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Metal Ion Release With Large-Diameter Metal-on-Metal Hip Arthroplasty

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Abstract: Preoperative and postoperative ion concentrations were measured in 29 metal-on-metal, large-diameter head total hip arthroplasty (LDH-THA) patients. Mean chromium, cobalt (Co), and titanium levels from LDH-THA were 1.3, 2.2, and 2.7 μg/L at 12 months. The open femoral head design showed significantly higher Co concentrations than the closed design (3.0 vs 1.8 μg/L, $P = .037$). Compared with previously published ion levels from a hip resurfacing system presenting the same bearing characteristics, Co levels were significantly higher in LDH-THA (2.2 vs 0.7 μg/L, $P < .001$). This study has demonstrated that the addition of a sleeve with modular junctions and an open femoral head design of LDH-THA causes more Co release than bearing surface wear (157% and 67%, respectively). Even if no pathologic metal ion threshold level has been determined, efforts should be made to minimize its release. We recommend modification or abandonment of the modular junction and femoral head open design for this specific LDH-THA system. **Keywords:** metal-on-metal articulation, large-diameter components, total hip arthroplasty, metal ion release, resurfacing, corrosion.

Metal-on-metal (MOM) articulation was reintroduced in total hip arthroplasty (THA) in 1988 by Weber [1]. Improved manufacturing technology and a better understanding of the factors influencing MOM component wear made this new generation of bearings promising [2-6], especially for young and active patients [5,7,8]. However, many concerns still remain regarding the effects of prolonged exposure to increased metal ion levels [9-16], such as hypersensitivity, carcinogenicity, and fetal exposure to metallic ions in pregnant women [17-19].

In an effort to reduce the amount of ion release from articulation wear, the science of tribology, mathematical models, and joint simulation studies have suggested that large-diameter components with small clearance minimize ion release [20-24]. However, articulating surface wear is not the only source of metal ion release. Taper junctions have been shown to cause significant metal ion release by fretting corrosion [25-31]. This phenomenon occurs in all THA modular implants, and severity might be associated with the number and quality of metallic junctions. Furthermore, the metal surface of implants can undergo corrosion due to contact with body fluids over time, thereby increasing ion release [28,32,33]. Corrosion ensues when the protective film is disrupted by fretting or micromotion, leading to contact between bodily fluids and metallic implants [28].

The main objective of this prospective cohort study was to report chromium (Cr), cobalt (Co), and titanium (Ti) concentrations in subjects with MOM large-diameter head (LDH) THA in comparison to preoperative levels. In addition, by comparing our results to previously published data on hip resurfacing (HR) systems possessing the exact same bearing characteristics [34,35], it should be possible to determine the effect of modularity and femoral head design on metal ion release.

Methods

Patient Cohort

Subjects with unilateral degenerative hip joint disease in whom a LDH-THA was planned (LDH Durom; Zimmer, Warsaw, Ind) were asked to participate in the study (date of surgery between August 2005 and December 2007). Twenty-nine patients accepted to be study subjects. The exclusion criteria were the presence of other metallic implants (ie, other joint arthroplasty,

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Table 1. Demographic Data on the LDH-THA Group

No. of Subjects		29
Sex	Men/women	15/14
	(%/%)	52/48
Age	Average (y)	50
	Range, SD	31-62, 7.9
BMI	Average (kg/m^2)	27
	Range, SD	20-36, 4.4
Preoperative diagnoses	Primary osteoarthritis (%)	23 (79)
	Childhood hip disease (%)	4 (14)
	Posttraumatic (%)	2 (7)
Bearing diameter	Average (mm)	47.6
	Range, SD	42-56, 3.4
Postoperative acetabular component abduction	Average (°)	44.7
	Range, SD	30-61, 8.3
Femoral offset		
Postoperative	Average (mm)	39.7
	Range, SD	31.5-45.6, 3.8
Contralateral	Average (mm)	40.7
	Range, SD	21.2-50.0, 6.1
Postop vs contralateral: *P* value		.230
Horizontal acetabular center of rotation		
Postoperative	Average (mm)	33.8
	Range, SD	24.9-70.7, 8.0
Contralateral	Average (mm)	34.6
	Range, SD	23.6-81.9, 10.4
Postop vs contralateral: *P* value		.257
Total hip offset		
Postoperative	Average (mm)	73.5
	Range, SD	58.9-104.3, 8.3
Contralateral	Average (mm)	75.3
	Range, SD	52.9-123.5, 12.7
Postop vs contralateral: *P* value		.103
WOMAC score	Average preoperative	56.5
	Range, SD	12-82, 16.2
	Average at 1 y	7.7
	Range, SD	0-61, 13.6
UCLA activity score	Average at 1 y	7.2
	Range, SD	4-10, 2.0

internal fixation device), renal insufficiency, and known cutaneous metal allergy. The reasons for incomplete data were late change in operating room schedule and/or research assistant not available for preoperative blood sample collection in 3 of 29 cases, with abandonment of blood collection in 4 of 29 cases after 2 venous puncture attempts (to avoid metal needle contamination) at 6 months' evaluation. All samples were collected for 12 months' evaluation (see Table 1 for patients' demographic details).

Implants

LDH Metasul wrought-forged, high-carbon content Cr-Co alloy (Co-28Cr-6Mo, 0.20%-0.25% C) modular femoral heads were impacted on wrought-forged, grit-blasted, uncemented Ti (TiNiVa) CLS/Sportorno femoral stems (Zimmer). Respecting contralateral side anatomy and aiming to reconstruct hip biomechanics, the attending surgeons chose 1 of 3 different neck angles available (125°, 135°, and 145°). Between the femoral head and stem, a tapered Cr-Co sleeve needed to be inserted, allowing neck length adjustment (−4, 0, +4, and +8 mm; Fig. 1). This sleeve added 2 taper junctions, one between the sleeve and the femoral stem neck and the other between the sleeve and the femoral head. The double-taper sleeve design was included to reduce femoral head inventory. At surgery, the sleeve was first inserted in the femoral head and impacted with 2 to 3 hammer blows. Afterward, the head and sleeve were impacted with 2 to 3 hammer blows on the femoral stem trunnion. LDH Metasul femoral heads with diameters of 50 mm and larger have an open design, whereas femoral heads with diameters of 48 mm and smaller have a closed design (Fig. 1). According to the manufacturer, femoral heads of at least 50 mm were made "open" to reduce their weight. Durom (Zimmer) acetabular components, which can be used with either HR or LDH-THA systems (Fig. 2), were coated with vacuumed Ti plasma spray for secondary bone integration and implanted by the press-fit technique. The original Durom acetabular component, "worldwide" version, implanted in the present study was not approved by the US Food and Drug Administration: a modified version with a thicker Ti coating as the only change is currently sold in the United States. High failure rates with the Durom

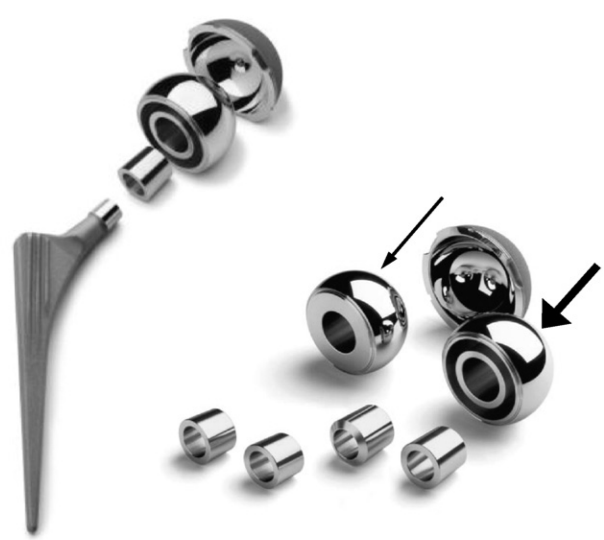

Fig. 1. Durom large-diameter head system (Zimmer) with different modular sleeves to adjust neck length. The small arrow points toward the closed head design; and the large arrow, the open head design.