New polyethylenes in total hip replacement

A PROSPECTIVE, COMPARATIVE CLINICAL STUDY OF TWO TYPES OF LINER

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Ultra-high-molecular-weight polyethylene sterilised in the absence of air and highly cross-linked polyethylene have been used to avoid osteolysis and loosening in total hip replacement. Our prospective randomised study has assessed the results using two different polyethylenes associated with the same prosthetic design. We assessed 45 Allofit acetabular components with a Sulene-polyethylene liner of conventional polyethylene gamma sterilised with nitrogen and 45 Allofit acetabular components with a Durasul-polyethylene liner sterilised in ethylene oxide, both matched with an Alloclassic stem with a 28 mm modular femoral head. The prostheses were implanted between May 1999 and December 2001. The mean follow-up was for 66.3 months (60 to 92). The linear penetration of the femoral head was estimated at 6 weeks, at 6 and 12 months and annually thereafter from standardised digitised radiographs using image-analysis software.

There was no loosening of any prosthetic component. There were no radiolucent lines or osteolysis. The mean rate of penetration calculated from regression analysis during the first five years was 38 μm/year (SD 2) for the Sulene group and 6 μm/year (SD 1) for the Durasul group (p = 0.00002). The rate of penetration of the Durasul group was 15.7% of that of the Sulene group.

Gamma sterilisation of ultra-high-molecular-weight polyethylene (UHMWPE) favours cross-linking, but produces free radicals which, in the presence of air, may oxidise and weaken the mechanical properties, increasing the production of wear debris, and in turn inducing osteolysis and prosthetic loosening. Different polyethylenes have been developed which are sterilised in the absence of air, but these may still oxidise and produce free radicals. Highly cross-linked polyethylenes (HXLPEs) attempt to avoid these complications. Several types are commercially available, but the manufacturing processes vary, and this affects the material properties and the content of free radicals. In vitro gravimetric analysis has shown that these materials wear substantially less than conventional material and that the original machining marks remain after prolonged testing. Examination of retrieved explants has also confirmed the persistence of machining marks which can be identified after re-warming the components. However, it has also been reported that the increased radiation dosage necessary for sterilisation could have a detrimental influence on the mechanical properties of UHMWPE, and compromise the fixation of the components using HXLPEs. Wroblewski, Siney and Fleming reported excellent clinical results in total hip replacement (THR) with early cross-linked polyethylene at a minimum follow-up of 1.5 years. Clinical studies with short follow-up using radiostereogrammetric analysis or other methods to assess the penetration of the femoral head with different HXLPEs have shown superior wear performance over that of conventional UHMWPE.

Our aim in this prospective, randomised study was to determine if an HXLPE implant showed improved wear in vivo compared with a nitrogen-sterilised UHMWPE implant using the same design of prosthesis.

Patients and Methods

Prosthesis

Between 1999 and 2001, we implanted acetabular components using liners made of nitrogen-sterilised UHMWPE (Sulene; Zimmer GmBH, Winterthur, Switzerland) or of HXLPE (Durasul; Zimmer which was sterilised by ethylene oxide). Identical acetabular shells (Allofit; Zimmer) and femoral components (Alloclassic; Zimmer) were used in all the hips. The characteristics of the materials are given in Table I.
The cementless Allofit acetabular shell was used in all patients and was made of pure titanium with a biradial shape and a rough surface. We used the cementless grit-blasted Alloclassic-Zweymüller femoral component which had a tapered straight stem, rectangular geometry and was forged in a niobium-containing titanium alloy (Ti-6Al-7Nb, Protasul-100). The 28 mm modular femoral head was made from stainless-steel Protasul-S30 (Zimmer) in the Sulene group (Ra < 15 nm) and from cobalt-chromium alloy Protasul-20 (Zimmer) in the Durasul group (Ra < 10 nm). The surface finish on the acetabular and femoral components had a mean roughness of 3 \( \mu m \) to 5 \( \mu m \).

A total of 90 patients were randomised to receive either an HXLPE (45) or nitrogen-sterilised UHMWPE (45) liner. The study was approved by our Institutional Review Board. Oral and written informed consent was obtained from all the patients and they were informed pre-operatively that they might receive new biomaterials for which the long-term results were not available. The mean clinical and radiological follow-up was for 66.3 months (60 to 92). The gender, age, weight, level of activity, quality of the femoral bone and diagnosis at the time of operation are given in Table II. The level of activity was classified by the scale of Devane et al.\textsuperscript{17} and the quality of femoral bone according to Dorr et al.\textsuperscript{18} All the operations were performed in the same manner through a posterolateral approach. The acetabular component was implanted using a press-fit technique. Supplementary screws were used depending on the stability of the component. Post-operatively, all patients received antibiotic prophylaxis (cephazolin, 1 g every eight hours for 48 hours) and subcutaneous heparin. They began partial weight-bearing on the second post-operative day and progressed until full weight-bearing was tolerated.

**Clinical and radiological evaluation.** The clinical evaluation included an assessment of pain, function and range of movement according to the six-level scale described by Merle D’Aubigné and Postel.\textsuperscript{19}

Standard anteroposterior (AP) radiographs of the pelvis and lateral views of the hip were taken immediately after operation, at 6 weeks, three, six and 12 months, and annually thereafter for at least five years following the same protocol. The patient was positioned supine, with both feet together. The X-ray tube was positioned over the symphysis pubis one metre from and perpendicular to the table to produce an exposure with a symmetrical view of the obturator foramen and including the lesser trochanter and iliac crests.\textsuperscript{12} To reduce interobserver error, measurements were made by the first author (EGR), who had not been involved in the surgery.

The position of the acetabular component was assessed according to the angle of abduction, the height of the centre of the hip as measured from the centre of the femoral head to the interdrop line and the horizontal distance of the acetabular component, measured from the centre of the femoral head to Köhlers line as described by Johnston et al.\textsuperscript{20}

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### Table I. Characteristics of the two polyethylenes

<table>
<thead>
<tr>
<th>Type</th>
<th>Material</th>
<th>Manufacturing method</th>
<th>Dose (kGray)</th>
<th>Temperature before radiation (ºC)</th>
<th>Post-irradiation melting</th>
<th>Sterilisation method</th>
<th>Storage method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulene (Zimmer)</td>
<td>GUR1020</td>
<td>Compression moulded sheets</td>
<td>25 to 40</td>
<td>Room temperature</td>
<td>Not applicable</td>
<td>Gamma nitrogen</td>
<td>Packing under nitrogen</td>
</tr>
<tr>
<td>Durasul (Zimmer)</td>
<td>GUR1050</td>
<td>Compression moulded sheets</td>
<td>95</td>
<td>125</td>
<td>150ºC for 2 hrs</td>
<td>Ethylene oxide</td>
<td>Vacuum impervious</td>
</tr>
</tbody>
</table>

### Table II. Details of the patients in both groups

<table>
<thead>
<tr>
<th>Age in yrs (range)</th>
<th>Weight in kg (range)</th>
<th>Grade of activity</th>
<th>Type of femur</th>
<th>Diagnosis</th>
<th>Sulene group (n = 45)</th>
<th>Durasul group (n = 45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>60.6 (25 to 88)</td>
<td>75.2 (52 to 106)</td>
<td>1 to 3</td>
<td>Champagne cup</td>
<td>Osteoarthritis</td>
<td>32</td>
<td>28</td>
<td>0.8111</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 to 5</td>
<td>Intermediate</td>
<td>Avascular necrosis</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cylindrical</td>
<td>Hip dysplasia</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Post-traumatic arthritis</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rheumatoid arthritis</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Perthes’ disease</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
The distribution of any radiolucent gaps on the initial post-operative radiograph and of radiolucent lines or osteolysis around the acetabular component on subsequent radiographs was recorded in the three zones described by DeLee and Charnley. Osteolysis was defined as a new expanding, sharply demarcated lucency. A radiolucent line was defined as a new linear radiolucent defect adjacent to the component or screws. Because of the difficulty of detecting radiolucent lines around uncemented components, we applied the current method of determining radiological bone ingrowth into an acetabular component using an indirect inference based on the absence of the two classical signs of loosening, namely, radiolucent lines and migration of the cup.

The radiographs were scanned digitally and linear wear was estimated according to the method of Dorr and Wan. Penetration of the femoral head into the liner was measured by a computer-assisted edge-detection system (AutoCAD 2000; AutoDesk Inc., Sausalito, California). The radiographs were digitised using a scanner (Epson Expression 1680; Seiko Epson Corporation, Nagano; Japan). The known size of the modular femoral head was used as an internal reference. The measurements were repeated five times and the mean was recorded. The reliability of the mean of these five measurements was 0.9536 (95% CI 0.9029 to 0.9801) (intraclass correlation coefficient). The amount of penetration on the post-operative radiograph at six weeks was taken as the reference for subsequent measurements, as has been applied in other series. Although all the radiographs were taken following the same protocol, they were also screened for quality before being included in the study analysis. Penetration of the head into the liner was determined from AP pelvic radiographs at annual intervals. The mean penetration (creep and wear) was determined using the slope of the linear regression at two levels, A at the mid of the stem and B 1 cm proximal to the tip. The distribution of radiolucent lines or osteolysis was recorded in the zones described by Gruen, McNeice and Amstutz. Osteolysis was classified according to the criteria of Goetz, Smith and Harris as extensive, intermediate and mild. Femoral osteopenia resulting from stress-shielding was graded according to the system described by Engh, Bobyn and Glassman as follows: grade 1, rounded femoral neck; grade 2, rounding off of the femoral neck and loss of medial cortical density at level 1; grade 3, loss of medial and anterior cortical density at levels 1 and 2; grade 4, cortical resorption extending below levels 1 and 2 into diaphysis. Fixation of the femoral component was classified as radiological ingrowth, fibrous stable or unstable according to the criteria for porous prostheses described by Engh, Glassman and Suthers. Subsidence was defined as a change of at least 5 mm in the distance between the top of the stem and the greater trochanter when the initial post-operative radiographs were compared with those taken at the follow-up evaluations.

**Statistical analysis.** Qualitative data are expressed as counts (tallying), number of cases and quantitative data by mean and range. Qualitative data were compared with the chi-squared test or Fisher’s exact test, and quantitative data were compared with the Student’s t-test or the Mann-Whitney U test, depending on the distribution of the data. The mean rate of femoral penetration was compared by using the Student’s t-test for comparing two regression coefficients. The level of significance was p < 0.05.

**Results**

There were two dislocations which were successfully treated by closed reduction and were included in the study. There were no infections. An intra-operative acetabular fracture occurred which healed satisfactorily after conservative treatment.

None of the patients had revision surgery during the period of the study. The mean Merle D’Aubigné and Postel score, improved from 8.1 to 16.7 points in the Sulene group and from 7.4 to 17.4 points in the Durasul group (Mann-Whitney test, p = 0.56 for pain; p = 0.38 for function; p = 0.30 for range of movement). All patients reported relief from pain and none had pain in the groin or thigh.

There were no significant differences in the groups for the mean angle of abduction, the mean horizontal distance and the mean vertical distance of the acetabular component. The position of the femoral component and the mean filling of the femoral canal were similar for both groups. Radiological data are detailed in Table III. All the acetabular and femoral components remained stable and none of the implants showed evidence of migration or subsidence. In no case were radiolucent lines or osteolysis observed around either component. Cortical hypertrophy or proximal osteopenia were not seen.

The mean rate of penetration of the head during the first five years was 38 µm/year (SE 2) for the Sulene group and 6 µm/year (SE 1) for the Durasul group. This difference was
statistically significant (Student’s t-test, p = 0.00002). The rate of penetration of the Durasul group was 15.7% of that of the Sulene group (Fig. 1).

Discussion
Wear of polyethylene remains the most common cause of failure of total hip prostheses. In comparing the rate of penetration of the femoral head when articulating with an HXLPE and a nitrogen-sterilised UHMWPE liner, we have attempted to eliminate potential confounding variables. The groups were matched by gender, weight, level of activity, quality of femoral bone and original diagnosis. Furthermore, all the THRs compared were performed at a single institution using the same design of component with the exception of the materials of the acetabular liner and the alloy used for the femoral head. The difference in these alloys was our one confounding variable. As in other series using a porous-coated titanium hemispherical acetabular component and Alloclassic femoral component, good clinical and radiological results were found at mid-term. All the patients had improved clinical results and there were no differences between the groups. There was no loosening of components and no evidence of proximal femoral osteopenia or cortical widening.

We used a computer-assisted method of edge-detection to assess the linear penetration of the liner. Penetration was estimated with a software package using the method of Dorr and Wan, which simplified the geometries involved in the non-spherical shape of the acetabular component and the irregularities of the outer shell. Although we have not validated this procedure, similar digitised methods have been validated previously using phantom models and retrieved components, but not on radiographs obtained in vivo.

The precision in phantom studies performed using computer-assisted measurement of the penetration of polyethylene is more accurate than that in radiological assessment because the scatter, soft-tissue absorption of the radiation, and the in vivo patterns of penetration cannot be recreated in the laboratory. A fixed position of the x-ray beam reduces the error in phantom studies, but in clinical radiographs, the positioning of the patient is slightly different in each film in the follow-up studies. Clinical pelvic radiographs also contain slight distortions of the metal shell and head, while computer-assisted measurement of polyethylene penetration assumes that the shell and femoral head are true circles on the radiographs. This makes it difficult to compare results between clinical and laboratory studies. Wan et al found that two-dimensional computer-assisted radiological measurements of penetration of the polyethylene had reproducible measurements on the same radiograph. However, measurements of different clinical radiographs from the same patient were not as precise because of the positioning differences mentioned above.

The clinical performance of the different polyethylenes used in our study with the same uncemented implant used in all the patients confirmed that of previous published reports. The reference radiograph made in the sixth week after operation showed greater penetration of the Sulene liner. The penetration pattern of the Durasul liner was similar to that in other series during the first two years.

<table>
<thead>
<tr>
<th></th>
<th>Sulene group (n = 45)</th>
<th>Durasul group (n = 45)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) acetabular abduction angle (º)</td>
<td>46.3 (6.3)</td>
<td>45.8 (7.2)</td>
<td>0.7266</td>
</tr>
<tr>
<td>Mean (SD) horizontal distance in mm</td>
<td>33.2 (2.7)</td>
<td>32.1 (3.1)</td>
<td>0.0759</td>
</tr>
<tr>
<td>Mean (SD) vertical distance in mm</td>
<td>21.3 (3.5)</td>
<td>19.3 (2.8)</td>
<td>0.0035</td>
</tr>
<tr>
<td>Position of the femoral stem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutral</td>
<td>40</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Varus</td>
<td>3</td>
<td>5</td>
<td>0.7591</td>
</tr>
<tr>
<td>Valgus</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mean (SD) filling of the femoral canal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level A</td>
<td>78.8 (6.7)</td>
<td>80.9 (7.1)</td>
<td>0.1522</td>
</tr>
<tr>
<td>Level B</td>
<td>87.1 (7.6)</td>
<td>89.4 (8.0)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
after operation.11,12 Early wear of polyethylene is usually attributable to creep or bed-inning in the first 18 to 24 months after operation.26 In our study, the pattern of the bed-inning process was similar in both groups. Our main finding was the continued increase in the difference between the two polyethylene types after the first two initial years. Wear occurring then is considered to be true wear. Consequently, the amount of annual penetration of the femoral head into the liner from the third year after operation is becoming more important clinically.13

Our period of follow-up was too short to allow definite conclusions to be drawn. However, there was a significant reduction in the annual linear penetration of the femoral head with the Durasul liner. Our study supports the better behaviour in vivo of the HXLPE in primary uncemented THRs compared with nitrogen-sterilised UHMWPE using the same type of implant in all cases. Despite these results, measurement of clinically occurring polyethylene wear cannot provide a full prediction as to the performance of HXLPE. Further follow-up is needed to document the biological and mechanical behaviour of this bearing surface and to determine whether it will reduce the incidence of osteolysis.

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.

Supplementary Material
A further opinion by Mr F Haddad is available with the electronic version of this article on our website at www.bjs.org.uk

References