#### ARTICLE IN PRESS

The Journal of Arthroplasty xxx (2017) 1-6



Contents lists available at ScienceDirect

### The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org



## Increased Serum Ion Levels After Ceramic-on-Metal Bearing Total Hip Arthroplasty: Influence of an Asian Lifestyle

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#### ARTICLE INFO

Article history:
Received 5 May 2017
Received in revised form
10 October 2017
Accepted 16 October 2017
Available online xxx

Level of Evidence: Prognostic study level III

Keywords: total hip arthroplasty serum ion lifestyle ceramic metal

#### ABSTRACT

*Background:* Recent clinical studies have suggested that systemic metal ion levels are significantly elevated at midterm follow-up in patients with ceramic-on-metal (COM) bearing. However, it is not clear whether there is a correlation between patient-related factors including the lifestyle and elevated levels of serum metal ions following COM total hip arthroplasty (THA).

Methods: Serum metal levels were measured in 201 patients (234 hips) including 121 COM patients (140 hips) and 80 non-COM patients (94 hips). The Harris Hip Score, University of California, Los Angeles activity scale score, and Western Ontario and McMaster Universities Osteoarthritis Index score were measured and radiographs were obtained for the analysis.

*Results*: Significantly higher levels of cobalt (Co) and chromium (Cr) were detected in the serum of the COM THA group (Co:  $1.86 \pm 4.0 \,\mu\text{g/L}$ ; Cr:  $1.81 \pm 2.87 \,\mu\text{g/L}$ ) than those of the non-COM THA group (Co:  $0.27 \pm 0.14 \,\mu\text{g/L}$ ; Cr:  $0.19 \pm 0.25 \,\mu\text{g/L}$ ; P < .001).

The serum metal levels of patients who achieved the squatting position and the kneeling position were significantly higher than those of patients who could not squat (Co: P = .033; Cr: P = .074) and kneel (Co: P = .049; Cr: P = .031). The metal ion levels of the COM THA group correlated with the total range of motion (Co: P = .0293; Cr: P = .0399).

*Conclusion:* Patients who underwent a 36-mm COM THA showed high serum metal levels although good clinical outcomes at the midterm follow-up. We found that COM THA patients who were capable of greater range of motion, squatting, and kneeling are at risk of metal ion—related problems.

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Although modern alternative hard-on-hard articulations such as ceramic-on-ceramic (COC) and metal-on-metal (MOM) bearings have been widely implemented to reduce wear-associated osteolysis and

Funding: This research was funded by Johnson & Johnson Medical North Asia.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2017.10.037.

The study was approved by institutional review board and was performed in accordance with all the ethical standards.

The research was performed at Korea University Guro Hospital, Seoul.

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loosening and increase total hip arthroplasty (THA) longevity [1,2], the outcomes are debatable and inconsistent [3]. Approximately 26% of revisions from MOM THAs and 13% from COC THAs were bearing related. The overall short-term to midterm revision rates were 2.2% and 5.4% for COC THA and MOM THA, respectively [4].

To avoid COC and MOM bearing complications, an innovative hybrid hard-on-hard bearing, ceramic-on-metal (COM) bearing, was introduced. With the COM bearing, the femoral head uses a BIOLOXVR Delta ceramic, and the liner is a metal alloy [5,6]. Compared with the "overall" MOM wear rate of 1.6 mm<sup>3</sup>/Mc, the COM wear rate was lower than 0.01 mm<sup>3</sup>/Mc, an apparent 100-fold reduction [7,8]. However, Affatato et al [9] reported that even in COM bearing use, mixing and matching components could not demonstrate effective wear behaviors and self-made hybrid matching should be handled with care, unless explicitly stated by producers. Furthermore, systemic metal ion levels are suggested to be significantly elevated at midterm follow-up [10—15]. Furthermore, a suboptimal component position is suggested

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**Table 1**Demographic and Radiographic Data and Functional Scores of the Study Population.

Characteristic	Group A (N = 121)	Group B (N = 80)	Group C (N = 36)			
Sex (Patients [hips])						
Male	93 (111)	33 (39)	12			
Female	28 (29)	47 (55)	24			
Age						
Mean (range)	51.61 (20-70)	48.11 (21-70)	40.28 (24-61)			
Diagnosis (patients [hips])						
ONFH	75 (92)	46 (54)				
Primary OA	11 (12)	4 (5)				
Secondary OA	16 (17)	20 (25)				
Trauma	18 (18)	6 (6)				
Infection	1(1)	4 (4)				
Follow-up (y)						
Mean (range)	3.46 (1-6)	3.1 (1-7.1)				
BMI						
Mean (range)	23.62 (16.16-34.55)	23.66 (16.16-32.47)				
Acetabular cup inclination						
Mean (range)	42.19 (24.3-58.5)	45.36 (25.1-66.3)				
Acetabular anteversion						
Mean (range)	28.84 (6.84-49.79)	28.29 (-6.02 to 45.95)				
Cup size						
Mean (range)	53.08 (50-60)	53.55 (48-58)				
Head size						
Mean (range)	36 (36-36)	32.08 (28-36)				

ONFH, osteonecrosis of femoral head; OA, osteoarthritis; BMI, body mass index.

to cause osteolysis and metallosis due to impingement and edge loading [16–20].

Another concern is that traditional Asian postures, such as squatting, kneeling, and cross-legged sitting, might cause impingements and metal ion level elevations in COM or MOM bearing THAs, because the prevalence of impingement after THA was higher than we expected [16,21–23]. However, it is still unclear regarding which patient group is at higher risk of elevated metal ion levels after COM THAs.

Therefore, the study aimed at (1) investigating and comparing the serum metal ion levels (serum Cr and Co) between patients who undergo COM THAs and those who undergo non-COM THAs (COC or ceramic-on-polyethylene [COP]) at short-term and midterm follow-up; (2) evaluating whether these serum levels correlate with any device-specific factors, such as component position and size, or patient-specific factors, such as sex, body mass index (BMI), age, activity level, and range of motion (ROM); and (3) investigating whether the metal ion concentrations increases in patients with the greatest ability to squat, sit cross-legged, and kneel in a traditional Asian posture.

#### Patients and Methods

This study was designed to compare serum metal ion levels and functional results of patients after COM THA vs non-COM (COC or COP) THA at short-term and medium-term follow-up and to determine the risk factors such as adequacy of implant position and patient activity which might influence systemic iron level. The study was approved by our institutional review board, and selected patients signed the approved consent forms for the use of their blood and clinical data.

A total of 404 primary THAs (356 patients), including 258 COM THAs (232 patients) and 146 non-COM THAs (124 patients), were performed by a single surgeon from August 2009 to December 2013. All patients undergoing THAs were enrolled if they met the inclusion and exclusion criteria.

The inclusion criteria were as follows: (1) age 20-70 years; (2) informed consent; (3) not morbidly obese; (4) clinically qualified for THA based on physical examination and medical history; (5) noninflammatory joint disease; (6) no history of THA or hip fusion; (7) surgery performed using a minimally invasive posterior approach by a single surgeon; and (8) standard postoperative care and rehabilitation protocol (the care providers were blinded to the implant type).

The exclusion criteria were as follows: (1) inflammatory joint diseases; (2) any current metal hardware; (3) arthroplasty in any other joint during the follow-up; (4) preoperative abnormal serum urea or creatinine levels; (5) severe medical disability limiting ambulation; (6) occupational exposure to Co or Cr; (7) proprietary multivitamins and minerals; (8) chronic steroid or immunosuppressive therapy; (9) metabolic bone diseases other than osteoporosis; and (10) plans to relocate to other geographical areas before the study completion.

All patients received identical porous-coated Pinnacle acetabular components (Pinnacle; DePuy, J&J, Warsaw, IN). The COM THA patients received equivalent acetabular liners of a high-carbon wrought cobalt-chrome-molybdenum alloy (Ultamet; DePuy), 36-mm femoral heads made of a zirconia-toughened alumina ceramic Biolox Delta modular head (DePuy), and Summit Tapered cementless femoral stems (Ti6Al4 V). For the non-COM bearing patients, ceramic liners or Marathon (DePuy) polyethylene liners with 32-mm or 28-mm ceramic heads and mostly Summit femoral stems (DePuy) were used.

The patients were divided into 3 groups based on the bearing type used. A total of 237 participants including a control group were included. The numbers of patients and implants and patient demographic data are presented in Table 1.

**Table 2**Comparison of Serum Ion Levels, ROM Score, Functional Scores, and Acetabular Cup Position Between the 3 Groups.

Group	Group A (N = 121)	Group B (N = 80)	Group C $(N = 36)$	P Value
Serum ion level (μg/	L)			
Cobalt	$1.86 \pm 4.00 (0.9; 0.3-34.2)$	$0.27 \pm 0.14  (0.2;  0.1  0.9)$	$0.27 \pm 0.18  (0.2;  0.2\text{-}1.1)$	.000
Chromium	$1.81 \pm 2.87 (1.1; 0.1-27.8)$	$0.19 \pm 0.25 (0.1; 0.1-2.3)$	$0.15 \pm 0.07 (0.1; 0.1-0.3)$	.000
ROM score				
Flexion	$123.1 \pm 16.8 (120.0; 70-150)$	$116.0 \pm 16.2 (120.0; 80-140)$	_	.002
Abduction	$43.8 \pm 10.6 (40.0; 20-80)$	$39.9 \pm 9.6 (40.0; 20-60)$	_	.018
Adduction	$33.5 \pm 8.6 (3.0; 15-50)$	$29.7 \pm 9.5 (30.0; 10-50)$	_	.006
ER	$39.9 \pm 8.9 (40.0; 10-80)$	$35.6 \pm 8.7 (40.0; 10-50)$	_	.009
IR	$32.4 \pm 10.0 (35.0; 10-60)$	$27.2 \pm 9.8 (30.0; 0-50)$	_	.001
Total ROM	$272.7 \pm 30.7 (280.0; 200-345)$	$248.5 \pm 32.3$ (250.0; 135-300)	_	.000
Functional score				
HHS	$95.4 \pm 5.4 (97.5; 69-100)$	$93.2 \pm 6.4 (94.8; 71-100)$	_	.013
WOMAC	$3.2 \pm 5.1 (1.0; 0-30)$	$3.5 \pm 5.4 (2.0; 0-40)$	_	.249
UCLA	$5.7 \pm 1.3 (5.5; 3-10)$	$5.6 \pm 1.2 (5.5; 3-8)$	_	.960
ACI	$42.2 \pm 7.1 (42.7; 24.3-58.5)$	$45.4 \pm 7.7 (45.2; 25.1-66.3)$	_	.003

Values are expressed as mean  $\pm$  SD (median; range).

ROM, range of motion; ER, external rotation; IR, internal rotation; HHS, Harris Hip Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; UCLA, University of California, Los Angeles; ACI, acetabular cup inclination; SD, standard deviation.

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