Adverse reaction to metal debris after ReCap-M2A-Magnum large-diameter-head metal-on-metal total hip arthroplasty

Jari Mokka[1], Mika Junnila[1], Matti Seppänen[1], Petri Virolainen[1], Tuukka Pölönen[2], Tero Vahlberg[2], Kimmo Mattila[3], Esa K J Tuominen[3], Juho Rantakokko[1], Ville Äärimaa[1], Juha Kukkonen[1], and Keijo T Mäkelä[1]

[1]Department of Orthopaedics and Traumatology, Turku University Hospital; [2]Department of Biostatistics, University of Turku; [3]Department of Radiology, Turku University Hospital, Turku, Finland.
Correspondence: keijo.makela@tyks.fi
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Background and purpose **The clinical findings of adverse reaction to metal debris (ARMD) following large-diameter-head metal-on-metal total hip arthroplasty (LDH MoM THA) may include periarticular fluid collections, soft tissue masses, and gluteal muscle necrosis. The ReCap-M2a-Magnum LDH MoM THA was the most commonly used hip device at our institution from 2005 to 2012. We assessed the prevalence of and risk factors for ARMD with this device.**

Methods **74 patients (80 hips) had a ReCap-M2a-Magnum LDH MoM THA during the period August 2005 to December 2006. These patients were studied with hip MRI, serum chromium and cobalt ion measurements, the Oxford hip score questionnaire, and by clinical examination. The prevalence of ARMD was recorded and risk factors for ARMD were assessed using logistic regression models. The mean follow-up time was 6.0 (5.5–6.7) years.**

Results **A revision operation due to ARMD was needed by 3 of 74 patients (3 of 80 hips). 8 additional patients (8 hips) had definite ARMD, but revision was not performed. 29 patients (32 hips) were considered to have a probable or possible ARMD. Altogether, 43 of 80 hips had a definite, probable, or possible ARMD and 34 patients (37 hips) were considered not to have ARMD. In 46 of 78 hips, MRI revealed a soft tissue mass or a collection of fluid (of any size). The symptoms clicking in the hip, local hip swelling, and a feeling of subluxation were associated with ARMD.**

Interpretation **ARMD is common after ReCap-M2a-Magnum total hip arthroplasty, and we discourage the use of this device. Asymptomatic patients with a small fluid collection on MRI may not need instant revision surgery but must be followed up closely.** ■

The medium-term outcome of some cementless large-diameter-head metal-on-metal total hip arthroplasty (LDH MoM THA) devices is poor (AOA 2012, NJR 2012, Smith et al. 2012). Individual patients whose devices are failing often experience pain, clicking, swelling, and a sensation of subluxation (Maurer-Ertl et al. 2011, Munro et al. 2013). This clinical finding in association with periarticular fluid collections, soft tissue masses, and gluteal muscle necrosis at corrective surgery is called adverse reaction to metal debris (ARMD) (Ollivere et al. 2009, Langton et al. 2010, Hart et al. 2012, Meyer et al. 2012). The reaction to metal debris from an arthroplasty device is often associated with increased concentrations of chromium and cobalt in the serum (Kwon et al. 2010, Langton et al. 2010). Taper junctions cause significant metal ion release through fretting corrosion (Hallab et al. 2004, Lavigne et al. 2011, Vendittoli et al. 2011). Magnetic resonance imaging (MRI) optimized to reduce image artifacts and distorsions by metallic implants is important for diagnosis of ARMD (Haddad et al. 2011). MRI analysis is useful for detecting soft tissue abnormalities and mass lesions even when plain radiographs are normal (Toms et al. 2008, Hart et al. 2012).

Cementless LDH MoM THA has been popular in Finland the past 8 years (Mokka et al. 2013). From 2005 to 2012, the ReCap-M2a-Magnum LDH MoM THA device (Biomet, Warsaw, IN) was the most common hip device at our institution, with over 1,000 implantations. We assessed the prevalence of ARMD in a cohort consisting of the first 80 ReCap-M2a-Magnum THA implantations performed, from August 2005 to December 2006. For the assessment, in addition to a clinical examination we used MRI, serum metal ion concentration determinations, and the Oxford hip score (OHS) questionnaire. On the basis of these results, we identified risk factors for ARMD.

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Table 1. Patient characteristics and results (74 patients, 80 hips). Data on swelling, clicking, sensation of subluxation, mean OHS (range), and OHS classification are given hipwise for 77 hips (data for 3 hips are missing). The data for mean inclination angle of the cup (range) are given hipwise for 80 hips

	Total	ARMD	ARMD probable or possible	ARMD not found
Patients, n	74	11	29	34
Males, n	24	4	13	7
Mean age, years (range)	67 (42–82)	66 (58–75)	70 (53–82)	65 (42–81)
Mean follow-up, years (range)	6.0 (5.5–6.7)	6.0 (5.6–6.3)	5.9 (5.5–6.3)	6.0 (5.6–6.7)
Mean serum cobalt, μg/L (range)	3.7 (0.4–42.5)	12.8 (2.9–42.5)	2.2 (0.8–7.7)	2.1 (0.4–4.4)
Mean serum chromium, μg/L (range)	3.6 (0.5–49.1)	12.4 (2.5–49.1)	2.1 (0.5–7.2)	2.0 (0.6–4.2)
Hips, n	80	11	32	37
Swelling, n	9	4	3	2
Clicking, n	16	6	5	5
Subluxation sensation, n	14	5	4	5
Mean inclination angle of the cup, degrees (range)	45 (23–62)	46 (37–62)	46 (28–57)	44 (23–55)
Mean OHSa (range)	41 (13–48)	36 (13–48)	41 (15–48)	42 (23–48)
OHS excellent, n	52	4	23	25
OHS good, n	10	1	4	5
OHS fair, n	9	5	2	2
OHS poor, n	6	1	2	3

ARMD: adverse reaction to metal debris.
OHS: Oxford hip score: 42–48, excellent; 34–41, good; 27–33, fair; 0–26, poor.

Patients and methods

74 patients (80 hips) underwent a ReCap-M2a-Magnum LDH MoM THA between August 2005 (when the device was first introduced at our institution) and the end of December 2006 (Table 1). The patients were examined between February 2012 and September 2012 with MRI, assessment of serum chromium and cobalt ion levels, the Oxford hip score questionnaire, and by clinical examination. The mean follow-up time was 6.0 (5.5–6.7) years. 10 patients could not participate due to medical conditions or death. 5 patients had undergone THA of both hips in one session and 1 patient had had both hips operated but in separate sessions. 27 patients had a MoM hip device in the contralateral hip joint and 40 patients had any hip device. The Biomet Bimetric stem and Hardinge approach were used in all study cases.

MRI was used to identify collections of fluid and soft tissue masses (Toms et al. 2008, Hart et al. 2012). MRI was performed on 77 hips regardless of patient symptoms. For MRI, 1.5T images were used, carefully 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. 1997, Hart et al. 2012). 1 patient with a study implant in both hips underwent computed tomography (CT) because of a pacemaker. 1 patient was identified radiographically as having a loose stem; the device was revised before MRI. An estimate of the volume of periarticular fluid collections and soft tissue masses was made. 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 pelvic and hip radiography; the radiographs were used to measure the inclination angle of the cup. Serum levels of cobalt and chromium ions were measured at follow-up. A total score of 42–48 points was considered excellent, 34–41 good, 27–33 fair, and 0–26 poor. Separate questions about clicking, a sensation of subluxation, and swelling of the hip were asked. 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 performing revision surgery at Turku University Hospital.

The prevalence of ARMD after ReCap-M2a-Magnum THA was assessed and the risk factors for ARMD were evaluated. ARMD was considered definite if the patient was revised for ARMD and if 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 ≥ 10 μg/L and/or there was a solid mass or a fluid collection of ≥ 50 mm on MRI (in any plane). In patients who had not undergone surgery, ARMD was considered to be probable or possible either if the serum chromium or cobalt concentration was ≥ 5μg/L and/or if there was a collection of fluid of any size by MRI.

We assessed the following risk factors for ARMD: age, sex, side, inclination of the cup, bilaterality, clicking, subluxation sensation, swelling, OHS total score, OHS group 1 (excellent) and OHS group 2 (good) vs. OHS group 3 (fair) and OHS group 4 (poor).

Table 2. Data on the 3 patients who required revision because of an adverse reaction to metal debris (ARMD)

A	B	C	D	E	F	G	H	I	J	K	L	M	N
58 F	33	M	No	Yes	Yes	2.5	3.8	41	Solid mass and fluid 60 × 30 × 30 mm	Pseudotumor	Cold-welded	ETO + revision of stem and cup	Neg
71 M	29	M	Yes	No	Yes	4.9	6.6	57	Fluid 29 × 76 × 62 mm	Milk-like yellowish fluid	Cold-welded	Revision of the stem + Avantage	Neg
65 F	32	M	Yes	Yes	No	13.5	24.0	45	Fluid 90 × 130 × 70 mm	Milk-like yellowish fluid, pseudotumor, gluteus medius muscle necrosis	Corrosion of trunnion and adapter	Avantage	Neg

A Age and gender
B OHS, See Table 1
C Pain
M = Moderate
D Clicking
E Subluxation sensation
F Swelling
G Serum chromium level µg/L
H serum cobalt level µg/L
I Cup inclination angle in degrees
J Magnetic resonance imaging
K Status of the hip at revision (all had ARMD)
L Status of the trunnion/head at revision
Cold-welded = the Magnum head could not be detached from the adapter and trunnion
M The procedure performed in revision
ETO = extended trochanter osteotomy to revise the stem
Avantage = the Biomet Dual-Mobility E1 mobile polyethylene liner.
N Bacterial culture

The M2a-Magnum modular head and the ReCap cup are high-carbon, as-cast single-heated components. The system is modular, with increasing head sizes and (concomitantly) progressively larger shell sizes. There is the option of adapting the neck length by using tapers of different length. The main components of the head and acetabular component are of a cobalt-chromium alloy and contain a small proportion of molybdenum and carbon. The stem, taper, and taper adapters are made of titanium, aluminium, and vanadium alloy. The radial clearance level of the M2a-Magnum articulation is maintained at 75–150 µm. The acetabular component is 6 mm thick at the dome and (on average) 3 mm thick at the rim (Biomet design rationale, Bosker et al. 2012).

Statistics

The prevalence of ARMD is expressed as a percentage with 95% confidence intervals (CIs). Potential risk factors for ARMD were analyzed by univariable multinomial logistic regression. The dependent variable ARMD consisted of 3 groups (definite cases, probable or possible cases, and no ARMD), with no ARMD used as the reference group. The results are expressed using odds ratios (ORs) with CIs. The multivariable logistic model was obtained using backward elimination. Any p-values < 0.05 were considered statistically significant. Statistical analyses were carried out using SAS for Windows, version 9.3.

Results

3 patients (3 hips) required revision due to ARMD (Table 2). ARMD was verified in the revision operation in all of these cases.

8 patients (8 hips) were considered to have definite ARMD based on our definition, but a revision operation had not been performed (11 of 80 hips altogether) (Table 3).

29 patients (32 hips) were considered to have a probable or possible ARMD. Altogether, there were 43 out of 80 hips with a definite, probable, or possible ARMD and 34 patients (37 hips) were considered not to have ARMD.

An MRI finding of a soft tissue mass or a collection of fluid of any size was found in 46 of 78 hips.

Univariable associations assessed with multinomial logistic regression analysis between certain risk variables and ARMD are presented in Table 4. A sensation of subluxation, clicking, swelling, and a poor OHS score were associated with ARMD. In the multivariable model, clicking and swelling remained statistically significant factors when we compared patients with ARMD to patients without ARMD (OR = 7, CI: 1.5–38; p = 0.02 and OR = 10, CI: 1.3–76; p = 0.03, respectively). Age remained significant when we compared patients with probable or possible ARMD to patients without ARMD (OR = 1, CI: 1.0–1.2; p = 0.02).

Table 3. Data on 8 patients who were considered to have ARMD but who had not undergone revision surgery. See Table 2 for explanation of abbreviations

A		B	C	D	E	F	G	H	I	J	K
70	M	47	No	No	No	No	49.1	11.3	41	Fluid 60 × 70 × 20 mm	Revision scheduled
60	F	37	Mild	No	Yes	No	7.8	10.0	53	Fluid 25 × 35 × 40 mm	Strict follow-up
61	M	32	Moderate	Yes	No	No	26.1	42.5	62	Fluid 60 × 70 × 22 mm	Revision scheduled
66	F	48	No	Yes	No	No	2.9	2.9	37	Solid and fluid 76 × 30 × 1 mm and 30 × 20 × 20 mm	Strict follow-up
66	F	45	Mild	Yes	Yes	No	10.2	6.7	50	No findings	Strict follow-up
63	M	47	Mild	No	No	Yes	9.1	8.4	40	Solid 60 × 60 × 90 mm	Revision scheduled
75	F	27	Moderate	Yes	Yes	No	5.4	14.1	39	Fluid 47 × 13 × 70 mm	Patient did not want revision
71	F	13	Hard	No	No	Yes	4.8	10.0	42	No findings	Strict follow-up

A–J: See Table 2
K Status of the patient

Table 4. Associations between certain risk factors for ARMD in patients with ARMD and patients without ARMD. Odds ratios (ORs) and 95% confidence intervals (CIs) by univariable multinomial logistic regression analysis. A sensation of subluxation, clicking, and a poor OHS score were related to ARMD. One unit increase in OHS score was considered statistically significant in the definite ARMD group

	ARMD vs. ARMD not found		ARMD probable or possible vs. ARMD not found	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Age	1.0 (0.95–1.1)	0.5	1.1 (1.0–1.2)	0.02
Gender (female vs. male)	0.6 (0.1–2.4)	0.4	0.4 (0.1–1.0)	0.05
Side	4.4 (1.0–19)	0.05	0.8 (0.3–2.0)	0.6
Subluxation sensation	5.0 (1.1–23)	0.04	0.9 (0.2–3.7)	0.9
Clicking	7.2 (1.6–33)	0.01	1.2 (0.3–4.4)	0.8
Swelling	9.4 (1.4–62)	0.02	1.8 (0.3–11)	0.5
Inclination angle of the cup	1.0 (0.95–1.1)	0.4	1.0 (0.97–1.1)	0.2
OHS score	1.1 (1.0–1.2)	0.03	1.0 (0.95–1.1)	0.7
OHS poor and fair vs. good and excellent	7.2 (1.6–33)	0.01	0.9 (0.2–3.7)	0.9
Bilateral ReCap-M2a-Magnum	0.4 (0.05–3.9)	0.5	0.6 (0.2–2.3)	0.5
Bilateral MoM THA	0.6 (0.1–2.4)	0.4	0.6 (0.2–1.6)	0.3
Bilateral THA	0.4 (0.1–1.8)	0.2	0.7 (0.3–1.7)	0.4

Discussion

3 of the 74 patients (3 of 80 hips) had undergone a revision operation because of ARMD. 8 additional patients (8 hips) were considered to have a definite ARMD during a mean follow-up time of 6 years. Furthermore, 29 patients (32 hips) had a probable or possible ARMD. Thus, 43 of 80 hips had a definite, probable, or possible ARMD. Based on these data, the continued use of ReCap-M2a-Magnum device cannot be encouraged. Clicking, swelling, sensation of subluxation, and a poor or fair Oxford hip score were associated with definite ARMD but not with probable or possible ARMD. Asymptomatic patients with a small fluid collection in MRI and slightly elevated serum metal ion levels may not need instant revision surgery. A systematic follow-up of these patients using metal ion levels, MRI, and symptom questionnaires is advisable.

Concern has been raised recently about the high failure rate of LDH MoM THA due to ARMD. In April 2010, the British Orthopaedic Association issued an alert to its members concerning LDH MoM THA (MHRA 2010). In May 2011, the American Food and Drug Administration ordered a post-marketing surveillance of MoM THA from 21 companies (FDA 2011). In May 2012, the Finnish Arthroplasty Association recommended that performance of LDH MoM THAs should be discontinued (FAA 2012).

The first reports of early clinical success of ReCap-M2a-Magnum THA (Kostensalo et al. 2012, Meding et al. 2012) and ReCap-Magnum hip resurfacing arthroplasty (HRA) (Gross and Liu 2012, van der Weegen et al. 2012) were promising. The short-term survival of the ReCap-M2a-Magnum THA was comparable to that of conventional cemented THA based on data from the Finnish Arthroplasty Register (Mokka et al. 2013). The cumulative revision percent of ReCap-M2a-Magnum THA at 5 years (3.6, CI: 2.4–5.3) is significantly lower than that of ASR THA (DePuy) (22, CI: 21–24) according to Australian registry data (AOA 2012). Cormet THA (Corin) and BHR THA (Smith and Nephew) do not have a lower revision risk than ReCap-M2a-Magnum THA at 5 years (6.0, CI: 4.1–8.7 and 5.5, CI: 4.5–6.7, respectively) (AOA 2012). However, registry studies have poor detection of early implant failures since radiological data on osteolysis and ARMD emerge late. Early clinical trials may focus solely on radiographic findings. Bosker et al. (2012) reported an incidence of CT/MRI-verified pseudotumors of 39% in 109 unilateral M2a-Magnum-ReCap THAs and a subsequent revision rate of 12%. These results are in accordance with our findings. We based the radiological diagnosis of fluid collections and soft tissue masses solely on MRI, except in 3 cases. 1 patient had a loose stem by radiography and a poor OHS score (24 points). She was revised with a Biomet Reach revision stem before the MRI was done. Her serum chromium and cobalt levels were 0.8 μg/L and 1.0 μg/L, respectively. There were no signs of ARMD at the stem revision. 1 patient underwent a bilateral CT scan because of a pacemaker and there was no evidence of ARMD. Her serum chromium and cobalt levels were 2.1 μg/L and 2.1 μg/L.

MRI-verified fluid collections and soft tissue masses were more common in our study than CT-verified fluid collections and soft tissue masses in the study of Bosker et al. (2012). Of note, we based our ARMD diagnosis, in addition to MRI findings, on serum metal ion levels, although elevated serum metal ion levels may not be considered to be a true reaction per se. 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 hip resurfacing arthroplasty (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 on MRI and the soft tissue destruction at the time of revision found in our patients is a cause for great concern. The indications and timing for revision surgery are not clear. Revision surgery should be performed under all circumstances before necrosis of the gluteal muscles ensues.

A limitation of our study was that the definition of ARMD in hips that had not undergone revision was not clear. Persistent pain after LDH MoM THA is associated with higher serum metal ion levels at a cutoff of about 8 μg/L (Lardanchet et al. 2012). There were 2 hips in our study that we considered to have ARMD due to high serum ion levels despite normal MRI findings (Table 3). These 2 patients had symptoms, and a strict follow-up was scheduled for them. Another limitation was that we included patients with bilateral metal-on-metal implants. Bilateral metal-on-metal implants may bias metal ion analyses. However, the cutoff level was increased from 8 μg/L—the level suggested by Lardanchet et al. (2012)—to 10 μg/L because we included bilateral MoM hips. We used a metal ion level of ≥ 5 μg/L as a criterion for probable or possible ARMD. The risk of a radiological pseudotumor in unilateral ReCap-M2a-Magnum THA patients with serum cobalt levels of > 5 μg/L is 4-fold compared to patients with serum cobalt levels of < 5 μg/L (Bosker et al. 2012). Due to potential bias caused by inclusion of bilateral MoM devices, we performed further analyses to assess bilaterality. Bilaterality was not associated with ARMD (Table 4). 2 of our 11 definite ARMD patients had normal serum ion levels (< 5 μg/L). 1 of these 2 patients needed revision and ARMD was verified at surgery (Tables 2 and 3). Normal metal ion levels may be misleading when ARMD is diagnosed, 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 as opposed to probable or possible ARMD. All fluid collections with a solid component and other soft tissue masses were considered to be definite ARMDs. The differentiation between MRI findings of ≥ 50 mm in any dimension and < 50 mm is artificial. We therefore hypothesize that a fluid collection of ≥ 50 mm in any dimension is a clinically significant amount of fluid with regard to a diagnosis of AMRD. Furthermore, one of the limitations of the present study is the lack of CT-based evaluation of implant position. It is also possible that the fluid collections detected by MRI may have been for reasons other than ARMD.

The association of the risk factors with ARMD was analyzed using multinomial logistic regression because ARMD consisted of 3 groups (definite cases, probable or possible cases, and no ARMD). The results were expressed using odds ratios (ORs). When interpreting these results, the reader should notice that OR is not equivalent to relative risk (RR) (Schmidt and Kohlmann 2008).

There were more female patients in the possible/probable ARMD group than in the group with no ARMD, and the patients in the former group were also older (Table 4). This is probably a chance finding, but it may need to be re-addressed in other studies. Likewise, the finding of the effect of laterality on ARMD occurrence was probably a chance finding.

Metal ion release differs between various models of LDH MoM THA. An adapter sleeve made of titanium, such as the one used with the ReCap-M2a-Magnum THA, probably does not contribute to the release of cobalt ions. Of 4 LDH MoM THAs (Biomet, DePuy, Smith and Nephew, Zimmer), the Biomet implant releases least cobalt (Lavigne et al. 2011). However, extensive corrosion on the taper and trunnion, contributing to the formation of metal debris, has been encountered in ReCap-M2a-Magnum THA revisions (Bosker et al. 2012). Well-positioned ReCap-M2a-Magnum components may be associated with increased production of debris from this junction. There is no association between CT/MRI-detected pseudotumor formation and the CT-detected position of ReCap-M2a-Magnum components (Bosker et al. 2012), or between MRI-detected pseudotumor formation and the CT-detected HRA cup position (Hart et al. 2012). These results are in accordance with our findings. In 2 of the 3 ARMD revisions that we performed in this study, the cold-welded Magnum head could not be detached from the adapter and trunnion (Table 2). Our experience supports the assumption that extensive corrosion on the taper and trunnion of the ReCap-M2a-Magnum device contributes to metal debris. Incidentally, there was a patient with sepsis and a deep prosthetic infection caused by Staphylococcus aureus. The cold-welded Magnum head could not be detached from the adapter and trunnion in this case either, but there were no other signs of ARMD. The chromium and cobalt levels were 6.3 μg/L and 7.7 μg/L, respectively. After 2 years, the sepsis relapsed. At surgery, there was the same finding of a cold-welded Magnum head. This patient was considered to have a possible or probable ARMD.

JM, MJ, MS, PV, and KTM designed the protocol. JM, MJ, MS, PV, JR, VÄ, JK, and KTM performed the surgery, recorded the intraoperative data, and wrote the manuscript. TP, TV, and KTM analyzed the data. KM and ET performed and interpreted the MRI imaging.

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