Periprosthetic Femoral Fracture within Two Years After Total Hip Replacement

Analysis of 437,629 Operations in the Nordic Arthroplasty Register Association Database

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Background: We used the Nordic Arthroplasty Register Association database to evaluate whether age, sex, preoperative diagnosis, fixation, and implant design influence the risk of revision arthroplasty due to periprosthetic fracture within two years from operation of a primary total hip replacement.

Methods: Included in the study were 325,730 cemented femoral stems and 111,899 uncemented femoral stems inserted from 1995 to 2009. Seven frequently used stems (two cemented stems [Exeter and Lubinus SP II] and five uncemented stems [Bi-Metric, Corail, CLS Spotorno, ABG I, and ABG II]) were specifically studied.

Results: The incidence of revision at two years was low: 0.47% for uncemented stems and 0.07% for cemented stems. Uncemented stems were much more likely to have this complication (relative risk, 8.72 [95% confidence interval, 7.37 to 10.32]; $p < 0.0005$). Age had no consistent influence on the risk for revision of cemented stems, but revision in the uncemented group increased with increasing age. A cemented stem was associated with a higher risk in male patients compared with female patients (hazard ratio, 1.95 [95% confidence interval, 1.51 to 2.53]; $p < 0.0005$), whereas an uncemented stem was associated with a reduced risk in male patients compared with female patients (hazard ratio, 0.74 [95% confidence interval, 0.62 to 0.89]; $p = 0.001$). The risk for revision due to early periprosthetic fracture increased during the 2003 to 2009 period compared with the 1995 to 2002 period both before and after adjustment for demographic factors and fixation (relative risk, 1.44 [95% confidence interval, 1.18 to 1.69]; $p < 0.0005$). The hazard ratio for the Exeter stem was about five times higher than that for the Lubinus SP II stem (hazard ratio, 5.03 [95% confidence interval, 3.29 to 7.70]; $p < 0.0005$). Of the five uncemented stems, the ABG II stem showed an increased hazard ratio of 1.63 (95% confidence interval, 1.16 to 2.28) ($p = 0.005$), whereas the Corail stem showed a decreased hazard ratio of 0.47 (95% confidence interval, 0.34 to 0.65) ($p < 0.0005$) compared with the reference Bi-Metric design.

Conclusions: The shape and surface finish of the femoral stem and its fixation could be related to the increased risk of some prosthetic designs. Even if the incidence of early periprosthetic fracture in general is low and other reasons for revision must be considered, specific attention should be given to the choice of fixation and stem design in risk groups.

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

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Previous reports from the Swedish Hip Arthroplasty Register noted that the early survival of uncemented total hip replacement is inferior to cemented fixation[1], partly due to early periprosthetic femoral fracture. Previous hip fracture is a risk factor for subsequent periprosthetic fracture[2-5] as well as age[6]. It is not clear if this early complication varies between different uncemented stem designs. The incidence is expected to rise in the future because of an increasing number of uncemented total hip arthroplasties and a longer life expectancy. Intraoperative femoral fractures appear to be more common because of increasing use of cementless fixation[2]. Perhaps the risk of fracture can be reduced with careful preoperative planning and surgical technique, but no data to date support this assumption.

Because of the comparatively rare occurrence of periprosthetic femoral hip fractures, large patient cohorts are needed to evaluate probable causes. Hip arthroplasty registries are an important tool for continuous monitoring of outcome after total hip replacement[7-9]. The Nordic Arthroplasty Register Association[10,11] (NARA) has compiled a common database based on the National Registers in Denmark, Finland, Norway, and Sweden, which, because of its size, may enable studies of this complication on the level of a specific implant design.

The aim of the present study was to evaluate whether age, sex, preoperative diagnosis, fixation, and specific implant design influence the risk of revision due to periprosthetic femoral fracture within two years from a primary total hip replacement.

Materials and Methods

From January 1, 1995, through 2009, 449,930 femoral stem implants (surface replacements excluded) were reported to the arthroplasty registers in Denmark, Finland, Norway, and Sweden. These four Nordic registers have nearly complete coverage. The completeness of data varies between 86% and 99% in the four countries. The NARA includes both primary total hip replacement and revision, as well as the data on the reason for revision. Patients are registered on the basis of their personal identity number, a national identification number covering the total resident population of a country. Numbers are issued by the tax agency as part of the population register. All revisions are continuously reported to the registers. The reason for revision is entered into a form by the operating surgeon and is validated by studies of case records. Revision is defined as exchange or removal of the entire prosthesis or at least one of its parts. In this study, only revision of the femoral component due to periprosthetic fracture within two years from the primary total hip replacement was used as an end point. Reoperation, defined as any other hip-related surgery following primary total hip replacement, leaving the primary total hip replacement implant intact, was not included as an end point as the registration of reoperation is not uniform in all four countries.

In 12,301 patients (2.7%), data were incomplete because of at least one missing parameter of sex, age, or type of implant, so these cases were excluded, leaving 437,629 total hip replacements, of which 325,730 (74.4%) were cemented (Table I).

The patients were divided into five age groups (younger than fifty years, fifty to fifty-nine years, sixty to sixty-nine years, seventy to seventy-nine years, and eighty years or more) and into six groups of diagnoses. To enable analysis of individual stem designs as one group, the different code numbers used in the four countries for a particular stem were recoded for each of the stems selected, which were the designs most frequently used. To be included, they should also have been used in at least three of the four countries included in the NARA collaboration. Seven implant designs were identified for further analysis: the two most frequently used cemented stems, the polished wedged Exeter (Stryker, Portage, Michigan; www.stryker.com) and the anatomic Lubinus SP II (Waldemar Link, Hamburg, Germany; www.linkorthopaedics.com); and five uncemented stems, the polished wedged CLS Spotorno stem (Zimmer, Warsaw, Indiana; www.zimmer.com) and four more anatomically shaped stems, Bi-Metric (Biomet, Warsaw, Indiana; www.biomet.com), Corail (DePuy, Warsaw, Indiana; www.depuy.com), and ABG I and ABG II (Stryker) (Table II). All stems available were included ignoring the choice of fixation on the cup side. All variations of each stem design were included provided that they had been used in at least fifty arthroplasties each.

Statistics

We used descriptive statistics for the presentation of demographic factors such as age, sex, preoperative diagnosis, fixation, and stem design. The crude survival at six months and two years following primary total hip replacement was computed for the seven specified implants. We used Cox regression analyses to calculate the crude and adjusted relative risk of revision due to periprosthetic fracture within two years of primary total hip replacement operation with 95% confidence interval (95% CI). We adjusted for the type of fixation (cemented or uncemented), age (less than fifty years, fifty to fifty-nine years, sixty to sixty-nine years, seventy to seventy-nine years, or eighty years or more), diagnosis (primary osteoarthritis, fracture, pediatric hip disease, inflammatory disease, idiopathic femoral head necrosis, and other diagnoses), and involved side (right or left). In a second model, we added year of operation separated into two groups (1995 to 2002 and 2003 to 2009) to evaluate if there was a trend over time.

All patients were followed until date of revision, death, or December 31, 2009.

Sex was excluded from these analyses because of non-proportionality and interaction between stem fixation and sex ($p < 0.0005$). There was also an interaction between stem fixation and age group ($p < 0.0005$) and a three-way interaction among stem fixation, sex, and age group ($p < 0.0005$), motivating a stratified analysis. Therefore, subgroup analyses on each sex separately were performed comparing cemented and uncemented stems. In further analyses,

TABLE I Choice of Stem Fixation in the Four Countries and Demographic Patient Data

	Cemented	Uncemented
Total no. of patients*	325,730	111,899
Share of cemented stems per country†‡		
Denmark	63%	
Finland	52%	
Norway	79%	
Sweden	90%	
Sex†§		
Male	36%	53%
Female	64%	47%
Patient age§# *(yr)*	71.4 ± 9.5	60.8 ± 11.3

*This category included all patients with cemented stems, uncemented stems, hybrid stems, and reverse hybrid stems. †The values are given as the percentage of patients. ‡Significant differences among countries were noted at $p < 0.0005$. §Significant values between groups were noted at $p < 0.0005$. #The values are given as the mean and the standard deviation.

TABLE II Numbers Revised within Six Months and Two Years for the Stem Designs in the Study

	Numbers Revised*		
	Within Six Months	Within Two Years	Numbers Available†
All cemented stems	117 (0.04%)	238 (0.07%)	325,730 (74.4%)
All uncemented stems	474 (0.42%)	530 (0.47%)	111,899 (25.6%)
Cemented stem designs			
Exeter	52 (0.06%)	120 (0.14%)	85,336 (26.2%)
Lubinus SP II	18 (0.02%)	32 (0.03%)	94,917 (29.1%)
Uncemented stem designs			
Bi-Metric	129 (0.54%)	135 (0.56%)	23,943 (21.4%)
CLS Spotorno	22 (0.29%)	25 (0.33%)	7692 (6.9%)
Corail	51 (0.28%)	51 (0.28%)	17,932 (16.0%)
ABG I	16 (0.38%)	19 (0.45%)	4186 (3.7%)
ABG II	39 (0.78%)	46 (0.92%)	5024 (4.5%)

*The values are given as the numbers of patients, with the row percentage in parentheses. †The values are given as the number of patients available, with the percentage of the total number of either cemented stems or uncemented stems in parentheses.

only the two selected cemented stems (Lubinus SP II and Exeter) or the five selected uncemented stems (Bi-Metric, CLS Spotorno, Corail, ABG I, and ABG II) were included in addition to the covariates presented above.

All calculations used the compiled database including all four countries. We used IBM SPSS Statistics, Version 20 (IBM, Armonk, New York). The proportional hazard assumption was controlled by plotting survival curves and

TABLE III Relative Risk of Revision Due to Periprosthetic Fracture

Variable	No. of Patients	Relative Risk*	P Value
Type of stem (unadjusted)			<0.0005
Uncemented	111,899	6.76 (5.80 to 7.88)	
Cemented†	325,730	1 (1)	
Type of stem (adjusted)			<0.0005
Uncemented	111,899	8.72 (7.37 to 10.32)	
Cemented†	325,730	1	
Age			
Younger than fifty years	22,999	0.42 (0.30 to 0.58)	<0.0005
Fifty to fifty-nine years	61,317	0.55 (0.44 to 0.69)	<0.0005
Sixty to sixty-nine years	131,350	0.85 (0.70 to 1.02)	0.07
Seventy to seventy-nine years†	157,269	1	
Eighty years or more	64,694	1.17 (0.91 to 1.49)	0.22
Diagnosis			
Primary osteoarthritis†	353,446	1	
Fracture	34,602	2.41 (1.95 to 2.98)	<0.0005
Pediatric hip disease	15,190	1.09 (0.76 to 1.57)	0.65
Inflammatory disease	15,843	1.25 (0.84 to 1.84)	0.27
Idiopathic femoral head necrosis	9881	1.99 (1.35 to 2.95)	0.001
Other	8667	2.02 (1.46 to 2.79)	<0.0005
Involved side			0.30
Right	239,609	0.93 (0.81 to 1.07)	
Left†	198,020	1	

*The values are given as the relative risk, with the 95% CI in parentheses. †This is the reference category for all cemented and uncemented stems, with sex excluded (see text).

TABLE IV Relative Risk of Revision Due to Periprosthetic Fracture Adjusted for Diagnosis (Primary or Secondary Osteoarthritis) and Involved Side in Age Groups and Separated by Female and Male Patients

Age Group and Fixation	No. of Patients	Relative Risk*	P Value
Female			
Younger than fifty years			0.02
Uncemented	7831	4.25 (1.28 to 14.06)	
Cemented†	3742	1	
Fifty to fifty-nine years			<0.0005
Uncemented	16,807	6.83 (3.40 to 13.73)	
Cemented†	15,895	1	
Sixty to sixty-nine years			
Uncemented	21,091	12.67 (8.30 to 19.36)	<0.0005
Cemented†	54,367	1	<0.0005
Seventy to seventy-nine years			<0.0005
Uncemented	10,729	16.84 (11.71 to 24.22)	
Cemented†	91,000	1	
Eighty years or more			<0.0005
Uncemented	2993	15.22 (9.52 to 24.33)	
Cemented†	43,146	1	
Male			
Younger than fifty years			0.09
Uncemented	8061	2.05 (0.70 to 5.99)	
Cemented†	3365	1	
Fifty to fifty-nine years			0.001
Uncemented	15,946	2.89 (1.56 to 5.35)	
Cemented†	12,669	1	
Sixty to sixty-nine years			
Uncemented	19,173	4.14 (2.83 to 6.06)	<0.0005
Cemented†	36,719	1	<0.0005
Seventy to seventy-nine years			<0.0005
Uncemented	7917	7.14 (4.75 to 10.73)	
Cemented†	47,623	1	
Eighty years or more			<0.0005
Uncemented	1351	5.89 (2.45 to 14.15)	
Cemented†	17,204	1	

*The values are given as the relative risk, with the 95% CI in parentheses. †This is the reference category for all cemented and uncemented stems.

by computing and plotting the Schoenfeld residuals for each covariate using R statistics.

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No external funding source was used in this study.

Results

The incidence of periprosthetic femoral fracture at two years was low: 0.47% for uncemented stems and 0.07% for cemented stems (Table II). There were 768 revisions (238 cemented and 530 uncemented) due to periprosthetic fracture within two years (Table II), constituting 9.5% of all revisions. Nearly all of the fractures with uncemented stems occurred within the first six months, and fractures with cemented stems occurred mainly after six months. At six months, the crude revision rate of uncemented stems due to periprosthetic femoral fracture was about ten times higher than that observed for cemented stems. At two years, the risk difference had decreased and was about six times higher (Table II).

Uncemented stems were more commonly used in male patients than in female patients and the mean patient age of the group with the uncemented stem at the time of arthroplasty was about ten years younger than in the group who underwent arthroplasty with a cemented stem (Table I), but all stems were used in all age groups.

The survival (and standard deviation) at two years regardless of the reason for revision was 98.3% ± 0.05% for cemented stems and 97.1% ± 0.04% for uncemented stems. The corresponding survival (and standard deviation) based on early periprosthetic femoral fracture was 99.9% ± 0.01% for cemented femoral stems and 99.5% ± 0.04% for uncemented femoral stems. Overall, the unadjusted relative rate for revision due to periprosthetic fracture was higher for uncemented stems (relative risk, 6.76 [95% CI, 5.80 to 7.88]) (Table III). After adjustment for age, diagnosis, and involved side, the relative risk increased further to 8.72 (95% CI, 7.37 to 10.32) (Table III). The risk of periprosthetic femoral fracture was increased for both preoperative femoral neck fracture and idiopathic femoral head necrosis (Table III).

The uncemented stems had a higher relative risk for revision compared with cemented stems increasing with age in both male patients and female patients (Table IV). In male patients younger than fifty years of age, we found no difference (relative risk, 2.05 [95% CI, 0.70 to 5.99]), but the number of revised stems due to fractures was very low (four cemented stems [0.1%] and twenty uncemented stems [0.2%]).

From 1995 to 2002, 15.3% of all stems were uncemented, increasing to 34.7% from 2003 to 2009. The unadjusted relative risk for revision within two years more than doubled in the period 2003 to 2009 compared with the period 1995 to 2002 (relative risk, 2.23 [95% CI, 1.95 to 2.67]; $p < 0.0005$). After adjustment for age, diagnosis, and sex, the relative risk had still increased, but had dropped to 1.44 (95% CI, 1.18 to 1.69) ($p < 0.0005$; detailed analysis not shown).

A separate analysis of the entire cemented and uncemented groups (see Appendix) showed that the influence of sex and age differed between the two types of stem fixation. In the cemented group, male patients were at a higher risk of revision compared with female patients (unadjusted hazard ratio, 1.84 [95% CI, 1.44 to 2.35]) (see Appendix), and previous hip fracture was a risk factor for subsequent periprosthetic femoral fracture (see Appendix).

In the uncemented group, male patients were at a lower risk of revision due to periprosthetic fracture (unadjusted hazard ratio, 0.69 [95% CI, 0.58 to 0.82]) (see Appendix).

The Lubinus SP II and Exeter stems constituted 55.3% of all of the cemented cases. There were thirty-two periprosthetic fractures in the Lubinus SP II group and 120 periprosthetic fractures in the Exeter group. In the regression analyses, the Exeter stem had about five times an increased risk to be associated with revision due to this complication (see Appendix).

The uncemented stem designs specifically studied constituted 52.5% of all of the uncemented stems. Compared with the reference and most frequently used Bi-Metric stem, the Corail stem was associated with a decreased risk both before and after adjustment for the covariates studied. The ABG II design showed an increased risk, whereas the CLS Spotorno and ABG I designs did not significantly differ from the Bi-Metric design (see Appendix).

Discussion

Periprosthetic femoral fracture is more common in uncemented stems and in polished cemented stems and is most frequent during the early postoperative months, increasing with age, especially in older women. We observed a variation in the risk ratio among the five specific uncemented stem designs studied. The ABG II design showed an increased risk and the Corail design showed a decreased risk compared with the Bi-Metric design.

Overall, the number of revisions due to early periprosthetic femoral fracture in the Scandinavian countries based on data from all national registers is low (Table II). The advantages of this study were that it represents a wide spectrum of orthopaedic surgeons with variable clinical experience and covers the whole Nordic region. Nonetheless, only a few designs of stems could be identified in sufficient numbers for a reliable evaluation of probable design-related features.

However, confounding factors associated with register studies require consideration. Uncomplicated periprosthetic fractures (e.g., those classified as Vancouver type A[12]) rarely result in revision and are not included in our study. If Vancouver type-B and C fractures with a high incidence of complications and reoperations[1] are treated without exchange of the prosthesis, this surgical procedure is not recorded as a revision and consequently is not included in the present analysis. This underreporting could also contribute to a distorted view of the fracture incidence.

Some implant-related parameters may be biased by factors not known by us, such as use of different types of incision, which is not consistently recorded in the NARA database. Minimally invasive incisions, which theoretically could produce a higher number of unrecognized fractures, have not been extensively used in the Nordic countries. In Sweden, for example, this approach was used in <1% of the cases.

Not unexpectedly, previous hip fracture was a risk factor for subsequent periprosthetic femoral fracture. The reason why idiopathic necrosis of the femoral head also is associated with an increased risk is not quite clear, but it could also be because of osteoporosis or poor bone quality due to other comorbidities[13]. Systemic abnormalities[14], treatment with corticosteroids, and alcoholism or substance abuse are known to be associated with reduced bone-mineral density[10] and increased risk of fracture.

Most of the early fractures around uncemented stems were revised within six months. Some of them might have appeared during surgery as minor fissures, which progressed to obvious clinical fractures during the rehabilitation period. Nonetheless, our analysis indicates that the incidence of early periprosthetic femoral fracture resulting in revision has increased during the later period analyzed even after adjustment for choice of stem fixation, age, and diagnosis. The reason for this increase is not known. Factors such as faster rehabilitation, shorter training period before surgeons may operate independently, change of implant, and patient selection could be possible causes.

Uncemented stems may be more prone to fracture should the patient sustain trauma to the hip, as long as the stem has not established biological fixation. One could speculate that similar mechanisms are responsible for the increased risk of fracture with polished stems not bonded to the cement mantle. Some previous studies using dual x-ray absorptiometry (DXA) have shown that, during the postoperative year, the loss of bone mineral density is most pronounced, which in some of the regions might be followed by a small recovery[15-17]. For the Exeter stem, the unadjusted survival showed a weak tendency to become less steep after about four to five months, possibly reflecting changes in bone metabolism. In the uncemented cases, the steep course of the survival curve up to two months postoperatively could reflect delayed revisions of intraoperative fractures and an increased risk of fracture before ingrowth of the stem.

Somewhat surprisingly, the influence of sex was reversed between use of cemented and uncemented fixation of the stem. Cementing the stem seems to have a protective effect against early periprosthetic fracture and the overall risk becomes very low. Physical activity and certain comorbidities associated with increased risk of trauma due to fall might become equally and more decisive factors than the bone quality. Our observation, contrary to previous findings[6], that age had no certain influence on the risk of early periprosthetic fracture around a cemented stem might support this theory.

Use of uncemented stems had an eightfold to ninefold increased risk for revision due to early periprosthetic fracture, which has been reported previously[2]. This risk increase was particularly high in female patients and, contrary to the findings with use of cement, the risk decreased in the younger age groups. Early periprosthetic fracture is the third most common complication following operation with hemiarthroplasty after femoral neck fracture[18] and the incidence is higher with use of an uncemented modern stem design, suggesting that uncemented fixation is not the first choice in older female patients and patients with previous femoral neck fracture.

The two most frequently used cemented femoral stems with high survival in the NARA database have completely different shapes and surface finishes. The anatomic Lubinus stem is designed to become fixed in the cement mantle, whereas the tapered Exeter stem is designed to subside inside the cement mantle to achieve an even load bearing. Thus, the reason for the increased fracture risk with this stem might be similar to the one presented for uncemented stems. This material property is likely used in the Exeter design as well as in the majority of polished stems.

Polished stems generally are at higher risk for a periprosthetic fracture[4,19,20]. However, polished stems have an excellent overall track record, particularly related to the risk of loosening and osteolysis. In the NARA database, the stem survival (and standard deviation) at fourteen years including all reasons for revision is 94.5% ± 1.0% for the Exeter stem and 95.4% ± 0.6% for the Lubinus stem, which is only marginally higher than the Exeter stem.

The increased risk for the ABG II stem and the corresponding decreased risk for the Corail stem are difficult to interpret. It seems that a wedge shape is superior to a more anatomic design even if, from a theoretical point of view, the situation should be reversed. A wedge-shaped stem could be expected to more frequently act as a stress riser with its comparatively sharp corners compared with a rounded design. It might be that other factors such as the time between the insertion and rigid osseous fixation is shorter for the Corail stem. The length of the stem could also be an issue, but does not agree with the observation that the relative frequency of periprosthetic fracture around the ABG I stem was only half of that observed with the ABG II stem.

Revision due to early periprosthetic femoral fracture is increasing in our study. Even if our analyses do not allow for establishment of a distinct age limit, they indicate that specific attention should be given to the bone quality in relation to choice of fixation in patients older than sixty years of age and especially in female patients.

Appendix

eA Tables showing the unadjusted and adjusted hazard ratios of risk of revision due to periprosthetic fracture in male and female patients in the cemented and uncemented groups and the unadjusted and adjusted hazard ratios of risk of revision due to periprosthetic fracture for the two selected cemented stems and the five selected uncemented stems are available with the online version of this article as a data supplement at jbjs.org. ■

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