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Treatment of Pseudotumors After Metal-on-Metal Hip Resurfacing Based on Magnetic Resonance Imaging, Metal Ion Levels and Symptoms

Walter van der Weegen, MSc [a], Thea Sijbesma, MD, PhD [a], Henk J. Hoekstra, MD [a], Koen Brakel, MD, PhD [b], Peter Pilot, PhD [c], Rob G.H.H. Nelissen, MD, PhD [d]

[a] Department of Orthopaedic Surgery, St. Anna Hospital, Geldrop, The Netherlands
[b] Radiology Department, St. Anna Hospital, Geldrop, The Netherlands
[c] Reinier de Graaf Gasthuis, Delft, The Netherlands
[d] Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands

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ABSTRACT

Peri-prosthetic pseudotumor formation can be a severe complication following Metal-on-Metal hip resurfacing arthroplasty (MoMHRA), with limited data on the optimal management of this complication. The aims of this study were (1) to evaluate the prevalence and severity of pseudotumors in a consecutive cohort of 248 MoMHRA (214 patients, mean follow-up 4.6 years, range: 1 – 8.2), and (2) to present a clinical guideline for their treatment based on severity grading with Metal Artefact Reduction Sequence Magnetic Resonance Imaging, metal ion levels and symptoms. Pseudotumor prevalence was 36.3%: 61 mild, 25 moderate and four were graded severe. Five revisions followed, all in symptomatic patients with elevated metal ion levels. Pseudotumor severity grading allowed us to be conservative with revision surgery for mild and moderate MoM disease.

Recently controversies occur on the benefit of metal on metal arthroplasty (MoM), due to an increasing number of studies on pseudotumors occurrence next to these types of hip replacements [1–3]. Adverse peri-prosthetic soft tissue reactions following MoM hip arthroplasty can include metallosis, Asymptomatic Lymphocyte Vasculitis-Associated Lesions (ALVAL) or pseudotumor formation [4]. Pseudotumors, defined as a solid or fluid mass which has developed in the peri-prosthetic soft tissue [5], are considered a severe complication of these MoM implants, which may cause pain, swelling, deep vein thrombosis and extensive soft tissue damage [6–8]. Interestingly, not all MoM prostheses seem to develop these pseudo tumor sequelae, and a debate exists on the prevalence of these pseudotumors, which ranges from less than 1% to 39% [9,10]. Currently the only treatment option in case of pseudotumors is revision surgery, during which the MoM articulation is replaced by a non-MoM articulation. However, outcome of revision surgery for pseudotumor is poor compared to MoM revision surgery for other reasons [11]. Incomplete pseudotumor resection and recurrence of pseudotumor, both a reason for re-operation, is reported by Liddle et al [12] while de Steiger et al found infection to be a major cause for re-revision surgery in MoM hip arthroplasty [13].

In clinical practice, symptoms (both general health as well as local at the hip region) and metal ion levels are also used next to MARS-MRI pathology about the hip, to guide not only surgical treatment, but also follow up of these patients, despite that controversy exists on the validity of these variables [2,14–16]. Furthermore, only poor consensus exists on detection of these MoM pseudotumors [2,17,18]. The aim of this study was to evaluate the prevalence and severity of pseudotumors in a consecutive cohort of MoM hip resurfacings using MARS-MRI. Secondly, a clinical guideline for the treatment of these MoM pseudotumors will be presented based on pseudotumor severity as graded with MARS-MRI, combined with metal ion levels and symptoms.

Patients and Methods

A consecutive cohort of 258 patients (296 MoM hip resurfacing procedures) who had surgery between September 2004 and November 2011. The MoM prosthesis in all patients was the ReCap resurfacing hip (Biomet, Bridgend, South Wales, UK). Data was prospectively collected as part of an Investigational Device Exemption study for this specific MoM hip resurfacing design (Registration: NCT00603395), before surgery, 6 weeks and one year post-surgery and yearly thereafter. Clinical outcomes and radiographs were collected per protocol from 2004 onwards. The study protocol was extended in 2011 to include baseline cross-sectional imaging (MARS-MRI or ultrasound) and metal-ion blood analysis for each patient

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Reprint requests: Walter van der Weegen, MSc, Department of Orthopaedic Surgery, St. Anna Hospital, Bogardeind 2, 5664 EH, Geldrop, The Netherlands.

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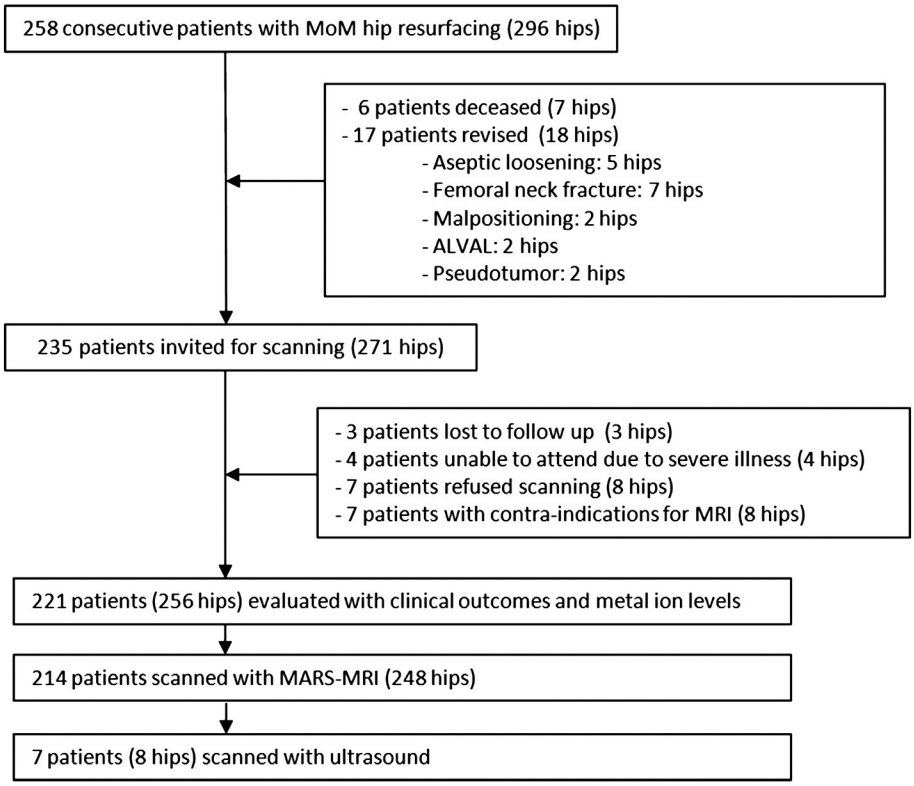

Fig. 1. Study Flow.

scheduled for follow up, as a response to the concerns raised on adverse reactions to metal debris.

Forty-one patients had a bilateral MoM hip implant, two of these had a different design contra lateral hip resurfacing from another hospital, one received a contra lateral MoM Total Hip Arthroplasty (THA) in our hospital. These three MoM hips were excluded from analyses, all other bilateral cases (n = 38) were analysed as separate cases. At the last follow-up in 2012, 17 patients (18 hips) had been revised of which details were published before [19]. After excluding 21 patients (23 hips) for reasons explained in Fig. 1, pseudotumor prevalence using MARS-MRI could be evaluated in 214 patients (248 hips). Mean age of the 235 invited patients was 53.7 years (range, 31–76), mean follow up was 4.6 years (range: 1 – 8.2). In seven patients (8 MoM hips) a contra-indication for MRI was present, these patients were examined using ultrasound examination of the hip area. Ultrasound examinations were performed in supine, prone and left or right side position with different planes (coronal, transversal and saggital) to detect hydrops and/or peri-articular masses and fluid collections; if needed duplex ultrasound was used to differentiate between vascular and non vascular lesions.

Clinical examination was done using the Oxford Hip Score (OHS) [20] and physical examination (i.e. hip Range of motion, groin swelling and palpation tenderness). Patients were also questioned about their general health. Since public awareness existed on possible general symptoms of the MoM, questions on symptoms which could be attributed to the MoM implant, were nevertheless posed: "Did general health changed since their hip surgery" in a dichotomous way. Special notice was given to symptoms derived from the NHS advise on follow-up for MoM patients: chest pain or shortness of breath, numbness or weakness, changes in vision or hearing, fatigue, feeling cold or weight gain [21].

An anterior-posterior radiograph of the pelvis and a lateral hip were made annually. At the latest follow up, particular attention was given to radiolucency, evidence of peri-articular masses and peri-prosthetic bone resorbtion. Radiographs were scored for position of the prosthesis (i.e. inclination of the cup, neck thinning etc). Blood serum samples were collected and assessed on cobalt and chromium concentrations. Samples were collected in metal-free vacutainers; the first 5 mL blood was discarded to eliminate metal contamination from the needle. Tubes were stored at 2-8 °C and sent to an external laboratory (Ziekenhuis Groep Twente, Hengelo, the Netherlands) for analysis. The metal ion levels in serum blood were determined using Atomic Absorption Spectrophotometry (AAS) analysis. The Medicines and Healthcare products Regulatory Agency (MHRA) statutory body that regulates resurfacing devices in the UK advocates 7 parts per billion (ppb) for chromium and cobalt after MoM hip arthroplasty as a

Table 1
MARS-MRI Scan Parameters.

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