Hydroxyapatite reinforced polyethylene — a mechanically compatible implant material for bone replacement

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For a number of years, various synthetic implant materials have been routinely utilized as replacements for bone. One major example is in total-hip replacement for which, in general, the femoral head is substituted by an alloy casting, secured in the marrow cavity by PMMA bone cement and seated in a high density polyethylene acetabular cup[1]. The alloys most used for this purpose have been austenitic stainless steel (AISI Type 316, 17-20 wt% Cr, 10-14 wt% Ni) and Co-Cr alloys (with 19-21 or 27-30 wt% Cr)[1]. These alloys, selected primarily on the basis of their biocompatibility, resistance to corrosion, adequate fracture toughness and fatigue strength have proved satisfactory, but not ideal, in such applications. As a result attention has been devoted recently to the application of even more 'inert' implant materials, such as alumina, although the brittle nature of ceramic materials presents a new problem, and various titanium alloys[1]. However, for all these implant materials, one intrinsic problem is that of implant 'loosening', i.e. with time the implant material tends to become detached from the bone. Such an event is not surprising in view of the disparity between the elastic deformation characteristics of the alloy or ceramic implants and those of bone itself. Young's modulus values, (which provide one measure of elastic deformation), are listed in *Table 1* for the various implant materials and bone to illustrate the significant differences in elastic behaviour. It should be noted that the Young's modulus of compact bone from the major support bones is a function of its orientation with respect to the longitudinal axis, which is a reflection of the anisotropic microstructure[2,3] and the limiting values are quoted. If any one of the alloy (or ceramic) implant materials is placed in contact with and bonded to bone, then for continuity to be maintained across the alloy-bone interface during a subsequent stress application, a distribution of stress between the two components is produced which depends on their respective Young's and shear moduli. Hence, if the elastic moduli are significantly different, then a substantial interfacial shear stress is developed which tends to produce de-bonding at the interface and a consequent 'loosening'. This situation is eased, in the sense that a higher shear stress for de-bonding is required, if the bone is 'cemented' to the implant alloy or ceramic. However the mis-match of elastic moduli still exists for the three component system, namely bone-bone cement-implant alloy, and hence the potential for implant loosening remains. One approach to overcome this problem would be to use an implant material with similar elastic moduli to those of bone. However, none of the currently available implant alloys or ceramics have these particular properties. The objective of this note is to report the development of a synthetic composite material with a similar Young's modulus to that of bone, based on components which, individually, are also biocompatible.

In considering the replacement of bone by a mechanically-equivalent synthetic material, it is pertinent to start from the microstructure of bone itself. From the standpoint of load-bearing properties, the significant constituents are collagen and hydroxyapatite, which in the major support bones have a preferred orientation along the long axis of the bone. It has long been established that bone may be considered primarily as a hydroxyapatite reinforced collagen composite[4-8], with the additional secondary effect due to the arrangement of osteons[9]. The volume fraction of the hydroxyapatite in mature bone is ~0.5 and its Young's modulus[7] is ~114 GNm^{-2} a value which is considerably greater than that for collagen,

Table 1 Comparison of Young's modulus values of current implant materials with those of compact bone

Material	Young's modulus (GNm^{-2})
Stainless steel	200
Co-Cr alloy	230
Titanium	106
Ti-6 wt% Al-4 wt% V	106
Al_2O_3	365
Bone (longitudinal orientation)	17.3-27.3
Bone (transverse orientation)	7.2-10.3

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($\sim$ 1 GNm^{-2})[4]. Hence, with comparable volume fractions for both constituents, hydroxyapatite is the major load bearing component of bone (in the elastic region, it can be shown that $\sim$97% of any applied load is supported by the hydroxyapatite[5]). The role of the collagen in this system may be considered as providing a matrix in which the hydroxyapatite is distributed. As hydroxyapatite is a brittle and notch sensitive solid, collagen acts to minimize the propensity for brittle fracture associated with a 100% ceramic (hydroxyapatite) structure.

In developing a synthetic equivalent of bone, the mechanical function of collagen as a matrix may be replaced by one of several ductile polymers, which have comparable values of Young's modulus. High density polyethylene, which is already utilized as an implant material and has a Young's modulus of $\sim$ 1 GNm^{-2}, was selected as particularly suitable for this purpose. For the reinforcing phase, hydroxyapatite, which is available either as an ashed derivative from bone or in various synthetic forms, was utilized[10].

Various natural and synthetic hydroxyapatite powder – polyethylene composites were prepared by a mixing technique[10], with the volume fraction of hydroxyapatite ranging from 0.10 to in excess of 0.60. Compression mouldings were produced from these materials[10] and measurements of Young's modulus were made by a refinement[11] of the ultrasonic analysis technique described previously[2]. The preliminary results, obtained from four samples at each volume fraction, for one particular combination, are shown in *Figure 1*, which demonstrates that hydroxyapatite effectively reinforces polyethylene, with an increase in Young's modulus obtained as the volume fraction of hydroxyapatite was increased. It can be seen that the magnitude of the increase in Young's modulus with volume fraction is approximately linear, although the absolute values are less than those predicted by rule of mixtures addition of the two components in the composite. However, the important point established is that at the 0.6 volume fraction level, the Young's modulus of the hydroxyapatite–polyethylene composite, at $\sim$ 12 GNm^{-2} exceeds the range of values obtained for transversely orientated bone. Further work is in progress to establish the effect of hydroxyapatite particle size, shape and distribution at the 0.6 volume fraction level and to

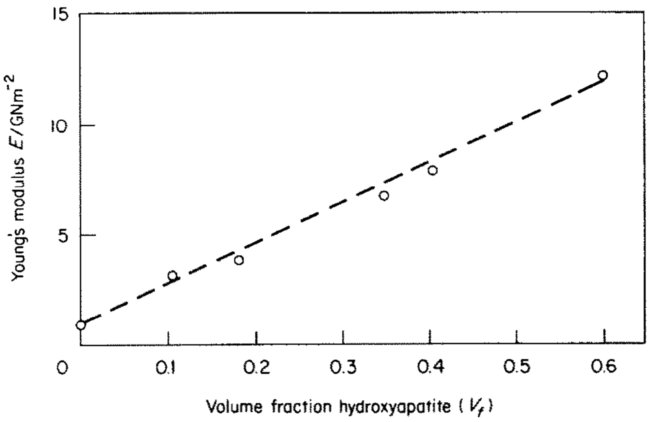

Figure 1 The effect of hydroxyapatite volume fraction (V_f) on the Young's modulus (E) of hydroxyapatite reinforced polyethylene. The results shown are for the combination of Podmore ashed bone (Ca/P ratio 1.66-1.72) and HDPE, HO2O-54P, B.P. Chemicals Limited

develop a preferred orientation, but the potential of the hydroxyapatite-polyethylene system as an elastically compatible implant material for bone has been established.

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