Metal-on-Metal Bearings in Cementless Primary Total Hip Arthroplasty

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Abstract: One hundred cementless titanium primary total hip arthroplasties with 28 mm Metasul bearings were prospectively studied (osteoarthritis in 76% of hips, mean age 59.6 years). Ninety-eight were reviewed after a 6-year average follow-up (range, 17–126 months) with clinical results graded excellent and good in 97%. One femoral component was revised for aseptic loosening at 7.8 years. Postoperative cobalt level was higher than the upper "normal" value (5 μg/L in whole blood) for 16 cases. No significant relationship could be established between cobalt concentration increase and any demographic or surgical data, including activity level, except anteversion of the cup >25°. In this early experience, impingement due to a head sleeve has been the main cause of dislocation and failure, and systemic cobalt survey appeared to be a good indicator of metal-on-metal bearing mechanical behavior.
Key words: metal-on-metal, cobalt ions, impingement, total hip arthroplasty.

In young and/or active patients, the longevity of total hip arthroplasties (THA) with metal-on-polyethylene (PE) bearing surfaces remains impaired by osteolysis related to PE wear debris. In 2002, a study of the Swedish National Hip Registry showed that patients less than 50 years old who received total hip arthroplasty for osteoarthrosis were the "higher risk group" for aseptic loosening [1]. The author's personal experience with 28 mm alumina ceramic-on-PE in primary cementless Alloclassic THA was encouraging, with a 10-year survival rate of 99% with aseptic loosening (ie, radiographic failure) as the endpoint [2]. Nevertheless, a multicenter series with the same components in patients less than 65 years old indicated an overall PE wear rate greater than 1 mm (range, .12–21 mm) in 11.3% of 115 hips and osteolysis in 3.5% after an average follow-up of 7.8 years [3]. These data highlight the need for better wear-resistant bearings to improve THA longevity in the young and active patient population.

Over the past 15 years, worldwide experience with metal-on-metal (MOM) Metasul bearings (Zimmer GmbH, Winterthur, Switzerland) has been increasing with European Economic Community marketing in 1995, United States Food and Drug Administration approval in 1999, and more than 250,000 couples used to date. Reported clinical results of these bearings by Weber [4] have been favorable although local metallosis and potential toxic effects due to metallic debris dissemination, in particular hematocarcinogenic and immunoallergic risks, remain of concern to some clinicians or researchers [5,6].

The aim of this study was to provide preliminary clinical results of a series of cementless prostheses with Metasul bearings used in primary THA. Two different femoral head designs were used and the

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Fig. 1. The grit-blasted titanium Alloclassic modular SL-stem and CSF-threaded ring with Metasul bearings of the current design without a head sleeve.

clinical performance and blood cobalt levels of those cases that had a femoral head sleeve were compared with those without this feature.

Material and Methods

From January 1994 to March 1999, 100 cementless primary Alloclassic-Metasul THA (Zimmer GmbH) (proximally hydroxyapatite coated in 9 stems) with threaded CSF cups (Fig. 1) were prospectively studied. They represent 55% of all primary THA performed by the same surgeon during the study period. The first 22 THAs had an early-generation Metasul couple (with femoral head sleeves) and the subsequent 78 THAs had the currently available Metasul bearing (without head sleeves).

Patient Demographics

The mean age at surgery of the 89 patients (56 men, 33 women; 11 bilateral) was 59.5 years (range, 29–73), mean weight was 75.5 kilograms (range, 50–112) and mean height was 167 centimeters (range, 152–187). Twenty-seven hip replacements (27%) were performed in Charnley class C patients. Patient activity level was graded according to the system described by Devane et al. [7]. The diagnoses were osteoarthritis in 75 hips, dysplasia in 12 hips, head osteonecrosis in 10 hips, and post-trauma in 3 hips. All surgeries were performed through a posterolateral approach in a laminar air-flow theater. Antibioprophylaxis was conducted with a second-generation cephalosporin for 24 hours. Thromboembolic prevention was conducted with a low-molecular-weight heparin and elastic stocking for 1 month. Nonsteroidal anti-inflammatory medication (Indomethacin) to prevent heterotopic bone formation (HBF) was used routinely with a 75 mg daily dose for 10 days if well tolerated. Non-weight bearing was advised for 10 days, and then allowed with 2 crutches and full weight bearing as tolerated thereafter.

Clinical and radiographic examinations by the author took place at 10 days, 1–2 months, 6 months, 1 year, and annually thereafter. Clinical results were graded according to the Postel-Merle d'Aubigné and Charnley (PMA-C) scoring system with a maximum of 18 points [8]. Radiographic results were described according to the 7 femoral Gruen zones and the 3 acetabular DeLee and Charnley zones on anteroposterior films [9,10]. Femoral implant stability and osseointegration were assessed according to the system described by Engh and Massin [11]. Cup anteversion was estimated from plain radiographs according to the simplified method described by Widmer [12]. Wear was measured according to the method described by Livermore et al. [13].

Systemic cobalt concentration survey was initiated in 1997. At each follow-up visit, blood samples were obtained according to a specific technique that was strictly followed to prevent contamination of the sample (for example, nonmetallic needles were used and the first 5 cc of blood was discarded). Cobalt levels were measured in whole blood by atomic absorption spectrometry by the same laboratory (Claude Levy Laboratory, Ivry-sur-Seine, France). The detection limit for cobalt was 1 microgramme per litre (μg/L). Values less than 5 μg/L were considered normal according to the LCL Laboratory specifications, slightly higher than the 3.9 μg/L threshold reference recommended by the Associated Regional and University Pathologists (ARUP) Guide to Clinical Laboratory Testing.

Survival analysis was performed with the Dobbs life table and 95% confidence interval (CI) with the Wilson quadratic method. The relative influence of patient age, gender, activity level, and cup anteversion on cobalt ion level was analyzed. Both univariate analysis (comparison of means) and logistic regression analysis were used. For the logistic regression model, the cobalt ion level was categorized

as either $<5\mu g/l$ or $\geq 5\mu g/l$. Activity level was categorized as high (Devane 5 and 4) or low, and cup anteversion was categorized as $<25°$ or $\geq 25°$. The analyses were conducted using SAS version 8.02 (SAS Institute, Cary, NC). Differences were considered as significant for P value $<.05$.

Results

Complications

Postoperatively, 1 phlebitis was successfully treated with prolonged anticoagulation. There were 1 early and 4 late (more than 4 months following surgery) dislocations (5%). Three were treated by closed reduction with no recurrence thus far. Two of the 4 hips that dislocated late were revised for the following reasons. In a 69-year-old male patient, dislocation occurred 2.9 years after surgery, but closed reduction was unsuccessful and required reoperation. At surgery, the metallic ball was obviously scratched. Impingement was detected by macroscopic examination of the retrieved Metasul bearings. The second late dislocation occurred at 2 years in a 73-year-old male patient, and revision was performed 6 months later due to recurrent dislocation.

No macroscopic metallosis was observed at revision of these 2 hips; both stems and cups were apparently osseointegrated and stable and were left in place. Only the bearing surfaces were exchanged with an elevated rim polyethylene-liner (unavailable with Metasul inlay). These 2 bearings were of the original Metasul design that had long head sleeves and metallic cup rim edges that could create early impingement (Fig. 2).

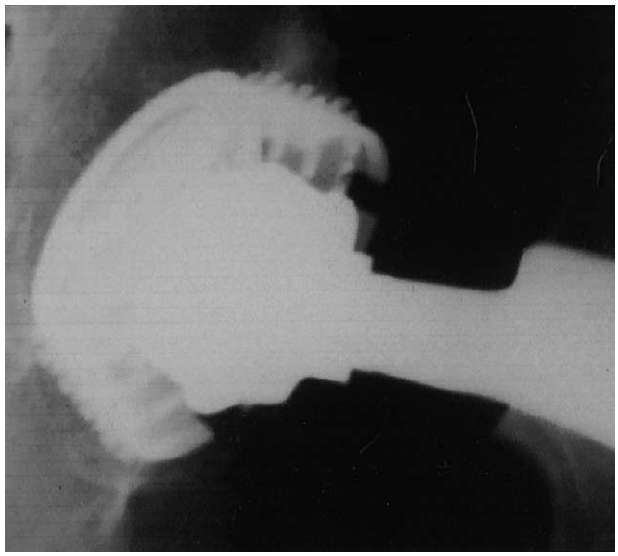

Fig. 2. Lateral view of the bearings of the early Metasul design of 1 of the 2 hips that dislocated late. Note the possible impingement between the head sleeve and the acetabular liner with the metallic rim edge. Note also that the artificial joint space is undetectable.

Clinical Results and Survival Analysis

At a mean follow-up of 6 years (range 17–126 months) 5 hips have been revised. In addition to the 2 dislocation failures, 1 hip with the nonsleeved femoral design was revised elsewhere at 17 months following index surgery for unexplained pain but cobalt concentration measurement was performed. Both components were stable and no metallosis was reported by the surgeon who performed the revision for a new Metasul total hip arthroplasty. One femoral component, with the sleeved design, was revised at 7.8 years in the author's institution for aseptic loosening with osteolysis in a 61-year-old active (Devane 4) female patient. Prerevision blood cobalt was 36 $\mu g/L$ and impingement due to Metasul head sleeve was confirmed intraoperatively. Another hip was revised in a 34-year-old active (Devane 4) male patient after 5 years *in situ*, despite excellent clinical result, because of a persistent high blood cobalt level that rose to 23.6 $\mu g/L$ before revision. At surgery, impingement between the extra-long sleeve and the Metasul inlay rim was obvious (Fig. 3A, B). Both implants were considered stable at surgery and only the bearings were changed.

Overall, complete pain relief, excellent range of motion, and perfect function were achieved in 83%, 68%, and 80% of hips, respectively. Mean PMA-C score increased from 11 points preoperatively to 17.3 points (maximum, 18 points) at last follow-up. The clinical results were graded excellent and good in all hips except for the revised cases and 1 patient who has multiple joint involvement due to neuromyopathic disease.

Survivorship of the index 100 Metasul-Alloclassic THA with stem and/or socket revision for aseptic loosening as the end point was 97.2% at 8 years (95% CI, 85.5–99.5%, with only 26 hips available for analysis at that last time point). At 8 years, the probability of revision of the Metasul bearings for any reason was 81.5% (95% CI, 57.7–93.5%) for the 22 couples with head sleeves and 98.7% (95% CI, 82.1–99.9%) for the 78 couples with the current Metasul design without head sleeves. The difference between revision rates of the early Metasul design (4/22, 18.2%) and the current design (1/78, 1.3%) was significant ($P=.008$).

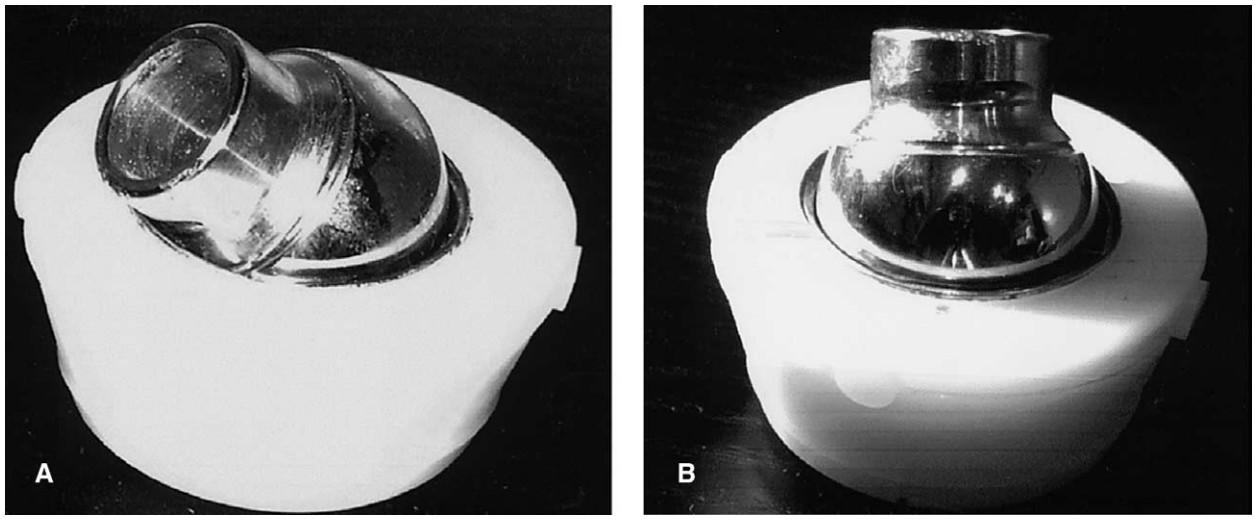

Fig. 3. The 1st generation Metasul bearings that were retrieved 5 years postoperatively for persistent elevated blood cobalt concentration that reached 23.6 μg/L 3 months before revision. (A) Obvious impingement between the extra long head sleeve and the metallic liner rim edge and (B) macroscopic evidence of fretting wear on the metallic sleeve.

Radiographic Results

On the femoral side of the arthroplasty, immediate postoperative radiographs showed varus stem position and proximal gaps in 17% and 3% of hips, respectively. At last follow-up (98 hips), calcar atrophy and spot welds were observed in 94% and 86% of hips, respectively. Proximal and reactive lucent lines (Gruen zones 1 & 7) were noted in 4.1% and proximal stress shielding in 5.2%. Besides the described hip with femoral osteolysis, 1 other hip in a 51-year-old, very active (Devane grade 5, 106 kgs) male baker showed proximal femoral osteolysis at 7 years (PMA-C, 17 points; blood cobalt, 4.2 μg/L). At last follow-up, osteolysis had not progressed and clinical results remained very good (17 points) with no pending revision.

On the acetabular side, immediate postoperative radiographs showed that threaded cups were implanted in mild protrusio and in abduction (>55° with the bi-ischiatic line) in 7% and 13.6% of hips, respectively. In 5 hips, cup anteversion with the Widmer method was greater than 25° (range 26–36°). Immediate postoperative gaps were noted in 37% but, at last follow-up, gaps had disappeared around 26 of these 37 cups. The previously described hip that was revised for femoral aseptic loosening showed slight osteolysis in acetabular DeLee and Charnley zone I, but the threaded cup was perfectly fixed at revision and was thus kept *in situ*. At 6-year mean follow-up, no wear was detectable between the immediate postoperative and the last frontal views for the 97 Metasul THAs available for this comparative study.

Measurement of Cobalt Ions

These 100 Alloclassic-Metasul THAs were implanted in an active population with 33% of patients graded 4 and 5 and no grade 1 in the Devane

Table 1. Overall Distribution of Cobalt Values in Whole Blood (Detection Limit, 1 μg/L)

Annual Follow-up (years)	Number of Hips Tested	Number of Hips With Co > 1 μg/L (%)	Mean Co Value (μg/L)	Maximum Co Value (μg/L)
1	40	26 (65%)	3.6	14
5	39	19 (49%)	3.8	25
7–9*	33	11 (33%)	2	4.2

Co = cobalt.
*After exclusion of the maximal value of 36 μg/L in the patient revised at 7.8 years.

classification system. In 99 hips available for study, postoperative cobalt concentration in whole blood (Table 1) remained below the detection limit (1 μg/L) in 23 but increased in 76 cases. Of those 76, postoperative blood cobalt level remains in the CL laboratory "normal range" (1–5 μg/L) in 60, but was noted at least on 1 occasion to exceed the upper "normal" value (>5 μg/L) for 16 THAs in 15 patients. A mechanical cause was suspected for 1 of them that dislocated at 4 months (nonrecurrent thus far), suggesting chronic impingement, and impingement with fretting wear was verified in the 2 aforementioned hips that were revised. A professional exposure was suspected in another patient who had worked 35 years in a mirror factory. For the remaining 11 hips (after exclusion of 1 case with abnormal preoperative cobalt level), no explanation can be offered.

Comparing the group of 16 hips that showed at least 1 increase in blood cobalt level greater than 5 μg/L to the 83 hips with no such increase, no statistically significant relationship could be established between elevated cobalt and patient demographics (including age (P=.61, R2=.45%), sex (P=.70, R2=.25%) and activity level (P=.44, R2=1.03%)), clinical results, or radiographic data, except high anteversion of the cup (>25°) noted in 4 of those 16 hips (P=.0037, R2=13.9%). In addition, the 4 corresponding prosthetic heads were of the early Metasul design with a sleeve that reduced the prosthetic joint range of motion. This combination of high anteversion and head sleeve may undergo posterior impingement. Such a situation was demonstrated at revision of 2 of these 4 THAs that showed the highest cobalt level of the series (23.6 and 36 μg/L). In addition, blood cobalt levels decreased spontaneously back to the "normal" range at the last available follow-up for 10 of the 14 other hips that showed at least 1 excessive cobalt value.

Discussion

Dislocation With Metal-on-Metal Bearings

In this series, the dislocation rate of metal-on-metal THAs (5%) was quite high. Of the 5 hips that dislocated, 3 belonged to the group of 22 hips with head sleeves. Since 1995, when the original Metasul head sleeve design was replaced by the current ball that had no sleeve, the author has observed a reduction in dislocation rate between THAs with sleeve head (13.6%) and THAs without sleeve (2 out of 78, 2.6%). Nevertheless, this difference does not reach the level of significance (P=.12).

In a clinical investigation comparing the rate of dislocation of another 28 mm metal-on-metal combination (Ultima, Johnson & Johnson, Leeds, UK) versus an alumina-on-PE bearing, Clarke et al. [14] found a dislocation rate of 0.9% and 6.2%, respectively, and this difference is significant (P=.02). Additional *in vitro* investigation revealed that the MOM bearing generated significant resistance to separation at all velocities. These authors concluded that MOM bearings were more stable to dislocation than ceramic-on-PE bearings as a result of the interfacial forces ("suction fit") provided by a thin, lubricating fluid. We verified this information in a series of 371 consecutive primary Alloclassic-THAs without sleeved components performed by 1 surgeon through the same posterolateral approach as that used by Clarke et al. Four of 170 THAs (2.3%) with the current 28 mm Metasul bearings and 14 of 171 THAs (8.2%) with 28 mm alumina ceramic-on-polyethylene bearings dislocated, and this difference in dislocation rate was also significant (P=.03) [15]. In light of these data, we can hypothesize that the 5% rate of dislocation observed in this study was mostly due to the reduction of the range of motion induced by Metasul head sleeve and not to the metallic nature of the bearing surfaces.

Cobalt Level Survey

In this series, no wear could be detected according to the method of Livermore et al. at 6 years average follow-up. In fact, usual radiographic methods are not helpful for the determination of wear of MOM bearings. As cobalt represents 60–70% of the Protasul-21 WF alloy, a survey of the systemic cobalt level (in whole blood or serum) could thus become the earliest helpful indicator of MOM *in vivo* function. This was suggested in 1997 by Brodner et al., who showed that MOM cementless THA could generate systemic cobalt release [16]. The same team recently published updated results in a group of 50 Alloclassic-Metasul THAs, with a median serum cobalt concentration of 1 μg/L and .7 μg/L at 1 and 5 years, respectively [17]. In our study, median blood cobalt concentration was 3.6 and 3.8 μg/L at 1 and 5 years, respectively, but comparison between these data is difficult due to the fact that measurements were performed in serum in the Brodner et al. study (serum cobalt reference interval of .1–4 μg/L according to the ARUP'S Guide), and in whole blood in our study (blood cobalt reference interval of .5–3.9 μg/L). Nevertheless, in these 2 studies, no significant correlation could be found between sys-

temic cobalt concentration and age, male gender, or patient activity level.

In our biologic survey in whole blood, the higher cobalt concentration reached 36 μg/L after 7.7 years *in situ* with loosening of the corresponding THA femoral component (although at 5 years, the clinical result was excellent and the stem was radiographically osseointegrated). After femoral revision and use of a metal-on-PE combination, blood cobalt decreased from 10.5 μg/L at 10 days to 2.5 μg/L at 2 months; and 2.2 years after revision, the clinical result was good (16 points) and blood cobalt was undetectable. The reasons for this femoral implant secondary aseptic loosening remain unclear, but histologic studies of tissue specimens performed by Prof. G. Willert showed cellular signs of delayed type hypersensitivity [18]. Because of this experience, the decision to change the MOM bearing for a metal-on-highly-cross-linked-PE combination was taken in another asymptomatic case that showed a high blood cobalt concentration of 23.6 μg/L at 4.7 years. One week after revision, blood cobalt fell to 8.8 μg/L and, 2 months later, the clinical result was excellent (18 points), the patient had returned to active labor, and blood cobalt had decreased to 3.9 μg/L. In both cases, impingement between the Metasul head sleeve and inlay rim was the cause of the metallic fretting wear and repeated blood cobalt measurements had never been in the reference range all along the survey. The long-term implications of increased cobalt levels are yet to be determined.

In this personal experience, impingement induced by head sleeves has been the main cause of failure, and cobalt concentration measurement has been a good indicator of the metal-on-metal bearing mechanical behavior. The absence of detectable wear and, above all, the lack of relationships among increased cobalt level, age, and high patient activity are encouraging findings for continued use of metal-on-metal bearings in young and/or active patients.

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