EXPERIENCE WITH BIOCOMPATIBLE CARBON AT RANCHO LOS AMIGOS HOSPITAL

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Biocompatible carbon, both in the form of vitreous carbon (VC) and as low temperature isotropic (LTI) (Pyrolytic) carbon vapor deposited on a graphite substrate, have been used with human subjects and patients at Rancho Los Amigos Hospital for five years. Two general configurations have been employed; vis, percutaneous electrodes in a form similar to collar buttons and as collars for direct skeletal attachments at the point of exposure through the skin.

Percutaneous Electrodes

Since December 1972, 127 percutaneous electrodes have been placed in volunteers and patients in the Contracture Prevention, Chronic Pain Relief and Sensory Feedback programs. Three materials have been evaluated; viz; vitreous carbon (VC), low temperature isotropic carbon (LTI) and titanium (TI). Clinical results have been nearly the same with all three materials. Electrical impedance is remarkably stable following insertion and is generally between 200-400 ohms, depending upon the spacing between electrodes. Little polarization is seen with the carbon electrodes, so the impedance is almost purely resistive.

Of the 127 electrodes used, 40 (38%) had to be removed because of infection or excessive skin irritation around the electrode and surrounding tissue. It has been anticipated that mechanical trauma will be reduced considerably, with a corresponding decrease in the failure rate, with the introduction of the magnetic connector shown in Figure 1. Twenty-three buttons with magnetic connectors have been used. Only two of these failed.

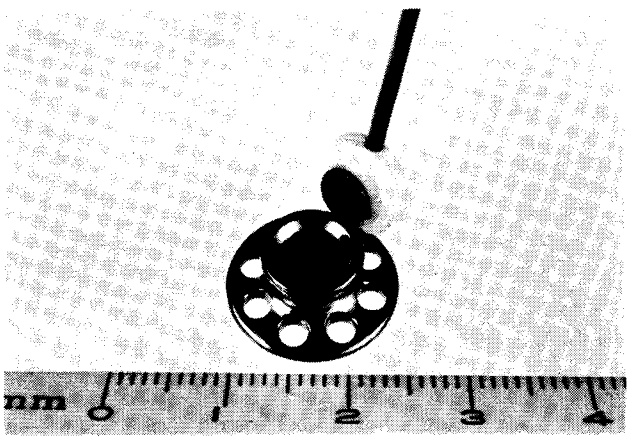

Fig. 1 Percutaneous Electrode with Connector

Intraneural electrodes which exit the skin through carbon buttons (Figure 2) have been fabricated for use in the Sensory Feedback Prosthesis program. In this case the carbon is insulated from the wire and the magnetic connector, and it is used only to provide percutaneous passage. The indifferent electrode (also shown in Figure 2) is identical except that a small carbon tip is attached to the coiled wire. The carbon tip is placed outside the nerve, but in close proximity to it.

Clinical experience at Rancho Los Amigos Hospital through 1976 is summarized in Tables I and II. Table I shows 127 buttons organized by type of material, and Table II shows these same buttons organized by category of application. An

Table I

Material	Number Successful	Avg. Mos. Successful	Longest Success	Number Unsuccessful	Avg. Mos. Until Failure	Success Rate
Titanium	21	8.4	20	16	8.5	57%
LTI	24	8.3	24.5	17	8.9	59%
VC	33	5.9	35	16	6.8	67%

Table II

Category	Number Successful	Avg. Mos. Successful	Longest Success	Number Unsuccessful	Avg. Mos. Until Failure	Success Rate
Volunteer	17	2.9	8	7	4.6	71%
Pain Relief	17	12.6	35	19	7.2	47%
Contracture Correction	38	6.9	24.5	20	10.2	66%
Sensory Feedback	6	7.0	9	3	8.0	67%

application is considered "successful" if an implanted button does not have to be removed for reasons other than the termination of the patient's treatment.

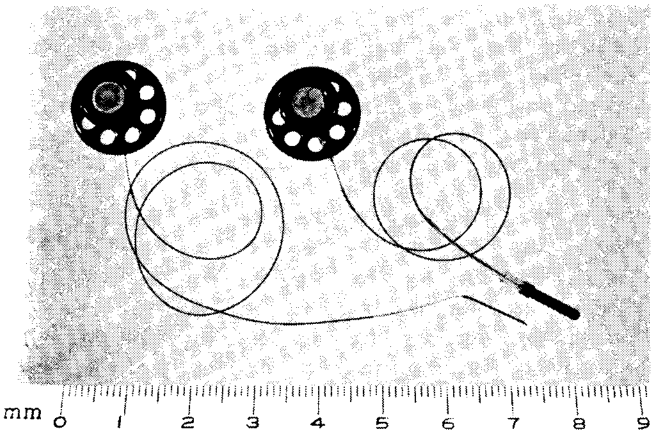

Fig. 2 Intraneural Electrode

Skeletal Attachment of Prosthesis

Through a unique collaboration among Rancho Los Amigos Hospital Rehabilitation Engineering Center, Kennedy Space Center of NASA, and General Atomic Company in San Diego, California, a system for directly attaching a limb prosthesis to the bone of the amputated limb of the stump of the amputee has been developed (Figure 3). A hollow metal intramedullary pin is cemented with methylmetacrylate into the amputee's bone. The metal unit is provided with a collar coated with low-temperature isotropic carbon. The skin closes around the carbon collar, creating a bacteriological seal and leaving the internal bore of the metal unit exposed to the outside. A quick-disconnect rod derived from Space applications is built into the prosthesis so that it can be inserted into the bore of the intramedullary unit for attaching the prosthesis. A normal stump socket on the prosthesis is used to absorb most of the limb load and to provide torsional stability.

This unit was implanted in one patient, who tolerated the implant for over a year. The skin around the carbon collar finally pulled away and became infected due to the mechanical forces exerted by the prosthesis necessitating removal of the device.

A new design (yet to be implanted) using a flexible element between the carbon and the intramedullary rod has been fabricated. It is hoped that this device will reduce the stresses between the skin and the carbon. It will be used on an upper extremity where skin stresses are expected to be less than on a lower extremity.

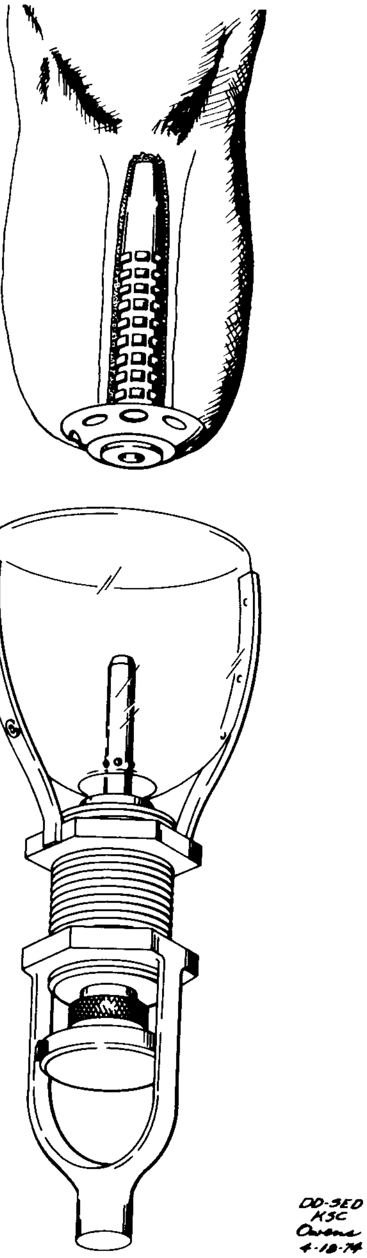

Fig. 3 B-K Prosthesis Attachment