Cementless Metal-on-Metal Versus Ceramic-on-Polyethylene Hip Arthroplasty in Patients Less Than Fifty Years of Age

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Dear Chief Editor

We are submitting the corrected version of our manuscript entitled "**Cementless Metal-on-Metal versus Ceramic-on-Polyethylene Hip Arthroplasty in Patients Less Than 50 Years of Age: A Comparative Study at 12- to 14-year Follow-Up**" for publication in your journal.

The abstract was shortened as recommended. The former results of the current series were deleted and the paper reporting those results was just remembered as a reference. Finally a new table was introduced detailing the Cr and Co concentrations in the whole blood at 12 years of follow-up. These data are reported separately for patients that had dental implants and bone plates that could influence the dosages.

It is submitted as a part of the special issue of the JBJS reporting data of the 8th Symposium of Joint Preserving and Minimally Invasive Hip Surgery. The guest editor for this special issue is Paul Beaulé, MD.

With thank the reviewer and the editor for considering this paper for publication.

Sincerely yours,

H. Migaud, MD

*Unblinded Title Page

Cementless Metal-on-Metal versus Ceramic-on-Polyethylene Hip Arthroplasty in Patients Less Than 50 Years of Age: A Comparative Study at 12- to 14-year Follow-Up

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Cementless Metal-on-Metal versus Ceramic-on-Polyethylene Hip Arthroplasty in Patients Less Than 50 Years of Age: A Comparative Study at 12- to 14-year Follow-Up

Abstract

We previously reported the outcomes of a case-control study at a minimum of 5-year follow-up, comparing metal-on-metal (MoM) and ceramic-on-polyethylene (CoP) bearings for cementless primary arthroplasty in active patients below 50 years of age. The current investigation, gives an update on these groups at a minimum 12 years of follow-up.

Thirty-nine MoM cementless hip replacements with 28-mm diameter Metasul articulation (30 patients, mean age 39 (23-49) years) were compared to a control group that included 39 cementless 28-mm diameter head CoP hip replacements (32 patients, mean age 40 (15-49) years). The groups were matched for age, activity level, preoperative Harris hip score, cup diameter, and indication for arthroplasty. All patients had a high level of activity with 81% rated as grade IV or V according to the Devane scale.

After a mean follow-up of 13 years (12-14), only 1 asymptomatic acetabular osteolysis occurred in the MoM group (2%) with no reoperations (0%) versus 18 osteolyses (46%) and 11 reoperations (28%) because of wear or osteolysis in CoP ($p<0.001$). In the MoM group, the Co median concentration in the whole blood was 0.95 µg/L (0.4 to 4.8) and Cr was 1.2 µg/L (0.1 to 5.6). The 12-year survival rate (reoperation as endpoint for any reason) was 100% in MoM and 70% in CoP [95% confidence interval: 63 to 77] ($p=0.003$).

MoM at 12 to 14 years of follow-up has demonstrated better radiological and survival results than CoP in young, very active patients. Current wrought MoM with 28-mm diameter head and high carbide concentration did not produce high rates of osteolysis and allergic reactions that are usually observed with cast, low-carbide MoM bearings after a shorter follow-up.

1 Level of evidence: Therapeutic level III. Retrospective comparative study

2 Key words: hip arthroplasty, metal on metal bearing, wear, polyethylene.

3

Introduction

The second generation of metal-on-metal (MoM) articulations was introduced in 1988 with Metasul™ to reduce the rates of wear and osteolysis with conventional polyethylene used as a bearing component[1]. Favorable outcomes were obtained in the general population up to 10 years of follow-up[2-4]. Likewise, in younger, active patients, this articulation type gave excellent results but with follow-up that did not reach 10 years[5,6]. In contrast, with MoM made of different alloys, higher rates of osteolysis and reoperation were reported with shorter follow-up[7-9]. Finally, the clinical performance of the 28-mm diameter Metasul™ articulation was rarely compared to polyethylene in young, active patients who are exposed the most to early wear and osteolysis[10]. The goal of the current work was to update this comparative study with a minimum follow-up of 12 years.

Materials and Methods

This study was approved by our Ethics Review Board. From March 1995 to November 1998, 39 cementless MoM prostheses were inserted as primary arthroplasty in 30 patients younger than 50 years of age (5 women and 25 men, 9 bilateral procedures) (Table 1). Inclusion was prospective and consecutive, according to the following criteria: patients under 50 years of age, involved in heavy professional or sports activities, with a diagnosis of arthrosis or avascular necrosis of the femoral head. Mean age at the time of surgery was 39.8 years (range 23-49). Eight patients were overweight with body mass index (BMI) above 30 kg/m^2. The diagnosis was femoral head necrosis in 20 hips and arthrosis in 19 hips (Table 1). Femoral head necroses were related to steroid use in 5 hips (4 patients), sequela of femoral neck fracture in 3 hips (3 patients), kidney transplantation in 3 hips (2

patients), and 9 necroses (6 patients) were idiopathic or presumably related to excessive alcohol consumption. Of the 19 arthroses, 15 were secondary to developmental hip dysplasia (12 patients), 2 cases (1 patient) were secondary to Legg-Perthes disease, 1 case occurred after acetabular fracture, and 1 case was an overweight female (BMI 51 kg/m^2). All patients were active according to the Devane scoring system[11]: 15 were rated as grade V (18 hips), 11 as grade IV (16 hips), and 4 as grade III (5 hips). In parallel, 15 patients were involved in sports, 13 at the leisure level and 2 as competitors. All surgeries were performed via a posterolateral approach under vertical laminar air flow. The cementless components consisted of: a) an Alloclassic Zweymuller stem (Zimmer, Winthertur, Switzerland), b) Armor hemispherical cup coated by titanium mesh (Zimmer), one or 2 additional screws were inserted whatever the stability of the cup after impaction according to the prospective procedure, and c) a 28-mm MoM articulation (Metasul, Zimmer) (Fig. 1). All patients received 24-hour prophylactic antibiotics started 1 hour prior to incision and low weight molecular heparin for 35 days from the day of surgery. Full weight-bearing was allowed 4 days after surgery except in 3 cases of bulk acetabular autografts to reconstruct a severely dysplastic acetabulum (full weight-bearing was permitted at 6 weeks after surgery for these 3 cases).

All patients were assessed yearly until 2003, then every 2 years until final follow-up. The Harris hip score (HHS)[12] served to evaluate hip function at final follow-up in 2010 with the French translation of the Oxford 12-item self-questionnaire[13]. Anteroposterior and lateral views at each visit were assessed at final follow-up by 2 observers (S.P., J.G.) who were not involved in the surgery. Femoral stem subsidence was detected by measuring the distance between the top of the lateral spike of the Zweymuller stem and the top of the greater trochanter. Cup migration was assessed by

measuring variations in position of the articulation center with respect to the acetabular teardrops. Discrepancies exceeding 5 mm were considered as migration. Particular attention was paid to osteolysis and radiolucencies in the 7 femoral zones according to Gruen et al.[14] and in the 3 acetabular zones according to DeLee and Charnley[15]. At final follow-up in 2010, Chromium (Cr) and Cobalt (Co) concentrations were quantified in whole blood by inductively-coupled plasma mass spectrometry. Blood samples were harvested with Co-free needles (Vasofix™, Braun, Melsungen, Germany) and Co-free tubes (Teklab, Durham, England). Blood ion levels were measured in another institution (Biominis, Evry, France) with a detection limit of 0.1 µg/L without knowledge of the results. In addition to blood ions, blood samples were harvested to quantify creatinine levels.

The MoM cohort was matched to an historical control group with cementless implants and ceramic-on-polyethylene (CoP) bearings from the same orthopedic department. This control group, including 39 hip replacements in 32 subjects, was selected by matching mean age, indication for hip replacement, activity level according to Devane score, preoperative HHS, and cup diameter (Table 1). The cementless implants consisted of: a) an ABG 1 stem (Stryker-Howmedica, Kalamazoo, MI), b) a Harris-Galante cup (Zimmer, Warsaw, IN), including a not highly cross-linked ultra-high molecular weight polyethylene insert sterilized by irradiation under vacuum, c) a 28-mm diameter zirconia head (Saint Gobain-Desmarquest, Montreuil, France). The surgical approach and staff as well as intra- and postoperative procedures were identical in the MoM and CoP cohorts. These groups were tracked in parallel from 2000 to the final follow-up in 2010. Blood ion levels were not measured in the CoP cohort.

Correlations between categorical variables were analyzed by the Chi-square test.

Discrete variables between cohorts and at different stages of follow-up were evaluated by ANOVA and t-test. When the samples were small, nonparametric tests were applied (Wilcoxon, Mann–Whitney and Fisher's exact test). Survivorship was analyzed according to the Kaplan-Meier test with reoperation for any reason as well as reoperation for wear and osteolysis (95% confidence intervals (95% CI) are detailed). Survival rates between cohorts were compared by the log-rank test. All statistical comparisons were made with a significance level of 5%.

Source of funding

There was no external source of funding for this study.

Results

Both cohorts were followed in parallel with an intermediate evaluation (after a minimum 5-year follow-up) reported in 2004[10]. For the current study in the MoM cohort, 3 patients (4 hips) died at a mean follow-up of 10.3 years (range 9-12 years) from reasons unrelated to their index surgery. The original prosthesis was in place at the time of death, and their hips were free of symptoms. No patient was lost to follow-up, but we were unable to obtain X-rays and blood ion values for 1 patient (2 hips), who completed his clinical evaluation and her hips were symptom-free. Mean follow-up, including the 2 patients who died after a minimum 10 years, was 151 months (range 144-166 months). HHS for the 27 patients (35 hips) assessed in 2010 improved from a pre-operative mean of 48.6 (range 28-80 points) to 92.8 (range 70-98 points) ($p<0.001$). At follow-up, all HHSs were equal to or greater than 90 points with the exception of 4 patients: 1 patient suffering from sciatic nerve palsy secondary to lumbar spine stenosis, 1 patient who underwent prior post-traumatic amputation of the

contralateral limb, and 2 patients suffering from contralateral avascular necrosis of the femoral head requiring arthroplasty. For these 27 patients, there was no decrease in HHS between 5 and 12 years of follow-up (from a mean of 97.5 (range 92 to 100 points) at 5 years to 92.8 (range 70 to 98 points) (p=0.17). Mean Oxford score at follow-up was 15.3 points (range 12 to 35 points). All patients rated their function as <20 points, with the exception of 5 patients: 3 of the 4 patients mentioned previously as having HHS <90 points (respectively rated at 25, 30 and 35 points) and 2 others rated their function as 24 and 25, respectively. The majority of patients were still very active at follow-up according to the Devane scoring system, 12 were rated as grade V, 12 as grade IV, and 3 as grade III. There was no significant decline in their activity level compared to their preoperative scores that were rated as grade V in 15 patients, grade IV in 11 patients, and grade III in 4 patients (p=0.1). At 5 years of follow-up, 15 patients were involved in sports (13 at the leisure level, 2 as competitors), and at 12 years of follow-up 14 were playing sports but none as competitors. Three of the 5 women included in the MoM cohort delivered 4 healthy babies; among them was the woman who had a bilateral procedure and a well-functioning kidney transplant. There was no pregnancy in the 5-year to 12-year follow-up.

X-rays were assessed at follow-up in 33 hips (26 patients). They were not available for 3 patients who died (4 hips) and for 1 patient (2 hips) who was not X-rayed in 2010. This last patient's hips were both asymptomatic with HHS of 99 points. None of the components migrated more than 5 mm. Only 1 hip had limited acetabular osteolysis in zone 1 combined with slight calcar resorption. This woman was asymptomatic with HHS of 94 points after 13 years of follow-up. No osteolysis was observed on the femoral side, but 3 hip radiolucencies limited to zone 1 were non-progressive on consecutive X-rays.

Ion concentrations in whole blood were assessed in 26 patients (33 hips) after a mean follow-up of 151 months (range 140-166 months) (Table 2). Median Co was 0.95 µg/L (range 0.4 to 4.8 µg/L) and median Cr was 1.2 µg/L (range 0.1 to 5.6 µg/L). At follow-up, 11 patients had Co >1 µg/L: 6 had bilateral MoM, 1 had kidney graft failure secondary to transplant infection not related to hip replacement, among the last 4 who had Co from 1.1 to 1.6 µg/L and were free of symptoms 3 had dental implants which could explain this result. Similarly, at latest follow-up, 14 patients had Cr >1 µg/L: 6 had bilateral MoM, and 8 (with concentrations ranging from 2.1 to 5.6 µg/L) were free of symptoms in 2010 and had no other factors to explain this result, with the exception of the patient who had kidney graft failure mentioned previously, 4 patients who had dental implants, and another who had 3 bone plates since 1988. The woman with limited acetabular osteolysis had Co and Cr concentrations of 0.8 µg/L and 1.2 µg/L, respectively. In the MoM cohort, there was no change in creatinine levels at 5- to 12-year follow-up from a mean 10.4 mg/L (range 8.6 to 14 mg/L) to 13.1 mg/L (range 5.7 to 112 mg/L) (p=0.5) (normal serum creatinine values are 7 to 12 mg/L). Transplant failure occurred in the patient with 112 mg/L in 2004 because of kidney graft infection unrelated to hip replacement. Serum creatinine was 112 mg/L in this patient at follow-up, and hemodialysis was undertaken until an iterative kidney graft was scheduled (Co and Cr were 1.2 µg/L and 4.6 µg/L, respectively). The other kidney graft recipient with a well-functioning MoM had slightly increased serum creatinine (15 mg/L) with a well-functioning kidney graft, and Co and Cr levels were both 1.5 µg/L.

In the CoP cohort, no patient was lost to follow-up, but 2 patients (2 hips) died from reasons unrelated to their hip surgery at 10 and 10.8 years, respectively, after the index procedure and with retention of well-functioning components. The results for

the CoP cohort were assessed after a mean follow-up of 168 months (range 110 to 206 months), including the 2 patients who died after 10 years or more of follow-up, but excluding the 13 patients who underwent revision and did not retain their original components. Follow-up of the CoP cohort in patients who retained their components was not different from that of the MoM cohort (p=0.08) (Table 3). After exclusion of the 13 revised hips, the clinical results were assessed in 24 hips (17 patients), and the radiological results in 22 hips (16 patients) as an additional patient (2 hips) was not X-rayed at follow-up. HHS was not different between the CoP and MoM cohorts preoperatively and at 5- and 12-year follow-up (Tables 1 and 3). There was no significant decrease in activity level among the 17 alive patients from the CoP cohort who did not undergo revision: according to the Devane classification, 3 patients were rated preoperatively as grade V, 11 patients as grade IV, 2 as grade II, and 1 as grade II versus 3 patients rated as grade V, 11 as grade IV, and 4 as grade III at 12-year follow-up. Severe osteolysis was observed on X-rays in the CoP cohort in 18 hips (46%), localized around the cup in 18 hips (in at least 2 zones), with combined femoral osteolysis in 4 hips (in zones 1 and 7). Eleven of these osteolyses required revision after a mean of 103 months (range 60 to 180 months). Two of these 11 revisions were justified by osteolysis combined with recurrent instability, and 9 revisions were done because of osteolysis and wear exceeding 2 mm of femoral head penetration. Two additional revisions were made because of femoral peri-prosthetic fracture type Vancouver B2 at 10 and 12 years respectively after the index procedure. In summary, 13 revisions were undertaken in the CoP cohort. Twelve-year survivorship with revision for any reason as endpoint was 70% (95% CI: 63% to 77%) in the CoP cohort versus 100% in the MoM cohort (log rank, p=0.0003). Twelve-year survivorship with revision for any reason as end point but excluding

peri-prosthetic fracture was 100% for the metal-on-metal cohort versus 75% (95% CI: 68% to 82%) for the CoP cohort (log rank, p = 0.001).

Discussion

The current study showed that second-generation MoM bearings improved arthroplasty survivorship and reduced the rate of osteolysis compared to CoP in young and active patients after minimum 12-year follow-up. The current 100% survivorship of Metasul™ at 12 years was higher than that reported with others MoM articulations composed of different alloys. With the Sikomet™ low-carbide articulation, considering revisions for osteolysis and aseptic loosening, Milosev et al.[7] observed a 93% survival rate at 10 years and Korovessis et al.[8] recorded 93% survival of stems and 98% of cups at 9 years. These results were noted in older patients (mean 57 and 55 years, respectively) with presumably lower activity but not detailed by these authors[7,8]. We observed only 1 case of osteolysis in a symptom-free patient who did not require revision but careful radiographic survey. In contrast, Park et al.[9], using the Ultima™ bearing made of forged on cast Co-Cr alloy, reported 5.9% osteolysis after only 2 to 4 years of follow-up. Osteolytic lesions are virtually rare with Metasul™ forged high-carbide alloy, even after follow-up exceeding 10 years: no osteolysis but 3 revisions out of 104 (2.8%) related to unexplained pain or aseptic lymphocytic vasculitis-associated lesions (ALVAL) were recorded by Eswaramoorthy et al.[3] after a mean 10 years of follow-up. Dastane et al.[4] reported 8 osteolytic lesions out of 69 hips (11.6%) after a mean 13 years of follow-up but all were limited to 2 to 3 mm or had the appearance of slight calcar resorption, and none required revision. To our knowledge, the current study is the first to convey the results of Metasul™ bearing with a minimum follow-up of 12 years and in a specific population of young, very active patients. One study limitation was the lack of CT-scan to improve the detection

of osteolytic lesions, as suggested by Holloway et al.[16]. Consequently, the current study probably underestimated peri-prosthetic osteolysis, particularly when considering X-rays versus histological data[17].

Our study had other limitations, as it was not randomized, but retrospective and comparative. In contrast, our population was homogeneous regarding age and activity level that was constant over the course of this investigation. The control group was matched in 2000 according to 6 criteria among patients from the same institution, and then both groups were followed in parallel for at least 10 years, giving a mean 13 years (12 to 14 years) of follow-up. Similarly, the number of patients included in both groups was small, but no patient was lost and the number of patients who died was limited and comparable in both groups. It is possible to argue that the control group did not receive modern prosthetic designs, particularly cross-linked polyethylene, and to underline the poor fixation mechanism of the Harris-Galante I insert[18]. In fact, the control group received a common design from the mid-nineties at the time the patients had surgery, and cross-linked polyethylene was not available then. Similarly, the use of zirconia instead of alumina heads is debatable as it may increase the rate of osteolysis[19]. However, no alumina was available with the ABG I™ stem, and some studies reported better results with zirconia instead of metallic heads functioning with polyethylene[20].

We observed Cr levels in the same range as did Maezawa et al.[21] who reported a mean value of 1.52 µg/L (0.3 to 5.5 µg/L) with Metasul™ at 5 years, and 1.68 µg/L (0.3 to 5.3 µg/L) at 7 years. Our results are also in accordance with Vendittoli et al.[22] who reported Cr at 1.62 µg/L (0.80 to 5.70 µg/L) and Co at 0.94 µg/L (0.24 to 4.89 µg/L) at 2 years with Metasul™. Our study confirmed that no renal function impairment was related to Metasul™ after a minimum 12 years of follow-up. The latter result is in

agreement with that of Marker et al.[23] who noted renal function preservation at 10 years in 75 patients who received Metasul™ articulations.

The present study demonstrates the better clinical performance of Metasul™ over CoP articulations in primary cementless arthroplasty in patients under 50 years of age. Both cohorts will be assessed with longer follow-up to confirm these encouraging results and to detect and monitor osteolysis occurrence.

Note: The authors thank Claude Rieker (PhD) for his careful help in revising this manuscript and Alain Duhamel (PhD) for his contribution to statistical analysis.

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Figure legends

Figure 1: 14-year follow-up X-rays after MoM replacement in a 32-year-old man because of post-traumatic necrosis of the femoral head (femoral neck fracture Garden 3 fixed by screws). There is no evidence of wear or osteolysis.

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Table 1

Table 1. Demographic characteristics of the matched cohorts

	Metal-on-metal	Ceramic-on-polyethylene	
No. of hips (patients)	39 (30)	39 (32)	
Gender	25 M, 5 F	16 M, 16 F	*p*=.009*
Age at surgery (years) (range, SD)	39.8 (23-49, 6.7)	40.5 (15-50, 8.7)	*p*=.76
Diagnosis (arthrosis/necrosis)	19 Arthrosis /20 AVN	21 Arthrosis / 18 AVN	*p*=.91
Devane activity score	15 (V), 11 (IV), 4 (III)	8 (V), 17 (IV), 5 (III), 2 (II)	*p*=.26
Charnley grade	12 (A), 15 (B), 3 (C)	16 (A), 9 (B), 7 (C)	*p*=.16
BMI (kg/m^2) mean (range, SD)	27.5 (20-51, 5.7)	24.9 (18-39, 4.1)	*p*=.04*
Preoperative Harris hip score (range, SD)	47.7 (15-80, 13.4)	50.2 (5-70,15.2)	*p*=.46
Cup diameter (mm) (range, SD)	54.7 (48-62, 3.6)	54 (48-60, 3.2)	*p*=.38

* Significant difference, AVN: avascular necrosis

Table 2

Table 2. Co and Cr concentrations (mean ± SD) in the whole blood at 12 years of follow-up in 26 patients (33 hips). Of the initial cohort of 30 patients (39 hips), 3 died (4 hips) and another patient (2 hips) had no blood ion measurement. The patients were pooled according to the presence of other potential source Co or Cr (dental implants (13 patients) or bone plate (2 patients)).

Patients	Co at 12 years	Cr at 12 years
All 26 patients	1.15µg/L ± 0.8µg/L (range 0.4 to 4.8)	1.4µg/L ± 1.3µg/L (range 0.1 to 5.6)
15 patients with bone plate or dental implants	0.9µg/L ± 0.49µg/L (range 0.4 to 1.8)	1.4µg/L ± 1.6µg/L (range 0.1 to 5.6)
11 patients without dental implants or bone plate	1.4µg/L ± 1.2µg/L (range 0.6 to 4.8)	1.3µg/L ± 0.9µg/L (range 0.1 to 2.8)
Significance between groups	*p*= 0.1	= 0.8

Table 3

Table 3. Comparison of cohorts at follow-up

	Metal-on-metal	Ceramic-on-polyethylene	
No. of hips from the initial cohorts (patients)	39 (30)	39 (32)	
No. of hips at final follow-up in patients alive with retention of the initial components (patients)	35 (27)‡	24 (17)◊	
Mean follow-up in months (range) of hips with component retention	151 (144-166)	168 (110-206)	*p*=.08
Harris hip score (range, SD) in patients alive with component retention	92.8 (70-98, 7.9)	91.2 (77-98, 6.6)	*p*=.4
Oxford-12 (range, SD) in patients alive with component retention	15.3 (12-35, 5.6)	15.4 (12-25, 4.5)	*p*=.2
No. of osteolysis in the initial cohorts (%)	1 (2%)	18 (46%)	*p*=.001
No. of hips with dislocation in the initial cohorts (%)	0	6 (2 had component exchanges) (15%)	*p*=.06
No. of surgical revisions in the initial cohorts (%)	0	13 (11)† (33%)	*p*=.003

‡ Of the initial MoM cohort, 3 patients died (4 hips) and none was revised.
◊ Of the initial CoP cohort, 2 patients (2 hips) died and 13 hips (13 patients) were revised.
* In each cohort, 1 patient (2 hips) was no X-rayed at follow-up in 2010.
†11 were revised because of wear and/or osteolysis and 2 because of periprosthetic femoral fractures.

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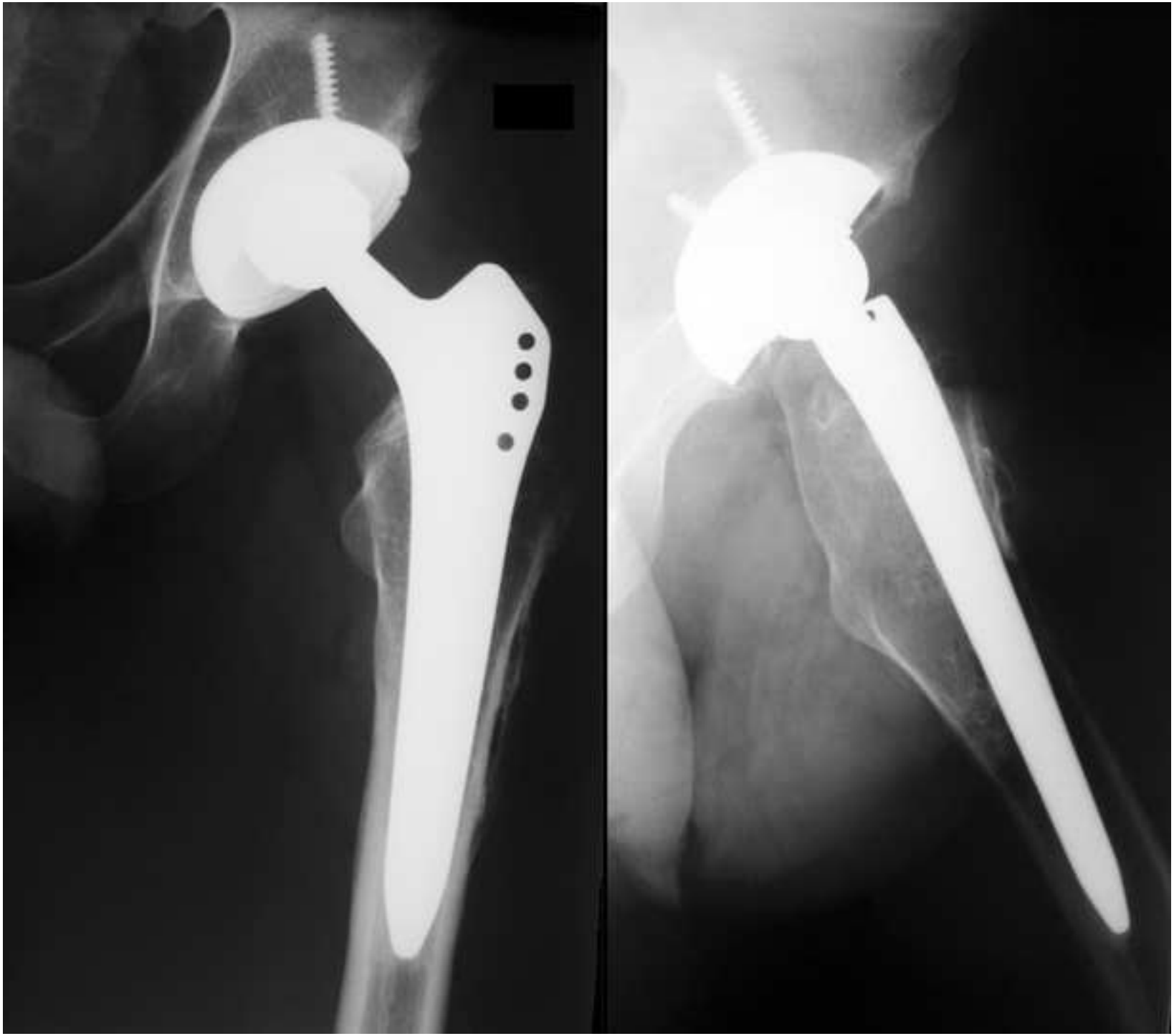

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Henri Migaud, MD, Sophie Putman, MD, Nicolas Krantz, MD, Laurent Vasseur, MD, Julien Girard, MD, MSc

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