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Large-diameter Metal-on-metal Total Hip Arthroplasty: Dislocation Infrequent but Survivorship Poor

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Abstract

Background Use of large-diameter metal-on-metal (MoM) articulations in THA increased, at least in part, because of the possibility of achieving improved joint stability and excellent wear characteristics in vitro. However, there have been subsequent concerning reports with adverse reactions to metal debris (ARMD), pseudotumors, and systemic complications related to metal ions.

Questions/purposes The purpose of this study was to determine at a minimum of 2 years' followup (1) the proportion of patients who experienced a dislocation; (2) the short-term survivorship obtained with these implants; (3) the causes of failure and the proportion of patients who developed ARMD; and (4) whether there were any identifiable risk factors for revision.

Methods We reviewed the results of 1235 patients who underwent 1440 large-diameter MoM primary THAs at our institution using two acetabular devices from a single manufacturer with minimum 2-year followup. Large-diameter MoM devices were used in 48% (1695 of 3567) of primary THAs during the study period. We generally used these implants in younger, more active, higher-demand patients, in patients considered at higher risk of instability, and in patients with adequate bone stock to achieve stable fixation without use of screws. Clinical records and radiographs were reviewed to determine the incidence and etiology of revision. Patients whose hips were revised were compared with those not revised to identify risk factors; Kaplan-Meier survivorship analysis was performed as was multivariate analysis to account for

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Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
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potential confounding variables when evaluating risk factors. Minimum followup was 2 years (average, 7 years; range, 2–12 years); complete followup was available in 85% of hips (1440 of 1695).

Results Dislocation occurred in one hip overall (< 1%; one of 1440). Kaplan-Meier analysis revealed survival free of component revision was 87% at 12 years (95% confidence interval, 84%–90%). The two most common indications for revision were ARMD (48%; 47 of 108 hips revised) and loosening or failure of ingrowth (31%; 34 of 108). Risk factors for component revision were younger age at surgery (relative risk [RR] 0.98 per each increased year; p = 0.02), higher cup angle of inclination (RR 1.03 per each increased degree; p = 0.04), and female sex (RR 1.67; p = 0.03).

Conclusions Large-diameter MoM THAs are associated with a very low dislocation rate, but failure secondary to ARMD and loosening or lack of ingrowth occur frequently. Patients with MoM THA should be encouraged to return for clinical and radiographic followup, and clinicians should maintain a low threshold to perform a systematic evaluation. Early diagnosis and appropriate treatment are recommended to prevent the damaging effects of advanced ARMD.

Level of Evidence Level IV, Therapeutic study.

Introduction

Use of large-diameter metal-on-metal (MoM) articulations in THA increased, at least in part, because of the possibility of achieving improved joint stability and excellent wear characteristics in vitro [11, 12, 28, 39, 55, 57]. Enhanced stability is afforded by greater ROM to impingement and increased jump distance, that is the distance required for the head to pull out from the acetabular shell to subluxate [39, 52]. Previous studies from our center with a MoM device with a 38-mm fixed-diameter head and cobalt-chromium (CoCr) monoblock shell reported no dislocations in the early 3-month postoperative period compared with an early incidence of 3% with 28-mm heads in a MoM device [12, 57]. More recently we reported on dislocation rates in primary THA with large heads, > 36 mm in diameter, in several material combinations, including 1635 large-diameter MoM THAs [39]. With a mean followup of 3 years, only one dislocation occurred. Recently there have been concerning reports of adverse reactions to metal debris (ARMD), pseudotumors, and systemic complications to metal ions [1, 9, 15, 19, 20, 35, 46, 47, 53, 54, 56, 63, 65]. Three large-diameter MoM devices have been voluntarily recalled by the manufacturers [64]. However, reports indicate considerable variation in ARMD frequency and outcomes between different devices and sometimes even for the same device [9, 16, 26, 29, 32, 34, 44, 46, 47, 60]. For example, although some researchers have reported good survival and a low incidence of ARMD with the Magnum™ device in THA (Biomet, Inc, Warsaw, IN, USA) [29, 44, 60], two studies have reported a high incidence of ARMD with pseudotumor formation when a comprehensive intensive screening protocol was implemented, revealing rates of 39% at 3.6 years in one study [9] and 54% definite, probable, or possible ARMD at a mean followup of 6 years [46].

There is much debate about and several unresolved issues with respect to large-diameter MoM THAs, including the appropriate indications for these devices, whether any large-diameter MoM THA devices are safe to use in some patient populations, what risk factors are for ARMD and device failure, what the long-term patient-reported outcomes and survival are of large-diameter MoM bearings in THA, and what is the best practice for monitoring patients who have these devices. It is estimated that more than 1,000,000 MoM bearings were used worldwide since 1996, and national registry data have indicated failure rates two to three times higher with these devices in THA compared with non-MoM bearings [30]. Likewise, our center reported a nearly twofold higher failure rate with MoM bearings in THA compared with metal-on-improved polyethylene bearings (4% versus 2%, respectively) [48]. Our early experience with MoM THA was very promising, and we became confident that we were providing the most durable, functional articulation possible for our patients. Then we began seeing some puzzling failures with unexplained pain, normal radiographic appearance, well-fixed components at the time of revision, and in some cases alarming soft tissue changes. Failures became more frequent and we learned more about ARMD as well as other modes of failure with these devices. We ceased using all metal-on-metal bearings several years ago but must continue to treat and care for our patients who have had MoM THA. Certainly further study of these devices and continued monitoring of patients with these devices are warranted to determine what the frequency of failure is for our center and determine how best to manage our patients who have large-head MoM THA.

This study therefore attempts to determine at a minimum of 2 years' followup (1) the proportion of patients who experienced a dislocation in a large series of large-diameter MoM THAs involving two designs by a single manufacturer; (2) the short-term survivorship obtained with these implants; (3) the causes of failure and the proportion of patients who developed ARMD in this series; and (4) whether there were any identifiable risk factors for revision such as sex, disease profile, procedure type, age, height,

Fig. 1 The M2a-38 design (Biomet, Inc, Warsaw, IN, USA) was introduced at our center in October 2001. It is a monoblock CoCr acetabular component with a fixed 38-mm inner diameter, increasing outer diameter, and applied Ti-PPS fixation surface.

Fig. 2 The Magnum^{TM} design (Biomet, Inc, Warsaw, IN, USA) was used in our center beginning in November 2004 through February 2010. It is a resurfacing style monoblock CoCr acetabular component coated with Ti-PPS and features a 3-mm fixed shell thickness, inner diameters up to 60 mm, and outer diameters up to 66 mm. It articulates with a modular CoCr head component that is effectively 6 mm smaller in diameter than the cup, which is mated with a titanium insert taper adapter.

weight, body mass index (BMI), preoperative clinical scores, cup diameter, cup angle, or stem diameter.

Patients and Methods

Study Design and Setting

We identified all patients who underwent THA at our center and reviewed those performed with MoM articulations with head diameters $\geq$ 38 mm and having minimum 2-year followup. All available clinical records and radiographs were reviewed to determine the frequency of dislocation and failure and the reason for failure. Patients who underwent revision of the acetabular component for any reason were compared with patients who were not revised to determine risk factors for failure.

Between October 2001 and February 2010, 1451 patients (1695 hips) underwent large-diameter MoM primary THA at our institution by two surgeons (AVL, KRB) using two devices from a single manufacturer (Biomet, Inc), which represents 48% (1695 of 3567) of the primary THAs performed during that period. Of the 1695 hips, 55 nonrevised hips were in 51 patients who either died within 2 years of surgery or had not returned for 2-year followup before their death. In addition, 200 nonrevised hips were in 180 patients who have been lost to contact before completing 2-year followup, leaving a cohort of 1440 hips (85%) in 1235 patients with minimum 2-year followup available for review. A monoblock CoCr acetabular component with a fixed 38-mm inner diameter, increasing outer diameter, and applied porous plasma-sprayed titanium (Ti-PPS) fixation surface, the M2a-38 (Biomet, Inc) (Fig. 1), was used until September 2005 in 636 THAs. A resurfacing style monoblock CoCr acetabular component coated with Ti-PPS, the Magnum^{TM} (Biomet, Inc) (Fig. 2), features a 3-mm fixed shell thickness, inner diameters up to 60 mm, and articulates with a modular CoCr head component, 6 mm smaller in diameter than the cup, that mates with a titanium insert taper adapter, and was used beginning in November 2004 in 804 THAs. Clinical records and radiographs were reviewed to determine incidence and etiology of acetabular revision. Patients whose THAs were revised were compared with patients with surviving THAs to identify risk factors.

Participants/Study Subjects

The main indications for the use of large-diameter MoM THAs during the study period were THAs in patients who were younger, more active, and more high demand, and who were perceived to have the potential for benefit from an alternate bearing. We also used them in patients who were considered at a higher risk of instability and dislocation postoperatively and in patients with adequate bone stock to achieve stable fixation without the use of adjunct screw fixation. A contraindication for the use of large-diameter MoM devices was in patients with a known history of renal insufficiency.

Description of Experiment, Treatment, or Surgery

The surgical approach for the majority of patients was direct lateral, used in 94% of hips (1351 of 1440). Of those,

a less invasive modification introduced in 2003 was used in 902 hips. A muscle-sparing anterior supine intermuscular approach was used in 6% (88 of 1440), and a less invasive posterior approach was used in one. All femoral components implanted were made by the same manufacturer as the MoM acetabular components used (Biomet, Inc): two were cemented, CoCr primary components and two were cementless, titanium revision components; all others were cementless, titanium primary stems with 78% Mallory-Head Porous (1121 of 1440), 21% TaperLoc Microplasty (301 of 1440), and 14 TaperLoc. All devices used in this study were cleared by the US Food and Drug Administration and were used according to labeling provided.

Aftercare

Patients were allowed immediate full weightbearing with the assistance of ambulatory aids. Ambulatory aids were discontinued because the patient walked with a minimal or no limp and without pain. All patients were instructed to use the same postoperative hip precautions for 6 weeks, including to sleep on their back, use an elevated toilet seat, use a cushion in all low chairs, not to flex at the waist past 90°, and to avoid excessive adduction such as crossing one leg over the other.

Variables, Outcome Measures, Data Sources, and Bias

Patients returned to our clinic for followup in the immediate postoperative period at approximately 6 weeks and then were instructed to return yearly thereafter or sooner if a problem arose. Patients were assessed at each followup time using the Harris hip score (HHS) [18] and, beginning in 2011, the UCLA activity score [3]. Patients presenting postoperatively with a painful THA were evaluated in a similar fashion to patients with painful THA of any bearing type including clinical history, physical examination, radiographs, and laboratory testing for infection, searching for possible extrinsic as well as intrinsic causes. Using a risk stratification process, if the THA is suspicious for ARMD, further testing may be performed including hip aspiration with manual cell count, whole body bone scan, electromyography, serum metal ion testing, ultrasound, CT scan, and/or magnetic artifact reduction sequence (MARS) MRI studies [30, 36]. Postoperative records were reviewed to determine the frequency of dislocation and the frequency and reasons for component revision. Our understanding of ARMD evolved over the course of the study and continues to evolve. In five patients revised before 2007 for unexplained pain, determination of ARMD was based mainly on intraoperative findings. Since that time, as better means of diagnosis have become more widely available, ARMD has been better identified before revision. Patients with components that were revised for any reason were compared with patients not revised in terms of preoperative demographics including age at surgery, sex, underlying disease profile, height, weight, BMI, preoperative HHS, and perioperative factors including procedure type, surgical approach, cup outer diameter, head diameter, neck length, and stem diameter. Radiographic assessment was performed to measure the inclination (abduction) angle of the acetabular component on the AP pelvis view at 6 weeks postoperatively. Measurements were done by a blinded observer (JBA) on digital radiographs using Intelerad software (Montreal, Quebec, Canada). The angle between the inferior aspect of the ischium and the face of the acetabular component was measured using a Cobb angle tool.

Statistical Analysis and Study Size

Analysis of device survival/failure times were displayed using Kaplan-Meier curves and significance testing was done using proportional hazards models. An initial exploratory analysis was performed looking at several potential risk factors (gender, BMI, activity level, stem diameter, age, etc) individually. Those factors that were associated with p values < 0.2 were used in a multivariable proportional hazards regression model and significance was assessed at the 0.05 level. Adjusted risk ratios and their 95% confidence intervals (CIs) are reported for significant factors. All analyses were carried out using JMP/11 Pro ® software (SAS Institute, Cary, NC, USA).

Demographics and Description of Study Population

Diagnosis by hip for the majority of patients was osteoarthritis (81% [1161 of 1440]), mean patient age at surgery was 58 years (SD 10), and 55% of patients were males (677 of 1235, 787 of 1440 hips) (Table 1). Activity level was categorized as light labor for the majority of patients (51%; 740 of 1440) followed by moderate manual labor in 28% (401 of 1440).

Accounting for All Patients and Study Subjects

All patients had minimum 2-year followup (mean, 7 years; range, 2–12 years). No patients were recalled specifically for this study; all data were obtained from medical records and radiographs.

Table 1. Demographic and perioperative variables for all patients with minimum 2-year followup

Characteristic	Overall	Range
Number of hips	1440	
Sex by hip		
Male	787 (55%)	
Female	653 (45%)	
Mean age (years)	58 (10)	19–91
Mean height (inches)	68 (4)	53–80
Mean weight (pounds)	205 (50)	103–488
Mean body mass index (kg/m^2)	31 (7)	17–69
Mean preoperative Harris hip score	51 (11)	2–90
Diagnosis for primary THA		
Osteoarthritis	1161 (81%)	
Avascular necrosis	132 (9%)	
Developmental dysplasia	60 (4%)	
Posttraumatic arthritis	23 (2%)	
Rheumatoid arthritis	18 (1%)	
Legg-Calvé-Perthes	19 (1%)	
Slipped capital femoral epiphysis	12 (1%)	
Acute fracture	11 (1%)	
Psoriatic arthritis	1 (< 1%)	
Ankylosing spondylitis	1 (< 1%)	
Osteopetrosis	1 (< 1%)	
Paget's disease	1 (< 1%)	
Activity level		
Sedentary	56 (4%)	
Semisedentary	153 (11%)	
Light labor	740 (51%)	
Moderate manual labor	402 (28%)	
Heavy manual labor	89 (6%)	
Surgical approach		
Direct lateral	1351 (94%)	
Anterior supine intermuscular	88 (6%)	
Posterior	1 (< 1%)	
Acetabular component		
M2a-38 (Biomet, Inc, Warsaw, IN, USA)	636 (44%)	
Magnum™ (Biomet, Inc)	804 (56%)	
Femoral component type		
Cemented cobalt-chromium	2 (< 1%)	
Standard titanium porous plasma-sprayed taper	1135 (79%)	
Short titanium porous plasma-sprayed taper	301 (21%)	
Revision titanium porous plasma-sprayed	2 (<1%)	
Mean cup diameter (mm)	55 (4)	46–66
Mean cup angle of inclination (degrees)	44 (6)	24–70
Mean stem diameter (mm)	12 (3)	5–20
Mean followup (years)	7 (3)	2–12
Mean postoperative Harris hip score	84 (16)	26–100
Mean postoperative UCLA score	5 (2)	1–10

In parentheses are SDs for mean values and percentages for counted values.

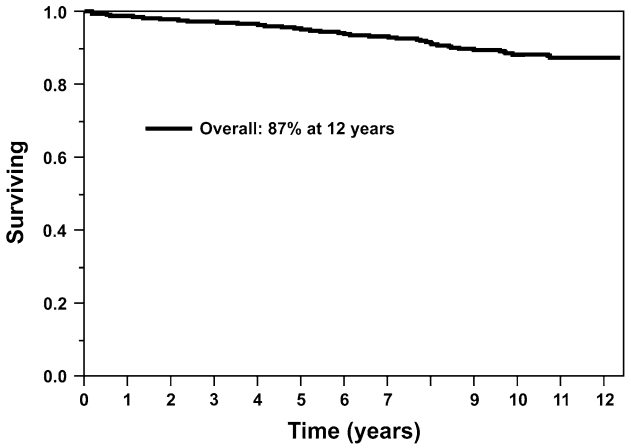

Fig. 3 Kaplan-Meier analysis revealed survival free of component revision was 87% at 12 years for the 1235 patients with 1440 large-diameter MoM THA in our study.

Results

Dislocation occurred in one hip of 1440 (< 1%) 2 years after primary THA, and the patient was treated with acetabular revision because of recurrent dislocation after closed reduction and cast-bracing. Unfortunately, the patient, although initially alert and oriented after the operative procedure, experienced a cerebrovascular accident in the afternoon on the day of surgery and died a few days later.

Kaplan-Meier analysis revealed survival free of component revision was 87% at 12 years (95% CI, 84%–90%) (Fig. 3). There was no difference in survival between the two acetabular devices used (Fig. 4). A total of 108 hips in 102 patients have been revised at a mean time of 4 years postoperative (range, same day to 11 years; SD 3). Ninety-six of these revisions have been the result of aseptic causes.

Indications for revision were dislocation in 1% (one of 108), acetabular aseptic loosening or failure of ingrowth in 31% (34 of 108) of revised hips, well-fixed acetabular components revised unrelated to the articulation in 9% (10 of 108), infection treated with two-stage exchange in 11% (12 of 108), acetabular malposition revised the same day in one hip, periprosthetic femoral fracture treated with stem

exchange only in 3% (three of 108), and ARMD with elevated serum metal ions, pseudotumor formation, and/or soft tissue damage present on revision in 44% (47 of 108). Complete revision operative records were available for 45 of 47 patients revised for ARMD. Corrosion at the neck/head junction was present in 40% (18 of 45) and pseudotumor was noted in 49% (22 of 45) of ARMD revised patients.

Age at surgery, cup angle of inclination, and sex were all risk factors for component revision after controlling for potentially confounding variables (Table 2). Increasing cup angle and female sex were associated with poor survivorship, whereas older patients had better outcomes. Height, weight, BMI, underlying diagnosis, preoperative HHS, activity level, surgical approach, cup type and diameter, and stem type and diameter were not risk factors for revision.

Discussion

MoM bearings were reintroduced in THAs in the 1990 s in response to the shortcoming of articulations with polyethylene, namely osteolysis and loosening secondary to polyethylene wear, and high rates of dislocation. Early results with MoM bearings certainly were promising [14, 37, 38]. Based on the success of large-diameter MoM bearings in hip resurfacing arthroplasty and a desire for enhanced stability and durability, MoM designs for THA evolved to larger diameter head sizes. Although dislocation rates have decreased with the move to larger head diameters, failure rates have increased (Table 3). Amid numerous reports of high failure rates and concerning reports with ARMD, pseudotumors, and systemic complications to metal ions [1, 6, 9, 16, 19, 20, 24, 31, 35, 40, 46, 47, 53, 54, 56, 63, 65], three large-diameter MoM devices have been voluntarily recalled by the manufacturers: the Articular Surface Replacement (ASR) by DePuy (Warsaw, IN, USA), the Durom by Zimmer (Warsaw, IN, USA), and the R3 by Smith & Nephew (Memphis, TN, USA) [64]. Published studies have reported considerable variation in frequency of ARMD and failure for large-diameter devices [9, 16, 26, 29, 32, 34, 44, 46, 47, 60]. Our center previously reported a higher frequency of revision in patients with MoM THA compared with metal-on-improved polyethylene THA [48]. In an effort to monitor the results of the treatments we perform and strive for the best possible care of our patients, continued followup of our patients with MoM THA is necessary. The present study therefore sought to evaluate a large group of these patients at a minimum followup of 2 years, specifically with respect to dislocation, implant survivorship, the causes of failure (and the frequency of ARMD), and risk factors for revision.

The first limitation of our study is that it was retrospective and therefore may be subject to selection bias. We tended to use large-diameter MoM devices in our younger, more active, more high-demand patients, and perhaps the higher activity levels in these patients resulted in higher rates of wear. Another limitation resulting from the retrospective nature is that 104 patients (126 hips) died during the study period, and 51 of those patients (55 hips) had not been seen for a 2-year clinical followup visit. Only 13 of the patients (14 hips) died before reaching 2 years

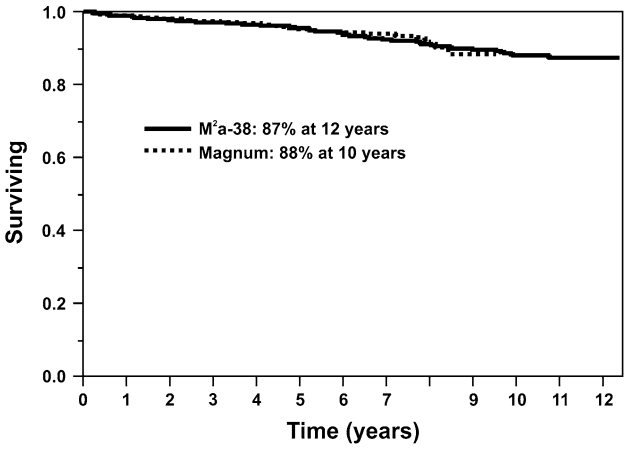

Fig. 4 Kaplan-Meier analysis for the two acetabular devices in our study showed no significant difference in survival, with 87% survival at 12 years for the M2a-38 (Biomet, Inc, Warsaw, IN, USA) and 88% survival at 10 years for the Magnum™ (Biomet, Inc).

Table 2. Risk factors for component failure

Characteristic	Proportion or mean in failures (n = 108)	Proportion or mean in nonfailures (n = 1332)	Risk ratio	Lower 95% CI	Upper 95% CI	p value
Mean age (years)	56 (11, 34–78)	58 (10, 19–91)	0.98 per each increased year	0.9602	0.9966	0.0213
Mean cup angle (degrees)	45 (7, 24–70)	44 (6, 25–66)	1.03 per each increased degree	1.0017	1.0673	0.0390
Sex						0.0315
Male	45 (42%)	742 (56%)	0.5996	0.3740	0.9557	
Female	63 (58%)	590 (44%)	1.6678	1.0463	2.6741	

In parentheses are SDs and ranges for mean values and percentages for counted values; CI = confidence interval.

Table 3. Published results with large-diameter (≥ 36 mm) metal-on-metal THA

Study	Device (patient factors)	Number of THAs	Mean followup (years)	Dislocations	Bearing survival (number revised)	ARMD incidence or mean ion levels
Cuckler et al., 2004 [12]	M2a-38	616	1 (0–2)	0 (0%)	100% (0)	0 (0%)
Stuchin, 2008 [59]	Birmingham	34	1	0 (0%)	100% (0)	0 (0%)
Parmaksizoglu et al., 2009 [51]	Magnum™ (Crowe IV DDH)	15	4 (3–5)	0 (0%)	100% (0)	0 (0%)
Berton et al., 2010 [7]	Durom	100	5	0 (0%)	93% (7)	0 (0%)
Cicek et al., 2010 [10]	Cormet/Optimom	54	4	0 (0%)	98% (1)	0 (0%)
Illgen et al., 2010 [24]	Durom	63	1	0 (0%)	89% (7)	1 (2%)
Long et al., 2010 [40]	Durom	207	2 (1–2)	1 (1%)	86% (30)	0 (0%)
Mertl et al., 2010 [45]	Durom	106	3	2 (2%)	100% (0)	0 (0%)
Zhang et al., 2010 [67]	25 Durom, 34 ASR (elderly)	59	5	0 (0%)	100% (0)	0 (0%)
de Steiger et al., 2011 [13]	ASR	4406	2–7	15 (0%)	95% (210)	26 (1%)
Bolland et al., 2011 [8]	Birmingham	199	5 (3–7)	0 (0%)	92% (17)	14 (7%)
Graves et al., 2011 [16]	ASR	N/A	N/A	N/A	92% at 5 years	N/A
	Ultamet/ArticulEze	(combined from Australian, England and Wales, and New Zealand registries)			97% at 5 years	
	Birmingham				95% at 5 years	
	R3				98% at 1 year	
	Bionik				92% at 3 years	
	Cormet				93% at 5 years	
	Icon				94% at 3 years	
	M^2a-38				95% at 5 years	
	Magnum™				98% at 3 years	
	Durom				95% at 5 years	
	Mitch TRH				99% at 1 year	
	Ultamet/S-ROM				96% at 5 years	
Langton et al., 2011 [31]	ASR	87	6	N/A	51% at 6 years	25 (29%)
Lavigne et al., 2011 [34]	Durom	49	2	N/A	98% (1)	3 µg/L mean blood Co
	Magnum™	19	2		100% (0)	1 µg/L mean blood Co
	ASR	10	2		100% (0)	1 µg/L mean blood Co
	Birmingham	11	2		100% (0)	2 µg/L mean blood Co
Malviya et al., 2011 [42]	Birmingham	50	2	0 (0%)	96% (2)	2 (4%)
Steele et al., 2011 [58]	ASR	105	2 (0–3)	0 (0%)	85% (16)	4 (4%)
Wynn-Jones et al., 2011 [65]	ASR	62	3 (1–4)	0 (0%)	87% (8)	6 (10%)
Yalcin et al., 2011 [66]	Cormet/Optimom (Crowe I and II DDH)	75	5 (3–6)	0 (0%)	100% (0)	0 (0%)

Table 3. continued

Study	Device (patient factors)	Number of THAs	Mean followup (years)	Dislocations	Bearing survival (number revised)	ARMD incidence or mean ion levels
Althuizen et al., 2012 [1]	Durom	64	3	0 (0%)	86% (6)	3 (5%)
Barrett et al., 2012 [5]	Pinnacle/Ultamet	779	4 (2–10)	3 (0%)	97% (21)	7 (1%)
Bernthal et al., 2012 [6]	ASR	70	(2–5)	0 (0%)	83% (12)	0 (0%)
Bosker et al., 2012 [9]	Magnum™	108	4 (3–5)	0 (0%)	88% (13)	42 (39%)
Hasegawa et al., 2012 [19]	Cormet	75	2	0 (0%)	97% (2)	2 (3%)
Hutt et al., 2012 [23]	Durom	84	4 (2–7)	0 (0%)	95% (4)	0 (0%)
Kindsfater et al., 2012 [27]	Pinnacle/Ultamet	85	6 (5–8)	2 (2%)	99% (1)	0 (0%)
Kostensalo et al., 2012 [29]	Magnum™	691	1	0 (0%)	98% (11)	0 (0%)
Lardanchet et al., 2012 [32]	Durom	24	1	1 (4%)	92% (2)	3 µg/L mean serum Co
	Magnum™	23		1 (4%)	100% (0)	2 µg/L mean serum Co
	Conserve	20		0 (0%)	100% (0)	8 µg/L mean serum Co
Meding et al., 2012 [44]	Magnum™	611	3 (2–5)	1 (0%)	100% (3)	0 (0%)
Stürup et al., 2012 [60]	85 M^2a-38, 271 Magnum™	358	4 (1–6)	1 (0%)	95% (17)	1 (0%)
Hasegawa et al., 2013 [20]	Cormet	108	2	0 (0.0%)	94% (7)	12 (11%)
Hosny et al., 2013 [22]	Birmingham	44	5	1 (2.3%)	93% (3)	2 (5%)
Jack et al., 2013 [25]	Birmingham	2101	(0–6)	N/A	95% at 5 years (50)	N/A
Levy and Ezzet, 2013 [35]	Conserve	66	2	0 (0%)	86% (9)	8/78
	Dynasty	12	2	0 (0%)	92% (1)	(10%)
Mokka et al., 2013 [47]	Magnum™	80	6 (5–7)	N/A	96% (3)	43 (54%)
Mokka et al., 2013 [46]	Birmingham	432	3 (0–6)	N/A	98% at 5 years	n/a
	ASR/Summit	495	2 (0–6)		97% at 5 years	
	Magnum™	4202	2 (0–5)		97% at 5 years	
	Durom/CLS	154	4 (1–5)		89% at 5 years	
	M^2a-38	2459	4 (0–8)		96% at 7 years	
	ASR/Corail	120	2 (0–4)		97% at 3 years	
	Durom/ML-taper	197	1 (0–4)		N/A	
Junnila et al., 2014 [26]	Magnum™	5464	3 (0–7)	N/A	97% at 4 years	N/A
	Birmingham	475	4 (0–8)		97% at 4 years	
	ASR	632	4 (0–8)		90% at 4 years	
Park et al., 2014 [50]	Magnum™ (neuromuscular weakness)	19	1	0 (0%)	100% (0)	0 (0%)

Table 3. continued

Study	Device (patient factors)	Number of THAs	Mean followup (years)	Dislocations	Bearing survival (number revised)	ARMD incidence or mean ion levels
Sugano et al., 2014 [61]	Pinnacle Ultamet*	4744	N/A (surgeries done 2000 to 2011 in Japan)	N/A	N/A	63 (1%)
	Conserve	1701				37 (2%)
	Cormet	491				15 (3%)
	Adept	636				7 (1%)
	M²a-Taper, Magnum™*	2777				24 (1%)
	FMP*	956				4 (0%)
	Birmingham	121				0 (0%)
Current study	M²a-38	636	8	1 (0%)	91% (59)	28 (4%)
	Magnum™	804	6	0 (0%)	94% (49)	19 (1%)

* Some smaller head sizes included; ARMD = adverse reaction to metal debris; DDH = developmental dysplasia; ASR = Articular Surface Replacement; N/A = not available; Co = cobalt. Manufacturers: M²a-38, Magnum (Biomet, Inc, Warsaw, IN, USA; Valance, France); Birmingham, R3 (Smith & Nephew, Memphis, TN, USA; Warwick, UK; London, UK; Hull, UK); Cormet (Corin Medical Ltd, Cirencester, UK); Durom, CLS, ML-Taper (Zimmer, Inc, Warsaw, IN, USA; Winterthur, Switzerland; Etupes, France); ASR, Pinnacle Ultamet, ArticulEze, S-ROM, Summit, Corail (DePuy, Inc, Warsaw, IN, USA; Leeds, UK); Bionik (Orthodynamics, Lübeck, Germany), Icon (International Orthopaedics, Geisingen, Germany); Mitch TRH (Stryker, Mahwah, NJ, USA); Conserve, Dynasty (Wright Medical Technology, Arlington, TN, USA; Rueil Malmaison, France), FMP (DJO Surgical, Vista, CA, USA).

postoperative. We know that eight of the patients (nine hips) had revisions before death. The other 96 patients (117 hips) had no known complications or revisions at the time of last followup. Another weakness of the study is that in addition to the 51 patients (55 hips) who died before a 2-year clinical assessment, minimum followup was not available for 200 hips in 180 presumed living patients. The Social Security Death Index was searched for all patients. Attempts were made to contact the patient at their last known address and phone numbers, by contacting referring and family physicians listed, and by searching available free Internet services. However, minimum 2-year clinical followup was available for 85% of patients.

Previous studies from our center with the M2a-38 reported no dislocations in the early followup period compared with an early proportion of 3% with 28-mm heads in a MoM device [12, 57]. We have reported on dislocation rates at our center in primary THA with large heads, $>$ 36 mm in diameter, in several material combinations, including 1635 large-diameter MoM THAs [39]. With mean followup of 3 years, only one dislocation occurred for a frequency of 0.06% compared with an earlier experience involving a primary direct lateral approach THA with small heads ($\leq$ 32 mm) in which the dislocation rate was 1% (12 of 1518) [41]. Likewise, in a report on 8059 cementless THAs with large-diameter MoM articulations from the Finnish Arthroplasty Register, the authors report 11 revisions resulting from dislocation for a rate of 0.1% compared with 175 dislocations in a series of 16,798 cemented metal-on-polyethylene THAs for a rate of 1% [47]. In another report from the Finnish Arthroplasty Register assessing risk of revision for dislocation by head diameter, the risk with head diameters $>$ 36 mm (10,444 hips) was 0.09 compared with 28-mm-sized implants [28].

The Kaplan-Meier survival of 87% at 12 years in the current series of large-diameter MoM THAs with these components is somewhat lower than rates reported in combined data from Australia, England and Wales, and New Zealand [16], data from the Finnish Arthroplasty Register [47], and three independent series (Table 3) [29, 44, 60]. Component survival in the current study was lower than our earlier reported experience with 779 primary THAs with metal-on-improved polyethylene in which we observed 98% survival at 4 years [48]. Likewise, in the 2013 report of the National Joint Registry for England, Wales, and Northern Ireland, the effect of the bearing with a single widely used cup/stem combination, the Pinnacle/Corail (DePuy), was analyzed [49]. They observed that at 8 years postoperatively, the chance of a first revision with a MoM bearing was 11% compared with 2% with a ceramic-on-polyethylene bearing.

The predominant indications for component revision in the current series were ARMD, observed in 48% of hips

revised (47 of 108), and aseptic loosening or failure of ingrowth, observed in 35% (38 of 108). There is considerable variation in published reports as to the risk of revision and ARMD incidence between different large-diameter MoM THA devices as well as for the devices used in the current study (Table 3) [9, 16, 26, 29, 32, 34, 44, 46, 47, 60]. Several studies have reported good survival and a low incidence of ARMD with the devices we used in this report [12, 29, 32, 34, 44, 47, 51, 57, 60, 61]. Two concerning studies involving the Magnum™ device in large-diameter MoM THA have reported a high incidence of ARMD with pseudotumor formation when a comprehensive screening protocol was implemented [9, 46]. Bosker et al. [9] performed CT scans in patients with Magnum™ THA and verified pseudotumors in 39% at mean 4-year followup. They observed a fourfold increased risk of pseudotumor formation when serum cobalt levels were > 5 µg/L and recommended close monitoring of all patients with MoM hip arthroplasty. Mokka et al. [46] conducted MARS MRI screening and serum metal ion testing of a group of patients with Magnum™ THA with mean 6-year followup and identified a 54% incidence of definite, probable, or possible ARMD. In a recent report involving patients with modular Pinnacle MoM THA (DePuy), screening with MARS MRI confirmed a 31% incidence of ARMD asymptomatic patients, raising concern that the need for routine cross-sectional imaging for all asymptomatic patients with MoM implants warrants further study [15].

We previously reported on our experience with all MoM articulations in primary THA through 2006 at our center and observed a higher incidence of failure in females than males [33]. In the current study with additional patients and further followup, we again observed a greater frequency of component failure in females than males (Table 2). Register data from Australia have shown higher risk revision for females than males who have undergone primary MoM THA with head sizes > 32 mm [4]. However, there was no appreciable difference in revision risk between males and females with head sizes ≤ 32 mm. Younger age in our study was a risk factor for revision (Table 2) with risk multiplied by 0.978 (decreased by approximately 2%) for each increased year of age at surgery. The Australian National Joint Replacement Registry also reported poorer results in younger patients with a cumulative percent revision for primary MoM THA of 21.8 at 12 years in patients < 55 years old and 12.1 in patients ≥ 75 years old [4]. Increased cup angle of inclination was a risk factor revision in the current study (Table 2) with an increased risk of 3% for each increase of one degree. Several studies of MoM resurfacing hip arthroplasty have correlated excessive angle of inclination with elevated serum and joint fluid levels of metal ions and increased wear secondary to edge loading [30]. However, in our study only 3% of cups overall (41 of 1440) and only 5% of cups (five of 108) in patients who underwent component revision had an angle of inclination $> 55°$. Height, weight, BMI, underlying diagnosis, preoperative HHS, activity level, surgical approach, cup type and diameter, and stem type and diameter did not correlate with risk of revision in the current study.

Large-diameter MoM THAs are associated with a very low dislocation rate. However, the revision rate with these devices was higher than expected. Failure secondary to ARMD or lack of ingrowth has been frequent. Taper corrosion may represent an additional source of metal debris. Risk factors for revision were younger age, female sex, and increased angle of cup inclination. In our practice we have discontinued the use of MoM devices. Patients with MoM devices, like all patients with total joint arthroplasties, should be encouraged to return for clinical and radiographic followup. Closer monitoring of patients with MoM implants has been recommended by several regulatory agencies and consensus groups of physicians [2, 16, 17, 21, 30, 36, 43, 62]. As we have previously stated, there should be a low threshold to perform a systematic evaluation of patients with MoM THA because early recognition and diagnosis will facilitate the initiation of appropriate treatment before significant adverse biological reactions occur [30, 36].

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