Large diameter head metal-on-metal bearings total hip arthroplasty: Preliminary results

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Accepted: 14 September 2009

KEYWORDS
Total hip arthroplasty; Large diameter; Large size head; Metal-on-metal bearings

Summary
Introduction: Although the use of the metal-on-metal bearings has been validated over the long term in total hip arthroplasty (THA) for standard 28 and 32 mm diameters, and over the medium term in resurfacing procedures, the use of larger metal head size in conventional THA has not yet been extensively reported.
Hypothesis: The large-diameter metal-on-metal head is beneficial in terms of implant stability without altering the result in terms of function and bone fixation compared to the standard 28 and 32 mm diameters.
Objective: The objective was to test this hypothesis by assessing the short-term clinical and radiographic results of a metal-on-metal large-diameter heads THA system, using cups from the resurfacing hip concept.
Material and methods: We conducted a retrospective study on a continuous series of 106 un cemented acetabular cups (Durom™) implanted in 102 patients (mean age, 66 years): 93 cases of primary or secondary coxarthrosis, 11 cases of aseptic osteonecrosis, one fracture of the femoral neck, and one case of rheumatoid arthritis of the hip. At 30 months of follow-up, the Harris Hip Score and the Merle d’Aubigné (PMA) score were calculated. The radiological investigation included comparison of the implant head with native head diameters, variations of acetabular center of rotation, inspection for implant migration, and search for a gap or radiolucent line.
Results: The series included two post-traumatic dislocations as well as spontaneously receding tendinitis of the gluteus medius with no further recurrence. The mean Harris Hip Score improved from 49.3 preoperatively to 91.6 at the latest follow-up and the mean PMA score ranged from...
12 to 17. The results were excellent for 70 cases, good for 31 cases, fair for three cases, and poor for two cases. In the last five cases, the overall results were undermined by low pain subscore, with no identifiable explanation. Restoration of the original head diameter was verified for 65 hips. No cup migration was observed. Measurement of the acetabular centre of rotation showed a mean lateralization of 1.1 mm. Of the 67 immediate postoperative gaps, only two did no disappear at follow-up. Implant head diameter, cup position, and the existence of a gap were not correlated with the clinical results.

Discussion: These results are comparable to 28 mm-diameter metal-on-metal heads in uncremented cups but with improved stability but without demonstrable alteration of the quality of the bone fixation. We found no mechanical or medical cause that could explain the five cases of persistent pain leading to fair or poor results. Long-term follow-up will validate these theoretical advantages in terms of wear and implant survival.

Level of evidence: IV. Retrospective series.

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Introduction

The use of Metasul in hip replacements since 1988 [1] was validated based on retrospective studies of first-generation metal-on-metal (MOM) total hip prostheses [2,3] and particularly the analysis of explants [4]. Its clinical results were the subject of many publications, particularly reporting young patients, with excellent long-term results [5]. At the same time, several teams [6,7] sought to optimize this MOM head in hip resurfacing procedures reintroduced in Great Britain by McMinn et al. [8], with a 95.3% 5-year survival rate according to Amstutz and Le Duff [9]. Modifications in the geometric characteristics of the head were secondarily applied to Total hip arthroplasty (THA) with theoretical benefits in implant wear and clinical benefits in terms of stability. With the objective of clinically validating these benefits, we report the results of a continuous series of 106 THAs using a Durom large-diameter MOM head with a minimal follow-up of 2 years.

Material and methods

Implants and operative technique

The Durom cup (Fig. 1) is a monoblock implant in Metasul wrought-forged high-carbon cobalt-chrome alloy (Cr: 26–30%, Co: balance, C: 0.05–0.3%, Mo: 5–7%), providing good resistance to corrosion. The cup range extends from 44 to 66 mm in diameter. The size includes 2 mm press-fit fins. The corresponding heads range from 38 to 60 mm.

The 3.7-mm-thick implant is covered with a 0.3 mm layer of porous titanium (Porolok). The minimal thickness was determined so as to ensure that the cup deforms less than 25 μm on impaction and less than 30 μm on loading. The 165° acetabular component is less than a hemisphere, flattened by 0.8 mm at the summit, thus allowing an equatorial press-fit fixation. The circumference of the cup is equipped with three fins for improved primary stability. The titanium coating, projected on the Co-Cr with a plasma torch, has a porosity of 25% ± 10% and roughness between 100 and 250 μm (Fig. 2).

The corresponding prosthetic heads are two-thirds of a sphere and have an 18/20 conical orifice receiving modular neck adaptors on Morse 10/12 and 12/14 tapers with three neck lengths available. Clearance is 150 μm, fixed for 38- to 56 mm joint diameters, slightly larger for 58- and 60 mm joints. Roughness is less than 0.005 μm and the deviation from spherical form less than 10 μm.

All surgeries were performed via the posterolateral abridged approach, preserving the joint capsule to provide lubrication of the operated hip, and using millimeter-level
reaming 1 or 2 mm above the cup’s nominal diameter to obtain press-fit 2 or 1 mm in the implant’s equator. More than half the cups used were size 50, 52, and 54, with the corresponding heads measuring 44, 46, and 48 mm, respectively. The femoral pivot was a cemented self-blocking, Muller-type stem in 78 cases and an Emeraude™ cementless stem in 28 cases.

Complete weightbearing and unrestricted walking were authorized beginning on the 2nd day after surgery. The patients were free to move about as they liked, with no postural instructions. The patient was also free to stop using canes as needed.

Patients

We retrospectively studied a continuous series of 111 THAs including 107 patients, operated on between June 2003 and October 2005. All the patients were in good general health, with normal renal function and sufficiently good bone quality for cementless implants and a MOM head. Sixty-four implantations were carried out in the Amiens University Hospital Orthopaedic Department, 28 at the Rennes Private Clinic, and 19 at Péronne Hospital. Three patients were lost to follow-up and two have died since their surgery of causes not related to the orthopaedic intervention. A total of 106 THAs (102 patients) were evaluated at revision. The mean follow-up was 30 months (range, 2 – 5 years).

The series included 61 women and 41 men with a mean age of 66 years (range, 32 – 87 years) at the time of surgery. According to the Charnley classification, 63 patients were classed A, 34 B, and five C. The patients’ activity level was assessed using the Devane score: 54 patients were classed 2, 40 were classed 3, and eight were classed 4. The etiologies were 83 cases of primary coxarthrosis, 11 cases of aseptic osteonecrosis, seven cases of secondary coxarthrosis (Fig. 3), two cases of coxarthrosis with acetabular dysplasia, one case of rapidly degenerative coxarthrosis, one fracture of the femoral neck, and one case of rheumatoid arthritis of the hip. The right hip was involved in 59 patients and the left hip in 47.

Assessment methods

The clinical analysis was based on the Harris Hip Score and Merle d’Aubigné (PMA) score before surgery and at the last follow-up. Two groups of patients were identified from the final Harris score. One group included the good and excellent results, the other the fair and poor results. The radiological analysis was performed preoperatively, postoperatively, and at the last follow-up, it included digitized AP views of the pelvis and AP and lateral views of the hip.

The measurements were taken using Imagika™ (View Tech™) software that allowed correcting the enlargement index brought to the diameter of the implant head and automatic calculation of the center of rotation based on three points placed at the periphery of the head. Two patients whose images did not respond to the reliability criteria as defined by Massin et al. were excluded from the radiological analysis.

The ratio of the diameters of the implant head and the native femoral head was calculated for each patient. The diameter was considered restored for a ratio between 0.95 and 1.05, reduced for a ratio less than 0.95, and increased for a ratio greater than 1.05.

The acetabular offset was measured between the symphysis pubis and the center of rotation of the native hip and the prosthesis. Medialization or lateralization was defined by a variation greater than 5 mm. The femoral offset was measured between the diaphyseal axis and the center of rotation on a line perpendicular to the diaphyseal axis. Cup migration was searched for using the Engh and Massin criteria, considering as significant a variation in height greater than 3 mm compared to the teardrop line, and/or an inclination variation over 6°.

Finally, the presence of a postoperative gap was sought, as well as the possible appearance of a radiolucent line, osteolysis, or reactive condensing line. The presence of a femoral radiolucent line or heterotopic calcifications was also noted.

The statistical calculations were made using the chi square test corrected for the number of patients, compar-
ing the two groups of patients defined using the Harris Hip Score, with a significance threshold set at 0.05.

Results

Complications

Two traumatic dislocations occurred in our series (1.8%), one immediately after surgery following a fall from bed, the other 3 years after surgery, secondary to a fall from a height. They were reduced orthopaedically, with no recurrence and with an excellent final result. One patient presented tendinitis of the gluteus medius resolved after localized infiltration. A pathological fracture of the obturator ring in a case of uterine cancer occurred 22 months after implantation, with no functional consequences, and consolidated after radiotherapy.

Clinical results

The mean Harris Hip Score (Table 1) increased from 49.3 (range, 12—81) to 91.6 (range, 58—100), with 70 results that were deemed to be excellent (66.2%), 31 good (29.2%), three fair (2.8%), and two poor (1.8%). The PMA score (Table 2) improved from 12 (range, 6—15) to 17 (range, 10—18) at the last follow-up. The mean flexion in the series was greater than 120° with most patients being able to squat with the heels in contact with the buttocks. The five fair and poor results were related to low pain subscore. These five patients presented diffuse pain, predominantly inguinal, with no patent sign of psoas tendinitis. This pain did not increase when standing on one foot and hopping was possible. Three had localized infiltration therapy, which provided moderate and transitory relief. The allergy tests remained negative. The chrome and cobalt serum rates, measured because of the pain symptoms, were not abnormally increased for these patients and no significant radiographic abnormality was observed. None of these patients took long-term antalgic treatment. It should be noted that the two patients presenting a poor result did not find their pain sufficient to undergo revision surgery.

Radiologic results

The ratio between the implant head and the femoral head was a mean 1.03 (range, 0.9—1.14), with a diameter deemed to be restored in 65 cases (61.3%), increased in 35 cases (33%), and reduced in six cases (5.7%). No statistically significant difference in the final clinical result was demonstrated in relation to this ratio (Fig. 4). Anteversion could not be detected with this type of implant. The mean cup inclination was 48.6° (range, 31—93°). One patient presented excessive verticalization of the cup (> 90°), but had refused early revision proposed by the operator (P.T.). He presented an excellent clinical result at 30 months of follow-up. There was no significant difference in cup orientation in relation to the groups formed based on the clinical results. No cup migration was observed at revision. The variation in the center of rotation position was a mean 0.07 mm horizontally and 0.06 mm vertically, never more than 3 mm. The variation in inclination was a mean 0.46° (−6° to +6°) and never more than 6°. The mean acetabular offset increased from 88.6 to 89.7 mm with a mean 1.1 mm lateralization (range, −12 to +17 mm). The mean femoral offset decreased from 36.1 to 35.7 mm, with medialization of 0.4 mm (range, −33 to +13 mm). Sixty-seven cups (63.2%) presented an immediate postoperative gap, 43 (40.5%) of which involved a single De Lee and Charnley zone, 59 (55.7%) were spread over two zones, and four (3.8%) covered the entire acetabular contour. In 10 cases (14.9%), these gaps were more than 2 mm deep. Of these last 10 patients, nine results were excellent and one was good. No statistically significant difference in the final clinical result was observed between the patients who had a postoperative gap and those who did not present one. Only two (3%) of these gaps had not filled at the last follow-up. The clinical result was excellent in these two patients. In addition, seven reactive condensation lines (6.6%) at the bone—implant interface appeared at revision, always after a postoperative gap. Four of these periacetabular condensations spread over zones I and II; three involved a single zone only. All of these patients had a good or excellent final clinical result. Periprosthetic ossifications were found.

### Table 1 Harris Hip Score.

<table>
<thead>
<tr>
<th>Harris score</th>
<th>Preoperative</th>
<th>At follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>13</td>
<td>42.3</td>
</tr>
<tr>
<td>Mobility</td>
<td>7.53</td>
<td>8.7</td>
</tr>
<tr>
<td>Function</td>
<td>28.7</td>
<td>40.6</td>
</tr>
<tr>
<td>Total</td>
<td>49.3</td>
<td>91.6</td>
</tr>
</tbody>
</table>

### Table 2 Postel-Merle d’Aubigné score.

<table>
<thead>
<tr>
<th>Postel-Merle d’Aubigné score</th>
<th>Preoperative</th>
<th>At follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>3</td>
<td>5.6</td>
</tr>
<tr>
<td>Mobility</td>
<td>5.3</td>
<td>5.7</td>
</tr>
<tr>
<td>Stability</td>
<td>3.7</td>
<td>5.6</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>17</td>
</tr>
</tbody>
</table>

In addition, the three patients lost to long-term follow-up had all been seen at 1 year and had an excellent clinical result. None of the patients lost to follow-up or deceased presented dislocation in the 1st postoperative year.
in 31 patients (29.2%): 13 grade 1, 10 grade 2, and eight grade 3. In four cases (3.8%), a femoral radiolucent line was observed at the bone—cement interface, with three in Gruen zone 1 and one in zones 1 and 7. All of these patients had a good or excellent clinical result. No osteolysis was visible at the femur or the acetabulum.

Discussion

Clinical results

The preliminary results of this series are comparable to those published for 28 mm Metasul™ MOM femoral heads combined with cementless fixed acetabular cups. Migaud et al. [14] found a mean score of 94.9 points at a mean follow-up of 68.7 months in 39 patients under 50 years of age who had had cementless Ti-6Al-7Nb acetabular cups (Zimmer GmbH). They observed no osteolysis, no migration, and no dislocation, with no surgical revision performed.

Similarly, Lombardi et al. [15] found a mean score of 93.1 points at a mean 5.7 years of follow-up in a multicenter prospective study of 53 patients who had undergone implantation of 28 mm MOM cementless prostheses. No significant difference was found for 46 protheses of the same type that used a metal-on-polyethylene bearing system. The authors noted three cases of dislocation reduced orthopaedically with no recurrence.

Saito et al. [16] reported the results of 106 Metasul™ 28-mm-diameter implants with cementless fixation reinforced by five screws. The final Harris Hip Score was 87.8 points at a mean 6.7 years of follow-up. No osteolysis or loosening was noted. Six patients presented a dislocation (5.7% of the series), including one recurrence.

In our series, at a mean 30 months of follow-up, the mean Harris score was 91.6 points (range, 58–100), with 95.3% good or excellent results. Of the fair or poor results observed (five cases), no cause could be demonstrated explaining the persistent pain.

Stability

The use of large diameters increases the distance that the prosthetic head must cover to come out of the cup and dislocate, as described by Huten [17]. This distance, called AB and defined by the formula: 

\[ AB = R_{head} \cdot \sqrt{2(1 - \cos \alpha)} \]

is proportional to the implant head, but also depends on the cup inclination. This distance, increased in dual-mobility cups, partly explains the advantages of these implants in terms of stability, confirmed by Philippot et al. [18] in a large multicenter series.

The long-term results of the MacKee-Farrar implants reported by Jacobson et al. [19] showed few dislocations despite a highly unfavorable head–neck ratio. This clear advantage in cup stability of the large diameters has even motivated Beaulé [20] to propose using 40- to 50 mm heads with custom-designed polyethylene inserts for treating recurring dislocations. The large diameters also make it possible to reduce dislocations by impingement [17], with marks often found on the explants, in particular during revisions for dislocation [21]. In a cadaver study, Bartz et al. [22] and Krushell et al. [23] observed no significant difference in the onset of impingement in hip flexion between the 28- and 32 mm heads. The neck–cup contact, directly dependent on the head–neck ratio, is considerably reduced only with large diameters. In an anatomic simulator study, Burroughs et al. [24] showed that impingement did not disappear beyond a 38 mm diameter, whereas they found 47% neck–cup contacts in the extreme positions with the 32 mm diameter. Eliminating these neck–cup impingements is even more important with MOM heads, because of the sometimes catastrophic effects of the debris from wear, thus justifying the use of a minimal 32-mm-diameter Metasul™ according to Migaud et al. [25].

The dislocation rate (1.8%) found in our series, despite the absence of immediate postoperative preventive instructions to the patients, confirms the notable improvement in implant stability compared to series using a 28 mm-diameter head. In comparison, Philips et al. [26] reported a 3.9% dislocation rate based on Medicare data (USA) of 60,000 THAs and Von Knock et al. [27], who reported a 2.9% rate on a continuous series of more than 16,000 THAs at the Mayo Clinic. Moreover, this incidence was higher for posterior approaches and reached 4–9.5% in a meta-analysis done by Weeden et al. [28]. In addition, in a randomized study comparing 78 THAs using 28 mm heads and 616 THAs with 38 mm heads, Cuckler et al. [29] found 2.5% dislocations at 3 months in the 28 mm group and none in the 38 mm group. Similarly, in a continuous series of 469 THAs using 38- to 56 mm heads, Peters et al. [30] found 0.04% dislocation at a mean follow-up of 36 months. Finally, it must be remembered that the two cases observed in our series had a traumatic etiology, one of which was in the immediate postoperative period. However, we believe that these implants should not be used as an antidislocation system, since their stability remains inferior to dual-mobility cups.

Joint range of movement

Although mobility needs vary from one culture to another (greater in Asia), and with age and sex, hip arthroplasty is increasingly intended for patients who remain active and request a more complete functional restoration beyond pain relief. Mulholland et al. [31] and Pedersen et al. [32] emphasized the need to obtain hip flexion greater than 120° for normal practice of daily activities. Yoshimine and Ginbayashi [33] also determined that maximal range of motion depended on cup inclination but particularly on the head–neck ratio when defining the oscillation angle θ (θ = A − 2sin⁻¹(1/2[col/R])) measured between two extreme neck positions. They recommended respecting an angle θ > 135° to prevent any impingement, whereas most of today’s implants have an angle θ between 100 and 130°. The increase in head diameter logically increases the joint oscillation angle; a 38/44 mm Durom™ cup allows flexion greater than 140°, whereas the minimal value recommended by the European norm EN ISO 12563 is 80°. However, although the mobility score results are very good (8.7/9 Harris score, 5/6 on the PMA score), they only partially reflect the joint range of motion values obtained (deceptive on the Harris score, with flexion > 90° considered optimal on the PMA scale).
Tribology and wear

The high-carbon Co—Cr—Mo alloy has long been recognized as the reference material for MOM prostheses. The femoral head diameter seemed important to consider given that resurfacing had become attractive for younger patients. Testing 36- and 54 mm prostheses in cast Co—Cr, Dowson et al. [34] found, respectively, wear at 1.25 and 0.79 mm$^3$/million cycles in the break-in phase and 0.35 and 0.17 mm$^3$/million cycles in the stationary phase (after 5 million cycles). Co—Cr wear was so low after 5 million cycles on a simulator that Saikko [35] was not able to measure any geometric differences on the profilometer (Taylorround) for a 50 mm MOM head. They reported a wear factor 275 times less than with a 28 mm metal-on-polyethylene head.

The amount of head—cup clearance on MOM bearing wear had already been emphasized by the analysis of old MOM prostheses. In a study of 17 explants (six Huggler and 11 Muller) with a mean follow-up of 11 years, Weber [4] demonstrated relatively little wear (<5 μm/yr) for clearance between 120 and 200 μm. In a series of McKee prostheses, Lu et al. [3] found increased wear when the clearance increased from 127 to 386 μm. The results of a study conducted by Chan et al. [36] on 16 implants, 28 mm in diameter (seven wrought-forged LCs, two wrought-forged HCs, and seven cast HCs), whose clearance varied from 30 to 110 μm tested on a simulator for 3 million cycles clearly demonstrated that wear increased exponentially with clearance, more so than with the differences in the material’s structure. Smith et al. [37] were the first to evaluate the influence of clearance on the large diameters. Testing the 54 mm diameters, they found four times less wear when breaking in and two times less in the stationary phase for clearance between 80 and 120 μm compared to clearance between 250 and 300 μm. Similarly, Rieker et al. [38] showed a reduction of nearly 70% in near linear wear when reducing head—cup clearance from 300 to 100 μm, with less wear in the breaking-in phase, leveling off during the stationary phase, contrasting with the linear measurements observed with large clearances. However, lowering the head—cup clearance below a threshold from 50 to 100 μm could be unfavorable for wear because of the manufacturing tolerances and the implant deformation during impaction and loading. These latter considerations may be responsible for an equatorial contact reproducing jamming, as was demonstrated on the McKee-Farrar prostheses failures during the 1970s [39]. The Durom™ heads and cups manufactured in wrought-forged high-carbon cobalt-chrome alloy therefore propose tribologic guarantees of minimal wear. However, the follow-up of our series today is insufficient to clinically confirm these experimental data.

Delayed hypersensitivity

Allergic reactions seem to be greater after THA using a MOM head. They were respectively reported in 11% of cases by Willert et al. [40] as type IV delayed hypersensitivity reactions. All of the metallic alloy components as well as the cement, such as benzoyl peroxide, can nevertheless be the cause of allergic phenomena, as demonstrated by Granchi et al. [41]. The clinical cases reported in the literature show up in most cases in the first postoperative year, manifested by unexplained pain [42], a pseudo-infectious context [43], or early loosening as demonstrated on radiographic examination [44] because of the onset of bone necrosis. Epicutaneous tests and in vitro lymphocyte proliferation tests can be useful to substantiate the diagnosis of these allergies whose incidence was estimated at 1—2% by Thomas et al. [45]. Only a pathologic examination of capsule samples during surgical revision can confirm a hypersensitivity reaction when typical perivascular lymphocyte proliferation is found [46]. However, only an objective history of skin allergy to a metal should be taken into account in the choice of implants. On the other hand, even though we found no official cases in this series, these allergy problems could be the source of some of the pain worsening the results of our patients classified as having fair or poor results.

Conclusion

The early results of this series of large-diameter MOM THAs demonstrate an advantage in terms of stability compared to the results usually reported for series in the literature, with functional gain, but at the price of a 4.7% rate of unexplained pain. Only clinical and radiological monitoring of this cohort over the long term can validate the theoretical advantages in terms of wear and survival of these implants.

Conflicts of interest

P.M., P.T. Occasional consulting for Zimmer.

References


