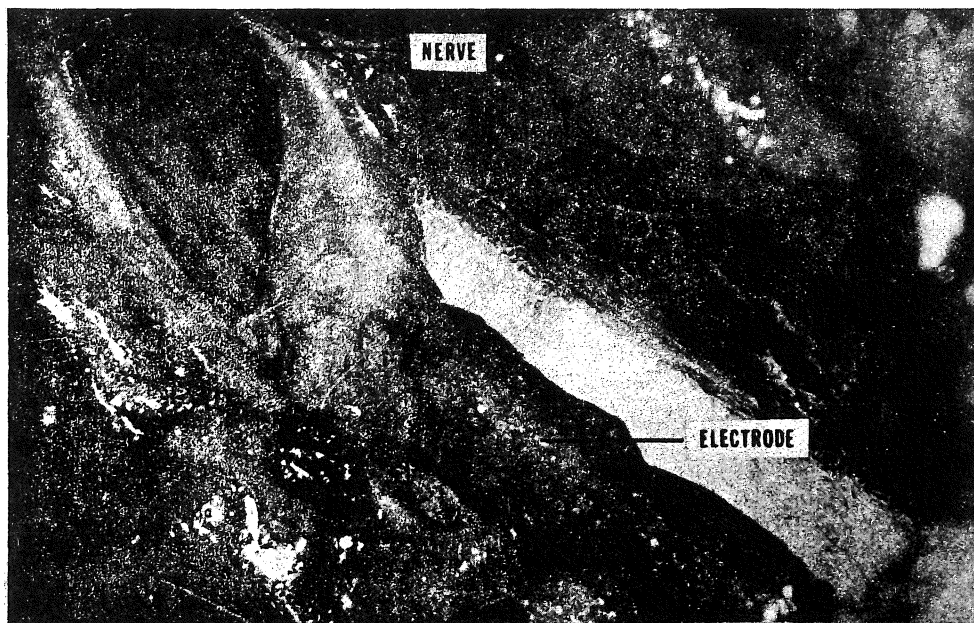


Fig. 2.

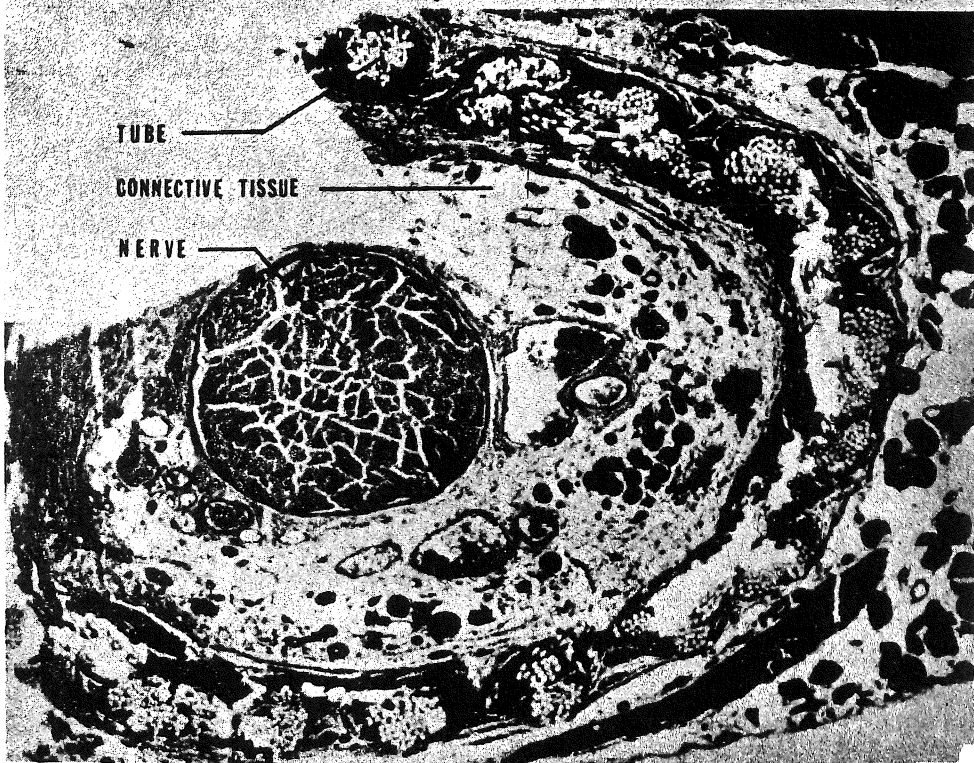


Fig. 3.

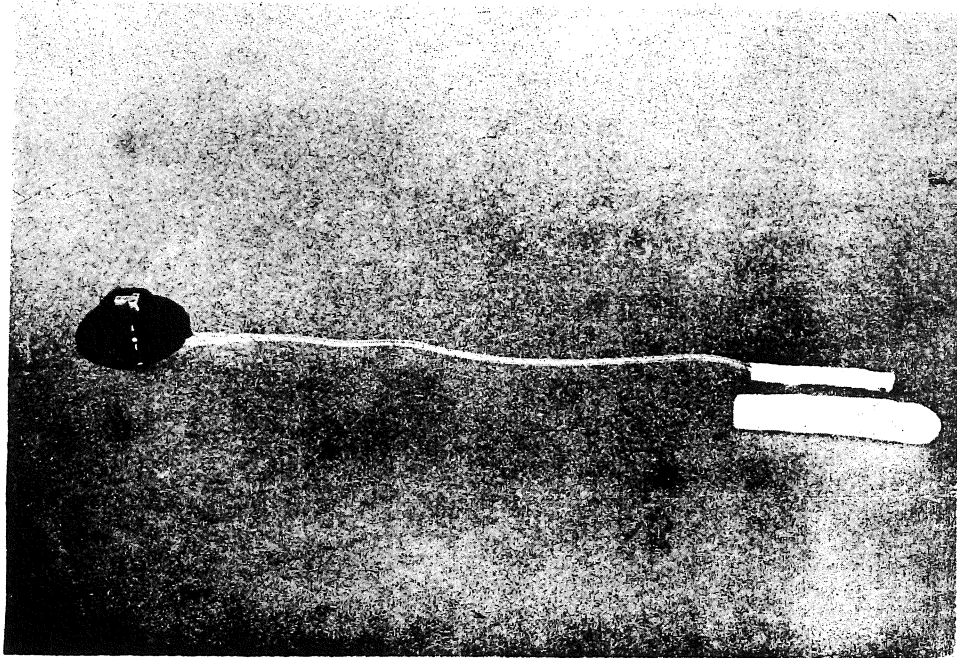


Fig. 4.

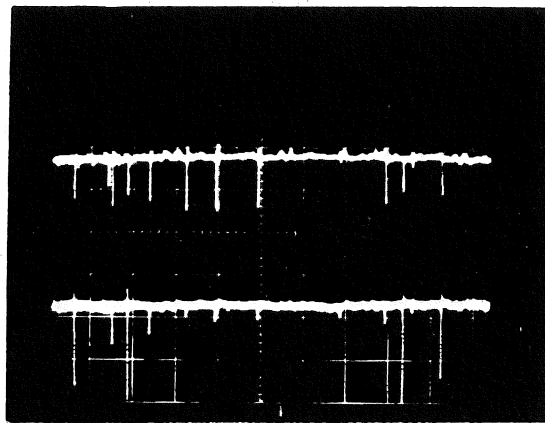


Fig. 5.