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Pre-clinical evaluation of the Cambridge acetabular cup

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Abstract It is postulated that the stifness of current acetabular designs compromises long-term component stability. We present a novel acetabular component design that is horseshoe shaped and has a large diameter bearing. It is made from composite materials and is designed to match the stiffness of subchondral bone. It is intended that stress shielding will be minimised and that the distribution of stress will be improved. The mechanical and biological suitability of the composite has been confirmed. A range of standard and non-standard, pre-clinical, tests have established the robustness and safety of the new component. The efficacy of the new design has been evaluated by clinical trial on 50 patients. Optimal results were obtained using the hydroxyapatite (HA) coated cups. Our results support the new design concept, with the caveat that biological fixation is imperative. Minor design modifications are recommended.

Introduction

In the healthy hip joint, load is transferred between segments of hyaline articular cartilage that cover the spherical part of the femoral head and the horseshoe shaped portion of the acetabular socket [1, 2]. In disease the articular cartilage and underlying subchondral bone are damaged. Following hip replacement, the natural stress distribution through the pelvis and proximal femur is distorted owing to mismatches of stiffness that are created at the interfaces between implant and host bone [3, 4]. The mismatch causes increased stress in some areas and relative "shielding" at others. Such change is believed to contribute to component loosening [5, 6]. One criterion for successful implant design and long-term component stability may be to recreate physiological load transfer at the interface between implant and host bone.

Recognising the importance of the bone-implant interface, a recent novel development in acetabular prosthesis design uses a flexible, perforated, roughened metallic cup, produced by Sulzer (Winthertur, Switzerland) that is able to follow the natural movements of the acetabulum. Initial clinical trials on 33 patients showed promising results after 3 years, with early osseous integration at the bone metal interface [7].

While metal alloys are widely used in femoral and acetabular prostheses these materials inevitably distort the

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natural stress pattern on adjacent host bone. Composite materials technology offers the potential to fabricate components with properties that more closely mimic those of host bone and to tailor the implants according to the requirements of specific applications. Thermoplastic polymers, with strong intermolecular bonds, show long-term resistance to moisture damage; potentially conferring good biocompatibility and durability.

We have utilised composite technology, using flexible materials of stiffness comparable to human bone, in the design of the Cambridge cup. Our aim has been to reproduce, as closely as possible, the physiological stress distribution of the healthy acetabulum. The acetabular component is modelled to replace the cartilage and underlying subchondral bone of the horseshoe-shaped articular portion of the acetabulum.

Materials and methods

In a previous paper the design principles of a novel flexible anatomical shaped acetabular cup, the Cambridge cup, are described (Field et al. submitted). In order to evaluate the design concept, components were fabricated using a combination of machining and injection moulding. The manufacturing procedure consisted of machining an external surface on an extruded rod of UHMWPE which was subsequently used as an insert to fit into an injection mould capable of producing the Cambridge acetabular cup. The blank had been machined with surface features that would ensure a mechanical interlock between the two materials. About 30% carbon fibre reinforced polybutyleneterephthalate (CFRPBT) was injection moulded over the outer surface of this machined rod to produce a composite backing for the overall construct. This construct was further machined to a final shape by hollowing out the UHMWPE. The final construct had an overall OD of 54.5 mm an ID of 45 mm, a backing composite thickness of 1.75 mm with the UHMWPE being the balance (Fig. 1). Six integrally moulded spikes protrude from the outer surface, over the load-bearing segment and are orientated in alignment with the primary load vector. Three regions of small indentations are found near the rim on the outer surface. Two expanding polymethylmethacrylate (PMMA) dowel housings, may be inserted through the arms of the cup into the ischium and pubis and locked by insertion of UHMWPE dowel pegs that are seated sub-flush to the bearing surface.

The outer surface of the component is plasma sprayed with a hydroxyapatite (HA) coating, to promote rapid bony attachment to the surface of the cup. Before spraying the six antirotation spikes are masked to avoid HA coating. The surface of the CFRBT is initially roughened by means of HA blasting using sintered HA powder particles of greater than 104 μm. Following this, the HA layer is deposited by plasma spraying to a thickness of 50–90 μm. Any excess HA on the six spikes is removed by means of a high-pressure waterjet.

In half of the cups prepared for implantation, the HA coating was removed by means of acid dissolution. All of the cups were subject to gamma irradiation of a minimum 25 Kgy.

A series of mechanical tests have been performed on the Cambridge cup to establish its endurance under load, the shear strength of the anti-rotation spikes, its performance under compression, tension and expansion and its stability on implantation. We have also undertaken biocompatibility tests to investigate the biological properties of the composite [8].

Component tests

Test 1

A fatigue rig was constructed to test 10 cups, in a saline environment maintained at body temperature to ensure material properties did not alter due to heating during testing. It was previously established that a 100 N compression force applied through callipers across the peg holes at the extremities of the arms of the horseshoe, would

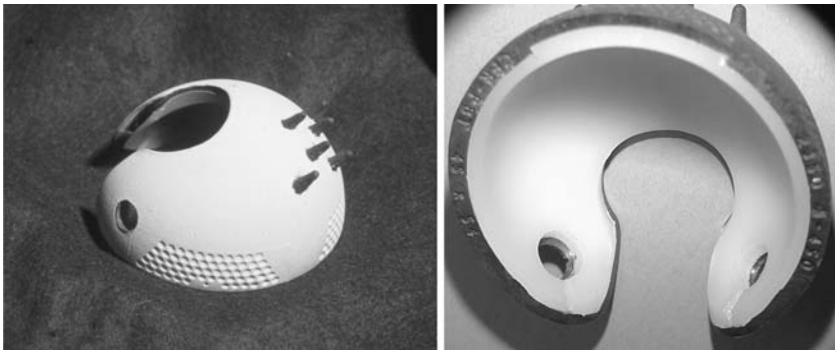


Fig. 1 The Cambridge acetabular cup—showing the outer CFRPBT shell and inner UHMWPE bearing

cause a total inward deflection of 2.4 mm. A femoral stem with a 44 mm head diameter was held in the cup, to provide support, while the 100 N force was applied at 10 Hz for a minimum of 125,000 and a maximum of 10,000,000 cycles. Each cup was compared against an untested component, before and after testing, for evidence of damage or separation of the UHMWPE, CFRPBT or HA layers.

Test 2

Cambridge cups, either gamma-irradiated or not, were used to determine the strength of the anti-rotation spikes. A shear force was applied close to the base of a spike, using a wedge bar in an Instron mechanical test rig. The force required to detach each spike was recorded.

Test 3

An Instron test rig was used, in compression and tension, to load specimens to failure. The test was intended to identify the maximal component compression deflection that would be tolerated during insertion and the maximal expansion deflection that would occur with over reaming and successful peg securement. Two cups were evaluated for each condition, and were secured through the peg holes in the two arms. In each case, the force and maximum deflection to failure were recorded.

Test 4

A further series of expansion tests, evaluating seven cups under load, were carried out in 57 mm and 58 mm diameter hemispherical cavities to simulate conditions in an over-reamed acetabulum. Each cup was positioned in the holding fixture and was secured to the hemispherical cavities by bolts through the peg holes, expanding the cup outwards to fill the hemispherical cavity in the AP direction at the extremities of the horseshoe. A 45-mm spherical head was used to load the cups to three times body weight. In each case, the force and maximum deflection to failure were recorded.

Test 5

A series of tests were undertaken to determine whether the frictional torque generated by movement of the femoral head against the cup would cause movement at the cup bone interface, at various compression loads. The test was carried out, in both lubricated and dry conditions with cups from which the HA coating had been chemically removed, in order to simulate worst-case conditions. Likewise the anti-rotation spikes were removed prior to testing and no pegs were used to augment stability. Tests were undertaken using fresh, bovine acetabulae, reamed to 54.5 mm and secured in a test rig.

Incremental compressive loads from 800 N to 4800 N were applied via a femoral component of 45 mm head diameter. At each predetermined load, the rig containing the acetabular component was rotated through an arc of ±90° on the femoral head. Movement between cup and bone was evaluated, using a line drawn across the junction of the two with Engineers' Blue Dye. The dye was further placed on the bearing surface to evaluate the deformation of the cup under load, highlighting the contact area between the head and cup.

Test 6

The effects of gamma irradiation and short cycle autoclaving on the flexural properties of CFRPBT were assessed on both standard samples and bone plates. Gamma-irradiated bone plates were also immersed in Ringer's solution for up to 137 days to determine any change in modulus. In addition discs of 2 mm thickness and 50 mm diameter were immersed for 122 days to monitor water absorption with time.

Test 7

The ability of the expanding PMMA dowels to provide initial component stability was assessed by a pull out test. The dowels were inserted into fresh bovine bone after pre-drilling to a diameter of 6 mm. The dowels were then expanded using either a UHMWPE core or a HDPE core; a pulling device then measured the pull out force for each dowel.

Hydroxyapatite coating tests

Test 1

The adhesion and mechanical resistance of the HA layer on the CFRBT were tested by means of a scratch test. The tests were performed on CFRBT strips coated using the same parameters as used for the cups. Test strips were of three types, as moulded, water-jet cleaned, and sandblasted + water-jet cleaned. The results were compared to standard test strips with HA coated Stainless Steel. Three strips of each type were tested. The HA layer was scratched, over a distance of 30 mm, with a point applying a 2 N pressure at a constant velocity. This movement was repeated several times in the same slot, always moving in a single direction. The depth of the point was measured by an inductive sensor with a resolution of 0.1 μm. The conductivity plot was also recorded to give a ratio of the distance where the stylus made contact with the base material, to the distance of the whole scratch. The tests were then repeated using a 65 mm scratch to exclude scratch length as a factor. The criteria for approval was fixed at 1 μm/scratch at 2 N.

Test 2

The adhesion and mechanical resistance of HA on to CFRBT were further assessed by means of a tensile bond test. The tests were performed on disks of CFRBT coated under the same parameters as employed for the cups. Test disks were of two types, as moulded or sandblasted. Comparison was made with standard Vitallium (cobalt chrome alloy), non-coated Titanium, Stainless Steel and non-coated CFRBT test samples. Three sets of test disks from each group were used. The disks were glued together using 3 M liquid glue. The disks were then separated using a tensile tester, measuring the force for separation. Microscopic inspection was then used to reveal the location of separation between the layers.

Test 3

The adhesion and mechanical resistance of HA on to CFRBT were further assessed by means of an impact test. The tests were performed on disks of CFRBT coated using the same parameters employed for the cups. The HA coated CFRBT disks were subjected to an impact from a 1 kg weight, with a 12 mm diameter ball as the contact surface. The weight was released from a height of 15 cm. Visual inspection of the surface for flaking gave an indication of the adhesion between the HA and CFRBT. The results were compared to impact tests performed on HA coated Stainless Steel disks, with three tests being performed on each group.

Test 4

The effects of the CFRBT and the coolant (liquid CO_2), used in the HA coating process, on the crystallinity of the HA layer was examined. The tests were performed on two CFRBT cups each with two 14 mm diameter CFRBT X-ray diffraction disks inserted. Two stainless steel X-ray diffraction disks were also mounted in each of two Vitallium^{TM} cups. Spraying with coolant on all cups was performed and a comparison made to show the influence of the base material on the X-ray diffraction. Further spraying runs with CFRBT cups sprayed with coolant and Vitallium cups sprayed without were performed to assess the affect of coolant on the process. The requirements were set at an α-TCP + β-TCP < 12%.

Test 5

The effect of the HA coating on the underlying CFPBT was examined using microscopy and FTIR. A small sample of the cup was taken post HA coating, the coating was removed with 10% hydrochloric acid and then cleaned with water. A cross sectional specimen was then mounted in acrylic bone cement and polished for reflection optical microscopy. Confirmation of results was obtained by FTIR.

Results

Component tests

Test 1

Before fatigue testing, a visual inspection revealed a small gap between the CFRPBT and UHMWPE layers that was consistently wider in the HA coated cups than in the cups with the coating removed. Subsequent cyclic testing caused a slight increase in separation of these layers, but without demonstrable damage to either layer. There was no evidence of catastrophic failure after 10,000,000. However, concern was raised over the appearance of the outside of the cup, brown coloured striated lines were seen to radiate out from the cut out section of the cup. Further analysis revealed that these lines were flow markings in the CFRBT as a result of the injection moulding process and there was no evidence of microfracture. The brown discolouration was thought to originate from corrosion of the steel components of the test rig being immersed in saline. Examination of the HA layer after testing did not identify any breakdown of the coating.

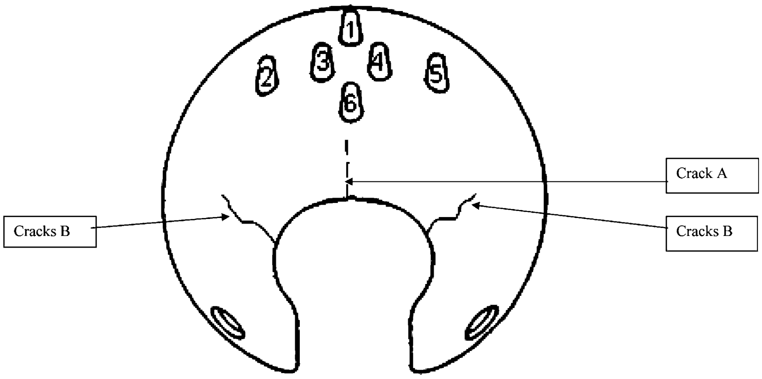
Test 2

The average shear strength of spikes 2–5 (Fig. 2) was found to be 167 N (SD ± 25 N) for the gamma-irradiated cup and 189 N (SD ± 22 N) for the non-irradiated specimen. Spike 1 showed higher shear strength of 294 N and 314 N, respectively due to a larger cross sectional area at the base and a different geometry. Increasing the speed of the shearing load did not affect the ultimate shear strength of the spikes. The observation that the spikes produced small craters on the outer surface of the cup was a cause for concern, as these could potentially act as stress raisers if the spikes were fractured in situ. Spike 6 was not tested.

Test 3

A series of results from compression and expansion to failure are shown in Table 1, the cups failed when compressed from 54.5 mm to 47 mm and when expanded from 54.5 mm to 58 mm. The cups perform better in compression than expansion, tolerating 7 mm of compression and only four mm of expansion before respective failure.

Fig. 2 The position of the spikes on the Cambridge cup. The cracks produced by loading are labelled



Test 4

Having identified that the unloaded cup would tolerate over-reaming of the acetabular cavity by 2.5 mm, to a diameter of 57 mm, this test evaluated the component in the 57 mm and 58 mm situations, while loaded. As before the cup remained undamaged at 57 mm. However, on repeating the test at 58 mm, the cup failed. Furthermore, in the previous test it had been noted that, in tension, the cup always cracked at the apex of the keyhole shape, (Fig. 2, Crack A). However, when the test was repeated with the cup loaded to three times body weight, by a 45 mm spherical head, the failure pattern changed; with cracks occurring at both sides of the keyhole shape, outside the loaded area (Fig. 2, Cracks B).

Test 5

In fixation tests without lubrication, relative movement between cup and bone was observed initially at higher loads and then at progressively lower loads. No movement occurred in tests where water was used as a lubricant between head and cup. Thus movement would therefore not be expected in vivo with lubrication by synovial fluid, even when all means of fixation (spikes, pegs and HA coating) are not functioning. The contact area between head and cup remained approximately the same throughout the tests, being mainly in the 100° predicted load bearing segment, as shown by the Engineers' Blue Dye. This indicated that the cup did not deflect under these conditions.

Table 1 Load to failure in compression and tension

	Cup	Failed (*N*)	Dimension at failure (mm)
Compression	1	216	47
	2	157	46.8
Tension	3	108	59
	4	93	57.5

Test 6

The mechanical properties of the base resin, polybutyleneterephthalate (PBT), are modified by including varying amounts of carbon fibre reinforcement. Table 2 shows that 30% carbon fibre content provides a modulus (stiffness) of around 16 GPa, which approximates to that of the subchondral bone [9]. Exposure of CFRPBT to gamma radiation and autoclaving did not cause significant change in modulus. When soaked in saline, water uptake stabilised at around 0.9% after about 60 days. The material showed no significant changes in mechanical property as a result of this water uptake.

Test 7

The bone quality for testing was found to be variable. In the hard bovine bone, the dowels were unable to expand without fracture. In softer bovine bone the PMMA dowel expanded well when a UHMWPE pin was inserted. The test using a HDPE pin did not expand the dowel satisfactorily.

HA coating tests

Test 1

The scratch test results show the progressive removal of HA without flaking and give similar results irrespective of the method of surface preparation. The results show a similar rate of removal to those of the stainless steel plate, at approximately 1 μm per scratch.

The coating on the Stainless Steel was removed at the same rate throughout the test whereas it became progressively harder to remove the coating from the CFRBT nearer the substrate. The conductivity indicated that total destruction of the HA layer was never reached.

Table 2 CFRPBT material strength and modulus

Test	Condition				
	As moulded (*a*)	Post-irradiation	After soaking in saline at 37°C for 60 days	After irradiation and soaking (*b*)	Reduction in property $(a - b) = c$ %
Flexural strength (Mpa)	158	166	151	146	1.6
Flexural modulus (Gpa)	17.2	18.7	17.0	16.6	3.5
Tensile strength (Mpa)	140	135	132	127	9.3

Microscopic examination of a cross section through a scratch confirmed that the HA coating was embedded in the surface of the CFRBT, which tended to deform under the pressure of the stylus. The scratch test shows that the strength of adhesion of HA on CFRBT is as strong as on a metal substrate.

Test 2

Following validation using standard samples, the HA coated CFRBT disks showed separation at an average of 17.59 MPa. In all samples the separation occurred within the CFRBT layer.

Therefore, the interface of the HA and CFRBT is stronger than the tensile strength of the CFRBT itself.

Test 3

The CFRBT plates did not deform under the impact and the impact mark was barely visible, there was no flaking of the coating. The Stainless Steel samples showed deformation of the plates and flaking of the HA coating. The impact test showed that the adhesion of HA on CFRBT is at least as strong as on a metal substrate.

Test 4

The percentage crystallinity of the HA on CFRBT disks was higher than the percentage crystallinity on the Stainless Steel disks. The Stainless Steel disks sprayed without coolant had a higher crystallinity than the CFRBT disks. The percentage crystallinity is decreased by using coolant. All X-ray diffraction values on the CFRBT were within the acceptable range.

Test 5

Microscopy of the CFRBT–HA interface revealed that no fusion barrier could be detected. FTIR analysis again showed no detectable difference was apparent between the inside and exposed surface compared to a standard injection moulded sample. The outside surface did show the presence of HA fused into the CFRBT surface. Therefore, the HA coating process was shown to have no detrimental effect on the CFRBT layer.

Discussion

The aim of pre-clinical testing is to evaluate whether a new device is capable of functioning as intended and to investigate potential mechanisms for failure. The novel nature of the Cambridge cup; a flexible, incomplete hemisphere relying on biological fixation and fabricated using a previously untested material, necessitated a set of tests to simulate the stresses of normal activity and the potential for catastrophic component failure in vivo.

The mechanical stability of the composite, functioning in a harsh environment is of primary concern. Test results from prolonged ageing in aqueous saline solution, and the effects of ionising radiation showed that little degradation in mechanical property occurred in this respect. The low levels of water uptake by the composite had little effect in modifying the modulus (or flexibility) of the material, whilst the effects of irradiation did not cause embrittling as determined by testing standard test samples.

The pre-clinical tests, on the complete cup, sought to identify whether the component was capable of enduring excessive levels of flexing and remain undamaged. It was identified that the cup could tolerate over-reaming by 2.5 mm, and still flex without breaking. The cup did crack, when over-reaming by 3.5 mm was tested. However, this mismatch exceeds the normal 2 mm size increment between components and no surgeon would expect a successful outcome with such discrepancy. With regard to compression flexing, the component tolerated closure of the side arms (that bound the cotyloid fossa) to almost 4 mm, per side, before cracking was observed. Such deformation vastly exceeds anything that will be encountered in life and impingement of the femoral head would occur at around 10% of this deflection.

As with any prosthetic implant, stable attachment and fixation to the host tissue is essential. The present design does not allow for the interference fixation that can be achieved through impaction of a rigid hemispherical component into an appropriately under-reamed acetabulum. Two attachment

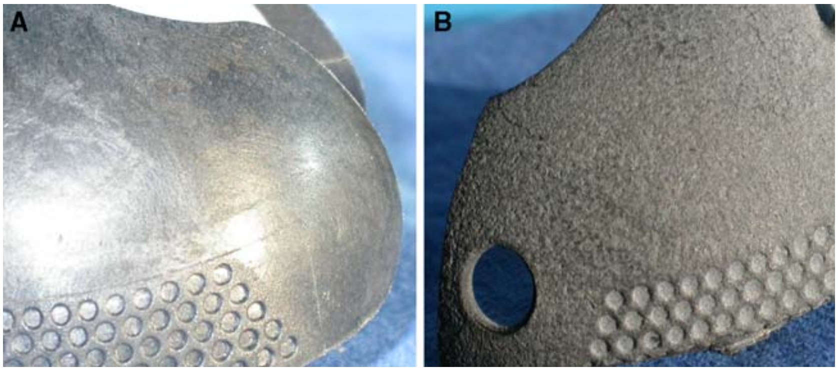


Fig. 3 The Cambridge cup as a moulded surface (**A**) and post HA acid dissolution with a rough surface (**B**)

mechanisms have been incorporated to enhance initial stability; one using the spikes to resist torsion and, the other, the peg and dowel fixation of the side arms.

The resistance of the spikes to breakage has been determined in shear mode. The values obtained are dependent upon their position on the cup, and vary between 167 N and 314 N. Although the individual values appear to be low, the collective contribution to torque resistance is significant, so long as good engagement is achieved. However, it is recognised that in osteoathritic degeneration, acetabular roof cysts may be present. While it is possible to graft such defects, this may still compromise the effectiveness of the spikes. Furthermore, it was noted that the spikes were difficult to align during implantation and that modification may facilitate surgical implantation.

The effect of the peg and dowel fixation is essentially determined by the quality of the bone into which the pegs and dowel is engaged. If the bone is soft and spongy, little fixation support can be expected and if the bone is too hard, fracture of the pegs can be expected. The soft bovine bone was thought to have been of a similar quality to the bone encountered in the region of the ischium and pubis where the dowels are intended to be inserted and has been shown to provide adequate fixation without component fracture.

The tests carried out, without either peg and dowel or spike fixation, indicated that the component's shape and surface finish do confer a significant resistance to movement on application of torsion force in conjunction with the magnitude of compression load that will occur in life. However, it cannot be guaranteed that the cup will not rotate in vivo, as the bovine bone model used for these tests is far from physiologically correct as the bone had different density, there were no muscle attachments and no physiological loading.

It was not possible to test the value of the surface indentations around the periphery of the cup in this preclinical work as there inclusion in the design is to provide a long-term bone ingrowth surface.

The HA coating has been applied by hot plasma spraying. Removal of the coating and subsequent examination of the component surface revealed that, during plasma spraying, the HA particles had become embedded through local melting of the CFRPBT. In consequence, following the HA removal, a roughened surface finish remains (Fig. 3). This is expected to enhance the long term stability by allowing bone ingrowth and microlock. The mechanical properties of the HA coating have been shown to perform in an equivalent manner to the currently accepted standards of HA on stainless steel and cobalt chrome.

Proving the design of the acetabular component, by mechanical and in-vitro testing, was complicated due to the combination of a flexible, incomplete hemisphere and the requirement for biological fixation. This would have required a simulation of the stiffness and flexibility of the pelvis, with biological fixation, to recreate fully the tribological system; a step beyond current simulator testing experience. It was also concluded that animal trials would provide little useful information, since the acetabular socket in most animals tends to be smaller than that of the human and the horseshoe-bearing surface is proportionally more rigid.

The Cambridge cup is intended to achieve biological fixation to host bone. If such fixation occurs, we hypothesise that the cup will deform in concert with the adjacent host bone; avoiding micro-motion at the prosthesis to bone interface and the generation of backside wear debris. It should reproduce physiological stresses and minimise stress shielding and bone resorption. Further evaluation of the Cambridge cup with clinical, radiographic, histological and biological analysis will determine whether stable, biological fixation can be maintained. If achieved, the conceptual goal of obtaining long term fixation and maintaining the natural stress environment around a natural diameter acetabular cup remains promising.

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References

1. M. H. M. HARRISON, F. SCHAJOWICZ and J. TRUETA, *J. Bone Joint Surg*. **35-B** (1953) 598
2. A. S. GREENWALD and J. J. O'CONNER, *J. Biomech*. **4** (1971) 439
3. M. E. LEVENSTON, G. S. BEAUPRE, D. SCHURMAN and D. R. CARTER, *J. Arthroplasty* **8** (1993) 595
4. R. E. FIELD and N. RUSHTON, *J. Biomed. Eng*. **11** (1989) 123
5. H. S. HEDIA, A. A. ABDL-SHAFI and N. FOUDA, *Biomed. Mater. Eng*. **10** (2000) 141
6. H. S. HEDIA, A. A. ABDL-SHAFI and N. FOUDA, *Biomed. Mater. Eng*. **10** (2000) 73
7. J. P. MAUMY, *Hip Int*. **11** (2001) 42
8. R. A. BROOKS, E. JONES, A. STORER and N. RUSHTON, *Biomaterials* **25**(17) (2004) 3429
9. H. B. SKINNER, *Clin. Orthop*. **235** (1988) 224