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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

Fei Liu PhD, Thomas P. Gross MD

Midlands Orthopaedics, P.A. Columbia, South Carolina

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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.

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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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Reprint requests: Fei Liu, PhD, Midlands Orthopaedics, P.A., 1910 Blanding St, Columbia, SC 29201.

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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,

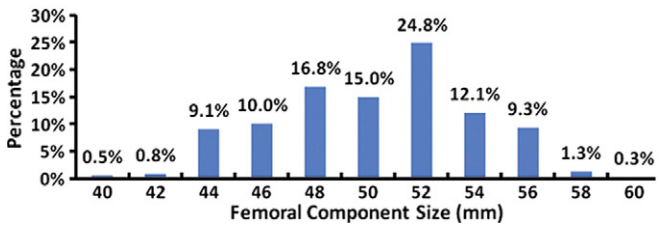

Fig. 1. Distribution of femoral component sizes in this study.

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Table 2
Surgical Data for the Study Groups.

	Average	Range
Length of Incision (in)	4 ± 1	0 to 12
ASA	2 ± 1	1 to 3
Operation Time (min)	111 ± 20	32 to 278
Estimated Blood Loss (EBL) (mL)	229 ± 113	20 to 725
Hospital Stay (days)	3 ± 1	0 to 8
Size of Acetabular Component (mm)	56 ± 4	46 to 66
Size of Femoral Component (mm)	50 ± 4	40 to 60

and gender were defined as nominal variables. The variables of femoral shaft angle, CROM, weight and duration of implantation were defined as the numerical variables.

Based on univariable logistic regression models, the significant risk factors were selected as explanatory variables to generate multivariable logistic regression models with the outcome still defined as the level of metal ion levels. The multivariable regression model identified the potential independent risk factors. Furthermore, a reduced multivariable regression model was built based on the two most significantly independent and meaningful risk factors. The possibility for metal ion levels ≥10 and ≥7 was predicted separately based on this model under different conditions in order to present more useful clinical information.

Results

Clinical and radiographic data for the study group are listed in Table 3. Twenty out of 761 (2.6%) cases in 15 patients (4 men vs. 11 women) had either Co or Cr ion level ≥10 μg/L; 38 out of 761 (5.0%) cases in 29 patients (12 men vs. 17 women) had either Co or Cr level ≥7 μg/L. In this study, eight adverse wear related failures in 7 patients (1 man vs. 6 women, 1%) were identified and revisions were performed. All these adverse wear related cases were associated with high metal ion level ≥15 μg/L. Two (2/761; 0.3%) patients with dislocations were identified in this study group. One was a man (AIA = 56°, Co = 10.5 μg/L, Cr = 6.2 μg/L) and the other was a woman (AIA = 41°, Co = 3 μg/L, Cr = 1.7 μg/L). Each patient has had two dislocations and has not been revised. Because our lowest metal ion level in a documented case of adverse wear failure was 15 μg/L, we chose 10 μg/L as a safe threshold for this study.

With a metal ion level of <10 μg/L or ≥10 μg/L as the outcome variable, weight, duration of implantation, implant brand (Biomet *vs.* Corin), gender, AIA and AIA grouped by <50° and ≥50°, femoral component size and femoral component size grouped by ≤48 mm and >48 mm were determined as significant risk factors for high metal ion level after metal-on-metal HRA based on univariate logistic regression models (Table 4). Weight, duration of implantation, implant brand (Biomet *vs.* Corin), gender, AIA grouped by <50° and ≥50°, and femoral component size grouped by ≤48 mm and >48 mm were included into a multi-variable logistic regression model I. According to the model generated based on these significant risk factors, the only independent significant risk factor was AIA grouped by <50° and ≥50° ($P < 0.0001$). However, a reduced multi-variable logistic regression model II, excluding the variable of gender, did identify both AIA grouped by <50° and ≥50° ($P < 0.0001$) and femoral component size grouped by ≤48 mm and >48 mm ($P = 0.02$) (Table 4) as independent risk factors. On the other hand, if we excluded the variable of the femoral component size grouped by ≤48 mm and >48 mm from the logistic regression model I, the reduced regression model III demonstrated that both AIA grouped by <50° and ≥50° ($P < 0.0001$) and gender ($P = 0.006$) were independent risk factors. Therefore, the variables of gender and femoral component size are correlated variables in the logistic regression model I.

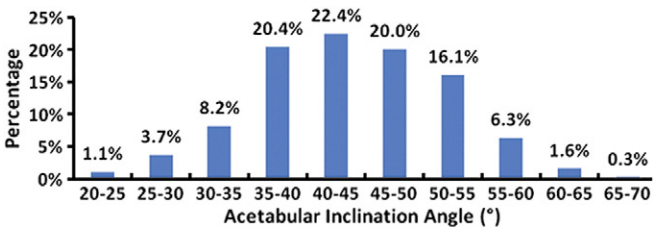

Fig. 2. Distribution of acetabular inclination angle (AIA) measured in this study.

Table 3
Clinical and Radiographic Data for the Study Group.

Variables	Average	Range
Clinical Data		
Preoperative		
HHS	56 ± 14	9 to 96
Postoperative		
Period of Follow-up (yrs)	4 ± 2	0.4 to 11
HHS	98 ± 7	33 to 100
UCLA Activity Score	7 ± 2	2 to 10
VAS Pain: Regular Days	0 ± 1	0 to 8
VAS Pain: Worst Days	1 ± 2	0 to 10
Radiographic Data		
FSA (°)	141 ± 8	102 to 178
AIA (°)	44 ± 8	16 to 66

FSA, Femoral Shaft Angle; AIA, Acetabular Inclination Angle.

Because adverse wear is highly correlated with small implant size and steep AIA, a detailed analysis was performed to characterize their interrelationship. The risk of having a high metal ion level of ≥10 μg/L was predicted from a reduced logistic regression model including only the explanatory variables of implant size and AIA (Fig. 3). The risk of having a high metal ion level of ≥7 μg/L was also predicted. Then, we were able to construct several possible safe zones based on these two ion level thresholds and 95% and 99% confidence intervals. These are

Table 4
Risk Factors Analyses for High Metal Ion Levels (≥10) After Metal-On-Metal Hip Resurfacing Based on Univariable Logistic Regression Models (α = 0.05).

Variables	Higher Risk	Type	*P*-Value
Univariate analysis			
UCLA Activity Score[b]	-	C	0.08
Femoral Shaft Angle	-	N	0.92
CROM[c]	-	N	0.15
BMI	-	N	0.22
BMI Grouped (<29 and ≥29)	-	C	0.46
American Society of Anesthesiologists (ASA) score[b]	-	C	0.15
Diagnosis (OA, Dysplasia, Others)	-	C	0.1
Age	-	N	0.35
Age Grouped (<55 and ≥55)	-	C	0.14
Weight	Lighter	N	0.01[a]
Duration of Implantation	Longer	N	0.001[a]
Brand(Biomet vs. Corin)	Corin	C	0.002
Gender (male/female)	Female	C	<0.0001[a]
Acetabular Inclination Angle (AIA)	Larger	N	0.0001[a]
AIA Grouped (<50° and ≥50°)	≥50°	C	<0.0001[a]
Size of Femoral Components[b]	44 and 48	C	0.008[a]
Size of Femoral Components (≤48/>48)	≤48	C	<0.0001[a]
Multivariate analysis[d]			
Weight	-	N	0.29
Duration of Implantation	-	N	0.68
Brand(Biomet vs. Corin)	-	C	0.46
AIA Grouped (<50° and ≥50°)	≥50°	C	<0.0001[a]
Size of Femoral Components (≤48/>48)	≤48	C	0.02

[a] Statistical difference.
[b] Treated as ordinal variables;
[c] Combined range of motion including flexion, abduction, adduction, and internal rotation.
[d] Gender is the variable correlated with Size of Femoral Components.

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listed in Table 5. We superimposed all wear failures, all cases of elevated ion levels, and all dislocations on this graph (Fig. 4). In this group of 761 cases there were only 2 cases with dislocations. So far, we have not found a lower limit of AIA where there were elevated ion levels or clinical failures.

We suggest using the AIA limit calculated using an ion threshold of 10 μg/L and a 99% confidence interval as our recommended safe zone (The column highlighted in Table 5). We named this safe zone "RAIL" (Relative Acetabular Inclination Limit), because the AIA limit is relative to the implant size. All AIA below this limit can be considered safe. Ninety-nine percent of cases with elevated ion levels had AIA above the RAIL.

After choosing the RAIL we determined that 451 (59%) of our cases met the RAIL. Of these, 2/451 (0.4%) had a high ion level above 10 μg/L, 0/451 had adverse wear failure and 0/451 had dislocations. The remaining 310 (31%) did not meet our RAIL. This group had 18/310 cases (5.8%) with high ion level above 10 μg/L, 8/310 (2.6%) adverse wear failures and 2/310 (0.6%) dislocations ($P < 0.00001$).

Discussion

Although metal-on-metal HRA has been shown to be a successful alternative to traditional THA, particularly for young and active patients [9,17,18], recently, elevated metal ion level and adverse wear related failures after this procedure have raised concerns among surgeons and patients [15,19]. We have demonstrated a safe zone for positioning acetabular components in metal-on-metal hip resurfacing (based on both AIA and femoral component size) in this study. Placement of the acetabular component with an AIA below the RAIL can prevent adverse wear failures, high ion levels ≥10 μg/L and dislocations. The implant sizes are based on the bearing size, which is the OD of the femoral component or the inner diameter of the (ID) of the acetabular component. This safe zone was computed from data obtained using the Corin Cormet 2000 and Biomet Recap/Magnum HRA implant systems, both of which have previously been demonstrated to have acceptable survival rates [9,13]. It may also apply to the Wright Conserve and the Smith Nephew BHR and other designs that have similar bearing designs as the Corin and Biomet HRA systems. It does not apply to the DePuy ASR, which has been recalled due to bearing design flaws. It is not yet clear how this safe zone applies to large bearing THR systems with the same metal-on-metal bearings. In these implants, trunion corrosion and/or wear may contribute additional metal ions [2].

The RAIL has two primary applications: postoperative evaluation of patients and intraoperative measurements of component positions to ensure placement of the acetabular components to avoid later complications. We have previously reported a method to secure accuracy of component placement using a single intraoperative X-ray and a previous target of AIA < 50° for all patients [20]. In that series, we failed to meet our target in only 4% of cases primarily due to the fact that it is difficult to obtain non-rotated intraoperative X-rays. Based on our current study, we realize that a lower target should now be set for bearing sizes smaller than 54 mm. Studies are currently underway to determine how often this target can be achieved using refined intraoperative X-ray techniques.

Lewinnek et al first proposed the concept of a "safe zone" for acetabular component position in 1978 [21]. They proposed a range of inclination (30–50°) and anteversion (5–25°) that would prevent dislocation of metal polyethylene 28 mm stemmed THAs. Nine hips complicated by dislocation out of 300 THA cases were evaluated. One hundred thirteen (113/300; 37.7%) X-rays were measured. Six of 9 (66.7%) of the dislocations occurred in revision, not primary, THA

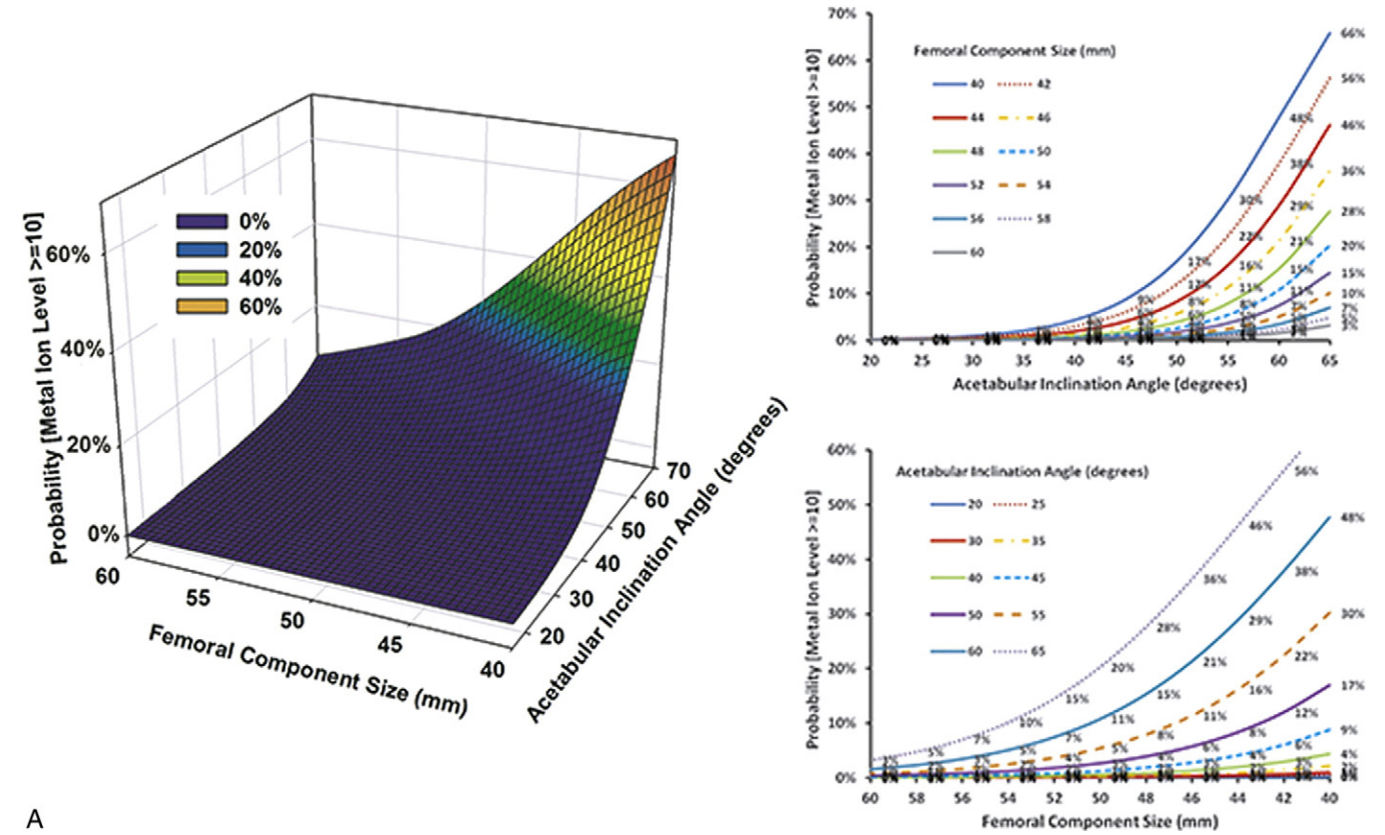

Fig. 3. Probabilities of metal ion level ≥10 μg/ml two-years or later post-operatively related to femoral component size and acetabular inclination angle: (A) 3D plot of the probabilities related to both femoral component sizes and acetabular inclination angles; (B) 2D plot related to only acetabular inclination angles for different femoral component sizes; (C) 2D plot related to only femoral component sizes at different acetabular inclination angles.

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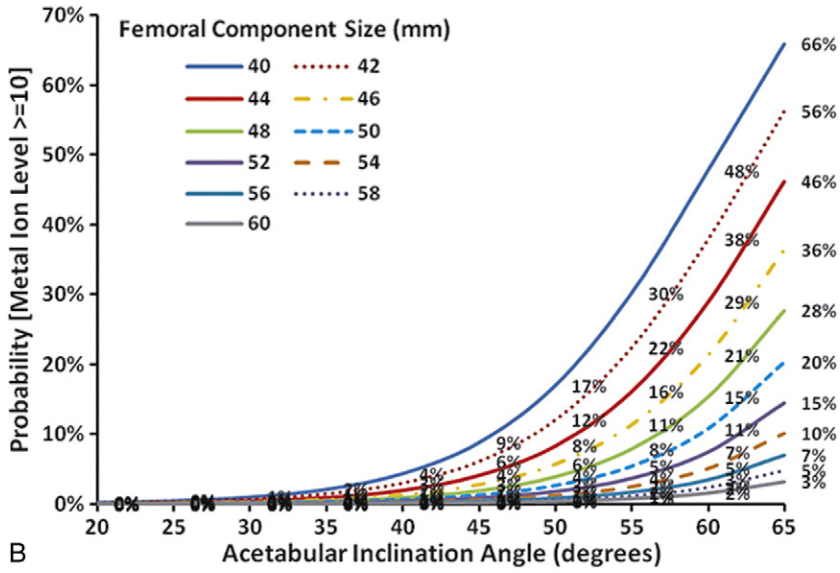

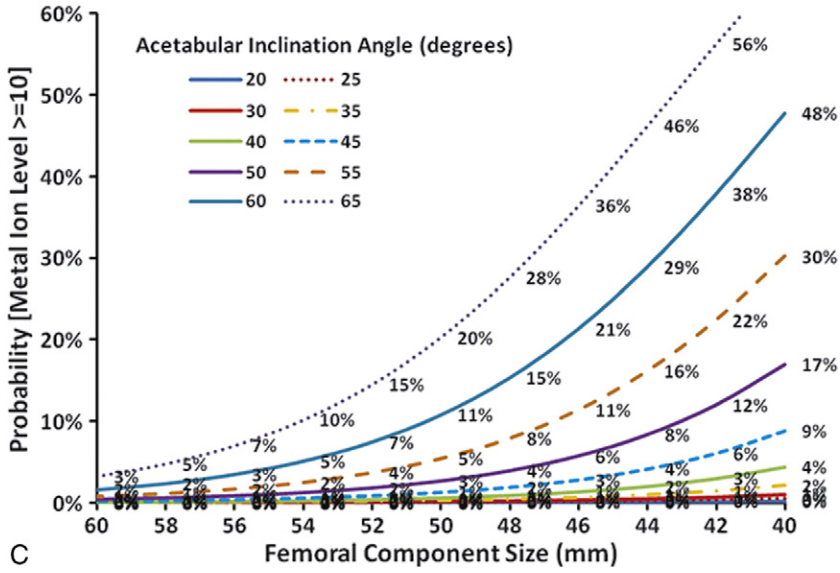

Fig. 3 (*continued*)

Table 5
The Thresholds of Acetabular Inclination Angles for Different Femoral Component Sizes With 99% or 95% Confidence Interval to Secure a Low Metal Ion Level.

Femoral Component Size (mm)	Metal Ion Level < 10 μg/L		Metal Ion Level < 7 μg/L	
	95% Threshold Angle (°)	99% Threshold Angle (°)	95% Threshold Angle (°)	99% Threshold Angle (°)
40	41	32	34	20
42	43	35	37	23
44	46	38	40	26
46	49	40	43	29
48	52	43	46	32
50	55	46	48	34
52	57	48	51	37
54	60	51	54	40
56	63	54	57	43
58	65	56	60	46
60	65	59	62	48

The column highlighted is our choice for RAIL.

cases. Revision arthroplasty is known to have a higher risk of instability than primary arthroplasty. When the inclination and anteversion of these 113 X-ray were graphed, an arbitrary "safe zone" was then drawn that included only 3 dislocations. The other 6 dislocations were outside of this "safe zone". It is apparent that this study was flawed. Despite these limitations, this "safe zone" has been universally accepted among hip surgeons for decades. Even though studies have confirmed that the zone is not truly safe, great efforts continue to be made with various technologies to target this zone [20,22,23].

In a retrieval study, DeSmet first reported that AIA > 55° was associated with adverse wear failures [4] with multiple resurfacing brands. Langton found that excessive inclination and anteversion correlated with adverse wear with the ASR and BHR implants [24]. Cobb confirmed this in a CT based retrieval study [1]. We previously found that there were no adverse wear failures in 2600 resurfacings over 12 years if the AIA < 50° and defined this as a "safe zone" for hip resurfacing [10]. In this study, we propose the RAIL as a more precise safe zone for hip resurfacing. We defined a safe zone to prevent metal ion levels above 10 μg/L with 99% of confidence interval based on 761

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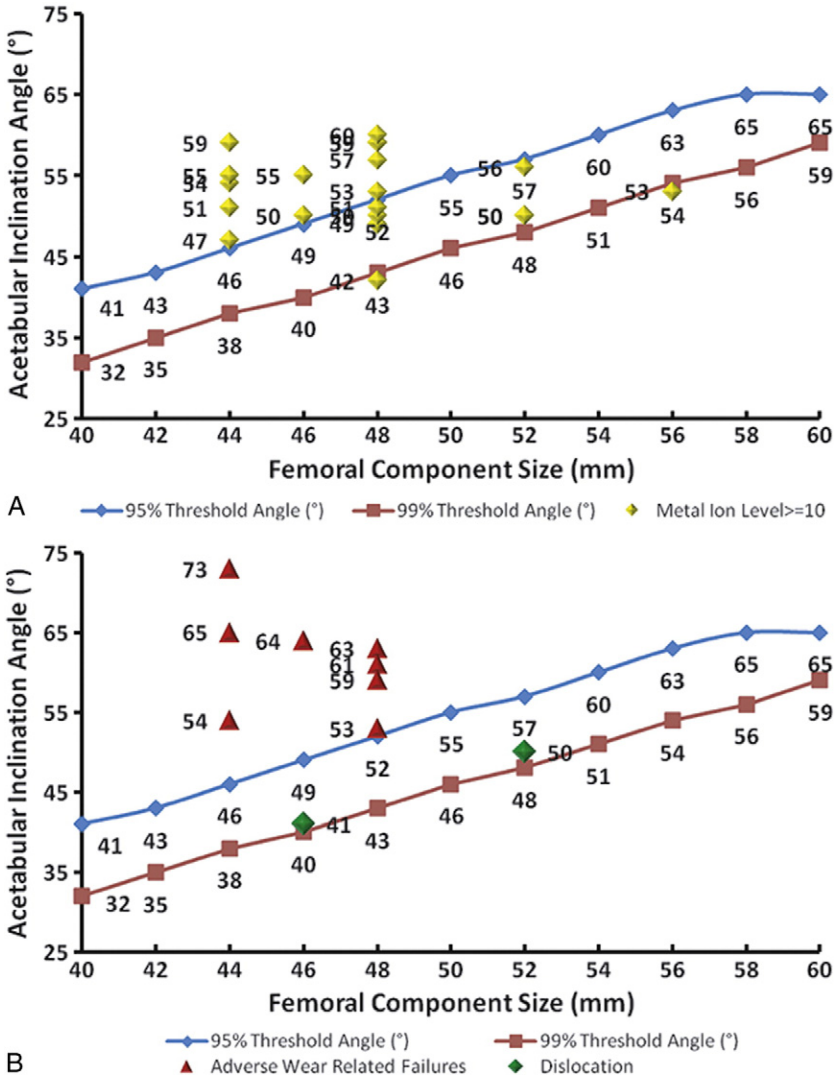

Fig. 4. Safe acetabular inclination angle ranges related to femoral component sizes with 95% and 99% confidence interval for metal ion level < 10 μg/L. (A) With the cases having metal ion level ≥ 10 μg/L in the present study; (B) with eight adverse wear related failures were identified at the time of this study and plotted according to acetabular inclination angle (AIA) in standing X-rays plus two dislocation cases.

cases with ion levels and non-rotated pelvis X-rays. To the best of our knowledge, this is the first time an accurate safe zone for acetabular component position relative to bearing size has been demonstrated for metal-on-metal hip arthroplasty. Our data indicate that the acceptable AIA decreases with implant bearing size (Fig. 4), and that a relationship exists between bearing size and safe AIA. Although this cannot be statistically proven due to the small number of cases at both extremes of bearing sizes, the relationship throughout the graph reinforces this possibility would hold true. It confirms DeSmet's insight that smaller implants, that are shallower by design, need to be placed more horizontally to avoid edge loading. Our data also show no adverse wear problems with low AIA; even in 9 extreme cases with AIA < 25°. In 761 cases, we have no cases of high ions or adverse wear failure due to an AIA that is too horizontal.

Although several studies have shown that excessive anteversion based on EBRA measurement [2] and CT measurement [1,25] is also a risk factor for adverse wear, a much weaker correlation with adverse wear exists for excessive anteversion than steep AIA [1]. We did not include a measure of anteversion. Therefore, our RAIL would likely be improved if anteversion was also controlled. We suspect that extreme anteversion or retroversion could be problematic even when the AIA is under the RAIL. However, if we were forced to include a measure of anteversion intraoperatively, this would be much more challenging than simply measuring the AIA on a non-rotated intraoperative X-ray. Even postoperative measurement of anteversion by CT is only possible in a few centers. Therefore, it is fortunate that a safe zone based on only AIA exists. We don't intend to suggest, however, that extreme anteversion or retroversion can be tolerated as long as the RAIL is achieved. We do use the transverse acetabular ligament and the qualitative appearance of anteversion on a non-rotated pelvis X-ray as a guide for setting anteversion to avoid extreme acetabular anteversion angles, but do not yet have adequate data to recommend a specific position.

Our data also suggest that female gender is an independent risk factor for adverse wear failure. The cause for this is not fully understood. Women do have smaller component sizes and account for most cases of dysplasia in our database, both of which could increase the failure rates after HRA [26]. However, our data seem to suggest that even with the same component size and AIA, a woman will be at higher risk for higher ion levels and wear failure than a man with the same implantation (size and position). Perhaps women require different implant positions or have different hip biomechanics than men. Women do have greater flexibility than men [27], but the CROM was not a factor that we could implicate in adverse wear failures in this study. However, if we keep the acetabular component under the RAIL, women can receive hip resurfacing with minimal risk of adverse wear failure.

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There were three somewhat unexpected negative findings in our study. First, longer duration of implantation was not a significant factor correlating with higher ion levels and adverse wear. In this study, metal ion levels were obtained from 2–13 years postoperative. One would expect that more wear failures occur with longer follow-up. However, our data seem to suggest that this is not true. One possible explanation is that all patients with elevated ion levels declare themselves by the time the 2-year running in period is completed. Longitudinal studies will be needed to further evaluate this question. Second, a higher UCLA activity score was not a significant factor correlating with higher ion levels and adverse wear. Again, this is counterintuitive, but it is consistent with a report from DeSmet that finds that runners have no higher ion levels than lower activity patients [4]. A type 2 error may be involved. Third, we could find no *lower* acceptable limit for AIA in our study. Although we could identify an upper AIA for each bearing size, we could find no cases where high ion levels occurred with very low AIA for *any* bearing size. Steep cups cause adverse wear; horizontal cups apparently do not cause adverse wear. They might cause some other, as of yet, unidentified problem. We have inadvertently achieved some very low angles. Surprisingly all of these patients have done well. We had 7 components (0.9%) with AIA $< 25°$ and two (0.3%) with AIA $< 20°$. However, due to the small number of components in this range, we cannot accurately predict their risk and therefore do not recommend placement below 25°, although this may be safe. Langton has presented data that suggest that a lower limit does exist for the recalled DePuy ASR implant [28]. But our data suggest that this may not apply to other implant systems. Type 2 errors may be involved.

The following weaknesses were identified in this study. First, the method of measuring ion levels could not be standardized. However, several studies have reported the correlation between different sample methods [5,29]. Despite the error introduced by this fact, we were able to demonstrate a robust safe zone. We believe the error introduced was mitigated by the fact that we used thresholds of ion levels (7 μg/L and 10 μg/L) rather than absolute values. This lack of standardization reflects the reality in private practice. Therefore, the RAIL is applicable to the realities of clinical practice. Second, because of the small numbers of patients (Table 1) at the extremes of implant size, we cannot be as certain of the results with these sizes. On the other hand, the linear relationship throughout Fig. 4 reinforces the fact that the RAIL probably also holds true at the extremes. Larger sizes are less problematic because there is a very large acceptable range for larger sizes according to the RAIL, and it is easy to err slightly more horizontal than the recommended limit during placement. Furthermore, we have not seen adverse wear failures in larger sizes. As others have shown, small sizes are where adverse wear occurs. Smaller bearing sizes (40 mm and 44 mm) are still problematic for 2 reasons. First the target range for acceptable AIA according to RAIL is very small, and we are less certain of the accuracy of this range because of the small numbers of cases analyzed.

We conclude the following for well-designed hip resurfacing implants:

1. High metal ion levels are strongly correlated with high AIA (on non-rotated pelvis X-rays), small component size and female gender.
2. A RAIL is proposed which is a linear relationship from 32° for bearing size 40 up to 59° for bearing size 60. This defines a safe maximum AIA for hip resurfacing.
3. If the AIA is below the RAIL, the risk of adverse wear failure or dislocation is close to 0% and the risk of a metal ion level above 10 μg/L is $\leq 1\%$.
4. Women with AIA under the RAIL have no failures, but above the RAIL, they are more likely to have adverse wear failure than men.
5. Higher activity and longer implantation time did not correlate with higher ion levels.
6. We were unable to identify a lower *unsafe* limit for AIA in the present study.

We have demonstrated that a robust safe zone exists for placing acetabular components in metal-on-metal hip resurfacing based on the risk of having high metal ion levels. This has not yet been demonstrated for any other type of hip arthroplasty. In the future, this must be further refined to include anteversion. Techniques need to be developed to allow surgeons to reliably hit this target.

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