Potential of polyetheretherketone (PEEK) and carbon-fibre-reinforced PEEK in medical applications

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Several polymers are widely used in current surgical, dental and pharmaceutical applications. These include some engineering thermoplastics, such as ultra-high molecular weight high-density polyethylene in joint replacements, some elastomers, such as silicones and polyetherurethanes in blood-contacting devices and a range of acrylic products that can be cured inside the body giving, for example, bone cements and dental restorations. In the context of the available polymer chemistry and polymer engineering, however, this range of biomedical polymers is not large and there is, currently, considerable interest in the development of different speciality polymers for medical use. We report in this letter some preliminary experiments directed at evaluating the potential of a relatively new engineering thermoplastic, polyetheretherketone (PEEK), and composites of this polymer with carbon fibres, for these applications.

Peek is a semi-crystalline polyaromatic linear polymer with a good combination of strength, stiffness, toughness and environmental resistance [1, 2]. It is manufactured by ICI plc under the trade name "VICTREX", PEEK. The polymer is also available as chopped carbon fibre-reinforced injection-moulded grades and as aromatic polymer composite (APC) (ICI Welwyn Garden City) a continuous carbon fibre/PEEK preimpregnated tape.

The interest in PEEK and carbon-fibre-reinforced PEEK in the context of medical engineering lies with the proven inertness of the polymer in many aggressive environments [3] and the potential to control the elastic modulus of the composites such that biomechanical compatibility with bone might be achieved. When any implanted device is attached to bone, which has a Young's modulus in the region of 20 GPa [4], there will inevitably be a modulus mismatch with the majority of materials. Traditional orthopaedic alloys used in bone and joint reconstruction or repair devices have a modulus 10 to 20 times greater than the bone. Thus, the device may sustain far higher stresses than the bone to which it is rigidly fixed, thereby shielding the bone from stress. Because bone requires the stimulus of mechanical stress to maintain its structure, the bone adjacent to the high modulus device becomes porotic and weaker [5, 6].

Polymers themselves do not have the appropriate mechanical properties for most load-bearing orthopaedic devices, but polymer-based composites may be arranged to have optimal elastic modulus. The use of short-fibre reinforcement imparts improvement in stiffness and strength dependent on the fibre content, but even greater benefits can be achieved with continuous-fibre reinforcement. The recent availability of APC allows the exact tailoring of modulus and strength by laying up the prepreg plies in specific directions. Examples of the range of properties now obtainable with these materials by injection moulding of chopped fibre grades and compression moulding of continuous fibre APC are shown in Table I. Because the flexural modulus of bone is in the region of 20 GPa, a composite with an equivalent modulus, or one slightly greater, could easily be made available.

Attempts have been made to use carbon-fibre-reinforced thermosetting resins for these applications [7, 8] but with some compatibility problems. Thermoplastics would appear to offer a more suitable matrix and, indeed, carbon-fibre-reinforced polyethylene and polysulphone have both been investigated [9, 10]. The intrinsic properties of PEEK and carbon-fibre PEEK suggest that they offer an excellent combination of properties and preliminary experiments to determine the tissue response to these materials have been performed.

Two PEEK samples of widely differing melt viscosities and, hence, molecular weights, were used for this work. PEEK (A) is a very low viscosity experimental resin whilst PEEK (B) is the commercially available injection-moulding-grade 450G.

A 50% chopped carbon-fibre-reinforced PEEK (A) and a 30% carbon-fibre-reinforced PEEK (B) were also studied. All four samples were injection moulded, using an Arburg injection-moulding machine with a

TABLE I Mechanical properties of PEEK and CF-PEEK

Sample	Weight fraction of fibre (%)	Flexural modulus (GPa)	Flexural strength (MPa)
PEEK	0	3.8	156
Chopped carbon-fibre-reinforced PEEK	30	21	343
Chopped carbon-fibre-reinforced PEEK	50	41	372
APC quasi-isotropic $[+45/0/-45/90]_{2s}$	68	47	803
APC cross ply 0°/90°	68	62	907
APC uniaxial 0°	68	125	1940

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TABLE II Effect of *in vivo* and *in vitro* ageing on the flexural modulus and strength of PEEK

Sample	Time (month)	Flexural modulus (GPa) (±s.d.)	Flexural strength (MPa) (±s.d.)
PEEK (B)			
Control		3.8	151
In vitro 37° C	2	3.8 (0.3)	149 (3)
In vitro 80° C	2	3.9 (0.4)	153 (7)
In vivo	2	3.8 (0.1)	150 (1)
In vivo	6	4.1 (0,1)	163 (2)
30% CF/PEEK (B)			
Control		22.1	345
In vitro 37° C	2	23.9 (1.8)	338 (7)
In vitro 80° C	2	22.9 (0.95)	342 (4)
In vivo	2	21.4 (0.3)	338 (8)
In vivo	6	23.2 (0.1)	348 (10)

barrel temperature of 380° C, into a heated mould held at 150° C to form disks or bars from which disks for implanting were machined.

Flexure bars of unfilled PEEK (B) and 30% carbon-reinforced PEEK (B) were aged *in vitro* (in phosphate-buffered saline at 37 and 80° C) and *in vivo* (subcutaneous implantation in rabbits) to assess any material changes occurring in the different environments. Table II indicates that little effect is apparent from either at 37 or 80° C *in vitro* or *in vivo* after 6 months.

The tissue response to these materials was determined following the implantation of 5-mm-diameter 2-mm-thick disks intramuscularly in rats. Procedures developed and used routinely in our laboratory, and described elsewhere [11, 12] were used. Samples were implanted for periods of 4, 9 and 30 weeks and the following observations were made.

PEEK A: At 4 weeks, the implant was surrounded by a loosely packed collagenous matrix with numerous capillaries and variable cellular infiltration. At 9 weeks a variety of cell types, especially including lymphocytes, remained in the region, but otherwise the area was unremarkable. By 30 weeks the capsule which had developed around the implant exhibited layers of oriented collagen, a low level of vascularity and relatively few cells (Fig. 1). There was little generalized cellular infiltration beyond the capsule border, although, interestingly, some fat deposition

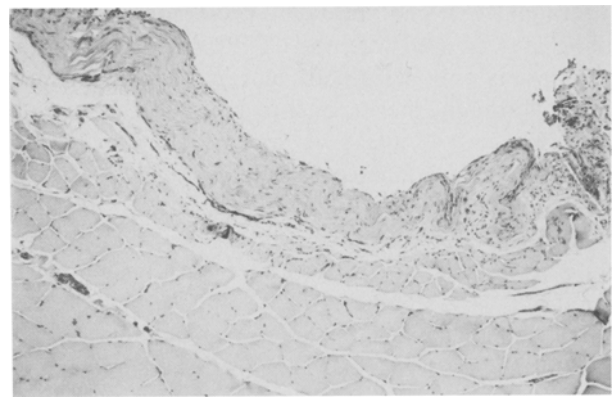

Figure 2 Oriented collagen in capsule around 50% CF/PEEK A at 30 weeks.

was evident. This response was, therefore, very mild with no evidence of significant irritation of the tissues.

PEEK B: At 4 weeks there was a high level of cellular infiltration, with a significant lymphocytic involvement. This had subsided by 9 weeks, although some macrophages were present. Compacted avascular collagen comprised the bulk of the capsule. The resulting reaction at 30 weeks was very similar to that of Material A.

50% CF/PEEK A: The degree of cellular infiltration at 4 weeks was variable and, in places, quite high. Fat deposits and fat cells were evident and the tissue was well vascularized. This inflammatory state subsided to show low levels of cellular activity at 9 weeks. At 30 weeks an avascular capsule containing oriented collagen layers had formed (Fig. 2), but again some fat deposits were noticeable at the periphery. Some cells that contained black particles were seen in the capsule, suggestive of the presence of a few carbon fibres.

30% CF/PEEK B: Extensive fat deposition occurred early in this response (Fig. 3). Collagen structures predominated with little evidence of cellular infiltration. At 9 weeks some black particles were seen in the tissue and there was evidence of some peripheral involvement in the muscle surrounding in the main area of reaction. At 30 weeks there was little evidence of infiltration of the capsule by cells and some fat deposits persisted. The reaction was mild, despite the presence of a few small black particles.

These observations suggest that PEEK elicits a minimal response from muscular tissue and that

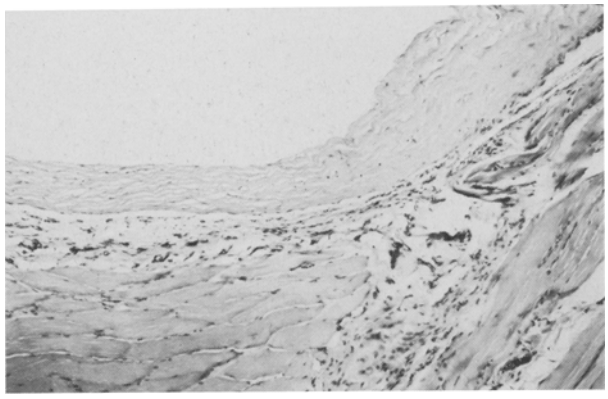

Figure 1 Capsule around PEEK A at 30 weeks. Haematoxylin and eosin stain.

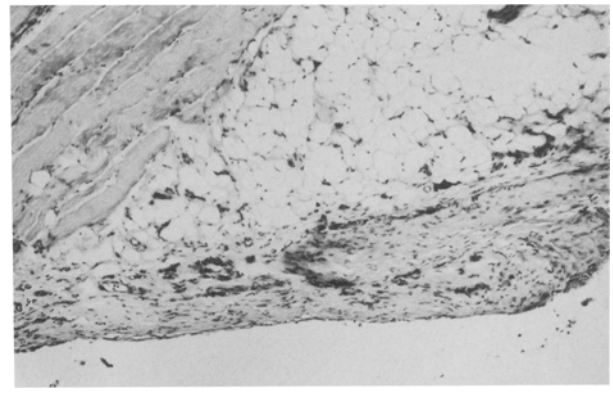

Figure 3 Fat deposits in response to 30% CF/PEEK B at 9 weeks. Haematoxylin and eosin stain.

although a few small particles, presumably of carbon fibre, may be seen with the CF PEEK materials, the response is only marginally more noticeable in these cases. Normally, the response to an implant of minimal reactivity at 4 weeks is an inflammatory/repair process, the inflammation subsiding by 9 weeks and leaving a relatively acellular collagenous capsule by 30 weeks. In this series, the extent of the initial inflammation was a little more prolonged, with some involvement at 9 weeks being evident, but, with PEEK and CF PEEK specimens, the mature collagenous capsule had formed by 30 weeks. The only remarkable feature was the deposition of fat, a feature which requries further study.

These observations, together with the lack of any "environmental" effect on material strength properties, would suggest that PEEK and CF PEEK are worthy of further investigation as implantable materials. Naturally, further studies of these materials in contact with bone would be required in order to assess their full potential in reconstructive orthopaedic surgery.

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