The INAIL-CECA Prostheses[1]

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In 1964, the research department, of the INAIL Prosthesis Center at Vigorso di Budrio, began the development of a myoelectrically controlled prosthesis for upper-limb amputees. During that year, prostheses were applied, experimentally, to one unilateral amputee and to one bilateral amputee in order to investigate the practicality of the controls and acceptability by the patients.

After evaluating the initial research, we set up a small scale production run of fifty sets of parts to determine the problems associated with the application of myoelectric prostheses, and, above all, for the purpose of eliminating any weak points that might come to light during their use.

This first phase of practical application lasted over a year. In 1965, when it was certain that the myoelectric prosthesis we had developed provided a definite advantage to the upper-limb amputee, we began mass production of this device.

At first, our myoelectric prostheses could be applied only to below-elbow amputees. If, at this initial stage, we had not foreseen the possibility of applying this principle to higher level upper-limb stumps, our program would have been terminated. In our opinion, the true value of myoelectrically controlled prostheses is found in the replacement of two, three, or four articulations.

For this reason, concurrently with mass production of the below-elbow myoelectric prosthesis, the research team began a program to develop a multichannel myoelectric control system that would make it possible and feasible to utilize more than six myoelectric signals in a high level upper-limb amputee.

Research in this difficult task extended over a period of three years and was conducted with financial support from the European Coal and Steel Community. The research was completed in 1970, and large scale application of the multichannel, myoelectrically controlled prosthesis was undertaken. This made possible the production of prostheses with myoelectric control over eight movements.

A myoelectrically controlled prosthesis for above-elbow or shoulder-disarticulation amputees must provide at least three movements; that of the hand, wrist, and elbow. In patients of this type, however, there are a limited number of muscles available that can be used for control, and thus the task is complicated.

An on-off myoelectric control delivers a single movement from each muscle. This approach is impractical for amputations at high levels due to the lack of signal sites. Also, in fitting these high level cases with either mechanical or "switch control" electric power, the movements are not as harmonious as they are in the natural arm. Nor is amputee acceptance of the prosthesis as high.

The situation is quite different when it is possible to give the patient control over gripping force of the hand directly proportional to muscle contraction and also give the patient control over the speed of its movement. This possibility was offered by the development of an electronic device that obtains at least two controls from a single muscle while, at the same time, provides proportional control.

The most important "break through" in this program came with the development of a two-part amplifier that made it possible to utilize various levels of muscle potential; levels that are quite distinct and can be controlled by the amputee. The first part consists of an integrated circuit differential amplifier followed by a transistor which further amplifies the signal. Regulation of the output level is achieved through a potentiometer. The second part transforms the output signal of the first part into a two-level signal.

[1] This article was originally presented by the author as the Ninth Louis J. Horowitz Lecture. The Department of Rehabilitation Medicine, New York University Medical Center, April 25, 1972.

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The lower-level signal controls a power transistor connected directly to the power supply for motor movement. Control that is proportional to the contraction of the muscle itself is thus obtained. When the power transistor is saturated, the upper-level signal begins to function, activating a relay which reverses the polarity of the motor, and continues functioning as long as the muscle remains contracted. Upon rapid release of the muscle contraction, the motor again, momentarily, reverses polarity, thus achieving a braking effect. The two movements are controlled independently and do not interfere with each other.

This new amplifier enabled us to utilize one muscle for two-signal myoelectric control, and during practical tests we recognized that the instruments normally used for determining muscle sites for the myoelectric prosthesis were inadequate. It was further observed that for the application of multichannel control, the amputee requires special training. To assist in training it was necessary to develop an instrument capable of registering muscle potentials while at the same time indicating to the amputee through signal lights optimum control of the muscle used to operate the prosthesis.

The training instrument known as a myometer is used to measure muscle potential, and to determine electrode location sites (Fig. 1). In addition, it is used to conduct practical tests on the amputee in the use of proportional multichannel control. These tests also give the technician the necessary information for correct adjustment to the two-level muscle signal to meet the requirements of individual amputees.

Several warning lights of different colors correspond to the movements for opening and closing the hand and for wrist rotation. The varying intensity of the signal lights indicates to the amputee the proportionality of his own muscle contraction.

Such an instrument is indispensable. It was designed to give the amputee opportunity for adequate practice, so that he can obtain the utmost function possible from his myoelectric artificial arm with multichannel control.

At this point of our research we discovered it was possible to obtain eight signals by utilizing the pectoral, biceps, deltoid, and triceps muscles leading to the application of a myoelectrically controlled prosthesis on an above-elbow amputee (Fig. 2).

It is interesting to note that the first amputee to experiment with the above-elbow prosthesis learned to control independently the various movements within a few days. Thus, for the first time, a practical prosthesis with myoelectric control of the hand, wrist and elbow function was achieved (Fig. 3).

With the new multichannel amplifiers six signals are necessary. Two signals remain available for control of such additional movements as wrist flexion-extension, humeral rotation, or, in the case of shoulder disarticulation, for articulation of a shoulder joint. So, with the availability of this multichannel

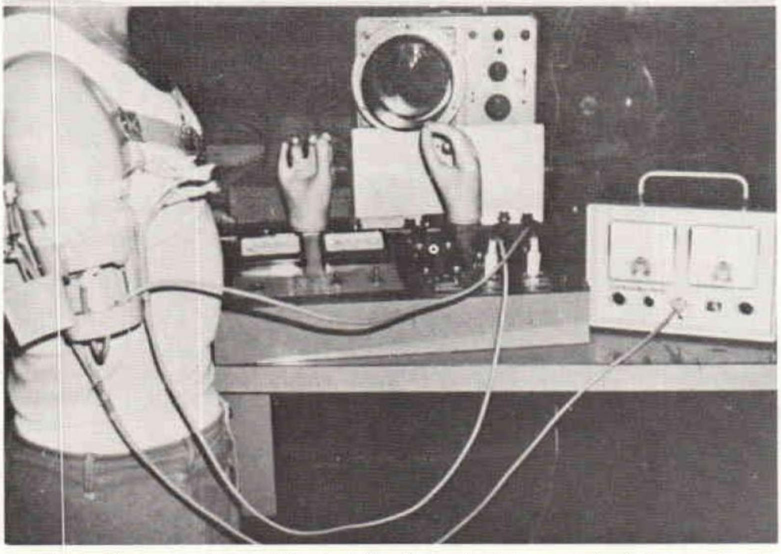

Fig. 1. The myometer used for training the patient in control of the prosthesis.

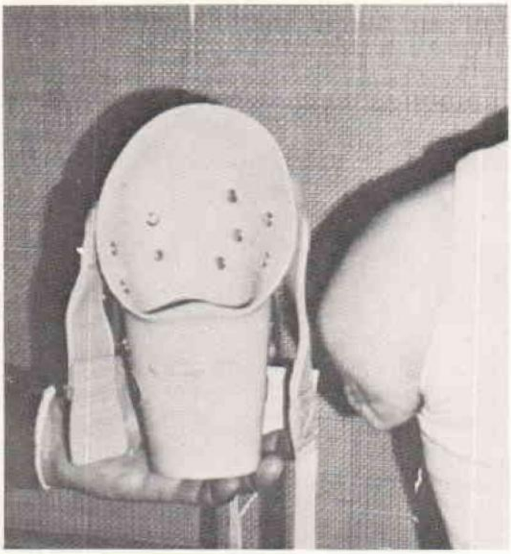

Fig. 2. View of an above-elbow socket for the myoelectric arm showing the positions of the electrodes.

myoelectric control system, it has now become possible to apply in a practical manner prostheses to all levels of upper-limb amputation (Fig. 4).

After the fabrication of a small quantity for experimental purposes, there began in 1971 the mass production of myoelectric prostheses for arm amputees. The INAIL Prosthesis Center of Vigorso de Budrio has, up to the present time, applied myoelectrically controlled prostheses to more than a thousand unilateral and bilateral upper-limb amputees.

None of the amputees encountered insurmountable difficulties in adapting themselves to the prosthesis. Many of them have been able to resume their former activity or take up a new kind of work, encouraged to do so by the excellent function of the prosthesis itself. The ages of the patients range from seven to seventy-five years.

At the present time, there is no type of prosthesis that can offer greater function. It should be emphasized that the application of a myoelectric prosthesis requires special techniques, training, and knowledge, and, above all, special equipment. It is only in this manner that maximum results can be obtained.

THE PROSTHESIS

The INAIL-CECA myoelectric system has been and will continue to be the object of continued improvement. Even today it is not possible to speak of a definitive system that is no longer capable of being improved.

It is extremely important that new technology be incorporated as it becomes available, but it must be recognized that continual

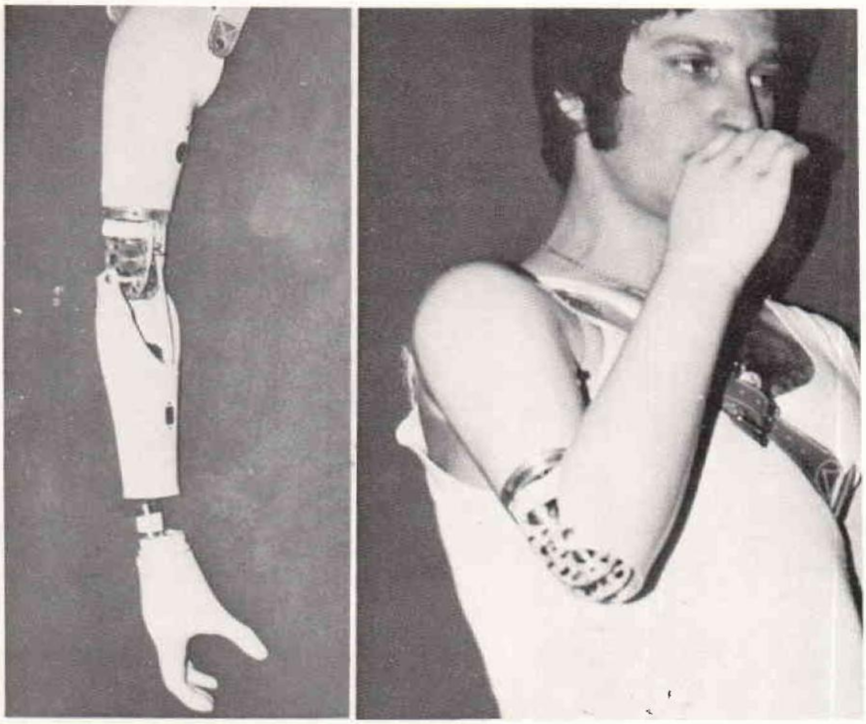

Fig. 3. Two views of the above-elbow myoelectric prosthesis.

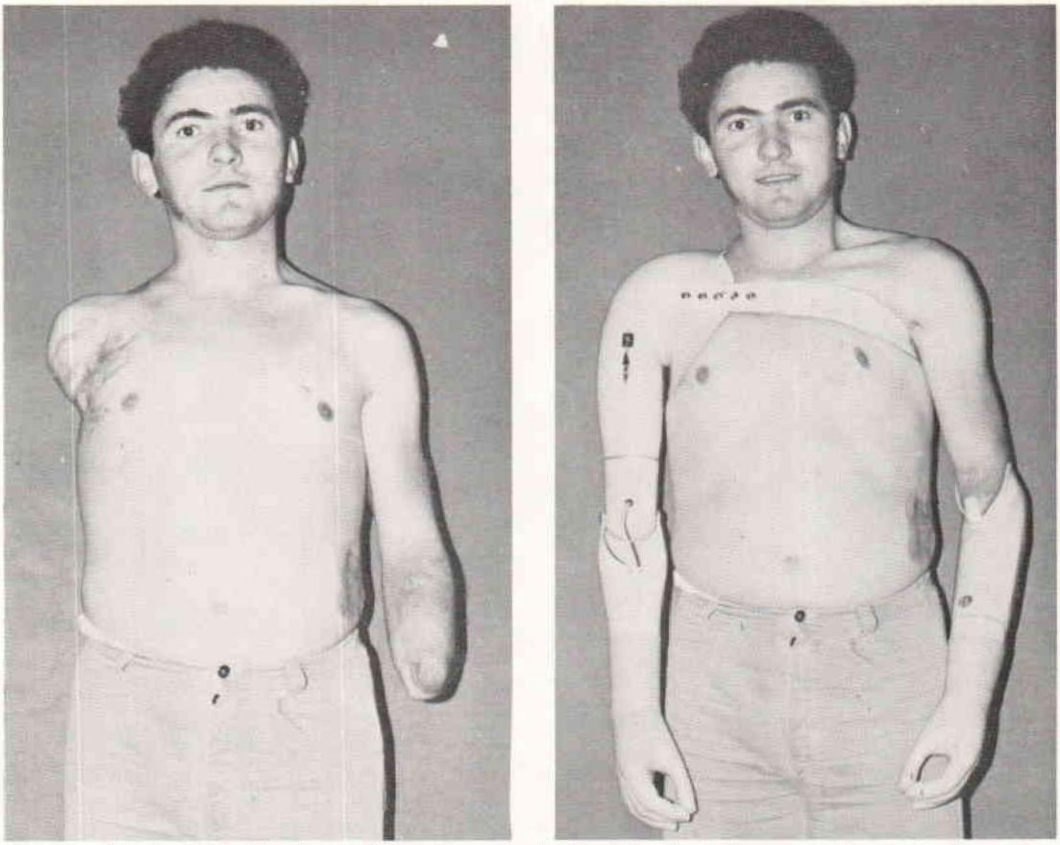

Fig. 4. A shoulder-disarticulation type patient with and without his myoelectric prosthesis.

changes create difficulties for the firms that manufacture components for prostheses. It may happen, in fact, that a product on the verge of being offered is rendered obsolete even before being placed on the market. Moreover, in order to control costs, it is necessary to produce large quantities. This is further complicated because the market is not now in a position to absorb large quantities. And, finally, it must be remembered, that, in the fabrication of a myoelectrically controlled arm, the prosthetist may, at times, be forced to develop his own special components for unique cases without being able to make use of commercially available parts all of which further complicates the problem.

Presently, we have available the following components (Fig. 5):

electrically powered hands
passive wrist units
stump activated wrist units
electrically powered wrist units
outside locking elbow hinges
electrically powered elbows
amplifier for single-channel systems
amplifier for multichannel systems
batteries for insertion in the prosthesis
batteries for external application

At the present time, we use an electric hand that is mass produced to our specifications by the firm of Otto Bock. It is known as the 8E8 Model Z6 hand. It provides a maximum opening of the fingers of more than ten centimeters (approximately 4 inches) and a gripping force of over 10 kilos (approximately 22 pounds). To date approximately 750 amputees who are engaged in widely varied activities have been fitted with this type of hand. In practice, the hand has given proof of durability and maximum function. The 8E8 hand does not lend itself, ideally, to proportional control because of its special gearing which transforms speed into force at the moment the fingers encounter resistance. While waiting for the new hand, created especially for proportional control, we use the older model.

PASSIVE WRIST UNIT

The passive wrist unit allows passive rotation of the hand through a range of 360°.

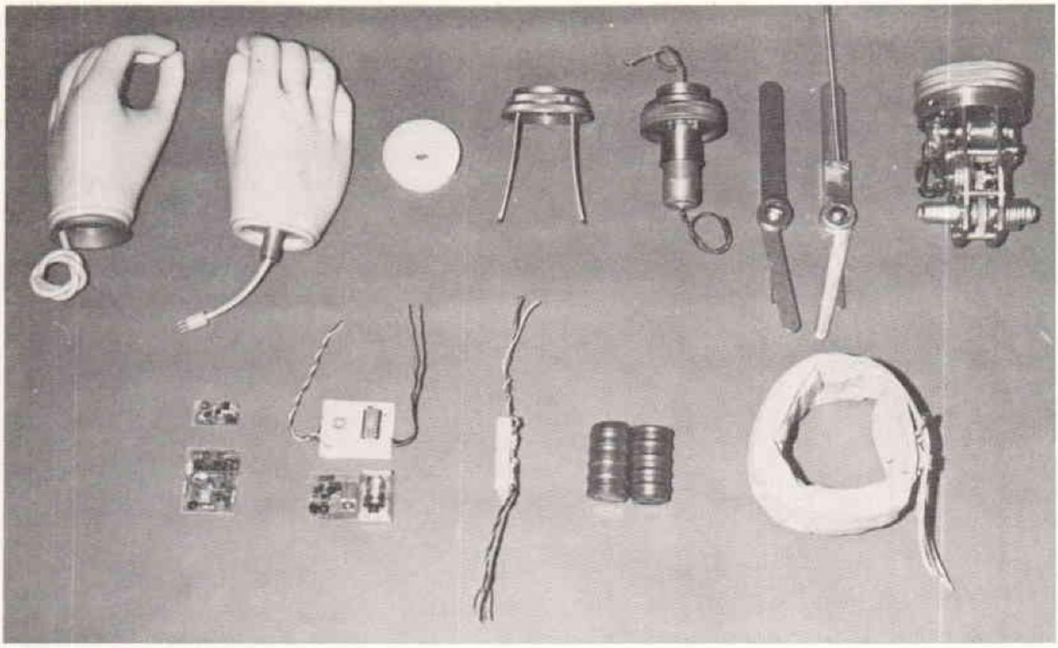

Fig. 5. The compenents available for use in fabrication of myoelectric prostheses.

Various friction designs maintain the hand in the desired position.

STUMP-ACTIVATED WRIST UNIT

The stump-activated unit is especially suitable for long stumps that have residual active pro- and supination of the wrist. These units are made in such a way that they require very little space and can, therefore, be used in fitting prostheses to very long stumps, even disarticulation of the wrist, since they do not create problems of excessive length in the artificial limb.

ELECTRICALLY POWERED WRIST UNIT

An electrically powered wrist unit that uses the same motor and gear reduction unit used in the hand was developed. In order to have a rational, yet economical approach, we feel it is important to standardize on the same drive system for all three components—hand, wrist, and elbow. This wrist unit is small enough to be used in prostheses for very long below-elbow stumps. It requires only 55 mm (2 1/8 in.) of linear space. The weight is about 180 gr. (6 1/4 oz.), range of motion is 360°, and the speed can be regulated by the proportional control. An additional feature is automatic locking.

OUTSIDE LOCKING ELBOW HINGES

Hosmer outside locking hinges are used for long above-elbow stumps especially in cases utilizing short sockets and hydrostatic pressure for suspension. Because locking and unlocking of this joint requires only minimal cable travel (3 mm) all control movements appear natural and harmonious.

ELECTRICAL POWERED ELBOW

The electric elbow uses the same type of motor as the hand and the wrist but with different gearing. The possibility of utilizing the reduction gear of the hand and wrist for the elbow is being explored. Presently, two motors are used in this elbow to drive the mechanism that makes possible a maximum speed of 1.2 sec. for the complete extension and flexion of the elbow. The lifting capacity is 1.5 kilograms (3.3 lbs.) with a lever arm of 45 cm (18 in.). The total weight of the elbow unit is 400 gr. (14 oz.). It can be used with proportional control.

AMPLIFIERS FOR SINGLE AND MULTICHANNEL CONTROL

The amplifier for both the single and the multichannel systems consists of two elements. One of the elements is the same for both systems, except for a slight modification in the final stage of the multichannel system.

The first element consists of an integrated circuit differential amplifier, with selective response on the frequencies between 200 and

500 Hertz. The gain at maximum sensitivity is about 50,000 times the input signal.

The single-channel system of the second element uses a miniaturized final amplifying unit that can be inserted into the hand itself. In the multichannel system, this element provides an output signal at two levels. The lower-level signal controls a power transistor directly connected to the power supply of the motor for movement, thus providing a control proportional to the contraction of the muscle itself. At the upper level, when the power transistor is in a state of saturation, a relay that inverts the polarity of the motor is activated and remains in operation as long as the muscle is contracted.

When the muscle is relaxed quickly, the motor passes, for an instant, to the preceding condition and a braking action is thus obtained. The two movements are controlled independently of each other and therefore do not interfere with each other. For example, in the myoelectric control of a hand the first level is utilized for proportional control for closing the hand and the second level for the opening of the hand.

BATTERIES

At present we use two types of batteries, the 225 DKZ type and the 450 D type manufactured by Varta. Both types are nickel-cadmium rechargeable batteries. The 225 DKZ type supplies 12 volts at 225 mA/h and weighs 130 gr. It is small enough for it to be contained wholly within the prosthesis. The 450 D type supplies 12 volts at 450 mA/h and weighs 280 gr. It is used with a battery case outside the prosthesis and can be worn anywhere on the body.

With the availability of the prefabricated components it is possible to provide a myoelectric prosthesis for all levels of amputation, ranging from a disarticulation of the wrist to disarticulation of the shoulder.

For the fabrication of the myoelectrical prosthesis, a special technique that uses a thin-wall inner socket has been adopted. Foam plastic is used to give the arm its final shape, and a thin lamination is applied over it. The foam plastic is then removed and the resulting hollow space is used to house electronic components and batteries.

By means of this technique, it has been possible to insert all electrical components into the prosthesis, with benefits not only from the point of view of appearance but also from that of practicality. Because all critical components are protected, they are not subject to damage as if they were mounted externally.

At the present time we have fitted over 1000 amputees with myoelectrical prostheses. These patients have returned to work and utilize their prostheses in manual activities that would not be possible without the use of their prostheses. It is interesting that there are only a very small number of persons who have had difficulty in adapting themselves to this type of prosthesis. The results of a study carried out on the first five hundred amputees we have fitted with the myoelectric prosthesis are presented here.

The levels of amputation for the first 500:

- 254 Right below-elbow amputees
- 168 Left below-elbow amputees
- 21 Bilateral below-elbow amputees
- 1 Bilateral above-elbow amputee
- 2 Bilateral amputees (right BE and disarticulation at left wrist)
- 1 Bilateral amputee (left BE and disarticulation at right wrist)
- 1 Bilateral amputee (right BE and left AE)
- 29 Right above-elbow amputees
- 18 Left above-elbow amputees
- 1 Disarticulation at right elbow
- 4 Disarticulation at left elbow

The results of the study are as follows:

- 54 amputees were able to resume their previous occupations
- 273 were able to take up another occupation
- 65 are students who wore their prostheses continuously
- 12 are housewives who use their prostheses in their housework
- 33 wear the prosthesis although they are so seriously disabled that they do not carry on any activity
- 28 wear the prosthesis occasionally
- 32 amputees do not wear the prosthesis because of the frequent need for repairs and the noiseness. These are disabled persons whose prostheses were constructed before 1969, when the first type of hand was perceptibly noisy. This hand is now being replaced with a new one.
- 3 amputees have not been able to wear their prosthesis because of allergic reactions.

The results reported are extremely encouraging if one considers that the study was carried out on the first five hundred amputees fitted with myoelectric prostheses, including a small number of amputees fitted in 1965-66 with the products of our first research efforts. If a comparison is made between the data of investigations carried out by this Centre and investigations by other countries in which the fitting of myoelectric prostheses has begun, one immediately notes the higher percentage of disabled who make effective use of the INAIL-CECA prosthesis. It is not arbitrary to state that such a high percentage has never before been attained.

I think that throughout the world the total number of amputees fitted with myoelectric prostheses must be between 5,000 and 6,000. The results have become more satisfactory since it became possible to apply myoelectrically controlled prostheses to above-elbow amputees and to disarticulations at the shoulder. The utilization of eight myoelectric signals has broadened the possible application of myoelectric prostheses, and, I am sure we still have many possibilities for further development.

SENSORY FEEDBACK

After completion of the research program for multichannel myoelectric control and, after the start of mass production of this type of prosthesis, research was directed towards the feasibiity of incorporating sensory feedback into the myoelectric prosthesis. When text books on limb prosthetics and the proceedings of various congresses are consulted, it will be found that they always refer to mechanical function with little, if any, reference to sensory function. It is a fact that an arm amputee has lost not only mechanical but also sensory function. Consequently, the research team at the Budrio Prosthesis Centre began research to give an artificial hand sensory feedback.

Much information can be transmitted to the human body through the visual and auditory senses. We know quite well how indispensible these senses are in daily life. It is not possible to restore eyesight, but we can restore the sense of touch, to a degree, by transmitting information through the skin using both mechanical vibrations and electrical stimuli.

According to experiments in physiology the skin is most sensitive to vibrations at 200 Hertz, but, vibrations over 150 Hertz are too intensive. For this reason, sinusoidal vibrations around 100 Hertz were tried first, the amplitude of which was modulated by the input signal.

At the beginning consideration was given to a mechanical vibrator. Later this was replaced by an electrical stimulator, because the mechanical devices were excessively bulky, and we began to realize that the information given by electrical stimulation was better perceived than were the mechanical vibrations.

Consequently, an electronic device was developed for sensory feedback information by means of skin stimulation. It consisted of an amplifier section and a final section. The power supply is 12 volts D.C.

The stimulator functions automatically and only when resistance between the fingers is encountered during prehension. As resistance increases, the frequency changes, and the patient is able to evaluate the degree of gripping force. The voltage output of the terminal section is about 75-80 volts. Frequency varies from 0-50 Hertz. The information time lag is so small as to present no problem.

The arrangement avoids excessive irritation of the skin and conserves power.

The electrodes for sensory feedback cannot be incorporated in the socket where the electrodes for myoelectric control are located, because skin stimulation may cause a muscle fibrillation that will upset the use of the control. The sensory feedback electrodes do not create any disturbance of this kind when they are applied on an arm band mounted on the outside of the socket.

The first application of a prosthesis with sensory feedback was on a blind woman with bilateral below-elbow amputations. It has given satisfactory results. Even we research workers were astonished at the accuracy of the information received by this patient, and at the precision with which she controlled the prosthesis.

This research is now at the stage of practical application. There is no doubt that, during this phase, the need for changes will become evident in order to obtain maximum function. One thing is certain, and that is that sensory feedback for an artificial arm must be given consideration because we know that a myoelectrically controlled prosthesis with sensory feedback information renders the amputee prosthesis relationship closer and more perfect, so that even from a purely functional point of view, it is possible to achieve the maximum that can be expected.