Chapter 9

Asymptomatic pseudotumours after metal-on-metal hip resurfacing show little change within one year

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Abstract

We aimed to establish the natural course of unrevised asymptomatic pseudotumours after Metal-on-Metal (MoM) hip resurfacing during a six to twelve month follow-up period. We used repeated Metal-Artefact Reduction Sequence (MARS)-Magnetic Resonance Imaging (MRI) scanning, metal ion analysis and clinical examination to study 14 unrevised cases (mean age 52.7 years) with pseudotumour and a control group of 23 cases (mean age 52.8 years) without pseudotumour. Mean postoperative time to the first MARS-MRI was 4.3 years (range: 2.2 to 8.3), mean time between first and second MARS-MRI was 8 months (range: 6 to 12). With the second MRI, 35 out of the 37 hips (95%) had not changed in pseudotumour severity, one new pseudotumour (Anderson C2 score, moderate) was observed and one pseudotumour was downgraded from C2 (moderate) to C1 (mild). In general, pseudotumour details were hardly changed. Repeated MARS-MRI within one year follow-up in unrevised patients with asymptomatic pseudotumours after MoM hip resurfacing shows little to no variation. In 23 controls without pseudotumour, one new pseudotumour was detected (4%). Since this is the first longitudinal study on pseudotumours using MARS-MRI, our findings need to be interpreted with caution.

Introduction

Metal on Metal prostheses caused a tremendous change in thought on performance of hip arthroplasty. Although problems with this type of implant are now known to society, the policy on what to do with the aftermaths of this implant are still obscure. A simple revision has mediocre results, the effect of the existing pseudotumours caused by these MoM implants is unknown since no follow-up studies are available. There is ample debate on the prevalence of pseudotumours following Metal-on-Metal (MoM) hip replacement.[1-4] Pseudotumours are believed to develop in reaction to the release of metal debris of the articulating metal surfaces. A retrieval study by Doorn et al report that about one trillion small nanoparticles are released per year in a MoM bearing (14,000 times more particles than with a polyethylene low friction articulation),[5] but little is known of the biological effects of the metals—predominantly cobalt, chromium, and molybdenum—that are released into the body by these implants.[6] Unlike most organic chemicals, metals cannot be eliminated from tissues by metabolic degradation, but only by renal or gastrointestinal excretion.[7] The formation of pseudotumours is believed to be either an allergic response to a normal level of metal wear particles, or a toxic effect of a very high level of particles.[8] Currently the only treatment of a pseudotumour is revision surgery in which the MoM articulation is replaced by a non-MoM articulation. Outcome studies on MoM revision surgery are scarce and have short follow up, but tend to report moderate results[9], with even a 25% re-revision rate being reported.[10] The clinical relevance of smaller pseudotumours detected with MARS-MRI is unknown. Moreover, there is a lack of knowledge on when and how fast pseudotumours develop, since all cross-sectional imaging studies on pseudotumours except one, have been retrospective in design with only one follow up. Almousa et al recently published the natural history of 15 pseudotumours in a sample unrevised asymptomatic patients using ultrasound examination, and observed both increase (n=6) in pseudotumour size, decrease (n=1) and complete disappearance of pseudotumours (n=3).[11] However, we do not know if and when new pseudotumours are detected with repeated cross-sectional imaging, and, in case of a pseudotumour without the need for immediate revision surgery, (i.e. smaller, less severely graded pseudotumours in asymptomatic patients with (near) normal metal ion levels), what the short term natural history of these pseudotumours is. Our primary aim was to study the

natural course of unrevised mild to moderate pseudotumours in unrevised patients during a six to twelve month follow-up period, using MARS-MRI; Our secondary aim was to study if new pseudotumours were observed in this follow-up period.

Patients and Methods

From a previously published cohort of 44 MoM hip replacements[12], 37 cases were available for prospective follow-up, who all had a second MARS-MRI (Table 9.1). Two cases were revised after the first MARS-MRI, and four patients (5 hips) refused further MARS-MRI scanning. MARS-MRI scan parameters are given in table 9.2, all MARS-MRI examinations were performed on a 1.5T MRI (Philips Medical Systems, Best, The Netherlands. Each patient had received a MoM hip resurfacing arthroplasty (ReCap, Biomet, Warsaw, USA) for primary hip osteoarthritis (OA). MARS-MRI was used to score severity of pseudotumours, which was graded by an experienced musculoskeletal radiologist (KB) and validated by a second musculoskeletal radiologist (RH), using the Anderson method (Table 9.3). This method has good interobserver reliability (κ=0.78, 95% confidence intervals: 0.68 to 0.88) as shown in the original publication by Anderson et al.[13] At follow-up, clinical examination, Oxford Hip Score,[14] and a MARS-MRI was made at mean 4.3 years (range: 2.2 to 8.3). Mean time between the first and second MARS-MRI was 8 months (range: 6 to 12). Pseudotumour details (classification, maximum diameter, localisation with respect to the hip joint -anterior, lateral or posterior-, wall thickness and solidity) are shown in table 9.4. We defined a pseudotumour as a peri-prosthetic cavity, either fluid-filled or having a solid content, which in case of being fluid-filled communicates with the hip joint. Pseudotumour wall thickness was measured at the site were wall thickness appeared to be thickest: ≥3mm was considered to be thick, <3mm was considered thin.[15] High MRI signal intensity was associated with fluid, low signal intensity with solid pseudotumour content. Bone marrow edema and compromise of nerve or blood vessel structures was systematically analysed for each MRI scan by both radiologists. Serum ion samples (Chromium and Cobalt) were collected at both MRI time points and analyzed as previously described.[12] Since little is known on short term variability of chromium and cobalt levels, a difference of +/- 5% between metal ion levels was considered a true difference. This was based on the findings by Khan that a short exercise bout resulted in 11% to 13% increased

metal ions concentration. The Oxford Hip Score (OHS) ranges between 48 (least problems) tot 0 (most problems) and was also recorded at both time points.

Table 9.1, *Patient demographics*

	Pseudotumour group (n=14)	Control group (n=23)	P (95% C.I.)
Age (years)*	52.7 (41-61)	52.8 (38-69)	0.65 (-4.4 to 6.9)
FU (years)*	5.3 (2.9-8.3)	4.9 (2.2-8.3)	0.56 (-8.6 to 1.6)
Femoral Component size (mm) **	51 (47.5-52)	50 (48-52)	0.90
Cup inclination*	51.4^0 (38-64)	50.2^0 (36-66)	0.48 (-8.4 to 4.1)
Oxford Hip score *	43.2 (48-39)	42.1 (48-27)	0.16 (-0.7 to 6.8)
Chrome (ppb)**	3.1 (1.2-5.1)	1.6 (0.9-2.9)	0.14
Cobalt (ppb)**	2.1 (1.2-5.1)	1.2 (0.8-1.8)	0.14

*mean is presented with range between brackets. ** median is presented with IQR between brackets

Table 9.2, *MARS-MRI details*

	TE (ms)	TR (ms)	TI (ms)	Slice thickness	FOV (mm)	Matrix	BW (HZ/pixel)	Coil
Coronal PDW	30	3000		2,5	230 x 197	328 x 220	435	sense body 16 ch
Coronal STIR	40	8645	130	2,5	230 x 198	256 x 168	437	sense body 16 ch
Transverse PDW	30	3576		3	240 x 199	344 x 198	437	sense body 16 ch
Transverse	40	105000	130	3	280 x 198	280 x 152	435	sense body 16 ch
Sagittal STIR	40	9570	130	3	230 x 230	256 x 189	438	sense body 16 ch

Table 9.3, *Anderson classification for MoM disease on MARS-MRI*

Grade	Description	Criteria
A	Normal or acceptable	Normal post-op appearances including seromas and small haematomas
B	Infection	Fluid-filled cavity with high signal T2 wall; inflammatory changes in soft tissues, ± bone marrow oedema
C1	Mild MoM disease	Periprosthetic soft tissue mass with no hyperintense T2W fluid signal or fluid-filled peri-prosthetic cavity; either less than 5 cm maximum diameter
C2	Moderate MoM disease	Peri-prosthetic soft tissue mass/fluid-filled cavity greater than 5 cm diameter or C1 lesion with either of following: (1) muscle atrophy or edema in any muscle other than short external rotator or (2) bone marrow edema: hyperintense on STIR
C3	Severe MoM disease	Any of the following: (1) fluid-filled cavity extending through deep fasci, (2) a tendon avulsion, (3) intermediate T1W soft tissue cortical or marrow signal, (4) fracture

Table 9.4, *Pseudotumor details per case*								
Casus	**Anderson score**	**Location***	**Wall**	**Max diam (mm)****	**Connected to joint**	**Nerve/blood vessel compromised**	**MRI signal*****	**Other**
1	C1	lateral	thick	40	yes	no	mixed	bone marrow edema
2	C1	dorsal	thin	18	yes	no	high	-
3	C1	dorsal	thin	19	yes	no	mixed	-
4	C1	lateral	thin	32	yes	no	high	-
5	C1	lateral	thin	50	no	no	high	-
6	C1	lateral	thin	50	yes	no	high	-
7	C1	dorsal	thin	30	yes	no	high	-
8	C2	lateral-dorsal	thin	53	yes	no	high	-
9	C2	dorsal-medial	thick	45	yes	no	mixed	-
10	C2	lateral	thin	69	yes	no	high	-
11	C2	lateral	thin	70	yes	no	high	-
12	C2	dorsal-lateral	thin	78	yes	no	high	-
13	C2	dorsal	thin	80	yes	no	high	-
14	C3	dorsal-ventral	irregular thick	70	yes	no	mixed	bone cyst

** relative to hip joint; **maximum pseudotumour in any direction; *** high MRI signal intensity is associated with fluid content, low signal intensity with solid content*

Statistical analysis

Descriptive statistics were used to report patient characteristics and observations such as the number, size and appearances of pseudotumours detected with MRI scanning. Metal ion data and pseudotumour dimension distributions were asymmetric and are expressed as a group median with interquartile range (IQR). Normal distributed data are represented by a mean and range. A qualitative analysis was done for each change in pseudotumour details. Differences in mean values were tested with (two-sided) t-test, differences in median values with the Mann-Whitney test. Significance level was defined at 0.05, 95% Confidence Intervals (C.I.) are provided were appropriate.

Results

Details of the 14 pseudotumours observed with the first MRI are given in table 9.4. At first MARS-MRI, the majority of pseudotumours (10/14) were fluid-filled cysts, only four showed a mixed MRI signal intensity indicating a more solid content. Three out of four solid pseudotumours were thick-walled, whereas all 10 fluid-filled pseudotumours were thin-walled. Maximum diameter ranged from 18mm to 80mm. One pseudotumour was graded as Anderson score C3 (severe MoM disease), six as Anderson C2 (moderate MoM disease) and 7 as Anderson C1 (mild MoM disease). Median Chromium and Cobalt for the solid pseudotumours was 3.1ppb (IQR: 1.7-5.6) and 2.1ppb (IQR: 1.8-4.5) versus 3.0 (IQR: 1.6-5.1) and 2.3 (IQR: 1.1-5.1) for the fluid-filled pseudotumours. There were no changes observed in pseudotumour position, wall thickness or content (based on MRI signal intensity) for any of the pseudotumours between both time points. Median pseudotumour diameter decreased from 50 mm (IQR: 32-70) to 46mm (IQR: 37-69). There were five pseudotumours where the maximum diameter had not changed, five pseudotumours had become smaller (mean absolute change -13mm, range: -32 to -2mm), and four had grown (mean absolute change +26mm, range: 7 to 33mm) (Figure 9.1). Thirty-five out of the 37 hips had not changed according to the Anderson grading system. In two cases (5%), the Anderson pseudotumour grade had changed between the two MRI scans: one C2 pseudotumour was observed on the second MRI, which had not been there at the first MRI scan (Figure 9.2A and 9.2B). One pseudotumour was downgraded from C2 to C1 (Figure 9.3A and 9.3B). See table 9.5. Median chromium increased from 1.7 ppb (IQR: 1.0-3.8) to 2.1 ppb (IQR: 1.1-3.6) and median cobalt decreased from

1.4 ppb (IQR: 0.9-2.5) to 1.3 ppb (IQR: 0.9-3.5) but no metal ion level had changed more than +/– 5%. In the pseudotumour group, mean OHS improved from 32.1 (range: 42 to19) points pre-operatively to 43.2 (range: 48 to 39) at first MRI follow-up time point (40.7, range: 48 to-31 at second MRI time point). In the control group OHS improved from 28.9 (range: 39 to 11) points pre-operatively to 42.1 (range: 48-27) at first MRI follow-up time point (42.2, range: 48 to 27 at second MRI time point).

Table 9.5, *Pseudotumour and metal ion levels comparison between first MRI (mean 4.3 years postoperative, range: 2.2 to 8.3) and second MRI (mean 5.0 years postoperative, range: 3.2 to 9.1)*

MRI 1→MRI 2	N	Pseud. size (mm) MRI 1*	Pseud. size (mm) MRI 2*	Chromium 1 (ppb)*	Chromium 2 (ppb)*	Cobalt 1 (ppb)*	Cobalt 2 (ppb)*
A→A	22	n/a	n/a				
C1→C1	7	40 (19-50)	38 (30-41)	1.4 (1.1-4.0)	1.7 (1.4-4.8)	1.8 (1.1-3.5)	1.2 (0.9-3.5
C2→C2	5	74 (51-80)	70 (68-78)	3.4 (1.1-6.0)	4.2 (1.6-13.1)	3.2 (1.2-5.4)	4.2 (1.9-8.9)
C3→C3	1	70	70	2.4	1.5	3.0	2.2
A→ C2	1	n/a	55	0.5	0.8	1.0	0.8
C2→C1	1	53	39	3.6	3.9	6.4	5.3

*median value is presented with IQR between brackets. Pseud.: indicates Pseudotumour

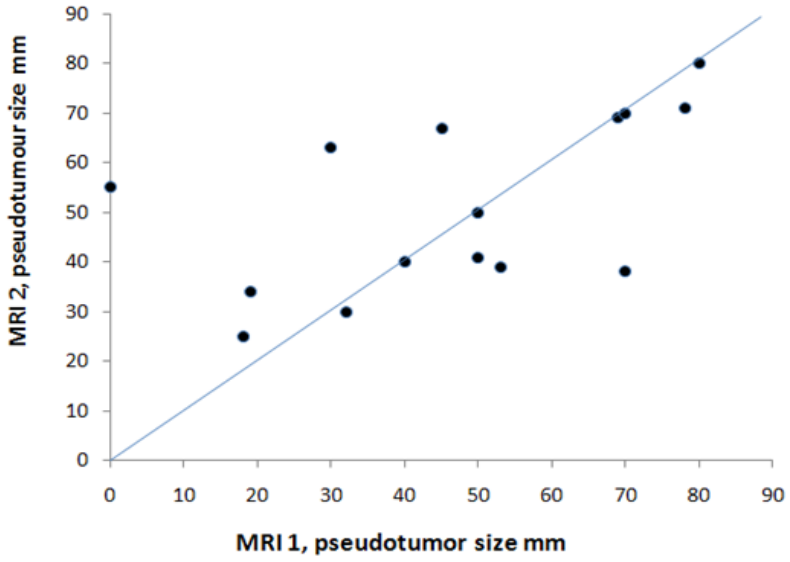

Figure 9.1, Absolute change pseudotumor size.

Change in treatment

After the first MARS-MRI, one patient was considered for revisions surgery and 13 for intense follow-up, without immediate need for revision surgery of their MoM implant. Based on the results of second MARS-MRI, metal ion levels and symptoms 6 to 12 month later, this clinical advice was not changed in any of the patients.

Description of the 2 cases changed in Anderson grading

Case 1

The first MRI images of a 67 year old male patient who did not have any evidence for pseudotumour formation at that time (Figure 9.2A) are compared with the images of the second MARS-MRI (Figure 9.2B) when a C2 pseudotumour was detected, 3.5 years after implantation. Time between scanning was 11 months. A thin-walled fluid-filled cyst developed lateral to the hip joint with a maximum diameter of 55 mm in cranio-caudal direction and a thin dorsal connection to the joint space. Based on size, signal intensity and connection to the joint space, this cyst was classified as a C2 pseudotumour. Between MRI scanning, OHS score deteriorated from 41 points to 33 points, although hip pain was unchanged (mild). Chromium and Cobalt levels remained stable at 0.9 and 0.8ppb respectively.

Case 2

In a 57 year old male patient, the pseudotumour was downgraded from C2 to C1, see figure 9.3A and 9.3B. This patient had bilateral MoM hip resurfacing, with bilaterally a pseudotumour observed. The pseudotumour on the right hip, reduced from 53 mm to 39 mm in the six months between MRI scanning. Consequently, the Anderson classification changed from C2 to C1. Between MRI scanning, OHS deteriorated from 44 to 36 points, with hip pain deteriorating from very mild to mild, while Chromium and Cobalt levels improved from 6.4 to 3.6ppb and from 5.3 to 3.9ppb respectively.

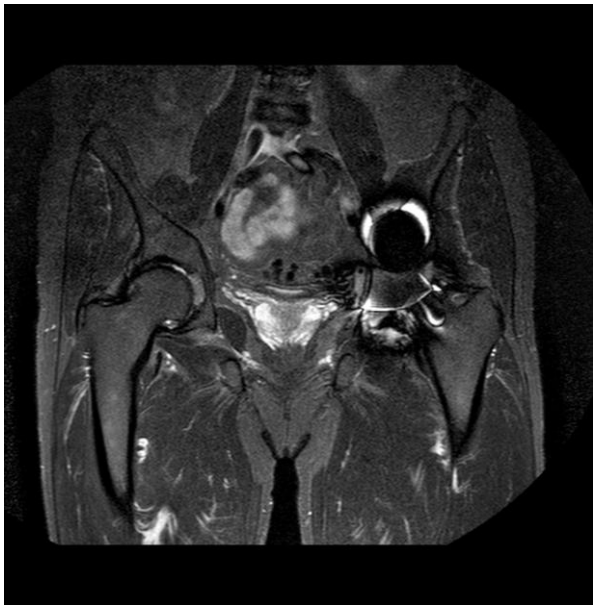

Figure 9.2A, First MARS-MRI.

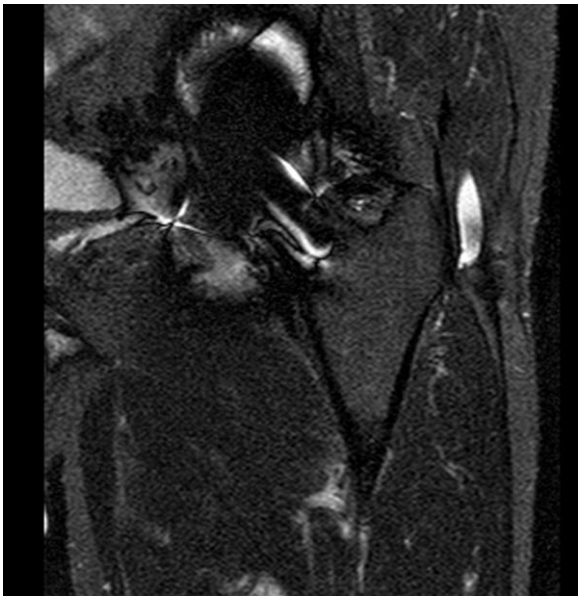

Figure 9.2B, Second MARS-MRI.

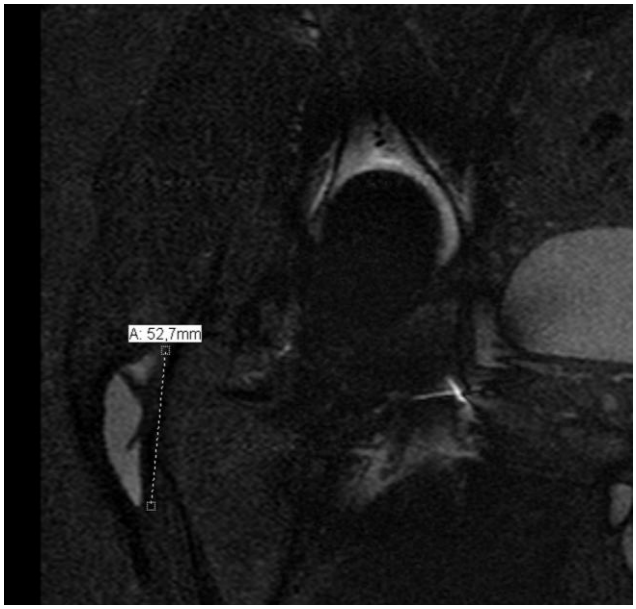

Figure 9.3A, First MARS-MRI.

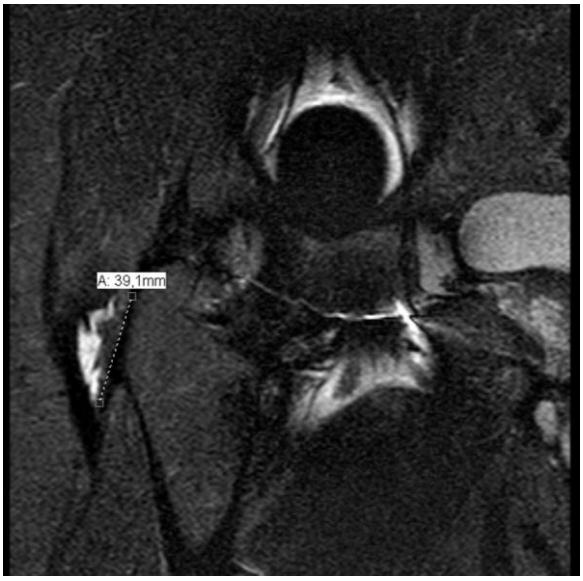

Figure 9.3B, Second MARS-MRI.

Discussion

We found that only 5% of the included, small to moderate sized, asymptomatic pseudotumours after MoM hip resurfacing, changed in severity using a six to twelve months interval to repeat MARS-MRI. In the control group without pseudotumour (23 hips), one new pseudotumour was detected (Anderson grade C2) but this patient had no change in metal ion levels or hip pain. In the pseudotumour group (n=14), pseudotumour severity was downgraded in one case (from Anderson grade C2 to C1). Accordingly, metal ion levels decreased in this patient but in contrast his hip pain deteriorated from very mild to mild.

Based on these results clinical treatment was left unchanged for all included patients, indicating that a >1 year interval between consecutive cross-sectional imaging appears to be safe. On this last topic no evidence is available. How much deterioration of symptoms and metal ion levels should trigger additional cross-sectional imaging cannot be concluded from our results, since we observed only a very small variation and sometimes contradictive development in metal ion levels and symptoms between both MRI time points. Longer follow up with an extensive screening protocol is needed. Analysing all included pseudotumours, maximum diameter both increased (n=6) and decreased (n=6), although the observed differences were small to very small. None of the pseudotumours changed in appearance or location.

Previous studies using cross-sectional imaging of pseudotumours after MoM hip arthroplasty were retrospective in design, used only one time point for imaging and had considerable variation in follow up duration.[3,16-18] Recently, Almousa et al published the first report using repeated ultrasonography (US) in a cohort of 15 pseudotumours and five isolated fluid collections in a variety of hip replacement types (13 MoM THA, four MoM hip resurfacings and three metal-on-polyethylene bearings).[11] In their series, three pseudotumours had such an increase in size (2.2-fold to 11.4-fold) that it was deemed clinically significant. In our series, we observed no clinically relevant change in pseudotumour size or severity. This might be explained by the shorter follow-up in our study (mean of eight months versus 25.8 months).

There is limited data available on when pseudotumours develop and on how fast pseudotumours change over time. There is also no consensus on the exact definition of a pseudotumor, with different lesions included such as solid pseudotumors or fluid-filled lesions (which might fluctuate more in time), making

it more difficult to guide clinical management of pseudotumours after MoM arthroplasty. Most orthopedic societies and national boards advise computer tomography (CT) or MARS-MRI only in symptomatic patients.[19-21] However, high prevalence rates of asymptomatic pseudotumours after cross-sectional imaging were reported by Kwon et al (6.5%), Wynn-Jones et al (36%) and Mistry et al (58.3%).[3,4,18] How pseudotumours can remain asymptomatic is not known. To our knowledge, no explanation for the absence of symptoms in case of pseudotumours has been presented in literature. Since we know that asymptomatic pseudotumours will be missed[12], the validity of the advices issued by the FDA and national boards can be questioned. Accepting the risk of missing pseudotumours might outweigh the potential risk of overtreatment based on positive MRI findings, since the clinical relevance of mild to moderate pseudotumours is not yet fully known. On the other hand, one can state that all MoM patients need to be investigated with cross-sectional imaging at least once, to establish a pseudotumour baseline status for each individual patient. Furthermore the FDA MoM safety communication does provide little detail on how to interpret more detailed cross-sectional imaging results and how observed pseudotumours should be treated. There is no study comparing the effectiveness of US, MRI or CT for detecting pseudotumors. US diagnostics is user dependent and provides less detailed imaging compared to MRI but the presence of a metal prosthesis does not compromise US imaging, it is relatively cheap to perform and is widely available, and is therefore considered the preferred initial investigative tool by several authors.[22,23] According to Fary et al CT diagnostics is not suitable as a screening tool for pseudotumor detection but they consider MRI a suitable tool for making a definitive diagnosis of a mass resulting from an adverse reaction to metal debris.[23] All three modalities have advantages and disadvantages regarding radiation, costs and accuracy and therefore it remains debatable which modality is best for (initial) screening for pseudotumor occurrence.

The exact description and grading of pseudotumours has not fully matured. As pointed out by Anderson et al, validation of a grading system is likely to take several years, since mild degrees of disease in asymptomatic patients do not warrant intervention, thereby preventing surgical or histopathological outcome data for this group. Only stability in a longitudinal study will be a useful marker of the validity of mild disease grades.[13] In our own studies experienced musculoskeletal radiologists reported a learning curve evaluating pseudotumours.

We therefore recommend that more than one radiologist is involved in analysing MARS-MRI's. Also, the use of maximum diameter as an important part of grading pseudotumour severity has limitations, and since the changes in pseudotumour size are very small during a six to 12 months period, measurement error has to be taken into account. Possible factors influencing the MR images when a pseudotumour is present, such as time of day or any physical activity shortly before acquiring the images need to be established. Furthermore, a long thin pseudotumour might be considered a grade C2 (moderate) or C3 (severe) pseudotumour based on maximum diameter, without actually involving a large volume. Besides maximum diameter, other considerations such as MRI signal intensity, cyst wall thickness and position might also be important to evaluate pseudotumour changes in time. The observation within our series that mild to moderate pseudotumours remained fairly stable with MARS-MRI evaluation over a six to 12 month period, for now validates our conservative approach for these pseudotumours, which is in agreement with other authors.[13,24] Using a >12 months interval to repeat cross-sectional imaging for smaller, non-revised asymptomatic pseudotumours, might help to control the enormous worldwide costs involved. Lloyd et al estimated that annual metal ion analysis and MRI scanning of MoM patients would increase UK nationwide costs with 72.6 million UK pounds for a 5 year period, compared to standard THA follow up costs.[25]

One even has to consider the possibility to treat larger asymptomatic pseudotumours conservatively if metal ion levels are normal and the pseudotumour is positioned in a relative safe position, although the current consensus is that larger pseudotumours need to be revised.[17,27,28] The need for revision is unquestioned for more extensive pseudotumours which cause symptoms, extensive soft tissue damage and compromise other structures such as blood vessels and nerves.

In conclusion, we show little value to repeat MRI within one year for mild to moderate sized asymptomatic pseudotumours after MoM hip resurfacing, since the few observed changes were minimal and did not change clinical treatment. But there is a value for repeated examinations with longer term follow-up as was shown by Almousa et al.[11] Since our study is the first longitudinal study on pseudotumours using MARS-MRI, our findings need to be interpreted with caution.

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