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SCIENTIFIC ARTICLE

Ultrasound findings in asymptomatic patients with modular metal on metal total hip arthroplasty

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Abstract
Objective The use of metal-on-metal and modular total hip arthroplasty is associated with potentially serious local and systemic complications. The primary aim of this study was to identify the prevalence of a pseudotumor in asymptomatic patients with a particular metal-on-metal hip prosthesis after a minimum follow-up of 5 years using ultrasound evaluation. A secondary purpose was to identify associations between the presence of pseudotumor and serum metal ion levels following implantation.
Methods We prospectively evaluated data collected from 36 asymptomatic patients who underwent implantation of a Profemur Z metal-on-metal total hip arthroplasty from January 2004 to January 2010. Serum metal ion levels were collected in 2012 and 2015. Hip ultrasounds were performed in 2015.
Results Pseudotumors were found in 7/36 patients (19.4%). The average pseudotumor size measured 38.2 cm^3 (range 7.35 cm^3–130.81 cm^3). Elevated metal ion levels were found in all patients at all time points. No statistical correlation was found between the presence of pseudotumor and patient age, age of the implant, component design, and any of the serum metal ion levels or ratios.
Conclusions One in every five asymptomatic patients with metal-on-metal implants was found to have a periarticular pseudotumor. There was no dose-dependent relationship found between elevated serum metal ion levels and the development of a pseudotumor. Our findings suggest that in patients with known elevated metal ion levels, continued monitoring of ion levels may not be a reliable predictor of pseudotumor formation, and ultrasound surveillance can and should be routinely used to document the presence and progression of pseudotumor.

Keywords Total hip arthroplasty · Metal-on-metal · Ultrasound · Pseudotumor · Profemur Z

Introduction

Metal-on-metal (MoM) hip arthroplasty initially gained popularity in the 1980s as an alternative to the traditional metal-on-polyethylene implants. The premise that less wear would occur throughout the lifetime of the implant served as sufficient reasoning for substitution of metal-on-polyethylene implants for MoM-hardened surface implants. Metal-on-polyethylene arthroplasty wear has been shown to generate particles that lead to osteolysis and early failure of the implants [1, 2]. However, similar studies have determined that wear also occurs with MoM implants [3–11], leading to the release of implant-derived cobalt and chromium ions both locally in the joint capsule and systemically in the bloodstream [12–16]. Metal ions dissipated by the uppermost nanocrystalline zone of the implant couple with natural proteins present in synovial fluid to produce wear particles that induce local osteoblast damage to the joint and pseudotumor formation [17].

Pseudotumor is a rare complication that occurs with several different types of hip arthroplasty, including both metal-on-polyethylene and MoM implants. Pseudotumor is described as a solid, granulomatous, or cystic mass or masses that may or may not be fluid filled and reside in the vicinity of a total hip arthroplasty (THA) [18–20]. Although the development of pseudotumor with MoM implants has been well documented,

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the exact pathology and natural history of these lesions remain unclear. Some studies have found an association between increased metal ion levels and the presence of pseudotumor [21–23], while others have found ion levels to be purely dependent on the implant used with no correlation to adverse local tissue response [24]. Currently, the US Food and Drug Administration recommends the use of advanced imaging in symptomatic patients with MoM implants, but there is mounting evidence to suggest that the pseudotumor formation is not limited to symptomatic patients [18, 25]. Determining the presence of pseudotumor in a patient is becoming increasingly important, as the presence of pseudotumor may ultimately lead to poor outcomes should a revision surgery be required [26, 27].

If current recommendations change to include screening of all patients, whether they are symptomatic or not, using magnetic resonance imaging (MRI) as a screening tool may not be economically feasible. The published 2016 CMS physician fee schedule payment of a hip ultrasound is $126.74 (US dollars), whereas metal artifact reduction sequence MRI is $517.51. For initial screening of the patients in this study, this represents a savings of $14,067 [28]. In addition to an economic advantage, using ultrasound as a screening tool has the advantages of being easy to administer, imposing minimal discomfort for the patient, and having repeatedly been found to be valid, reliable, and reproducible [25, 29–31].

Component malposition and edge loading were previously understood to be the predominant drivers of MoM prosthesis failure, but recent studies have also looked at the modularity of implants as an additional source of premature failure [21, 32, 33]. Although modularity of hip implants allows greater flexibility for surgeons to specify the leg length, offset, and version for their patients, it also creates a new potential site of corrosion. Mechanically assisted crevice corrosion has been implicated in contributing to increased metal debris and adverse local tissue responses [32, 34, 35].

The purpose of this prospective analysis was to use ultrasound to determine the prevalence of pseudotumor in asymptomatic patients with a dual modular THA at a minimum of 5 years of follow-up. Secondarily, we explore the correlation of serum metal ion levels at two time points with the presence of pseudotumor.

Methods

Pre-hoc power analysis was performed in a fashion similar to previously published reports evaluating asymptomatic pseudotumors in MoM implants [36]. The prevalence of pseudotumor in the setting of well-positioned and malpositioned implants was estimated to be 4 and 60%, respectively [36]. A priori statistical significance was set at a p-value of 0.05 and a power of 90%. Minimum sample size was determined to be 26 patients.

Under institutional review board approval, we evaluated prospectively collected data from 36 patients, who underwent implantation of dual-modular THA [Profemur Z (PFZ); Fig. 1; Wright Medical Group Inc., Memphis, TN] by the senior author from January 2004 to January 2010. The collected data spanned a 5–11-year period from the time of index procedure. Implant specifications were collected from operative procedure notes. All 36 patients were informed of the nature of the investigational study and provided informed consent. Symptomatic patients and those having undergone revision arthroplasty were excluded from the study. Serum metal ion levels, including titanium, cobalt, and chromium, were collected in 2012 and 2015 and were analyzed by the Mayo Clinic Laboratory (Rochester, MN). Hip ultrasounds were performed on each patient between February and March 2015 by a single musculoskeletal radiologist with greater than 25 years of experience in musculoskeletal ultrasound using a GE Logiq ultrasound machine (General Electric, Buckinghamshire, UK) equipped with a 5-MHz curved linear-array and a 9-MHz linear-array transducer.

A standardized protocol for sonographic imaging was used to determine the presence of soft-tissue pseudotumor, as previously described by van Holsbeeck et al. [37]. Pseudotumor formation was defined as the presence of a solid or cystic mass at the site of THA. Solid masses were characterized as non-compressible lesions and were variable in appearance, with hyperechoic, hypoechoic (Fig. 2), or mixed/heterogeneous (Figs. 3, 4 and 5) echogenicity; in this series, no solid mass was completely hyperechoic, but masses that contained >50% hyperechoic tissue were considered hyperechoic. Cystic masses were characterized as compressible lesions and were typically hypoechoic to anechoic with posterior acoustic enhancement. The presence, size, and position of any fluid, cystic mass, or solid mass adjacent to the hip were documented, along with any involvement of surrounding neurovascular structures. A minimum size of 1 cm in any plane was defined as a significant abnormality.

Univariate non-parametric tests were used to compare the two groups. Fisher's exact tests were used for categorical variables and Wilcoxon two-group tests were used for continuous variables. For the purposes of analysis, serum metal ion values below the level of detection were set to half of the level of detection. All analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC). Statistical significance was set at $p < 0.05$.

Results

Thirty-six patients met our inclusion criteria; 20 of the THAs were right sided and 16 were left sided. The mean age of the population was 57.9 ± 9.7 years. The average BMI of our cohort was 32.3 ± 6.07. The average femoral head component size was 40.6 ± 6.1 mm. Patient

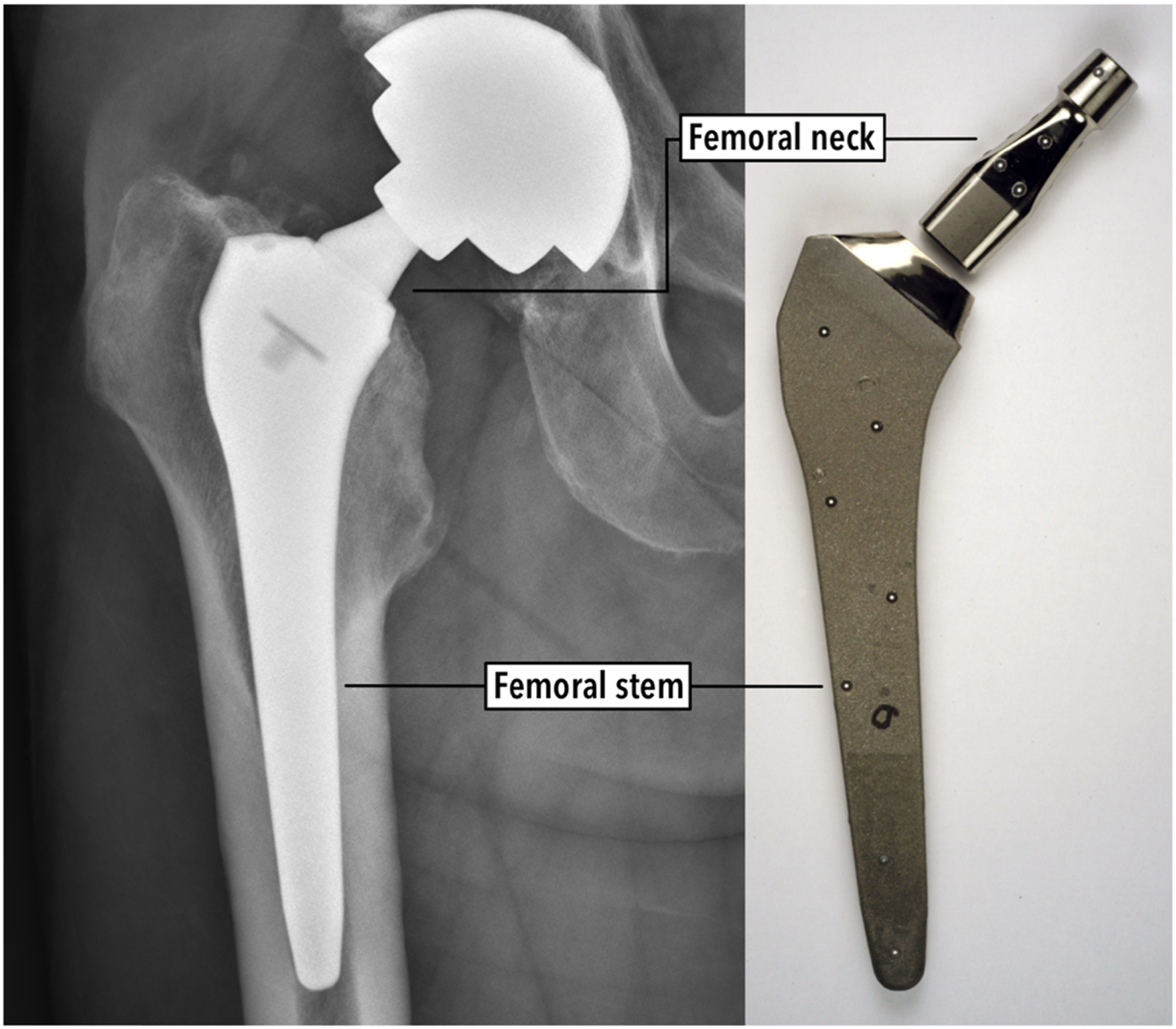

Fig. 1 Dual modular total hip arthroplasty. AP radiograph (left) of the right hip with a dual modular total hip arthroplasty. Disassembled components of the femoral neck and stem (right) of a dual modular total hip arthroplasty; the femoral neck component is available in different sizes and configurations to be customized to each individual patient

demographics and implant data are listed in Table 1. The mean duration of prosthesis implantation at last follow-up was 84.3 ± 20.7 (range 61–135 months). Serum chromium and cobalt ion levels among all patients, irrespective of the presence of pseudotumor, were on average 29 times and 30 times higher than the upper limit of normal for chromium and cobalt, respectively, as defined by the Trace Elements Laboratory-London Health Sciences Center [25].

Seven of 36 patients (19.4%) had pseudotumor on ultrasound examination. Three of the pseudotumors were predominantly cystic in nature, while the remaining four were described as a solid mass. The average size of the pseudotumors measured 38.2 ± 51.2 cm^3 (range 7.35 cm^3–130.81 cm^3) (Table 2). In patients without pseudotumor, the serum levels (ng/ml) of titanium, cobalt, and chromium were 3.1 ± 2.9, 3.6 ± 3.9, and 2.8 ± 2.5 in 2012 and 3.4 ± 4.3, 13.4 ± 38.8, and 5.7 ± 12.0 in 2015, respectively. Patients with pseudotumor had titanium, cobalt, and chromium levels of 3.3 ± 2.4, 8.4 ± 9.4, and 6.6 ± 10.1 in 2012 and 4.3 ± 3.7, 6.0 ± 4.9, and 5.5 ± 6.9 in 2015. The ratio of cobalt to chromium was 1.4 ± 1.1 in 2012 and 1.8 ± 1.1 in 2015 in patients without a pseudotumor and 2.0 ± 1.3 in 2012 and 1.8 ± 1.4 in 2015 in patients with a pseudotumor (Table 3). There were no statistically significant relationships found between the presence of pseudotumor and serum metal ion levels at either time point.

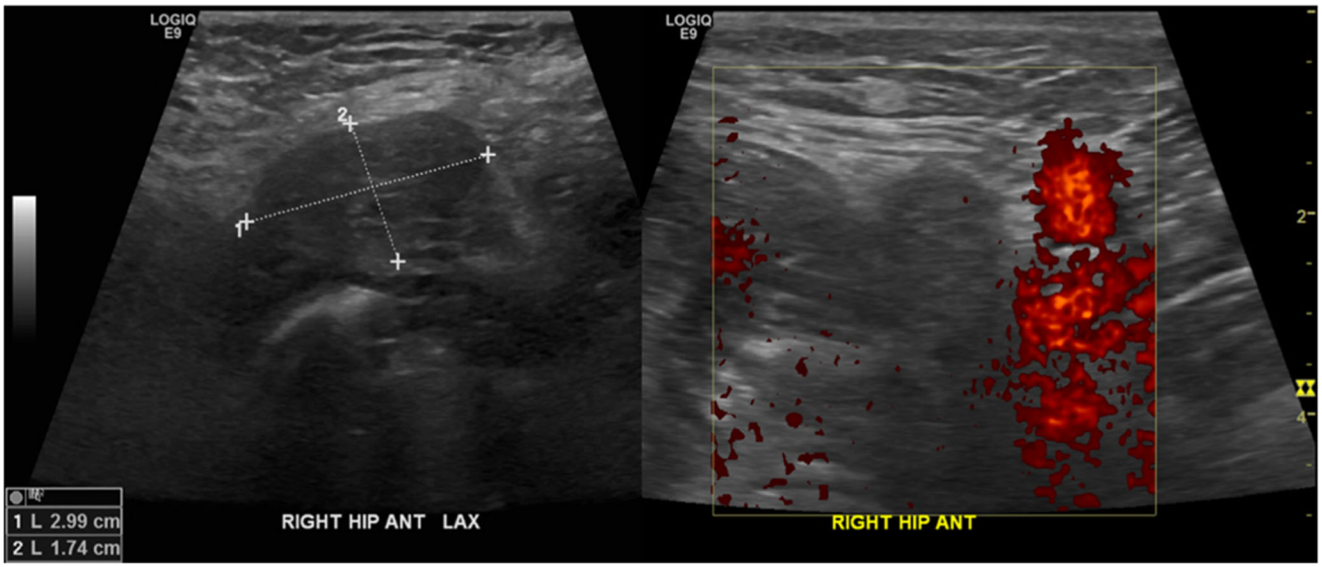

Fig. 2 A 65-year-old asymptomatic female with a metal-on-metal right total hip arthroplasty. Long-axis (left) grayscale sonographic image and power Doppler sonographic image (right) of the anterior right hip shows a 3.0 × 1.7 × 1.5-cm ovoid mass in the region of the iliopsoas bursa that is hypoechoic compared to adjacent muscle and does not demonstrate internal vascularity on power Doppler imaging

None of the other covariates including age, sex, and component design (stem, neck, and cup) were able to predict the formation of a pseudotumor. There was no significant difference between serum metal ion levels and the volume or sonographic appearance of the pseudotumors.

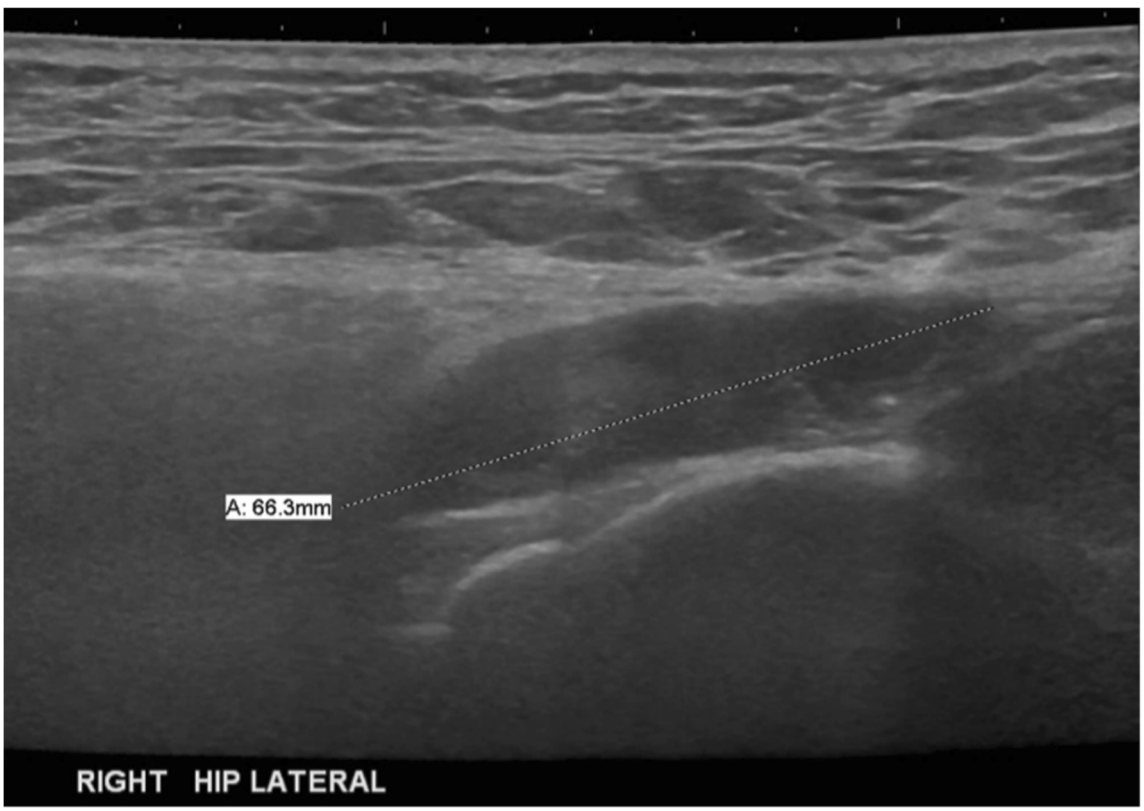

Fig. 3 A 57-year-old asymptomatic male with a metal-on-metal right total hip arthroplasty with a complex solid-appearing pseudotumor at the posterior joint capsule. Grayscale sonographic image at the lateral aspect of the joint shows a mixed hyper- and hypoechoic, complex fluid collection lateral to the greater trochanter. A known deeper fluid collection with apparent communication with the joint on prior imaging was not well seen by ultrasound

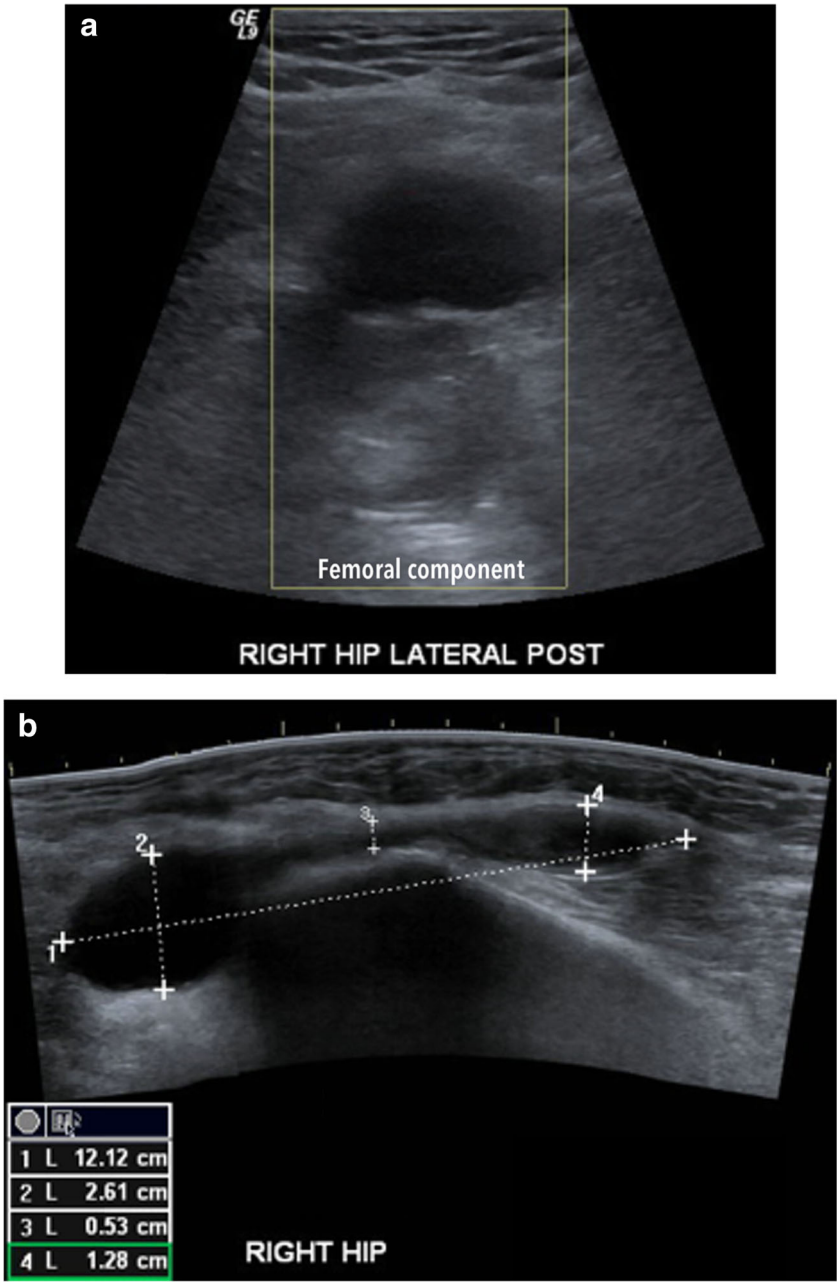

Fig. 4 A 66-year-old asymptomatic male with a metal-on-metal right total hip arthroplasty. Long-axis power Doppler (A) and short-axis extended field of view (B) grayscale sonographic images of the right hip show a large bilobed, anechoic, and hypoechoic complex mass with posterior acoustic enhancement at the surgical scar along the lateral aspect of the right thigh adjacent to the greater trochanter. Total volume of the fluid collection/pseudotumor measures approximately 91.48 cm^3. No internal vascularity is seen on power Doppler imaging (A)

Discussion

Initially introduced to provide the surgeon with an improved ability to customize hip arthroplasties, modular taper junctions at the head-neck and neck-body of the femoral component of the arthroplasty have been found to contribute to particulate wear [32, 34]. Garbuz et al. found that modular junctions contributed more to serum metal ion levels in modular MoM THA when compared to MoM hip resurfacing arthroplasties [35]. The Profemur Z is a dual modular prosthesis with a titanium body, a titanium or cobalt-chromium neck, and a cobalt-chromium head. Mechanically assisted crevice corrosion has been documented in similar modular prostheses [21, 33, 38, 39]. Not only does mechanical wear at the modular interfaces generate particulate debris, adding to the total metal ion burden, but also a synergistic effect has been proposed where corrosion at the modular interface can lead to third body wear at the bearing surface, as well as cathodic polarization effects, which can decrease resistance to further wear [34]. As all patients in this study were asymptomatic, retrieval analysis was not performed in this study; thus, we can only hypothesize the presence of similar modular corrosion among our study population.

To our knowledge, this is the first study to use ultrasound to screen for the presence of pseudotumor in a group of asymptomatic patients who had a prior THA

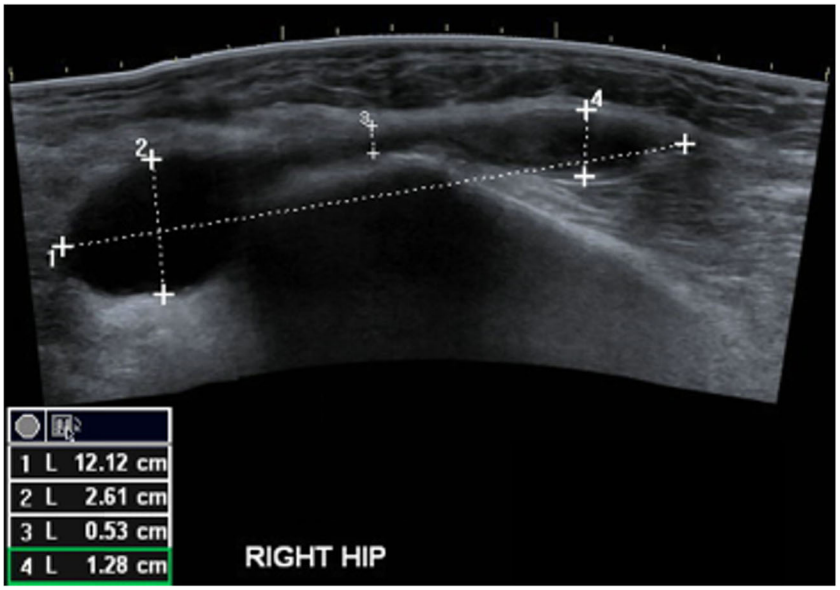

Fig. 5 A 66-year-old asymptomatic male with a metal-on-metal right total hip arthroplasty. Long-axis power Doppler (A) and short-axis extended field-of-view (B) grayscale sonographic images of the right hip show a large bilobed, anechoic, and hypoechoic complex mass/fluid collection with posterior acoustic enhancement at the surgical scar along the lateral aspect of the right thigh adjacent to the greater trochanter. No internal vascularity is seen on power Doppler imaging (A)

with the dual modular PFZ prosthesis. There have been prior studies analyzing previously recalled implants, specifically the ASR XL (DePuy Orthopaedics, Warsaw, IN) [18, 23], which documented extensive adverse local tissue responses secondary to the presence of wear particles. As of yet, however, there have been no studies evaluating these devices that remain on the market and their potential side effects.

The MRI-metal artifact reduction sequence has been the predominant method of pseudotumor detection in many previous studies [20, 32, 40]. Recently, however, there has been an increased demand for the use of ultrasound as a reliable screening tool for pseudotumor presence [31, 36]. Advantages of ultrasound include that it is quick to perform, relatively unaffected by metal implants, affordable, and widely available. Garbuz et al. found that

Table 1 Patient demographics

Variable		All ($n = 36$)	No pseudotumor ($n = 29$)	Pseudotumor ($n = 7$)	*P*-value
Age (years)		57.9 ± 9.7	57.9 ± 10.3	58.1 ± 7.6	0.796
Side	Right	20 (56%)	15 (52%)	5 (71%)	0.426
	Left	16 (44%)	14 (48%)	2 (29%)	
Neck angle	Neutral	3 (8%)	3 (10%)	0 (0%)	0.436
	Varus/valgus	1 (3%)	1 (3%)	0 (0%)	
	AR 8	15 (42%)	12 (41%)	3 (43%)	
	AR 15	8 (22%)	6 (21%)	2 (29%)	
	ARVV 1	4 (11%)	2 (7%)	2 (29%)	
	ARVV 2	4 (11%)	4 (14%)	0 (0%)	
Neck length	Short	27 (75%)	23 (79%)	4 (57%)	0.312
	Long	8 (22%)	5 (17%)	3 (43%)	
Cup design	Dynasty	21 (58%)	15 (52%)	6 (86%)	0.120
	Conserve	11 (31%)	11 (38%)	0 (0%)	
	Lineage	4 (11%)	3 (10%)	1 (14%)	
Cup size (mm)		53.6 ± 4.9	53.1 ± 4.7	55.7 ± 5.3	0.248
Head size (mm)		40.6 ± 6.1	40.8 ± 6.1	40.0 ± 6.3	0.968

AR 8/15, anteverted/retroverted 8° or 15°; ARVV 1/2, anteverted/retroverted 4° and 6° varus/valgus

There were no statistically significant variations between patients with and without the presence of pseudotumor. Age, cup size, and head size are listed as mean ± standard deviation. All implanted necks were titanium

Table 2 Characteristics of pseudotumors within the study cohort

	Patients N (%)	Volume Mean ± SD (cm^3)	Range (cm^3)
All pseudotumors	7 (19.4%)	38.17 ± 51.19	5.38–130.81
Solid mass	4 (11%)	8.09 ± 2.77	5.38–11.96
Cystic mass	3 (8.3%)	78.28 ± 60.23	12.54–130.81

SD, standard deviation

Pseudotumors were characterized as either solid or cystic in nature; cystic lesions, either anechoic to hypoechoic or complex/heterogeneous in echotexture, had some degree of posterior acoustic enhancement and compressibility, while solid lesions did not

ultrasound had a sensitivity of 100% and specificity of 96%, while MRI had a sensitivity of 92% and specificity of 100% for the detection of pseudotumor in MoM THA [35]. In addition to its clinical success, the affordability of ultrasound cannot be understated. With an estimated half-million MoM arthroplasties in the USA alone, a single follow-up study cost differential between ultrasound and MRI could produce savings upwards of $195 million (US dollars) [28, 35].

Previous studies examining pseudotumor development among MoM implants have shown drastic variation in disease prevalence, ranging from 32 [25] to 61% [18]. This may in part be due to the lack of a true definition of what image findings constitute a pseudotumor. Our study found that approximately one in five patients with asymptomatic PFZ implants had a pseudotumor identifiable by ultrasound. There was no association between serum metal ion levels and pseudotumor architecture, ranging from cystic, solid, or mixed masses. The etiology of this varying architecture remains largely unknown and is likely multifactorial. Individual patients have varying histologic reactions that likely play a role, including inflammatory cell infiltration, particulate density, metal ion concentration, and soft tissue organization. The size range of these lesions was highly variable and showed no correlation with all measured serum metal ion levels. This finding is similar to previously published reports that document elevated serum metal ion levels in patients with pseudotumor, but failed to identify a dose-dependent relationship [25]. Chang et al. found significant dose-dependent relationships between pseudotumor formation and metal ion levels when using a cutoff of 5 ng/ml to make it a dichotomous variable rather than using continuous values [12]. Although not statistically significant, there was a trend in our study toward higher serum metal ion levels in patients with pseudotumors at follow-up in 2012. However, this trend was not present at a subsequent follow-up in 2015. This suggests that metal ions likely play a central role in the development of pseudotumor, but there is a wide variety of influencing factors, including the individual patient reaction to metal products [40], that have not been completely elucidated as of yet.

Our study has several limitations. As previously mentioned, there was no retrieval analysis of the devices from our asymptomatic cohort. Therefore, it is difficult to conclude whether or not the modular interface is the primary source of metal ion debris via corrosion. Second, the cohort was limited in size; although a substantial portion (19.4%) of the patients had an asymptomatic pseudotumor, we were unable to find any correlation between covariates that may have had prognostic value regarding treatment recommendations for an asymptomatic patient with an MoM implant. However, we believe that this study does add to the growing body of evidence that suggests ultrasound should be used to monitor even asymptomatic patients with elevated metal ion levels to determine the presence or absence of pseudotumor. While we acknowledge the existence of limitations, to

Table 3 Serum metal ion levels

Variable	All ($N = 36$)	No pseudotumor ($N = 29$)	Pseudotumor ($N = 7$)	*P*-value
Metal ion level-2012 (ng/ml)				
Titanium	3.1 ± 2.8	3.1 ± 2.9	3.3 ± 2.4	0.510
Cobalt	4.5 ± 5.6	3.6 ± 3.9	8.4 ± 9.4	0.136
Chromium	3.6 ± 5.0	2.8 ± 2.5	6.6 ± 10.1	0.663
Cobalt:chromium	1.5 ± 1.2	1.4 ± 1.1	2.0 ± 1.3	0.254
Metal ion level-2015 (ng/ml)				
Titanium	3.5 ± 4.1	3.4 ± 4.3	4.3 ± 3.7	0.306
Cobalt	12.1 ± 35.1	13.4 ± 38.8	6.0 ± 4.9	0.518
Chromium	5.7 ± 11.1	5.7 ± 12.0	5.5 ± 6.9	0.677
Cobalt:chromium	1.8 ± 1.2	1.8 ± 1.1	1.8 ± 1.4	0.729

Ion levels were drawn at two time points, first in 2012 and later in 2015. There were no significant correlations between serum metal ion levels at either time point or cobalt-to-chromium ratio and the presence of pseudotumor

our knowledge, this remains the only study of asymptomatic pseudotumor in patients with a dual modular MoM prosthesis, specifically the PFZ implant.

Conclusion

The prevalence of pseudotumor identified using ultrasound in asymptomatic patients with a dual modular hip prosthesis was 19.4%. The presence of pseudotumor did not correlate with component pairings, serum metal ion levels, or cobalt-to-chromium ratios. As metal ion analysis alone may be unreliable for predicting the presence of pseudotumor after MoM hip arthroplasty, along with the cost-restrictive nature of advanced imaging with metal artifact reduction sequence MRI, ultrasound, with its reported high sensitivity of detection, can play a critical role in diagnosis and routine monitoring of pseudotumor in asymptomatic patients.

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Compliance with ethical standards

Conflicts of interest None.

Support Internal.

Institutional review board status Approved.

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