Total hip replacement with a zirconium oxide ceramic femoral head

A RANDOMISED ROENTGEN STEREOPHOTOGRAMMETRIC STUDY

We investigated the wear characteristics and clinical performance of four different total hip joint articulations in 114 patients. Wear and migration was measured by roentgenstereophotogrammetric analysis at five years or at the last follow-up. The mean annual wear was 0.11 mm for a stainless steel/Enduron articulation, 0.34 mm for stainless steel/Hylamer cup, 0.17 mm for zirconium oxide ceramic/Enduron and 0.40 mm for zirconium oxide ceramic/Hylamer. The difference between the groups was significant (p < 0.008) except for stainless steel/Hylamer vs zirconium oxide ceramic/Hylamer (p = 0.26).

At present, 12 patients have undergone a revision procedure, four at five years and eight thereafter. No patient who received a stainless steel/Enduron articulation at their primary replacement required revision.

Conflicting results have been reported about the performance of the zirconium oxide ceramic femoral head, but our findings suggest that it should not be used with a polymethylmethacrylate acetabular component. Hylamer has already been withdrawn from the market.

A growing body of knowledge supports the concept that wear debris from ultra-high-molecular-weight polyethylene (UHMWPE) contributes to the failure of total hip arthroplasties. Alternative materials, such as aluminium oxide ceramic for the femoral head and polyoxymethylene for the acetabular component have been used in an attempt to increase both the longevity and wear resistance of the implants. However, fractures of the alumina head and failure of the new plastics has stimulated the search for alternative articulations.

Zirconium oxide ceramic was introduced as an alternative to aluminium oxide ceramic. Femoral heads made from zirconium oxide ceramic are considered to be less likely to fracture and to have a lower wear rate against UHMWPE than femoral heads made from stainless steel or cobalt chrome. However, only a few clinical studies on zirconium oxide UHMWPE articulations have been published and they report conflicting results. In 1991, DePuy-Dupont Orthopedics (Newark, New Jersey) marketed a new UHMWPE product called Hylamer. This UHMWPE product was reheated under pressure so that the long polymer chains realigned to form extended regions of folded chains. Hylamer was expected to have less creep, better yield strength and less wear. However, it has now been withdrawn from the market after several studies demonstrated high rates of wear and revision.

This present study, therefore, aimed to assess the wear characteristics and clinical performance of 22.225-mm femoral heads made from zirconium oxide ceramic or stainless steel, either articulating against standard UHMWPE or Hylamer.

Patients and Methods

Between 1996 and 1998, 120 consecutive patients with osteoarthritis, aged from 50 to 75 years, were randomly allocated to receive a primary total hip arthroplasty (THA) using a Charnley-Elite Plus femoral stem (DePuy, Leeds, UK) and one of four possible articulations. The cemented acetabular components were either made of standard UHMWPE (Enduron) or Hylamer and the femoral heads of either stainless steel or zirconium oxide ceramics. The ethical committee at Lund University approved this investigation.

Laboratory wear studies had indicated that Hylamer had a wear factor which was 32% less than standard UHMWPE (Enduron) and that femoral heads made from zirconium oxide ceramic had a wear factor 60% less than those made from stainless steel. Based on these figures and with a power of 80% and an alpha value of 0.05, we planned to include 50 patients...
with the same number of hips in each of the four groups. However, when 120 patients had been recruited, new results on wear rates from hip-simulator tests indicated that Hylamer had only 9% less wear than Enduron. This fact, combined with the first clinical reports of increased wear of Hylamer, led us to stop the recruitment of more patients.

We excluded six of the 120 patients, five because of illness or death within the first two years of surgery but unrelated to the hip surgery and one who underwent several revision procedures within the first year because of recurrent dislocation. Consequently, 114 patients remained, 62 women and 52 men (Pearson chi-squared test, $p = 0.5$) with a mean age at surgery of 64 years (50 to 76) and a mean body-weight of 80 kg (45 to 117). Forty-six patients had a left THA and 68 a right THA. There were no significant differences in size of acetabular component, side, age, weight or height among the patients in the four groups (one-way analysis of variance (ANOVA); $p = 0.71$).

Between the two- and five-year reviews, five patients had died and four had been revised thus leaving 105 patients for follow-up at five years. Data for the revised patients were available from their last follow-up examination before revision.

Examinations were undertaken within one week post-operatively, and after three and/or six months, 12, 24 and 60 months. This included a clinical assessment, and radiographic and roentgen stereophotogrammetric analyses. For the clinical evaluation we used the Harris hip score. The radiographic examination included an anteroposterior view of the hip and pelvis and a lateral view of the hip. The radiographs were assessed simultaneously by two of the authors (ÅC and JB). Any migration of the acetabular component or the presence of radiolucent lines as classified according to Önsten et al$^{14}$ was recorded post-operatively (Table II).

Table II. Roentgenstereophotogrammetric analysis limits for significant movement at a 99% confidence limit for migration (mm), rotation (˚) and wear (mm) according to Önsten et al$^{14}$

<table>
<thead>
<tr>
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<th>Longitudinal</th>
<th>Transverse</th>
<th>Sagittal</th>
<th>Total</th>
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<tbody>
<tr>
<td>Migration (mm)</td>
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<td></td>
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<tr>
<td>Socket</td>
<td>± 0.2</td>
<td>± 0.2</td>
<td>± 0.3</td>
<td>± 0.5</td>
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<tr>
<td>Stem</td>
<td>± 0.2</td>
<td>± 0.2</td>
<td>± 0.5</td>
<td>± 0.5</td>
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<tr>
<td>Rotation (˚)</td>
<td>± 0.3</td>
<td>± 0.3</td>
<td>± 0.3</td>
<td>± 0.2</td>
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<tr>
<td>Wear</td>
<td>± 0.2</td>
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The discrepancy in measurement between the so-called true value of a micrometre and RSA of a phantom was calculated as the displacement of the femoral head in relation to the geometric centre of gravity of the markers in the acetabular component, both as proximal and total displacement (the length of the resulting vector). Limits for significant movement and penetration of polyethylene over time, with 99% confidence intervals, have been calculated previously (Table I). The discrepancy in measurement between the so-called true value of a micrometre and RSA of a phantom simulation of polyethylene penetration has been calculated to be 0.010 mm (SD 0.15; accuracy 0.42).

The standard Enduron components were made from the base resin GUR 415 moulded as a ram-extruded bar. The Hylamer components were made from GUR 415 which had been reheated under pressure (235 MPa), which realigned the long polymer chains, to form the UHMWPE. The crystalline structure of short sections of folded chains was, therefore, converted to extended chains of folded regions, increasing the crystallinity of the polyethylene from 50% to more than 80% without degrading the product. The sterilisation process used was gamma irradiation in air. A cemented Charnley-Elite Plus femoral component was used in all patients.

**Prostheses and operative technique.** Five surgeons (TVS, LS, IO, AC, JB) performed the operations in a clean-air enclosure. Systemic antibiotics (cloxacillin) and gentamicin-loaded bone cement (Palacos with gentamicin; Schering-Plough, Kenilworth, New Jersey) were used routinely. The patients were operated on in the supine position and their hip exposed through a lateral approach without a trochanteric osteotomy.

A Charnley ogee polyethylene acetabular component (DePuy, Warsaw, Indiana) with an outer diameter of between 40 and 47 mm was used. The patients were randomised to receive one of four combinations:

1) SE, stainless steel femoral head (DePuy, Leeds, UK) combined with an Enduron acetabular component; 2) SH, stainless steel femoral head combined with a Hylamer acetabular component; 3) ZE, zirconium oxide ceramic femoral head (DePuy-Johnson and Johnson) combined with an Enduron acetabular component; 4) ZH, zirconium oxide ceramic femoral head combined with a Hylamer acetabular component.

The 22.225-mm modular stainless steel femoral head was made from high-nitrogen stainless steel and the 22.225-mm modular zirconium oxide ceramic femoral head was made from zirconium oxide, partially stabilised with yttrium oxide and heated in a batch furnace produced by Prozyr; St. Gobain Advanced Ceramics, Montreuil Cedex, France. Both types of femoral head were produced to a minimum specification of 5 µm roundness and 0.05 µm Ra roughness.

**Results**

**Clinical results.** There was no difference among the groups with respect to their pre-operative pain scores (Kruskal-Wallis ANOVA; $p = 0.7$) or pre-operative total scores (one-way ANOVA; $p = 0.5$), nor was there any significant difference post-operatively (Table II).
Revisions. By five years after surgery, four acetabular components had been revised. At the time of writing, 12 acetabular components have been revised after a mean of 59 months (26 to 84) for wear and loosening. In addition, two patients have been advised to have their acetabular components revised, but have elected to postpone the procedures. They have been classified as pending failures. Of these 14 failures, 13 had a Hylamer articulation and one an Enduron articulation (Table II).

Radiographic and RSA observations
Wear. The three-dimensional total wear values for the four different articulations are shown in Figure 1 and the mean annual wear rate is shown in Table III. The three-dimensional vector wear at the last examination was not normally distributed in the SE group. The difference in three-dimensional total wear between all the groups was significant (Mann-Whitney U test; p < 0.008) except between groups SH and ZH (p = 0.4).

The annual wear rate in the SE group was low but when Enduron was combined with a femoral head made from zirconium oxide ceramic (ZE group) the annual wear rate was significantly increased at five years (p < 0.008) but not at two years (p = 0.07).

Including Hylamer in the articulation resulted in a three- to fourfold increase in annual wear (p < 0.008), a feature which could already be seen by two years.
Acetabular component. Radiographically, six acetabular components were deemed to be loose. All had been revised or revision had been suggested. Complete radiolucent zones were seen in 16 hips (Table II).

Migration. All combinations with Hylamer migrated significantly more than any other combinations. This difference was only significant for longitudinal (y) migration and at five years (Table III).

Discussion

We were unable to verify the 60% reduction in wear which has been reported in in vitro studies\(^8\) for femoral heads made of zirconium oxide ceramic rather than stainless steel. In contrast, the total and annual wear using zirconium oxide ceramic was actually increased by approximately 50%.

There are three earlier clinical studies which have analysed standard UHMWPE wear in hips with a femoral head made from zirconium oxide ceramic. Hernigou and Bahrami\(^6\) calculated the annual wear at five years to be 0.04 mm but this increased to 0.41 mm at 12 years. Low five-year values (0.03 mm and 0.09 mm) were also reported by Allain et al\(^5\) and Wroblewski et al,\(^7\) respectively. We found a considerably higher annual wear (0.17 mm) at five years and, with the report by Hernigou and Bahrami\(^6\) in mind, it may be that annual wear will increase further with time. These authors also analysed three retrieved heads for surface roughness and roundness; compared with unused implants the characteristics were inferior. Structural changes within the zirconium-oxide ceramic which affect the surface and mechanical properties of implants have also been reported for other retrieved zirconium oxide ceramic femoral heads.\(^16\)

For ethical reasons, our study had to be interrupted; as a consequence, fewer patients than planned were recruited. However, this did not affect the statistical power of the study as the differences between groups were large.

The contour of the zirconium oxide ceramic femoral heads on the radiographs was not as distinct as that of stainless steel, which might have made analyses of head penetration difficult. However, in a previously published RSA study we found that the type of prosthetic component did not influence the measurement error.\(^15\) It has also been suggested that wear measured in the supine position can be misinterpreted as compared with weight-bearing images as the unloaded femoral head might not achieve maximum penetration into the UHMWPE.\(^17\) In a recent study, we could not corroborate this suggestion and found an excellent correlation between assessments of supine and weight-bearing wear measurements.\(^18\)

Zirconium oxide ceramic femoral heads were introduced in 1985 as an alternative to aluminium oxide ceramic and with the aim of decreasing the risk of ceramic fracture. Zirconium oxide ceramic’s ability to withstand fracture is four times greater than that of aluminium oxide ceramic (0.0085% vs 0.0004% to 0.01%, respectively).\(^19\) Between the end of 2000 and February 2004, 363 fractures of zirconium oxide ceramic femoral heads had been reported to the manufacturer (St. Gobain Advanced Ceramics). The fractures had only occurred in product configurations manufactured between January 1998 and September 1999 in a tunnel furnace.

As with other authors\(^9,10\) we could not confirm the 32% reduction in wear initially reported for Hylamer.\(^8\) On the contrary, we found the wear of Hylamer to be three to four times greater than the standard stainless steel articulation. Similar values have been reported by others for the zirconium oxide ceramic/Hylamer combination (Table IV).\(^20-22\)

At two years, the suboptimal performance of Hylamer regarding wear was more than evident. At two years, there was no difference in longitudinal migration of the acetabular components which might predict the forthcoming increase in revision rate for the Hylamer groups. However, by five years, the difference became clear. In the evaluation of new acetabular components with new designs and new bearing surfaces it would, therefore, be wise to study both wear and migration patterns.

The revision rate at the time of writing, when all patients have not yet passed their seven-year review, is about 20% in the Hylamer groups. The Harris hip score at five years did not reflect this increase in revision rate. Hylamer is no longer commercially available but surgeons have been advised that all patients with a Hylamer component should be reviewed.

The annual total wear in the SE group in our study compares well with the 0.1 mm annual wear in an earlier series of Charnley arthroplasties reported from our hospital.\(^14\) In addition, in a series of uncemented Harris-Galante I acetabular components combined with a 22.225-mm Charnley femoral component, the mean annual wear rate was 0.1 mm.\(^14\) For other prosthetic designs with a 28-mm or 32-mm femoral head, the annual wear measured by the same method has ranged from 0.07 to 0.13 mm.\(^23-25\) Studies with
aluminium oxide ceramic on standard UHMWPE have shown annual wear rates of 0.10 mm,\textsuperscript{26} but as low as 0.02 mm/year with aluminium oxide ceramic articulating with cross-linked polyethylene.\textsuperscript{27} All these values are lower than the zirconium oxide ceramic combinations in our current study. Femoral heads made of zirconium oxide ceramic are, to our knowledge, now only produced in Japan (Japan Medical Materials Corp., Osaka, Japan). The risk of fracture of these femoral heads and concerns about their long-term performance, as well as the conflicting reports about annual wear and revision rates, suggest that these femoral heads should not be used in total hip replacement. Hylamer is no longer commercially available.

### Supplementary Material

A further update by Professor Laurent Sedel is available with the electronic version of this article on our website at www.bjs.org.uk

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### References