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OUTCOME IN PATIENTS WITH TROCHANTERIC AND SUBTROCHANTERIC FEMORAL FRACTURES

ASPECTS ON SURGICAL METHODS, QUALITY OF LIFE AND COGNITIVE FUNCTION

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Dedicated to the health of the elderly.

CONTENTS

ABSTRACT

A hip fracture is a significant cause of increased morbidity and mortality in elderly people and Scandinavia presents the highest incidence of hip fractures worldwide. The hip fracture is a serious consequence of osteoporosis which demands acute surgery with a high risk of complications and a threat to a continued independent living. Trochanteric and subtrochanteric femoral fractures constitute approximately 50% of all hip fractures.

The overall aim of the thesis was to evaluate the outcome in patients with stable trochanteric (*Study II*), unstable trochanteric (*Studies I* and *III*) and subtrochanteric (*Studies I* and *IV*) femoral fractures with aspects of the surgical methods, including assessments of functional outcome and the health-related quality of life (HRQoL). Moreover, the aim was to evaluate whether severe cognitive dysfunction could predict functional outcome, HRQoL and mortality (*Study V*).

In an RCT, 217 patients, mean age 84, with an unstable trochanteric or subtrochanteric fracture were allocated to treatment by either a standard Gamma nail (SGN) or a Medoff sliding plate (MSP) (*Study I*). The SGN showed good results in both unstable trochanteric and subtrochanteric fractures. Moreover, the SGN showed a reduced number of severe general complications and wound infections compared to the MSP. The MSP in the biaxial dynamisation mode had a low failure rate in patients with unstable trochanteric fractures but a high failure rate in the smaller group of patients with subtrochanteric fractures.

In a prospective cohort study, 148 patients, mean age 83, with a stable trochanteric fracture treated with a sliding hip screw (SHS) were included (*Study II*). The results confirm a favourable outcome after a stable trochanteric fracture treated with an SHS with a low reoperation rate and a good functional outcome and only limited deterioration in HRQoL.

In a prospective cohort study, 117 patients, mean age 84, with an unstable trochanteric fracture treated with the trochanteric Gamma nail (TGN) were included (*Study III*). The results showed that an unstable trochanteric fracture treated with the TGN had a substantially negative impact on the patient's musculoskeletal function as well as on the patient's HRQoL. The need for revision surgery was low in patients with a 3-part fracture, while the reoperation rate among those with 4-part fractures was significantly higher. The by far most common fracture complication, i.e. a secondary lag screw penetration/cut-out, was successfully treated with a total hip replacement.

In a prospective cohort study, 53 patients, mean age 82, with a subtrochanteric fracture treated with the long Gamma nail (LGN) were included (*Study IV*). The results showed that a subtrochanteric fracture treated with the LGN had a substantially negative impact on the patient's musculoskeletal function as well as on the patient's HRQoL. However, the need for revision surgery was comparatively low.

In *Study V* 213 patients from *Study I* were included. The results showed that a systematic use of a validated instrument for assessing cognitive function, the SPMSQ, identified patients with severe cognitive dysfunction and effectively predicted their outcome regarding walking ability, ADL function and mortality. The results strongly suggest that the SPMSQ can be recommended for use in the elderly hip fracture population in routine health care.

LIST OF PAPERS

This thesis is based on the following papers, which are referred to in the text by their Roman numerals (*Studies I–V*).

I. The standard Gamma nail or the Medoff sliding plate for unstable trochanteric and subtrochanteric fractures. A randomised, controlled trial.
Miedel R, Ponzer S, Törnkvist H, Söderqvist A, Tidermark J.
J Bone Joint Surg Br. 2005 Jan;87 (1):68-75.

II. Quality of life after a stable trochanteric fracture - a prospective cohort study on 148 patients.
Ekström W, Miedel R, Ponzer S, Hedström M, Samnegård E, Tidermark J.
J Orthop Trauma. 2009 Jan;23 (1):39-44.

III. Musculoskeletal function and quality of life after an unstable trochanteric fracture treated with a cephalomedullary nail
Miedel R, Ponzer S, Törnkvist H, Tidermark J.
Submitted.

IV. Musculoskeletal function and quality of life in elderly patients after a subtrochanteric femoral fracture treated with a cephalomedullary nail.
Miedel R, Törnkvist H, Ponzer S, Söderqvist A, Tidermark J.
J Orthop Trauma. 2011 Apr;25(4):208-13.

V. The influence of cognitive function on outcome after a hip fracture.
Söderqvist A, Miedel R, Ponzer S, Tidermark J.
J Bone Joint Surg Am. 2006 Oct;88(10):2115-23.

LIST OF ABBREVIATIONS

ADL	Activities of daily living
AO	Arbeitsgemeinschaft für Osteosynthesefragen
ASA	American Society of Anesthesiologist classification
DCS	Dynamic condylar screw
DHS	Dynamic hip screw
DVT	Deep vein thrombosis
EQ-5D	The 5–dimensional scale of the EuroQoL
EQ-5D index score	The utility score generated from the EQ-5D
Fx	Fracture
GN	Gamma nail
HA	Hemiarthroplasty
HRQoL	Health-related quality of life
IMHS	Intramedullary hip screw
J-M	Jensen-Michaelsen classification for trochanteric fractures
LGN	Long Gamma nail
LPFN	Long proximal femoral nail
MSP	Medoff sliding plate
ns	Not significant
PFN	Proximal femoral nail
QALYs	Quality-adjusted life years
QoL	Quality of life
OTA	Orthopaedic Trauma Association
RCT	Randomised controlled trial
SAHFE	Standard Audit of Hip Fractures in Europe
SGN	Standard Gamma nail
SHS	Sliding hip screw
SMFA	Short Musculoskeletal Function Assessment
SPMSQ	Short Portable Mental Status Questionnaire
TGN	Trochanteric Gamma nail
TAD	Tip-apex distance
THR	Total hip replacement
TTO	Time trade-off
VAS	Visual analogue scale

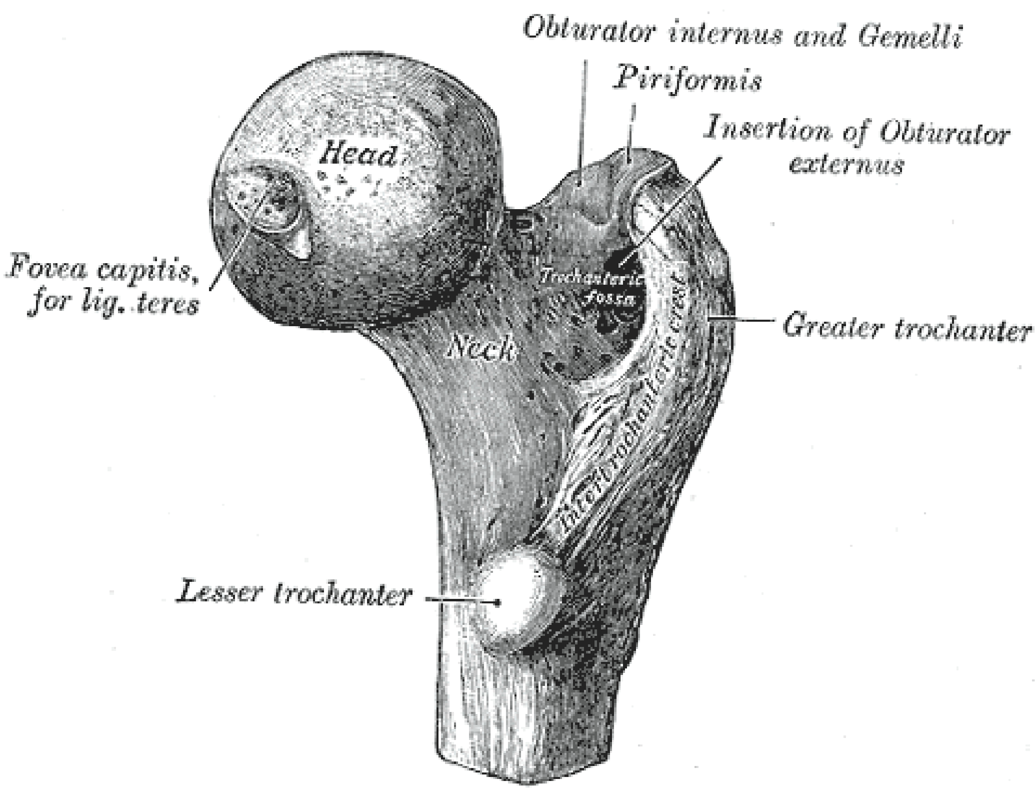
INTRODUCTION

HISTORICAL BACKGROUND

In a historical flashback one of the first descriptions of a trochanteric fracture was given by Astley Cooper, an English surgeon and anatomist, in his treatise from the year 1851 as follows:.'..fracture of the femur through the trochanter major, passes obliquely upwards and outwards from the lower portion of the neck but instead of traversing the neck completely, it penetrates the base of the trochanter major; the line of fracture being such as to separate the femur into two fragments, one of which is composed of the head, neck and trochanter major, and the other of the shaft with the remaining portions of the femur"[1] (**Figure 1).**

He was also the first to distinguish between fractures of the neck of the proximal femur (intracapsular) and those outside of the joint capsule (extracapsular) through the trochanteric level.[2]

Figure 1. The upper part of the right femur viewed from behind and above.



From www.bartleby.com

Cooper recommended treatment such as bed rest, use of crutches or cane and wearing an elevated shoe to help hasten the recovery after a trochanteric fracture. The diagnosis and treatment of trochanteric fractures were later studied by Dupuytren, Malgaigne, Velpeau and Whitman. In 1902 Royal Whitman described the reduction and treatment of trochanteric femoral fractures recommending abduction, traction under anaesthesia, internal rotation and a spica cast for immobilisation.

Healing rates may have been acceptable with non-surgical methods, but mortality and morbidity rates were high due to complications such as pneumonia, pressure sores, muscle atrophy and thromboembolic complications, all associated with prolonged bed immobilisation and inactivity. Another drawback of non-operative treatment was mal-union of the fracture, resulting in leg shortening and/or malrotation and this in turn leading to impaired walking ability. Despite the fact that a number of studies[3-6] demonstrated the advantage of surgery in the treatment of trochanteric fractures, non-operative treatment still persisted as a standard treatment for many years. Even after 1949 when Evans described internal fixation and mobilisation of trochanteric fractures as a life-saving measure, conservative treatment had its pleaders.[7]

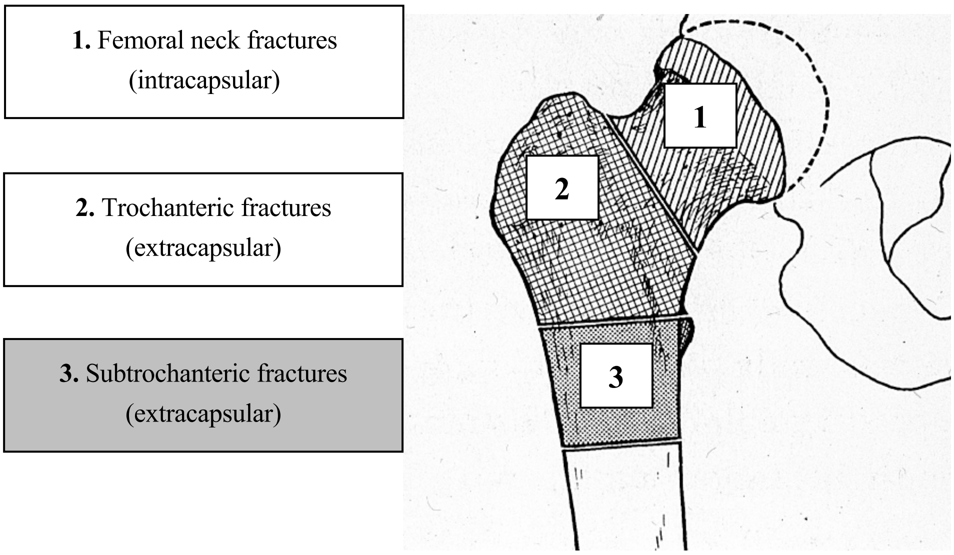
HISTORY OF HIP FRACTURE RESEARCH AT SÖDERSJUKHUSET

The first published thesis from Södersjukhuset on hip fractures was presented by Mats H Nilsson in 1984 pertaining to the treatment of trochanteric fractures using the Ender intramedullary fixation. At that time the use of Ender nails was one of the most prevalent methods in the treatment of trochanteric fractures at Södersjukhuset. The year after, 1985, Akke Alberts presented his thesis on 'Radionuclide Scintimetry after Femoral Neck Fracture with Special Reference to Prediction of the Healing Course'. From the late 1990s a new scientific organisation was gradually built up at the Orthopaedic Department Södersjukhuset, Karolinska Institutet, supporting clinical research. In 2002 Jan Tidermark published his thesis 'Quality of Life and Femoral Neck Fractures' thereby contributing to a paradigm shift in Sweden for the treatment of displaced femoral neck fractures in elderly patients with primary hip replacement instead of internal fixation. Tidermark's work was continued by Richard Blomfeldt in 2006 with the thesis 'Surgical Treatment of Patients with Displaced Femoral Neck Fractures'. Three years later (2009) Anders Enocson defended his thesis, 'Dislocation of Hip Arthroplasty in Patients with Femoral Neck Fractures', analysing factors influencing the stability of hip replacement with special reference to the surgical approach and emphasising the advantage of using the anterolateral approach to avoid dislocations of the prosthesis after hip replacement in patients with femoral neck fractures. In 2011 Carl Johan Hedbeck defended his thesis entitled 'Arthroplasty in Patients with Femoral Neck Fractures', evaluating the different types of arthroplasty in the treatments of patients with displaced femoral neck fractures. As a result of this continuous scientific work, a treatment algorithm for patients with femoral neck fractures has been introduced.

EPIDEMIOLOGY

Trochanteric (pertrochanteric/intertrochanteric) as well as subtrochanteric fractures belong to the group of proximal femoral fractures, i.e. hip fractures, an entity to which also femoral neck fractures is subordinated. Femoral neck fractures constitute 51%, trochanteric fractures 38% and subtrochanteric fractures 8% of all hip fractures[8] (**Figure 2**). The basocervical fracture is a rare fracture in the transition zone between the femoral neck and the trochanteric region constituting only 3% of all hip fractures.[8]

Figure 2. Hip fractures.



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According to the Swedish National Hip Fracture Registry (2009),[8] the proportion of trochanteric fractures appears to increase at the expense of femoral neck fractures.

CLASSIFICATION

In managing fractures in general, it is important to have a reliable classification system. A valid fracture classification should be simple enough to provide guidelines for clinical treatment, comprehensive enough to be used in clinical outcome studies and reasonably reliable and reproducible.[9,10]

In order to classify trochanteric fractures, several classification systems have been published. Most of the classifications are based on the anatomical description of the fracture patterns observed,[7,11] while others are designed to provide prognostic information on the prospect of achieving and maintaining reduction[12] or are based on the fracture mechanism.[13]

One of the most frequently used ones is the Jensen-Michaelsen classification system,[14] which is a modification of the Evans classification.[7] The modified grading proposed by Jensen and Michaelsen was intended to improve the predictive value of the Evans system and to indicate which fractures could be reduced anatomically and which were unstable with a risk of secondary displacement.

The following fracture types can be identified (**Figure 3**):

1. The undisplaced 2-part fracture (J-M 1).
2. The displaced 2-part fracture (J-M 2).
3. The 3-part fracture with a fracture of the greater trochanter (J-M 3).
4. The 3-part fracture with a fracture of the lesser trochanter (J-M 4).
5. The 4-part fracture with a fracture of both the greater and lesser trochanter (J-M 5).

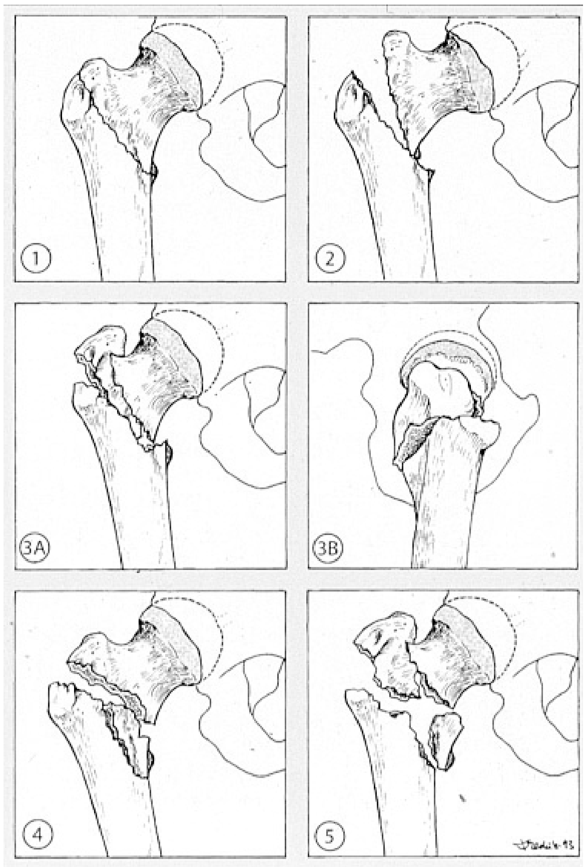

Figure 3. The Jensen-Michaelsen classification for trochanteric fractures.[14]

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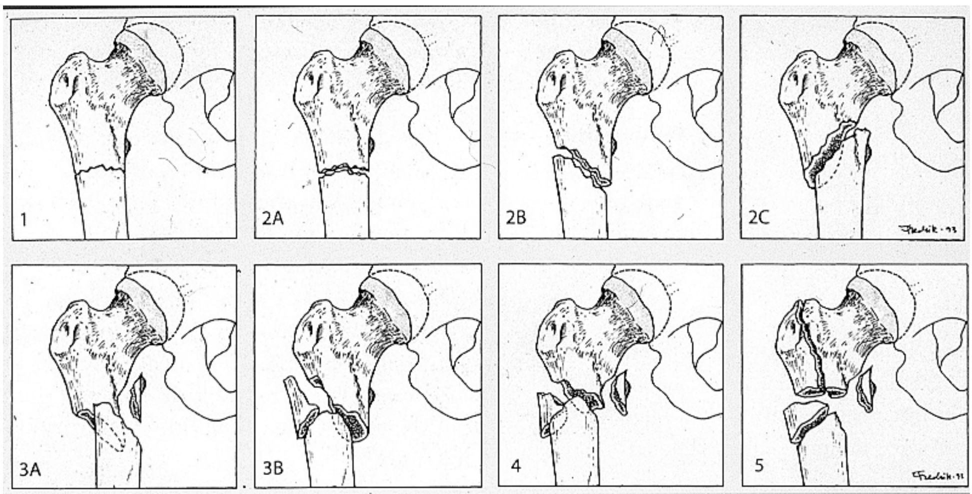
According to the Jensen-Michaelsen classification, the undisplaced 2-part fracture and the displaced 2-part fracture (J-M 1 and 2) are defined as stable. The 3- and 4-part fractures with a fracture of the lesser, the greater or both trochanters (J-M 3-5), are defined as unstable.

The subtrochanteric region of the femur is defined as the region between the lesser trochanter and 5 cm distal to it with or without extensions into the trochanteric region. One of the most frequently used classifications is the Seinsheimer classification.[15]

The following fracture types can be identified (**Figure 4**):

1. The non-displaced fracture with less than 2 mm of displacement of the fracture fragments (S1).
2. The displaced 2-part fracture, which can be classified into the following subgroups:
   2A: the transverse 2-part fracture (S2A)
   2B: the spiral 2-part fracture with the lesser trochanter attached to the proximal fragment (S2B)
   2C: the spiral 2-part fracture with the lesser trochanter attached to the distal fragment (S2C)
3. The 3-part fracture, which can be classified into the following subgroups:
   3A: the spiral 3-part fracture in which the lesser trochanter is a part of the 3rd fragment which has an inferior spike of the cortex of varying length (S3A)
   3B: the spiral 3-part fracture in which the lesser trochanter is not a part of the 3rd fragment (S3B)
4. The comminuted fracture with 4 or more fragments (S4)
5. The subtrochanteric fracture with an extension through the greater trochanter (S5)

Figure 4. The Seinsheimer classification for subtrochanteric fractures.[15]



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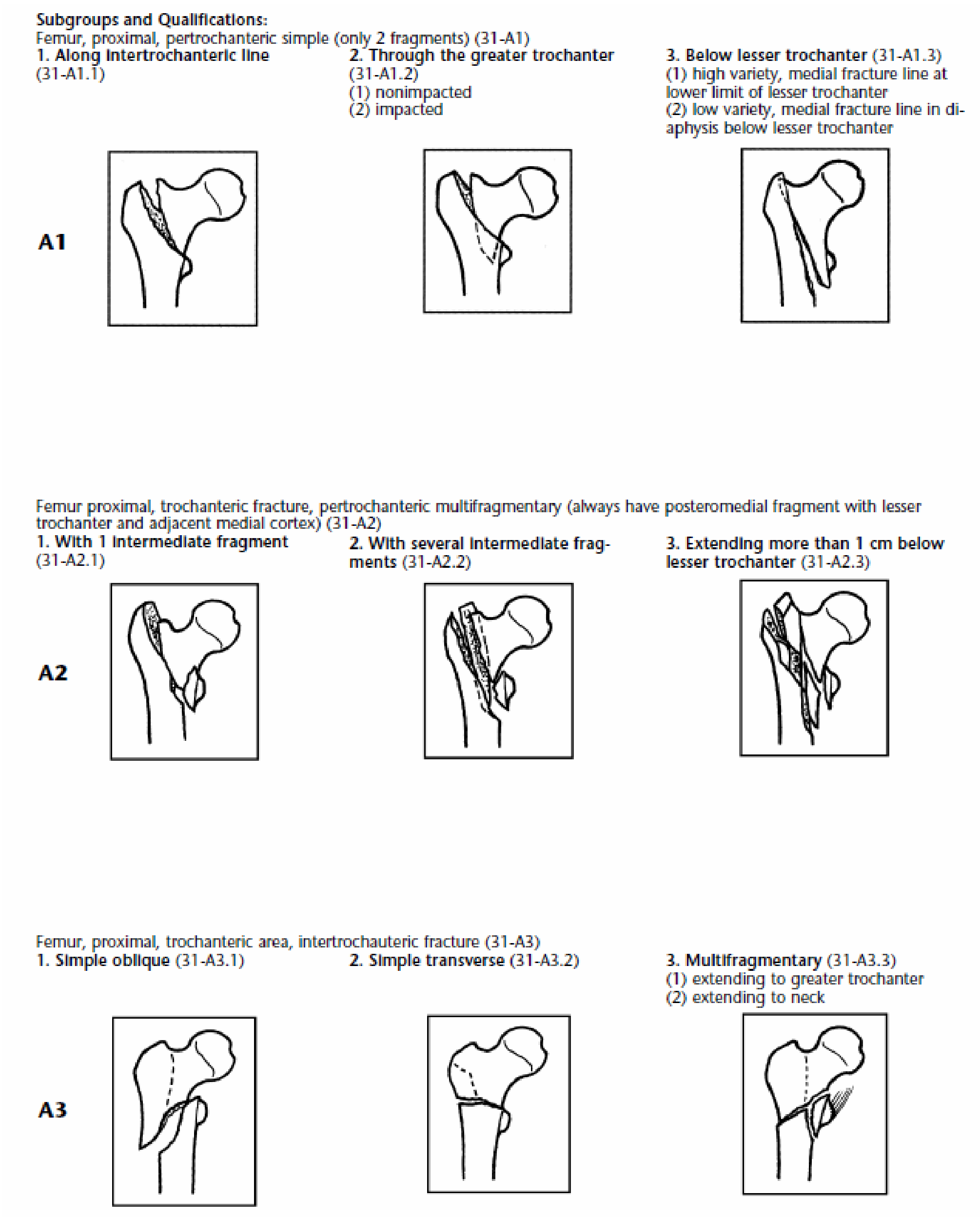
According to the Seinsheimer classification, the 2-part fractures (S1 and S2) are defined as potentially unstable. The 3-part fractures and the comminuted fractures (S3-S5) are defined as unstable.

Another relatively frequently used classification is the OTA classification,[16] which was developed from the AO classification.[17] This classification can be used to classify both trochanteric and subtrochanteric fractures (**Figure 5**).

Figure 5. The OTA classification for trochanteric and subtrochanteric fractures.[16]



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In a comparison between the Jensen-Michaelsen and the AO classification systems for trochanteric fractures, van Embden et al.[18] reported a moderate inter- and intra-observer reliability for the Jensen-Michaelsen classification with kappa values of 0.48 and 0.56, respectively, while the inter- and intra-observer reliability for the AO classification was considered poor with kappa values of 0.40 and 0.43, respectively. Unsatisfactory inter- and intra-observer reliability for the AO classification has also been reported by Schipper and co-workers[19] with kappa values of 0.33/0.34 and 0.48, respectively.

Also the reliability of the Seinsheimer classification for subtrochanteric fractures has been questioned.[20] However, in a review of the literature by Loizou et al. (2010),[21] the authors identified 15 different classification systems for subtrochanteric fractures and pointed out that the Seinsheimer classification was the most frequently used one followed by the AO classification. The other reviewed classification systems were used to a much lesser extent.

In conclusion, there is not yet an ideal classification system for trochanteric and subtrochanteric fractures. In this thesis we have opted to use two of the most frequently used ones, in *Studies I, II, III* and *V,* the Jensen-Michaelsen classification[14] for trochanteric fractures and in *Studies I, IV* and *V,* the Seinsheimer classification[15] for subtrochanteric fractures. In *Study IV* the OTA classification[16] was added as a complement.

EVOLUTION OF INTERNAL FIXATION

As early as in 1850, Langenbeck tried to reduce and fix a fracture with the use of an intramedullary nail, a treatment very difficult without the availability of preoperative radiographs and a perioperative X-ray image intensifier. The development of different fixation devices has accelerated during the last 70 years. For trochanteric fractures, the development was at first focused on different types of extramedullary devices, i.e. plates, and later also on intramedullary devices, i.e. nails.

Extramedullary fixation

Rigid nail-plate systems were described by Thornton in 1937 and a one-piece nail-plate was introduced by Jewett in 1941 with a fixed angle between the blade to be introduced into the femoral neck and head and a side-plate to be fixed with screws onto the lateral cortex of the femur. In 1947 McLaughlin[22] introduced an evolution of this concept which allowed various blade-plate angles. However, there were problems with this concept since the system did not allow sliding compression along the femoral neck, which resulted in a high frequency of penetration of the femoral head into the acetabular joint. The honour for the invention of a system that allowed compression (dynamisation) along the femoral neck and thereby impaction of the fracture was ascribed to Ernst Pohl, an engineer in the local hospital of Kiel, Germany.[23] The Pohl device was later modified and today there are a number of implants based on his principle referred to as the sliding hip screw (SHS). Most of the implants utilise a screw introduced into the femoral head, but some use a nail and, more recently, a spiral blade. One of the most frequently used SHSs is the dynamic hip screw (DHS; **Figure 6**) which was used in *Study II* of this thesis.

Figure 6. The DHS used in a trochanteric fracture allowing compression along the femoral neck (arrow).

A more recent evolution of the SHS is the Medoff sliding plate (MSP) introduced by Robert J. Medoff in 1990.[24] This system allows sliding both along the femoral neck and the femoral shaft (biaxial dynamisation). Moreover, the system allowed the surgeon to lock the dynamisation along the femoral neck (uniaxial dynamisation) in subtrochanteric fractures in order to prevent medialisation of the femoral shaft, which is considered to be a particular problem when using plate fixation in some subtrochanteric fractures and unstable trochanteric fractures. However, uniaxial dynamisation should only be utilised in subtrochanteric fractures solely located below the barrel of the plate, otherwise there is a high risk of lag-screw penetration. In clinical practice, the differentiation between low trochanteric fractures and high subtrochanteric fractures may be difficult and lead to erroneous uniaxial dynamisation in trochanteric fractures, and uniaxial dynamisation therefore requires frequent radiographic follow-ups and readiness for staged dynamisation in a number of cases to prevent lag-screw penetration.[25] The MSP in the biaxial dynamisation mode was used in *Studies I* and *V* of this thesis (**Figure 7**).

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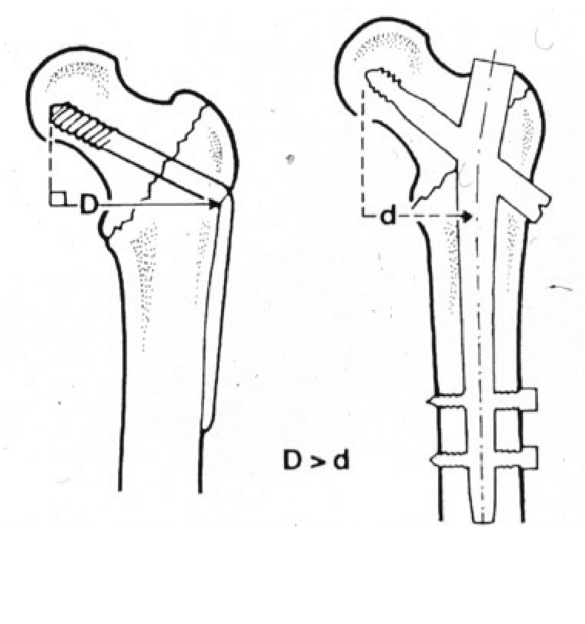
Figure 7. The MSP in the biaxial dynamisation mode used in a subtrochanteric fracture so as to allow compression along both the femoral neck and the femoral shaft (arrows).

Intramedullary fixation

An early intramedullary method for the treatment of trochanteric fractures was the Ender technique[26,27] with closed reduction and fixation with multiple C-formed solid nails inserted from the medial condyle and spreading in the femoral head. The technique was popularised during a short period of time and acceptable outcomes, compared with the fixed angled nail plates, were reported. However, the technique had several draw-backs, e.g. intraoperative fractures at the entry site, lack of optimal fixation leading to displacement into varus and external rotation and distal sliding of the nails, resulting in knee pain and frequent reoperations.[28-31] The technique was abandoned by many surgeons when the SHS was introduced. However, the theoretical advantages of closed reduction and intramedullary nailing, i.e. potentially reduced surgical trauma, reduced blood loss and a reduced infection rate, inspired further evolution of the intramedullary nailing technique for trochanteric fractures.

The principle *per se* was attractive and a new nail concept was developed at the Strasbourg Centre of Traumatology and Orthopaedic Surgery. The principle of this new nail with a biomechanical advantage in the form a shorter lever arm is illustrated in **Figure 8**.

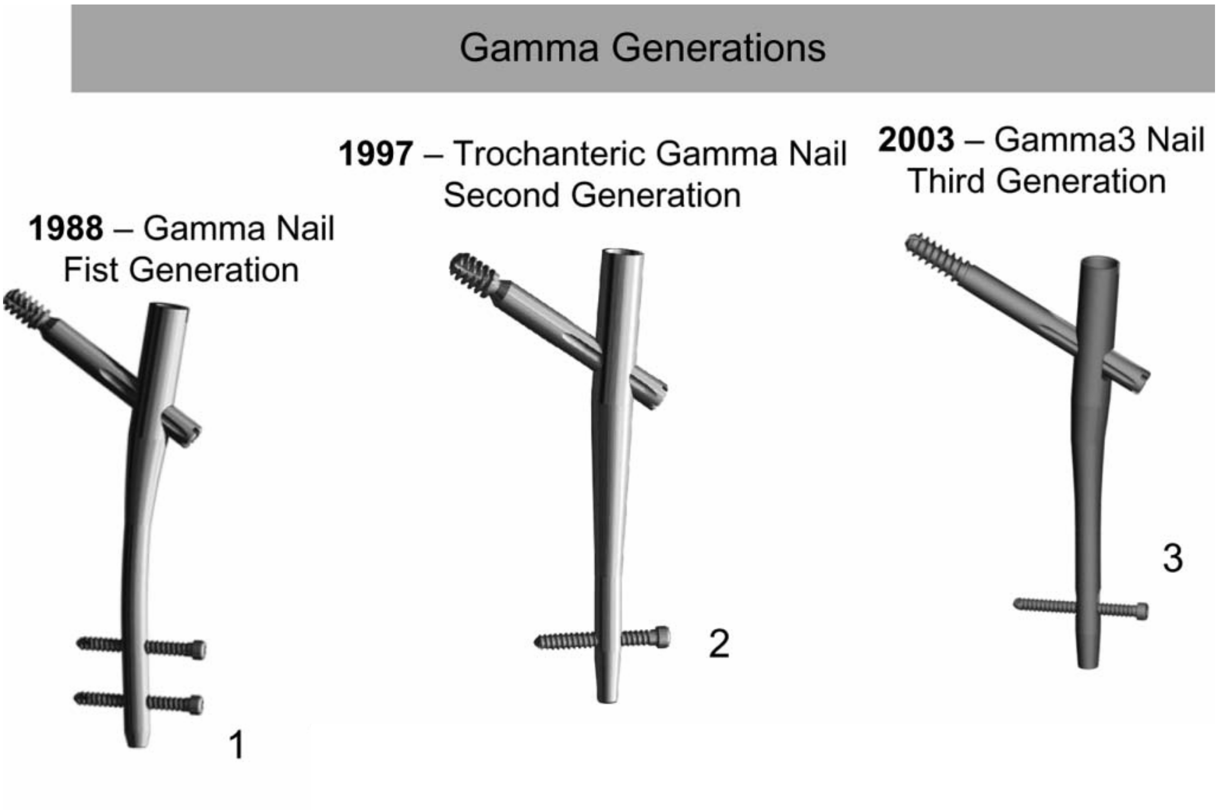
Figure 8. The different biomechanical properties comparing the intramedullary nail with the extramedullary plate.



Initially, there were several biomechanical and technical problems during the development of the nail, e.g. inadequate screw diameter, only one angle available, problems with sliding of the lag screw, etc. Many changes were made in the light of the biomechanical test results, and the insertion of the first clinical prototype of the Gamma nail was performed in December 1986 according to G.Taglang.

The Gamma-style nails with a reinforced proximal section that allows fixation in the femoral head and neck region with a larger lag screw and designed for insertion at the tip of the greater trochanter are referred to as cephalomedullary nails. This group of nails includes a number of nail designs from different producers, including the proximal femoral nail (PFN, PFNA), the Intra-medullary hip screw (IMHS) and the standard Gamma nail (SGN), as well as later designs of the Gamma nail, i.e. the trochanteric Gamma nail (TGN) and the long Gamma nail (LGN). The evolution of the short Gamma nails is displayed in **Figure 9**.

Figure 9. The evolution of the short Gamma nail.



The first generation of the Gamma nail, the SGN, with a diameter of 11 mm, length of 200 mm, valgus bend of 10° and neck angle of 125º or 130º, was used in patients with unstable trochanteric fractures (J-M 3–5)[14] and high subtrochanteric fractures[15] in *Studies I* and *V* (**Figure 10**).

Figure 10. The SGN used in a patient with an unstable trochanteric fracture.

The early studies on the SGN reported a high frequency of intra- or postoperative fractures of the femur,[32-34] which forced many surgeons to abandon the implant. Retrospectively, this particular problem was probably due to a combination of suboptimal design of the nail and, probably even more important, a suboptimal surgical technique. The length of the SGN (200 mm) in combination with 10º of valgus created a three-point fixation of the non-elastic implant within the proximal femur, leading to a concentration of stress at the distal part of the implant.[35,36] Furthermore, the reporting on the work of the participating surgeons in many of the studies on the SGN included the surgeons' learning curve[33,37] and an inadequate and traumatic surgical technique was sometimes used for insertion of the nail and the distal locking screw.

The second generation Gamma nail, the TGN, with a diameter of 11 mm, length of 180 mm, valgus bend of 4º and neck angle of 125º or 130º, was used in patients with unstable trochanteric fractures (J-M 3-5)[14] in *Study III* (**Figure 11**).

Figure 11. The TGN used in a patient with an unstable trochanteric fracture.

This second generation nail in combination with improved surgical technique has reduced, or possibly eliminated, the problem of iatrogenic femoral fractures.

Recently, after the start of the studies in this thesis, an additional evolution of the Gamma nail has been introduced, i.e. the Gamma3 nail (**Figure 12**). This design includes a self-tapping thread of the lag-screw, a thinner diameter (5 mm) of the distal locking screw and a titanium alloy.

Figure 12. The Gamma3 used in a patient with an unstable trochanteric fracture.

The long Gamma nail (LGN) designed for use in patients with subtrochanteric fractures[15] was used in *Study IV* (**Figure 13**).

Figure 13. The LGN used in a patient with a subtrochanteric fracture.

The optimal treatment, extramedullary or intramedullary fixation, of trochanteric and subtrochanteric fractures is still a matter of dispute, especially in the group of patients with unstable trochanteric fractures. At the time when the first study of this thesis (*Study I*) was started (October, 1998), the cephalomedullary nails were questioned primarily due to the reported high incidence of iatrogenic femoral fractures. However, since then, improved implant design and improved surgical technique have probably resolved this particular problem. Bhandari et al.[38] performed a meta-analysis to identify the risk of femoral shaft fracture associated with the Gamma nails following treatment of extracapsular hip fractures. They found that in previous studies (1991–2000), the risk of femoral shaft fracture increases by 4.5 times when compared with the use of the SHS. However, in more recent studies (2000-2005), the Gamma nail was not associated with a significantly increased risk of femoral shaft fracture.

Fracture complications

The most frequent fracture complications after trochanteric fractures are lag-screw penetration (cut-out) due to varus collapse of the fracture (**Figure 14**) and excessive medialisation of the femoral shaft, the latter seen in unstable trochanteric and subtrochanteric fractures treated with extramedullary fixation devices (**Figure 15**). Non-union after a trochanteric fracture is a rare complication, but it is seen more often in subtrochanteric fractures (**Figure 16**).

Figure 14. Lag-screw penetration (cut-out) due to varus collapse after an unstable trochanteric fracture treated with a TGN.

Figure 15. Medialisation of the shaft after a subtrochanteric fracture treated with an MSP.

Figure 16. Non-union in a subtrochanteric fracture with a fatigue breakage of the LGN.

ASSESSMENT OF OUTCOME

In order to be able to improve treatment methods and to assess the impact of the injury/disease upon the patients' overall function, there is a need for validated outcome instruments. In studies on the treatment of injuries and diseases of the hip, the outcome is frequently reported using basic measures such as range of motion, fracture healing and the need for revision surgery. Additionally, the functional outcome is often reported using region-specific outcome instruments such as Charnley´s numerical classification.[39] Two major disadvantages of many of these specific instruments is that they do not allow a comparison of the outcome in patients with different or multiple injuries/diseases of the musculoskeletal system and they are not self-reported, i.e. they do not report the outcome from the patients' own perspective.

The Short Musculoskeletal Function Assessment (SMFA)[40] allows a comparison between patients with all types of musculoskeletal injuries and diseases, including multiple injuries. SMFA is one of the outcome measures developed in collaboration with the American Academy of Orthopaedic Surgeons and has been translated and validated for several languages, including Swedish.[41]

The SMFA does not, however, allow a comparison of patients with injuries/diseases outside the musculoskeletal system. Therefore, the outcome is preferably reported with the inclusion of an assessment of the HRQoL, which offers an opportunity to compare the outcome with patients suffering from injuries/diseases not solely affecting the musculoskeletal system.

Reporting the patients' own assessment of their HRQoL will contribute to a more complete picture of how the injury/disease influences all areas of life and thereby enhance our ability to improve future healthcare programmes. The EuroQol (EQ-5D)[42] is a non-disease-specific instrument for describing and evaluating the HRQoL. The instrument comprises several dimensions and can be used across different patient populations. Moreover, the EQ-5D incorporates preferences for evaluating the health states and produces a single index (EQ-5D $_{index}$ score) that can also be used to construct quality-adjusted life years (QUALYs).

The SMFA was used in *Studies III* and *IV* and the EQ-5D was used in all studies in this thesis.

COGNITIVE FUNCTION

Delirium (acute confusional state) and dementia are two common risk factors in patients with hip fractures**.** Furthermore, dementia is one of the most common risk factors for delirium and the two conditions often co-exist.[43-46] A common denominator for both of these conditions is the presence of cognitive dysfunction. Cognitive dysfunction is defined as a disturbance in the patient's mental processes related to thinking, reasoning and judgement. Previous studies indicate that patients with impaired cognitive function have an increased risk for general as well as fracture-related complications,[47] problems in assimilating rehabilitation,[48] prolonged hospital stay,[46] poor long-term outcome[46,49,50] and an increased mortality rate.[49,51] Besides measures to prevent and treat the delirium,[52] a thorough understanding of the hip fracture patient's ability to co-operate and follow postoperative regimens is crucial in the planning of the surgical treatment and postoperative rehabilitation.

Despite this knowledge, an assessment of cognitive function is still lacking in nursing and medical records for a substantial number of older people with hip fractures.[53,54] Moreover, the routine assessment often differs from the assessment obtained by the use of a validated instrument, especially in patients with impaired cognitive ability. In a published study, the ward nurses' assessment correctly identified only 58% of patients with impaired cognitive function.[53]

The systematic use of a validated instrument has the potential to improve the assessment of cognitive function and also entails the possibility of establishing robust criteria for identifying the most vulnerable patients and thereby facilitating optimal treatment and rehabilitation.

In *Study V* we evaluated whether severe cognitive dysfunction, assessed with a validated instrument, the Short Portable Mental Status Questionnaire (SPMSQ),[55] could predict the outcome regarding function, the health-related quality of life (HRQoL) and mortality in elderly patients with hip fractures.

STATING THE PROBLEM

In the middle of the 20th century Sweden had a population of approximately 7 million people. Today the number of inhabitants in Sweden has reached 9 455 000 and, according to the prognosis, the 10-million barrier will be broken in 2024.[56] The life expectancy for women is assumed to increase from 83 years in 2008 to 87 years in 2060 and the corresponding figures for men are 79 and 85 years. The constantly increasing life expectancy affects the age structure with a steady growth of the group of elderly in the population. In today's Sweden 1.6 million people are aged 65 years and older, thus constituting 18% of the population and, according to the estimations, the corresponding figures for the year 2060 will be 2.7 million constituting 25% of the population.[56]

The statistical foundation for the future demographics combined with each person's life-time risk of having a fragility fracture clearly demonstrates the huge public health problem we are facing. Growing populations with longer life expectancies and the increased proportion of elderly will result in increased suffering and costs related to osteoporosis. Among fragility fractures, hip fractures are considered the most serious in terms of cost and morbidity and there has been a constant increase in the annual number of hip fractures worldwide. According to a recent prognosis, the number of patients with hip fractures per year will rise to 2.6 million in 2025 and further to 6.26 million in 2050. Scandinavia still has the highest incidence of hip fractures in the world,[57-60] but the most considerable increase will take place in Asia and Latin America.[57,61-63] However, while there are some studies indicating a trend break,[58,59,64-69] hip fractures are considered to become a progressively larger public health burden.[70]

A hip fracture represents probably the most devastating consequence of osteoporosis and a mild trauma in terms of mortality, morbidity, disability, quality of life and hospital care and cost. For the patient it is not only a difficult physiological trauma, but also a psychological trauma that threatens continued autonomy. The fear of sustaining a hip fracture with loss of independence is great among elderly people in the community, which was clearly demonstrated in the study by Salkeld et al.[71] from 2000 where 80% of old women expressed the opinion they would rather die than suffer from a hip fracture with a bad outcome.

The quality of care of older people with hip fractures demands even more attention and improvements in treatment are necessary, including preoperative assessment, surgical method and postoperative rehabilitation. The overall aim of this thesis was to contribute to evidence-based treatment algorithms for the different types of trochanteric and subtrochanteric femoral fractures, including studies reporting the outcome with patient-assessed functional outcome measures including HRQoL.

AIMS OF THE STUDIES

Study I

The primary aim was to compare the outcome in patients with unstable trochanteric and subtrochanteric fractures randomised to internal fixation with the SGN or the MSP in an RCT with a one-year follow-up. The secondary aim was to describe the HRQoL according to the EQ-5D within in this group of patients.

Study II

The aim of this study was to report the long-term outcome for patients with stable trochanteric fractures treated with an SHS with special regard to the HRQoL in a prospective cohort study with a two-year follow-up.

Study III

The primary aim was to report the outcome using the SMFA and, secondly, to report the HRQoL according to the EQ-5D after an unstable trochanteric fracture treated with a cephalomedullary nail in a prospective cohort study with a one-year follow-up.

Study IV

The primary aim was to report the outcome using the SMFA and, secondly, to report the HRQoL according to the EQ-5D after a subtrochanteric fracture treated with a cephalomedullary nail in a prospective cohort study with a one-year follow-up.

Study V

The primary aim was to evaluate whether severe cognitive dysfunction, assessed with a validated instrument, the SPMSQ, could predict the outcome regarding function, HRQoL and mortality in elderly patients with hip fractures within the context of an RCT with a one-year follow-up. The secondary aim was to describe the background data in relation to cognitive function.

PATIENTS

ETHICS

All studies were conducted according to the Helsinki Declaration and the separate protocols were approved by the local Ethics Committee. In *Studies II, III* and *IV,* where only patients without severe cognitive dysfunction (SPMSQ $\geq$ 3) were included ,and with regard to the patients without severe cognitive dysfunction (SPMSQ $\geq$ 3) in *Studies I* and *V,* all patients gave their informed consent to participate. In *Studies I* and *V* where also patients with severe cognitive dysfunction (SPMSQ < 3) were included, the informed consent for these patients was given by a close relative or guardian.

INCLUSION CRITERIA AND FOLLOW-UP

Study I

217 patients with an acute unstable trochanteric fracture (J-M 3 -5)[14] or subtrochanteric fracture[15] treated at Södersjukhuset during the period from October 1998 to January 2002 were entered in an RCT (**Table 1**). Patients with pathological fractures and patients with rheumatoid arthritis or osteoarthritis were not included. The patients were randomised (opaque sealed-envelope technique) to internal fixation with an SGN or an MSP. For implant-related reasons, fractures extending more than 5 cm distal to the lesser trochanter were excluded. If the MSP was to be used in such fractures, the most proximal cortical bone screws would prevent sliding of the plate and, for the SGN, the length of the nail (200 mm) was considered to be insufficient. The patients were summoned at 4 (mean 4.2) and 12 (mean 13.0) months. At the final follow-up 24 patients (22%) in the SGN group and 31 (29%) in the MSP group were deceased. Three patients (4%) in each group were lost to follow-up.

Study II

148 patients with an acute stable trochanteric fracture (J-M 1 and 2)[14] treated with an SHS at any of the 4 university hospitals in Stockholm during the period from January 1 to December 31, 2003, were included in a prospective cohort study (**Table 1**). The inclusion criteria were absence of severe cognitive dysfunction and independent walking capability with or without walking aids before the fracture. Patients with pathological fractures were not included. The patients were summoned at 4 (mean 4.9), 12 (mean 12.9) and 24 (mean 24.8) months. At the final follow-up 43 patients (29%) were deceased and 13 (12%) were lost to follow-up.

Study III

117 patients with an acute unstable trochanteric fracture of the femur (J-M 3 -5)[14] treated with a cephalomedullary nail (TGN) at Södersjukhuset during the period from April 2004 to December 2007 were included in a prospective cohort study (**Table 1**). The inclusion criteria were absence of severe cognitive dysfunction and independent walking capability with or without walking aids before the fracture. Patients with pathological fractures were not included. The patients were summoned at 4 months (mean 4.2) and 12 (mean 12.2) months. At the final follow-up 24 patients (21%) were deceased and 13 (11%) were lost to follow-up.

Study IV

53 patients with an acute subtrochanteric fracture of the femur[15,16] treated with a long cephalomedullary nail (LGN) at Södersjukhuset during the period from January 2004 to December 2007 were included in a prospective cohort study (**Table 1**). The inclusion criteria were age 60 years or more, absence of severe cognitive dysfunction and independent walking capability with or without walking aids before the fracture. Patients with pathological fractures were not included. The patients were summoned at 4 months (mean 4.0) and 12 (mean 12.3) months. At the final follow-up 8 patients (15%) were deceased and 6 (13%) were lost to follow-up.

Study V

The 217 patients from *Study I* with an acute unstable trochanteric fracture (J-M 3-5)[14] or a subtrochanteric fracture[15] were entered in this prospective study focusing on the influence of cognitive function on outcome (**Table 1**). An assessment of cognitive function at inclusion was lacking in 4 patients, leaving 213 patients in the study group.

Table 1. Patient inclusion algorithm for all studies.

Study I **n = 217**		**Study II** **n = 148**	**Study III** **n = 117**	**Study IV** **n = 53**	**Study V** **n = 213**
Unstable trochanteric fx and subtrochanteric fx		Stable trochanteric fx	Unstable trochanteric fx	Subtrochanteric fx	The 213 patients from *Study I* with data on cognitive function according to the SPMSQ
Randomised SGN	Randomised MSP	SHS	TGN	LGN	
n = 108	n = 109	n = 148	n = 117	n = 53	n = 213

METHODS

AGE AND GENDER

In *Studies I* and *V* the mean age was 84 years (65 to 99) and with 81% of the patients being women. In *Study II* the mean age was 83 (68 to 101) years and 74% of the patients were females. In *Study III* the mean age was 84 years (52 to 98) with 74% being women. In *Study IV* the mean age was 82 years (61 to 94) and 77% of the patients were females.

FRACTURE CLASSIFICATION

The patients in all studies had either a trochanteric or a subtrochanteric femoral fracture. All radiographs were analysed by two senior consultants (involved in the studies and not blinded to the clinical outcome) with extensive experience in the field of hip fracture surgery. In case of disagreement between the two, a second opinion from a third senior consultant was obtained.

The trochanteric fractures were classified according to the Jensen-Michaelsen[14] classification system. According to this classification, the undisplaced 2-part fracture and the displaced 2-part fracture (J-M 1 and 2) are defined as stable and the 3- and 4-part fractures with a fracture of the lesser, the greater or both trochanters (J-M 3-5) are defined as unstable. The subtrochanteric fractures were classified according to the Seinsheimer classification system[15] and in *Study IV*, additionally also according to the OTA classification systems.[16]

In *Studies I* and *V* we included patients with unstable trochanteric and subtrochanteric fractures. In *Study II* only patients with stable trochanteric fractures were included, in Study *III* only patients with unstable trochanteric fractures and in *Study IV* only patients with subtrochanteric fractures.

CO-MORBIDITY

In *Studies I* and *V* co-morbidity was assessed according to the Ceder classification[72] and graded as A - full health, B - another illness not affecting rehabilitation and C - another illness affecting rehabilitation.

In *Studies II, III* and *IV* the patients' general physical health status was assessed by the attending anaesthetist according to the American Society of Anesthesiologists (ASA) classification.[73] 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; ASA 5, a moribund patient who is not expected to live 24 hours with or without surgery. There were no patients with ASA 5 in any of the studies.

In *Studies I* and *V* all patients were examined and cleared by an anaesthetist before inclusion. The assessment included a decision as to whether the patient was fit enough for both randomisation procedures.

RANDOMISATION

The randomisation procedure in *Studies I* and *V* was performed with independently prepared, numbered, opaque and sealed envelopes.

COGNITIVE FUNCTION

Cognitive function was assessed with the Short Portable Mental Status Questionnaire (SPMSQ)[55] in all studies. This 10-item mental test (**Table 2**) classifies cognitive function into four 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. In *Studies II, III* and *IV* only patients with absence of severe cognitive dysfunction (SPMSQ ≥ 3) were included.

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

The activities of daily living (ADL) status was assessed using the Katz index[74] in all studies. This index is based on an evaluation of the functional independence or dependence of patients in bathing, dressing, going to the toilette, transferring, and continence and feeding. ADL index A indicates independence in all 6 functions and index B independence in all but one of the 6 functions. Indexes C-G indicate dependence in bathing and additionally one to 5 more functions.

PREOPERATIVE WALKING ABILITY

In all studies all patients had independent walking ability with or without walking aids before the fracture.

LIVING CONDITIONS

In all studies the patient's living condition was categorised as independent (living in one's own home or in housing for the elderly) or as institutionalised (living in a nursing home or hospital).

TREATMENT MODALITIES

The patients in *Studies I* and *V* were randomly allocated to treatment by either internal fixation with an SGN (diameter 11 mm, length 200 mm, valgus bend 10°, neck angle 125º or 130º; Stryker Howmedica, Sweden) or an MSP (neck angle 135º, 6-hole plate; Swemac, Sweden; **Figures 10 and 7,** respectively). For the SGN, a proximal mini-invasive incision was performed and followed by reaming of the medullary canal to 13 mm distally and 17 mm proximally whereupon the nail was introduced. The set screw (antirotation screw) and distal locking screw were used in all cases. The MSP was used in the biaxial dynamisation mode, which allows sliding along both the femoral neck and shaft. In fractures proximal to the entry site of the plate barrel, the entry hole was enlarged up to 2.5 cm distally in order to allow axial compression.

In *Study II* the SHS used in all cases was a DHS (Synthes, Sweden; **Figure 6).**

In *Study III* fracture fixation was carried out with a TGN (diameter 11 mm, length 180 mm, valgus bend 4º, neck angle 125º or 130º; Stryker Howmedica, Sweden; **Figure 11).** A proximal mini-invasive incision was performed and followed by reaming of the medullary canal to 13 mm distally and 17 mm proximally whereupon the nail was introduced. The set screw (antirotation screw) and distal locking screw were used in all cases.

In *Study IV* fracture fixation was carried out with an LGN (Stryker Howmedica, Sweden; **Figure 13).** A proximal mini-invasive incision was made and followed by reaming of the medullary canal to 13 mm distally and 17 mm proximally, whereupon the nail was introduced. The set screw (antirotation screw) and distal locking screws were used in all cases. In cases where acceptable reduction of the fracture was not accomplished by closed means, a fracture reduction clamp was introduced to secure acceptable reduction during reaming and introduction of the nail.

In all studies fracture reduction and fixation were carried out with the patient lying supine on a fracture table. All surgeons were instructed to insert the nail by hand, never to use the hammer and not to use the awl before drilling for the distal locking screw in order to minimise the risk of femoral shaft fractures. All patients received trombo-embolic prophylaxis and perioperative intravenous antibiotics. All patients were mobilised with full weight-bearing as tolerated.

PERIOPERATIVE DATA

The mean operating time, the intraoperative blood loss, the need for blood transfusions and the experience of the surgeon were recorded in all studies.

In *Study I* the mean operating time was 61 (22 to127) minutes in the SGN group and 65 (20 to 122) minutes in the MSP group (ns). The intraoperative blood loss was 280 (50 to 1000) in the SGN group and 400 (25 to 2400) ml in the MSP group ($p < 0.01$). The need for blood transfusions was 860 (0 to 2700) ml in the SGN group and 800 (0 to 3000) ml in the MSP group (ns). The experience of the surgeons did not differ between groups. Approximately 50% of the operations in both groups were performed by consultants.

In *Study II* the mean duration of surgery was 47 (14 to 105) minutes and the mean intraoperative blood loss was 160 (50 to 1000) ml. The surgeon was a certified specialist in orthopaedic surgery (post-registrar or consultant) in 66% of the cases and a registrar in the remaining 44%.

In *Study III* the mean duration of the surgical procedure was 74 (28 to 210) minutes and the mean intraoperative blood loss was 268 (0 to 1200) ml. The surgeon was a certified specialist in orthopaedic surgery (post-registrar or consultant) in 48% of the cases and a registrar in the remaining 52%.

In *Study IV* the mean duration of the surgical procedure was 101 (36 to 260) minutes and the mean intraoperative blood loss was 500 (100 to 2000) ml. The surgeon was a certified specialist in orthopaedic surgery (post-registrar or consultant) in 55% of the cases and a registrar in the remaining 45%.

COMPLICATIONS

Severe general complications (cardiac, pulmonary, thrombo-embolic or cerebrovascular) were recorded in *Studies I, III, IV* and *V*.

Wound infections were recorded in all studies. Deep wound infection was defined as an established infection beneath the fascia requiring surgical revision and superficial wound infection was defined as a cutaneous/subcutaneous infection requiring antibiotic therapy.

RADIOLOGICAL ASSESSMENT

The fracture reduction and implant position were assessed on the postoperative radiographs in *Studies I, III, IV* and *V*. The radiographs were analysed by two senior consultants (involved in the studies and not blinded to the clinical outcome) with extensive experience in the field of hip fracture surgery. In case of disagreement between the two, a second opinion from a third senior consultant was obtained. In *Study II* the postoperative fracture reduction and implant position were not assessed.

The reduction was categorised as good with normal alignment or in slight valgus in the AP view, less than 20° of angulation in the lateral view and no more than 4 mm of displacement of any fracture fragment. The reduction was considered acceptable if two of these criteria were fulfilled, otherwise reduction was considered poor. The screw position within the femoral head was defined as described by Kyle[75] with the femoral head divided into three columns on the AP and lateral views to create 9 zones. A screw position in the middle third in the lateral view combined with a position in the inferior or middle third in the AP view, as well as a posterior position in the lateral view combined with a central position in the AP view, was categorised as good.[76] The minimum screw tip-head circumference distance (corrected for 15% of magnification) was measured in the AP and the lateral views.[77]

In *Studies I, III, IV* and *V* the patients were summoned for a clinical and radiographic examination at 4 and 12 months. In *Study II* the patients were interviewed by phone at 4, 12 and 24 months and patients reporting problems were scheduled for a follow-up visit including a radiographic examination.

Technical failures were defined as lag-screw penetration, excessive redislocation, e.g. medialisation of the femoral shaft, breakage or loosening of the implant, intra- or postoperative femoral shaft fracture or non-union of the fracture. Migration of the lag-screw within the femoral head or varus angulation of the fracture without lag-screw penetration was not regarded as a technical failure.

The fracture was defined as healed if there were visible trabeculations across the fracture line. Non-union was defined as an absence of radiographically visible trabeculations across the fracture line, including early displacement or progressive displacement.

ASSESSMENT OF CLINICAL OUTCOME

In the outcome analysis of the RCT (*Studies I* and *V*) all patients remained in their primary randomisation group regardless of secondary procedures according to the intention-to-treat principle.

In the outcome analysis in all studies, all clinical variables except hip motion were assessed by an unbiased observer (a research nurse not involved in the surgery or clinical decisions).

HIP FUNCTION

In all studies hip function was assessed using Charnley´s numerical classification,[39] which defines the clinical state of the affected hip joint in three dimensions: Pain (at the hip), Movement (hip motion) and Walking (ability to walk). Each dimension is graded from 1 to 6 with 1 = total disability and 6 = normal state **(Table 3).**

Table 3. Charnley´s numerical classification.

	Pain	Movement	Walking
1	Severe and spontaneous	0–30°	A few metres or bedridden
2	Severe on attempting to walk, prevents all activity	60°	Time and distance very limited with or without walking aids
3	Tolerable, permitting limited activity	100°	Limited with walking aids, difficult without. Able to stand long periods
4	Only after some activity, disappears quickly with rest	160°	Long distance with walking aids, limited without
5	Slight or intermittent, pain on starting to walk but becoming less with normal activity	210°	No walking aids, walks with a limp
6	No pain	260°	Normal

MUSCULOSKELETAL FUNCTION (SMFA)

In *Studies III* and *IV* the musculoskeletal function was assessed using the SMFA. SMFA is a 46-item questionnaire[40,41] that comprises two 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 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 to100, a higher score indicating poorer function.

A comparison of the preinjury ratings with the values of a Swedish reference population was not possible because there is none available for the SMFA. However, the pre-fracture SMFA ratings of our study populations were similar to the normative "uninjured" value for the age group > 60 years old in the North American population.[78,79]

HEALTH-RELATED QUALITY OF LIFE (EQ-5D)

In all studies the HRQoL was rated using the EQ-5D.[42] The reliability and validity of the EQ-5D has been evaluated in different patient populations and, in a recent review of the assessment of the quality of life among older people in which a number of instruments were evaluated, it was concluded that there was 'good evidence' for the validity, reliability and responsiveness of the EQ-5D.[80]

The EQ-5D has 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 (**Table 4**).

Table 4. The EQ-5D self-classifier.

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.	
Mobility	
I have no problems in walking about	□
I have some problems walking about	□
I am confined to bed	□
Self-care	
I have no problems with self-care	□
I have some problems washing and dressing myself	□
I am unable to wash and dress myself	□
Usual activities (e.g. work, study, housework, family or leisure activities)	
I have no problems with performing my usual activities	□
I have some problems with performing my usual activities	□
I am unable to performing my usual activities	□
Pain/Discomfort	
I have no pain or discomfort	□
I have moderate pain or discomfort	□
I have extreme pain or discomfort	□
Anxiety/Depression	
I am not anxious or depressed	□
I am moderately anxious or depressed	□
I am extremely anxious and depressed	□

Dolan et al.[81] used the time trade-off (TTO) method to rate these different states of health in a large UK population (UK EQ-5D Index Tariff). We used the preference scores (EQ-5D $_{index}$ scores) generated from this population when calculating the scores for our study population. A value of 0 indicated the worst possible state of health and a value of 1 indicated full health. This is a divergence from the UK EQ-5D Index Tariff where some health states were given negative scores. But the appropriate scaling of negative scores is questioned[82] and the same approach was used when generating the values for an age-matched Swedish population.[83]

All studies included an assessment of the patients' HRQoL the week before the fracture (recall). To validate the method of rating the prefracture HRQoL and to analyse recall bias, the EQ-5D $_{index}$ scores prior the fracture were compared with those of the age-matched Swedish reference population (**Table 5**).[83] Regarding recall bias, a recent study reports that older patients can accurately recall their previous health status up to 6 weeks.[84]

In *Study V* the information was collected from a proxy for patients with severe cognitive dysfunction (SPMSQ<3). A close relative or caregiver was asked to rate how he or she thinks the patient would rate his or her health if he or she were able to communicate. This approach has also been used previously for the EQ-5D in patients with cognitive dysfunction and dementia.[85-87]

Table 5. EQ-5D $_{index}$ scores for the relevant age groups of the age-matched Swedish reference population.

	EQ-5D$_{index}$ scores		
Age (years)	**60–69**	**70–9**	**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 84 years, 81% being female) the prefracture EQ-5D $_{index}$ score was 0,64 in patients without severe cognitive dysfunction (SPMSQ ≥3).

In *Study II* (mean age 83 years, 74% being female) the prefracture EQ-5D $_{index}$ score was 0, 69.

In *Study III* (mean age 84 years, 74% being female) the prefracture EQ-5D $_{index}$ score was 0.79.

In *Study IV* (mean age 82 years, 77% being female) the prefracture EQ-5D $_{index}$ score was 0.85.

In S*tudy V* in the subgroup of 50 patients with SPMSQ < 3 (mean age 86 years, 78% being female) the prefracture EQ-5D $_{index}$ score was 0.24. In the subgroup of 163 patients with a SPMSQ ≥ 3 (mean age 83 years and 82% being female) the prefracture EQ-5D $_{index}$ score was 0.64.

STATISTICAL METHODS

In *Study I* the statistical software used was SPSS 11.5 for Windows. The Mann-Whitney U-test was used for scale variables and ordinal variables in independent groups. Nominal variables were tested using the Chi-square test or Fisher's exact test. A Wilcoxon signed ranks test was used to compare scores between baseline and follow-up. A correlation analysis was performed using Spearman's rho test. All tests were two-sided. The results were considered significant at $p < 0.05$. Trend values, $0.05 \geq p < 0.1$, are displayed; all other values are reported as not significant (ns).

In *Study II* the statistical software used was SPSS 15.0 for Windows. The Wilcoxon signed-ranks test was used when comparing EQ-5D data. The tests were two-sided. The results were considered significant at $p < 0.05$.

In *Study III* the statistical software used was SPSS 18.0 for Windows. Nominal variables were tested using the Chi-square test or Fisher's exact test. The Wilcoxon signed-ranks test was used when comparing EQ-5D data. The tests were two-sided and the results were considered significant at $p < 0.05$.

In *Study IV* the statistical software used was SPSS 17.0 for Windows. Nominal variables were tested using the Chi-square test or Fisher's exact test. The Wilcoxon signed-ranks test was used when comparing EQ-5D data. The tests were two-sided and the results were considered significant at $p < 0.05$.

In *Study V* the statistical software used was SPSS 13.0 for Windows. The Mann-Whitney U-test was used for scale variables and ordinal variables in independent groups. Nominal variables were tested using the Chi-square test or Fisher's exact test. A Wilcoxon signed ranks test was used to compare scores between baseline and follow-up. All tests were two-sided. A Cox regression analysis was performed in order to evaluate factors of importance for mortality. The results were considered significant at $p < 0.05$. All other values are reported as not significant (ns).

RESULTS

STUDY I

Baseline data

Baseline data for all patients included (n = 217) are displayed in **Table 6**. There were no significant differences between the SGN and MSP groups regarding baseline data or fracture type. There was a trend towards slightly older patients in the SGN group, 84.6 years in the SGN group compared to 82.7 years in the MSP group (p = 0.058).

Table 6. Baseline data for all included patients (n = 217)

	SGN (n = 109)	MSP (n = 108)
Mean age in years	84.6	82.7
Mean cognitive function (SPMSQ)	5.7	5.8
Mean EQ-5D $_{index}$ score prefracture*	0.66	0.63
Gender, female, n (%)	92 (84)	84 (78)
Mobility, no walking aid or just one stick, n (%)	67 (62)	71 (66)
ADL A&B, n (%)	82 (75)	72 (67)
Co-morbidity Ceder A&B, n (%)	45 (41)	48 (44)
From independent living, n (%)	92 (84)	95 (88)

* Only patients with SPMSQ ≥ 3

Surgical outcome

Six patients in the SGN group were operated on using a method at variance with the randomisation. Three of these patients sustained an intraoperative femoral fracture. Two of them were caused by an inadequate surgical technique. In spite of the recommended operative technique, a hammer was used during insertion of the nail in one case and a wrong entry point was used in another, leading to excessive force during insertion of the nail. The intraoperative fractures were all recognised during the primary procedure and the SGN was replaced in all cases with an LGN with uneventful outcomes. In two patients an LGN was used owing to misinterpretation of the study protocol by the surgeons. Finally, in one case the surgeon considered open reduction necessary and therefore changed intraoperatively to an MSP.

The reduction and screw position were assessed after the termination of the study and the primary postoperative radiographs were retrieved in 195 patients. In the SGN group, the reduction was considered good in 63% of the patients as compared to 40% in the MSP group (p < 0.005). In 6 out of 9 patients undergoing reoperation owing to technical failures (the primary postoperative radiographs were not retrievable in one case), the reduction was not considered good (p = 0.074). The screw position was considered good in 87% in the SGN group and 93% in the MSP group (ns). There was a trend towards more frequent reoperations owing to technical failures among patients with an unacceptable screw position (p = 0.094). The mean minimum screw tip-head circumference distance was 6 (1–14) mm in the SGN group and 7 (1–18) mm in the MSP group (p = 0.099). There was no correlation between this difference in distance and the need for reoperation owing to technical failure.

Severe general complications, including deaths, before the 4-month follow-up were more frequent in the MSP group ($p < 0.05$). The mortality rate in the SGN group was 10% and 3% of the patients had another severe complication (cardiac, pulmonary, thrombo-embolic or cerebrovascular) compared to 20% and 4%, respectively, in the MSP group.

The number of technical failures did not differ between groups as shown in **Table 7**.

Table 7. Technical failures with reference to fracture type.

	SGN (n = 109)		MSP (n = 108)	
	n	**(%)**	**n**	**(%)**
Trochanteric fractures (n= 189)	93	(85.3)	96	(88.9)
No complication	87	(93.5)	91	(94.8)
Lag-screw penetration	3	(3.2)	4	(4.2)
Redisplacement/medialisation	0	(0)	1	(1.0)
Intraoperative femoral fracture	3	(3.2)	0	(0)
Subtrochanteric fractures (n = 28)	16	(14.7)	12	(11.0)
No complication	16	(100)	10	(83.3)
Lag-screw penetration	0	(0)	0	(0)
Redisplacement/medialisation	0	(0)	2	(16.7)
Intraoperative femoral fracture	0	(0)	0	(0)

The three patients in the MSP group with redisplacement/medialisation had radiographically excessive medialisation of the femoral shaft and severe pain at the hip, making further ambulation impossible. One of the patients in the MSP group with a minor lag-screw penetration declined further surgery. Another patient in the MSP group (case no. 91) (**Table 8**) with a radiographically healed fracture had the implant removed after 10 months owing to local pain. After a few weeks a stress fracture in the femoral neck was diagnosed and the patient underwent reoperation with a total hip replacement (THR) with an uneventful outcome. This case was not included among technical failures in the MSP group.

There was a trend towards more frequent reoperations in the MSP group (**Table 8**). The total number of reoperated patients was 3 out of 109 (2.8%) in the SGN group and 9 out of 108 (8.3%) in the MSP group (p = 0.072). The reoperation rate for unstable trochanteric fractures was 3 out of 93 (3.2%) in the SGN group and 6 out of 96 (6.3%) in the MSP group (ns). Regarding subtrochanteric fractures, there were no reoperations in the SGN group (n = 16) as compared to 3 in the MSP group (n = 12) (p = 0.067). Fracture healing was demonstrated radiographically at the final follow-up in 136 out of 146 available patients and clinically in the rest. There were no postoperative femoral shaft fractures in any of the groups during the 12-month follow-up.

Table 8. All reoperated patients (n = 12).

Randomisation	Indication	Reoperation	Time	Fx type
No. 43 MSP	Deep infection	Multiple revisions, Healed fx at 12 months	1.6 months	S5
No. 59 SGN	L-S penetration	THR	3.6 months	J-M 3
No. 68 MSP	L-S penetration	Girdlestone arthroplasty Lost at 12-month f-u	3.4 months	J-M 4
No. 91 MSP	1/ Local pain 2/ Stress fx in the femoral neck	1/ Extraction of MSP 2/ THR	1/ 10.3 months 2/ 10.9 months	J-M 5
No. 96 MSP	L-S penetration	THR	5.8 months	J-M 5
No. 104 SGN	L-S penetration	THR	4.4 months	J-M 5
No. 139 MSP	L-S penetration	THR	1.3 months	J-M 4
No. 152 SGN	L-S penetration	THR	12.1 months	J-M 5
No. 159 MSP	Redisplacement, medialisation	1/ DCS 2/ THR	1/ 1.0 months 2/ 7.4 months	S2C
No. 161 MSP	Redisplacement, medialisation	LGN	0.4 months	S2C
No. 169 MSP	Redisplacement, medialisation	PFN	0.5 months	J-M 5
No. 219 MSP	Deep infection	Girdlestone arthroplasty Deceased after 2.8 months	1.0 months	J-M 5

Time = time elapsed from the primary operation; DCS = dynamic compression screw; PFN = proximal femoral nail; L-S penetration = lag-screw penetration.

There was a trend towards more frequent postoperative infections in the MSP group (p=0.05). There were 6 superficial wound infections in the MSP group as compared to two in the SGN group. Furthermore, there were two deep wound infections in the MSP group, one leading to a Girdlestone arthroplasty and the subsequent death (case no. 219) of a 94-year-old woman and one leading to multiple revisions but finally a healed fracture in a 91-year-old woman (case no. 43) (**Table 8**).

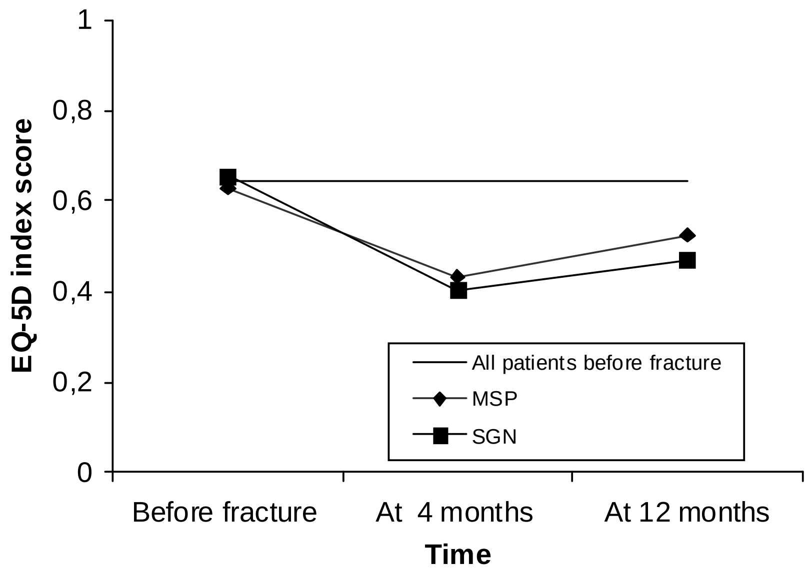
Functional outcome and HRQoL

There were no significant differences in ADL between the groups at any of the follow-ups. At 4 months, 49% in the SGN group and 60% in the MSP group were categorised as indexes A & B; at 12 months, the figures were 57% and 63%, respectively. Hip function (**Table 9**) and the HRQoL according to the EQ- 5D (**Figure 17**) did not differ between the groups at any of the follow-ups. The reduction in HRQoL (EQ-5D $_{index}$ score) between prefracture and both follow-ups was highly significant in both groups ($p < 0.005$).

Table 9. Hip function according to the Charnley score for all patients available at each follow-up. No significant differences between randomisation groups on any occasion.

		SGN	MSP
		Mean	**Mean**
Pain	4 months (n = 163)	4.8	4.7
	12 months (n = 155)	5.3	5.2
Movement	4 months (n =153)	4.9	4.7
	12 months (n = 152)	4.9	4.8
Walking	4 months (n = 165)	2.5	2.6
	12 months (n = 155)	2.8	2.9

Figure 17. HRQoL for all patients without severe cognitive dysfunction (SPMSQ ≥ 3) before fracture and available at each follow-up. (n = 162 at inclusion, n = 142 at 4 months and n = 134 at 12 months). No significant differences between randomisation groups on any occasion.



STUDY II

Baseline data

Baseline data for all patients included (n=148) are displayed in **Table 10.**

Table 10. Baseline data for all patients included (n = 148).

Mean age in years		83.2, range 68 to 101
Gender, female, n (%)		109 (74)
Mean cognitive function (SPMSQ)		7.6, range 3–10
Mean EQ-5D $_{index}$ score prefracture		0.69, range 0.0–1.0
Walking aids, n (%)	**None**	60 (41)
	Stick or crutches	33 (22)
	Walking frame	55 (37)
ADL A and B, n (%)		129 (89)*
From independent living, n (%)		134 (91)
ASA , n (%)	**1**	5 (3)
	2	68 (46)
	3	72 (49)
	4	3 (2)

* 3 missing values

Surgical outcome

In total during the two- year follow-up period, 4 patients (3%) were reoperated upon. All reoperations were performed within 6 months and in three of them the indication was lag-screw penetration due to varus collapse of the fracture (**Table 11**). The lag-screw position after the index operation in two of the patients reoperated upon was unsatisfactory with a cranial (AP view) and dorsal (lateral view) position.

Table 11.Data on the 4 patients reoperated upon.

Indication	Reoperation/reoperations	Time (months)
L-S penetration	1/ HA	1.3
	2/ First dislocation – closed reduction	1.5
	3/ Second dislocation – Girdlestone arthroplasty	1.5
Redisplacement	Reosteosynthesis	2.1
L-S penetration	THR	3.0
L-S penetration	THR	5. 3

Time = time elapsed from the primary operation; L-S penetration = lag-screw penetration.

There were no deep infections. Five patients (3%) had superficial infections requiring antibiotic therapy.

Functional outcome and HRQoL

Pain at the hip, walking ability and ADL function for all patients available at each follow-up is displayed in **Table 12**. At the final follow-up 81% of the patients reported no or only slight or intermittent pain at the hip (Charnley score 5-6). 55% had regained their prefracture walking ability, 66% had the same level of ADL function and 89% of the patients who were living independently before the fracture were still living independently after 24 months.

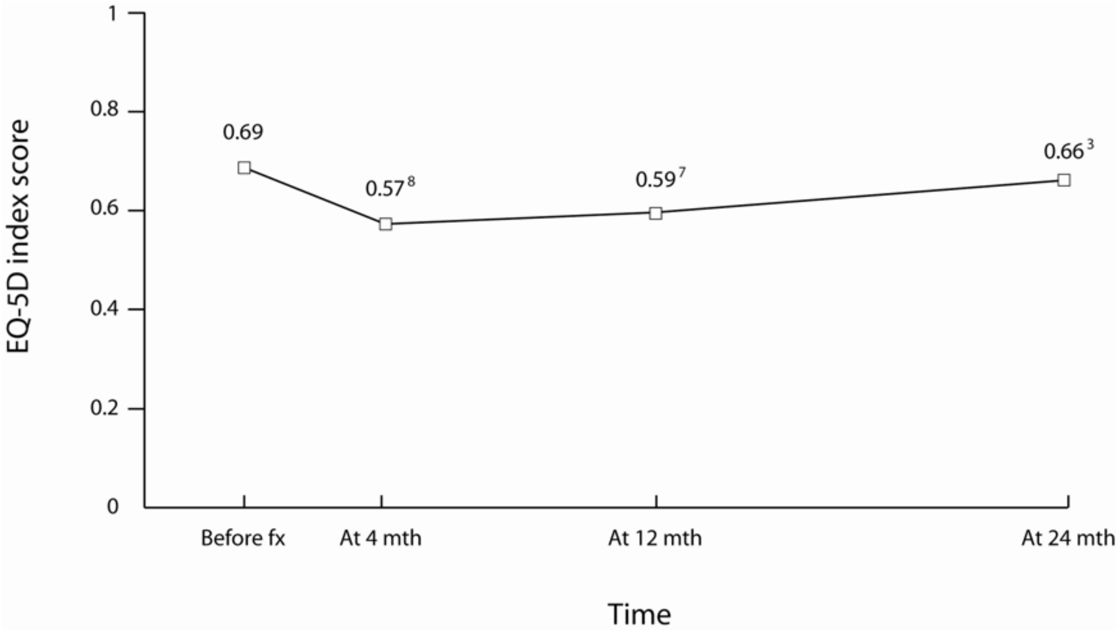
Table 12. Pain at the hip, walking ability and ADL function for all patients available at each follow-up (4 months, n=124; 12 months, n=112; 24 months, n=92).

Pain, mean Charnley score	4 months	5.1 [5]
	12 months	5.3 [8]
	24 months	5.4 [4]
Pain, Charnley score 5 or 6, n (%)	4 months	86 (72) [5]
	12 months	80 (77) [8]
	24 months	71 (81) [4]
At least similar walking ability as prefracture, n (%)	4 months	58 (46)
	12 months	58 (52) [1]
	24 months	50 (55) [1]
At least similar level of ADL function as prefracture, n (%)	4 months	74 (62) [5]
	12 months	67 (63) [5]
	24 months	59 (66) [3]
Still independent living, n (%)*	4 months	103(89) [1]
	12 months	87(85) [5]
	24 months	76 (89) [2]

The figures in superscript refer to the number of missing values on each follow-up occasion.
* The calculation is based on the number of patients available at each follow-up who were living independently before the fracture.

The EQ-5D $_{index}$ score decreased from 0.69 before the fracture to 0.57 at 4 months ($p < 0.001$) and 0.59 at 12 months ($p < 0.05$). At 24 months the EQ-5D $_{index}$ score, 0.66, did not differ from the prefracture level ($p = 0.522$) (**Figure 18**).

Figure 18. The EQ-5D $_{index}$ score for all patients available at each follow-up. At inclusion n = 148; 4 months, n = 124; 12 months, n = 112; 24 months, n = 92.



The figures in superscript refer to the number of missing values on each follow-up occasion.

STUDY III

Baseline data

Baseline data for all patients included (n = 117) are displayed in **Table 13.**

Table 13. Baseline data for all patients included (n = 117).

Mean age in years		84.1, range 52 to 98
Gender, female (%)		86 (74)
ASA, classification (%)	**1**	5 (4)
	2	51 (44)
	3	48 (41)
	4	13 (11)
Mean cognitive function (SPMSQ)		8.6, range 4 to 10
From independent living (%)		116 (99)
ADL A and B (%)		111 (95)
Walking aids (%)	**None**	53 (45)
	Stick or crutches	27 (23)
	Walking frame	37 (32)
Mean SMFA*	**Dysfunction Index prefracture**	24.8, range 0.0 to 89.7
	Bother Index prefracture	14.3, range 0.0 to 91.7
Mean EQ-5D $_{index}$ score	**prefracture**	0.79, range 0.0 to 1.0
Fracture type (%)	**JM3**	33 (28)
	JM4	21 (18)
	JM5	63 (54)

* 4 missing values.

Surgical outcome

Two out of 33 (6.1%) patients with a J-M type 3 fracture, 1 out of 21 (4.8%) patients with a J-M type 4 fracture and 11 out of 63 patients (17.5%) with a J-M type 5 fracture were reoperated upon (p = 0.14). A comparison based instead on the number of fracture fragments, i.e. 3 fragments (J-M types 3 and 4) vs. 4 fragments (J-M type 5) demonstrated a significantly lower reoperation rate after a 3-part fracture, i.e. 3 out of 54 (5.6 %), compared to after a 4 part fracture, i.e. 11 out of 63 (17.5 %) (p = 0.048).

Overall, independently of fracture type, the radiological reduction was considered good in 70 fractures (60%), acceptable in 39 (33%) and poor in the remaining 8 (7%) fractures. The corresponding values in the J-M 5 group (n = 63) were 29 (46%), 28 (44%) and 6 (10%). Good reduction was accomplished more often in the J-M type 3 and 4 fractures, in 25 out of 33 (76%) and 16 out of 21 (76%), respectively. There was a trend towards more frequent reoperations in patients with poorly reduced fractures: in 3 out of 8 (38%), compared to 11 out of 109 (10%) in patients with acceptable or good reduction (p = 0.054).

The screw position was considered good in 113 of the 117 patients (97%). There was no correlation between the screw position and the number of reoperations. The overall minimum screw tip-head circumference distance was a mean of 7.6 (-1 to 20) mm. The distance did not differ significantly between patients who were reoperated upon compared to those who were not: mean 6.4 mm compared to 7.8 mm.

14 patients (12.0%) were reoperated upon due to technical failures (**Table 14**). All reoperations but one were due to secondary lag-screw penetration and cut-out. In one patient (No. 101) the lag screw was replaced with a shorter one early on after the index operation due to lag-screw penetration seen on the first postoperative X-ray. One additional patient (No. 69) was also reoperated upon with replacement with a shorter lag screw after approximately one month. The remaining 12 patients received a hip replacement: in 10 patients a total hip replacement (THR) and in two a bipolar hemiarthroplasty (HA). The rationale for choosing HA in patients with a lag-screw penetration may be questioned since most often the penetrating screw has caused significant erosion in the acetabulum. In one of our patients (No. 112) the reason was that there was no obvious acetabular lesion. In the other patient (No. 11), the lesion in the acetabulum was considered intraoperatively to be negligible, and not affecting the outcome of the HA. This assessment in conjunction with the patient's age, 95, was the reason why the surgeon opted to use an HA. All reoperations were performed within the first 6 months after the index procedure.

No patient sustained a postoperative fracture of the femoral shaft distal to the nail during the 12-month follow-up period and no intraoperative femoral fractures were discovered.

Table 14. Data on all patients reoperated upon, including indication, type of operation and time from index surgery (n = 14).

Patient No.	Fx type	Indication	Reoperation/s	Time, months
No. 101	JM 4	L-S penetration	Change of L-S	0.3
No. 112	JM 5	L-S penetration/cut-out	Bipolar HA	0.5
No. 111	JM 5	L-S penetration/cut-out	THR	0.6
No. 69	JM 5	L-S penetration/cut-out	Change of L-S	1.1
No. 21	JM 5	L-S penetration/cut-out	THR	1.4
No. 95	JM 5	L-S penetration/cut-out	THR	1.7
No. 34	JM 5	L-S penetration/cut-out	THR	2.0
No. 114	JM 5	L-S penetration/cut-out	THR	2.4
No. 11	JM 3	L-S penetration/cut-out	Bipolar HA	2.6
No. 83	JM 5	L-S penetration/cut-out	THR	2.7
No. 107	JM 5	L-S penetration/cut-out	THR	3.1
No. 84	JM 5	L-S penetration/cut-out	THR	5.4
No. 20	JM 5	L-S penetration/cut-out	THR	5.4
No. 36	JM 3	L-S penetration/cut-out	THR	5.8

Time = time elapsed from the primary operation; L-S = lag-screw

Functional outcome and HRQoL for all patients

Hip function according to the Charnley hip score and general musculoskeletal function according to the SMFA for all patients available at each follow-up are displayed in **Table 15.** The SMFA Dysfunction Index increased from 24.8 before the fracture to 43.8 and the value at 12 months was 42.4. The SMFA Bother Index increased from 14.3 before the fracture to 36.2 at 4 months and 33.7 at 12 months. The deterioration on both follow-up occasions compared to before fracture was highly significant for both indices ($p < 0.001$ in all 4 comparisons). There were no significant differences in outcome regarding neither the Charnley hip score nor the SMFA on comparing the different fracture types (data not shown).

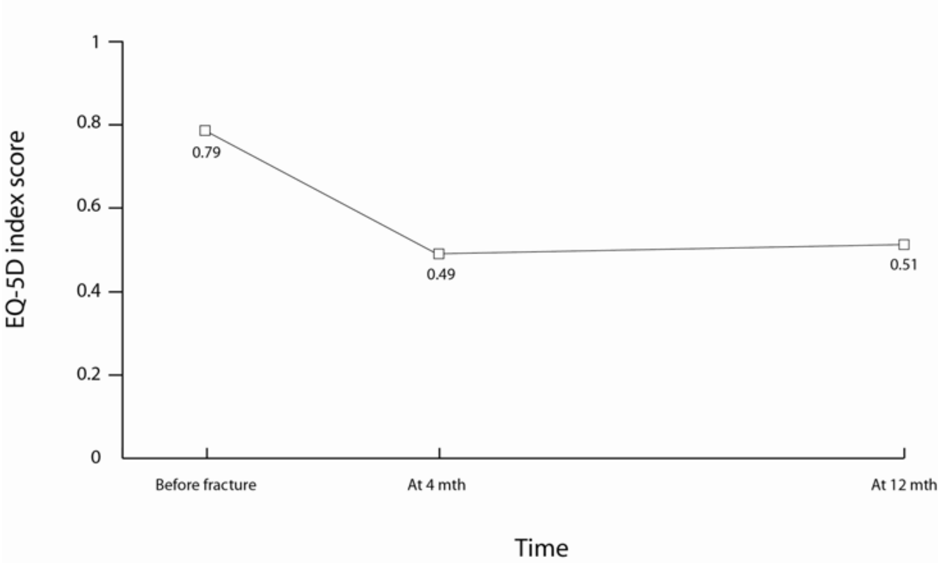
Table 15. Hip function according to the Charnley score and musculoskeletal function according to the SMFA for all patients available at each follow-up (n = 103 at 4 months and n = 80 at 12 months).

	4 months	**12 months**
	Mean	**Mean**
Charnley score pain	4.6^{1}	4.8
movement	5.2^{6}	5.4^{1}
walking	3.0^{1}	3.4
SMFA Dysfunction Index	43.8^{5}	42.4^{2}
Bother Index	36.2^{5}	33.7^{2}

The figures in superscript refer to the number of missing values.

The EQ-5D index score decreased from 0.79 before the fracture to 0.49 at 4 months ($p < 0.001$) and remained at almost the same level at 12 months: 0.51 ($p < 0.001$ for both follow-ups compared to before fracture) (**Figure 19**).

Figure 19. The EQ-5D index score for all patients before fracture and available at each follow-up (n = 117 at inclusion, n = 103 at 4 months and n = 80 at 12 months).



There were no significant differences in outcome regarding the EQ-5D index score on comparing the different fracture types (data not shown).

At the final follow-up 88% of the patients (70/80) were still categorised as indexes A or B and 93% (74/80) were still living independently.

Outcome for patients reoperated upon with a THR

Since a THR is the most common and the most appropriate reoperation in the majority of patients with trochanteric fractures suffering from a secondary lag-screw penetration/cut-out, it could be of interest to analyse the outcome for these patients separately. The SMFA Dysfunction Index increased from 23.5 before the fracture to 51.3 at 4 months and the value at 12 months was 43.4. The corresponding values for the SMFA Bother Index were 12.3, 39.8 and 36.6, respectively. The EQ-5D $_{index}$ score decreased from 0.82 before the fracture to 0.33 at 4 months and 0.58 at 12 months.

STUDY IV

Baseline data

Baseline data for all patients included (n = 53) are displayed in **Table 16.**

Table 16. Baseline data for all patients included (n = 53).

Mean age in years		82.3, range 61–94
Gender, female (%)		41 (77)
ASA classification (%)	**1**	3 (6)
	2	22 (41)
	3	27 (51)
	4	1 (2)
Mean cognitive function (SPMSQ)		8.9 (1.4), range 3–10
From independent living (%)		55 (100)
ADL A and B (%)		52 (98)
Walking aids (%)	**None**	30 (57)
	Stick or crutches	13 (24)
	Walking frame	10 (19)
Mean SMFA* (SD)	**Dysfunction Index**	17.9 (9.2), range 0–40
	Bother Index	9.7 (12.1), range 0–52
Mean (SD) EQ-5D $_{index}$ score prefracture		0.85 (0.16), range 0.23–1.0
Fracture type (%)	**S2A**	2 (4)
	S2B	4 (8)
	S2C	11 (21)
	S3A	15 (28)
	S3B	1 (2)
	S5	20 (38)

* One missing value

Surgical outcome

There was no significant correlation between fracture type and the need for revision surgery. The reduction was considered good in 26 patients (50%) and acceptable in the remaining 26 (50%). None of those with good reduction were reoperated upon, while 6 (23%) of those with acceptable reduction had reoperations ($p < 0.05$).

In total six patients (11%) were reoperated upon, five were due to technical failures and one resulted from an ipsilateral distal femur fracture (**Table 17**). Of the technical failures, three were due to lag-screw penetration and a non-union developed in two. The patient sustaining a distal shaft fracture was treated with plate fixation. The lag-screw position was considered good in 48 (92%) of the 52 patients. We found no significant correlation between reoperations and lag-screw position. The mean minimum lag-screw tip-head circumference distance was 7 (SD 3, range 1–14) mm and patients reoperated upon had a significantly increased distance, 10 (SD 3) mm compared to 6 (SD 3) mm in those not reoperated upon ($p < 0.005$). There were no deep infections.

Table 17. Data on all patients reoperated upon including indication, type of operation and time from index surgery (n = 6).

Patient No.	Fx type	Indication for reoperation	Type of reoperation	Time, months
No. 9	S2B	L-S penetration	THR	1.1
No. 34	S2C	Fx close to tip of the nail	LCP	2.0
No. 24	S2C	L-S penetration	THR	4.1
No. 38	S5	Non-union	THR	9.1
No. 45	S5	1/ Delayed union	Dynamisation	10.3
		2/ Non-union	DCS	13.8
No. 28	S5	Minimal L-S penetration, healed fx	Extraction of LGN	16.0

Time = time elapsed from the primary operation; L-S = lag-screw; LCP = Locking compression plate.

Functional outcome and HRQoL

Hip function results according to the Charnley hip score and general musculoskeletal function according to the SMFA for all patients available at each follow-up are shown in **Table 18**. The SMFA Dysfunction Index increased from 18 before the fracture to 46 at 4 months and to 43 at 12 months. The SMFA Bother Index increased from 10 before the fracture to 43 at 4 months and 40 at 12 months. The deterioration at both follow-ups compared to pre-fracture was highly significant for both indices ($p < 0.001$ in all 4 comparisons).

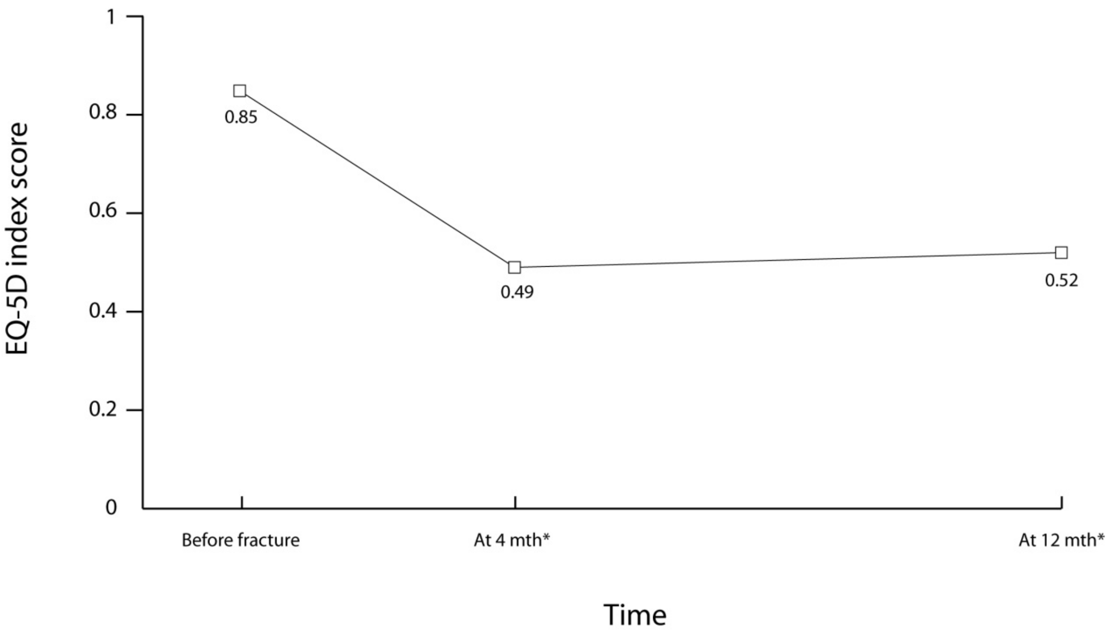
Table 18. Hip function according to the Charnley score and musculoskeletal function according to the SMFA for all patients available at each follow-up (n = 46 at 4 months and n = 39 at 12 months).

	4 months	12 months
	Mean	Mean
Charnley, score pain	4.5[1]	4.7
movement	4.9[2]	5.1[2]
walking	3.0[1]	3.7
SMFA Dysfunction Index	45.9[1]	43.2[1]
Bother Index	42.6[1]	39.8[1]

The figures in superscript refer to the number of missing values.

The EQ-5D $_{index}$ score decreased from 0.85 before the fracture to 0.49 at 4 months ($p < 0.001$) and remained at almost the same level at 12 months, 0.52 ($p < 0.001$; p values are given for the difference between follow-ups and before fracture) (**Figure 20**).

Figure 20. The EQ-5D $_{index}$ score for all patients before fracture and available at each follow-up (n = 53 at inclusion, n = 46 at 4 months and n = 39 at 12 months).



* One missing value at 4 and 12 months, respectively.

At the final follow-up, 90% of the patients (37/41) were still categorised by index A or B in ADL status and 98% (40/41) were still living independently.

STUDY V

Baseline data

The baseline data for all patients included (n = 213) are shown in **Table 19.** Compared to patients with SPMSQ ≥ 3, patients with SPMSQ < 3 were older, were more often admitted from an institution and had a lower HRQoL, an increased need for walking aids and more impaired walking ability and were more dependent in ADL before the fracture. The surgical interventions, SGN or MSP, were evenly distributed between the two groups (data not shown).

Table 19. Baseline data for all patients included (n=213) with regard to cognitive function according to the SPMSQ.

	SPMSQ < 3 **n = 50**	**SPMSQ ≥ 3** **N = 163**	**p**
Mean age in years	86.1	82.8	< 0.005
Mean EQ-5D $_{index}$ score prefracture*	0.24	0.64	< 0.001
Hip function, mean score walking	3.0	4.0	< 0.001
Gender (female), n (%)	39 (78)	133 (82)	ns
Walking aid, none or just one stick, n (%)	21 (42)	114 (70)	< 0.001
ADL A & B, n (%)	10 (20)	141 (87)	< 0.001
Independent living, n (%)	26 (52)	157 (96)	< 0.001
Co-morbidity Ceder C, n (%)	50 (100)	76 (47)	< 0.001

* 1 missing value

Surgical outcome

The postoperative infection or reoperation rate did not differ between the groups. In the SPMSQ < 3 group, there were two superficial infections (4.0%) and, in the SPMSQ ≥ 3 group, there were 6 superficial and two deep infections (4.9%). The total number of reoperations in the SPMSQ < 3 group was 2 out of 50 (4.0%) compared to 10 out of 163 (6.1%) in the SPMSQ ≥ 3 group.

Mortality

General complications besides mortality did not differ between the groups. The one-year mortality rate was 24 out of 50 (48%) in patients with SPMSQ < 3 and 29 out of 163 (18%) in patients with SPMSQ ≥ 3 ($p < 0.001$). The mortality rate for men was 20 out of 41 (49%) and 33 out of 172 (19%) for women ($p < 0.001$). The mortality rate was 10 out of 58 (17%) in patients ≤ 80 years of age and 43 out of 155 (28%) in patients > 80 years of age (ns).

We performed a Cox regression analysis in order to further evaluate factors of importance for mortality during the first 12 months. Cognitive function according to the SPMSQ, age and gender were tested as independent variables in the model. The analysis showed that an SPMSQ score < 3 and male gender were associated with increased mortality during the first 12 months (**Table 20**).

Table 20. The estimated hazard ratio (HR) and 95% confidence interval (CI) for patients deceased at the 12-months follow-up in relation to cognitive function, age and gender (Cox regression).

		Deceased before the 12-month follow-up		
		HR	**95% CI**	**p**
SPMSQ	**≥ 3**	1 (reference)		
	< 3	3.4	1.9-6.1	<0.001
Age	**≤ 80 years**	1 (reference)		
	> 80 years	1.5	0.7-3.1	ns
Gender,	**female**	1 (reference)		
	male	3.9	2.2-6.9	<0.001

The estimated cumulated survival in relation to cognitive function adjusted for age and gender (Cox regression) is displayed in **Figure 21** and the corresponding survival curve for the estimated cumulated survival in relation to gender adjusted for cognitive function and age (Cox regression) is shown in **Figure 22**.

Figure 21. The estimated cumulated survival in relation to cognitive function adjusted for age and gender (Cox regression); SPMSQ < 3 (n = 50) and SPMSQ ≥ 3 (n = 163).

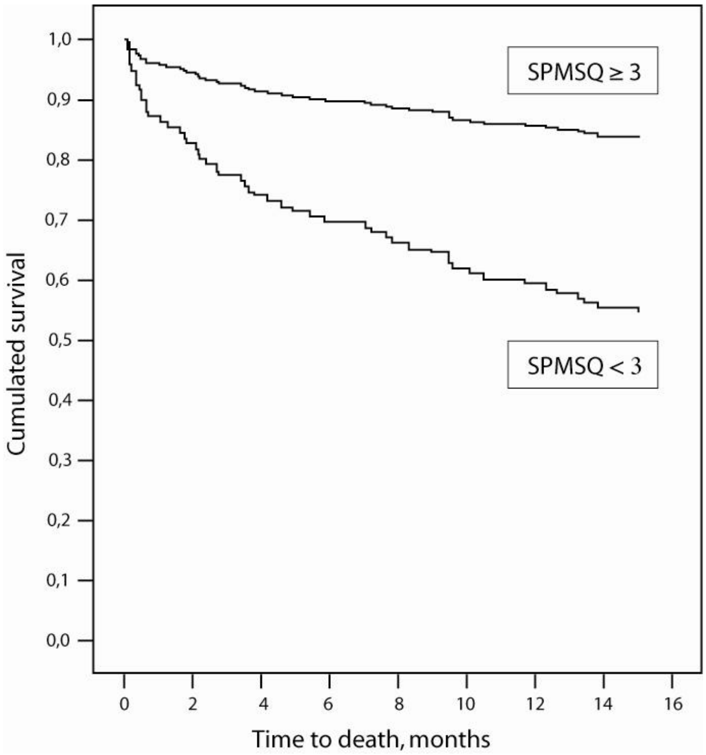
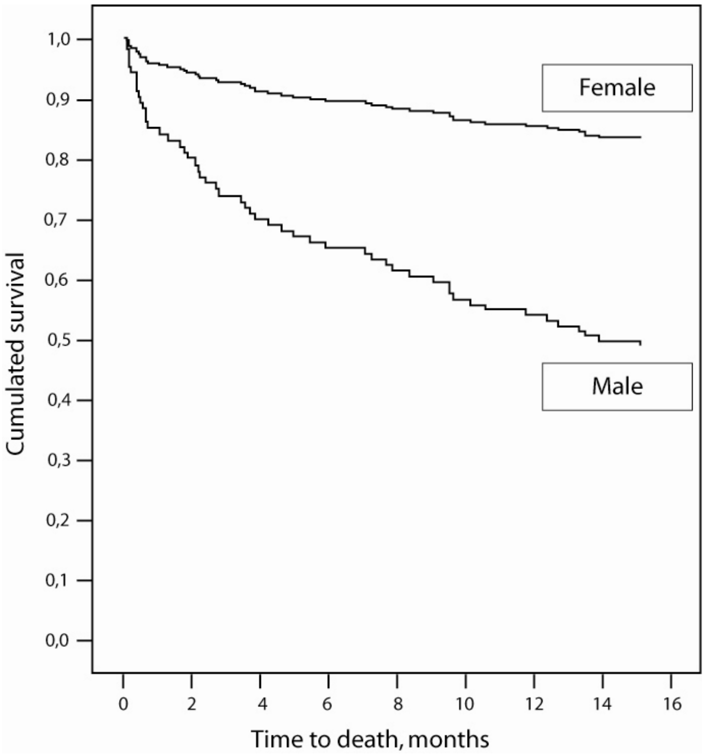


Figure 22. The estimated cumulated survival in relation to gender adjusted for cognitive function and age (Cox regression); female (n = 172) and male ≥ 3 (n = 41).



Functional outcome and HRQoL

The results regarding hip function, i.e. walking ability and pain, are displayed in **Table 21**. Patients with SPMSQ < 3 had a significantly more impaired walking ability on all occasions compared to patients with SPMSQ ≥ 3. Furthermore, they showed a significant deterioration in walking ability with 36% of the patients wheel-chair-bound or bedridden at the final follow-up. This contrasted with the pain assessment, which was similar in both groups.

Table 21. Hip function according to the Charnley score for all patients before the fracture (n = 213) and for all patients available at each follow-up (n = 164 at 4 months; n = 154 at 12 months). Mean values and percentages of patients with the score 1 (worst possible) are displayed.

		SPMSQ < 3		**SPMSQ ≥ 3**		
		Mean	**Score 1**	**Mean**	**Score 1**	**p**
Walking	Before fracture	3.0	0%	4.0	0%	<0.001
	At 4 months	1.8	32%	2.7	11%	<0.001
	At 12 months*	1.9	36%	3.0	9%	<0.001
Pain	At 4 months**	4.9	3%	4.7	1%	ns
	At 12 months*	5.5	0%	5.2	1%	ns

* 1 missing value; **2 missing values

As could be expected, patients with SPMSQ < 3 were more dependent in ADL function on all occasions (**Table 22**).

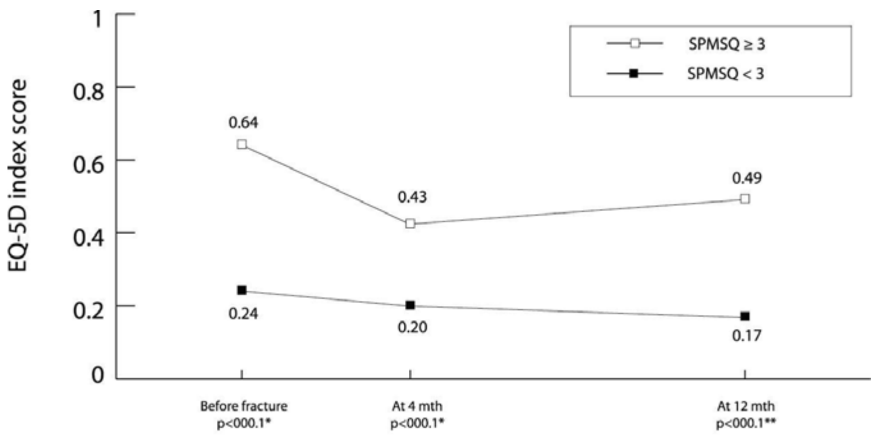
Table 22. ADL status among randomisation groups according to Katz for all patients before the fracture (n = 213) and for all patients available at each follow-up (n = 164 at 4 months; n = 154 at 12 months). Mean values and percentages of patients with the score 6 (worst possible) are displayed.

		SPMSQ < 3		**SPMSQ ≥ 3**		
		Mean	**Score 6**	**Mean**	**Score 6**	**p**
ADL	Before fracture	3.2	24%	0.5	0%	<0.001
	At 4 months	4.7	29%	1.6	7%	<0.001
	At 12 months	4.3	39%	1.5	5%	<0.001

Moreover, they also showed a significant deterioration with 39% being totally dependent in all functions at the final follow-up. This inability to manage activities of daily living is mirrored in the high percentage of patients with SPMSQ < 3 who were institutionalised at the time of the 12-month follow-up: 16 out of 23 patients (69%) compared to 14 out of 131 (11%) for patients with SPMSQ ≥ 3 ($p < 0.001$).

Patients with SPMSQ < 3 had a significantly lower EQ-5D $_{index}$ score at inclusion and on each follow-up occasion and also showed a continuous deterioration in HRQoL in contrast to patients with SPMSQ ≥ 3, who had significant improvement in the EQ-5D $_{index}$ score between the 4- and 12-month follow-ups ($p < 0.05$) (**Figure 23**).

Figure 23. The EQ-5D $_{index}$ score for patients with (SPMSQ < 3) and without (SPMSQ ≥ 3) severe cognitive dysfunction, including all patients before the fracture (n = 213) and for all patients available at each follow-up (n = 164 at 4 months; n = 154 at 12 months).



* 1 missing value; ** 2 missing values

GENERAL DISCUSSION

The overall aim of the thesis was to evaluate the outcome in patients with stable trochanteric (*Study II*), unstable trochanteric (*Studies I* and *III*) and subtrochanteric (*Studies I* and *IV*) femoral fractures with aspects of surgical methods, including an assessment of functional outcome and HRQoL. Moreover, the aim was to evaluate whether severe cognitive dysfunction, assessed with a validated instrument, the SPMSQ, could predict the outcome regarding function, HRQoL and mortality (*Study V*).

FAILURE RATES AND REOPERATION RATES

2-part fractures

The results of Study *II* confirmed the good surgical outcome and low reoperation rate after a stable trochanteric fracture (J-M 1 -2)[14] treated with an SHS. Our finding of a 3% reoperation rate was in conformity with previous studies.[88,89] The reoperation rate, presented separately for stable trochanteric fractures treated with cephalomedullary nails, are difficult to find in the literature since most studies include a mixed population of stable and unstable fractures. However, equally good results after a stable trochanteric fracture have been reported by Leung et al.[90] with the prototype for the TGN and by Zou and co-workers for the PFNA.[91] The MSP with its potential for compression along the femoral shaft has, theoretically, no major advantages compared to the SHS in patients with stable trochanteric fractures. However, the MSP has also been used in this fracture type and showed good results.[92]

3- and 4-part fractures

The findings of *Study I* show generally good results with both the SGN and MSP in patients with unstable trochanteric fractures with technical failure rates of 6% (including 3% intraoperative femoral fractures) and 5%, respectively. Furthermore, there was a trend towards a decreased number of reoperations in the SGN group: 3%, compared to the MSP group, 6%.

The results with the SGN in *Study I* compared favourably with those of previous reports on the SHS[88,89,93-96] and were comparable to those previously reported for the MSP.[25,88,92,96] The main problem remained the risk of intraoperative fractures (2.8% in *Study I*), although, in the majority of cases, they were induced by an inappropriate surgical technique. All the intraoperative fractures were detected during the primary procedure and the fixation could easily be converted to an LGN. Consequently, this technical problem did not necessitate any secondary revision procedures. The absence of postoperative femoral fractures during the 12-month follow-up implies that some of the previously reported early femoral shaft fractures are, in fact, unrecognised intraoperative fractures. The problem with femoral shaft fractures will be discussed more thoroughly later.

The good result with the MSP used in the biaxial dynamisation mode in unstable trochanteric fractures was confirmed in *Study I*. The failure rate of 5% compares favourably with those in previous studies on the SHS[77,88,89,94-96] and is somewhat better than those reported for the MSP in the Swedish multicentre study, i.e. 7%[97], but not as good as those reported by Lunsjö et al.[92], 2.0%, and Watson et al.[88], 4%. In clinical practice, the differentiation between low trochanteric fractures and high subtrochanteric fractures is difficult and may lead to erroneous uniaxial dynamisation in trochanteric fractures. This was the situation in the Swedish multicentre study[97] where the locking set screw was erroneously used in 29 out of 268 patients and contributed to lag-screw penetration in 9 patients. The suboptimal results of uniaxial dynamisation in unstable trochanteric fractures was also demonstrated in an early study by Lunsjö et al.[98] with 7% lag-screw penetrations. To partly overcome this, a shorter 4-hole MSP was introduced with obligatory biaxial dynamisation,[99] but the problem of correct interpretation and classification of the fracture type in clinical practice still remains.

In *Study III* including only patients with unstable trochanteric fractures treated with the TGN, the rate of technical failures and the need for revision surgery, 12%, were surprisingly high compared to *Study I* displaying a technical failure rate of only 6% in patients with unstable trochanteric fractures treated with the SGN. All but one reoperations in *Study III* were due to secondary lag-screw penetration and cut-out. In one patient the lag-screw penetration was seen on the first postoperative X-ray, indicating a surgical error. Excluding this case still gives a reoperation rate of 11% and the reason for this difference in reoperation rates between *Study III* (TGN) and *Study I* (SGN) is difficult to interpret. The study populations did not differ regarding age, gender or fracture type, nor were there any detectable differences regarding fracture reduction and implant position.

A comparison with other recently published prospective studies including patients with unstable trochanteric fractures is difficult to make since most studies include a mixed population of patients with stable and unstable trochanteric fractures[100-102] or a mixed population of patients with trochanteric and subtrochanteric fractures.[103] In the RCT by Papasimos and co-workers[104] comparing cephalomedullary nails (TGN and PFN) with SHS (DHS, AMBI hip screw), the reoperation rate was 8% in the nail group and 13% in the plate group. In the subgroup of unstable trochanteric fractures in the study by Ekström et al.[103] comparing a cephalomedullary nail (PFN) with the MSP, 7% of the patients in the nail group required a reoperation compared to 1% in the MSP group.

Other possible explanations for our relatively high failure rate after TGN, besides chance, could be insufficient sliding of the TGN lag screw, a suboptimal surgical technique with erroneous locking of the lag screw or differing degrees of osteoporosis. We are not aware of any previous clinical studies indicating problems with sliding of the lag screw in the TGN, but in a biomechanical study, Loch and co-workers[105] investigated the forces required to initiate sliding with different intramedullary nails and SHS. Mechanical jamming of the lag screw did not occur with the Gamma nail but, in comparison, the Gamma nail required the highest forces to initiate sliding, a finding common also for other devices with a short barrel. In order to further analyse the failures in *Study III,* we performed a second survey of the postoperative X-rays in the 13 patients who experienced a secondary lag-screw penetration/cut-out and we could only find one case where jamming of the lag screw may be suspected. This makes insufficient sliding and erroneous locking of the lag screw less likely as explanations for the worse result for TGN in *Study III*. Of course, there could be other details in the surgical technique that are not detected by our classification of reduction and implant position. The existence of a learning curve in acquiring technical skills in orthopaedic surgery is well known. The speed of learning is dependent, among other factors such as on surgeon-related ones, operating team experience, surgical volume in the department[106,107] and the educational atmosphere. Earlier comparative studies between the hip compression screw and the Gamma nail have also indicated that the nail was associated with significant learning curves.[108] However, there were no differences concerning the experience of the participating surgeons in *Studies I* and *III* that would indicate different levels of surgical skill. The surgeons in both studies were all certified specialists in orthopaedic surgery and approximately 50% of the operations were performed by consultants. Finally, the question regarding differing degrees of osteoporosis can not be answered since no assessments of osteoporosis were made in our study populations.

An important additional finding in *Study III* was a significantly higher reoperation rate among patients with 4-part (J-M 5) fractures compared to those with a 3-part fracture (J-M 3 and 4), 17% vs 6%. Lunsjö et al. [97] reported a similar finding with almost all failures in patients with 4-part fractures (J-M 5). This finding indirectly supports the validity of the Jensen-Michaelsen classification[14] and also indicates that further efforts are needed to reduce the failure rate in the particularly unstable 4-part fracture.

Subtrochanteric fractures

Among the limited number of patients with subtrochanteric fractures in *Study I,* there were no failures in the SGN group, as compared to 2 out of 12 in the MSP group, both owing to pronounced medialisation of the femoral shaft. For the limited group of subtrochanteric fractures, the failure rate was surprisingly high for the MSP. The two reoperations because of technical failures were due to excessive medialisation in patients with Seinsheimer type S 2 C fractures, also referred to as the reversed oblique subtrochanteric fracture. The explanation may be that the MSP was used in the biaxial dynamisation mode. Lunsjö et al.[96] reported only 2% of technical failures in subtrochanteric fractures when the MSP was used in the uniaxial dynamisation mode. However, as previously mentioned, uniaxial dynamisation requires frequent radiographic follow-up and readiness for staged dynamisation in a number of cases to prevent lag-screw penetration[25] and, in clinical practice, the differentiation between low trochanteric fractures and high subtrochanteric fractures may be difficult to assess and may lead to erroneous uniaxial dynamisation in trochanteric fractures.

In *Study IV* including only patients with subtrochanteric fractures treated with the LGN, the rate of technical failures and the need for revision surgery, 11%, were of the same magnitude as reported in two previous studies on elderly patients with subtrochanteric fractures treated with cephalomedullary nails. Robinson et al.[109] reported an overall reoperation rate of 9% and Ekström et al.[110] of 8%. The Seinsheimer type S2C in particular has had a high complication rate in patients treated with extramedullary implants, including the MSP (*Study I),*[111] but this does not seem to be a problem when the fixation is with intramedullary devices.

FRACTURE HEALING COMPLICATIONS

The main reason for revision surgery in *Study II* including only patients with stable 2-part fractures treated with SHS was lag-screw penetration/cut-out, which has also been shown to be the predominant cause of revision in most other studies.[77,89,94,112]

The only indication for a reoperation in *Study III* including only patients with unstable 3- and 4-part fractures treated with a TGN was also lag-screw penetration/cut-out, a finding which, to some extent, is in contrast with previous studies on patients with unstable trochanteric fractures where a combination of complications is often reported. These complications include lag-screw penetration/cut-out, intra- or postoperative femoral fractures, non-union, including breakage or loosening of the osteosynthesis and redislocation with excessive medialisation of the femoral shaft, the latter a complication only seen after plate fixation.[97,99,113]

In *Study I* including patients with both unstable trochanteric and subtrochanteric fractures randomised to treatment with the SGN or MSP, the failures in the SGN group were equally divided between lag-screw penetration/cut-out and intraoperative femoral fractures. In the MSP group the failures were divided between lag-screw penetration/cut-out and redislocation with excessive medialisation of the femoral shaft.

Finally, in *Study IV* including only patients with subtrochanteric fractures treated with the LGN, the main indications for reoperation were similar to those reported from the studies by Ekström et al.[110] and Robinson et al.,[109] i.e. lag-screw penetration/cut-out and non-union. Additionally, one patient sustained a fracture close to the tip of the nail after a new falling accident.

The vast majority of the lag-screw penetrations/cut-outs in all studies occurred during the early postoperative phase, most often within 6 months, while the non-unions after subtrochanteric fractures (*Study IV*) were diagnosed and treated later, between 6 and 12 months. As expected, redislocation with excessive medialisation of the femoral shaft was seen only in patients with unstable 3-and 4-part trochanteric fractures and subtrochanteric fractures treated with plate fixation (MSP; *Study I*).

Non-union was seen after subtrochanteric fractures (*Study IV*) while there were no patients with non-union after a trochanteric fracture.

In summary, the main mode of failure in trochanteric fractures, regardless of treatment method, intramedullary or extramedullary, was lag-screw penetration/cut-out. Additionally, after extramedullary fixation there is a risk for redislocation with excessive medialisation of the femoral shaft.

In subtrochanteric fractures the modes of failure regardless of treatment method, intramedullary or extramedullary, were lag-screw penetration/cut-out and non-union. Additionally, after extramedullary fixation there is a risk for redislocation with excessive medialisation of the femoral shaft.

WOUND INFECTIONS

As previously mentioned, the cephalomedullary nails have theoretical advantages owing to the improved biomechanics with a shorter lever arm leading to a more stable fracture construct. Furthermore, the percutaneous insertion technique may result in less soft tissue trauma and thereby reduce bleeding and the incidence of infection. The theoretical advantages of the percutaneously inserted SGN appeared to be partly confirmed in *Study I* with more limited intraoperative bleeding, although this was not confirmed in the form of a reduced need for transfusions, a reduced number of severe general complications and a reduced number of wound infections. The reduced number of severe general complications is noteworthy inasmuch as the randomisation resulted in a trend towards slightly older patients in the SGN group, i.e. 84.6 years, compared to 82.7 years in the plate group. The most probable explanation for these findings is the less extensive surgical trauma with the cephalomedullary nail. However, a significantly lower rate of wound infections after nail fixation compared to plate fixation has not yet been confirmed in the Cochrane meta-analysis RCTs,[33] but somewhat lower infection rates have been reported in single studies.[90,100,114,115]

FEMORAL SHAFT FRACTURES

In *Study I* there was 3% intraoperative fractures in the SGN group, although, in the majority of cases, they were induced by inappropriate surgical technique. All the intraoperative fractures were detected during the primary procedure and the fixation could easily be converted to an LGN. Consequently, this technical problem did not necessitate any secondary revision procedures. The absence of postoperative femoral fractures during the 12-month follow-up implies that most of the previously reported early femoral shaft fractures after the first-generation Gamma nail are, in fact, unrecognised intraoperative fractures. An implant with an inherent risk of femoral fractures is not optimal, but this risk may be partly due to the specific design of the SGN and partly due to an inadequate surgical technique. The length of this first generation Gamma nail (200 mm) in combination with 10º of valgus creates a three-point fixation by the non-elastic implant within the proximal femur, leading to a stress concentration in the femur at the distal part of the implant.[35,36] In 1992 Leung et al. published their findings for a modified Gamma nail with a length of 180 mm and only 4º of valgus bend, which resulted in no femoral fractures.[90] This modified Gamma nail very much resembles the second-generation Gamma nail, the trochanteric Gamma nail (TGN), which was used in *Study III.*

There were neither intra- nor postoperative fractures of the femur during the one-year follow-up in *Study III,* indicating the TGN with an altered design compared to the SGN with a lower valgus bend and a shorter nail, reduces the risk of iatrogenic femoral fractures. Moreover, it has been emphasised more and more over the years that the nail should be introduced gently without using a hammer and that the distal locking screw should be inserted using an adequate and atraumatic technique in order to avoid iatrogenic femoral fractures. Our finding of no intra- nor postoperative fractures of the femur after the TGN is in conformity with the results of a meta-analysis from 2009 by Bhandari and co-workers.[38] They found that studies conducted after the year 2000 did not report a significantly increased risk of femoral shaft fractures when the Gamma nail was used. Their objection to a previous systematic review[116] reporting an overall increased risk of femoral shaft fracture was that the previous review did not take into account the effect of implant design or the time period during which the studies were conducted. The overall conclusion was that previous concerns relating to an increased risk of femoral shaft fracture with the Gamma nails had been resolved with the further developed implant design and improved surgical learning curve with the device.[38]

To the best of our knowledge, there is as yet no prospective study on the third generation of Gamma nails, i.e. the Gamma3.

SALVAGE PROCEDURES

The majority of the patients with lag-screw penetrations/cut-outs in *Studies I* and *III* were treated with a hip arthroplasty, in the majority a THR, which is a logical salvage procedure since the penetrating lag crew has most often caused significant erosion of the acetabulum. Moreover, in *Study III* we could report that the patients who received a THR showed, as expected, a substantial decline in HRQoL at the 4-month follow-up due to their complication and reoperation. The recovery at the 12-month follow-up after revision surgery was surprisingly good, showing an improvement in the SMFA indices and the EQ-5D $_{index}$ score to a level that was at par with that of patients who had an uneventful outcome. The same pattern has been reported in patients with displaced femoral neck fractures undergoing a secondary THR after failed internal fixation.[117,118] This finding is supported by previous studies. Cho et al.,[119] who concluded that THR appears to be a more reliable salvage procedure for failed trochanteric fracture fixation regarding functional outcome and pain relief compared to bipolar HA. D`Arrigo and co-workers[120] found a significant improvement on comparing the pre- and postoperative status after a THR as a salvage procedure for failed treatment of a trochanteric fracture in elderly patients. Similar findings were presented by Haidukewych et al.,[121] but often with a need for calcar-replacement and long-stem implants.

In *Study I,* 2 out of 3 patients with excessive medialisation after an MSP were successfully treated with a long cephalomedullary nail. In the third case, a primary revision to a DCS was done but resulted eventually in a THR. In our opinion, the most appropriate solution for patients with excessive medialisation after plate fixation is reosteosynthesis with a long cephalomedullary nail.

In *Study IV,* one of the patients with a subtrochanteric non-union was treated with revision osteosynthesis with DCS and compression and the other with a conversion to a THR. This illustrates the two options available. In most cases in elderly patients the best choice is, in our opinion, a THR, while a revision osteosyntesis may be preferable in the younger patients with better bone quality and a longer life expectancy.

SURGICAL TECHNIQUE

The basic principles of the surgical technique for the SHS/MSP and the cephalomedullary nails are quite different. Surgeons experienced in the technique for inserting the lag-screw in the SHS or MSP are used to initially positioning the lag-screw optimally and then applying the side-plate. For the cephalomedullary nails, the procedure starts with inserting a nail with a fixed neck angle and then inserting the lag-screw. If an optimal guide-wire position is not achieved after proper insertion of the nail, the surgeon has to improve the reduction or change to a nail with a different neck angle. This may induce surgeons inexperienced in the nailing technique to accept a suboptimal lag-screw position, which in turn would contribute to a worse outcome. We know from several studies that besides reduction, an optimal lag-screw position within the femoral head[75-77] is an important factor for determining the prognosis.

We inserted the SGN (*Study I*), TGN (*Study III*) and LGN (*Study IV*) via a proximal mini-invasive incision followed by reaming of the medullary canal to 13 mm distally and 17 mm proximally, whereupon the nail was introduced. The nails were recommended to be inserted gently by hand and no hammer was allowed for insertion of the nail and no awl was allowed for creating the starting point for the locking screw. It is important to bear these factors in mind in order to minimise the risk of iatrogenic femoral shaft fractures, and our protocol is probably the main reason for the low rate of femoral shaft fractures after the SGN (*Study I*) and no fractures after the TGN (*Study III*).

In *Study I* we used the MSP in the biaxial dynamisation mode which allows sliding along both the femoral neck and the femoral shaft. In fractures proximal to the entry site of the plate barrel, the surgical technique requires that the entry hole for the barrel has to be enlarged up to 2.5 cm distally in order to allow axial compression along the femoral shaft. To be able to make this decision, the surgeon has to differentiate between low trochanteric fractures and high subtrochanteric ones, which may be difficult in routine healthcare. This may be a possible explanation for why the MSP is not perceived as being as user-friendly as the SHS or the cephalomedullary nails and why its use in clinical practice has been limited despite the good results reported in clinical trials.

HIP FUNCTION

The Charnley hip score was used in all studies and the results for each study are presented in **Table 23.**

Table 23. The results for the pain and walking dimensions of the Charnley hip score in *Studies I–IV*.

	Pain		**Walking ability**	
	4 months	12 months	4 months	12 months
Study I				
SGN	4.8	5.3	2.5	2.8
MSP	4.7	5.2	2.6	2.9
Study II				
DHS	5.1	5.3		
Study III				
TGN	4.6	4.8	3.0	3.4
Study IV				
LGN	4.5	4.7	3.0	3.7

Although the different study populations were comparable regarding age, mean 82–84 years, their walking ability before fracture differed, which makes the interpretation of walking ability between studies and comparisons with other studies very difficult. In *Study I* 36% of the patients used some form of walking aid already before their fracture. The corresponding figure in *Study II* was 59%, in *Study III* 55% and in *Study IV* 43%.

Generally speaking, reports on pain and functional outcomes for patients with trochanteric fractures are sparse in the literature.[122] An interesting finding in *Study I* was that there were no differences regarding hip function according to the Charnley hip score on comparing the SGN and MSP. Perhaps this implies that functional outcome does not differ substantially on comparing intra- and extramedullary fixation and that the main focus for improving the treatment should be on reducing the number of technical failures, especially those leading to revision surgery. In several studies,[88,97,123-125] no significant differences between nails and plates are shown, except for the study by Ahrengart et al.[126] reporting more pain associated with the intramedullary nail and the study by Ekström and co-workers[103] reporting better walking ability after 6 weeks following treatment with a PFN compared to an MSP.

MUSCULOSKELETAL FUNCTION ACCORDING TO THE SMFA

It is even more difficult to compare the outcome for our patients regarding musculoskeletal function according to the SMFA with those of previous studies because there are only a few papers reporting longitudinal SMFA data[78,127] and only one including hip fracture patients. In a recently published retrospective cohort study with a mean follow-up of 50 months in 26 multitrauma patients, 13 of whom were treated with a sliding hip screw in combination with a retrograde nail and 13 with a reconstruction nail, Peskun and co-workers[128] reported a Dysfunction Index of 33 in both groups and a Bother Index of 37 and 39, respectively. Despite severe injury in a multitrauma population, the reported outcome was better than that reported by our patients. This finding is probably partly explained by the younger patient population (mean age 44 years).

The results of *Study III,* including only patients with unstable trochanteric fractures treated with the TGN, showed a substantial deterioration in musculoskeletal function as demonstrated by the significant increase in the SMFA Dysfunction and Bother Indices. The impairment in musculoskeletal function was of the same magnitude in both indices of the SMFA. The Dysfunction Index changed from 25 before fracture to 42 at 12 months and the corresponding values for the Bother Index were 14 and 34. The deterioration of these indices was similar to those reported in *Study IV* including only patients with subtrochanteric fractures treated with the LGN. Also this fracture resulted in a substantial deterioration in musculoskeletal function, as demonstrated by the significant increase in the SMFA Dysfunction and Bother Indices of the same magnitude in both indices. The Dysfunction Index changed from 18 before fracture to 43 at 12 months and the corresponding values for the Bother Index were 10 and 40.

The deterioration in musculoskeletal function according to the SMFA for the patients with unstable trochanteric (*Study III*) and subtrochanteric (*Study IV*) fractures was reflected by a similar deterioration in HRQoL according to the EQ-5D in both fracture types.

QUALITY OF LIFE ACCORDING TO THE EQ-5D

Patients without severe cognitive dysfunction in all studies reported a significant deterioration in HRQoL according to the EQ-5D during the first postoperative year, although there were differences in the magnitude.

The patients with stable trochanteric fractures in *Study II* experienced deterioration in their quality of life during the first postoperative year and the Δ EQ-5D $_{index}$ score at one year was -0.10 and at two years the survivors had almost regained the same level of quality of life as before the fracture.

In *Study III* including only patients with unstable trochanteric fractures the Δ EQ-5D $_{index}$ score at one year was -0.28 and in *Study IV,* including only patients with subtrochanteric fractures, the Δ EQ-5D $_{index}$ score at one year was -0.33. In *Study I,* including both patients with unstable trochanteric and subtrochanteric fractures randomised to treatment with SGN or MSP, the Δ EQ-5D $_{index}$ score at one year was -0.15 without any significant differences between the randomisation groups. Unfortunately, the follow-up times in *Studies I, III* and *IV* were only one year, so we do not know for sure if there was an improvement during the second year as in the situation after a stable trochanteric fracture (*Study II*), although it seems less likely.

Our overall interpretation was that the outcome regarding HRQoL after a stable trochanteric fracture is comparably good, while the outcome after an unstable trochanteric or subtrochanteric fracture is clearly worse.

For comparison, patients with undisplaced or displaced femoral neck fractures treated with internal fixation have a reduction of the EQ-5D $_{index}$ score during the first year after surgery of 0.10 and 0.22, respectively,[129] and for patients with displaced femoral neck fractures treated with bipolar HA and THR the Δ EQ-5D $_{index}$ score at one year is -0.17 and -0.10 to 0.12, respectively.[117,130]

ASSESSMENT OF OUTCOME

Does a quality of life assessment add any valuable information? Up to now there had been a very limited number of papers evaluating the HRQOL after trochanteric fractures and even fewer using a validated quality-of-life instrument in the assessment. There is a growing opinion that measures of quality of life should be used to evaluate all healthcare interventions.[131] The quality of life assessment serves as a complement to conventional outcome measures in orthopaedic surgery, such as fracture-healing complications, reoperations and mortality, and also as a complement to disease-specific outcome instruments, e.g. scores evaluating hip function. The EQ-5D is brief and easy to use in elderly patients[132,133] and has been validated in hip-fracture patients.[134-136] Moreover, it also allows combining different dimensions of health to form an overall index, such as required for healthcare evaluations[137] and for constructing quality-adjusted life years (QALYs),[138] a measure frequently used in cost-effectiveness analyses.

NAIL OR PLATE?

'Despite the ever increasing literature on the topic of hip fractures, the optimal treatment of hip fractures remains unknown and controversial,' Bhandari et al. 2009.[139] In accordance with this statement, there is no consensus among orthopaedic surgeons regarding the treatment of extracapsular hip fractures, i.e. trochanteric and subtrochanteric fractures. There is a general agreement on the aims of surgical intervention to decrease pain, provide a construct stable enough to withstand early transfers, mobilisation and weight-bearing and the objective in the long term of re-establishing the patient's prefracture level of function and independence. One of the major controversies is whether cephalomedullary nails or extramedullary implants should be used in the different types of trochanteric and subtrochanteric femoral fractures. Concerns about the Gamma nails and other cephalomedullary nails have been confirmed by early meta-analyses and randomised trials demonstrating an increased risk of femoral shaft fractures during and after the operation. Furthermore, other incentives for the use of the nails have been debated. In a study by Forte et al. from 2010[140] on a large Medicare series from the years 2000–2002, the authors looked at provider factors associated with the use of intramedullary nails for trochanteric fractures and found that the use of nails was strongly associated with early-career surgeons and surgeon training programmes. Surgeons operating at more than one hospital were overrepresented as well as hospitals with teaching status and high-volume hip surgery as well. An aspect of a more delicate issue is the use of nails affected by the close co-operation of teaching hospitals with manufacturers, and also the Medicare payment system may lead to choices of implants in contrast to evidence-based medicine principles. Anglen et al.[141] conducted a review of the American Board of Orthopaedic Surgery database from 1999 to 2006 on nail or plate fixation of trochanteric femoral fractures among young surgeons and described a changed pattern of practice in favour of nails despite, according to the authors, a lack of evidence in the literature supporting this change.

The largest and latest meta-analysis on this issue, the Cochrane review from 2010,[33] concluded that there is no evidence supporting the use of the Gamma nail or other types of cephalomedullary nails as compared to the SHS in trochanteric fractures. Regarding the more distal reverse and transverse transtrochanteric fractures and subtrochanteric fractures, the conclusion was that the cephalomedullary nails may have advantages over the extramedullary devices. Furthermore, pooled data in this review did not show any differences between the implants regarding lag-screw penetration/cut-out and non-union. The authors pointed out that the increased risk of intraoperative and later femoral fractures around or below the implant was a particular problem with the nails. A discreet reservation regarding this problem was made when discussing nails of more modern design and more recent studies. It is noteworthy that recently conducted studies showed low or no incidence of intraoperative fracture of the femoral diaphysis and few or no subsequent fractures of the femur around the implant.[100,101,104]

As previously discussed, the increased risk of femoral shaft fractures when using cephalomedullary nails appears to be solved with newer designs of the nails and improved surgical technique. The meta-analysis by Bhandari et al. from 2009[38] dividing all included studies into three groups in relation to the time when they were conducted concludes that previous concerns about an increased femoral shaft fracture risk with Gamma nails have been resolved with improved implant design and improved learning curves with the device. Earlier meta-analyses and randomised trials should be interpreted with caution in the light of more recent evidence. This statement is in conformity with our results in *Study III* using the second-generation Gamma nail, the TGN, with no intra- or postoperative femoral fractures. The third and most recent generation of Gamma nails, the Gamma3 has not yet been compared in a large prospective or randomised trial in patients with trochanteric fractures.

The use of cephalomedullary nails in patients with subtrochanteric fractures is also supported by a recent meta-analysis[142] stating that there is evidence indicating reduced operating time and a reduced fixation failure rate with the use of intramedullary implants. This conclusion is in conformity with the results of *Study IV* utilising the LGN in patients with subtrochanteric femoral fractures.

As previously discussed, the MSP has displayed good results in clinical studies[92,96,97,103] and yet its use in clinical practice is limited. One major objection has been lacking user-friendliness and the need for consistent fracture classification in order to use the implant optimally.

In summary, our interpretation of current evidence is as follows: there is sufficient evidence supporting the advantages of using cephalomedullary nails in the treatment of subtrochanteric fractures. Moreover, cephalomedullary nails of newer generations are also safe to use in patients with stable and unstable trochanteric fractures since problems with intra-operative and subsequent fractures of the femoral shaft related to earlier designs have been solved in recent designs and with a modern atraumatic surgical technique. However, whether there are any obvious advantages with the new cephalomedullary nails compared to the SHS, including functional outcome and HRQoL, will require future large, collaborative studies that are sufficiently powered to evaluate the subgroups of patients with stable and different types of unstable trochanteric femoral fractures.[38,139]

THE INFLUENCE OF COGNITIVE FUNCTION ON OUTCOME

We used the Short Portable Mental Status Questionnaire (SPMSQ) on admission to the orthopaedic ward in *Study V* to identify patients with severe cognitive impairment in a cohort of elderly hip fracture patients. According to the recommendation, the definition for severe cognitive dysfunction was < 3 correct answers on the SPMSQ (SPMSQ < 3) and the baseline and outcome data for these patients were compared to those of patients without severe cognitive dysfunction (SPMSQ ≥ 3).[47,55] Not surprisingly, patients with SPMSQ < 3 were significantly older, were admitted more often from institutions, were more dependent in ADL and had an inferior walking ability and a significantly lower HRQoL even before the fracture. Severe cognitive impairment, along with male gender, was a strong predictor of increased mortality during the first year after the fracture. Despite the high mortality rate in this particular group, which probably affected the most vulnerable patients, patients with SPMSQ < 3 had a worse functional outcome as demonstrated by 36% of the patients being wheel-chair-bound and almost 39% being totally dependent in ADL functions at the final 12-month follow- up.

The one-year mortality in hip fracture patients differs significantly between studies depending on the inclusion criteria. An increased mortality rate during the first year after a hip fracture has been reported previously,[143] and, in conformity with our results, the rate is higher in men.[144,145] The significantly higher one-year mortality rate in patients with SPMSQ < 3, as compared to patients with SPMSQ ≥ 3 in our study on patients with trochanteric and subtrochanteric fractures, is also in conformity with previous studies on patients with femoral neck fractures.[87,130] Two recently published randomised controlled trials included patients with displaced femoral neck fractures. In the first trial, only patients with SPMSQ ≥ 3 were included[130] and in the second trial only patients with SPMSQ < 3.[87] There was a vast difference in outcome on comparing the results of the two studies. In the study including patients with SPMSQ < 3, the one-year mortality rate was 28% and at the one-year follow-up 38% of the patients were non-ambulant and 31% dependent in all functions of ADL.[87] The corresponding figures in the study including patients with SPMSQ ≥ 3 were 7%, 2% and 1%, respectively.[130] This supports the notion that the cut-off level of < 3 correct answers in the SPMSQ is a strong predictor of a poor outcome regarding walking ability, ADL function and mortality in all patients with hip fractures, regardless of the specific fracture type.

The prefracture HRQoL for patients with SPMSQ < 3 was significantly lower than in patients with SPMSQ ≥ 3. The prefracture EQ-5D $_{index}$ score, 0.24, for patients with severe cognitive impairment was extremely low compared to this age group in the Swedish reference population, i.e. 0.74[83], and also compared to hip fracture patients without severe cognitive dysfunction.[129,130] However, it was at the same level as has been reported in patients with femoral neck fractures and severe cognitive dysfunction: 0.26.[87] Patients with SPMSQ < 3 showed a continuous deterioration in HRQoL in contrast to patients with SPMSQ ≥ 3, who showed significant improvement in the EQ-5D $_{index}$ score between the 4- and 12-month follow-ups. The same pattern has also been demonstrated previously in patients with femoral neck fractures,[87,130] probably reflecting the natural course of the dementia/cognitive impairment, the difficulty for these patients to assimilate rehabilitation and, possibly, inadequate rehabilitation resources for this specific patient group.

Cognitive dysfunction, assessed by the SPMSQ, has previously been reported to be a good predictor of mortality.[51] However, in the study by Svensson et al.,[50] cognitive function was a good predictor of independent living at one year, but not of mortality. In contrast to our study, the cut-off level of > 7 correct answers was used, i.e. the outcome for patients without signs of cognitive dysfunction was compared with those of patients displaying different levels of cognitive impairment. Using this higher cut-off level may be hazardous since it has been shown that the level of cognitive function fluctuates during the hospital stay. These fluctuations in cognitive function are most pronounced in patients with moderate and mild cognitive impairment on admission, whereas the fluctuation in cognitive function in patients assessed as lucid or severely cognitively impaired at admission are usually minor.[47] In the study by Strömberg et al.,[47] which focused on the natural cause of the cognitive state assessed with the SPMSQ in 256 consecutive hip fracture patients, only approximately 2–3% of patients who were severely cognitively impaired (SPMSQ < 3) at admission were lucid at discharge (SPMSQ >7). Among patients assessed as lucid (SPMSQ >7) on admission, less than 2% were cognitively impaired at discharge. Among patients assessed as moderately impaired (SPMSQ 3–5) at admission, approximately 70% improved their cognitive function during the hospital stay while approximately 5% deteriorated. This fluctuation in cognitive function was even more pronounced in the group of patients with mild cognitive impairment (SPMSQ 6–7) at admission, more than 80% of whom became lucid during their hospital stay.

What is the risk of not identifying patients with severe cognitive dysfunction in routine healthcare? Obviously, it is of major importance for the caregiver to be aware of the special needs in this selected patient group.[47,50] Firstly, regarding delirium, there are several recent intervention studies indicating that the condition can be prevented and treated.[146-149] Secondly, in patients with displaced femoral neck fractures, the surgeon who is unaware of the patient's cognitive status might choose an inappropriate operative method. In contrast to the general opinion that displaced femoral neck fractures in the elderly are best managed with an arthroplasty,[150] there are studies indicating that this may not be true in the selected group of patients with severe cognitive dysfunction,[87,151] especially not a THR, where the dislocation rate is unacceptably high in cognitively impaired patients.[152] Finally, these vulnerable patients could receive insufficient nursing care when nurses wrongly perceive them to be cognitively alert.[53]

There are a number of short mental tests for assessing cognitive function. The most widely used one is the Mini-Mental State Examination (MMSE).[153] This test includes 13 items and comprises drawing and manual handling of items. However, when conducting this test, a sitting position at a desk is preferable, which is a main drawback when assessing hip-fracture patients. The SPMSQ questionnaire includes 10 items and is usually administered verbally, although it may be administered in writing to patients with hearing deficits. The SPMSQ has been validated as having a similar sensitivity and specificity to that of the Mini-Mental State Examination.[154] In an overview article (Smith et al.),[155] the authors concluded that the SPMSQ is quick and easy to administer. Its validity was rated as very good and the instrument was considered to be a good screening tool. Moreover, the SPMSQ appears to be valid as a severity-rating instrument. With regard to the simplicity of the test, interrater reliability was not considered to be a problem, and the test-retest reliability has been shown to be very good: greater than $r = 0.80$.[156] The overall conclusion was that the SPMSQ should probably be used more often than it is.

In conclusion, by using the recommended cut-off level in the SPMSQ and based on one assessment at admission to the orthopaedic ward, we could identify hip fracture patients with severe cognitive dysfunction and predict their poor outcome regarding walking ability, ADL function and mortality. Cognitive dysfunction should be considered a major risk factor in the selection of the surgical method and planning for medical and nursing care. Previous studies have shown that it may be possible to improve the disappointing outcome for this patient cohort by improved rehabilitation regimens.[146-149] A prerequisite for improvement is that patients with cognitive dysfunction are identified and an easy-to-use and validated instrument is mandatory for the assessment. The results of this study and previous ones on hip fracture patients[87,129,130,157] strongly suggest that the SPMSQ can be recommended.

LIMITATIONS AND STRENGTHS

The fact that our interpretation of the SMFA (*Studies III* and *IV*) and EQ-5D (*Studies I-V*) data was based on our patients' ability to correctly recall their health status prior to the hip fracture may be considered a weakness. However, since a prospective collection of preinjury HRQoL data is not possible in trauma studies, we have to rely on preinjury recall or a comparison with population figures. But again, our patients' assessment of their preinjury musculoskeletal function according to the SMFA was in conformity with that of the North American reference population[78,79] and the preinjury EQ-5D $_{index}$ score was comparable to the corresponding age groups of the Swedish reference population.[83]

Study I has some additional limitations. Firstly, in spite of the power analysis prior to the study, it turned out to be underpowered. Some of the differences regarding failure and reoperation rates, especially in the smaller group of subtrochanteric fractures, did not reach statistical significance. On the other hand, the differences in absolute numbers were small in the group of trochanteric fractures and the sample size required to statistically secure differences would probably have to exceed what is possible to assemble at one institution. Secondly, six patients in the SGN group were operated on by a method at variance with the randomisation, in three of them owing to intraoperative femoral shaft fractures where a conversion to an LGN was necessary. In the remaining three, the altered choice of implant was due to a misinterpretation of the study protocol by the participating surgeons. We believe that keeping these patients in the intention-to-treat analysis was more appropriate than to exclude them.

Another limitation of *Study II* was that at each follow-up the patients were interviewed by phone and only patients reporting problems were scheduled for a follow-up visit including a radiographic examination.

The limited number of patients in *Study IV* may be considered a weakness. However, this type of fracture is rare, constituting only 5−10%[25] of all hip fractures and there are very few studies with larger study populations.[109,110]

In *Study V* co-morbidities were assessed with the Ceder scale,[72] which by definition placed all patients with severe cognitive dysfunction in the worst category, C. Owing to this fact, we could not evaluate the influence of other co-morbidities on outcome including mortality. A different classification, e.g. the ASA classification, would have been more appropriate and it would most certainly have been a good predictor of mortality, but not necessarily of the worse functional outcome.[158] Another weakness of *Study V* was that some of the data were collected in different ways. For patients with severe cognitive dysfunction (SPMSQ < 3), the information was collected from a proxy. A close relative or caregiver was asked to rate how he or she thinks the patient would rate his or her health if he or she were able to communicate. There is generally good proxy-patient agreement for concrete, observable variables, e.g. walking ability, ADL or living conditions, but not so good for non-observable variables: e.g. pain or anxiety/depression. However, in patients with dementia and severe cognitive dysfunction, this is the only way to assess the outcome, not only regarding the HRQoL but also for variables such as living status, ADL status and the pain and walking dimension of the Charnley hip score.[39] This approach has also been used previously for the EQ-5D in patients with dementia.[85,86]

The major strength of all studies in the thesis is that they are all prospective and one (S*tudy I*) is a randomised controlled trial. Furthermore, all studies include well-defined study populations and the outcomes were assessed with validated outcome instruments and the two main outcomes measures, SMFA (*Studies III* and *IV*) and EQ-5D (*Studies I-V,* except patients with severe cognitive dysfunction in *Study V*: please see above), were self-reported and thereby reduced the risk of bias. The drop-out rates at the various follow-ups were acceptable in this fragile age group and not of such magnitude that the validity of the conclusions should be jeopardised.

In summary, we believe our results are representative of our patient populations and that our conclusions are valid.

CONCLUSIONS

Study I

The results of the study showed that the SGN displayed good results in both unstable trochanteric and subtrochanteric fractures. The limited number of intraoperative femoral fractures did not influence the outcome or necessitate further reoperations. Moreover, the SGN showed a reduced number of severe general complications and reduced the number of wound infections compared to the MSP. The MSP in the biaxial dynamisation mode showed a low failure rate in unstable trochanteric fractures but a high failure rate when used in the biaxial dynamisation mode in the smaller group of subtrochanteric fractures. The negative influence of an unstable trochanteric or subtrochanteric fracture on the quality of life was substantial regardless of the choice of implant.

Study II

The results of the study confirm the favourable outcome after a stable trochanteric fracture treated with an SHS with a low reoperation rate and a good outcome regarding pain at the hip and only limited deterioration in the HRQoL.

Study III

The results of the study showed that an unstable trochanteric fracture treated with the TGN had a substantial negative impact on the patient's musculoskeletal function as well as on the patient's HRQoL. The need for revision surgery was low in patients with a 3-part fracture (J-M 3 and 4), while the reoperation rate among those with a 4-part (J-M 5) fracture was significantly higher. The by far most common fracture complication, i.e. a secondary lag-screw penetration/cut-out, was successfully treated with a THR.

Study IV

The results of the study showed that a subtrochanteric fracture treated with the LGN had a substantially negative impact on the patient's musculoskeletal function as well as on the HRQoL. However, the need for revision surgery was comparatively low.

Study V

The systematic use of the SPMSQ at admission to the orthopaedic ward identified patients with severe cognitive dysfunction and effectively predicted their outcome regarding walking ability, ADL function and mortality. The results of this study strongly suggest that the SPMSQ can be recommended for use in the elderly hip fracture population in routine healthcare.

ABSTRACT IN SWEDISH

Höftfrakturer är en betydande orsak till ökad sjuklighet och dödlighet hos äldre personer och Skandinavien har den högsta incidensen av höftfrakturer i världen. En höftfraktur är en allvarlig konsekvens av osteoporos som kräver akut kirurgi med hög risk för komplikationer och utgör ett hot mot ett fortsatt självständigt liv. De trokantära och subtrokantära femurfrakturerna utgör ca 50 % av alla höftfrakturer.

Det övergripande syftet med avhandlingen var att utvärdera behandlingsresultaten hos patienter med stabila trokantära (*Studie II*), instabila trokantära (S*tudie I* och *III*) och subtrokantära (S*tudie I* och *IV*) femurfrakturer med avseende på kirurgiska metoder inklusive en utvärdering av funktion och hälsorelaterad livskvalitet (HRQoL) enligt EQ-5D. Därutöver var syftet att utvärdera om svår kognitiv dysfunktion kunde prediktera patienternas resultat avseende funktion, HRQoL och mortalitet (S*tudie V*).
I en randomiserad studie behandlades 217 patienter, medelålder 84 år, med instabil trokantär eller subtrokantär fraktur med antingen en första generationens Gammaspik (SGN) eller en Medoff glidskruv/platta (MSP) (*Studie I*). SGN visade goda resultat vid såväl instabila trokantära som subtrokantära frakturer. Dessutom uppvisade SGN ett minskat antal allvarliga allmänna komplikationer och infektioner jämfört med MSP. MSP i biaxialt dynamiseringsläge uppvisade en låg komplikationsfrekvens hos patienter med instabila trokantära frakturer men en högre komplikationsfrekvens i den mindre gruppen av patienter med subtrokantära frakturer.

I en prospektiv kohortstudie inkluderades 148 patienter, medelålder 83 år, med stabil trokantär fraktur behandlad med en glidskruv/platta (SHS) (*Studie II*). Resultaten hos dessa patienter bekräftade tidigare publicerade goda resultat med låg reoperations-frekvens, bra funktionellt resultat och endast en begränsad försämring av HRQoL.

I en prospektiv kohortstudie inkluderades 117 patienter, medelålder 84 år, med instabil trokantär fraktur och som behandlades med andra generationens Gammaspik (TGN) (S*tudie III*). Resultaten visade en betydande negativ inverkan på patientens muskuloskeletala funktion enligt SMFA och hälsorelaterade livskvalitet enligt EQ-5D. Behovet av revisionskirurgi var låg hos patienter med en 3-fragmentsfraktur men signifikant högre hos patienter med 4-fragmentsfraktur. Den i särklass vanligaste frakturkomplikationen, redislokation av frakturen med följande genomskärning av skruven genom lårbenshuvudet, behandlades framgångsrikt med en total höftledsplastik.

I en prospektiv kohortstudie inkluderades 53 patienter, medelålder 82 år, med subtrokantär fraktur behandlade med lång Gammaspik (LGN) (*Studie IV*). Resultaten visade en betydande negativ inverkan på patientens muskuloskeletala funktion enligt SMFA och hälsorelaterade livskvalitet enligt EQ-5D. Däremot var behovet av revisionskirurgi förhållandevis lågt.

I S*tudie V* inkluderades 213 patienter från S*tudie I*. Resultaten visade att en systematisk användning av ett validerat instrument för bedömning av kognitiv funktion, SPMSQ, identifierade patienter med svår kognitiv dysfunktion och predikterade effektivt deras resultat avseende gångförmåga, ADL-funktion och mortalitet. Resultaten från denna studie talar starkt för att SPMSQ kan rekommenderas för användning hos den äldre höftfrakturpopulationen inom sjukvården.

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ORIGINAL PAPERS I - V