

Alumina on alumina versus metal on conventional polyethylene : A randomized clinical trial with 9 to 15 years follow-up

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We report the long-term results of a randomized clinical trial that compares, in total hip arthroplasty in a young population, metal-on-conventional polyethylene and alumina-on-alumina ceramic bearings. One hundred and forty hips in 116 patients were randomized. Re-operation, revision rate, clinical scores, and radiological signs of osteolysis and loosening were compared at average follow-up of 12.3 (9-15) years. At final FU, 107 hips were available for clinical evaluation. Eight (11.6%) revisions were performed in the

ation. Eight (11.6%) revisions were performed in the polyethylene group versus 1 (1.4%) in the ceramic group (p = 0.017). All revisions in the polyethylene group were related to bearing wear : 4 for aseptic loosening with severe osteolysis, 1 for polyethylene induced compressive granulomatous tumor, and 3 for severe liner wear. The only revised case from the ceramic group was secondary to mechanical stem loosening. Mean annual polyethylene wear was 0.19 mm/year; wear was not measurable in the ceramic group.

Our study confirms, in the long-term, the superiority of ceramic-on-ceramic pairing in comparison to metal-on-conventional polyethylene and supports their use in young, active patients.

Keywords : hip arthroplasty, bearing surfaces, ceramic, polyethylene, wear, osteolysis.

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INTRODUCTION

Metal-on-conventional polyethylene (MoP) in total hip arthroplasty (THA), a bearing surface with good long-term results in elderly patients, has been established as the gold standard (*12*). However, conventional polyethylene (CPE) wear-related complications are the second most common reason for revision, as of 2006 (19.7% of all revisions in the USA) (6). Implant wear is a function of use, and younger patients normally have more active lifestyles and are thus at increasing risk of post-operative prosthetic failure due to polyethylene (PE) wear and secondary osteolysis (*1,8,19,24,28,31,40,45,46,56, 58*). Reduction of bearing wear is crucial and has stimulated the development of alternative bearing

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surfaces, such as alumina-on-alumina ceramic (CoC), metal-on-metal, and different types of highly cross-linked polyethylenes (XLPE).

CoC bearings have been in use since 1970 (4), with promising results in some patient cohorts (16,33, 62,72,73). The main advantages of CoC bearings are their favourable tribological properties (41,54), scratch resistance (16,43), decreased wear (3,65,66), and lower ceramic particle bioactivity (9,10,42) with lower risk of osteolysis and limited systemic effects (11,16,44,50,53). On the other hand, several potential disadvantages of CoC bearings have been observed : higher cost, risk of fracture (mean 0.006%) (27), diminished intra-operative versatility related to neck length and liner (no elevated lip), and squeaking (0% to 2.5%) (13,60).

To establish the true clinical value of CoC bearings, a randomized controlled trial (RCT) comparing their long-term results with gold standard bearings (CPE) was essential. In 1996, we undertook such a RCT (67). The primary outcome was to determine if CoC has a lower aseptic revision rate than MoP and, as secondary outcome, if CoC provide better functional scores. With short-term follow-up (mean 6.5 years) results were similar between groups (67). However, as expected, longer follow-up was needed to observe significant differences so in the present paper, we report the mean of 12.3 years FU of the same patient groups.

MATERIALS AND METHODS

Trial design

From 1996 to 2001, patients > 18 years old or < 70 years with degenerative hip joint disease who were candidates for THA, and without the following exclusion criterias : presence of an active infection, severe osteoporosis, non-cooperative patient, severe hip instability, pregnancy, and a measured acetabular diameter of less than 50 mm, were recruited by 3 orthopaedic surgeons. Participants were randomly assigned to MoP or CoC bearing surface group. A randomization table was created with Statgraphic Plus 2.2 software (Manugistics Inc., Rockville, 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. For "intention-to-

treat" analysis, clinical results from all available patients were taken into account.

Power analysis

With an expected rate of loss to follow-up of 15%, an estimated sample size of 70 in each group was needed to provide a power of 80% to detect a clinically meaningful difference of 15% in revision rate with an alpha error of 0.05.

Participants

One hundred and forty hips in 116 patients were randomized. Sixty nine hips in 58 patients received MoP (37 patients with unilateral MoP, 11 with bilateral MoP, and 10 with MoP on one side and CoC on the other side) and 71 hips in 68 patients received CoC (55 patients with unilateral CoC, 3 with bilateral CoC, and 10 with MoP on one side and CoC on the other side). The scientific and ethics committee approved the research protocol and all subjects gave written informed consent before participating in the study. Demographic characteristics of the enrolled patients are presented in Table I.

Implants

The same hybrid THA was implanted in all patients (Ceraver Osteal, Roissy, France). The cemented femoral implant has a smooth titanium alloy (TiAl) surface covered by a layer of titanium oxide (TiO_2) . It has a collar and a cervico-diaphyseal angle of 132°. The uncemented acetabular implant (Cerafit®) is made of titanium. Screw holes are available for supplementary primary fixation, and a titanium mesh covers the outer surface for secondary fixation (with current Cerafit implant, osseointegration surface has been replaced by a hydroxyapatite plasma spray coating). The bearing surfaces were either an alumina insert with an alumina femoral head of 32 mm for the CoC group, 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 for the MoP group. No liner had an elevated lip.

Surgical technique

One dose of intravenous antibiotics was administered pre-operatively and continued for 24 hours postoperatively (cefazolin 1 g or clindamycin 600 mg every

	MoP	CoC
Numbers randomized	69	71
Gender (ratio M/F)	38/31	30/41
Age (in years)	56.8 (min 29, max 70, SD 10.7)	54.9 (min 23, max 70, SD 12.5)
Side Right/Left	38/31	38/33
Weight (in Kg)	73.5 (min 45, max 107, SD 12.6)	77.4 (min 48, max 160, SD 21.5)
BMI	27.3	28.2
Height (in cm)	167	168
Diagnosis:		
OA	43	44
AVN	10	11
DDH	4	2
Childhood pathology	4	1
Inflammatory diseases	8	12

Table I. - Demographic characteristics and differential diagnoses of the enrolled patients

8 hours). An anterolateral approach (modified Hardinge) was taken in 122 hips (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. Utilization of screws was left to the surgeon's discretion. The femoral canal was prepared with rasp only, and we attempted to insert the largest possible implant. The stem was cemented with low-viscosity cement (Simplex[®], Stryker), according to a second-generation method (47).

Clinical evaluation

Clinical results were compared pre-operatively and at last follow-up using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) (2) and the Merle d'Aubigné-Postel scale (PMA) (17), and University of California Los Angeles score (UCLA) were compared at last follow-up. As an "intention-to-treat" analysis, clinical results from all available patients were taken into account (excluding 7 early reoperation cases leading to discontinued intervention).

Radiologic evaluation

Antero-posterior radiographs of the pelvis and a crosstable lateral radiograph of the hip taken post-operatively and at last follow-up were analyzed. The selected radio-

graphs 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) (29). All radiographs were reviewed and measured by two assessors. The assessment of radiographs was not done blind because of the difference in density between stainless steal and alumina femoral heads. Description of radiolucent line and local osteolysis were done with the use of Gruen's zones for the femur (35) and Charnley-De Lee for the acetabulum (22). Radiolucent line was defined as a lucent area in close proximity to the implant either more than 2mm thickness or evolutive. Osteolysis was recorded for either cavitary defect (scalloping), or calcar resorption which seems not to be a consequence of calcar remodeling with the calcar becoming round and thinner. Implant stability was evaluated according to criteria described by Engh et al (26). Heterotopic ossification was recorded according to the Brooker et al classification (7). Linear head penetration of the acetabular liners was measured by changes in the vectorial distance between the cup and head centres (64) using Imagika software having 0.13mm mean measurement error (68). 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 to the inter-teardrop line (48). Femoral and cup offset was evaluated by the perpendicular distance from the centre of rotation of the femoral head to, respectively, the centre line of the femur's diaphysis and to the perpendicular line to the tear-drop line crossing the ipsilateral tear-drop (49).

Statistical analysis

Continuous variables are presented as means ± SD, and categorical variables, as frequencies and percentages. For primary and secondary outcomes, the MoP and CoC groups were compared by Chi-square and t-tests for categorical and continuous variables respectively. Survival curves according to the Kaplan-Meier method are also presented. Additional analysis was undertaken in the MoP group on the relationship between different clinical outcomes and patient characteristics (such as age at surgery, weight, body mass index), and revisions and radiolucent lines were assessed by t-tests. Correlations were calculated between wear and continuous clinical outcomes. The Chi-square test analyzed the relationship between osteolysis and annual wear (categorized by 0.2 mm/year as threshold). Fisher's exact test was used instead of the Chi-square test when expected frequencies were too low. The significance level was defined as p < 0.05. For additional analysis, results with p-values between 0.05 and 0.20 are reported as possible trends, considering the study's limited power. Statistical analyses were performed with SPSS 20.0 software (SPSS Inc., Chicago, IL, USA).

RESULTS

Of the 140 hips included in this study, 52 CoC and 55 MoP were available at last FU for clinical evaluation, with radiographic data on 42 CoC and 47 MoP (patients only reached by phone). Eleven CoC hips and 5 MoP hips were considered lost to FU (11.4%). No significant difference in patient demographics was found between patients lost to FU and available subjects (p = 0.229-0.958). Average FU was 12.3 years (minimum 9.0, maximum 15) for the MoP group, and 12.3 years (minimum 9.0, maximum 14.6) for the CoC group.

Aseptic revision rates between groups were significantly different : 8/69 (11.6%) in the MoP group (average revision time 10.8 years) versus 1/70(1.4%) in the CoC group (p = 0.017) (see Kaplan-Meier chart, Fig. 1). Aseptic revision in the MoP group involved 3 cases of isolated severe liner wear > 3 mm, 3 femoral and 1 acetabular osteolyses lead-



Fig. 1. — Kaplan-Meier chart with aseptic loosening as end-point.

ing to implant loosening, and 1 granulomatous pseudo-tumour causing crural nerve compression with associated femoral osteolysis. In the CoC group, the only revision was related to mechanical stem loosening at 8 years. In the MoP group, significant correlations were noted between revision and higher annual wear (0.30 mm/year versus 0.20 mm/year, p = 0.009), higher total linear wear (3.12 mm versus 2.26 mm, p = 0.028) and higher acetabular inclination (55.2° versus 46.7°, p = 0.024).

Better clinical scores were obtained in the CoC group, but a significant difference was only found with UCLA score (5.6 versus 4.8, p = 0.015), a tendency was observed with the PMA scale (16.5 versus 15.5, p = 0.068) and no difference with the WOMAC scale (10.7 versus 16.6, p = 0.10). Although not significant, the MoP group tended to report higher pain levels when putting shoes or at rest 13% versus 4% (p = 0.161), when rising from a chair 16% versus 6% (p = 0.123), after the first steps 16% versus 8% (p = 0.236) or after a long walk 29% versus 19% (p = 0.26). In the MoP goup, patients with either revision, radiographic signs of osteolysis or radiolucent lines did not have significantly different functional scores compared to those without (p = 0.302 - 0.978).

The linear wear in the CoC group was below detection limit of the Imagika software. In contrast, in the MoP group, for the unrevised hips, total linear wear averaged 2.3 mm (SD 1 mm, range 0.4 to 4.3 mm). At last FU, 10 MoP cases had more than 3.0 mm total linear wear ; they are being followed closely as they may need revision surgery. Annual wear averaged 0.19 mm/year (SD 0.08 mm/year, range 0.04 to 0.36 mm/year) with 29/47 of hips being above 0.2 mm/year. Both total wear and annual wear rates in the MoP group were significantly different from those in the CoC group (p < 0.001). We did not find significant correlations between annual PE wear and implantation length (p = 0.64), cup inclination (p = 0.6), femoral offset (p = 0.88), UCLA activity score (p = 0.91), PMA score (p = 0.5), and WOMAC scale (p = 0.76).

Local osteolysis zones were noted around components in 10/47 of MoP (5/39 MoP not revised and 5/8 MoP revised) versus 1/42 of CoC (including the sole revised case) (p = 0.032). In the MoP group, 1 stem not revised has cement fracture and stem subsidence and is considered loose secondary to osteolysis. All MoP patients with osteolysis had mean annual wear of more than 0.2 mm/year, meaning that 10/29 of hips with more than 0.2 mm/year wear developed osteolysis. Partial progressive radiolucent lines around components were observed in 10/47 of MoP 3/42 of CoC (p = 0.075). No ceramic fracture or squeaking occurred during the FU period.

DISCUSSION

As THA is being offered to younger patients, we need to choose the best implants for optimal performance. With MoP bearings, osteolysis resulting from CPE wear debris is one of the most common causes of implant failure in this young population. Current new, alternative bearings are still under evaluation (*61*). Direct comparison of the performances of CoC and MoP bearings is needed to determine their real value in the long-term.

Our findings should be viewed in the light of our study limitations. First, we considered CPE as the control group. When this study was designed (1994-1995), CPE was the gold standard friction pairing. However, there is increasing evidence showing the clinical advantages of XLPE versus CPE (28,47). On the other hand, as reported in the 2010 Swedish Hip

Register, 60% of PE used in Sweden are CPE and in 2011, Malchau et al raised concerns regarding the fast XLPE adoption with limited scientific data (47). More recently, Engh et al showed in a randomized study comparing XLPE and conventional PE at 10 years follow-up, a lower revision rate for wear related complication (0% vs 5.3%, p = 0.003) and reduced wear 0.04 versus 0.22 mm/y (p < 0.001) favouring the XLPE (25). Even if a similar study should be undertaken comparing XLPE as a control group, our study is the longest follow-up RCT comparing CoC to MoP bearing. As shown with this study, long enough follow-up is needed to truly determine the value of alternative bearings in THA. Secondly, Ceraver's PE sterilisation method changed over our study period. Ethylene oxide was used for the cases in the first 2 years and gamma irradiation in argon thereafter. Our study design did not allow us to compare performances of the two PE types. Third, metal backed PE components with PE thinner than 8 mm have been associated with increased wear rate (23,37). In the present study, Cerafit acetabular shells of 50 mm and 52 mm had 8.6 and 9.6 mm PE thickness (at 30° from their pole). In our study, 9 PE hips had shells of 50 mm and 6 of 52 mm and no statistical correlation was found between revision rate and shell size (p = 0.22), nor when shell size was divided in two groups $:\le 52 \text{ mm}$ and > 52 mm (p = 0.1). Fourth, radiographic study with plain films underestimates the extent of osteolysis compared to computed tomography, which is more sensitive (34). Finally, 16 hips (11.4%) were lost to FU, 11 CoC and 5 MoP (p = 0.125). No significant difference in patient demographics was apparent between the lost-to-FU group and the group available at last FU.

At average FU of 12.3 years, a significant difference in the aseptic revision rate favoured the CoC group : 1/71 (1.4%) versus 8/69 (11.4%) in the MoP group (p = 0.017). In addition, 10 unrevised MoP hips had more than 3 mm PE linear wear, and 5 others had progressive local osteolysis with 1 loose femoral stem on radiography. All revisions in the MoP group were the consequence of wear-related complications, and the most significant factors correlated with revision risk were increased annual wear (0.3 mm/year in the revised group versus 0.2 mm/year for non-revised, p = 0.01) and higher acetabular component inclination (p = 0.024). In contrast, the sole revision in the CoC group was performed for a mechanically-loose femoral stem associated with an undersized cemented titanium stem.

In the literature, only 1 RCT (16) compared the same bearings -144 CoC vs 72 MoP - with mean 10.3-year FU (10 to 12.4 years). Patient mean age was 53.7 years. The MoP group had higher osteoly-

sis (26% vs 0%) and revision rates for any reason (10.5% vs 3.1%). Six patients were revised in the CoC group : 1 ceramic fracture at 9.2-year FU, 2 periprosthetic fractures, 2 infections, and 1 instability. Ten were revised in the MoP group : 3 severe osteolyses, 3 instabilities, 2 infections, 1 fracture, and 1 leg length discrepancy. Only 1 implant was loose (1 cup in MoP group) (*16*). Our results are comparable to those in other observational studies and registries (Tables II & III).

Table II. —	Results from observational studies describing outcomes of MoP and CoC bearing surfaces
	at long-term FU in young patients

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	Bearing	FU	Age of group	Number	Number of	Osteolysis rate	Mean	Implant
	surface	(years)	(years)	of hips	revisions		annual wear	survival rate
							(mm/year)	
Crowther and	MoP	11	Mean 37 years	56	5 loosenings,	23% pelvis	0.15	NA
Lachiewicz (14)			-		2 osteolyses, 1	osteolyses		
					infection, 1 pain			
Emms et al (24)	MoP	11.6	Median 54	280	62 hips (22.5%)	17.1% of the	0.25 in	91.2% at
			years		mostly loosening,	remaining	revised	10 years
			-		osteolysis, worn	cup, 15% of	group	56.3% at
					liner exchange	the remaining		14 years
					0	stem		
Boyer <i>et al</i> (5)	CoC	10	< 50 years	76	1 loosening, 1	None	Not studied	92% at
					ceramic fracture,			10 years for
					1 infection, 1			any reason
					instability			
Yeung et al (72)	CoC	10.9	Mean 58 years	244	1 stem loosening,	None	Not studied	99.6% at
			2		1 infection,			10 years
					4 fractures.			for aseptic
					4 psoas			loosening
					tendinitis 1			98% for any
					nerve polsy			reason
					nerve paisy			10aSUII

Table III. - Results from hip registers describing outcomes of MoP and CoC bearing surfaces

	Bearing surface	Age of group (years)	Number of hips	Implant survival rate
2007 Swedish Hip Register (38)	MoP	50 to 59 years	NA	90% at 10 years 78% at 16 years in men and 68% in women
Finnish Arthroplasty Registry (46)	МоР	55 to 64 years	NA	95% at 10 years 81% at 15 years
2011 Australian National Joint Replacement	МоР	NA	8,482 at 7 years 668 at 10 years	95.2% at 7 years 92.9% at 10 years
Registry (30)	CoC	NA	6,946 at 7 years 301 at 10 years	95.8% at 7 years 94.6% at 10 years

We were unable to measure any wear on the ceramic couple as its wear rate is below the detection limit of the Imagika software. Our PE linear wear rate of 0.19 mm/year is similar to wear rates reported by other authors in such young patients (0.141-0.246 mm/year) (8,14,21,24,40). Excessive acetabular component abduction is a well-recognized factor associated with increased PE wear (1,22,59,71) and should be avoided. In our study, revised hips had mean acetabular component abduction of 55.2°, which is above the recommended range of 35-45° (35,52). Surprisingly, we did not find positive correlations between annual wear rate and acetabular component abduction (p = 0.6). In contrast, in our short-term study (mean 6.5 years), increased cup inclination was highly correlated with increased annual wear rate (p = 0.004)(67). This difference could be partially explained by the 6 patients who underwent revision between both studies ; these patients had very high wear rates and high cup inclination. After their revision, they stopped contributing to the group data.

In our study, 10/47 of the MoP group incurred osteolysis, and the annual wear threshold of 0.2 mm/year seemed to be significant for osteolysis development (p = 0.025). We believe that such ostelolysis was secondary to granulomatous reaction to PE debris as consequence of the macrophagic activation (1). No osteolytic reactions were noted in our CoC group. Some observational studies have demonstrated a low osteolysis rate (15,16,43) and non-significant macrophage activation with CoC (57). In vitro investigations comparing macrophagic reaction to either alumina or CPE particle debris have shown that low alumina debris is needed to activate macrophages but macrophage apoptosis occurred sooner and more extensively than with PE debris, which may explain the lower inflammatory response to alumina particles and the lower incidence of osteolysis (11,53). Without being significant (p = 0.075), the radiolucent line rate was superior in the MoP group, 10/47 vs 3/42, and could be explained in the MoP group by an osteolytic reaction at the bonecement interface.

With the small study group and number of implants used, no squeaking was reported spontaneously by patients, not even when specifically asked at last FU. Most studies have reported squeaking rates ranging from 0 to 2.5% (*16*,60,63). Cogan *et al*, implanting the same Ceraver devices as us, found 2.6% in 265 THA (*13*). Some studies have recorded squeaking rates as high as 20.9% (*33*,36,55) but implant malposition, implant designs and femoral stem types might have been responsible for such results (*39*,69,70).

The long-term results of this investigation demonstrate the advantages of CoC compared to metal on standard PE. A similar study should be undertaken to evaluate CoC benefits in comparison to metal on cross-linked PE in the young, active patients.

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190

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