



Comparison of alumina-alumina to metal-polyethylene bearing surfaces in THA : A randomized study with 4- to 9-years follow-up

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We report the clinical and radiological results of 140 primary THAs, randomized to receive metal-polyethylene or alumina-alumina bearing surfaces. At last follow-up (average 79 months), no significant difference was found on clinical scores (WOMAC and Merle D'Aubigné) between the two groups. However, linear wear of 1 mm or more of the liner was observed in 89% (50/56) of polyethylene cases, whereas no measurable wear was noted in the alumina-on-alumina group. Calcar resorption was noted in 34% (19/56) of cases in the polyethylene group versus 6% (3/51) in the alumina group. Although no aseptic loosening was present in either group, 2 hips in the polyethylene group underwent revision for severe liner wear, and 2 more are pending. No specific complication was associated with alumina components. This study is in line with other reports indicating that alumina-alumina bearing surfaces have better wear properties than metal-on standard polyethylene and should be considered for THA in young and active patients.

Keywords : arthroplasty ; hip ; alumina ceramic ; polyethylene ; wear ; randomized.

INTRODUCTION

The introduction of metal-polyethylene bearing surfaces revolutionised total hip arthroplasty (THA) (19). It made THA a reproducible operation with excellent mid- and long-term results (6, 20, 51, 77). Historically, THA was first reserved for elderly

patients with end-stage disease (20). Later on, as indications for THA were extended to younger and more active patients (5, 17, 21, 29, 43, 86), the number of failures leading to revision hip surgery increased due to wear-induced osteolysis and biologic loosening of the implants at mid- and long-term (1, 73, 74).

Alumina bearing surfaces, introduced by Boutin in 1970 (12), demonstrated promising short-term results (36, 42, 63, 65, 82, 83). In the Boutin series with the first generation of alumina-alumina implants, after a follow-up of 20 years, 25 hips in 77 patients were revised (33%) mostly due to failure of the all ceramic cemented acetabular cup (37), which

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approximated the long-term results of Charnley's arthroplasties (6).

Alumina ceramic is composed of a hard bioinert substance which resists third-body wear (13, 60) and has good tribologic properties (better wettability, low coefficient of friction), which significantly decreases the volume of wear particles generated (27, 28). Many design and manufacturing factors determine the clinical outcome of alumina-alumina bearing surfaces: low percentage of impurities, low average grain size, small range of grain size distribution, optimal component sphericity, and optimal clearance between the head and cup (14, 28, 29). With modern alumina-alumina bearings, good results are obtained in the short-term in young active patients (10).

Other studies have reported problems with alumina-alumina bearing surfaces (52, 64, 91). These were related to poor alumina quality (89, 91), suboptimal component position (cup abduction > 45°) (2, 28, 47, 89), acetabular cup size inferior to 48 mm (37, 66), suboptimal femoral head design causing impingement and fracture (32), head size inferior to 32 mm or imperfect Morse type junction, both of which increase the risk of head fracture (67). Reported drawbacks of alumina-alumina bearing have included difficulty inserting the alumina liner into the metal-back shell (8, 31, 34), component fracture during surgery (33), restricted range of acetabular component sizes, limited head and neck size range, and the necessity of using alumina components for revision THA when a component fracture occurs.

Mid-term problems include: fracture of the femoral head (5-7 per 10,000 after 10 years of implantation) (16, 32), mechanical acetabular loosening attributed to a different modulus of elasticity between human bone (especially in the elderly) and alumina (36, 63, 79, 91). In addition, one case of carcinogenesis has been associated with alumina (71).

Skinner wrote: "Despite more than 25 years of clinical experience with ceramic materials as bearing surfaces, their role in modern joint replacement surgery remains to be clearly defined" (84). The objective of our study is to compare the clinical and radiological results on alumina-alumina to metal-polyethylene bearing surfaces in THA.

Table I. — Exclusion criteria.

Age less than 18 years or more than 70
Active infection of the hip
Severe osteoporosis compromising bone fixation of the implant
Non-cooperative patient
Severe instability of the hip
Pregnancy
Acetabulum of less than 50 millimetres diameter

MATERIALS AND METHODS

From 1996 to 2001, patients aged less than 70 years, with degenerative hip joint disease and candidates for THA, were recruited by 3 orthopaedic surgeons. The exclusion criteria are presented in table I. The research protocol was approved by the scientific and ethics committees and all subjects gave written informed consent before participating in the study.

Study design

Participants were randomly assigned to 2 treatment groups: metal-polyethylene and alumina-alumina bearing surfaces. A randomization table was created with Statgraphic Plus 2.2 software (Manugistics Inc., Rockville, MD, USA). Randomization was revealed by the research nurse to the surgeon in the operating room. The patient was kept blinded to the implanted bearing surfaces until 12 months after surgery.

Implants

The same hybrid THA was implanted in all patients (Ceraver Osteal, Roissy, France) (fig 1). The cemented femoral implant has a smooth titanium (TiAl) (78, 79) surface covered by a layer of titanium oxide (TiO₂). It has a collar and a cervico-diaphyseal angle of 132°. The uncemented acetabular implant is made of titanium. Screw holes are available for supplementary primary fixation, and a titanium mesh covers the outer surface for secondary fixation. The bearing surfaces were either an alumina insert with an alumina femoral head of 32 mm (78), or a polyethylene insert (Chirulen 1020, sterilized with ethylene oxide in 1996 and 1997, and with gamma irradiation in argon from 1997 to 2001) with a 28-mm stainless steel femoral head. The minimal acetabular shell size was 50 mm with alumina and 48 mm with polyethylene. No liner had an elevated lip.



Fig. 1. — Ceraver Osteal cemented femoral stem and acetabular component. Patients were randomized to receive an alumina insert and a 32-mm alumina femoral head or a polyethylene insert and a 28-mm stainless steel femoral head.

Surgical technique

One dose of intravenous antibiotics was administered pre-operatively and continued for 24 hours post-operatively (cefazolin 1 g or clindamycin 600 mg every 8 hours). The patients were positioned in the lateral decubitus position. Asepsis was performed with proviodine 1% solution, paper sheets were used for draping, and plastic fields covered the surgical area. An antero-lateral approach (modified Hardinge) was used in 122 hips (senior author, ND), and a posterior approach in the remaining 18 hips. The acetabular component was implanted according to a press fit technique with 2-mm under-reaming (23). Utilization of screws was left to the surgeon's discretion. The femoral canal was prepared with rasps only, and we attempted to insert the largest possible implant, as suggested by the manufacturer. The stem was cemented with low-viscosity cement (Simplex®, Styker, Allendale, NJ), according to a second-generation technique (62).

Functional evaluation

Clinical function was evaluated pre-operatively and at last follow-up with the Western Ontario McMaster Osteoarthritis Index (WOMAC) (3, 4, 50, 57) and the Merle d'Aubigné-Postel scale (25, 59).

Radiological evaluation

Antero-posterior radiographs of the pelvis and a lateral radiograph of the hip taken post-operatively and at last follow-up were analyzed. Femoral loosening was considered definite with: a continuous lucent line of more than 2 mm, cement fracture, stem fracture or vertical subsidence of more than 5 mm when measured from the centre of the femoral head to the most medial point of the lesser trochanter or to the tip of the greater trochanter (39, 54). Heterotopic ossification was recorded according to the Brooker *et al* classification (15).

The selected radiographs were scanned with a high-resolution (300 dpi) optical scanner (Vidar VXR-12, Herndon, VA, USA) and analyzed with Imagika™ software (View Tech, CMC Corp., NJ, USA) (35, 88). All radiographs were reviewed and measured by two orthopaedic surgeons. The assessment of radiographs was not done blind because of the difference in density between polyethylene and alumina. For statistical analysis, average values were used for scaled data. Linear head penetration of the acetabular liners was measured on digitized antero-posterior pelvis radiographs by changes in the vectorial distance between the cup and head centres (85). The vertical inclination of the acetabular component was measured by reference to a horizontal line between the teardrops; its height was measured from the distance between the inferior border of the cup and the inter-teardrop line (56). Femoral offset was evaluated by the perpendicular distance from the centre line of the femur to the centre of rotation of the femoral head (58). Acetabular loosening was classified as definite with continuous radiolucency of more than 2 mm, component migration of more than 3 mm, component rotation, or the presence of broken screws (56).

Statistical analysis

All statistical analyses were performed with SPSS 10.07 software for Windows (SPSS Inc., Chicago, IL, USA). Student's t test and the chi square test compared the 2 groups for continuous and categorical variables, respectively. Continuous variables are presented as mean \pm SD, and categorical variables as frequency and

Table II. — Patient Perioperative Data

	Metal-Polyethylene	Alumina-Alumina	p
Numbers randomised	69	71	
Sex			0.093
Male	38	30	
Female	31	41	
Age in years	56.8 (min 29, max 70, SD 10.7)	54.9 (min 23, max 70, SD 12.5)	0.317
Side			0.986
Right	38	38	
Left	31	33	
Weight (in kg)	73.5 (min 45, max 107, SD : 12.6)	77.4 (min 48, max 160, SD : 21.5)	0.188
Diagnosis			0.869
Osteoarthritis	43	44	
Femoral head avascular necrosis	10	11	
Hip dysplasia	4	2	
Epiphysis pathology	4	1	
Inflammatory disease	8	12	
Tumour	0	1	

percentage. To evaluate relationships between different factors with insert wear, the ANOVA regression test was applied. Significance was defined as $p < 0.05$.

RESULTS

One hundred and forty primary total hips in 116 patients were randomized : 69 in the polyethylene group, and 71 in the alumina group. Table II shows the demographic characteristics and differential diagnoses of the enrolled patients.

During follow-up, 7 THAs were considered as failures and clinical data collection was stopped after revision surgery : 6 cases for post-operative deep infection (5 patients, 5 alumina-alumina, 1 metal-polyethylene) and 1 case for early post-operative socket migration secondary to a non-displaced intra-operative acetabular fracture (metal-polyethylene group). Three patients (4 hips : 3 alumina-alumina and 1 metal-polyethylene) died during the follow-up period. Of the remaining 129 hips, we were unable to reach 10 patients for the last follow-up evaluation (1 bilateral THA, for a total of 11 hips, with a lost-to-follow-up rate of 7.9%). Ten patients did not attend the last follow-up

visit, but were by contacted and evaluated by telephonic interview (1 bilateral THA, for a total of 11 hips).

Thus, we are left with 96 patients with 118 THAs (75 unilateral and 22 bilateral, 60 polyethylene THAs and 58 alumina THAs) for clinical evaluation and 86 patients with 107 THAs (65 unilateral, and 21 bilateral, 56 polyethylene THAs and 51 alumina THAs) for radiological evaluation at last follow-up.

Average follow-up was 79 months (min 48, max 108). Hip dislocation occurred in 3 hips (all in the polyethylene group), 2 with a single episode, and 1 recurrent dislocation (still being treated conservatively). Both groups presented similar pre-operative function scores : WOMAC ($p = 0.986$) and Merle d'Aubigné ($p = 0.667$). Although significant improvement between the pre-operative and post-operative clinical evaluations (WOMAC ($p < 0.001$) and Merle d'Aubigné-Postel scores ($p < 0.001$)) was found for both groups, there was no significant difference between them at last follow-up (WOMAC ($p = 0.435$) and Merle d'Aubigné ($p = 0.447$)). Ninety-five percent (57/60) of the polyethylene hip patients reported a



Fig. 2. — Post-operative antero-posterior pelvic radiograph (65 months post-op) of a metal-polyethylene implant in a patient with severe wear of the acetabular liner.

good or a very good outcome with the Merle d'Aubigné score versus 93% (54/58) in the alumina group ($p = 0.722$).

On radiographic evaluation, polyethylene wear of 1 mm or more was measured in 89% (50/56) (table III). Average linear wear per year of implantation was 0.31 mm (min 0.09, max 0.55, SD 0.12). A significant correlation (ANOVA test) was found between polyethylene linear wear per year and reduced femoral offset (compared to contralateral normal femoral offset, $p = 0.015$) and elevated cup inclination ($p = 0.004$). There was no significant correlation between wear and length of implantation ($p = 0.0864$), sex ($p = 0.257$), age ($p = 0.132$), pre-operative activity level ($p = 0.59$) and Merle d'Aubigné score ($p = 0.992$). With the measurement technique used, we were unable to find significant liner wear in the alumina group. Signs of loosening, the presence of osteolysis and heterotopic ossification results are presented in table III. Although no aseptic loosening occurred in either group, 2 metal-on-polyethylene THAs were revised for severe liner wear, and revision is pending in two more, one for severe polyethylene wear > 3 mm (fig 2) and the other for progressive femoral osteolysis (fig 3A). In comparison, only one revision (1/58, or 2%) for progressing proximal femoral osteolysis (secondary with a small femoral stem which led to an oscillation) is pending in the



Fig. 3. — Two cases of progressive proximal femoral osteolysis, one in the metal-polyethylene group (A, 81 months post-op) and one in the alumina-alumina group (B, 54 months post-op).

alumina group (fig 3B). No osteolysis was noted on the acetabular side .

DISCUSSION

Bearings of choice for young active patients undergoing THA are still controversial. New bearings have been developed to achieve longer survival. Cross-linked polyethylene and metal-on-metal bearings have shown reduced wear in several *in vitro* and *in vivo* studies (40, 46, 49, 68). The long-term consequences of elevated systemic metallic ions secondary to wear of metal-on-metal bearings are unknown (87). Alumina is viewed as the bearing with the best tribologic properties and produces the least bioactive wear particles (38).

In the literature, only one prospective randomized study (24) compared the clinical and radiological results of alumina-on-alumina and metal-on-polyethylene implants. After a mean follow-up of 62 months, the revision rate was 2.7% for alumina and 7.5% for polyethylene. Although the authors found an association between femoral osteolysis and wear of the polyethylene liner, the average polyethylene wear per year was not reported.

Our study was of a similar design : prospective and randomized. Randomized clinical trials remain the study design of choice to compare the outcomes of different treatments (41). With this study design,

Table III. — Radiographic evaluation at last follow-up

	Metal-Polyethylene	Alumina-Alumina	p
N	56	51	
Vertical acetabular angle (degrees)	46.26 (min 18, max 68, SD 8.8)	45.13 (min 31, max 62, SD 7.1)	0.318
Total linear wear of acetabular liner (mm)	2.0 (min 0.8, max 4.5, SD 0.8)	0	<0.0001
Annual linear wear of acetabular liner (mm per year)	0.31 (min 0.09, max 0.55, SD 0.12)	0	<0.0001
Acetabular radiolucent line			
Continuous (3 zones)	0	0	
One or two zones	7% (n=4)	2% (n=1)	0.230
Acetabular loosening	0	0	
Femoral radiolucent lines			
Continuous (7 zones)	0	0	
One zone or more	7% (n=4)	8% (n=4)	0.882
Femoral osteolytic cavities	5% (n=3)	6% (n=3)	0.732
Calcar resorption	34% (n=19)	6% (n=3)	0.001
≥ 1 mm- 5 mm	30% (n=17)	4% (n=2)	
Down to lesser trochanter	4% (n=2)	2% (n=1)	
Femoral loosening	0	0	
Heterotopic ossification any grade (Brooker classification)	59% (n=33)	53% (n=27)	0.233
Grade 1	36% (n=20)	35% (n=18)	
Grade 2	2% (n=12)	16% (n=8)	
Grade 3	2% (n=1)	0%	

we were able to minimize bias related to patient factors influencing wear and THA results. We chose Ceraver Osteal implants because of the manufacturer's long experience with ceramic implants and the good mid- to long-term results published with this system (28, 37, 70). Even though suboptimal results have been associated with other titanium stems (90), the performance of the Ceraver Osteal® cemented stem is reportedly excellent (36, 65, 69, 70, 81). The Cerafit® acetabular implant also showed good mid-term results with 93.4% survival at 9-year follow-up (9, 36).

At last follow-up, our clinical results were good or very good for both groups, and patients in both groups were equally satisfied with their surgery. None of the reported peri-operative complications

directly related to the ceramic component occurred (fracture or malposition of the acetabular alumina liner) (31, 34). In our study, alumina-alumina THA did not incur any specific complications or increased peri-operative complication risk compared to metal-polyethylene THA. Four of the 6 THA infections developed during a short time period and were attributed to a sterilization problem at our centre, which was subsequently corrected. In one patient, bilateral hip infection was attributed to a late haematogenous spread.

As reported in the literature, young active patients are at risk for accelerated wear and failure with a metal-polyethylene THA. In our study, at an average 79 months of follow-up, significant linear wear was already observed in the metal-

polyethylene group (average 0.31 mm/year). Similar (11, 26, 92) or lower wear rates have been associated with metal-on-standard-polyethylene bearing components in young active patients (22, 45). We found a significant correlation between annual linear polyethylene wear, femoral offset reduction ($p = 0.0153$) and increased cup abduction ($p = 0.0044$). In other clinical studies, femoral offset restoration was shown to improve hip biomechanics and to significantly decrease polyethylene wear (72, 76). Increased cup inclination has also been reported to correlate with wear of the polyethylene liner (7, 44, 61). The suggested explanation for this correlation is that an excessively vertical position of the socket increases the articular load per unit of surface area, eventually leading to acetabular cup wear and supero-lateral migration of the femoral head (30,48, 53,75).

As demonstrated by Schmalzried *et al*, polyethylene wear is not a factor of time, but a factor of use (76). In fact, wear is related to many factors (activity level, cup inclination, femoral offset (58, 72, 76) but we were unable to find a statistically significant correlation between total polyethylene wear and the length of implantation ($p = 0.086$), sex ($p = 0.257$), age ($p = 0.132$) or pre-operative activity level ($p = 0.59$).

Similar rates of limited radiolucent lines or osteolytic cavities were noted in both groups (table III). However, there was a significant difference in calcar resorption : 34% in the polyethylene group versus 6% in the alumina group ($p = 0.001$). Since patients in both groups received the same cemented femoral implant, the difference in the incidence of calcar resorption in this series can only be related with the biological reaction in response to increased particulate debris in the metal-polyethylene group.

Because of polyethylene wear, 2 THAs were revised, and 2 more revisions are pending at an average of 79 months (4/60) ; in comparison, there has been no revision, and only one is pending (1/58) in the alumina group. Our patients were selected for this study because of their young age (less than 70 years old), their good health status and high activity level. If polyethylene wear follows the same rate (0.3 mm/year) over the next few

years, we expect high rates of osteolysis and aseptic loosening in the metal-polyethylene group.

The two severe progressive osteolytic lesions found (1 in each group, fig 3) need further discussion. These patients were asymptomatic ; their blood tests were normal, and their implants were in good position. The so-called "pump effect" could have been produced by collar oscillation under load of these titanium stems (similar cases were presented by D.R. Van der Jagt at the 2004 Combined Orthopaedic Associations meeting, Sydney, Australia). Joint fluid and particulate debris are pushed under pressure by the collar at the medial bone-cement junction, creating an osteolytic cavity in this specific area. The problem seems to be specific to cemented titanium stems with a collar. As discussed by Bizot *et al*, femoral osteolytic lesions could also, in some cases, be related with fretting of the titanium mesh which was present in the early type of Ceraver acetabular cup (9).

THA with alumina-alumina pairing is a very attractive therapeutic option for young active patients. The results of this study demonstrate the safety and advantages of these bearing surfaces compared to metal-polyethylene (33, 80).

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