Arthroplasty for Femoral Neck Fracture

Results of a nationwide implementation

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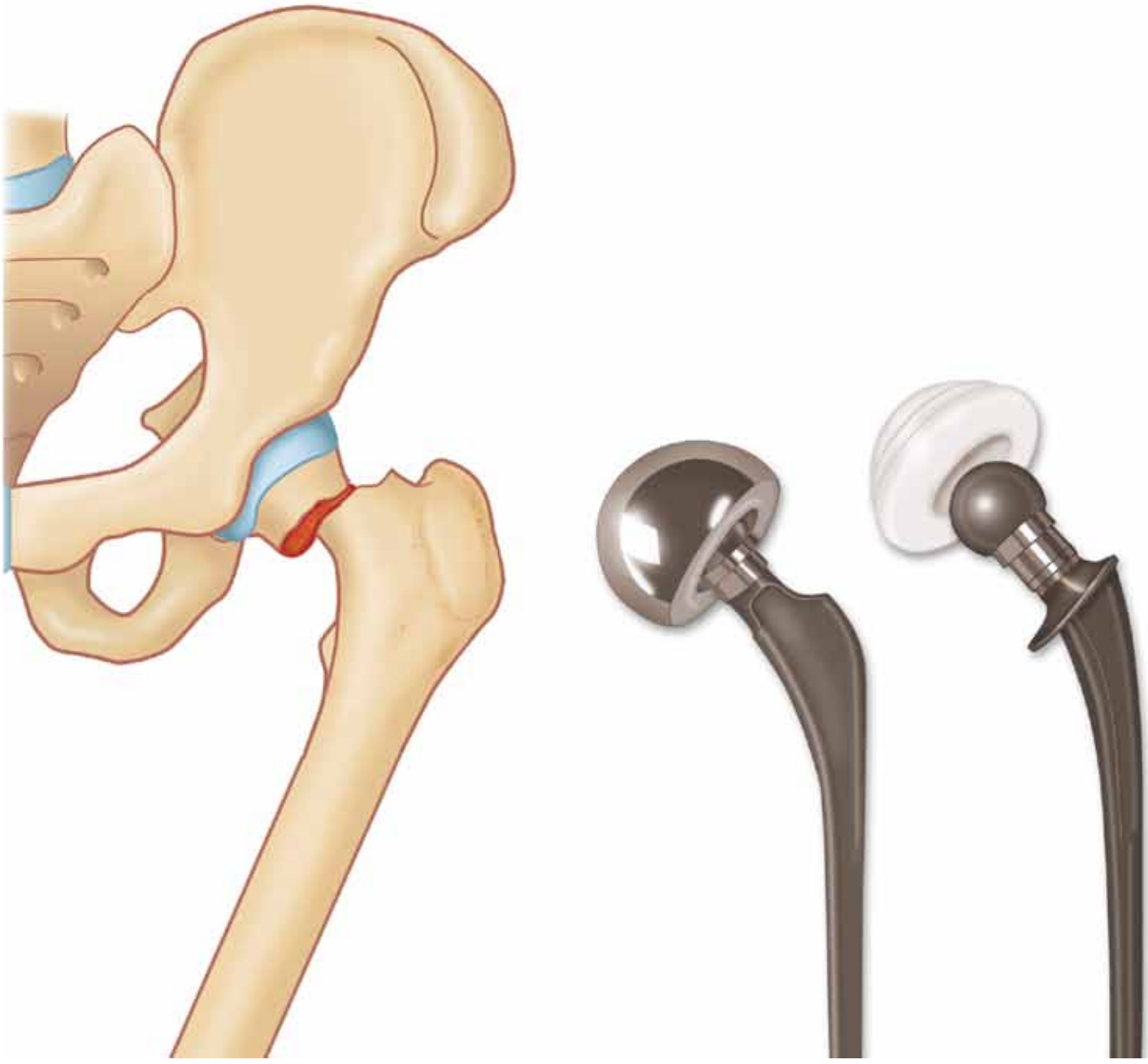

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av

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Abstract

Hip fractures are devastating for the individual and a substantial economic burden for society. The treatment for displaced femoral neck fracture is a choice between internal fixation, total hip arthroplasty and hemiarthroplasty. As a result of several randomized trials, the treatment has shifted in Sweden from mostly internal fixation towards arthroplasties. There have been concerns about long-term arthroplasty complications such as aseptic loosening and periprosthetic fracture. In addition to investigating this issue, the focus of this thesis was on identifying the optimal treatment methods for patients with this displaced femoral neck fractures, regarding choice of implant and surgical technique.

In a 10-year follow-up of a randomized multicenter trial on 450 mentally lucid and relatively healthy patients above 70 years with displaced femoral neck fractures, patients treated with internal fixation had continuously higher rates of major complications compared to those treated with arthroplasty (46 % compared to 9 % at 10 years). Patients with successful healed fractures reported more pain and reduction of mobility at four months than those successfully treated with arthroplasty, and they never attained a better result than the latter. Those results indicate that there are no excess long-term complications after arthroplasty and refute the assumption that retaining the patient's femoral head is beneficial.

The Swedish Hip Arthroplasty Register records total hip arthroplasties since 1979 and hemiarthroplasties since 2005. All hospitals performing arthroplasty surgery in Sweden are participating and completeness of recordings is near 100 %.

In a study based on data from the Swedish Hip Arthroplasty Register, patients with fracture-related *total hip arthroplasty* had a higher revision rate than those treated for other reasons (mainly osteoarthritis); 4.4 % compared to 2.9 % at 7 years. Revision rates were similar after acute fracture procedures and procedures performed secondary to failed internal fixation. Contrasting, *hemiarthroplasties* in the Swedish Hip Arthroplasty Register performed secondary to failed internal fixation were associated with a doubled risk of re-operation compared to those performed for acute fracture. Anterolateral surgical approach had a lower risk of total hip arthroplasty revision regardless of reason and hemiarthroplasty re-operation due to dislocation. Bipolar and uncemented hemiarthroplasties were risk factors for re-operation; the former due to dislocation, infection and periprosthetic fracture, the latter mainly due to periprosthetic fracture. Males had higher risk of total hip arthroplasty revision and hemiarthroplasty re-operation as well as higher risk of death within one year following the injury.

Nationwide, the proportion of hemiarthroplasty procedures for acute fractures increased from 2005 through 2009 at the expense of those secondary to failed internal fixation. Use of monoblock type implants decreased to below 1 %. Modular implants increased generally, while in 2009 bipolar implants decreased in favor of unipolar. Uncemented implants and posterior surgical approach decreased. Assumedly, those changes are results of reports from clinical trials and the Swedish Hip Arthroplasty Register.

In collaboration between the Swedish Hip Arthroplasty Register and the National Hip Fracture Register, all Swedish patients with displaced femoral neck fractures during 2009 received a mailed patient-reported outcomes questionnaire (79 % response rate). Patients above 70 years, with total hip arthroplasty reported less pain and were more satisfied than those treated with internal fixation or hemiarthroplasty at a median of 14 months after the fracture. Among patients below 70, those treated with total hip arthroplasty had less pain and were more satisfied than those with internal fixation.

The results presented in this thesis support the use of arthroplasty as primary treatment for displaced femoral neck fractures and indicate that use of total hip arthroplasties could be increased even further. The higher risk of re-operation with bipolar implants implies that unipolar hemiarthroplasty may be preferable for the oldest. Finally, the results suggests that anterolateral surgical approach and cemented implants are preferable in fracture-related arthroplasty surgery.

Key words

Hip fracture, femoral neck fracture, total hip arthroplasty, hemiarthroplasty, long-term results, demography, patient-reported outcome, health-related quality of life, pain, satisfaction

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Results of a nationwide implementation

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I **Long-term follow-up of replacement compared with internal fixation for displaced femoral neck fractures. Results at ten years in a randomised study of 450 patients.**

Leonardsson O, Sernbo I, Carlsson Å, Åkesson K, Rogmark C.

J Bone Joint Surg Br. 2010; 92(3): 406-12.

II **Outcome after primary and secondary replacement for subcapital fracture of the hip in 10 264 patients.**

Leonardsson O, Rogmark C, Kärrholm J, Åkesson K, Garellick G.

J Bone Joint Surg Br. 2009; 91(5): 595-600.

III **Changes in implant choice and surgical technique for hemiarthroplasty. 21,346 procedures from the Swedish Hip Arthroplasty Register 2005-2009.**

Leonardsson O, Garellick G, Kärrholm J, Åkesson K, Rogmark C.

Acta Orthop. 2012; 83(1):7-13.

IV **Higher risk of re-operation for bipolar and uncemented hemiarthroplasty. 23,509 procedures after femoral neck fractures from the Swedish Hip Arthroplasty Register 2005-2010.**

Leonardsson O, Kärrholm J, Åkesson K, Garellick G, Rogmark C.

Accepted for publication in Acta Orthop 2012.

V **Patient-reported Outcome after Displaced Femoral Neck Fracture.**

A National Survey of 4,467 Patients.

Leonardsson O, Rolfson O, Hommel A, Garellick G, Åkesson K, Rogmark C.

Manuscript submitted.

Abbreviations

ASA	American Society of Anesthesiologists
EQ-5D	The five-dimension self-assessment instrument from the EuroQol group
HA	Hemiarthroplasty
IF	Internal fixation
NHFR	Swedish National Hip Fracture Register – Rikshöft
the Register	Swedish Hip Arthroplasty Register
SHAR	Swedish Hip Arthroplasty Register
THA	Total hip arthroplasty (synonymous with THR)
THR	Total hip replacement (synonymous with THA)
VAS	Visual analogue scale

Definitions

Anterolateral (transgluteal) approach	Also known as “direct lateral approach”. Surgical approach to the hip joint where the ventral portions of the gluteus medius and minimus tendons are split, followed by anterior dislocation (Gammer and Hardinge).
Bipolar hemiarthroplasty	Hemiarthroplasty that articulates internally, between a small and a larger implant head, as well as articulating against the acetabulum.
Completeness	Proportion of registered procedures on an individual level compared to the total number of procedures.
Coverage	Proportion of participating clinics compared to the total number of clinics.
Hemiarthroplasty	Hip arthroplasty only replacing the femoral head while leaving the acetabulum intact.
Modular hemiarthroplasty	Hemiarthroplasty manufactured in separate pieces with the possibility of modification during assembly.
Monoblock	Type of prosthesis manufactured and delivered in one piece without the possibility of modification.
Posterior approach	Surgical approach to the hip joint where the gluteus maximus is split in the fiber direction, and the short extensor rotators are divided, followed by posterior dislocation (Moore).

Primary arthroplasty	Arthroplasty procedure performed as the first surgical intervention for a fracture.
Re-operation	Any further surgery to the hip.
Revision	A re-operation with exchange or removal of any part of the prosthesis.
Secondary arthroplasty	Arthroplasty procedure performed subsequent to any other fracture treatment.
Total hip arthroplasty	Hip arthroplasty replacing the femoral head as well as the acetabulum.
Unipolar hemiarthroplasty	Hemiarthroplasty that articulates only against the acetabulum.

Introduction

Hip fractures are devastating for the individual and a substantial economic burden for society. The exact number of hip fractures worldwide is impossible to determine, but the global incidence in the year 2000 has been estimated at 1.6 million and the projections for the future suggest further increasing numbers[58, 71]. The cost of a hip fracture varies between different parts of the world. The total cost in Sweden during the first year after the fracture, has been calculated at 130,000 SEK[16]. Thus, in addition to the suffering of the individual including morbidity and excess mortality, the economic strain on society due to hip fracture is immense.

In Sweden roughly 18,000 individuals yearly sustain hip fractures. Half of the fractures affect the femoral neck, and the rest are located in the trochanteric and subtrochanteric regions. The focus of this thesis is on *displaced femoral neck fractures,* affecting around 6,000 to 6,500 individuals every year in Sweden, and the main question is the optimal treatment for this type of fracture in different patient groups.

In the past, the predominant treatment in Scandinavia for *undisplaced* as well as *displaced* femoral neck fractures, has been different sorts of internal fixation (i.e. screws or nails) in order to achieve fracture healing. Around the millennium shift, failure rates of 35 to 50 percent were reported for internal fixation of *displaced* femoral neck fractures, in a number of randomized studies from Sweden[70, 100, 102, 118]. This lead to a relatively swift increase in the use of arthroplasty for this type of fracture. Since then the increase has been particularly pronounced for hemiarthroplasty[116].

Initially, there were concerns about the greater surgical trauma of arthroplasty procedures. So far, however, no randomized study has shown a clear difference between internal fixation and arthroplasty concerning mortality[9, 103]. The higher retail price of a hip prosthesis has been a matter of hesitation towards arthroplasty treatment. As a consequence of its better clinical results, the cost efficiency for arthroplasty is in fact equal to or better than that of internal fixation, with regard to the whole treatment process including home care and rehabilitation, outpatient visits, re-admissions and re-operations[66, 69, 101].

Remaining concerns about arthroplasty treatment have been those of long-term complications, such as aseptic loosening and periprosthetic fracture, as well as acetabular erosion in hemiarthroplasty. Long-term data from patients treated with arthroplasty as planned procedures, mainly for osteoarthritis, cannot be transferred to fracture patients, as hip fracture patients are generally more aged and frail than those treated for osteoarthritis. Prior to study I in this thesis, hip fracture studies has generally had too short follow-ups to address such long-term issues. A final argument for internal fixation has been the assumed benefit for the patient of preserving the femoral head after a fracture.

Patients suffering failure of internal fixation after a fracture are in most cases treated with hemiarthroplasty or total hip arthroplasty. However, being elderly and particularly frail, those patients are at risk of substantially deteriorating health while waiting for a salvage treatment[15, 86].

Beyond the rates of *complications* and *re-operations* for the different treatment alternatives, the *experience of the patient* after a femoral neck fracture is not entirely known. The aim of hip fracture treatment is to return the patients to their pre-fracture level of function and health-related quality of life. Because of the acute and unexpected nature of a fracture however, it is difficult to measure the pre-fracture level in a reliable way. Previous reports indicate that after an initial prominent decline a relatively stable level of health-related quality of life is established 4 to 12 months after the fracture (although lower than the pre-fracture level)[13, 61, 118, 119].

The Swedish Hip Arthroplasty Register records total hip arthroplasties since 1979, and has a very high completeness of procedures on an individual level. The majority of the total hip arthroplasty procedures are performed as planned surgery, mainly because of osteoarthritis, whereas approximately 10 percent are performed due to hip fracture. In 2005, a hemiarthroplasty registration was established as part of the Swedish Hip Arthroplasty Register, and the completeness of procedures was high from the start[55].

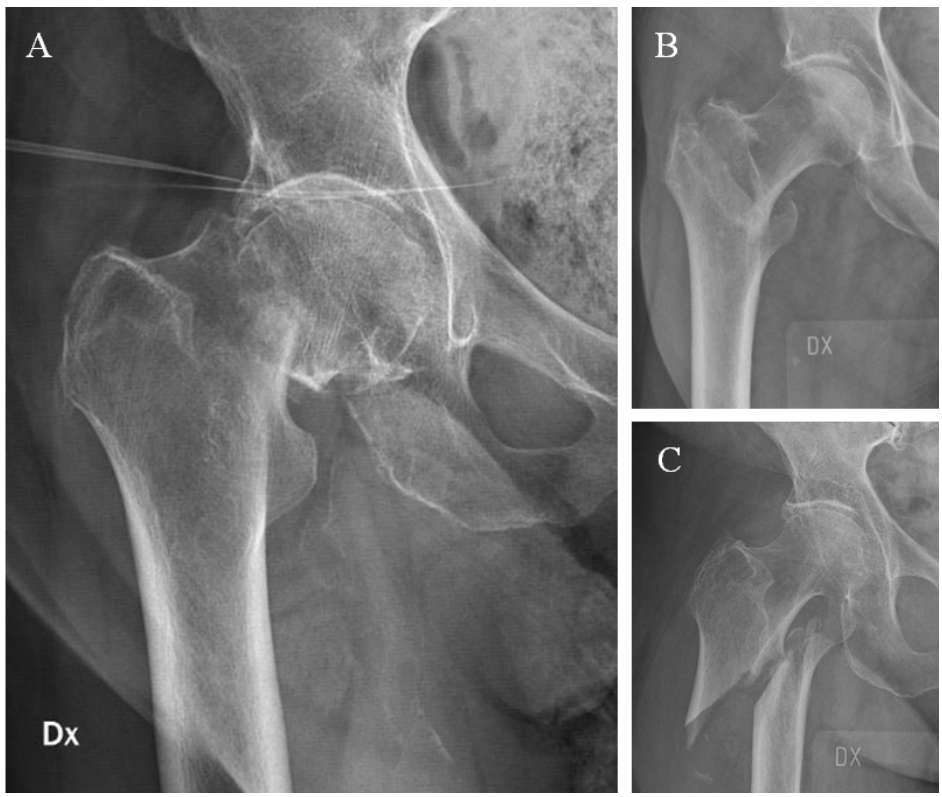
The overall aim of this thesis was to evaluate the treatment for displaced femoral neck fractures and to identify the optimal treatment methods for different patients. Beyond the choice of arthroplasty as primary treatment, the objective was to identify the optimal *type* of arthroplasty and surgical technique for the different patient groups, bearing in mind the concerns of long-term complications for arthroplasty, such as aseptic loosening, periprosthetic fracture and acetabular erosion.

Background

Definitions and classification

Roughly half of the approximately 18,000 hip fractures in Sweden each year are located to the femoral neck, and the remainder in the trochanteric and subtrochanteric regions (Figure 1 A-C). Important risk factors are osteoporosis and propensity to fall. The mechanism of injury is most commonly low-energy trauma. The typical patient is elderly, female and frail[27, 33, 114, 116].

Figure 1. Hip fracture types. A. Femoral neck fracture, B. Trochanteric hip fracture, C. Subtrochanteric hip fracture.



A fracture at the femoral neck risks disrupting the blood supply to the femoral head, thus obstructing fracture healing. This risk is highest for displaced fractures. The most commonly used system for classifying the degree of displacement is that of Garden from 1961[54], which is based on the anteroposterior radiographic view. Garden I and II (valgus impacted fracture and complete fracture without displacement) are considered undisplaced, whereas Garden III and IV (complete fracture with partial displacement and complete fracture with full displacement) are considered displaced, accounting for two thirds of the femoral neck fractures[116].

Considerations in the choice of treatment

In many ways the choice of treatment for a patient with a displaced femoral neck fracture is a compromise. The different treatment alternatives all have their pros and cons. As a result of the very high complication rate for internal fixation, the preferred treatment for elderly patients is total hip arthroplasty or hemiarthroplasty. The superior function of a total hip arthroplasty[5, 12, 74] is deemed particularly advantageous for the youngest and physically most active of the elderly patients, whereas the assumed lesser risk of dislocation[9, 89] of hemiarthroplasty is preferred for the most frail as well as cognitively impaired patients. The somewhat inferior hip function with a hemiarthroplasty is accepted in view of the most aged patients' lesser physical demands. In addition, a hemiarthroplasty procedure is shorter and physically less strenuous for the patient.

Although it is impossible to foresee the endurance of an individual prosthesis, it is obvious that the risk of re-operation after arthroplasty is higher if the patient has a longer remaining life. Also, the youngest patients are assumed to have the best ability to heal a fracture and if necessary withstand further surgery, and are therefore often offered internal fixation. In view of the limited surgical trauma internal fixation is sometimes chosen for very sick or moribund patients. Despite a number of trials, however, the concerns of increased mortality after arthroplasty in this patient group has not been clearly confirmed[9, 89, 103]. Neither has any evidence of the assumed advantage of preserving the patient's femoral head been presented.

The treatment protocols for displaced femoral neck fractures often depend to a high degree on the patient's age. However, additional factors including functional level (as discussed above), mental status, neurological disorders as well as alcohol and drug abuse - i.e. biological age - also need to be considered. Patients with cognitive impairment might not adhere to postoperative instructions and may therefore run a higher risk of prosthesis dislocation, especially with total hip arthroplasty[70]. Moreover, it is especially difficult for cognitively impaired patients

to be successfully rehabilitated to their pre-fracture level of function. Consequently, these patients may not be able to benefit from the advantages of total hip arthroplasty as opposed to hemiarthroplasty[105, 110]. Although not much evidence is available on the topic, neurological disorders as well as alcohol and drug abuse is often considered to increase the risk of arthroplasty complications in general and dislocation and infection in particular[2, 63].

Sex and mortality

Approximately two out of three individuals in Sweden sustaining femoral neck fractures are women[114]. Hip fracture can be viewed as a marker for poor health, and to reach the hip fracture threshold a certain amount of risk factors are required. Women sustaining hip fractures are generally older than men (84 compared to 81 years in Sweden)[116] and more affected by osteoporosis[96], whereas male hip fracture patients despite their lower age generally have a poorer health. This is reflected by a larger proportion of male hip fracture patients than female classified as American Society of Anesthesiologists (ASA) grade 4 (severe systemic disease that is a constant threat to life)[3] in the Swedish National Hip Fracture Register[116]. Also, alcohol and drug abuse is presumably more common in male hip fracture patients than female. Altogether, these are plausible reasons for the overall worse outcome for males after hip fracture both in respect of complications and mortality[30, 41, 65, 72, 109].

Mortality after a hip fracture is high regardless of treatment method. The risk of death during the first year after a hip fracture is at least doubled compared to that of age-matched non-hip fracture controls and the risk increase is most pronounced in men[1]. In a recent large case-control study for example, the median survival for men of 85 years or older with a hip fracture was less than three months[123]. However, it is important to acknowledge that despite the high mortality some patients survive for a substantial amount of time. In the same study 6 percent of all patients were still alive 22 years after their hip fracture. This particular patient group puts especially high demands on their implants.

Internal fixation

Internal fixation, most commonly by means of two or more nails or screws (Figure 2), is often a relatively short and atraumatic surgical procedure. The aim of internal fixation is to achieve fracture healing. Internal fixation is generally recommended as treatment for *undisplaced* fractures even though it leads to complication rates around 10 to 20 percent[11, 26]. For *displaced* femoral neck fractures this method is affected with healing complications in 35 to 50 percent of the patients and its place in the treatment for this fracture type in elderly patients has been strongly questioned during the last decades[9, 103]. The predominant healing complications are avascular necrosis and non-union (including early re-displacement) due to disturbed blood-supply to the femoral head and instability of the fixation[90, 102, 118]. In the event of failure of internal fixation, arthroplasty is often chosen as salvage procedure. However, during the period before a salvage procedure, in many of these aged and frail patients health-related quality of life and hip function deteriorate further[15, 86].

Figure 2. Two pins for internal fixation.

Total hip arthroplasty

A total hip arthroplasty (Figure 3) replaces the femoral head as well as the acetabulum by two separate prosthesis parts articulating against each other.

Figure 3. Total hip arthroplasty implant.

Hip function can be relatively well restored with a total hip arthroplasty[5, 12, 74, 118]. However, the dislocation rate of fracture-related total hip arthroplasties is generally reported higher than the rate of those performed as planned procedures for other reasons; mainly osteoarthritis[7, 9, 77, 89]. This is probably a result of a better range of motion for fracture patients than patients with more chronic hip problems and restricted mobility prior to surgery. Also, a cognitively impaired patient or a patient with alcohol or drug abuse, most probably would not be eligible for any *planned* arthroplasty surgery. In contrast, if presenting with femoral neck fractures, those patients as well as others, require prompt treatment. Considering their poor ability to follow postoperative instructions, this might also contribute to the higher dislocation risk after fracture.

Hemiarthroplasty

In a hemiarthroplasty procedure the femoral head is replaced whereas the acetabulum is left intact. There are three principally different types of hemiarthroplasties; monoblock type, modular unipolar and modular bipolar hemiarthroplasties.

Monoblock type hemiarthroplasties (Figure 4) are manufactured and delivered in one piece without the possibility to modify the neck length or the off-set of the prostheses.

Figure 4. Monoblock type hemiarthroplasty implant.

Historically, this type of implant has been popular. However, at least the uncemented Austin-Moore prosthesis has a well-documented poor outcome both regarding re-operation and patient-reported pain[14, 40, 57, 68, 76, 99].

Modular hemiarthroplasties are manufactured in pieces and assembled in surgery. In order to achieve optimal fit in relation to the patient's individual constitution, different implant head lengths can be chosen.

The head of a *unipolar* modular hemiarthroplasty articulates directly against the acetabular cartilage, whereas a *bipolar* has an additional internal articulation between a small implant head and a larger one (Figure 5 A and B). The larger implant head in turn articulates against the acetabulum.

Figure 5. Hemiarthroplasty implants. A. Unipolar, B. Bipolar.

The initial modular prostheses were unipolar, whereas bipolar implants were developed in the 1970s in order to address the issue of acetabular erosion seen with unipolar implants. Depending on patient selection, the reported rates of radiologic acetabular erosion in unipolar implants vary from 2 to 66 percent[5, 18, 34, 112]. In contrast to the situation in a unipolar prosthesis where all hip movement takes place between the prosthesis head and the acetabulum, the lion's share of movement in a bipolar prosthesis should ideally occur between the small and the larger implant head, thus decreasing the friction against the acetabular cartilage. The degree of movement that actually occurs between the small and the larger head once the prosthesis has been implanted in a patient, is however not

completely clear. A few radiographic studies on this topic have shown various results; from most of the movement occurring between the small and the larger head to all movement occurring between the prosthesis and the acetabulum, i.e. the prosthesis actually functioning as a unipolar implant[22, 23, 95].

Bipolar prostheses are generally assumed to supply a better hip function than unipolar, and in a randomized study from 1998 Cornell et al. reported better range of motion and higher walking speed in patients treated with bipolar implants[28]. With this exception though, no clear advantage for bipolar implants compared to unipolar modular implants regarding hip function, re-operations or morbidity had been shown when this thesis was planned[18, 36, 98].

Special considerations for arthroplasty

Surgical approach

The vast majority of arthroplasties are performed by one of three surgical approaches[55], i.e. anterolateral according to Hardinge[59] or Gammer[53] and posterior according to Moore[82], respectively. The surgical approach according to Moore is performed through a posterior incision with the patient in a lateral position. After the gluteus maximus muscle is divided in the fiber direction, the short rotator muscles are divided at their insertion, and the hip joint is dislocated posteriorly. The Hardinge and the Gammer approaches are similar to each other in terms of technique, but the patient's position is supine in the Hardinge approach and lateral in the Gammer approach. The incision is anterolateral and the ventral portions of the gluteus medius and minimus are divided at the tendo-muscular transition, after which the hip joint is dislocated anteriorly.

Dislocation is a troublesome complication after hip arthroplasty, and a number of studies have shown higher dislocation risks for hemiarthroplasty and total hip arthroplasty with posterior approach[8, 21, 75, 121, 124]. At the time this thesis was planned, however, there were no high-quality studies on dislocation risks with different surgical approaches in *fracture-related* total hip arthroplasties.

Fixation of the prosthesis

A hip arthroplasty can be implanted with or without bone cement (i.e. polymethyl methacrylate or PMMA). One incentive to use uncemented implants is the shorter surgical time, since the waiting time during cement polymerization is avoided. Still, the greater surgical challenge of inserting an uncemented implant must also be taken into account, since hip fracture surgery is a common emergency procedure often performed by less experienced surgeons on duty[46]. The previously available high quality randomized trials on cemented versus uncemented arthroplasties indicate less pain and better hip function with cemented hemiarthroplasties[40, 87, 111]. However, the uncemented alternative in all those studies was Austin-Moore prostheses, an implant less and less in clinical use, and hence the relevance of these studies is nowadays diminished. Until recently, no randomized trial on cemented versus uncemented *contemporary* implants was available, but results from the Australian National Joint Replacement Registry indicate a higher risk of revision with uncemented hemiarthroplasty stems[57].

On the other hand, when using a cemented implant the risk of intraoperative fat embolization must be considered, and for fracture patients moderate cement pressurization and thorough lavage of the femoral canal can be advocated[17, 91, 97].

International treatment variations

In the search for the optimal treatment for displaced femoral neck fractures in particular, different communities have chosen different paths. In Sweden and Norway, the tradition has previously been to use mainly internal fixation, whereas in Finland hemiarthroplasty has been the method of preference[52, 67, 116]. A telephone survey in the UK in year 2000 and a retrospective cohort study in Alberta, Canada, regarding the years 1993 through 1999 both revealed a relative inclination of the surgeons to use uni- or bipolar hemiarthroplasty for patients with femoral neck fractures, although local variations were common[31, 32].

This pronounced variation in implant preference in particular, and in health care organization in general, might introduce performance bias and difficulties to interpret the results when studies from different countries are compared.

Swedish Hip Arthroplasty Register

After the introduction of a new surgical technique, such as a new implant or fixation method, continuous evaluation and quality control can be achieved in a large register study.

The principal aim of the Swedish Hip Arthroplasty Register is to analyze the whole process of hip arthroplasty surgery and to identify factors predicting the outcome[55]. By means of prompt feedback the individual hospitals can compare their own treatment results with the national average and evaluate whether or not an in-depth analysis is needed. Thus a national register is an important tool in the constant striving to improve quality of treatment and care[56, 64].

Fracture patients in the Register

Total hip arthroplasties are recorded in the Swedish Hip Arthroplasty Register since the start in 1979. Although the Register contains arthroplasty procedures regardless of diagnosis, historically the main focus has been on the large group of patients with planned procedures performed most commonly for osteoarthritis or rheumatoid arthritis. The fracture patients constitute approximately 10 percent of the entire total hip arthroplasty registration, and have not been assessed separately prior to study II in this thesis. With the continuous development of the Register, this patient group has become increasingly acknowledged and in 2005 an additional hemiarthroplasty registration was established, thereby gathering all patients with fracture-related arthroplasties in the Register.

Quality of data

The quality of a register analysis is largely dependent on the quality of the data contained in the register data base. To ascertain a high quality in the Register data base, all participating clinics are requested to perform a yearly control comparison of the data in the Register with the clinics own patient records. Also, the Register has an online warning system for incorrect entries, such as erroneous personal identity number, operated side and implants. In addition, the medical records of all patients undergoing re-operation are examined by the Register coordinators. Despite these efforts some arthroplasty patients might not be recorded in the Register. Naturally, efforts must be put into minimizing this selection bias.

The number of departments participating in the registration in comparison to the number actually performing arthroplasty surgery (*coverage*) is an estimate of the proportion of all performed procedures that could potentially be recorded in the

Register. *Completeness* of procedures is the proportion of individual procedures reported to the Register as compared to all procedures actually performed in the country. Coverage and completeness are regularly calculated in comparison to the Swedish National Patient Register and are published in the annual reports. Coverage has long been 100 percent in the Register. Completeness in the total hip arthroplasty registration is also very high (around 97 to 98 percent). Having established routines for reporting to the Register, the clinics' reporting of hemiarthroplasty procedures was high already from the start (89 percent completeness in 2005 increasing to 96 percent in 2006)[55].

Feedback

In order to improve practice and to stimulate the participating clinics to perform detailed local activity analyses, a wide range of outcome variables from the Register are reported openly at individual hospital level. In addition to publishing annual reports, the Register holds annual seminars in association with the Swedish Orthopedic Association as well as in its own management, to inform the orthopedic community of findings and results. Finally, in-depth analyses are presented as traditional scientific papers.

National registrations globally

Globally there are approximately 20 national registers dedicated to *total hip arthroplasties*, and the number is gradually increasing. Contrariwise, in addition to Sweden official national registrations of *hemiarthroplasties* with implant data on an individual level and an acceptable completeness of procedures can be found only in Norway, Australia and Slovakia[52, 57, 85].

Methods of measuring outcome

The traditional way of measuring outcome, in register studies as well as other study types, is analyzing re-operation rates or implant survival. However, re-operation rate is a blunt measuring instrument, since a number of reasons could lead to a non-surgical treatment in a patient with a suboptimal result. The patient may be medically unfit, or may decline further surgery. Also, the indication for re-operation may be deemed less compulsory in elderly patients, or the patient may adapt to a lower level of hip function. Thus, in order to embrace all aspects of the

treatment result the patients' subjective experience also must be taken into account. This is done by means of different patient-reported outcome measures where the patients are asked to estimate the result from their own perspective, in respect of different dimensions (e.g. pain, satisfaction, hip function, social function). Patient-reported outcomes are of paramount importance for the continuous effort to develop treatment and patient care. In a national follow-up program within the Swedish Hip Arthroplasty Register, health-related quality of life, as measured by the EQ-5D instrument (see page 42), was introduced in 2002 for total hip arthroplasty patients before and after the surgical procedure. After an arthroplasty procedure for *osteoarthritis*, an increase in health-related quality of life can be seen[55, 104], whereas a decrease is seen after a *fracture* procedure compared to the pre-fracture situation[12, 13].

The acute and unexpected nature of a fracture however, implicates certain problems in collecting patient-reported outcomes in this patient group. Particularly, health-related quality of life after a fracture is largely dependent of the patient's baseline health (i.e. before the fracture). This baseline information is difficult to obtain, especially in an aged patient group. In one randomized study the patients were asked during their initial hospital stay to estimate their pre-fracture level of health-related quality of life by recall. The estimations compared well with age-matched results from population studies[117]. This approach is, however, resource consuming and as a continuously used method it would place high demands on the individual hospitals around the country.

Study methodology

This thesis includes one randomized controlled trial (study I), and four prospective observational studies (study II, III, IV and V). The study types each have different theoretical and methodological features.

In a randomized controlled trial (RCT) the participants are randomly allocated to an intervention group or a control group. The idea is to achieve unbiased distribution of all confounding factors influencing the study outcome. In addition, it is possible to blind the participants, and sometimes also the researcher to the allocations. A randomized controlled trial investigates the effect of a specific treatment under controlled circumstances (*efficacy*) and results from a well-designed RCT are ranked as the highest level of evidence; level I. Disadvantages of RCTs include the fact that they are time-consuming and costly[47]. This makes trials on a larger scale impractical. Hence, RCTs are not suitable for investigations of uncommon complications, requiring high statistical power. There is also the

issue of volunteer bias, which could lead to a selection of the most interested patients.

Results from register studies are generally considered as evidence level II in respect of evidence based medicine[25]. In a register study patient data are extracted without the researcher intervening in any way. From a methodological point of view a register study is a prospective observational study, in theory hypothesis generating rather than hypothesis testing. By experience, however, results from large register studies have shown considerable reliability, provided the studies are performed in a stringent manner and all limiting factors taken into account[6, 56, 108]. The large number of patients in a nationwide register is a great strength that enables studies of unusual complications demanding high statistical power. In contrast to RCTs, register studies investigate the *effectiveness* of an intervention in respect of the actual conditions for the patient group in question. Being a very common emergency procedure, hip fracture surgery is often performed routinely by surgeons with various degrees of experience. Thus, in a nationwide register study, performance bias can be avoided and the results can be generalized for the whole country. On the other hand, in contrast to RCTs, outcomes can only be adjusted for factors which are recorded in the database. It is impossible to control all background factors leading the surgeon to a particular treatment choice, thus allowing for possible selection bias.

In summary, the two study methods complement each other since a randomized trial measures the *efficacy* of an intervention, whereas a register study measures its *effectiveness* in a real-life setting.

Aims

Based on the state of knowledge at the time for planning this thesis, the overall aim was to identify the optimal treatment for patients with displaced femoral neck fractures. Specifically, the objectives were

- To compare treatment of femoral neck fractures with arthroplasty and internal fixation, up to 10 years after the injury with regard to major complications and patient-reported outcomes.
- To compare re-operation rates after total hip arthroplasty because of fracture to those performed for other reasons.
- To compare re-operation rates among patients treated with total hip arthroplasty primarily after hip fracture and those with total hip arthroplasty as salvage treatment after failed internal fixation.
- To describe the hemiarthroplasty population in Sweden and the changes in implant choice and surgical technique during the first 5 years of the hemiarthroplasty registration in the Swedish Hip Arthroplasty Register.
- To identify risk factors for re-operation and to evaluate mortality in patients with modular hemiarthroplasties.
- To investigate whether a patient-reported outcome questionnaire is practically feasible as follow-up method after a femoral neck fracture in the setting of a nationwide register.
- To evaluate patient-reported outcomes after internal fixation, hemiarthroplasty and total hip arthroplasty to test if the current treatment in Sweden leads to satisfying results.

Patients

A summary of the number of procedures and the characteristics of the studies is displayed in table 1.

Study I

Four hundred and fifty patients were initially included from 1995 through 1997 in a multi-center study with 12 participating hospitals in the south of Sweden. Inclusion criteria were a displaced femoral neck fracture, age 70 years or older and mental lucidity. Patients with rheumatoid arthritis were not included. A total of 41 patients were subsequently excluded for various reasons, resulting in 324 women and 85 men. The patients were randomized to internal fixation (n=217) or arthroplasty (n=192). In the arthroplasty group the patients received total hip arthroplasty or hemiarthroplasty according to their mental and physical status. This resulted in 103 patients with total hip arthroplasty and 89 with hemiarthroplasty. The mean age was 81.5 and 81.6 years in the internal fixation group and the arthroplasty group (range 70-95 in both groups). In addition to the previously reported follow-up occasions up to two years[102], the patients were followed-up at 5 and 10 years, at which time 313 (77 percent) of the patients were deceased.

Studies II, III and IV

The patients in studies II, III and IV were retrieved from the Swedish Hip Arthroplasty Register.

In **study II** 10,264 total hip arthroplasty procedures performed 1999 to 2005 after femoral neck fractures were assessed. Of the procedures 7,716 (75 percent) were performed on women. In total 4,577 procedures were performed due to acute femoral neck fractures and 5,687 due to failed internal fixation. The mean age was 75 years in both groups (SD 8.4 and 10.7). A control group of 76,520 total hip arthroplasties performed as planned procedures for other reasons (mainly

osteoarthritis) during the same study period, were also introduced in the study (mean age 68 years, SD 10.9).

In **study III** all 21,346 hemiarthroplasty procedures during 2005 through 2009 reported to the Swedish Hip Arthroplasty Register were assessed. Procedures on women accounted for 72 percent (n=15,303). The median age for women was 85 years (range 42 to 104) and for men 84 years (10 to 102).

For **study IV** a total of 23,509 hemiarthroplasty procedures performed from 2005 through 2010 were selected. The procedures were performed either for acute femoral neck fracture or secondary to failed internal fixation, and only procedures with modular implants were included. Additionally, all procedures were performed through standard anterolateral or posterior surgical approaches. Women accounted for 71 percent (n=16,757) of the procedures. The median age in women was 85 years (42-104) and in men 84 years (19-105).

In papers II and III the number of procedures is in some places denominated as the number of patients. However, a few individuals were analyzed with two consecutive surgical procedures on opposite sides (in study II 1.7 percent and in study III 3.5 percent of the individuals). The actual number of individuals is consequently somewhat smaller than the number of patients indicated. The implications of this are minor as the result of each hip procedure can be viewed as an individual outcome.

Study V

All patients recorded in the *Swedish Hip Arthroplasty Register* with total hip arthroplasties or hemiarthroplasties during 2009 because of acute femoral neck fractures were selected. In addition, all patients recorded in the Swedish *National Hip Fracture Register* with internal fixation, total hip arthroplasty or hemiarthroplasty because of *displaced* acute femoral neck fractures were retrieved, resulting in a total of 6,022 patients. After exclusion of 46 patients with unclear surgical data and 74 with contralateral hip fractures during the same year as well as 1,435 deceased patients, 4,467 patients remained for the survey. The median age was 83 years (range 18-103) and 72 percent (n=2,530) were women.

Table 1. Number of procedures and characteristics of the different studies.

	No. of procedures	Year of surgery	Study characteristics
Study I	409	1995 through 1997	Multicenter RCT[a]. IF[b], THA[c] and HA[d]. Mobile and mentally lucid patients ≥70 years. 10 years follow-up.
Study II	10,264	1999 through 2005	Prospective observational study from the SHAR[e]. Primary vs secondary fracture related THA.
Study III	21,346	2005 through 2009	Prospective observational study from the SHAR. Changes over time in HA treatment.
Study IV	23,509	2005 through 2010	Prospective observational study from the SHAR. Risk factors for re-operation after HA treatment.
Study V	4,467	2009	Prospective observational study from the SHAR and the NHFR[f]. Patient-reported outcome after IF, HA and THA.

[a]Randomized controlled trial, [b]Internal fixation, [c]Total hip arthroplasty, [d]Hemiarthroplasty, [e]Swedish Hip Arthroplasty Register, [f]National Hip Fracture Register

Ethics

All studies in this thesis were performed in accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects.

Studies I and V were specifically approved by the Regional Ethical Review Board in Lund. All patients gave informed consent, and were free to renounce their participation at any point.

In studies II, III and IV patient data was extracted from the Swedish Hip Arthroplasty Register database without any direct contact between the researcher and the subjects. The Register has a general approval from the Local Ethical Review Board in Gothenburg for continuously collecting prospective observational data on hip arthroplasties. The collection of data is regulated by the Patient Data Act[92] and Personal Data Act[93]. All data from the Register is presented in aggregated form without the possibility to identify any individual participant. According to the Patient Data Act the patients must be informed before registration, and this is usually done in writing preoperatively. Importantly, all patients are free to withdraw their participation at any time

Methods

Randomization

The randomization of patients in study I was performed in blocks of 10 and allocation was determined by means of sealed numbered opaque envelopes.

Outcomes

Failure, re-operation and revision

In study I the primary outcome was treatment failure. Failure of internal fixation was defined as non-union including early re-displacement, avascular necrosis or deep infection, whereas neither local irritation at the pin ends nor extraction of the pins or screws constituted failure. Arthroplasty failure was defined as two or more prosthesis dislocations, periprosthetic fracture, aseptic loosening or deep infection.

In studies II and IV the end-points were revision (a re-operation with exchange or removal of any part of the prosthesis) and re-operation (any further surgery to the hip) as reported to the Swedish Hip Arthroplasty Register.

Potential risk factors for failure, revision and re-operation were also evaluated in multivariate regression analyses. In study I the analysis was performed with covariates sex, age, time to surgery, surgical approach, pre-operative function, type of trauma, osteoporosis and smoking. In study II and IV the covariates were sex, age, surgical approach, implant type and diagnosis (primary or secondary procedure). In study IV a subgroup analysis was performed including covariates ASA grade[3] and cognitive impairment in addition to the above mentioned ones.

Patient-reported outcome measures

Patient-reported outcomes were investigated in studies I and V.

In study I, a composite patient-reported outcomes questionnaire, constructed by the study designers (appendix 1), was used. The 12 item questionnaire, pertaining to the patients' social and medical as well as functional levels (preoccupation with the injury, type of accommodation, returning to pre-fracture accommodation, need for walking aids, ability to walk in stairs, need for professional or other personal assistance, hip pain when walking, hip pain at rest, returning to pre-fracture walking ability, additional medical visits due to the affected hip, additional surgery of the affected hip), was used at both the five-year and the ten-year follow-up. At five years the questionnaire was mailed to the patients, whereas at ten years a majority of the remaining patients attended a clinical visit where the questionnaire was filled out.

The patient-reported outcomes in study V were measured with a composite nine-item questionnaire similar to the one used in the regular follow-up in the Register, including Charnley's functional categories, health-related quality of life, pain and satisfaction with the surgical result (appendix 2).

Charnley's functional categories are used to classify the patients according to the influence of the contralateral hip and other medical conditions on their functional level. Category A signifies a patient with only one hip involved and no other medical condition interfering with walking whereas B signifies a patient with both hips involved but no other medical condition interfering with walking. Category C denotes a patient with some other medical condition impairing walking capacity.

Health-related quality of life was measured by EQ-5D[45]; a generic patient-reported instrument from the EuroQol group. The instrument pertains to health in five dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels of severity, resulting in a total of 243 possible health states, each with a unique EQ-5D index. To adjust for the subtle differences in the various translations of the EQ-5D form and for cultural differences in response pattern, a number of different tariffs for computing the EQ-5D index have been developed. Lacking a specific Swedish tariff, the UK tariff based on time trade-off valuation is used[38]. The minimum value is -0.594 and the maximum is 1.0. In order to compute an EQ-5D index all dimensions must be filled out. If two severity levels in the same dimension were marked, the least severe response was chosen. If all three severity levels in the same dimension were marked, the whole EQ-5D form was discharged.

Pain was measured by a patient-reported horizontal visual analogue scale (pain-VAS) ranging from 0 (no pain) to 100 (unbearable pain) which refers to the average level of pain from the fracture affected hip during the last month.

The patients' satisfaction with the surgical result was measured by a similar visual analogue scale (satisfaction-VAS) also ranging from 0 (very satisfied) to 100 (dissatisfied). The scale is continuous, but also has denotations resembling those of a Likert scale. Self-reported values of 41 or more represent "uncertain to dissatisfied", whereas values of 40 or less denote "satisfied".

Mortality

Mortality was evaluated in respect of the different treatment groups in study I and II. In study IV, a multivariate regression analysis of one-year mortality was performed with covariates sex, age, implant fixation (cemented or uncemented), ASA grade and cognitive impairment.

Statistics

Descriptive data are presented as means with standard deviations or medians with ranges. In study V medians with interquartile ranges are added to describe the distribution of absolute results. In study IV the patients were stratified into three age groups (less than 75 years, 75 to 85 years and more than 85 years at the time of surgery) and in study V into two (below and above 70 years). In addition, subgroup analyses were performed in study V on patients aged 70 to 80 years and above 80 years. Chi2-test was used to test differences in proportions between groups.

Survival analyses

In studies I, II, and IV implant survival was analyzed according to Kaplan-Meier; in studies II and IV supplemented with 95 percent confidence intervals. In studies I and IV log rank-test was used.

Multivariate analyses

The risk of revision and re-operation (hazard ratio) was calculated with Cox regression analyses in studies I, II and IV. In study II each covariate was compared to the rest of the fracture group.

In study IV an additional Cox regression analysis on one-year mortality was performed disregarding if the patient had been re-operated or not.

The differences between the treatment groups in study V as regards mean EQ-5D index, pain and satisfaction, were adjusted for sex and age in an analysis of covariance (ANCOVA).

Correlation

In study V, the correlation between time from surgery to response and the patient-reported outcomes was tested by Pearson's correlation test.

Level of significance

The level of significance was generally set at $p \leq 0.05$. However, with respect to the issue of multiple comparisons in study I the level was set at $p < 0.01$ regarding mortality and patient-reported outcomes. Similarly, in study V a p-value of 0.01 or less was considered statistically significant.

Summary of papers

Paper I

Long-term follow-up of replacement compared with internal fixation for displaced femoral neck fractures.

Is arthroplasty as treatment for displaced femoral neck fracture superior to internal fixation in the long term?

This paper presents a ten-year follow-up of a randomized trial comparing *internal fixation* and *arthroplasty* for displaced femoral neck fractures[102]. Twelve hospitals in the south of Sweden participated by including patients above 70 years operated from 1995 through 1997. Patients with cognitive impairment or rheumatoid arthritis as well as those who were bedridden or institution dwelling were excluded. The patients were randomized to internal fixation or arthroplasty. The arthroplasty patients received total hip arthroplasty or hemiarthroplasty according to the Sernbo score; an assessment of the patient pertaining to age, home situation, walking ability and mental status (Table 2). A total of 409 patients were available for the analyses.

Results

Mortality

Mortality was similar in both groups at all follow-up occasions; 49 percent (n=202) after five years and 75 percent (n=308) after ten.

Failure

At ten years a total of 99 (46 percent) cases of failed *internal fixation* were identified, compared to 17 (9 percent) failed *arthroplasties* ($p<0.001$). In total, 91 of the patients with failed internal fixation received a salvage arthroplasty, and the

most common reasons were non-union and avascular necrosis. Five of those subsequently underwent revision surgery. In the initial arthroplasty group, eight patients had revision surgery.

Four of the failures of internal fixation occurred late (between two and ten years after the injury). Three of them were due to avascular necrosis, whereas one had unspecific pain severe enough to merit an arthroplasty procedure.

In the arthroplasty group five of the failures occurred late, all in total hip arthroplasties; two patients had aseptic loosening, one had aseptic loosening and a simultaneous periprosthetic fracture and two had recurrent dislocations.

Table 2. The Sernbo score. A sum of 15 points or more indicates that the patient should be treated with total hip arthroplasty, less than 15 hemiarthroplasty.

		points
Age		
	70 to 80 years	5
	Above 80 years	2
Habitat		
	Own home	5
	Sheltered home	2
Walking aids		
	One cane or none	5
	Canes, walking frame	2
Mental status		
	Alert	5
	Slight confusion	2

(Leonardsson et al. J Bone Joint Surg Br. 2010; 92(3): 406-12. Adapted with permission)

Dislocation

A total of ten patients (5 percent in total) in the arthroplasty group had recurrent dislocations. In addition to this, seven patients had single event dislocations amounting to a total dislocation rate of 9 percent.

Patient-reported outcomes

There were no statistical differences between the treatment groups regarding patient-reported pain or function at neither the five- nor the ten-year follow-up occasions.

Successfully healed fractures and successful arthroplasties

In a separate analysis only including patients with *successfully healed fractures* and patients with *successful arthroplasties*, a larger proportion of internal fixation patients reported pain when walking ($p=0.001$) and reduction of mobility due to hip pain ($p<0.001$) at 4 months. At the later follow-up occasions no statistically significant differences between the groups were found.

Risk factors for failure

A Cox regression analysis including the covariates sex, age, time to surgery, surgical approach, smoking, osteoporosis, type of trauma, pre-operative function identified no risk factor for failure.

Paper II

Outcome after primary and secondary replacement for subcapital fracture of the hip in 10,264 patients.

Is the risk of total hip arthroplasty revision higher in patients treated for failed internal fixation than in those treated for acute fracture?

In this study from the Swedish Hip Arthroplasty Register 10,264 patients treated with total hip arthroplasty from 1999 through 2005 due to *femoral neck fracture* were compared to 76,520 patients treated with total hip arthroplasty for *other reasons* (mainly osteoarthritis; control group) with regard to revision surgery. Within the fracture group the patients treated for acute fracture (primary total hip arthroplasty) were compared to the patients treated after failed internal fixation (secondary total hip arthroplasty). Regression analyses were also performed within the fracture group to identify risk factors for revision.

Results

Patients

The proportion of patients in the fracture group with acute femoral neck fracture increased from 24 percent in 1999 to 57 percent in 2005.

Mortality

At the end of the study period 1,302 patients (28 percent) in the primary total hip arthroplasty group and 1,940 (34 percent) in the secondary had died (no significant difference).

Revision in the fracture group and the control group

A Kaplan-Meier survival analysis showed a significantly larger proportion of revised total hip arthroplasties in the *fracture group* (4.4 percent, 95 percent confidence interval, 95% CI 3.8-5.1) at seven years compared to the *control group* (2.9 percent, 2.7-3.1).

Revision due to dislocation was more common in the fracture group (1.9 percent; 95% CI 1.5-2.2) than in the control group (0.7 percent; 0.6-0.8). Revision because of periprosthetic fracture was also more frequent in the fracture group (0.8 percent; 0.5-1.1 and 0.2 percent; 0.1-0.2). Revision rates due to infection and aseptic loosening did not differ between the groups.

Revision in the primary and secondary fracture group

The incidence of total hip arthroplasty revision did not differ between the group treated for *acute fracture* and the group treated *secondary to failed internal fixation*. Subgroup analyses of sex and the different reasons for revision did not change this result.

Risk factors for revision of total hip arthroplasty after fracture

In a Cox regression analysis a number of factors proved to influence the risk of revision due to any reason and due to different reasons respectively. Compared to *females*, *males* had a higher risk of revision regardless of reason (relative risk, RR 2.2; 95% CI 1.7-2.7) as well as because of dislocation (1.9; 1.4-2.6), periprosthetic fracture (2.7; 1.4-5.1), aseptic loosening (2.4; 1.3-4.3) and infection (2.3; 1.3-3.9). The two most common total hip arthroplasty stems, namely *Lubinus SP II* and *Exeter*, had lower risk of revision due to any reason (RR 0.48; 0.37-0.63 and 0.60; 0.44-0.81) compared to *the rest of the group*. Similarly, *anterolateral surgical approach* had 37 percent lower risk (RR 0.63; 0.50-0.81) than *posterior*. A posterior approach was associated with a 1.7 times higher risk of revision because of dislocation (95% CI 1.2-2.3) but a lower risk due to aseptic loosening (RR 0.38; 0.19-0.75).

Paper III

Changes in implant choice and surgical technique for hemiarthroplasty.

How has the treatment in Sweden with respect to hemiarthroplasty changed during the last years?

This is a descriptive study of the hemiarthroplasty population in Sweden and the changes that occurred since the establishment of the hemiarthroplasty registration as part of the Swedish Hip Arthroplasty Register in 2005.

Results

Completeness and procedure rates

Completeness of hemiarthroplasty procedures in the *Swedish hip Arthroplasty Register* compared to the Swedish *National Patient Register* increased from 89 percent in 2005 to 96 percent in 2006 through 2009. A total of 21,346 hemiarthroplasty procedures were recorded in the Register from 2005 through 2009 and the yearly number of procedures (adjusted for the increasing completeness) increased by seven percent from 2005 to 2009.

Patients

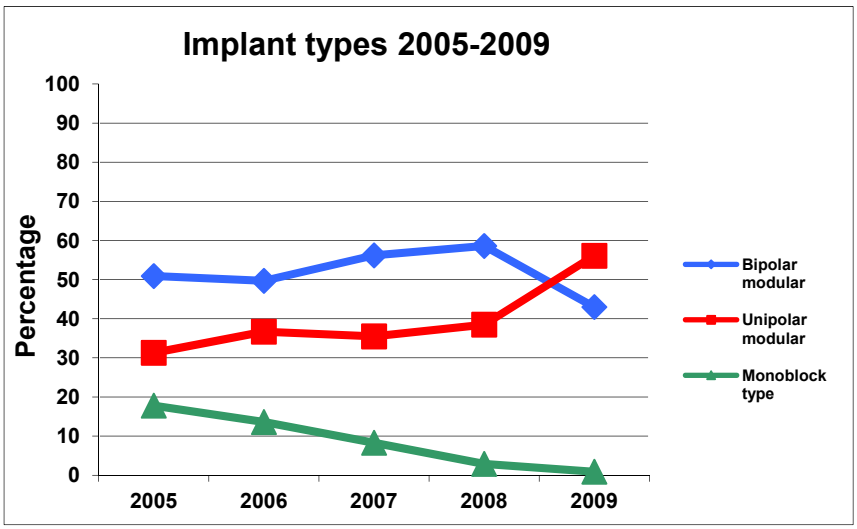
During the study period, the median age at surgery increased for men from 83 to 84 years and for women from 84 to 85 years. The proportion of patients above 85 years increased from 40 to 47 percent. Procedures because of acute fracture increased from 91 to 94 percent whereas those due to failed internal fixation decreased from 7 to 4 percent. Despite their lower age, more men than women (7 compared to 5 percent) were classified as ASA grade 4 (severe systemic disease that is a constant threat to life) whereas more women than men (47 compared to 36 percent) were classified as ASA grade 1 or 2 (normal, healthy patients or patients with mild systemic disease).

Implants and surgical technique

The use of monoblock type implants decreased from 18 percent in 2005 to 0.9 percent in 2009, whereas both unipolar and bipolar modular implants increased generally until 2008. In 2009 the use of bipolar implants decreased in favor of unipolar; 43 and 56 percent, respectively (Figure 6). The proportion of

uncemented implant stems decreased from 10 to 3 percent. Anterolateral surgical approach (Gammer and Hardinge together) increased from 47 to 56 percent whereas posterior approach decreased from 53 to 44 percent.

Figure 6. Implant types used over time.



(Leonardsson et al. Acta Orthop. 2012; 83(1):7-13. With permission.)

Paper IV

Higher risk of re-operation for bipolar and uncemented hemi-arthroplasty.

Which are the risk factors for re-operation in hemiarthroplasty patients?

Patients in the Swedish Hip Arthroplasty Register recorded with hemiarthroplasty because of fracture during 2005 through 2010 were included in this study. Inclusion criteria included surgery performed with one of the three dominating surgical approaches (anterolateral with the patient in a supine position[59], anterolateral with the patient in a lateral position[53] and posterior with the patient in a lateral position[82]) and use of modular (uni- or bipolar) hemiarthroplasty. This resulted in a total of 23,509 procedures in 22,642 patients. The median follow-up was 18 months (range 0-72) for all patients. For the patients that were still alive at the end of the study period the median follow-up was 24 months (0-72). The objectives were to identify risk factors for re-operation in contemporary hemiarthroplasties and to evaluate postoperative mortality.

Results

Rates of re-operation and revision

During the study period 888 re-operations were performed (3.8 percent) and 715 of these (3.0 percent) were revisions. The most common reasons for re-operation as well as revision were prosthesis dislocation and infection (Table 3).

Table 3. Numbers of re-operations and revisions for different reasons.

	Re-operation *n*	Revision *n*
Dislocation	393	373
Infection	275	174
Fracture	131	93
Acetabular erosion	41	41
Pain	17	16
Aseptic loosening	9	9
Other reasons	22	9
Total	888	715

Risk for re-operation

A Cox regression analysis revealed a number of factors influencing the risk for re-operation.

Bipolar implants proved to be a statistically significant factor with a higher risk of re-operation than *unipolar*, generally (Hazard ratio, HR 1.28; 95% CI 1.11-1.47) as well as due to dislocation (1.42; 1.15-1.76), infection (1.31; 1.01-1.68) and periprosthetic fracture (1.70; 1.15-2.52). In contrast, bipolar implants were associated with a lower risk because of acetabular erosion (0.30; 0.15-0.61).

Uncemented stems were associated with a higher risk of re-operation than *cemented* ones, in general (1.54; 1.12-2.13) mostly due to periprosthetic fracture (20.0; 9.1-43.8).

Males had a higher risk than *females*, regardless of reason (1.22; 1.06-1.41) and because of periprosthetic fracture (2.15; 1.52-3.05).

Procedures performed *secondary to failed internal fixation* were associated with a higher risk of re-operation generally (2.11; 1.69-2.64) as well as because of dislocation (2.52; 1.83-3.48) and infection (2.63; 1.82-3.81), compared to *acute fracture* procedures.

Patients *below 75 years* had a higher risk of re-operation (1.82; 1.48-2.23) compared to those *above 85*, as did patients *between 75 and 85* (1.16; 1.004-1.34).

The surgical approach was not a significant risk factor in general, but an *anterolateral* approach had a lower specific risk of re-operation due to dislocation (0.72; 0.58-0.89) than *posterior*.

C*emented polished* stems were associated with a higher risk of re-operation due to periprosthetic fracture (13.5; 7.4-24.6), but in terms of general risk there was no significant difference compared to *cemented matte* stems.

Mortality

The one-year mortality was 24 percent and at the end of the study period 44 percent of the patients had died. A Cox regression analysis including patients operated during 2008 through 2010 adjusted for age group, implant fixation (cemented or uncemented), ASA grade and cognitive impairment revealed a higher risk of death within one year for men (HR 1.78; 95% CI 1.64-1.94). The method of implant fixation was not a significant risk factor.

Paper V

Patient-reported outcome after displaced femoral neck fracture.

Which treatment for displaced femoral neck fracture gives the best patient-reported outcome?

A national survey of patient-reported outcomes after displaced femoral neck fracture was performed. Through collaboration between the *Swedish Hip Arthroplasty Register* and the Swedish *National Hip Fracture* Register 5,902 patients treated with internal fixation, total hip arthroplasty or hemiarthroplasty during 2009 were retrieved. A composite patient-reported outcomes questionnaire, including health-related quality of life, pain from the fracture affected hip and satisfaction with the treatment result, was mailed to the surviving 4,467 patients in the fall 2010. The differences between the treatment groups were adjusted for age and sex. In addition to evaluating the patient-reported outcomes we aimed to investigate the feasibility of a mailed questionnaire as means for a patient-reported outcomes follow-up on a national scale.

Results

The response rate was 79 percent (3,513 returned questionnaires), ranging from 72 to 75 percent response in the different sections of the questionnaire. The median time from surgery to response was equal in all treatment groups (14 months, range 7-22).

Patients *above 70 years* treated with total hip arthroplasty reported less pain, were more satisfied and had higher EQ-5D index than those treated with internal fixation or hemiarthroplasty. Internal fixation patients had the highest level of pain and were least satisfied.

Among patients *below 70 years*, those treated with total hip arthroplasty reported less pain and were more satisfied than those treated with internal fixation.

There was no substantial correlation between the time from surgery to response and the outcome in any of the sections.

Strengths and limitations

In study I the heterogeneity in implant choices and techniques could be considered a limitation. In order to ensure a high level of surgeon experience the participating surgeons were allowed to use the implants and surgical techniques which they usually preferred. This avoided a learning curve but at the same time inferred a mix of implant types and surgical techniques. On the other hand, the study was designed to evaluate a *treatment algorithm* rather than a specific implant using a specific technique.

Although significant effort was put into creating relevant questions, the patient-reported outcomes questionnaire in study I is not a validated form. One should bear in mind that this study was designed in the early 1990s; nowadays validated measuring instruments are recognized as the given choice in study design.

Failure was defined by the contact surgeons at the individual hospitals according to the study protocol. Still, some degree of interobserver differences is possible.

There are a few principal limitations to register studies. In a nationwide registration, the issue of selection bias and susceptibility bias must be considered. The treatment choices are made by the individual surgeons based on patient characteristics that may not be recorded in the Register. If one specific implant is used in one particular hospital only, results for this implant may reflect the hospital's performance rather than the implant features. As few implant brands are used in Sweden, the implants studied are indeed used in several hospitals.

Closed reductions of dislocations are not recorded in the Register. Previous attempts to include those in the Register have resulted in poor completeness of this variable. As a consequence, the decision was to exclude closed reductions from the Register. In respect of dislocations, open surgery is mainly chosen after recurrent episodes. Accordingly, the actual number of patients *with dislocations* is larger than the number of patients *re-operated because of dislocations*, including those with single dislocation events.

Initially, the completeness of ASA grade and cognitive impairment reporting was not optimal. Reports of dementia are based on any previous diagnosis of such and/or the surgeon's assessment, and classified in a simple manner as none, suspected or evident. It could be argued that a validated form, such as the Mini-Mental State examination[49] or the Short Portable Mental State Questionnaire[94]

should be used, but this may result in a lower level of completion. Consequently, some patients may be incorrectly classified with evident or suspected cognitive impairment as a result of a transient confusion related to the injury.

There might be a risk of under-reporting of re-operations to the Register, and the reported rate must be recognized as a minimum number. However, the risk of a systematic error influencing the results is considered insignificant, since all hospitals are given the same injunction to check their reported data every year, and as the implants studied are used in several hospitals.

The strengths of this thesis are the large number of patients, both in the randomized study and the register based studies, as well as the high level of completeness in the Register. Together with the multicenter approach in study I and the fact that the surgeons used familiar implants and techniques this allows for generalization of results for the whole country, avoiding performance bias. Also, a nationwide register study of this size allows for investigation of relatively unusual complications, which require a high level of statistical power.

General discussion

The results presented in this thesis indicate no excess long-term complications in patients treated with arthroplasty for displaced femoral neck fracture. The recent shift towards arthroplasty as primary treatment choice for displaced femoral neck fractures is reflected in the findings; a number of changes in implant choice and surgical technique were found. The results indicate that the treatment shift is beneficial to the patients in terms of complications and patient-reported outcomes, and that the use of arthroplasty in general and total hip arthroplasty in particular could probably be increased even further at the expense of internal fixation. Additionally, several technique and implant factors that need to be considered in arthroplasty surgery were identified.

Long-term results of arthroplasty

During the first phase in the introduction of arthroplasty for displaced femoral neck fractures the proponents of internal fixation argued that the new protocol might implicate an abundant need for revision of arthroplasty in the long run because of aseptic loosening and periprosthetic fractures.

In study I the surviving patients in the randomized trial were followed up to 10 years, and the superior results for arthroplasty persisted, without any tendency of excess complications during the late follow-up occasions. One previous randomized trial had longer follow-up, 13 years, also reporting reliable long-term results for total hip arthroplasty[99]. The inferior result for hemiarthroplasty in that study is probably attributable to the specific implant choice (Austin-Moore). In addition to that study, however, no randomized trial prior to study I in this thesis, has had sufficiently long follow-up to address this type of concerns[9, 89, 103]. Recently, a seven to ten years follow-up of a randomized trial showed low revision rates for total hip arthroplasty but higher for hemiarthroplasty[4]. The fact that only healthy, active patients with a good walking ability were included may have contributed to the poor outcome with hemiarthroplasty. Finally, in a yet unpublished 17-year trial total hip arthroplasty continuously resulted in better function and fewer re-operations than internal fixation[20].

In agreement with the results in study I, the revision rate for total hip arthroplasty up to seven years in study II and the re-operation rate for hemiarthroplasty up to five years in study IV were also low. Concurring satisfactory long-term results have been reported from other national registers as well[52, 57, 85].

In addition to the superior outcome with respect to implant failure, the arthroplasty patients in study I never reported more pain or worse function than internal fixation patients. This is especially interesting since most patients in the internal fixation group in the long-term had either a healed fracture or a salvage arthroplasty after failed internal fixation. Together with the results from the analysis of successfully healed fractures and successful arthroplasties, this refutes the axiomatic, although never scientifically supported argument, that a healed fracture is advantageous compared to a replaced hip joint. Similar conclusions have previously been reported from trials with shorter follow-up periods[51, 74].

Furthermore, 42 percent (n=91) of the patients initially treated with internal fixation subsequently received a salvage arthroplasty, of which 5 cases also led to revision surgery compared to 8 after primary arthroplasty. Hence, treatment with internal fixation in the end also amounts to a certain risk of arthroplasty revision.

Treatment development over time

The use of arthroplasty (in particular hemiarthroplasty) as primary treatment for displaced femoral neck fractures has clearly won broad acceptance in the Swedish orthopedic community during the last decade (study II and III). The results presented in this thesis support this paradigm shift, with low rates of re-operation and revision after arthroplasty in study I, II and IV as well as generally less pain and more satisfaction in comparison with internal fixation in study V.

In addition to the increasing proportions of procedures performed acutely as opposed to those performed secondary to failed internal fixation (study II and III), several important changes in surgical technique and implant choice has occurred during the last decade, as seen in study III. The use of monoblock type implants has diminished. Moreover, an increasing use of anterolateral transgluteal approach and a decreasing use of uncemented hemiarthroplasties were seen as well as an abrupt decrease in the use of bipolar implants in 2009. Assumedly, those changes depend on clinical trials as well as the Swedish Hip Arthroplasty Register reporting higher risk of re-operation with these technique and implant choices[14, 44, 55, 99]. The Register seems particularly influential for the bipolar implants as the clinical trials still fail to show any clear clinical differences between the uni- and the bipolar implants[18, 28, 36, 60, 98].

The Swedish orthopedic community in general has a conservative attitude towards the introduction of new implants and techniques. Consequently, in the treatment of hip fractures a small number of specific implants account for the majority of both total hip arthroplasty and hemiarthroplasty procedures. For instance, two particular stems were used in 71 percent of the total hip arthroplasty procedures and 68 percent of the hemiarthroplasty procedures (study II and III). Similarly, the three most common surgical approaches were used in 99 percent of the procedures and 94 percent of the implants were cemented (study III).

This contrasts with the experience in other countries. In a review of total hip arthroplasties in the UK 1995, a total of 62 different available implants were reported and only one accounted for more than 20 percent of the market[84]. A significant implant diversity is also seen in Australia with the dominating hemiarthroplasty stem during 2007 through 2010 accounting for only 24 percent of the procedures[57]. In Norway, the two most common stems account for 43 percent of the primary hemiarthroplasty procedures, the three most common surgical approaches are used in 98 percent of the cases and 78 percent of the implants are cemented[52].

Treatment choice

Total hip arthroplasty or hemiarthroplasty

The rates of re-operation and revision in this thesis are relatively low for both total hip arthroplasty and hemiarthroplasty. The crude rates of revision *due to dislocation* of total hip arthroplasty and hemiarthroplasty in study II and IV, were equal; 1.5 and 1.6 percent respectively. The rate of re-operation of hemiarthroplasty *due to acetabular erosion* in study IV was very low; 1.7 per thousand (see below).

A few reports suggest a higher risk of dislocation with total hip arthroplasty, whereas others have found similar risks for both arthroplasty types. This inconsistency may be influenced by other factors, such as surgical approach[9, 19, 89].

Although not studied in this thesis, functional outcome must also be considered. There are seven randomized trials comparing total hip arthroplasty and cemented modular hemiarthroplasty (although the study by Mouzopoulos et al. included both cemented and uncemented implants[83]). Four of the studies indicate better function after total hip arthroplasty than hemiarthroplasty even after up to four years follow-up in healthy, cognitively lucid and relatively active patients[5, 61, 74, 79]. Three of them did not show any functional difference between the implant types[39, 83, 120].

In study V, total hip arthroplasty in patients *above 70 years* lead to less pain and a higher degree of satisfaction than hemiarthroplasty. In two randomized trials health-related quality of life was better for the total hip arthroplasty patients[61, 74], as study V suggests, even though our results are limited by the lack of pre-fracture data. Two smaller trials did not demonstrate any difference between the groups[5, 79].

Few patients over 80 years receive total hip arthroplasties (study V) and several counties use very few total hip arthroplasties in fracture cases overall[107]. Altogether, this supports an increasing use of total hip arthroplasty, particularly in the higher age group.

In the comparatively small group of patients *below 70* years with displaced femoral neck fractures, total hip arthroplasty patients have less pain and are more satisfied than those treated with internal fixation (study V). Within the younger patient group only a minority receive hemiarthroplasty; presumably those with a poor pre-fracture health and a low level of activity. Still, there was a tendency towards more pain and less satisfaction in this group as well, compared to the total hip arthroplasty group.

In summary, the findings suggest that more patients could be considered for total hip arthroplasty. *Biological age* may be a more appropriate criterion for total hip arthroplasty eligibility than *chronological*. Thus, all patients with a reasonable health, mental status and level of activity as well as a relatively long remaining life expectancy (approximately more than a few years) could be considered for total hip arthroplasty without upper chronological age limit.

Recently, efforts have been put into establishing scores for predicting mortality after hip fracture[80]. The Sernbo score, estimating biological age and developed during the planning of study I, has recently been validated by a British research group as a strong predictor of mortality[35]. Recognizing remaining life-span as an important factor in the choice of treatment, these scores could be used for that purpose as well.

However, whereas internal fixation and hemiarthroplasty surgery are considered relatively facile surgical procedures, total hip arthroplasty may be technically more demanding[62]. If those procedures should be performed primarily by surgeons with a high level of experience, in view of the large number of hip fracture patients around 80 to 85 years, this might pose a challenge on the health care organizations. On the other hand, a continuous national audit, as performed by the Swedish Hip Arthroplasty Register, will tell if quality is maintained even if fracture-related total hip arthroplasties are spread on all hands in emergency orthopedic surgery.

Unipolar or bipolar hemiarthroplasty

Study IV showed a higher re-operation risk for bipolar than unipolar hemiarthroplasties. The reason for this is not clear. The finding of a higher risk generally as well as because of dislocation, infection and periprosthetic fracture might indicate some general problem with this implant type. For instance, prolonged surgery time due to assembly of the bipolar head may play a role. Possibly, this finding could be incidental or related to some unknown confounder. It is, nevertheless, in agreement with previous analyses from the Register on different stem-head combinations, showing a higher risk of revision for bipolar hemiarthroplasty compared to unipolar, using the same stem (Lubinus and Exeter stems with their uni- and bipolar heads respectively)[55]. In view of the many different aspects influencing outcome (e.g. implant stem, head, surgical approach, and patient characteristics) this is a highly complex matter. The problem could be influenced by specific implants as analyses from the Register have also shown a higher risk of *re-operation because of dislocation* specifically with the Vario Cup implant head (accounting for approximately half of the bipolar heads) compared to all other bipolars[55].

Those findings contrast in part with reports from the Australian National Joint Replacement Registry, where bipolar prostheses at least in younger patients and after a long follow-up period have a lesser risk of revision than unipolar. This may be a reflection of patient selection, since the typical hemiarthroplasty patient in Australia is younger than her Swedish counterpart[57].

Our analyses also revealed a higher risk of re-operation because of acetabular erosion with unipolar hemiarthroplasties. Still, as mentioned, the total number of patients re-operated because of erosion was very low; 1.7 per thousand (study IV). Subclinical occurrence might be much higher; in a recent trial 20 percent of the patients with unipolar implants showed radiographic signs of acetabular erosion after 12 months compared to 5 percent of those with bipolar implants. However, presence of radiographic erosion was not associated with a clearly lower health-related quality of life compared to those without this finding[60]. Erosion is a slowly developing complication, and presumably more imminent for active individuals, both in terms of its progress and the pain it infers. Hence, this complication might also develop undetected as the elderly patient adapts to a more sedentary life.

In addition to implant-related complications, the functional outcome also must be taken into account. The assumed better functional outcome for bipolar prostheses is supported by one randomized trial[28], while four others did not show any clear advantage regarding function or health-related quality of life[18, 36, 60, 98].

Altogether, the higher re-operation risk shown in study IV, the higher retail price, and no proven clinical advantages for *bipolar* implants, suggest *unipolar* implants

may be the recommendable choice, at least for the biologically aged with short remaining life-expectancy. This matter, however, needs further investigation. Along with the suggested increase of total hip arthroplasty this may imply a diminished demand for bipolar hemiarthroplasty.

Cemented or uncemented implants

In study IV a 54 percent higher risk of re-operation for uncemented than cemented implants was found. The risk was particularly influenced by periprosthetic fractures amounting to a 20 times higher risk of re-operation for this specific reason.

Previous investigations of outcome after *contemporary* cemented and uncemented fracture-related arthroplasties are sparse; several of the earlier trials are either of poor methodological quality or assess implants at present of low use[39, 40, 87, 106, 111].

However, two recent high quality randomized trials comparing modern uncemented hemiarthroplasties with cemented ones did not detect any differences between the groups regarding complications including periprosthetic fractures[37, 48]. In view of the comparatively low absolute number of re-operations because of periprosthetic fracture, this could be a result of insufficient statistical power to detect a difference in the clinical trials. Furthermore, neither study demonstrated any difference regarding function or health-related quality of life between patients with cemented and uncemented implants. A third trial indicated higher rates of complications and periprosthetic fractures with uncemented hemiarthroplasty[115]. Functional outcome was better with cemented implants at six weeks. Register reports from the Australia suggest higher revision rates in the early postoperative period for uncemented modular hemiarthroplasties than cemented[57].

Use of cemented implants did not significantly influence mortality at one year after hemiarthroplasty surgery in study IV. This is in accord with previous trials as well as a Cochrane review from 2006[37, 48, 88, 115].

The concerns regarding *intra-operative* death caused by embolization of fat and bone marrow contents associated with cementation (bone cement implantation syndrome)[24] is however one argument for using uncemented implants. A recent, so far unpublished, study from the Norwegian Hip Fracture Register suggests a higher risk of death within 10 days after cemented hemiarthroplasties compared to uncemented, but already after 30 days mortality was equal[122]. An Australian register study showed a higher risk of death during the first day when using cemented implants compared to uncemented. However, beyond one week a higher mortality risk with *uncemented* implants was reported up to one year[29].

Although catastrophic when occurring, intra-operative death is rare; the rate in fracture patients has been reported at 0.18 percent[91]. Improved anesthetic and surgical techniques as well as better pre-operative optimization of the patients may have contributed to the low rate. Also, even assuming earlier deaths for a very low number of frail patients with cemented implants, this must be weighed against the higher risk of periprosthetic fracture. A second fracture and another surgical procedure is a serious setback for an elderly patient implicating increased morbidity and mortality[10, 78], a fact that might explain the mortality pattern in the Australian study. Finally, a modern, hydroxyapatite coated stem is approximately 40 to 50 percent more expensive than a conventional cemented stem including bone cement and a distal plug.

The higher risk of periprosthetic fracture with uncemented implants, and its consequences, may outweigh the *possible risk* of earlier death for a very small number of patients; especially since no *functional* advantage related to uncemented fixation of the stem has been shown. With this in mind, cemented implants are probably preferable for fracture patients. The risk of bone cement implantation syndrome should be minimized by thorough lavage of the femoral canal and avoidance of excessive pressure cementation[17, 97].

Surgical approach

The surgical approach is an important technical detail when performing arthroplasty surgery. In study II and IV an anterolateral approach according to Hardinge or Gammer was found to reduce the risk of revision overall and because of dislocation for total hip arthroplasty, as well as re-operation because of dislocation for hemiarthroplasty.

This is consistent with other reports on both total hip arthroplasty and hemiarthroplasty for fracture[42, 44, 121].

A posterior approach has been suggested to decrease the risk of long-term aseptic loosening in total hip arthroplasty for osteoarthritis[55], and this was also a finding in study II for hip fracture patients. Re-operation for aseptic loosening of hemiarthroplasty was extremely rare, precluding further analysis (study IV).

Dislocation, and particularly *recurrent* dislocation is a troublesome complication affecting the patients negatively with a loss of health-related quality of life, reflecting the patients concern about having another dislocation[43]. Also, whereas dislocation is most commonly an early complication, aseptic loosening occurs late; thus only in individuals with a long remaining life-expectancy.

Dislocations treated with closed reduction are not reported to the Register, and surgeons often restrain from re-operation until dislocation has become recurrent. Consequently, the true number of patients with dislocations is higher than the numbers reported in study II and IV.

In summary, given the seriousness of recurrent dislocations and its early occurrence, anterolateral approach is preferable even if there is no long-term difference between the approaches.

Arthroplasty as salvage procedure

In the event of failed internal fixation, arthroplasty is often chosen as salvage procedure. The results in study II and IV are somewhat contradictive concerning the outcome after procedures for acute fracture (primary procedures) compared to those after failed internal fixation (secondary procedures). In study II the risk of revision for *total hip arthroplasties* performed as secondary procedures was similar to those performed as primary procedures. In contrast, secondary *hemiarthroplasty* doubled the risk of re-operation in study IV. This inconsistency could be a result of patient selection. The surgeons are probably more prone to advocating total hip arthroplasty as salvage procedure for relatively young and *healthy* patients, whereas the older patients with poorer health often may receive hemiarthroplasty. The younger and healthier patients might have a better ability to endure a second surgical procedure, and this selection is reflected in the lower mean age for the total hip arthroplasty patients in study II; 75 years compared to 84 for the hemiarthroplasty patients in study IV.

Our results regarding *hemiarthroplasty* agree with the report of Frihagen et al.[50]. Conversely, our results on *total hip arthroplasty* are in contrast with previous reports indicating higher complication rates for secondary procedures[15, 81].

As the absolute number of re-operations for secondary arthroplasty is relatively low, the results suggest that both total hip arthroplasty and hemiarthroplasty are reliable methods in the event of a failed internal fixation. Still, the complication rates after a secondary arthroplasty must be added to the initial complication risks for internal fixation. Thus, especially in an elderly patient, the objective should be to achieve a satisfactory and definitive treatment immediately in the acute situation.

Mortality

Male sex was identified as a risk factor for mortality (study IV). This has been described in numerous previous studies, but the reason is not completely understood[109, 113]. Even when adjusting for ASA grade and cognitive impairment the risk was still higher among men. This is in concordance with the report of Kannegaard et al. where the excess mortality in men after hip fracture could not be fully explained by their higher comorbidity burden[73]. A possible explanation could be that ASA grading is a relatively blunt instrument for estimating health. Male hip fracture patients might have a lower level of activity and an unhealthier life-style than women, something that is not necessarily reflected in their ASA grade.

In some cases, sex could be a factor to consider in the treatment choice; i.e. for biologically aged males with their very short remaining life-expectancy (less than three months for males above 85 years)[123] treatment with hemiarthroplasty is satisfactory.

Patient-reported outcome measures in the Register

The high response rate in study V with 72 to 75 percent completion in the different sections, demonstrates that a follow-up including patient-reported outcomes within the Swedish Hip Arthroplasty Register is feasible also for hip fracture patients.

Although we find the response rate acceptable in this frail patient group, the non-responders need to be considered. Twenty-one percent of the questionnaires were not returned. An additional two percent were returned empty and eight percent were returned only partially filled out. The reason for this is unclear, but it is conceivable that the response rates are particularly low in the oldest and those with cognitive impairment. This is to some extent supported by the fact that the responding patients were slightly younger than the non-responders. It is also notable that 19 percent of the returned questionnaires were filled out by proxy. In the planning of the study we wanted to acquire a sufficient amount of information, without compromising the response rates by making the questionnaire overly complex for the patients to fill out. Our results suggest that a more comprehensive questionnaire should probably not be used for this patient population.

The Norwegian Hip Fracture Register already records health-related quality of life, but the response rates are not described in the annual reports[52].

The aim of hip fracture treatment is to return the patients to their pre-fracture level of function and health-related quality of life. Patient-reported outcome measures as a part of the follow-up is of utmost importance, in order to evaluate how well this

aim is fulfilled. Already in 2002 a national program including patient-reported outcome measures for total hip arthroplasties was initiated within the Swedish Hip Arthroplasty Register. The program includes pre-operative measurement as well as follow-up measurements after 1, 6 and 10 years. As of yet, the program has not been introduced in the hemiarthroplasty registration.

Although organizing a continuous follow-up including patient-reported outcomes for fracture patients puts high demands on the individual hospitals as well as the Swedish Hip Arthroplasty Register, it would be of immense importance in the evaluation of treatment and care throughout the country. The next step is to assess the resources required for such a follow-up and to weigh this against the benefit of patient-reported outcome data in this large patient group.

Clinical implications

Based on the findings presented in this thesis in combination with results from other studies, some suggestions regarding the treatment of displaced femoral neck fractures can be made.

It is now reasonably clear that arthroplasty is preferable as the treatment of choice for all displaced femoral neck fractures except in the youngest patient group. For young patients, approximately under 60 years, there is virtually no scientific evidence on which to base treatment guidelines.

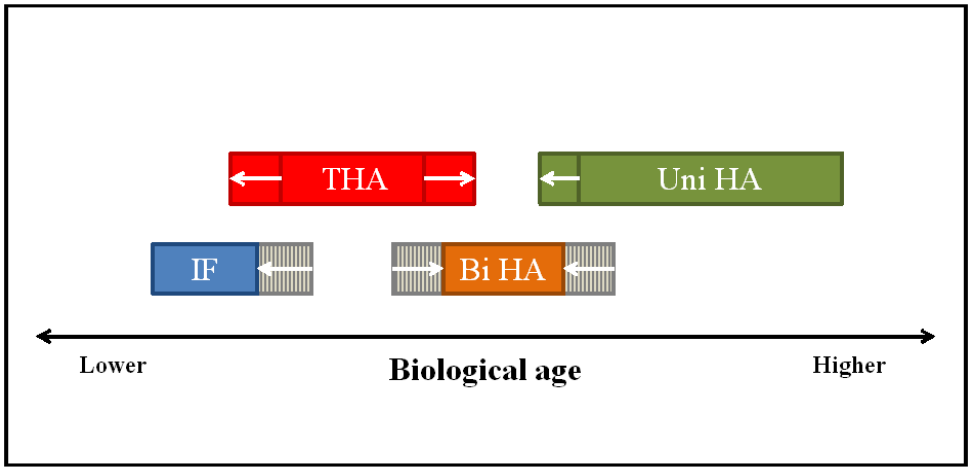
In the elderly group, total hip arthroplasty seems to be the best choice from the patients' point of view, with a low degree of pain and a high level of satisfaction. This treatment may be particularly advantageous for active and cognitively intact patients with relatively long remaining life-expectancy.

Compared to the present situation in Sweden, total hip arthroplasty could probably be used for more patients; both younger and older. The criterion for total hip arthroplasty eligibility could tentatively be relatively low *biological* age; an upper *chronological* age limit may not be needed.

For the biologically more aged patients hemiarthroplasty is probably satisfactory, and for the *oldest*, unipolar implants are considered sufficient. In view of the suggested increase of total hip arthroplasty, the remaining group of patients considered for bipolar hip may be very small and the demand for this implant type reduced (Figure 7).

Finally, in respect of surgical technique and implant fixation, anterolateral transgluteal surgical approach and fixation with cement is suggested for all fracture-related arthroplasties.

Figure 7. Graph schematically illustrating the suggested treatment changes in respect of biological age; decreased use of internal fixation (IF) and bipolar hemiarthroplasty (Bi HA), increased use of total hip arthroplasty (THA) and unipolar hemiarthroplasty (Uni HA).



Conclusions

The following conclusions were reached in respect of patients with displaced femoral neck fractures.

- There are no excess long-term complications for fracture-related arthroplasties within a 10-year follow-up.
- Patients treated with internal fixation without major complication never reach better results regarding pain or function than patients treated successfully with arthroplasty.
- Total hip arthroplasty is a safe method for primary fracture treatment as well as salvage treatment after failed internal fixation.
- Swedish orthopedic surgeons continually modify their practice as a way to improve the treatment and care for the patients, most likely influenced by findings and reports from the Swedish Hip Arthroplasty Register.
- Bipolar hemiarthroplasty is associated with a higher risk of re-operation than unipolar in general as well as because of dislocation, infection and periprosthetic fracture.
- Uncemented hemiarthroplasty has a higher risk of re-operation than cemented, mainly because of periprosthetic fracture.
- Anterolateral surgical approach has a lower risk of total hip arthroplasty revision regardless of reason, and of hemiarthroplasty re-operation due to dislocation, compared to posterior approach.
- A mailed patient-reported outcomes questionnaire is a feasible method for a national follow-up of hip fracture patients, with an acceptable response rate.
- Total hip arthroplasty leads to the lowest level of pain and the highest level of satisfaction in patients above as well as below 70 years.

Future research

During the last decades, hip fracture research has gradually established arthroplasty as gold standard for displaced femoral neck fractures. Still, there are some insufficiently explored areas.

Whereas the literature provides relatively ample evidence on *elderly* patients with displaced femoral neck fractures, very little can be found regarding younger patients, i.e. approximately less than 60 years old. As of yet, the common choice of internal fixation for young patients is based rather on logic reasoning than actual scientific evidence, i.e. a higher risk of arthroplasty revision due to long remaining life-expectancy as well as an assumed better ability to cope with a salvage operation in the event of failed internal fixation. With special attention put on this group, those patients could also be offered an evidence based treatment. However, this patient group is heterogeneous both in respect of health state and the type of trauma resulting in the fracture, putting high methodological demands on the study design, especially in terms of patient selection.

Although this thesis indicates a higher risk of re-operation with bipolar than unipolar hemiarthroplasty, this matter needs further attention as the few randomized trials are insufficient. Already, different stem-head combinations have been analyzed in the Register with a similar result, supporting the concern about bipolar implant heads. Still, the possible influence of confounders remains to be ruled out. To disentangle this issue definitively, a large trial with specific stem-head combinations may be the solution. In particular acetabular erosion needs to be explored in relation to patient-reported outcomes such as pain, function and health-related quality of life.

The treatment for *undisplaced* fractures is sparsely investigated. With a lesser risk of disruption of the blood supply to the femoral head, internal fixation is often the treatment of choice. The complication rates after internal fixation are, however, still higher than that of arthroplasty for *displaced* fractures. The reliable results after arthroplasty for *displaced* femoral neck fracture, confirmed in this thesis, raise the question if arthroplasty is the preferable treatment for *undisplaced* fractures as well. This issue could be addressed by means of a randomized trial comparing complications, mortality and patient-reported outcome after internal fixation and arthroplasty.

Summary in English

Hip fractures are devastating for the individual and a substantial economic burden for society. The treatment for *displaced femoral neck fracture* is generally a choice between internal fixation, total hip arthroplasty and hemiarthroplasty. As a result of several randomized trials, treatment of these fractures has shifted in Sweden during the last decade, from mostly internal fixation towards more arthroplasties.

Remaining concerns were those of long-term arthroplasty complications such as aseptic loosening and periprosthetic fracture. In addition to investigating this issue, the focus of this thesis was on identifying the optimal treatment methods for patients with displaced femoral neck fractures, regarding choice of implant and surgical technique.

Study I is a 10-year follow-up of a randomized multicenter trial on 450 mentally lucid and relatively healthy patients above 70 years with displaced femoral neck fractures. The patients were randomized to internal fixation or arthroplasty; total hip arthroplasty or hemiarthroplasty depending on age and level of activity. During the follow-up, the rate of major complications was continuously higher in the internal fixation group as compared to the arthroplasty group (46 percent compared to 9 percent at 10 years).

In a separate analysis, patients with *successful healed fractures* reported more pain and reduction of mobility at four months than those treated with *arthroplasty without major complications*, and they never attained a better result than the latter regarding pain or function.

Hence, those results indicate that there are no excess long-term complications after arthroplasty, and refute the assumption that retaining the patient's femoral head is beneficial.

The **Swedish Hip Arthroplasty Register** records total hip arthroplasties since 1979 and hemiarthroplasties since 2005. All hospitals performing arthroplasty surgery in Sweden are participating and completeness of recordings is near 100 percent.

In **study II**, 10,264 fracture-related *total hip arthroplasty* procedures from the Swedish Hip Arthroplasty Register were compared to total hip arthroplasty procedures performed for other reasons; mainly osteoarthritis. The revision rate

was higher in the fracture group; 4.4 percent compared to 2.9 percent at seven years. Within the fracture group, revision rates were similar after acute fracture procedures and procedures performed secondary to failed internal fixation. Contrasting, in **study IV**, with 23,509 included procedures, *hemiarthroplasties* performed secondary to failed internal fixation were associated with a doubled risk of re-operation compared to those performed for acute fracture.

Anterolateral surgical approach (Hardinge and Gammer) had lower risk of *total hip arthroplasty* revision regardless of reason and *hemiarthroplasty* re-operation because of dislocation in **study II and IV**.

Additionally, *bipolar* and *uncemented* hemiarthroplasties were identified as risk factors for re-operation in **study IV**; the former because of dislocation, infection and periprosthetic fracture, the latter mainly because of periprosthetic fracture.

Compared to females, males had higher risk of total hip arthroplasty revision and hemiarthroplasty re-operation in **study II and IV**. Males also had higher risk of death during the first year following the injury (**study IV**).

In **study III** the development in the hemiarthroplasty population from 2005 through 2009 (n=21,346) demonstrated an increasing proportion of procedures for acute fracture and a decreasing proportion of procedures performed secondary to failed internal fixation. In respect of implant choice, use of monoblock type implants decreased to below one percent. Modular implants increased generally, but in 2009 bipolar implants decreased in favor of unipolar. Moreover, use of uncemented implants and posterior surgical approach decreased. Assumedly, these changes are results of reports from clinical trials as well as the Swedish Hip Arthroplasty Register.

In **study V**, 4,467 patients from the Swedish Hip Arthroplasty Register and the Swedish National Hip Fracture Register, with displaced femoral neck fractures received a mailed patient-reported outcomes questionnaire. The overall response rate was 79 percent. Patients *above 70* years with total hip arthroplasty reported less pain and were more satisfied than those treated with internal fixation or hemiarthroplasty at a median of 14 months after the fracture. Among patients *below 70*, those treated with total hip arthroplasty had less pain and were more satisfied than those treated with internal fixation.

The results presented in this thesis support the use of arthroplasty as primary treatment for displaced femoral neck fractures and indicate that the use of total hip arthroplasties could be increased even further in this patient group. The higher risk of re-operation with bipolar implants implies that unipolar hemiarthroplasty may be preferable for the oldest. Finally, the results suggest that anterolateral surgical approach and cemented implants are recommendable in fracture-related arthroplasty surgery.

Populärvetenskaplig sammanfattning

En höftfraktur kan vara katastrofal för den drabbade individen och är en ekonomisk belastning för samhället. I Sverige ådrar sig ca 18 000 personer årligen olika typer av höftfrakturer. Uppskattningsvis hälften av frakturerna är cervikala (lårbenshalsbrott). I denna avhandling diskuteras i första hand *felställda cervikala höftfrakturer*, vilka drabbar ca 6 000 patienter årligen i Sverige.

Behandlingen av felställda cervikala frakturer innebär ett val mellan osteosyntes (spikning eller skruvning) och höftprotes (konstgjord höftled). Principiellt finns två typer av höftproteser: totalprotes där både ledkulan och ledskålen byts ut, och halvprotes där endast ledkulan byts ut. Höftproteser kan också insättas antingen med eller utan bencement. Traditionellt har man i Sverige tidigare främst använt osteosyntes för denna frakturtyp. En rad kliniska studier runt millennieskiftet visade mycket dåliga resultat för osteosyntes, vilket har lett till ett ändrat behandlingsmönster med en större användning av höftproteser.

Långtidsrisken för komplikationer efter höftprotesbehandling, såsom lossning eller protesnära fraktur, har anförts som argument mot den ökade protesanvändningen. Förutom att undersöka detta var målet med denna avhandling att identifiera den bästa behandlingen för patienter med felställda cervikala höftfrakturer avseende val av protes och operationsteknik.

Studie I är en 10-årsuppföljning av en randomiserad multicenterstudie, omfattande 450 patienter över 70 år med felställda lårbenshalsfrakturer. Patienterna, som var mentalt klara och relativt friska, fördelades slumpmässigt till antingen osteosyntesgruppen eller protesgruppen. I protesgruppen behandlades patienterna med totalprotes eller halvprotes utifrån ålder och aktivitetsnivå. Patienterna som behandlats med osteosyntes hade under hela uppföljningtiden fler allvarliga komplikationer än de som behandlats med protes (46 procent jämfört med 9 procent efter 10 år).

Patienter som behandlats med *osteosyntes utan allvarliga komplikationer* angav mer smärta och sämre rörlighet 4 månader efter frakturen, än de med *protes utan allvarliga komplikationer*, och osteosyntespatienterna nådde aldrig en bättre nivå än protespatienterna avseende smärta eller höftfunktion.

Resultaten tyder på att långtidskomplikationer efter protesbehandling inte är något stort problem samt motbevisar antagandet att det för patienten är en fördel i sig, att behålla sitt ledhuvud.

Svenska Höftprotesregistret registrerar totala höftproteser sedan 1979 och halvproteser sedan 2005. Samtliga kliniker som utför höftproteskirurgi i Sverige deltar också i registret, och täckningsgraden avseende individuella höftprotesoperationer är nära 100 procent.

I **studie II** jämfördes 10 264 frakturrelaterade *totalprotesoperationer* från Svenska Höftprotesregistret med totalprotesoperationer utförda av andra orsaker, framförallt höftartros (kontrollgrupp). Omoperation var vanligare i frakturgruppen än i kontrollgruppen: 4,4 procent jämfört med 2,9 procent efter sju år. Inom frakturgruppen var omoperation lika vanligt förekommande oavsett om man opererats på grund av akut fraktur eller misslyckad osteosyntes. I **studie IV**, inkluderande 23 509 operationer, var däremot omoperation dubbelt så vanligt för dem som opererats med *halvprotes* efter misslyckad osteosyntes.

Protesoperationer kan tekniskt utföras på olika sätt. Så kallad främre snittföring var kopplat till en lägre risk för omoperation av *totalprotes* generellt, och *halvprotes* på grund av luxation (urledvridning) i **studie II och IV**.

Bipolära (proteser med ett mindre innerhuvud ledande mot ett större yttrehuvud, till skillnad från unipolära som endast har ett stort huvud, ledande mot ledskålen) och ocementerade halvproteser visade sig i **studie IV** vara riskfaktorer för omoperation; de förra på grund av luxation, infektion och protesnära fraktur, de senare framförallt på grund av protesnära fraktur.

Män hade i **studie II och IV** jämfört med kvinnor en högre risk för omoperation av både totalprotes och halvprotes. Män löpte också större risk att dö under det första året efter frakturen (**studie IV**).

I **studie III** undersöktes hur användandet av halvprotes förändrats under perioden 2005 till 2009 (21 346 operationer). En ökande andel operationer utförda på grund av *akut fraktur* konstaterades, medan de som utförts efter *misslyckad osteosyntes* minskade. Användningen av så kallade *monoblock*-proteser (proteser som tillverkas i ett stycke) minskade till under en procent. *Modulära* proteser (proteser som tillverkas i delar och sätts ihop vid operation, med möjliget för kirurgen att modifiera längd osv) ökade generellt, medan användningen av *bipolära* proteser 2009 minskade till förmån för *unipolära*. Dessa förändringar beror sannolikt på resultat från kliniska studier och från Svenska Höftprotesregistret.

S**tudie V** omfattade 4 467 patienter från Svenska Höftprotesregistret och det nationella höftfrakturregistret Rikshöft. En enkät skickades till patienterna året efter att de ådragit sig felställda cervikala höftfrakturer. Den totala svarsfrekvensen var 79 procent. Patienterna ombads svara på hur de upplevde sin situation med

avseende på sin skadade höft och den behandling de fått. Patienter *över 70 år*, som behandlats med totalprotes angav mindre smärta och var mer nöjda med operationsresultatet än de som behandlats med osteosyntes eller halvprotes. I patientgruppen *under 70 år*, angav de som behandlats med totalprotes mindre smärta och var nöjdare än de som behandlats med osteosyntes.

Resultaten i denna avhandling stöder användandet av höftprotes som förstahandsmetod vid felställda cervikala höftfrakturer. Sannolikt bör också totalprotesanvändningen ökas ytterligare i denna patientgrupp. Att risken för omoperation är högre med bipolära halvproteser gör att unipolära proteser kan vara att föredra för de äldsta patienterna. Slutligen tyder resultaten på att frakturrelaterad proteskirurgi bör utföras via främre snittföring och med cementerade proteser.

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Appendix 1

Patient-reported outcomes questionnaire from study I

Löpnummer: _____

Fyll i det alternativ som stämmer bäst med Din dagliga situation:

1. Jag tänker…

Aldrig	1 ☐	…på att jag har skadat höften
Sällan	2 ☐	
Ibland	3 ☐	
Ofta	4 ☐	
Alltid	5 ☐	
Kan ej svara	6 ☐	(t.ex. p.g.a. demens)

2. Jag bor i….

Egen lägenhet	1 ☐
Villa eller radhus	2 ☐
Servicelägenhet eller ålderdomshem	3 ☐
Konvalescenthem	4 ☐
Gruppboende	5 ☐
Gruppboende för senildementa	6 ☐
Sjukhem	7 ☐

3. Jag bor kvar där jag bodde för tio år sedan….

Nej	1 ☐
Ja	2 ☐

4. Jag behöver vanligtvis…

Inget hjälpmedel	1 ☐	….när jag går
Bara käpp utomhus	2 ☐	
Alltid en käpp	3 ☐	
Två käppar, rullator eller liknande	4 ☐	
Stöd av annan person	5 ☐	
Jag kan inte alls gå	6 ☐	

5. Jag kan gå i trappa…

Nej	1 ☐
Ja	2 ☐

6. Jag får hjälp av hemtjänst (eller vårdpersonal)…

Aldrig	1 ☐
Mindre än en gång per vecka	2 ☐
En gång per vecka	3 ☐
2 – 4 gånger per vecka	4 ☐
Dagligen	5 ☐

7. Jag får hjälp av anhörig eller vän…

Aldrig	1 ☐
Mindre än en gång per vecka	2 ☐
En gång per vecka	3 ☐
2 – 4 gånger per vecka	4 ☐
Dagligen	5 ☐

Löpnummer: _____

8. När jag går har jag… Mycket ont 1 ☐ …i den skadade höften
Lite ont 2 ☐
Inget ont 3 ☐

9. När jag sitter stilla har jag… Mycket ont 1 ☐ …i den skadade höften
Lite ont 2 ☐
Inget ont 3 ☐

10. Jag går lika bra som före olycksfallet (då jag bröt lårbenshalsen) för tio år sedan…
Ja 1 ☐
Nej, höften besvärar 2 ☐
Nej, något annat försämrar min gång 3 ☐

11. Jag har behövt söka läkare under de senaste **tre/åtta** åren på grund av besvär från min skadade höft…
Nej 1 ☐
Ja 2 ☐

12. Jag har blivit opererad på nytt i min skadade höft under de senaste **tre/åtta** åren…
Nej 1 ☐
Ja 2 ☐

Om 'ja' – på vilket sjukhus? _____

Kommentarer: _____

_____

_____

Appendix 2

Patient-reported outcomes questionnaire from study V

Svenska höftprotesregistret RIKSHÖFT

Markera Ditt svar på nedanstående frågor genom att kryssa i en ruta (så här ☒):

Har Du besvär från **den andra** höften? ☐ Ja ☐ Nej

Har Du av någon **annan** anledning svårt att gå?
(T.ex. smärtor från andra leder, ryggvärk, kärlkramp eller andra sjukdomar som påverkar Din gångförmåga.) ☐ Ja ☐ Nej

---

Markera, genom att kryssa i en ruta i varje nedanstående grupp (så här ☒), vilket påstående som bäst beskriver Ditt **allmänna hälsotillstånd** i dag (ej enbart beroende på den aktuella höften).

Rörlighet
Jag går utan svårigheter ☐
Jag kan gå men med viss svårighet ☐
Jag är sängliggande ☐

Hygien
Jag behöver ingen hjälp med min dagliga hygien, mat eller påklädning ☐
Jag har vissa problem att tvätta eller klä mig själv ☐
Jag kan inte tvätta eller klä mig själv ☐

Huvudsakliga aktiviteter *(t ex arbete, studier, hushållssysslor, familje- och fritidsaktiviteter)*
Jag klarar av mina huvudsakliga aktiviteter ☐
Jag har vissa problem med att klara av mina huvudsakliga aktiviteter ☐
Jag klarar inte av mina huvudsakliga aktiviteter ☐

Smärtor/besvär
Jag har varken smärtor eller besvär ☐
Jag har måttliga smärtor eller besvär ☐
Jag har svåra smärtor eller besvär ☐

Oro/nedstämdhet
Jag är inte orolig eller nedstämd ☐
Jag är orolig eller nedstämd i viss utsträckning ☐
Jag är i högsta grad orolig eller nedstämd ☐

Skala 1 - Smärta

Sätt **ett kryss** på det streck som Du tycker motsvarar Din genomsnittliga smärtupplevelse från den aktuella höften under senaste månaden:

Ingen smärta — Maximal smärta

lätt | måttlig | medelsvår | svår | outhärdlig

Skala 2 - Tillfredsställelse

Sätt **ett kryss** på det streck som Du tycker motsvarar hur nöjd Du är med operationsresultatet:

Mycket nöjd — Missnöjd

mycket nöjd | nöjd | måttligt | tveksamt | missnöjd

(kryssa endast i en ruta)

Jag har besvarat frågorna personligen (viss praktisk hjälp accepteras) ☐

Anhörig/vårdpersonal har besvarat frågorna enligt deras kännedom om mig ☐

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