

Inferior outcome after intraoperative femoral fracture in total hip arthroplasty

Outcome in 519 patients from the Danish Hip Arthroplasty Registry

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Background Intraoperative femoral fracture is a well-known complication of primary total hip arthroplasty (THA). Experimental studies have indicated that intraoperative fractures may affect implant survival. Very few clinical data are available, however.

Methods We used data from the Danish Hip Arthroplasty Registry to identify patients in Denmark who underwent a primary THA due to primary osteoarthritis between 1995 and 2005 (n = 39,478). Data were linked to two national Danish databases in order to conduct time-dependent implant survival analyses. Implant survival and relative risk estimates were calculated for patients treated nonoperatively and for patients treated with osteosynthesis after sustaining intraoperative femoral fractures during THA surgery. THAs performed without sustaining intraoperative femoral fracture served as the reference group.

Results 282 patients (0.7%) were treated nonoperatively due to intraoperative femoral fracture and 237 patients (0.6%) were treated with osteosynthesis. In the 0–6 month postoperative period, the adjusted relative risk (RR) of revision was 1.5 (95% CI: 1.1–1.7) for patients treated nonoperatively and 5.7 (3.3–10) for patients treated with osteosynthesis. In the period from 6 months to 11 years postoperatively, we did not find any statistically significant differences in the RR of revision between the groups.

Interpretation Intraoperative fractures increase the relative risk of revision during the first 6 postoperative months. Thus, patients should be informed about the risk of revision after sustaining an intraoperative femoral fracture. Furthermore, initiatives aimed at reducing

the risk of revision in the first 6 months following THA should be considered in patients with intraoperative fractures, including immediate change to a larger stem with distal fixation and restricted weight bearing.

The effect of intraoperative periprosthetic fractures on implant survival and clinical outcome in general is unclear. An adverse effect of intraoperative femoral fractures on bone ingrowth in uncemented femoral implants has been reported in studies based on dogs. It has therefore been suggested that intraoperative fractures may affect the implant survival or functional outcome of THA (Jasty et al. 1992, Schutzer et al. 1995). In contrast, the few existing clinical studies have reported good results after intraoperative femoral fracture regarding pain and walking ability (Schwartz et al. 1989, Berend et al. 2004). These studies were, however, based on small numbers of patients. To our knowledge, the time dependency between intraoperative femoral fractures and implant survival has not been studied before. As implant survival is difficult to predict in this context, it is thus difficult to inform patients about short- and long-term implant survival after intraoperative femoral fractures. Knowing the risk of implant failure after intraoperative femoral fracture may be useful for the perioperative treatment of the complication.

We assessed the short- and long-term implant survival after intraoperative femoral fracture. In

addition, we compared the length of hospital stay, the risk of re-admission to the orthopedic department, and the risk of reoperation during the 3-month period after primary THA in patients who did and in those who did not sustain an intraoperative femoral fracture.

Patients and methods

Sources of data

The Danish Hip Arthroplasty Registry (DHR). The DHR is a nationwide clinical database that was established on January 1, 1995 with the purpose of improving the monitoring and quality of primary and revision total hip arthroplasty surgery in Denmark (Lucht 2000). All orthopedics departments in the country ($n = 45$) report to the register, including 8 departments located in private hospitals. Registration of primary THA and revisions is compulsory, but registration of follow-up examinations is voluntary. Preoperative, intraoperative, and postoperative data are collected prospectively using standard forms. The intraoperative data are filled in by the operating surgeon immediately after surgery. The DHR was recently validated and the quality of data was found to be high (Pedersen et al. 2004).

The National Registry of Patients (NRP). The NRP, which was established in 1977 (Andersen et al. 1999), records information of all discharges from public somatic hospitals in Denmark. The NRP contains information on dates of admission and discharge, surgical procedures performed, and up to 20 diagnoses for every discharge. Since 1993, the diagnosis has been classified according to the Danish version of the International Classification of Diseases (tenth edition). All discharge diagnoses are assigned by the physician who discharges the patient. Using the NRP, it is possible to reconstruct the complete inpatient history of each patient.

The Civil Registration System (CRS). A unique personal identification number is given to all Danish citizens at birth and all Danish residents. The CRS records information on changes in vital status of all Danish citizens including changes of address, date of emigration, and (since 1968) the date of death. Accurate linkage between the public Danish registers at the patient level is possible using the personal identification number.

Study population

From the DHR, we identified all primary THA procedures performed in Denmark between January 1, 1995 and December 31, 2004 due to primary osteoarthritis ($n = 39,778$). We excluded 83 patients with missing data on intraoperative complications, 10 patients who lived in Greenland or changed their personal identification number and therefore could not be properly followed up, 9 patients with an incorrect revision date or missing indication for revision, and 29 patients with both acetabular and femoral complications intraoperatively. We also excluded 176 patients with intraoperative complications other than fracture of the femur (e.g. excessive bleeding, reaming of the femoral canal, or broken tools). Thus, 39,471 primary THA procedures with complete follow-up were available for the analysis.

Intraoperative fracture

Fracture was defined as any fissure or fracture of the femur that was noticed intraoperatively and reported to the DHR. The patients were divided into 3 categories: patients without intraoperative fracture, patients with intraoperative femoral fracture that was treated nonoperatively only (with restricted weight bearing), and patients with intraoperative femoral fracture that was treated with osteosynthesis during primary surgery. In a sub-analysis, these groups were stratified according to whether there was uncemented and cemented fixation of the femoral stem.

Outcomes

The primary outcome was time to failure, i.e. revision, defined as a partial or complete removal or exchange of the components. Conditions not requiring removal or exchange of the components were not included. Follow-up started on the day of primary THA and ended on the day of revision, death, emigration, or December 31, 2004—whichever came first. The follow-up after primary THA was divided into two periods. The initial period commenced on the day of surgery and continued until a revision was performed, or until 6 months after surgery. If patients did not undergo revision in the initial period they were included in the second period, which lasted until the end of follow-up.

The second outcome was re-admission to an orthopedics department, defined as admission due to deep or superficial wound infections, postoperative mechanical complications of the THA, or closed reduction due to dislocation. Conditions requiring open surgical treatment were not included. Follow-up started on the day of primary THA and ended on the day of readmission, or 3 months postoperatively.

The third outcome was reoperation, including open surgery due to partial or complete revision, open reduction, femoral osteosynthesis, deep or superficial infection, and operations due to wound problems. Follow-up started on the day of primary THA and ended on the day of reoperation, or 3 months postoperatively.

The fourth outcome was the length of hospital stay, defined as time from admission to discharge from the orthopedics department after primary THA. Data on length of hospital stay were available for 35,190 of 39,471 patients (89%).

Covariates

Data on covariates, including sex, age, fixation technique, and co-morbidity were obtained from the DHR and the NRP. Age at the time of primary THA was divided into 5 groups: 10–49 years, 50–59, 60–69, 70–79, and 80 years or more. Fixation technique was divided into 3 groups: cemented, uncemented, and hybrid. Co-morbidity at the time of surgery was assessed by computing the Charlson co-morbidity index (Charlson et al. 1987), which includes 19 major disease categories, translated into corresponding ICD-8 and ICD-10 hospital discharge codes used in the NRP. The index applies a weighting of 1, 2, 3, or 6 points to each of the 19 disease categories and is then summated. We categorized the patients as belonging to one of 3 different levels: low index (corresponding to those with no previously recorded disease categories in the Charlson co-morbidity index), medium index (patients with 1 or 2 such disease categories), and high index (patients with more than 2 such disease categories).

Statistics

We constructed Kaplan-Meier curves for THA prostheses. We used life table techniques to compute the cumulative incidence of each outcome (the

proportion of the population that had the outcome of interest). Cox's regression analysis was used to compute hazard ratios and 95% confidence intervals as a measure of the relative risk (RR) while controlling for age, sex, fixation technique, and co-morbidity. In all analyses, patients without intraoperative complications were used as reference. The Cox proportional hazards model was found suitable after applying log-log plots and Schoenfeld residuals. To calculate the adjusted relative risk estimates for re-admission to the orthopedics department and risk of reoperation, we used the same Cox model.

Calculation of p-values was done using the Student t-test and qq-plots were assessed to test for normal distributions. For all analyses, we used Stata statistical software, release 9.0 (StataCorp, College Station, Texas).

Results

519 primary THAs (1.3%) had an intraoperative femoral fracture. These femoral fractures were treated nonoperatively or with an osteosynthesis, in 282 cases (0.7%) and 237 cases (0.6%), respectively (Table 1). The average length of follow-up was 4.8 years.

Follow-up of intraoperative femoral fractures for 0–6 months

The overall cumulative failure rate was 0.9% for patients without intraoperative fracture and 3.4% for patients with intraoperative femoral fracture. The highest cumulative failure rate was 5.7%—for patients treated with osteosynthesis of an intraoperative femoral fracture. Femoral fracture was generally associated with an increased adjusted RR of revision of 3.3 (95% CI: 2.1–5.1) when compared with patients without an intraoperative fracture (Table 2). The adjusted RR was 1.5 (95% CI: 1.1–1.7) if the fracture was treated nonoperatively, whereas it was 5.7 (95% CI: 3.3–10) if the fracture was treated with osteosynthesis (Figures 1 and 2). Comparing cemented and uncemented stem fixation, we found no statistically significant differences in the relative risk estimates for these groups.

Revisions were performed due to dislocation, femoral fracture, or deep infection in all 3 groups.

Table 1. Characteristics of patients who underwent primary THA with and without intraoperative femoral fracture

	No complications n = 38,952	All n = 519	Femoral fracture	
			Conservative n = 282	Osteosynthesis n = 237
Gender				
Female (%)	21,974 (56)	355 (68)	191 (68)	164 (69)
Male (%)	16,978 (44)	164 (32)	91 (33)	73 (31)
Age group (years)				
10–49 (%)	1,096 (3)	18 (4)	8 (3)	10 (4)
50–59 (%)	5,365 (14)	109 (21)	54 (14)	55 (23)
60–69 (%)	12,415 (32)	148 (29)	82 (30)	66 (28)
70–80 (%)	14,456 (37)	181 (35)	104 (37)	77 (33)
≥ 80 (%)	5,620 (14)	63 (12)	34 (12)	29 (12)
Fixation technique				
Femur				
Cemented (%)	31,204 (80)	344 (66)	198 (70)	146 (62)
Uncemented (%)	7,748 (20)	175 (34)	84 (30)	91 (38)
Acetabulum				
Cemented (%)	20,066 (52)	172 (33)	101 (36)	71 (30)
Uncemented (%)	18,886 (49)	347 (67)	181 (64)	166 (70)
Charlson co-morbidity index ^a				
Low (%)	26,695 (69)	349 (67)	187 (66)	162 (68)
Medium (%)	10,155 (26)	137 (26)	79 (28)	58 (24)
High (%)	2,102 (5)	33 (6)	16 (6)	17 (7)

^a Low: 0; medium: 1–2; high: ≥ 3.

Table 2. Relative risk of revision after intraoperative femoral fracture in primary THA for the first 6 months postoperatively

	No. of patients	Revisions	Crude relative risk (95% CI)	Adjusted relative risk ^a (95% CI)
No complications	38,952	357	1.0 (ref)	1.0 (ref)
Femoral fracture				
conservative	282	4	1.5 (0.6–4.2)	1.5 (1.1–1.7)
osteosynthesis	237	13	6.2 (3.5–11)	5.7 (3.3–10)

^a Adjusted for gender, age, fixation technique, and co-morbidity.

In the initial 6-month period, the most important reason for revision in the osteosynthesis group was dislocation (9 /13 patients). This represented an adjusted RR of revision due to dislocation of 7.2 (95% CI: 3.4–14.1). The remaining revisions in this period were performed due to fracture (in 3 of 13 patients) and due to deep infection in one patient. In comparison, patients without intraoperative fracture were revised due to dislocation in 210/357 cases (59%) and due to fracture in 26/357 cases (7%) in the same period.

Follow-up of intraoperative femoral fractures for 6 months to 11 years

The 10-year cumulative failure rate was 8.9% (95% CI: 8.3–9.6) for patients without intraoperative complications. For patients with intraoperative femoral fracture it was 6.9% (95% CI: 6.9–14) for patients treated nonoperatively and 13.5% (95% CI: 8.4–22) for patients treated with osteosynthesis. Patients treated nonoperatively had an adjusted RR of revision in this period of 1.0 (95% CI: 0.6–2.0) whereas patients treated with osteosynthesis had an adjusted RR of 1.5 (95% CI: 0.8–2.9) (Table

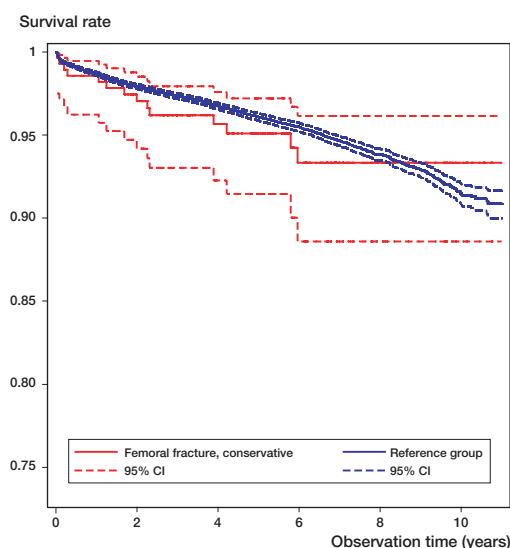


Figure 1. THA survival curve for patients with conservatively treated intraoperative femoral fracture and for the reference group (no femoral fracture intraoperatively). Note that the y-axis does not start at zero.

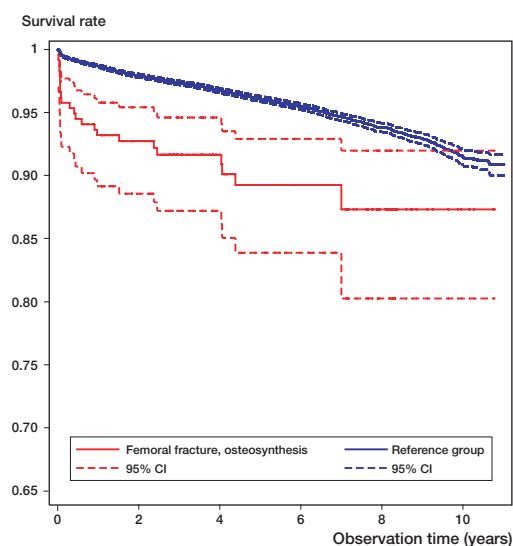


Figure 2. THA survival curve for patients with intraoperative femoral fracture treated with osteosynthesis and for the reference group (no femoral fracture intraoperatively). Note that the y-axis does not start at zero.

Table 3. Relative risk of revision after intraoperative femoral fracture in primary THA for the period 6 months to 11 years postoperatively

	No. of patients	Revisions	Crude relative risk (95% CI)	Adjusted relative risk ^a (95% CI)
No complications	38,157	1240	1.0 (ref)	1.0 (ref)
Femoral fracture conservative	272	10	1.0 (0.6–2.0)	1.1 (0.6–2.0)
osteosynthesis	222	10	1.5 (0.8–2.8)	1.5 (0.8–2.9)

^a Adjusted for gender, age, fixation technique, and co-morbidity.

3). Stratified analyses according to fixation technique did not reveal any substantial differences in the relative risk estimates between cemented and uncemented stems; however, the statistical precision was modest in these analyses.

In the follow-up period of 6 months to 11 years, the main reasons for revision in all groups were aseptic loosening of either one or both of the components, deep infection, or dislocation. We did not find any substantial differences between the groups regarding indications for revision.

Re-admission, reoperation, and hospital stay

In a 3-month period after primary THA, 373 patients (cumulative incidence of readmission:

0.9%) were re-admitted to an orthopedics department. Patients treated with osteosynthesis for intraoperative femoral fracture appeared to have a considerable excessive risk of re-admission within the first 3 months, according to the adjusted RR of 2.0 (95% CI: 1.0–4.0) (Table 3). The re-admissions were mainly due to closed reduction of the THA (Tables 4 and 5).

There were few reoperations within 3 months of primary surgery, and the relative risk estimates did not indicate any differences among the groups.

The median hospital stay in relation to primary THA was 11 days in the reference group. For patients who sustained an intraoperative femoral fracture, the median hospital stay was 13 days both

Table 4. Relative risk of re-admission after primary THA for the first 3 postoperative months after intraoperative femoral fracture

	No. of patients	Readmissions ^a	Crude relative risk (95% CI)	Adjusted relative risk ^b (95% CI)
No complications	38,952	334	1.0 (ref)	1.0 (ref)
Femoral fracture	519	14	1.6 (1.0–2.8)	1.6 (0.9–2.7)
Conservative	282	6	1.3 (0.56–2.9)	1.2 (0.6–2.8)
Osteosynthesis	237	8	2.1 (1.0–4.1)	2.0 (1.0–4.0)

^a Re-admission: readmissions to an orthopedics department or closed reduction for dislocation in the 3-month postoperative period.
^b Adjusted for gender, age, fixation technique, and co-morbidity.

Table 5. Relative risk of reoperation after primary THA for the first 3 postoperative months after intraoperative femoral fracture

	No. of patients	Reoperations ^a	Crude relative risk (95% CI)	Adjusted relative risk ^b (95% CI)
No complications	38,952	334	1.0 (ref)	1.0 (ref)
Femoral fracture	519	5	1.1 (0.5–2.7)	1.1 (0.5–2.7)
Conservative	282	2	0.8 (0.2–3.3)	0.8 (0.2–3.3)
Osteosynthesis	237	3	1.5 (0.5–4.6)	1.4 (0.5–4.3)

^a Reoperations: open surgery involving revision of the implant, osteosynthesis, open reduction, infections or wound problems in the 3-month postoperative period.
^b Adjusted for gender, age, fixation technique, and co-morbidity.

in the nonoperatively treated and the osteosynthesis groups. This was significantly longer than in the reference group ($p < 0.001$).

Discussion

The strengths of our study include the availability of nationwide population-based data resources of high validity and the participation of a large number of surgeons (Pedersen et al. 2004). We obtained detailed and prospectively collected information from the databases, including data that are otherwise rarely available such as laterality of both primary THAs and revisions and the complete hospitalization history of each patient since 1977. The databases were linked through the use of the unique personal identification number of each patient. In addition, the sample size of our study was substantially greater than those of existing studies.

This study also has some limitations. The intraoperative complications were registered by the

surgeon immediately after surgery. Thus, intraoperative complications such as fracture that are diagnosed postoperatively are not registered. Schwartz et al. (1989) reported that 50% of their intraoperative femoral fractures were diagnosed on postoperative radiographs. The incidence of intraoperative femoral fractures in our study may therefore have been under-reported, and there may have been some patients with fracture in our reference group. This lack of specificity may have led us to underestimate the differences in outcomes between the patients with intraoperative fractures and those without them.

The completeness of registration of revisions in the DHR of 90% could affect outcome rates and may well give rise to information bias. However, we have no reason to believe that the completeness of registration would have varied in our intraoperative femoral fracture groups. Moreover, as with all observational studies, we cannot entirely exclude the possibility of unaccounted confounding (e.g. experience of surgeon, patient's use of medication,

and level of physical activity during follow-up). Data on these factors were not available.

The authors of previous reports have concluded that intraoperative femoral fractures in primary THA do not compromise either the functional results or the implant survival if implant stability is achieved (Schwartz et al. 1989, Kavanagh 1992, Mont et al. 1992, Sharkey et al. 1992, Toni et al. 1994, Berend et al. 2004). Berend et al. (2004) followed a series of 50 patients with uncemented THAs treated with cerclage wires or cables due to intraoperative femoral fracture. They showed an implant survival rate of 100% after an average follow-up of 7.5 years (Berend et al. 2004). However, this study only included minor fractures and the results are therefore not directly comparable with our findings. In contrast, Fitzgerald et al. (1988) reported a 7.5% revision rate in 40 uncemented THAs with intraoperative femoral fracture after 1 year of follow-up. However, this study group consisted of both primary and revision arthroplasties. The authors reported 3 revisions resulting from unstable implants and 1 patient requiring revision because of thigh pain.

In this large registry-based study, we observed a more than 5-fold increased risk of revision in the first 6 postoperative months for patients with intraoperative femoral fracture who were treated with osteosynthesis. The revisions were performed due to dislocation or refracture in the initial period. The THAs probably became dislocated as a result of rotation of the stem due to an unstable implant. Implant survival was unaffected in the follow-up period of 6 months to 11 years. This may indicate that if stability of the femoral stem and fracture healing has been obtained within the first 6 months, one can expect an unchanged implant survival. These results apply to the more severe fracture types where osteosynthesis is necessary.

The unaffected implant survival in the nonoperatively group indicates that minor fractures do not compromise the long-term results of THA. Restricted weight bearing by these patients appears to be sufficient to obtain good implant survival.

Our findings of an increased incidence of intraoperative fractures in uncemented fixation of the stem agrees with the results of some other studies (Schwartz et al. 1989, Toni et al. 1994, Moroni et al. 2000). One might be concerned that an unce-

mented prosthesis with intraoperative fracture would have had an increased risk of revision compared to a cemented prosthesis. This is not the case, as we found no differences in the risk of revision regarding the fixation technique used for the femoral stem.

We expected an increased risk of reoperations in the first 3 months postoperatively, but this was not confirmed in our study. This may have been due to a conservative strategy of the surgeon, awaiting stability of the implant, or fracture healing. After an intraoperative femoral fracture, the period of protective weight bearing is usually prolonged for 2–4 months or until radiographic evidence of fracture healing. Thus, a 3-month period may be too short to show differences in the risk of reoperation.

Our results indicate that there may be an association between intraoperative fracture and re-admission to an orthopedics department in the 3 months postoperatively. The re-admissions were mainly for closed reduction due to dislocated THAs. This reflects the increased risk of revision in the osteosynthesis group due to dislocation during the first 6 postoperative months. There were no differences between the groups concerning re-admission due to wound problems, or to deep or superficial infections.

In Denmark, it is generally accepted that surgeons must inform patients before surgery about complications that could possibly impair the clinical result if the incidence is more than 1%. We found substantially increased revision rates after intraoperative femoral fractures requiring osteosynthesis. Thus, patients should be informed about this risk. Furthermore, initiatives aimed at reducing the risk of revision in the first 6 months following THA should be considered in patients with intraoperative fractures, including immediate revision of the stem to a larger stem with distal fixation and restricted weight bearing.

Contributions of authors

TMT: study design, data analysis and manuscript. ABP and SPJ: study design, data analysis and manuscript. KS: head of the research group, study design and manuscript.

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No competing interests declared.

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