Implantation of a large-diameter femoral head prosthesis with a metal-on-metal bearing surface reduces the risk of dislocation, increases the range of movement, minimises the risk of impingement and, in theory, results in little wear.

Between February 2004 and March 2007 we implanted 100 consecutive total hip replacements with a metal-on-metal bearing and a large femoral head into 92 patients. There were 51 men and 41 women with a mean age of 50 years (18 to 70) at the time of surgery.

Outcome was assessed using the Western Ontario McMaster University osteoarthritis index and the Harris hip score as well as the Devane activity score. These all improved significantly (p < 0.0001). At the last follow-up there were no cases of dislocation, no impingement, a good range of movement and no osteolysis, but seven revisions, two for infection and five for aseptic loosening. The probability of groin pain increased if the other acetabular component inclination exceeded 50° (p = 0.0007). At 4.8 years of follow-up, the projected survival of the Durom acetabular component, with revision for any reason, was 92.4% (SD 2.8) (95% confidence interval 89.6 to 95.2).

The design of the component made it difficult both to orientate and seat, which when combined with a poor porous coating, produced unpredictable fixation and a low survival at five years.

As total hip replacement (THR) is increasingly carried out in younger and more active patients,1-3 it becomes even more important to prolong the lifespan of the joint and to reduce the risk of complications, especially dislocation.

The bearing surface has a critical role in determining the survival of the implant. Despite the relative failure of the first generation of metal-on-metal prostheses,4 long-term studies of the same prostheses,5,6 have shown that there is minimal wear of the bearing surface under certain tribological conditions.7-13 These studies have led to the development of second-generation metal-on-metal bearings,14-16 the first of which was introduced into clinical practice by Weber17 in 1988.

Cuckler et al18 have shown that the use of a large-diameter prosthetic head (≥ 36 mm) reduces the risk of dislocation. The relationship between the head and the neck in this type of implant also results in a greater range of movement19 and minimises the risk of impingement.19,21 This is particularly beneficial with metal-on-metal bearings, as impingement will generate wear debris, with resultant metallosis and osteolysis.22 There is also a correlation between increased serum levels of metal ions and the inclination of the acetabular component after metal-on-metal surface replacement of the hip.23

The purpose of this study was to evaluate the clinical and radiological results of a THR which has a large-diameter head and a metal-on-metal bearing. We wished to determine the early functional outcome, the incidence of dislocation and whether there were any specific problems related to the design, means of fixation or placement of the implant.

Materials and Methods
Between February 2004 and March 2006, we implanted 100 consecutive THRs with a large-diameter head and a metal-on-metal bearing into 92 patients. There were 51 men and 41 women, with a mean age of 50 (18 to 70) at the time of surgery. The entry criteria were a primary joint replacement in a patient under the age of 70, a minimum activity score of 3 on the Devane scoring system24 and sufficient bone stock for a cementless implant. Their mean body mass index (BMI) was 27.8 (18.0 to 50.8), 28 patients (30%) had a BMI > 30 and nine
patients (10%) > 35. According to this scoring system, 49 hips were grade 5, 28 grade 4 and 23 grade 3. The primary diagnosis was osteoarthritis in 64 hips and avascular necrosis of the femoral head in 36. Of the 64 arthritic hips, 39 were primary and 17 were secondary to hip dysplasia, slipped capital femoral epiphysis in four, Perthes’ disease in two, villonodular synovitis in one and Staphylococcus-related arthritis in one. The 36 cases of avascular necrosis were caused by steroid use in 13, fracture of the neck of the femur in three and kidney transplantation in one; 19 were idiopathic or due to excessive alcohol consumption. Overall, 13 hips (11 patients) had undergone surgery before being included in the study including a Chiari pelvic osteotomy in one, external fixation of a fracture of the neck of the femur in three, a shelf procedure in four, core decompression of the head of the femur in three and synovectomy in two.

Each procedure was carried out through a posterolateral approach in an operating theatre with vertical laminar flow. All patients received prophylactic antibiotics for 24 hours, starting one hour prior to skin incision. No patient was given specific medication to prevent heterotopic ossification, but all underwent abundant and vigorous intra-operative lavage with sterile saline.

All the components were uncemented. We used an Alloclassic Zweymuller SL Stem, (Zimmer GmbH, Winterthur, Switzerland) made of Ti-6Al-7Nb alloy with a grit-blasted surface but no hydroxyapatite coating. This was combined with a Durom acetabular component (Zimmer GmbH), which is a monobloc, flattened hemispherical implant with a constant wall thickness of 4 mm (3.7 mm of Metasul and 0.3 mm of a pure titanium, plasma-sprayed coating, PoroLock TiVPS) and a large-diameter head, which was 8 mm smaller than the outside diameter of the acetabular component and 6 mm smaller than its nominal size, with a metal-on-metal articulation (Metasul, Zimmer GmbH) (Fig. 1). The opening angle (the subtended angle) was fixed at 165° instead of 180° for traditional THR bearings. The acetabulum was underreamed by 2 mm as recommended by the manufacturer, and the component impacted into place. Primary fixation was completed with three equatorial fins. Full weight-bearing was allowed two to four days after surgery. No specific instructions were given to prevent dislocation.

Each patient was reviewed annually by two observers (CB, JG) who were not involved in the surgery. The minimum period of follow-up was fixed at 24 months. Hip function was assessed using the Postel-Merle d’Aubigné scoring system,25 the Harris hip score (HHS)26 and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC).27 The ‘hop test’ (hopping on the affected leg without support) was used to evaluate hip function.28 Clinical examination included assessment of the range of movement, and each hip was tested for impingement. This was diagnosed if there was pain and a mechanical block on maximum flexion and internal rotation or in maximum extension and external rotation.

Anteroposterior and lateral radiographs were taken postoperatively, annually and at the last follow-up. These were assessed by three observers (CB, HM, JG). Radiological loosening was defined by the criteria of Engh, Bobyn and Glassman29 for the femoral component and of Massin, Schmidt and Engh30 for the acetabular component. Migration of the femoral stem was measured by quantifying any change in distance between the tip of the proximal part of the femoral stem (the lateral spike of the SL stem) and the tip of the greater trochanter. Inclination of the acetabular component was measured from a line drawn between the teardrops (Fig. 1). Movement of > 5 mm between follow-up radiographs was taken to represent migration.30 Radiographs were examined for evidence of osteolysis, spotwelds, bone condensation and reactive lines. In each of the seven femoral zones of Gruen, McNeice and Amstutz31 and the three acetabular zones of DeLee and Charnley,32 Heterotopic ossification was graded using the system devised by Brooker et al.33

Statistical methods. All statistical analyses were performed with Statview software (Abacus Concepts Inc., Berkeley, California). The results are expressed as frequencies and percentages for categorical variables, and as means and ranges for numerical variables. Percentages were compared using the chi-squared test or Fisher’s exact test. The evolution of the different scores was analysed using the Wilcoxon paired rank test. Groups were compared using the Mann-Whitney rank test. The significance level was set at 5%. Kaplan-Meier survival analysis was conducted using revision for any reason as an endpoint, and any aseptic revision with exchange of the Durom acetabular component as the endpoint (95% confidence intervals (CI) are detailed).

Fig. 1

Anteroposterior radiograph of the pelvis of a patient with a Harris hip score of 100/100, showing bilateral total hip replacement with the implants used in our series: an Alloclassic stem and Durom acetabular component with Metasul Large Diameter Head (Zimmer GmbH). On the left, the acetabular component inclination is 50°. Numerous spotwelds (arrows) are present. No gap is apparent.
integrated according to the criteria of Engh et al. All but one of the stems were osseointegrated. Radiologically, there were no signs of osteolysis or radiolucency. Four patients required revision of the acetabular component because of aseptic loosening. The details of these cases are given in Table III. In each case the acetabular component was probably osteointegrated (Engh score < 10).

On the acetabular side, a post-operative gap measuring up to 7 mm in depth affected 35 hips of which 34 were seen in zone II, and involved more than 50% of the circumference of the acetabular component on anteroposterior (AP) radiographs in a third of cases (12 hips). No correlation was apparent between the presence of a gap and the occurrence of groin pain (p = 0.33) or the re-operation rate (p = 0.5). All gaps filled up in less than a year, with the exception of one case (without clinical effect; HHS = 96 on follow-up). At final follow-up 23 hips had developed heterotopic ossification: 17 were Brooker grade 1 and six were Brooker grade 2. There were four per-operative fractures: two of the femur which were treated by cerclage wiring and delayed weight-bearing for six weeks, and two partial acetabular wall fractures which were treated by partial weight-bearing for four weeks.

Four patients required revision of the acetabular component because of aseptic loosening. The details of these cases are given in Table III. In each case the acetabular component inclination was negatively correlated with the WOMAC score (p = 0.005). In other words, the more the inclination of the acetabular component increased, the more the clinical and functional score deteriorated (Fig. 2) (p = 0.005). The probability of moderate to severe groin pain, as determined from the HHS, was greater if the inclination angle exceeded 50° (p = 0.0007). Receiver operating characteristic curve analysis fixed the threshold at 51° (sensitivity = 0.73; specificity = 0.84). Likewise the more the acetabular component inclination angle increased, the greater the rate of re-operation (Fig. 2) (p = 0.001). Moreover, we also noted that an inclination angle of > 50° in the frontal plane significantly increased the risk of iliopsoas irritation (p = 0.02). On the other hand, several factors did not apparently influence the occurrence of groin pain or the re-operation rate (age at surgery, BMI, indication for hip replacement, Devane score, acetabular component diameter, sign of component fixation according to Massin et al).
The Durom large diameter head acetabular component was revised to an AlloFit Metasul acetabular component (Zimmer GmbH). There were no signs of metallosis. Macroscopic analysis of the four explants showed a complete absence of bone ongrowth to the porous surface of the Durom components (Fig. 3). The patient’s groin pain resolved in each case.

The fifth patient had severe groin pain and a perceptible and audible sensation of instability and edge-loading on clinical testing for impingement (Table III). The component inclination angle was 60°. A CT scan showed 21° of acetabular component anteversion and 17° of anteversion of the femoral component. The levels of metal ions in whole blood were 81 μg/l for cobalt and 22 μg/l for chromium. An extensive synovectomy was carried out because of marked metallosis and the acetabular component was revised to a dual-mobility cup (Polarcup, Endoplus, Corbevoie, France) to prevent further dislocation. A satisfactory outcome was achieved. Macroscopic analysis of the explanted acetabular component showed bony ingrowth over 25% of its surface. The bearing surface showed some corrosion on both sides at the upper pole.

At the final follow-up the survival of the Durom acetabular component, with revision for any reason as the endpoint, was 92.4% (SD 2.8) (95% CI 89.6 to 95.2), and with aseptic revision of the component as the endpoint, was 94.3% (SD 2.5) (95% CI 91.8 to 96.8).

**Discussion**

Few series have reported the results of THR using a large-diameter head, and even then, follow-up has been for less than four years. Large-diameter heads have been shown to improve the stability of a THR by reducing the risk of impingement and by increasing the distance the prosthetic head has to travel to dislocate. Beaule et al used 40 mm to 50 mm custom-made polyethylene heads for the treatment of recurrent dislocation. We encountered no problems with instability in our series.

The projected survival rate in our series at 58 months was rather indifferent (92.4% (SD 2.8)), owing principally to the four failures of acetabular fixation (Table III). Dorr similarly reported a 6% revision rate from 165 Durom THRs, which he attributed to a failure of acetabular implantation, although the post-operative radiographs usually appeared normal. In our experience, similar findings elicited the diagnosis of acetabular component non-fixation on clinical examination (painful hop test) without taking into account the radiological aspect and after having eliminated infection by articular puncture. By contrast, in its 2006 annual report, the Swedish Hip Arthroplasty Registry reported a survival rate of 99.5% after three years in a series of 222 THRs using the Durom acetabular component. Panousis et al had similar results in a series of

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**Table III.** Clinical and radiological features of the five patients who required revision of the acetabular component for aseptic loosening

<table>
<thead>
<tr>
<th>Case</th>
<th>Clinical features</th>
<th>Acetabular component inclination (°)</th>
<th>Particular radiological signs around the acetabular component</th>
<th>Other signs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Major groin pain on the ‘hop test’</td>
<td>52</td>
<td>Spotwelds+++</td>
<td>No acetabular component mobility</td>
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<tr>
<td>2</td>
<td>Major groin pain on the ‘hop test’</td>
<td>62</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Major groin pain on the ‘hop test’</td>
<td>60</td>
<td>Reactive line</td>
<td>No osteolysis</td>
</tr>
<tr>
<td>4</td>
<td>Major groin pain on the ‘hop test’</td>
<td>55</td>
<td>Reactive line</td>
<td>Integrated femoral stem</td>
</tr>
<tr>
<td>5</td>
<td>Groin pain and instability on clinical testing</td>
<td>60</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

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Distribution of groin pain (a) and aseptic acetabular component revision (b) according to acetabular component inclination. Both histograms show a harmful effect of high acetabular component inclination.
200 Durom resurfacings, with only one acetabular failure at an average follow-up of 4.6 years. Vendittoli et al\textsuperscript{43} had no acetabular component failures at a mean of 24 months in their series of 64 resurfacings.

Only one factor, an acetabular component inclination angle of $>50^\circ$, appears to increase the risk of postoperative pain and subsequent revision. Mont and Schmalzried\textsuperscript{44} noted that the bending moment placed on the acetabular component by lateral head contact may reduce the extent of bone ongrowth, and compromise secondary fixation. It is also possible that the porous surface of the Durom acetabular component may also play a role. In our series, there was no bone ongrowth in four of the five explanted components. For effective secondary bone fixation, it seems to be accepted that the pore size of the surface covering should be between 100 $\mu$m and 400 $\mu$m.\textsuperscript{45-49} Bobyn et al\textsuperscript{45} noted that fixation was weakest with a pore size between 20 $\mu$m and 50 $\mu$m, which is virtually identical to those on the Durom components that we implanted (20 $\mu$m to 60 $\mu$m), although the nature of their surface covering was different.

There were specific problems relating to the design of the Durom acetabular component. The three 0.5 mm peripheral fins on the component effectively increased its outside diameter by 3 mm. In order to obtain adequate primary fixation these had to be completely sunk into acetabular bone. Despite this there were gaps in 35 hips, albeit asymptomatic, and 33 hips had an inclination of more than $50^\circ$ which proved to be the main factor in groin pain and revision. We believe that, in sclerotic bone, the fins may not be sufficiently engaged, which reduces the surface area of contact between the bone and the implant, thereby impairing secondary bone fixation. This effect is potentiated by the relative failure of the coating to promote bone ongrowth because of its inadequate pore size.

We noted an abnormally high incidence of groin pain in 18 hips (18%). This was three times higher than that encountered when the same surgical team used the Armor acetabular component (Centerpulse-Zimmer GmbH, Winterthur, Switzerland) with the same femoral component.\textsuperscript{1} Except in the cases with defective acetabular fixation (10%), groin pain was due to iliopsoas impingement (8%
of patients in the series). Its prevalence was ten times higher than that reported by Ala Eddine et al50 (4.4%) and by Bricteaux, Beguin and Fessy51 (4.3%). We believe this is due to the prominence of the fins.

The diagnosis was suspected clinically and confirmed by CT-guided injection of local anaesthetic into the iliopsoas bursa.52 In each case the CT scan showed anterior prominence of the acetabular component (Fig. 4), which placed the fins in contact with the tendon of iliopsoas. A component inclination > 50° significantly increased the risk of iliopsoas impingement (p = 0.02). The management of iliopsoas impingement whether by infiltration, tenotomy, or prosthesis exchange) remains controversial.50,51,53,55 Prevention remains the best treatment: sufficient acetabular component anteversion prevents protrusion of its anterior rim: excessive opening of the component should also be avoided.

We found a significant incidence of post-operative gaps (35%) in our series. Full impaction did not ensure proper embedding, consequently, we made reference marks on the acetabular rim once the tried implant was correctly positioned in order to ensure that the component was properly seated. After this change in our surgical technique, we saw no further gaps. However, groin pain did not disappear, and this, combined with our identification of poor bone ongrowth (Fig. 3) in five acetabular component removals, prompted us to abandon the design.

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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.

Supplementary material

Three further figures are available with the electronic version of this article on our website at www.jbjs.org.uk

References


