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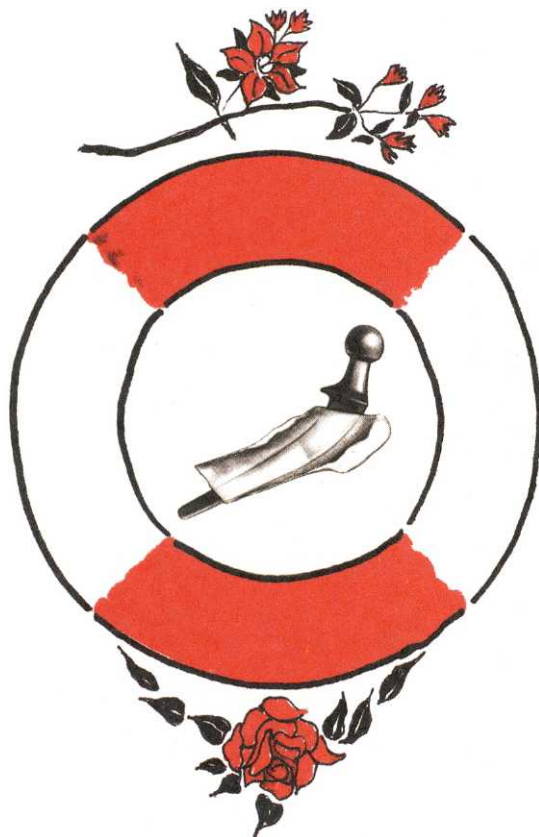


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The periprosthetic femur fracture

A study from the Swedish National
Hip Arthroplasty Register



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A study from the Swedish National Hip Arthroplasty Register

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- I. Lindahl H, Malchau H, Herberts P, Garellick G
Periprosthetic femoral fractures. Classification and demographics of 1,409 late periprosthetic femoral fractures from the Swedish National Hip Arthroplasty Register.
J Arthroplasty 2005; Vol 20 (7) pp 857-865
- II. Lindahl H, Regnér H, Herberts P, Garellick G, Malchau H
Three hundred and twenty one periprosthetic femoral fractures.
J Bone Joint Surg (Am) 2006. In print
- III. Lindahl H, Eisler T, Odén A, Garellick G, Malchau H
Risk factors associated with the late periprosthetic femur fracture. A study of 113,523 primary THA and 12,516 revisions.
Submitted for publication
- IV. Lindahl H, Malchau H, Odén A, Garellick G
Risk factors for failure after treatment of a periprosthetic fracture of the femur.
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- V. Lindahl H, Odén A, Malchau H, Garellick G
The excess mortality due to periprosthetic femur fracture. A study from The Swedish National Hip Arthroplasty Register.
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The Sahlgrenska Academy
AT GÖTEBORG UNIVERSITY

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Abstract

Post-operative periprosthetic femur fracture is a severe complication after total hip arthroplasty (THA). The incidence of periprosthetic femur fractures seems to be increasing because of several factors, including a growing population with THAs and an increasing life expectancy. Furthermore, after four decades of THA surgery, the number of patients with revised THAs has also risen. Periprosthetic femur fracture is more common after revision surgery.

The overall aim was to study the postoperative/late periprosthetic femur fracture in a nationwide prospective study and to estimate the national incidence. Other aims of this study were: 1. To identify patient related risk factors associated with sustaining a late periprosthetic femur fracture. 2. To identify implant related risk factors associated with sustaining a periprosthetic femur fracture. 3. To evaluate patient related outcome after treatment of a periprosthetic fracture by the use of generic and disease-specific instruments. 4. To describe the treatment and analyze failure rate using the need of further surgery as failure endpoint definition. 5. To identify implant and patient related risk factors associated with failure of treatment for a periprosthetic fracture.

The Swedish National Hip Arthroplasty Register is a unique instrument concerning studies of uncommon complications after THA surgery. The current study is, to our knowledge, the largest reported material (1,049) of postoperative/late periprosthetic femur fractures. The annual incidence of periprosthetic femur fracture varied between 0.045% and 0.13%, and increased towards the end of the study period.

Between 1979 and 2000, 1,049 periprosthetic femur fractures were reported to The Swedish National Hip Arthroplasty Register. We analyzed the correlation to diagnosis, gender, implant type, stem fixation, and time interval from index operation to fracture. Patients operated from 1999 to 2000 (321) were followed prospectively. A clinical follow-up was done (mean 2.5 years) at each local hospital and a Registry follow-up (mean 5 years) with re-operation as an endpoint was performed. By use of the Poisson regression model we identified risk factors associated with periprosthetic fracture and risk factors associated to failure.

A majority of the patients had a loose stem at the time of fracture. These findings stress the importance of longitudinal clinical and radiographic follow-up of patients operated on with a THA. Female gender and osteoarthritis were associated with a decreased risk while age, rheumatoid arthritis and hip fracture had an increased risk for sustaining a periprosthetic fracture. In the revised group the strongest predictor was the number of revisions performed before the fracture. The anatomically shaped Lubinus SP II prosthesis had a significantly decreased risk, and patients with the Charnley or the Exeter prostheses had significantly increased risk for periprosthetic fracture.

Patients operated for a periprosthetic femur fracture had on average a poor clinical outcome at 2.5 years follow-up both concerning the health related quality of life and the hip specific assessment. High frequencies of major complications and re-operations were found. Approximately every fifth patient was in need of further surgery during the study period and 50% of them were re-operated on within 12 months post-operatively. The 5-year survivorship with re-operation as failure endpoint was 74.8 ± 5%.

The general poor results after surgical treatment of periprosthetic femur fractures indicate the need of further studies in this field.

Key words: periprosthetic femur fracture, loose stem, risk factors, patient outcome, THA.

The Periprosthetic Femur Fracture

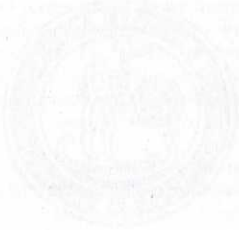
A study from The Swedish National Hip Arthroplasty Register

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2006

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Paper 1-5 , Appendix

List of papers

This thesis is based on five publications, which are referred to in the text by Arabic numerals 1-5.

1. Periprosthetic femoral fractures. Classification and demographics of 1,049 late periprosthetic femoral fractures from the Swedish National Hip Arthroplasty Register.

Lindahl H, Malchau H, Herberts P, Garellick G
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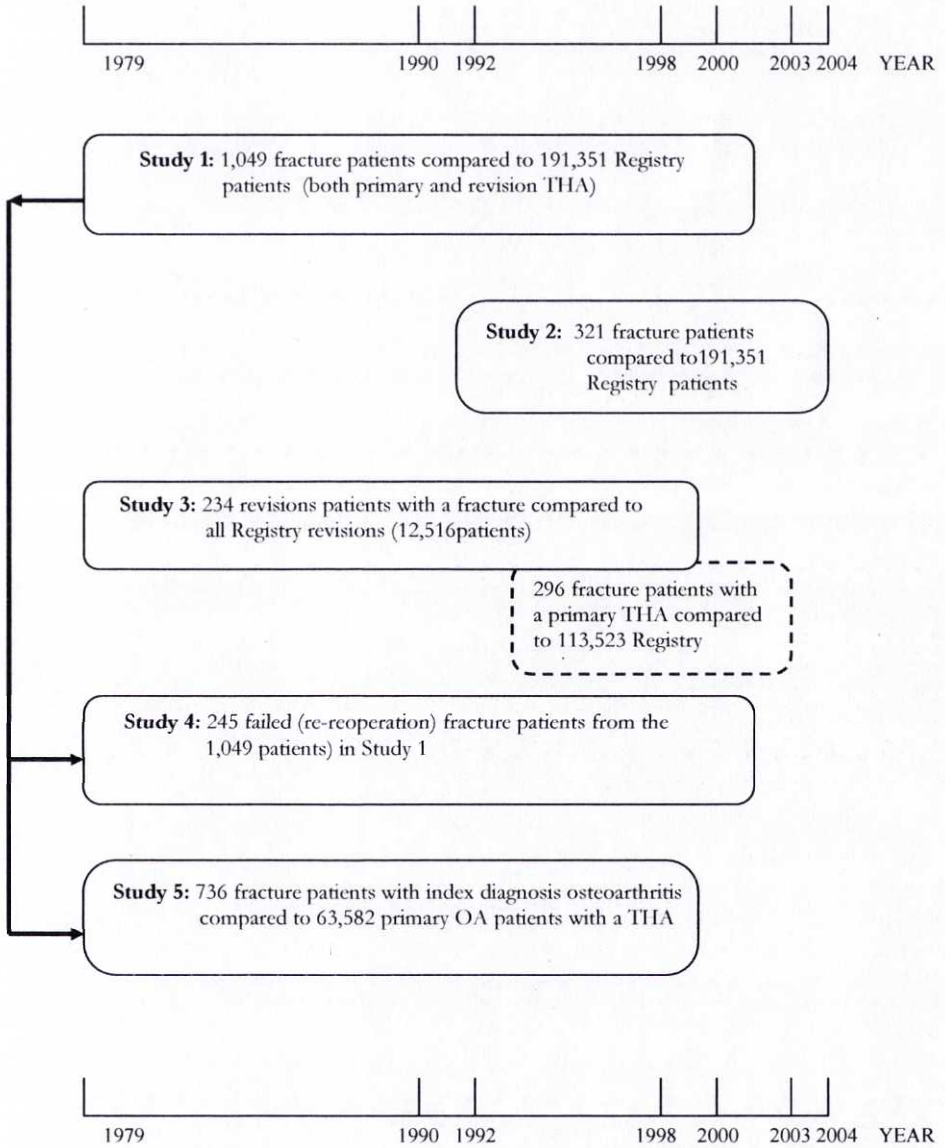
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Submitted for publication

Patients and follow-up time



*Pappa, varför kan du inte sluta skriva och leka med
mig istället?*

Maja 7 år

Svensk sammanfattning

Introduktion

En protesnära femurfraktur utgör en teknisk utmaning för kirurgen, som i samma operation ofta tvingas lösa problemet med en lös protesstam, omfattande benförluster och fraktur. Fyra år efter en primär protesoperation är protesnära femurfraktur den näst vanligaste orsaken till revision vid långtidsuppföljning i Sverige. Den troliga orsaken är att populationen med höftprotesopererade patienter ökar kontinuerligt och att både yngre och äldre opereras i större omfattning än förr. Vidare har, efter nästan 50 år av höftproteskirurgi, antalet patienter med en reviderad eller rereviderad höft ökat. Revisionsoperation i sig är en riskfaktor.

Hittills publicerade studier av sena protesnära frakturer rapporterar relativt små material och belyser oftast en behandlingsmetod utan jämförelser. Protesnära fraktur rapporteras till det svenska Nationalregistret för Höftledsplastiker, vilket ger en unik möjlighet att prospektivt samla ett större material för adekvat statistisk analys.

Material och metod

Mellan 1979 och 2000 rapporterades 1 049 sena protesnära femurfrakturer till Registret. Med sen fraktur menas en postoperativ fraktur. I denna grupp (Studie 1) studerades patientdemografi, implantatrelaterade faktorer och överlevnadsanalys enligt Kaplan-Meier med ändpunkten reoperation.

Patienter opererade för en protesnära fraktur mellan 1999 och 2000 följdes prospektivt (Studie 2), som en rikstäckande multicenterstudie med klinisk (Harris Hip Score, EQ-5D, VAS avseende smärta och tillfredsställelse) och röntgenologisk uppföljning 1–4,5 år postoperativt. Materialet analyserades främst med avseende på patient- och implantatrelaterade faktorer samt utfall av frakturbehandlingen. Via Registrets databaser var det möjligt att göra jämförelser mellan frakturgruppen och övriga patienter opererade under samma tidsperiod. Patienterna delades i två grupper: dels de som ådrog sig en fraktur kring en primärplastik, dels de som reviderats en eller flera gånger före frakturtilfället.

Klassifikation av frakturerna gjordes enligt Vancouvermodellen som delar in dem på tre nivåer samt tar hänsyn till stamstabilitet och benkvalitet. I Studie 1 gjordes Vancouverklassifikationen utifrån ortopedens och röntgenavdelningens ursprungliga bedömning och i Studie 2 utifrån röntgenbilder.

Riskanalyserna i Studie 3, 4 och 5 utfördes med hjälp av Poissons regressionsanalys och överlevnadskurvor med reoperation som ändpunkt beräknades enligt Kaplan-Meier. Den röntgenologiska utvärderingen gjordes av en oberoende radiolog. En interobservationsanalys gjordes mellan opererande kirurgs bedömning och radiologens. Ett intraobservations-test innefattande 50 röntgenbilder och 2 månader mellan bedömningarna gjordes.

Resultat Studie 1

Av de 1 049 patienterna hade 688 en primärplastik och 361 hade genomgått en eller flera revisioner vid frakturtilfället. Medelåldern var 74 år i bägge grupperna med en nästan identisk könsfördelning. Det genomsnittliga tidsintervallet från primärplastik till fraktur var 7,4 år. Den ackumulerade incidensen var 0,4% för primärgruppen samt 2,1% för den reviderade gruppen. Patienter med primärdiagnoserna RA och höftfraktur var signifikant vanligare i frakturgruppen jämfört med totala antalet patienter som opererats med höftplastik under samma period ($p < 0,001$, Fischers exakta test). Den största andelen frakturer (82%)

klassificerades som Vancouver B1 eller B2. En stor majoritet av femurkomponenterna var lösa vid tillfället för fraktur, bland de primära 70% och bland de reviderade 44%. Orsaken till frakturen var i de flesta fall ett mindre trauma.

En implantatrelaterad faktor kunde också konstateras, där Charnley- och Exeterproteserna var signifikant överrepresenterade i frakturgruppen ($p < 0,001$, Fischers exakta test). Lubinusprotesen var klart underrepresenterad ($p < 0,001$, Fischers exakta test). Det var en hög postoperativ komplikationsfrekvens (18%) och 23% av patienterna var reopererade på grund av någon komplikation innan 31 december 2002. Överlevnadsanalys enligt Kaplan-Meier visade på en 10-årsöverlevnad på 73,2 \pm 4,4% i primärgruppen samt 64,9 \pm 6,6% i revisionsgruppen.

Resultat Studie 2

I denna studie, som innefattade mer samtida behandlingsmetoder, ingick 321 patienter varav 230 hade en primärprotes vid frakturtilfället. Som i Studie 1 fann man en hög andel lösa proteser vid frakturtilfället, bland de primära 66% samt bland de reviderade 49%. Charnley- och Exeterprotesen var överrepresenterade samt Lubinusprotesen underrepresenterad ($p < 0,001$, Fischers exakta test). Överlevnad enligt Kaplan-Meier var efter 54 månader 73,5 \pm 7,0% för primärgruppen samt 77,3 \pm 8,8% för revisionsgruppen. Den 31 december 2002 var 22% reopererade.

Vid en granskning av de preoperativa röntgenbilderna fann vi en dålig överensstämmelse mellan radiologens bedömning och den bedömning som gjorts av den behandlande kirurgen. Detta gällde framför allt frakturer kategoriserade som Vancouver B1 och B2. Vid analys fann man en hög andel (23%) reoperationer bland de fall som klassificerats som B1. I en samtida behandlingsalgoritm är frakturer av typ B1 och C (med stabilt fixerad stam) de enda fall där man kan rekommendera osteosyntes utan stamrevision. Resultatet i studien indikerar att den opererande kirurgen sannolikt gjort en felaktig preoperativ bedömning beträffande femurkomponentens fixation.

Resultat Studie 3

I denna studie var målsättningen att genom multivariat regressionsanalys försöka identifiera eventuella riskfaktorer associerade till protesnära femurfraktur. Av frakturpatienterna identifierades 296 patienter med en primär höftledsplastik opererade 1992–2003 samt 234 patienter med en eller flera revisioner opererade 1979–2000. Dessa jämfördes med 113 523 primära höftledsplastiker respektive 12 516 reviderade patienter. I primärgruppen var medeluppföljningstiden 4,9 år med en medeltid från primäroperation till fraktur på 4,2 år. Motsvarande siffror i revisionsgruppen var 8,3 år samt 3,0 år. I analysen inkluderades såväl patient-, implantat- samt tidsfaktorer.

Vi fann att primärdiagnosen RA samt tidigare höftfraktur var associerad till ökad risk. Detta gällde även val av protesstam. Charnley- och Exeterstammar gav en ökad risk medan en Lubinusstam minskade risken. Ålder och tid efter primäroperationen var också förenat med högre risk. Kvinnor hade en lägre risk.

I gruppen reviderade var det framför allt antalet revisioner som gav en ökad risk för en protesnära femurfraktur. Analysen visade en minskad risk om revisionen var utförd på universitets- eller regionsjukhus.

Resultat Studie 4

I denna studie ville vi undersöka om det fanns eventuella faktorer i patientdemografi, val av implantat eller operationsmetod som skulle kunna vara en bidragande orsak till den höga

reoperationsfrekvensen bland patienter med en protesnära fraktur. Av de 1 049 rapporterade protesnära frakturerna blev 245 reopererade. Data rörande dessa patienter analyserades med hjälp av Poissons regressionsanalys.

Patienter som preoperativt bedömts ha en fastsittande stam och opererats med plattfixation hade en signifikant ökad risk för reoperation. Ålder och tid sedan frakturoperationen var också faktorer som påverkade riskförloppet (äldre och kort tid efter operation) var associerat till ökad risk. Om däremot patienten bedömdes ha en lös stam och opererades med revision var det en minskad risk för misslyckande. Användande av en Lubinus SP revisionsstam gav också minskad risk. Faktorer som kön, primärdiagnos, tidigare revision eller om bentransplantation använts påverkade inte risken i någon riktning.

Resultat Studie 5

Det primära målet med denna studie var att studera eventuell överdödlighet i samband med protesnära fraktur hos patienter med primärdiagnos artros. Sekundärt ville vi också jämföra risken för död mellan patienter med en protesnära fraktur, patienter med en höftprotes samt hela befolkningen.

Vi fann en ökad dödlighet i samband med operation för protesnära fraktur. Mortaliteten var högre än vid operation för en primär höftplastik. Dödligheten inom frakturgruppen sjönk snabbt inom ett halvt år och stabiliserades. Dock kom den fortsättningsvis att ligga över gruppen med en primär höftledsplastik. Jämfört med befolkningen i övrigt hade frakturpatientgruppen samma dödlighet som denna. Dock med ett undantag, i de lägre åldersgrupperna (under 70 år) var överdödligheten högre jämfört med befolkningen. Någon ökad frekvens av övriga sjukdomar i de yngre åldersgrupperna kunde inte påvisas.

Sammanfattning

Studien har resulterat i tre huvudsakliga fynd:

- En majoritet av de sena protesnära femurfrakturerna sker kring en lös femurstam.
- Det finns signifikanta protesdesignrelaterade riskfaktorer för protesnära fraktur efter en primärplastik.
- Resultaten efter behandling av denna svåra komplikation har både historiskt och i nutid varit dåliga med hög frekvens av komplikationer och reoperationer.

Med tanke på de dåliga resultaten kan man diskutera om dessa svåra fall skall centreras till specialenheter. Mot detta talar att dessa akutpatienter inte alltid är transportabla. Fallen bör opereras av team med god kompetens och erfarenhet både vad gäller fraktur- och proteskirurgi. Raka femurkomponenter hade en klart ökad risk för sen protesnära femurfraktur och detta faktum kan få betydelse för val av cementerade standardproteser i framtiden.

Slutligen kan följande rekommendationer ges:

- Bestäm alltid om stammen är lös och vid tveksamhet explorera leden.
- Revidera alltid en lös stam.
- Följ protesopererade patienter med någon form av regelbunden röntgenologisk uppföljning.
- Intervenera i tid, framför allt om stammen är lös.

Abbreviations

AP	Anteroposterior
HHS	Harris hip score
HZ	Hazard ratio
ORIF	Open reduction and internal fixation
OA	Osteoarthritis
PPF	Periprosthetic femur fracture
RA	Rheumatoid arthritis
THA	Total Hip Arthroplasty
THR	Total Hip Replacement (synonymous with THA)
Index operation	The primary THA operation
Revision	Exchange of the stem in a patient with a THA
Primary	The primary THA was in place at fracture time
Revised	The patient was revised one or several times prior to the periprosthetic fracture.

Introduction

The postoperative periprosthetic femur fracture has been considered to be an uncommon complication of total hip arthroplasty (THA). However, there is a worldwide increasing number of primary and revision THAs performed each year. The progress in general medical practice and the development of implants now allows operation on both younger and older patients and the increasing life span of the patient consequently has led to a greater population of patients at risk.

The incidence of postoperative periprosthetic femur fracture has been discussed in the literature and there have been reports ranging from 0.1% up to 20%. After revision surgery the incidence is reported to be higher. Risk factors associated with a late periprosthetic femur fracture have been discussed in the literature, but there are few studies concerning this. Factors concerning the implant are loosening with or without osteolysis. Proposed patient related factors are female gender, metabolic bone disease, rheumatoid arthritis (RA), osteoporosis and preoperative femoral deformity.

The treatment of periprosthetic femur fracture is technically demanding and a challenge. The surgeon often has to deal not just with a fracture of the femur. If the implant is loose and there is osteolysis combined with a markedly diminished bone stock, the treatment might be demanding for the surgeon. He then has to deal with a fracture and revision in the same procedure. Orthopedic fracture treatment is often guided by different fracture classifying systems. These are mostly based on the fracture pattern. Several attempts classifying periprosthetic femur fractures have been done. In order to be useful the system has to be reliable and valid. Some classification systems depend purely on the location of the fracture while others include the pattern of the fracture. During recent years the importance of including the implant stability and the quality of the bone stock has been well documented. It is also possible to compare the results from different centers after interventions for the same pathology, when using an adequate classification system. Today the Vancouver classification, which is tested for its validity and reliability, is the internationally widely most used.

The treatment of periprosthetic femur fracture, as in most orthopedic traumatology, could be divided into conservative or surgical treatment. Historically, conservative treatment has played a large role in the treatment of periprosthetic femur fractures. Difficulty with angular malalignment, jeopardizing revision surgery in cases of loosening, long hospitalization and a considerable complication rate has led to a shift in favour of surgical management. New fracture treatment methods have also helped to put surgery as a first method of choice. In combination with the development in revision surgery, advances in instrumentation, the establishment of bone banks has led to surgical approach as the method of choice. The goal of treatment is early union with an anatomical alignment and length and the re-establishment of the bone stock, with an early mobilization and a return to pre-fracture function.

However, the most important aims must be the effort to prevent a fracture. To be able to do this, it is important to analyze patient data in order to identify risk factors associated to the fracture. In cases of fracture it is, on the other hand, of importance to analyze surgery and outcome in order to optimize the treatment methods. Since the periprosthetic femur fracture for the average clinic is relatively uncommon, The Swedish National Hip Arthroplasty Register gives a unique opportunity to analyze the problem. One of the advantages of a national implant register is the ability to study and to statistically analyze an uncommon complication.

The periprosthetic femur fracture

Epidemiology

Periprosthetic fracture of the femur after total hip arthroplasty (THA) surgery was first described by Horwitz and Lenobel (1954). They published a case-report of a female who sustained an intertrochanteric fracture around the stem of a cemented hemiarthroplasty. The fracture was reconstructed using transfixing screws and wire loops, and the prosthesis was reinserted into the reduced femur. Parish and Jones (1964) reported 7 cases in 1964. The authors claimed a need for a classification system of periprosthetic fractures and proposed a system related to the location of the fracture; intertrochanteric, subtrochanteric and mid-shaft fractures. Two years later Sir John Charnley (1966) described a periprosthetic femur fracture in a female. She was treated with a cemented Thompson prosthesis after a failed cervical hip fracture. Seven months later she fell and sustained an oblique fracture in the proximal part of the femur. She was treated with balanced traction and the fracture healed after 3 months. Whittaker et al (1974) presented a report of 20 cases in 19 patients which included 17 hemiarthroplasties and 3 cemented THAs. Depending on fracture location they were treated with early mobilization, traction, long stem revision or plates.

The periprosthetic femur fracture can be classified as intraoperative and postoperative fractures. The intraoperative fractures mostly occur during the insertion of the femoral stem.

Depending on the fixation method used, differences in incidence have been reported. An incidence of 0.1% to 1% has been reported (Kavanagh 1992) with cemented stems. An increase of intraoperative fractures is reported with the introduction of uncemented stems. Berry (1999) reported an incidence of 0.3% in cemented and 5.4% in uncemented THAs. Intraoperative fractures in uncemented THAs often are a consequence of the effort to obtain a sufficient press-fit to gain initial stem stability.

After revision surgery an even higher incidence has been reported (Tsiridis et al 2003) Berry reported an intraoperative fracture rate of 3.6% in cemented and 20.9% in uncemented revision THAs. In revision surgery, peroperative accidental cortical perforation, windows, screw holes or bony defects are the risk factors reported.

The incidence of late postoperative periprosthetic femur fracture seems to be increasing worldwide (Berry 1999; 2003). Total hip arthroplasty surgery is very successful, which has led to broadening of the indications for THA, with more younger and more elderly patients now undergoing the procedure. The average life expectancy is increasing; consequently, there are more elderly patients, who have had a hip implant for many years. The risk of loosening due to poor bone quality and/or periprosthetic bone loss is obvious. The use of THA in younger and more active patients means that the pool of patients at risk of developing local osteolysis and at risk for high-energy trauma is growing. Furthermore, after four decades of THA surgery, the number of THA patients with revised and re-revised hips has increased substantially.

The true incidence of the fracture is difficult to estimate, since the patient populations reported in the literature are heterogeneous. The incidence is depending on many factors: the patient demographics, the number of revised patients in the total fracture group, the use of cemented or uncemented prostheses, and finally, follow-up routines in order to detect loosening/osteolysis and revise before fracture.

Different authors have tried to estimate the incidence. Löwenhielm et al (1989) found the accumulated risk of postoperative fractures after THA surgery to be 25.3/1,000 patients over a 15-year period, while Beals and Tower (1996) estimated the incidence of such frac-

tures over the life span of a prosthesis to be <1%. The Mayo Clinic Joint Registry reported 1.1% postoperative periprosthetic femur fracture after 23,980 primary THAs (Berry 1999) (performed 1969 to 1999). They reported a higher incidence after revision surgery with 4% fractures after 6,349 revision THAs.

Risk factors for postoperative late periprosthetic femur fracture

There are few articles concerning risk factors associated with periprosthetic femur fracture. Mont and Maar (1994) did a review of the literature and ended up with 487 patients from 26 papers. They concluded that in each study there was a small number of ingoing patients. The authors discussed classification, treatment and results, but were not able to identify any risk factors associated with periprosthetic fracture.

Jensen et al (1988) presented 131 patients with 139 periprosthetic femur fractures from five departments. A multivariate analysis revealed an association between fracture location and radiographic signs of loosening. Fracture extending distally from the tip of the stem, was usually observed in stable stems, whereas proximal fractures around the stem predominantly occurred with fixed non-cemented or loose cemented stems. Any further analysis of patient demographics as risk factors was not performed.

Beals and Tower (1996) performed a retrospective multicenter study including 93 patients with periprosthetic fracture. They found that the location of the fracture was related to the fixation and type of stem. Fractures located around the mid part of the stem did not occur in cemented stems. These fractures were found in patients with uncemented stems. Fractures at the tip of the stem were found in patients with a cemented loose stem. Fractures distal to the stem tip were most common in patients with a fixed cemented stem.

Among the cemented prostheses 27% were considered loose. Several authors have reported loosening as a factor predisposing the patient for periprosthetic fracture (Bethea et al 1982; Ritschl and Kotz 1986; Jensen et al 1988; Incavo et al 1998; Tower and Beals 1999).

One factor described as a risk factor (Tsiridis et al 2003; Hsieh et al 2005) is periprosthetic bone loss with or without osteolysis. Localized periprosthetic bone loss in association with loose cemented THA was early described by Harris et al (1976) and Jones and Hungerford (1987). The latter authors introduced the concept of "cement-disease" which led to the development of cementless implants. The problem with osteolysis was not solved with cementless implants, at least not with the first generation of uncemented stems. The currently dominating theory is that osteolysis partially is a phenomenon (Schmalzried et al 1992; Maloney and Smith 1996) related to particle debris (more to the size, form and number than type of particles), and therefore in recent years referred to as "particle disease". Biological and genetic components are probably also involved in the process of osteolysis. Focal femoral osteolysis has been described in patients with a stable cemented femoral component (Maloney et al 1990) as well as in patients with well-fixed uncemented stems (Maloney et al 1990).

Brown and Ring (1985) reported osteolytic changes in the proximal part of femur in patients with uncemented porous-coated cobalt chrome stems. They found a high frequency of fractures of the greater trochanter. The same type of fracture was described in a paper by Hsieh et al (2005). In a retrospective study, they found 23 fractures of the greater trochanter among 887 patients with an uncemented stem. They claimed that the osteolytic lesions were correlated with excessive polyethylene wear.

Wu et al (1999) analyzed 16 cases of periprosthetic femur fracture in a total of 454 cementless THAs. Significant patient characteristics associated with fracture were high age, a low flare index and that the quality of the bone, according to Singh's index, were low. They found no specific index diagnosis that implied significantly increased risk. Löwenhielm et al

(1989) could not find any association with the index diagnosis.

Sarvilinna et al (2003; 2004; 2005) have published reports from the Finnish Arthroplasty Register, analyzing risk factors for a periprosthetic femur fracture. Forty periprosthetic fractures treated with revision from 1990 to 1999 were analyzed. Gender, implant type or age was not identified as significant risk factors. In a case control study with 31 hips, patients operated with a THA after a hip fracture had a higher risk for periprosthetic fracture. In another case control study, 16 patients with periprosthetic femur fractures were compared to 48 patients with primary THAs after a hip fracture. Low age at the time of hip fracture and a polished, tapered implant design were associated with higher risk.

Classification systems

Radiographic classification systems for general fracture treatment are common. An adequate classification system should guide the surgeon into a treatment algorithm. Several classification systems have been proposed for the periprosthetic femur fracture.

Parrish and Jones (1964) introduced a classification related to the location of the fracture.

Table 1. Classification of the post-operative periprosthetic femur fracture

Parrish 1964	Fractures in the trochanteric area	Fractures of the midshaft	Fractures at the distal end of the shaft			
Whittaker 1974	Type 1 Intertrochanteric	Type 2 Around stem	Type 3 Below stem			
Johansson 1981	Type 1 Proximal to stem tip	Type 2 Around stem tip	Type 3 Below stem tip			
Betha 1982	Type A Below the stem tip	Type B Around stem	Type C Comminute			
Jensen 1988	Type 1 Proximal part	Type 2 Around stem tip	Type 3 From stem tip			
Mont 1994	Type 1 Intertrochanteric	Type 2 Around stem	Type 3 Around tip	Type 4 Below tip	Type 5 Comminute	Type 6 Supracondylar
Towers 1995	Type 1 Intertrochanteric	Type 2 Around stem	Type 3a, 3b and 3c Around tip	Type 4 Supracondylar		
Brady 1999	Type A Trochanteric fracture (Ag = greater Am = minor)	Type B1 Fracture around stable stem	Type B2 Fracture around a loose stem	Type B3 Fracture around a loose stem and osteolysis	Type C Distal to the stem	

Whittaker et al (1974) claimed that a classification system also should be related to the stability of the stem as well as the fracture location. As in all other fields of orthopedics, several centers have introduced their own classification system (Table 1).

Some classification systems depend only on the location of the fracture (Parrish and Jones 1964; Johansson et al. 1981) (Figure 1). Other systems include the location and the pattern of the fracture (Betha et al 1982; Mont and Maar 1994). As Whittaker proposed, as early as 1974, recent classification systems include the stability of the stem

A classification system should be valid and reliable. The Vancouver classification is tested for validity and reliability (Brady et al. 1999; Brady et al. 2000) and probably is the most widely used system. Factors included in this classification system are the location of the fracture, the stability of the stem and

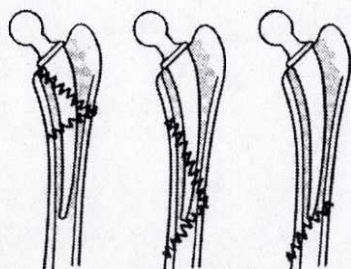


Figure 1. Fracture classification according

the amount of bone loss. The fracture is primarily divided into A, B or C depending on its location. Type A fracture (Figure 2) is trochanteric, either in the greater trochanter (AG) or in the lesser trochanter (AL). Type B fractures occur around the stem. They are subclassified based on the stability of the implant and the quality of the bone stock. In type B1 fractures (Figure 3), the stem is stable, whereas in B2 fractures (Figure 4), the stem is loose. The B3 fractures (Figure 5) are those in which the stem is unstable with extensive bone loss. Type C fractures (Figure 6) occur distally to the stem tip. The Vancouver classification system has been assessed for reliability by looking at the intra and interobserver agreement and validity by comparing the radiographic classification and the intraoperative findings (Brady et al 2000).



Figure 2. Vancouver A



Figure 3. Vancouver B1



Figure 4. Vancouver B2

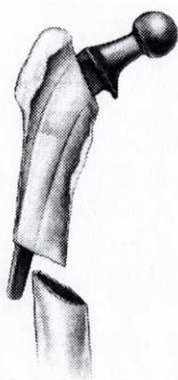


Figure 5. Vancouver B3



Figure 6. Vancouver C

These pictures were first published in an article by Brady et al. *Orthop Clin North Am* 30:249-57, 1999

Treatment

Historically non-surgical treatment and traction has played a role in the management of periprosthetic femur fractures. The non-operative treatment was recommended by several authors (McElfresh and Coventry 1974) in the 1970s. Johnsson et al (1981) concluded, from a retrospective review of 35 patients, that fractures proximal to the tip of the stem should be treated conservatively if the stem was stable since the probability of union was good and surgical procedure could be avoided. Roffman (1989) as late as 1989, reported fracture healing with traction in periprosthetic fractures. However, out of 7 patients only 4 were treated with traction.

Adolphson et al (1987) reported 21 non-surgically treated patients of which 29% (6/21) were in need of surgical intervention because of malunion or malalignment. Somers et al (1998) reported 34 patients treated conservatively and 26% (9/34) had to be operated due to failure. A high complication rate (dislocation, decubitus and stiff knee) was observed.

Mont and Maar (1994) published a literature review in 1994. The authors categorized fractures into five types based on location and treatment method in six categories. Satisfactory results (united fracture and no pain) were found in 33% (1/3) to 77% (59/77), depending on the fracture location. Despite 77% satisfactory results in fractures distal to the implant, treated with traction, they do not recommend traction treatment. Tower and Beals (1999) recommended non-surgical treatment only in patients with a proximal fracture and with a well-fixed stem.

The contemporary treatment is, based on a literature review, difficult to evaluate. Most series have relatively few patients treated with one specific method and without a control group. However, in most review papers (Wilson et al 2001; Schmidt and Kyle 2002; Tsiridis et al 2003; Learmonth 2004; Parvizi et al 2004), there is an agreement on how to treat a periprosthetic fracture surgically. In a contemporary treatment algorithm (Schmidt and Kyle 2002) the basic treatment methods are revision, revision with open reduction and internal fixation (ORIF) and ORIF alone. In the different treatment alternatives, use of bone grafting is optional, but in B3 fractures considered essential. The use and benefits of cortical onlay allograft (strut graft) is documented in several papers (Chandler et al 1993; Chandler and Tigges 1998; Wong and Gross 1999; Barden et al 2003; Barden et al 2003).

ORIF alone

ORIF alone is a recommended treatment method for a fracture with a stable stem (Vancouver A, B1 and C fractures). Various methods have been discussed. The use of cerclage alone does not give a sufficiently rigid fixation, except in the trochanteric area. Fredin et al (1987) concluded that cerclage may be adequate if the stem is firmly anchored and the fracture is not dislocated, but the method does not provide sufficient stability to permit immediate mobilization and the authors did not recommend it. Mont and Maar (1994) recommend cerclage for fractures in the trochanteric area. In fractures below the trochanteric region, cerclage was not recommended.

Another possibility, probably the most used today, is plate fixation. There are so-called "ordinary" plates with screws (Courpied et al 1987; Serocki et al 1992), plates fixated with bands or cables/wires (Haddad et al 1997; Tadross et al 2000; Venu et al 2001), special plates that have claws (Uchio et al 1997; Otremski et al 1998; Ahuja and Chatterji 2002) and angle blade plates (Schatzker 1998) to choose between.

Mont and Maar (1994) presented unsatisfactory results (malunion, nonunion and reoperation) in more than 50% of the patients in all types of fractures treated with plate fixation. Jensen et al (1988) reported unsatisfactory results (refracture and nonunion) in 43% (6/14) of the patients treated with plate fixation. Later reports (Courpied et al 1987; Jukkala-Par-

tio et al 1998; Siegmeth et al 1998; Siegmeth et al 1998) have shown better results using plates.

The screw plate is probably the most used. Park et al (2003) reported 13 patients treated with screw plate fixation, of which 38% (5/13) had to be reoperated. The complications were related to the proximal screw, violating the cement mantle or in the case of uncemented implants, failed to gain sufficient purchase. Other plate systems have been developed, partially because of problems with the proximal screws. One technique, initially presented by Ogden and Rendell (1978), used Parham band proximally and is known as the Ogden concept (Ogden and Rendell 1978; Zenni et al 1988; de Ridder et al 2001). The idea is to use a band at the proximal end of the plate, to avoid cement or stem interference and a more rigid fixation with screws at the distal end. However, the use of broad bands has been related to bone loss in the area around the band (Buxton et al 1986; Jones 1986), which could limit the use of broad bands.

Combination plates (Figure 7) have been introduced, which instead of a band uses a cerclage wire or cable proximally and screws distally. The outcome using these plates have been reported in several studies (Venu et al 2001; Haddad et al 1997; Tadross et al 2000; Agarwal et al 2005). Table 2, presents the outcome with the use of different plates.

Table 2. The outcome with different plates

Author	Year	Plate	No	Healed	Re.op.	Complication
Ridder et al	1999	Partridge	222	189		23
Zenni et al	1987	Ogden	19	16	3	
Goupid et al	1987	Screw plate	29	29		3
Serocki et al	1992	Screw plate	10	9	1	
Hopf et al	1996	Screw plate	36	21	15	
Jukkala-Partio et al	1998	Screw plate	35	15	10	27
Park et al	2003	Screw plate	13	5		3
Tsiridis et al	2005	Screw plate	7	4	2	
Haddad et al	1997	Combination	4	3	1	1
Tadross et al	2000	Combination	7	5	2	3
Venu et al	2001	Combination	12	9	3	
Tsiridis et al	2003	Combination	3	1	2	
Agarwal et al	2005	Combination	16	12	3	1
Abhaykumar and Elliot	2000	LISS	7	7		

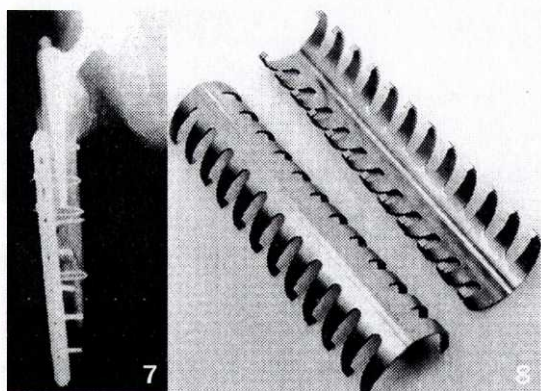


Figure 7. A combination plate

Figure 8. The Mennen plate

Another type of plate (Figure 8) is the clamp plate (Mennen plate). Papers reporting good results (healing of fracture) (Radcliffe and Smith 1996; Uchio et al 1997; Kligman et al 1999) and papers with poor results (high frequency of re-operations) (Petersen 1998; Ahuja and Chatterji 2002) using this plate are presented in Table 3.

Table 3. Outcome using the Mennen plate

Author	Year	No	Healed	Re.op.	Complication
Dave et al	1995	1	1		
Rackliffe and Smith	1996	5	5		
Udnoi et al	1997	6	6		
Peterson	1997	5	2	3	
Otenski et al	1998	14	10	5	1
Klingman	1999	9	9		
Ahuja and Chatterji	2002	16	4	10	
Noorda and Wuisman	2002	35	26	8	

For C fractures the angle stable blade plate and the intramedullary nail have been used. These methods are normally used in supracondylar fractures of the femur (Schatzker 1998), but also used in periprosthetic fractures distal to the implant. There are no reports with clinical results in the literature of these methods. A potential problem with these devices is the increased stress between the distal end of the stem and the plate or nail ("kissing point") with an increased risk for a new fracture (Figure 9).



Figure 9. "Kissing point"

The so called less invasive stabilization system (LISS) (Wenda et al 1997; Frigg et al 2001) is possible to use for periprosthetic fractures, especially in patients with osteoporosis (Figure 10). Bio-mechanical evaluation has proven that LISS is a stable fixation system (Zlowodzki et al 2004; Fulkerson et al 2006). Abhaykumar and Elliott (2000) presented 7 patients operated with this technique, and all fractures healed.



Figure 10. A LISS plate

The use of cortical onlay allograft (strut graft) in combination with plates is described in a study by Haddad et al (2002). Four centers reported 40 patients with a fracture around a well-fixed femoral stem. Thirty-nine of the 40 fractures healed. Three had more than 10 degrees of malalignment, and one a deep infection. A combination of plate and strut graft provides a stable fixation with the potential to restore bone stock and increase cortical strength.

Revision

The proposed treatment for fractures with a loose stem (Vancouver B2 and B3) is revision with or without ORIF (Berry 2003; Springer et al 2003). Betha et al (1982) reported 75% (23/31) stem loosening in association with periprosthetic fracture. Tower and Beals (1999) reported 42% (25/59) with a loose stem which indicated that the B2 and B3 fractures were common.

The preferred method in B2 fractures, with good bone quality and a loose stem, is revision. In the literature, revision with an uncemented long stem is advocated (Jukkala-Partio et al 1998; Macdonald et al 2001; Springer et al 2003). If the fracture is combined with loosening and osteolysis, different methods are proposed. Macdonald et al (2001) reported healing in 100% (14/14) of the fractures with loose stems when long uncemented extensively porous coated stems were used for treatment. O'Shea et al (2005) reviewed 22 patients with loosening and osteolysis that were treated with fully

porous-coated implants and reported satisfactory result (HHS>80) in 77% (17/22) of the patients and with complication in 23% (5/22) (subsidence, infection and delayed union). Several other centers, (Incavo et al 1998; Macdonald et al 2001; Springer et al 2003) using long fully coated stems, have reported good (fracture healing) results.

Impaction grafting technique with morselized cancellous bone is used in revision surgery (Gie et al 1993; Slooff et al 1996). This technique has been used in the treatment of periprosthetic femur fractures, but there are no results presented in the literature.

The use of distally fixed long stems is another treatment option preferable in B3 fractures. Kolstad (1994) reported 22 fractures of which 100% (9/9) treated with a distally fixed stem (Wagner), healed. In the rest of the patients, treated with cemented revision, loosening was reported in 53% (7/13) of the stems. Mulay et al (2005) reported 24 patients treated with a distally fixed stem and with complications in 33% (8/24). Berry (2003) reported 8 patients with Vancouver B3 fractures treated with long distally fixed uncemented stems of which all at follow-up (mean 1.5 year) showed fracture healing.

Another concept in order to overcome the difficulties associated with stem loosening and osteolysis in periprosthetic fractures is uncemented stems with distal locking screws. These are marketed by different companies and are possible to get in different designs with different stem surfaces. There are, however, few reports in the literature with treatment outcome. Sexton et al (2004) presented a poster at the AAOS meeting with a 15-year follow-up of the Kent hip prosthesis in 37 cases. They found that the 15-year survival rate in patients less than 70 years was only 68% and recommended the procedure for patients over 70 years. The problem is that distal interlocking screws provide sufficient fixation for fracture healing, but they are not sufficient for stem fixation.

In patients with severe bone loss the use of tumor prostheses is a possibility. This is not a common method but it can be considered. The use of these total femur replacements was reported by Ritschl and Kotz (1986) and Klein et al (2005).

Bone grafting

All the treatment options could be combined with cortical onlay allograft (Figure 11). The method was first described 1989 by Penenberg et al. How to use this technique has been described in several papers (Chandler et al 1993; Brady et al 1999; Wong and Gross 1999). The graft is usually a femur or tibial shaft split into equal parts. These grafts should bypass the fracture 10 cm proximally and distally. The graft (or one plate and one graft) is held to the host bone with cerclage cables or wires. The success of this method is not only the augmentation (Howell et al 2004) but also the biological aspect. The graft is supposed to incorporate and increase the bone stock. In combination with onlay allograft it is possible to use morselized allograft.

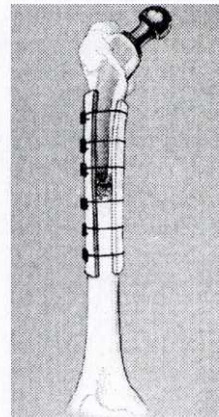


Figure 11. Cortical onlay allograft.

Aims of the study

Overall aim

- To study the postoperative/late periprosthetic femur fracture in a nationwide perspective.

Specific aims

- To estimate the national incidence of periprosthetic fractures.
- To identify patient related risk factors associated with sustaining a late periprosthetic femur fracture.
- To identify implant related risk factors associated with sustaining a late periprosthetic femur fracture.
- To evaluate patient outcome after treatment of periprosthetic fracture by use of generic and disease-specific instruments.
- To analyze survival rate after surgical intervention of periprosthetic femur fracture using the need of further surgery as failure endpoint definition.
- To identify implant and patient related risk factors associated with failure of treatment for a periprosthetic fracture.
- To estimate the probability of death caused by the periprosthetic femoral fracture in patients with the index diagnosis osteoarthritis.

Summary of papers

Paper 1. Periprosthetic femoral fracture. Classification and demographics of 1,049 periprosthetic femoral fractures from the Swedish National Hip Arthroplasty Register.

Introduction: Postoperative periprosthetic femoral fracture is a severe complication after THA surgery. The incidence of periprosthetic femoral fractures seems to be increasing because of several factors, including a growing population with THAs and an average life expectancy which is increasing. Furthermore, after four decades of THA surgery, the number of patients with revised THAs has also risen. Periprosthetic femoral fracture is more common after revision surgery.

Patients and methods: Between 1979 and 2000, 1,049 periprosthetic femoral fractures were reported to The Swedish National Hip Arthroplasty Register. We estimated the incidence after primary or revision surgery and analyzed the correlation to diagnosis, gender, implant type, stem fixation, and time interval from index operation to fracture. The analyzes were based on hospital records. No radiographic results were included in the Registry or in this report, because the study extended over 22 years and the x-rays for many cases were unavailable. Fractures were classified according to the Vancouver classification system on the basis of the radiologist's and surgeon's report.

Results: A total of 688 patients with a fracture after a primary THA and 361 patients with fractures after revision THA were reported. The mean age was 74 years. The annual incidence varied between 0.045% and 0.13%.

Patients with index diagnoses RA and hip fracture were significantly more common ($p < 0.001$) in the fracture group, compared with all primary THA patients. Eighty-two percent of the fractures were classified as Vancouver types B1 and B2. Twenty-three percent were "known loose" and 47% were "unknown loose". In the revised group, the corresponding figures were 21% and 23% respectively. A comparison of all primary THAs performed in Sweden and the fracture group revealed a significant increase of fractures with the Charnley ($p < 0.001$) and with the Exeter stem ($p < 0.001$) and a significant decrease for the Lubinus stem ($p < 0.001$).

The total complication rate was 18%. By December 31, 2002, 23% of the patients had undergone revision surgery for various reasons. Of those, 46% underwent revision surgery during the first 12 postoperative months. The overall 10-year survival rate for the entire fracture group with repeated surgery of any kind as failure endpoint was $69.9 \pm 3.8\%$.

Conclusion: The most important finding in this study was that 70% of the stems in the primary group were loose. Another major finding in our study was the significant association between the type of implant and the risk for periprosthetic fracture. There was a poor overall result and a high reoperation rate.

Paper 2. Three hundred and twenty-one periprosthetic femoral fractures.

Introduction: We have, in a prospective nationwide study, analyzed periprosthetic femoral fractures reported to The Swedish National Hip Arthroplasty Register from 1999 to 2000. The Registry included 242 393 primary procedures, 28 045 reoperations and 22 840 revisions at the end of the study (December 31, 2004). This gives a unique opportunity to analyze this uncommon complication. The purpose of this study was to evaluate the demographics and incidence of periprosthetic femoral fractures and to evaluate the treatment and

outcome of these fractures in order to identify risk factors associated with the fractures and treatment.

Patients and methods: During the period, 321 periprosthetic femoral fractures were reported to the Registry. 230 occurred after a primary THA and 91 after a revision procedure.

A clinical follow-up was done (mean 2.5 years) at each local hospital. A standardized follow-up protocol was used: All patients completed a questionnaire containing 11 items including Charnley categories, visual analogue scales concerning pain and satisfaction, and EQ-5D. The examiner determined the Harris hip score and radiographic examinations were performed. The fractures were classified according to the Vancouver classification. A Registry follow-up (mean 5 years) with reoperation as endpoint was performed.

Results: The annual incidence was 0.13% in 1999 and 0.11% in 2000. 52% were female. Patients who received a hip prosthesis after a hip fracture were significantly ($p < 0.001$) more common in the fracture group compared to patients with the index diagnosis OA or RA. Sixty-six percent in the primary group and 51% in the revised group had a loose stem. There was a significant over-representation of the Charnley ($p < 0.001$) and the Exeter ($p < 0.001$) stems and a significant under-representation of the Lubinus ($p < 0.001$) stem.

A major finding was that the surgeon's grading of the B1 fracture was not in agreement with the study radiologist in more than 34% of the cases. Patients with a fracture categorized as B1 operated with ORIF had a high failure rate.

The first year mortality was 13%, and 14% of the patients had a major postoperative complication prior to discharge. By December 31, 2004, 22% had been reoperated (17% during the first 12 postoperative months).

The mean Harris hip score after operation was 67 for Charnley categories A and B and 59 for Charnley C. The mean value for pain was 23 (0 – 100, none – unbearable) and the mean value for overall satisfaction was 27 (0 – 100, satisfied – dissatisfied). The mean EQ-5D index was 0.59.

Conclusion: One important observation in this study was that the majority of the stems were loose. Other major findings were the significant implant related risk factors for failure.

The underestimation of the frequency of loose implants (the surgeon classified B2 fractures as B1) likely explains the high failure rates observed in patients with B1 fractures. If there is doubt in terms of stem stability, a revision combined with ORIF is recommended.

The high rates of major complications, reoperations and poor clinical outcome indicate substantial morbidity for patients with a periprosthetic fracture. Several authors have claimed the need for a treatment algorithm for late femoral periprosthetic fractures. The results of this study strongly support such a need.

Paper 3. Risk factors associated with the late periprosthetic femoral fracture.

Introduction: Periprosthetic femoral fracture is an uncommon and severe complication after primary and revision THA surgery. This study aims to identify risk factors for such fractures.

Patients and methods: The Swedish National Total Hip Arthroplasty Register has captured 113,523 primary THAs from 1992 to 2003. Between 1979 and 2000 12,516 revision THAs have been registered. In the group of primary THAs, we identified 296 hips operated on due to a periprosthetic femoral fracture. Among the group with one or more previous revision arthroplasties, 234 patients had had a reoperation due to a periprosthetic femoral fracture. In the analysis we identified both patient related as well as implant and time related factors as-

sociated with periprosthetic fracture. Surgical technique factors were analyzed separately.

Results: Age was a factor that decreased the risk. Another factor was calendar time since operation. For every year of increased follow-up there is a continuous increase in the risk for sustaining a periprosthetic femur fracture. The Lubinus stem and index diagnosis OA was related to a lower risk. The Charnley and Exeter stem, index diagnoses RA and hip fracture, were all related to a higher risk. Factors without significant association were the type of hospital, the surgical approach, the type of cement used and the head size.

In patients with one or several revisions prior to the fracture, the number of revisions done prior to the periprosthetic femur fracture was a strong negative predictor. This is also reflected by the fact that for each year after the first revision there is a continuous decrease of the risk factor. If the revision was performed at a university hospital it decreases the risk for future periprosthetic fracture and if performed at a county hospital it increases the risk. The index diagnosis was of no significant importance in the revision group.

Conclusion: Factors related to index diagnosis could be explained by the difference in bone quality in the different groups. We believe that stem design plays a major role in the different risk ratio connected to different implants. In the revised group, a decreased risk was associated to surgery performed at university hospitals. In conclusion, we were able to find factors associated to both increased and decreased risks for periprosthetic fracture.

Paper 4. Risk factors for failure after treatment of a periprosthetic fracture of the femur.

Introduction: Periprosthetic fracture of the femur is an uncommon complication after total hip replacement, but appears to be increasing. We undertook a nationwide observational study to determine the risk factors for failure after treatment of these fractures, examining patient and implant related factors, type of fracture (Vancouver classification) and the outcome.

Patients and methods: Between 1979 and 2000, 1,049 periprosthetic femur fractures were reported to The Swedish National Hip Arthroplasty Register. Of these, 245 had a further operation after failure of their initial management. Data were collected from the Registry and hospital records. The material was analyzed by the use of Poisson regression models.

Results: We found that the risk of failure of treatment was reduced for Vancouver type B2 fractures ($p = 0.0053$) if revision of the implant was undertaken ($p = 0.0033$) or revision and open reduction and internal fixation ($p = 0.0039$) were performed. Fractures classified as Vancouver type B1 had a significantly higher risk of failure ($p = 0.0001$). The strongest negative factor was the use of a single plate for fixation ($p = 0.001$). The most common reasons for failure in this group were loosening of the femoral prosthesis, non-union and refracture.

Conclusion: Many fractures classified as Vancouver type B1 ($n = 304$), were in reality type B2 fractures with a loose stem which were not recognized. Plate fixation was inadequate in these cases. The difficulty in separating type B1 from type B2 fractures suggests that the prosthesis should be considered loose until proven otherwise.

Paper 5. The excess mortality due to periprosthetic femur fracture.

Introduction: The primary aim was to estimate the probability of death caused by the periprosthetic femur fracture among patients with osteoarthritis and therefore the risk of death after fracture was estimated disregarding the relationship to the fracture event. Secondary aims were to elucidate the magnitude of the risk of death compared to after a THA and compared to the general population.

Patients and methods: From 1979 to 2000, 1,049 patients with a periprosthetic fracture were registered. Patients with the primary diagnosis of osteoarthritis were selected, ending up with 736 patients. Data from 63,582 patients operated on with a THA from 1979 to 2000 and with the diagnosis of osteoarthritis were analyzed for comparison. The mortality was compared to that of the general Swedish population aged 50 years or more. Death hazard functions were estimated by Poisson regression analysis.

Results: Patients with OA receiving a primary THA had an excess mortality due to the operation. The risk was steeply decreasing during a short time (0.08 year) after the operation and reached a minimum 0.8 month after the hip replacement. The death hazard after a year or more was equal to that of the general population for age 60 and below. For the higher age groups the risk was substantially lower and increased parallel to the risk of the general population. In the fracture group there was excess mortality in connection to fracture operation but there was a large decrease of the risk during the first six months after the fracture. One year after fracture, the mortality risk was higher than that of the general population for the age group 50-70 years. The mortality risk was equal compared to the general population for ages above 70 years. At the age of 70 years, the estimated probability of death due to the fracture was 2.1% for men and 1.2% for women. At the age of 80 years at fracture, the corresponding probabilities were 3.9% and 2.2% for men and women, respectively.

Conclusion: This current study showed that the risk of death among patients with OA and a periprosthetic fracture was initially high but after six months it was the same as for the general population - except for patients younger than 70 years. Why patients with OA and a periprosthetic fracture had a higher morbidity compared to patients with OA and a THA is difficult to explain. We could not demonstrate higher co-morbidity in the fracture group and further research is needed.

Patients with OA and a periprosthetic fracture, after initially high mortality, reaches the same mortality as the general population. This stresses the importance of adequate surgery.

Material and Methods

The Registry study

The Swedish National Hip Arthroplasty Register was initiated in 1979 (Ahnfelt 1986) and is a nationwide prospective observational study. The mission of the Registry is to improve the outcome of THA surgery. The rapid growth of new surgical techniques in conjunction with an accelerating development of new hip implant technology warrants a continuous and objective monitoring of the results paralleled with precise educational efforts. For many years, the purpose of The Swedish National Hip Arthroplasty Register was to monitor surgical techniques and prophylactic measures to minimize complications by persistent continuous feedback to all centers that provide access to THA procedures and to provide a warning system for rapid implant failures. A substantial part of the feedback system (reporting), all publications, annual reports, and scientific exhibitions, are communicated via a web site (www.jru.orthop.gu.se). All 79 public and private orthopedic units in Sweden participate voluntarily. Copies of medical records from all reoperations and revisions are collected for further scientific studies. The results are presented as annual reports in Swedish and English (www.jru.orthop.gu.se).

There are four different databases in the Registry. In the primary THA database, all primary operations were registered since 1979. Until 1991, only the number of primary operations and the type of implant used was reported from the individual units annually. The demographics and diagnoses were estimated through figures given by Statistics Sweden (www.scb.se) and continuously validated by site specific samples. From 1992, data have been collected by patient ID regarding baseline information from the primary procedure and any subsequent open procedure. The implant has been characterized in detail during this later period. The number of patients registered by December 31, 2004 was 242,393.

Since 1979, copies of the medical records on all patients with a subsequent open operation have been mailed to the Registry. Information is captured from the records and this constitutes the reoperation database. This database holds information of more than 80 parameters per reoperation. At the end of 2004 it contained 28,045 reoperations of which 22,840 were revisions with partly or complete exchange/extraction of the components. The third database capture the prophylactic measures against aseptic loosening, infection and details of the surgical technique. The variables recorded are surgical approach, cementing technique including type of cement and mixing, the use of brush, pulsatile lavage, the use of distal femur plug and proximal seal. Type of antibiotic, length and administration mode is registered. The data is reported per department per year.

The fourth database was initiated in 2002 and data collection is still not implemented at all units (60/79). It captures patient-related outcome parameters. The primary aim is to increase the sensitivity of the Registry. All patients complete a questionnaire containing 10 items including Charnley categories (Charnley 1979), a pain and satisfaction visual analogue scale and the EQ-5D (EuroQol 1990) preoperatively and at 1 year postoperatively with the intention to repeat the measurement at 6 and 10 years postoperatively. The EQ-5D is a generic health measurement instrument. It can be presented as a health profile or as a global health index with a weighted total value for health; the minimum value is -0.594 and the maximum value is 1.0. When the index is used for cost-utility analyses, all negative values are set to 0.0.

Since all orthopedic departments report to the Registry, a unique possibility is provided to perform nationwide studies on uncommon complications. In Study 1, the Registry was used to identify patients with a periprosthetic fracture. All

medical records were collected. The patients were subdivided in two groups, one with the primary THA in situ (later referred to as primary group) and the other with patients having one or several revisions prior to the fracture (later referred to as revised group). The Registry databases were used to compare demographics between the fracture group and all primary THAs performed in Sweden. To get more exact information about the patients and implants, the comparison was limited to patients operated from 1992 to 2000.

In Study 2, patients with a fracture from 1999 to 2000 were reported directly to the author. As in Study 1, the fracture patients were divided into a primary and a revised group. The Registry data was used in the same manner as in Study 1. The clinical follow-up was done 1 to 4,5 years (mean 2.4) after operation and all patients were followed concerning further surgery reported to the Registry as the endpoint (December 31,2004).

In Study 3, patients with revisions prior to fracture were analyzed in comparison with all patients revised from 1979 to 2000. The "primary" fracture group was compared to all primary THAs operated from 1992 to 2003.

In Study 4, patients from Study 1, which were reoperated, were compared to the whole fracture group.

In Study 5, fracture patients with the primary diagnosis osteoarthritis (OA) were analyzed in comparison with all patients with a primary THA and the diagnosis OA that were operated from 1979 to 2000.

Medical records

Patient data in the fracture group, used in the demographic analysis in Studies 1 and 2, were collected from the medical records. Information concerning age, gender, index diagnoses, co-morbidity, trauma causing the fracture, stem loosening, type of implant, operation method, postoperative complications and reoperations were collected.

The trauma causing the fracture was categorized as spontaneous fracture (patient rising out of a chair or turning around), minor, low energy trauma and major, high energy trauma. Stem loosening was categorized as known loose (patient on waiting list for revision or aware of the loose stem), unknown loose (the loosening was detected at fracture time) and stable.

Radiographic methods

In Study 1, the fractures were classified according to the Vancouver system. Since this study in part was retrospective, we did not use radiographs for the fracture classification. It was not possible to access many of the radiographs as they were either recycled or impossible to locate. The author (H.L.), using the surgeon's interpretations and the assessment from the radiologist, did the classification.

One of the aims in Study 2 was to do a prospective radiographic follow-up. An experienced and independent radiologist (H.R.) analyzed all the radiographs. Pre- and postoperative radiographs and follow-up radiographs after 1 to 4.5 years were collected. The Vancouver classification system (Brady et al 1999) was used.

The radiographic definition of stem loosening was described by Harris et al (1982). The criteria for loosening were divided into three categories; definite loosening, probable and possible. The criteria for these three categories have been modified over the years and the terms probable and possible are now excluded (Mulroy and Harris 1990; Mulroy and Harris 1997). In this study, the stem was considered loose if there was a 100% continuous radiolucent line in the cement/stem-bone interface with or without osteolysis, stem debonding, cement fracture or obvious subsidence. Concerning the fracture, the postoperative reposition was defined as exact or with dislocation. If revision with cement was performed,

cement leakage was notified. At follow-up, healing of the fracture was classified according to callus formation and if the fracture line still was visible or not. Also noted were loosening, breakages of plates, screws or wires.

Interobserver study

The fractures were first classified using the surgeon's opinion of the fracture combined with the assessment done by the local radiologists. All the radiographs were sent to a blinded and independent observer (experienced radiologist) who classified the fracture from the radiographs. These two observations were then compared in an interobserver analysis.

Intraobserver study

An intraobserver analysis performed by the study radiologist analyzing 50 radiographs with a 2 month interval between the observations was done

Outcome methods

In Study 1, all living patients operated between 1979 and 1998 received a follow-up questionnaire (see appendix). The questionnaire included 5 questions: two about impaired walking capacity due to problems with the other hip or due to other medical conditions (leading to a reassignment of the patient to different Charnley categories (Charnley 1979) one about whether the patient had undergone a second surgery (validation by Registry data), one about satisfaction with the treatment, and one about pain (none, mild, moderate, severe, or intolerable).

In Study 2, the follow-up was done at the local hospital 1 to 4.5 years (mean 2.4) post-operatively. A standardized follow-up protocol was used (see appendix). All patients completed a questionnaire containing 11 items including Charnley categories (Charnley 1979), two visual analogue scales covering pain (0 – 100, none – unbearable) and satisfaction (0 – 100, satisfied – dissatisfied) and EQ-5D (The_EuroQoL_Group 1990). The examiner completed the Harris hip score (HHS) (Harris 1969; Söderman and Malchau 2001) which is a widely used disease specific assessment tool in hip replacement surgery. Mortality was obtained from the Population Register in Sweden (www.socialstyrelsen.se).

Statistical methods

Comparisons with respect to categorical variables were performed using the chi-square test, Fisher's exact test and with continuous variables by t-test. A p-value of $p < 0.05$ was considered statistically significant and two-tailed tests were performed.

Implant survivorship was analyzed according to Kaplan-Meier (Kaplan and Meier 1958) and reoperation of any kind was defined as the endpoint. The 95% confidence limits (1.96 x standard error mean) were indicated on the survival curves.

In Studies 3, 4 and 5 we have used the Poisson model. The assessment of risk depending on several variables has been performed in various fields during the last decades by use of Cox regression analysis (Altman 1997). The underlying model of proportional hazards means substantial restrictions, which we can overcome through the Poisson regression model (Breslow and Day 1987). Thus, we can achieve a number of advantages compared to the Cox model. The hazard functions will be continuous functions of time, and the change of risk by time can be studied explicitly, i.e. estimated and tested. A continuous hazard function of reoperation can be used to calculate the survival of an implant (or the need for further surgery eg. refracture) for a patient when the death hazard function is also included. Such

calculations can be done from any starting point; at operation, one year afterwards, etc. The relative importance of a risk variable is allowed to depend on time. A decline or increase in the importance with time can be tested and estimated. In many applications, several time parameters are of interest to study simultaneously: time since surgery, current age and calendar time. Also, that can be achieved by use of the Poisson regression. In the simple situations, when the Cox model can be applied, Poisson regression can also be used and the results will be almost identical.

General Discussion

Epidemiology

One of the aims of Study 1 was to estimate the annual number of periprosthetic femur fractures in Sweden between 1979 and 2000. In many review articles the incidence (or risk) of periprosthetic femur fracture has been discussed. Most published studies describe one type of fracture treated with a single type of surgical method and the outcome is reported (Serocki et al 1992; Jukkala-Partio et al 1998; Sandhu et al 1999; Ahuja and Chatterji 2002). There is little information about the overall incidence (the risk) of periprosthetic fracture in a broader perspective taking, eg. time since operation, into account.

Beals and Tower (1996) identified 93 patients in a region with periprosthetic femur fracture. If the patient was primarily operated in the same region was not determined. The authors, however, estimate the incidence to be less than 1% over the life span of the implant. Löwenhielm et al (1989) evaluated the incidence of fracture, after a primary THA, in 1,442 patients operated at one hospital from 1968 to 1983. The annual incidence varied between 0 and 1.25% and the distribution of fractures was not uniform in the postoperative period. The accumulated incidence was 2.25% between 10 to 11 years after the primary THA. The incidence of fracture after THA is described in a paper (Berry 1999) from the Mayo Clinic Joint Register. They found a 1.1% incidence of postoperative periprosthetic femur fracture in a total of 23,980 primary THA, during the total follow-up period and 4% after 6,349 revision THAs.

In Study 1, we found an annual incidence that varied between 0.045% and 0.13%. As

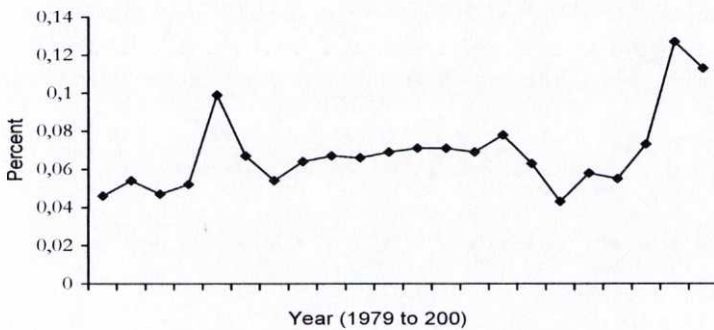


Figure 12. The annual incidence of periprosthetic femur fracture

shown in Figure 12 there was a tendency that the incidence was increasing over time, which was in concordance with many other reports (Kavanagh 1992; Lewallen and Berry 1998; Abendschein 2003; Tsiridis et al 2003).

There are some peaks and some drops that are difficult to explain. Löwenhielm et al reports a similar finding. In order to evaluate if there was a systematic failure in the reporting of fractures, the total numbers of THAs performed at each hospital were compared to the numbers of fractures reported from each hospitals. There was no evidence of systematically underreporting. However, fractures in the trochanteric region (Vancouver A) and below the implant (Vancouver C) are probably underreported in the early register years. Since these fractures seldom engage the stem, they have probably, in some cases, been considered femur fractures (not periprosthetic) and not reported to the register.

The incidence of periprosthetic femur fracture is increasing in Sweden as showed in Figure

12. Since 2000, periprosthetic fracture is the third most common reason for revision after aseptic loosening and dislocation (Annual report 2004). From four years after a primary THA and onwards the periprosthetic femur fracture is the second most common reason for revision (Table 4).

Table 4. Reason for revision from the Registry (Annual report 2004)

Reason for revision	0 – 3 years	4 – 6 years	7 – 10 years	> 10 years	Total	Share
Aseptic loosening	2,578 48.1%	3,280 84.2%	4,315 86.8%	4,139 86.4%	14,312	75.2%
Deep infection	1,018 19.0%	173 4.4%	118 2.4%	59 1.2%	1,368	7.2%
Dislocation	937 17.5%	139 3.6%	130 2.6%	138 2.9%	1,344	7.1%
Periprosthetic fracture	264 4.9%	195 5.0%	272 5.5%	322 6.7%	1,053	5.5%
Technical error	415 7.7%	31 0.8%	27 0.5%	22 0.5%	495	2.6%
Implant fracture	45 0.8%	57 1.5%	96 1.9%	92 1.9%	290	1.5%
Miscellaneous	57 1.1%	15 0.4%	11 0.2%	14 0.3%	97	0.5%
Pain only	48 0.9%	7 0.2%	3 0.1%	4 0.1%	62	0.3%
Total	5,362 100%	3,897 100%	4,972 100%	4,790 100%	19,021	100%

Explanations for the observed increase may be related to widened indications for THA and a secondary increase in numbers of revisions in combination with an aged population with a THA in situ. Other explanatory factors include osteoporosis, misaligned stems with inhomogeneous cement mantle, osteolysis related to wear of the bearing surfaces and stress-shielding, as well as repeat revision surgery. Asymptomatic loosening and periprosthetic osteolysis can remain undetected for a long time since clinical and radiographic follow-up is seldom undertaken in the regular OA patient with a well-documented implant in situ. However, the overall incidence in Sweden is low compared to most other reports.

Difficulty to obtain a true incidence is obvious. A better approach might be to present it as a risk analysis per patient years. In Figure 13 the hazard function for a periprosthetic fracture over time is calculated.

Risk of periprosthetic femur fracture (PFF)

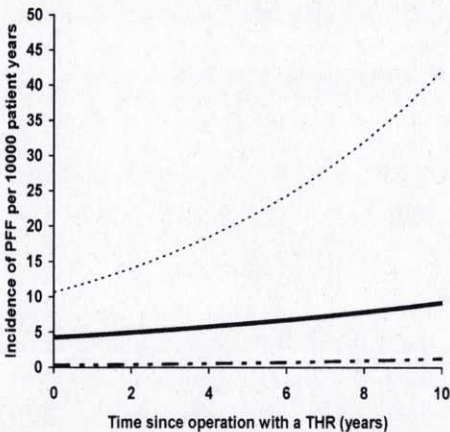


Figure 13. The figure shows the hazard functions for all patients (the bolded curve in the middle), for a high risk patient (the uppermost curve) and for a low risk patient. The two extreme curves are examples, where the patients in both cases are assumed to be 65 years of age at the primary operation taking place 1992, but the values of other risk variables are unfavorable and favorable, respectively (Study 3). From the hazard function shown above it could be calculated that the probability of a periprosthetic femur fracture within 10 years was 0.64% (all patients), 2.25% (high risk) and 0.07% (low risk).

Risk factors

There are only a few published reports about risk factors (Sarvilinna et al 2004; 2005). In some review studies, (Tsiridis et al 2003; Learmonth 2004) proposed patient related risk factors are age, female gender, osteoporosis, and factors related to the implant or earlier surgical procedures such as loose stems, femur osteolysis, perforation and stress risers like, eg., old screw holes.

Gender

Many series have shown a slight dominance of fractures in females over males; 70% (14/20) Whittakers et al, 60% (21/35) Johansson et al, 52% (16/31) Bethea et al, 68% (17/25) Ruiz and 55% (47/86) Beals and Tower. Jensen reported opposite findings with a marked male dominance 77% (104/131). Some authors (Haddad et al 1999; Tsiridis et al 2003) have claimed that females have a higher risk for fracture.

In Study 1, the gender distribution was almost equal, 52% female (546/503). There was a slight dominance of females (54% (352/336)) in the revised group compared to the primary group (51% (194/167)). In Study 2, the gender distribution was the same (52% female (167/154)) as in Study 1. A female risk could not be confirmed in the current studies (1 and 2). Compared to the gender distribution of all THAs in Sweden (60% female), there are fewer females in the fracture group (52% female). On the contrary, in Study 3, we found a significantly lower risk for fracture among females, both in the primary and the revised group.

The gender distribution in different age groups is presented in Figure 14. Younger males are probably more exposed to high-energy trauma and consequently would be over represented in the younger population, but this could not be demonstrated in the current study. There is almost an equal gender distribution among younger patients. Among the elderly, there was a dominance of females. The higher average length of life for females can explain this finding.

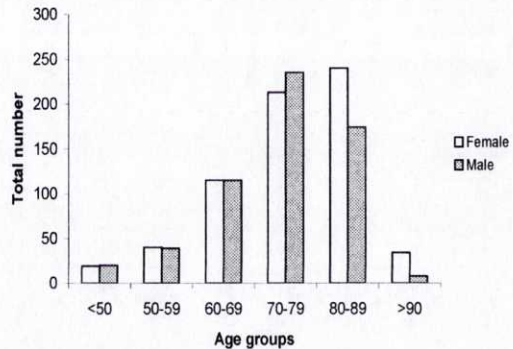


Figure 14. The gender distribution in different age groups

Age

Age is another demographic parameter which could be associated with the risk of a periprosthetic fracture. In Study 1, the mean age was 74 years. For primary and revised patients, it was 75 and 72, respectively. In Study 2, the mean age was 78 years for the primary group and 74 for the revised. In the literature there is a variance in presented mean age ranging from 60 years (Johansson et al 1981) to 77 years (Ruiz et al 2000). It is relatively clear that it is the older population with a THA that is affected and is at risk. In Study 3, age was defined as a risk factor. The risk ratio (RR) was 1.01 for every year of aging.

However, in Study 1, the age range was 20 to 97 years. Even very young patients were represented in the material. We also found that patients in the fracture group had a significantly lower mean age at index operation compared to patients with a primary THA. In most reports, there is a wide range in age and when dealing with late periprosthetic femur fracture, the mean age probably is of less importance. The mean age at fracture time is dependent on

at what age the index operation is done and follow-up routines at the clinic. More relevant is time from index operation to fracture.

Index diagnoses

Study 1 revealed a significant overrepresentation of patients with RA and hip fracture as index diagnoses compared to all primary THAs. This finding was confirmed in Study 3. The hazard ratio (HR) for patients with index diagnosis hip fracture was twice as high for patients with RA (2.98 versus 1.56). With the index diagnosis OA there was a significantly decreased risk. Sarvilinna et al (2004) in a case control study reported that the index diagnosis hip fracture was a risk factor for a later periprosthetic fracture.

Trauma

The majority of trauma causing the fracture was categorized as minor trauma (in the primary group 81% and in the revised group 70%). "Spontaneous" fracture was significantly more common in the revised group. Major trauma was uncommon with only 6% in the primary and 4% in the revised group. Beals and Tower (1996) reported a similar distribution between different types of trauma causing periprosthetic fracture.

One conclusion might be that the trauma is of less importance compared to bone loss in the femur. Revised patients often have stress risers like penetrations, bone loss, screw holes or bony defects. It is important, when revision is performed, to protect weak bone with a plate, onlay grafts or other internal augmentation which allows weight bearing.

Implant characteristics

In Study 1, 70% (485/688) of the patients in the primary group and 44% (160/361) in the revised group had a known or unknown loose stem. In Study 2, including patients operated with a contemporary cementing technique, there was also a high frequency of loose implants. In the literature, aseptic loosening, bone loss and osteolysis has been well described (Schmalzried et al 1992; Maloney and Smith 1995; Paprosky and Burnett 2002) and also in patients with a periprosthetic femur fracture (Bethea et al 1982; Fredin et al 1987; Jensen et al 1988; Tower and Beals 1999). The finding in the current study confirms that loosening is a highly significant risk factor.

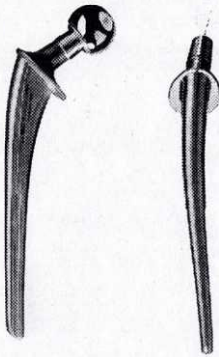


Figure 15. The Lubinus stem

We found significant implant related risk factors in Studies 1, 2 and 3. In the literature a high incidence of intraoperative periprosthetic femur fracture is reported, among patients operated with uncemented press-fit implants (Kavanagh 1992; Ries 1997). Löwenhielm et al (1989) found different fracture patterns with different stems. Lubinus stems were associated with fractures of the distal femur while patients with Charnley-Muller, Christiansen and Brunswick prostheses had a more proximal fracture pattern. Sarvilinna et al (2005) found an increased risk for fracture among patients with the Exeter stems compared with all other types of stems.

Cement was and still is the most widely used type of fixation for THA in Sweden (Malchau et al 1993). The three most used stem designs during the study period were the Charnley, the Lubinus and the Exeter prostheses. The Lubinus stem was significantly underrepresented in the fracture group while the Charnley and the Exeter prostheses significantly were overrepresented (Studies 1, 2 and 3). The demographics of these three groups showed no notable difference

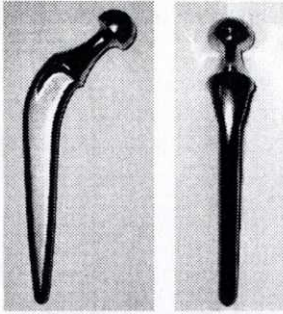


Figure 16. The Charnley stem

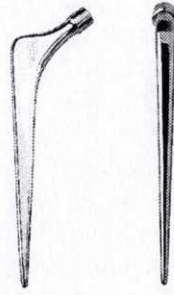


Figure 17. The Exeter stem



Figure 18a. Malpositioning of the stem with osteolysis.



Figure 18b. The C-2 problem.

concerning mean age at fracture time, gender and time from index operation, and primary diagnosis. Therefore stem design probably is a risk factor.

There are some major differences in design between the three implants. The Lubinus prosthesis (Figure 15) is anatomically shaped, with a large collar and matt surface.

The Charnley (cobra model, Figure 16) stem is straight and with a bulky flange and a mini collar. The surface has a matt finish. The Exeter (Figure 17) stem is straight and symmetric, it has no collar, is double tapered and the surface is polished.

Malpositioning of the Charnley stem is a well described phenomenon (Garellick et al 1999; Garellick et al 1999), especially when using an anterolateral approach. Inadequate cement mantle with implant-bone contact has been correlated with femoral osteolysis at the tip and risk for loosening in the long-term (Garellick et al 1999; Garellick et al 1999), the so called C-2 problem (Figure 18a and b). The polished, tapered Exeter stem normally subsides during the first postoperative years (Huiskes et al 1998; Verdonshot and Huiskes 1998). The tapered design, increased hoop stresses in the cement mantle and surrounding femur could predispose to a periprosthetic fracture and explain the observation in the current study. The Lubinus is anatomically shaped and provides the stem with a more uniform cementing mantle.

It is difficult to draw any conclusions regarding the effect of the revision stem since we at present do not have information on the type of bone defect, bone-grafting procedures and how well the stem by-passed the most distal defect. However, the anatomical configuration of the Lubinus SP II stem, which is frequently used in longer versions in Sweden, might explain its superior survival for much the same reasons as in the primary setting.

Environmental and technique factors

Most orthopedic clinics in Sweden use similar cementing techniques. The only surgical tech-

nique factor in the current study that increased the risk for fracture was the use of femur brush. It is difficult to explain, but earlier annual reports from the Registry show that it does not reduce the risk of revision due to aseptic loosening. The explanation for this finding is not obvious, but could be related to failures from the early and mid-eighties where brushing of the femur was the only way of cleaning the trabecular bone in femur. After rasping the femoral canal, devascularized cancellous bone probably needs to be removed to provide cement inter-digitations in living bone in order to achieve stable fixation. Failure to do so might lead to a fibrous interface, which is a harbinger of osteolysis and loosening and in the end, a periprosthetic fracture. The current use of pulsatile lavage helps to remove the devascularized cancellous bone.

Hospital type and risk

The THA is a common operation and is performed at most orthopedic units in Sweden. Based on the capture population there are four different types of hospital in Sweden; university or regional hospitals, central hospitals, rural hospitals and private hospitals.

In patients with a primary THA, there was no increased risk for a periprosthetic fracture associated with the type of hospital performing the primary THA. In the revision group, there was a decreased risk for fracture if the revision was performed at a university hospital (RR 0.56, 95% CI 0.36-0.89). This implies that this type of technically demanding surgery should be referred to units with special interest and experience in this kind of surgery.

Revision prior to fracture

Revision surgery is, in the literature, regarded as a risk for later periprosthetic femur fracture (Kavanagh 1992; Garbuz et al 1998; Lewallen and Berry 1998; Tsiridis et al 2003). The number of previous revisions (HR 2.36, 95% CI 0.98-5.65) was the factor that strongest correlated to later periprosthetic fracture in this group of patients (Study 3). Many of these patients had bone defects related to earlier revision surgery, such as bone penetration and cortical windows. This finding is reflected in the fracture classification and pattern. In the revision group, there were more patients with B1 fractures compared to the primary group (44% versus 21%). There was an opposite finding for B2 fractures with 38% in the revision group compared to 61% in the primary group. Patients with a stress riser (revised patients) more often have a horizontal single fracture line, while primary patients (with loosening) have a more comminuted fracture. It is important at revision surgery to prevent stress risers and use plates or strut grafts bridging weak parts.

Fracture treatment

Treatment of periprosthetic femur fracture is presented either in review articles (Booth 1994; Kelley 1994; Garbuz et al 1998; Jukkala-Partio et al 1998; Berry 2002; Schmidt and Kyle 2002; Gruner et al 2004; Learmonth 2004) or in articles presenting one special treatment method (Serocki et al 1992; Ries 1996; Sandhu et al 1999; Tadross et al 2000; Mennen 2003). Although, Study 1 includes 1,049 cases, it has some methodological limitations which the authors are aware of. The data is collected over a period of 22 years and at least in the beginning of the period, treatment methods to some extent are historical.

In Table 4 the fracture treatment (categorized as revision, revision + ORIF and ORIF alone) is correlated to Vancouver class. As recommended in treatment algorithms, most B1 fractures were treated with ORIF. In the B2 category, where revision is recommended, still 9% were treated with ORIF alone. In Vancouver category A and C, where by definition the

fractures do not engage the stem many patients were operated with revision or a combination of revision and ORIF.

The contemporary treatment (Study 2) is shown in Table 5. One difference compared to Study 1 was the shifting of treatment towards ORIF in B1 category. There was no other major difference in treatment methods in the two time periods.

The total number of patients treated with revision and/or revision and ORIF in all Vancouver categories was 60% (193/321). Cemented long stems were mostly used (75% (145/193)) and the rest (25% (49/193)) were treated with long, distally fixed, uncemented prostheses (Wagner or Lubinus MP). The mode of fixation at revision was based on the surgeon preference and reflects his experience in revision THA surgery. Cement was, in general, the preferred mode of fixation at rural and central hospitals and most of the uncemented implants were used at the university hospitals. In a comparison of stems, there was no difference in reoperation rate (ns. $p=0.26$, Fishers exact test).

The bone deficiency of the 34 B3 fractures was classified according to Paprosky and Burnett (2002). No bone loss was found to be of the more severe Paprosky type III or IV. The majority was Paprosky type II (26) and the rest had Paprosky type I bone deficiencies. The treatment was revision in 33 of the 34 B3 fractures and there was one resection arthroplasty. In 15 patients, impacted cancellous allograft was used, (Gie et al 1993; Slooff et al 1993; 1996) one patient had a cortical onlay allograft, and in 12 patients, a long, distally fixed uncemented stem was used.

In Sweden the use of cemented THA is most common. The Registry reported, in 2004, the use of cemented stems in 95% of all primary THAs. In the treatment of periprosthetic

Table 4. Treatment in different Vancouver categories from 1979 to 2000

Method	A (n=47)	B1 (n=304)	B2 (n=555)	B3 (n=43)	C (n=100)
Revision	26% (12)	13% (41)	35% (191)	70% (30)	6% (6)
Revision + ORIF	45% (21)	21% (63)	56% (312)	30% (13)	31% (31)
ORIF	29% (14)	66% (200)	9% (52)	0	63% (63)

Table 5. Treatment in different Vancouver categories from 1999 to 2000

Method	A (n=8)	B1 (n=90)	B2 (n=158)	B3 (n=34)	C (n=31)
Revision	25% (2)	10% (9)	31% (49)	68% (23)	6% (2)
Revision + ORIF	50% (4)	5% (5)	55% (86)	30% (10)	10% (3)
ORIF	25% (2)	83% (74)	12% (19)	0	74% (23)

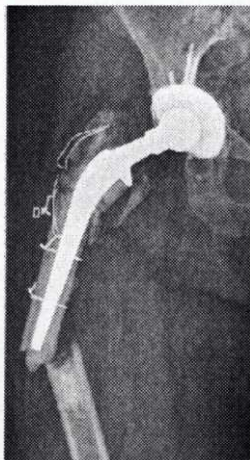


Figure 19. Vancouver B3

fractures, most patients were revised with a cemented THA. In the literature, revision with cemented stems have been proposed (Johansson et al 1981; Bethea et al 1982; Fredin et al 1987; Beals and Tower 1996; McLauchlan et al 1997; Sandhu et al 1999) but in the past 7-10 years, focus has been on uncemented revision (Moran 1996; Incavo et al 1998; Macdonald et al 2001; O'Shea et al 2005; van der Wal et al 2005). From the Mayo clinic, (Springer et al 2003) 118 hips in 116 patients were evaluated after being treated with THA revision due to Vancouver type-B periprosthetic femoral fracture. Their conclusion was *"At the present time, we use uncemented, extensively porous-coated, long-stemmed implants for the majority of revisions performed for the treatment of periprosthetic femoral fractures. We continue to use cemented long-stemmed implants for selected older patients with poor bone and a simple fracture pattern that can be reduced anatomically to preclude cement extrusion."* The difference in revision surgery

for periprosthetic fracture between North America and Northern Europe is obvious. Uncemented stems are more of a standard procedure in North America. In Sweden, cemented revision for periprosthetic fracture is the most used treatment method. However, it seems that the fully coated stem is a good option according to Springer et al (2003) and other authors (Incavo et al 1998).

The more complicated B3 fracture (Figure 19) with extensive bone loss, is a technically demanding operation (Chandler et al 1993; Chandler and Tigges 1998; Brady et al 1999; Logel et al 1999; Wong and Gross 1999; Haddad et al 2002; Barden et al 2003; Barden et al 2003). Many authors (Barden et al 2003) advocate the use of structural allograft in combination with revision. This method is seldom used in Sweden. One reason is that allograft is not easily available in Sweden. Another reason might be the good results that have been achieved with the use of impacted cancellous allograft in revision surgery (Gie et al 1993). This concept has also been used in the fracture situation. There are, however, still no long term results reported in the literature.

In Sweden, the long distally fluted uncemented stem is more frequently used. Authors describing this method have reported good results (Kolstad 1994; Berry 2003) and it seems to be a viable alternative in patients with poor proximal bone stock.

Treatment with ORIF alone was performed on 118 patients in all Vancouver classes. In 11% of the cases, an angulated plate from the knee was used and in 4%, only cerclage. In the rest of patients, either a conventional screw plate (24%) or a screw plate combined with wires or cables (61%) was used. Only a few of these fractures were treated with double plating.

Treatment outcome

The result of fracture treatment was analyzed according to Kaplan-Meier, with reoperation of any kind defined as the endpoint (Studies 1 and 2). The survivorships are presented in Figures 20 to 23. Neither in the primary nor in the revision group, were there any differences in survivorship at 5.5 years. However, in Study 1, with a longer follow-up, the survival for the revised group has continued to decrease until 13 years follow-up. Whether, at 13 years follow-up, the patients in Study 2 will have the same poor survivorship remains to be demonstrated.

The first year reoperation rate was 10% and the first year mortality was 9% in Study 1 and the corresponding values in Study 2 were 17% and 13%, respectively. The difference

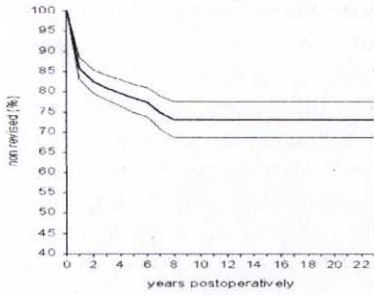


Figure 20. Survival rate for operated PFF (primary), with failure defined as reoperation. 10-years survivorship $73.2 \pm 4.4\%$

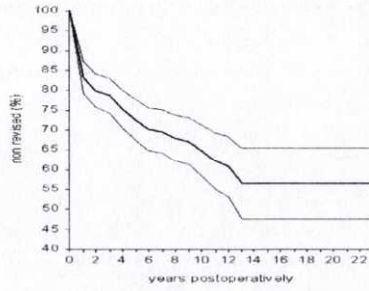


Figure 21. Survival rate for operated PFF (revised), with failure defined as reoperation. 10-years survivorship $64.9 \pm 6.6\%$

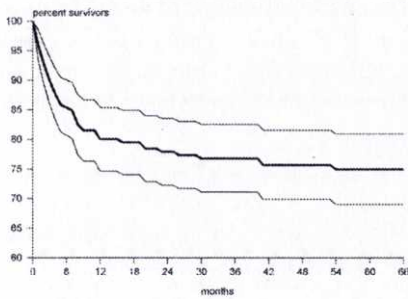


Figure 22. Survival rate for operated PFF (primary), with failure defined as reoperation. 5.5-years survivorship $74.9 \pm 6.0\%$

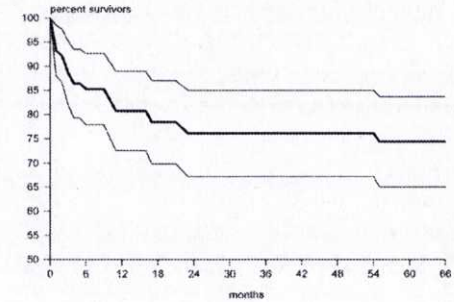


Figure 23. Survival rate for operated PFF (revised), with failure defined as reoperation. 5.5-years survivorship $74.4 \pm 6.7\%$

could be explained by a more aggressive attitude towards reoperation in later years. The need for further surgery (Study 2) with respect to the initial surgical treatment and the Vancouver classification is presented in Table 6.

The reoperation rate was high in Vancouver class B1 and B2 treated with ORIF alone. The dominating reasons for reoperation among patients with Vancouver B1 were non-union, refracture and loosening, which indicates problems related to operation method. Of the remaining B1 fractures treated with ORIF, 23% (12) had no signs of fracture healing and 14% (7) had callus formation but a visible fracture line.

We believe that the high failure rate in B1, to some extent, could be explained by incorrect classification of the fracture. Many of the fractures classified as B1 fractures were B2

Table 6. Reoperation rate in different Vancouver classes

Method	A (n=8)	B1 (n=90)	B2 (n=158)	B3 (n=34)	C (n=31)
Revision	0	33% (3/9)	10% (5/49)	13% (3/23)	0
Revision+ ORIF	0	20% (1/5)	23% (20/86)	20% (2/10)	33% (1/3)
ORIF	0	30% (22/74)	32% (6/19)	0	25% (6/23)

fractures, which will be discussed in the paragraph radiological assessment. Achieving good quality fracture radiographs is difficult and gives subsequent difficulties in the classification and stem fixation estimation. This leads to an incorrect operative approach.

In most treatment algorithms (Berry 2002; Abendschein 2003; Learmonth 2004) the use of plates in B1 (by definition a stable implant) is the proposed surgical approach. The most used plates today are the combination plate or a conventional screw plate. There are several papers describing the use of plates (Haddad et al 1997; Jukkala-Partio et al 1998; Tadross et al 2000; Venu et al 2001; Park et al 2003; Tsiridis et al 2003; Agarwal et al 2005; Tsiridis et al 2005) and in some reports with a high failure rate. This could, to some extent, be explained in the use of single plates. Different biomechanical laboratory studies (Stevens et al 1995; Schmotzer et al 1996; Dennis et al 2000; Dennis et al 2001; Kuptniratsaikul et al 2001; Lin et al 2002; Ren et al 2002) have supported the use of combination plate with wire or cable proximal and screws distal and the use of two, orthogonally positioned plates. The use of strut graft combined with a plate gives good mechanical stability and the combination with a lateral plate and an anterior strut graft are considered the gold standard for B1 fractures.

In the B2 group, 19 patients were treated with ORIF alone, in most cases, due to the patient's age and short life expectancy. The high a failure rate (32%) in this group strongly support the idea that it is not advisable to use ORIF as a "salvage procedure". Instead of two operations they should have been revised the first time.

Failures in the B3 group, in five cases, were due to loosening and in one case, recurrent dislocation. Impacted cancellous graft was used when revision was performed. Probably, in the fracture revision situation the achieved stability is not as good as in "ordinary" revision. The high rate of loosening indicates this problem.

Most patients with Vancouver C fracture were treated with ORIF alone with failure rate of 25%. The stress riser created between the plate and the distal part of the implant ("kissing point") is one important factor for failure. The importance that the plate bypasses the tip of the stem must be stressed.

Radiological outcome

At follow-up Mean 2.4 years), the fracture radiographs were available in 307 patients (96%) and postoperative radiographs in 295 patients (92%). The missing radiographs had either been destroyed or the patient had died postoperatively. The total number of patients with radiographic follow-up after the initial postoperative radiographic examination was 281 (88%). The remainders were either deceased (28) or not able to take part in the radiographic examination (12).

Not presented in any paper is the outcome (cut out by referee due to page limitation). Fifty percent (139/281) of the fractures were healed with no visible fracture line and callus formation, 13% (37/281) had no signs of healing and 37% (105/281) had either a visible

Table 7. Vancouver classification of the radiographs by operating surgeon and based on the lead author's interpretation of the medical records (primary grading) compared to the one done by the study radiologist (secondary grading).

Primary/secondary grading (n=321/n=307)	A=5	B1=67	B2=144	B3=41	C=50
A=8	A=4	B1=1	B2=2		
B1=90	A1=1	B1=31	B2=22	B3=8	C=23
B2=158		B1=29	B2=99	B3=18	C=6
B3=34		B1=2	B2=15	B3=15	C=1
C=31		B1=4	B2=6		C=20

fracture line with callus or poor callus formation. In 10 patients problems with plate or screw breakage were observed and 25 patients had a loose stem. These findings indicate that the failure rate is higher than failure presented as re-operation rate.

In the radiological interobserver study (Table 7) the majority of the disagreement was within the Vancouver B fractures. A major finding was that the surgeon's grading of the B1 fracture was not in agreement with the study radiologist in more than 34% (31) of the cases. The underestimation of loose stems, likely explains the higher failure rate observed in the B1 category. A reason for this could be the suboptimal quality of the acute fracture radiographs as indicated above. If there are problems in grading the radiographs the surgeon has to rely on some other parameter such as the fracture pattern or if there are signs of cement fracture or debonding due to fracture line. If stability still is a problem to decide, there is a reason to explore the joint to be sure (Figure 24).



Figure 24. How to categorize?

Risk factors for failure after treatment

The finding that type B1 periprosthetic fractures were associated with an increased risk of failure appears to be contradictory. It would be expected that a fracture around a stable stem should unite after adequate ORIF. We suspect that the reason for the poor outcome was that the surgeon, in many cases, misinterpreted the stability of the stem and classified a type B2 fracture as type B1, and subsequently undertook treatment with plate fixation without revision of the stem. The high percentage (59%) of revisions performed after a failure in the plate group lends support to our assertion. When the surgeon classified the fracture as type B2, loosening of the stem would have been obvious and revision of the stem performed. Thus the more 'difficult' type B2 fractures were treated by a more appropriate approach with a paradoxical decreased risk for failure. The reason for the higher rate of infection among patients with plate fixation compared with those with revision lacked clear explanation. It could be that all revised patients received the standard THA antibiotic prophylaxis in contrast to the patient treated with isolated plate fixation. Furthermore, plate fixation may have been performed by less experienced surgeons.

Patient outcome

Patient outcome after treatment for periprosthetic fracture seldom is reported in the literature. Furthermore, as in most fracture studies, the pre-fracture data (Lowenheim et al 1989; Beals and Tower 1996; Somers et al 1998) are not available. Ruiz et al (2000) evaluated how many of the patients that went back home and how many that were mobile unaided. Healing of the fracture is as considered "excellent" in many reports, but the definition of this parameter is frequently not presented in the papers (Barfod et al 1986; Ahuja and Chatterji 2002).

In Study 2, we compared mean EQ-5D index in the fracture group with the index in 1,400 age-matched primary THA patients (6 years after operation). We found that the mean index in the fracture group was significantly worse. It was a consistent finding in all Charnley categories. Compared with other studies (Incavo et al 1998; Agarwal et al 2005; O'Shea et al 2005), the Harris hip score was low in this study. Sixty-one percent (Study 1) reported moderate to heavy pain after operation and in Study 2, the mean value for pain (VAS) was 23 (0-100).

The measurement of patient outcome indicates that the health related quality of life was low and many patients had substantial pain problems. However, in Study 1, 76% were satisfied with the result of the operation. That the patients were satisfied despite the poor outcome recorded by EQ-5D and the HHS seems contradictory. It could be explained as one patient said "*I know it was a very difficult operation, so I am glad to be able to walk afterwards*".

Excess mortality due to periprosthetic femur fracture

The excess mortality due to periprosthetic femur fracture was estimated in patients with OA (Study 5). It is known that patients with osteoporosis have a high mortality when having a hip fracture (Kanis et al 2003). Patients with OA generally do not have osteoporosis, (Burger et al 1996; Arokoski et al 2002; Hochberg et al 2004) and there is no evidence for a higher risk of death in this population.

We found that patients with a periprosthetic femur fracture had an excess mortality due to the surgery. Mortality subsequently decreased over a period of six months, but for the age group 50-70, the risk of death was higher compared to the general population. In the age group 70 years and older, the mortality risk was the same as for the general population. Age was the most important factor in the excess mortality.

The typical periprosthetic fracture is to some extent possible to prevent. In the light of the increased mortality at surgery, prevention once again must be stressed. The observed higher mortality in the younger group is difficult to explain. The Norwegian Arthroplasty Register has reported the same including all diagnoses (Lie et al 2000). Maybe this age group needs extra attention since they obviously are at risk for death compared to the general population. The finding that older patients in the fracture group had the same mortality risk as the general population is important. This stresses the importance of good surgery in the older patients even if the treatment is technically demanding. It is important to do it right the first time.

Conclusions

Overall conclusion

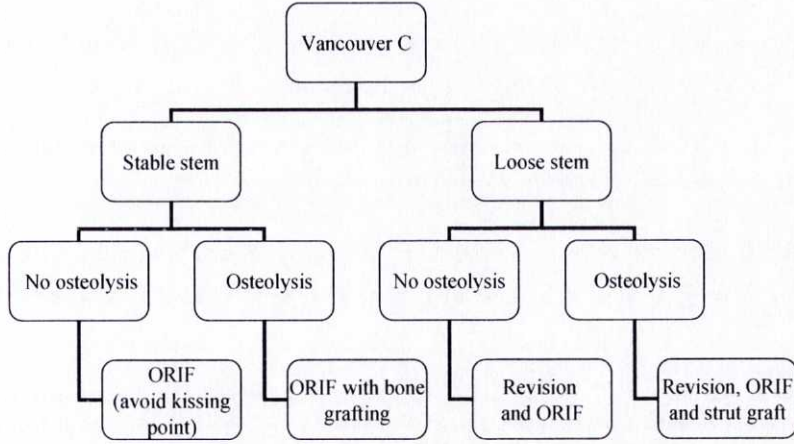
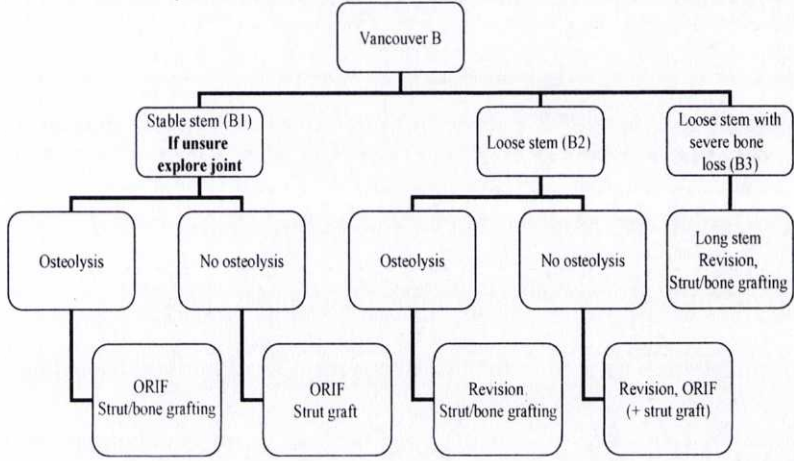
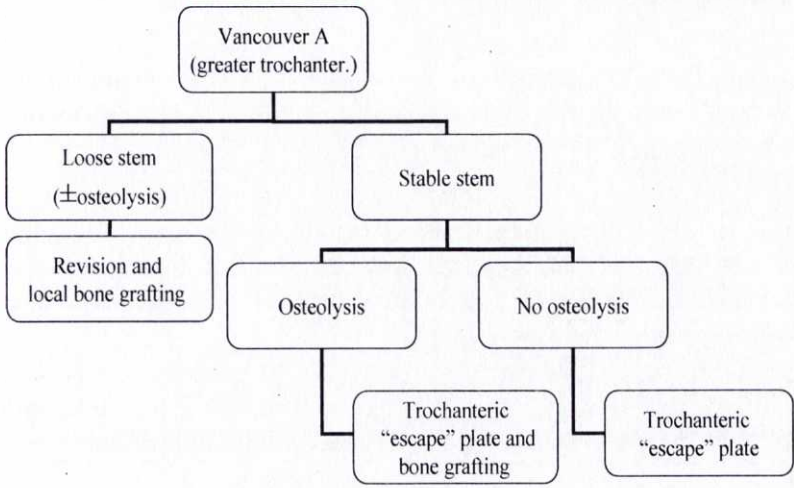
- The Swedish National Hip Arthroplasty Register is a unique instrument for studies of uncommon complications after THA surgery. The current study is to our knowledge the largest reported material (1,049) of late periprosthetic femur fractures.

Specific conclusions

- It is difficult, due to several confounding factors, to obtain the true incidence of periprosthetic femur fractures. The found annual incidence of periprosthetic femur fracture varied between 0.045% and 0.13%, and increased towards the end of the study period.
- Female gender and osteoarthritis were associated with a decreased risk while age and index diagnoses rheumatoid arthritis and hip fracture had an increased risk for sustaining a periprosthetic fracture. In the revised group the strongest predictor was the number of revisions performed before the fracture.
- The anatomically shaped Lubinus SP II prosthesis had a significantly decreased risk. The Charnley and the Exeter prostheses had significantly increased risk for periprosthetic fracture. A majority of the patients had a loose stem at the time for fracture. This finding stresses the importance of longitudinal clinical and radiographic follow-up of patients operated with a THA.
- Patients operated for a periprosthetic femur fracture had on average poor clinical outcome at a mean follow-up of 2.5 years both concerning health related quality of life and disease-specific assessment.
- We found high frequencies of major complications and reoperations. Approximately every fifth patient was in need of further surgery during the study period and 50% of them were reoperated within 12 months postoperatively. The 5-year survivorship with reoperation as endpoint was $74.8 \pm 5\%$.
- The strongest negative factor associated with failure, was the use of a single plate in cases with a stem considered as stable at fracture surgery. This paradoxical finding is probably due to an underestimation of stem loosening.
- There was an excess mortality at fracture event in patients with OA. The mortality rate decreased during 6 months and stabilized on a similar level as the general population in Sweden, except in patients younger than 70 years.
- The general poor results after surgical treatment of periprosthetic femur fractures indicate the need of further studies in this field.

Recommendations

- A very important issue is prevention of periprosthetic fractures. In 2002, a follow-up routine for all patients operated with a THA in Sweden was initiated by the Registry. reoperatively and at 1, 6 and 10 years postoperatively all patients complete a questionnaire and a radiographic examination is performed. This follow-up system aims to become a standardized and nationwide routine. Loosening and wear, with or without periprosthetic bone loss, is generally a progressive and clinically silent process, and therefore patients come for consultation only at a late stage. With early detection of asymptomatic changes revealed only by radiography and a subsequent surgical intervention at an earlier stage, may lead to a decrease of the incidence of late periprosthetic fractures. In the current study risk factors associated with both patient demographics and implant design have been identified. According to these findings a patient with an increased risk for sustaining a periprosthetic fracture could be followed more frequently.
- Implant related factors were a major finding and a collarless straight and short stem were associated to a higher risk compared an anatomically shaped, longer and collared stem. These findings might be of importance when choosing a cemented hip prosthesis for routine use.
- A reliable and valid classification system is important and the treatment should be guided by the classification of the fracture. The Vancouver system meets most of these criteria and is therefore considered the gold standard and now widely used. We found, however, in this study a low agreement between observers in the B category. An underestimation of stem loosening with suboptimal treatment and a high failure rate was one consequence and hence we recommend verifying the stem stability by joint exploration in Vancouver B. Another problem is that not all patients can be categorized by the Vancouver system. One example is a patient with a stable stem but with osteolysis at the stem tip and a fracture. We propose that loosening and osteolysis must be considered first. Secondary, according to fracture localisation, proper treatment can be discussed. We suggest, based on the above considerations, an expanded Vancouver classification system as well as a partly new treatment algorithm.



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