

Pseudotumours, cobalt and clinical outcome in small head metal-on-metal versus conventional metal-on-polyethylene total hip arthroplasty

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Abstract

Background: Metal-on-metal total hip arthroplasty (MoM THA) is associated with the formation of pseudotumours. Studies mainly concern pseudotumour formation in large head MoM THA. We performed a long-term follow-up study, comparing pseudotumour incidence in small head metal-on-metal (SHMoM) THA with conventional metal-on-polyethylene (MoP) THA. Predisposing factors to pseudotumour formation were assessed.

Methods: From a previous randomised controlled trial comparing SHMoM (28 mm) cemented THA with conventional MoP cemented THA, patients were screened using a standardised CT protocol for the presence of pseudotumours. Serum cobalt levels and functional outcome were assessed.

Results: 56 patients (33 MoP and 23 MoM) were recruited after mean follow-up of 13.4 years (SD 0.5). The incidence of pseudotumours was 1 (5%) in the SHMoM THA cohort and 3 (9%) in the MoP THA cohort. Prosthesis survival was 96% for both SHMoM and MoP THAs. Serum cobalt levels did not exceed acceptable clinical values (<5 µg/L) whereas no differences in cobalt levels were detected at follow-up between both groups. Oxford and Harris Hip Scores were good and did not differ between SHMoM and MoP THA.

Conclusions: This long-term follow-up study shows a low incidence of pseudotumour formation and good functional outcome in cemented head-taper matched SHMoM and MoP THA.

Keywords

Cobalt, metal-on-metal, pseudotumour, small head, total hip arthroplasty

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Introduction

Total hip arthroplasty (THA) has proven to be an excellent treatment for treating osteoarthritis of the hip. Since Sir John Charnley, the metal-on-polyethylene (MoP) bearing has been the gold standard, outperforming 1st-generation metal-on-metal (MoM) THAs like the McKee THA.¹ However, polyethylene (PE) wear leading to particle-induced osteolysis and component loosening has been considered a drawback of the MoP articulation couple. Therefore, in the late 1980s, 2nd-generation MoM bearings were developed, with improvements in fixation, metallurgy, sphericity and radial clearance. These new MoM designs showed promising wear performance,^{2,3} but as there was a lack of comparative clinical trials,

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in the late 1990s our institute performed a randomised controlled trial (RCT) to compare clinical performance of small head (SH) MoM with small head MoP THA (both 28-mm femoral head diameter). Secondary outcomes were cobalt ion levels, radiology and survival. The 5- and 10-year follow-up data have been published previously, showing no difference in clinical performance.^{4,5}

During follow-up, due to reports of possible pseudotumour formation and increased ion levels in large head THA and resurfacing MoM articulations,⁶ our institute decided to recall all MoM THA patients. All available patients were screened for the presence of pseudotumours according to the guidelines issued by the Dutch Orthopaedic Society.⁷ The MoP study cohort of the RCT was screened as well, in order to compare both MoM and MoP cohorts.

The primary aim of this study was to compare the incidence of pseudotumours in SHMoM THA with conventional MoP THA after long-term follow-up. The secondary aim was to compare cobalt levels, functional outcome and radiological outcome in both groups to assess their relationship to articulation type and pseudotumour formation.

Materials and methods

The initial study compared cemented SHMoM THA with MoP THA.⁴ Study design and procedures were approved by the local Medical Ethics Committee (METC 97-19). Patients included suffered from non-inflammatory degenerative joint disease of the hip. 5 orthopaedic surgeons and 2 orthopaedic residents performed the surgery via a posterolateral or direct lateral approach in lateral decubitus position.

Randomisation was based on sequentially numbered opaque sealed envelopes, produced by an external institution not involved in the selection, care or evaluation of the patients.

The MoM patient group (101 patients, 102 hips) received an M2A cup (Biomet, Warsaw, IN, USA), manufactured by moulding a block of conventional PE (ArCom, Biomet) around a highly-polished cobalt-chromium-molybdenum alloy bearing insert. The MoP patient group (97 patients, 98 hips) received a cemented conventional PE acetabular component (ArCom, Biomet). A Stanmore cemented femoral stem was used, combined with a 28-mm modular femoral head, both made of a cobalt-chromium-molybdenum alloy.

Screening protocol

99 out of 195 patients participating in the original RCT were found to be eligible and were contacted for pseudotumour screening. The other 96 patients were excluded because they were deceased (90) or had undergone revision surgery (6) during follow-up (Figure 1). 29 patients had undergone a contralateral (non-RCT) MoP THA, which was also included in the pseudotumour screening. The screening protocol consisted of a radiological assessment (plain

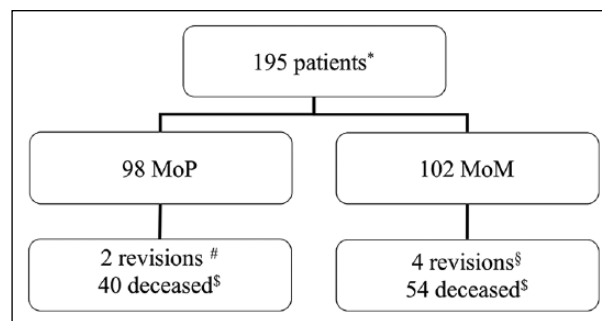


Figure 1. Flow chart of the randomised controlled trial.

*incl 5 bilateral THAs: 1 MoM/MoM, 1 MoP/MoP, 3 MoP/MoM.

#total revisions for aseptic loosening, cultures negative.

§2 acetabular revisions for aseptic loosening (one suggestive of ALVAL), 1 acetabular revision for instability, 1 prosthesis removal (girdlestone) for aseptic loosening.

§1 bilateral MoM/MoM, 2 bilateral MoM/MoP, 1 bilateral MoP/MoP.

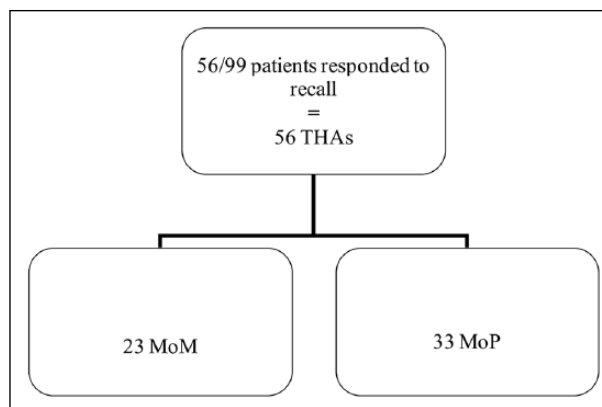


Figure 2. Flow chart of the 56 patients involved in pseudotumour screening.

Nota bene: 29 patients with contralateral non-RCT MoP THA (27 unilateral patients left for cobalt and HHS/OHS measurements).

radiograph of the pelvis and computed tomography [CT]), assessment of functional outcome (Oxford Hip Score [OHS]⁸ and Harris Hip Score [HHS]⁹) and measurements of serum cobalt levels. In total 56 patients responded to the recall (33 MoP THA and 23 MoM THAs) (Figure 2). There were 43 non-responders: three patients refused to cooperate, one patient had dementia and the other 39 (19 MoM, 21 MoP) patients were lost to follow-up and could not be traced. The baseline characteristics of the 2 groups were comparable, except for the surgical approach, with a mean age of almost 80 years at follow-up (Table 1). The local Medical Ethics Committee approved the procedures employed in this study (METC 2011-44).

Radiological evaluation

Conventional hip radiographs as well as computed tomography were performed. We used CT as cross modality imaging of choice over MRI as it is less expensive and more readily

Table 1. Demographics and surgical characteristics MoM versus MoP.

	MoM THA (<i>n</i> = 23)	MoP THA (<i>n</i> = 33)	<i>p</i> -value
Sex (male/female)	6/17	7/26	0.67
Mean age (years (SD))	78.8 (5.7)	78.7 (6.5)	0.93
Mean follow-up (years (SD))	13.2 (0.4)	13.5 (0.5)	0.06
Surgical approach (posterolateral/direct lateral)	19/4	19/14	<0.05

MoM, metal-on-metal; MoP, metal-on-polyethylene.

Table 2. CT-grading system for pseudotumours.¹³

Grade	Description	Criteria
I	Normal or acceptable	thickening of the capsule up to 4–6 mm.
II	Reactive	thickened capsule >6 mm with or without bulging but not more than the neck of the prosthesis and without eccentric enlargement with regard to the capsule
III	Mild MoM disease	consists of a bulging capsule both anterior and posterior
IV	Moderate MoM disease	represents eccentric bulging or enlargement of the capsule, which is often seen inferomedial to the prosthetic head
V	Severe MoM disease	is reserved for the so-called bursitis mimicker, often posterolaterally with extensive filling of the bursa subtrochanterica, or anteriorly by filling of the bursa iliopectinea, which can extend quite impressively into the abdominal compartment

MoM, metal-on-metal.

available than magnetic resonance imaging (MRI) and has been shown to be a good predictor of revision in relevant cases.^{10–12} CT scans were obtained using a 16-slice CT scanner (Philips, Best, The Netherlands) and viewed in a bone window to minimise metal artifact without the use of a metal suppression protocol. Window-width to window-level values were set at 2000:650. A CT grading system was used to describe the amount of postoperative synovial reaction (Table 2).¹³ Grade IV or V findings, which consist of a solid, semisolid, or cystic eccentric extension of the capsule, resulting in an increase in the volume of the capsule that could not be attributed to an infection, malignancy, bursal or scar tissue were classified as a pseudotumour. No minimum size was applied to define a pseudotumour. All CT scans were performed and reviewed by an experienced musculoskeletal radiologist (MFB) using the same protocol as previous studies on MoM THA^{10,14,15}

The inclination of the acetabular component was measured on a supine anteroposterior pelvic hip radiograph. Inclination angles which exceeded 50° were regarded as outliers.^{16,17} Acetabular radiolucent lines were described according to Delee and Charnley,¹⁸ femoral radiolucent lines were described according to Gruen et al.¹⁹ Radiological cup loosening was defined according to the Zicat criteria.²⁰ Polyethylene wear was estimated using single image analysis with Roman software.²¹

Serum cobalt

Serum cobalt levels were measured using inductively coupled plasma mass spectrometry (ICP-MS; Agilent

7500 series, Agilent Technologies, Lexington, MA, USA). The reference value (defined as the upper limit in the general population) for cobalt in our laboratory was <0.40 µg/L. On the basis of guidelines from the Dutch Orthopaedic Society, serum cobalt levels were defined as being elevated when they equalled or exceeded 5.0 µg/L.⁷

Functional outcome

Patients completed the OHS as part of their clinical assessment. The HHS was assessed by an orthopaedic nursing specialist. Assessors and patients were not blinded.

Statistical analysis

Descriptive statistics were used to describe the demographic characteristics of the study population. Binary logistic regression analysis was performed to assess differences in the risk of pseudotumour formation between MoM THA and MoP THA. Gender and follow-up time were checked for confounding or effect modification. Additionally, we investigated whether having a pseudotumour on the contralateral (non-index) side would have an effect on the incidence of pseudotumours on the index side. For effect modification, a *p* value of ≤0.10 of the interaction term was used to indicate significance. For the analyses of cobalt levels and functional outcome (OHS and HHS), only patients with a unilateral THA (*n* = 27) were included as bilateral THAs may affect serum cobalt levels and functional outcome.

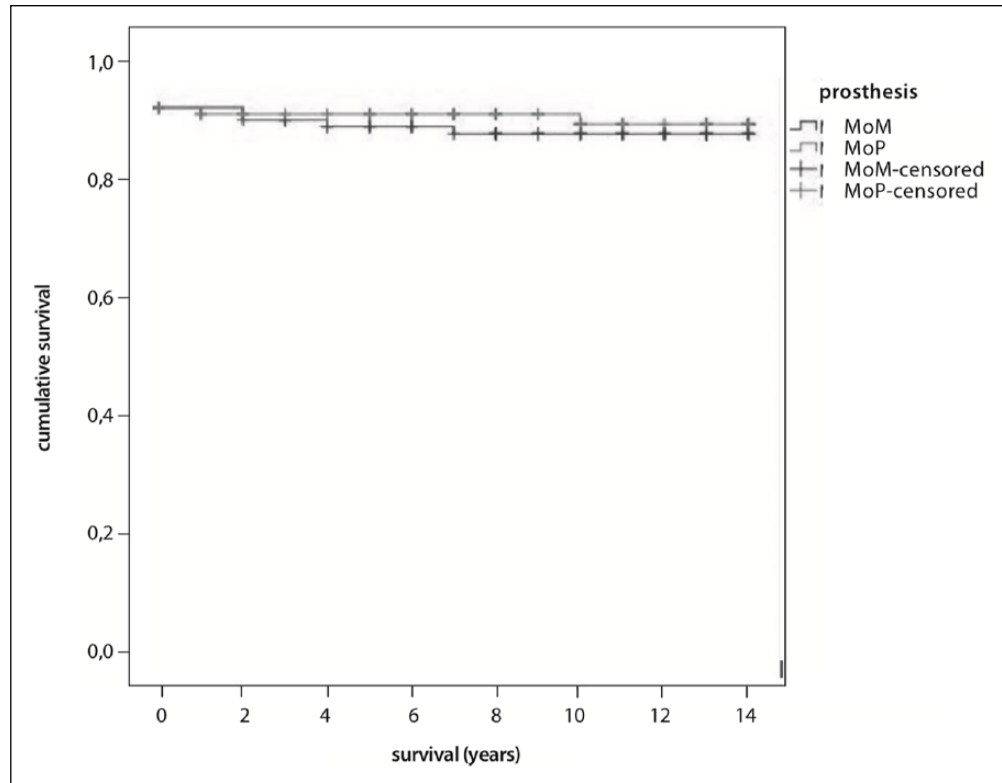


Figure 3. Kaplan–Meier survival curve describing survival of both MoM and MoP THAs after a mean follow-up of 13.4 years. Endpoint was defined as revision of any component.

The Mann–Whitney *U*-test was used to determine a significant difference in serum cobalt levels at recall between MoM and PE. Chi-square and Fisher’s exact tests were used to assess associations between cobalt ion levels and pseudotumour formation, and between inclination of the acetabular component, pseudotumour formation and serum cobalt levels. To assess differences in (the recovery of) physical functioning between the MOM and PE group, generalised estimating equations (GEE) analyses were performed (exchangeable working correlation structure and robust estimation of the covariance matrix). Data were checked for effect modification and existence of confounding factors.

Statistical analysis was performed using IBM-SPSS Statistics v23 (IBM, Armonk, NY, USA). A *p* value ≤ 0.05 was considered to be statistically significant.

Results

The mean duration of follow-up at the time of recall was 13.4 years (standard deviation [SD] 0.5; range 13–14 years). Survival was 96% for both MoM and MoP THAs (Figure 3). None of the revisions was primary pseudotumour-related, however in one MoM acetabular revision (33 months p.o.) because of component loosening, histology was suggestive of ALVAL (Figure 1).

CT

54 patients (22 MoM, 32 MoP) had a CT scan (2 patients refused due to claustrophobia). Of these, 1 MoM (4.5%) and 3 MoP THAs (9.4%) were classified as having a pseudotumour ($p = 0.64$). 1 patient (MoP) had a pseudotumour on the contralateral (non-index) side. Logistic regression analysis of articulation type and pseudotumour incidence determined gender and follow-up time to be significant confounders, and no effect modification was observed.

Cobalt

Of the 56 patients, 27 had a unilateral THA (10 MoM, 17 MoP). These patients were included in the analyses of cobalt levels. None of these patients had elevated cobalt levels. Taking the patients with bilateral THAs into account as well, additionally only one patient had cobalt levels ≥ 5 $\mu\text{g/L}$ (7.39 $\mu\text{g/L}$). This was a female with a MoM THA and a contralateral non-RCT MoP cemented THA with no signs of pseudotumour on CT and well-functioning hips (HHS 91, OHS 20). As a consequence, none of the patients with a pseudotumour on CT showed elevated cobalt levels.

At recall, median cobalt levels did not differ between MoM (1.25 $\mu\text{g/L}$, range 0.34–4.09) and MoP THA (0.6 $\mu\text{g/L}$, range 0.5–4.0).

Table 3. Number of hips with radiolucent lines at recall.

Zone	MoM (n = 23)	MoP (n = 33)	p value
Stem (Gruen)			
1	2	3	1.00 ⁺
2	1	0	0.41 ⁺
3	1	0	0.41 ⁺
4	1	0	0.41 ⁺
5	1	0	0.41 ⁺
6	1	1	1.00 ⁺
7	1	1	1.00 ⁺
Cup (Delee)			
1	9	12	0.83*
2	3	8	0.50 ⁺
3	3	5	1.00 ⁺
No of hips with radiolucency	10 (43%)	16 (48%)	0.71

MoM, metal-on-metal; MoP, metal-on-polyethylene.

*Chi-square test.

⁺Fisher's Exact test.

In both groups, cobalt levels gradually increased over time. However, no difference between groups were noted and, overall, cobalt levels did not exceed acceptable clinical values.

Radiological outcome

Radiographs were obtained from all 56 patients and acetabular component inclination angles were measured for all 56 patients. Both groups, MoM and MoP, showed comparable inclination ranges. No correlation could be found between higher inclination values and elevated cobalt levels or the existence of pseudotumours.

Periprosthetic radiolucent lines were observed in MoM as well as MoP THAs. However, no differences in pattern or incidence of radiolucent lines were found between either of these groups (Table 3). Furthermore, no correlation was found between radiolucent lines and pseudotumour existence. Radiological loosening was seen in 1 MoM (cup + stem) and 1 MoP (cup) THA. The first patient (aged 89) was wheelchair-bound (due to severe epilepsy and after contralateral hip surgery) and declined a revision operation (HHS 53, OHS 38). The second patient (aged 83) was asymptomatic (HHS 90, OHS 26), with no signs of excessive PE wear. PE wear was determined for all 33 MoP THAs. The mean overall PE wear was 1.6 mm (SD 0.7). The 2 MoP THAs associated with pseudotumour formation on CT did not show excessive PE wear (resp. 0.9 and 1.3 mm).

Functional outcome

Functional outcome (HHS and OHS) did not differ between MoM and MoP THA (Table 4). Also, the presence

Table 4a. Results of GEE analysis of Harris Hip Scores per type of prosthesis.

Effect	Regression coefficient (95% CI)	p-value
Prosthesis type	1.0 (-1.6 - 3.6)	0.45
Time	Preoperative 0 ^a	
	5 year 40.1 (35.9 - 44.4)	<0.001
	10 year 39.4 (35.8 - 43.0)	<0.001
	Recall 37.1 (32.6 - 41.6)	<0.001

CI, confidence interval; Reference group: PE.

^aSet to zero because the preoperative measurement was used as reference.

Table 4b. Results of GEE analysis of Oxford Hip Scores per type of prosthesis.

Effect	Regression coefficient (95% CI)	p-value
Prosthesis type	0.6 (-2.0 - 3.3)	0.64
Time	Preoperative 0 ^a	
	5 year -23.5 (-25.8 -21.2)	<0.001
	10 year -16.2 (-19.2 -13.2)	<0.001
	Recall -15.3 (-18.4 -12.2)	<0.001

CI, confidence interval; Reference group: PE.

^aSet to zero because the preoperative measurement was used as reference.

of a pseudotumour did not significantly influence the HHS or OHS (Table 5).

Discussion

The primary objective of this study was to compare the incidence of pseudotumours in SHMoM THA with conventional MoP THA after long-term follow-up. Both types of THA showed a comparable low incidence of pseudotumour formation of 4.5% and 9.4% respectively after a mean follow-up of >13 years. In our recent study on pseudotumour incidence in LHMoM THA versus conventional MoP THA, remarkably much higher incidences were found (53.7% and 21.8% resp.), using the same CT-screening protocol.¹⁵ We stated pseudotumour formation to be caused by an adverse tissue reaction to metal debris (ARMD) and it also, hypothetically at least in MoP THAs, could be a consequence of an adverse reaction to polyethylene particles ('particle disease'). Several suggestions can be made to explain the differences we found in radiological pseudotumour incidence between the SHMoM and LHMoM THA in our two studies. The most important point is the fact that, apart from the different femoral head sizes, different taper connections have been used. In our previous study, the large head (38-60 mm) MoM THA consisted of a titanium stem taper-adaptor junction and a cobalt-chromium head and shell. The small head (28 mm)

Table 5a. Results of GEE analysis of Harris Hip Scores per presence of pseudotumour.

Effect	Regression coefficient (95% CI)	p value
Pseudotumour	-6.8 (-15.4-1.7)	0.12
Time		
Preoperative	0 ^a	
5 year	40.1 (35.7-44.5)	<0.001
10 year	39.6 (35.9-43.3)	<0.001
Recall	36.9 (32.3-41.5)	<0.001

CI, confidence interval.

Reference group: no pseudotumour.

^aSet to zero because the preoperative measurement was used as reference.

Table 5b. Results of GEE analysis of Oxford Hip Scores per presence of pseudotumour.

Effect	Regression coefficient (95% CI)	p value
Pseudotumour	0.8 (-3.7 - 5.4)	0.72
Time		
Preoperative	0 ^a	
5 year	-23.4 (-25.8 -21.1)	<0.001
10 year	-16.4 (-19.5 -13.3)	<0.001
Recall	-14.9 (-18.1 -11.8)	<0.001

CI, confidence interval.

Reference group: no pseudotumour.

^aSet to zero because the preoperative measurement was used as reference.

Stanmore MoM THA used in our present study consists of a cobalt-chromium stem taper connecting with a cobalt-chromium head and acetabular inlay. It is known that dissimilar alloy combinations in taper connections are more prone to galvanic and fretting corrosion.^{22,23}

Another factor is the increased moment arm from the centre of the head to the centre of the pressure on the trunion in the LHMOM THAs. This leads to increased torsion and friction at the taper junction, resulting in increased corrosion and eventually even in taper fractures.^{22,24} Furthermore, the use of the adapter-sleeve in the LHMOM THA cohort results in three taper junctions potentially contributing to corrosion and metal debris formation.

As there was a lower incidence of pseudotumours in SHMoM THA, there also was a lower incidence of pseudotumour (9.4%) in the cemented MoP THA study cohort in comparison with the incidence (21.8%) in our previous study with uncemented MoP THA. Again, a possible explanation could be the taper connection. The cemented Stanmore MoP THA in the present study has a CoCr-CoCr stem taper-head connection, whereas the uncemented Malloryhead MoP THA of our former study consists of a Ti-CoCr taper connection; again, a dissimilar alloy combination, causing galvanic and fretting corrosion.

Survival, defined as revision for any reason, after 13.4 years was 96% for both MoM and MoP THAs in our study. Considering the NICE criteria (hip arthroplasties should have an overall survival after 10 years of >95%),²⁵ we can assume that the SHMoM THA is a suitable option for clinical practice. Previous studies with comparable follow-up but in younger patients (under and around 50 years of age) also reported rather reasonable survival rates in SHMoM THAs.²⁶⁻³⁰

Recently Lombardi et al.³¹ published results on their experience with a SHMoM THA (uncemented M2a Taper). Aseptic component survival after 10 years was 96%, after 15 years 92% and after 19 years 73%. 70% of revisions (14/20) performed were related to ARMD. Lübbecke et al.³² compared SHMoM THAs (Metasul inlay in metal-backed uncemented titanium shell with PE surface) with CoP (ceramic on PE) THAs and reported an incidence of 1.1% ARMD in revisions of MoM THAs. After 10 years the revision rate clearly increased for the MoM cohort, probably due to late adverse reactions to metal. All pseudotumours occurred in THAs in which revisions were performed more than 12 years postoperatively. Survival of MoM and CoP cohorts were comparable after 10 years of follow-up; however, after 12 years the MoM cohort showed a significantly decreased survival (91.7% vs. 97.7%). These data suggest that an excellent 10-year survival, as in our study, does not preclude future failures in the longer term relating to MoM articulation, especially during the second decade. But again, these 2 studies also report on SHMoM THAs containing titanium stems or titanium acetabular shells, which makes extrapolation of results to our cemented CoCr head-taper matched MoM THAs difficult. Of note, several of the previously mentioned long-term follow-up studies on SHMoM THAs involved much younger patients than our study population,²⁶⁻³⁰ so it seems that younger age and (hence) a more active lifestyle does not influence the outcome.

The secondary aim of our study was to compare cobalt levels, functional outcome and radiological outcome in both groups to assess their relationship to articulation type and pseudotumour formation. Cobalt levels did not increase above critical levels (>5 µg/L), except for 1 patient with a bilateral THA (MoM/MoP). This is in accordance with the finding that no cases of ARMD were described in our SHMoM THA group. Hallows et al.³³ studied cementless SHMoM (28-32 mm), LHMOM (>38 mm) and conventional MoP (28-36 mm) as control groups. Cobalt levels of the MoM THAs were significantly increased as compared with the (MoP) control group. All these THAs, however, consisted of cementless titanium stems coupled with cobalt-chromium heads. In our study, we combined cemented cobalt-chromium-molybdenum stems with cobalt-chromium heads, which could possibly explain our finding of lower cobalt levels. We could not

find any other comparative study reporting on cobalt levels in THAs with this particular taper/head combination.

Radiological outcome did not show any differences between the MoM and MoP patient groups. Functional outcome was comparable between two groups. Because of the low incidence of pseudotumours, no relation could be found between radiological outcome, functional outcome and the existence of a pseudotumour.

This study has its limitations. We were not able to describe a complete follow-up of the original study cohorts. Due to the relatively older patient population (mean age around 70 years at surgery), a significant number of patients (90) died within this long-term follow-up. Another issue is the relatively large number of patients lost to follow-up. This was, however, in line with our expectations, considering the number of patients available for the 10-year report on these cohorts.⁵ In order to estimate the outcome effect of the non-responders, we performed a non-response analysis. Non-responders differed only in age (83.7 vs. 78.7 years). For gender, prosthesis type and functional outcome (as measured at 10-year follow-up) no differences were found.

In spite of these limitations, we were able to present a long-term follow-up of 2 comparable cohorts of small head MoM and MoP THAs regarding pseudotumour incidence, ion levels and functional outcome.

Conclusion

We report good implant survival in cemented head-taper matched small head MoM THA after 13.4 years of clinical follow-up with a low incidence of pseudotumour formation and cobalt levels comparable with MoP THA. Functional outcome was good for patients with both SHMoM and MoP THAs.

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