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The Effect of Acetabular Inclination on Metal Ion Levels Following Metal-on-Metal Hip Arthroplasty

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ABSTRACT

Acetabular inclination angles have been suggested as a principal determinant of circulating metal ion levels in metal-on-metal hip arthroplasties. We aimed to determine whether inclination angle correlates with ion levels in arthroplasties using the Articular Surface Replacement (ASR) system. Patients undergoing ASR arthroplasties had blood metal ion levels and radiograph analysis performed a mean of 3.2 years after surgery. Inclination angle showed only a weak correlation with cobalt ($r = 0.21$) and chromium ($r = 0.15$) levels. The correlation between inclination angle and cobalt levels was significant only with small femoral components, although it was still weak. Multiple regression showed a complex interaction of factors influencing ion levels but inclination angle accounted for little of this variation. We conclude that the acetabular inclination angle is not a meaningful determinant of metal ion levels in ASR arthroplasties.

Metal-on-metal total and resurfacing hip arthroplasty has become increasingly popular with the advent of modern metal-on-metal bearings [1]. Metal-on-metal arthroplasty has several proposed advantages over conventional metal-on-polyethylene arthroplasty, such as substantially lower rates of wear, especially with the use of large-diameter femoral heads [2], a lower incidence of osteolysis [3] and greater stability with fewer dislocations [4]. Hip resurfacing arthroplasty (HRA) is believed to have several additional advantages including conservation of femoral bone stock [5], increased activity levels [6] and technically straightforward subsequent revision arthroplasties with less morbidity [7]. However, concerns remain about the potential adverse effects of metal-on-metal bearings including issues relating to the elevated circulating metal ion levels found in patients with metal-on-metal bearings [8], such as concerns over metal hypersensitivity and osteolysis [9–11], pseudotumor formation [12], their potential to cause chromosomal aneuploidy and translocation [13], transplacental transfer [14] and potential carcinogenic effects [15].

As a result of these concerns there has been much interest in determining which technical, mechanical and patient factors will affect component wear and circulating metal ion levels, which, it has been postulated, are a marker for the degree of wear [16,17]. Some studies have suggested that the inclination angle of the acetabular component in metal-on-metal resurfacings strongly correlates with the wear found on retrieved components [18] and is one of the principal determinants of metal ion levels [16,19,20]. Component malpositioning, particularly the acetabular inclination angle, is thought to cause edge loading and localized wear and to therefore be the main cause of increased wear and higher metal ion levels rather than the patient's level of activity, which does not correlate with metal ion levels [20,21]. These studies show a variety of cutoff points for the acetabular inclination angle above which metal ion levels or the extent of component wear are significantly raised [16,19], leading some authors to conclude that accurate placement and orientation of the acetabular component in metal-on-metal hip arthroplasty is essential to reduce metal ion levels and recommend not only more reproducible techniques to achieve this, but also improved instrumentation and possibly navigation [16,20]. These factors may be particularly relevant to the Articular Surface Replacement (ASR) system.

The Articular Surface Replacement XL system (DePuy International Ltd, Leeds, United Kingdom) is a metal-on-metal hip arthroplasty system that was designed for use in hip resurfacing as the ASR Hip Resurfacing system, or as the ASR XL total hip arthroplasty using a stemmed femoral component articulating with the same ASR acetabular component used for resurfacing. In August 2010, DePuy voluntarily recalled the ASR system after reports from joint registries of a high revision rate associated with the system. Since then, the ASR system has been associated with even higher failure rates [22]. Some

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authors have suggested that the design of the less than hemispherical ASR acetabular component, with its relatively smaller arc of coverage, makes it prone to sub-optimal fluid–film lubrication and edge loading [16,22] and the preparation and insertion of the acetabular component is a possible source of technical errors that may cause early failures [22]. However, whether surgical or technical factors could significantly account for the high failure rates of the ASR system is debatable. We aimed to determine whether the acetabular inclination angle correlates with metal ion levels in metal-on-metal hip arthroplasties in one of the largest series to date of patients with hip arthroplasties using the ASR system.

Materials and Methods

Following DePuy's recall of the ASR hip resurfacing and XL stemmed implant system in August 2010, our institution began compiling a database of all patients who had arthroplasties performed using an ASR system from January 2005 to November 2009. All follow-up data including blood metal ion levels and radiograph analysis data were collected prospectively. Ethical approval for the study was sought from our institution's medical research ethics committee and the requirement for formal approval was waived according to institutional guidelines on this type of study.

The procedures were performed by five consultant grade surgeons. The components and surgical technique did not change throughout the study period. Regardless of whether patients received the ASR hip resurfacing or ASR XL stemmed femoral component, all patients received the same type of ASR acetabular component.

At follow-up, all patients were reviewed and examined by a consultant orthopedic surgeon and had samples taken for analysis by an independent laboratory for whole blood cobalt and chromium ion levels. At the same visit, standard standing anteroposterior radiographs of the pelvis were taken. These were interpreted by an independent, blinded consultant radiologist at a different local institution and used to calculate the inclination angle of the acetabular cup. The values of whole blood cobalt and chromium ion levels and the acetabular inclination angles were recorded on the database along with other patient demographic and clinical data.

The database was analyzed to determine which, if any, factors influenced metal ion levels. Statistical analysis was performed by a post-doctoral statistician (G.K.) using SAS versions 9.2 and 9.3 (SAS Institute Inc., Cary, NC, USA). Simple summary statistics were computed for all variables in the database and univariate analyses conducted on these variables. Spearman's nonparametric correlation coefficients were computed between the predictor variables and cobalt and chromium ion levels. Continuous variables were compared using the two-sample *t*-test and the Wilcoxon rank sum test for variables with large outliers. *P* values less than 0.05 were considered significant.

A multiple linear regression model was constructed to determine which of several variables influenced whole blood chromium and cobalt ion levels and stepwise regression was used to find the best models to predict ion levels.

A previous study on the ASR system showed a significant correlation between acetabular inclination angle and metal ion levels in patients with femoral component head sizes 51 mm or less and no correlation for those with femoral components 53 mm or greater [16]. Patients were therefore grouped and analyzed according to these femoral component sizes to determine their effect on metal ion levels.

Results

Our database included 346 ASR arthroplasties. Twenty-five patients had revision arthroplasties performed prior to the global recall and metal ion blood sampling and were therefore excluded from analysis. Twelve patients died before follow-up, 3 patients emigrated and were lost to follow-up and data were incomplete for 13 patients. Of the 25 patients who were revised prior to the global recall, 24 were revised due to pain/patient dissatisfaction and 1 for periprosthetic infection leading to systemic sepsis. Metal ion testing was not performed on any of these patients. In relation to their prerevision acetabular angle, the mean measured angle was 49.6° with a range of 40° to 61°. The remaining 293 ASR arthroplasties on 261 patients were therefore included for analysis.

Table 1
Clinical, Demographic and Outcome Data.

	Number
Mean age in years (sd)	60.6 (10.5)
Male patients	198 (68%)
Median time from operation to follow-up in days (range)	1172 (403–3938)
ASR femoral resurfacings	80 (68% male)
ASR XL femoral components	213 (68% male)
Mean femoral component size in mm (sd)	51 (4)
Mean patient height in cm (sd)	169 (10.0)
Male	174 (7.4)
Female	159 (6.2)
Median patient weight in kg (range)	84 (45–145) (45-132[a])
Male	88 (55–132)[a]
Female	72 (45–119)
Mean patient BMI in kg/m^2 (sd)	29.6 (5.0)
Median acetabular inclination angle in degrees (range)	49 (5–72) (29–72)[b]
Male	49 (29–70)[b]
Female	48 (30–72)
Median whole blood cobalt level in nmol/l (range)	82 (1–3619) (1–1735)[a]
Male	76 (1–1849)
Female	110 (5–1735)[a]
Median whole blood chromium level in nmol/l (range)	58 (2–1994) (2–951)[a]
Male	54 (2–826)
Female	83 (6–951)[a]

[a] Omitting the highest value.
[b] Omitting the smallest value.

Table 1 shows the basic demographic and clinical data for the sample. Two hundred thirteen patients had ASR XL femoral head and stem implants and 80 patients had femoral resurfacing implants. One hundred ninety-eight patients (68%) were male and the mean age of the patients was 60.6 years (SD = 10.5 years). The median time between surgery and follow-up review with metal ion blood sampling and radiological assessment was 1172 days (3.2 years; range: 403–3938 days). The median acetabular inclination angle was 49° (range: 5–72 years). Overall, the median whole blood cobalt and chromium ion concentrations were elevated from normal (82 and 58 nmol/l respectively).

Table 2
Analysis of Correlation of Various Independent Variables With Cobalt and Chromium Ion Levels.

	Whole Blood Co levels		Whole Blood Cr levels	
	Correlation Coefficient	*P* Value	Correlation Coefficient	*P* Value
Acetabular inclination angle				
All hips	0.21	<0.001	0.15	0.01
Femoral resurfacings	0.19	0.10	0.18	0.12
XL femoral components	0.20	0.003	0.14	0.04
Weight	−0.09	0.12	−0.11	0.07
Height	−0.12	0.05	−0.10	0.10
BMI	−0.03	0.64	−0.07	0.28
Age	0.04	0.46	−0.12	0.04
Femoral head size	−0.16	0.007	−0.13	0.02
Duration since surgery	0.06	0.29	0.16	0.005
Whole blood Co	1.00		0.87	<0.001
Whole blood Cr	0.87	<0.001	1.00	