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ARTHROPLASTY IN PATIENTS WITH FEMORAL NECK FRACTURES

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To my family

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ABSTRACT

The aim of this thesis was to analyze hip function and the health-related quality of life (HRQoL) in patients with a displaced fracture of the femoral neck treated with a cemented total hip arthroplasty (THA) or a hemiarthroplasty (HA), unipolar or bipolar. Moreover, the purpose was to analyze factors influencing the stability of the THA with special reference to the surgical approach and to evaluate the responsiveness of the Short Musculoskeletal Function Assessment (SMFA), i.e. the instrument's ability to capture clinically important changes, in patients with femoral neck fractures.

A four-year follow-up of a randomized controlled trial (RCT) of 120 elderly patients (mean age 81 years) with a displaced femoral neck fracture randomly allocated to treatment by either THA or bipolar HA (*Study I*). The results confirmed the better outcome regarding hip function and HRQoL after THA as compared to HA in the longer time perspective.

In an RCT, 120 elderly patients (mean age 86 years) with a displaced fracture of the femoral neck were randomly allocated to treatment by either unipolar HA or bipolar HA (*Study II*). The study showed that unipolar HA and bipolar HA appeared to produce equivalent clinical outcomes regarding hip function and HRQoL after one year, but with a significantly higher incidence of acetabular erosion in the unipolar HA group.

In a cohort study, 713 consecutive hips in a series of 698 patients having undergone a primary THA (n = 311) for a displaced femoral neck fracture or a secondary THA (n = 402) due to a fracture healing complication after a femoral neck fracture were included (*Study III*). The results showed that the anterolateral surgical approach was associated with a significantly lower risk of dislocation than the posterolateral approach with or without posterior repair.

In order to evaluate the responsiveness of the SMFA, the 120 patients from *Study I* were included (*Study IV*). To evaluate the internal responsiveness of the SMFA, the observed change and the Standardized Response Mean (SRM) in relation to the change in the Dysfunction Index and the Bother Index were calculated. In order to calculate external responsiveness, an External Criterion (EC) was constructed by using the Harris Hip Score. Receiver Operating Characteristic (ROC) curves and logistic regression analysis were used in the evaluation. The results of the study showed that the SMFA indices had good internal responsiveness and acceptable external responsiveness in patients with femoral neck fractures.

In conclusion, THA is recommended as the primary treatment for the active, healthy elderly patient with a femoral neck fracture and long life expectancy. In the most elderly patients, bipolar HA and unipolar HA seem to produce equally good clinical results in the shorter time perspective, but the significantly higher incidence of acetabular erosion in the unipolar HA group may imply that bipolar HA should be the preferred treatment. Moreover, in order to minimize the risk of dislocation, we recommend the use of the anterolateral approach for THA in patients with femoral neck fractures. Finally, the SMFA can be recommended for use as one of the measures to evaluate the outcome after a femoral neck fracture.

LIST OF PAPERS

- I. Comparison of bipolar hemiarthroplasty with total hip arthroplasty for displaced femoral neck fractures. A concise four-year follow-up of a randomized controlled trial.
Hedbeck CJ, Enocson A, Lapidus G, Blomfeldt R, Törnqvist H, Ponzer S, Tidermark J.
Journal of Bone and Joint Surgery (Am), 2011 Mar; 93(5): 445-50.

- II. Unipolar hemiarthroplasty versus bipolar hemiarthroplasty in the most elderly patients with displaced femoral neck fractures: a randomised, controlled trial.
Hedbeck CJ, Blomfeldt R, Lapidus G, Törnqvist H, Ponzer S, Tidermark J.
Int Orthop. 2011 Feb 8. Epub ahead of print.

- III. Dislocation of total hip replacement in patients with fractures of the femoral neck. A prospective cohort study on 713 consecutive hips.
Enocson A, Hedbeck CJ, Tidermark J, Pettersson H, Ponzer S, Lapidus L.
Acta Orthopaedica, 2009 Apr; 80(2): 184-9.

- IV. Responsiveness of the Short Musculoskeletal Function Assessment (SMFA) in elderly patients with femoral neck fractures.
Hedbeck CJ, Tidermark J, Ponzer S, Blomfeldt R, Bergström G.
Quality of Life Research, 2011 May; 20(4): 513-21.

LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
AVN	Avascular necrosis
BMI	Body Mass Index
EC	External criterion
EQ-5D	The 5-dimensional scale of the EuroQol
EQ-5D _{index} score	The quality of life score generated from the EQ-5D
HA	Hemiarthroplasty
HHS	Harris Hip Score
HR	Hazard ratio
HRQoL	Health-Related Quality of Life
IF	Internal fixation
ns	Not significant
OA	Osteoarthritis
RA	Rheumatoid arthritis
RCT	Randomized controlled trial
ROC	Receiver operating characteristic
SMFA	Short Musculoskeletal Function Assessment
SPMSQ	Short Portable Mental Status Questionnaire
SRM	Standardized response mean
THA	Total hip arthroplasty
95%CI	95% confidence interval

INTRODUCTION

BACKGROUND

A hip fracture is probably the most feared and devastating consequence of osteoporosis in the increasing elderly population and a major challenge for healthcare and society. The number of hip fractures every year in Sweden is approximately 18,000,¹ and worldwide, the number of hip fractures was estimated to be 4.5 million annually in the year 2050.² Osteoporosis is the most important risk factor for a hip fracture and, consequently, most of the patients are women, approximately 70%.¹ Even after modern treatment, the individual patient has an increased mortality risk and is likely to experience a major negative impact on hip function and quality of life, which in turn may lead to a loss of autonomy.³⁻⁶

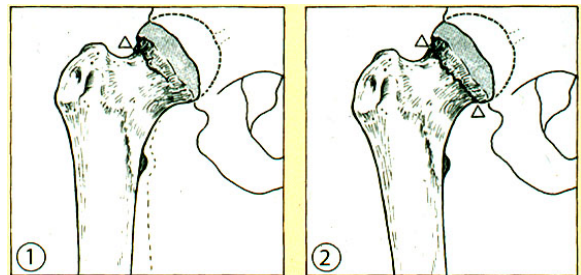
Femoral neck fractures constitute approximately 50% of all hip fractures. The valgus-impacted Garden I fracture and the undisplaced Garden II fracture (**Figure 1**) are referred to as undisplaced femoral neck fractures and constitute approximately 30% of the femoral neck fractures.^{1,7} It should be emphasized that the Garden classification is based on the anterior-posterior (AP) view. Some dorsal angulation in the lateral view is not uncommon in Garden I fractures.

Figure 1. Garden's classification.

Undisplaced fractures of the femoral neck.

1. Garden I, valgus impacted fracture.
2. Garden II, undisplaced fracture.

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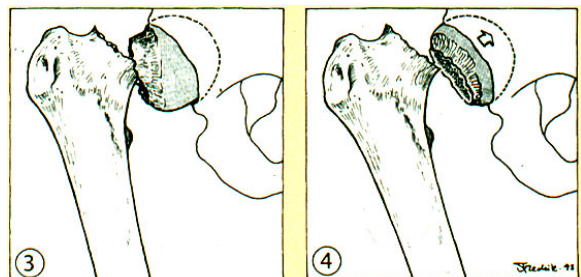
The partially displaced Garden III fracture and the fully displaced Garden IV fracture (**Figure 2**) are referred to as displaced femoral neck fractures and constitute approximately 70% of the femoral neck fractures.^{1,7}

Figure 2. Garden's classification.

Displaced fractures of the femoral neck.

3. Garden III, partially displaced fracture.
4. Garden IV, fully displaced fracture.

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Historically, internal fixation (IF) has been the preferred treatment for all types of femoral neck fractures in the Scandinavian countries which resulted in a large number of fracture healing complications and reoperations, mainly among patients with displaced fractures.³⁻⁴ However, during the last decade several studies have indicated the importance of a treatment algorithm based upon the individual patient's age, functional demands, prefracture walking ability, cognitive function, and risk factors.⁸⁻¹⁰

One reason for the long-lasting controversy regarding the optimal treatment for the elderly patients may be explained by the ambition to find a single surgical method to treat all patients with a displaced fracture of the femoral neck. However, the population of elderly patients with femoral neck fractures comprises several subpopulations with different functional demands, risk factors, and life expectancies. Furthermore, the surgical treatment of displaced femoral neck fractures differs from the treatment of many other hip fractures because the available treatment modalities, IF, hemiarthroplasty (HA), and total hip arthroplasty (THA), differ regarding surgical impact, complications, and the long-term outcome.

INTERNAL FIXATION

Fracture healing complications after a femoral neck fracture in elderly patients treated with IF are usually divided into non-union (including early redisplacement or progressive displacement) and avascular necrosis (AVN). The follow-up period has to be at least two years to reveal the majority of the fracture healing complications. However, AVN may occur even later, at least up to 4 years after the fracture.⁸ The number of secondary arthroplasties after failed internal fixation is not acceptable as a single outcome measure since the indications for an arthroplasty are nearly always relative and must be balanced against surgical risks. This decision differs between surgeons and because of local therapeutic traditions and resources. Furthermore, it has been shown that a secondary arthroplasty after failed IF will result in inferior hip function compared to a primary arthroplasty.¹¹⁻¹²

Internal fixation (**Figure 3**) has been uncontroversial in the treatment of undisplaced (Garden I and II) femoral neck fractures.^{7, 13} Among patients with undisplaced fractures, the rate of fracture healing complications after IF is in the range of 5–10%⁴ in most studies and good results regarding function and the health-related quality of life (HRQoL) can be expected.^{4, 14} The opinion that the overall outcome is good has recently been challenged by Rogmark et al. in a study including 224 consecutive patients with undisplaced femoral neck fractures treated with IF in which 40% of the



patients stated that they had pain while walking and 9% needed a secondary arthroplasty.¹⁵ However, this remains to be investigated in an RCT to see if a primary arthroplasty would yield a better overall outcome.

Figure 3. Internal fixation of a femoral neck fracture.

Internal fixation is also the method of choice in young patients with displaced fractures. The rate of fracture healing complications in the younger age group has been less well reported, but due to these patients' longer life expectancy and, consequently, higher risk of revision surgery after an arthroplasty, IF is the preferred method. Most previous studies have used 60–70 years as the lower age limit for arthroplasty, i.e. the upper limit for IF, in patients with displaced fractures.^{10, 16-20}

Among elderly patients with displaced fractures, the rate of fracture-healing complications after IF is considerably higher, being, in most studies with an at least 2-year follow-up, in the range of 35–50%.^{4, 10, 16-21} Moreover, many patients experience impaired hip function and a reduced health-related quality of life (HRQoL) despite an uneventfully healed fracture.^{14, 22-23}

The alternative treatment for elderly patients with displaced femoral neck fractures is a primary hip arthroplasty.

ARTHROPLASTY

There are mainly 3 types of arthroplasty used in patients with femoral neck fractures: THA, bipolar HA, and unipolar HA. The cemented Exeter® stem used as a unipolar HA, bipolar HA, and THA are shown in **Figure 4**.

Figure 4.

Unipolar HA



Bipolar HA



THA



THA is well documented in osteoarthritis (OA) and rheumatoid arthritis (RA) and has also shown good results after treatment of patients with femoral neck fractures in more recent studies.^{8, 10, 20}

There are 2 different types of HA: unipolar and bipolar. Unipolar HA features a fixed head articulating directly with the acetabulum, while the bipolar HA is designed to allow movement not only between the acetabulum and the prosthesis, but also at a joint within the prosthesis itself. The prosthesis has a spherical inner metal head that fits into a polyethylene shell (the inner joint), which in turn is enclosed by a metal cap that articulates with the acetabulum. The theoretical advantage of the bipolar HA is a reduction of acetabular wear due to the dual-bearing system. On the other hand, a

potential disadvantage is the risk of polyethylene wear that may contribute to mechanical loosening in a longer time perspective and there is also a risk of inter-prosthetic dissociation in certain bipolar HAs necessitating open reduction.²⁴ However, dissociation appears to be rare in modern bipolar surgical systems.

In the treatment of patients with femoral neck fractures most orthopedic surgeons select prosthetic designs that are intended to be used with bone cement. This selection is in conformity with a current meta-analysis stating that a cemented prosthesis is the recommended treatment with less reported pain and better walking ability compared to uncemented prostheses.²⁵ However, the frequently used Austin Moore HA from the 1950s, which is designed for insertion without cement, was used in a number of the studies included in the meta-analysis and an additional conclusion from that meta-analysis²⁵ is that this prosthesis should not be used due to inferior results.²⁵⁻²⁶

There is, up to now, only 1 RCT comparing a modern uncemented hydroxyapatite-coated arthroplasty with a cemented arthroplasty. The study by Figved et al.²⁷ included 220 patients randomized to a cemented bipolar hemiarthroplasty or a hydroxyapatite-coated bipolar hemiarthroplasty. The results showed essentially comparable outcomes for all the outcome measures studied, but there were 6% of intraoperative and postoperative periprosthetic fractures in the uncemented group compared to 2% in the cemented group. No cement-related complications were recorded. The role of uncemented stems in patients with femoral neck fractures needs to be further investigated and, meanwhile, the golden standard is a cemented arthroplasty.²⁵

TOTAL HIP ARTHROPLASTY VS. BIPOLAR HEMIARTHROPLASTY

There are more and more data indicating that ambulant elderly patients with a displaced fracture of the femoral neck should be treated with a primary hip arthroplasty,^{8, 10, 16-17, 19-20, 23, 28} while there is still controversy regarding the choice of arthroplasty, i.e. unipolar HA, bipolar HA, or THA. The most recent Cochrane review of this issue, with the latest update in December, 2009,²⁵ presented 4 studies comparing cemented HA with THA.^{20, 29-31} The meta-analysis showed a trend towards better functional outcome after THA, but no conclusion could be drawn because of insufficient power and further randomized trials with an adequate length of follow-up were recommended.

In clinical practice, the opinion among orthopedic surgeons seems to be that HA is the preferred treatment for elderly patients with low functional demands, while the choice of arthroplasty type for healthy, active, elderly patients is more controversial.¹³ The most common complication after THA in patients with femoral neck fracture has been dislocation of the prosthesis, which may be one reason why some surgeons hesitate to perform a primary THA. However, recent studies have shown that utilization of an anterolateral approach³² and judicious patient selection can reduce the dislocation rate to a level at a par with that expected after THA in patients with arthritic hips, i.e. 0–2%.^{20, 23, 33} Of special interest regarding the choice of HA versus THA are also data from studies with longer follow-up times including active patients treated with a primary HA. In active patients there are potential problems of acetabular erosion which may result in impaired hip function and the need for revision arthroplasty.^{19, 30}

BIPOLAR HEMIARTHROPLASTY VS. UNIPOLAR HEMIARTHROPLASTY

In a recent international survey questionnaire sent to 442 orthopedic surgeons, 94–96% preferred a hip arthroplasty for a patient aged 80 years or more with a Garden type III or IV fracture. The choice was a unipolar HA in 60% and a bipolar HA in 32–33%.¹³ However, the choice between a unipolar and a bipolar HA is controversial and difficult to make. In the most recent Cochrane review regarding this topic,²⁵ there are 7 randomized controlled trials (RCTs) comparing unipolar HA with bipolar HA. In 3 of the trials the now outdated Austin Moore prosthesis was used. The evaluation of the remaining 4 trials using cemented stems³⁴⁻³⁷ resulted in the conclusion that there is inadequate evidence to support or refuse the use of a bipolar prosthesis and that further trials are required. Moreover, the theoretical advantage of the bipolar HA suggesting that it may lead to a reduction of acetabular wear due to the dual-bearing system has not been evaluated in an RCT using a modern HA with identical stems in both the unipolar and bipolar groups.

DISLOCATIONS AFTER TOTAL HIP ARTHROPLASTY

Despite the good results for a THA reported in recent randomized controlled trials with regard to the need for revision surgery, hip function,^{17, 20, 23} and HRQoL,^{8, 20, 23} the proportion of patients treated with a THA in routine healthcare is not as high as would be expected.¹³ As previously mentioned, the risk for dislocation may be one major reason why orthopedic surgeons hesitate to perform a THA. Several studies confirm that the dislocation rate after a THA for a femoral neck fracture is considerably higher than what can be expected after a THA for OA or RA.³⁸⁻⁴⁰ The principal surgical approaches for insertion of a THA are anterolateral³² or posterolateral.⁴¹ Additionally, the posterior approach can be performed with or without reattachment of the short external rotators and/or the posterior joint capsule (posterior repair).

The influence of the surgical approach upon stability is difficult to evaluate within the context of a conventional randomized controlled trial since most surgeons have their individual preference regarding this issue. The best approach is probably randomization by surgeon or a large prospective cohort trial in which the surgical approach used is in conformity with the treating surgeon's preference.

ASSESSMENT OF OUTCOME, SMFA

In orthopedic studies the outcome is frequently reported using basic measures such as range of motion, fracture healing, the need for revision surgery, and mortality. Additionally, in modern studies the functional outcome is more and more often reported using region- or disease-specific outcome instruments which are now available for most body regions and for a number of diseases and injuries.⁴²⁻⁴³ The major disadvantage of these specific instruments is that they do not allow a comparison of the outcome in patients with different or multiple injuries/diseases, which is necessary in cost-effectiveness analyses used in healthcare evaluations.⁴⁴ To partly overcome this disadvantage, instruments for assessing HRQoL have been used.

HRQoL is a wide-ranging concept affected in a more complex way not only by the injury or disease itself, but also by comorbidities and events in the patient's

environment. However, due to their design, the quality-of-life instruments may be less sensitive for detecting small but yet important changes, i.e. they may have a limited responsiveness.⁴⁵⁻⁴⁶

The Short Musculoskeletal Function Assessment (SMFA) was developed by Swiontkowski et al. to study differences in the functional status of patients with a broad range of musculoskeletal disorders.⁴⁷ The SMFA can be used to assess and compare all types of musculoskeletal injuries and diseases, also in patients with multiple injuries, and has the potential to be a universal instrument for assessing the outcome in patients with musculoskeletal disorders. The SMFA is one of the outcome measures recommended by the American Academy of Orthopaedic Surgeons and has been translated into several languages and recently also into Swedish and validated for patients with various orthopedic injuries and disorders (the SMFA-Swe).⁴⁸

Responsiveness is related to an instrument's ability to capture clinically important changes.⁴⁵⁻⁴⁶ Two major aspects of responsiveness can be described, namely, internal and external responsiveness.⁴⁹ Internal responsiveness refers to situations in which the respondents are measured at at least 2 points in time between which it can be expected that a change has taken place in the studied variable or variables. External responsiveness employs an external criterion (EC) representing a standard to which the instrument whose responsiveness is to be evaluated is compared, e.g., by using correlation analyses or ROC curves.⁴⁶ The determining factor here is the association between the EC and the other measure, which implies that the EC must represent the qualities the researcher wishes to capture with the new measure. Use of both forms of responsiveness has been recommended to obtain a comprehensive and accurate picture of the responsiveness of a measure.⁴⁹

The responsiveness of the SMFA has not been evaluated more specifically for elderly patients with a hip fracture and the previous validation study of the SMFA-Swe did not include any hip fracture patients.⁴⁸

OVERALL AIM OF THE THESIS

The overall aim of this thesis was to analyze hip function and HRQoL in patients with a displaced fracture of the femoral neck treated with cemented THA or HA, unipolar or bipolar (*Studies I and II*). Moreover, the purpose was also to analyze factors influencing the stability of the THA with special reference to the surgical approach (*Study III*) and to evaluate the responsiveness of the SMFA, i.e. the instrument's ability to capture clinically important changes in patients with femoral neck fractures (*Study IV*).

AIMS OF THE STUDIES

STUDY I

The primary aim was to determine whether the superior hip function of a THA as compared to a bipolar HA after one year persisted during the four-year follow-up. The secondary aim was to analyze the degree of acetabular erosion in the HA group during the same period of time.

STUDY II

The primary aim was to analyze the outcome regarding hip function and HRQoL after a displaced femoral neck fracture in the most elderly lucid patient randomized to either a unipolar or bipolar HA. The secondary aim was to analyze the degree of acetabular erosion and its influence upon outcome.

STUDY III

The aim was to analyze factors influencing the stability of a THA with special reference to the surgical approach within the context of a large prospective cohort trial including consecutive patients with a femoral neck fracture.

STUDY IV

The aim was to evaluate the internal and external responsiveness of the SMFA, i.e. the instrument's ability to capture clinically important changes, in patients with hip fractures within the context of a randomized controlled trial.

PATIENTS

ETHICS

All studies were conducted in accordance with the Helsinki Declaration and all protocols were approved by the local Ethics Committee. The patients in *Studies I, II, and IV* gave their informed consent to participate. *Study III* was a prospective cohort trial including consecutive patients based on a clinical audit database. Informed consent was not considered necessary in that study.

INCLUSION CRITERIA AND FOLLOW-UP

STUDY I

120 patients with an acute displaced femoral neck fracture (Garden III and IV)⁷ randomized to a cemented bipolar HA or a cemented THA were included (**Table 1**). The inclusion criteria were age 70–90 years, absence of severe cognitive dysfunction, independent living status, and independent walking capability with or without walking aids. Patients with pathological fractures and displaced fractures older than 48 hours and patients with RA or OA were not included. All patients underwent the allocated operation.

The outcomes at the 4 and 12-month follow-up have been reported previously.²⁹ The present study included a 24 (mean 24.4) and a 48-month (mean 48.4) follow-up for clinical and radiographic examinations. Six patients, 5 in the HA group and 1 in the THA group, were lost to the final follow-up at 48 months.

STUDY II

120 patients with an acute displaced fracture of the femoral neck (Garden III and IV)⁷ randomly allocated to treatment by either unipolar HA or bipolar HA were included (**Table 1**). The inclusion criteria were age more than 80 years, absence of severe cognitive dysfunction, independent living status, and independent walking capability with or without walking aids. Patients with pathological fractures and displaced fractures older than 48 hours and patients with RA or OA were not included.

The patients were summoned at 4 (mean 4.2) and 12 (mean 12.6) months for a clinical and radiographic examination. Only 1 patient was lost to the final follow-up.

STUDY III

713 consecutive hips in a series of 698 patients who had undergone a primary THA (n = 311) for a displaced femoral neck fracture (Garden III or IV)⁷ or a secondary THA (n = 402) due to a fracture-healing complication after a femoral neck fracture between January 1, 1996, and December 31, 2005 were included (**Table 1**).

Data on the type of prosthesis including head size, indication for surgery (primary or secondary), surgical approach, level of surgeon's experience (registrar or post-registrar/consultant), and reoperation were recorded. A 6 to 8-week prospective follow-up was carried out within the context of a clinical audit. The patients were asked to report if any complication had occurred after surgery and, if so, where it had been

diagnosed and treated. Furthermore, all individual patient records were searched until December 31, 2006, or death, to find information about any dislocations and associated reoperations.

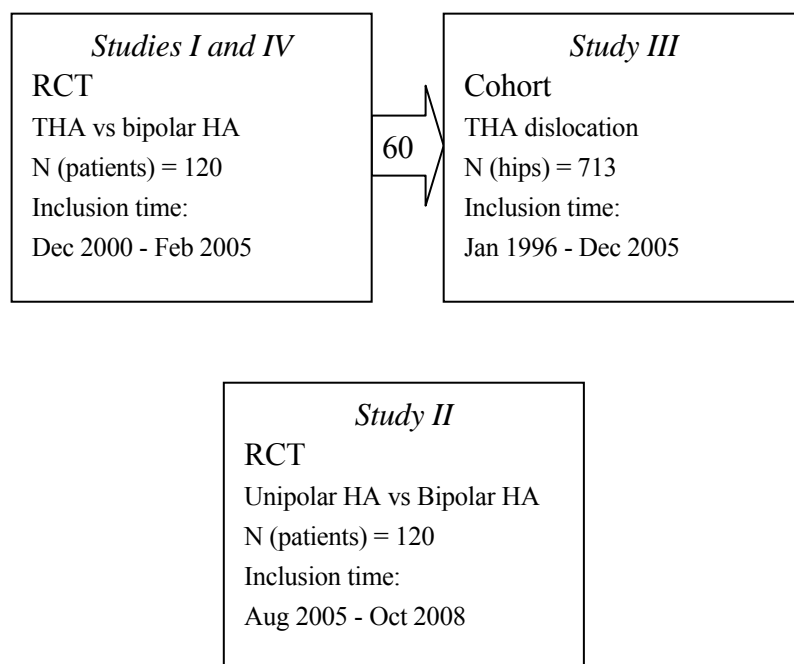
The median follow-up time was 4.3 years for all cases and 4.9 years for those who were still alive on December 31, 2006.

STUDY IV

The 120 patients with an acute displaced femoral neck fracture (Garden III and IV)⁷ randomized to a primary bipolar HA or a THA from *Study I* were included in this study (**Table 1**).

The patients were summoned at 4 months (mean 4.1) for an assessment of the Harris hip score (HHS)⁵⁰ and SMFA.⁴⁷⁻⁴⁸ Four patients were deceased before the 4-month follow-up and another 5 had missing values for the SMFA at inclusion and/or follow-up, leaving 111 patients in the study group.

Table 1. Patient inclusion for all studies.



METHODS

AGE AND GENDER

In *Studies I* and *IV* the mean age was 81 years and 84% of the patients were women. In *Study II* the mean age was 86 years and 76% of the patients were females. In *Study III* the mean age was 77 and 80% were women.

FRACTURE CLASSIFICATION

All patients in *Studies I, II,* and *IV* had a displaced fracture of the femoral neck (Garden III and IV).⁷ In *Study III* the patients operated upon with a primary THA (n=311) had a displaced femoral neck fracture, but among those operated upon with a secondary THA (n = 402) due to a fracture healing complication after IF, a limited number may have primarily had an undisplaced fracture (Garden I and II).

Please see Introduction for a presentation of the Garden classification.⁷

ASA CLASSIFICATION

In *Studies I, II,* and *IV* the patient's general physical health status was assessed by the attending anesthesiologist according to the American Society of Anesthesiologists (ASA) classification.⁵¹ ASA 1 indicates a completely healthy person; ASA 2, a person with a mild systemic disease; ASA 3, a person with severe systemic disease that is incapacitating; ASA 4, a person with an incapacitating disease that is a constant threat to life; and ASA 5, a moribund patient who is not expected to live 24 hours with or without surgery.

ANESTHESIOLOGICAL ASSESSMENT

All patients in *Studies I, II,* and *IV* were examined and cleared by an anesthesiologist before inclusion. The assessment included a decision as to whether the patient was fit enough for both randomization procedures.

RANDOMIZATION

The randomization procedures in *Studies I, II,* and *IV* were performed with independently prepared, numbered, opaque, and sealed envelopes.

COGNITIVE FUNCTION

Cognitive function was assessed with the Short Portable Mental Status Questionnaire (SPMSQ).⁵² This 10-item mental test (**Table 2**) classifies cognitive function into 4 categories: 8–10 correct answers = cognitive function intact; 6–7 correct answers = cognitive function mildly impaired; 3–5 correct answers = cognitive function moderately impaired; and 0–2 correct answers = cognitive function severely impaired. Only patients without severe cognitive function (SPMSQ ≥ 3) were included in *Studies I, II,* and *IV*.

In *Study III* we did not routinely use any validated instrument for assessing cognitive function. However, information regarding diagnosed dementia was available.

Table 2. SPMSQ.

1.	What is the date today?	Right / Wrong
2.	What day of the week is it?	Right / Wrong
3.	What is the name of this place?	Right / Wrong
4.	What is your telephone number or alt. street address?	Right / Wrong
5.	How old are you?	Right / Wrong
6.	When were you born?	Right / Wrong
7.	Who is the prime minister now?	Right / Wrong
8.	Who was the prime minister before him?	Right / Wrong
9.	What was your mother's maiden name?	Right / Wrong
10.	Subtract 3 from 20 and keep subtracting 3 from each new number all the way down.	Right / Wrong

ADL

Activities of daily living (ADL) status were assessed with the Katz ADL Index⁵³ in *Studies I* and *II*. The index is based on an evaluation of the functional independence or dependence of patients in bathing, dressing, using the toilet, transferring, continence, and feeding. ADL index A indicates independence in all six functions and index B independence in all but 1 of the 6 functions. Indexes C-G indicate dependence in bathing and at least one more function.

LIVING CONDITIONS

In *Studies I* and *II* living conditions were categorized as independent (i.e. own home, senior citizens home or block of service apartments) or as institutionalized (i.e. in care groups for demented patients or in nursing homes).

HARRIS HIP SCORE

In *Studies I, II* and *IV* hip function was assessed using the Harris hip score (HHS).⁵⁰ The HHS assesses hip function in 4 dimensions: pain (0–44), function (0–47), absence of deformity (0–4), and range of motion (0–5). The maximum score possible is 100. The HHS has shown high validity and reliability in patients with OA treated with a THA and is recommended for use to study the clinical outcome after femoral neck fractures⁵⁴ and hip arthroplasties.⁵⁵

SMFA

The Short Musculoskeletal Function Assessment (SMFA) was used in *Study IV*.⁴⁷⁻⁴⁸ The 46-item SMFA questionnaire comprises 2 parts: the Dysfunction Index with 34 items and the Bother Index with 12 items. The Dysfunction Index assesses the

patients' perceptions of the amount of difficulty they experience in the performance of certain functions (25 items) and how often they encounter difficulties when performing certain functions (9 items). The Dysfunction items are grouped into 4 categories: daily activities, emotional status, function of the arm and hand, and mobility. Each item has a 5-point response format (1 point for good function and 5 points for poor function). The Bother Index asks the patients to assess how much they are bothered by problems in different areas of life (e.g. recreation, work, sleep, and rest). These items also have a 5-point response format (1 point for not bothered at all and 5 points for extremely bothered). The scores of the Dysfunction and Bother Indices are calculated by summing up the responses to the items and then transforming the scores according to the formula: (actual raw score – lowest possible raw score) / (possible range of raw score) x 100. This transformation gives the final scores ranging from 0 to 100, a higher score indicating poorer function. In *Study IV* only the summed Dysfunction and Bother Indices were used. A comparison of the preinjury ratings with the values of a reference population was not possible because there is as yet no available Swedish reference population for the SMFA.

EQ-5D

Quality of life was assessed with the EuroQol.⁵⁶ The EuroQol consists of 4 components: the health status part (EQ-5D), a visual analogue scale (EQ-VAS), the valuation part, and background data. The first part, the 5-dimensional scale (EQ-5D), was used in *Studies I and II*. The EQ-5D is a standardized non-disease-specific instrument that measures the quality of life in 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is divided into 3 degrees of severity: no problem, some problems, and major problems.

We used the preference scores (EQ-5D_{index} scores) generated from a large UK population (UK EQ-5D Index Tariff) when calculating the scores for our study populations.⁵⁷ A value of 0 indicated the worst possible health state and a value of 1 indicated the best possible health state. This is a divergence from the UK EQ-5D Index Tariff where some health states were given negative scores. However, the appropriate scaling of negative scores is controversial⁵⁸ and the same approach was used when generating the values for an age-matched Swedish population.⁵⁹

All studies included an assessment of the patients' HRQoL the week before the fracture. To validate the method of rating the prefracture HRQoL and to analyze recall bias, the EQ-5D_{index} scores prior the fracture were compared with those of the age-matched Swedish reference population (**Table 3**).⁵⁹ Regarding recall bias, a recent study reports that older patients can accurately recall their previous health status up to 6 weeks.⁶⁰

Table 3. The EQ-5D_{index} scores for an age-matched Swedish reference population.





Age (years)	EQ-5D _{index} scores		
	60–69	70–79	80–88
Total	0.80	0.79	0.74
Male	0.83	0.81	0.74
Female	0.78	0.78	0.74

In *Study I* (mean age 81 years, 84% female) the prefracture EQ-5D_{index} score was 0.80. In *Study II* (mean age 86 years, 76% female) the prefracture EQ-5D_{index} score was 0.81.

RADIOLOGICAL ASSESSMENT

All radiographs in the HA groups in *Studies I* and *II* were analyzed with regard to acetabular erosion by a radiologist blinded to the clinical outcome. Acetabular erosion was graded according to the criteria of Baker et al.³⁰ as grade 0 (no erosion), grade 1 (narrowing of articular cartilage, no bone erosion), grade 2 (acetabular bone erosion and early migration), and grade 3 (protrusio acetabuli) (**Figure 5**).

Figure 5. Acetabular erosion according to Baker et al.³⁰.

Grade	Radiographic Appearance
0 Normal	
1 Narrowing of articular cartilage; No bone erosion	
2 Acetabular bone erosion; Early migration	
3 Protrusio acetabuli	

Reprint from Baker, R.P., et al., Total hip arthroplasty and hemiarthroplasty in mobile, independent patients with a displaced intracapsular fracture of the femoral neck. A randomized, controlled trial. *JBJS Am*, 2006. **88**(12): p. 2583-9. With the permission of the publisher.

STATISTICAL METHODS

The statistical software used in *Studies I, II, and IV* was PASW/SPSS 17.0 for Windows and, in *Study III*, SPSS version 15.0 for Windows.

In *Studies I, II, and III* the Mann-Whitney U-test was used for scale variables and ordinal variables in independent groups. Nominal variables were tested by the Chi-square test or Fisher's exact test. All tests were two-sided. The results were considered significant at $p < 0.05$. In *Study II* p values of $0.05 \geq p \leq 0.2$ were regarded as trend values. Additionally, in *Study II* the Wilcoxon signed-ranks test was used to compare the EQ-5D between before fracture and at follow-ups and in *Study III* we also used the Cox regression to evaluate factors associated with prosthetic dislocation after the operation. The associations are presented as hazard ratios (HRs) with 95% confidence intervals (CIs). The associations were tested using the Wald test and were considered significant at $p < 0.05$.

In *Study IV* a paired samples t test was used to compare changes between scores from the prefracture state (pre) and 4 months later (post). A correlation analysis was performed using Spearman's rho test. All tests were two-sided. The results were considered significant at $p < 0.05$. However, statistical significance is partially dependent on sample size, which is not relevant in analyses of responsiveness,^{49, 61} and therefore statistical significance should not be regarded as the central result. Nevertheless, statistical significance is of some value when comparing different indices in the same study, provided that the measures are based on the same sample size, which is the case in this study. *Change score*: the observed change mean (prefracture–4 months). *Standardized Response Mean (SRM)*: the observed change divided by the standard deviation of the observed change. The SRM provides a measure for comparing instruments and the construct makes it less sensitive to sampling sizes than the often used standardized effect size (SES).⁶² The SRM is regarded as large (> 0.8), moderate (0.5–0.8), or small (< 0.5).⁶²⁻⁶⁴ Confidence intervals (95%) for the SRM were calculated assuming that the change scores were normally distributed with a mean of zero and the standard deviation set to 1 over the square root of the sample size.⁶² ROC curves were used to depict the sensitivity and specificity of different change scores. This analysis gives information about the size of the area under the curve, which is the probability of correctly identifying patients with the defined outcomes according to the HHS (EC) from randomly chosen pairs of patients with different outcomes. This area ranges from 0.5, meaning no discriminatory accuracy, to 1.0, which approached perfect accuracy in distinguishing patients by this criterion. The calculation of ROC curves depends on the existence of a dichotomized EC. Odds ratios from separate logistic regressions were calculated with the EC as the dependent variable and the change scores as independent variables. Nagelkerke's R^2 was used to estimate the variance in the EC explained by the independent variable. It should be noted that the estimation of Nagelkerke's R^2 should not be interpreted as being similar to R^2 in a linear regression model since R^2 values from logistic regressions are usually low compared to R^2 figures from linear regression models.⁶⁵ However, Nagelkerke's R^2 can be meaningful when regression models are compared, as in this study.

RESULTS

STUDY I

Baseline data

Baseline data for all patients included (n = 120) are displayed in **Table 4**.

The previously published 1-year results indicated that a THA gave better hip function than a bipolar HA as soon as after 1 year and without increasing the complication rate.²⁹

Table 4. Baseline data for all patients included.

	HA (n = 60)		THA (n = 60)	
	Mean	(SD)	Mean	(SD)
Age	80.7	(5.1)	80.5	(5.1)
Cognitive function, SPMSQ	9.0	(0.8)	9.1	(1.0)
EQ-5D _{index} score prefracture	0.80	(0.17)	0.80	(0.21)
	n	(%)	n	(%)
Gender, female	54	(90)	47	(78)
Mobility, no walking aid or just one stick	55	(92)	56	(93)
ADL A or B	59	(98)	58	(97)

Surgical outcome

The overall mortality rate at 48 months was 26%. The mortality rate in the THA group was 28% and in the HA group 23% (p = 0.533).

There were no significant differences in hip complications or reoperations between the groups (p = 0.609 and 0.244, respectively). In the THA group there were 3 hip complications, all requiring reoperation. One patient suffered an early deep infection requiring soft tissue revisions prior to definitive wound closure. This patient was treated with antibiotics during 4 months and showed no signs of infection and had a good clinical result at the 48-month follow-up. Another patient in the THA group sustained a periprosthetic fracture after a fall 4 months after the arthroplasty procedure, which was treated successfully with plate fixation. Finally, 1 patient in the THA group had a hematogenous infection after a dog bite requiring extraction of the prosthesis 31 months after the index operation. A revision arthroplasty was performed 5 months later and showed no signs of infection and a good clinical result was confirmed at the 48-month follow-up. In the HA group 1 patient sustained an acetabular fracture with minor displacement after a fall 44 months after the index operation and was treated non-operatively.

There were no dislocations in any of the groups during the 48-month follow-up.

Acetabular erosion

At the final follow-up after 48 months, 37 of the 41 available patients in the HA group had an assessable radiographic examination. A total of 5 patients displayed acetabular erosion, all grade 1 (narrowing of articular cartilage, no bone erosion), giving an overall rate of erosion of 14%. The first appearance of the erosion was at 4 months in 1 patient, at 12 months in 1, at 24 months in 2 and at 48 months in 1.

Functional outcome and HRQoL

The differences in hip function in favor of the THA group appeared to increase after the 12-month follow-up and the difference was significant in the total HHS score as well as in the dimensions pain and function at both the 24- and 48-month follow-ups ($p < 0.001$ for the total score and the dimension of pain and $p < 0.05$ for the dimension of function) (**Table 5**). There were no significant differences in pain or function according to the HHS on comparing patients with acetabular erosion to those without, nor did they differ regarding age or gender (data not shown).

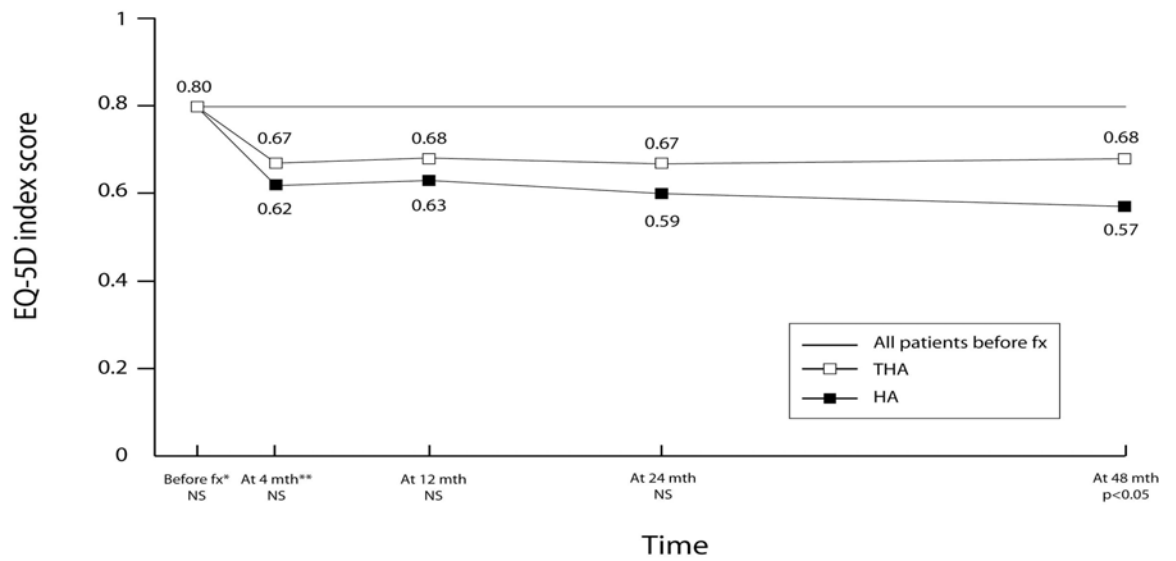
Table 5. Mean Harris hip score for all patients available at each follow-up.

	4 months			12 months			24 months			48 months		
	HA*	THA	p	HA	THA	p	HA	THA	p	HA	THA	p
Total score	77.5	82.5	0.011	79.4	87.2	<0.001	77.9	87.2	<0.001	75.2	89.0	<0.001
I. Pain	40.0	42.0	0.121	39.1	43.1	<0.001	37.8	42.7	<0.001	35.1	43.0	<0.001
II. Function	28.8	31.9	0.021	31.6	35.3	0.037	31.3	35.7	0.024	31.4	37.2	0.013
III. Absence of deformity	4.0	4.0	1.0	4.0	4.0	1.0	4.0	4.0	1.0	4.0	4.0	1.0
IV. Range of motion	4.7	4.7	0.598	4.7	4.7	0.435	4.8	4.8	0.671	4.7	4.8	0.714

* 2 missing values

The EQ-5D_{index} score was assessed to be higher in the THA group at each follow-up, but the difference was statistically significant only at 48 months ($p < 0.039$) (**Figure 6**). There was no significant difference in ADL or living conditions between the groups at 24 and 48 months (data not shown).

Figure 6. The EQ-5D_{index} score before fracture and for all patients available at each follow-up.



*1 missing value in each group. **2 missing values in the HA group and 1 in the THA group. P values given for differences between groups.

STUDY II

Baseline data

Baseline data for randomization groups (n = 120) are shown in **Table 6**.

Table 6.

Baseline data for all patients included.

	Unipolar HA	Bipolar HA
	(n = 60)	(n = 60)
Mean age in years (range)	87.4 (80-100)	85.5 (80-96)
Mean cognitive function SPMSQ (range)	8.5 (5-10)	8.5 (5-10)
Mean EQ-5D_{index} score prefracture (range)	0.80 (0.16-1.0)	0.81 (0.16-1.0)
Mean BMI (kg/m²)**	22.8 (17 to 38)	23.8 (17 to 33)
Gender, female (%)	49 (82)	42 (70)
Walking aids (%)		
None	38 (63)	46 (77)
Stick or crutches	8 (13)	7 (12)
Walking frame	14 (23)	7 (12)
ADL A or B*	58 (97)	58 (97)
ASA, classification (%)		
1	2 (3)	0 (0)
2	29 (48)	30 (50)
3	27 (45)	29 (48)
4	2 (3)	1 (2)

The overall mean age was 86.4 (range 80–100) years with 76% of the patients being female. The proportion of males was slightly higher in the bipolar group, 30% compared to 18% in the unipolar group. The mean prefracture EQ-5D_{index} score for all patients was 0.81 and 30% used some form of walking aid. Ninety-seven percent of the patients were independent in ADL function or dependent in only 1 function and 96% were assessed as ASA 2 or 3.

Surgical outcome

The overall 1-year mortality rate was 17%: 12% in the unipolar HA group and 22% in the bipolar HA group (p = 0.14). The mortality rate was significantly higher among male patients, 35%, compared to 11% among female patients (p = 0.003).

There were no differences in the duration of surgery, intraoperative blood loss, or need for blood transfusions on comparing the randomization groups (data not shown).

In the unipolar HA group there were 3 (5%) hip complications: 2 prosthetic dislocations and 1 deep infection. In the bipolar HA group there were 6 (10%) hip

complications: 1 prosthetic dislocation, 2 deep infections, and 3 periprosthetic fractures. All hip complications necessitated reoperations. The differences in the complication and reoperation rate between the groups were not significant ($p = 0.30$).

Functional outcome and HRQoL

Hip function according to the HHS was similar at both follow-ups (**Table 7**).

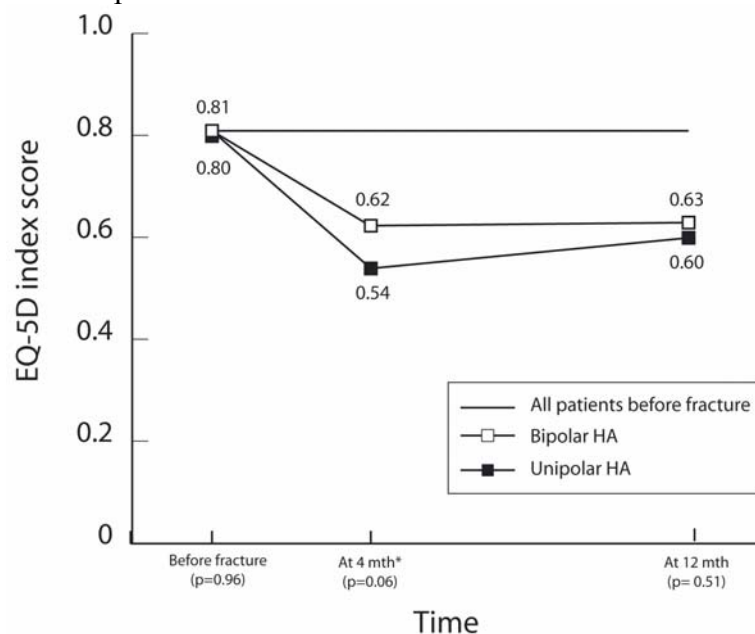
Table 7. Mean Harris hip score for all patients available at each follow-up.

	4 months			12 months		
	Unipolar*	Bipolar	p	Unipolar	Bipolar	p
Total score	73.8	75.5	0.17	78.2	77.7	1.0
I. Pain	39.5	40.3	0.22	41.3	40.5	0.92
II. Function	25.6	26.6	0.38	28.3	28.6	0.91
III. Absence of deformity	4.0	4.0	1.0	4.0	4.0	1.0
IV. Range of motion	4.7	4.6	0.05	4.7	4.6	0.26

* 1 missing value

The EQ-5D_{index} score is displayed in **Figure 7**. There was a trend toward a better quality of life in the bipolar HA group at 4 months ($p = 0.06$) while the difference at 12 months was not significant.

Figure 7. The EQ-5D index score before fracture and for all patients available at each follow-up.



* 2 missing values in the unipolar group and 1 missing value in the bipolar group.

In the unipolar HA group the EQ-5D_{index} score decreased from 0.80 before the fracture to 0.54 at 4 months. At 12 months the score was 0.60. The values at both follow-ups were significantly lower than before the fracture ($p < 0.001$ for both comparisons).

In the bipolar HA group the EQ-5D_{index} score decreased from 0.81 before the fracture to 0.62 at 4 months. At 12 months the score was 0.63. The values at both follow-ups were significantly lower than before the fracture ($p < 0.001$ for both comparisons).

There were no differences in ADL or living conditions between the groups at any of the follow-ups (data not shown).

Acetabular erosion

At the final follow-up after 12 months, 93 of the 99 (94%) available patients had an assessable radiographic examination: 49 out of 53 (93%) in the unipolar HA group and 44 out of 46 (96%) in the bipolar HA group. Ten out of 49 patients (20%) in the unipolar HA group displayed acetabular erosion compared to 2 out of 44 (5%) in the bipolar HA group ($p = 0.03$). Neither one of the 2 patients in the bipolar HA group treated with a unipolar HA displayed any signs of acetabular erosion. Excluding these 2 patients from the analysis gives a rate of acetabular erosion of 5% (4 out of 42) in the bipolar HA group and the difference between groups is still significant ($p = 0.03$). In the unipolar group the acetabular erosion was grade 1 in 8 patients and grade 2 in 2 patients. In the bipolar group 1 patient had a grade 1 erosion and 1 patient a grade 2 erosion.

There was a trend towards worse hip function among patients with an acetabular erosion ($n = 12$) at 12 months compared to those without ($n = 81$), HHS score 70.4 and 79.3, respectively ($p = 0.09$) and also a trend towards a lower quality of life, EQ-5D_{index} score 0.48 and 0.63, respectively ($p = 0.13$).

Acetabular erosion occurred more frequently among patients with BMI $< 24 \text{ kg/m}^2$ ($n = 48$) compared to those with BMI $> 24 \text{ kg/m}^2$ ($n = 37$), 21% (10/48) and 5% (2/37), respectively ($p = 0.04$). Eight patients had missing values for BMI.

STUDY III

Baseline data

Baseline data for all patients (713 hips in 698 patients) included in relation to surgical approach are displayed in **Table 8**.

Table 8. Baseline data for all patients included in relation to surgical approach.

		All (n=713)	Anterolateral (n=463)	Posterolateral (n=250)	p value
		Mean (SD)			
Age		76.8 (9.0)	77.2 (8.4)	76.1 (10.1)	0.1
		n (%)			
Sex	Female	573 (80)	374 (81)	199 (80)	0.8
	Male	140 (20)	89 (19)	51 (20)	
Indication	Primary	311 (44)	251 (54)	60 (24)	<0.001
	Secondary	402 (56)	212 (46)	190 (76)	
Surgeons' experience	Resident	77 (11)	64 (14)	13 (5)	<0.001
	Post-resident	636 (89)	399 (86)	237 (95)	
Femoral head size	22-mm	171 (24)	14 (3)	157 (63)	<0.001
	28-mm	542 (76)	449 (97)	93 (37)	

Dislocation of the THA occurred in 41 of the 713 hips, giving an overall dislocation rate of 6%. The anterolateral surgical approach was associated with a lower risk of dislocation than the posterolateral approach with or without posterior repair, 2%, 12%, and 14%, respectively ($p < 0.001$). The multivariable Cox regression analysis showed that the posterolateral approach was the only factor associated with a significantly increased risk of dislocation with HR 6 (2–14) for the posterolateral approach with posterior repair and HR 6 (2–16) for the posterolateral approach without posterior repair (**Table 9**). The patient's age, sex, the indication for surgery, the experience of the surgeon, and the femoral head size did not influence the dislocation rate.

There was no selection of patients with dementia for any of the surgical approaches. Among patients operated on using the anterolateral approach, 18 out of 463 (4%) had diagnosed dementia compared with 6 out of 250 (2%) operated on using the posterolateral approach ($p = 0.4$).

The first dislocation occurred early (within 6 weeks) in 24 out of 41 patients. Closed reduction was successful for 39 out of 41 patients with a primary dislocation. One of the remaining 2 patients (posterolateral approach) was reoperated on with a socket wall augmentation device and had no further dislocations. The other patient (anterolateral approach) underwent open reduction, got a deep infection, and had the prosthesis extracted. Twenty-five of the 39 the patients who were initially successfully treated with closed reduction had recurrent dislocations: 6 of the 8 patients operated upon using the anterolateral approach and 19 of the 31 patients treated using the posterolateral

approach ($p = 0.7$). Revision surgery due to instability was performed in 11 of the 41 patients (including the 2 patients treated with a primary open procedure) during the study period: 3 of 9 patients operated upon using the anterolateral approach, and 8 of 32 patients treated using the posterolateral approach ($p = 0.7$).

Table 9. Cox regression evaluating factors associated with dislocation.

	Explanatory	n	Dislocation rate (%)	Multivariable	
				HR ¹ 95% CI	p value
Age	< 78 years	349	6.6	1 (reference)	
	≥ 78 years	364	4.9	0.8 (0.4-1.5)	0.4
Gender	Male	140	5.9	1 (reference)	
	Female	573	5.0	1.2 (0.5-2.7)	0.7
Indication	Primary	311	4.5	1 (reference)	
	Secondary	402	6.7	0.8 (0.4-1.6)	0.5
Surgeon's experience					
	Registrar	77	3.9	1 (reference)	
	Post-registrar	636	6.0	0.9 (0.3-2.8)	0.8
Femoral head size					
	22-mm	171	13.5	1 (reference)	
	28-mm	542	3.3	0.7 (0.3-1.5)	0.4
Surgical approach					
	A-L	463	1.9	1 (reference)	
	P-L with posterior repair	110	11.8	5.5 (2.1-14)	<0.001
	P-L without posterior repair	140	13.6	5.7 (2.0-16)	0.001

On comparing patients operated on using the anterolateral or posterolateral approach, there were no differences regarding nerve injuries, deep infections, or mortality within the first year after surgery. Revision surgery for other reasons than dislocation and general complications within the first 6 weeks, such as pneumonia and cardiovascular, thromboembolic, and cerebrovascular events, were also equally distributed between the 2 groups (data not shown).

STUDY IV

Baseline data

Baseline data and measurement characteristics for the Dysfunction and Bother Indices for all patients included (n = 111) are given in **Table 10**. As can be seen, no ceiling effects (i.e. worst possible score, SMFA = 100) were displayed for the measures, but the Bother Index has a relatively high percentage of floor effects (i.e. best possible score, SMFA = 0).

Table 10. Baseline data on all patients included.

	Mean (SD)	
Age, years	80.5 (5.0)	
Cognitive function, SPMSQ	9.0 (0.9)	
	N (%)	
Gender, female	93 (84)	
Mobility, no walking aid or just one stick	103 (93)	
ADL A or B ¹	109 (98)	
Comorbidity, Ceder A or B ²	95 (86)	
	Dysfunction Index	Bother Index
Mean (SD)	21.5 (12.4)	14.4 (17.7)
Median	18.4	8.3
Range	0–60	0–92
Floor effect (%)	1.8	27.9
Ceiling effect (%)	0	0

Responsiveness

Internal responsiveness: Observed changes were statistically significant for both indices and an inspection of the SRMs showed a large effect size for the Dysfunction Index and a moderate effect size for the Bother Index (**Table 11**).

External responsiveness: On the basis of the change scores from both the Dysfunction and Bother Indices, it was possible to discriminate between patients with a less good outcome versus those with a moderately good or good outcome. This was indicated both by a visual inspection of the ROC curves (**Figures 7& 8**) and by the statistically significant figures regarding the area under the curve (**Table 12**). However, it was not possible to differentiate patients with a good versus a moderately good outcome using the change scores from the SMFA Indices (**Figure 9, Table 12**).

The logistic regressions provided support for the external responsiveness of the two rating scales (**Table 12**) for discriminating between patients with a less good outcome versus a moderately good or good outcome. However, the ability of the change scores from the SMFA Indices to differ between patients with moderately good versus a good outcome was limited as reflected in the confidence intervals including unity and low figures from Nagelkerke's R. The percentage of correctly classified cases was 64%

(good/moderately good), 80% (good/less good), and 74% (moderately good/less good) for both the Dysfunction and Bother Indices.

The logistic regressions consistently used the less favorable outcome according to the HHS (of the two compared outcomes) as the reference category. The analyses provide support for the external responsiveness of the two rating scales (**Table 12**) in that the risk of having a less good outcome decreases as the value of the change scores becomes more positive (indicated by an odds ratio above unity).

A complementary correlation analysis of the change scores of the two indices was also performed and yielded a coefficient (Spearman's rho) of 0.72, i.e., the overlap between the indices was relatively large.

Table 11. Internal responsiveness statistics for the Dysfunction and Bother Indices for all patients included (n = 111).

Variable	Observed change ¹	p value ²	SRM
	Mean (SD)		(95% CI)
Dysfunction Index	-13.3 (13.8)	< 0.001	0.96 (0.78; 1.15)
Bother Index	-15.4 (20.2)	< 0.001	0.76 (0.58; 0.95)

¹ Observed change prefracture–4-month follow-up. Negative figures indicate a deteriorated function.

² p values are given for differences between prefracture status and the 4-month follow-up. Paired samples t test.

Table 12. External responsiveness for change scores from the Dysfunction and Bother Indices (SMFA). Values from the Harris hip score were used as an external criterion (EC); please see Patients and Methods.

	ROC	Logistic regression	
	Area under the curve (95% CI)	Odds ratio (95% CI)	Nagelkerke R ²
Dysfunction index			
Good vs. moderately good	0.56 (0.44; 0.68)	1.02 (0.98; 1.07)	0.021
Good vs. less good	0.83*** (0.72; 0.94)	1.14** (1.06; 1.24)	0.44
Moderately good vs. less good	0.73** (0.62; 0.85)	1.07** (1.03; 1.12)	0.24
Bother index			
Good vs. moderately good	0.58 (0.46; 0.70)	1.02 (0.99; 1.04)	0.02
Good vs. less good	0.82*** (0.70; 0.94)	1.08** (1.03; 1.14)	0.36
Moderately good vs. less good	0.70** (0.57; 0.83)	1.04** (1.01; 1.06)	0.17

*** p < 0.001, ** p < 0.01. The “less good outcome” was a reference category in all logistic regressions except in the analyses of good versus moderately good outcome, where “moderately good” was the reference.

Figure 7. Receiver operating characteristics (ROC) for change scores from the Dysfunction and Bother Indices (SMFA). A moderately good versus a less good outcome according to the Harris hip score was used as an external criterion (EC); n = 80.

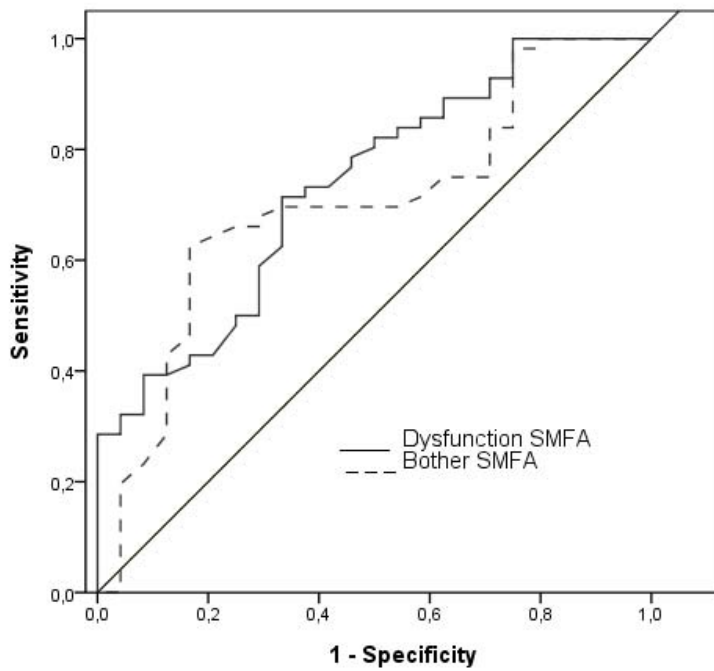


Figure 8. Receiver operating characteristics (ROC) for change scores from the Dysfunction and Bother Indices (SMFA). A good versus a less good outcome according to the Harris hip score was used as an external criterion (EC); n = 55.

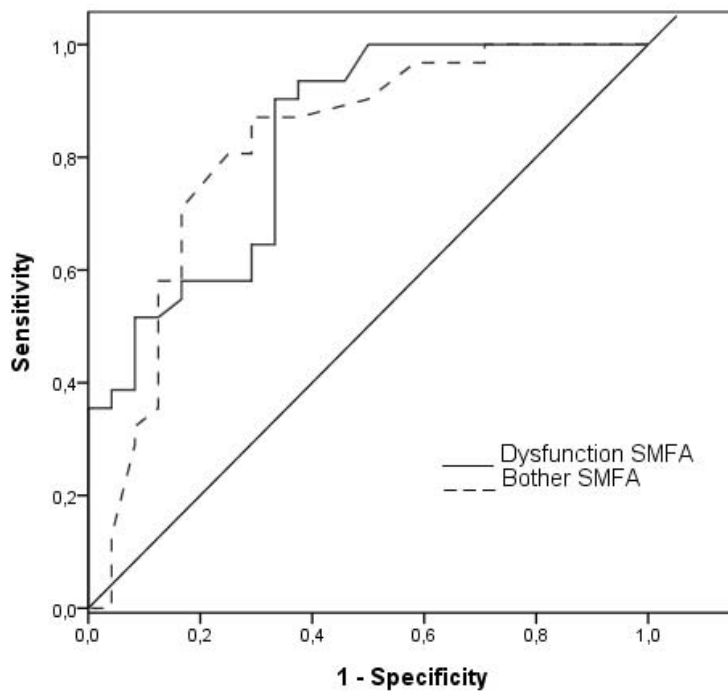
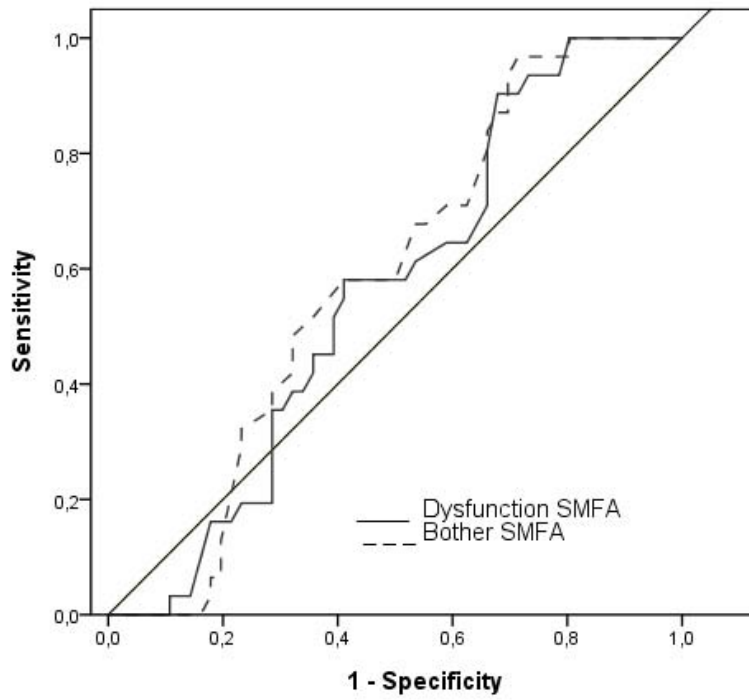


Figure 9. Receiver operating characteristics (ROC) for change scores from the Dysfunction and Bother Indices (SMFA). A good versus a moderately good outcome according to the Harris hip score was used as an external criterion (EC); n = 87



GENERAL DISCUSSION

The purpose of this thesis was to determine whether the superior outcome for THA as compared to bipolar HA after 1 year persisted during a 4-year follow-up (*Study I*) and to compare the outcome after a unipolar or bipolar HA in the most elderly lucid patient after a displaced femoral neck fracture (*Study II*). The secondary aim of *Studies I* and *II* was to analyze the degree of acetabular erosion in the HA groups. Moreover, we analyzed factors influencing the stability of a THA with special reference to the surgical approach within the context of a large prospective cohort trial including consecutive patients with a femoral neck fracture (*Study III*). Finally, we evaluated the internal and external responsiveness of the SMFA, i.e. the instrument's ability to capture clinically important changes, in patients with hip fractures within the context of a randomized controlled trial (*Study IV*).

TOTAL HIP ARTHROPLASTY VS. BIPOLAR HEMIARTHROPLASTY

The results of *Study I* confirmed the better outcome with regard to hip function and HRQoL after a THA as compared to a bipolar HA in elderly, lucid patients with a displaced fracture of the femoral neck also in the longer time perspective. The results imply that a THA performed via an anterolateral approach should be the preferred method of treatment for the active, relatively healthy patient with a long life expectancy. However, the low rate of acetabular erosion after 4 years and the relatively good hip function in the bipolar HA group imply that a bipolar HA may suffice as treatment for the oldest patients with lower functional demands.

As previously mentioned, the most recent Cochrane review of this issue,⁶⁶ found 4 studies comparing cemented HA with THA.^{20, 29-31} The study by Dorr et al. from 1986,³¹ which, by today's standards, cannot be considered to be strictly randomized (hospital record numbers), could not detect any differences between cemented bipolar HA, uncemented bipolar HA, and cemented THA among the 89 patients included. Keating et al.²⁰ compared IF, bipolar HA and THA in a multicenter RCT and concluded that arthroplasty was clearly superior to IF. The comparison between bipolar HA and THA included 138 patients and the 2-year results for THA appeared to be better than those for bipolar HA. However, the authors concluded that their finding was based on a relatively small number of patients and recommended that it should be replicated in other trials. Another circumstance which may affect the interpretation of their results is that, actually, only 84% of the patients in the THA group underwent the allocated operation. Finally, Baker et al.³⁰ compared a cemented unipolar HA with a cemented THA in 81 patients. The functional outcome, based on the Oxford hip score⁶⁷ and self-reported walking distance, significantly favored the THA group, while the HRQoL according to SF-36⁶⁸ did not differ significantly between the groups.

After the latest update of the Cochrane review in Dec. 2009, 2 additional RCTs comparing HA and THA have been published. The study by Macaulay and co-workers⁶⁹ included 40 patients randomized to either HA (unipolar or bipolar) or THA. Although the overall results for hip function, as assessed by HHS and WOMAC⁷⁰ and HRQoL according to SF-36, were in favor of the THA group, the differences were not statistically significant, most probably due to a lack of study power. However, some of the subscores, such as the WOMAC function subscore and the SF-36 bodily pain

subscore, were reported to be significantly better in the THA group. In 2010 Bekerom et al.⁷¹ reported the 5-year outcome for patients randomized to treatment with a THA or a bipolar HA. The overall conclusion of the study differs markedly from other RCTs. Because of a higher intraoperative blood loss, an increased duration of the operation, and a higher number of early and late dislocations, the authors do not recommend THA as the treatment of choice in patients aged ≥ 70 years with a fracture of the femoral neck. The overall dislocation rate in the THA group was as high as 7%, which may be explained by the use of the posterolateral approach in almost 20% of the patients. The dislocation rate among those operated upon via an anterolateral approach was 1% compared to 19% among those operated upon using a posterolateral approach. The high dislocation rate may be one explanation for the surprisingly low HHS score in the THA group, i.e. 75, which is substantially lower than our results after 4 years with a score of 89 (*Study 1*). On the other hand, the HHS score in the bipolar HA group, 72, was almost at par with our results after 4 years, i.e. 75 (*Study I*). It has been shown that dislocations, especially recurrent ones, have a negative influence on the patients' perception of their quality of life due to their impaired hip function.⁷²

The better hip function in favor of the THA group reported at 1 year²⁹ persisted and appeared to increase during the following 3 years, resulting in a difference of almost 14 points in the HHS at the final 4-year follow-up in *Study I*. This difference in hip function is clinically relevant and is the most likely explanation for why patients in the THA group assessed their HRQoL to be better than the HA group did at the final follow-up. Our results also confirm the findings of previous RCTs,^{20, 30-31, 69} showing that a THA provides better hip function than an HA and that this difference in favor of THA probably increases with time.

There were an increased number of hip complications, although not differing significantly, in the THA group: 3 compared to 1. However, 2 of these complications, the periprosthetic fracture and the late hematogenous infection, could not be related to the surgical method *per se*, while, theoretically, the early deep infection could be related to the fact that THA is a slightly more time-consuming surgical procedure. In conformity with our results, none of the previous modern RCTs^{20, 30, 69} comparing THA and HA have shown a significantly increased risk of hip complications after THA. This may partly be explained by a lack of power in all studies to detect differences regarding this issue. On the other hand, even if there is a minor increase in the risk of hip complications after THA as compared to HA, the risk-taking may be justified, considering the better hip function after THA, especially in active patients with a long life expectancy.

There were no dislocations in any of the groups during the 4-year follow-up, thus confirming that dislocation is not a major problem when using an anterolateral approach. Another important factor explaining the absence of dislocations was that we opted not to include patients with severe cognitive dysfunction. Patients with cognitive dysfunction are not the target population for THA owing to a reported increased risk of dislocation after the procedure¹⁷ and also to an increased risk of complications and a shorter life expectancy.⁷³⁻⁷⁴

BIPOLAR HEMIARTHROPLASTY VS. UNIPOLAR HEMIARTHROPLASTY

The results of *Study II* did not demonstrate any differences regarding complications, hip function, and HRQoL in elderly patients with a displaced fracture of the femoral neck randomized to either a unipolar HA or a bipolar HA. However, already after 1 year, radiological signs of acetabular erosion were significantly more frequent after the unipolar HA than the bipolar HA, i.e. 20% vs. 5%. Furthermore, acetabular erosion appeared to have a negative effect on functional outcome and HRQoL. Overall, the outcome in both groups was good considering the old (mean age, 86 years) and frail study population.

Our overall results displaying no differences in complications, hip function, and HRQoL are in conformity with the previous 4 RCTs comparing cemented unipolar HA with cemented bipolar HA. Cornell et al.³⁴, 1988, reported no differences in functional outcome in a small study including 48 patients with a 6-month follow-up. Calder and co-workers,³⁷ 1996, published the results of a study including 250 patients, all aged 80 years or more, with a 1.5–2-year follow-up. A higher proportion of patients returning to their preinjury condition was found in the unipolar HA group, but no other differences were found. Davison et al.³⁵, 2001, presented the results from the same study for the 187 patients aged 65–79 years with a minimum 2-year follow-up. No differences between randomization groups were reported, but the interpretation is limited by the fact that 18% of the patients were lost to follow-up. Finally, Raia et al.³⁶, 2003, reported the results of a study including 115 patients randomized to a more modern cemented unipolar HA or bipolar HA with identical stems. At the 1-year assessment there were no significant differences between the groups in terms of surgical complications, functional outcome, or HRQoL according to the SF-36. In our study (*Study II*) there was a trend towards better HRQoL according to the EQ-5D at 4 months in the bipolar HA group, but the difference in favor of the bipolar HA was more limited at the 12-month follow-up and not significant. The EQ-5D_{index} score of 0.63 at 12 months for the bipolar HA group was equal to what we previously reported for patients treated with a bipolar HA (*Study I*) and, as expected, both groups reported a significant deterioration in their quality of life compared to before the fracture.

The percentage of hip complications in *Study II*, although not statistically significant, was higher in the bipolar HA group, i.e. 10%, compared to 5% in the unipolar HA group. The main difference was due to 3 patients in the bipolar HA group sustaining a periprosthetic fracture owing to a new fall during the first 2 months after the index operation. As identical prosthetic stems were used in both groups, this particular complication can hardly be blamed on the bipolar design. The other hip complications occurring, i.e. deep infection and prosthetic dislocation, were evenly distributed between the groups. The overall dislocation rate was 2.5%, which is what can be expected after an HA performed using the anterolateral approach.³³ The number of general complications apart from mortality did not differ between groups, but there was a trend towards a higher mortality rate in the bipolar group, i.e. 22%, compared to 12% in the unipolar group. This difference in mortality rate is explained by the random selection of a higher proportion of men to the bipolar group, i.e. 30%, compared to 18% in the unipolar group. As expected, the mortality rate was significantly higher among male patients, i.e. 35%, compared to 11% among female patients. This higher mortality

rate among male hip fracture patients is well known and has been confirmed by earlier studies.⁷⁴

ACETABULAR EROSION

In *Study II* we found an increased rate of acetabular erosion after the unipolar HA as compared to the bipolar HA, i.e. 20% vs. 5% after 1 year. In *Study I* with a 4-year follow-up, the rate of acetabular erosion after bipolar HA had increased to 14%. In *Study II* comparing the unipolar and bipolar designs there was a trend towards worse hip function and a lower HRQoL among patients with acetabular erosion at 1 year, a finding that was not confirmed in *Study I* comparing bipolar HA and THA.

Acetabular erosion has been considered to be one important factor for impaired hip function and, in previous reports, the rate of acetabular erosion has ranged from 2%³⁷ to 36%⁷⁵ for unipolar designs and from 0%³⁷ to 26%⁷⁶ for bipolar designs.

There is only one previous study reporting acetabular erosion based on a systematic radiological follow-up and also introducing the same grading system as in the present study. Baker et al.³⁰ reported acetabular erosion in 21 out of 32 patients treated with a unipolar HA after a mean follow-up of 39 months, giving an overall rate of acetabular erosion of 66%. The erosion was assessed as grade 1 in 13 patients, grade 2 in 8, and grade 3 in 2 patients. These results are in sharp contrast to those of *Study I* with only 14% acetabular erosion 4 years after a bipolar HA. One possible explanation for the difference between the two studies is the patients' activity level as reflected by age. The mean age at inclusion in the study by Baker et al.³⁰ was 75 years, compared to 81 years in our study. This opinion is supported by the study by D'Arcy and Devas⁷⁷ including 361 femoral neck fractures in 354 patients treated with a cemented unipolar HA where the rate of acetabular erosion was highest and the clinical results worst in the younger patients. Another, perhaps even more important explanation, is the different prosthetic designs used in the studies, unipolar versus bipolar. This explanation is supported by the results from *Study II* with a rate of acetabular erosion of 20% already after 1 year after a unipolar HA compared to 5% after a bipolar HA.

Does the increased rate of acetabular erosion have any implications for clinical practice? Considering the advanced age of the population in *Study II*, mean 86 (range 80–100) years, and a mortality rate of 17% after 1 year, it is uncertain whether this increased rate of acetabular erosion after the unipolar HA will result in a substantial deterioration in hip function and quality of life during the patients' remaining life span. On the other hand, the expected mean survival of an 80-year-old Swedish woman and man in Sweden is, 9.5 and 7.8 years, respectively.⁷⁸ These figures indicate that even in this very old population, some of the patients will probably experience problems due to acetabular erosion, while it is less likely that the wear of polyethylene in the bipolar head would result in symptomatic loosening of the prosthesis. Moreover, unipolar HAs are frequently used today in patients considerably younger than 86 and these younger, probably more active patients, will more likely experience problems related to acetabular wear.

There are studies on earlier designs of the bipolar prosthesis showing that the bipolar HA already functions as a unipolar HA a few months (3–12) after surgery,⁷⁹⁻⁸⁰ but the results of *Study II*, displaying a significantly higher rate of acetabular erosion in the unipolar HA group, indicate that there is a real advantage in favor of the bipolar design,

which is most probably due to the function of the dual-bearing system. In the most frequently used sizes, the increment for the unipolar head was 1.5 mm and for the bipolar head 1.0 mm. In our opinion, this small difference in size will not significantly affect the surgeon's ability to optimally match the acetabular dimension. However, there was a lower size limit on available bipolar heads. Under this size the inner polyethylene lining becomes too thin. This is reflected in *Study II* by the 2 patients randomized to a bipolar HA who had a primary unipolar HA because their acetabulum was smaller than the smallest available bipolar head. It is possible to circumvent this particular problem by using a 22-mm inner head, which is currently available for the Exeter® bipolar HA and gives a smallest outer diameter of 41 mm.

There were no inter-prosthetic dissociations in the bipolar HA groups in *Studies I* and *II*, thus supporting the notion that this is not a problem with modern bipolar prosthetic designs.

Another interesting finding in *Study II* was that acetabular erosion occurred more frequently in patients with a low BMI (< 24) than in those with a high BMI (> 24), i.e. in 21% compared to 5%. The explanation is unclear. It would be understandable if a high body weight resulted in increased acetabular wear, but there is obviously some other more important mechanism in operation. One possible mechanism could be osteoporosis. We know that low weight is associated with osteoporosis,⁸¹ but since we did not evaluate the degree of osteoporosis with DXA in our patients, this remains a hypothesis.

DISLOCATIONS AFTER TOTAL HIP ARTHROPLASTY

The dislocation rate of 2% after the anterolateral approach in *Study II* was similar to that reported for THA using the anterolateral approach previously. Tidermark et al.²³ reported a 2% dislocation rate after THA in an RCT comparing IF and THA and there were no dislocations in any of the arthroplasty groups in *Study I* comparing bipolar HA and THA. These figures are similar to the 1% dislocation rate reported for all arthroplasties in the multicenter RCT by Keating et al.²⁰, comparing IF, bipolar HA, and THA. A higher dislocation rate (8%) was reported by Baker et al.³⁰ in an RCT comparing IF with THA also using the anterolateral approach.

The significantly higher dislocation rate after the posterolateral approach in *Study III* with (12%) and without posterior repair (14%), was of the same magnitude reported for the THA group in RCTs utilizing the posterolateral approach. Skinner and co-workers,²⁸ reported a 13% dislocation rate for THA in an RCT comparing IF, unipolar HA, and THA. In a 13-year follow-up of the same patient population, the dislocation rate in the THA group had increased to 20%.¹⁹ This cumulative long-term risk of dislocation has been highlighted in other recent studies.^{39, 82} In another RCT comparing IF and THA, Johansson et al.¹⁷ reported a 22% dislocation rate after THA.

Two thirds of the patients had at least one recurrent dislocation after the first closed reduction. Furthermore, revision surgery due to instability was performed in 11 out of 41 of the patients during the study period, which was slightly lower than the 35% reported by Woo and Morrey in a study with a similar follow-up period.⁴⁰ These high figures underline the fact that instability is a severe complication often necessitating major revision surgery in order to regain stability, a procedure that is far from always

being successful. Woo and Morrey reported that the instability persisted in one third of the hips revised due to recurrent dislocations.⁴⁰

Repair of the posterior structures, i.e. the short external rotators and/or the posterior joint capsule, has been reported to increase stability after a posterolateral approach. In a recent meta-analysis by Kwon et al.⁸³ comprising 4115 patients from 5 studies, the dislocation rate for THA was 0.5% for patients with a posterior repair and 5% for those without. However, the conclusion that a posterior repair greatly reduces the risk of dislocation is probably most valid for patients with degenerative joint disease. Only two of the included studies reported on the preoperative diagnosis and, in those, only a minority of the patients were ones with fractures of the femoral neck or with sequelae after femoral neck fractures, 5% and 15%, respectively.

Factors influencing the stability of an HA in patients with femoral neck fractures with special reference to the surgical approach within the context of a prospective cohort trial have recently been reported.³³ Although the patients selected for HA were generally older, 84 years, and less active than patients selected for THA in *Study III*, the comparisons between the two studies are of interest. Also after HA, the anterolateral approach was associated with a significantly lower risk of dislocation than the posterolateral approach with or without posterior repair, i.e. 3%, 9%, and 13%, respectively. The multivariable regression analysis showed that the posterolateral approach was the only factor associated with an increased risk for dislocation and the results also showed a trend towards improved stability with a posterior repair. The positive effect of a posterior repair in patients treated with an HA could not be confirmed in *Study III* on THA.

A larger femoral head size has been suggested to reduce the risk of dislocation. This has been reported in clinical studies⁸⁴⁻⁸⁶ as well as in experimental ones⁸⁷, while some studies have not demonstrated this positive effect.⁴⁰ Our univariable regression analysis suggested a lower dislocation risk for the 28-mm head than for the 22-mm head.

However, this finding was explained by the fact that the majority of the patients operated upon with a 22-mm femoral head were operated upon using a posterolateral approach, and the finding could not be verified in the multivariable analysis. Perhaps the size of the head needs to be over 28 mm in order to improve the stability.⁸⁶ On the other hand, most of the fracture patients are females and, in a considerable number of patients, we have used an acetabular component with an outside diameter of 40 mm. Increasing the femoral head size to 32 mm or more might reduce the thickness of the polyethylene to a critical level and could thereby jeopardize the long-term outcome.

We did not find any difference in the dislocation rate between primary and secondary THAs, which is in contrast to some previous studies. In a prospective case-control study, McKinley and Robinson¹² reported an increased number of dislocations after a secondary THA (20%), compared to a primary one (8%), all being performed via a posterior approach. A similar finding was reported by Woo and Morrey,⁴⁰ i.e. 12% after a secondary THA and 9% after a primary one. There are no obvious reasons why a secondary THA should have an increased dislocation rate. On the one hand, the surgical procedure during a secondary THA is often more technically demanding. In addition, these patients have often suffered a long time with pain and disability before the secondary THA, probably resulting in poor muscle function. On the other hand, the secondary THA is usually an elective procedure with an optimized patient. Moreover, the stiff joint capsule developed during the often long time to failure of the internal

fixation may also decrease the risk of instability, comparable to that of patients with a degenerative joint disease.

It has been reported that inexperienced surgeons have a higher incidence of dislocation than more experienced ones.⁸⁸ We could not confirm this finding, which may be due to the fact that the routine at our department requires that an inexperienced surgeon is always assisted by a more experienced one.

RESPONSIVENESS OF THE SMFA

The focus of *Study IV* was on evaluating the responsiveness of the SMFA in patients with hip fractures. The results showed that the responsiveness, defined as the ability of the SMFA to detect clinically important changes,⁸⁹ was found to be generally good. Both the Dysfunction and the Bother SMFA Indices displayed good internal responsiveness as expressed by significant change scores and by moderate to large SRMs. The external responsiveness of both SMFA indices was also acceptable as indicated by the ROC curve and logistic regression analyses showing that both indices were able to discriminate between patients with a less good outcome versus a moderately good or good outcome based on the EC. However, the ability of the SMFA Indices to differentiate between patients with a moderately good versus a good outcome could not be confirmed.

The SMFA was developed as an instrument to be used for a wide range of patients with common musculoskeletal disorders seen in clinical practice.^{47, 90} Previous studies have shown that different injuries appear to have a similar functional impact as seen from the patient's perspective.⁹¹⁻⁹⁵ However, as far as we know, there are no previous published studies focusing specifically on patients with hip fractures.

On looking at the prefracture SMFA ratings of our study population, it can be noted that, in comparison to the North American “uninjured” population normative values for the age group > 60 years,⁹⁶⁻⁹⁷ our patients had somewhat better (lower) scores. This fact can either be regarded as confirmation that our patients were rather healthy before the hip fracture or that their prefracture ratings were affected by recall bias, i.e. the patients considered themselves healthier before the fracture than they actually were. We asked the patients during hospitalization to rate retrospectively their health status the week before the fracture. Since a prospective collection of baseline data for a specific injury population is impossible, the alternative methods often used are preinjury recall, used in this and other trauma studies⁹⁸⁻¹⁰⁰, and/or population values. In our previous studies on hip fracture patients,⁹⁹⁻¹⁰⁰ we have used the same approach for the EQ-5D⁵⁷ and found that the patients’ ratings were very similar to those of an age-matched Swedish reference population.⁵⁹ Moreover, there is a recent study reporting that older patients can accurately recall their previous health status up to 6 weeks.⁶⁰ Therefore, we believe that the effect of recall bias can be considered to be limited and that it is more likely that our somewhat lower SMFA values were related to a generally healthy elderly population. Our patients were independent walkers from independent living conditions without serious comorbidities and were assessed by the anesthesiologist to be fit enough for a primary hip arthroplasty, meaning that there were no other serious current health problems that would affect their preinjury SMFA scores.⁹⁶

Previously published SMFA data suggest that the patients' opinion of the total negative impact of a musculoskeletal injury on functional outcome is higher than what is generally expected and relatively often in contrast to traditional physician-oriented clinical outcome assessments.⁹⁶ As expected, the SMFA scores of our patients were significantly higher (worse) at 4 months compared to their preinjury ratings. A comparison with previous studies is difficult since there are only a few papers reporting longitudinal SMFA data^{96, 101} and, as far as we know, only one on hip fracture patients. In a recently published retrospective cohort study with a mean 50-month follow-up on 26 multitrauma patients with ipsilateral intertrochanteric hip and femoral shaft fractures, Peskun and co-workers¹⁰² reported results on the Dysfunction Index that were comparable to ours, while their results for the Bother Index were worse, probably reflecting the outcome after a more severe injury in a multitrauma population.

The internal responsiveness was good for both the Dysfunction and Bother Indices based on the relatively large observed change between the prefracture status and the 4-month follow-up and the moderate to large SRMs, moderate for the Bother Index and large for the Dysfunction Index. The internal responsiveness can be quantified by the standardized effect size (SES) and/or the SRM. As previously stated,⁹⁹ the SRM is probably the preferred statistical measure as it employs the standard deviations of the change scores as the denominator, which may be advantageous in comparison with the often used SES, where the standard deviation of the baseline scores is used, and thus does not reflect changes over time. As mentioned earlier, a relatively large decline in function can be expected during the early phases of rehabilitation after a hip fracture and, regarding internal responsiveness, this relatively large change in the present study may make an evaluation of the ability of the indices to detect smaller changes in function more difficult. However, we interpret the large change scores and SRMs for the SMFA indices as an indication of their responsiveness even to smaller changes in function.

With regard to the ROC curve and logistic regression analyses, both indices yielded relatively similar and significant results, providing support for the external responsiveness of both indices to discriminate between patients with a less good outcome in relation to patients with a moderately good or good outcome. However, the changes in both of these SMFA Indices could not significantly differentiate between patients with a good outcome versus a moderately good outcome. This may be due to the differences in item content of the SMFA versus the HHS and that it takes a more pronounced change in the HHS to be reflected in the SMFA indices. Furthermore, the group with a "less good outcome" comprise a larger span of values (all values below a score of 74.4 on the HHS), i.e., the most deteriorated patients.

There is no consensus on the construction of the EC except that it should reflect clinically important differences between patients. In our study we used the HHS score from the 4-month follow-up as the EC since, according to the inclusion criteria, the patients did not have any current hip problems before the fracture event. This appears to be reasonable since very few patients had pronounced problems with their mobility and ADL, or suffered from other comorbidities. Consequently, the HHS scores at the 4-month follow-up were thought to mirror changes in hip function.

To construct the EC, we used a distributional method, i.e., half a standard deviation above and below the mean, to define patient groups with clinically meaningful differences in outcome. As recommended in a recent review by Revicki et al.,¹⁰³ the

best way to find minimally important differences (MIDs) for an instrument is to consult several sources of information to find relevant cut-off scores. Optimally, so-called anchor-based methods should also be used in this quest. However, since no anchor-based recommendations could be found in the literature for the HHS, we chose the described method. Half a standard deviation appears to be a reasonable estimate of a clinically meaningful difference.¹⁰³⁻¹⁰⁵ Nevertheless, the paucity of recommended cut-off scores in this respect for the HHS can be regarded as a limitation of the study and we admit that the search for clinically meaningful differences can be both problematic and a great challenge.¹⁰⁶

No ceiling effects for any of the SMFA indices were noted, i.e. none of the patients had the worst possible state of health before the injury, which is reasonable considering the health status of the study population. The floor effect, meaning that the patient had the best possible score, was more pronounced. Two percent of the patients reported the best possible score on the Dysfunction Index while almost 28% reported the best possible score on the Bother Index, i.e. 28% of the patients did not worry about their musculoskeletal function prior to the fracture. This may reflect a good level of social service and support for these patients as well as it may indicate that they have adjusted to their current functional level. The floor effect is not expected to be a problem in elderly patients with hip fractures, a condition with major morbidity, but it could be a potential limitation in longitudinal studies where the studied injury/disease may influence functional outcome to a lesser extent than a hip fracture.

The focus of the SMFA is the function of the musculoskeletal system and it thereby offers an opportunity to study patient groups with different injuries/diseases affecting the musculoskeletal system by using the same measure. However, in our opinion, the SMFA should be used preferably together with a validated instrument assessing HRQoL. This gives us the opportunity to compare the outcome with that of patients suffering from injuries/diseases not solely affecting the musculoskeletal system, e.g. using the EQ-5D, which is brief and easy to use in elderly patients¹⁰⁷ and has been validated in hip fracture patients¹⁰⁸ and displayed good responsiveness.⁹⁹⁻¹⁰⁰ Moreover, it also allows combining different dimensions of health to form an overall index, the EQ-5D_{index} score, as required for healthcare evaluations⁴⁴ and for constructing quality-adjusted life years (QALYs), a measure frequently used in cost-effectiveness analyses.

In conclusion, our study demonstrates that the SMFA had good internal and external responsiveness in patients with hip fractures and can therefore be recommended to be used as one of the measures for evaluating the outcome after a hip fracture in both clinical studies and clinical practice.

STRENGTHS AND LIMITATIONS

The strengths of *Studies I* and *II* were the randomized controlled design, the well-defined population, the use of validated outcome instruments, mostly self-reported, and the high follow-up rate. Moreover, acetabular erosion was assessed by a radiologist blinded to the clinical outcome and using a previously published grading system for acetabular erosion. A limitation of the studies was that, although all clinical variables except hip motion were assessed by an unbiased observer, this observer was not

blinded to the type of surgical intervention, which may add a risk of bias. However, as most of the outcome measures, including EQ-5D and HHS, except for range of motion, were self-reported, the risk of bias is assumed to be limited. Furthermore, the fact that our interpretation of the quality-of-life data is based on our patients' ability to correctly recall their health status prior to the hip fracture may be considered a weakness. However, since it is not possible to collect preinjury HRQoL data prospectively in trauma studies, we have to rely on preinjury recall or a comparison with population figures. Our patient-assessed prefracture EQ-5D_{index} score was slightly higher than in comparable age groups of the Swedish reference population,⁵⁹ which may be explained by our inclusion criteria, which selected healthier elderly individuals. Furthermore, a recent study reports that older patients can accurately recall their previous health status for up to 6 weeks.⁶⁰ Therefore, we believe that the effect of recall bias can be considered to be limited. In summary, we believe our results are representative of this patient population and that our conclusions are valid.

A limitation of *Study III* was the lack of a preoperative assessment of cognitive function based on a validated instrument. Cognitive dysfunction seems to be a substantial risk factor for dislocation in hip fracture patients treated with a THA¹⁷ and we have for a long time avoided performing THA on patients with severe cognitive dysfunction/dementia. Only 3% of our patients had diagnosed dementia, and there did not seem to be a selection bias with regard to dementia to any of the approaches. However, performing a THA may be necessary in individual patients with severe cognitive dysfunction/dementia, e.g. in patients with severe pain due to AVN. Another limitation of *Study III* was that the implant position was not assessed. Theoretically, the higher dislocation rate after the posterolateral approach may, besides from the soft tissue injury, partly be a result of a higher frequency of poorly positioned implants. However, the condition for optimal implant position is an important characteristic of the surgical approach. The strengths of *Study III* were the large number of consecutively entered patients, the relatively long follow-up time, and the validation of dislocation data via the Swedish National Board of Health and Welfare's nationwide registry. Since this particular issue is difficult to assess within the context of a conventional randomized study, a large prospective cohort trial such as the present one, including consecutive patients and in which the selection of the surgical approach at each point in time was determined by the individual surgeon's preference, is a good approach only surpassed in quality by a trial using randomization by surgeon. Therefore, we have good reason to assume that our conclusions regarding the studied risk factors for dislocation are valid for this patient cohort.

A limitation of *Study IV* was the relatively small sample size; however, the power of the study appeared to be sufficient to support the conclusion that the SMFA has a good internal and external responsiveness in elderly patients with hip fractures. The strength of *Study IV* was that the questionnaire was completed by the patients within a prospective trial with a high follow-up rate.¹⁰⁹ An additional strength is that we have reported the data elements for the SMFA, as recently recommended by Barei et al.,⁹⁶ thereby providing the possibility of future pooling of SMFA data from several studies including patients of different ages with different injuries/diseases affecting the musculoskeletal system. In summary, responsive outcome measures are necessary for evaluating the efficacy and effectiveness of patient care. For instance, an outcome instrument with unknown or unsatisfactory responsiveness for a specific condition may

not be able to detect a favorable outcome for a certain treatment and lead the researchers to draw the erroneous conclusion that the treatment was ineffective. Therefore, evaluating the responsiveness for different outcome instruments in defined patient populations, preferably within the context of a prospective trial, is an important task for research.¹⁰⁹ Moreover, several methods are available to evaluate responsiveness^{49, 109} and, accordingly, in this study we have employed a number of these methods to assess responsiveness in a comprehensive manner.

CONCLUSIONS

STUDY I

The results of the study confirmed the better outcome for hip function and quality of life after THA as compared to HA in elderly, lucid patients with a displaced fracture of the femoral neck. The results imply that THA should be the preferred treatment method for the active, relatively healthy patient with a long life expectancy. However, the low rate of acetabular erosion after four years and the relatively good hip function after a modern bipolar HA imply that a bipolar HA may suffice as treatment for the oldest patients with lower functional demands.

STUDY II

The results of the study showed that unipolar HA and bipolar HA appeared to produce equivalent clinical outcomes regarding hip function and quality of life after one year, but the significantly higher incidence of acetabular erosion in the unipolar HA group may imply that bipolar HA should be the preferred treatment.

STUDY III

The results of the study showed that the anterolateral surgical approach was associated with a significantly lower risk of dislocation than the posterolateral approach with or without posterior repair. In order to minimize the risk of dislocation, we recommend the use of the anterolateral approach for THA in patients with femoral neck fractures.

STUDY IV

The SMFA had good overall responsiveness in patients with hip fractures and, based on our results, we conclude that the SMFA can be recommended for use as one of the measures to evaluate the outcome after a hip fracture.

IMPLICATIONS FOR PRACTICE

Based on the results of studies in this thesis and previous research,^{8, 10, 20, 23, 30, 69} we recommend an arthroplasty performed using an anterolateral approach³² for elderly patients with a displaced femoral neck fracture.

For the active, relatively healthy patient with a long life expectancy and without severe cognitive dysfunction, a THA is recommended, and, for the oldest patients with lower functional demands, an HA.

Which type of HA should we select for the most elderly patients with displaced fractures of the femoral neck? Based on the results of our study and previous ones,³⁴⁻³⁷ there does not appear to be any clinical disadvantage with the bipolar design. On the contrary, the results of our study showed that the rate of acetabular erosion was significantly lower after the bipolar HA, which in turn may indicate an advantage for the bipolar design in the longer time perspective. The only factor that really challenges the bipolar design is the marginally higher cost. Since there were no differences in duration of surgery, need for blood transfusions, hospital stay, and complications, this difference probably represents the total difference in primary costs for the two treatment modalities. This investment may well be justified in order to reduce the risk of future problems owing to acetabular erosion in elderly patients who surpass our expectations regarding life expectancy and functional level.

ABSTRACT IN SWEDISH

Syftet med denna avhandling var att analysera höftfunktion och hälsorelaterad livskvalitet hos patienter med felställd fraktur på lårbenshalsen som opererats med cementerad total höftledsplastik (THA) eller halvplastik (HA), unipolär eller bipolär. Syftet var dessutom att analysera faktorer som påverkar stabiliteten av THA speciellt med avseende på den kirurgiska snittföringen och att utvärdera responsiveness för utvärderingsinstrumentet Short Musculoskeletal Function Assessment (SMFA), dvs dess förmåga att uppfatta kliniskt viktiga förändringar hos patienter med brott på lårbenshalsen.

I en 4-års uppföljning av en randomiserad kontrollerad studie (RCT) fördelades slumpvis 120 äldre patienter, medelålder 81 år, med ett felställt brott på lårbenshalsen, till operation med antingen THA eller bipolär HA (*Studie I*). Resultaten bekräftade det bättre utfallet avseende höftfunktion och hälsorelaterad livskvalitet efter THA jämfört med HA i ett längre tidsperspektiv.

I en RCT, randomiserades 120 äldre patienter, medelålder 86 år, med en felställd fraktur på lårbenshalsen, till operation med antingen unipolär HA eller bipolär HA (*Studie II*). Studien visade att unipolär HA och bipolär HA tycktes ge likvärdiga kliniska resultat när det gäller höftfunktion och hälsorelaterad livskvalitet efter ett år, men med en signifikant högre förekomst av acetabular erosion (slitage av ledskålen) i den unipolära HA gruppen.

I en kohortstudie inkluderades 713 konsekutiva höfter i en serie på 698 patienter som genomgått en primär operation med THA (n = 311) pga ett felställt brott på lårbenshalsen eller en sekundär operation med THA (n = 402) pga en läkningskomplikation efter ett brott på lårbenshalsen (*Studie III*). Resultaten visade att främre snittföring var förknippad med en signifikant lägre risk för protesluxation (urledvridning) än bakre snittföring med eller utan sutur av de bakre kapselstrukturerna. För att utvärdera responsiveness hos SMFA inkluderades de 120 patienterna från *Studie I* i ytterligare en studie (*Studie IV*). Intern responsiveness hos SMFA utvärderades genom att beräkna den observerade skillnaden och standardized response mean (SRM) i förhållande till förändringen i Dysfunction Index och Bother Index. För att beräkna extern responsiveness konstruerades ett externt kriterium (EC) baserat på Harris Hip Score. Receiver Operating Characteristic (ROC) kurvor och logistisk regressionsanalys användes i utvärderingen. Resultatet av studien visade att SMFA uppvisade god intern responsiveness och acceptabel extern responsiveness hos patienter med brott på lårbenshalsen.

Sammanfattningsvis rekommenderas THA som primär behandling hos de aktiva, friska äldre patienterna med en fraktur på lårbenshalsen och samtidig förväntad lång återstående livslängd. Hos de allra äldsta patienterna verkar bipolär HA och unipolär HA ge lika bra kliniska resultat i det kortare tidsperspektivet, men fyndet av betydligt högre förekomst av acetabular erosion i den unipolära HA-gruppen kan innebära att bipolär HA bör vara att föredra som behandling. För att minimera risken för protesluxationer rekommenderar vi dessutom användning av främre snitt vid operation med THA hos patienter med brott på lårbenshalsen. Slutligen kan SMFA rekommenderas för användning som ett av mätinstrumenten för att utvärdera resultat efter behandling av ett brott på lårbenshalsen.

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HR² = Human Relations x Hazard Ratio

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ORIGINAL PAPERS I-IV

- I. Comparison of bipolar hemiarthroplasty with total hip arthroplasty for displaced femoral neck fractures. A concise four-year follow-up of a randomized controlled trial.
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- II. Unipolar hemiarthroplasty versus bipolar hemiarthroplasty in the most elderly patients with displaced femoral neck fractures: a randomised, controlled trial.
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