Dual Mobility Cups: Effect on Risk of Revision of Primary Total Hip Arthroplasty Due to Osteoarthritis

A Matched Population-Based Study Using the Nordic Arthroplasty Register Association Database

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Background: The dual mobility acetabular cup (DMC) was designed to reduce prosthetic instability and has gained popularity for both primary and revision total hip arthroplasty (THA). We compared the risk of revision of primary THA for primary osteoarthritis between patients treated with a DMC and those who received a metal-on-polyethylene (MoP) or ceramic-on-polyethylene (CoP) bearing.

Methods: A search of the Nordic Arthroplasty Register Association (NARA) database identified THAs performed with a DMC during 1995 to 2013. With use of propensity score matching, 2,277 of these patients were matched (1:1), with regard to sex, age, component fixation, and year of surgery, with patients with an MoP or CoP bearing. We estimated the cumulative incidence of revision taking death as a competing risk into consideration and performed competing risk regression with revision or death as end points.

Results: There was no difference in the overall risk of revision between the DMC group and the propensity-score-matched MoP/CoP group (adjusted hazard ratio [HR] = 1.18; 95% confidence interval [95% CI] = 0.87 to 1.62). Patients with a DMC bearing had a lower risk of revision due to dislocation (adjusted HR = 0.09; 95% CI = 0.03 to 0.29) but a higher risk of revision caused by infection (adjusted HR = 3.20; 95% CI = 1.49 to 6.85).

Conclusions: There was no difference in overall risk of revision between the DMC and MoP/CoP groups. The DMCs protected against revision due to dislocation but THAs performed with this bearing were more commonly revised because of infection. There may have been a selection bias toward placing DMC implants in patients with greater frailty as the mortality rates were higher in the DMC group than in the age and sex-matched MoP/CoP group.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Instability leading to recurrent dislocation is a frequent and serious complication after total hip arthroplasty (THA)[1]. Worldwide, it is the third leading cause of revision of primary THAs with contemporary implant designs[2,3]. Several preventive measures, such as use of constrained liners or large bearing articulations, have been employed to reduce the risk of dislocation. The dual mobility cup (DMC) was designed to take advantage of the stabilizing effect of a large plastic femoral head articulating against the acetabular component and a second articulation with a smaller metal head within the plastic component. This type of cup was invented by Gilles Bousquet and André Rambert in the 1970s in France, where it has been used extensively, but it did not become popular outside of France until recently[4,5]. The DMC bearing theoretically functions as a large-head bearing, increasing the range of motion and the jumping distance, thereby minimizing prosthetic neck impingement before dislocation can occur[6-9]. Since the early 1980s, investigators studying smaller case series have reported that DMC implants reduce the risk of revision associated with recurrent dislocations[6-8,10-16], to as low as 0%[10]. In some of these studies of case series, the authors expressed concerns about a higher frequency of revisions linked to polyethylene wear and

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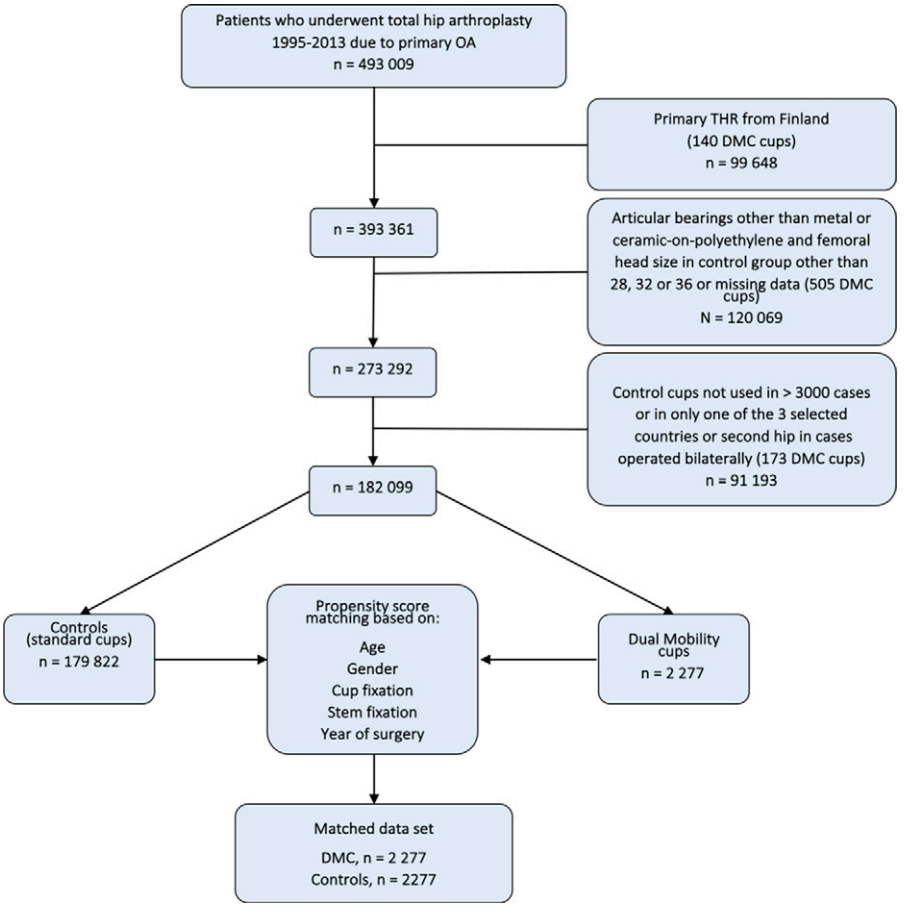

Fig. 1

Flowchart of study population. OA = osteoarthritis, and THR = total hip replacement.

osteolysis[7,8,17,18]. The limitations of the current literature include heterogeneous patient cohorts with a variety of indications for primary THA, inappropriate control for confounding, and a lack of comparable control cohorts[7,8,16,17,19-21].

We are not aware of any previous studies evaluating the performance of DMC bearings on the basis of data from a national register. The current literature focuses mainly on whether DMC implants reduce the risk of revision surgery linked to dislocation. We argue that, from a patient and surgeon perspective, overall revision rates have to be evaluated.

We performed a population-based prospective cohort study based on the Nordic Arthroplasty Register Association (NARA) database. Our primary aim was to evaluate the overall risk of revision of primary THAs done with the DMC, compared with those done with a metal-on-polyethylene (MoP) or ceramic on-polyethylene (CoP) design, in patients with primary osteoarthritis. Our secondary aim was to compare the risks of revisions with specific causes between those 2 groups.

Materials and Methods

This study was performed and reported according to the REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) guidelines regarding research conducted on routinely collected medical data[22].

The background population consisted of approximately 26 million inhabitants of Norway (5.0 million), Finland (5.5 million), Denmark (5.6 million), and Sweden (9.6 million). Because very few DMCs were used in Finland, this country was excluded, resulting in a study population of slightly more than 20 million.

Data Sources

The NARA database consists of pooled and individually anonymized data from the national hip arthroplasty registers of Denmark, Norway, Finland, and Sweden. Each register has validation routines based on national patient registers. The data provided by each register are entered into the NARA database minimal data set format on submission, a process that includes deletion of personal identification numbers. The data were treated with full confidentiality, and identification of individual patients was not possible as a result of the anonymization of the NARA database[23,24].

Study Population

We identified all primary THAs performed because of osteoarthritis with a DMC or with a standard cup with an MoP or CoP bearing. The polyethylene liner of the standard cup could be made of either ultra-high molecular weight polyethylene or highly cross-linked polyethylene, and the head could have a

diameter of 28, 32, or 36 mm. The fixation technique could be cemented, uncemented, hybrid, or reverse hybrid.

The NARA database contains records on 620,261 primary THAs performed from 1995 to 2013, with 493,009 of them performed because of primary osteoarthritis (Fig. 1). As stated, all cases from Finland were excluded because of the low number of DMCs (n = 140), in order to homogenize the study population. THAs with bearing surfaces other than MoP or CoP were excluded as well. When a patient had received bilateral THA, the first THA was included and the second was excluded according to the assumption of independent observations[25,26]. To make the control group as representative as possible, only cups used in at least 2 of the 3 countries and with >3,000 registrations were included. Patients with missing data on covariates that would be required to adjust for confounding or missing information regarding the bearing surface were excluded. Table I lists the cups eligible for matching. After the exclusion process, 2,277 hips with a DMC and 179,822 with an MoP or CoP bearing were eligible for propensity score matching. Twenty-three of the 678 excluded THAs performed with a DMC outside Finland were revised during the period of observation (Fig. 1). The percentage of revisions in this group was slightly smaller than that in the included hips (Table II).

Ethics

The study was approved by The Danish Data Protection Agency (approval number 2012-41-0515) and the Ethical Review Board, Gothenburg, Sweden (approval number 734-14).

TABLE I Cups Included in the Analysis*

Type of Cup	No.
DMC	
Saturne	1,821
Avantage	431
POLARCUP	25
MoP/CoP	
Trilogy	23,360
Pinnacle	8,383
Exceed ABT	6,261
Mallory-Head	3,446
Trident	4,351
Lubinus	60,288
Marathon	13,801
Charnley Elite Ogee	13,735
Contemporary	14,013
ZCA	10,635
Exeter RimFit	5,736
Exeter	15,813
Total	179,822

*After selection according to Figure 1.

TABLE II Reasons for Revision of Included and Excluded THAs with a DMC

	Included and Matched (N = 2,277)		Excluded* (N = 678)	
Reason for Revision	No.	%	No.	%
All reasons	97	4.3	23	3.4
Aseptic loosening	16	0.7	6	0.9
Deep infection	32	1.4	10	1.5
Periprosthetic femoral fracture	28	1.2	3	0.4
Dislocation	2	0.1	1	0.15
Pain	11	0.5	1	0.15
Other reasons	8	0.4	2	0.3

*Cases were excluded because of missing or obviously incorrect data (n = 505) or because the hip was the second hip in a patient with a bilateral THA (n = 173).

Statistical Analysis

Patients entered the study on the date of their primary THA and were followed until revision, death, emigration, or the end of the follow-up period (December 31, 2013), whichever came first. Revision was defined as a new surgical procedure, including partial or complete removal or exchange of any component of the implant. Revision for any reason was the primary outcome, and revision for specific causes was the secondary outcome.

The time from the primary operation to censoring or revision was the underlying time scale used in the time-to-event analysis. The survival analysis included observation up to 9 years, which was chosen because there were too few outcomes after 9 years for statistical analysis. The specific causes of revision were stratified as reported to the NARA register and included dislocation, periprosthetic femoral fracture, aseptic loosening, deep infection, pain, and "other reasons."

Descriptive statistics were used for presentation of demographic data and implant characteristics. Follow-up times were presented as the median and interquartile range (IQR) for the MoP/CoP and DMC cohorts and for the different types of DMC components.

The DMC and MoP/CoP cohorts differed across all included characteristics and covariates (Table III). To control for these differences, which would have otherwise produced biased estimates of relative revision risk, propensity score matching was applied. This method enabled us to identify a subcohort of DMC and MoP/CoP-treated patients who had a similar baseline probability of receiving the DMC. The method matches hips according to their conditional probability of being in a "treated" or "non-treated" group, represented by a propensity score. For this purpose, we used logistic regression to calculate a propensity score for each DMC and MoP/CoP-treated patient. The propensity score is a single scalar variable that is calculated from all available variables

TABLE III Patient and Surgery-Related Characteristics of DMC and MoP/CoP Cohorts Before and After Propensity Score Matching

	Unmatched Cohort				Propensity Score-Matched Cohort*			
	DMC (N = 2,277)		MoP/CoP THA (N = 179,822)		DMC THA (N = 2,277)		MoP/CoP THA (N = 2,277)	
Characteristics	No.	%	No.	%	No.	%	No.	%
Mean age *(yr)*	75.47		69.51		75.47		75.51	
Female sex	1,381	60.6	105,506	58.7	1,381	60.6	1,363	59.9
Fixation technique								
Cemented	359	15.8	114,750	63.8	359	15.8	356	15.6
Uncemented	1,329	58.4	35,408	19.7	1,329	58.4	1,285	56.4
Hybrid	523	23.0	10,211	5.7	523	23.0	567	24.9
Reverse hybrid	66	2.9	19,453	10.8	66	2.9	69	3.0
Year of surgery								
1995-2001	0	0	15,841	8.8	0	0	0	0
2002	1	0	7,087	3.9	1	0	1	0
2003	78	3.4	9,384	5.2	78	3.4	63	2.8
2004	96	4.2	10,232	5.7	96	4.2	94	4.1
2005	137	6.0	10,958	6.1	137	6.0	125	5.5
2006	157	6.9	12,680	7.1	157	6.9	145	6.4
2007	201	8.8	13,126	7.3	201	8.8	204	9.0
2008	198	8.7	13,083	7.3	198	8.7	202	8.9
2009	215	9.4	15,797	8.8	215	9.4	216	9.5
2010	262	11.5	16,844	9.4	262	11.5	265	11.6
2011	327	14.4	17,709	9.8	327	14.4	346	15.2
2012	300	13.2	18,495	10.3	300	13.2	302	13.3
2013	305	13.4	18,586	10.3	305	13.4	314	13.8
Surgical approach								
Posterior	2,162	94.9	107,545	59.8	2,162	94.9	1,905	83.7
Anterolateral or other	115	5.1	72,277	40.2	115	5.1	372	16.3

*Patients were not matched for surgical approach.

that are known to be associated, in this case, with the risk of receiving a DMC[27]. Matching according to the propensity score makes it possible to control for many covariates even though the number of outcomes might be low and hence makes it possible to control for known confounding. This allows for a less biased estimate of revision rates when performing comparative survival analysis[28]. In order for the regression adjustment to be trusted, the difference between the mean propensity scores of the 2 groups should be small and the ratio of the variance of the propensity score between the 2 cohorts should be near 1[27].

Nearest-neighbor propensity score matching was employed by matching the DMC-treated hips to the MoP/CoP-treated hips in a 1:1 ratio and fitting a logistic regression model based on the covariates of age, sex, acetabular component fixation, stem component fixation, and year of surgery[28]. Age and sex were included in the model because studies of large national registers have shown them to influence the risk of revision[29]. Implant fixation technique was included because

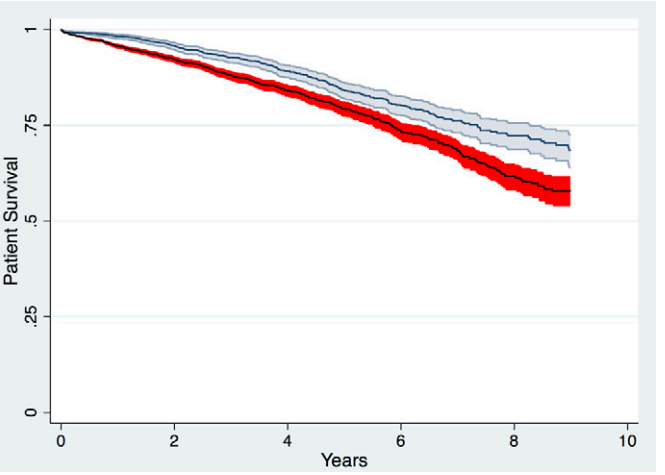

Fig. 2

Survival of patients with an MoP/CoP bearing (gray) or a DMC (red) with 95% CI bands, with death as the end point.

TABLE IV Follow-up Times for MoP/CoP and DMC Bearings and Different Types of DMCs

	No. of Hips	No. of Revisions	Median Follow-up (IQR) *(yr)*	Total Risk Years for Implant
MoP/CoP	2,277	72	3.20 (1.47-5.39)	8,423
DMC	2,277	97	2.99 (1.31-5.40)	8,168
Type of DMC implant				
Saturne	1,821	76	3.56 (1.90-5.97)	7,328
Avantage	431	21	1.15 (0.53-2.68)	799
POLARCUP	25	0	1.82 (0.80-2.59)	41

outcomes differ between cemented and uncemented prostheses and thus fixation technique constitutes a known selection bias. We did not compare different brands of cups because there were too few of each for us to perform meaningful stratification. We did not have information on medical comorbidities and thus were not able to match on the basis of such parameters. The data set derived with the propensity score matching was well balanced, with no significant differences across the matched covariates. The mean of the propensity scores was within an 8th decimal of 1, and the ratio of the variance of the propensity score between the DMC and MoP/CoP cohorts was 1. As balance diagnostics for differences between covariates after matching, we calculated "the standard difference in means," which should be <0.25 to be regarded as trustworthy[30]. These ranged between 0.00 and 0.04 for the covariates included in our propensity score matching.

After the propensity score matching was performed, we found a significant difference in mortality between the DMC and MoP/CoP cohorts (Fig. 2). We therefore used Fine-Gray competing risk regression with revision of the primary THA as the end point and death as a competing risk factor[31]. The absolute risk regression function was employed to obtain crude and adjusted hazard ratios (HRs)[32]. Any p value of <0.05 was considered significant. Statistical analyses and propensity score matching were performed using IBM SPSS statistical software version 23.0 and R statistics version 3.2.0.

Results

Description of the Study Population

The characteristics of the study population are presented in Table III. Females more frequently received a DMC than males. According to the propensity score matching, the mean age for the DMC and MoP/CoP groups was the same: 75.47 and 75.51 years. The DMC group consisted of 1,821 Saturne cups (Amplitude), 431 Avantage cups (Biomet, France SARL), and 25 POLARCUPs (Smith & Nephew). Details on median follow-up and risk years for each design are presented in Table IV. The number of patients included in the study increased throughout the inclusion period, mainly because of increasing use of DMCs, especially in Denmark and Sweden (Table III). The posterior approach was used in the majority of the hips (94.0% in the DMC group and 63.9% in the MoP/CoP group). The remaining cases were operated on using an anterolateral or any other approach (not specified in the NARA database). A total of 97% of the DMCs were reported to have a 28-mm metal head insert in the unconstrained polyethylene liner. Larger heads were incorrectly reported in the remaining cases because DMC implants do not exist with head sizes other than 28 mm. In the MoP/CoP cohort, there was an equal distribution of the different head sizes (28, 32, and 36 mm).

The pooled median follow-up time (and IQR) was 2.99 years (1.31 to 5.40 years) and 3.20 years (1.47 to 5.39 years) for the DMC and MoP/CoP cohorts, respectively (p = 0.08).

At 9 years, patient survival, based on the Kaplan-Meier estimator, was 58% in the DMC group and 69% in the MoP/CoP group. Because the 95% confidence intervals (CIs) did not overlap, this was considered a significant difference (Fig. 2).

Overall Revision Risk

During the study period, 97 first-time revisions were registered in the DMC cohort and 72, in the MoP/CoP cohort. At 2 years, the cumulative incidence of revision linked to any cause was 2.6% (95% CI = 2.0% to 3.3%) in the DMC cohort and 3.6% (95% CI = 2.8% to 4.4%) in the MoP/CoP cohort. At 9 years, the cumulative incidences of revision were 4.1% (95% CI = 3.1% to 5.2%) and 6.3% (95% CI = 4.7% to 8.1%) for the DMC and MoP/CoP cohorts, respectively (Fig. 3). We found no difference in the overall revision rate between the DMC and MoP/CoP cohorts at 9 years (adjusted HR = 1.18; 95% CI = 0.87 to 1.62; p = 0.29).

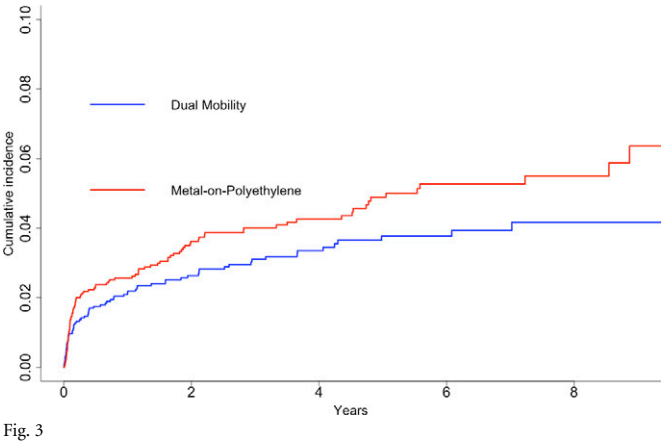

Fig. 3

Cumulative incidence of revision for any cause of THAs with an MoP/CoP bearing or a DMC.

TABLE V Main Indications for Revision of THAs with DMC or MoP/CoP Bearing

Indication	DMC (N = 2,277)		MoP/CoP (N = 2,277)	
	No.	%*	No.	%*
All reasons	97	3.2	72	4.2
Aseptic loosening	16	16.4	14	19.4
Deep infection	32	32.9	11	15.2
Periprosthetic femoral fracture	28	28.8	14	19.4
Dislocation	2	2.1	24	33.3
Pain	11	11.3	2	2.7
Other reasons	8	8.2	7	9.7

*Percentages for revisions with specific causes are of the total number of revisions.

Cause-Specific Revision Risk

The most common indication for revision was deep infection in the DMC cohort and dislocation in the MoP/CoP cohort (Table V). The dislocations in the MoP/CoP cohort were distributed equally among the 28, 32, and 36-mm head sizes.

The DMC cohort had a lower risk of revision linked to dislocation (adjusted HR = 0.09; 95% CI = 0.03 to 0.29) (Table VI) than the MoP/CoP cohort but a higher risk of revision associated with infection (adjusted HR = 3.20; 95% CI = 1.49 to 6.85). There was no difference in the risk of periprosthetic femoral fracture between groups. The DMC cohort had a higher risk of revision for "other reasons" (adjusted HR = 4.89; 95% CI = 1.58 to 15.09) and because of pain (adjusted HR = 3.89; 95% CI = 1.08 to 14.03). It was not possible to calculate the adjusted HR for revision linked to aseptic loosening because of a non-converging model; however, the crude HR (1.16; 95% CI = 0.56 to 2.40) indicated no difference in the risk of revision due to aseptic loosening between the 2 groups.

Discussion

To our knowledge, this is the first prospective cohort study based on national registers focusing on primary THAs with DMCs.

This study demonstrated no significant difference in the overall revision rate between DMCs and MoP/CoP bearings. However, we found significant differences in the specific causes of the revisions, with the DMC associated with a lower risk of revision due to dislocation and a higher risk of revision due to infection than the MoP/CoP bearings.

A report by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) indicated no difference in the overall revision rate between THAs

TABLE VI Crude and Adjusted HRs for Specific Causes of Revisions in MoP/CoP and DMC Cohorts*

Reason for Revision	No. of Revisions	Crude HR (95% CI)	Adjusted HR (95% CI)	P Value for Adjusted HR
Aseptic loosening				
MoP/CoP	14	1 (ref.)	1 (ref.)	
DMC	16	1.16 (0.56-2.40)	NCM†	0.07
Deep infection				
MoP/CoP	11	1 (ref.)	1 (ref.)	
DMC	32	3.61 (1.70-7.66)	3.20 (1.49-6.85)	0.003
Periprosthetic femoral fracture				
MoP/CoP	14	1 (ref.)	1 (ref.)	
DMC	28	2.00 (1.05-3.81)	1.94 (0.99-3.80)	0.06
Dislocation				
MoP/CoP	24	1 (ref.)	1 (ref.)	
DMC	2	0.03 (0.01-0.15)	0.09 (0.03-0.29)	<0.0001
Pain				
MoP/CoP	2	1 (ref.)	1 (ref.)	
DMC	11	4.46 (1.01-19.64)	3.89 (1.08-14.03)	0.004
Other reasons				
MoP/CoP	7	1 (ref.)	1 (ref.)	
DMC	8	1.91 (0.85-4.28)	4.89 (1.58-15.09)	0.006

*MoP/CoP was considered the reference bearing. †NCM = a non-converging model because all revised cases were operated on through a posterior approach. Adjustments were made for a posterior approach.

done with a DMC and conventional THAs[33]. In that report, the cumulative revision rate was 2.5% at 5 years after THA with a DMC in patients with primary osteoarthritis, which corresponds to 3.7% and 4.8% for DMC and MoP/CoP bearings, respectively, in our study. A direct comparison of our observations with those in previous studies is difficult because few or none of the case series on survival of DMCs provided relative risk estimates of overall survival and specific causes of revision compared with a suitable control group[4,7,8,10,15-18].

The findings of Combes et al. (93% survival rate for DMCs at 10 years)[34] and Hamadouche et al. (94.2% at 6 years)[18] are in line with our observation of a cumulative incidence of revision for any cause of 4.1% at 9 years after THA with a DMC.

Our findings indicate that the DMC design effectively reduces the risk of revision associated with dislocations compared with a standard MoP or CoP articulation, confirming the studies by the inventors[7,8]. One confounder that could influence the risk of revision due to dislocation might be the difference in the head sizes used in the MoP/CoP cohort. However, when we stratified the results according to the 28, 32, and 36-mm head sizes in the MoP/CoP cohort, we found no difference in the number of recorded revisions linked to dislocation.

An important finding in this study was the increased risk of revision due to deep infection in the DMC cohort, which is in line with a French multicenter study[35]. The authors of that study stated that the increased infection rate might be associated with patient selection rather than the implant itself[35]. The authors of other studies have excluded revisions due to deep infection from their analysis, which may not be appropriate[36]. The increased risk may be due to confounding by indication because the DMCs were used in patients with greater frailty, who are at increased risk for infection. We were not able to adjust for medical comorbidity, which is a well-known risk factor for deep infection[29]. In addition, our finding of higher mortality in the DMC group after the matching supports the notion of greater fragility in that group.

The strengths of this study include its independent population-based cohort design with prospective collection of data and a large sample size. The NARA registers are similar in relation to the availability of each country's health-care system to patients and comparable in terms of the demographics in the Nordic countries[23]. The NARA registers have a high degree of completeness and coverage and therefore provide a representative study population. By propensity score matching, we could—at least to a certain extent—reduce confounding.

This study has several limitations. The NARA common data set lacks a number of variables that might have skewed the matching, such as comorbidity and the presence of dementia[28]. A higher comorbidity score and a longer duration of surgery have been associated with a higher risk of infection[29]. Patients who receive a THA with a DMC could have a higher disease burden because of the inherent indications for the use of DMCs and hence a higher risk of revision, particularly due to deep infection. We were not able to adjust for implant-related variables such as component size or use of a 22 or 28-mm femoral head in the DMC articulation, which might constitute a confounder, with 28-mm heads being more prone to wear-related complications. The risk of revision due to polyethylene wear and subsequent component failure may be underestimated as the follow-up time in this study was limited to 9 years.

In conclusion, THAs with a DMC were associated with the same overall risk of revision as those with an MoP or CoP bearing in patients with osteoarthritis. THAs with a DMC were associated with a lower risk of revision due to dislocation but a higher risk of revision due to infection, pain, or other reasons. There was no difference in the risk of revision for aseptic loosening. ■

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