A SENSORY FEEDBACK SYSTEM FOR AN UPPER-LIMB AMPUTATION PROSTHESIS

Frank W. Clippinger, M.D.
Roger Avery *
Bert R. Titus

Duke University Medical Center
Department of Surgery - Orthopaedics
Durham, North Carolina 27706

A project to provide sensation from an upper-limb amputation prosthesis has been underway at Duke University since early 1971. This was initially made possible through the generosity of Mrs. Carlton Hooks of Thomasville, North Carolina, who provided funds for a pilot study. Since December 1, 1972, the project has been aided by contract from the Veterans Administration with an expected termination date of November 30, 1975.

Providing sensation for the amputee from his prosthesis has been a challenge for many years, but until recently there has been no practical solution. Function of the normal hand is dependent on sensory feedback. In addition to information regarding imminent injury, calibration of force of grasp and pinch, recognition of the shape of an object, and knowledge of the position of the hand in space contribute largely to the dexterity that we take for granted.

The traditional prosthesis that we have supplied for the upper-limb amputee does not have this capability. The amputee must receive much of this information by visual contact and the remainder through pressure changes between his stump and the socket and between his skin and the harness. There is no intrinsic sensory feedback from his terminal device which he must use as an anesthetic tool.

Biceps cineplasty used with voluntary closing hook did provide some additional information, as pressure between the fingers could be calibrated by interpretation of pressure changes between the surface of the tunnel and the peg. Cineplasties have not been acceptable widely in the

* Avery Laboratories, Farmingdale, New York.
United States, however, because of the difficulty in maintaining the skin in good condition within the depths of the tunnel.

Another partial solution is the split forearm or Krukenberg amputation with which objects can be grasped between the radius and the ulna. This has been recommended primarily for blind amputees in whom function is negligible in a conventional prosthesis and the unacceptable cosmesis is not a great handicap.

During the past 25 years, there have been several attempts to provide the amputee with a sensory mechanism.

Wilms and Siehlow (1) in Liechtenstein in the early 1950’s trained amputees whom they fitted with electrically motored prostheses to correlate their phantom sensation with motion and function.

Beeker, During, and den Hertog (2) reported from Utrecht, Netherlands, in 1966, a prosthesis in which a signal from a piezoelectric crystal deformation, after amplification, was delivered to the patient through skin electrodes as a shock. This apparently is an on-off system without proportional control.

In 1968, Pfeiffer (3) at the Sepulveda Veterans Hospital and Rhode and Fabric at the Augusta Veterans Hospital developed a pressure transducer and applied it to thumb and forefinger covers in insensitive hands. This delivered information to the patient through an auditory signal using a hearing-aid earpiece. There is no record that this system has been used in an amputation prosthesis.

Since the middle 1960’s, Alles, Mann, and others (4, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15) at the Massachusetts Institute of Technology have been working with sensory feedback systems using mechanical or electrical input systems to remote areas of the patient’s skin or via a hearing-aid earpiece to the ear. The concept was developed originally for the purpose of providing information as to the position of the MIT-Liberty Mutual myoelectric elbow.

In 1969, Kawamura and Sueda (6) at Osaka developed a prosthesis for below-elbow amputees in which a mechanical vibrator stimulated the skin at the end of the stump within the socket. This was a proportional system with the rate of vibration being controlled by an amplified signal from a strain gage transducer in a modified voluntary opening Dorrance hook.

Miniaturization of electric circuits and components has made possible the development of small electrical devices that can be implanted in the human body. Mooney (6) at Rancho Los Amigos Hospital has used an implanted induction-powered radio receiver-pulse generator for motor stimulation of the peroneal nerve in hemiplegic patients. Nashold (7) in the Division of Neurosurgery at Duke University has also used a similar device to stimulate the spinal cord or peripheral nerves for control of intractable pain. After review of these projects, it seemed likely that this
type of system could be used to produce sensory stimulation from the terminal device of a prosthesis if the following criteria could be met:

1. The electrode would be placed on the median nerve, and the mental image should be that of the peripheral cutaneous distribution of that nerve—the thumb, index, long, and half the ring finger.
2. Voltage must be sufficient to produce a stimulus, but not at a painful level.
3. A transducer in the terminal device must be capable of varying frequency related to activity.
4. The entire system, including the amplifier, transmitter, and power source, must be small enough to fit within the prosthesis to avoid extraneous wires, battery packs, etc.
5. The system must be sufficiently durable to withstand normal use of an amputation prosthesis.
6. The design must be such that the patient can don and adjust it one-handed.

The implant designed by Avery Laboratories was selected (Fig. 1). This is an inductively coupled RF receiver, small enough to implant in the arm, measuring 2.9 by 0.9 cm. It is tuned to 2.05 MHz ±5 percent and the capability is 0-25 V and 0 to 400 Hz. It is embedded in biocompatible epoxy and is encased in Silastic. A Silastic sheet skirt incorporating Dacron mesh is attached.

The skirt is used to suture the unit to the fascia to prevent migration. The output of the implant is a capacitively coupled pulse producing a zero net direct current flow in the nerve at rates and amplitudes that are determined by the external transmitter.
Figure 2 illustrates diagrammatically the feedback system. The initial patients would be below-elbow amputees to minimize the mechanical problems of prosthetic use. The implant is placed subcutaneously in the medial aspect of the distal arm, away from interference from any part of the prosthesis. The prosthesis would be activated in a conventional manner using a Figure-8 harness and cable control. It is necessary, if pressure is to be varied, that a voluntary closing terminal device be used. An APRL hook with the locking cam removed was selected. While this would force the amputee to “hold on” to an object, it was felt that this was a normal function, and removal of the cam would eliminate the additional force and subsequent pressure increase necessary to unlock the hook.

Two patients who had had the implant inserted and attached to the median nerve in the forearm for the treatment of phantom limb syndrome were available for study. On stimulation, both described a paresthesia referable, as expected, to the peripheral distribution of the median nerve—the thumb, index, and long fingers. In both patients, the power could be adjusted to a comfortable level and both could distinguish very small changes in frequency between 0 and 100+ Hz. This implied that the basic concept was correct.

The present project calls for a trial of the system on 15 patients: 10 below- and five above-elbow amputees. To date, 10 patients—eight below- and two above-elbow amputees—have had the implant inserted and seven have been fitted with prostheses. Surgery has required 2 days hospitalization.
In the below-elbow amputee, general anesthesia and tourniquet hemostasis were used. A 2½-in. incision is made over the (Fig. 3) medial aspect of the arm above the elbow and the subcutaneous tissue is separated from the superficial layer of the deep fascia, forming a pocket large enough to accommodate the receiver. The plexus of superficial veins that lies on the fascia is not disturbed.

A second incision is made over the volar surface of the forearm, the muscles are separated, and the median nerve identified, usually at the level of the distal border of the pronator teres muscle. The distal portion of the nerve is not dissected free and the distal neuroma is not disturbed or resected.

A subcutaneous tunnel is made between the two incisions. The receiver is placed in the pocket above the elbow and the electrode fitting and the lead wire are passed to the distal incision. To prevent migration, the skirt on the receiver is attached to the underlying fascia with three or four sutures of 3-0 Mersilene.

The electrode fitting is passed around the nerve and the flanges (Fig. 4) are sutured together. No sutures are placed in the epineurium and the fitting is just snug enough on the nerve to insure electrode contact.
Excess lead wire is coiled and placed between the muscles, the tourniquet is released, any bleeding is stopped, the wound is closed and a compression dressing is applied.

Following removal of the sutures, the patient is allowed to resume activity wearing his old prosthesis.

To date, there have been no wound complications. One patient had an area of ecchymosis over the volar side of the forearm. This resolved without problem.

**TESTING RESPONSE**

All patients have been tested at the time of suture removal using a precisely calibrated stimulator box from the dorsal column stimulator system. Table 1 outlines the patients and their statements regarding response. This is totally subjective and one has to rely on the patient's individual interpretation and his ability to communicate it. All implants have functioned satisfactorily. In most of the below-elbow amputees, visible contraction of the median nerve supplied muscles in the forearm has been observed. This becomes tetanic at about 35 Hz. All patients have had a threshold which produces a tingling paresthesia that they have stated is not uncomfortable at a power level of 0.8 V. or less, and this has been referred to at least a portion of the sensory distribution of the median nerve in the hand. Variations in the mental image are felt to be due to differences in orientation of the electrode on the nerve. As the frequency is increased, the paresthesia perceived increase in frequency to blend into a constant paresthesia at about 35 Hz. Above this level, the sensation changes, described as being either a mental image of fist clenching or a change in distribution of the paresthesia — other fingers appearing. Above 100 Hz, two patients state that sensation disappears, the others describe a vibration again.

One patient says that his hand feels as though it is within his stump. All the others perceive the hand at about normal length and position. When they attempt to pronate and supinate the forearm, the hand follows.

None of the patients has experienced a change of threshold or response since the implant was inserted. There has been nothing so far to suggest a change in resistance or impedance across the nerve or significant development of perineural fibrosis.

**THE PROSTHESIS**

The prosthesis fitted is a conventional limb with double wall socket, triceps pad, flexible elbow, Northwestern Figure -8 harness and cable
control (Fig. 5). The terminal device is an APRL hook with the locking cam removed and fitted in reverse, with the thumb on the ulnar side of the forearm. This has been done to accommodate the transducer and prevent it from being subjected to repeated trauma across the face of the socket. The transmitter antenna is secured to the arm over the implant with Velcro straps.

**ELECTRONICS**

The transducer is a strain gage bridge. In the first prosthesis it was mounted on the base of the stationary finger of the APRL hook. This had the advantage of producing a stimulus with push and pull activities as well as grasp, and the patient apparently enjoyed the fact that he could adjust the system so he could rub his hook lightly and feel it. However, in this position, the transducer is quite vulnerable to damage and requires a complex protective cover. In addition, the deviation at this point is both lateral and rotary producing a somewhat erratic response.

In the subsequent prosthesis, the strain gage has been mounted in the cable system where it is protected, and the force is linear.

A spring-loaded on-off switch is fitted into the end of the transducer housing. When the prosthesis is not being used or the cable is slack, the system is off, thus preventing constant battery drain.

The electronics package is mounted on a stainless steel (Fig. 6) chassis which incorporates a curved cover plate fitted with a snap lock door for access to the battery compartment and adjustment screws. Figure 7 is a diagram of the electronic system. The power source is a 9V transistor battery which in use has a life of 4 to 6 weeks and is easily and inexpensively changed.
<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Implant</th>
<th>Threshold</th>
<th>Response</th>
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</table>
| 1       | 36  | Left BE            | 5/15/71   | 0.7V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-100 Hz - Fist clenching  
            |       |                    |           | 100 Hz+ - Vibration           |
| 2       | 30  | Left BE            | 2/72      | 0.5V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-100 Hz - Long finger→ index→ thumb→ ring  
            |       |                    |           | 100 Hz+ - Vibration           |
| 3       | 47  | Right BE           | 12/29/72  | 0.7V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-100 Hz - long→ index→ thumb flexing  
            |       |                    |           | 100 Hz+ - Vibration           |
| 4       | 27  | Bilat. BE Blind    | 2/73      | 0.7V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-200 Hz - Initially hand swelling  
            |       |                    |           | after 2 weeks, fist clenching  
            |       |                    |           | 200 + Hz - Vibration           |
| 5       | 25  | Left Be Right BK   | 10/9/73   | 0.8V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-90 Hz - Flexion thumb, index, long  
            |       |                    |           | 90 Hz+ - Decreasing signal     |
| 6       | 23  | Bilat. BE          | 12/6/73   | 0.5V      | 0-35 Hz - Increasing vibration  
            |       | (right)            |           | 35-100 Hz - Index-long, thumb flexing  
            |       |                    |           | 100 Hz+ - Loss of signal       |
| 7       | 21  | Right BE           | 1/22/74   | 0.8V      | 0-35 Hz - Increasing vibration  
            |       | Severe hand deformity, left  |           | 35-100 Hz - Fist clenching  
            |       |                    |           | 100 Hz+ - Decreasing signal    |
| 8       | 44  | Right BE           | 6/29/73   | 0.6V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-100 Hz - Increasing tightness of index, long, thumb  
            |       |                    |           | 100+ Hz - Decreasing vibration |
| 9       | 19  | Left AE            | 8/2/74    | 0.9V      | 0-35 Hz - Increasing vibration  
            |       |                    |           | 35-80 Hz - Paresthesia  
            |       |                    |           | long— index— thumb  
            |       |                    |           | 80+ Hz - Vibration             |
The entire electronic system, including the antenna and strain gage, can be removed for service and a new unit inserted and adjusted in a few minutes.

In use the sequence of events is as follows: The first $\frac{1}{8}$ in. of cable travel turns the system on; further cable travel closes the hook until it touches some object or the other finger. At this point, the strain gage is activated and stimulation begins which increases in frequency proportional to the increase in force.
PROSTHETIC RESPONSE AND ACCEPTANCE

The subjective response to stimulation has been essentially the same with the prosthesis as with the testing equipment. The only major variation is that several patients have volunteered that they not only perceived the amount of pressure they are exerting but also the consistency of the object they are squeezing—soft, resilient, or hard. Presumably, these patients are correlating the cable travel with the rapidity of the increase in frequency. This was an unexpected finding, although Kawamura and Sueda (6) reported a similar response in patients wearing their vibrating system.

None of the patients has had a problem converting to a voluntary closing hook, nor have they complained of the necessity to “hold on.” Without a lock in the terminal device, length of the forearm-hook complex is important, and some patients have had a problem with secure grasp close to the body such as handling their trouser buttons, belt, and zipper.

Thus far, none of the patients has abandoned the system, although one is considering it, as he says the time required for service interferes with his business. He has not, however, been fitted with the removable and replaceable unit as yet. He has an intermediate electronics package which has had a maintenance problem.

PROBLEMS

The biggest problem has been related to the APRL hook which is too bulky and too long. A smaller terminal device is needed and such is under development at present. This is a conversion of a Dorrance hook to a voluntary closing capability by means of a return spring mounted in the hub. It should be available by the end of 1974.

The size of the electronic package produces some limitations, particularly for amputees with long stumps. Ultimately, subminiaturization would be advantageous.

The entire system including battery weighs 220 gm. This has not been a disadvantage, although it is mounted in the distal forearm. Subminiaturization would also produce weight reduction.

Electronics failures in the present unit have been related to excessive wear of the wire leading from the strain gage to the electronic pack in the forearm. Three failures have occurred, necessitating repair. There have been no implant failures.

FUNCTIONAL TESTING

Comparative functional testing between the conventional prosthesis
and the sensory feedback system has not been done. This is planned for all subjects between December 1974 and November 1975. A protocol is being developed and the results will be incorporated at the time of our report.

SUMMARY

1. Early results suggest that the concept is correct; that nerve stimulation with resulting appropriate interpretation and mental image can be obtained by use of an implanted induction powered nerve stimulator and at voltage levels that are comfortable.
2. A proportional control can be obtained and interpreted, and the system can function as a prosthetic replacement for the missing end organ and nerve.
3. Further experience is needed for the above-elbow amputee.
4. A new voluntary closing terminal device is needed and is being developed.
5. Testing needs to be done comparing function with sensory feedback with that obtained with a conventional prosthesis.

REFERENCES

10. Mann, R.W.: Recent Progress in the Development of an Electro-Myographically


