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FINAL REPORT

INVESTIGATION OF THE MEDICAL APPLICATIONS OF THE UNIQUE BIOCARBONS DEVELOPED BY NASA

Rehabilitation Engineering Center
Rancho Los Amigos Hospital
Downey, California 90242

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Vert Mooney, M.D., Principal Investigator
James B. Reswick, Sc.D., Director, Rehabilitation Engineering Center

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INTRODUCTION

Our definition of a percutaneous implant is an object foreign to the body placed through the skin such that a permanent defect is created. The concept has been described in the past for many purposes, but not until the last 20 years have investigators been able to keep a device implanted without rejection and/or infection. The applications of such a device include hemodialysis (Stryker, et al., 1971), power supply (Miller, et. al., 1971), charging for cardiac pacemakers (Rogers, et al., 1967), and neuroelectric stimulation of nerves and/or muscles (Mooney and Hartmann, 1974; Mooney, Hartmann, McNeal and Benson, 1974). Also included in this is recording with clear signals from nerves (Kadefors, et al., 1970), skeletal attachment of artificial limbs (Mooney, et al., 1971), and dental implants (Grenoble, et al., 1973).

The problems created by having a percutaneous device present are mainly those of low grade and/or deep infection with ultimate rejection of the implant. In our experience at Rancho Los Amigos Hospital since 1968, using primarily percutaneous pure carbon, we have found that if proper care is taken, most infections will heal without need of implant removal. This proper care is protection from repeated minor trauma and local antibiotics if inflammation or drainage starts.

There are two main hemostatic mechanisms by which an implant may remain free of deep infection. One mechanism is a discharge of squamous epithelial cells from the down-growing of the epithelium layer extruding outward along the neck of the implant. This cellular debris carry with them the bacteria and other contaminating elements out from the deep layers. A second mechanism is an enclosing wall of synovial type

tissue lining the entire implant, sealing it from the deep tissue layers. However, this second mechanism seems to be more susceptible to minor trauma, the implant is less well anchored to tissue, and it may eventuate in the expulsion of the device in a "popping-out" or button-hole manner.

DESIGN AND MATERIALS

The initial design was a silastic device with a center of pure carbon (Fig. 1).

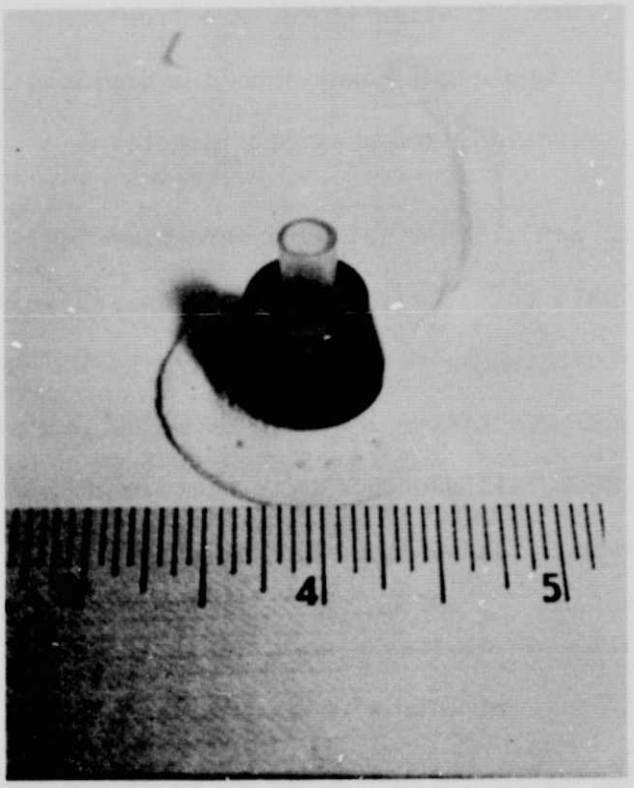

Figure 1. Early implant design, silastic with a carbon center.

This implant was similar to the ones used by Nelson (1969) and Stryker (1971). The implant was used for chronic dialysis patients with the carbon center acting as an interface. The subcutaneous

portion of this was a dacron skirt sewn and glued into the silastic to allow for tissue ingrowth and fixation.

The difficulties with this type of implant arose from the failure to find a good method of bonding the silastic to the carbon ring. Many epoxies were tried, but all of them eventually broke down and allowed fluids to leak externally, thus creating a passageway for an infection to penetrate internally. Moreover, the object was too large for practical use and the skin-implant interface would not heal well. The size of the implant did not allow it to move freely with the supple skin. Thus, the skin would pull away from the implant, allowing for further leakage, irritation, and possibly infection.

Our next experience was with an all pure carbon design, both low temperature isotrophic (LTI) and vitreous carbon (VC). We experimented with several different types of shapes and sizes. The early "daisy" design did not allow good tissue ingrowth as we had hoped. In addition, it did not have a neck tall enough, so it would tend to sink below the level of the skin which would epithelialize over it.

In the next generation of devices a satisfactory design was attained. This device has a flange in which are spaced numerous holes. Initially the holes were both of too small a diameter and too great a depth to allow for adequate vascularization of the ingrowing tissue. The latest designs incorporate large holes of similar design which has alleviated this problem (Fig. 2 on page 5).

A further advance was made in materials utilizing both unpolished and polished LTI carbon. A major difference with the titanium (TI) devices

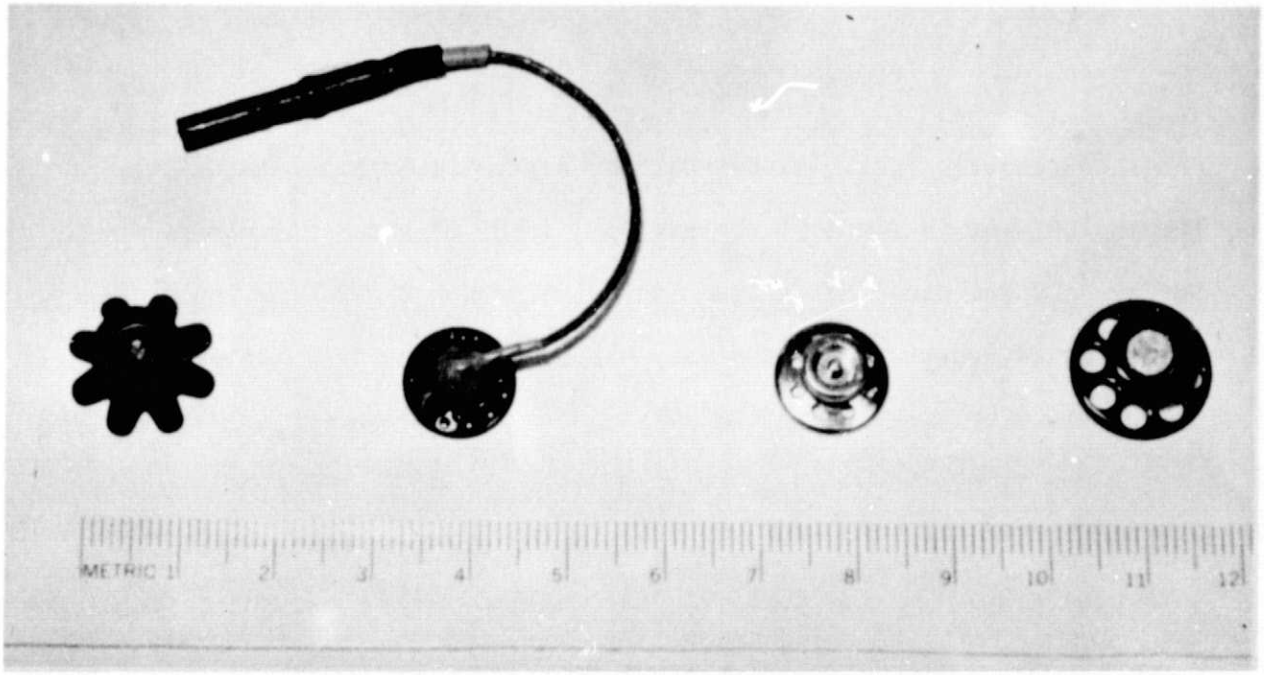

Figure 2. Succeeding designs; from the left, early "daisy" shape, polished carbon with permanent connector, Titanium with pin connector, polished carbon with magnetic connector.

is that they have a polished surface. Grenoble, et al., (1973) evaluating dental implants, found that the tissue seemed to affix better to unpolished surfaces which he felt afforded a better implant fixation.

To evaluate whether a polished surface would actually make a significant percutaneous device, three volunteers at Rancho Los Amigos Hospital agreed to have six buttons implanted in their anterior thighs. Three titanium and three different type carbon buttons were implanted for a 12-week duration. The devices were removed in-mass with a tissue block so that the interface could be microscopically studied without any difficulty.

Prior to removal, India Ink was held by a thimble-type apparatus over the implant for 15 minutes. On removal, (Fig. 3) shows the undersurface and the excellent tissue ingrowth through the 2.8 mm. holes. Following 24 hours, the tissue was sharply dissected from the implant

Figure 3. Undersurface of removed button showing good tissue growth.

and stained with hemotoxalin and eosin. The ones that had good tissue seal around the neck showed no evidence of the India Ink penetrating to the deeper layers and into the synovial-type lining that exists

around most of the buttons. In the buttons that had some infection or leakage there was not a tight seal. It can be seen in (Fig. 4) that the India Ink penetrates the deeper layers, intermixing with the red blood cells in the areas of the synovial lining around the surface of the button.

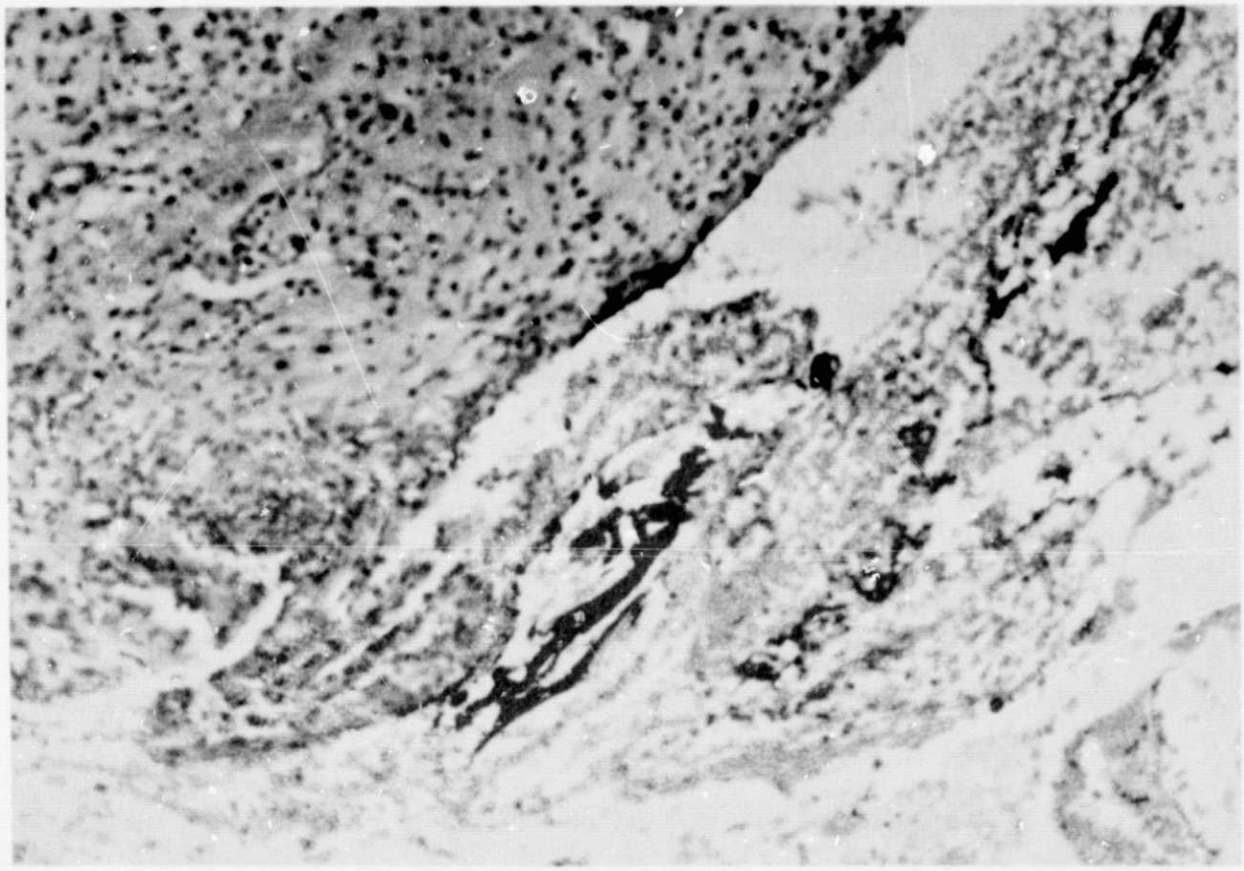

Figure 4. Microscopic view showing India Ink penetration into the synovial lining.

On histological examiniation we found no difference between any of the buttons, either titanium or carbon. They all had a similar number of reactive cells, a similar amount of inflammation, no outright rejection, and all seemed to be well seated into the subcutaneous tissue. Thus, we felt that polished TI could easily be utilized for the devices along with carbon.

PERCUTANEOUS ELECTRICAL CONNECTORS (BUTTONS)

Design

The percutaneous buttons we are presently using are of two materials- low temperature isotrophic (LTI)[1] and titanium (TI)[2] and are both of the same design and dimensions. There are three different neck sizes to accommodate the different skin depths at various anatomical sites. For example, for use in a fatty area, one needs a longer neck to insure that it will not be buried under the subcutaneous tissue. The dimensions for the neck heights are 1.8 mm., 3 mm., and 4.4 mm. The diameter of the base is 15 mm. and there are eight holes of 2.8 mm. diameter in the flange. This 2.8 mm. diameter was found to be satisfactory for tissue growth.

Connector Systems

An additional problem we had, aside from device design and materials, was an effective connector system. Our earlier generation permanent connector would catch on clothes, etc., leading to an eventual infection with drainage around the base of the device. The advances made in developing a simple, less traumatic connector have recently been described by Mooney, et al., (1976).

Briefly, a magnet is mounted in the head of the device as well as the external lead. The lead is self-centering when brought in close proximity to the device. This design allows an easy disconnect if there is a sudden force pulling on the lead, avoiding irritation at the skin-implant interface. Figure 5 as seen on page 9 is a device

1. General Atomic Company, La Jolla, California.
2. Medtronic, Inc., Minneapolis, Minnesota.

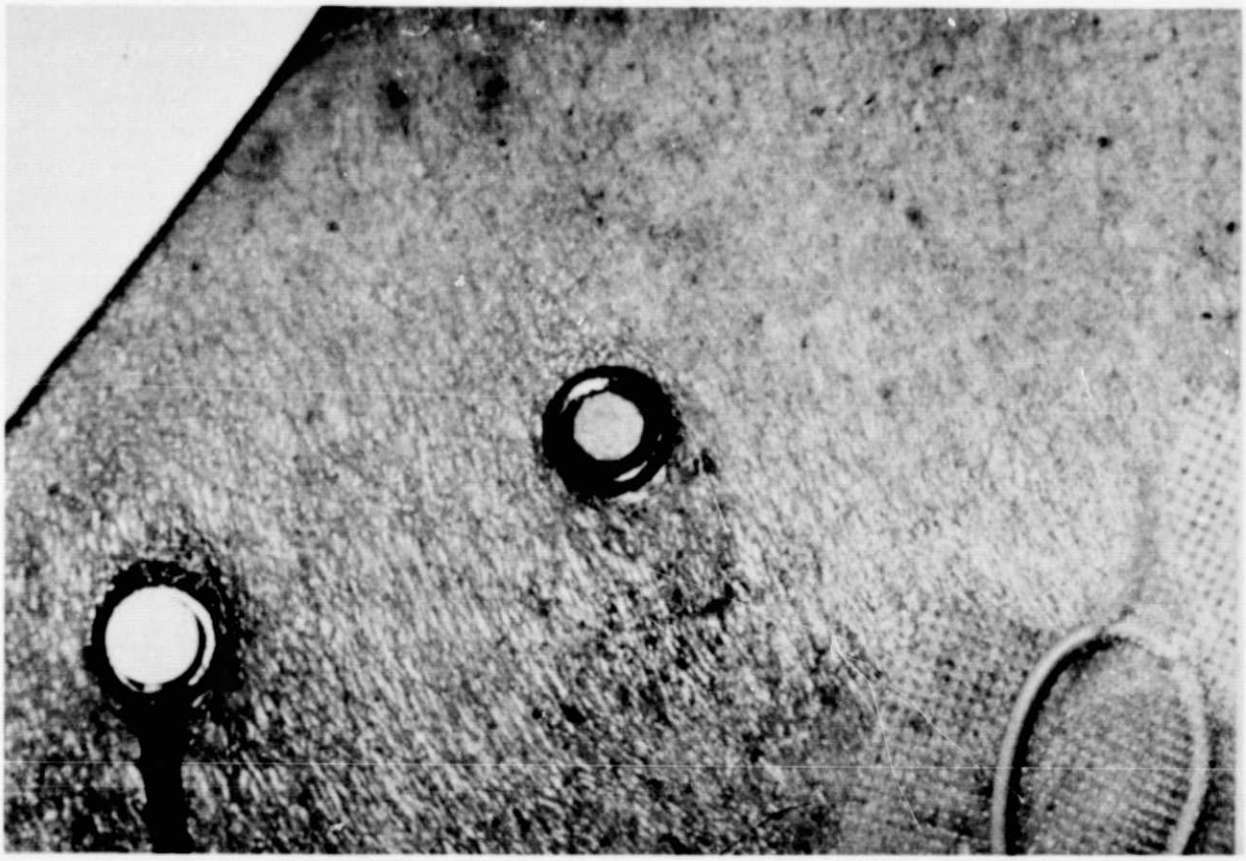

Figure 5. Percutaneous button with magnetic connector in place.

that has been implanted for eight weeks, and has undergone six weeks of repeated connection/disconnection up to 40 times a day without serious trauma or problems. Currently, development is underway on a bipolar magnetic connector.

Types

There are four different types of electrodes, depending on the type of conduction and stimulation that is needed. Type I is used when just the presence of electrode at the skin surface is needed. It has generalized distribution of current and is primarily used in the clinical

application for chronic pain relief, using one of the transcutaneous nerve stimulators currently available. Before the patient has these buttons implanted, he uses surface electrodes to determine the site for stimulation. The electrode connective devices are implanted for convenience sake. We have had a number of patients who have had these implanted in place for one or two years with minimal problems, mainly related to the connector systems.

Type II is for more direct application of current and allows for greater tolerance of high current densities. It is insulated except for the bottom portion, protecting the cutaneous aspect from stimulation and irritation. Thus, the patient can tolerate more current for motor point stimulation. The button is placed over the motor point that has been predetermined by surface stimulation. Its primary use is for stimulation of muscles that are either weak from disuse atrophy, e.g., postoperative atrophy, or weak secondary to spinal cord injury or stroke. In addition, these are used in a stimulation program combined with surgical release for contracture correction (Mooney, et al., 1976).

The third button, Type III (Fig. 6 as seen on page 11), is one with a wire electrode leading from the button down to a nerve or muscle for implantation. The entire button is insulated except for the tip of the wire. This button is for exact motor or sensory stimulation, thereby avoiding a diffuse stimulus. In addition, it can be applied for recording nerve action potentials. It is also an important component in a sensory feedback system for upper extremity prostheses. The lead wire is a teflon coated wire attached to a 30-gauge needle, the last centimeter bare for contact. The needle is passed through the epinerium

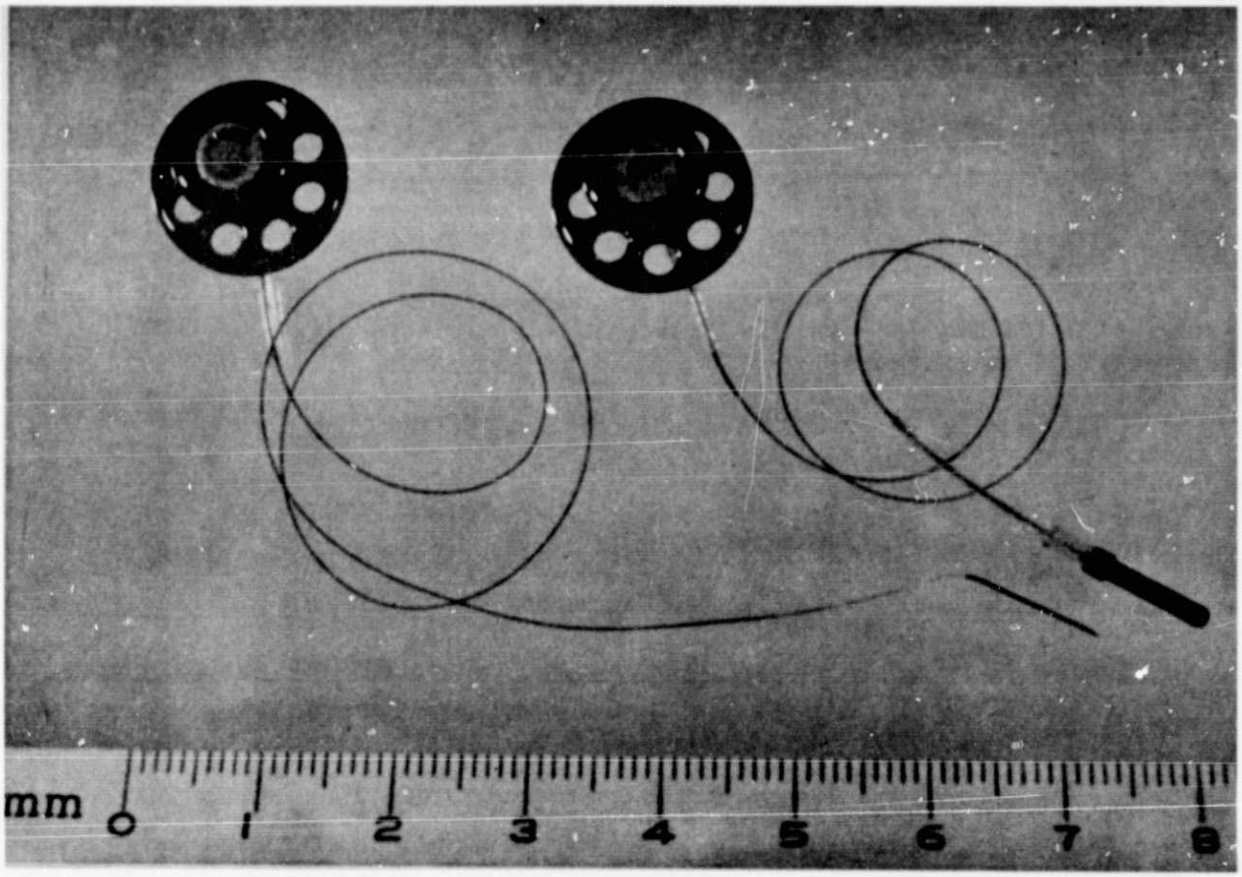

Figure 6. Left - Type III percutaneous electrode with intraneural wire electrode. Right - Modified Type III with carbon probe in place of the intraneural tip.

of the nerve for approximately 11-13 mm. distance and then out so the needle can be cut off leaving the bare wire for stimulation (Fig. 7 page 12). We have shown on experiments of cat nerves that this does not disrupt the nerve sheaths and does not cause any irritation or malfunction of the nerve.

The Type IV button is one with a larger bipolar lead terminating with a wrap-around electrode which is sutured around the nerve. This has been used in a program for contracture correction using peripheral motor nerve stimulation.

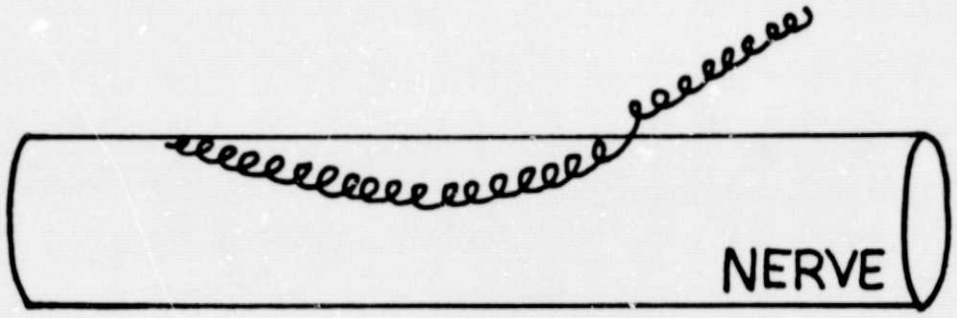

Figure 7. Schematic drawing of an intraneural electrode. The approximately 1 cm length of coiled wire inside the nerve is deinsulated.

Implantation Technique

Implantation of non-wire connected devices can be done in the office or out-patient operating room in about ten minutes per implant (Fig. 8).

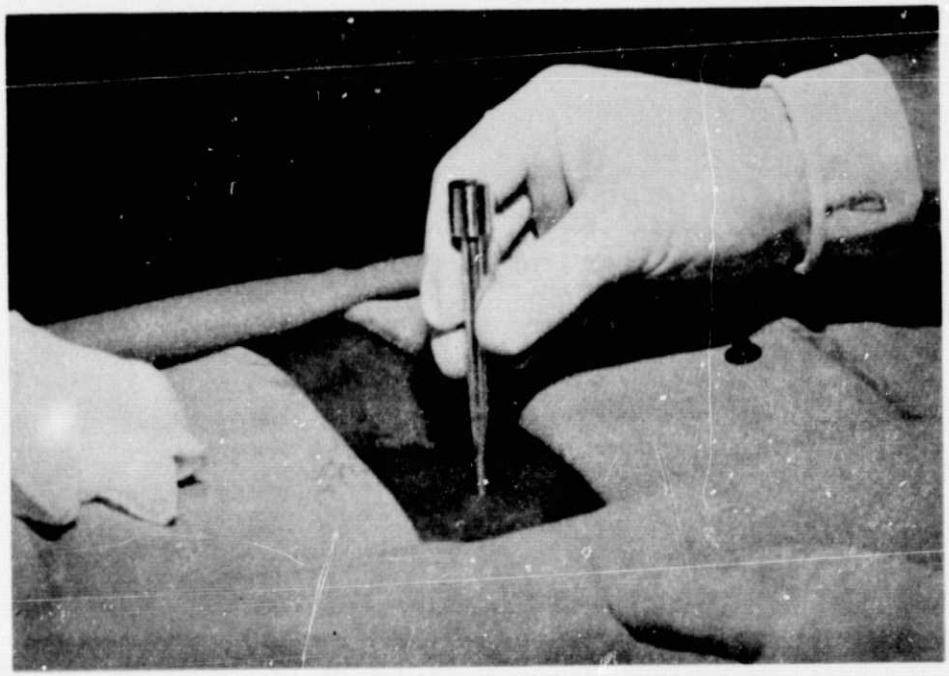

Figure 8. Implantation of button using a biopsy hole-punch under local anesthesia.

It is done simply as follows: The site chosen for implantation is prepped with an antiseptic solution and draped off in the surrounding

area. The site should be in an anatomically convenient area away from joints which allow too much skin motion. A small amount of local anesthesia, e.g., xylocaine, is injected into the site where the implant is to be placed. A 2 cm. incision is then undermined for approximately a 1-1/2 cm. space to the side of the incision. A biopsy-type hole-punch is then used to make the hole through which the button will be pushed. The punch size is 5 mm. diameter and made over the area undermined. Then, using a sizing button (similar to the ones implanted permanently), which has a neck with three neck sizes defined, it is determined which size neck is appropriate in that area. Once the correct implant is chosen, it is slipped similarly through the incision and brought through the punch hole. The incision is then closed with interrupted non-absorbable sutures and an antibiotic ointment is placed on the wound, which is then dressed with a simple gauze dressing.

Post-implantation care is similar to any other small incision. Sutures are usually removed in ten days to two weeks, although we do not start any stimulation via the implants for at least two weeks to allow time for the tissue to stabilize.

Clinical Application

At Rancho Los Amigos Hospital, we have implanted over 125 percutaneous electrode devices, with a total of over 965 implant-months experience. As stated above in the description of the various types, our clinical applications presently include chronic pain relief, contracture correction, and sensory feedback. Results indicate an overall success rate of 60% with the separate breakdown of results described in Tables 1-3.

TABLE I

TOTAL		MATERIAL	
Type I	73	Vitreous Carbon	49
Type II	32	Low Temperature Isotrophic	41
Type III	11	Titanium	37
Type IV	11		
	127		127

TABLE II

CATEGORIES FOR PERCUTANEOUS ELECTRODES

	No. Buttons	No. Patients
Pain Relief	36	11
Contracture Correction	58	22
Sensory Feedback	9	3
Volunteer (no stimulation)	24	7
TOTAL	127	43

TABLE 3

SUCCESS RATE

Category	No. Successful	Avg. Mo. Successful	Longest Success	No. Unsuccessful	Avg. Mo. Until Failure	Success Rate
Titanium	21	8.4	20	16	8.5	57%
LTI	24	8.3	24½	17	8.9	59%
VC	33	5.9	35	16	6.8	67%
Volunteer	17	2.9	8	7	4.6	71%
Pain Relief	17	12.6	35	19	7.2	47%
Contracture Correction	38	6.9	24½	20	10.2	66%
Sensory Feedback	6	7.0	9*	3	8.0	67%

*Still in Place

Sensory Feedback for Prostheses

It is generally recognized that the success of functional substitution and the rate of successful patient fitting is far better for lower limb prostheses than upper limb devices. Certainly the function of grasp and release is more difficult to replace and control than the swing and stance phases of lower limb prosthetic function. But perhaps a more devastating loss in the upper limb amputee is the absence of sensation which provides the normal hand with the feedbakc necessary for manual dexterity. The purpose of this project was not only to provide the amputee with a powered myoelectrically controlled prosthesis, but also to provide substitute sensory feedback through the peripheral nervous system.

Since this study was conceived to identify the applicability of neuroelectric feedback systems to the upper limb amputee using myoelectric controlled and electronically powered prostheses, it was decided to challenge the question of applicability to various type of amputee problems.

Three different types of amputees were studied. The first amputee was already an experienced and truly functional user of a cable driven below-elbow prosthesis. He was tested to objectively identify the amount of non-visual feedback of terminal device position that are inherent in a functional user. This amputee was used to verify the technical feasibility of the transcutaneous neuroelectric feedback system. The second amputee fit with the system was a recent below-elbow amputee who had not yet become expert

in the use of any prosthesis. He was fit with the VA-NU powered prosthesis, with the neuroelectric feedback system. He was also fit with a standard prosthesis for comparison. The third subject was a recent bilateral below-elbow amputee who had the neuroelectric feedback system applied to the non-dominant limb (left) and specific comparisons concerning the use and function of the two prostheses were made.

The first patient could find no advantage to the feedback, as he was accustomed to wearing conventional prostheses for eight years. On this basis he asked to be discontinued from the study and the Type III carbon buttons were removed under local anesthesia in the clinic.

The second patient (R.H.) was fit with a myoelectric hand, but

Figure 10. Patient A.G. without prostheses and with the cable driven prostheses. The prosthesis on his left is equipped with the feedback system, which passes signals to his nerves via percutaneous carbon buttons.

interference between the electric controls and the sensory feedback system caused continuous malfunctions, despite an extensive amount of filtering and redesign work. Other problems, which may not have been related to the implants caused this patient to reject the sensory feedback system.

The third patient (A.G.) was a success (Fig. 10 on page 17). He was right handed but is presently left hand dominant due to his preference for the feedback system, which he has been using. He states it "Gives me the sensation that the prosthesis is part of me." Extensive testing has shown that the patient's ability to differentiate sizes of objects held in the hook is far better with the feedback system (Fig. 11).

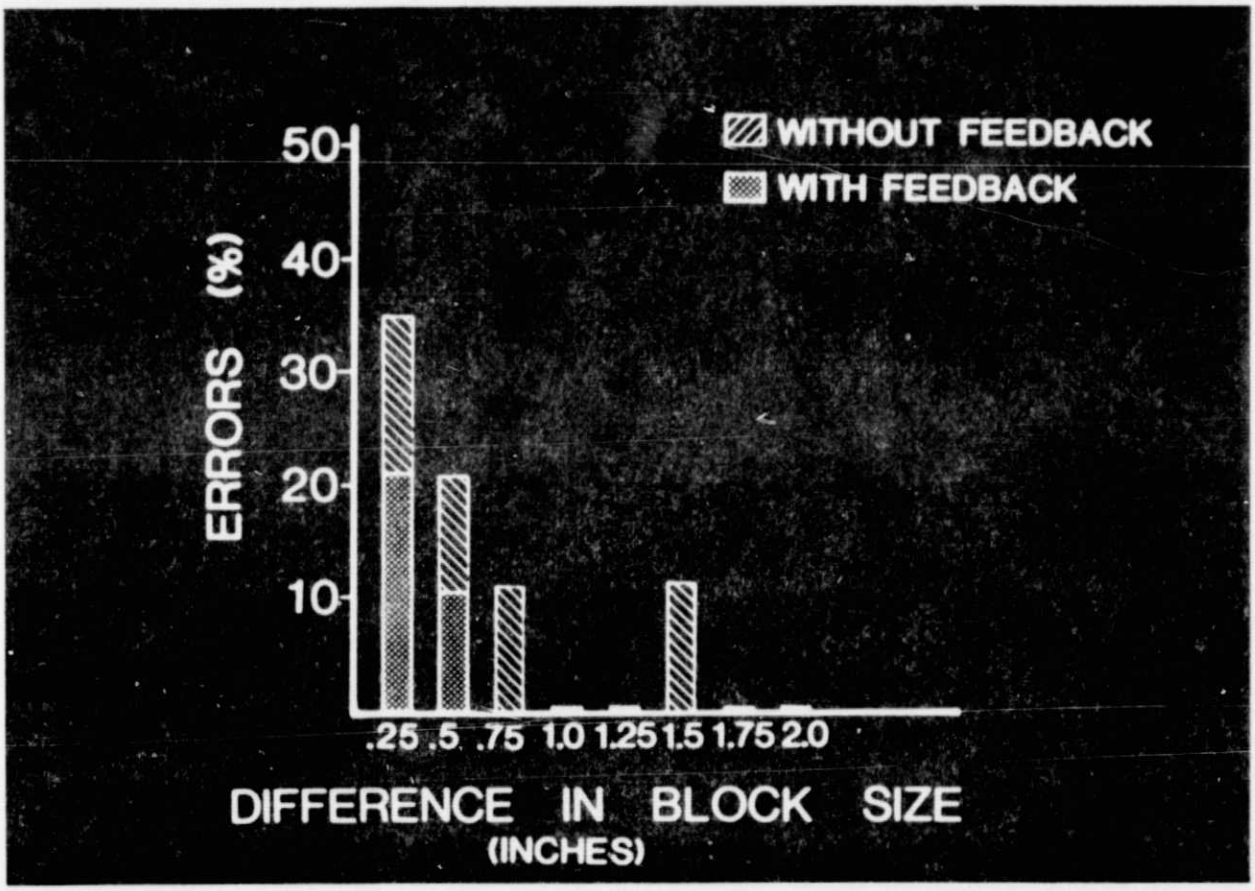

Figure 11. Comparison of the ability of a patient to differentiate block sizes with and without neuroelectric feedback. Errors decreased by 40 to 50% when the neuroelectric feedback system was utilized.

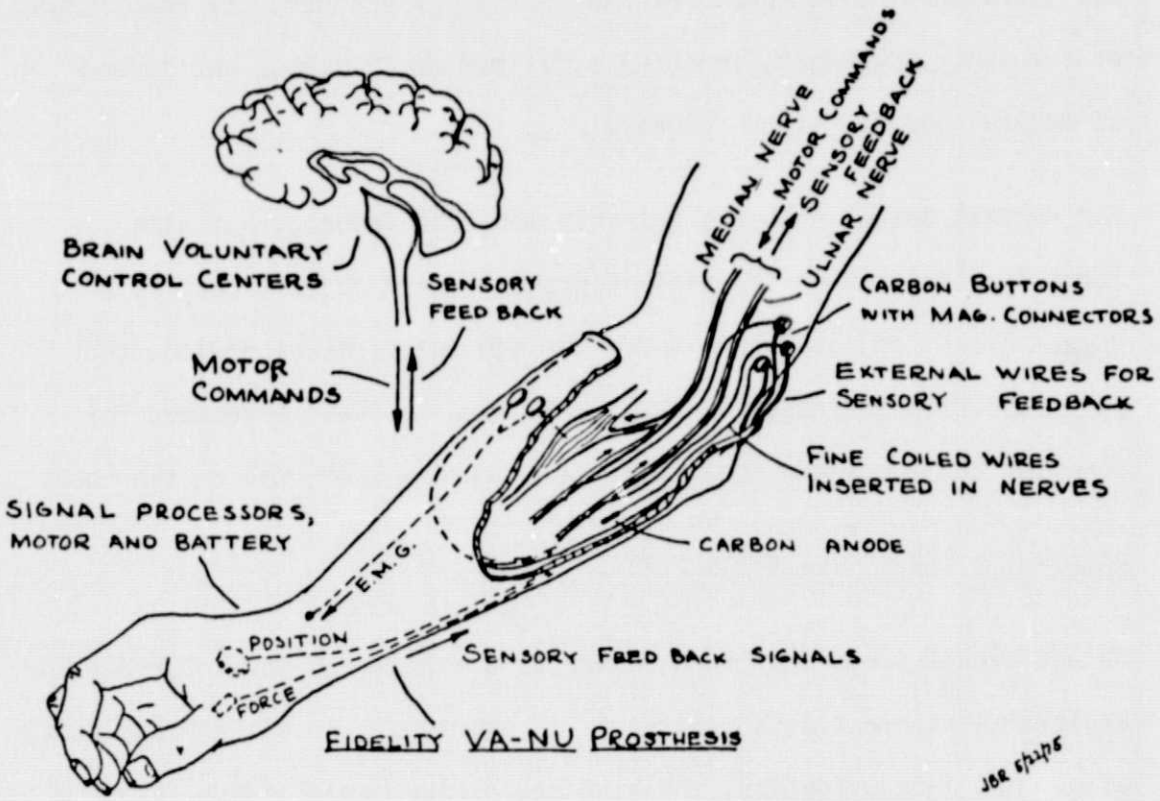

Figure 12. Conceptual illustration of the sensory feedback system applied to a powered, myoelectrically controlled prosthesis.

Currently, information on both position and force are presented by electrical stimulation of the ulnar nerve (Fig. 12). A single electrode 2 mil. in diameter of helically coiled stainless-steel wire is buried in the nerve. A one centimeter length is deinsulated and threaded through the nerve at the time of surgery. An indifferent, or ground, electrode is also implanted.

When the hook or hand is closed with no object between the two fingers, no signal is applied to the nerve. When the hook is opened slightly,

a train of electrical pulses are transmitted into the nerve by way of the intraneural electrode. As the hook opens further, the repetition of frequency increases, reaching a maximum of 80 pulses per second at maximum opening (four inches).

The current design provides not only position feedback but also force feedback. When the patient grasps a hard object, such as a wooden block, and applies a force through the terminal device, the pulse duration increases linearly with force. The transducers for position and force are specially constructed and mounted on the hook.

PROSTHETIC SUSPENSION VIA SKELETAL IMPLANT

An additional use of carbon has been as a transcutaneous interface for skeletal attachment of a prosthesis in amputees. At the present state of our art in prosthetics, the high above-elbow amputee possesses a particular problem with regard to suspension and prosthesis control. Conventional means of suspension consist of shoulder harnessess and straps, both of which are cumbersome and acosmetic. The short residual limb often has too limited a lever arm for effective control of the prosthetic limb.

Our present design was developed with the cooperation of the National Aeronautics and Space Administration and Dr. Jack Bokros of General Atomic Company. It consists of a stainless steel with carbon collar implant that is cemented with methylmethacrylate to the intramedullary canal of the bone in the amputee's stump (Fig. 13 on page 21, 14 on page 22).

The implant is then brought through the skin with the unpolished carbon collar as an interface. Suspension of a prosthesis is now achieved

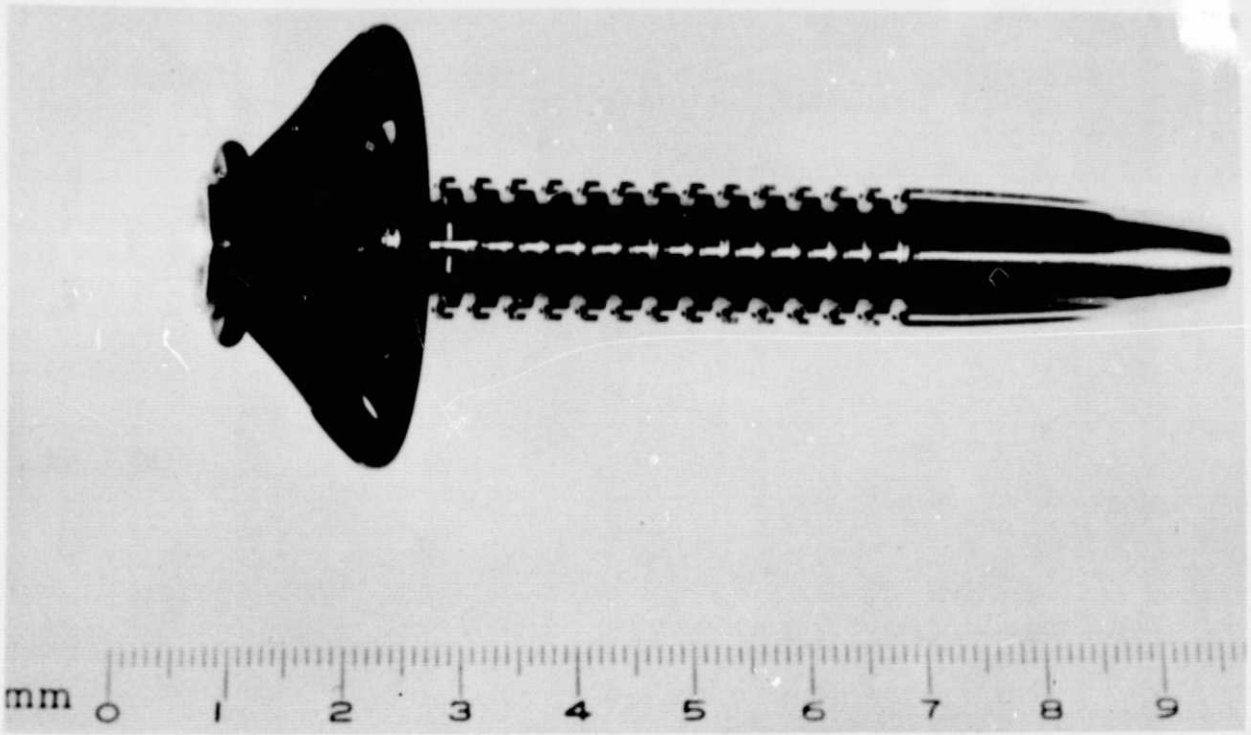

Figure 13. Intramedullary skeletal fixation device. Stainless-less steel rod with a carbon collar.

via a quick disconnect device that locks into the shaft of the implant. Initially designed for the below-knee amputee, it was found that the trauma with even simple ambulation was enough to prevent maintenance of a good seal at the skin-interface, resulting in leakage and/or infection.

Presently, the skeletal implant is being applied to the above-elbow amputee, avoiding the conventional suspension system. To date, the carbon/stainless steel implant has been utilized in three amputees. Because the patients were failures with regard to fitting by the conventional system, we had hoped the new device would be more acceptable. Post-operatively, the patients' new fittings were delayed secondary to a superficial wound infection, which at the

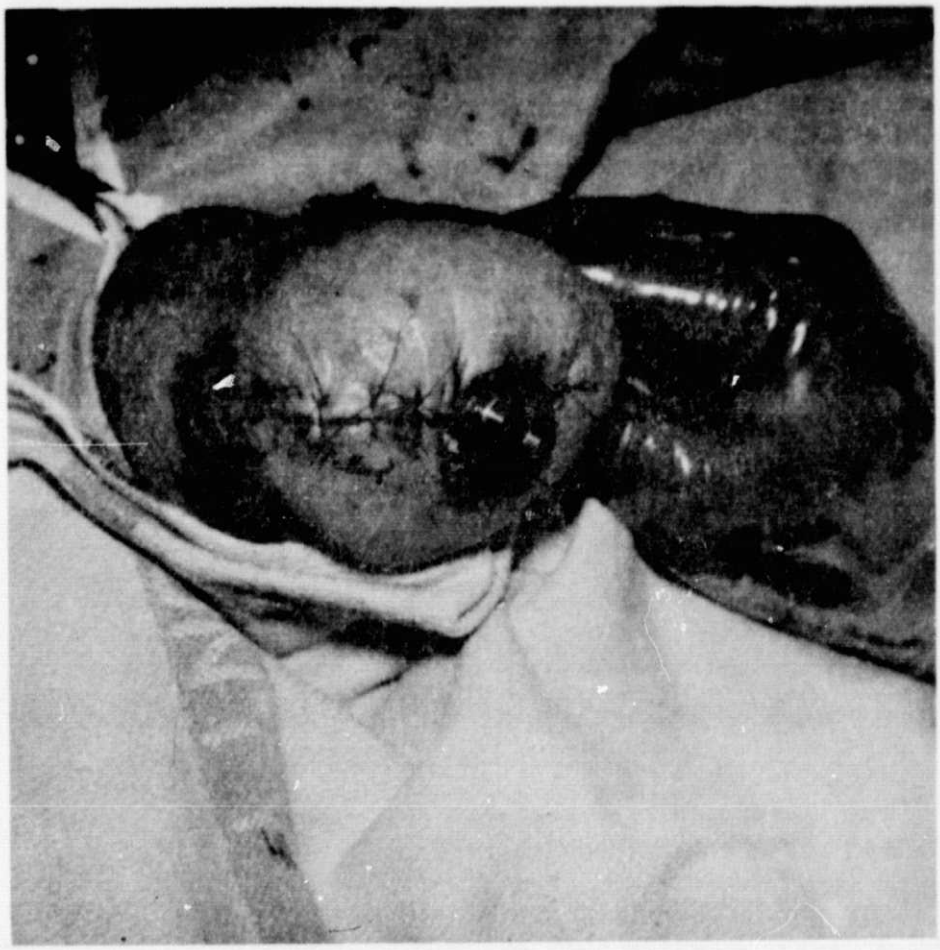

Figure 14. Skeletal prosthesis attachment unit implanted in leg of amputee.

time of discharge was controlled with local skin care. Unfortunately, all implants have required removal in less than six months post-implantation secondary to chronic infection aggravated by mechanical irritation. At present, further evaluation is necessary to determine the efficacy of the device for human amputee use.

DISCUSSION

Our experience with chronic percutaneous passage is summarized in Table 4 on page 23. The first criteria for successful percutaneous

passage is that the material be biocompatible. As Table III suggests, our greatest experience has been with vitreous carbon, and with this material we have also had out most significant success. Lesser success is noted with LTI carbon and even slightly less with Titanium. These discrepancies are not statistically significant, but our clinical impression remains that vitreous carbon has apparently unique characteristics from the standpoint of tissue compatibility.

Our experience has taught us, however that the major problem is not

TABLE 4

CRITERIA FOR ELECTRODE IMPLANTATION

1. Biocompatible material.
2. Device not fixed to deep tissue.
3. Mobility to move with skin.
4. Insert only in area of normal tissue.
5. Insert in best anatomical area.
6. Keep as flush to skin as possible.

at the level of biocompatibility, but rather mechanical forces. If the device cannot move with the skin itself, the stress concentrations at the skin-implant interface become excessive and gradually an inflammatory reaction results. In fact, the majority of our failures must be on account of excessive mechanical activity rather than any problems related to bacterial flora, allergic reaction, etc.

We have found that healthy skin tolerates this intrusion quite well. If left free of excessive mechanical stresses, the implant can exist

through the skin with a minimum of special attention. Washing twice daily is sufficient in those patients whose hygienic habits are normal. However, where the skin is poorly vascularized or where the implant will frequently abut against skeletal prominences, failure is likely. Finally, the implant must not protrude through the skin to such a level that it will easily catch upon objects. Many of our earlier failures were due to the electrical mechanical connector wherein the wire "tether" attached to the implant would not release with sufficient ease so that constant tugging occurred at the interface. With the new electro-magnetic connector, our success rate has been higher. One might look upon this work as merely demonstrating that the body can "encapsulate" the foreign material if this material is sufficiently non-irritating. This indeed may be an adequate summary. Certainly we have had no evidence that the body will extrude the implants. Nor have we had any evidence that proliferating cellular material in the depth of the implant will form granulomata and clusters of cells. Epithelial desquamation only occurs at the neck of the implant and has not been demonstrated to occur in a deeper area.

We think this work does demonstrate that an adequate bacterial seal can be achieved for a prolonged period of time at the human skin-implant interface. This experience hopefully will encourage others to try alternative approaches in order to compare experience.

SUMMARY

Experience with 127 percutaneous implants in 43 patients and volunteers has been presented. A prolonged success of these implants can be

expected if mechanical factors are reduced to a minimum. At this point, there is insufficient statistical data to indicate which of three biocompatible materials is ideal, but pure carbon has demonstrated the highest level of success.

REFERENCES CITED

1. Grenoble, D.E., Kim, R.L., Voss, R., Melrose, R.J., Wullschlager, G., Knoell, A.C. and Gupta, K.K.: Development and Testing of a Vitreous Carbon Dental Implant. Proceedings of the 18th National SAMPE Symposium, 1973.

2. Kadefors, R. and Reswick, J.B.: A Percutaneous Electrode for Long-Term Monitoring of Bio-Electric Signals in Humans. Med. and Bio. Eng., 18:129, 1970

3. Miller, J. and Brooks, C.E.: Problems Related to the Maintenance of Chronic Percutaneous Electronic Leads. J. Biomed. Mater. Res. Symp., 2:251-267, 1971.

4. Mooney, V., Predecki, P.K., Renning, J. and Gray, J.: Skeletal Extension of Limb Prosthetic Attachments--Problems in Tissue Reaction. J. Biomed. Mater. Res. Symp., No. 2 (Part 1): 143-159

5. Mooney, V. and Hartmann, D.B.: Percutaneous Passage. Biomed. Elec. Tech., 329-339, 1970.

6. Mooney, V., Hartmann, D.B., McNeal, D. and Benson, J.: The Use of Pure Carbon for Permanent Percutaneous Electrical Connector Systems. Arch. Surg., 108:148-153, 1974.

7. Mooney, V., and Roth, A.M.: Advances in Permanent Percutaneous Electrode Systems. Biomaterials, Medical Devices and Artificial Organs, 4:2, 1976, (in press).

8. Nelson, P.J.: Silastic Skin Button for Chronic Exteriorization of Tubing in Dogs. J. Appl. Physiol., 27:763-764, 1969.

9. Rogers, A. and Morris, L.B.: Percutaneous Leads for Power Control of Artificial Hearts. Trans. Amer, Soc. Artif. Int. Organs, 13:146-150, 1967.

10. Striker, G.E. and Tenckhoff, H.A.M.: A Transcutaneous Prosthesis for Prolonged Access to the Peritoneal Cavity. Surgery, 69: 70-74, 1971.