

# Adverse reaction to metal debris after Birmingham hip resurfacing arthroplasty

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Submitted 2014-02-12. Accepted 2014-12-05.

**Background and purpose** — Concern has emerged about local soft-tissue reactions after hip resurfacing arthroplasty (HRA). The Birmingham Hip Resurfacing (BHR) was the most commonly used HRA device at our institution. We assessed the prevalence and risk factors for adverse reaction to metal debris (ARMD) with this device.

**Patients and methods** — From 2003 to 2011, BHR was the most commonly used HRA device at our institution, with 249 implantations. We included 32 patients (24 of them men) who were operated with a BHR HRA during the period April 2004 to March 2007 (42 hips; 31 in men). The mean age of the patients was 59 (26–77) years. These patients underwent magnetic resonance imaging (MRI), serum metal ion measurements, the Oxford hip score questionnaire, and physical examination. The prevalence of ARMD was recorded, and risk factors for ARMD were assessed using logistic regression models. The mean follow-up time was 6.7 (2.4–8.8) years.

**Results** — 6 patients had a definite ARMD (involving 9 of the 42 hips). 8 other patients (8 hips) had a probable ARMD. Thus, there was definite or probable ARMD in 17 of the 42 hips. 4 of 42 hips were revised for ARMD. Gender, bilateral metal-on-metal hip replacement and head size were not factors associated with ARMD.

**Interpretation** — We found that HRA with the Birmingham Hip Resurfacing may be more dangerous than previously believed. We advise systematic follow-up of these patients using metal ion levels, MRI/ultrasound, and patient-reported outcome measures. ■

The medium-term revision risk of many hip resurfacing arthroplasty (HRA) devices is high (AOA 2012, NJR 2012).

Concern has emerged about soft-tissue reactions after HRA (Pandit et al. 2008, Glyn-Jones et al. 2009). Patients whose devices are failing often experience pain and swelling in the groin (Macpherson and Breusch 2011). The finding of large sterile effusions of the hip and/or macroscopic necrosis/metallosis associated with joint failure and pain may be referred to as adverse reactions to metal debris (ARMD) (Langton et al. 2010). Furthermore, asymptomatic pseudotumors are common after HRA (Kwon et al. 2011, Matthies et al. 2012). The reaction to excess metal wear debris is often associated with increased serum metal ion levels (Langton et al. 2010, Kwon et al. 2010). Magnetic resonance imaging (MRI) optimized to reduce image artifacts and distortions caused by metallic implants is an important tool in diagnosing local soft-tissue abnormalities and mass lesions (Haddad et al. 2011). MRI analysis is useful in delineating soft-tissue abnormalities and mass lesions even when radiographs are normal (Hart et al. 2012).

HRA has been popular in Finland during the last 10 years (Seppänen et al. 2012). From 2003 to 2011, the BHR HRA (Smith and Nephew, Warwick, UK) was the most commonly used HRA device at our institution, with 249 implantations. We analyzed the prevalence of ARMD in an early BHR cohort consisting of 42 BHR HRA implantations performed from April 2004 to March 2007. BHR HRA is considered to be the best-performing HRA, with 10-year registry follow-up (AOA 2012). For the assessment, in addition to a physical examination, we used radiographs and MRI of the hip, serum metal ion concentrations, and the Oxford hip score (OHS) questionnaire. On the basis of these results, we tried to identify risk factors for ARMD.

## Patients and methods

32 patients (42 hips) had undergone a BHR HRA between April 2004 and the end of March 2007 (Table 1). There were 24 male patients (31 study hips). The mean age of the patients was 59 (26–77) years. The patients were examined between March 2012 and June 2012 with MRI, assessment of serum metal ion measurements, the Oxford hip score (OHS) questionnaire, and physical examination. The mean follow-up time was 6.7 (2.4–8.8) years. None of the patients had undergone BHR HRA of both hips in 1 session; 10 patients had had both hips operated during the study period with BHR HRA, but in separate sessions (20 hips). 1 patient with a study implant also had a BHR HRA in the contralateral hip, but it was inserted outside the study period (2010). 1 patient had a Synergy-BHR (Smith and Nephew) large-head metal-on-metal (MoM) replacement (THR) in the contralateral hip; 1 patient had a cemented Muller THR (Zimmer, Warsaw, IN) in the contralateral hip. Posterior approach was used in all cases. 1 hip had recurrent dislocations. There were no femoral neck fractures, infections, nerve damage, or other complications.

The BHR cup has a hemispherical design with the cast-in POROCAST ingrowth surface. This HA-coated ingrowth surface does not require heat treatment to attach beads, and therefore preserves the carbide structure. This surface is integral to the cup and is not a spray-on coating. The BHR femoral component is cemented to femoral bone. The BHR HRA uses an as-cast cobalt chrome metal-on metal-bearing surface with a highly polished finish. In theory, cobalt chrome in its as-cast form has superior wear resistance to other forms of the alloy (BHR Product Manual).

MRI was used to identify fluid collections and soft-tissue masses (Toms et al. 2008, Hart et al. 2012). MRI was performed on 40 hips regardless of the patient's symptoms. 1 patient refused MRI examination due to claustrophobia. For 1 patient, a revision operation had been performed earlier for ARMD without MRI imaging. We used 3 1.5T MR imagers (Philips Ingenia (2012); Philips Medical Systems, Best, the Netherlands; Siemens Avanto (2008) and Siemens Aera (2012); Siemens, Erlangen, Germany). The pulse sequences used were optimized to reduce metal-induced artifacts (Hargreaves et al. 2011). MARS (metal artifact reduction sequence) MRI is a recently developed technique that provides good metal artifact suppression while minimizing image blurring and scanning time (Eustace et al. 1998, Hart et al. 2012). One imager (Siemens Aera) was equipped with an advanced metal artifact reduction technique—Slice Encoding for Metal Artifact Correction—with view angle tilting (SEMAC-VAT) (Sutter et al. 2012). At least 2 sequences covering the whole pelvic area were obtained in the coronal and axial planes (STIR and T2 or T1) followed by smaller field-of-view images in 3 planes centralized in the joint with implant (STIR, T1, and T2).

Images were examined by radiologists experienced in ARMD-related MRI diagnostics. Special attention was paid

to detection of periarticular fluid collections and soft-tissue masses. Pathology was measured in 3 planes and stored for analysis. For this, MRI images were examined in 3 planes for measurement of the maximal anterior-posterior, superior-inferior, and medial-lateral diameters.

All patients underwent conventional radiography of the pelvis and hip; the radiographs were used to measure the inclination angle of the cup. Radiographs were taken in upright position. Cup inclination angles were analyzed from digital pelvic radiographs using digital angle measurement. There was no osteolysis or heterotopic ossification in any of the hips. In 1 patient, there was a partial radiolucent line under the cup in Gruen zone I, but the cup position was not changed and it was considered stable.

Serum metal ion measurements (cobalt and chromium) were performed at follow-up. For ion measurements, 5–7 mL of whole blood was taken in a test tube containing heparin (for example, Venosafe or Vacuette trace elements). The Finnish Institute of Occupational Health performs all the cobalt and chromium ion measurements in Finland using inductively coupled plasma mass spectrometry. The analyses have been accredited (FINAS T013).

The OHS questionnaire was completed by 31 patients at the time of follow-up (40 hips). Clicking, a sensation of subluxation, and swelling of the hip were considered separately. The OHS questionnaire was not filled out preoperatively or at routine outpatient visits. All patients were clinically evaluated by 1 of the 5 orthopedic surgeons who performed revision surgery at the Turku University Hospital.

The prevalence of ARMD after the BHR HRA was assessed and risk factors for ARMD were evaluated: age, sex, head size ( $\geq 54$  mm vs.  $\leq 50$  mm), diagnosis (secondary vs. primary OA), inclination of the cup, and bilaterality. The association of patient symptoms with ARMD was analyzed separately. The symptoms assessed were clicking, subluxation sensation, swelling, OHS total score, and relation of poor/fair versus good/excellent OHS score. OHS group 1 was considered excellent, group 2 good, group 3 fair, and group 4 poor.

ARMD was considered definite if the patient was revised for ARMD and the operative finding was compatible with ARMD. ARMD was also considered definite in those cases where a revision operation had not been performed but the serum chromium or cobalt level was  $\geq 10$   $\mu\text{g/L}$ , and/or where there was a solid mass or a fluid collection of  $\geq 50$  mm in MRI (in any plane). In patients who had not undergone surgery, ARMD was considered to be probable either if the serum chromium or cobalt concentration was  $\geq 5$   $\mu\text{g/L}$  and/or if there was a fluid collection of any size by MRI.

A radiograph and an MRI image of a BHR hip with a pseudotumor are presented in Figure 1.

## Statistics

Potential risk factors for ARMD were analyzed by binary logistic regression with random intercept for patient. The

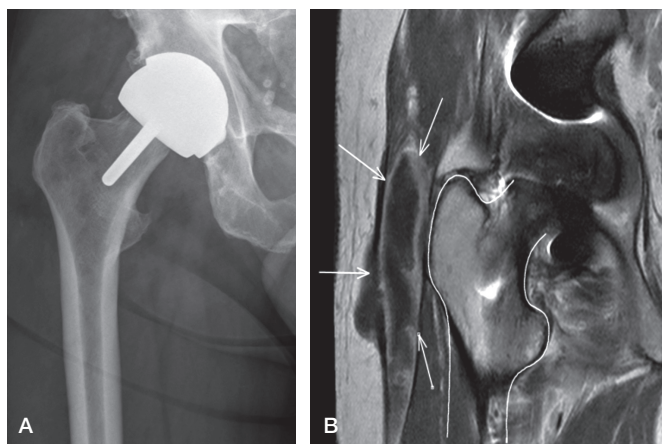


Figure 1. A radiograph (panel A) and an MRI image (panel B) of a BHR hip with a pseudotumor.

dependent variable ARMD consisted of 2 groups (definite or probable cases and no ARMD), with no ARMD being used as the reference group. Results are expressed as crude odds ratios (ORs) with 95% confidence intervals (CIs). Multiple binary logistic regression including risk factors with  $p < 0.40$  in a bivariable model, forward selection, and backward elimination methods (inclusion criteria,  $p < 0.20$ ) were used to investigate the potential confounding effect of other risk variables. Exact chi-square test was used to analyze clicking and swelling due to 0 cell counts. were considered statistically significant. Statistical analysis was carried out using SAS for Windows version 9.3.

Table 1. Characteristics of 32 patients and results for 42 corresponding hips. Data on swelling, clicking, and subluxation sensation are given hipwise for 41 hips (the data on 1 hip are missing). Data on mean OHS (range) and the OHS classification are given hipwise for 40 hips (the data on 2 hips are missing). Data on mean (range) age, follow-up, and inclination angle of the cup are given hipwise for 42 hips

	Total	ARMD	Probable ARMD	ARMD not found
Patients, n	32	6	8	18
Males, n	24	6	7	11
Serum cobalt, $\mu\text{g/L}^a$	2.5 (0.8–14.9)	6.9 (1.2–14.9)	1.5 (0.8–2.6)	1.5 (0.8–2.6)
Serum chromium, $\mu\text{g/L}^a$	2.1 (0.6–7.6)	4.4 (1.1–7.6)	1.5 (1.0–2.4)	1.6 (0.6–2.5)
Hips, n	42	8	8	24
Age, years <sup>a</sup>	59 (26–77)	63 (49–70)	58 (26–76)	58 (38–77)
Follow-up, years <sup>a</sup>	6.7 (2.4–8.8)	6.0 (2.4–7.0)	6.8 (6.3–7.3)	7.0 (6.2–8.8)
Swelling, n	2	2	0	0
Clicking, n	2	2	0	0
Subluxation sensation, n	6	2	1	3
Inclination angle of the cup, degrees <sup>a</sup>	47 (37–64)	47 (42–61)	50 (39–64)	46 (37–60)
OHS <sup>a</sup>	44 (21–48)	40 (33–48)	45 (32–48)	44 (21–48)
OHS excellent, n	30	3	7	20
OHS good, n	6	4	0	2
OHS fair, n	2	1	1	0
OHS poor, n	2	0	0	2

<sup>a</sup> Mean (range)

ARMD: adverse reaction to metal debris;

OHS: Oxford hip score (42–48 = excellent, 34–41 = good, 27–33 = fair, and 0–26 = poor).

## Ethics

Ethical approval was not required due to adherence to national guidelines on the follow-up of metal-on-metal hip arthroplasty patients. The study was performed according to the ethical standards of Turku University Hospital and the Helsinki Declaration.

## Results

6 patients (9 of 42 hips) were considered to have a definite ARMD. 4 of these hips were revised for ARMD (Tables 1 and 2). 8 patients (8 hips) were considered to have a probable ARMD. Altogether, there were 17 hips with a definite or probable ARMD. 18 patients were considered not to have ARMD.

Male sex was associated with definite ARMD, although not statistically significantly so (OR = 11, CI: 0.7–165;  $p = 0.08$ ). However, sex ( $p = 0.2$ ), bilateral MoM ( $p = 0.3$ ), and head size ( $p = 0.7$ ) were not statistically significant in the multiple logistic regression model (Tables 3 and 4). Sex was the only risk factor included in the final model using forward selection and backward elimination methods.

OHS score (crude OR = 0.97, CI: 0.85–1.1;  $p = 0.7$ , for 1 unit increase in this continuous variable) or OHS poor/fair vs. good/excellent relation (crude OR = 1.6, CI: 0.09–27;  $p = 0.7$ ) were not associated with ARMD. Furthermore, subluxation sensation (crude OR = 1.7, CI: 0.16–18;  $p = 0.6$ ) was not associated with ARMD. Clicking and swelling were not associated with ARMD either ( $p = 0.07$  for both; Fisher's exact test).

## Discussion

We found that BHR HRA may be more dangerous than previously thought. 4 of 42 hips were revised for ARMD. There was a trend of male sex being associated with definite ARMD.

One limitation of the present study was that the definition of a non-revised ARMD was not clear. Persistent pain after metal-on-metal hip implants has been shown to be associated with higher serum metal ion levels with a probable cutoff of  $8 \mu\text{g/L}$  (Lardanchet et al. 2012). A cutoff level of  $10 \mu\text{g/L}$  has been used previously in assessing ARMD in association with metal-on-metal hip implants (Mokka et al. 2013). There was 1 hip in our study that we considered to have ARMD due to high serum ion levels, without MRI findings. Another limitation was that we included patients with bilateral metal-on-metal implants, which may have biased

**Table 2.** Data on the 6 patients (9 hips) with a definite adverse reaction to metal debris (ARMD). None of the patients had major muscle destruction. The 64 M, 69 M, and 62 M patients had both hips with ARMD. The ARMD diagnosis of the right hip of 64 M was based on operative findings in a revision operation in 2009

Age	Sex	Side	OHS	Pain	Clicking	Sublux.	Swelling	s-Cr, µg/L	s-Co, µg/L	Cup incl. (°)	MRI	Revision or follow-up
64	M	Right	NA	Moderate	No	Yes	No	NA	NA	48	NA	Revised
64	M	Left	35	Moderate	Yes	Yes	Yes	3.9	4.5	43	Solid and fluid 55 × 35 × 110 mm	Revised
69	M	Right	44	Mild	No	No	No	7.6	13.5	61	Fluid 30 × 40 × 65 mm and 85 × 80 × 30 and solid 20 × 20 × 50	Revised
69	M	Left	44	No	No	No	No	7.6	13.5	47	Fluid 57 × 46 × 10 mm	Follow-up
49	M	Right	33	Hard	Yes	Yes	Yes	4.3	4.5	42	Fluid 70 × 26 × 23 mm	Follow-up
62	M	Right	39	No	No	No	No	7.6	14.9	48	No findings	Follow-up
62	M	Left	39	No	No	No	No	7.6	14.9	43	Some fluid	Revised
59	M	Right	41	Moderate	No	No	No	1.6	2.9	47	Fluid 50 × 5 × 5 mm	Follow-up
67	M	Right	48	No	No	No	No	1.1	1.2	47	Fluid 13 × 19 × 50 mm	Follow-up

OHS: See Table 1. Sublux.: subluxation sensation; s-Cr: serum chromium level; s-Co: serum cobalt level; Cup incl.: cup inclination angle; MRI: magnetic resonance imaging; NA: not available.

**Table 3.** Results of testing of associations between risk factors and ARMD using logistic regression with random intercept for patient, with crude odds ratios (ORs) and 95% confidence intervals (CIs)

Risk factor	ARMD definite or probable (n = 17) vs. ARMD not found (n = 25)	
	OR (95% CI)	p-value
Age at follow-up	1.03 <sup>a</sup> (0.93–1.13)	0.5
Sex (male vs. female)	10.8 (0.7–165)	0.08
Inclination angle of the cup	1.05 <sup>a</sup> (0.93–1.2)	0.4
Bilateral MoM	0.33 (0.05–2.1)	0.2
Bilateral THA	0.55 (0.09–3.4)	0.5
Diagnosis secondary vs. primary OA	2.0 (0.27–14)	0.5
Head size (≥ 54 vs. ≤ 50 mm)	4.1 (0.66–25)	0.1

ARMD: adverse reaction to metal debris;  
MoM: metal-on-metal implant; THA: total hip arthroplasty  
OA: osteoarthritis.  
<sup>a</sup> For 1 unit increase (continuous variable).

**Table 4.** Results of testing of associations between risk factors and ARMD using a multiple logistic regression model with random intercept for patient, with adjusted odds ratios (ORs) (including risk factors with p < 0.40 in bivariable model) and 95% confidence intervals (CIs)

Risk factor	ARMD definite or probable (n = 17) vs. ARMD not found (n = 25)	
	OR (95% CI)	p-value
Sex (male vs. female)	7.6 (0.29–204)	0.2
Bilateral MoM	0.40 (0.05–3.2)	0.3
Head size (≥ 54 vs. ≤ 50 mm)	1.6 (0.16–16)	0.7

For abbreviations: See Table 3.

metal ion analyses. However, we increased the cutoff level from 8 µg/L suggested by Lardanchet et al. (2012) to 10 µg/L

due to the inclusion of bilateral HRAs. We used a metal ion level of ≥ 5 µg/L as a criterion for probable ARMD. Due to the possible bias caused by inclusion of bilateral HRAs, we performed further analysis to assess bilaterality and found that it was not associated with ARMD. 4 of our 6 definite ARMD patients had normal serum metal ion levels (< 5 µg/L). 1 of these patients was revised, and ARMD was verified at the operation. Normal serum metal ion levels may be misleading in detecting ARMD, and metal ion measurements alone should not be used for ARMD screening (Macnair et al. 2013).

Another limitation of the present study was that the approximate size of the fluid collections by MRI was used to define definite ARMD and to differentiate it from probable ARMD. All fluid collections with a solid component were considered to be definite ARMDs. The dichotomy between MRI findings ≥ 50 mm in any dimension and < 50 mm is artificial. We thus hypothesize that a fluid collection ≥ 50 mm in any dimension is a clinically significant amount of fluid with regard to a diagnosis of ARMD. Furthermore, 1 of the limitations of the present study was the lack of CT-based evaluation of implant position. However, no association has been found between MRI-detected pseudotumor formation and CT-detected HRA cup position (Hart et al. 2012), which is in accordance with our findings.

Another limitation of our study was that not all patients who were operated in our unit during the period April 2004 to March 2007 were included. At the start, we wanted to follow up patients who had been operated 2004–2005. However, the contralateral hips of many of these patients were operated with a BHR implant later, up to 2007. We decided to include these patients with bilateral hips (although one was operated later). However, there were many BHR operations in 2006 and 2007 that were not included in this screening study due to lack of resources. The total number of BHR hips inserted at our unit

during the period April 2004 through March 2007 was 116 (42 of which were included in the study). We understand that there may have been selection bias, although it was not intentional. However, we believe that this did not undermine our results. ARMD was common, and several revisions for ARMD were performed.

Possible association of the risk factors with ARMD was determined using binary logistic regression (definite or probable cases vs. no ARMD). Results were expressed using ORs. When interpreting these results, the reader should be aware that OR is not equivalent to relative risk (RR) (Schmidt and Kohlmann 2008). The risk factors assessed were not statistically significantly associated with ARMD, probably due to the relatively small number of hips in the study. The same was true of possible associations between symptoms of the patients and ARMD (OHS score, relation of OHS poor/fair versus good/excellent, subluxation sensation, clicking, swelling).

Concern has been raised recently about the high failure rate of HRA due to ARMD. In May 2012, the Finnish Arthroplasty Association recommended that performance of HRAs should not be continued (FAA 2012). However, the first reports of the clinical success of BHR were promising (Treacy et al. 2005, Steffen et al. 2008, Heilpern et al. 2008). The short-term survival of the BHR was found to be comparable to that of conventional cemented THR, based on data from the Finnish Arthroplasty Register (Seppänen et al. 2012). The cumulative revision percentage of BHR at 5 years (3.6%, 95% CI: 3.2–4.0) and at 10 years (6.7%, 95% CI: 6.0–7.5) is relatively low, based on Australian registry data (AOA 2012). However, registry studies are poor at detecting early implant failure, since radiological data on osteolysis and ARMD emerge late. Early clinical trials may focus solely on radiographic findings. Bisschop et al. (2013) reported a 28% prevalence of CT-verified pseudotumors in 149 BHR HRAs after an average follow-up of 3 years. These results are in accordance with our findings. However, we based the radiological diagnosis of fluid collections and soft-tissue masses solely on MRI, except in 2 cases. The prevalence of fluid collections verified by MRI in our study was higher than that of CT-verified pseudotumor in the study by Bisschop et al. (2013). The follow-up time in the present study was longer, which is probably related to the high prevalence of ARMD. However, our aim was to detect the prevalence of ARMD based on MRI findings, serum metal ion levels, and surgical findings and not only the prevalence of radiologically detected pseudotumors. The clinical relevance of asymptomatic fluid collections detected by MRI in patients with normal metal ion levels is unclear. The prevalence of MRI-verified pseudotumors in HRA patients with a painful hip is similar to that in asymptomatic HRA patients (Hart et al. 2012). However, the high rate of fluid collections seen by MRI and the soft-tissue destruction at the time of revision found in our patients is a cause for great concern. A systematic follow-up of these patients using metal ion levels, MRI/ultrasound, and symptom-based questionnaires is advisable.

MJ, JM, MS, PV, and KTM designed the study protocol. MJ, JM, MS, PV, JR, VÅ, AI, and KTM performed the surgery, recorded the intraoperative data, and wrote the manuscript. TP, TV, and KTM analyzed the data. KM and ET designed the MRI protocol and participated in image interpretation and revision of the manuscript for intellectual content.

This study was funded by a research grant from Turku University Hospital and a grant from the Orion-Farmos Research Foundation.

No competing interests declared.

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