

Prevalence of and Risk Factors for Hip Resurfacing Revision

A Cohort Study Into the Second Decade After the Operation

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Background: Most metal-on-metal hip resurfacing (MoMHR) designs have experienced high short-term failure rates because of pseudotumors. The impact of this complication into the second decade after the procedure is unknown. We investigated (1) the prevalence of, and risk factors for, all-cause and pseudotumor-related revision at up to 15 years following MoMHR and (2) whether risk factors were sex-specific.

Methods: This single-center prospective cohort study included 1,429 MoMHRs (1216 patients; 40% female) implanted between 1999 and 2009. Patients were contacted in 2010 and 2012 as per national recommendations. Patients with symptoms related to the hip and/or suboptimal Oxford Hip Scores (≤ 41 of 48 points) underwent cross-sectional imaging and blood metal-ion sampling. Revision diagnoses were established using operative and histopathological findings. Multivariate Cox proportional hazard models were used to assess the association of predictor variables with the time to all-cause and pseudotumor-related revisions.

Results: One hundred and eighty MoMHRs (12.6%) were revised for all causes, and 111 (7.8% of the series and 61.7 % of all revisions) were revised because of pseudotumor. Survival analysis showed the 15-year cumulative revision rate for all causes to be 19.5% (95% confidence interval [CI] = 16.2% to 23.2%) and the 15-year rate of revision due to pseudotumor to be 14.0% (95% CI = 11.0% to 17.7%). Small femoral head size (hazard ratio [HR] per 2 mm = 0.92, 95% CI = 0.88 to 0.97; $p = 0.003$) and certain implant designs (HR = 1.55 to 3.01; $p \leq 0.029$) significantly increased the all-cause revision risk. Female sex (HR = 2.03, 95% CI = 1.19 to 3.44; $p = 0.009$) and young age (HR per year = 0.98, 95% CI = 0.96 to 1.00; $p = 0.020$) significantly increased the pseudotumor-related revision risk but not the all-cause revision risk. Risk factors for all-cause and pseudotumor-related revision were sex-specific. In females, small femoral head size ($p = 0.014$) increased the all-cause revision risk, and young age was the only predictor of pseudotumor-related revision ($p = 0.019$). In males, implant design was the only predictor of all-cause revision ($p \leq 0.015$) and pseudotumor-related revision ($p = 0.001$).

Conclusions: The prevalence and rates of revision for all causes and pseudotumor were high at up to 15 years following MoMHR. Predictors of revision differed between all-cause and pseudotumor-related revisions and were sex-specific. These factors must be appropriately weighted when risk-stratifying patients with MoMHRs for surveillance.

Level of Evidence: Prognostic Level II. See Instructions for Authors for a complete description of levels of evidence.

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High short-term failure rates (9.7% to 12.6% at 10 years) have been reported for most metal-on-metal hip resurfacing (MoMHR) designs^{1,2}. Revisions have

commonly been due to pseudotumors^{3,4}, with the prevalence of this complication increasing annually¹. Pseudotumor-related revision rates of 4% at 8 years have been reported⁵, with rates

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TABLE I Indications for Revision Surgery (N = 180)

Indication for Revision	No. (%) of Revised Hips		
	Whole Cohort	Females Only	Males Only
Pseudotumor	111 (61.7)	72 (67.3)	39 (53.4)
Femoral neck fracture	29 (16.1)	9 (8.4)	20 (27.4)
Aseptic loosening of acetabular component	8 (4.4)	7 (6.5)	1 (1.4)
Unexplained pain	7 (3.9)	5 (4.7)	2 (2.7)
Deep infection	5 (2.8)	2 (1.9)	3 (4.1)
Aseptic loosening of femoral component	4 (2.2)	3 (2.8)	1 (1.4)
Malposition of acetabular component with or without malposition of femoral component	4 (2.2)	3 (2.8)	1 (1.4)
Dislocation	4 (2.2)	2 (1.9)	2 (2.7)
Osteonecrosis of femoral head	4 (2.2)	3 (2.8)	1 (1.4)
Aseptic loosening of both components	2 (1.1)	1 (0.9)	1 (1.4)
Pain from impingement	1 (0.6)	0 (0)	1 (1.4)
Heterotopic ossification	1 (0.6)	0 (0)	1 (1.4)
Total	180 (100)	107 (100)	73 (100)

up to 25% at 6 years for implants withdrawn from the market⁶. Regular surveillance is therefore recommended for patients with MoMHR implants⁷⁻⁹.

Risk factors for all-cause MoMHR revision include female sex, small femoral components, implant design, and hip diagnoses other than primary osteoarthritis¹⁰⁻¹³. Pseudotumor risk factors are similar^{4,5} but also include malposition of the acetabular component^{14,15}. Sex and femoral component size have complex interactions. Smaller components are more common in females as a result of anatomical differences, with females more frequently having abnormal acetabular anatomy compromising component placement,^{5,11} as well as metal allergies, which have been implicated in pseudotumor formation^{3,16}. Authors of large MoMHR cohort studies have reported mixed conclusions regarding sex and femoral head size; some have suggested that female sex is the most important risk factor for failure^{10,17}, while others have suggested that small components^{11,18} or a combination of both factors are the most important¹². Regulatory authorities recently recommended against future implantation of the Birmingham Hip Resurfacing (BHR) prosthesis in all female patients and in males requiring small components (≤ 48 mm), with regular follow-up advised for these subgroups¹⁹.

Although studies assessing the prevalence of, and risk factors for, MoMHR revision have involved large cohorts, they have been limited by short-term follow-up (mean, 3.4 to 7.1 years)^{5,10-12,17,18}, with only one study specifically reporting pseudotumor prevalence and risk factors⁵, to our knowledge. The prevalence of all-cause and pseudotumor-related revision into the second decade following MoMHR arthroplasty is unknown, and given previous study limitations the reported risk factors for revision may be inaccurate. Knowledge of the correct revision predictors is important to inform follow-up regimens²⁰, given that >1 million MoM hip prostheses have been implanted and require surveillance.

Registry studies potentially underestimate MoMHR revisions by up to 39%, with outcomes frequently coded incorrectly²¹. Furthermore, registries introduced pseudotumor as a revision indication only in 2009, without recording histopathological results¹. Therefore, large cohort studies with detailed data and revision indications determined with histopathological analysis are the best way to assess the prevalence of all-cause and pseudotumor-related revisions.

We investigated (1) the prevalence of, and risk factors for, all-cause and pseudotumor-related revisions at up to 15 years following MoMHR, and (2) whether risk factors were sex-specific.

Materials and Methods

This single-center prospective cohort study included patients treated with primary MoMHR between June 1999 and December 2009. Only patients with a minimum of 1 year of follow-up were included. There were 1,429 MoMHRs (1,216 patients) eligible for inclusion. Seven surgeons who had no role in the design of the implants performed all operations using four designs: BHR (Smith & Nephew), Conserve Plus (Wright Medical Technology), ReCap (Biomet), and Cormet (Corin).

All patients were contacted in 2010 and 2012 because of alerts from the Medical and Healthcare products Regulatory Agency (MHRA)^{7,22}. This contact involved a postal questionnaire inquiring about hip problems (pain, swelling, noises) and asking for completion of the Oxford Hip Score questionnaire (OHS; 0 = worst outcome and 48 = best outcome)^{23,24}. Patients with hip symptoms and/or a suboptimal OHS (≤ 41 of 48 points)²⁵ were evaluated as per MHRA recommendations⁷, using cross-sectional imaging²⁶ and testing of blood metal-ion levels.

Data extracted from our prospectively maintained database included demographics (sex and age), primary hip diagnosis, and details regarding the MoMHR (design, component size, and whether the patient had bilateral implantation). The database and hospital records were reviewed for all patients to determine whether the MoMHR had been revised (including date, indication, surgical findings, and components removed/implanted). Revision surgery was defined as removal or exchange of any MoMHR component. The diagnoses

TABLE II Patient and Implant Factors: No Revision Versus Revision for Any Indication and No Pseudotumor-Related Revision Versus Pseudotumor-Related Revision

	Whole Cohort (N = 1,429)	No Revision (N = 1,249)	Revision for Any Indication (N = 180)	P Value	No Pseudotumor- Related Revision (N = 1,318)	Pseudotumor- Related Revision (N = 111)	P Value
Sex (no. [%])				<0.001*			<0.001*
Male	853 (59.7)	780 (62.4)	73 (40.6)		814 (61.8)	39 (35.1)	
Female	576 (40.3)	469 (37.6)	107 (59.4)		504 (38.2)	72 (64.9)	
Mean age (range) (yr)	53.8 (16.5-85.5)	53.9 (16.5-85.5)	52.6 (19.5-71.8)	0.111	54.0 (16.5-85.5)	51.5 (28.7-69.9)	0.011*
Laterality (no. [%])				0.246			0.814
Unilateral	1,003 (70.2)	870 (69.7)	133 (73.9)		924 (70.1)	79 (71.2)	
Bilateral	426 (29.8)	379 (30.3)	47 (26.1)		394 (29.9)	32 (28.8)	
Hip diagnosis (no. [%])				0.880			0.439
Primary osteoarthritis	1,253 (87.7)	1,096 (87.8)	157 (87.2)		1,155 (87.6)	98 (88.3)	
Dysplasia	122 (8.5)	107 (8.6)	15 (8.3)		115 (8.7)	7 (6.3)	
Other	54 (3.8)	46 (3.7)	8 (4.4)		48 (3.6)	6 (5.4)	
Mean femoral head size (range) (mm)	48.4 (38-58)	48.7 (38-58)	46.8 (38-54)	<0.0001*	48.6 (38-58)	46.6 (38-54)	<0.0001*
Implant (no. [%])				0.098			0.481
Birmingham Hip Resurfacing	641 (44.9)	563 (45.1)	78 (43.3)		591 (44.8)	50 (45.0)	
Conserve	631 (44.2)	551 (44.1)	80 (44.4)		584 (44.3)	47 (42.3)	
ReCap	139 (9.7)	123 (9.8)	16 (8.9)		128 (9.7)	11 (9.9)	
Cormet	18 (1.3)	12 (0.96)	6 (3.3)		15 (1.1)	3 (2.7)	

*A significant difference ($p < 0.05$).

leading to the revision were determined using results of preoperative investigations and operative records. A revision was considered to be due to a pseudotumor if the operative and histological findings confirmed this²⁶. If a revision had been performed elsewhere, the institution was contacted to obtain data. Revisions were identified as having occurred elsewhere when the patient informed us by telephone or mail, the patient provided revision details while being seen for other reasons, or the primary surgeon identified a revision in their registry profile¹.

For the assessment of implant survival, patients were censored on the date of revision surgery or, if the MoMHR was not revised, on the date of their most recent clinical examination or questionnaire completion. The last potential follow-up date for this study was August 24, 2015. No patient who had undergone MoMHR was awaiting revision at the time of writing.

Statistical Analysis

The outcomes of interest were the time from the MoMHR to revision (1) for any indication and (2) due to pseudotumor. Predictive factors considered were age at the time of MoMHR surgery, sex, unilateral or bilateral MoMHR, primary diagnosis (primary osteoarthritis, dysplasia, or other), MoMHR design, and femoral component size. Differences in these covariates between the revision and non-revision groups were assessed using unpaired *t* tests for numerical data and either the chi-squared test with Yates' correction or Fisher's exact test for categorical data.

Survival analysis was performed using the Kaplan-Meier method. Cox proportional hazards models (univariate and multivariate) were used to assess the association of the predictor variables with the time to revision for each

survival end point. For continuous predictors, fractional polynomial regression modeling was used to assess the assumption of linearity with outcome, with data categorized if the assumption was not satisfied. Likelihood ratio tests were used to assess evidence of 2-way interactions between sex and other predictors. Because of collinearity of sex and femoral component size, all subsequent analyses were stratified by sex. The significance level was $p < 0.05$, with 95% confidence intervals (CIs) also used.

Results

One hundred and eighty MoMHRs (in 156 patients) were revised for all causes at a mean of 4.8 years (range, 0.01 to 15.5 years) after the arthroplasty (Table I). The remaining 1,249 MoMHR implants (in 1,060 patients) remained in situ at the time of the latest follow-up, at a mean of 8.4 years (range, 1.0 to 15.4 years); the median OHS was 46 points (interquartile range, 42 to 48 points) at this time. A follow-up questionnaire was available for 94.9% (1,185) of the surviving hips (see Appendix).

All-Cause Revision

Prevalence and Risk Factors

The prevalence of all-cause revision was 12.6% (180 of 1,429). Risk factors for all-cause revision, which are summarized in Table II, were sex-specific.

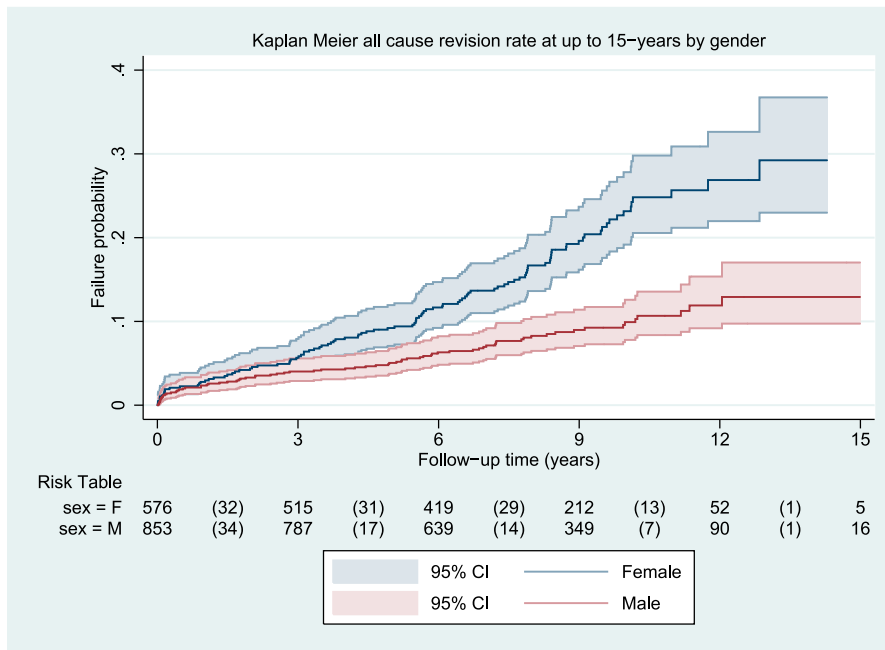


Fig. 1

Results of Kaplan-Meier survival analysis of the all-cause MoMHR revision rate up to 15 years for each sex. The shaded areas represent the respective upper and lower limits of the 95% CIs. The risk table indicates the number of hips at risk at 3-year intervals, with the number of hips revised during the 3-year interval in parentheses. The all-cause revision rate at 13 years was 29.2% (95% CI = 23.0% to 36.7%; 27 hips at risk) in females compared with 12.9% (95% CI = 9.7% to 17.0%; 57 hips at risk) in males. A univariate Cox proportional hazards model demonstrated that female sex was a significant predictor of all-cause revision (HR = 2.25, 95% CI = 1.67 to 3.04; $p < 0.001$).

Survival Analysis

The all-cause MoMHR cumulative revision rate was 19.5% (95% CI = 16.2% to 23.2%) at 15 years. Factors associated with a significantly increased revision risk in the univariate analyses

were female sex (Fig. 1), small femoral head size, and implant design. Multivariate Cox models (Table III) demonstrated that small femoral head size ($p = 0.003$) and non-BHR implants ($p \leq 0.029$) significantly increased revision risk; however, the

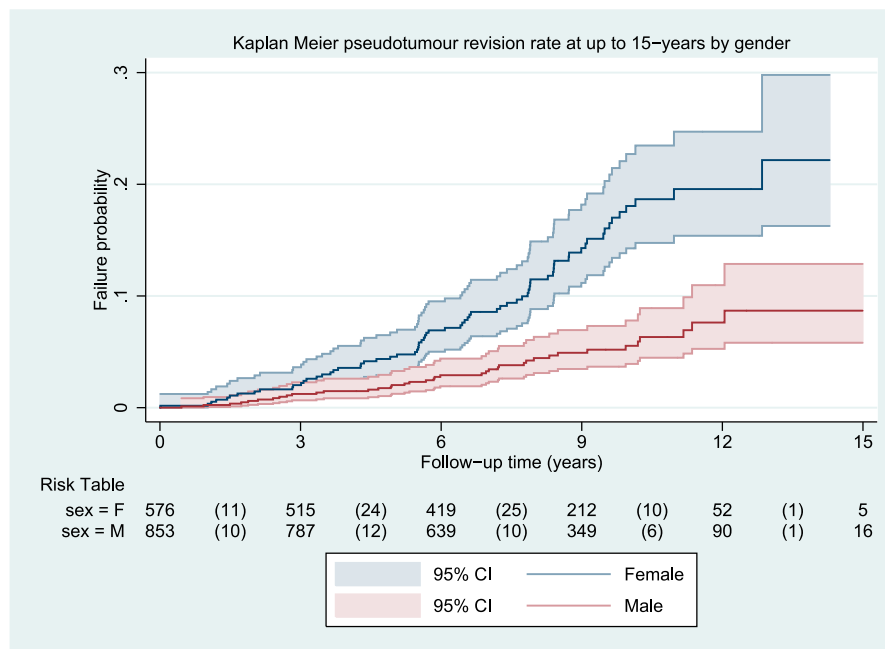


Fig. 2

Results of Kaplan-Meier survival analysis of the pseudotumour-related MoMHR revision rate up to 15 years for each sex. The shaded areas represent the respective upper and lower limits of the 95% CIs. The risk table indicates the number of hips at risk at 3-year intervals, with the number of hips revised during the 3-year interval in parentheses. The pseudotumour-related revision rate at 13 years was 22.2% (95% CI = 16.3% to 29.8%; 27 hips at risk) in females compared with 8.7% (95% CI = 5.8% to 12.9%; 57 hips at risk) in males. A univariate Cox proportional hazards model demonstrated that female sex was a significant predictor of pseudotumour-related revision (HR = 2.86, 95% CI = 1.93 to 4.22; $p < 0.001$).

TABLE III Multivariate Cox Proportional Hazards Models for Identifying Patients at Risk of Revision for Any Indication and for Pseudotumor*

Covariate	Revision for Any Indication					
	Whole Cohort		Females Only		Males Only	
	HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
Female vs. male	1.48 (0.98-2.22)	0.062	NA	NA	NA	NA
Age (per year)	0.99 (0.98-1.01)	0.252	0.98 (0.96-1.00)	0.062	1.01 (0.98-1.03)	0.594
Bilateral vs. unilateral	0.86 (0.62-1.21)	0.399	0.90 (0.58-1.41)	0.645	0.83 (0.48-1.42)	0.492
Hip diagnosis						
Primary osteoarthritis	1.00	Baseline	1.00	Baseline	1.00	Baseline
Dysplasia	0.80 (0.46-1.40)	0.441	0.75 (0.41-1.40)	0.370	0.62 (0.15-2.55)	0.505
Other	1.37 (0.65-2.85)	0.407	1.92 (0.79-4.67)	0.152	0.74 (0.18-3.10)	0.681
Femoral head size (per 2-mm)	0.92 (0.88-0.97)	0.003†	0.92 (0.85-0.98)	0.014†	0.94 (0.87-1.02)	0.166
Implant						
Birmingham Hip Resurfacing	1.00	Baseline	1.00	Baseline	1.00	Baseline
Conserve	1.55 (1.10-2.17)	0.012†	1.14 (0.73-1.76)	0.568	2.51 (1.41-4.46)	0.002†
ReCap	1.86 (1.07-3.25)	0.029†	1.48 (0.66-3.31)	0.346	2.78 (1.22-6.31)	0.015†
Cormet§	3.01 (1.30-6.95)	0.010†	3.49 (1.36-8.94)	0.009†	1.88 (0.25-14.11)	0.539

*HR = hazard ratio, and NA = not applicable. †A significant difference ($p < 0.05$). ‡Value cannot be estimated as there were no hips in this particular subgroup. §Although Cormet implants had a statistically significantly increased risk of all-cause revision in females, it is acknowledged that only 18 Cormet designs were implanted in the whole cohort.

effect of female sex ($p = 0.062$) was no longer significant in the multivariate model for the whole cohort.

When the MoMHRs were divided by the sex of the patient (Table III), a multivariate Cox model analysis of the female group demonstrated that small femoral head size ($p = 0.014$) and implantation of a Cormet design ($p = 0.009$) significantly increased revision risk. However, only 18 Cormet designs were implanted in this series. The multivariate model for the male group identified Conserve ($p = 0.002$) and ReCap ($p = 0.015$) MoMHRs as the only factors significantly increasing revision risk.

Pseudotumor-Related Revision

Prevalence and Risk Factors

Of the 1,429 MoMHRs, 111 (7.8%) in 95 patients were revised because of pseudotumor at a mean of 6.1 years (range, 0.5 to 15.5 years). Pseudotumor accounted for 61.7% of all revisions (Table I). Risk factors for pseudotumor-related revisions are summarized in Table II and were sex-specific.

Survival Analysis

The pseudotumor-related revision rate for all MoMHRs was 14.0% (95% CI = 11.0% to 17.7%) at 15 years. Univariate analyses demonstrated that factors significantly increasing the risk of pseudotumor-related revision were female sex ($p < 0.001$; Fig. 2), small femoral head size ($p < 0.001$), young age at the time of the MoMHR ($p = 0.011$), and Conserve ($p = 0.009$) and ReCap ($p = 0.007$) implants. All factors remained significant in the multivariate model (Table III).

When the MoMHRs were divided by the patient's sex (Table III), a multivariate Cox model showed young age to be the only covariate significantly increasing pseudotumor-related revision risk in the female group ($p = 0.019$). Small femoral head size was not significantly associated with pseudotumor-related revision in females ($p = 0.189$). The multivariate model identified Conserve ($p = 0.001$) and ReCap ($p = 0.001$) implants as the only factors significantly increasing pseudotumor-related revision risk in the male group.

Discussion

We believe this to be the first independent study providing information on revision risk into the second decade following MoMHR. The prevalences of revision for all causes (12.6%) and for pseudotumor (7.8%) were high, with 15-year revision rates of 19.5% and 14.0%, respectively. The predictors of all-cause revisions (small femoral head size and non-BHR implants) differed from the predictors of pseudotumor-related revisions (female sex, small femoral head size, young age, and Conserve and ReCap implants). Furthermore, the predictors were sex-specific; implant design was the only predictor of all-cause and pseudotumor-related revisions in males whereas, in females, small femoral head size was the only predictor of all-cause revisions and young age was the only factor predicting pseudotumor-related revision.

To our knowledge, 15-year outcomes have been reported in only one study, by a surgeon involved in the design of a commonly used hip resurfacing implant²⁷. That study showed an overall revision rate of 4.2% following 1,000 BHRs. Our inferior rates are likely related to numerous factors, including patient

TABLE III (continued)

Whole Cohort		Revision for Pseudotumor			
		Females Only		Males Only	
HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
2.03 (1.19-3.44)	0.009†	NA	NA	NA	NA
0.98 (0.96-1.00)	0.020†	0.97 (0.95-1.00)	0.019†	0.98 (0.95-1.02)	0.370
1.05 (0.69-1.61)	0.813	1.24 (0.74-2.09)	0.410	0.81 (0.38-1.73)	0.581
1.00	Baseline	1.00	Baseline	1.00	Baseline
0.53 (0.24-1.18)	0.120	0.57 (0.25-1.30)	0.180	†	1.00
1.51 (0.64-3.59)	0.348	1.68 (0.57-4.97)	0.351	1.23 (0.29-5.34)	0.778
0.94 (0.88-1.00)	0.045†	0.95 (0.87-1.03)	0.189	0.94 (0.84-1.04)	0.235
1.00	Baseline	1.00	Baseline	1.00	Baseline
1.77 (1.14-2.73)	0.011†	1.19 (0.70-2.05)	0.518	4.37 (1.86-10.26)	0.001†
2.79 (1.40-5.55)	0.003†	1.89 (0.72-4.94)	0.196	6.54 (2.14-19.97)	0.001†
2.40 (0.74-7.77)	0.143	1.86 (0.44-7.83)	0.400	4.12 (0.52-32.91)	0.181

selection, surgical experience, and implant design, with only 45% of our cohort having a BHR. Our 10-year all-cause revision rate of 15.3% (95% CI = 13.2% to 17.8%) is also higher than the 9.7% to 12.6% recorded in registries^{1,2}, although registries may underreport revisions²¹.

Although pseudotumor was the most common indication for revision (62% of all revisions), other large cohort studies with shorter follow-up have identified femoral neck fracture, component loosening, and osteonecrosis as primary modes of MoMHR failure^{10,11,17}. The prevalence and rates of revision due to pseudotumor have increased substantially compared with the 1.8% prevalence and 4% rate of pseudotumor-related revision at 8 years noted in an early report⁵. Regular surveillance of MoMHRs from 2010 to 2012 and onward is an important contributory factor^{7-9,28}; therefore, pseudotumor may become a more frequent revision indication compared with other modes of failure. However, registries may not accurately reflect pseudotumor-related revision rates for some time, given that pseudotumor did not become a revision indication until 2009¹ coupled with potential underreporting of MoMHR revisions²¹.

Predictors of all-cause revision risk were small femoral head size (8% increased risk per 2-mm decrease in head size) and non-BHR implants (1.6 to 3.0 times increased risk). Our findings support those from two large studies that also demonstrated small head size to be a more important predictor of all-cause revision than female sex^{11,18}. Small head size makes patients more prone to femoral component loosening and femoral neck fracture¹⁸. Furthermore, small components are sensitive to malposition, which can lead to edge loading, increased wear, and pseudotumor^{14,15}. Our findings regarding implant design confirm those from joint registries^{1,2,10}, designing surgeons^{27,29}, and independent centers^{15,30,31}, and support using the BHR in appropriately selected patients. Although others have reported hip

dysplasia and osteonecrosis as risk factors for MoMHR failure^{10,11,27}, this was not observed in our study.

Predictors of all-cause revision were sex-specific. Small femoral head size was the most important predictor in females, and implant design was the only predictor in males. “Small” femoral head size differs between males (≤ 48 mm) and females (≤ 42 mm). Diametrically smaller components have lower tolerances for positioning error and are at increased risk of revision^{11,14,15,18}. Therefore our data suggest that small head size is a significant predictor of revision in females regardless of implant design. However, there is a slightly greater margin for error when positioning small components in males, so males may have a good outcome with a small component if an established MoMHR design is used. Despite the BHR being the best-performing MoMHR device worldwide^{1,2,10}, our data support recent recommendations to not implant small femoral heads in females¹⁹.

Pseudotumors have predominantly been reported in females^{3,4,10,17}. Our study showed that pseudotumor-related revision was predicted by female sex (2 times increased revision risk) and young age (2% increase in revision risk per year younger). Our data suggest that, in contrast to all-cause revision, pseudotumor-related revision is more strongly predicted by female sex than by small femoral head size. Females have an increased risk of pseudotumor for various reasons. First, they have larger native head-neck ratios, which can be considerably reduced following MoMHR, thereby increasing the risk of edge loading and high wear³². Using smaller implants in females, who more frequently have abnormal acetabular anatomy^{10,11,27}, increases the risk of malposition, which can also cause high wear^{14,15}. Females also have an increased risk of metal allergy¹⁶, which may contribute to pseudotumors. Increased hip movement and flexibility as well as specific gait patterns in females^{33,34} may cause impingement and/or edge loading with subsequent pseudotumor formation.

Such kinematics may be increasingly important in young active individuals, therefore explaining why young age is associated with pseudotumors in females.

In addition to MoMHRs, stemmed MoM total hip replacements (THRs) and, more recently, some non-MoM designs have had high short-term failure rates^{1,2,35,36}. Pseudotumors develop after stemmed THRs as a result of wear and/or corrosion at modular junctions—namely, the femoral head-taper junction^{35,36}. This problem may have become more apparent because of modifications to stem design and the use of larger femoral heads. Although patients with these devices also need regular surveillance^{28,37}, it is important to note that, because of clear design differences, the risk factors identified in our MoMHR cohort cannot be extrapolated to stemmed MoM and non-MoM implants. It is therefore recommended that studies similar to ours be performed for patients with stemmed devices so that these patients can be risk-stratified for surveillance.

It is important for the orthopaedic community to learn lessons from the problems experienced with MoM bearings and modular THRs. After preclinical testing, the introduction of any new technology must undergo a rigorous and transparent process. This should include usage by small groups of experts, ideally as part of prospective randomized trials and independently controlled surveillance programs. Surgeons using new technologies during the early stages have a responsibility to report problems in a timely fashion to the manufacturers and to independent authorities^{7,9}. The results of this initial experience must

be interpreted in combination with registry data^{1,2} before widespread introduction of new technologies. Adopting this approach will allow innovation to continue while ensuring patient safety.

The strengths of our study include the large sample size and longer follow-up compared with previous reports^{5,10-12,17,18}. Systematic methods, including contacting other centers, were used to identify all revisions. All revision indications were retrospectively confirmed using operative and histopathological findings, allowing us to identify revisions that were due to pseudotumor before this diagnosis was established^{3,4}. In contrast, registries^{1,2,11-13}, which are substantially limited by a lack of histopathological data, did not recognize pseudotumors until 2009 and underreport revisions²¹. Another strength of our study is that we employed robust survival analysis methodology, including sex-specific analysis. Also, the generalizability of our findings was improved by the fact that procedures were performed at a non-designing center with numerous surgeons using a range of common implants.

A limitation of our study and subsequent cohorts is the potential for surveillance bias. Because surgeons were unaware of pseudotumors before 2007³, this complication was underreported. However, our retrospective review identified pseudotumors in patients who underwent revision for other indications prior to 2007. Pseudotumors were more likely to be recognized after 2007, with patient recalls in 2010²² and 2012⁷, which included asymptomatic individuals^{38,39}. The increased awareness of pseudotumors and regular patient surveillance are likely to further inflate the reported pseudotumor prevalence and

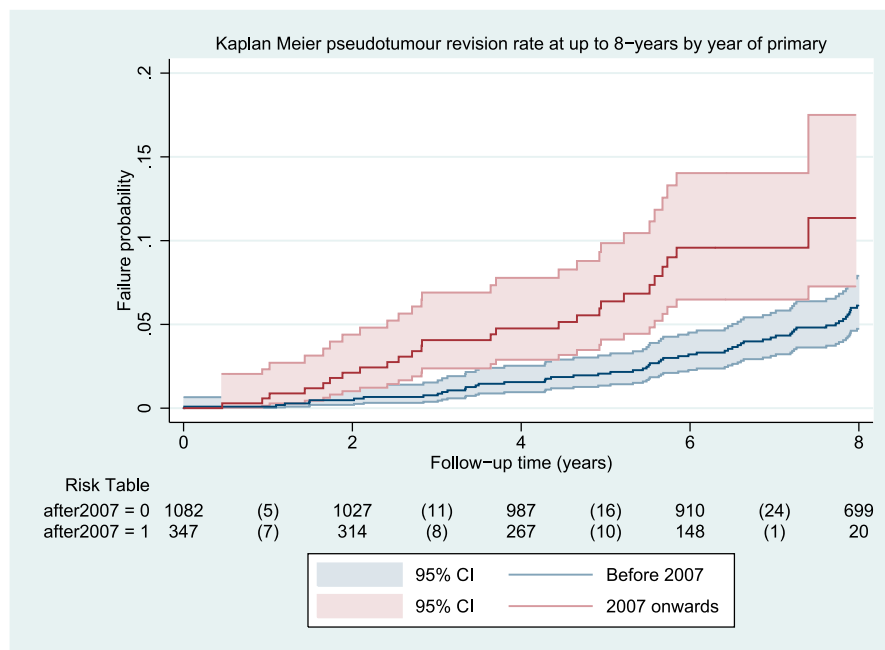


Fig. 3
Results of Kaplan-Meier survival analysis of the pseudotumor-related MoMHR revision rate up to 8 years according to whether the primary surgery was performed before or after 2007. The shaded areas represent the respective upper and lower limits of the 95% CIs. The risk table indicates the number of hips at risk at 2-year intervals, with the number of hips revised during the 2-year interval in parentheses. A univariate Cox proportional hazards model demonstrated that MoMHRs implanted from 2007 onward were at a significantly increased risk of pseudotumor-related revision compared with those implanted prior to 2007 (HR = 2.44, 95% CI = 1.51 to 3.95; $p < 0.001$).

revision rates. Our data support an increasing pseudotumor revision rate over time, with pseudotumor-related revision risk being 2.44 times higher for MoMHRs implanted after 2007 compared with those implanted before 2007 (hazard ratio [HR] = 2.44, 95% CI = 1.51 to 3.95; $p < 0.001$) (Fig. 3). Furthermore, revision indications have changed over time. Surgery was initially performed only in symptomatic patients with large lesions³, but in light of poor short-term outcomes following revision⁴⁰ our indications now include mildly symptomatic patients with smaller pseudotumors.

It remains unclear why pseudotumor prevalence and revision rates are continuing to increase into the second decade following MoMHR, rather than plateauing as one would expect given that the poorly performing designs and the prostheses implanted with technical errors were revised early after the procedures. Possible explanations for the continued increase in pseudotumor-related revision rates include closer patient surveillance, different revision indications, extended follow-up, or a combination of these factors, but clearly additional work is needed to explain why pseudotumor-related revisions are continuing to be identified with long-term follow-up.

Traditional metal-on-polyethylene THRs may fail as a result of aseptic loosening both early (because of technical errors) and late (due to wear), and it is possible that pseudotumors develop both early and late following MoMHRs for similar reasons. Revision of MoMHRs complicated by pseudotumor have proved technically challenging because the lesions can be invasive, involve neurovascular structures, and cause substantial bone and soft-tissue destruction^{3,40}. This has led to poor short-term outcomes following pseudotumor-related revisions, with high complication (50%) and rerevision (38%) rates as well as inferior functional outcomes compared with those following primary THRs^{40,41}. Another concern is that the outcomes of revisions of metal-on-polyethylene THRs appear to be more favorable than those following pseudotumor-related revisions. The 10-year implant survival rate following revision of THRs due to late aseptic loosening was reported to be 84% in a large cohort, with patients with surviving implants having good functional outcomes⁴². Similar outcomes have been demonstrated in other studies following revision THR^{43,44}. Given that many MoMHR implants may still require revision because of pseudotumor and the substantial difference between the outcomes following revisions of MoMHRs and those following revision of THRs, regular surveillance of patients with MoMHRs is important coupled with a low threshold for considering revision surgery. Indeed, there is already evidence that such a strategy may improve patient outcomes following MoMHR revision⁴⁵.

Our study had other recognized limitations. The findings may not apply to other MoMHR designs. Also, revision was used

to define failure as it represents a problem serious enough to warrant surgery. However, some patients who did not undergo revision may have had radiographic evidence of failure or asymptomatic pseudotumors³⁹. These additional cases might eventually increase our reported prevalence and rates of revision, but the natural history of asymptomatic pseudotumors remains uncertain⁴⁶. It is not clear whether all such lesions eventually require revision⁴⁶, as the frequency of asymptomatic pseudotumors is similar between patients with MoM implants and those with non-MoM implants⁴⁷. An additional limitation is that, although our survival analysis was robust, there is a potential for residual confounding. Finally, our findings could have been influenced by some patients not completing the postal questionnaire and the possibility that some underwent revision abroad.

In conclusion, this study of a large cohort of MoMHRs showed a high prevalence and rate of all-cause and pseudotumor-related revisions at up to 15 years following primary arthroplasty. Predictors of revision differed between all-cause and pseudotumor-related revisions, and were sex-specific. These factors must be appropriately weighted and incorporated into current worldwide follow-up recommendations^{7-9,28} for risk-stratifying patients with MoMHRs for surveillance.

Appendix

eA A table showing patient and implant factors for surviving MoMHRs in patients who completed the follow-up questionnaire versus those who did not complete the questionnaire is available with the online version of this article as a data supplement at jbjs.org. ■

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