Metal-on-metal hip resurfacing: is it forgiven for malorientation?

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Background

Despite the benefits and clinical success of modern metal-on-metal articulations, there are many concerns about the release of metal ions and their hazardous effects. The exact mechanism and risk factors are a matter of debate. The goal of this prospective study was to evaluate the effect of cup abduction angle and other independent factors (age, sex, prosthetic head size, and period of follow-up) on the levels of serum metal ions in patients after metal-on-metal hip resurfacing (MOMHR) arthroplasty.

Patient and methods

Between January 2010 and June 2013 a total of 50 patients were operated upon and followed up after a unilateral MOMHR, with an average follow-up period of 28.3 months. The patients' ages ranged between 20 and 50 years. There were 24 male and 26 female patients. Clinical and radiological evaluations were made and serum metal ion levels were measured. Correlations between serum metal ion levels and different variables were also evaluated.

Results

The average preoperative Harris hip score was 46.24. This increased to 90.12 at the end of follow-up. There was a statistically significant increase ($P < 0.05$) in serum cobalt and chromium levels at the sixth postoperative month, compared with the preoperative levels. However, the condition was significantly ($P < 0.05$) reversed after the first year. Cup abduction angle was associated with an insignificant effect ($P > 0.05$) on hip function (Harris hip score) but was associated with a significant increase ($P < 0.05$) in serum ion levels. Prosthetic head size was associated with a statistically significant ($P < 0.05$) inverse relation with metal ion levels.

Conclusion

The present study found that three main variables had a statistically significant effect on metal ion release: namely, cup orientation, size of the prosthetic head, and period of follow-up. Of them, the only controllable factor that can be carefully addressed during surgical procedures is the first one. Hence, cup inclination during surgery must be considered carefully in order to reduce early failures when performing large-bearing MOMHR.

Keywords:
cup abduction angle, metal ions, metal-on-metal hip-resurfacing arthroplasty

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Introduction

The first metal-on-metal (MOM) articulation for total hip replacement was introduced in 1960 but the resultant surgeries had high rates of component loosening and wear due to manufacturing problems [1–3]. In the late 1980s, an MOM design with improved clearance, metal hardness, and reproducible smooth surfaces was reintroduced and was known as second-generation MOM bearing [4].

Despite the benefits and clinical success of modern MOM articulations, concerns about wear-related release of metal ions persist. Elevated chromium (Cr) and cobalt (Co) levels have been found in both the serum and remote organs of patients with MOM bearings [5–7]. Studies have also demonstrated excessive wear with metal shells in women with smaller-diameter components, as well as in hips in which the shell is oriented more vertically in the pelvis (a high abduction angle) [8–12].

The risk of local adverse reactions of MOM has been reported to correlate with the level of systemic metal ion concentrations. Complications include runaway wear, pseudotumor formation, and acute lymphocytic vascular-associated lesions [13,14].

However, the related risks and the long-term course of postoperative metal ion concentrations still require further investigations [15–20].

The mechanism of metal ion release is complex and multifactorial. It is thought to be affected by patient factors, surgical procedure, and implant variables (rim contact, impingement, acetabular component deformation, and thickness of fluid film lubrication) [21]. Several reports have been published regarding acetabular component position as it relates to serum metal ions and cup loosening [16,18]. Cups implanted with inclinations ranging from 45 to 60° showed signs of increased edge loading, loosening, and serum metal ion levels [22,23].

The main objectives of this prospective study were to:

(i) Measure whole blood Cr and Co ion concentrations in patients with metal-on-metal hip resurfacing (MOMHR) arthroplasty and

(ii) Evaluate its relation with certain independent variables [cup abduction angle, sex, age, head size, Harris hip score (HHS), and duration of follow-up].

Patients and methods

This was an independent study that included 50 patients who were operated upon between January 2010 and June 2013 in Tanta University Hospital. All patients underwent MOMHR procedures for different indications, as shown in Table 1, and they were followed up prospectively, with an average follow-up period of 28.3 months (range 12–36 months). There were 24 male and 26 female patients with an average age of 38 years (range 20–50 years).

MOM Birmingham hip-resurfacing (BHR) implants (Midland Medical Technologies, Bromsgrove, UK) were used in all patients with hybrid fixation (cemented femoral component and a press-fit acetabular component).

All surgical procedures were performed by the same surgical team through the standard posterior approach.

Exclusion criteria

In addition to the usual contraindication for hip arthroplasty, we added other specific contraindications for MOM arthroplasty: impaired renal function, child-bearing age, and presence of a known metal allergy.

For accurate assessment of systemic release of metal ions from the bearings, we paid particular attention to other potential sources of metal ions. Thus, we excluded the following groups of patients: patients receiving medications containing metal ions, such as cardiac patients, bilateral cases, those with other metallic implants, and patients with a history of occupational exposure to Co and Cr.

Postoperative assessment

The follow-up was performed at 1 month, 3 months, 6 months, and 1 year postoperatively, and then every year. During each visit, the patient was assessed clinically and radiologically. Clinical evaluation was performed using the HHS to rate the postoperative hip function. Radiographic evaluation was performed to assess cup abduction angle, implant loosening, and hardware-related complications. Standard anteroposterior and lateral plain radiographs of both hips were obtained in the true size with a 6-ft distance. Cup abduction angle (Fig. 1) was measured as the angle between two lines: the first one was the line extending between the superolateral edge and the inferomedial edge of the cup and the second line was the one extending between teardrops on both sides.

Laboratory evaluations of metal ion levels in the blood were performed preoperatively and then every 6 months postoperatively. Blood samples were obtained from antecubital veins of fasting patients using a disposable intravenous cannula and collected in metal-free vacutainers. To avoid contamination from the needle, the first 5 ml of blood withdrawn was discarded. Serum was separated by centrifugation at 400*g* for 10 min at 4°C. The ion content was measured using a graphite atomic absorption spectrometer. The measurements of the levels of metal ions (Co and Cr) are summarized in Table 2. Any complications during the follow-up period were recorded.

As the metal ion release is multifactorial and its level depends on various factors, the correlation between independent variables (cup abduction angle, sex, age, head size, HHS, and duration of follow-up) and dependent variables (concentration of Co and Cr) was studied to identify the effect of each variant on the level of metal ions. We eliminated the effect of differences in surgical technique, implant design, and material by using the same surgical technique and implant design in all cases.

Statistical analysis

Statistical analysis was conducted using the mean and SD, and univariate analysis was carried out with SPSS (v.16; SPSS Inc., Chicago, Illinois, USA).

Mean value $(\overline{X})$: the sum of all observations divided by the number of observations:

$$\overline{X} = \frac{\sum x}{n},$$

where Σ is the sum and n is the number of observations.

SD: it measures the degree of scatter of individual variances around their mean:

$$\text{SD} = \sqrt{\frac{\Sigma\,|x - x|^{-2}}{n-1}}.$$

Analysis of variance (ANOVA) test: ANOVA was conducted using the computer program SPSS for Windows for comparison of quantitative data at different time points in the same group.

Results

The preoperative and serial postoperative levels of metal ions (Co and Cr) are summarized in Table 2. Using the paired sample *t*-test, there was a statistically significant increase ($P < 0.05$) in serum Co and Cr at the sixth month postoperatively compared with the preoperative level. However, the condition reversed after that, and there was a significant decrease ($P < 0.05$) in the first, second, and third year of follow-up.

The angle of inclination of the acetabular component (cup abduction angle) ranged between 40 and 55°, with an average of 46.24° (Table 1). There was a statistically significant increase ($P < 0.05$) in both serum Co and Cr with the increase in cup abduction angle (Table 3).

The average preoperative HHS was 46.24. This was increased to 90.12 at the end of follow-up. There was a statistically insignificant difference ($P > 0.05$) between the cup abduction angle and postoperative HHS (Table 4).

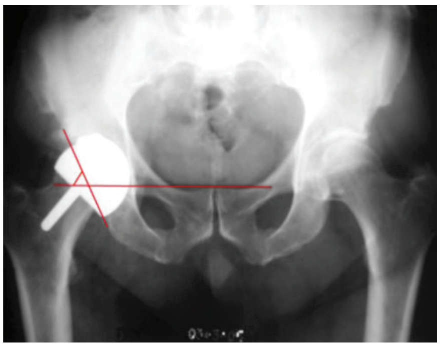
On using the paired sample *t*-test, a statistically insignificant difference ($P > 0.05$) was observed between postoperative serum Co and Cr levels and postoperative HHS.

The sizes of the prosthetic head ranged between 44 and 58 mm, with an average of 50.12 mm. On using the ANOVA test, an inverse relationship was observed between head size and the level of serum Co and Cr, and this was statistically significant ($P < 0.05$) (Table 3).

On using ANOVA, no statistically significant difference ($P > 0.05$) was observed between different age groups as regards serum Co and Cr, nor with regard to the sex of the patient (Table 3).

Complications occurred in eight (16%) patients in this study. However, none of them underwent revision procedure for the prostheses until the end of follow-up. Infection occurred in three (6%) patients. Two of them were treated with open drainage and urgent debridement without removal of the prostheses, whereas in the third case the infection was superficial and subsided with the use of parenteral antibiotics. The other complications included: two (4%) patients with postoperative DVT; one (2%) patient with sciatic nerve palsy due to postoperative hematoma, which improved without interference; and two (4%) patients of myositis ossificans.

Figure 1



Measurement of cup abduction angle on plain AP. The radiograph showed vertical orientation of the cup.

Discussion

Metals, particularly Cr and Co, are the most commonly used materials in manufacturing the bearing surfaces of total hip prostheses [1]. Although new designs of MOMHR provide excellent wear rates and offer the advantages of large femoral heads with preservation of bone stock, wider range of motion, better functional outcomes, and lower rates of dislocation, they are vulnerable to many side effects, such as the biological effects of metals [24–29].

It is well documented that metal ion levels observed after an MOM total hip replacement are elevated

Table 1 Patient characteristics in the study

Age group	
Group 1 (20≥ to 30)	13
Group 2 (>30 to 40)	33
Group 3 (>40 to 50)	4
Sex	
Male	24
Female	26
Prosthetic head size	44–58 mm (average 50.12 mm)
Cup abduction angle	40–55° (average 46.24°)
Diagnosis	
Primary OA hip	27
DDH	5
Old Perthes’	3
Rheumatoid arthritis	4
Avascular necrosis	4
Post traumatic	7

Table 2 Preoperative and serial postoperative metal ions level in the study

Time points	Metal ions level (μg/l)	
	Co	Cr
Preoperative	0.05–0.93 (average 0.29)	0.04–0.9 (average 0.24)
6 months	0.45–6.08 (average 2.52)	0.14–5.8 (average 2.26)
1 year	0.09–5.01 (average 1.53)	0.09–3.99 (average 1.27)
2 years	0.05–2.05 (average 0.82)	0.11–2.06 (average 0.78)
3 years	0.09–1.08 (average 0.49)	0.09–1.1 (average 0.45)

Co, cobalt; Cr, chromium.

Table 3 The correlation between different variables and the serum levels of cobalt and chromium

	6 month postoperative metal ions level (μg/l)		Last follow-up metal ions level (μg/l)		
	Mean Co	Mean Cr	Mean Co	Mean Cr	*P* value
Sex					
Female	3.38	2.63	0.7	0.57	>0.05
Male	1.37	1.71	0.125	0.29	
Age (years)					
20–30	4.13	3.64	0.72	0.65	>0.05
>30–40	3.38	2.34	0.69	0.56	
>40–50	1.60	1.77	0.18	0.24	
Head size (mm)					
44–50	3.44	2.58	0.74	0.790	<0.05
51–58	1.82	2.01	0.19	0.158	
Cup abduction angle (deg.)					
40–44	2.04	2.06	0.23	0.38	
45–49	2.71	2.26	0.41	0.47	<0.05
50–55	3.72	2.99	0.63	0.76	
HHS					
Excellent	1.41	2.35	0.57	0.47	>0.05
Good	1.46	1.67	0.42	0.43	
Fair	0.89	2.07	–	–	
Poor	–	–	–	–	
Period of follow-up	2.60	2.274	0.490	0.453	<0.05

Co, cobalt; Cr, chromium; HHS, Harris hip score.

Table 4 Comparison between cup abduction angle and Harris hip score

Cup abduction angle (deg.)	HHS after 6 months		HHS after 1 year		HHS at last follow-up	
	Mean	SD	Mean	SD	Mean	SD
40–44	87.53	3.47	90.84	5.32	89.07	5.70
45–49	87.81	3.60	90.48	3.84	90.24	4.09
50–55	85.75	4.34	92.25	4.42	92.50	3.87
P_1			>0.05			
P_2			>0.05			

HHS, Harris hip score; P_1, comparison between HHS after 6 months and HHS after 1 year; P_2, comparison between HHS after 1 year and HHS at last follow-up.

compared with those observed after conventional metal-on-polyethylene implants [25]. Co and Cr have been seen to be substantially elevated in the blood and urine of patients in the former group [24–29].

In a study by Grubl *et al.* [30] the median serum Co concentration was 1 μg/l at 1 year after surgery and 0.7 μg/l at 5 years, and the median serum Cr level was 1.1 μg/l at 1 year after surgery and 0.75 μg/l at 5 years after surgery [30]. Jacobs *et al.* [7] recorded mean serum levels of 2.9 μg/l for Cr and 3.8 μg/l for Co [7]. Other studies reported that the upper limit of normal serum level for both Co and Cr is 0.5 μg/l [26,31]. However, no preoperative ion concentrations were recorded [7].

More recently, Back *et al.* [32] quantified the preoperative and postoperative serum Cr and Co levels of 16 patients who had undergone Birmingham hip replacements (Smith and Nephew, Memphis, Tennessee, USA). At 1 year, a mean level of Cr of 4.0 μg/l (range 0.6–9.9 μg/l) and a mean level of Co of 2.4 μg/l (range 1.1–6.7 μg/l) were observed. These extreme values of 9.9 μg/l for Cr and 6.7 μg/l for Co might have a greater risk of long-term sequelae to metal ion exposure [32].

The variation in the levels in different studies can be attributed to several factors, such as differences in the inclusion criteria, in patient characteristics, and in implant design between studies. Other factors such as environmental exposure, occupation, and medications may also play a role in the elevation of metal ion levels. Moreover, there were no records of preoperative ion concentrations in some other studies [7,30,31]. To increase the accuracy of the results of the present work, we depend on the preoperative metal ion level as a reference point after application of the exclusion criteria.

As the metal ion release is multifactorial and depends on many variables, we try to eliminate the effect of some of these variables (e.g. occupational exposure, presence of other metallic implants, and receipt of medications containing metal ions, such as cardiac medicines) through our exclusion criteria. To decrease surgery-related factors (such as technique and approach), all cases were performed by the same surgical team and through the same approach (posterior approach). The effect of other variables – namely, cup abduction angle, prosthetic head size, age, sex, and duration of follow-up – were especially evaluated in the present work.

Cup abduction angle, which was measured in the current study as an indicator of cup inclination, has a statistically insignificant effect ($P > 0.05$) on postoperative HHS (the indicator of hip function). However, cup inclination was found to be a significant risk factor ($P < 0.05$) for increasing metal ion levels. These levels were found to be markedly elevated with higher degrees of the inclination angle. This supports the concept that MOM articulation has very little tolerance to malposition [8,10,12,16].

A traditionally acceptable 45° inclination angle leaves no room for error in these nonhemispheric cups, particularly in smaller-sized cups. Cups implanted with inclinations ranging from 45 to 60° resulted in a smaller amount of coverage laterally over the head, which could lead to edge loading, resulting in elimination of fluid film lubrication and increased metal wear. This is consistent with the reports of edge loading and component loosening as well as with the increase in metal ion levels that was noted in patients with inclination angles averaging 45° or more [16,18].

Ollivere *et al*. [11] studied the rate and mode of early failure in 463 BHRs. They reported a 3.1% failure rate for metallosis-related revision at 5 years, with risk factors for revision, including female sex and a high abduction angle, combined with excessive anteversion [11]. In the present study, sex was not found to be a risky factor, as female patients were associated with statistically insignificant higher levels of metal ions. This finding may be explained by the accidental implantation of head with diameters between 45 and 49 mm in most of our female patients, which is slightly bigger than the usually used head sizes in the female population in general. Studies that find female sex a risk factor for elevated metal ions attributed this elevation to the usage of small head sizes [8–12].

Tribological studies show that a large diameter component would create a thicker fluid film between the femoral head and the acetabular component surface. With a thicker fluid film, less contact would occur between the components, and wear would be reduced [33]. This supports our finding of the statistically significant ($P < 0.05$) inverse relationship between head size and metal ion release in the present study. However, there are no published in-vivo results to confirm this [33]. The evidence to date reveals high Cr and Co ion levels on using hip resurfacing compared with the 28 mm head size of the traditional (standard) hip arthroplasty [7,28,30].

Vendittoli *et al*. [34] found a weak inverse correlation between metal ion level and the size of the prosthetic head and a direct relation with cup abduction angle of the acetabular component [34]. Daniel *et al*. [35] found lower metal ion concentration in patients whose hips had been resurfaced with BHR, and no significant difference in ion levels was observed as regards the size of the implant. However, only two femoral sizes (50 and 54 mm) were examined, and the orientation of the acetabular component was not taken into account in their series [35].

Different metallurgical and manufacturing factors such as the quality of the surface finish, component sphericity, radial clearance, manufacturing process (forged vs. cast metal), and metal carbon content may influence the wear of MOM bearings [23]. In the present study, all cases were replaced by the same type of prosthesis in an effort to minimize the effect of these factors on the end result.

As regards the effect of the duration of follow-up on the levels of serum metal ions, the present study, as many other studies [7,30,31], found that serum Co and Cr levels showed an abrupt elevation that was about two-fold to three-fold in the first 6 months after implantation of MOM hip prostheses, followed by a period of stationary course and then a gradual decline. This is proven in the present study as a statistically significant ($P < 0.05$) increase in serum Co and Cr levels was found in the sixth month postoperatively compared with the preoperative level, but the condition reversed after that, and there was a significant decrease in serum Co in the first, second, and third year of follow-up. However, we did not detect any adverse reactions or side effects from these elevated metal levels. A longer follow-up duration may be needed to certify this.

The present study reported that three main variables had a significant effect on metal ion release: namely, cup orientation, size of the prosthetic head, and period of follow-up. Of them, the only controllable factor that can be carefully addressed during surgical procedures is the first one. Hence, considerable attention must be paid to cup inclination during cup implantation to minimize edge loading and subsequent metal ion release.

The current study has some limitations. The effect of weight on metal ion release was not evaluated. It is known that the joint lubrication of the prosthetic head can be affected by joint loading [16,18]; however, none of our patients was obese or noncompliant with the postoperative instructions of partial weight bearing.

Another limitation is the effect of femoral neck version on metal ion release as we were unable to measure it on a simple plain radiograph.

Conclusion

MOMHR offers several advantages to the patients, including bone stock preservation, wider range of motion, better functional outcomes, and lower rates of dislocation, and is therefore particularly attractive for young active patients. However, considering the large diameter of the coupling components, there are concerns regarding postoperative metal ion release.

We address cup positioning as a major risk factor for elevated metal ion levels; hence, careful orientation of the acetabular component may be mandatory for the longevity of the prosthesis.

We did not detect any adverse reactions or side effects from these elevated metal levels, but longer follow-up may be needed to certify this.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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