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

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INTRODUCTION
Over two and one-half years ago, a proposal was developed at this facility (Rancho Los Amigos Hospital) to investigate the potential medical applications of "unique bioCarbons." This project was developed in order to take advantage of the unusual tissue compatibility characteristics of pure carbon.

Several basic assumptions were made at the time of the construction of this proposal: (1) The reactions at tissue interface between the living system and the prosthetic device is the most important factor in the successful applications of substitute mechanisms for biologic systems. (2) Of all tissue reaction locations, the skin interface with a prosthesis is the most demanding. (3) In that the whole purpose of our interest in pure carbons is for medical applications, there is no other experimental model for medical applications of percutaneous devices than human skin. Thus, all experimental studies would have to be done on humans. (4) No attempt would be made to develop some new material, but rather the purpose of the proposal was to utilize commercially available pure carbons and develop designs which would be applicable for medical applications.

In that the use of human subjects for trial of carbon devices was deemed necessary, true medical needs for skin interface challenges were used. Medically, especially in the environment of an orthopedic
rehabilitation unit, the most consistent need for percutaneous challenge is in a skeletal traction. Thus, construction of skeletal traction devices with carbon interface at the skin was considered the most reasonable location for prosthetic-human interface challenge. It was hoped that by constructing carbon devices of various commercially available materials and using these for a skeletal traction some understanding in the difference of tissue reaction related to different types of pure carbon could be understood. Phase I of the proposal was the construction of carbon traction devices.

A true medical need, but conceptually more advanced than current medical practice, was the development of a neuroelectric plug-in device. Currently, a multitude of implanted electrical power systems are being used and, in addition, there are a multitude of applications of external neuroelectric stimulation and control. A reliable connect-disconnect system for electrical communication with internal structures and devices is considered a significant medical need. Although at the time of the proposal a specific design for such a device was not at hand, its potential was recognized.

It was recognized that a significant interface problem exists between the attachment of a prosthesis and the skeletal structures. This was also a challenging environment for pure materials and considered a reasonable location for testing bioapplications. A bone bridge experiment was constructed wherein the tissue interface between bone and prosthetic device would have had to suffer not only the trauma of tissue reaction to foreign substance, but also the mechanical stresses of
Finally, the fourth phase of the proposal was considered the ultimate application of the entire system—a connect-disconnect system for a limb prosthesis. This particular problem was the center of interest of this unit at Rancho Los Amigos Hospital and was considered the severest challenge of all medical applications for tissue interface problems. In the scope of the proposal it was not considered that a truly reliable system could be developed, but rather that the principles could be sufficiently understood so that a system could be designed which had the expectation of success.

Since the writing of the original proposal, a number of events have occurred which have considerably changed the scope of the work done. The first phase was largely unsuccessful. Although we had tentative agreement from several colleagues as to the applications of bioCarbon traction devices, and, indeed, had approximately forty such devices manufactured in cooperation with Cutter Laboratories, the number of true human applications was quite small. One reason for this is that the carbon design with a dacron flange required surgical application of skeletal traction through a hole measuring approximately 3/4 of an inch. This is in contrast to the normal skeletal traction systems wherein a skin perforation under any circumstances would not exceed 3/16 of an inch. There were very few skeletal traction applications wherein the potential trade-off of infection-free traction passage was worthy of the larger surgical incision necessary to achieve carbon utilization. In essence, no reliable data was developed from the
skeletal traction phase of the project.

On the other hand, the particular design utilized for the skeletal traction device was applied at this unit for prosthetic suspension. Two patients had implantation of tubes transversely in their stumps with the skin interface of the carbon traction device. These patients had their prosthetic devices suspended by way of this system. Indeed, this system from a skin interface aspect functioned beautifully. The successful skin interface aspects of these designs confirmed the medical applications of pure carbon. Examples of these applications are described later in the report.

In contrast to the poor result of the Phase I skeletal traction design, the neuroelectric plug-in system of Phase II progressed rapidly from the standpoint of concept and human applications. The accompanying paper, entitled "The Use of Pure Carbon for Permanent Percutaneous Electrical Connector Systems", which has been accepted for publication in the Archives of Surgery, outlines our progress and applications in this area. Although considerable development is still necessary in the engineering of the plug-in systems, it has been demonstrated to be a reliable device and represents an excellent example of medical application of Aerospace Technology which fulfills a true need. Our Final Report largely deals with examples of this application.

The use of pure carbons at the skeletal interface in the bone bridge experiment has faded considerably in our interest at the present time. The bone bridge experiment was undertaken using twelve animals. For many technical reasons, a successful skeletal interface between prosthetic
material and the skeletal system was not achieved in any but one type of system. This system was that of methylmethacrylate bone cement. Currently, this mode of skeletal fixation of prosthetic devices is being widely used clinically, and, indeed, with considerable success. The limitation of carbon as a skeletal interface system basically is the requirement of bone ingrowth time into the interstices of the carbon interface. (Figure 1)

Figure 1
Intermedullary bone spaces in femur of dog comparing dacron covered silastic to set-in-place methylmethacrylate.

At this time, unfortunately, it is clinically unacceptable, especially when the carbon system competes with, on the whole, an extremely successful system using methylmethacrylate. For the present
we have abandoned further interest in substitute skeletal fixation systems.

The skeletal fixation of limb prostheses, however, remains an achievable goal. In spite of the failures with the transverse suspension system, further work in this area has continued. We have had one successful application of a connect and disconnect system for an upper extremity prosthesis using an intramedullary device. We believe that we now have sufficiently understood principles so that a clinically reliable prosthetic fixation system is feasible.

CASE HISTORIES

Case A is a sixty-eight year-old male who has had diabetes five years and a right below knee amputation approximately five years ago. The patient fell out of a wheelchair two weeks previously and suffered a fracture of the right upper femur trochanteric region. The patient required traction to the right stump to hold the fracture reduced.

On March 22, 1972 surgery was performed. A 3/16 inch smooth Steinmann pin was inserted through the right tibia posterior to the tibial tubercle. A medial side insertion of percutaneous interface seal buttons (silastic-dacron-carbon) was made. The lateral side was treated as usual - a traction pin through the skin.

Removal of tibial traction pin and percutaneous button with excisional biopsy of surrounding skin was performed. Bony overgrowth at the right tibular tip was removed to make a better prosthetic fit. Preoperative course - all wounds healed per primus (4/20/72).
Case B is a 26 year-old male with a history of seizure disorder. He is a triple amputee (right high above elbow, right hip disarticulation, left below knee amputation), who uses left below knee prosthesis for wheelchair locomotion. He has difficulty with suspension of the left prosthesis.

Patient had surgery April 20, 1972 for the insertion of percutaneous endoskeletal fixation tube in proximal left tibia. Implantation of the silastic-dacron-carbon device at medial and lateral projections of tube required deep implantation adjacent to periosteum. Wounds were slow to heal because of deep placement. The wound was well healed around the carbon. (Figures 2, 3, 4 and 5)
Figure 2
Silastic carbon device coming through the skin soon after surgery.

Figure 3
Transcortical Device
Figure 4

Transparent socket with pylon for definitive prosthesis, suspended by carbon skeletal fixation device
Figure 5

Closeup of transparent socket with pylon for definitive prosthesis, suspended by carbon skeletal fixation device.
The patient had removal of percutaneous endoskeletal fixation tube and silastic dacron carbon devices at medial and lateral sides on August 24, 1972 due to infection around the tube. It should be noted that the carbon devices remained free from infection.

In March, 1973 the patient had two carbon electrodes placed over the muscles of his left below the knee stump. A stimulation program was begun to enlarge the muscles in his stump to help suspend a prosthesis. However, due to the precarious position of the buttons, subject to much physical trauma, the buttons were removed August 5, 1973. At the time of removal, there was no sign of tissue inflammation and tissue sections are pending. Currently, the patient is being considered for a skeletal attachment device.

Case C is a 46 year-old female. The reason for the skeletal fixation device was previous severe burns of the left arm with high left arm amputation at axilla level. Due to the short stump and grafts over the skin burn about the left shoulder, the patient was unable to wear any upper limb prosthesis.

Insertion of percutaneous endoskeletal fixation tube through the left humerus stump just below surgical neck was made April 27, 1972. Two skin interface seal buttons were inserted: the anterior was silastic-dacron under a carbon collar and the posterior was polyurethane. 

(Figure 6)
Both wounds healed initially.

On September 14, 1972 the polyurethane percutaneous implant was removed and replaced with a bioCarbon percutaneous implant due to infection and drainage on the posterior side with the polyurethane. The wounds healed. (Figures 7, 8, 9, 10)
Figure 7
Anterior - Silastic-dacron under carbon collar.
Posterior - Polyurethane removed and replaced with carbon collar.

Figure 8
X-ray skeletal fixation device through humerus.
Figure 9

Transparent socket fitted to stump for definitive prosthesis, suspended by carbon skeletal fixation device
Since the patient's surgeries, she has been seen on an outpatient basis. The patient was not wearing the prosthesis because of discomfort around the pin deep in the bone. When the patient was seen in clinic, it was determined that infection was present around the bone portion of the implant. X-rays confirmed this. It is a significant fact that the carbon interface at the skin was free of infection and inflammation.
However, removal of the devices was necessary in January 1973, carried out with subsequent complete healing of the skin.

Case D. In March 1971, a volunteer had a carbon device implanted in his arm. The device has remained free of infection to date. (Figure 11)

In mid-January 1973, a volunteer had a bioSnap implanted over his peroneal nerve to evaluate the use of this device in functional neuro-muscular stimulation. (Figure 12) Later, a second device was implanted overlying 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 electrodes can correct this phase of the problem.

The button on the left leg remains infection-free and functioning well. There was slight infection present in the right leg, which has since cleared. The only residual is that the subcutaneous portion of the button is partially exposed. Hopefully, epithelization will solve this problem. Again, the ability of carbon to resist infection has been demonstrated.
Figure 11

Implant of carbon device in arm. Infection-free (3/71 - 8/73)

Figure 12

BioSnap implanted over peroneal nerve (1/15/73 - 8/73) Infection-free.
Case E is a 55 year-old female with severe arachnoiditis following multiple surgical procedures on her thoracic and lumbar spine. She was originally admitted to the Problem Back Treatment Center and implantation of a dorsal column stimulator was anticipated. After a 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 size cutaneous stimulating device. The patient, at this point, was tolerating the stimulation very well and no longer needed the narcotics on which she was admitted. (Figure 13, 14, 15)
Figure 13
Button - 4 Weeks after implant

Figure 14
Button - 6 weeks post-implant
Figure 15

Both devices at 4 weeks and 6 weeks, respectively

In January 1973, the patient had difficulty with connectors to the carbon buttons. Several designs were tried, however none made a satisfactory connection and, presumably because of continuous manipulation and irritation from the device and the wires going to it, some drainage and infection developed around the button. All stimulation was therefore discontinued for a period of one week when, as a temporary solution, connection to the device was made externally.

In March 1973, the patient reported that the upper button had been subjected to a significant trauma which almost tore it loose and a slight infection had been present for about two weeks. The button was watched closely for several months, and it then became necessary to
replace it with a type I device for pain control. The patient is scheduled for surgery August 23, 1973.

It should be noted that the patient states she could "not live without her stimulation on the lower button."

Case F is a 40 year-old male. The patient was in a deep coma, and, because of severe spasticity, developed flexion contractures of both upper and lower extremities. (Figure 16)

Figure 16
Patient with flexion contractures before implant

This in turn led to the development of pressure sores and made the patient a nursing problem. Release of his contracted knees could be carried out surgically, however, through stimulation of muscles in his leg, the effect of surgical releases could be improved and maintained.
In December 1972, a bioCarbon device which allowed connection of electrodes to his femoral nerves was implanted. Since that time, his contractures were almost completely worked out, and the carbon device continued to remain clean and infection-free. (Figure 17, 18)

Figure 17

2 Months after stimulator program was begun
Pressure sores healed eliminating the nursing problem
Three months postoperatively, the device continued to work well. The carbon proved to be very effective and the patient's contractures had essentially been pulled out by chronic neuromuscular stimulation. The device was removed on March 8, 1973 because the flexion contracture of his right leg had been pulled out. At the time of removal, the carbon collar was free from infection and the device was working well.

Case G is a 28 year-old male with a head injury of unknown etiology. The patient had a spastic right upper extremity which was developing a flexion contracture at the elbow. In February 1973 he had a phenol block in the nerve to the elbow flexors and two bioSnap-type electrodes were implanted over the motor points of the elbow extensors for the purpose of exercising the arm. (Figure 19, 20)

A stimulation program was begun two weeks postoperatively of the tricep
to overcome the spasticity of the elbow flexors.

Figure 19

Implant of carbon bioSnaps (2/22/73) - stimulation program begun
5/22/73 for release of flexion contractures.
After sixteen weeks of continuous muscle stimulation, the patient's program was terminated because the electrodes were no longer needed functionally for the patient's rehabilitation program.

Case H is a 62 year-old male with tuberculous meningitis and contractures. (Figure 21) The left contracture was of such a degree that surgical release was necessary. A type 4 device was implanted around the patient's left femoral nerve. Simultaneously, two type I devices were implanted in the skin over the femoral nerve. A comparison could then be made of stimulation through each of these electrode systems.
Figure 21

Patient shown with flexion contracture

Three months postoperatively the carbon collar around the wire to his femoral nerve was functioning satisfactorily. There was good healing around the device and the two cutaneous electrodes over his femoral nerves were in satisfactory condition. However, stimulation through the electrodes did not produce adequate contraction of the leg and were therefore not being used.

The devices were removed May 10, 1973 because the patient had received the maximum benefit from neuroelectric stimulation. The patient is now able to sit in a wheelchair and his decubitis ulcers are virtually healed.
Case I is a 50 year-old female that had sustained a severe stroke and had flexion contractures of both lower extremities. A totally implanted electrode on one side had been used to stimulate her knee extensors and pull out the contractures. In order to compare the cutaneous stimulation with the totally implanted device, two buttons were placed in the skin over the femoral nerve in March 1973. (Figure 23, 24)

Stimulation was postponed because of problems with the stimulator and the connecting wires. The buttons, however, continued to heal well. Two months postoperatively stimulation was attempted through the buttons, however, it was apparent that the current necessary to activate the femoral nerve was painful. This suggests that further design modifications will have to be made in the carbon device to be practical in this application.
Figure 23
BioSnaps implanted 3/22/73 - stimulation begun 5/2/73

Figure 24
Devices in place - infection-free
Case J is a 58 year-old male stroke victim with severe spastic contractures of both lower extremities. Surgical hip and knee releases were performed, and on April 1973 a carbon-type 4 device was placed over the right and left femoral nerves. The patient also had six type I buttons to surface stimulate the nerves. (See appendix for complete description of approaches using carbon for neuroelectric stimulation page 8 and 9.) For reasons unknown, the implant on the right side did not function well. The left neuro implant functioned quite well. It was felt that the left leg was somewhat stronger secondary to stimulation.

The type I buttons also produced good muscle action. All of the buttons have been removed in accordance with the protocol of the femoral nerve program. We are awaiting tissue sections.

Case K is a 25 year-old female. On May 31, 1973, two devices were implanted because of severe hip and knee flexion contractures. A stimulation program was begun one week postoperatively.

On July 20, 1973 torque testing of the knee extensors was carried out and the torque generated by stimulating the myoelectrode versus the neuroelectrode was compared. Only a slight difference was found, indicating that perhaps only a myoelectrode is necessary for clinical application. The myoelectrode requires much less surgery, implying broader clinical application.

To date, both buttons of type 3 and 4 are continuing to be infection-free and functioning well.

Case L, a 33 year-old female, had two electrodes implanted over pain points in the left lumbar area on May 29, 1973. A stimulation program was begun, but was limited because of infection. On July 3, 1973
(six weeks after implantation), the devices were removed because of continued pain from mechanical irritation. The difficulty was in the placement of the electrodes rather than the electrodes themselves.

Case M, a 50 year-old female, had two type I carbon devices implanted June 6, 1973 to facilitate electrical stimulation to block pain. The patient has undergone a program of stimulation which has been successful. The devices continue to be totally free of infection and functioning well.

Case N is a 71 year-old male and a triple amputee. In May 1973, the patient had an intramedullary device implanted for a direct skeletal attachment of a limb prosthesis. The device will allow the attachment of a below elbow prosthesis which is necessary for self-care activities and walking (to hold a crutch). (Figure 25, 26)

Figure 25
Connector system for skeletal fixation of limb prosthesis. Lower portion indicates carbon collar fastened to implanted receiver system. Superior portion indicates prosthetic connector system.
Two months postoperative, the carbon button at the end of the skeletal attachment device had the skin retract from the medial surface exposing the entire medial flange. The patient underwent surgery to advance the flaps around the carbon button. Prior to and postoperative, there was no sign of infection.

The patient was fitted with a Fidelity-type electric below elbow hand. The prosthesis appears to be very functional and a cosmetic cover will be attached. (Figure 27)

Figure 26
Connector system on patient (71-year-old diabetic with Syme's and above-knee amputation as well).
Figure 27

Prosthesis in place before fabrication of cosmetic cover.
SUMMARY

The goals of this small pilot project determining feasible medical application of unique bioCarbon have been achieved. The clinical application of these carbons to solve human problems has been demonstrated. By taking advantage of the unique characteristic of traversing the skin without threat of infection, practical clinical applications of medical engineering technology have been demonstrated.

But the demonstration of successful application of carbon technology to human medical problems has created new problems which need solution before general clinical utilization of these materials are available. First, in terms of the material itself, questions remain. Is pyrolytic carbon different from vitreous carbon in terms of biocompatibility? To answer the question, a series of patients must have devices of similar physical design and dimensions implanted side by side to note any difference in reaction between the two. Although this plan was originally to be determined by the skeletal traction system, it was not carried out because of the lack of general application of the carbon collar skeletal traction. Smaller devices of the bioSnap-type design, which would be applicable for neuro or myoelectrical stimulation, are more appropriate test devices.

Another unresolved problem concerns the nature of electrical fields in relation to a carbon implant. Would myo-electrical stimulation be improved if only a portion of the implant were electrically active, the rest functioning purely as a tissue interface? Would less energy, and thus less potential pain, result from an electrode of this design?
Only human trial can evaluate this factor because sensation is a variable that cannot be excluded.

One of the most significant engineering problems that remains is that of the electrical connect-disconnect system interface with the carbon. Although the carbon has demonstrated itself to be highly compatible with tissues, building a reliable connector system into the carbon shell remains a considerable engineering challenge. Today, we do not have a reliable system and feel that we must permanently cement the connectors to the carbon for clinical application to have a competent electrical stimulation system. If the neuroelectric connector system is to be clinically applicable, the engineering of these connectors must be accomplished so that a reliable, inexpensive and serviceable system can be developed. The drawing in the accompanying paper suggests only one solution, many others are probably feasible. In this area, however, without a reliable connector system all the advantages of infection-free percutaneous passage will not be available for clinical application.

With the demonstration of the unusual biological acceptability of pure carbons, and with a recognition of their potential as electrodes, other utilization of these materials is worthy of consideration. Placement of electrodes indefinitely within muscle or nerve seems potentially feasible if these electrodes cause no local tissue reaction. If we can demonstrate this to be a fact, many applications in the area of chronic muscle stimulation seem reasonable. As an example, an implanted electrode could be placed within the muscles of an adolescent girl with curvature of the spine and under chronic stimulation of the appropriate muscles effect straightening of the curvature. (This has already been demonstrated
in animals elsewhere.) Retained carbon electrodes could cause new bone formation at the site of a nonunion fracture. Once the bone has formed about the electrode to heal the fracture, it can be left in place indefinitely. (Fracture healing using a very minimal level of direct current and stainless steel electrodes has already been demonstrated in animals and humans. The electrode systems are current limitations of this method.) Further experimental studies regarding the electrical characteristics and configuration of carbon electrodes are necessary.

The feasibility of prosthetic connector systems has likewise been demonstrated. The pilot problem achieved what had never before been considered possible; a limb prosthesis fixed to a bone that can be connected and disconnected at the will of the amputee. The engineering of this connector system, however, requires a great deal more sophistication before it will be available for clinical application. Nonetheless, it is quite reasonable to expect that prosthetic fittings of the future will utilize the system once standardization of specifications and attachment strings become available.

In summary, this small pilot study has well demonstrated the feasibility of infection-free passage through the skin. It has shown that vitreous carbon is an unusual material with unique biocompatibility potential. However, to take full advantage of this material, we must develop considerably more experience with engineering interface to carbon. Neuroelectric connector systems and prosthetic connect-disconnect systems are such examples.
1. **Bioacceptability, Biocompatible, Biostable.** Refers to the ability of a material or process to be placed within a biological environment and remain there without invoking a rejection or reaction from the biological environment.

2. **Bioelectric.** Refers to electrical energy within a biological environment applied to the outside.

3. **Button.** A carbon device of specific shape and dimension as shown in Figure 13.

4. **Contracture.** Deformity of a joint because of shortening of tissues on one side frequently seen in strokes and head injuries.

5. **Conventional Socket.** The cup-shaped portion of a typical artificial limb into which the stump is placed.

6. **Device.** The total unit with all attached wires and the connectors to it.

7. **Dorsal Column Stimulator.** An electronic stimulator produced by the Medtronic Corporation used to relieve pain by applying direct stimulation to the spinal cord. The electrodes from the stimulator lie within the spinal canal and the present system uses a stimulator connected to an antenna which activates a passive receiver implanted under the skin which then connects with the electrode. The coupling is made via two induction coils.

8. **Endoskeletal.** Refers to the interior portion of elements of the skeletal system, i.e., the medullary canal of a bone or the joint space.

9. **General Anesthesia vs. Local Anesthesia.** General anesthesia requires putting the patient to sleep and carries with it more risk to the patient
than local anesthesia, which merely involves numbing the area around the place where an incision will be made. The former requires more equipment and more personnel than the latter.

10. **Limb Prosthesis.** An artificial arm or leg.

11. **Medullary Canal.** The spongy internal portion of a bone filled with fat, blood and thin wafers of bone.

12. **Motor point.** A point on the skin over a muscle at which stimulation can be applied to activate the muscle and produce a contraction.

13. **Myoelectrode.** An electrode placed into the body of a muscle.

14. **Neuroelectrode.** An electrode wrapped around a nerve.

15. **Neuroelectric Stimulation.** Passing electric current into a nerve in order to activate that nerve and reproduce the physiological effect of such nerve activation.

16. **Percutaneous Passage.** Bringing a material through the skin as opposed to transcutaneous, which implies going across the skin without violating it.

17. **Peroneal Nerve.** The nerve lying below the knee on the outer aspect of the lower leg which activates the muscles of the toes and foot causing the toes and foot to move away from the floor toward the head.

18. **Shell.** The portion of a carbon device which is made of carbon and interfaces with the skin.

19. **Skeletal Fixation.** Direct attachment of external prosthesis to a long bone by use of an intramedullary rod.

20. **Skeletal Interface.** Area of direct apposition between bone and a material.
21. **Skeletal Suspension.** Hanging something, such as an artificial limb, directly from the bone.

22. **Skeletal Traction.** Traction applied upon the long bones by means of a metal rod, carbon rod, etc.

23. **Transparent Socket.** A clear socket used as a visual method employed by prosthetists to determine the intimacy of the stump-socket relationship.