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Department of Physiology

14 August 1969

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NASA CONTRACT NO. NSR 05-018-087

PROGRESS REPORT:

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Period covered: April 10 to July 9, 1969

1. SUMMARY

During this reporting period the major efforts were concentrated in completing the development of the blood pressure measuring system, in developing a differential venous pressure transducer, in investigating implant materials and shapes, and in evaluation of atrial size measurement as a redundant measurement for central venous pressures.

2.0 BLOOD PRESSURE

Circuits to transduce and amplify blood pressures are now complete. Several workable models have been described in previous reports. These units have subsequently been improved. The most probable workhorse version is illustrated in Figure 1 with the engineering data in Figures 2 and 3.

3.0 SENSOR DEVELOPMENT

A more realistic measurement of venous pressure has necessitated the development of a special high sensitivity differential sensor. Proper application of this sensor (Figure 4) will permit measurement of central venous pressures relative to several interpleural spaces. The balloon as illustrated in Figure 4, or a similarly constructed one will be placed in the desired space and the sensor portion implanted in the vena cava or atria. The calibration curve for the sensor is shown in Figure 5.

4.0 ATRIAL SIZE MEASUREMENT

The dynamic measurement of the atrial size could perhaps give higher resolution data on the condition of the venous system since the circulatory compliance is a grossly variable quantity. This parameter could be used as a redundant measure for central venous pressure or be of independent benefit. The electronic technique for obtaining this measurement is similar to that employed for blood flow (reported in last report dated October 10, 1968 to April 9, 1969). PROGRESS REPORT NASA CONTRACT NO. NSR 05-018-087

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5.0 IMPLANT MATERIALS

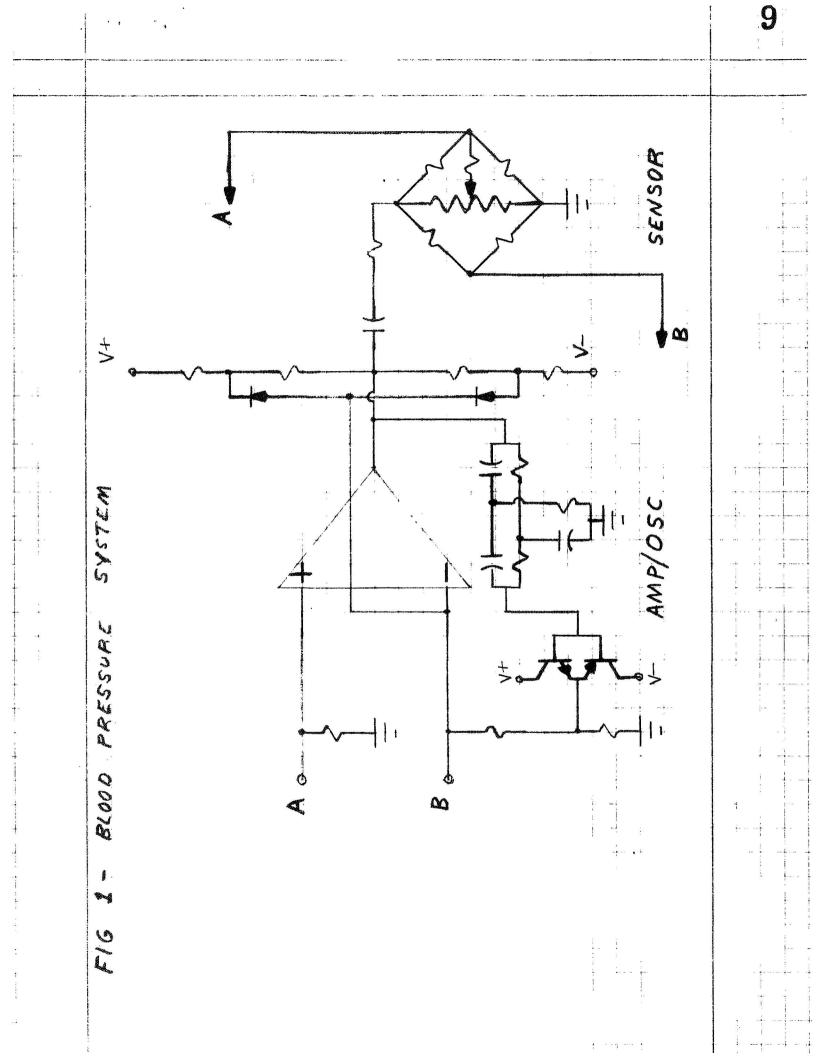
Investigation into acceptable implant material has resulted in the consideration of elemental carbon. A report on this material is contained in Appendix A. Fabrication of samples for USC evaluation is currently underway.

> Original Copy Signed By John P. Meehan, M.D.

John P. Meehan, M.D. Principal Investigator

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FIGURE 4 VENOUS PRESSURE TRANSDUCER

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APPENDIX A

ELEMENTAL CARBON AS A BIOMATERIAL

SUMMARY

The human body is a remarkable complex of interacting subsystems. Of these, perhaps the most noteworthy are the disease, infection, and physical damage defense and restoration functions--constant and everwatchful protectors against systemic invaders. These essential defenses are, however, a seriously inhibiting factor in medical science's attempts at human repair and rehabilitation. The body's defenses, over a period of time, resist, reject, and/or destroy intruding matter.

Carbon has been used in certain obscure applications as a biocompatible material for several hundred years. For example, it has been extensively utilized as a natural pigment for body tattooing by subcultures in Melanesia, Asia, and some areas of Africa. During this time, it was considered to have no useful structural properties and thus found its principal applications in more advanced cultures as lubricants and nonstructural electrical system components. Currently, however, carbon, graphite, and composite forms of these materials have been developed to a high degree of chemical purity, with adequate structural integrity to meet rigorous aerospace applications, such as ablative heat shields and rocket nozzle liners. These new materials have physical properties comparable to metals in many structural applications. They are available as filaments, woven fabrics, braided sleeving, and massive material. This latter form can be processed by molding or casting prior to pyrolyzing, and can be machined or ground after pyrolysis. They promise to be suitable prosthetic materials in applications where the unique biocompatibility of carbon and graphite are significant. The potential of these recently developed materials to biomedical systems was first recognized in this country in late summer of 1967.

Information on these materials has been communicated to researchers involved in rehabilitation medicine in such fields as orthopaedics, cardiology, vascular

surgery, neural diseases, plastic surgery, and others. Interest has been evidenced by many of these researchers, and a number of investigations have been undertaken. Some preliminary data have been obtained from shortterm in vivo tests. All investigations undertaken to date show promising results, particularly in the area of tissue acceptance. Problems of technique and design are beginning to be identified, and a substantial number of specific applications have also been identified for study. The investigators involved express the feeling that these materials demand a searching and thorough evaluation, because preliminary results indicate a strong potential for clinical acceptance in many areas.

ORIGIN

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Personal research efforts of the writer during the summary of 1967 enabled him to identify a pressing need for improved biocompatible materials, particularly in rehabilitation medicine and medical research activities. Metals and polymers conventionally used for implantation within living tissue generally evidence time-dependent degradation, usually accompanied by more or less deleterious effects on host tissues. Some investigations are being undertaken using ceramic materials for such purposes, but with only limited success at this time.

A fortunate convergence of several unrelated incidents led the writer to undertake the investigation of an entirely new family of materials having the apparent biocompatibility and other physical properties needed for a number of implant applications. These materials were the newer forms of carbon developed to fill aerospace and other advanced technology requirements, such as ablators for space vehicle re-entry heat shields and rocket thrust chamber liners. Concurrent with an investigation of fabrication methods for an ablator was the discovery that Dr. C. O. Bechtol of UCLA Medical Center was soliciting support for a materials investigation to improve a hip prosthesis for arthritics. It also happened that the writer was aware of a broken pencil lead (graphite) in his hand that had been there

about thirty years. Dr. Bechtol was contacted and apprised of the characteristics of the ablative material and expressed interest in investigating it. Dr. Bechtol further pointed out that a number of subcultures have employed carbon body tattooing with no adverse effects for as far back as historical records are available. With the knowledge that structurally adequate forms of carbon were currently available, he expressed a desire to evaluate some of them in in vivo animal tests.

Based on this, Dr. Worden Waring of Rancho Los Amigos Hospital was contacted to discuss the material problems being encountered at that institution. Again a good deal of interest in carbon as an implant material was evident.

Referrals from Drs. Bechtol and Waring aroused interest at several other research organizations. Sources of material were obtained and processing capability was developed as required to support the participation of a number of investigators. To date (April 1969), fourteen groups of medical researchers have been supplied with sample parts, ranging from scrap material to complex designs, for in vivo evaluation. Information on the material and the investigative results through December 1968 have been furnished to an additional twenty-six organizations that have been identified as potential participants. Several of these are already involved or are preparing to start in vivo testing of specific applications of these materials as soon as suitable hardware can be provided.

INVESTIGATIONS

The initial effort to evaluate the biomaterial potential of elemental carbon was directed toward eventual use for hip prostheses by Dr. C. O. Bechtol of UCLA. The most severe problem encountered with the previously used metal prostheses was granulation of small metal or metal salt particles from the prosthetic bearing surfaces. Therefore, Dr. Bechtol ground the provided specimen material (Hitco carbon-phenolic composite), implanting the resulting fine powder intramuscularly in several rats. These rats were maintained

in exercise cages for periods of six to nine months before sacrifice. Histological evaluation was encouraging and further tests were initiated. It is interesting to note that this material was not fully pyrolyzed, however, the tissue damage expected from the aromatic constituents was not evident after six months of exposure.

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Two bone plates (one composite material and one vitreous carbon) were fabricated and implanted on canine femurs to evaluate the galvanic corrosion and fretting encountered under the head of the attach screws--one of the most frequent failure modes found with the metal plates currently in use. Implantation was made in Dr. Bechtol's laboratory in October 1968, and is expected to be terminated after about a year in place. A vitreous carbon intramedullary pin is also being evaluated. It is implanted in a canine femur.

Dr. Worden Waring of Rancho Los Amigos Hospital is interested in materials for permanently implanted myoelectrodes (probes for acquiring the electrical (?) impulse that initiates muscular activity). Various carbon filaments were considered for this application and Thornel 25 was selected for initial testing. Material was obtained and in February 1968 a total of three percutaneous implants were emplaced in two human volunteers. Healing was satisfactory in all cases, but the filaments broke off at the surface of the skin after a few days. After seventy-two days, one implant was excised from each subject and histological evaluation showed complete tissue acceptance of the carbon filaments. Not only was there no evidence of reaction or rejection in the tissues, but no discernible effect was noted on the carbon filaments in spite of their very small diameter (\approx 5.0 micron) and consequent high surface-to-volume ratio. The third implant remained in place for over a year without incident and has now been excised and evaluated with entirely satisfactory results.

To overcome the problem of supporting the filaments at the skin line, a design for a percutaneous bushing was developed and a trial implant was made in a volunteer in early August 1968. This is still in place and has

been maintenance free for the intervening eight months. It has maintained a continuous "dry" interface with the epithelial tissue, which is believed to be peculiar to elemental carbon materials. Other materials maintain a small, unhealed surface directly adjacent to the intrusion. A novel incident associated with this implant points up another unique characteristic of carbon in this application. Severe abuse resulted in the implant being loosened, which allowed some foreign materials to enter between the skin and the carbon shaft, after approximately four months in place. A slight infection formed, which was drained through the interface annulus by pressure on the surrounding skin. The implant healed to its original condition in about four days and has given no trouble since that time. Implants generally are known to require removal if any infection appears, because the presence of foreign materials (other than carbon) seems to inhibit the body's infection-fighting capability. No environmental protection has been provided during the entire period. The sensation level around the implant is roughly equivalent to that associated with a healthy fingernail. Apparently the skin has formed a sphincter around the shaft of the implant, providing an adequate bacterial seal under normal circumstances.

Following referral by Dr. Bechtol, Dr. Franklin Ashley, also at UCLA Medical Center, became interested in the potential use of carbon in plastic surgery. In late 1968, tests were initiated to establish tissue reaction. Carbon cloth and felt specimens were implanted subcutaneously in several rats. Healing and maintenance have been satisfactory and there seems to be a total absence of the normal tendency of scratching or rubbing the implant area encountered with other materials. Samples of a porous form of vitreous carbon have been furnished to Dr. Ashley for evaluation as potential material in the cosmetic replacement of damaged facial bone, and efforts have been undertaken to fabricate whole bones and joints of carbon for replacements in the hands and feet. These parts involve complex contours and intricate surface detail, and the necessary fabrication techniques are not yet resolved. Both of these areas may offer excellent potential for the application of filament-reinforced carbons as they become more available. The carbon felt,

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fabric, and porous vitreous carbon investigations are all associated with the <u>cosmetic</u> rebuilding of damaged or missing tissues. Carbon replication of small bones, intended for the replacement of severely degraded natural parts, is particularly attractive because of its apparently unlimited useful life in the bioenvironment.

Dr. Donald Laub of Stanford Medical Center has very recently expressed strong interest in undertaking similar investigations pointed toward contour rebuilding through soft tissue replacement and cranial protheses improvements. Specimen materials of a number of carbon forms have been provided for his initial consideration.

Dr. Wiley Barker of UCLA Medical Center is evaluating carbon materials for vascular applications. Several types of carbon cloth and sleeving, and some thick-walled vitreous carbon tubes have been provided for this purpose. A stoma, sized for a rabbit or small canine, has also been provided. This was fabricated from vitreous carbon with both the flange and the tube fenestrated to encourage tissue ingrowth. Additional stoma, catheters, and thin-walled tubes are being fabricated from vitreous carbon for Dr. Barker to evaluate. He has expressed interest in duplicating dacron tubing currently used for vascular replacement from carbon, but no means of accomplishing this has been identified to date.

A vitreous carbon catheter has been designed, fabricated, and delivered to Dr. Samuel Kountz of the University of California Medical Center for permanent catheterization of the renal arteries of rodents. Designs for A-V fistual for other animal investigations under his direction are being studied.

Preliminary discussions have been held with Dr. J. P. Meehan of the University of Southern California Meical Center concerning undertaking a number of vascular prostheses investigations. Detail planning for this program is scheduled for late May of this year with first implantations being undertaken in early summer.

Dr. Colin Daly of the University of Washington Medical Center has been furnished with carbon cloth specimens for tissue compatibility evaluation.

Dr. Vert Mooney of Rancho Los Amigos is evaluating a number of carbon for potential orthopaedic applications. Chief among these is a percutaneous bone extension for amputees. This will permit structural attachment of prosthetic advices to skeletal members external to the body, without bearing on the stump left by the amputation. The first evaluation in this series was the implantation of a small pin of composite material in the femur of a rabbit. Sacrifice at eight weeks showed the bone tightly grown to the pin with no evidence of abnormal tissue reaction at any of the interfaces, although there was some question as to whether carbon particles (grinding dust that was adhered to the specimen surface) had migrated into the adjacent bone tissues. This pin was fabricated from the same carbon-phenolic used by Dr. Bechtol for the original in vivo test.

Shortly after the termination of this test, two human volunteers accepted implants in this program. The first was a bone pin in the tibia. Unfortunately, the hole was drilled too large to retain the pin and it slipped through into the medullary canal. It has remained there without incident for several months. The second was a percutaneous button similar to those already described. After approximately three months in place, this button was removed. Histological evaluation of the adjacent tissues showed no evidence of any form of abnormality. This was followed by the implantation of a bone pin with a percutaneous extension in another human volunteer. This implant was firmly retained by the ulna, and the skin had healed satisfactorily around the percutaneous extension after approximately four weeks, in spite of a substantial relative motion ($\approx \frac{1}{2}$ inch maximum) between the skin and bone at the chosen location. Healing was without incident, except for the slowness attributed to minor reopenings of the wound, resulting from occasionally flexing the arm beyond the elastic limits of the newly formed skin. Unfortunately, the percutaneous portion of this pin was broken off just below the surface of the ulna and had to be removed after about five weeks.

It is interesting to note that, in spite of substantial excursion, the skin was able to accommodate and heal satisfactorily around the stationary pin. Current investigation in this series involves implantation of a dozen different forms of carbon in canine femurs for comparative evaluation of tissue reaction. Clemson University has recently initiated a one-year evaluation of bone tissue compatibility utilizing five animals and seven forms of carbon, and Rancho Los Amigos is expanding their program to incorporate filamentreinforced composites and other new materials.

Dr. Mooney is also evaluating the potential of carbon cloth as an interface material between tissues and some less-biocompatible material such as metal or ceramic. The current experiment consists of wrapping leg bones of rabbits with two thicknesses of carbon cloth so that it lays between the bone surface and the adjacent tissues. Healing and maintenance in these tests have been satisfactory. Interesting fallout from these tests is anticipated. This technique may provide a means of supporting crushed or shattered bone fragments in position for healing. Further, the requirement for post-healing surgery would be eliminated because carbon's compatibility permits its permanent retention.

Substantial interest has developed recently in electrode applications that utilize the tissue compatibility of carbon as a healing aid to protect metallic devices at the skin intercept. Specimens are in fabrication for Dr. James Reswick at Case Institute for myoelectrode application and he is already using some carbon buttons for preliminary investigations in this field. The implant, made at Rancho in August 1968 and subjected to electrical measurements in Dr. Reswick's laboratory in February 1969, was found to be comparable, as a myoelectrode, with the best conventionally used surface electrode. This would indicate that such implants specifically designed and located for myoelectrode application offer real promise.

Two carbon buttons were furnished to Dr. Karl Frank, National Institute for . Neural Diseases and Stroke, for evaluation as neural electrodes. Carbon

bushings carrying platinum electrodes are currently in preparation. These are also under evaluation by Dr. Don McNeil at Rancho Los Amigos. A carbon ring carrying a multi-circuit disconnect is being fabricated for Dr. Frank and is expected to find broad acceptance in neural and brain research. Interest has been expressed by Dr. Arthur Guy at the University of Washington Medical Center in adapting this design to provide a cranial window for animals. The design appears to be well suited to this purpose. Other investigators have expressed some interest in this concept for providing observation windows in internal membranes such as the wall of the stomach; specimens for this use are being designed.

In late 1968, Dr. Henry Lee of Epoxylite Corp. was contacted regarding the potential of carbon materials for application to the percutaneous lead his company is developing under a National Institutes of Health grant. Several of the devices being evaluated were modified to include a vitreous carbon collar around the polymer boss intruding the skin. These were implanted in canines and showed good healing at the skin intercept, although other problems prevented the results from being conclusive. This investigation is continuing with additional all-carbon implants, which are understood to have been furnished by Gulf General Atomics Corp.

In mid-1968, Mr. Harry Chromie of Surgitool Inc. was advised of the characteristics of vitreous carbon and its potential advantages as a material for replacement heart valves, which his company manufactures for Dr. DeBakey and others. A number of specimens, suitably sized for in vivo evaluation in canines, were furnished to him by a carbon manufacturer. It is understood that these parts are currently implanted. Subsequently, information was provided to Drs. Bowman, Milch, and Hastings of the National Heart Institute, and Dr. Starr of the University of Oregon. All have expressed interest in the application of carbon to problems of both valves and percutaneous entry. It has recently been learned that Drs. Starr and Kay at the University of Southern California Medical Center have implantations in place utilizing carbon discs in heart valves. One is a canine aortic valve and the other a bovine mitral valve. This is believed to have evolved from the Surgitool interest.

Dr. Y. Nose' of Cleveland Clinic requested A-V fistula for external heart shunts and hemodialysis ports for animal implantation. A pair of 3-mm repyrolyzed Hitco carbon--phenolic tees and a pair of 8-mm vitreous carbon tees have been prepared and furnished to him for these programs.

An inquiry was received from Dr. Homsy of the Methodist Hospital in Houston, concerning carbon as a reinforcing agent for a biopolymer being developed by his group. Two approaches were suggested and materials for evaluation were sterilized and shipped to him. The first was ball-milled vitreous carbon frit (-200 +325), and the second $\frac{1}{4}$ -inch chopped fibers of Hitco carbon yarn. Both materials are high-purity carbon that has demonstrated wetability by other polymers, therefore a similar result is anticipated with the polymer under investigation. Recent communication from Dr. Homsy reports very promising results from these tests and indicates that the investigation is continuing. It is understood that the objective of this project is to develop a suitable material for bone prostheses.

Effort is currently under way on the fabrication of six complex percutaneous implants for Mr. T. S. Hargist of the Medical College of South Carolina. These are designed to support two silastic tubes and one small electrical cable at a very flat angle through the skin over the rib cage. Study of design details of a controllable blocking flange for colostomy or ileostomy has also been undertaken for this group. Both these tasks have previously been attempted using silastic materials with less than complete success; however, substitution of carbon materials for improved structural properties and tissue interface compatibility appears to offer improved results. It is quite probable that the stoma will finalize as a composite of silastic and carbon, exploiting the peculiar properties of both materials.

Specimen materials have been furnished and some specimens fabricated for Dr. William Stone of the National Institute of Scientific Research. Aside from basic tissue compatibility evaluation, three specific areas have been approached. The first of these is the potential use of vitreous carbon in

ultramicrotome knives for electron-beam microscope specimen preparation. The second lies in exploiting the apparent non-wetability of highly polished vitreous carbon surfaces by blood or other biological fluids to develop a standard for quantifying blood-coagulation phenomena. This concept is being studied by Dr. Henry Henstell. The third area is the application of vitreous carbon to the percutaneous portion of arterial and venous shunts for use with the artificial heart.

A specific application very similar to the last item is the provision of percutaneous bushings for implantable transducer cables. Samples for evaluation in this area have been prepared and are being furnished to the Konigsberg Instrument Company and offered to other investigators indicating a direct interest in this problem.

OBJECTIVES

As this project developed and meaningful communication with the medical profession was attained, many ideas for application of carbon materials were examined, each lying within the specific field of interest of a particular doctor or group of doctors. Approximately one year after the original conceptual discussions, thirty-six definable applications, potentially responsive to some form of carbon implantation, had been identified. These fall into five general categories: (1) orthopaedic, (2) internal ducts, (3) internal membranes, (4) percutaneous, and (5) miscellaneous. There are undoubtedly additional applications not yet identified, although it is felt that the principal areas of rehabilitation medicine have been considered.

During this same period, sources and types of carbon were investigated. A usable inventory of information on commercially available forms of carbon, the established physical and chemical properties of these forms, and some

knowledge of the current developmental effort in the carbon industry has been assembled. This knowledge has been employed in discussions with investigators as it became available. In several cases this led to the identification of listed applications through the simple expedient of examining the "best fit" between available properties of the materials and the recognized need of the doctors.

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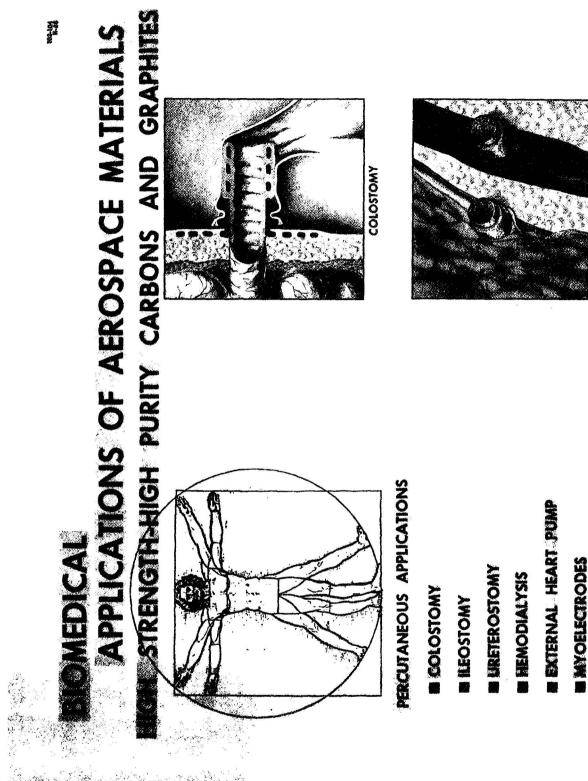
As previously noted, the initial identification came in the field of orthopaedic surgery; specifically, the replacement of arthritic or damaged hip 'joints. Discussions broadened to include prosthetic joints in general, intramedullary pins, implantable splints or bone plates, structural bone grafts, percutaneous bone extensions for amputee or birth defect incidents, and cosmetic (nonstructural) bone grafts. A number of carbon forms appear to offer substantial promise in this area.

Additional identifications generated from the requirement for percutaneous electrodes for research pointed toward functional control of powered orthotic devices by natural muscle signals. Discussions of this application led to the broadening of the percutaneous category to include implanted supports (stoma) for waste receptacles for colostomy, ileostomy, and ureterostomy. Permanently implanted arterial and veinous shunts (A-V fistula and/or cannula) for hemodialysis treatment and external heart pump attachment were also considered. Of the various forms of carbon currently under investigation, vitreous carbon appears to provide the best combination of properties for this category. Reinforced composites are also under investigation for these uses, principally because of their ready availability. Conventional processing techniques can produce precision components from pyrolyzed stock, eliminating the delay encountered during final pyrolysis of the vitreous carbon.

Discussions of implantable waste receptable cupports led to identifications in the area of internal surgery (membrane and duct repairs). Several approaches to this are under investigation. Thin-walled carbon tubes, fabrics, and felts appear to offer advantages in such applications. Compatibility of several of these materials is currently undergoing in vivo evaluation in laboratory animals. The possible application of carbon felt to the problem of tissue replacement led into the field of plastic surgery and the further investigation of carbon felts and fabrics for skin grafts and contour restoration. Cosmetic bone grafts were also considered in this aspect, as was replacement of entire bones in hands and feet (to correct severe arthritic conditions). This latter application has been found to present severe fabrication problems and further consideration is being held in abeyance pending development of satisfactory processing techniques. Of particular difficulty is the requirement to replicate exactly an entire bone, including local surface irregularities. Effort to meet this latter requirement has not been encouraging.

In the course of investigating the above areas, several applications were identified that are not conveniently categorized. These include replacement heart valve components, bladder discharge controls, heart pacemaker cables, otological replacements, and permanent membranes for hemodialysis machines. Several commercially available forms of carbon appear to offer promise for these purposes. Some additional applications have been discussed without arriving at any definite investigative plan, and other very specific identifications can be expected to emerge as the medical profession becomes more aware of this embryonic technology.

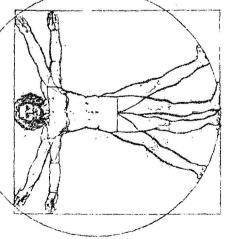
Further broadening of the investigative base is being encouraged by every available means in the belief that clinical application of these materials is greatly dependent upon a confidence that can exist only after a general awareness within the medical profession is attained.



HEMODIALYSIS

ENEURAL ELECTRODES





ORTHOPAEDIC APPLICATIONS

STRUCTURAL BONE EXTENSIONS

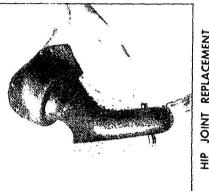
PROSTHETIC JOINTS

BINTRAMEDULLARY PINS

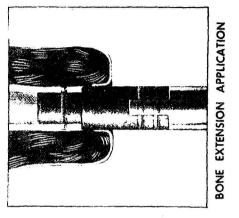
MIMPLANTABLE SPLINTS

COSMETIC BONE GRAFTS

STRUCTURAL BONE GRAFTS



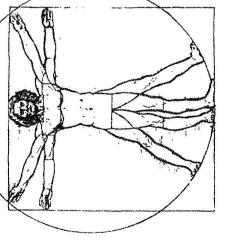
HIP JOINT REPLACEMENT



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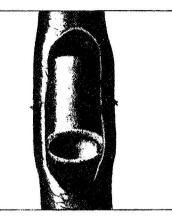
HIGH STRENGTH-HIGH PURITY CARBONS AND GRAPHITES



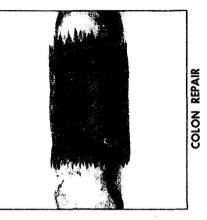
INTERNAL DUCT REPAIRS

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B TRACHEA	BRONCHIA	OESOPHAGUS		

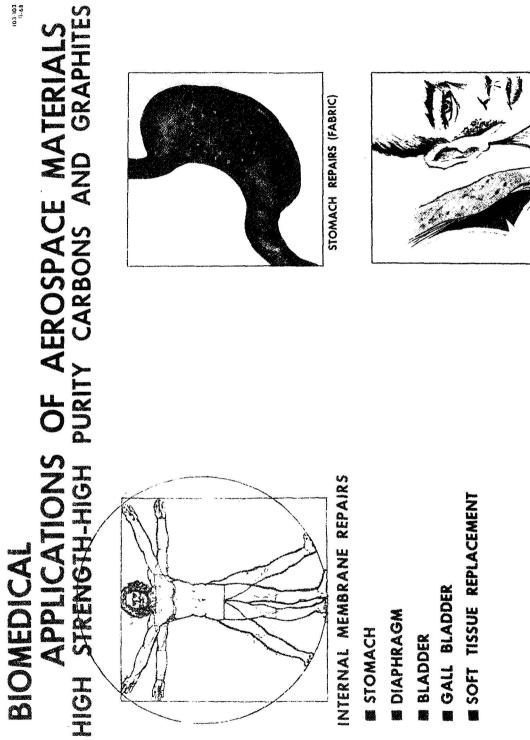
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ARTERY REPAIR

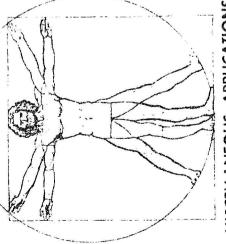


103-105



SOFT TISSUE REPLACEMENT (FELT)





MISCELLANEOUS APPLICATIONS

WHEART VALVE

BLADDER DISCHARGE VALVE

MEART PACEMAKER CABLES

SKIN GRAFTS

HEMODIALYSIS MEMBRANES

CTOLOGICAL REPAIRS



HEART VALVE



SKIN GRAFT APPLICATION (FABRIC)

103-102 11 68