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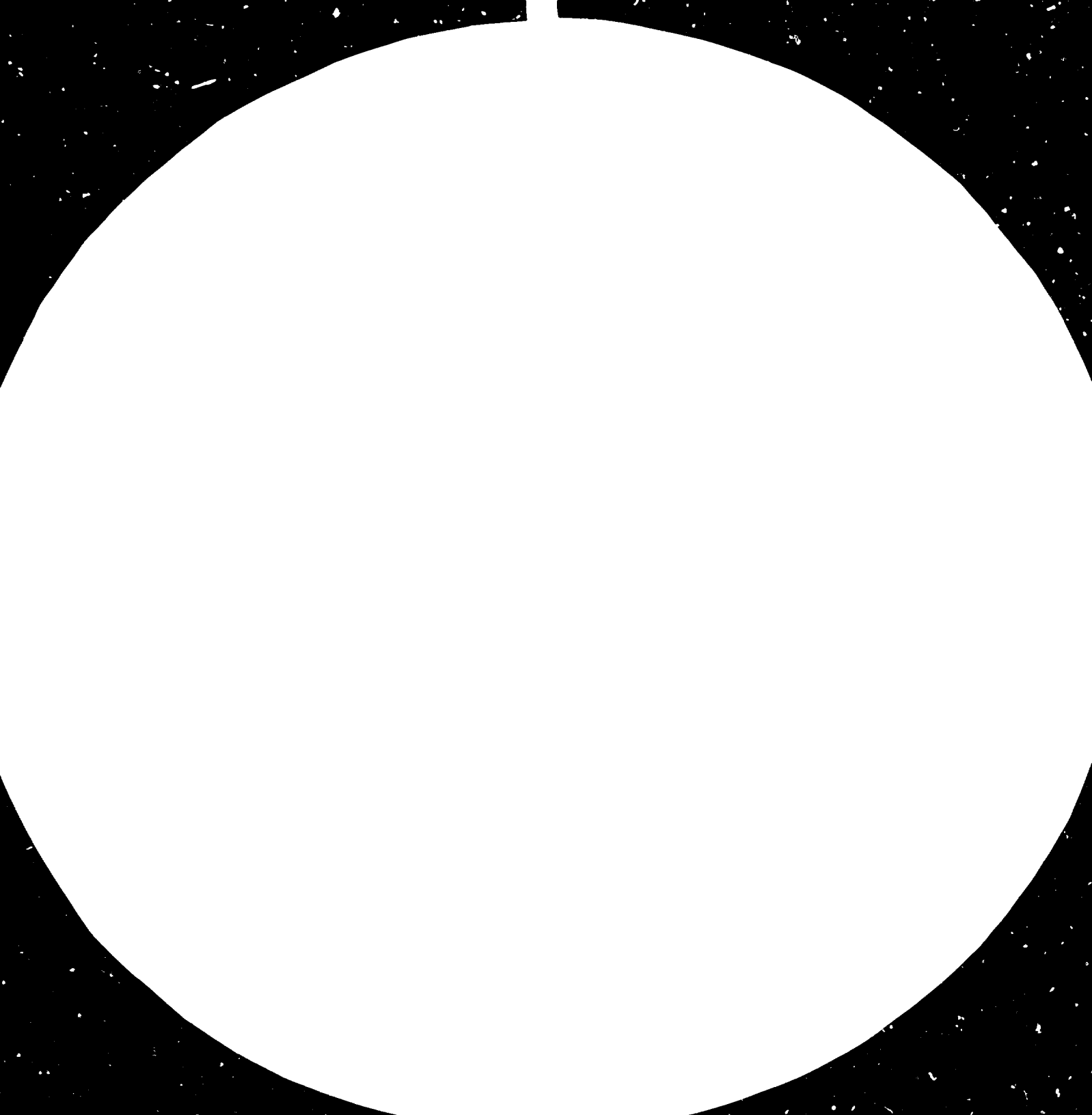
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BIOMEDICAL APPLICATIONS OF CARBON FIBRES*

by

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1. Carbon As A Surgical Implant Material

Carbon is a natural selection for a biomaterial, comprising as it does, one of the major components of the human body. However, it was not investigated for use because at the time of increasing interest in surgical implant materials, the technology had not developed to make it in a form suitable for medical use. Metals were the materials of choice for replacement of the load bearing joints in the body and in combination with polyethylene (ultra high molecular weight) seemed to be satisfactory, at least for the age group of patients considered. As deficiencies in metals began to be realised, corrosion and fatigue, and with the demand for replacement surgery in ever younger patients newer materials were sought. Another factor was the mismatch in mechanical properties between metals and living bone. The stiffness of metallic implants leads to interruption in the normal physiological stress loadings and leads to bone resorption. This has led to lower rigidity materials, in particular for fracture fixation devices.

In cardiovascular surgery the biocompatibility problem is more difficult due to the complex nature of blood interactions with foreign materials and the consequences of changing the blood flow patterns by use of less compliant materials.

Various ceramic materials have been studied, notably alumina for orthopaedic use and apatite for dental surgery. Clinical experience is still being gained with these and attention has also turned to various forms of carbon. The biocompatibility had been established by work of Benson and particularly Bokros who studied blood and soft tissue.

Already LTI isotropic carbon, a pyrolytic form made by vapour deposition of carbon from hydrocarbons on to carbon substrates is used in heart valves and in excess of 200,000 have been inserted in patients. Biocompatibility in terms of non-thrombogenicity is excellent for the material used in the disc occluder in a prosthetic valve, but wear has been observed and failures reported. Vitreous forms of carbon, prepared from an organic polymer precursor, have been investigated for tooth root implants.

Coatings of carbon on to various substrates have been investigated since this is a means whereby the bulk mechanical properties of the substrate material can be utilised with the compatible surface produced by the coating. Particularly low temperature methods now available (ULTI carbon) mean that plastics and heat sensitive materials can be treated. Dacron knitted vascular prostheses are one example. Various methods for coating blood contact devices are being developed.

In bulk carbons three types are being studied a) high strength isotropic carbon, b) silicone carbide/ carbon composites and c) carbon fibre reinforced carbon (cfrc), generally for orthopaedic application (joint replacements).

This paper is only concerned with the latter, cfrc, being a fibre based product.

2. Carbon Fibre

Since the development of carbon fibre it has seen application in many areas in leisure products and industrial developments, particularly aerospace.

The first medical application of carbon fibre was in the repair of tendons and ligaments and more recently for repairing defects in the cartilage of joint surfaces. It appears that the fibre induces formation of collagenous fibrous tissue ordered in the direction of the carbon fibre filaments. The carbon fibre is partially fragmented and considerable deposits are observed in the regional lymph nodes. One of the problems in replacement of knee ligaments by carbon fibre appears to be the laxity which gives a poor end result. Tendon replacement seems to be more satisfactory but the fragmentation may be a cause for concern.

Braided carbon fibre, made up of 32 tows with a braid angle of 43° has been used in medial collateral ligament repair in sheep, the end being inserted under a bone shelf to provide anchorage. This anchorage was found to be firm when implants were later examined and connective tissue surrounded the strands under the shelf with single fibres embedded in bone. Oriented collagen fibres were observed associated with the strands. In a similar experimental series in which the braid was fed through a drill hole in the bone histology confirmed the presence of irregular collagen bundles in the direction of the ligament but less dense than normal. Fragments of fibre were seen intracellularly. The observation was that at one year there remained a granulomatous tissue showing that it is a foreign body reaction but well oriented. Complications reported included intraarticular dissemination of fibre fragments, rupture and failure of tissue ingrowth.

The application of carbon fibres to these replacements does not seem to be a completely satisfactory technique and is not suitable for use near to the skin. The tissue formed around the braid, although partly organised does not seem to be normal tendon or ligament and long-term use is probably not yet indicated.

Biocompatibility is dependent on several factors not simply tissue response as usually understood. Mechanical factors are equally as important and therefore present results may depend as much on mechanical design deficiencies. A study on different braiding methods has established the differences and has optimised the design to a 43° braid angle with 32 tows (each 3000 filaments). In vivo sheep experiments and laboratory tensile testing and fatigue studies were performed, for the latter the braids were attached in human cadaver knees. The importance of an elastic fixation was demonstrated.

Experimental use as a patch for hernia repair is reported using it in the form of a non-woven fabric. A polyacrylo nitrile fabric was made and then carbonised at 1000°C . Dense tissue permeation was observed with inflammatory reaction up to 8 weeks. In contrast to polyester patches, the carbon ones increased in strength with time of implantation.

3. Carbon Fibre Reinforced Composites - General Comments

An important distinction in the properties of carbon composites in general compared with the other forms of carbon is that fibre delamination is a strength determining factor. They have an advantage that a short duration overload will not cause catastrophic failure although some fibres will be broken. As a consequence of delamination effects, strength effectively decreases as the l/d ratio (thickness/support distance) decreases,

i.e. as the span increases. This imposes design limitations on biomedical uses and may account for the unacceptable level of breakage found when endeavouring to use this material as a bone plate (B. McKibbin personal communication).

The use of unidirectional or multidirectional composites is an area for discussion. The best strength properties are given by unidirectional reinforcement but only when the loads are applied parallel to the fibre direction. The natural reinforcement patterns of bones in general accord with this concept and certainly the pattern of trabeculae in the head of femur show the lines of reinforcement to correspond to the directions of the principal stresses. However, bone is a living material which constantly responds via cellular activity to the variations in load patterns. It also will repair damage. Since a replacement material may not be placed in the exact alignment with the stress patterns, since these may change anyway, and since the stress distributions are very complex in vivo, it would seem better to use a multidirectional or cross ply, laminate. This is a compromise and results in some loss of strength but does give assurance against torsional forces as well as those which are purely tensile.

Fibre content will also considerably affect strength and Young's modulus. These increase linearly with increasing fibre content. For biomedical applications it is probably preferred to opt for maximum possible fibre content and to rely on variations in fibre properties (e.g. low modulus/high strength, high modulus/low strength) to achieve product modification. Particularly in the case of resin based composites, a minimum amount of resin is preferred to optimise properties and aid quality control.

The relationship between Young's modulus of an implant and bone properties is an area of controversy. It is observed in clinical practise that a stiff implant material will lead to loss of bone density and thus of strength of bone material. To avoid this, it is suggested that low modulus materials should be used. However, since stiffness depends on the section of the device, i.e. it is design dependent, modulus reduction alone is not the solution. Some reduction in modulus will be beneficial but not the extent of reduction of strength to a dangerously low level.

The use of hybrid composites has not been really explored for biomedical use. Some of our results with carbon-Kevlar_R hybrids showed that although toughness was enhanced Kevlar was unacceptable for biocompatibility reasons (unpublished work).

One limiting factor in surgical implant design with metal alloys is the inadequate fatigue life shown by the surgical materials. Cyclic loadings in an insufficiently supported load-bearing prosthesis lead to rapid failure by a corrosion enhanced process. Since carbon fibre composites do not show a yield point and the strain at failure is greater than would be expected in normal clinical use they are unlikely to fail in service. Progressive delamination and therefore loss in rigidity is observed and some of the weaker fibres may fail progressively, but catastrophic failure other than by high velocity impact, is not likely. (See later).

4. Carbon Fibre Reinforced Carbon

Carbon fibre reinforced carbon made by gas phase densification of a carbon fibre matrix may be made with unidirectional or multidirectional reinforcement. The properties of a unidirectional material are given in Table 1.

TABLE 1.

Carbon Fibre Reinforced Carbon (19)

Density	g/cm ³	1.7
Flexural Strength	MN/m ²	800
Youngs Modulus	10 ³ MN/m ²	140
Compression Strength	MN/m ²	800

The high strength, low modulus combination led to the proposal for its use in the stem portion of an upper femoral prosthesis. Various methods for producing cfrc have been described

It is clearly important for biocompatibility to be established and Neugebauer et al implanted fragments into the femoral medullary canal of rabbits. Some particles were found in other parts of the animal but without foreign body reactions. No bone destruction was seen. There was a small amount of fibrosis and foreign body giant cell reaction and also some new bone formation. Toxic effects and severe inflammatory reactions were not observed.

5. Carbon Fibre Reinforced Plastics (cfrp)

5.1 Carbon Fibre Reinforced Polyethylene:

Ultra high molecular weight polyethylene (UHMWPE) is well established for use in prosthetic joint replacements. It does, however, wear and also suffers from a certain amount of creep. Reinforcement with carbon fibre has been proposed. One of the problems is that UHMWPE is difficult to mould due to its high (>10⁶) molecular weight and it would be difficult to obtain a good composite. Using a slightly

lower molecular weight product this has been achieved. This was also investigated using high density polyethylene , for greater ease of fabrication. As reported, when mechanical properties were optimised, the wear rate was reduced in comparison with results reported by others.

Creep results indicate that the reinforced polymer may have a more steady state behaviour than the unreinforced.

A carbon fibre reinforced UHMWPE (Poly Two_R -Zimmer USA) has been introduced into clinical practise. In vivo studies on abraded particles introduced into mice indicated a similar tissue response to that observed with unreinforced polymer although it should be noted that the volume of debris produced is important.

It appears that there is a lack of compatibility between fibres and polymer and this requires further investigation.

5.2 Carbon Fibre Reinforced Epoxies (cfre)

This project developed from work on water emulsified epoxy resins and the reinforcement of these as potential orthopaedic implant materials. However, for load-bearing devices conventional systems are required and attention turned to use of pre-preg to make laminated composites. Type II fibre was used in a heat hardening resin system.

Two aims in the programme were to attempt to reduce the effects of stress protection in bone arising from use of stiff metallic implants and to provide better fatigue life. It is important in fracture treatment to provide stable fixation so that healing can proceed. This

occurs naturally by an internal bridging process (callus formation). Rigid metal implants lead to a by-passing of this stage in healing and rely for their function on a minimal gap between the broken ends of bone. The plate is thus supported in a new bone/plate/screws system. If excess movement occurs the plate will fatigue rapidly (a few weeks).

Laboratory fatigue studies in reversed plane bending at 10Hz were carried out on bone plate designs (8 hole DCP) while sodium chloride solution at 37°C was circulated round the plates. Stainless steel controls showed a maximum safe load for 2×10^6 cycles minimum lifetime (corresponding 1-2 years in a patient) to be 6Nm. None of the carbon fibre composite plates broke at 2×10^6 cycles for loads up to 13.8Nm. Reduction in stiffness was observed and used as a measure of endurance limit and an upper limit of 10.5Nm was proposed. A stiffness reduction of 10.3% was noted. The endurance limit is approximately 30% better than that for stainless steel and of course, catastrophic failure did not occur.

Following in vivo functional testing in sheep, human trials were begun for tibial fractures and have been reported . Approximately 30 fractures were so treated and in all cases satisfactory healing was obtained. Stainless steel screws were used. The trial has now been extended to forearm fractures for which this is more clearly a recommended treatment and satisfactory stability and healing have been obtained. The level and type of activity in the forearm is quite complex and results may in fact show a relationship to these factors. The healing pattern is distinctively different from that seen in the tibia but this may affect the relative stiffness of the two different systems.

Calculation shows that the cfrc tibial plates were of comparable stiffness to the recommended steel plates and the main advantage was the improved fatigue properties for a greater possible range of elastic deformation.

Laboratory studies show that the method used by the surgeon can have profound effects on the overall stiffness of the system and may, in fact, mask differences in materials.

Strain gauged plates have also been used to determine effects of screw fixation on plate characteristics and recent developments in telemetry should permit direct in vivo evaluation to take place.

A full analysis of results is presently being performed and includes results of healing, tissue reaction, plate properties post implantation in patients . Long term studies are also in hand to study the biological performance. This, it is hoped, will lead to development of joint prostheses and a programme of design evaluation and mechanical testing is under way and will incorporate our latest developments in ceramic materials.

Polysulphone is another matrix polymer receiving attention Hunt has extensively studied its potential as a lower modulus implant material.

Other groups also report work on composite bone plates using carbon fibre reinforced carbon (see earlier).

5.3 Carbon Fibre Reinforced Acrylics

Acrylic bone cement used to stabilise the position of joint endo-prostheses has limitations in long-term durability and work has begun

to study the benefit obtained by carbon fibre reinforcement.
Mechanical properties are improved and biocompatibility is being evaluated.

A possible use for reinforcement of acrylic dentures has been investigated and as anticipated fatigue life of the material is improved but the scatter in results, for various reasons, makes evaluation of a complete denture difficult.

Composite bone plates based on polypropylene and on a diacrylate resin have also been examined. Poor fibre-matrix adhesion led to fibre migration and cell culture studies are not completely satisfactory for the diacrylate material.

