

# Longitudinal Followup of Incidentally Detected Pseudotumors in Patients with Metal on Metal Implants: A Retrospective Study

## Abstract

**Background:** This study describes the significance and temporal evolution of incidentally detected, presumed, metal-induced reactive periprosthetic masses in patients with metal on metal (MoM) hip arthroplasty and its management. The literature concerning the temporal evolution of these lesions is meagre and so it is still unclear, whether asymptomatic patients with periprosthetic collections should undergo revision. **Materials and Methods:** Patients with MoM hip replacements fitted with a recalled implant (ASR, DuPuy) often undergo magnetic resonance imaging with metal artifact reduction sequences to look for complications. From a cohort of 136 asymptomatic patients, with 181 MoM hips, hips with a mention of periprosthetic masses in their reports at first presentation, and a repeat scan within 6 months to 3 years were selected for this retrospective study. Patients with complications such as loosening, osteomyelitis, and muscle/tendon tears were excluded from the study, and the final study cohort consisted of 55 MoM hips and 61 periprosthetic masses. Ethics committee approval is not required in our institution for retrospective studies. The followup scans of each patient were compared, and the periprosthetic masses were described to have progressed, regressed, or remained unchanged. **Results:** Comparison revealed that 29 of the 61 reactive masses remained unchanged, 20 regressed, while only 12 showed progression. The study, therefore, has maximum power as the outcome of interest, i.e., regression or unchanged status of the pseudotumors, was seen in approximately 80% (more than half) of the study group. The *P* value of the study was <0.005. **Conclusion:** Periprosthetic soft tissue masses are not uncommon in patients with MoM hips. The majority of them in asymptomatic individuals remain stable or regress in the short to medium term, and close followup or decisions on revision surgery may not be warranted in asymptomatic patients.

**Keywords:** Arthroplasty hip, artifacts, complications, magnetic resonance imaging, musculoskeletal abnormalities, metal-on-metal implant

**MeSH terms:** Replacement, arthroplasty, hip, magnetic resonance imaging, retrospective studies

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## Introduction

Metal on metal (MoM) implants for total hip arthroplasty have been used since the early 1960s.<sup>1</sup> Their use has increased because of the theoretical advantages of decreased wear and increased functional outcome in younger and more active patients.<sup>2</sup> However, with their widespread use and with the introduction of metal artifact reduction magnetic resonance imaging (MRI) sequences, there has been increased awareness of the development of sterile inflammatory masses associated with these implants.<sup>2-6</sup>

These masses, also known as metal-induced soft tissue or pseudotumors,<sup>3</sup> are believed to be a result of hypersensitivity reaction to the release of metal debris from the articulating surfaces. Various other names

are used interchangeably for these soft tissue masses such as “aseptic lymphocyte-dominated vasculitis-associated lesions,”<sup>7</sup> “inflammatory masses,” or “adverse reactions to metal debris.”<sup>8</sup>

Although these lesions were initially described in patients investigated for hip pain, the high level of concern with metal-induced hypersensitivity has made metal artifact reduction sequences (MARS) MRI, a routine tool used in many patients with MoM implants, irrespective of symptoms, to detect and manage this complication. This has led to increased detection of these soft tissue masses.<sup>9</sup> The treatment for a pseudotumor is revision surgery, during which the MoM articulation is replaced by a non-MoM articulation to halt metal debris release and consequent metal-induced reaction.<sup>9</sup> However, it is

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unclear, whether asymptomatic patients with periprosthetic collections should undergo revision. The literature concerning the temporal evolution of these lesions is meager.<sup>2</sup>

This study, therefore, was carried out to describe the significance and temporal evolution of such incidentally detected, presumed, metal-induced reactive periprosthetic masses in patients with MoM hip arthroplasty and thus help decide the further plan of management.

## Materials and Methods

Patients with MoM hip replacements fitted with a recalled implant (ASR, DuPuy) often undergo MRI at our institute with MARSs to look for complications such as loosening, infection, muscle/tendon tears, and periprosthetic masses. Ethics committee approval is not required in our institution for retrospective studies.

All these scans are performed on a 1.5T (Sonata, Siemens, Germany) using a standard MARS protocol.<sup>10-12</sup> The protocol includes coronal short tau inversion recovery, T1- and T2-weighted, axial T1- and T2-weighted, and sagittal T2-weighted sagittal sequences. The serum chromium level was not done.

From a cohort of 136 asymptomatic patients, with 181 MoM hip replacements including 110 total hip replacement (THR) and 71 resurfacings; patients with a mention of periprosthetic soft tissue masses in their reports at first presentation were selected for the study. The patients were asymptomatic with respect to local as well as systemic symptoms and were scanned only because the implant was recalled. The duration between surgery and first scan ranged between 2 and 15 years. The study design was a retrospective cohort study. Of the 181 MoM hips, eighty had periprosthetic masses.

Periprosthetic soft tissue was defined as abnormal fluid/intermediate-to-low-signal intensity lesion adjacent to the prosthesis on T1- and T2-weighted images [Figure 1].

These scans were then reviewed, and the soft tissue was characterized according to Hauptfleisch *et al.*,<sup>13</sup> on the basis of their signal intensity and wall thickness as follows: Type 1 - cystic masses with wall thickness <3 mm [Figure 2]; Type 2 - cystic masses with wall thickness >3 mm but less than the diameter of the cystic component [Figure 3]; and Type 3 - predominantly solid masses [Figure 4].<sup>13</sup> The wall thickness of the wall was measured at the site where it appeared to be the thickest. Soft tissues with internal septations but with wall thickness less than 3 mm were categorized as Type 2, whereas those with wall thickness greater than 3 mm and associated septae or debris were categorized as Type 3.

Patients with other associated complications such as loosening, osteomyelitis, and muscle/tendon tears were excluded from the study. Patients who had undergone any form of treatment for the pseudotumors were excluded

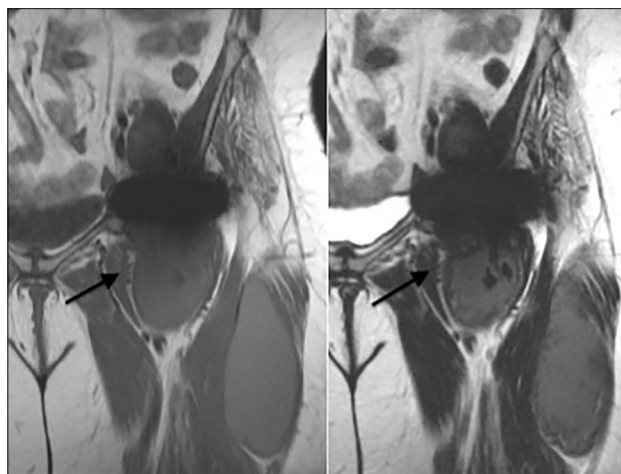


Figure 1: Coronal T1- and T2-weighted metal artifact reduction sequences images showing a large multiloculated, low T2 signal intensity periprosthetic soft tissue mass on the left (arrow)

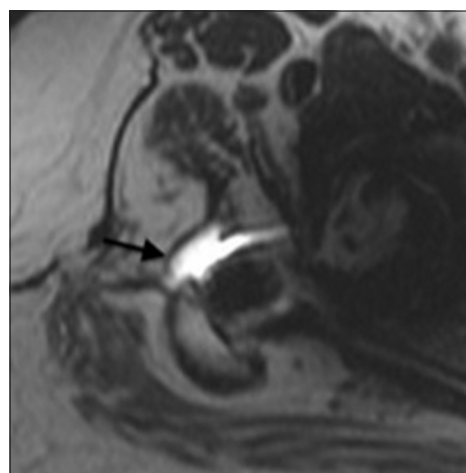


Figure 2: Axial T2-weighted metal artifact reduction sequences image showing a Type 1 cystic mass with wall thickness <3 mm (arrow)

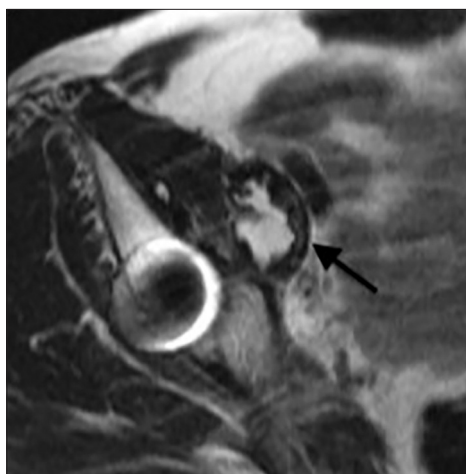


Figure 3: Axial T2-weighted metal artifact reduction sequences image showing a Type 2 cystic mass with wall thickness >3 mm (arrow)

from the study. Patients with muscle atrophy and focal osteolysis were included in the study.

Twenty one of the eighty hips had the mentioned complications, namely, loosening, osteomyelitis, and muscle/tendon tear were excluded from the study.

Fifty three patients with 59 MoM hips fulfilled the criteria for inclusion in the study. A search was then made among the rest for those who had a repeat scan within 6 months to 3 years. Patients who had remained asymptomatic in the interim were not scanned before 1 year. Forty five patients with 55 MoM hips (range 16 resurfacing and 39 THR) had a repeat scan between 6 months and 3 years from the first scan and constituted the final cohort of the study. The mean and the median time between the first and second scan was 14 months (range 6–26 months). The study group consisted of 30 males and 15 females. The age group of the patients varied between 26 and 85 years [Table 1].

The first and followup scan of each of these patients was reviewed and compared on the workstation, by two expert radiologists, and all findings were arrived at by consensus.

The previously visualized soft tissue was meticulously analyzed, and maximum dimensions were measured in all three planes. Maximum wall thickness, presence or absence of septae, and relationship of the mass to the surrounding structures were also defined. Both scans of the same patient were compared image-by-image, side-by-side on the workstation, to assess for any changes in size or morphology. Review for the presence of any new collection or complications such as osteolysis and tendon/muscle tear was also made.

Progression was defined as an increase in the size of collection, when averaged over the three maximum dimensions, or a change in morphology with an increase in wall thickness, development of septae, or increase in the soft tissue component in a lesion with unchanged size [Figure 5]. Regression was defined as a decrease in the size of collection, when averaged over the three maximum dimensions [Figure 6], or a change in morphology with decrease in the soft tissue component [Figure 7] or wall thickness but with unchanged size. Soft tissues, which remained same both in size and morphology, were labeled unchanged [Figure 8].

Comment was also made on the presence of a new collection, if any. Meticulous review for any new complication in the interim such as osteolysis and tendon/muscle tear was also made.

### Statistical analysis

The patient characteristics and pseudotumor features such as the number, size, and appearance were reported descriptively. Normally distributed data were represented by a mean, and asymmetrical data were expressed as a median. Each change in pseudotumor details was analyzed

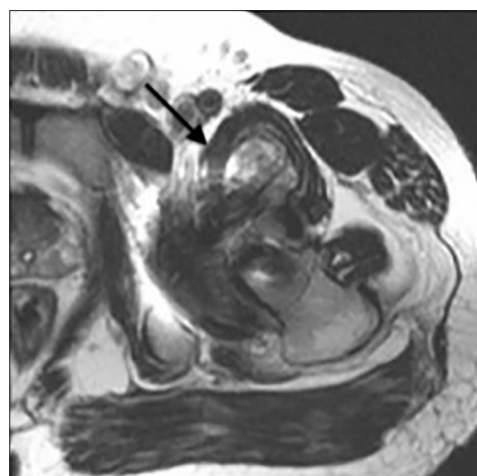


Figure 4: Axial T2-weighted metal artifact reduction sequences images showing Type 3, predominantly solid mass with wall thickness >3 mm and associated septae or debris (arrow)

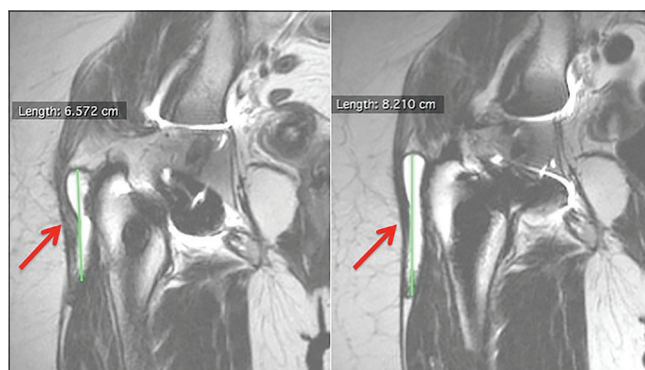


Figure 5: Coronal T2-weighted metal artifact reduction sequences images showing increase in superoinferior length of the previously visualized collection on the followup scan after 8 months

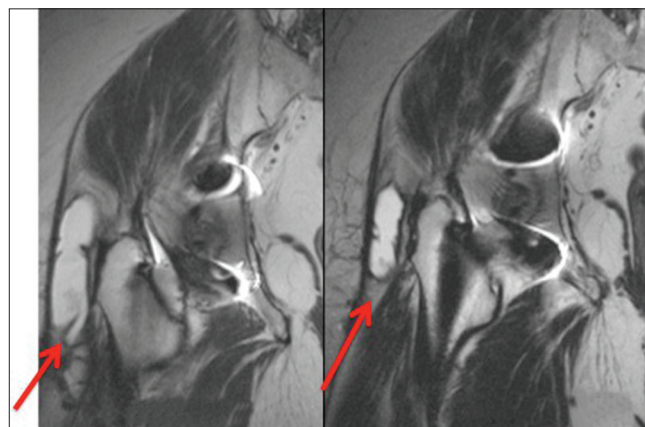


Figure 6: Coronal T2-weighted metal artifact reduction sequences images showing decrease in superoinferior length of the previously visualized collection on the followup scan after 13 months

qualitatively as well as quantitatively. The *P* value was calculated using Chi-square method.  $P < 0.05$  was used to define statistical significance. The outcome of interest was defined as regression or unchanged status of the pseudotumors.



**Table 1: Details of the study cohort**

Age	Sex (M/F)	Hips	THR/resurfacing	Duration (Months)	No. of pseudo tumors	Type of pseudotumors
35	M	Both	Resurfacing	6	One in each	Type 1 in right, Type 3 in left
85	F	Rt	THR	7	One	Type 1
62	F	Both	THR	8	Two in right, one in left	One type 1 and one type 3 on right, Type 3 on left
61	M	Rt	THR	10	One	Type 1
50	M	Lt	THR	10	One	Type 1
26	M	Rt	Resurfacing	11	One	Type 2
35	M	Both	THR	12	One in each	Type 1 on both sides
46	F	Both	THR	12	One in each	Type 2 on both sides
65	M	Both	THR	12	One in each	Type 3 on right, Type 2 on left
57	M	Both	THR	12	One in each	Type 2 on both sides
67	F	Rt	THR	12	One	Type 3
39	M	Rt	THR	12	One	Type 1
41	F	Rt	Resurfacing	12	Two	Both type 2
73	M	Lt	THR	13	Two	Both type 1
48	F	Lt	THR	13	One	Type 1
28	M	Lt	THR	13	One	Type 1
64	F	Rt	THR	13	One	Type 2
63	F	Lt	Resurfacing	13	One	Type 1
49	M	Lt	THR	13	One	Type 3
72	M	Rt	THR	13	Three	One type 1 and two type 2
62	M	Rt	THR	14	One	Type 2
37	F	Lt	THR	14	One	Type 1
57	M	Lt	THR	14	One	Type 2
31	M	Rt	THR	14	One	Type 1
44	M	Lt	THR	14	One	Type 1
30	F	Lt	Resurfacing	14	One	Type 2
57	M	Rt	Resurfacing	15	One	Type 1
38	M	Rt	THR	15	One	Type 1
53	M	Lt	Resurfacing	15	One	Type 3
43	F	Both	THR	16	One in each	Type 1 in right, type 3 in left
37	M	Both	Resurfacing	16	One in each	Type 3 in right, type 2 in left
32	F	Lt	THR	16	One	Type 1
33	M	Lt	Resurfacing	16	One	Type 2
64	F	Lt	THR	17	One	Type 1
59	M	Lt	THR	17	One	Type 1
42	M	Lt	THR	18	One	Type 1
43	F	Both	Resurfacing	18	One in each	Type 3 on right, type 1 on left
53	M	Lt	THR	18	One	Type 1
62	F	Lt	THR	18	One	Type 1
78	M	Lt	THR	19	One	Type 1
43	F	Lt	Resurfacing	20	One	Type 1
51	M	Rt	Resurfacing	22	One	Type 1
44	M	Rt	THR	24	One	Type 2
42	M	Both	THR	24	One in each	Type 1 on both sides
63	M	Rt	Resurfacing	26	Two	Both type 1

## Results

Scans of the 45 asymptomatic patients with 55 MoM hips (16 resurfacing and 39 THR) and 61 periprosthetic masses were reviewed. Four hips had more than one pseudotumor, of which three had two pseudotumors and one had three.

These were also included in the same cohort, to avoid any selection bias in result.

Sixteen of the 61 collections were thick walled and 10 of these 16 showed internal septae or debris. Ten of the 45 thin-walled collections showed septae or debris. Of the

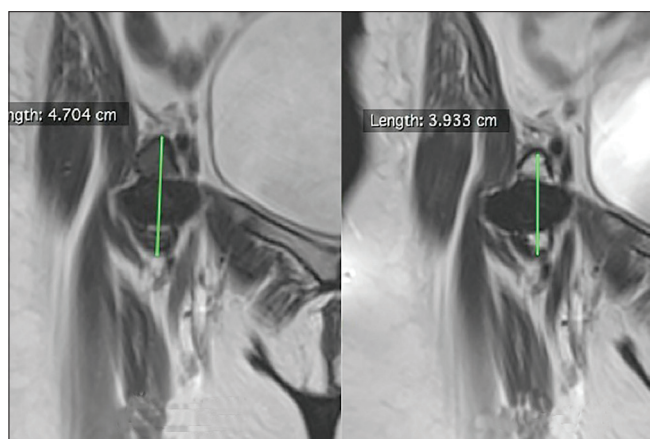
61 collections, 34 were Type 1; 17, Type 2; and 10, Type 3. Forty six collections had a maximum diameter <5 cm and 15 had a maximum diameter ≥5 cm.

Comparison of the followup scans revealed that 29 of the 61 reactive masses remained unchanged in shape, size, and morphology over time [Figure 5]. Two of the reactive masses showed regression with change in morphology and decrease in the low signal intensity soft tissue component though remaining unchanged in size [Figure 6]. Eighteen of the 61 masses decreased in size, three of which completely resolved [Figure 7]. The average percentage decrease in the dimensions was approximately 40% when averaged over all the three dimensions in the 18 scans, which showed regression. The maximum decrease in any one dimension was 6.8 cm. Only 11 of the 61 lesions showed an increase in size on the followup scan [Figure 8], while one showed progression with an increase in the septae within the collection but without an appreciable change in size. The average percentage increase in the dimensions was approximately 90% when averaged over all the three dimensions in the 11 scans, which showed progression. The maximum increase in size in either dimension was 3.5 cm, and average increase was 6 mm when averaged over all three dimensions [Graph 1].

The outcome of interest, i.e., regression or unchanged status of the pseudotumors, was seen in approximately 80% of the study group. The study, therefore, has maximum power statistically as more than half of the study group has the outcome of interest.

The  $P < 0.005$  was seen for the entire study group as well as for the individual subgroups of pseudotumors, which progressed and regressed when calculated separately.

Of the 34 Type 1 pseudotumors, 19 remained unchanged, 8 regressed, and 7 progressed. Among the 17 Type 2 pseudotumors, 7 remained unchanged, 8 regressed, and 2 progressed, and of the 10 Type 3 pseudotumors, 3 remained



**Figure 7:** Coronal T2-weighted metal artifact reduction sequences images showing regression with decreased size of the collection as well as a decreased low signal component of the collection on the followup scan after a year

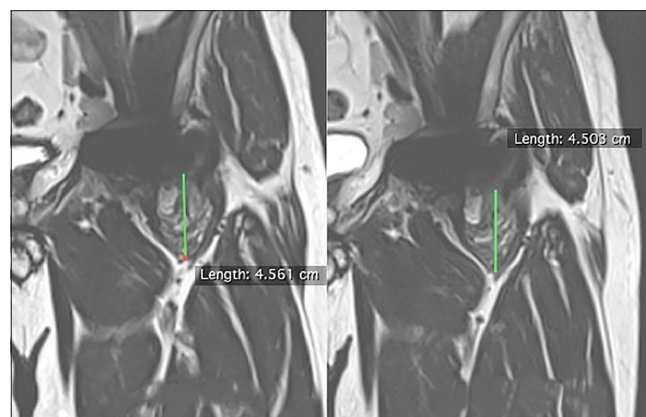
unchanged, 4 regressed, and 3 progressed [Graph 2]. The  $P$  value of the fate of the three pseudotumors subtypes was 0.34; thereby implicating that the incidence of unchanged, progressed, and regressed pseudotumors in the three groups is comparable.

Of the 46 pseudotumors with maximum diameter <5 cm, 25 remained unchanged, 11 showed a decrease in size, 2 showed regression in terms of decrease in soft tissue component while the remaining 8 increased in size. Of the 15 pseudotumors ≥5 cm, an increase in size was seen in 3, one was labeled to have progressed due to increase in soft tissue component while 7 and 4 pseudotumors decreased and remained unchanged in size, respectively [Graph 3]. The  $P$  value of the fate of the pseudotumors on the basis of their size at presentation was 0.17; thereby implicating that the incidence of unchanged, progressed, and regressed pseudotumors in the two groups is comparable.

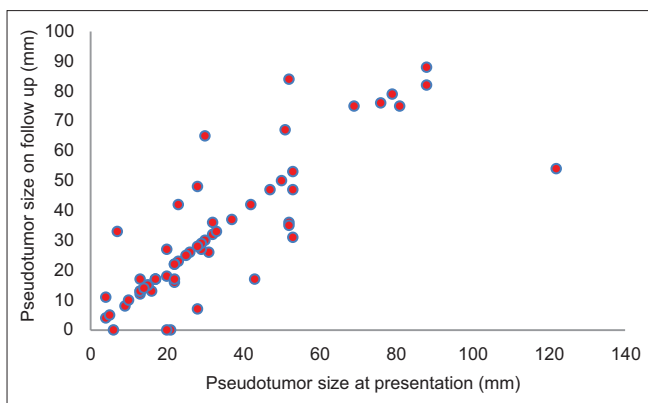
New periprosthetic mass was found in only 5 of the 55 hips. Mild progression of muscle atrophy was seen in one hip. Focal osteolysis was also seen in six hips at presentation, five of which remained unchanged in size and morphology on the followup scan. Mild increase in the size of only one of the six cases was seen. No other new complication was noted in either of the patients on followup. None of the patients turned symptomatic either.

## Discussion

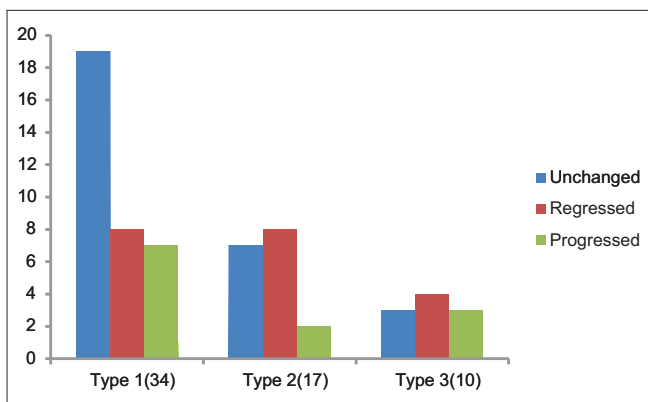
We found that only 20% (12/61) of the asymptomatic pseudotumors detected after MoM hip replacement, increased in severity, over 6 months to 3 years interval. The maximum increase in size in either dimension being 3.5 cm, and the average increase being 6 mm when averaged over the three dimensions for each mass. Nearly 47% (29/61) of the pseudotumors remained unchanged over the months. A substantial 33% of the masses showed regression with almost complete resolution of three collections.



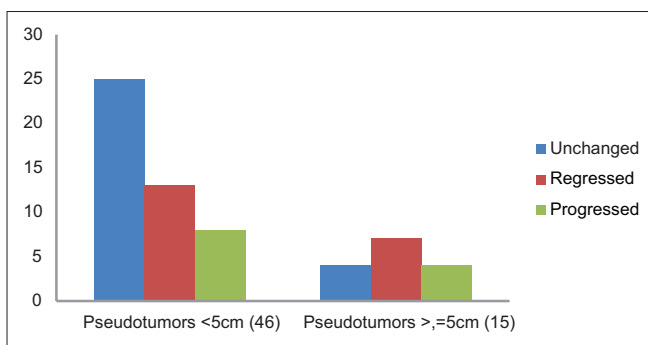
**Figure 8:** Coronal T2-weighted metal artifact reduction sequences images showing unchanged size and morphology of the pseudotumor on the followup scan after 13 months



Graph 1: Scatter diagram showing the pattern of change in tumor size



Graph 2: A bar diagram showing the fate of specific pseudotumor type according to morphology at presentation



Graph 3: A bar diagram showing the fate of specific pseudotumor type according to size at presentation

Progression was seen in only 21% (7/34) and 12% (2/17) of Type 1 and Type 2 pseudotumors, respectively, with 30% (3/10) of the Type 3 pseudotumors showing progression. A significant 40% (4/10) of the Type 3 pseudotumors, however, showed regression on followup.

Majority of the pseudotumors remained stable or regressed, irrespective of the size, though the percentage of tumors which progressed was more when the size at presentation was  $\geq 5$  cm.

van der Weegen *et al.*<sup>9</sup> found that only 5% of the small-to-moderate-sized asymptomatic pseudotumors

after MoM hip resurfacing changed in severity, over a 6–12-month interval. Ebreo *et al.*,<sup>2</sup> in their retrospective study on serial MARS-MRI findings in 28 mm diameter MoM THR, concluded that progression from normal to abnormal, or from mild to more severe MoM disease, takes place slowly over several years. Almousa *et al.*,<sup>14</sup> in their cohort of 15 asymptomatic pseudotumors, followed with ultrasonography over a mean of 3.6 years, also found that only three pseudotumors had an increase in size that was deemed clinically significant.

Our observations also suggest that the vast majority (80%, i.e., 49/61) of asymptomatic pseudotumors remain stable or regress. While longer followup will yield more information, in the short-medium term, the mere presence of a periprosthetic soft tissue mass in an asymptomatic individual perhaps should not be a reason to consider revision surgery. We also believe that close followup of these lesions may also be unwarranted as long as the patient is asymptomatic.

The limitations of this study were that >50% (46/61) of the pseudotumors followed up were <5 cm in maximum diameter, most of the pseudotumors were Type 1 (34/61), the collections in the trochanteric bursa were included in the periprosthetic soft tissue even when communication with joint space was not seen, and that the study included only MoM implants.

## Conclusion

Periprosthetic soft tissue masses are not uncommon in patients with MoM hips. The majority of them in asymptomatic individuals remain stable or regress in the short to medium term. While longer followup will yield more information, in the short-medium term, the mere presence of a periprosthetic soft tissue mass in an asymptomatic individual perhaps should not be a reason to consider revision surgery. We also believe that close followup of these lesions may also be unwarranted as long as the patient is asymptomatic.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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