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A Safe Zone for Acetabular Component Position in Metal-On-Metal Hip Resurfacing Arthroplasty: Winner of the 2012 HAP PAUL Award

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ABSTRACT

A safe zone for acetabular component positioning in hip resurfacing (RAIL: Relative Acetabular Inclination Limit) was calculated based on implant size and acetabular inclination angle (AIA). For AIA below the RAIL, there were no adverse wear failures or dislocations, and only 1% of cases with ion levels above 10 μg/L. Other than high inclination angle and small bearing size, female gender was the only other factor that correlated with high ion levels in the multivariate analysis. Seven hundred sixty-one hip resurfacing cases are included in this study. The UCLA activity score, femoral shaft angle, body mass index, weight, American Society of Anesthesiologists score, combined range of motion, diagnosis, age, gender, implant brand, AIA, bearing size, and duration of implantation were analyzed to determine the potential risk factors for elevated metal ion levels. These findings apply to sub hemispheric metal-on-metal bearings with similar coverage arcs as the Biomet and Corin hip resurfacing brands. Additional problems may occur when these bearings are connected with trunions on stems for total hip arthroplasty.

The cause of adverse wear failures in metal bearings is controversial and multifactorial [1,2]. The Oxford Group famously published a large report indicating an extremely high rate of failure due to pseudotumors of 4% at 8 years using implants that have a good track record [3]. They were uncertain of the cause of these pseudotumors and reported that these failures were *not* due to problems with component positioning. DeSmet had previously found that failures due to adverse wear in hip resurfacing are characterized by the finding of metalosis in surgery, and were correlated with elevated blood levels of metal ions [2,4–6]. Furthermore, adverse wear was correlated with acetabular component inclination angles (AIA) in excess of 55°. Smaller component sizes were more likely to suffer from this mode of failure because the coverage arc is usually smaller by design with smaller sizes in most implant systems. In extensive studies with the now recalled DePuy Articular Surface Replacement (ASR) implant (Depuy, Warsaw, IN), Langton has found that the risk of adverse wear failure is correlated strongly with higher AIA but also with excessive anteversion [2]. Because the ASR has been recalled due to a flawed design, information about implant position as it relates to adverse wear failure cannot be generalized to other well-designed implants. However, Hart has confirmed these principles with more precise CT based analysis of implant positions and retrieval wear analysis of various acetabular components [1]. Numerous studies have now shown that the risk of adverse wear failures is usually much lower than that reported at Oxford; typically under 0.5% overall, or 1% by 8 years with well-designed components [2,7–9]. The recalled ASR is an exception.

We have published a low rate of adverse wear failure with the Biomet and Corin devices of 0.3% in 2600 cases with an average follow-up of 4 years [10]. The Kaplan Meier time weighted failure rate was 1% at 8 years. All of our adverse wear failures were in components less than 50 mm and were characterized by the findings of markedly elevated blood metal ion levels and metalosis. We found that an AIA <50° was a safe zone in which adverse wear failures were not seen. Our report was based on the incidence of revision for adverse wear failures. It should be emphasized that this safe zone is implant specific and does not apply to the ASR device. However, it may most likely apply to other devices with a similar coverage arc by design. Since 2010, we have begun collecting metal ion levels for routine monitoring of hip resurfacing patients [5]. As a result, we have been able to diagnose patients with adverse wear failure much sooner, sometimes when they only have minor symptoms. Therefore, it seemed logical to use the criteria of elevated metal ion levels as well as actual adverse wear failures to refine the safe zone for AIA in hip resurfacing. Additionally, using this more sensitive measure for adverse wear, we wanted to know if there were any additional risk factors for adverse wear.

Materials and Methods

Institutional Review Board approval was obtained for the current retrospective study. Since February 2010, we began requesting

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routine metal ion testing for all patients who had reached a minimum of 2 years of follow-up to be sure patients were beyond the initial running-in period [11]. At time of this study, we were able to obtain tests on 623 patients (428 men vs. 195 women) with 777 (777/1940; 40%) hip resurfacings. All these cases were performed by a single surgeon (T.P.G) between July 1999 and December 2009. A total of 768 (768/777; 99%) of these cases have AIA measured on AP pelvis X-rays. Depending on the length of follow-up of the patient, metal ion levels were taken anywhere between 2 years and 13 years postoperatively. The patients were asked to stop taking any vitamins or supplements for at least one week before the test. Our preferred testing site was Quest Diagnostics (Madison, NJ, USA), but tests from other facilities were accepted. Therefore, we had 768 cases with both metal ion test results and quality AP pelvis X-rays available in our database OrthoTrack (Midlands Orthopaedics, P. A. Columbia, SC, USA) that formed the study group. In patients with levels higher than 10 μg/L, a computerized tomography (CT) scan or magnetic resonance imaging (MRI) was recommended even if they were asymptomatic in order to identify whether they had evidence of adverse wear related soft tissue mass. If they had significant soft tissue masses, revision was recommended. Eight adverse wear failures (seven patients) were discovered. In two patients with bilateral hip resurfacing, only one hip was affected and revised. In these patients, the unaffected hip was excluded from the study. Five patients who had another failure mechanism other than adverse wear were also excluded.

Therefore, 761 cases in 613 patients (422 men *vs.* 191 women) finally comprised the study group. There were 154 patients (302 cases) that had bilateral HRA. There were six bilateral patients, who had a HRA on one side and a metal-on-metal total hip arthroplasty (THA) on the other side.

Because over 70% of our patients are from out of state and because of our patients' medical insurance contracts, it was impossible to standardize the exact testing parameters and the lab sites. We did request whole blood measurements in our prescriptions. A total of 598 (79%) cases were tested at Quest labs; 58 (8%) were done at LabCorp (Burlington, NC, USA); the remainder were performed in various other labs around the country. Often labs did not follow our prescription; therefore whole blood, serum, and plasma levels were obtained in different cases. The Cobalt (Co) results were whole blood in 485, serum in 62 cases, plasma in 151, and were not specified in the remainder. The Chromium (Cr) results were from whole blood in 422, serum in 147 cases, cases, plasma in 62 cases, and were not specified in the remainder.

The demographic and diagnosis information of the study group was listed in Table 1. Most femoral component (bearing) sizes were between 44 mm to 56 mm (Fig. 1). Four prostheses from two manufacturers were employed in this study: 3 uncemented and 117 hybrid Corin Cormet 2000 (Corin Group, Cirencester, Gloucestershire, United Kingdom) [9,12]; 309 hybrid and 332 fully porous coated Biomet ReCap-Magnum (Biomet, Warsaw, Indiana, United States) [13]. Surgical information was listed in Table 2. According to our protocol, post-operative follow-up visits were requested at six weeks, one year, two years, and every other year thereafter. Standardized clinical questionnaires and supine anterior-posterior (AP) and cross table lateral radiographs were requested on each visit. Unless complications were reported, physical examinations were required only at six weeks and one year postoperatively. Office visits were preferred, but remote follow-up was accepted. Remote follow-up consisted of submitting a patient questionnaire, or completing the questionnaire via phone interview, and having radiographs and physical exam reports sent to our office. Clinical data consisting of Harris Hip Scores (HHS), UCLA activity scores, and visual analogue scale (VAS) pain scores for normal and worst days were calculated from patient questionnaires. AP pelvis and lateral radiographs were analyzed for component position, shifting, and radiolucencies. Acetabular inclination angles (AIA) and femoral shaft angles were measured for all radiographs. Clinical data were maintained, radiographic measurements were performed, and all complications and revisions were recorded using our patient database OrthoTrack (Midlands Orthopaedics, Columbia, South Carolina). Most acetabular inclination angles were between 35° to 55° in this study (Fig. 2).

Table 1
Demographics and Diagnoses of the Study Group.

Variables (# of Cases = 761)	Average	Range
Age at surgery (yr)	52 ± 8	17 to 76
Weight (lbs)	186 ± 39	107 to 370
BMI	27 ± 4	17 to 51
T-score	0 ± 1	−2.9 to 6.7
	Number	Percentage
Gender (N = 613 patients)		
Males	422	69.0%
Females	191	31.0%
Diagnosis		
Osteoarthritis	621	81.6%
Dysplasia	77	10.1%
Osteonecrosis	27	3.5%
Post Trauma	13	1.7%
Legg-Calvé-Perthes	9	1.2%
Rheumatoid Arthritis	2	0.3%
SCFE	1	0.1%
Post Infection	1	0.1%
Other	10	1.3%

Statistical Methods

We set the level of significance $\alpha = 0.05$ in this study. We decided to study two different thresholds for metal ion levels. The lowest ion levels in a documented adverse wear failure case were 15 μg/L. Therefore, for the first analysis we defined high levels as ≥10 μg/L, for the second analysis we used a threshold of ≥7 μg/L, which has been recommended by other studies [14,15]. If either the Co or the Cr levels were above the chosen threshold, the patient was entered into the "high" category. All other patients were in the "low" category.

First, univariable logistic regression models were generated to identify any significant risk factors for high metal ion levels. In these logistic regression models, the metal ion levels were designated as categorical variables (<10 vs. ≥10; or <7 vs. ≥7) and defined as the outcome. The UCLA activity score, combined range of motion (CROM), femoral shaft angle, body mass index (BMI), weight, ASA score, diagnosis, age, implant brand, gender, AIA, bearing size, and duration of implantation were each defined as explanatory variables. The explanatory variables of BMI, age, and AIA were initially defined as numeric variables; then they were grouped into two groups based on our previous studies or suggested by other references [16] and defined as nominal variables. The variable of ASA score was defined as an ordinal variable. The bearing size (outer diameter of femoral component) was also defined as an ordinal variable with values from 40 mm to 60 mm in 2 mm increments; then, bearing size was separated into two groups (≤48 and >48) and defined as a nominal variable. The variable of UCLA activity score was defined as an ordinal variable with values from 0 to 10. The variables of diagnosis, brand,

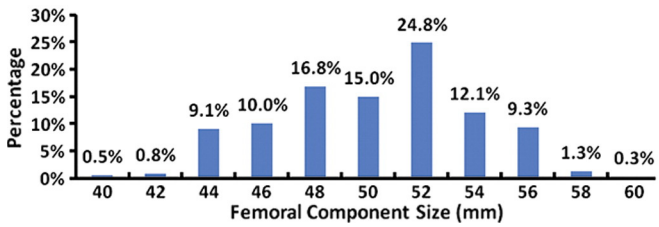

Fig. 1. Distribution of femoral component sizes in this study.