PROSPECTIVE CLINICAL AND JOINT SIMULATOR STUDIES
OF A NEW TOTAL HIP ARTHROPLASTY USING ALUMINA
CERAMIC HEADS AND CROSS-LINKED POLYETHYLENE
CUPS

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We report the findings from independent prospective clinical and laboratory-based joint-simulator studies of the performance of ceramic femoral heads of 22.225 mm diameter in cross-linked polyethylene (XLP) acetabular cups. We found remarkable qualitative and quantitative agreement between the clinical and simulator results for the wear characteristics with time, and confirmed that ceramic femoral heads penetrate the XLP cups at only about half the rate of otherwise comparable metal heads.

In the clinical study, 19 hips in 17 patients were followed for an average of 77 months. In the hip-joint simulator a similar prosthesis was tested for 7.3 million cycles.

Both clinical and simulator results showed relatively high rates of penetration over the first 18 months or 1.5 million cycles, followed by a very much lower wear thereafter. Once an initial bedding-in of 0.2 mm to 0.4 mm had taken place the subsequent rates of penetration were very small. The initial clinical wear during bedding-in averaged 0.29 mm/year; subsequent progression was an order of magnitude lower at about 0.022 mm/year, lower than the 0.07 mm/year in metal-to-UHMWP Charnley LFAs.

Our results show the excellent tribological features of alumina-ceramic-to-XLP implants, and also confirm the value of well-designed joint simulators for the evaluation of total joint replacements.

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Long-term studies of the Charnley low-friction arthroplasty (LFA) have repeatedly shown an exponential correlation between the depth of socket wear and the incidence of socket migration (Wroblewski 1985a, 1986; Wroblewski, Taylor and Siney 1992; Wroblewski and Siney 1993). In patients under 40 years of age at the time of the LFA, reviewed after an average of 9.3 years, Wroblewski (1985a) stated that "socket wear/creep and the resultant loosening appear to be the one factor limiting the life of the arthroplasty". He suggested that a search for materials which would reduce friction and wear might be more rewarding than devising new methods of component fixation (Wroblewski 1990).

Charnley (1979) considered that the activity level of the patient affected wear rates and therefore the penetration of the head, but many other factors may be important. Examination of explanted ultra-high-molecular-weight polyethylene (UHMWP) acetabular cups has failed to provide conclusive evidence of batch-to-batch variations in the polymer or of the effect of degradation upon wear rate after up to 18 years (Weightman et al 1991).

Ingress of acrylic cement particles into the articulation has been blamed, and the opacifiers barium sulphate and zirconium dioxide have been shown to damage the surface finish of femoral heads (Isaac et al 1992). Deterioration in the surface quality of the hard counterface has been linked to increasing wear rates (Dowson, Taheri and Wallbridge 1987). Ceramic surfaces have a potential advantage over the metals currently used for femoral heads because of their excellent geometrical form and surface topography, together with enhanced hardness and scratch resistance. They would be less likely to be damaged by acrylic cement and its opacifiers.
We have evaluated the performance of alumina ceramic femoral heads of 22.225 mm diameter articulating with cups made of cross-linked polyethylene in a prospective clinical study of 19 implants over periods of up to 100 months. The pattern of wear was entirely consistent with that shown in an independent laboratory study on a joint simulator of a similar alumina-ceramic femoral head against a cross-linked polyethylene (XLP) acetabular cup.

PATIENTS, MATERIALS AND METHODS

Clinical study. In a prospective clinical study of LFAs performed in 1986, all 19 femoral stems were of the Charnley flanged design, manufactured from high-nitrogen-content, cold-formed stainless steel (Ortron-CFT; Chas F. Thackray-DePuy International Ltd, Leeds, UK). The top of the neck had a parallel rather than a tapered form. A cup-shaped UHMWP sleeve some 0.2 mm in thickness was pressed on to the neck to form an interposed cushion layer between the metal stem and the ceramic head. This assembly was made at the time of manufacture (Fig. 1). All acetabular cups were of the standard, long-posterior-wall, flanged, Charnley design and were made of cross-linked polyethylene.

Surgical technique. We used a transtrochanteric approach (Wroblewski and Shelley 1985) with fixation of the stem by Palacos cement (Schering-Plough Ltd, Welwyn Garden City, UK) containing 0.5 g gentamicin per 40 g mix. A femoral bone block was placed in the intramedullary canal (Wroblewski and van der Rijt 1984). On the acetabular side, we used a cement pressuriser and the flange was trimmed to size (Shelley and Wroblewski 1988).

Measurement of penetration. Penetration of the femoral head was determined radiologically at each follow-up, using the method of Griffith et al (1978) which has been shown to have an accuracy of ± 0.10 mm. Joint simulator study. Between 1981 and 1985 a versatile hip-joint simulator was designed, built and commissioned in the Department of Mechanical Engineering in the University of Leeds (Dowson and Jobbins 1988). The initial studies were made on stainless-steel femoral heads of 22.225 mm diameter in polyethylene acetabular cups. Wear studies over $3.12 	imes 10^6$ loading cycles showed average penetration rates of 0.054 mm/million cycles. This figure agreed reasonably well with the average result of 0.07 mm/year from clinical and radiological evaluation of the performance of these Charnley joints (Griffith et al 1978).

In the current laboratory study, we used an XLP cup similar to that employed in the clinical trial. Current investigations of the tribological characteristics of UHMWP and XLP suggest that they have similar wear characteristics, but that the cross-linked material is more resistant to creep.

In an initial study we found that an alumina ceramic femoral head of 22.225 mm diameter had a penetration rate into a UHMWP cup which was only 50% to 70% of that of a stainless-steel head (Dowson, Jobbins and Seyed-Harraf 1993). In these experiments, we measured penetration by a casting (replica) and an optical shadowgraph technique. We later developed a new system for the measurement of the wear of acetabular cups and the penetration of femoral heads in joint simulators, based on the use of co-ordinate and roundness measuring machines (Collins 1990). We used this latter measuring system to evaluate the penetration of alumina ceramic femoral heads of 22.225 mm diameter into XLP acetabular cups. We give only the penetration data for a ceramic femoral head and an XLP cup to enable
direct comparison with the prospective clinical findings.

In the simulator, the test joint is located in an anatomical position and subjected to a simulated walking cycle (Paul 1967) at a frequency of 1 Hz. The test lubricant was deionised water and the environmental temperature of the test cell was maintained at 37°C. The volume changes within the XLP acetabular cup were determined throughout the test by the co-ordinate measuring system considering 0.1 mm ‘slices’ of the cup.

RESULTS

Clinical study. There were 17 patients and 19 hips in the clinical study. There were 12 men, two having bilateral LFA, and five women; their mean age at the time of operation was 53 years 2 months (23 years 7 months to 79 years 7 months) and their mean weight at operation 76 kg (54 to 102). The pathology was primary osteoarthritis in nine hips, osteoarthritis secondary to congenital dysplasia or subluxation in four, with post-traumatic changes, rheumatoid arthritis and necrosis of the head each in two hips.

The mean follow-up was 77 months (11 to 100). Four patients died during follow-up at 11, 42, 44 and 49 months after operation, respectively, and one patient with multiple sclerosis could not be followed up after 35 months. The mean follow-up period for the other 14 hips was 91 months.

Radiological penetration. The recorded penetrations ranged from 0.4 mm in the first 15 months to only 0.2 mm after 8 years 3 months. Relatively rapid initial penetration rates were recorded during the first and sometimes the second year. After this wear was very much less up to the longest review at 100 months. There was a marked similarity in the penetration characteristics in both the clinical and the simulator studies. This similarity forms the main thrust of this report.

The mean rate of socket penetration for the entire group of patients for the whole period of the study, measured in the customary way by dividing the final measurement of penetration by the period of implantation, was 0.057 mm/year. By contrast, the mean of the first measurable penetrations determined in the same way, after an average of 18 months, was 0.23 mm/year. The latest overall average penetration rate for the 14 remaining patients was only 0.035 mm/year (95% CI 0.029 to 0.042). In the nine hips in which follow-up exceeded eight years the average overall penetration rate was only 0.034 mm/year (95% CI 0.025 to 0.044).

The mean rate of penetration between the first recorded measurement and the final reading, determined in a consistent manner by subtracting the first recorded penetration from the final measurement and dividing by the elapsed period, was only 0.005 mm/year (–0.029 to 0.031). It has been shown previously that a depth of penetration of less than 2 mm on radiographs tends to overestimate the true penetration (Wroblewski 1985b), suggesting that the true figures were even lower in this group than those given above.

Details of the clinical cases and the results of penetration measurements are shown in Table I. Figure 2 includes the latest measurement recorded for each hip identified by the case number in Table I. The shaded envelope encloses all the recorded penetrations except part of the trace for case 18, in which positive penetration was recorded only after...
six years of follow-up. The zero penetrations recorded for this exceptional hip at 22 months and 50 months were the only data points to lie outside the shaded envelope shown in Figure 2.

Joint-simulator study. The joint-simulator tests recorded the penetration of an alumina-ceramic femoral head of 22.225 mm diameter into an XLP acetabular cup over 7.3 million cycles (Fig. 3). The results are shown as a line superimposed on the shaded envelope for the clinical study, taking one million cycles as roughly equivalent to one year of clinical use. The general form of the graphs is very similar, particularly in showing relatively high initial penetration followed by a very much lower rate. There is good qualitative and quantitative agreement between the two sets of results.

DISCUSSION

The unusual pattern of initial and relatively rapid bedding-in of alumina-ceramic femoral heads into XLP acetabular cups, with a greatly reduced subsequent penetration rate, has not previously been reported in clinical practice. Low, overall penetration rates for the conventional Charnley LFA with a stainless-steel femoral head have been described after 20 years (Wroblewski, McCullagh and Siney 1992), and as early as 1979 Charnley noted that long-term survival of the LFA was accompanied by a gradual reduction in the average rate of penetration. This distinctive behaviour has been confirmed in both our clinical and laboratory simulator studies.

Most previous measurements of wear in joint simulators have used gravimetric methods; these reveal the loss of material from the acetabular cup, but do not necessarily give reliable estimates of penetration, because of the influence of creep. This is particularly important in the initial stages of penetration, when creep predominates. Newer dimensional measurement methods record volume changes generated by both creep and wear and are related more directly to clinical penetration as recorded radiologically.

The close agreement which we found between simulator and radiological measurements confirms the role of creep in the initial stages of penetration and shows that well-

Table I. Details of patients with 19 alumina ceramic/XLP hip replacements and the results of radiological measurement of penetration

<table>
<thead>
<tr>
<th>Case</th>
<th>Sex</th>
<th>Weight (kg)</th>
<th>Side</th>
<th>Age at operation (yr)</th>
<th>Date of operation</th>
<th>Date and penetration (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>75</td>
<td>L</td>
<td>50.7</td>
<td>10.4.86</td>
<td>22.7.86 27.7.86 20.7.88 18.7.90 17.7.92 13.7.94</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>87</td>
<td>L</td>
<td>49.8</td>
<td>18.9.86</td>
<td>0 0.4 0.4 0.4 0.4 0.2</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>62</td>
<td>R</td>
<td>35.7</td>
<td>11.4.86</td>
<td>7.1.87 6.1.88 9.8.89 3.11.94 0.2 0.39 0.41 0.31</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>95</td>
<td>L</td>
<td>50.8</td>
<td>5.6.86</td>
<td>21.10.86 26.5.87 12.6.87 16.12.88 1.5.90 27.5.92 21.10.92 8.11.94</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>80</td>
<td>L</td>
<td>26.4</td>
<td>12.2.87</td>
<td>17.9.86 16.9.87 14.9.88 12.9.90 0.2 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>62</td>
<td>L</td>
<td>35.7</td>
<td>14.7.86</td>
<td>8.7.87 17.8.88 31.10.90 18.11.92 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>72</td>
<td>L</td>
<td>75.0</td>
<td>7.7.86</td>
<td>5.11.86 4.11.87 11.5.88 10.5.89 0.2 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>76</td>
<td>L</td>
<td>53.7</td>
<td>22.5.86</td>
<td>3.9.86 21.10.87 19.10.88 16.10.90 0.2 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>89</td>
<td>R</td>
<td>53.3</td>
<td>15.5.86</td>
<td>27.8.86 26.8.87 24.8.88 26.7.89 14.8.91 11.5.94 0.2 0.4 0.4 0.4 0.4 0.4</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>57</td>
<td>R</td>
<td>23.5</td>
<td>3.4.86</td>
<td>16.7.86 12.3.87 0.2 0.23 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>92</td>
<td>R</td>
<td>51.6</td>
<td>10.3.86</td>
<td>18.3.86 8.7.87 6.7.88 4.7.90 1.7.92 2.7.94 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>12†</td>
<td>F</td>
<td>68</td>
<td>L</td>
<td>57.8</td>
<td>6.3.86</td>
<td>71.87 18.11.87 6.7.88 8.2.89 0.2 0.21 0.41 0.41 0.2 0.2</td>
</tr>
<tr>
<td>13(d)</td>
<td>M</td>
<td>80</td>
<td>R</td>
<td>66.4</td>
<td>1.5.86</td>
<td>20.8.86 9.10.87 10.11.89 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>14(d)</td>
<td>F</td>
<td>54</td>
<td>R</td>
<td>79.6</td>
<td>10.3.86</td>
<td>18.3.86 17.6.87 20.7.88 8.11.89 0 0.19 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>15</td>
<td>M</td>
<td>92</td>
<td>L</td>
<td>51.6</td>
<td>10.3.86</td>
<td>18.3.86 8.7.87 6.7.88 4.7.90 1.7.92 2.7.94 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>16</td>
<td>F</td>
<td>54</td>
<td>R</td>
<td>58.4</td>
<td>25.2.86</td>
<td>4.4.86 20.10.87 28.11.89 11.9.2 0 0.21 0.21 0.21 0.21 0.21</td>
</tr>
<tr>
<td>17(d)</td>
<td>F</td>
<td>76</td>
<td>R</td>
<td>70.9</td>
<td>25.2.86</td>
<td>20.6.86 29.5.87 25.1.88 19.7.89 21.3.90 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>102</td>
<td>R</td>
<td>48.8</td>
<td>3.4.86</td>
<td>16.7.86 25.2.87 24.2.88 20.6.90 8.7.92 21.3.90 8.10.94 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
<tr>
<td>19</td>
<td>M</td>
<td>71</td>
<td>L</td>
<td>71.7</td>
<td>24.2.86</td>
<td>18.8.68 17.6.87 15.6.88 14.6.89 13.6.90 19.6.91 23.6.93 0 0.2 0.2 0.2 0.2 0.2</td>
</tr>
</tbody>
</table>

* patient died
† no further follow-up, multiple sclerosis
designed simulators can adequately reproduce these aspects of the clinical performance of arthroplasties. There is much interest in the development of joint simulators and the standardisation of test procedures; we believe that our study provides the first careful correlation of radiological and joint-simulator results for a specific type of implant.

The average overall rate of penetration of ceramic heads into XLP cups was 0.057 mm/year over periods of up to 8 years 4 months, with a remarkably low long-term average over eight years of about 0.034 mm/year. These low rates followed rapid initial penetration in the first two years and compare favourably with those for metallic heads in UHMWP cups (Table II). Griffith et al (1978) described a rate of 0.07 mm/year over similar follow-up periods from seven to nine years, which is twice the rate which we report for alumina-on-XLP cups.

A previous review of clinical penetration rates for alumina ceramic heads into UHMWP cups, in relation to those for metallic heads, showed an overall ratio of 2:1 in favour of the ceramic implants (Dowson 1994). This review covered reports by Oonishi, Igaki and Takayama (1989), Ohashi, Inoue and Kajikawa (1989), Okumura et al (1989), Egli et al (1990) and Zichner and Willert (1992). The last authors monitored the radiological displacement of Müller-type femoral heads of two different metals and alumina over periods comparable to those which we considered. They noted that the measuring system could not distinguish between wear and creep, or cold flow, but they also confirmed a relatively large initial penetration which they attributed to creep, and found that alumina ceramic femoral heads penetrated more slowly than metal heads into polyethylene cups. Zichner and Willert (1992) questioned the validity of laboratory testing, since the simulator results of Semlitsch et al (1977) had suggested a 20:1 reduction in wear for the ceramic heads. We have now shown that clinical and laboratory simulator results can be in excellent accord.

The initial bedding-in of alumina ceramic heads into XLP cups is probably attributable mainly to creep, rather than to wear. The initial creep does not produce particulate debris; such debris will be related to the very small wear rates recorded after the first 18 months. It is important to note that the radial clearance between the head and the cup which we used in the simulator tests was unusually small at only 18 μm. This would have the effect of reducing the mean initial stress and creep penetrations below the levels for this type of implant used in clinical practice. Dowson, Jobbins and Sayed-Harraf (1993) have shown theoretically that a larger radial clearance can lead to a relatively rapid initial penetration rate, even if attributable to wear alone. As regards true ‘wear’, the new implants are entirely acceptable as far as penetration alone is concerned. Continuation of the very low late clinical penetration rate of 0.022 mm/year may show that use of the alumina ceramic

### Table II.

<table>
<thead>
<tr>
<th>Rate (mm/yr)</th>
<th>Details and authors</th>
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</thead>
<tbody>
<tr>
<td>0.07</td>
<td>At 7 to 9 years (Griffith et al 1978)</td>
</tr>
<tr>
<td>0.096</td>
<td>At 15 to 21 years (Wroblewski 1986)</td>
</tr>
<tr>
<td>0.20</td>
<td>At 4 to 17 years in patients under the age of 40 years at the time of surgery (Wroblewski 1985a)</td>
</tr>
<tr>
<td>0.21</td>
<td>In cases revised for a loose socket (Wroblewski 1985b)</td>
</tr>
<tr>
<td>0.07</td>
<td>At 15 to 25 years (Wroblewski, Taylor and Siney 1992)</td>
</tr>
<tr>
<td>0.02</td>
<td>With an average of 20 years’ follow-up, where the head of the metallic femoral head remained undamaged (Wroblewski et al 1992)</td>
</tr>
</tbody>
</table>
and XLP combination is the next logical step in the evolution of the Charnley LFA. To date, there have been no problems with the reduced diameter of the femoral neck, the UHMWPE sleeve or the alumina ceramic head.

The encouraging findings which we report from the first eight years of the clinical study need to be supported by an even longer follow-up of penetration measurements by conventional means and by extended joint-simulator studies. Our hypothesis needs confirmation.

**Conclusions.** We found that alumina ceramic femoral heads of 22.225 mm diameter with XLP acetabular cups gave a good clinical performance up to 8 years 3 months. Penetration was relatively rapid (0.29 mm/year) during the first year or 18 months and very small thereafter (0.022 mm/year). The laboratory studies on a hip-joint simulator showed excellent qualitative and quantitative confirmation of these characteristics and confirmed the value of carefully designed simulators in the prediction of performance.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

**REFERENCES**


