The influence of acetabular cup angle on the wear of "BIOLOX Forte" alumina ceramic bearing couples in a hip joint simulator

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The wear of "Biolox Forte" alumina ceramic bearing couples has been investigated at two different acetabular cup angles in a physiological hip joint simulator. All cups were set in the anatomical position of 45° inclination in the M/L plane for the first two million cycles and then four of the six cups were re-aligned to 60° for a further three million cycles.

A "running-in" wear of 0.14 mm^3 per million cycles was observed for the first million cycles, after which a steady state wear rate of 0.05 mm^3 per million cycles was observed. Increasing the acetabular cup angle to 60° did not significantly affect the wear rate.

Introduction

There are considerable concerns over the long term effects of ultra high molecular weight polyethylene (UHMWPE) wear debris in total hip arthroplasty (THA) and these have prompted renewed interest in alternate bearing materials. Alumina/alumina ceramic bearing couples have been used in THA since 1970 [1]. However the numbers implanted have been small compared to the more widely used metal or ceramic/UHMWPE designs. Hip joint simulator studies of alumina ceramic couples have reported very low wear [2, 3] and these are consistent with some clinical studies which have also reported low wear [4, 5]. Other clinical studies, however, have shown occasional cases of higher wear of both heads and cups [6, 7]. An increased angle of inclination of the acetabular cups has been cited as a possible cause of the accelerated wear [6, 7]. Indeed, simulator studies by Refior *et al*. [2] with alumina ceramic components lubricated with water have shown increased wear with increased acetabular cup angle. This concern about the sensitivity of the bearing performance to cup angle has been a factor limiting its use.

In 1995 an improved hot isostatically pressed (HIPed) alumina ceramic, "BIOLOX forte," for THA was introduced [8]. This material has a smaller grain size (1.8 μm mean grain size specified by the manufacturer), lower porosity and higher density (3.98 Mg/m^3) than previous materials (typical density 3.95 Mg/m^3). The manufacturers have claimed that this new material wears less than earlier materials. A recent publication [9] reported extremely low wear of the femoral head with this "BIOLOX forte" material in a biaxial rocking type hip joint simulator. In this biaxial rocking simulator the cup was not positioned anatomically but in an inverted position and with a low angle of inclination to the femoral head. However, to date there have been no simulator studies of the effect of acetabular cup angle on the wear of this improved alumina in relevant bearing couples.

The purpose of this study was to investigate the influence of acetabular cup angle on the wear of HIPed alumina ceramic couples in a physiological hip joint simulator. We also investigated the effect of small differences in radial clearance (20 μm compared to 30 μm) on component wear.

Materials and methods

All bearing components were manufactured from "BIOLOX forte" alumina ceramic with a nominal diameter of 28 mm, manufactured by CeramTec AG, Plochingen, Germany. This material differed from alumina ceramics used previously in that it was HIPed at the final stage of manufacture and so had an increased density of 3.98 Mg/m^3. Three of the bearing couples had a radial clearance of 20 μm and three had a radial clearance of 30 μm. The ceramic acetabular components were held in metal backings (ABGII titanium alloy hemispherical shells, manufactured by Howmedica [now part of Stryker International]), three of which had a smooth internal taper and three had a rough internal taper. Modular ceramic heads were held on "Orthinox" stainless steel stems with a 12/14 neck taper. The hip simulator used

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was an in-house designed machine which positioned the cup, head and stem in the anatomical position. The simulator applied a single time-dependant vertical load and cyclic internal/external rotation of the acetabular cup with the flexion/extension of the femoral head being independantly controled as previously described [10]. This simulator has been extensively used for studies of the wear of UHMWPE acetabular cups. The loading cycle consisted of a simplified twin peak waveform with peaks of 3 kN and a trough of 1 kN with a pre-load of 50 N applied during the remaining 0.45 s of the cycle. The two motions applied to the prostheses were independently controled. The flexion/extension motion of $+30^\circ$ and -15° was applied to the femoral component with an internal/external rotation of $+/-$ 10° applied to the acetabular cup, with the motions 90° out of phase. This produced an open elliptical wear path. These kinematic conditions have been shown to reproduce similar wear rates and features as when three independently controled motions are used for UHMWPE acetabular cups. A feature of this simulator was that it tested the head and cup in an anatomical position, with the face of the cup inclined to the axis of the femur and the femoral head mounted at an anatomical position on the femoral stem. The contact mechanics and motions were similar to those found *in vivo* with the contact area located on the superior quadrant of the acetabular cup.

All of the components were initially mounted in the correct anatomical position with the cup inclined at 45° to the vertical load axis above the head. The femoral heads were mounted on stems which were cemented into stainless steel holders. The metal backings for the acetabular components were also cemented into stainless steel holders. The wear of the ceramic components was measured gravimetrically using a Mettler balance which read to 0.01 mg. All testing was carried out using 25% v/v bovine serum with 0.1% v/v sodium azide added as an anti-bacterial agent. The test was run at a frequency of 1 Hz with the lubricant being replaced approximately every 330 000 cycles.

This first phase of the test involved 2 million cycles of the machine with measurements made at 1 and 2 million cycles. After 2 million cycles four of the cups (two of each clearance) were re-aligned to 60° in an attempt to simulate the more severe wear seen clinically [6].

The experimental procedure followed was very similar to previous hip simulator studies. All components were thoroughly cleaned and weighed before the test began. At each measurement interval the components were removed from the simulator and cleaned with soapy water, placed in an ultrasonic cleaner for 20 min and finally cleaned with acetone. The outer taper lock surface of the cups had areas of metal transfer from the titanium shells. These areas were noticeably larger on those components used with the rough taper surface shells. The transfer appeared after the first 0.5 M cycles and did not appear to increase greatly after that interval. Therefore, at 2, 3 and 4 million cycles the cups were cleaned as normal, weighed and then as much of the metal as possible was removed using bathroom scourer, cleaning solution and an ultrasonic bath. All cups were then re-weighed in order to estimate the amount of metal transfer. All weight changes for the cups were corrected for this metal transfer.

After testing, the surfaces of the components were examined using a Rank Taylor Hobson Talysurf 6 contacting profilometer, a WYCO NT2000 white light interferometer and Scanning Electron Microscopy (SEM).

Results

The cumulative volume loss plotted against number of loading cycles averaged for all six bearing couples is presented in Fig. 1. There was no difference in the wear rates of the cups with the two different radial clearances of 20 and 30 μm. The higher wear in the first two million cycles due to ''running-in'' wear is shown in Fig. 1. The two straight lines are linear regression fits of the data in the groups 0–2 and 2–5 million cycles. The difference in wear rates is more clearly seen from the data in Fig. 2 which presents a histogram of the average incremental wear rates per million cycles of all six pairs in the two groups mentioned above. The error bars in all figures represent 95% confidence limits.

The cumulative volume loss for the two different acetabular cup angles is shown in Fig. 3. The straight lines on the graphs are linear regression fits for the data 0–2 and 2–5 million cycles. There was no significant difference in the total volumetric wear for the cups inclined at 45° and 60° (Fig. 3). This is more clearly demonstrated in Fig. 4, which shows the mean incremental volumetric wear rates for the cups at two different angles between 2 and 5 million cycles as well as the initial ''running-in'' period. There was no statistical difference between the wear rates between 2 and 5 million cycles, both sets of data showing low steady state wear.

Surface analysis

Talysurf contacting profilometry showed that there was no significant change in surface roughness at any stage on either component. The contact area surface roughnesses remained constant at approximately 0.005 μm Ra. Three dimensional Talysurf contacting profilometry in

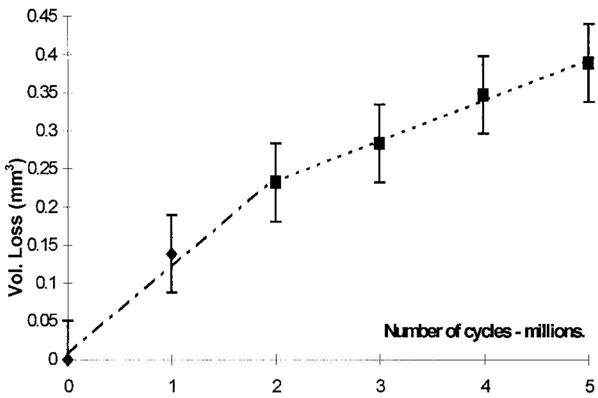

Figure 1 Average cumulative weight loss of all stations (mean $+/-$ 95% CL).

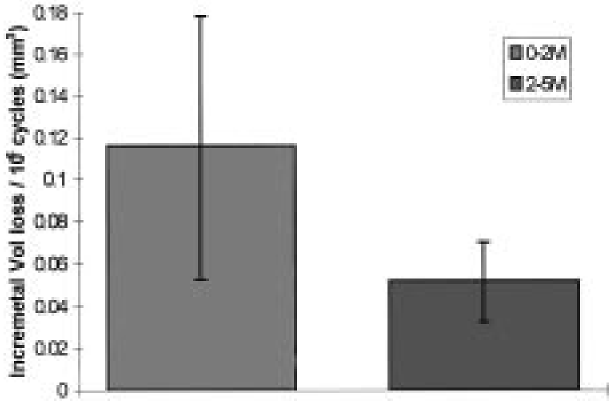

Figure 2 Incremental wear rates per million cycles for all stations. (Mean +/− 95% CL).

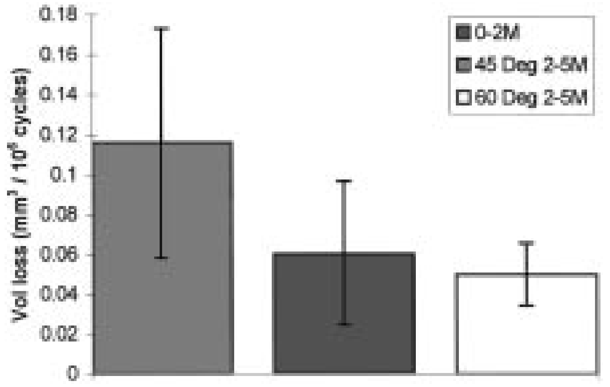

Figure 4 Incremental wear rates for the two acetabular cup angles. (Mean +/− 95% CL).

the contact area also showed no discernable wear features.

Closer inspection of the wear surfaces however, using a WYKO NT2000 3D interferometric surface measurement instrument revealed wear features not detectable using contacting profilometry. Fig. 5 shows the unworn area of the femoral head. Small scale pitting and short curved scratches were visible in the contact areas of both femoral and acetabular components, as illustrated in Fig. 6 which shows the worn area of a femoral head. The pitting may have been caused by small scale grain removal and the scratches may have been caused by a third body wear mechanism. Polishing marks from manufacture were also visible on the surfaces, as shown in Fig. 5. The worn area of the cup was larger than that of the head. Additionally scanning electron microscopy was carried out but very few wear features were observed.

Discussion

The results indicated that neither radial clearance or cup angle had a significant effect on wear rate. The first million cycles showed larger volumetric wear which was probably due to ''running-in'' wear which was approximately 0.14 mm^3. Similar effects have been reported in several other studies [2, 3]. The wear then decreased over the next million cycles to a steady state wear of approximately 0.05 mm^3 per million cycles.

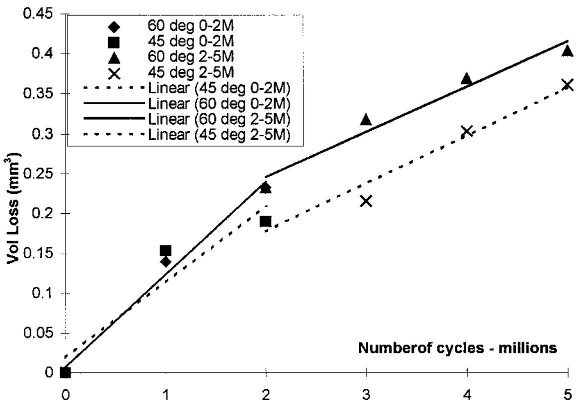

Figure 3 Cumulative weight loss for the two cup angles.

The four cups which were re-aligned to be inclined at 60° in the M/L plane at two million cycles did not show a difference in their wear rate as a result of the different contact mechanics. This was in contrast to earlier studies and also what has been seen clinically with ''BIOLOX'' couples. Refior *et al.* [2] presented data for non-HIPed alumina cups repositioned from 45° to 60° which showed an increase in wear rate by between 25% to 65%. This was certainly not the case for the simulator studies reported here for the HIPed ''BIOLOX forte'' ceramic tested in 25% v/v bovine serum. The simulator used in this test has produced clinical wear rates for metal/UHMWPE prostheses of approximately 35 mm^3 per million cycles under the same testing conditions as the study described here [10]. At present there is little clinical experience with retrieved HIPed ceramic couples (which were introduced in 1995) to compare with this simulator data. The wear rate of the HIPed alumina found in the simulator test was very low and the wear mechanism may have been that of relief polishing of the grains and small scale grain excavation. Explant studies of the earlier un-HIPed alumina bearing couples have shown grain boundary fracture and grain pull-out as the main wear mechanism in worn areas. Severe conditions such as a steep cup angle may accelerate the wear, via this mechanism, to produce large volume loss (''severe wear'') [6]. Further simulator studies are required to investigate whether the previously used un-HIPed material exhibits increased wear with a 60° cup angle in this simulator, as found in the study by Refior *et al.* [2]. From these results it would appear that HIPed alumina is more wear resistant compared to the older un-HIPed materials. This could be due to its improved material properties: smaller grain size and higher density. An increased cup inclination angle can decrease contact area and therefore increase the contact stresses, which may lead to adverse lubrication conditions. It is possible that the increased stresses present in this test were not high enough to push the wear mechanism into larger scale grain excavation.

Hip simulators can also be considered to provide ideal conditions for lubrication, as there is continuous motion. The lubricant, 25% bovine serum, contains many proteins and lipids which may provide boundary lubrication. This boundary lubrication may protect the

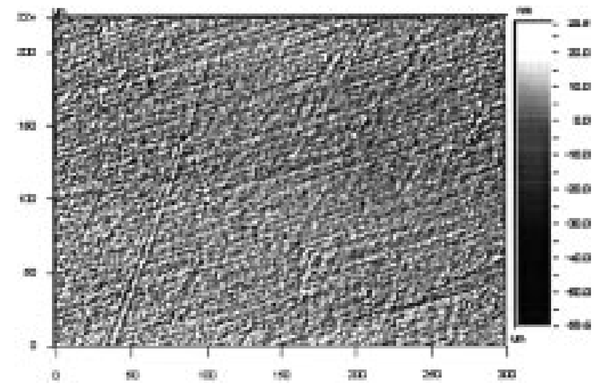

Figure 5 Unworn area of head.

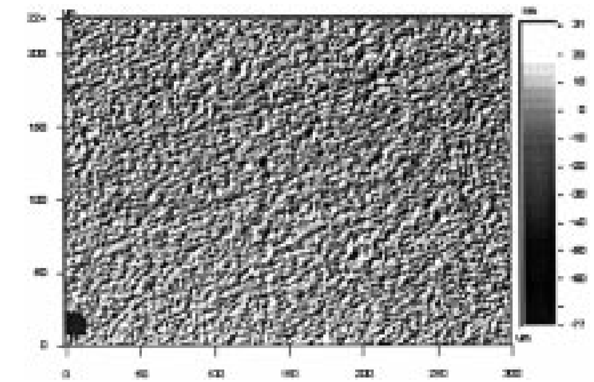

Figure 6 Worn area of head.

bearing surfaces from the more severe wear mechanisms such as grain boundary fracture and hence wear on the scale seen clinically. This may offer an alternative explanation for the different effects found with increased cup inclination angle in this study and the study of Refior *et al.* [2] which used distilled water as a lubricant. For UHMWPE acetabular cups in hip joint simulators reasonable agreement can be found between simulator wear rates and clinical data [10]. For ceramic/ceramic bearing couples in which the steady state wear rates are very low, approximately 500 times less than for metal/UHMWPE, the wear rates and mechanisms found in the simulator under normal walking conditions have not reproduced the more severe wear rates and wear mechanisms found on some retrieved components. It may be necessary in future studies to consider simulating alternative, harsher tribological conditions *in vitro* in order to replicate the more severe clinical wear mechanisms.

Conclusions

1. Running-in wear of approximately $0.14\,mm^3$ occurred during the first million cycles.
2. Steady state wear in the hip simulator was $0.05\,mm^3$ per million cycles for this material.
3. These steady-state wear rates were approximately 500 times less than those found with UHMWPE acetabular cups.
4. Altering acetabular cup angles did not increase the wear rate in this simulator test.

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