LTI carbon is a clinically accepted material for use in prosthetic devices. Its unique combination of properties makes LTI carbon especially useful in the construction of artificial heart valves and other cardiovascular devices. It is: Thromboresistant Compatible with plasma proteins and cellular components of blood Non-biodegradable Wear resistant Immune to fatigue

The physiologically inert nature of LTI carbon allows it to survive in the difficult transcutaneous situation and can provide access to the circulatory and nervous systems for a broad spectrum of applications.

The ability to survive in the transcutaneous situation and its mechanical similarity to bone make LTI carbon a logical artificial tooth root material. Long-term animal tests are confirming the use of LTI carbon as a dental implant to support a bridge or single tooth.

Because of the wear resistance of LTI carbon it is a potential material for use in prosthetic joints.

The biocompatibility of LTI carbon has been established through investigations of many groups. Bruck, in a recent review, has summarized the results (Table 1). As shown in the table, the thromboresistance of LTI carbon is very good to excellent in both the canine vena cava test of Gott and the renal embolus test of Kesserow. In in-vitro tests the calcium replacement clotting time is not affected by prolonged exposure to LTI carbon surfaces. The material had no effect on the plasma proteins tested by Halbert and no significant effect on the activity of plasma enzymes.

LTI carbon has been in use clinically since 1969; there have been no contraindications

> Table 1 Biological Properties of LTI Carbons

| In | Vivo | |
|----|---------------|-----------|
| | Vena cava | |
| | 2 hr | Excellent |
| | 2 weeks | Excellent |
| | Renal embolus | Very good |
| | | |

In Vitro Effect on plasma None proteins Effect on plasma None to slight enzymes Calcium replacement clotting time Not prolonged Adherence of erythrocytes (WB) Light leucocytes (WB) None platelets Moderate (PRP) Platelet aggregation and activa-Slight tion Cell growth Near 100% (amnion) Zeta potential (Krebs) Negative Critical surface 50 dynes/cm tension

attributable to the material. Problems of long-term biodegradation in the body, such as those often encountered when polymers are implanted for long periods, have not been observed with chemically inert LTI carbons.

LTI carbon may be cleaned by detergent washing and sterilized either by steam auto-claving or with ethylene oxide.

The mechanical properties of LTI carbon may be tailored for specific applications. The fracture strength varies from about 50,000 psi to 100,000 psi depending on density and alloy content. The modulus of elasticity can also be adjusted through processing and falls in the range of the values reported for that of bone.

Wear studies have been shown LTI carbon-LTI carbon bearing surfaces to have a lower wear rate than any other combination of surfaces presently being used in total hip prostheses.

Shim has reported that LTI carbon is not susceptible to fatigue. Repeated stressing up to near the fracture stress will not cause failure. The endurance limit coincides with the single cycle fracture stress.

In comparative tests, the endurance limit of alloyed LTI carbons was more than double that of vitreous carbon.

Applications of LTI Carbon 1. Cardiovascular

LTI carbon was introduced clinically in early 1969; more than 170,000 parts for prosthetic heart valves have been delivered for clinical use. The wear rates predicted by in-vitro or in-vivo animal tests suggest that significant wear will not occur even during the lifetime of a young patient. The wear resistance together with the fact that the material is not subject to fatigue or biodegradation makes it the material of choice for long-term implantation either in Valves or as the components of cardiac assist devices.

2. Transcutaneous Leads

The ability to have a continuous, long-term access through the skin allows for diagnostic and treatment procedures not previously possible. Applications of LTI carbon transcutaneous leads in humans include those for skeletal attachment of prosthetic limbs, and lead-throughs for electrical stimulation of the nervous system. Other applications, still in animal testing, include devices that provide access to the blood for renal dialysis and ports for the controlled administration of drugs.

3. Dental Implants

The biocompatibility of LTI carbon, its strength and ability to perform transcutaneously, and its elastic match with bone make it especially suitable for use as an artificial tooth root. Tests in primates that were begun in 1971 confirm the viability of the approach. Encouraged by further animal tests, human tests were begun in 1975.

4. Orthopedic

Its biocompatibility, high strength and resistance to wear make LTI carbon an attractive material for use in orthopedic applications, particularly in total joint reconstruction.

Summation

Because of the very encouraging results obtained with LTI carbon in such applications as cardiovascular devices, transcutaneous leads, and dental implants, expanded efforts are being directed toward other applications in bioengineering. It is anticipated that LTI carbon and other new carbons will be instrumental in advancing the science and technology of prosthetics.