A commentary by Steven A. Olson, MD, is linked to the online version of this article at jbjs.org.

Reduced Revision Risk for Dual-Mobility Cup in Total Hip Replacement Due to Hip Fracture

A Matched-Pair Analysis of 9,040 Cases from the Nordic Arthroplasty Register Association (NARA)

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Background: The dual-mobility acetabular cup (DMC) has an additional bearing consisting of a mobile polyethylene component between the prosthetic head and the outer metal shell. This design has gained popularity in revision total hip arthroplasty (THA) and in primary treatment of femoral neck fractures with the anticipation of a reduced risk of THA instability. Our primary aim was to evaluate the overall revision risk of these cups on the basis of data from the Nordic Arthroplasty Register Association (NARA) database, and our secondary aim was to study specific revision causes including dislocation.

Methods: Propensity score matching for age, sex, fixation of the cup and stem, and the year of surgery (2001 to 2014) was used to match 4,520 hip fractures treated with a DMC to 4,520 hip fractures treated with conventional THA (control group). Competing risk regression analyses with revision or death as the end point were used. Revision was defined as a secondary surgical procedure in which any component of the implant was removed or exchanged. In addition, revision of the cup was analyzed.

Results: The DMCs had a lower risk of revision compared with conventional THA, with an adjusted hazard ratio (AHR) of 0.75 (95% confidence interval [CI] = 0.62 to 0.92). This was consistent after adjusting for surgical approach. DMCs had a lower risk of revision due to dislocation (AHR = 0.45 [95% CI = 0.30 to 0.68]) but we found no difference regarding revision for deep infection. Revision of the acetabular component, both in general and due to dislocation, was more frequent with the use of conventional cups. The risk of death was higher in the DMC group (AHR = 1.49 [95% CI = 1.40 to 1.59]).

Conclusions: The use of a DMC as primary treatment for hip fracture was associated with a lower risk of revision in general and due to dislocation in particular. The total number of DMCs analyzed (4,520) likely exceeds any cohort of DMC-treated fractures published to date.

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

Despite a decreasing incidence during the last decades, the number of femoral neck fractures is expected to increase[1]. Arthroplasty is a widely accepted treatment for a displaced femoral neck fracture in elderly patients[2]. Traditionally, hemiarthroplasty has been preferred, in part because of a lower dislocation rate compared with total hip arthroplasty (THA)[3-5]. However, THA has been shown to provide a lower rate of reoperations, less pain, better functional outcomes, and better mobility compared with hemiarthroplasty in some studies[4-9]. Still, a major problem with THA for fractures is a dislocation rate of 10%, which is 5 times higher than the rate when THA is used for osteoarthritis[10]. Dislocation and infection are the 2 most frequent reasons for revision after THA for fracture[11,12].

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The dual-mobility cup (DMC) has an additional bearing consisting of a mobile polyethylene component between the prosthetic head and the outer metal shell. It was developed in France in the 1970s by Bousquet for patients at high risk for postoperative instability[13]. The DMC is associated with lower rates of dislocation in primary surgery[14] and revision surgery[15], but the overall revision rate has seldom been accounted for in comparisons with conventional THA. The long-term results have not been thoroughly studied, although some case series have shown promising outcomes[16]. Ten-year survival rates between 91% and 95% have been reported, with the better results being in cases treated by the inventor's group and in association with cement fixation[17].

Patients treated with primary THA for hip fracture frequently receive a DMC because of a high risk of dislocation. Theoretical disadvantages of using a DMC include intraprosthetic dislocation, which is a rare device-specific complication[14]. Many reasons for DMC revision are common to conventional THA, such as wear, osteolysis, aseptic loosening, and infection. To our knowledge, there is no evidence to show that the incidence of these complications is higher with the DMC than with conventional THA[17,18]. Proponents of DMCs recommend them to counteract the increased risk of dislocation observed with the posterior approach. In addition, they are recommended for patients with a high risk of postoperative instability, particularly the elderly[17].

Previous studies of DMCs have several shortcomings. They focused mainly on revisions due to dislocation and mostly presented Level-IV evidence. Several were performed by the initial inventor and his group[13,16,17]. Only a few studies have investigated fracture treatment exclusively[19-22]. Attempts to perform a randomized controlled trial (RCT) have failed[23].

Therefore, we conducted a population-based prospective cohort study based on data from the Nordic Arthroplasty Register Association (NARA) to examine the risk of revision in general and also due to specific causes in patients treated with a DMC for a hip fracture.

Materials and Methods

The study was done within the NARA collaboration, using a database consisting of pooled and individually anonymized data from the national hip arthroplasty registers of

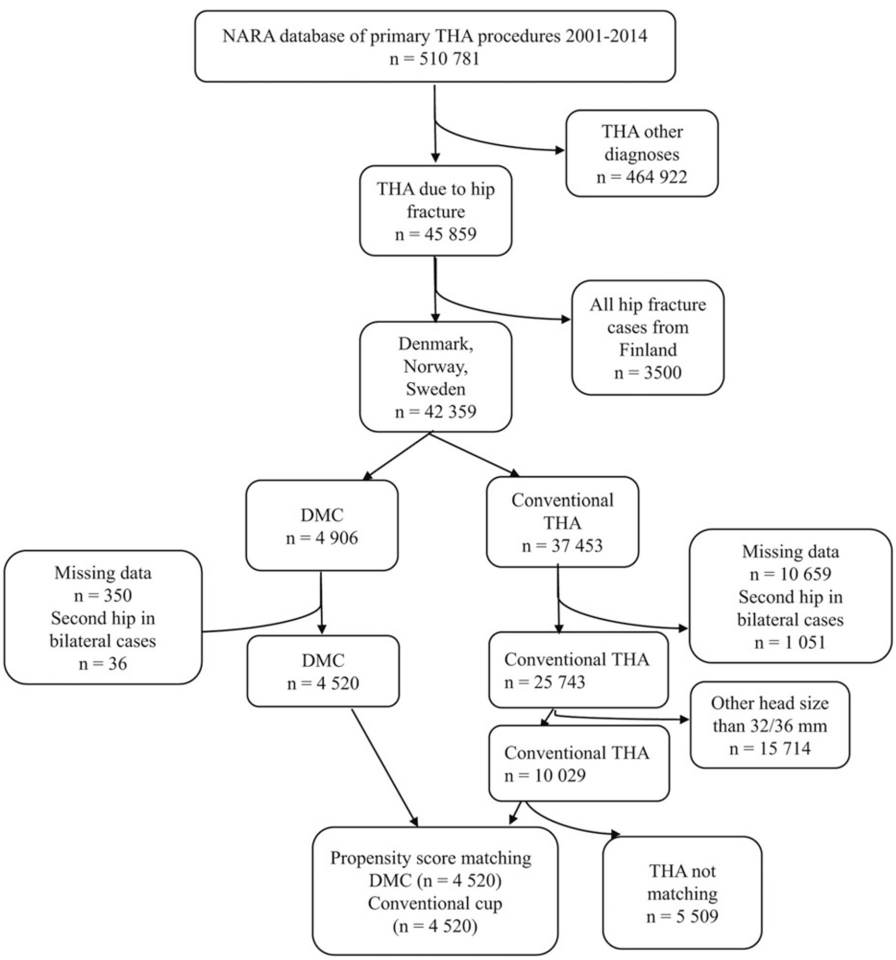

Fig. 1
Flowchart for the study.

TABLE I Patient Characteristics

	Conventional Cup*	DMC*	Total*	Standardized Mean Difference
Variables used in propensity score matching				
Mean age *(yr)*	74.6 ± 10.9	77.0 ± 10.8	75.5 ± 10.0	0.22
Female sex	3,087 (68.3%)	3,152 (69.7%)	6,239 (69.0%)	0.02
Fixation				0.1
Cemented	1,811 (40.1%)	1,480 (32.7%)	3,291 (36.4%)	
Uncemented	1,619 (35.8%)	1,368 (30.3%)	2,987 (33.0%)	
Hybrid	796 (17.6%)	1,320 (29.2%)	2,116 (23.4%)	
Reverse hybrid	294 (6.5%)	352 (7.8%)	646 (7.1%)	
Year of surgery				0.03
2001	4 (0.1%)	25 (0.6%)	29 (0.3%)	
2002	4 (0.1%)	22 (0.5%)	26 (0.3%)	
2003	13 (0.3%)	54 (1.2%)	67 (0.7%)	
2004	65 (1.4%)	90 (2.0%)	155 (1.7%)	
2005	110 (2.4%)	170 (3.8%)	280 (3.1%)	
2006	170 (3.8%)	233 (5.2%)	403 (4.5%)	
2007	328 (7.3%)	262 (5.8%)	590 (6.5%)	
2008	382 (8.5%)	325 (7.2%)	707 (7.8%)	
2009	503 (11.1%)	368 (8.1%)	871 (9.6%)	
2010	548 (12.1%)	478 (10.6%)	1,026 (11.3%)	
2011	613 (13.6%)	551 (12.2%)	1,164 (12.9%)	
2012	599 (13.3%)	598 (13.2%)	1,197 (13.2%)	
2013	622 (13.8%)	704 (15.6%)	1,326 (14.7%)	
2014	559 (12.4%)	640 (14.2%)	1,199 (13.3%)	
Other variables				
Posterior approach	3,129 (69.6%)	3,691 (81.7%)	6,820 (75.4%)	
Fracture side: left	2,291 (50.7%)	2,331 (51.6%)	4,622 (51.1%)	
Country				
Denmark	2,470 (54.6%)	3,882 (85.9%)	6,352 (70.3%)	
Norway	385 (8.5%)	373 (8.3%)	758 (8.4%)	
Sweden	1,665 (36.8%)	265 (5.9%)	1,930 (21.3%)	
Cup fixation				
Cemented	2,105 (46.6%)	1,832 (40.5%)	3,937 (43.6%)	
Uncemented	2,415 (53.4%)	2,688 (59.5%)	5,103 (56.4%)	

*The values are given as the number and percentage of patients, except for age, which is given as the mean and standard deviation.

Denmark, Norway, Finland, and Sweden[24]. The data from each country were entered into the NARA database minimal data set. Personal identification numbers were omitted. The Nordic countries (Denmark, Sweden, Finland, and Norway) have a background population of approximately 26 million inhabitants. In this study, Finland was excluded because few DMCs had been used in that country, resulting in a final background population of 20 million individuals. The study population comprised patients in whom a hip fracture had been treated with primary THA with a DMC or with conventional bearings including a femoral head with a diameter of 32 or 36 mm (n = 3,228 and n = 1,292, respectively). A conventional polyethylene liner was used in 3,029 (67%) of the DMC cases, cross-linked polyethylene was used in 919 (20%), and data on the type of polyethylene were missing for 572 (13%). In the control group (conventional cups), we chose to accept any articulating surface to maintain optimum symmetry for the variables included in the propensity score matching. The articulating surface of the cup in this group was cross-linked polyethylene (n = 2,560, 57%), conventional polyethylene (n = 1,854, 41%), metal (n = 17), or ceramic (n = 13). Data on the type of articulating material were missing for 76 (2%). The DMC brands used were the Saturne (Amplitude) (n = 2,772), the Avantage (Zimmer Biomet) (n = 1,468), and the Polarcup (Smith & Nephew) (n = 280). The most common conventional cups were Trilogy (Zimmer Biomet) (n = 1,210), Lubinus IP (LinkBio) (n = 1,016),

TABLE II Revisions

	Conventional Cup			DMC			Total		
	No.	% of All Revisions	Overall Rate	No.	% of All Revisions	Overall Rate	No.	% of All Revisions	Overall Rate
No revision	4,277		94.6%	4,339		96.0%	8,616		95.3%
Any revision	243	100%	5.4%	181	100%	4.0%	424	100%	4.7%
Revision for:									
Aseptic loosening	28	11.5%	0.6%	16	8.8%	0.4%	44	10.4%	0.5%
Deep infection	69	28.4%	1.5%	64	35.4%	1.4%	133	31.4%	1.5%
Periprosth. fract.	39	16.0%	0.9%	41	22.7%	0.9%	80	18.9%	0.9%
Dislocation	85	35.0%	1.9%	34	18.8%	0.8%	119	28.1%	1.3%
Pain only	3	1.2%	0.1%	3	1.7%	0.1%	6	1.4%	0.1%
Other	19	7.8%	0.4%	23	12.7%	0.5%	42	9.9%	0.5%

Pinnacle (DePuy Synthes) (n = 570), ZCA (Zimmer Biomet) (n = 357), and Exceed ABT (Zimmer Biomet) (n = 355).

The register does not record details on fracture type. The cohort included all acute proximal femoral fractures for which the surgeon considered THA to be the best option. The majority were likely displaced femoral neck fractures.

The outcomes studied were either any type of revision (a secondary surgical procedure in which any component of the implant was removed or exchanged) or revision of the cup (a secondary procedure that included exchange or removal of the cup or liner with or without exchange or extraction of the femoral head or stem). The indications for revision specified in the database were dislocation, periprosthetic femoral fracture, aseptic loosening, deep infection, pain, and other reasons.

The NARA data set includes 510,781 primary THAs implanted from 2001 to 2014. Of these, 42,359 were performed because of hip fracture in Denmark, Norway, or Sweden. The cups included in the control group were designed for a metallic or ceramic head with a diameter of 32 or 36 mm. When a patient had been operated on both sides during the study period, the second hip was excluded from the study, as were cases with missing data on key variables; this left 4,520 hips with a DMC cup and 10,029 control cases for propensity score matching (Fig. 1). We used logistic regression analysis to calculate a propensity score for each DMC and control group patient. The score is a single scalar variable calculated from variables associated with the chance of being treated with a DMC[25]. As we were limited to variables available in the registers, only age, sex, fixation of the cup and stem, and year of surgery could be used for matching, which was done according to the nearest-neighbor method in a 1:1 ratio. The Nordic registers use different comorbidity scores. The American Society of Anesthesiologists (ASA) score is reported in Sweden and Norway. In Denmark, the Charlson Comorbidity Index is calculated via cross-linking with other national registers. As these scores are not easily transferable to each other, we did not match on comorbidity. Using propensity score matching, we identified a set of patients, or surgical interventions, with a similar probability of receiving either of the 2 implant types based on the matching variables used. After matching, there were 4,520 patients (hips) in each group. The standardized mean differences for the variables used for matching ranged between 0.02 (sex) and 0.22 (age).

TABLE III Competing Risk Regression Analyses with Revision (Any Component or Cup) or Death as End Point

	HR*	95% CI	P Value
Revision of any component			
Revision for any cause			
Unadjusted	0.754	0.620-0.916	0.004
Adjusted for approach	0.730	0.598-0.891	0.002
Mortality for any cause			
Unadjusted	1.493	1.403-1.590	<0.001
Adjusted for approach	1.471	1.381-1.568	<0.001
Revision for:			
Dislocation			
Unadjusted	0.451	0.298-0.681	<0.001
Adjusted for approach	0.414	0.271-0.633	<0.001
Deep infection			
Unadjusted	0.990	0.693-1.413	0.954
Adjusted for approach	1.060	0.727-1.546	0.760
Aseptic loosening			
Unadjusted	0.544	0.294-1.006	0.052
Adjusted for approach	0.500	0.267-0.935	0.030
Cup revision			
Revision for any cause			
Unadjusted	0.778	0.606-0.999	0.049
Adjusted for approach	0.709	0.548-0.918	0.009
Revision for dislocation			
Unadjusted	0.353	0.215-0.580	<0.001
Adjusted for approach	0.320	0.192-0.532	<0.001

*HR = hazard ratio for DMC, with conventional THA as the reference.

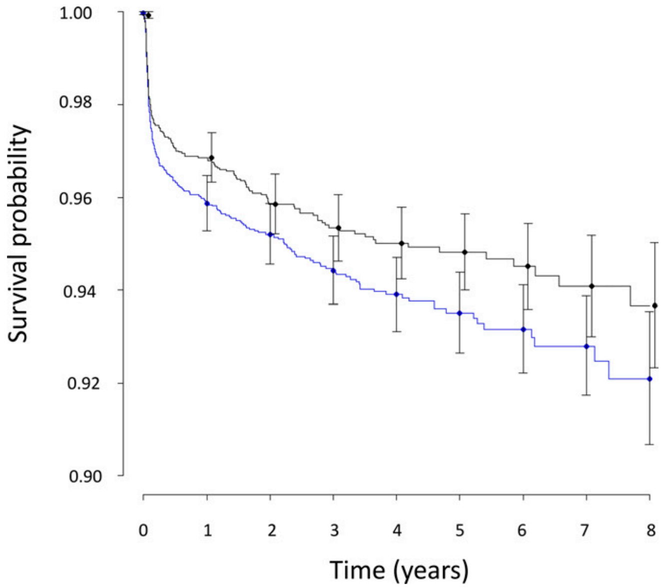

Fig. 2

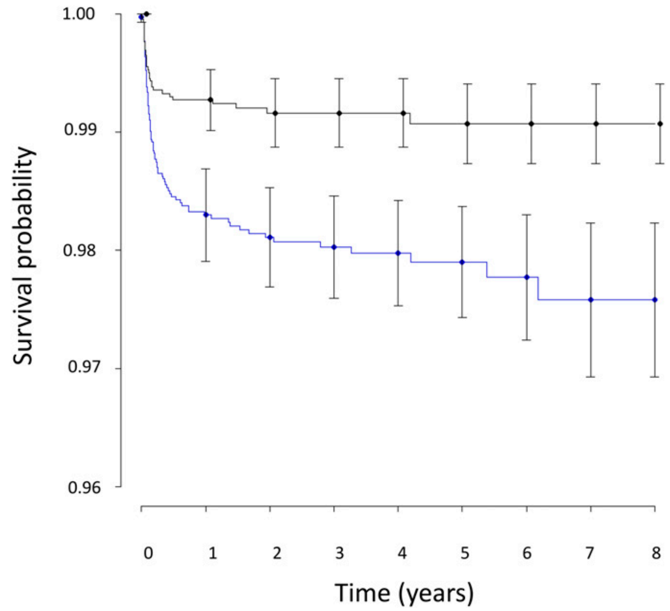

Fig. 3

Fig. 2 Kaplan-Meier curves (with 95% CIs) for implant revision due to all causes. Black line = DMC, and blue line = conventional THA. **Fig. 3** Kaplan-Meier curves (with 95% CIs) for implant revision due to dislocation. Black line = DMC, and blue line = conventional THA.

We used Fine-Gray competing risk regression analyses[26], with revision of the primary THA as the end point and death as a competing risk factor, to calculate the adjusted hazard ratio (AHR) and 95% confidence interval (CI). Adjustments were made for surgical approach, as a posterior approach is a strong risk factor for dislocation[27]. Survival analysis was performed with the Kaplan-Meier method.

We did not compare different DMC brands because there were too few outcome events. In addition, both the DMC brand and the surgical approach were associated with specific countries—i.e., matching or comparing these variables would have meant matching or comparing countries. That would have introduced bias as indications, standard of care, and public health systems may differ among countries.

The study was approved by The Danish Data Protection Agency (reference number 2012-41-0515) and the Regional Ethical Review Board in Gothenburg, Sweden (734-14). The study adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines[28].

Results

Patients registered during 2001 to 2014 were followed until revision, death, emigration, or the end of the follow-up period (December 31, 2014), whichever event occurred first. The median follow-up was 2.4 years (range, 0 to 14 years) for all cups, 2.1 years (range, 0 to 14 years) for the DMCs, and 2.7 years (range, 0 to 14 years) for the conventional cups. Despite matching, the DMC group had a higher mean age and shorter median follow-up.

The variables used in the propensity score matching together with other characteristics are listed in Table I. The posterior approach was more frequently used in the DMC group.

There were 243 revisions (5.4%) in the conventional cup group and 181 (4.0%) in the DMC group. The reasons for revision are presented in Table II.

The DMCs had a lower overall risk of revision compared with the conventional THAs (AHR = 0.75 [95% CI = 0.62 to 0.92]). This was consistent with the findings after we adjusted for approach. Furthermore, the DMCs had a lower risk of revision due to dislocation (Table III). These findings are illustrated by the survival curves shown in Figures 2 and 3.

No significant difference was identified regarding revision due to infection. After adjustment for approach, use of the DMC was associated with a slightly lower risk of aseptic loosening (Table III).

Revision of the cup due to dislocation or any reason was lower in the DMC group both with and without adjustment for surgical approach. Other reasons for cup revision were not analyzed separately because of infrequent events (Table III).

Crude mortality was higher in the DMC group (Table IV), with an AHR of 1.5 (95% CI = 1.4 to 1.6) compared with those treated with a conventional cup (Table III).

TABLE IV Mortality During Follow-up Period

	Conventional Cup	DMC	Total
Alive	3,318 (73.4%)	2,707 (59.9%)	6,025 (66.6%)
Dead within 1 year	331 (7.3%)	720 (15.9%)	1,051 (11.6%)
Dead after 1 year	871 (19.3%)	1,093 (24.2%)	1,964 (21.7%)

Discussion

In patients with a femoral neck fracture, the use of a DMC was associated with a lower overall risk of revision and revision due to dislocation in particular. Our findings are based on data from the NARA collaboration, which includes data from nationwide registers. They support findings of a lower risk of revision due to dislocation in previous clinical trials[19-22].

Our study focused on all complications leading to revision surgery and not selectively on dislocation, in contrast to earlier studies[19-22]. A new implant may have clinical benefit in one aspect, which can be outweighed by increasing other complications. Regarding DMCs, there has been much focus on dislocation while the risks of aseptic loosening and infection have not been fully investigated. One clinical study of DMCs for fractures showed a favorable overall revision rate[21], but none of the other studies analyzed revision rates in general[19,20,22,23]. Regrettably, an attempt to perform an RCT recently failed because of the nature of the patients with hip fracture[23].

We found no differences in the risk of revision due to infection between DMCs and conventional THA. In another study from the NARA group on patients with osteoarthritis, DMCs were more often revised for infection than conventional THAs. The authors suggested that selection of frailer and therefore more infection-prone patients for treatment with a DMC was the most likely explanation for this, but implant features and/or perioperative handling may also have contributed[18]. Such a selection bias is likely less pronounced in our patient cohort, which included exclusively those with a hip fracture. In addition, a greater reluctance to perform revisions in fracture cases because of high morbidity may play a role.

DMCs were associated with a somewhat lower risk of revision due to aseptic loosening. This issue was not identified in earlier studies[19-23]. According to a study of patients treated for osteoarthritis from 1998 to 2003[17], DMCs were associated with a higher risk of aseptic loosening and were not recommended for young, active patients. That study may not be relevant either to patients with a fracture or to modern implants, as patients who undergo THA for a fracture are much older than those who have a THA for osteoarthritis and as none of the cups in the aforementioned study had highly cross-linked polyethylene. Patients with osteoarthritis and those with a fracture have different activity levels, comorbidities, and remaining life expectancy. Remaining life expectance may be the most important factor as aseptic loosening is a long-term complication. Furthermore, during recent years, different types of highly cross-linked polyethylene have been increasingly used with this device, including in the Nordic countries, which probably will influence the revision rate over the long term.

We found that patients selected to receive a DMC had a higher mortality rate. We assume that surgeons regard DMC to be an option between conventional THA and hemiarthroplasty. Since current knowledge seems to guide us to use hemiarthroplasty in the most frail, least active patients and THA in those without physical or cognitive limitations[27], there is an intermediate group with particular needs to address. It may be that these are individuals with distinct risk factors for dislocation (neurological disease, alcohol abuse, and cognitive disorders)[29] and they are the group in whom DMCs are used. Hence, their general health status is inferior to that of individuals selected for conventional THA. Regrettably, the Nordic databases do not record the same comorbidity indexes, so we were unable to adjust for general health status.

By using competing risk analysis, we calculated an outcome while considering the fact that more patients in the DMC group will die before they require a revision. The higher mortality rate of patients with a DMC is most probably related to patient factors. Surgeons might tend to select DMC cups for frail patients, but this source of bias could not be addressed in our study. The possibility that the DMC cups themselves have an influence on mortality cannot be completely ruled out, but it seems very unlikely. Dislocation, on the other hand, is to a great extent implant-related.

Strengths and Limitations

Pooling of data from different countries highlights the variations in treatment strategies. Within the Nordic countries, the choice of approach varies from almost exclusively posterior in Denmark, to equal distributions of posterior and lateral in Sweden, to a majority of lateral approaches in Norway[30,31]. As Denmark contributed the largest number of DMCs to the study, the posterior approach predominated in the DMC group. By adjusting for approach, we aimed to overcome this. In our study, the percentage of cemented prostheses was higher than that in earlier studies[19,22,23], especially those performed outside the Scandinavian countries. This reflects the relatively high frequency of cement use in the Nordic countries.

The total number of fractures (9,040) included in this DMC study exceeds the numbers in any other study of DMC-treated fractures published so far[19-22]. Elderly patients with a hip fracture can be difficult to include in RCTs[23] and often only the healthiest patients are included. This may jeopardize the external validity of an RCT. In register studies, the external validity is high because all patients are included. On the other hand, selection bias is inherent as surgeons' choices of treatment method are based on patient factors that were not available for adjustment in our limited data set.

A limitation of the present study is that the NARA database does not contain information on ASA scores or variables that can be used for calculation of comorbidity indexes. However, we believe that age and sex are relatively good proxies. Two recent studies showed a combination of age and sex to be a better predictor of mortality after elective THA[32] and fracture THA[33] than the Charlson and Elixhauser Comorbidity Indexes. In a U.S. study, age was found to be better than ASA class for predicting adverse events after elective THA and the Charlson Comorbidity Index had the lowest discriminative ability in this regard[34].

Our data reflect only revisions reported to the registry. This means that implant complications and inferior clinical outcomes not resulting in a revision are unknown. The completeness of the reporting of primary procedures to the Nordic registries is excellent according to a NARA report[24]. The corresponding percentage of revisions that are reported may vary[35,36]. Reoperations without the exchange or removal of implant components are not included in the NARA database at all. In addition, many patients may be treated only with closed reduction(s) after dislocation of a THA that had been done for a fracture, as they are considered not medically fit to undergo surgical revision of the prosthesis. Finally, some elderly individuals may have a complication without seeking a health care provider. We did not try to provide a "true" rate of complications, only those that led to an implant exchange or removal.

Conclusions

We found that THA with a DMC for a hip fracture resulted in a lower overall risk of revision compared with conventional THA. The main reason for the lower risk of revision was a lower risk of revision due to dislocation. This conclusion is drawn from 3 national cohorts of patients operated on with a variety of implants and predominantly with a posterior approach. ■

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