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Clinical Results and Metal Ion Levels After Ceramic-on-Metal Total Hip Arthroplasty: A Mean 50-Month Prospective Single-Center Study

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A B S T R A C T

Background: The aim of our study was to investigate the clinical results and serum metal ion levels in a cohort of patients who received total hip arthroplasty (THA) with ceramic-on-metal (CoM) bearings.

Methods: From September 2009 to December 2011, 78 patients (89 hips) who underwent THA with CoM bearings were involved in this study. Harris Hip Score, Short-Form 12, and Western Ontario and McMaster Universities Osteoarthritis Index scores were measured and radiographs were taken for radiographic analysis. Serum metal ion levels of cobalt (Co), chromium (Cr), molybdenum (Mo), and titanium (Ti) were measured using high-resolution inductively coupled plasma-mass spectrometry.

Results: Severy-four patients (85 hips) were followed up at a mean of 50 months. At the end of follow-up, HSS, Short-Form 12, and Western Ontario and McMaster Universities Osteoarthritis Index scores were improved significantly compared with preoperative values. No intraoperative and postoperative complications occurred, and no radiolucency, osteolysis, and loosening was found from radiographic examination. Metal ion analysis showed that serum metal ions levels were significantly elevated compared with normal values. Spearman correlation analysis revealed that there was a correlation between 3 metal ion levels and body mass index(Co: $r = 0.49$, $P < .01$; Cr: $r = 0.47$, $P < .01$; Mo: $r = 0.36$, $P = .04$). No correlation was found between metal ion levels and age, cup abduction angle, cup anteversion angle, acetabular version, bilateral arthroplasty, cup screw used, hip stem implant type, or femoral head size.

Conclusion: Our study concluded that the use of a CoM THA is effective clinically, but the systemic metal ion levels are significantly elevated at midterm follow-up. Whether the elevated metal ion levels will induce an adverse reaction is unknown and long-term follow-up is need.

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Currently, the number of patients receiving total hip arthroplasty (THA) is increasing, especially for young patients. With contemporary methods of fixation demonstrating durable long-term results, researchers are now focused on the development of bearings surfaces that can withstand higher demands [1–3]. Although contemporary bearings are clinically reliable, some problems still need to be addressed, including wear of polyethylene components, metal ion release from metal components, pseudo-tumor formation, lymphocyte-dominated vasculitis-associated lesion for metal-on-metal (MoM) bearings, toughness of ceramic components, potential risk of fracture, and squeaking for ceramic-on-ceramic (CoC) bearings [4–8]. All of these drawbacks become particularly relevant in cases of THA for young patients, who tend to be more active and heavier and have a longer life expectancy compared with old patients [9,10].

A mixture of different hard bearing surfaces created a novel option: the ceramic-on-metal coupling (CoM), in which a ceramic femoral head articulates with a metal acetabular insert. Most hip simulator analyses proved that this alternative bearing has significant advantages, which include a lower risk of fracture and squeaking compared with CoC bearings and reduced wear and metal debris production compared with MoM bearings [11–15]. However, these previous analyses only reflected in vitro results, with only 4 published studies reporting clinical results after THA with CoM bearings [16–19]. Furthermore, these 4 clinical studies did not come to the same conclusion that CoM bearings had similar performance with CoC bearings and produced fewer metals ion than MoM bearings.

Hence, we investigated the clinical results and assessed the serum metal ion levels in a cohort of patients receiving THA with CoM bearings at a mean of 50 months. Our previous study showed that metal ion levels increase 6- to 7-fold 24 months after CoM THA, and the difference between CoM and MoM was significant [20]. This current study is a midterm follow-up, and our primary hypothesis was that CoM bearings had comparable clinical outcomes to those following the use of other

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bearings, and metal ion levels were elevated compared with a normal control group.

Materials and Methods

All patients undergoing THA in our arthroplasty center between September 2009 and December 2011 were considered for inclusion in this study. Patients were eligible for participation if they had end-stage joint disease and if a treating surgeon believed their premorbid activity profile and general condition made them suitable for a THA with a CoM surface. No age restriction was imposed. Exclusion criteria included failure to give consent, known metal allergy, renal impairment, previous metal materials implantation, or previous joint arthroplasty with MoM bearings. A total of 78 patients (89 THAs) were included in the study.

The operations were carried out by a senior orthopedist under general anesthesia. All patients received an identical Pinnacle acetabular component (Ti_6Al_4V) with a CoM surface. This CoM bearings surface comprised a ceramic femoral head made from zirconia-toughened alumina (Biolox Delta; Ceramtec AG, Plochingen, Germany) articulating against a wrought high-carbon, cobalt-chrome-molybdenum alloy (Ultamet) acetabular liner. Corail or Summit uncemented stems (Ti_6Al_4V) were used depending on the femoral medullary cavity shape. All components were supplied by DePuy International Ltd, Leeds, United Kingdom.

The surgical techniques used for the procedure were identical for all patients. A posterolateral approach with full capsular repair was performed. The acetabular component was impacted until fully seated, with a goal of 45° abduction and 15° anteversion. The acetabular component was fixed tightly with a 1-mm press fit. If primary press-fit fixation was not satisfactory, a Pinnacle cancellous screw was used for additional fixation. All included patients were allowed for full weight bearing using crutches for the first day after operation.

Patients completed the Harris Hip Score [21], Short-Form 12 (SF-12) [22], and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [23] both preoperatively and at the end of the follow-up period. At follow-up examinations, patients were asked if any other illnesses, such as skin allergy or malignancy, occurred and whether they had persistent pain or discomfort in the prosthetic hip. Standardized anteroposterior and lateral radiographs were taken at 100% magnification for radiographic analysis. The Pradhan method [24] was used to determine the acetabular component abduction angle and anteversion angle, using computer-assisted software (Canvas, version 9.0; Deneba Systems, Miami, Florida). Additionally, radiographs were reviewed for evidence of osteolysis, aseptic loosening, and implant migration.

Serum metal ion levels of cobalt (Co), chromium (Cr), molybdenum (Mo), and titanium (Ti) were measured using high-resolution inductively coupled plasma-mass spectrometry (7700 series; Agilent Technologies, Waldbronn, Germany), which proved to be a more powerful and high-performing technology than graphite furnace atomic absorption spectrometry [25]. Blood collection and processing methods were designed to minimize contamination, as we reported previously [26]. The blood samples were collected preoperatively and at the end of follow-up using triplicated polypropylene syringes, one for the infusion set and adapter and the others for measurement. The samples were transferred to lithium heparin tubes and were frozen before use.

Statistical Analyses

Data were recorded as means and SDs. Student paired *t* test was used to compare pre–functional scores and follow-up functional scores, as well as to compare metal ion levels and to estimate the median difference with 95% confidence intervals. Spearman correlation analysis was used to evaluate the relationship between metal ion levels and seven risk variables: age, body mass index (BMI), acetabular component abduction and anteversion angle, acetabular version (Developmental Dysplasia of the Hip [DDH] hip disease or non-DDH hip disease), bilateral arthroplasty, cup screw used, hip stem implant type (Corail or Summit), and femoral head size. All statistical analyses were performed using SPSS software (version 13.0; SPSS, Chicago, Illinois), and $P < .05$ was considered to be statistically significant.

Results

Of the 78 enrolled patients, 74 patients (85 THAs) finished follow-up, whereas 4 patients were unable to complete the study for personal reasons. The mean follow-up time was 50 months (25-58 months). The baseline characteristics and functional scores of the included 74 patients are shown in Table 1. The mean age of the patients was 54 (22-77) years, and 32 (43%) were women. Preoperative diagnoses included avascular necrosis (34 patients; 40 hips), femoral neck fracture (12 patients; 12 hips), DDH (12 patients; 14 hips), primary osteoarthritis (8 patients; 9 hips), secondary osteoarthritis (7 patients; 9 hips), and rheumatoid arthritis (1 patient; 1 hip). Corail stem was implanted in 72 hips (85%) and Summit stem was implanted in 13 hips (15%). The ceramic femoral head was 28 mm in 23 hips (27%) and 36 mm in 62 hips (73%). Pinnacle cancellous screws were used in 19 hips (22%) for better fixation.

No intraoperative and postoperative complications occurred in the entire cohort of 74 patients, such as dislocation, infection, deep vein thrombosis, or pulmonary embolism. There was no other observed adverse event, such as squeaking, ceramic fracture, metal sensitivity, persistent groin pain, or erythema and itching in the area of the prosthetic hip. At a mean follow-up time of 50 months, the mean HSS, SF-12, and WOMAC scores showed a significant improvement compared with preoperative scores (Table 2). The mean HSS increased from 37 points preoperatively to 93 points during follow-up. The mean SF-12 physical and metal component scores were increased from 30 and 44 points preoperatively to 49 and 52 points, respectively. The mean WOMAC domains A, B, and C improved from 11, 2, and 43 points preoperatively to 7, 1, and 8 points, respectively.

At the end of the mean 50 months of follow-up, 70 patients received radiographic examinations. Radiographs showed that the abduction angle and anteversion angle of the acetabular components were 40° ± 5° (28°-52°) and 14° ± 2°(11°-18°), respectively. There was no radiolucency or osteolysis in either the acetabular or femoral side, and there was no evidence of migration.

Metal ion analysis showed that serum levels of metal ions were significantly elevated in patients undergoing THA compared with normal values (Table 3). Compared with our previous 24-month study [20], Co ion levels were statistically elevated during the 50-month follow-up ($P = .005$), and no statistical difference was found for Cr ion levels at different follow-up periods ($P = .904$; Table 4). Spearman correlation analysis showed that there was no correlation between the metal ion levels and age, abduction angle, anteversion angle, acetabular version, bilateral arthroplasty, cup screw used, hip stem implant type, or femoral head size (Table 5). There was a correlation between 3 metal ion levels and BMI index (Co:

Table 1
Baseline Characteristics and Functional Scores of the Included Patients.

Characteristics/Functional Score, mean ± SD	
Mean age (y; range)	53 ± 13 (22-77)
Gender (M/F)	42/32
Mean height (cm; range)	164 ± 7 (145-176)
Mean weight (kg; range)	62 ± 11 (44-88)
Mean BMI (kg/m^2; range)	23 ± 4 (17-34)
Mean HSS (range)	37 ± 14 (16-68)
Mean SF-12 (range)	
Physical component	30 ± 6 (19-41)
Mental component	44 ± 9 (20-64)
Mean WOMAC (range)	
Domain A (pain, 0-20)	11 ± 3 (6-17)
Domain B (stiffness, 0-8)	2 ± 1 (0-4)
Domain C (function, 0-68)	43 ± 7 (30-60)

M, male; F, female.