Catastrophic failure of the Elite Plus total hip replacement, with a Hylamer acetabulum and Zirconia ceramic femoral head

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We report catastrophic early failure of a cemented total hip replacement comprising a modular femoral component with a Zirconia ceramic head and an acetabular component of cross-linked ultra-high molecular-weight polyethylene (Hylamer). Between 1995 and 1999 we implanted 29 hips in 26 patients with a mean age of 49.2 years. Survivorship analysis in this group revealed a failure rate of 67.6% at five years. All hips which failed did so because of aseptic loosening with progressive osteolysis or radiolucencies. We therefore recommend early and regular review of all patients with this combination of implants and early revision surgery in order to avoid massive bone loss.

Hylamer is an ‘enhanced’ ultra-high-molecular-weight polyethylene (UHMWPE) which is prepared under high pressure and temperature. This manufacturing process changes the crystalline structure to an extended chain and was thought to cause enhanced physical properties including increased density, melting point, yield strength, tensile strength, modulus of elasticity, creep resistance and fatigue resistance. It was also expected to lengthen its survival in clinical use. Results of testing in vitro indicated a decreased rate of wear of 9%. Studies in a hip simulator have shown that the wear resistance of Hylamer sterilised with gamma irradiation in air was comparable with that of conventional UHMWPE sterilised in the same manner. These encouraging laboratory findings were again demonstrated when Hylamer, sterilised by gas plasma, was found to have rates of wear comparable with those of non-sterile conventional polyethylene, even after extensive ageing.

At the time of its introduction, Hylamer was thought to represent a significant advance and that its use would reduce osteolysis. Early clinical reports suggested that the new material was at least as good as conventional polyethylene. In all our patients, a modular 28 mm Zirconia ceramic head was used. The rate of wear of polyethylene against a Zirconia femoral head has been reported to be lower than that measured for CoCr, SUS 316L alloy and alumina ceramic femoral heads. These findings have been confirmed from retrieval analysis studies which suggested that ceramic femoral heads gave better results in terms of wear than metallic heads.

In 1995, the senior author (GHA) was using the Charnley total hip replacement (THR) for all primary hip arthroplasties, but in view of the above evidence, decided to use the Hylamer/Zirconia articulation combined with the Elite Plus stem in younger patients. It was felt that this would combine the proven designs of the Charnley stem and Ogee cup with superior articulating surfaces. We now report the findings at five to six years.

Patients and Methods

Between 1995 and 1999 we implanted 29 Charnley Elite hips (DePuy) with Hylamer acetabular components and Zirconia modular femoral heads into 26 consecutive patients. The mean age of the patients was 49.2 years (31 to 57). There were 12 women and 17 men. The THRs were undertaken by a single surgeon (GHA).

The operative technique was the same in all hips. An anterolateral approach was used with the patient supine. Third-generation cementing techniques were employed using Palacos R cement inserted into the pressure-lavaged and dried acetabulum, approximately three minutes after mixing. The flanged Hylamer acetabular component pressurised the cement as it was inserted. The femur was prepared using the Elite femoral rasps followed by pressure lavage. A cement restrictor was used. Antibiotic-loaded Simplex cement (Howmedica) was pressurised into the femoral canal using a cement gun. A 28 mm Zirconia ceramic femoral head was used.

The case notes and radiographs of all patients who underwent revision surgery were reviewed retrospectively. All patients who had not undergone revision surgery had a
clinical and radiological review including the measurement of the Harris, Oxford and Merle D’Aubigné and Postel hip scores. Non-weight-bearing anteroposterior (AP) radiographs of the pelvis and lateral views of the hip were taken. The criteria for revision surgery included radiological evidence of progressive radiolucency in two or more zones of DeLee and Charnley of the acetabulum, or three or more zones of Gruen, McNeice and Amstutz of the femur. Revision surgery was carried out when there was evidence of progressive osteolysis in any zone of the acetabulum or femur, noted on sequential radiographs (Fig. 1). The films were digitised using a Sony – DSC-P1 camera and analysed using Adobe PhotoShop V 5.5. Wear of the acetabular component was calculated from the digitised films using the diameter of the femoral head (28 mm) as a constant reference. The radiographs were taken non-weight-bearing. There may therefore be some underestimation of Hylamer wear in this group.

**Statistical analysis.** Life-table survivorship analysis was performed as described by Murray, Carr and Bulstrode with confidence intervals calculated by the method described by Peto et al on a preformatted Excel spreadsheet program. Hip scores were compared, using the Mann-Whitney U test, to analyse any differences between those hips which had failed and those which had not, according to the above radiological criteria. Kruskal-Wallis ANOVA analysis was used to assess differences in the wear of the acetabular component between those in whom the hip had failed and those in whom it had not. Acetabular wear in all hips was analysed using regression analysis. The statistical programs used for analysis were SPSS Analyse-it version 1.62 (SPSS, Chicago, Illinois) and Excel (Microsoft).

**Results**

Of the 26 patients, one was lost to follow-up at four years. No patient has died, but nine of the 29 hips have been revised and six are awaiting revision surgery. The median time to failure was 36 months (18 to 68; SD 15). These failures occurred in seven women and eight men, all as a result of aseptic loosening. From the study group, 13 functioning Elite plus hips were available for clinical and radiological review, and 28 were reviewed radiologically for wear of the acetabular component. Radiographs were available before revision surgery in nine subjects.

No revisions were undertaken for infection, dislocation or periprosthetic fracture. One acetabular prosthesis became dislodged in a road-traffic accident and required revision surgery, but this prosthesis was known to have progressive radiolucencies before the accident and was therefore included as a failure. Survivorship analysis, using revision surgery or being listed for revision surgery as the definition of failure, reveals a survival rate of 32.4% at five years (Table I, Fig. 2). There were no statistically significant differences (p > 0.05) between the 13 hips which had not failed and the six which have and are awaiting revision surgery with regard to the mean Harris hip scores, and the Oxford and Merle D’Aubigné and Postel hip scores.
Analyses of wear of the acetabular components still in situ, with radiographs taken before revision surgery revealed a mean wear of 1.86 mm (SD 0.73) at a mean follow-up of 36 months (SD 15). Regression analysis (Fig. 3) was weak because of the small sample size and wide spread of data. At 36 months (SD 14), in those hips which have already failed, the mean wear was 2.04 mm (SD 0.9), and in those which have not yet met the criteria for failure, the mean wear of Hylamer was 1.74 mm (SD 0.6). Kruskal-Wallis ANOVA analysis revealed no significant differences (p > 0.05) in wear between the two groups.

**Discussion**

Our review of 29 Charnley Elite hips with Hylamer acetabular components and Zirconia modular femoral heads revealed a failure rate of 67.6% at five years. This series offers no direct control group for comparison and therefore raises the issue of operator error. All the postoperative radiographs, however, have been reviewed by independent

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**Table I.** Life-table survival analysis of Elite Plus THRs with a Hylamer acetabulum and Zirconia ceramic head

<table>
<thead>
<tr>
<th>Years since operation</th>
<th>Number at start</th>
<th>Number of failed</th>
<th>Number withdrawn (dead)</th>
<th>Number lost to follow-up</th>
<th>Adjusted number at risk</th>
<th>Annual failure rate (%)</th>
<th>Annual success rate (%)</th>
<th>Cumulative survival rate (%)</th>
<th>Standard error (%)</th>
<th>95% (Peto) lower to upper confidence limit for cumulative survival rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 1</td>
<td>29</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>29.0</td>
<td>0.00</td>
<td>100.00</td>
<td>100.00</td>
<td>0.00</td>
<td>100.00 to 100.00</td>
</tr>
<tr>
<td>1 to 2</td>
<td>29</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>29.0</td>
<td>13.79</td>
<td>86.21</td>
<td>86.21</td>
<td>5.95</td>
<td>74.55 to 97.86</td>
</tr>
<tr>
<td>2 to 3</td>
<td>25</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>25.0</td>
<td>20.00</td>
<td>80.00</td>
<td>66.21</td>
<td>7.70</td>
<td>51.12 to 81.29</td>
</tr>
<tr>
<td>3 to 4</td>
<td>20</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>20.0</td>
<td>15.00</td>
<td>85.00</td>
<td>51.21</td>
<td>8.00</td>
<td>35.53 to 66.88</td>
</tr>
<tr>
<td>4 to 5</td>
<td>17</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>16.5</td>
<td>12.12</td>
<td>87.88</td>
<td>39.09</td>
<td>7.51</td>
<td>24.37 to 53.81</td>
</tr>
<tr>
<td>5 to 6</td>
<td>15</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>15.0</td>
<td>6.67</td>
<td>93.33</td>
<td>32.42</td>
<td>6.88</td>
<td>18.93 to 45.91</td>
</tr>
</tbody>
</table>

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**Table II.** Mean Harris hip, Oxford and Merle d’Aubigné and Postel scores (± SEM) for the six hips which have failed and the 13 which have not after implantation with a cemented Elite Plus THR with a Hylamer acetabulum and Zirconia ceramic head

<table>
<thead>
<tr>
<th>Score</th>
<th>Best possible</th>
<th>Failed</th>
<th>Not failed</th>
<th>p value (Mann-Whitney U test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harris hip</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>44</td>
<td>29 ± 63</td>
<td>35 ± 2.2</td>
<td>0.30</td>
</tr>
<tr>
<td>Function</td>
<td>47</td>
<td>34 ± 38</td>
<td>35 ± 3.3</td>
<td>0.30</td>
</tr>
<tr>
<td>Deformity</td>
<td>4</td>
<td>4 ± 0.2</td>
<td>4 ± 0.3</td>
<td>0.40</td>
</tr>
<tr>
<td>Range of movement</td>
<td>5</td>
<td>3 ± 0.6</td>
<td>3 ± 0.4</td>
<td>0.40</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>70 ± 8.8</td>
<td>77 ± 5.0</td>
<td>0.35</td>
</tr>
<tr>
<td>Oxford</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best to worst</td>
<td>12 to 60</td>
<td>27 ± 5.2</td>
<td>27 ± 3.3</td>
<td>0.38</td>
</tr>
<tr>
<td>Merle d’Aubigné and Postel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>6</td>
<td>4.5 ± 6.0</td>
<td>5.1 ± 0.4</td>
<td>0.20</td>
</tr>
<tr>
<td>Function</td>
<td>6</td>
<td>4.7 ± 0.5</td>
<td>5.2 ± 0.4</td>
<td>0.20</td>
</tr>
<tr>
<td>Range of movement</td>
<td>6</td>
<td>5.2 ± 0.3</td>
<td>5.3 ± 0.2</td>
<td>0.40</td>
</tr>
</tbody>
</table>
experts appointed by the Medical Devices Agency, who found no evidence of such error. During the period in question all patients aged less than 60 years were treated using this prosthesis, thus giving no direct control group. Older patients were given a standard Charnley femoral component combined with an Ogee cup inserted using the same exposure and cementing technique. Only one of 169 THRs undertaken by the senior author during the same time period has shown similar radiological signs of loosening and without obvious wear of the acetabular cup. This hip has not yet been revised and the radiological appearance could indicate either aseptic loosening or low-grade infection. We therefore conclude that the results reported relate to an intrinsic feature of the prosthesis rather than to any aspect of surgical technique.

In 1997, a study by Sychterz, Shah and Engh found no significant difference in the amount or rate of penetration of the head in 80 Hylamer and 140 Enduron polyethylene liners at a mean of 3.6 years. This was despite the Hylamer liners being used in younger patients with higher demands. Retrieval analysis of 34 Hylamer and eight polyethylene liners, at a mean of 3.3 and 1.6 years, respectively, from metal-backed acetabular components, indicated that Hylamer appeared to behave similarly, but not superiorly, to conventional polyethylene with regard to linear wear rates, oxidation levels and mechanical properties. Although the sample size in this series was small and no statistically significant difference was found, the Hylamer liners had a liner wear rate of 0.32 mm/year compared with 0.20 mm/year for conventional polyethylene liners. The wear rates in our patients have been approximately double the Hylamer wear in this series.

There is now mounting evidence that Hylamer has not lived up to its initial high expectations. The initial finding that the wear resistance of Hylamer sterilised with gamma irradiation in air was comparable with that of UHMWPE has been disputed by a further hip simulator study. This found that wear of Hylamer cups, sterilised by gamma irradiation in air, was 2.3 times greater than that of cups made of conventional polyethylene sterilised in the same way. Hylamer acetabular liners have also performed poorly in a series of 143 THRs of which six (4.2%) had been or were scheduled for revision surgery because of eccentric wear, at an approximate follow-up of three years. Survivorship analysis of the Hylamer liner, with failure defined as revision because of eccentric wear, was calculated to be 86% at four years. A further study by Schterz et al. on previously encouraging results, reported significantly greater rates of head penetration and wear rates in Hylamer liners than in Enduron liners in Duraloc acetabular components at a mean follow-up of 5.9 years. There have been a number of reports of problems of accelerated wear and osteolysis with Hylamer liners in acetabular components and with the use of Hylamer-M spacers in AMK total knee prostheses with extensive osteolysis associated with large areas of pitting and delamination of the material.

The crystalline properties of Hylamer have been implicated as a possible cause for this increased wear and subsequent osteolysis while it has also been suggested that a time-dependent decrease in wear resistance in Hylamer sterilised by gamma irradiation in air may explain the wear and osteolysis. In previous reports of Hylamer wear in THR liners, they were used in conjunction with an uncemented metal acetabular shell. Our series differs from these previous reports in that the whole acetabular component was made of Hylamer, and that the increased wear caused progressive radiolucencies, osteolysis and clinical failure of the arthroplasty (Fig. 1).

An attempt has been made by others to explain the increased rates of wear of Hylamer acetabular liners. There appears to be a difference in the wear resistance of the liners as a function of the shelf life; liners with a shorter shelf life showed a volumetric wear rate of 30% less than those with a longer shelf life. In all of our hips, the acetabular components were implanted within the limits of the manufacturer’s expiry date.

There is a substantial problem associated with the Hylamer-Zirconia articulation in our series. While we suspect
Hylamer to be the weak link in the articulation, the Zirconia femoral head may contribute to the problem. In the light of the rate of failure in this series, all postoperative radiographs were critically reviewed according to the criteria indicated by Ritter et al. We were unable to identify technical errors such as malpositioning of the implant or deficiency of the cement mantle which would account for the observed failures.

We have demonstrated no clear difference in the mean hip scores of those patients whose hips have failed and those whose hips have not yet met the criteria for failure. The ‘surviving’ hips are at an early stage and may yet fail and the sample size is small and of low statistical power. In view of the inability to diagnose failure by clinical methods alone, it is imperative that all patients with this implant in situ be reviewed regularly. Of great concern also is that most of those patients whose hips are currently in situ and have not yet met the criteria for failure have early radiolucencies. We feel that it is likely that all of those patients will require revision surgery within ten years.

It has been previously noted that preclinical laboratory testing of materials may not be entirely reliable, as illustrated by this implant. In vivo studies are essential when considering the performance of an implant. No new implant or significant modification to an existing model should be given permission for clinical use except within the strict confines of a controlled trial.

No benefits in any form have been received or will be received from a indicated by Ritter et al. graphs were critically reviewed according to the criteria.

References


