THE USE OF PURE CARBON FOR PERMANENT PERCUTANEOUS ELECTRICAL CONNECTOR SYSTEMS

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ABSTRACT

Pure carbon has been used as an electrode in the clinical application of long-term neuromuscular stimulation as well as a connector for permanent neuroelectrodes. The history of this material and some examples of the material in use are presented.

INTRODUCTION

The infection free passage of a device through skin offers an opportunity for expanded use of various modern medical engineering assist devices. For instance, if one could develop a permanent percutaneous device several opportunities in the area of implanted electrical devices become apparent. Rechargeable batteries which would be smaller and more reliable than current power sources could be used. Using an electrical connector system, routine recharging could be available through such a connect-disconnect system.

Permanent connectors could be constructed which would monitor

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bioelectric signals necessary to control various assist devices. The simplest example would be bioelectric signals from a synergistic muscle which would control externally powered prostheses or braces. Currently, one of the limits of successful bioelectric devices is inability for receiver systems to receive a "pure signal" by way of surface electrodes. Cardiac electrical activity could be permanently monitored. Metabolic functions such as blood glucose levels could be precisely monitored and in turn trigger appropriate pharmacologic response.

The ability to achieve precise and controlled stimulation of nervous tissue offers an unusual opportunity for improved function. When permanent connections with the nervous system are available, partially paralyzed muscles or those paretic secondary to upper motor neuron disease could be functionally stimulated by external power and control sources. Using temporary connector systems precise stimulation of musculature following reconstructive surgery would allow controlled joint and muscle activity without the need of cerebral participation with its associated psychological and motivational variabilities. Using permanent percutaneous devices, pain which can be anatomically localized would be overwhelmed by electrical stimulation of the nervous system at a rate and frequency which is noxious.

The suggestions mentioned above as well as many other which come to mind in such areas as non-electrical power assists, fluid conduits, substitute sphincters--all these await a permanent infection free skin intrusion. It is the purpose of this paper to describe our experience

with a system which gives promise for the achievement of permanent skin intrusion.

BACKGROUND

The search for a permanent, infection-free percutaneous passage at this facility began with an attempt to achieve the skeletal fixation of a limb prosthesis. The first human implantation of such a device was performed here in 1968 with the skin interface portion of the device utilizing a Dacron velour backed by Silastic. This method was suggested by Hall,[1] who used it on several animals; however, eventually all failed at the bone bond. In our experience, persistant moisture was always present at the skin-Dacron velour interface, presumably due to the repeated superficial tearing at that interface. This drainage progressed to infection of the entire fixation device and therefore, as with the animal experiments of Hall, the devices had to be removed.

In 1968, we were made aware of a new material--vitreous carbon--which, because of its extreme purity, was considered to be biologically inert. About the time of the failure of our skeletal fixation device, the potential of this material was graphically demonstrated to us. A tiny carbon peg protruded without drainage through the skin of the arm of an engineer (J.B.) who was convinced of its biomedical applications. Thus, beginning in 1968, various vitreous carbon devices have been implanted into the skin of over fifty volunteer patients and staff at Rancho Los Amigos Hospital. Increasingly favorable clinical experience has encouraged us to pursue the use of this material in various designs

for permanent percutaneous passage.[2]

The first application of pure carbon for the percutaneous passage of electrical signals was reported by Kadefors and Reswick.[3] They used a two by four millimeter dumbbell shaped piece of vitreous carbon supplied by Benson to facilitate the long-term monitoring of myoelectric signals from forearm musculatures. One flange of the device lay in the subdermal layer with the remainder of the device protruding externally for about two millimeters. These authors were pleased with the low impedance which they recorded, and in the five months of the experiment noted no significant interface problem.

At Rancho a device using pure carbon over a silastic cylinder and a silastic faced with Dacron velour flange in the subcutaneous tissue was used for the skeletal suspension of a limb prosthesis in two patients.[4] This particular application demonstrated a satisfactory seal at the skin interface over a prolonged period of time. Due to chronic infection at the bone (not at the skin interface) both of these devices had to be removed after about six months implantation. Drainage from the osteomyelitis appeared around the metal pin in the center of the device rather than around the carbon which implied failure of the bond between the pin and the silastic rather than failure of the interface between skin and carbon.

With the need in this facility to electrically activate nerves and muscles in various types of chronic patients, a system of devices was designed to facilitate long-term neuromuscular stimulation.

MATERIAL

Pure carbon in the vitreous or glassy form is a relatively new type of material. It was first developed and characterized in England in 1963 and initially patented by Plessy Company, Ltd. of Great Britain. Its original development was an outgrowth of space travel needs. To be able to withstand the environmental rigors of rocket engines and re-entry shields, a nondestructable, very tough material was necessary.[5] The remarkable purity of this material, however, was soon recognized and its potential biological significance suggested.[6] In 1967, the Technology Utilization Office of the National Aeronautics and Space Administration, through contract with the Rocketdyne Division of North American Aviation Company, began to promulgate the potential biologic applications of vitreous carbon to the medical field.[7]

Vitreous (glassy) carbon might be more properly referred to as polymeric carbon as it is, in fact, a pseudomorph after the polymer from which it is derived. It has been described as "a network structure consisting of tangled ribbon molecules which are cross-linked by highly strained carbon-carbon covalent bonds with a wide spectrum of bond energies."[8] This material is derived through pyrolysis (thermal degradation) of any of several aromatic thermosetting polymers. It is a hard, impermeable solid with a specific gravity of less than 1.5. It has good electrical and thermal conductivity (comparable to series 300 stainless steel) and is chemically inert to all known reagents at ambient temperatures. Its hardness, approximately 8 Mohs, and impermeability

enable it to accept a high surface polish. It appears to have zero polarization potential in the bioenvironment and shows no galvanic activity with saline solutions.

The average purity of commercial material ranges from 50 to 200 parts per million of ash (impurity content) and this can be substantially improved by closely controlling the manufacture of the precursor polymer. Physical properties are satisfactory for bioapplication with a tensile strength near 20 KSI, compressive strength of 100 KSI and a Young's Modulus 3 to 4 x 10^6.

All of the carbon devices implanted in this study are characterized as vitreous carbon and were manufactured by Benson.

An alternative form of pure carbon which apparently has similar biologic activity and surface characteristics is pyrolytic carbon. Although this material was not used in the applications reported here, there is no reason to suspect that it would not be equally as successful. This material is created by the gas deposition of elemental carbon upon a graphite substrate. Pyrolytic carbon is somewhat tougher than vitreous carbon and the fracture stress of high density pyrolytic carbons are about two times larger than those of the glassy carbons.[9] Technical limitations on the thickness of pyrolytic carbon coatings that can be obtained tend to constrain exploitation of this advantage.

Carbon has been used with considerable success in Dental Implants. Over 100 have been performed with no reported infections.[10]

CLINICAL APPLICATION

The most prolonged use of pure carbon for infection-free percutaneous passage is in the skin overlying the right deltoid of a healthy, active male (V.M.) This was implanted in March, 1971 and at the time of this writing, has not been inflamed, drained, or extruded. As in the case of all other pure carbon percutaneous applications, no specific precautions are taken once the skin has healed. No dressings protect the protruding device and no special medications are applied to the skin. The subject participates in all normal activities such as surfing, tennis, skiing, and swimming. There is no discomfort related to this device in any way (Fig 1). There is no functional application of this implant and it is used strictly to monitor long-term tissue reaction.

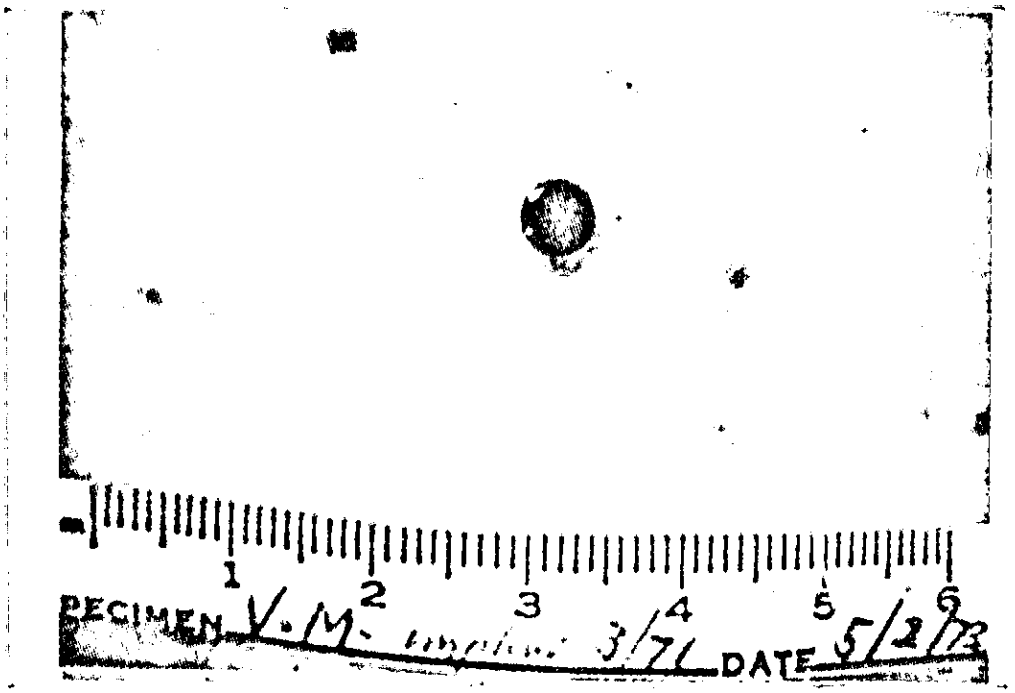

Fig 1--Carbon collar button in upper arm of volunteer at 26 months.

Several approaches using carbon for neuroelectric stimulation have been developed. All of them use a basic carbon device based on a design of Benson (Fig 2, 3, 4 and 5).

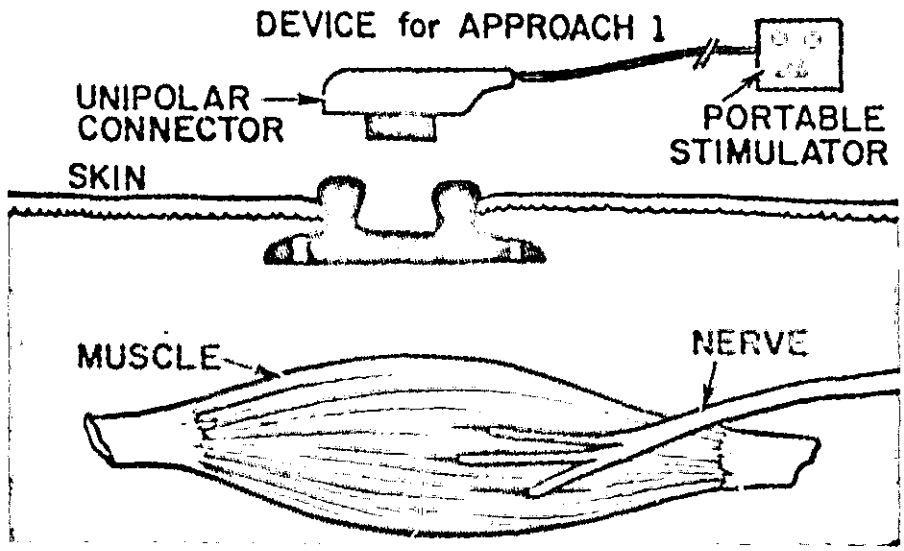

Fig 2--Illustration of system for regional stimulation such as for pain control.

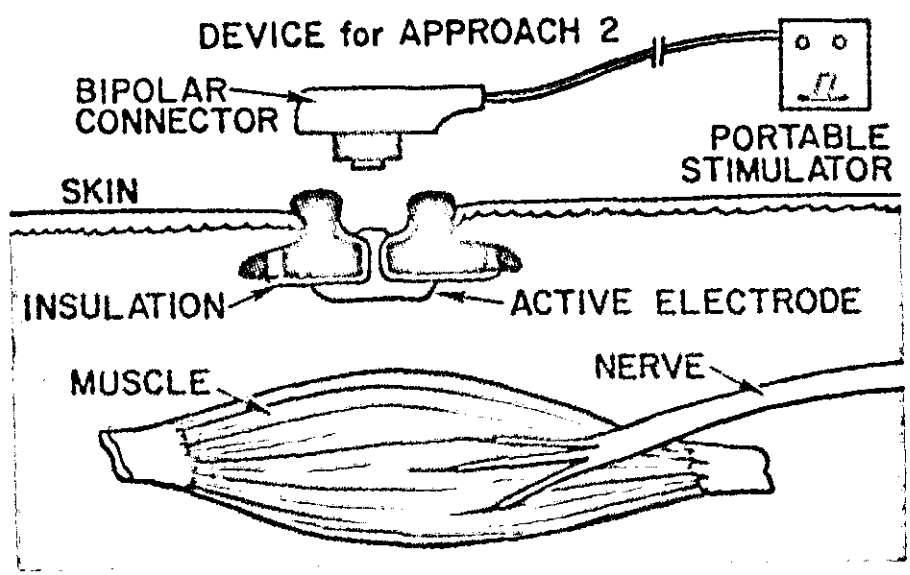

Fig 3--Illustration of system for localized motor point stimulation.

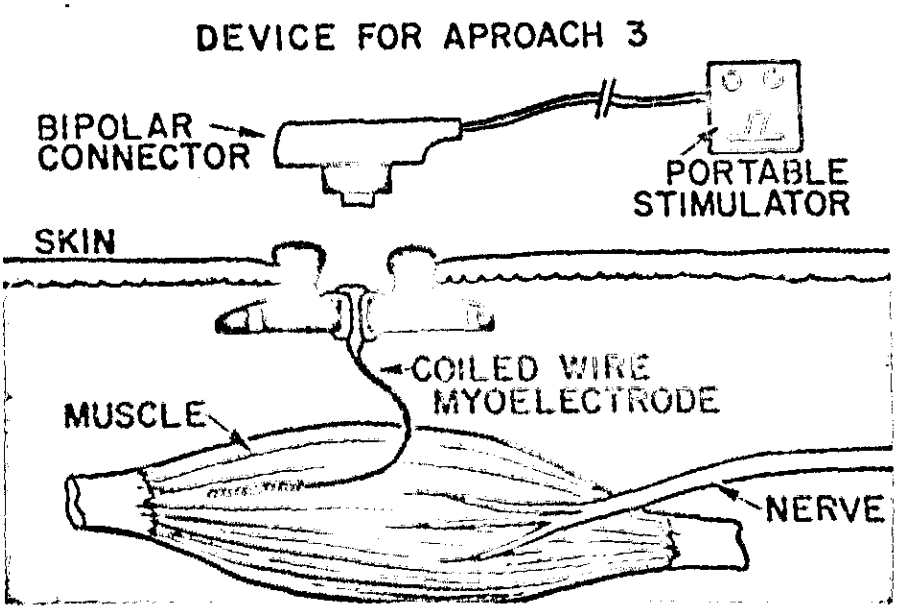

Fig 4--Illustration of system for individual muscle stimulation.

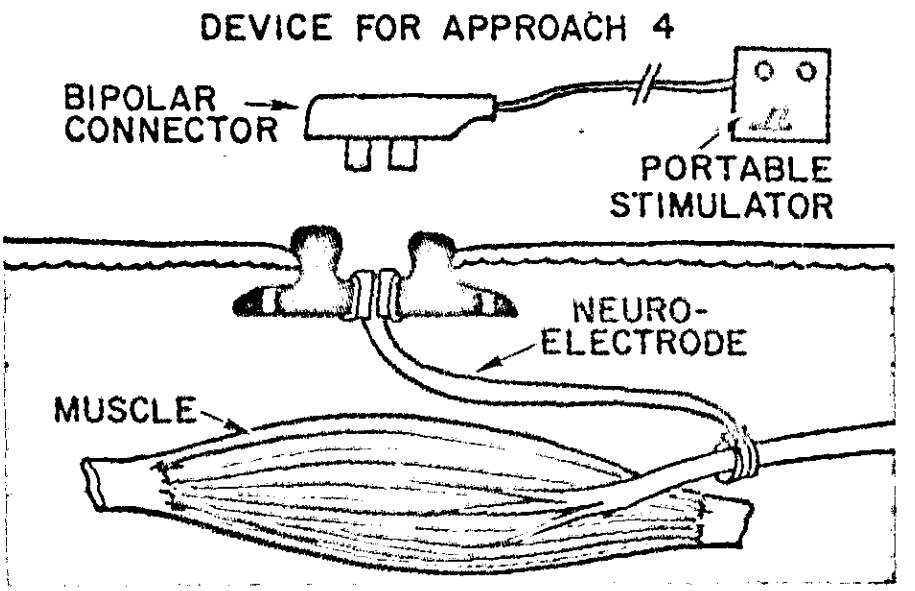

Fig 5--Illustration of system for neuroelectrodes (or other wire electrodes.)

All four types have been implanted in volunteer patients and are functional. In the initial devices, the connector system was unreliable and therefore, the electrical connection was through wires permanently attached by conductive epoxy cement.

APPROACH 1--CASE HISTORY

A 55-year old female with severe arachnoiditis following multiple surgical procedures on her thoracic and lumbar spine was admitted to the Problem Back Treatment Center with anticipation of the implantation of a dorsal column stimulator. After thorough workup and investigation of her anatomic as well as psychological status, it was apparent that she had true anatomic sources of pain. Empirically, it was found that various sites on her skin acted as trigger points and when electrically stimulated with a cutaneous stimulating device, consistent and persistent relief of her pain could be attained. Because maintaining moist surface electrodes was extremely inconvenient, especially in the upper thoracic spine area, two carbon buttons were implanted under local anesthesia over the trigger point sites. These were then connected by wire to the transistor radio sized cutaneous stimulating device. This patient is tolerating the stimulation very well and no longer needs the narcotics on which she was admitted. There are currently no problems with the skin interface which remains dry, non-inflammatory and non-tender. At one point, one of her carbon electrodes was repeatedly traumatized and a small amount of drainage developed. This was treated by minimizing trauma to the area and carefully cleansing the device several times a

day. The inflammation and drainage subsided completely, and the devices remain in use six months post implantation (Fig 6).

Fig 6--Carbon devices implanted in the skin over pain points for electrical stimulation to block pain.

Five other applications using the same devices have been done for muscle stimulation and for the control of pain. Currently, all skin interfaces remain without gross infection.

APPROACH 2

This type of device has been implanted in one volunteer. It overlies the peroneal nerve just anterior to the neck of the fibula. Its purpose is to test the efficiency of stimulating the dorsiflexion musculature of the right foot for correction of drop foot secondary

to upper motor neuron disease through a carbon device. Although the skin interface has not been a problem, the mode of energy transmission is not well understood and at this time stimulation through the device is no less painful than with surface stimulators. The only advantage at present is convenience of electrode placement. At the present time, we feel that improved design of the electrode can correct this phase of the problem (Fig 7).

Fig 7--Carbon electrode over the motor point of the Peroneal muscles.

APPROACH 3--CASE HISTORY

A 27-year old patient with severe flexion contractures of her left lower extremity secondary to spasticity from a head injury was presented because the contractures prevented adequate nursing care to the patient's decubitus ulcers. The deformities were relieved surgically

and in order to prevent reforming of contractures, myoelectrodes were implanted into the quadriceps muscle group for chronic stimulation. The implantation was performed through a small incision through which the myoelectrode was inserted into the muscle. The carbon device was slid subcutaneously to a small hole created by a cork borer in the skin. Stimulators are connected to the carbon device at regular intervals (Fig 8).

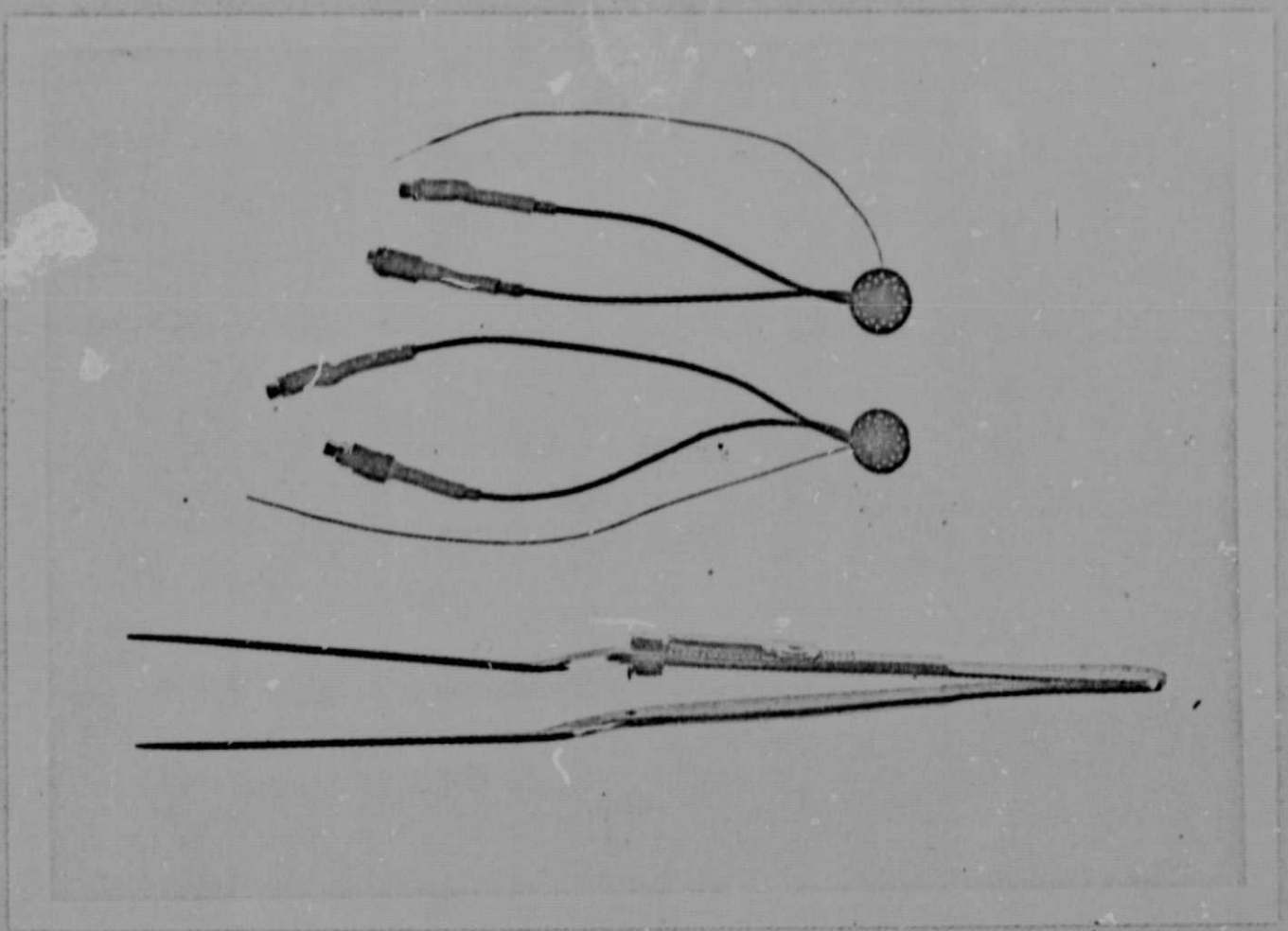

Fig 8--Myoelectrodes with permanent wire connections and modified Bayonette forceps for insertion.

APPROACH 4--CASE HISTORY

A 50-year old male developed flexion contractures of his hips and knees secondary to spasticity from an old TB meningitis. The patient had major decubitus ulcers over both trochanters and his sacrum and because of the contractures of his knees it was impossible to prone the patient adequately. He underwent surgical release of the flexion contractures, however, this failed to correct his deformity completely because of its long-standing nature and the contractures of non-muscle tissue crossing the knee joint. An electrode was placed around the femoral nerve and the wire from this electrode brought out through the skin through a carbon collar (Fig 9).

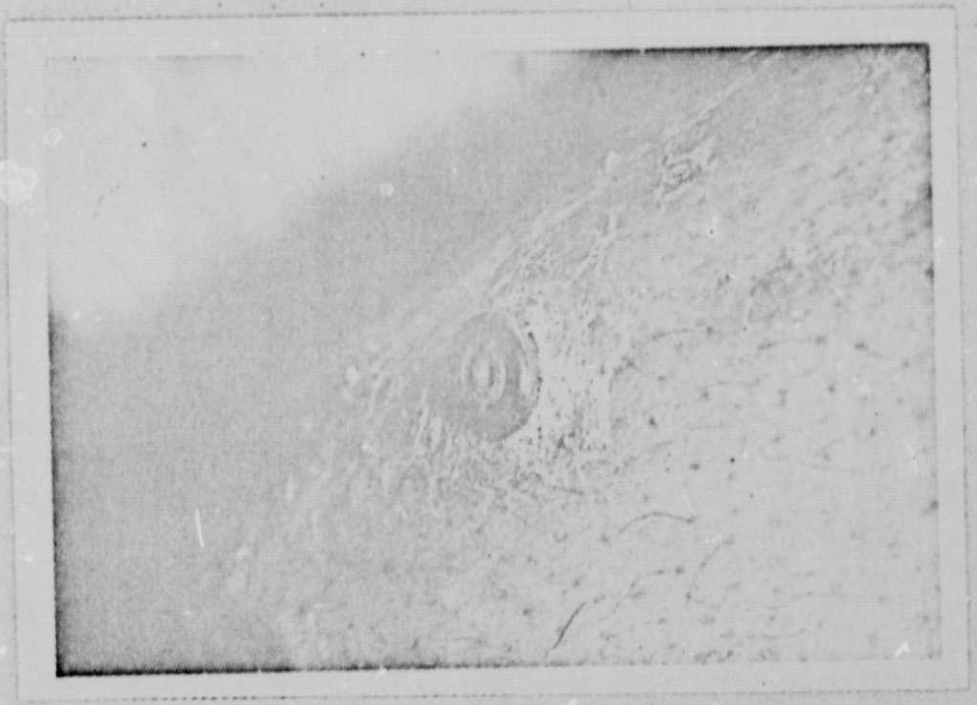

Fig 9--Carbon device containing connector to neuroelectrode.

Regular stimulation was initiated to exercise the patient's quadriceps musculature and virtually full extension was achieved. After four weeks, the patient was begun on a proning program and his decubitus ulcers have improved considerably. The patient is now up in a wheelchair and his care is such that he may be returned home rather than to a nursing home (Fig 10).

Fig 10--Patient with stimulator to exercise quadriceps muscles connected through carbon device.

DISCUSSION

This paper demonstrates some of the potential applications of pure carbon connector devices for permanent percutaneous passage of electrical signals. Many other applications come to mind and by no means is this

meant to be a comprehensive discussion of the use of such devices in medicine. However, several points are worth emphasizing.

The most important factor in determining the success of a permanent percutaneous passage device is the absence of drainage around the device. As long as this interface remains dry, a bacteriostatic seal will be maintained. There are two approaches to the design of percutaneous passage devices. One entails the ingrowth of epithelial and subcutaneous tissues into the device whereas the other expects the seal to be maintained by close apposition of dry epithelium to the device. Because devices and materials brought through the skin have an elasticity different than that of skin, any motion of the skin will produce shear forces at the interface. These forces will be of sufficient magnitude to disrupt any fingers of tissue which have grown into the device. Thus, an ingrowth device in the functional state will always be surrounded by micro hemorrhage and necrotic cellular debris. This is an environment which is most conducive to infection and ultimately extrusion.

The smooth nonporous surface of the carbon implant allows the surface epithelium to grow up to the device and then turn down along the neck. The cells continue to desqumate in the most outer portions of the down growth and therefore, improve the dry seal that is achieved. Once epithelial downgrowth has been achieved, a gradual transition into a modified epithelial cell type occurs which encapsulates the remainder of the device. These are not desquamating cells and seem to remain viable in direct physical apposition to the material, presumably because of the inert characteristic of the carbon material. Resistance

to torque forces is achieved by perforating the flange (Fig 11) but this is not necessary to avoid extrusion of the device.

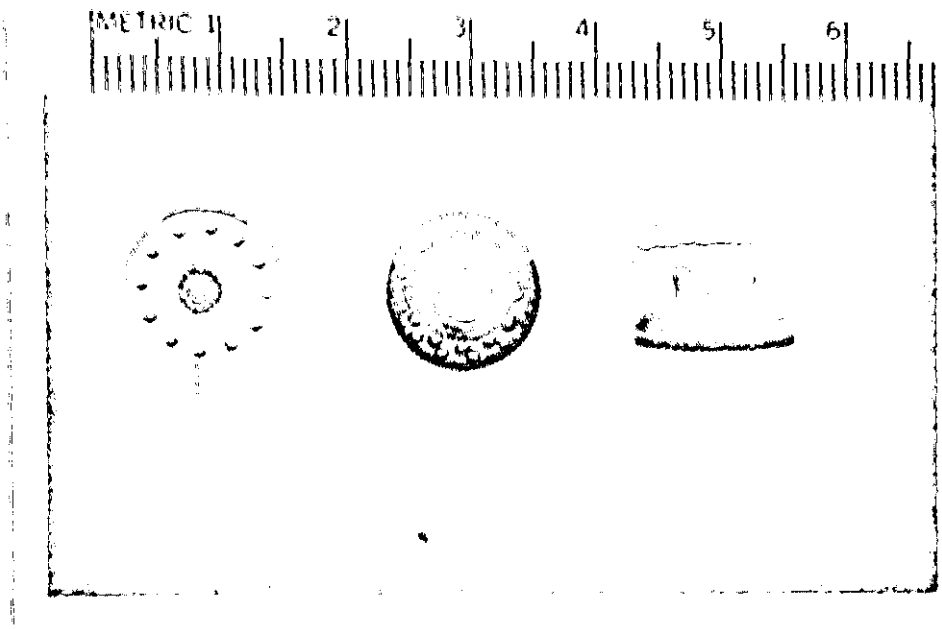

Fig 11--Carbon device with perforated flange for anchoring.

In none of the implanted devices to date, has there been any problem with attempts at extrusion or rejection of the carbon device by the tissues (Fig 12, 13, 14 and 15).

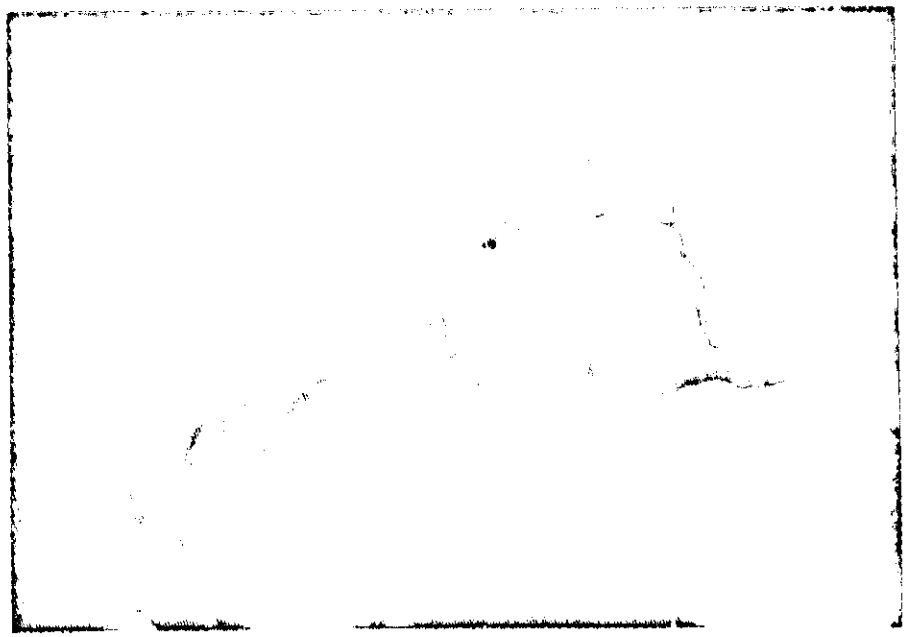

Fig 12--Gross specimen of carbon device with skin apposed to carbon.

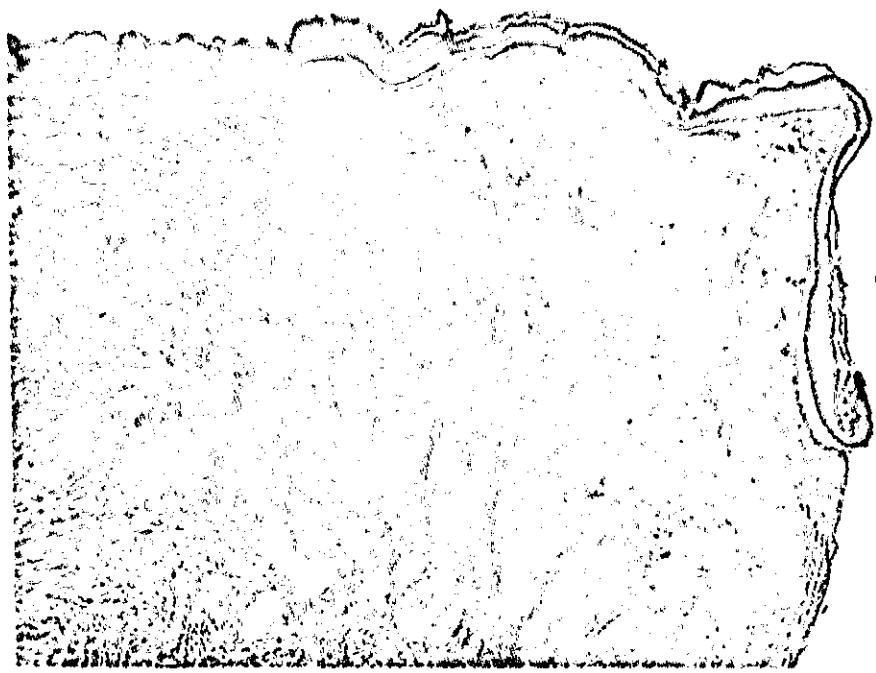

Fig 13--Low power photomicrograph of above specimen showing scar tissue and regeneration epithelium growing up to and down along carbon device (device removed before sectioning.)

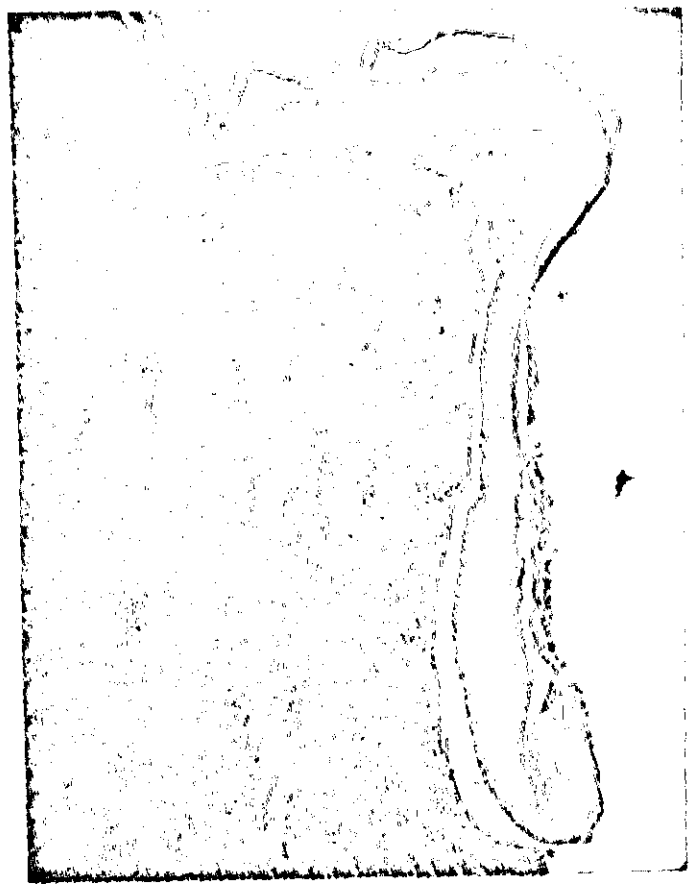

Fig 14--Intermediate power showing epithelium "turning the corner.". Note absence of inflammatory reaction.

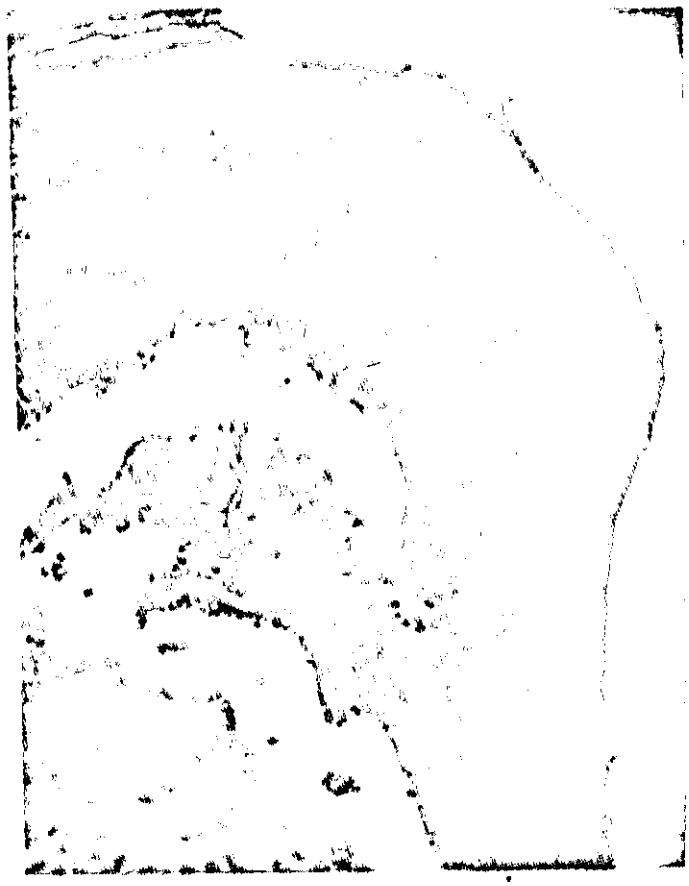

Fig 15--High power showing normal skin cell architecture in apposition to carbon device.

General clinical application of percutaneous electrical connector systems depends upon a standardized system which can be utilized for multiple internal electrical energizing or monotoring phenomena. The Rancho connector system is depicted in the following drawing. As is evident from the drawing, a firm electrical connection is made by the spring loaded connector, to the metal rings inside the carbon shell. These are insulated so as to produce independent circuits. The device

has the capability of connections to any form of electrical power source on the outside as well as any form of electrode on the inside by standardizing the connection which may be applicable. Possible applications are electrodes to nerves and muscles for stimulation or recording; problem pacemaker leads; bone stimulation electrodes; or battery recharging connections. The system as is depicted is currently under consideration by several engineers for fabrication (Fig 16).

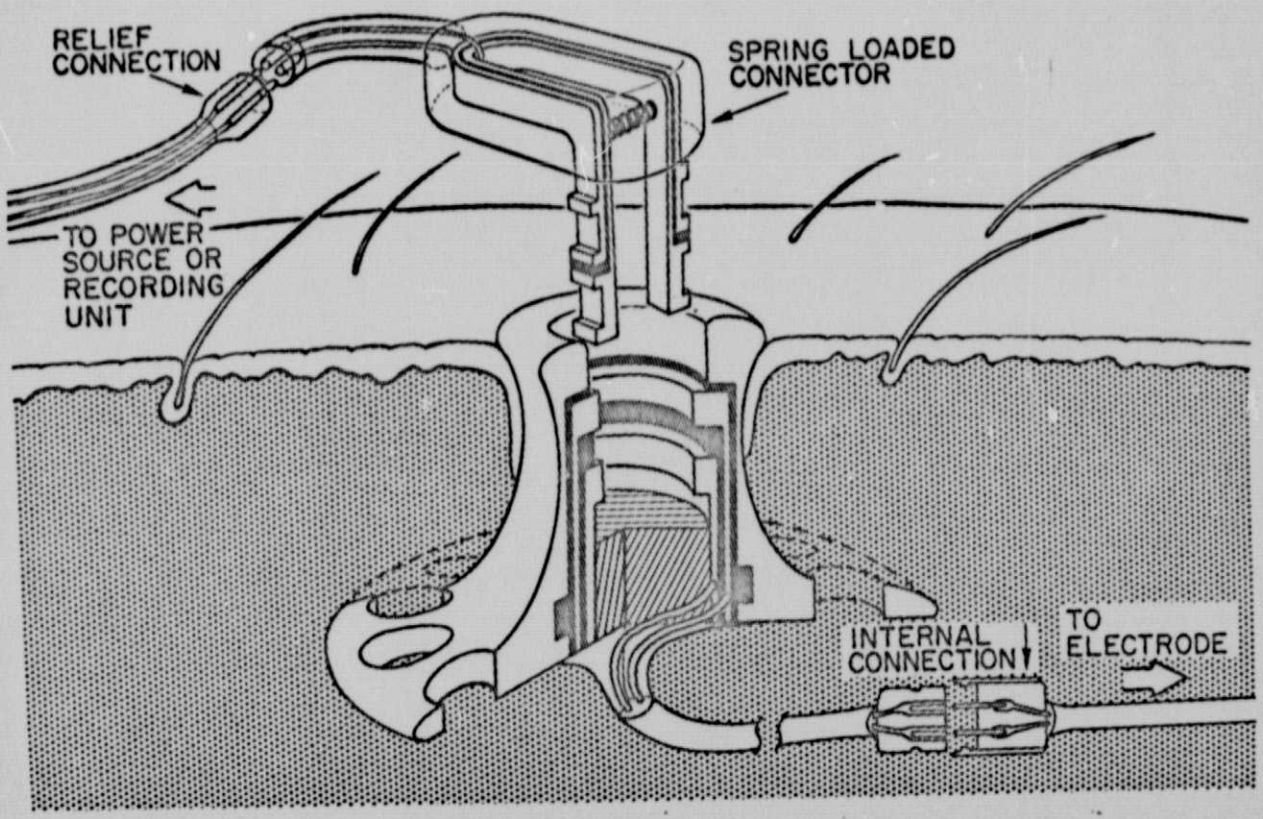

Fig 16--The Rancho Connector System. Carbon shell contains insulated metal rings which grip prongs of the spring loaded connector. Internal and external connections allow system to be used on many electrical transmission systems.

SUMMARY

The clinical experience in the use of pure carbon for percutaneous passage at Rancho Los Amigos Hospital may be summarized by breaking it into three phases of activity. In the first phase from 1968 to early 1972, over forty carbon devices were implanted into the skin of volunteer patients and staff to test the potential use of this material for a dry, infection-free skin intrusion. The experience during these four years was satisfactory and therefore, in the second phase over the past year, approximately twenty functional devices were implanted in patients and volunteers. The success of the devices over the past year, which might be described as the phase of limited clinical trial, has given us sufficient confidence to enter into a third phase during which time extensive clinical use of electrical connector systems incorporated into carbon shells will be undertaken. In addition to several projects involving neuromuscular stimulation, carbon will also be used for direct skeletal attachment of limb prostheses and long-term electrical stimulation of bone healing. We hope other investigators will find carbon devices to satisfy their need for long-term infection-free percutaneous passage.

This work supported in part by NASA #NAS8-28117 and NAS8-28320.

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