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Research Article

Prevention of Metallosis in Hip Resurfacing: Confirmation of the RAIL Guideline in 2466 Cases

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Abstract

Background: In 2013, we published the first specific, individualized safe zone for acetabular component placement in metal-on-metal hip resurfacing. We developed these safe-zone criteria, known as the relative acetabular inclination limit (RAIL), by analyzing patient blood ion levels and standing pelvis radiographs of 777 hip resurfacing arthroplasties done before 2010; we reported on these cases in our previous 2013 RAIL manuscript and define them as our current control group. We aim to expand on our previous report but analyzing a larger study group; we hypothesize that the RAIL guidelines describe a method of acetabular component placement which minimizes risk of adverse wear-related failure and excessive blood metal ion levels for the described implant systems.

Methods: Our current study group comprises 2466 consecutive metal-on-metal hip resurfacing arthroplasties performed by a single surgeon between 2010 and 2016, establishing a minimum of 2-year follow-up for all cases. The Biomet Magnum™ MoM hip resurfacing system was used in all cases.

Results: We met RAIL in 100% of these cases, and none displayed signs of metallosis or adverse wear-related failure. Approximately 98% of these unilateral cases presented optimal blood ion levels.

Conclusions: These data expand upon our previous safe-zone study and further validate the RAIL criteria with a separate, larger patient cohort. This study suggests that RAIL can be achieved reliably and that metal wear may be altogether preventable in hip resurfacing arthroplasty with proper acetabular component positioning.

Keywords: *Metallosis; Hip Resurfacing; Relative Acetabular Inclination Limit (RAIL)*

Introduction

The use of metal-on-metal (MoM) bearings in hip resurfacing arthroplasty (HRA) has become more popular after advantageous changes to implant design and encouraging early clinical outcomes [1-4], but the fear of metal wear and ion release still limits the availability of MoM hip arthroplasty. Metal wear may lead to implant loosening, metallosis, and the formation of pseudotumors [1,5,6]; some patients require revision surgery due to adverse wear-related failure (AWRF).

Many researchers suggest metal wear correlates to acetabular inclination angles (AIA) [7-9]. Specifically, DeSmet described the correlation between metal wear and AIA beyond 55° [9]. However, this recommendation was not yet strict enough for smaller component sizes with lower coverage arcs; thus, smaller HRA devices continued to fail at an unacceptable rate due to AWRF, especially in women. We expanded on the inclination limit idea by defining an individualized safe zone, or relative acetabular inclination limit (RAIL), for intraoperative cup alignment based on implant size [10]. The concept addresses the issue of smaller cups with lower coverage arcs, which cannot tolerate steeper inclination angles

without developing edge-loading and subsequent wear failure [9]. The RAIL guideline applies to sub-hemispheric MoM bearings with similar coverage arcs as the Biomet Magnum™ and Corin Cormet™ HRA brands. We postulate that the RAIL guidelines describe a method of acetabular component placement which minimizes risk of AWRF for the Biomet Magnum™ MoM HRA system.

To confirm this claim, we present the current study detailing clinical outcomes of HRA cases implanted per the RAIL. Our primary objective is to prove the efficacy of RAIL in preventing abnormal metal ion levels, with a secondary aim of demonstrating the high-degree of accuracy with which the RAIL can be achieved using a normalized-to-standing intraoperative radiograph (NSIOR) technique.

Patients and Methods

Patient cohort

We implemented the RAIL in 2009, and in early 2010, we began positioning implants via NSIORs. We had fully implemented both techniques in their current forms by January 2010. Therefore, we chose this time as the beginning date for our study group. We compared clinical outcomes of the study cohort to a control group of 1546 cases (1024 patients) performed between 2004 to 2009 (Group 1). We defined 2004 as the lower limit since a different device was used before. The study group consists of 2466 Biomet MoM HRAs (1834 patients) performed between 2010 and 2016 (Group 2) with a minimum of 2 years follow-up. All patients in both groups had Biomet Magnum-ReCap™ MoM HRA implant systems placed via the minimally invasive posterior approach typically utilizing a 4-inch incision. All cases were performed by a single surgeon (TPG). Clinical outcomes from patients' 2-year follow-ups were compared to minimize time interval bias. Per standard protocol, we requested metal ions for all group 2 patients at 2 years postoperative. This protocol was not in place for group 1. In February 2010, we contacted all existing patients that were at or beyond 2-years postoperative and requested metal ion results. Therefore, metal ion results for group 1 are reported at a later interval, on average. Metal ion levels are useful indicators for potential failure from excessive implant wear [11] even before the onset of symptoms. We converted serum and plasma test results for cobalt (Co) and chromium (Cr) to whole blood ion level values using Smolder's method [12,13] and subsequently used whole blood values for all comparisons. Based on previous research [10,11,12], we define 5 ion level categories (Table 4): normal, optimal, acceptable, problematic, and potentially toxic. Data were gathered retrospectively from our clinical database, where all data is recorded prospectively per standard of care. No patients were lost to follow-up. Data collection for our previous 2013 RAIL paper ended in 2009; thus, the current study group represents a separate cohort with which to validate RAIL.

Table 1 presents demographic data. Both groups were demographically similar, but group 2 patients were slightly older with lower bone density; however, we have never selected against patients on a basis of age, gender, or diagnosis. Historically, smaller femoral component survivorship is significantly worse compared with larger sizes [14]. After our RAIL guidelines, we became more comfortable operating on patients with smaller femoral heads - group 1 mean femoral component size was 50.8 mm and group 2 was 49.8 mm ($p < 0.0001$). Mean follow-up was longer for group 1, which includes cases with earlier surgery dates.

Variable	Group 1	Group 2	P-value
Date Range	11/2004 - 1/2010	1/2010 - 6/2016	--
# of Cases	1546	2466	--
# Deceased*	19 (1.2%)	3 (0.1%)	< 0.0001*
Demographics	--		
#, % Female	411 (26.6%)	670 (27.2%)	0.682
Age (Years)	51.7 ± 8.4	53.7 ± 8.4	< 0.0001*
BMI	27.2 ± 4.6	27.3 ± 4.8	0.514
T-Score	0.0 ± 1.3	-0.1 ± 1.2	0.003*
Diagnoses (#, %)	--		
Osteoarthritis	1216 (78.7%)	1939 (78.6%)	0.984
Dysplasia	163 (10.5%)	309 (12.5%)	0.057
Osteonecrosis	76 (4.9%)	113 (4.6%)	0.624
Post-Trauma	37 (2.4%)	32 (1.3%)	0.009*
LCP/SCFE	34 (2.2%)	46 (1.9%)	0.459
Other	20 (1.3%)	27 (1.1%)	0.569

***Table 1**: Demographics for two study cohorts.*

Intraoperative technique

We developed NSIORs to consistently achieve RAIL. We hypothesize that most implant wear occurs in the standing position, so we developed the RAIL based on standing radiographs. Previous studies on acetabular component positioning [6,14-17] do not define x-ray position, potentially contributing a source of error in accurate component position measurements. In a small group of outlier patients [18], the AIA measured on standing film was over 5 degrees greater than the AIA measured on supine radiographs. We define this variation as dynamic posterior tilt of the pelvis. Because 5 - 10% of patients exhibit significant dynamic tilt, we base all our analyses and intraoperative positioning on standing pelvic x-rays.

The RAIL guidelines depend on AIA and component size. Though anteversion (AV) and contact patch to rim distance also affect implant wear [16,19], the main focus of this paper is the effect of controlling AIA. However, we do control AV by aligning the implant within ± 10° of the transverse acetabular ligament (TAL); this 20° AV range has been advocated as "safe" [18,20]. In the 5 - 10% of cases where the TAL is not visible, we use qualitative appearance of the cup. Though this method has room for improvement, it continues to wholly prevent AWRF, in our experience. In the future, CT based intraoperative guidance may be possible.

The RAIL guideline (Figure 1) specifies a maximum allowable AIA for each bearing size. We use 25° as our lower limit to prevent impingement [21]. Figure 2 lists the relationship between bearing size and coverage arcs; although we developed the RAIL based on data from the Corin Cormet 2000 and Biomet Magnum-ReCap™ systems, the RAIL technique should theoretically work for any HRA implant with similar coverage arc. Alternatively, surgeons can customize these positioning guidelines for any HRA implant using the formula in figure 2 relating coverage arc to AIA.

Bearing Size (ID, mm)	Standing AIA (AIA, deg)	Coverage Arc (α, deg)
40	32	155.8
42	35	156.9
44	38	157.9
46	40	158.8
48	43	159.6
50	46	160.4
52	48	161.1
54	51	161.8
56	54	162.4
58	56	163.0
60	59	163.6

Relevant Equations

$(AIA)=1.34*(ID)-21.2$

$(AIA)=3.45*(\alpha)-507$

Figure 1: *Presents the maximum allowable AIA for each Magnum-ReCap bearing size.*

Bearing Diameter	Conserve + (WRIGHT)	Conserve Biofoam (WRIGHT)	Magnum (Biomet)	BHR (S&N)	ADEPT (MatOrtho)	MITCH (Stryker)	ICON (IO)
36	158.85	166.56					
38	159.46	166.8	154.6	155.3	161.43	161.43	155.3
40	159.88	166.88	155.8	156.5	161.32	161.32	156.5
42	160.39	167.07	156.9	157.6	161.28	161.28	157.6
44	160.74	167.13	157.9	158.6	161.25	161.25	158.6
46	161.17	167.31	158.8	159.5	161.21	161.21	159.5
48	161.46	167.35	159.6	160.3	161.13	161.13	160.3
50	161.83	167.51	160.4	161.1	161.11	161.11	161.1
52	162.18	166.58	161.1	161.8	161.04	161.04	161.8
54	162.8	167.05	161.8	162.5	161.02	161.02	162.5
56	162.99	167.1	162.4	163.1	160.96	160.96	163.1
58	163.17	167.14	163	163.7	160.94	160.94	163.7
60	163.33	167.18	163.6				
Average coverage arc (α)	161.40	167.05	159.66	160.00	161.15	161.15	160.00

Sources:
Manufacturer/Drawings
The Hip Resurfacing Handbook

Figure 2: *Details the coverage arcs for various hip resurfacing systems.*

Normalized-to-standing intraoperative radiographs

A digital x-ray machine with an 8 x 10" non-tethered remote plate and viewing screen is required to achieve NSIORs. Fluoroscopy fields are too small, and non-digital radiographs are time consuming. We use the Shimadzu Dart (Shimadzu Corporation, Kyoto, Japan), but any digital x-ray machine should suffice. We bring paper copies of preoperative supine and standing AP pelvis x-rays to the operating room. The acetabular component is prepared and implanted according to the following criteria:

- AIA is between 25° and the RAIL for the specific bearing size.
- AV is within 10° of the TAL.
- The anterior inferior quadrant of the component is not protruding above the acetabular wall (to avoid psoas contact).

If these criteria cannot be met with the trial implant, the acetabulum is reamed deeper and the position is reassessed. Initially, the implant is gently impacted. It is reoriented as needed using a plastic tipped tamp. Next, it is impacted harder with a secondary impactor and 5-pound hammer. The femoral component is implanted, and the hip is reduced. The wound is packed with antibiotic pads. A supplemental drape is placed along the anterior side of the table. The x-ray plate is placed on a rolling stand, covered by a sterile drape, and pushed against the posterior side of the table. The table is rolled by the anesthetist to neutralize rotation. The x-ray beam is brought in from the front and directed perpendicular across the table to obtain a cross-table AP film of the pelvis (Figure 3). The surgeon (TPG) immediately views this film.

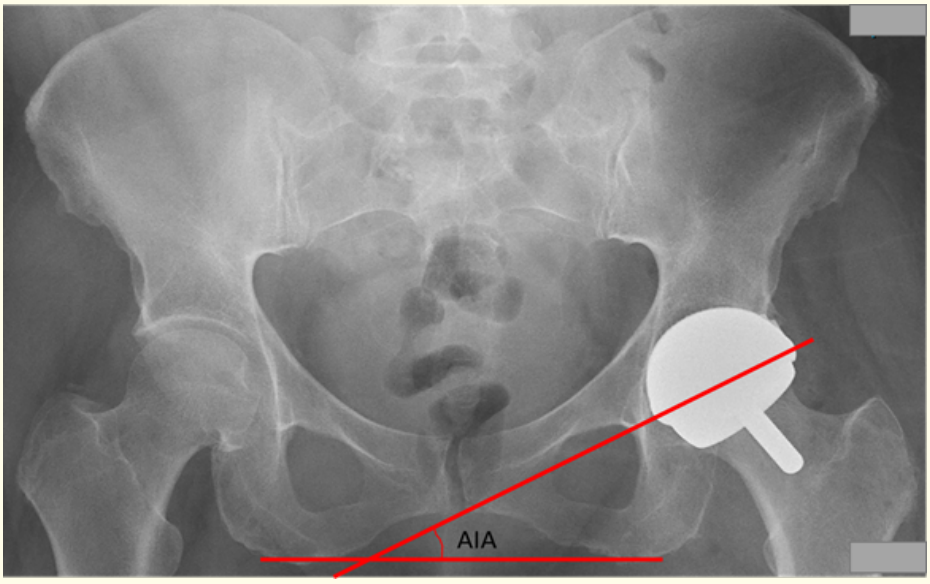

Figure 2: *Details the coverage arcs for various hip resurfacing systems.*

To obtain an NSIOR, we follow these steps: (1) Rotation is normalized by rolling the table based on relative widths of the obturator foramina. (2) Pelvic tilt is normalized by reproducing the height of the foramina on the standing preoperative pelvic x-ray. We achieve this by adjusting cranial/caudal tilt of the x-ray beam. (3) Duplicate x-rays are obtained until pelvic position matches the preoperative standing pelvic x-ray. (4) The image is then transmitted wirelessly to the operating room computer. A specially-trained assistant performs a digital measurement of the AIA, which is then confirmed by the surgeon (TPG). The AV and degree of seating of the implant are qualitatively judged. (5) If the implant position is inadequate, we reposition the acetabular component and repeat. If the criteria are satisfied, the case is closed in routine fashion.

In the recovery room, a supine pelvis x-ray is obtained; as soon as the patient can walk, a standing pelvis x-ray is obtained prior to discharge. These x-rays are used to determine if RAIL has been met.

Statistical analyses

All analyses were carried out at a 95% confidence interval using XLSTAT (Addinsoft, New York, NY, USA). Mean values were compared using a Students' t-test. Ratios were compared using a Z-score test for two population proportions.

Results

Table 2 also presents mean AIAs and a comparison of AIA measured intraoperatively to the supine and standing immediate postoperative x-rays. Group 2 NSIOR acetabular measurements differed from final standing AIA by a mean of 2.7°; mean cup inclination significantly decreased after the new guidelines ($p < 0.0001$).

	Group 1	Group 2	p-value
1. Intraop AIA (°)	37.9 ± 4.9	34.3 ± 3.7	< 0.0001*
2. Initial Standing Postop (°)	43.3 ± 7.3	34.1 ± 4.8	< 0.0001*
3. Latest Standing (°)	43.9 ± 7.9	34.4 ± 5.0	< 0.0001*
Mean Difference (1->2) (°)	3.3 ± 4.1	2.4 ± 2.1	0.0067*
Mean Difference (1->3) (°)	3.8 ± 4.2	2.7 ± 2.3	0.0022*
P-Value 1->2	< 0.0001*	0.2278	
P-Value 1->3	< 0.0001*	0.441	

***Table 2**: Intra- and post-operative acetabular inclination angles.*

We present metal ion data for both groups in table 3, which is supplemented by ion categories in table 4. Cobalt and chromium values were largely the same between groups. Group 2 had significantly fewer bilateral cases categorized with "problematic" ion levels (p = 0.03). Similarly, 10 group 1 cases (0.8%) presented suboptimal ion levels, whereas there was only one such case (< 0.1%) in group 2 (p = 0.007).

Latest whole blood metal ion levels for two study cohorts								
Variables	**Group 1 (11/2004 - 1/2010)**			**Group 2 (1/2010 - 6/2016)**			**P-values between Group 1 and Group 2**	
	Unilateral (N = 778)	**Bilateral (N = 768)**	**P-value**	**Unilateral (N = 1342)**	**Bilateral (N = 1124)**	**P-value**	**Unilat 1 vs 2**	**Bilat 1 vs 2**
Co* (µg/L)	1.2 ± 1.4	1.8 ± 1.8	< 0.0001*	1.1 ± 1.0	1.7 ± 1.2	< 0.0001*	0.1554	0.2628
Cr* (µg/L)	1.0 ± 1.1	1.4 ± 1.5	< 0.0001*	0.9 ± 0.7	1.4 ± 1.3	< 0.0001*	0.0676	1.000
#, % Patients Tested (Total)	1276 (82.5%)		--	1386 (56.2%)		--	< 0.0001*	
F/U Interval (Years)	5.2 ± 2.3	5.5 ± 2.4	0.0280*	2.5 ± 1.0	2.8 ± 1.4	< 0.0001*	< 0.0001*	< 0.0001*
#, % Levels Converted	233/568 (41.0%)	279/625 (44.6%)	0.2077	166/615 (27.0%)	162/572 (28.3%)	0.6101	< 0.0001*	< 0.0001*
Normal (#, %)	472/568 (83.1%)	353/625 (56.5%)	< 0.0001*	501/615 (81.5%)	333/572 (58.2%)	< 0.0001*	0.4593	0.5419
Optimal (#, %)	551/568 (97.0%)	604/625 (96.6%)	0.7188	603/615 (98.0%)	557/572 (97.4%)	0.4413	0.2460	0.4533
Acceptable (#, %)	13/568 (2.3%)	15/625 (2.4%)	0.8966	11/615 (1.7%)	15/572 (2.6%)	0.3271	0.5419	0.8026
Problematic (#, %)	4/568 (0.7%)	5/625 (0.8%)	0.8493	1/615 (0.2%)	0/572 (0.0%)	0.3371	0.1527	0.0324*
Potentially Toxic (#, %)	0/568 (0.0%)	1/625 (< 0.1%)	0.3421	0/615 (0.0%)	0/572 (0.0%)	1.000	1.000	0.3371
# cases AWRF	7/1546 (0.5%)		---	0/2466 (0.0%)		---	0.0008*	

***Table 3:** Most recent whole blood metal ion levels for two study cohorts.*

	Normal[1]	Optimal[2]	Acceptable[3]	Problematic[3]	Potentially Toxic[2]
Unilateral					
• Co	< 1.5 µg/L	< 4.0 µg/L	4 - 10 µg/L	10 - 20 µg/L	> 20 µg/L
• Cr	< 1.5 µg/L	< 4.6 µg/L	4.6 - 10 µg/L	10 - 20 µg/L	> 20 µg/L
Bilateral					
• Co	< 1.5 µg/L	< 5.0 µg/L	5 - 10 µg/L	10 - 20 µg/L	> 20 µg/L
• Cr	< 1.5 µg/L	< 7.4 µg/L	7.4 - 10 µg/L	10 - 20 µg/L	> 20 µg/L

Table 4: *Metal ion reference table.*

1: Laboratory normal for patients without metal bearings; 2: According to DeSmet /van der Straeten; 3: According to our previous analysis.

Every group 2 case met RAIL, while only 86.5% of group 1 cases with intraoperative radiographs (29.8% of total) met the guideline ($p < 0.0001$). Similarly, there were 7 cases of AWRF in group 1 and none in group 2 ($p = 0.0008$). Rate of AWRF is still significant when compared with group 2 cases with 3- ($p = 0.002$), 4- ($p = 0.006$), 5- ($p = 0.01$), and 6-year ($p = 0.04$) follow-up. This is despite smaller implant size in group 2 ($p < 0.0001$), which historically have lower survivorship than larger components [14].

Excluding wear failures, there was a total of 22 acetabular failures in group 1 (1.4%) and 6 in group 2 (0.2%) ($p < 0.0001$). There were two cases of unexplained pain in group 1 (0.1%) and one in group 2 (< 0.1%) ($p = 0.31$); none presented abnormal metal ion levels or pseudotumors. There were two instances of instability or dislocation in group 1 (0.1%) and one in group 2 (< 0.1%) ($p = 0.31$). There were 18 loose acetabular components in group 1 (1.2%) and two in group 2 (< 0.1%) ($p < 0.0001$). Failed cases were excluded from analyses of clinical outcomes and metal ion results.

Discussion and Conclusions

Despite showing promise as a successful alternative to traditional THA, HRA has been limited by fears of elevated metal ions and AWRF. We previously established a safe zone, known as the RAIL, to demonstrate an appropriate method for minimizing metal ion levels. At the time of this publication, the last instance of AWRF was from a case done in early 2009, before the combination of NSIOR and RAIL had been implemented. This study, comprising a separate cohort of cases, validates the RAIL guideline independently and demonstrates that it can be achieved in 100% of cases using the described NSIOR technique. With NSIORs, we are now able to predict AIA of immediate standing radiographs within 2.4° and of most recent standing x-rays within 2.7°, on average.

In this study, the RAIL guideline was achieved in 100% of 2466 cases; this resulted in zero cases of AWRF, and only one case (< 0.1%) with potentially problematic ion levels within a 2- to 8-year follow-up period. This compares to 7 cases (0.5%) with AWRF ($p = 0.003$) and 10 cases (0.8%) with problematic or potentially toxic ion levels ($p = 0.007$) in the control group with an 8- to 14-year follow-up.

Although outliers with suboptimal ion levels were reduced and AWRF eliminated, we did not see significant difference in mean ion levels between the two groups. Based on research by Jiang., *et al.* and Daniel., *et al.* [5,22], metal ion levels peak at 1 year then decline steadily in well placed implants. Metal ion tests were taken at 2 years follow-up, on average, for group 2, while they were taken at approximately 5 years for group 1. Therefore, mean ion levels in group 1 might have been higher if testing had been done earlier. Longer follow-up may clarify this.

There were notable shortcomings in this study. The first is the unequal follow-up duration between both groups, which could affect ion level comparison. However, all patients had a minimum 2 years of follow-up; at this interval, we should have noticed early signs of wear

[5,22]. The second limitation is that only 56.2% of the study group had their ions checked. Without knowing the ion levels of the remainder of cases, we could be missing latent cases of AWRF. Many of these patients refused testing because they say they are doing well. The cost and inconvenience of going to a special lab seems to be too much for patients that show excellent clinical outcome. Additionally, HHS, UCLA activity score and mean AIA were no different in those that did and did not have routine ion testing. Therefore, we do not suspect any unreported AWRFs. A third limitation is that our minimum follow-up duration was 2 years, which some may argue is not long enough for AWRF to appear. However, there was no incidence of AWRF in any RAIL cases at or beyond 5 years postoperative. Next, our RAIL method of acetabular component positioning does not take AV into consideration. However, Haan., *et al.* [1] found that AV directly correlates with inclination measurement. Although we intend to expand our protocol to attain more detailed three-dimensional acetabular measurements, we have found minimizing AIA alone is sufficient in eliminating wear failures. Lastly, the number of patients with intraoperative radiographs differed between the two groups. Because we did not regularly collect intraoperative radiographs until October 2008, we could only analyze intraoperative measurements for 29.8% of our control group, versus 100% in group 2. However, radiographs were obtained non-selectively for all patients after August 2008, and immediate postoperative x-rays have always been collected.

In summary, the significant reduction in wear failures and mean blood ion levels indicates a meaningful improvement after the establishment of the RAIL guidelines. This individualized safe zone for acetabular component placement in MoM HRA can be achieved reliably; we have met RAIL in 100% of 2466 HRA cases since 2010. Further, the NSIOR method allows us to accurately predict standing AIA within about 3° at later follow-up. We provide a formula that surgeons can use to create their own RAIL guidelines for any HRA implant system of varying coverage arc. We hope further RAIL studies analyzing other resurfacing systems will promote confidence so surgeons need not avoid MoM HRA due to fear of metal-wear complications.

Disclosure

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