Treatment of trochanteric and subtrochanteric hip fractures

Sliding hip screw or intramedullary nail?

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Scientific environment

"The Intertan Study" (papers I and IV) was performed at the Orthopaedic Department, Haukeland University Hospital (HUS), and in close teamwork with the Clinical Research Unit and the Department of Radiology at HUS. "The Intertan Study" was also based on a close collaboration with 4 other Norwegian hospitals; Levanger Hospital, Akershus University Hospital, Diakonhjemmet Hospital, and Vestfold Hospital.

Papers II and III were based on data from, and written together with colleagues from the Norwegian Hip Fracture Register (NHFR). This register is an integrated part of the Norwegian Arthroplasty Register (NAR) and the Orthopaedic Department, Haukeland University Hospital, Bergen

Since 2009 I have been a PhD-candidate at the Department of Surgical Sciences, University of Bergen, Bergen, Norway.

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1. List of abbreviations

SHS	Sliding hip screw
TSP	Trochanteric stabilizing plate
IM nail	Intramedullary nail
RCT	Randomized controlled trial
AO/OTA	Arbeitsgemeinshaft für Osteosyntesefragen / Orthopaedic Trauma Association
NHFR	Norwegian Hip Fracture Register
NAR	Norwegian Arthroplasty Register
TAD	Tip-apex distance
TUG-test	Timed Up & Go-test
VAS	Visual analogue scale
HHS	Harris hip score
EQ-5D	EuroQuol-5Dimensions (quality of life measure)
n	Numbers
Et al.	And co-workers
ASA-class	American Association of Anaesthesiologists classification of co-morbidities
P-value	Probability

2. Acknowledgements

The first part of this thesis is based on "The Intertan Study", initiated late 2006 and started February 2008. The process of study planning, enrolment and follow-up of nearly 700 patients in 5 different Norwegian hospitals would not have been possible without enthusiastic participation and major efforts by many good colleagues. Clinical testing, radiological assessments, recording of data, and data management required a lot of recourses at different levels in all participating hospitals, and for these efforts, I am deeply in gratitude to all colleagues at Levanger Hospital, Akershus University Hospital, Diakonhjemmet hospital, Vestfold Hospital, and Haukeland University Hospital. Those responsible for running the every day inclusion, follow-up, and documentation in these hospital; **Leif Kibsgaard, Paul Fuglesang, Stefan Bartels, Richard Olsson, Henrik Støren, Jo Andreas Ording, Wilhelm Bugge,** and **Tarjei Vinje** should be mentioned in particular**.** Working with you has been a great pleasure, and your commitment has been invaluable.

Smith & Nephew, the manufacturer of the new TRIGEN INTERTAN Intramedullary nail, with its national chief of trauma products, **Wenche Pretorius** was essential in bringing colleagues from different hospitals together. Without the practical and financial support from Smith & Nephew, we could not have accomplished this clinical trial. The collaboration with Smith & Nephew has solely been a positive experience, and I have been impressed by their patients through out this process.

I would not have been able to organize or complete "The Intertan study", or this PhD-thesis, without backup from my employer, the Orthopaedic Department at Haukeland University Hospital and the Head of the Department, professor **Ove Furnes**. From the beginning he has encouraged me and supported this research project, and his genuine enthusiasm for research has been inspirational to me and all the colleagues in our department. Our always optimistic and positive Director of Orthopaedic Clinic, **Lars-Oddvar Arnestad,** also deserves generous credit. Not only has he been paying my salary the years I have been working on this thesis, but despite limited financial

resources he has also been able to expand the medical staff, and thereby facilitating more research in our department.

After starting “The Intertan Study” I was also supported with a research grant from the regional health authorities, **Helse Vest**. This grant made it possible to become a fulltime researcher for longer periods, and this certainly made my life and the premises for my research much easier. For this I am very grateful.

I have been extremely happy to have the **Clinical Research Unit** at Haukeland University Hospital on board in our Intertan study group. The importance of this cooperation cannot be overestimated. They handled the everyday flow of large amounts of data for more than two years and my e-mails were always answered quickly and with a smile. **Lene, Elisabeth, Torild, Hilde, and Snorre**, thank you for always being there! I would also like to thank **Geir Egil Eide** and **Ernst Omenaas**, Centre for Clinical research for valuable input while planning the study.

Radiologist **Stein-Harald Kjellevold** classified fractures, and even more importantly and time consuming; all x-rays were scrutinized for the quality of reduction, implant position, and any disturbance of the healing process in the radiographic follow-up of the patients. This has been an enormous effort and also a crucial part of our study, - for this I am very grateful. The collaboration with **the Department of Radiology at Haukeland University Hospital**, and **Janneke Korsvold** in particular, was also of major importance and has been a great pleasure.

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Further I am grateful to our physiotherapists **Therese Engen, Ove Dyrstad, and Heid Nygard** for their devoted in-hospital assessment of patients and later follow-up in the outpatient clinics.

The second part of this thesis is based on data from the **Norwegian Hip Fracture Register** (NHFR), and I would like to honour the pioneers **Einar Sudmann, Norvald**

Langeland, Lasse Engesæter, and Leif Ivar Havelin who initiated and started the Norwegian Arthroplasty Register (NAR) in the 1980's. Later, in 2005, the hip fracture register was established after dedicated work by **Lasse Engesæter, Ove Furnes, Jonas Fevang, and Jan-Erik Gjertsen** in particular. Without their visions, enthusiasm, and endurance, no such registries would have existed today. I am privileged to work with the staff and colleagues in the NAR/NHFR, and I hope this collaboration will persist and enable me, and also inspire others, to continue our research and efforts to improve the treatment of hip fracture patients in the future. I would also like to thank **all Norwegian surgeons** who on a daily basis report their operations to the hip fracture register. Without them, these national registries would have been worthless, -please keep up your good work.

The last years, until August 2012, I have devoted most of my time to this research projects, and to make this possible, my good friends and colleagues at the Orthopaedic Trauma Unit have taken care of all the clinical work. I am extremely glad to be a part of a unit with such good colleagues, always enthusiastic, smiling, and doing the best to optimize the treatment for each individual patient. **Knut Fjeldsgaard, Jan Scrama, Hege Framnes, Håvard Dale, Randi Hole, Yngvar Krukhaug, Tarjei Vinje, Trygve Methlie, Omar Arnason, and Pål Høvding**, you are really the best!! And to **Hege** in particular, I am very grateful for all your efforts while running the Trauma Unit during my absence.

Scientific writing has been the most fun, but also most challenging part of my thesis. The collaboration with all of my co-authors has made this a great experience. **Birgitte Espehaug, Tarjei Vinje, Jan-Erik Gjertsen, Ove Furnes, Stein-Harald Kjellevold,** thank you for your patients and all valuable contributions during my years of struggle trying to get papers written and accepted for publication. I also highly appreciate your contributions while planning "The Intertan Study", and the discussions with **Birgitte,** and her statistical input, have been crucial for this scientific work. In addition, two colleagues deserve special credit for taking part in all of my research from day one until the completion of this thesis.

Leif Ivar Havelin, professor, former Head of the Orthopaedic Department, and present chairman of the NAR/NHFR board, has been my co-supervisor. Through out the years we have had many interesting discussions and I have learned a lot from you. Whenever I have been heading in the wrong direction, you brought me, or the writing process, back on the right track. Thank you for all your efforts, scientific feedback, and inspirational discussions.

Jonas Fevang, Head of the Children's Unit in our Department, has been my main tutor and good friend through ups and downs in research the last years. Behind his somewhat laid-back appearance, there is a knowledgeable, clear- thinking, hard-working, and dedicated scientist. Your enthusiasm for hip fracture science has been very motivating, your commitment to scientific accuracy has been impressive, and working with you these last years has been a great pleasure.

I also thank my parents **Marit and Jon**, and brother **Bjørn and Hilde** for always being there, and for supporting me and my family, whenever this has been needed.

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3. Abstract

Background:

Trochanteric and subtrochanteric fractures are usually treated with a sliding hip screw (SHS) or an intramedullary (IM) nail, and the question whether a SHS or an IM nail should be the preferred implant for all or subgroups of fractures has not come to a final conclusion. In recent years, there has been a trend towards more use of IM nails, but this trend has not been driven by better results in well designed clinical trials. Regardless of type of implant, complications have to be encountered and to which extent modern implants have improved results remains unclear.

Aims:

It was our first aim to assess whether treatment with the new TRIGEN INTERTAN intramedullary nail resulted in less postoperative pain, better function, and improved quality of life for patients with trochanteric and subtrochanteric fractures compared to treatment with the SHS (**Papers I and IV**). Surgical complications and reoperation rates were also assessed.

Secondly, we wanted to compare postoperative pain, function, quality of life, and reoperation rates for patients operated with IM nails and SHS for different subgroups of trochanteric and subtrochanteric fractures at a national level **(Papers II and III)**.

Patients and methods:

684 elderly patients with trochanteric and subtrochanteric fractures were included and treated with a SHS or the Intertan nail in a multicenter randomized controlled trial (RCT) **(Paper I)**. The patients were assessed during hospital stay and at 3 and 12 months postoperatively. The 159 patients with reverse oblique trochanteric (AO/OTA type A3) and subtrochanteric fractures were separately analyzed and discussed in depth **(Paper IV)**.

Using data from the Norwegian Hip Fracture Register in papers II and III, we analyzed 7643 operations for simple two-part trochanteric fractures (AO/OTA type A1) **(Paper II)** and 2716 operations for reverse oblique and subtrochanteric fractures **(Paper III)** after treatment with either a SHS or an IM nail.

Results:

As presented in **Papers I and IV,** patients operated with the Intertan nail had slightly less pain at early postoperative mobilization compared to those operated with a SHS, but we found no difference at 12 months. Regardless of fracture type, mobility, hip function, quality of life, and surgical complication rates were comparable for the two groups at 12 months.

In simple two-part trochanteric fractures (**Paper II**) the SHSs had a lower complication rate compared to IM nails one year postoperatively (2.4% and 4.2% for SHS and IM nail, respectively, $p = 0.001$). Only minor, and clinically insignificant differences between the groups were found for pain, patient satisfaction, and quality of life.

In **Paper III**, conversely, we found that the patients operated with an IM nail had a significantly lower failure rate compared to the SHS one year postoperatively (3.8% vs. 6.4%, respectively, $p = 0.011$). Small differences regarding pain, patient satisfaction, quality of life, and mobility were also in favor of IM nailing.

Conclusions:

Pain, function, quality of life, and reoperation rates were similar for the Intertan nail and the SHS in trochanteric and subtrochanteric fractures 12 months postoperatively.

Data from our hip fracture register, however, favored the SHS in simple two- part trochanteric fractures, whereas IM nails had the lower complication rate and better clinical results in reverse oblique and subtrochanteric fractures. Accordingly, a differentiated treatment algorithm based on fracture type could be considered.

4. List of publications

Paper I Kjell Matre, Tarjei Vinje, Leif Ivar Havelin, Jan-Erik Gjertsen, Ove Furnes, Birgitte Espehaug, Stein-Harald Kjellevold, Jonas Meling Fevang

TRIGEN INTERTAN Intramedullary Nail Versus Sliding Hip Screw. A Prospective, Randomized, Multicenter Study on Pain, Function, and Complications in 684 Patients with an Intertrochanteric or Subtrochanteric Fracture and One Year of Follow-up. J Bone Joint Surg Am. 2013 Feb 6;95(3):200-8.

Paper II Kjell Matre, Leif Ivar Havelin, Jan-Erik Gjertsen, Birgitte Espehaug, Jonas Meling Fevang

Intramedullary Nails Result in More Reoperations Than Sliding Hip Screws in Two-part Intertrochanteric Fractures. Clin Orthop Relat Res. 2013 Apr;471(4):1379-86.

Paper III Kjell Matre, Leif Ivar Havelin, Jan-Erik Gjertsen, Tarjei Vinje, Birgitte Espehaug, Jonas Meling Fevang

Sliding hip screw versus IM nail in reverse oblique trochanteric and subtrochanteric fractures. A study of 2716 patients in the Norwegian Hip Fracture Register. Injury; Online 8 January 2013

Paper IV Kjell Matre, Jan-Erik Gjertsen, Leif Ivar Havelin, Tarjei Vinje, Ove Furnes, Birgitte Espehaug, Jonas Meling Fevang

Is the sliding hip screw still an option in the treatment of transverse or reverse oblique intertrochanteric and subtrochanteric fractures?

A PROSPECTIVE, RANDOMISED, MULTICENTRE TRIAL COMPARING THE TRIGEN INTERTAN INTRAMEDULLARY NAIL WITH THE SLIDING HIP SCREW IN 159 PATIENTS.

To be submitted.

5. Introduction and background

5.1 Overview, hip fractures in general

Hip fractures are common in the elderly, and for the individual patient a hip fracture may cause short and long term pain, impaired function, and reduced quality of life. Up to one half of the patients may not regain their prefracture walking capacity, and independent living may no longer be possible (1). The mortality after hip fractures is high, and the overall one year mortality for the elderly patients with hip fractures is approximately 20-25% (2,3).

Because of the large numbers of fractures, and patients with advanced age, hip fractures also represent a major challenge to hospitals, other health care providers, and society. In addition, due to the aging of the population the next decades, the numbers of hip fractures and health care expenses are expected to increase considerably. This will further enhance the focus on prevention of fractures and optimization of the treatment. The importance of a well-performed surgical treatment in hip fracture care is undisputable, however, treating the patients from a holistic point of view is probably even more important in order to improve the overall outcome for these patients.

Today, approximately 10000 hip fractures occur in Norway each year (4). Compared to the Norwegian estimates, however, the future demographic changes, and the increased burden on health care systems, will be even more challenging in other countries and continents. By the year 2050 up to 6.3 million hip fractures have been estimated each year world-wide (5).

The large individual and societal consequences of hip fractures world-wide, considering the perspectives of an aging population in particular, also underlines the need for persistent and increasing research on hip fracture care in the future.

The main focus of this thesis has been on the trochanteric and subtrochanteric hip fractures and their surgical treatment.

5.2 Classification of hip fractures

Hip fractures are classified into different subgroups depending on the anatomical localization and degree of fracture complexity (**Fig 1a**). There are two main categories, the intracapsular (femoral neck) fractures and the extracapsular (trochanteric and subtrochanteric) fractures.

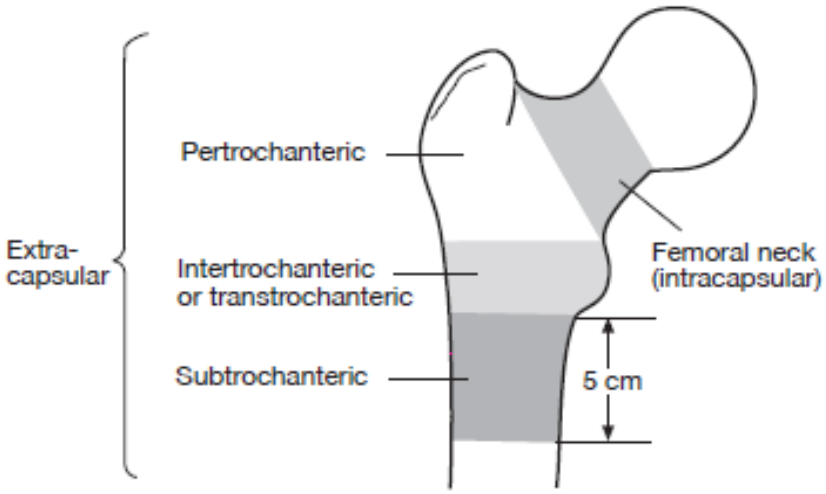


Fig 1a: *Classification of hip fractures.Intracapsular = femoral neck fractures. Extracapsular = pertrochanteric, intertrochanteric, and subtrochanteric fractures.*

These are further divided into sub-categories. According to data in the Norwegian Hip Fracture Register (NHFR) approximately 60% of hip fractures are femoral neck fractures, 35% are trochanteric fractures, and 5% are subtrochanteric fractures (6). Different classifications have been used to describe hip fractures. In the NHFR we are using the Garden classification (7) for femoral neck fractures and the AO/OTA classification (8) for trochanteric fractures **(Fig 1b)**.

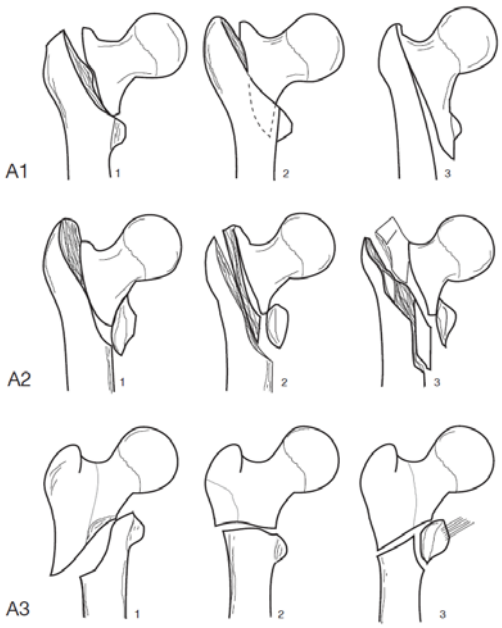


Fig 1b: *AO/ OTA classification of trochanteric hip fractures.*

Subtrochanteric fractures are classified as fractures with the main fracture line below, but within 5 cm from the lesser trochanter (**Fig 1a**). The classification of hip fractures into subgroups is fundamental to be able to define specific treatments for specific fractures, as well as to compare and interpret results in research.

5.3 The surgical treatment of hip fractures

In general, hip fractures require surgical treatment, but the treatment and implant selection varies, depending on the fracture type (classification). For instance, the treatment of an undisplaced femoral neck fracture is totally different from the treatment of a displaced subtrochanteric fracture. Whereas femoral neck fractures are usually treated with a hip arthroplasty (elderly patients with displaced fractures) or screw-fixation (in undisplaced fractures or in young patients)**,** trochanteric and subtrochanteric fractures are usually treated with a sliding hip screw (SHS) or an intramedullary (IM) nail **(Fig 2).** Other implants are also used, but less frequently.

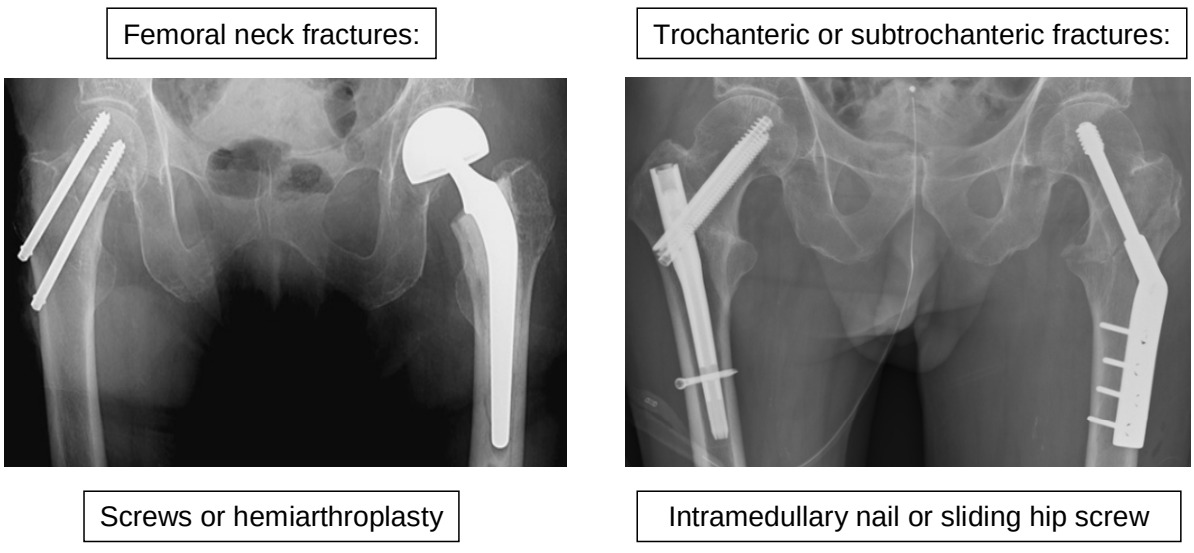


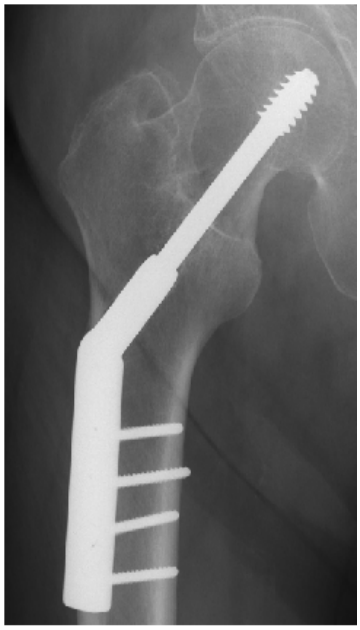
Fig 2: *Common treatment options in hip fracture surgery*

There are important differences in biomechanics and surgical exposure for a SHS and an IM nail. The **SHS** is a combination of a screw and plate system, where the screw within the femoral head and neck fragment is connected through a barrel to a plate

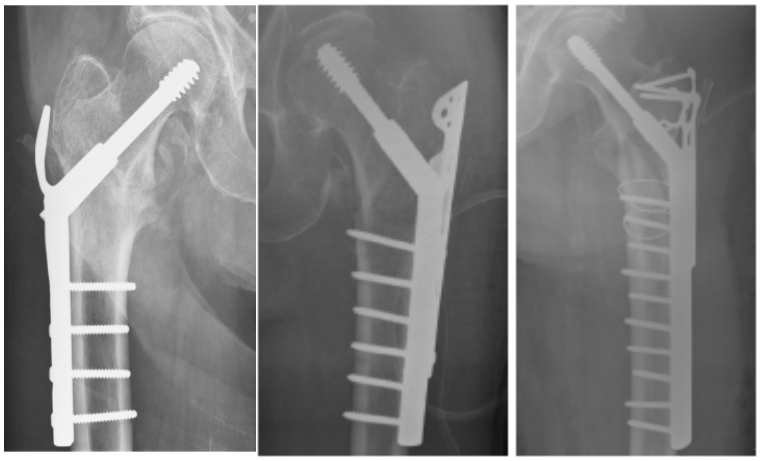
placed onto the lateral surface of the femur (outside the bone), allowing some fracture impaction (*"sliding"* hip screw) over the fracture site at mobilization (**Fig 3a and b).**

Fig 3: *The sliding hip screw*

a) Schematic



b) Postoperative x-ray



c) Different trochanteric stabilizing plates (TSPs) used together with a sliding hip screw

This surgery is usually performed with an open approach through skin and muscle onto the lateral surface of the femur. A trochanteric stabilizing plate (TSP) may be added to the SHS to enhance the stability for certain fracture types (**Fig 3c).** The **IM nail**, on the other hand, is an implant where both the femoral head-neck screw and the

nail itself are placed within the bone ("intramedullary" means nail in the central canal of the femur) (**Fig 4**). Also this implant allows some controlled impaction at the fracture site along the axis of the femoral head and neck screw, which may be an advantage for some trochanteric fractures. An IM nail can usually be applied performing a closed reduction of the fracture and a mini-invasive surgical approach to insert the implant, requiring less surgical dissection of soft tissues around the fractured bone.

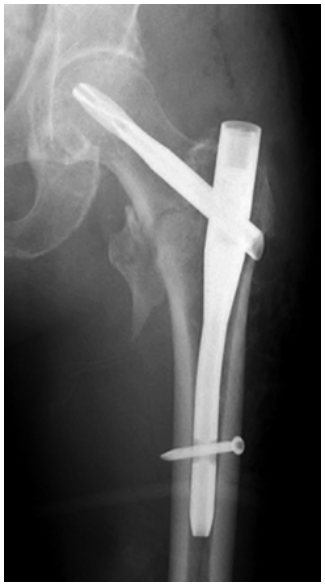


Fig 4: *An intramedullary nail (In this case a TFN, Trochanteric fixation nail, from Synthes)*

5.4 The literature and current controversies

The SHS is the best documented implant in the treatment of trochanteric hip fractures, and in several studies the SHS has also been associated with the better results in terms of complication and reoperation rates, compared to IM nails (9,10,11). This is particularly the case for the two-part trochanteric fractures (AO/OTA type A1), and for studies performed some years ago. In addition, the SHS has been the less expensive implant. Nevertheless, despite the SHS frequently being considered as the gold standard in most trochanteric fractures, in some countries, e.g. the U.S., there has been a recent trend towards a more widespread use of IM nails in these fractures. This development has, however, not been supported by better results for IM nailing in the literature (12,13,14). Historically, IM nails have resulted in more intra- and postoperative peri-implant femoral fractures compared to the SHS, and whether, or to which extent, modern IM nails decrease the number of such complications needs to be proven. In a recent review by Bhandari et al.(15), the change of postoperative femoral fracture rates after Gamma-nailing over time was assessed, and a trend towards less and finally no difference between the SHS and the Gamma nail was found in more recent studies. Therefore, interpreting earlier RCTs and meta-analyses with caution was recommended. However, no studies published after 2005, or studies on other types of IM nails, were included in their review. Cutout of the implant in the femoral head, the most common surgical complication in these fractures, and all other general and surgical complications, have been equally

distributed between the two groups of implants according to updated meta-analyses (9,10).

The subgroup of intertrochanteric ("reverse oblique", AO/OTA type A3) and subtrochanteric fractures is usually assessed as highly unstable, and for several reasons the SHS is often considered inappropriate for the treatment of these fractures. The mechanical forces in the subtrochanteric area are high, and the sliding hip screw with its lateral and extramedullary position is, at least from a biomechanical and theoretical point of view, considered inferior to an IM nail. In addition, due to the sliding mechanism parallel to a reverse oblique fracture line, the SHS without a TSP is considered inappropriate for the reverse oblique fracture type in particular. Better biomechanical properties and lower failure rates are highlighted by several authors who recommend IM nailing as the treatment of choice in such fractures (16,17,18,19). However, results are not unambiguous, and more favorable reoperation rates for the SHS have been reported in other studies (20,21,22). In Norway the SHS, preferably with an additional TSP, is still the most frequently used implant also for reverse oblique and subtrochanteric fractures. Adding a TSP may enhance fracture stability and prevent the medialization of the femoral shaft and thus justify the SHS also in these fractures. Several clinical studies have reported favorable results using this construct (23,24,25), and the ability of the TSP to resist dislocating forces causing excessive lag screw sliding and medialization of the femoral shaft has also been confirmed in biomechanical studies (26,27).

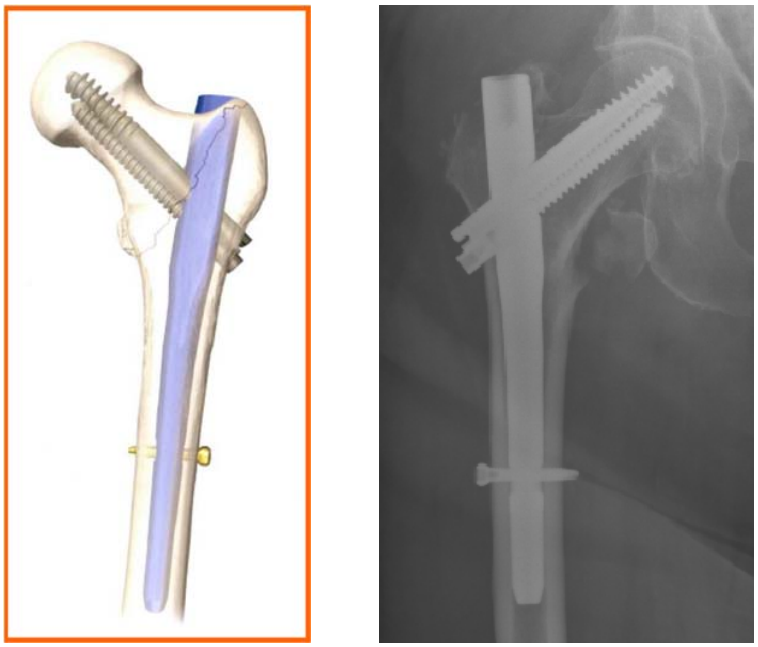
There is no clear or undisputable conclusion in the literature as to which implant or treatment option is the best for trochanteric and subtrochanteric hip fractures. Frequently, the SHS and the IM nails are considered equivalent for the stable trochanteric fractures. For unstable pertrochanteric (AO/OTA type A3) fractures, however, and unlike Norwegian traditions, Kregor and colleagues from the Evidence-Based Orthopaedic Trauma Working Group recommended that IM nailing should be the preferred treatment (17). Kuzyk and co-workers came to a similar conclusion for subtrochanteric fractures (28). Nevertheless, both review articles acknowledged limitations in the scientific documentation and stated that larger comparative trials

were needed to give clear recommendations. This lack of evidence, and the remaining controversies regarding the implant selection for trochanteric and subtrochanteric fractures, was the main reason for conducting the different studies within the scope of this thesis.

5.5 The Intertan nail

The Intertan nail (TRIGEN INTERTAN intramedullary nail, Smith & Nephew, Memphis, Tennessee) was introduced in 2006 as yet another nail to treat these fractures (29). According to the manufacturer, the nail had improved biomechanical properties and was providing better rotational stability due to its anatomical shape and two interdigitating screws in the femoral head and neck fragment **(Fig 5a and b)**.

Fig 5: *The Intertan nail*



a) Schematic *b) Postoperative x-ray*

It was argued that the implant also facilitated the possibility of controlled intraoperative compression of the fracture, and that its feathered tip was designed to prevent intraoperative and later femoral fractures from occurring. In biomechanical testing there had been a favorable resistance to cutout of the implant in the femoral

head compared to other nails (30), and the early clinical experience was promising. In theory, a more stable implant and mini-invasive surgery could have advantages, in the early postoperative phase in particular, compared to a potentially more unstable implant operated with an open procedure (the SHS). Less pain, better functional mobility, and possibly a shorter stay in hospital could be benefits if this hypothesis came true. Such improvements, however, would have to be confirmed in well designed clinical trials.

The gold standard in clinical research is the randomized controlled trial (RCT), and it was our first goal to assess in a large multicenter RCT whether the Intertan nail, compared to the SHS, really improved clinical results and reduced complication rates in patients with trochanteric and subtrochanteric fractures (Papers I and IV).

However, not all scientific questions can be answered in RCTs.

5.6 The Norwegian Hip Fracture Register

There are some well known limitations to RCTs. Studies are often very time consuming, costly, and with limitations to the length of follow-up and number of patients included. Consequently, it may take a long time before results can finally be presented, and the lack of statistical power is a common problem. Therefore, some scientific questions are better answered in well designed register studies. In these studies, with larger numbers of patients included, we may detect small, but still clinically relevant differences between implants and surgical methods. In fact, unless large RCTs or meta-analyses of RCTs have been performed, register studies may be the only option to prove small differences regarding outcomes like complication and reoperation rates. Such considerations were the background for conducting the studies based on data from the Norwegian Hip Fracture Register in this thesis (Papers II and III). In simple two-part trochanteric fractures, differences in complication rates between SHS and IM nails are usually small, and secondly, the reverse oblique and subtrochanteric fractures are rather uncommon. In these situations and for outcome

parameters like complication and reoperation rates in particular, register studies may provide the best available evidence.

The NHFR was established in 2005, and based on reports from the operating surgeons data are collected on all acute hip fractures and reoperations nation wide. In addition, questionnaires regarding pain, patient satisfaction, and quality of life are sent to the patients 4, 12, and 36 months postoperatively (31). By the end of 2011, more than 55000 acute hip fractures were registered in the NHFR.

As data from the hip fracture register show, there is currently no consensus among Norwegian surgeons or hospitals regarding the implant selection for different trochanteric and subtrochanteric fractures.

6. Aims of the studies

“The Intertan Study” (1)

Paper I

The aim of this randomized clinical trial was to assess whether treatment with the new Intertan nail results in less postoperative pain, a shorter length of hospital stay, or improved function for elderly patients with trochanteric and subtrochanteric fractures compared to treatment with the SHS. In addition, we wanted to assess complication and reoperation rates.

Norwegian Hip Fracture Register Study (1)

Paper II

The aim of this observational study was to compare reoperation rates, pain, and quality of life for patients treated with IM nails or SHSs in simple two-part trochanteric fractures (AO/OTA type A1) using data from the Norwegian Hip Fracture Register. It was of particular interest if our current strategy of treating these fractures with a SHS was supported by results from our register, or, on the contrary, if the results would support recent international trends towards a more frequent use of IM nails even in these fractures.

Norwegian Hip Fracture Register Study (2)

Paper III

The aim of this second register based study was to analyze data from the Norwegian Hip Fracture Register on reverse oblique trochanteric (AO/OTA type A3) and subtrochanteric fractures, and to assess any difference in pain, satisfaction, quality of life, or reoperation rates for patients treated with IM nail or SHS. For this group of fractures the implant selection has been even more controversial. Our treatment policy

of most frequently using a SHS for these fractures has been questioned, and this study could add valuable information to the relatively sparse literature on this topic.

“The Intertan Study” (2)

Paper IV

As a part of “The Intertan Study” our aim with this study was to assess a similar set of outcome parameters (as in Paper I) for the reverse oblique intertrochanteric and subtrochanteric fractures in a separate subgroup analyses. In-depth analyses of these fractures, similar to the second NHFR study, could also add important information and possibly indicate whether our treatment policy of using a SHS (with or without a TSP) in these fractures is still acceptable or not. To the best of our knowledge, this was the first RCT comparing a SHS to an IM nail for the reverse oblique fracture type.

7. Patients and methods

Papers I and IV

Patients and fractures

Papers I and IV were based on "The Intertan Study", a multicenter study involving patients from five Norwegian hospitals (Levanger Hospital, Vestfold Hospital, Akershus University Hospital, Diakonhjemmet Hospital, and Haukeland University Hospital). Follow-up and outcome variables were similar for the two studies. 684 patients older than 60 years with trochanteric and subtrochanteric fractures were included in this study from February 2008 until February 2009 (341 Intertan, 343 SHS) **(Paper I)**. Of these, 159 patients with inter- and subtrochanteric fractures were also included in the in-depth study of **Paper IV** (78 Intertan, 81 SHS). Approximately 30% of the patients sustaining a hip fractures are cognitively impaired, therefore it was important to include also this group of patients. Patients with pathologic fractures were excluded, and patients sustaining a contralateral fracture during follow-up were not included a second time. Trochanteric fractures were classified by an independent radiologist according to the AO/OTA classification in A1-, A2-, and A3-fractures with subgroups **(Fig 1b).** Fractures below, but with the main fracture line within 5cm from the lesser trochanter, were classified as subtrochanteric **(Fig 1a).**

Surgical implants

The Intertan nail was used in a short or a long version with distal locking. All nails had two integrated screws into the femoral head-neck fragment **(Fig 5).** Two different SHS implants were used, the Compression Hip Screw (Smith & Nephew, Memphis, Tennessee,) and the Dynamic Hip Screw (Synthes, Basel, Switzerland). An optional trochanteric stabilizing plate (TSP), either as an integrated part of the SHS or added as a separate devise onto the SHS, was used when indicated (**Fig 3c**). With only minor differences in design, and similar biomechanical principles for the two sliding hip screws and their TSPs, they were considered as one group.

The study protocol recommended the use of long nails and a SHS with an additional TSP in reverse oblique trochanteric (AO/OTA type A3) and subtrochanteric fractures, but these guidelines were not consistently followed by the surgeons. Consequently, in the subgroup analyses (Paper IV), 57 (70 %) out of 82 patients operated with a SHS had an additional TSP, and 51 (66%) out of 77 of patients operated with a nail, received a long nail in this subgroup of fractures.

The SHS, with or without a TSP, was the standard treatment for all trochanteric and subtrochanteric fractures at the participating hospitals before we started the study. Therefore, a training program for the use of the Intertan nail was carried out before patients were enrolled.

Follow-up and outcome measures

With a special focus on the early postoperative rehabilitation, the in-hospital course of the patients was followed closely, including assessment of postoperative pain (Visual analogue scale, VAS) and functional mobility (timed Up & Go (TUG-) test (32)), complications, blood loss, and length of hospital stay. In addition, postoperative x-rays were examined for fracture reduction and implant position, including the tip-apex distance (TAD) as described by Baumgaertner (33). Clinical examination, including the Harris hip score (HHS) (34) (**Appendix 1**) and filling out an EQ-5D questionnaire (35) (**Appendix 2**), were scheduled at 3 and 12 months postoperatively. Depending on local preferences in each hospital, the clinical examination of the patients was carried out by a physician or a physiotherapist, or in collaboration between these professionals. In some hospitals, also a study nurse was involved.

Early postoperatively pain, functional mobility, and length of hospital stay were the primary outcomes in this study. Pain-scores and TUG-test performance were measured at all follow-up visits. Secondary outcomes were the patients' living conditions, walking ability, hip function (HHS), quality of life (EQ-5D), complication and reoperation rates, and mortality. In addition, x-rays were assessed for the TAD, fracture shortening, medialization of the femoral shaft, changes in the femoral neck-

shaft angle, and for any disturbance of the fracture healing 3 and 12 months postoperatively **(Appendix 3)**.

Statistical methods

Randomization; The patients were randomly allocated to one of the two implants using sealed, opaque, and consecutively numbered envelopes. Block randomization with varying block sizes unknown to the surgeon was used to ensure near-equal treatment numbers within each hospital.

Sample size: A difference in VAS scores of ≥10 points was considered a clinically relevant difference. 63 patients in each group were required to have an 80% chance of detecting such a difference in VAS scores with a 5% significance level with an assumed standard deviation (SD) of 20. There is to our knowledge no well-defined clinically significant difference for the TUG-test. However, 112 patients would be required in each group to detect a mean difference of 3 seconds (10% of 30 seconds) with an assumed SD of 8 seconds. To detect a reduction in the length of hospital stay of 1 day (SD 3), 142 patients would be needed in each group. A difference in reoperation rates of 5% versus 7% would require more than 2000 patients in each group to detect a significant difference with 80% power and $p < 0.05$. Accordingly, this study was not designed to have reoperation rate as a primary outcome. A high mortality rate, a high number of cognitively impaired patients, and an expected high dropout rate were considered when the sample size for the study was determined. Thus, assuming a one-year an attrition rate of up to 40%, we aimed to recruit at least 500 patients in the study within one year.

To test for group differences, the Pearson chi-square test was used for categorical variables and the Student's t-test was used for continuous variables. Due to an uneven distribution between the two groups, linear regression analyses with adjustment for the differences in cognitive impairment and surgeons' experience were performed. We also performed additional analyses for primary outcomes after excluding the cognitively impaired patients. The results were analyzed according to the intention-to-treat principle, where patients remained in the group to which they were allocated at

baseline. The plan was to examine all patients the 5th postoperative day, but this was not possible in all cases. Accordingly, the in-hospital pain and TUG-test results were analyzed with adjustment for differences in the time of patient examination in linear regression analyses. Finally, Kaplan-Meier analysis was used to estimate one year mortality, and the log-rank test was used to test for statistically significant differences. P-values less than 0.05 were considered statistically significant (two-sided tests).

Papers II and III

Patients and fractures

The papers II and III were based on patients of all ages operated for subgroups of trochanteric and subtrochanteric fractures recorded in the Norwegian Hip Fracture Register **(Appendix 4)**. By the end of 2010, 47,178 primary operations for hip fractures operated at 58 different Norwegian hospitals had been reported to the register. Of these 17,148 were primary operations for trochanteric (n = 14,822) and subtrochanteric (n = 2,326) fractures. Only fractures treated with a SHS or an IM nail were included in our studies, and pathological fractures were excluded. The classification of fractures was based on the same principles as in Papers I and IV (AO/OTA classification).

In **Paper II**, 7,643 operations for simple two-part trochanteric fractures (AO/OTA type A1, Fig 1b) were analyzed. The average age of the patients was 81.7 years, and 71% were women.

In **Paper III**, 2,716 operations, 390 intertrochanteric (reverse oblique trochanteric, AO/OTA type A3, Fig 1b) and 2,326 subtrochanteric fractures (Fig 1a) were analyzed. The average age of the patients was 79.3 years, 75% were women.

Implants

The NHFR has detailed information about the operations performed and the implants used. Implant dimension and brand name of plates, screws and nails are usually known in detail.

In **Paper II,** 83% (n = 6355) of the operations were performed with a SHS. A trochanteric stabilizing plate was added in 8% of these cases. Of the remaining nailing procedures (n = 1288), 96% were performed with a short nail. Long IM nails were used in only 4% of the nailing procedures.

The SHS was the most common implant also in **Paper III,** and comprised 66% out 2,716 operations (1,792 SHS and 924 IM nails). For implant specific subgroup analyses, we also divided the implants into 4 different categories; the "plain" SHS, the SHS with an additional TSP, and short and long nails. An additional TSP was used in 63% (n = 1120) out of the 1,792 SHS operations, and long nails were used in 74% (n = 688) of the nailing procedures. We did not perform any analyses based on brand names in either of the two papers.

Follow-up and outcome measures

Using a standardized questionnaire at 4, 12, and 36 months postoperatively, the patients or their care-givers were asked to answer questions regarding different outcome measures, such as quality of life (EQ-5D), pain (VAS), patient satisfaction (VAS), and general health status (VAS). An evaluation of similar outcome measures preoperatively was also performed in retrospect at the 4 months follow-up. In addition, any reoperation, including type of operation and the cause of the reoperation, was reported to the NHFR by the operating surgeons.

All patients in study II and III were observed for any reoperation until December 31, 2010 (follow-up 0-6 years), and in **Paper III**, the questionnaire regarding pain and quality of life was sent to all living patients during follow-up from 2005 to 2010. In **Paper II**, however, all patients operated with IM nails or a SHS with a TSP received a questionnaire from 2005 to 2010, but for patients treated with a simple SHS, all patients in 2005, 2006, and 2010, but only a randomly selected group of patients in 2007 to 2009, were asked to answer the questionnaire.

The reoperation rate was the primary outcome in both studies. In addition, quality of life issues, including the mobility (ability to walk), pain, and patient satisfaction were

secondary outcomes. The EQ-5D$_{index}$ score is the utility score derived from the 5 dimensions (mobility, degree of self care, ability to perform usual activities, pain/discomfort, and anxiety/depression) in the EQ-5D questionnaire. This was calculated for all patients, 0 indicating a situation similar to death, 1 being the best possible score for quality of life.

Statistical methods

Similar statistical methods were used for the two register based studies. To test for group differences for categorical outcome variables like reason for reoperation, type of reoperation, and walking ability, we used the Pearson chi-square test. The Student's t-test was used for analyzing continuous outcome variables like pain, patient satisfaction, and EQ-5D$_{index}$ score. In the survival analyses, the endpoint was any reoperation, and Kaplan-Meier analyses were used to determine the proportion of reoperations after one and three years (and mortality in Paper II). The log-rank test was used to test for statistical significance of differences in survival between the two groups. A multiple Cox regression model with adjustment for potential confounding by age, gender, ASA-class, and cognitive impairment (and fracture type in Paper III) was used to assess the relative risk of reoperation for the two treatment groups. The National Population Register provided information on deaths and emigrations. P-values less than 0.05 were considered statistically significant (two-sided tests). To adjust for potential differences in baseline characteristics between the two groups, additional analyses using the propensity score method were performed in Paper III.

Source of funding (Papers I – IV)

"The Intertan Study" was supported by Smith & Nephew, but the company had no influence on the study protocol, performance of the study, data analysis, or the presentation of the results. I also received a grant from the Regional Health Board of Western Norway to complete the work on this multicenter trial and for further hip fractures research included in my PhD thesis. The Norwegian Hip Fracture Register is funded by the same Regional Health Board.

8. Summary of results

Paper I

Overall, pain, function, and reoperation rates were similar for the Intertan nail and the SHS in trochanteric and subtrochanteric fractures 3 and 12 months postoperatively in this RCT. Patients treated with the Intertan nail had slightly less pain in the early postoperative period, and because of less blood loss fewer patients received a blood transfusion in that group. However, this did not influence in-hospital complication rate or length of hospital stay, which was also similar for both groups. This study also confirmed that postoperative femoral fractures remains a problem even with modern nail designs, as more peri-implant fractures occurred in the Intertan group.

Paper II

Based on data from the NHFR, we found that IM nailing of simple two-part trochanteric fractures (AO/OTA type A1) had a significantly increased risk of reoperations within one year postoperatively compared to operations with a SHS (4.2% and 2.4% reoperation rate for IM nail and SHS, respectively , $p = 0.001$). At three years the percentages were 7.1% and 4.5% for IM nail and SHS, respectively. Only minor and clinically irrelevant differences between the groups were found for other outcome measures (pain, patient satisfaction, and quality of life).

Paper III

This observational study compared results after operations with SHSs (n = 1792) and IM nails (n = 924) for reverse oblique (OA/OTA type A3) and subtrochanteric fractures. One year postoperatively patients with reverse oblique trochanteric and subtrochanteric fractures operated with a SHS had a higher reoperation rate compared to those operated with an IM nail (6.4% and 3.8%, respectively, $p = 0.011$). This difference also persisted and even increased three years postoperatively (reoperation rates of 10.2% and 6.7%, respectively). Adjusted for age, gender, ASA-class, cognitive

impairment, and fracture type there was a 43% increased risk of having a reoperation after operation with a SHS compared to an IM nail. Small differences regarding pain, patient satisfaction, quality of life, and mobility were also in favor of IM nailing.

Paper IV

In this second part of "The Intertan Study", comparing the SHS and an IM nail for reverse oblique trochanteric (AO/OTA type A3) and subtrochanteric fractures, we found no significant difference regarding pain, function, quality of life, or complication and reoperation rates between the two treatment groups. The estimated blood loss and number of patients receiving blood transfusions, however, were slightly higher in the SHS group.

9. Discussion

9.1 Methodological considerations

Papers I and IV

The randomized controlled trial represents the gold standard in clinical research. Confounding factors should be ruled out through randomization, and the only difference between the groups should theoretically be one single variable under examination. Compared to other RCTs on fracture treatment, the number of patients included in our study was a major strength. To our knowledge, this is the largest published series of its kind, and for the subgroup of reverse oblique and subtrochanteric fractures, it is the only RCT reported in the literature comparing SHS and IM nail. In addition, due to the multicenter design, many different surgeons and several hospitals participated in the study, thereby closely resembling a real-life setting. This also increases the external validity of our study.

However, despite obvious advantages, there are also some well known limitations to RCTs, our studies included;

Number of patients: Even in our study with almost 700 patients included, we did not have the statistical power to draw valid conclusions with regard to differences for rare outcomes such as surgical complications and reoperations. For example, to detect statistically significant differences in reoperation rates, either the difference in number of events between the two groups have to be large, or a huge number of patients have to be included. None of these conditions were satisfactorily met in our study.

Blinding: Ideally, both patients and follow-up examiners should be blinded to the treatment. However, in this large multicenter study we considered the ideal solution difficult to obtain, in particular since this was a study comparing surgical implants and operative methods including different skin incisions. In addition, masking of x-rays and patients would be very time-consuming, and an extra set of independent reviewers in five different hospitals would have been required for follow-up assessments.

Follow-up: For RCTs in general, achieving a high proportion of long term follow-up can be a challenge, and for elderly patients frequently living in nursing homes in particular. Accordingly, assessing long term effects or long term differences between treatment options in RCTs can be difficult. This was also a challenge in our study, however, long term losses to follow-up were equally distributed between the two groups. In addition, we had a main focus on in-hospital pain and function in the early postoperative period. Still, we were not able to examine all patients the same postoperative day. This could have influenced our results, but using a multiple linear regression we could adjust for differences in day of examination.

Validity: Depending on details in study design, conducting a RCT does not guarantee that the results found in one study are necessarily applicable to others. For instance, differences in patient selection (inclusion or exclusion criteria) and surgeons' qualifications may reduce the external validity of an otherwise well performed study. In the present study, and despite the random allocation of patients, the groups were slightly different with regards to patients' cognitive status and the experience of the surgeons. In our statistical analyses, however, we were able to adjust for these differences. Further, by conducting a multicenter study, and including a large number of patients, we tried to minimize the risk for any potential bias between the groups. To a certain degree, the large number of patients also compensate for limitations due to losses to follow-up, and the inclusion of demented patients frequently unable to respond adequately to different research questions. Thereby, we believe the results from our studies are also valid to others. However, the results do not necessarily apply to other types of IM nails.

Papers II and III

Despite being the gold standard, RCTs cannot answer all research questions. For instance, and as already described, RCTs may not have the statistical power to detect small, but still relevant differences in complication or reoperation rates. For such questions, and for long term follow-up, observational studies based on national registries, such as the Norwegian Hip Fracture Register, may have advantages.

For three important reasons, at least, register-based observational studies were appropriate for our research question; whether to use a SHS or an IM nail in trochanteric and subtrochanteric fractures. First, in general, differences in outcome for the two implants are small, if at all existing. This is true even for complication and reoperation rates. Because of these small differences, and a limited number of patients included in randomized trials, even meta-analyses of randomized trials may struggle to prove any significant difference between the two implants (9). Observational studies including thousands of patients might be a better way to address this problem. Second, and mainly relevant for Paper III, some fractures are rather uncommon. Therefore, collecting enough patients in RCTs within a reasonable time frame might not be possible. Finally, results reflecting a national average of surgeons and hospitals may actually be more relevant and correct, compared to results from RCTs performed in selected centers and by dedicated and more experienced surgeons. These strengths also apply to our register-based studies presented in Papers II and III.

Nevertheless, there are also some limitations to our register studies. Inherently, in a register-based study, patient or surgeon-related confounders not covered in the register data may influence the results. Further, fracture classification was performed by the individual surgeon, and the accuracy of the classification may therefore represent some uncertainty. Not surprisingly, the response rate from these often elderly patients is rather low, approximately around 50%. Even though we assume that surgical revisions are more consistently reported by the surgeons, the completeness of these data has not been validated. There is, however, no reason to believe that reoperation rates after the two different implants should be reported differently. Therefore, even though some

uncertainty regarding the absolute reoperation rates may exist, the *differences* between the implants should be reliable. Finally, IM nails and SHSs were assessed as two implant groups, and not as a series of different brands with minor differences between implants. Accordingly, our results represent an average for several implants within each group, and might not apply equally to each individual implant (brand).

The major strength of these studies is the large number of patients included, and as patient characteristics regarding age, gender, average ASA-score, and cognitive function at baseline were similar for the two groups, a selection bias is less likely. A selection bias is also less probable as treatment policy and implant selection in our country usually is a matter of administrative decisions in each hospital, and less based on the surgeons' individual preference. Accordingly, we believe our main findings in these studies are valid.

Overall, observational studies represent an important adjunct to RCTs, and for certain questions they may even provide the best available evidence (36). But still, and for reasons as mentioned above, results should be interpreted with caution. This also applies to our papers II and III.

9.2 Results

Papers I and IV

Overall, we found comparable results for patients operated with Intertan nails and SHSs in the present study (Papers I and IV). The Intertan group had slightly less pain at early postoperative mobilization, but this difference was not reflected in better functional mobility or shorter length of hospital stay. Regardless of fracture classification, no differences in pain, function, quality of life, or complication rates were evident at 3 or 12 months follow-up. This is in line with most recent studies and meta-analyses (9,14,15,37,38), but finding similar results for the subgroup of reverse oblique and subtrochanteric fractures has to our knowledge previously not been published in any RCT (Paper IV).

For an individual patient a VAS pain score difference of 10 points is considered a clinical relevant difference (39). Although this may be interpreted differently at a group level, a difference of 4 points in the early postoperative phase, as in the present study, is probably of minor clinical relevance. The mean estimated blood loss was 80 ml higher in the SHS group, but assessing "internal" blood loss after nailing is difficult. More patients in the SHS group received a blood transfusion, but we had no protocol for transfusing patients, and the hemoglobin level at the time of transfusion was not known. The difference in blood loss, or number of blood transfusions, did not seem to influence the length of stay or in-hospital complication rates. Therefore, the clinical significance of these differences is debatable.

The timed Up & Go test (32) and the Harris hip score (34) are common outcome measures assessing function after hip fractures (40), and were both used in the present study. However, regardless of outcome measure used, we did not detect any significant difference in function between the two implant groups during follow-up. This is also in accordance with recent meta-analyses (9,10,41).

Since the introduction of IM nailing in trochanteric fractures, peri-implant femoral fractures have been well known complications (42,43,44,45) **(Fig 6).** But according to Bhandari et al. (15), assessing different generations of the Gamma-nail and postoperative femoral fracture rates over time, this should no longer be an issue with modern nail design and more experience. Nevertheless, the Cochrane review (9) still comes to a different conclusion and in a recent study on Intertan nails, 6% postoperative femoral fractures were found (46). In our study we had five postoperative femoral fractures (1.5%) in the Intertan group, all within the first three months. Only one postoperative fracture occurred in the SHS group, but the difference in postoperative femoral fractures was not statistically significant (p = 0.10). Still, this

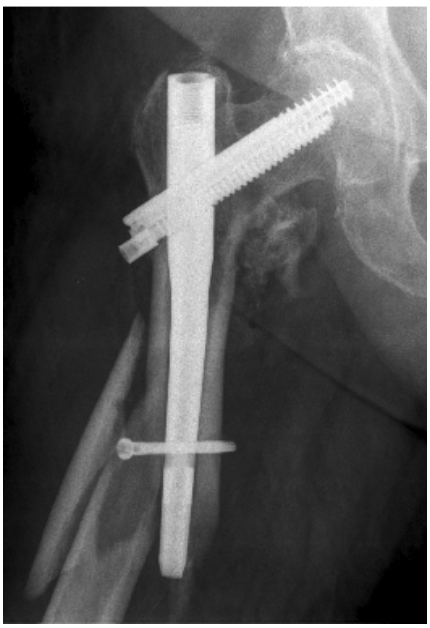


Fig 6: *A postoperative femoral fracture at the tip of an Intertan intramedullary nail.*

implies that the problem with fractures around the tip of IM nails has not been completely solved.

So far, no consistent difference in cutout rates between IM nails and SHS has been found in randomized trials (9). In a biomechanical study comparing the Intertan nail to other nail designs favorable results in terms of cutout were obtained for the Intertan nail (30). However, in a prospective study with one year follow up, Rücker et al. (47) reported 2 cutouts in 48 patients operated with the Intertan nail. In the present study, cutout was the most common cause of failure of the osteosynthesis regardless of type of implant, and we found no significant difference between the treatment groups **(Fig 7).**

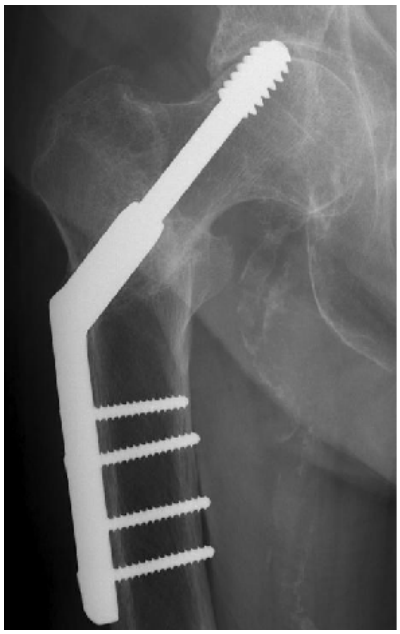
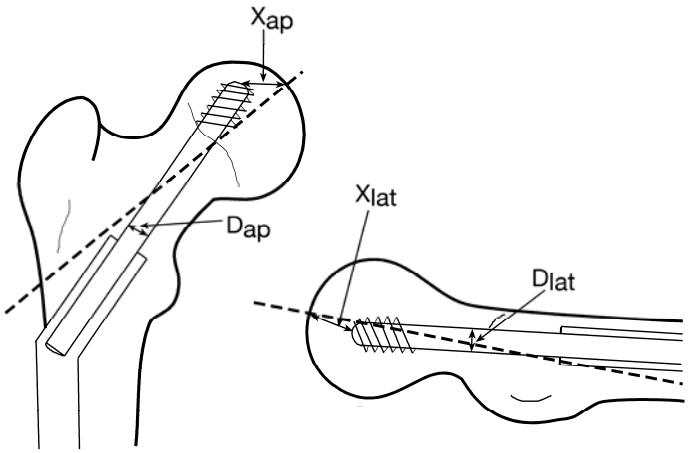


Fig 7: *A sliding hip screw with a "cutout" of the head-neck screw through the femoral head.*

It is well known that poor reduction and implant position give a poor prognosis in hip fracture treatment (33,48,49,50,51). In the present study, cutout and other surgical complications were associated with a higher tip-apex distance (TAD) **(Fig 8)**, poor reduction, or reduction more into varus, but independent on type of implant. Accordingly, an increased focus on surgical perfection, rather than implant selection, will probably best address this problem. Fewer patients in the Intertan group had a medialization exceeding 5 mm,



$$TAD = (X_{ap} \times \frac{D_{true}}{D_{ap}}) + (X_{lat} \times \frac{D_{true}}{D_{lat}})$$

Fig 8: *The tip-apex distance (TAD) according to Baumgaertner; The sum of the distance between the tip of the nail/screw and the apex of the femoral head in the frontal and the lateral plane (adjusted for magnification).*

probably because of the intramedullary position of the nail, providing a solid resistance to excessive sliding along the axis of the lag screw. The increased medialization for the SHS group could not be prevented by the TSP, but our data does not allow us to quantify to which extent a TSP still may have helped. Despite radiographic differences in femoral neck-shaft angle, shortening, tip-apex distance, and medialization, no difference in pain, function, or surgical complication rate between the two groups was evident.

The results presented above refers to overall results for all patients and all fracture types in our RCT (n = 684, Paper I), but practically the same results and conclusions also applies to the fractures assessed in our subgroup analysis (Paper IV). However, due to fewer patients in that study (n = 159), the statistical power is of course less.

We are not aware of any RCT comparing the use of a SHS (including a TSP) with IM nailing in patients with inter- and subtrochanteric fractures, but two RCTs (52, 53) comparing an IM nail to other extramedullary implants in intertrochanteric fractures are reported in the Cochrane Database Review (9). One study found a higher reoperation rate for patients treated with a Dynamic Condylar Screw compared to the Proximal Femoral Nail (52), whereas one study comparing patients operated with a blade plate or a Gamma nail found no difference in reoperation rates (53). These studies, however, included only small numbers of patients (n = 39 and n = 26, respectively). Contradicting findings were also reported for patients with subtrochanteric fractures, comparing either a 95º blade plate (54), or the Medoff sliding plate (55,56) to an IM nail. According to our study, and recognizing some limitations regarding statistical power, the SHS (including a TSP) seems to be a valid option also in these fractures. No major differences were found for most clinically relevant outcomes. Finally, we found no significant difference between the groups regarding the surgical time.

It is frequently argued that nailing is an easy and quick procedure, and that it is applicable to all types of trochanteric and subtrochanteric fractures. This might be

correct, but based on the results from the present study it might also be argued that even the SHS is applicable to all kind of trochanteric and subtrochanteric fractures.

Papers II and III

Paper II: Our main finding was a higher rate of complications and reoperations after IM nailing compared to SHS operations in simple two-part trochanteric fractures. Reoperation percentages at one year of 2.4% and 4.2% for SHS and IM nail, respectively, were comparable to other reports on trochanteric fractures. In line with our results, one recent meta-analysis of randomized trials concluded that the failure rates after IM nailing in stable trochanteric fractures were higher than failure rates after using a SHS, and IM nailing of these fractures could not be recommended (57). Our reoperation rates were slightly higher than those reported for stable fractures in that review, but lower than reported in other studies where stable and unstable fractures have not been separated (11,44,45). Even though absolute numbers of reoperations vary among studies, the consistent overall difference in favor of the SHS seems to persist. Postoperative femoral fractures rates were high using the first generations of IM nails (58,59,60,61). Therefore, reporting failure rates after IM nailing including nails no longer in use, may distort the results in updated reviews (9,10,62). This problem has already been discussed referring to the study on Gamma nails by Bhandari et al.(15). However, our data include only recent generations of implants, and therefore indicate that reoperation rates continue to be higher after IM nailing compared to the SHS in simple two-part trochanteric fractures.

Secondly, we found no difference in pain or quality of life between the two implant groups during follow-up. The assessment of pain for patients with hip fractures has not been standardized, and several outcomes for pain have been reported in the literature (9,41). Therefore, comparing results is difficult. Nevertheless, regardless of implant and outcome measure used, and in accordance with our results, recent meta-analyses report no major difference in pain between implants and operative methods in trochanteric fractures (57). Our finding of “no difference” in the reported quality of life between the implants using the EQ-$5D_{index}$ score indicates that the difference in

reoperation rates was not enough to influence the patients' perception of quality of life. One year postoperatively, however, more patients in the IM nail group rated their mobility and ability to perform usual activities with the best score. The differences were minor and temporary, but still, these EQ-5D dimensions describe important factors for patients to maintain their independency. We are not aware of any other study assessing quality of life using the EQ-5D-questionnaire in simple two-part trochanteric fractures. However, the most updated and comprehensive review of RCTs comparing SHSs and IM nails in trochanteric fractures concluded that there was no difference in terms of quality of life issues like pain, walking ability, or the number of patients regaining their prefracture level of independency after trochanteric fractures (9).

Paper III: Treating reverse oblique and subtrochanteric fractures with a SHS is by some authors considered inappropriate, in particular due to biomechanical considerations (17,19,63). However, the evidence in the literature is sparse and conflicting, and the debate whether to use a SHS or a nail in these fractures has not come to a final or indisputable conclusion.

Our reoperation rates of 3.8% and 6.4% at one year for IM nails and SHS, respectively, are in the lower range compared to most other studies on reverse oblique and subtrochanteric fractures (20,44,55,64,65,66,67,68), and significantly higher failure rates, for the SHS in particular, have been reported in some studies (16,54,69). In a retrospective review of 55 patients with reverse oblique fractures operated with different types of implants over a 10 year period, Haiducewych et al.(16) reported a failure for 9 out of 16 patients operated with a SHS (56%). However, what we consider mandatory for the reverse oblique fractures, no TSP was used in their operations. Other implants were also associated with high failure rates in the same study, but due to a retrospective study design and a small number of patients, conclusions on failure rates and implant selection based on that study alone should be drawn with caution. Brammar and colleagues (21) found a considerably lower overall fracture healing complication rate of 9% in a review of 101 reverse oblique trochanteric fractures, and no statistically significant difference in reoperation rates

between SHS and IM nail was found in that study. More favorable complication rates for the SHS have also been reported in other studies (20,24,67).

The additional use of a TSP (in 63% of our SHS-operations), for the reverse oblique fracture type in particular, may to some extent account for the lower rate of reoperations in our study. However, we had no x-rays available for initial fracture classification or later follow-up, and therefore, assessing the exact significance of the TSP in this register study was not possible. In addition, clinical data recorded in our hip fracture register are limited, and a randomized controlled study design would probably be the best way to assess any usefulness of the TSP. Recent improvements in implant design, and surgeons becoming more aware of surgical pitfalls in treating these fractures, may also have had a positive impact on failure rates. Incomplete reporting is another possible explanation for our rather low reoperation rates. In addition, as some elderly, demented, or frail patients may have been considered unsuitable candidates for further surgery, we might suspect the actual failure rates to be higher than our reoperation rates indicate. Therefore, the *difference* in reoperation rate between the two implants is probably more important than the absolute numbers. We may have underestimated the reoperation rates, but any under-reporting of reoperations should most likely be similar for the two groups.

Historically, a high rate of peri-implant fractures has been a major concern after IM nailing for trochanteric fractures. In the present series of 924 patients treated with IM nails only two patients were reported with a second femoral fracture around the implant during a follow-up of 12 months. This is in line with the findings by Bhandari et al.(15), but such a low rate of peri-implant fractures might also represent an under-reporting of these injuries to the register. However, as suggested by Bhandari and coworkers, improvements in operative technique and implant design could be other reasonable explanations. Finally, the frequent use of long IM nails (74%) in the present study may have prevented some peri-implant fractures.

Due to a large number of patients in the present study, also small differences in pain, patient satisfaction, and EQ-5D$_{index}$ score reached statistical significance**.** The clinical

relevance of these minor differences, though, is debatable. A difference in VAS pain score of 3-4 points for the individual patient is not clinically relevant (39), but at a group level, such a difference should not be neglected. Similar, statistically significant differences regarding patient satisfaction within the first year cannot be ignored, but the importance of a statistically non-significant difference of 0.02 in the EQ-5D$_{index}$ score at one year in our study should not be overemphasized. Still, with a similar level of mobility at baseline, the patients' self-assessment of significantly better mobility in the IM nail group 4 and 12 months postoperatively is an important finding and very relevant for this group of patients.

Less pain in the IM nail group may be a result of mini-invasive surgery and/or better stability of the implant in the initial postoperative phase, whereas long term differences could be due to more local pain from protruding hardware or more secondary fracture displacement and malunions in the SHS group. Detailed information on such issues is, however, not retrievable from our register data. Pain is most probably also influential on patient satisfaction and quality of life measures, and may to some extent explain the slightly superior results in favor of the IM nail for these outcomes.

9.3 Interpretations

Papers I and IV

Describing our overall results might be straight forward, but the interpretation of these data is not equally simple. For instance, comparing one IM nail to the SHS does not mean that these results are applicable to all IM nails. Further, results obtained in our hands may not be reproducible by others. In the present study, we offer no answer to how much we would be willing to pay for slightly less blood loss and a reduced number of blood transfusions, assuming results and complication rates are otherwise similar. In addition, what is the actual importance of slightly less pain (4-5 points on a visual analogue scale) the first postoperative days (with a similar length of hospital stay)?

The interpretation of our data might be compared to the two different perceptions of **Fig 9**.

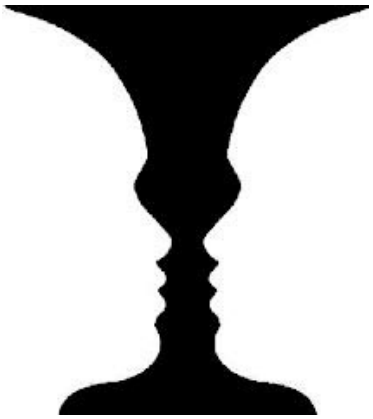


Fig 9: *Rubin's vase.*

Looking at the same picture, some observers will probably see a black candle, whereas others will immediately see the white profile of two faces. Similar, the results from "The Intertan Study" can be interpreted in different ways. From our own perspective, we found no hard evidence in the present study to support a change in treatment policy for trochanteric or subtrochanteric fractures, and the SHS has remained our implant of choice. However, based on the same results, it is also possible to come to a different conclusion. One might argue that it has finally been proven that modern nails have no more complications than the SHS, and that the overall results in the present study is actually in favor of the IM nail. Accordingly, the discussion whether the SHS or an IM nail is the best implant for some or all of these fractures will continue.

Improving outcome and reducing complication rates in these patients and fractures remains a challenge. To achieve a good outcome, our results also emphasize the importance of surgical perfection, and optimizing fracture reduction and implant position is probably more important than the choice of implant. Finally, the interpretation of different outcome measures must also take study limitations and power calculations into account. This should not be forgotten.

Papers II and III

Paper II: Only contemporary implants used between 2005 and 2010 were studied, and our main finding was a significantly higher rate of reoperations after IM nailing compared to the SHS in simple two-part trochanteric fractures. Our study had some limitations, but with similar baseline characteristics for the two groups, and with results representing a national average of surgeons and hospitals, we suspect no major bias in the study. The results are also in accordance with recent meta-analyses of

randomized controlled trials. Therefore, despite modern trends suggesting otherwise, the SHS still seems to be the best treatment for simple two-part trochanteric fractures.

Paper III: In this study, patients with reverse oblique trochanteric and subtrochanteric fractures operated with a SHS had a significantly higher reoperation rate compared to those treated with an IM nail. For similar reasons as mentioned above (Paper II), we believe this is a true difference caused by the implants and operative methods, and not to be explained by any bias between the groups. In addition, 4 and 12 months postoperatively we also found a small difference in pain, patient satisfaction, and quality of life (including walking ability) in favor of the nail. Based on these results, and as opposed to our current practice, a change in our treatment algorithm for these unstable fracture types could be considered. For those already treating these patients with an IM nail, the current study provides scientific evidence to support such an approach.

10. Conclusions

In our randomized controlled trial (Papers I and IV), the TRIGEN INTERTAN nail was equivalent to the sliding hip screw in terms of pain, function, and complication and reoperation rates 12 months postoperatively, and these results were similar regardless of fracture type. Poor fracture reduction and implant position were clearly associated with increased complication and reoperation rates. Accordingly, to achieve a favorable outcome for these fractures and patients, the implant selection seems to be less important than attention to surgical details.

In our register studies (Papers II and III), we found that the SHS seems to be the best implant with the least number of complications and reoperations for two-part trochanteric fractures (AO/OTA type A1). For the reverse oblique trochanteric (AO/OTA type A3) and subtrochanteric fractures, however, an IM nail seems to provide the best results. Corresponding changes in our current treatment strategy could be considered.

11. Future perspectives

Despite years of experimental and clinical research, including improvements of implant design and surgical techniques, treating trochanteric and subtrochanteric fractures remains a challenge. Complications still occur, reoperations have to be encountered, and the patients frequently do not reach their pre-fracture level of function or independency. Accordingly, there is still room for improvements.

An elderly osteoporotic lady falling at home represents the classic history of how hip fractures occur. Analyzing this simple history indicates how hip fractures may be prevented. Through measures addressing the problem of osteoporosis, the overall physical capacities of the elderly, the environmental factors in the patients' home, and the increased risk of falling, a devastating hip fracture may to some extent be preventable. In addition, there are major challenges in how we take care of our elderly hip fracture patients after having performed our surgical treatment.

In my opinion, the following topics should be emphasized in the future.

11.1 Implementation of results

The studies presented in this thesis, give some recommendations regarding the best treatment for selected trochanteric and subtrochanteric fracture types. For those treating these fractures differently today, a change in treatment policy could be considered. However, we should not forget that improving the care of hip fracture patients is more than just selecting a proper surgical implant.

11.2 Prevention of hip fractures

Osteoporosis is a global epidemic, in particular in the western world, and it is recognized as one major risk factor for sustaining hip fractures. Nutritional deficiencies or side-effects of other medical treatment may increase the problem of postmenopausal osteoporosis. Defining the best strategies to identify patients at risk, to motivate physicians to initiate screening for osteoporosis, and to start the correct

treatment before it is already too late, are challenges to be addressed in future clinical practice and research.

If elderly people didn't fall, most hip fractures would have been avoided. Accordingly, introducing effective **falls prevention programs** should be one major goal in the prevention of hip fractures. However, as the reasons why patients fall are multi-factorial, there is no easy way to prevent this from happening. A detailed analyses and more knowledge about falls; when, where, why, how, and for whom do they occur, is required to optimize the resources and to target interventions in the best way. Clear and well proven strategies should be developed, but to achieve these goals, major efforts and clear priorities from health care providers and the society will be required. Improving elderly patients' balance, strength and general physical capacity would undoubtedly be beneficial, but how to achieve these goals, and to assess individual effects of different steps undertaken to reduce the number of falls needs to be explored.

Hip protectors have been shown to be effective when they are used. Further research and product development should be encouraged, and methods to improve compliance should be established.

11.3 Implants and surgical treatment

Surgical technique: So far, no surgical implant or operative technique has been able to prevent surgical or mechanical failures in trochanteric and subtrochanteric fractures. And probably no implant or operative technique can compensate for poor fracture reduction or wrong implant position in the femoral head-neck fragment. Therefore, a structured educational program and continuous attention to surgical details in the treatment of these fractures might be a better way to improve results, as compared to never-ending discussions regarding implant selection. To document the efficiency of such an approach would further enhance the focus on surgical perfection and its importance for a successful outcome.

In recent years, there have been several reports on mini-invasive plate and screw osteosynthesis, and results have been encouraging. However, as opposed to mini-

invasive plating techniques for other fractures, for most surgeons this has not been established as a standard treatment for trochanteric and subtrochanteric fractures. Whether these techniques and corresponding implants could be favorable to all trochanteric fractures and patients, and even to surgeons not specifically dedicated to mini-invasive techniques, remains to be clarified.

Indications: Furthermore, rather than discussing whether a SHS or an IM nail is the best treatment for all trochanteric or subtrochanteric fractures, we should study and discuss to which *subgroups of fractures or patients* a SHS or an IM nail might be the best option. Our results suggest that a differentiated treatment algorithm probably best assures the individual patient a good outcome. Before we can draw definitive conclusions, and possibly tailor the treatment according to specific fracture and patient criteria, more research and detailed analyses of fracture and patient characteristics and outcome is required.

Implant design and mechanical properties: The basic mechanical principle for the modern sliding hip screw has remained practically unchanged since its introduction in the 60-ties and 70-ties. Similar, the basic principle for IM nails has been unchanged since the introduction of nailing in the treatment of trochanteric fractures in the late 80-ties.

However, modifications and improvements to previous generations of implants are continuously launched on the marked, and sometimes new concepts are presented. One such change is the principle of angular stability between screw and plate systems and between nails and their locking bolts. Another is the use of two integrated screws in the femoral head-neck fragment, until now most frequently used for IM nails (Intertan), but also available for recent plate and screw configurations.

The osteoporotic structure of the bone in most hip fracture patients creates a poor environment for a stable fracture fixation. Therefore, attempts have been made to improve the bone-implant interface, and hydroxyapatite-coating of the implant surface and augmentation with cement around the femoral head-neck screw have been used to enhance screw fixation. The results so far indicate that there is still a way to go.

As the number of hip fractures will continue to rise, and mechanical failures will keep haunting patients and surgeons, the evolution of new products, and the search for the ideal implant will probably continue in foreseeable future. This implant should be dynamic, but stable, and the implant itself should aid the reduction and improve the healing capacity of the bone. And not the least, it should be cheap and easy to use. The question is will we ever get there?

Finally, in my opinion, the surgical treatment and the implant selection should not merely be based on modern trends or beliefs that new implants or techniques are automatically better than existing methods. Any new implant or concept should be tested in well designed clinical trials before being launched on a large scale.

11.4 Rehabilitation

The benefits (or limitations) of rehabilitation need to be clarified and scientifically documented for this group of elderly patients. In addition, and relevant to most health care systems with financial and other limitations, defining how to select the patients who will benefit the most from a structured rehabilitation program will be a major challenge.

In general, as orthopaedic surgeons we are probably not doing enough for our patients after having repaired their fractures. Treating a hip fracture is not merely about repairing fractured bone, but even more importantly, it is a matter of restoring patients overall function and independency. Successful fracture healing is one prerequisite to achieve such a result, but fracture healing alone does not guarantee a pain free, well functioning, and independently living patient. Accordingly, more focus and research should be invested in how to optimize hip fracture care from a holistic approach, and not merely from a surgical point of view.

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13. Appendixes

Appendix 1

Harris hip score

Appendix 2

EQ-5D questionnaire

Appendix 3

Radiographic assessments

Appendix 4

Norwegian Hip Fracture Register forms

Appendix 1:

Harris hip score

Sett ring rundt det riktigste svaret

Smerter:

Pain	None		44
	Slight	Occasional ache or awareness of pain of low grade, no compromise of activities	40
	Mild	No effect on average activities, rarely may have moderate pain following unusual activities, may take aspirine	30
	Moderate	Pain tolerable but patient makes concessions to his pain, some limitations of ordinary activities but able to work regulary, may require pain medicine stronger than aspirin occasionally	20
	Marked	Severe pain at times, but ambulatory; serious limitations of activities; takes pain medicine stronger than aspirine usually or frequently	10
	Disabled	Severe pain even in bed; pain forces patient to bed; crippled by pain ; bedridden	0

ADL –funksjoner:

Walking stairs (Trappegang)	Foot over foot without use of banister (rekkverk)	4
	Foot over foot using banister	2
	Stairs in any manner	1
	Unable to do stairs	0
Transportation	Able to enter public transportation	1
Sitting	Comfortable in any chair for one hour	5
	Comfortable in a high chair for one-half hour	3
	Unable to sit comfortably in any chair	0
Shoes and socks	Puts on socks and ties shoes with ease	4
	Puts on socks and ties shoes with difficulty	2
	Unable to put on socks and tie shoes	0

Gangfunksjon:

Limp (Halting)	None	11
	Slight	8
	Moderate	5
	Severe	0
The support required to walk comfortably and smoothly	None	11
	Single cane (stokk) for long walks	7
	Single cane most of the time	5
	One crutch (krykke)	3
	Two canes	2
	Two crutches (samt rullator / gåstol)	0
	Not able to walk at all (årsak:……..)	0
Distance walked (Gangdistanse)	Unlimited	11
	Six blocks (1- 2km)	8
	Two or three blocks (< 1km)	5
	Indoors only	2
	Bed and chair	0

Deformitet:

Abscence of deformity points are given if the patient demonstrates none of the listed deformities - Less than 30^0 fixed flexion contracture - Less than 10^0 fixed adduction - Less than 10^0 fixed internal rotation in extension - Limb-lenght discrepancy exceeding 3,2 cm	4
Feilstillinger i *en* av parametrene større enn dette gir 0 poeng for deformitetsscore	0

Trendelenburg: (Sett ring rundt riktig svar)

Høyre side	Negativ	Positiv	Kan ikke utføres
Venstre side	Negativ	Positiv	Kan ikke utføres

Testen er ”positiv” (unormal) på standbenets side dersom pasienten ikke klarer å holde bekkenet i vater når det andre benet løftes.

Anisomeli: (Sett ring rundt riktig svar)

Høyre side er ……..cm lengre enn / kortere enn venstre

Bevegelsesutslag:

Høyre hofte				Venstre hofte			
Ekstensjon		Fleksjon		Ekstensjon		Fleksjon	
Utrotasjon		Innrotasjon		Utrotasjon		Innrotasjon	
Abduksjon		Adduksjon		Abduksjon		Adduksjon	

Eksempel:
Ved Ekstensjon 0° og fleksjon 85° angi: 0° 85°. Ved fleksjonskontraktur 15° og fleksjon 100° angi -15° 100°

Rotasjon måles på ekstendert hofte med foten som indikator for rotasjon.

Signatur:……

Appendix 2:

EQ-5D - questionnaire

VISIT V / 12 måneders kontroll

Utvalg fra EQ-5D

PASIENTSPØRRESKJEMA INTERTAN – STUDIEN

Spørsmål om livskvalitet, smerte, funksjon og tilfredshet

1. Dato for utfylling av skjema: |__|__| |__|__| |__|__|

2. Spørreskjemaet er besvart av:

[1] Meg selv

eller ved hjelp av….(kryss av i ruten som gjelder)

[2] Slektning (ektefelle, barn)
[3] God venn eller annen nærstående
[4] Annen privat person
[5] Hjemmesykepleier/hjemmehjelp
[6] Annen person, angi hvem:_____

…….
Signatur

Vi har tidligere spurt deg hvordan du hadde det før du pådro deg bruddet i hoften, samt 1 og 3 måneder etter operasjonen.

I de 5 neste spørsmålene ønsker vi å vite hvordan livssituasjonen din er <u>NÅ:</u>

3. Hvordan opplever du gangevnen din?

[1] Jeg har ingen problemer med å gå omkring
[2] Jeg har litt problemer med å gå omkring
[3] Jeg er sengeliggende

4. Hvordan klarer du personlig stell?

[1] Jeg har ingen problemer med personlig stell
[2] Jeg har litt problemer med å vaske meg eller kle meg
[3] Jeg klarer ikke å vaske meg eller kle meg

5. Hvordan klarer du dine vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- og fritidsaktiviteter)?

[1] Jeg har ingen problemer med å utføre mine vanlige gjøremål
[2] Jeg har litt problemer med å utføre mine vanlige gjøremål
[3] Jeg er ute av stand til å utføre mine vanlige gjøremål

6. Smerter eller ubehag?

[1] Jeg har verken smerte eller ubehag
[2] Jeg har moderat smerte eller ubehag
[3] Jeg har sterk smerte eller ubehag

7. Angst eller depresjon?

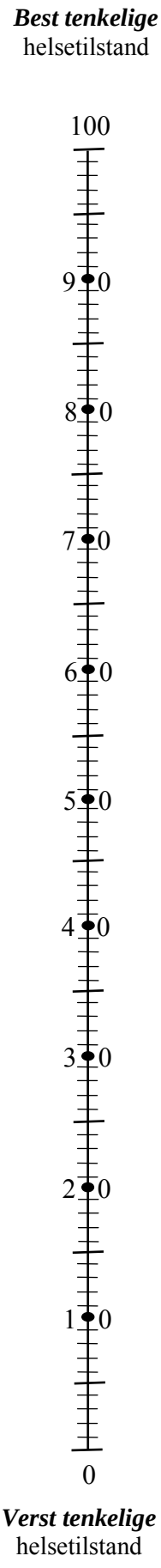
[1] Jeg er verken engstelig eller deprimert
[2] Jeg er noe engstelig eller deprimert
[3] Jeg er svært engstelig eller deprimert

8. Din helsetilstand i dag.

For å hjelpe folk til å si hvor god eller dårlig en helsetilstand er, har vi laget en skala (omtrent som et termometer) hvor den beste tilstanden du kan tenke deg er merket 100 og den verste tilstanden du kan tenke deg er merket 0.

Vi vil gjerne at du viser på denne skalaen hvor god eller dårlig helsetilstanden din er i dag, etter din oppfatning. Vær vennlig å gjøre dette ved å trekke en linje fra boksen nedenfor til det punktet på skalaen som viser hvor god eller dårlig din helsetilstand er i dag.

Din egen helsetilstand i dag



SMERTE

9. Sett <u>et kryss</u> på den streken som du synes tilsvarer din gjennomsnittlige smerteopplevelse fra den opererte hoften den siste måneden:

Ingen smerte — Maksimal smerte

I——I——I——I——I——I——I——I——I——I——I

lett moderat middels sterk uutholdelig

TILFREDSHET

10. Sett <u>et kryss</u> på den streken som du synes tilsvarer hvor fornøyd du er med operasjonsresultatet:

Fornøyd — Misfornøyd

I——I——I——I——I——I——I——I——I——I——I

svært fornøyd fornøyd middels fornøyd misfornøyd svært misfornøyd

Takk for at du tok deg tid til å svare på spørsmålene. Dine svar er svært nyttige for oss.

Appendix 3:

Radiographic assessments

VISIT I og II, innleggelse og operasjon
Radiologiske registreringer i INTERTANSTUDIEN
F.nr. (11 sifre) ……
Navn: …… **Reg.nr.**: |__|__|__|

Sykehus: ☐[1] Diakonhjemmet ☐[2] Levanger ☐[3] AHUS ☐[4] SIV ☐[5] HUS

Visit I (innleggelse)

Røntgen dato (ddmmåå):…….

Bruddklassifikasjon:
AO klassifikasjonen for trokantære brudd:

A1	A 1.1 ☐[1]	A1.2 ☐[2]	A1.3 ☐[3]
A2	A 2.1 ☐[4]	A2.2 ☐[5]	A2.3 ☐[6]
A3	A 3.1 ☐[7]	A3.2 ☐[8]	A3.3 ☐[9]

Russell klassifikasjonen for subtrokantære brudd:
Ia ☐[1] Ib ☐[2] IIa ☐[3] IIb ☐[4]

Stabilitet (i henhold til Evans /Kyle): Stabil fraktur ☐[1] Ustabil fraktur☐[2]

Kommentarer:……..

Visit II (postoperativt)

Røntgen dato (ddmmåå):…….

Frakturreposisjon frontalplan:

"Neck-shaft angle": ……grader

Avvik fra normalen:

Neutral / Valgus 0 - 5° ☐[1]	Valgus 5 -15° ☐[2]	Valgus > 15° ☐[3]
Neutral / Varus 0 - 5° ☐[4]	Varus 5 -15° ☐[5]	Varus >15° ☐[6]

Dislokasjon **("displacement"):**

Skaft vs proksimalt:	Ingen ☐[0]	0 - 4mm ☐[1]	>4mm ☐[2]	> 10mm ☐[3]
Trokanter minor:	Ingen ☐[0]	0 - 4mm ☐[1]	>4mm ☐[2]	> 10mm ☐[3]
Trokanter major:	Ingen ☐[0]	0 - 4mm ☐[1]	>4mm ☐[2]	> 10mm ☐[3]

Forkortning: Ingen ☐[0] < 5 mm ☐[1] 5 -10mm ☐[2] > 10mm ☐[3]

> 20mm ☐[4] > 30mm ☐[5] > 40mm ☐[6]

Forlengelse: Nei ☐[0] Ja ☐[1] ……..mm

Frakturreposisjon sideplan:

Vinkelfeilstilling **:**

Antekruvasjon: Neutral (-5 - 5°) ☐[0] 5- 20° ☐[1] >20° ☐[2]

Retrokurvasjon: 5 - 20° ☐[3] >20° ☐[4]

Dislokasjon **("displacement"):**

Skaft vs trochanter: Ingen ☐[0] 0 - 4mm ☐[1] >4mm ☐[2] > 10mm ☐[3]

Trokanter minor: Ingen ☐[0] 0 - 4mm ☐[1] >4mm ☐[2] > 10mm ☐[3]

Trokanter major: Ingen ☐[0] 0 - 4mm ☐[1] >4mm ☐[2] > 10mm ☐[3]

Klassifisering av reposisjon (a.m. Baumgaertner):

"Good" ☐[1] "Acceptable" ☐[2] "Poor" ☐[3]

Implantatplassering:

Tip-Apex Distance (TAD): Front ……. mm Side ……. mm Sum……mm

Skrueplassering i caput:

Frontplan: Superiort ☐[1] Sentralt ☐[2] Inferiort ☐[3]

Sideplan: Anteriort ☐[1] Sentralt ☐[2] Posteriort ☐[3]

Sum plassering i caput:
(sett ring rundt riktig kvadrant)

Superiort (AP –plan)

1	2	3
4	5	6
7	8	9

Posteriort (sideplan) — **Anteriort (sideplan)**

Inferiort (AP-plan)

Korteste avstand fra leddet (tuppen av skruen til subchondralt ben): ……. mm

……

Dato /Signatur:

VISIT V, 12 MÅNEDERS KONTROLL
Radiologiske registreringer i INTERTANSTUDIEN

F.nr. (11 sifre) ……
….
Navn: …… **Reg.nr.**:
|__|__|__|

Sykehus: ☐[1] Diakonhjemmet ☐[2] Levanger ☐[3] AHUS ☐[4] SIV ☐[5] HUS

Røntgenbilder tatt (dd.mm.åå): |__|__| |__|__| |__|__|

Reoperert siden 3 måneders ktr: Nei ☐[0] Ja ☐[1]……

Tilheling: Nei ☐[0] Ja ☐[1] Usikker ☐[2]

Frakturstilling frontalplan:

"Neck-shaft angle": ……grader Endring fra sist:…….grader

Avvik fra normalen:

Neutral / Valgus 0 - 5° ☐[1] Valgus 5 -15° ☐[2] Valgus > 15° ☐[3]

Neutral / Varus 0 - 5° ☐[4] Varus 5 -15° ☐[5] Varus >15° ☐[6]

Forkortning i bruddet:

Ingen ☐[0] < 5 mm ☐[1] 5 -10mm ☐[2] > 10mm ☐[3]

> 20mm ☐[4] > 30mm ☐[5] > 40mm ☐[6]

Medialisering av skaftet: ☐……mm (endring fra 3 mnd ktr)

Andre kommentarer:……

Implantatendringer:

Uendret siden sist: ☐[0]

Endring siden sist: ☐[1]

……mm

"Cut-out" av skruen: Gjennom caput ☐[1]
Bevegelse av skruen i caput ☐[2] …….mm
Ledd-penetrasjon/migrasjon ☐[3]
Teleskopering av skruen i collum/caput ☐[4]

Løsning av implantat fra femur ☐[5]
Skruebrekkasje (glideskrue) ☐[6]
Skruebrekkasje (sperreskrue nagle) ☐[7]

Andre endringer:……..

……
Dato /signatur

Appendix 4:

Norwegian Hip Fracture Register form, 2005 - 2008

NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
Møllendalsbakken 11
5021 BERGEN
Tlf: 55976452

F.nr. (11 sifre).....

Navn:.....

(Skriv tydelig ev. pasient klistrelapp – **spesifiser sykehus**.)

Sykehus:.....

HOFTEBRUDD

PRIMÆRE OPERASJONER PÅ BRUDD I PROKSIMALE FEMURENDE og ALLE REOPERASJONER, inkludert lukket reponering av hemiproteser.

Ved primæroperasjon med totalprotese og ved reoperasjon til totalprotese brukes kun hofteproteseskjema. Alle produktklistrelapper settes i merket felt på baksiden av skjemaet.

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

SIDE (ett kryss) (Bilateral opr.= 2 skjema)
☐1 Høyre ☐2 Venstre

OPR TIDSPUNKT (dd.mm.åå) |__|__| |__|__| |__|__| kl |__|__|

BRUDD TIDSPUNKT (dd.mm.åå) |__|__| |__|__| |__|__| kl |__|__|

Dersom det er usikkerhet om brudd tidspunkt, fyll ut neste punkt.

TID FRA BRUDD TIL OPERASJON I TIMER
☐1 0-6 ☐2 >6-12 ☐3 >12-24 ☐4 >24-48 ☐5 >48

DEMENS
☐0 Nei ☐1 Ja (Se test på baksiden) ☐2 Usikker

ASA-KLASSE (se bakside av skjema for definisjon)
☐1 Frisk
☐2 Asymptomatisk tilstand som gir økt risiko
☐3 Symptomatisk sykdom
☐4 Livstruende sykdom
☐5 Moribund

ÅRSAK TIL PRIMÆROPERASJON (TYPE PRIMÆRBRUDD)
(Kun ett kryss)
☐1 Lårhalsbrudd udislokert (Garden 1 og 2)
☐2 Lårhalsbrudd dislokert (Garden 3 og 4)
☐3 Lateralt lårhalsbrudd
☐4 Pertrokantært to-fragment
☐5 Pertrokantært flerfragment
☐6 Subtrokantært
☐7 Annet .....

TYPE PRIMÆROPERASJON (Kun ett kryss)
(Fylles ut bare ved primæroperasjon - eget skjema for totalproteser)
(Spesifiser nøyaktig produkt eller fest evt produktklistrelapp på baksiden)
☐1 To skruer eller pinner
☐2 Tre skruer eller pinner
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Glideskrue og plate
☐6 Glideskrue og plate med trochantær støtteplate
☐7 Vinkelplate
☐8 Kort margnagle uten distal sperre
☐9 Kort margnagle med distal sperre
☐10 Lang margnagle uten distal sperre
☐11 Lang margnagle med distal sperre
☐12 Annet, spesifiser.....

Navn / størrelse ev. katalognummer.....

ÅRSAK TIL REOPERASJON (Flere enn ett kryss kan brukes)
☐1 Osteosyntesesvikt/havari
☐2 Ikke tilhelet brudd (non-union/pseudartrose)
☐3 Caputnekrose (segmentalt kollaps)
☐4 Lokal smerte pga prominerende osteosyntesemateriale
☐5 Brudd tilhelet med feilstilling
☐6 Sårinfeksjon – overfladisk
☐7 Sårinfeksjon – dyp
☐8 Hematom
☐9 Luksasjon av hemiprotese
☐10 Osteosyntesematerialet skåret gjennom caput
☐11 Nytt brudd rundt implantat
☐12 Løsning av hemiprotese
☐13 Annet, spesifiser.....

TYPE REOPERASJON (Flere enn ett kryss kan brukes)
(Spesifiser nøyaktig produkt eller fest evt produktklistrelapp på baksiden)
☐1 Fjerning av implantat (Brukes når dette er eneste prosedyre)
☐2 Girdlestone
(= fjerning av osteosyntesemateriale/hemiprot. og caputresten)
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Re-osteosyntese
☐6 Drenasje av hematom eller infeksjon
☐7 Lukket reposisjon av luksert hemiprotese
☐8 Åpen reposisjon av luksert hemiprotese
☐9 Annet, spesifiser.....

Navn / størrelse ev. katalognummer.....

FIKSASJON AV HEMIPROTESE
(For totalprotese sendes eget skjema til hofteproteseregisteret)
☐1 Usementert
☐1 med HA ☐2 uten HA
☐2 Sement med antibiotika Navn.....
☐3 Sement uten antibiotika Navn.....

PATOLOGISK BRUDD (Annen patologi enn osteoporose)
☐0 Nei
☐1 Ja, type.....

TILGANG TIL HOFTELEDDET VED HEMIPROTESE (Kun ett kryss)
☐1 Anterolateral
☐2 Lateral
☐3 Posterolateral
☐4 Annet, spesifiser.....

ANESTESITYPE
☐1 Narkose ☐2 Spinal ☐3 Annet, spesifiser.....

PEROPERATIVE KOMPLIKASJONER
☐0 Nei
☐1 Ja, hvilke(n).....

OPERASJONSTID (hud til hud).....minutter.

SYSTEMISK ANTIBIOTIKAPROFYLAKSE
☐0 Nei ☐1 Ja, Hvilken (A).....

Dose (A).....Totalt antall doser.....Varighet .....timer

Ev. i kombinasjon med (B).....

Dose (B).....Totalt antall doser.....Varighet .....timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, hvilken type.....

Dosering opr.dag.....Første dose gitt preopr ☐0 Nei ☐1 Ja

Senere dosering.....Antatt varighet.....døgn

Ev. i kombinasjon med .....

Dosering.....Antatt varighet.....døgn

Strømpe ☐0 Nei ☐1 Legg ☐2 Legg + Lår Antatt varighet .....døgn

Mekanisk pumpe ☐0 Nei ☐1 Fot ☐2 Legg Antatt varighet.....døgn

Lege.....
Legen som har fylt ut skjemaet (navnet registreres ikke i databasen).

Norwegian Hip Fracture Register form, 2008 - 2011

NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
Møllendalsbakken 11
5021 BERGEN
Tlf: 55976452

F.nr. (11 sifre).....

Navn:.....

(Skriv tydelig ev. pasient klistrelapp – spesifiser sykehus.)

Sykehus:.....

HOFTEBRUDD

PRIMÆRE OPERASJONER PÅ BRUDD I PROKSIMALE FEMURENDE og ALLE REOPERASJONER, inkludert lukket reponering av hemiproteser. Ved primæroperasjon med totalprotese og ved reoperasjon til totalprotese brukes kun hofteproteseskjema. Alle produktklistrelapper settes i merket felt på baksiden av skjemaet.

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

SIDE (ett kryss) (Bilateral opr.= 2 skjema)
☐1 Høyre ☐2 Venstre

OPR TIDSPUNKT (dd.mm.åå) |__|__| |__|__| |__|__| kl |__|__|

BRUDD TIDSPUNKT (dd.mm.åå) |__|__| |__|__| |__|__| kl |__|__|

Dersom det er usikkerhet om brudd tidspunkt, fyll ut neste punkt.

TID FRA BRUDD TIL OPERASJON I TIMER
☐1 0-6 ☐2 >6-12 ☐3 >12-24 ☐4 >24-48 ☐5 >48

DEMENS
☐0 Nei ☐1 Ja (Se test på baksiden) ☐2 Usikker

ASA-KLASSE (se bakside av skjema for definisjon)
☐1 Frisk
☐2 Asymptomatisk tilstand som gir økt risiko
☐3 Symptomatisk sykdom
☐4 Livstruende sykdom
☐5 Moribund

TYPE PRIMÆRBRUDD (ÅRSAK TIL PRIMÆROPERASJON) (Kun ett kryss)
Se baksiden for klassifikasjon
☐1 Lårhalsbrudd udislokert (Garden 1 og 2)
☐2 Lårhalsbrudd dislokert (Garden 3 og 4)
☐3 Lateralt lårhalsbrudd
☐4 Pertrokantært tofragment (AO klassifikasjon A1)
☐5 Pertrokantært flerfragment (AO klassifikasjon A2)
☐9 Intertrokantært (AO klassifikasjon A3)
☐6 Subtrokantært
☐7 Annet ……

TYPE PRIMÆROPERASJON (Kun ett kryss)
(Fylles ut bare ved primæroperasjon - eget skjema for totalproteser)
(Spesifiser nøyaktig produkt eller fest evt produktklistrelapp på baksiden)
☐1 To skruer eller pinner
☐2 Tre skruer eller pinner
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Glideskrue og plate
☐6 Glideskrue og plate med trochantær støtteplate
☐7 Vinkelplate
☐8 Kort margnagle uten distal sperre
☐9 Kort margnagle med distal sperre
☐10 Lang margnagle uten distal sperre
☐11 Lang margnagle med distal sperre
☐12 Annet, spesifiser……..

Navn / størrelse ev. katalognummer……

ÅRSAK TIL REOPERASJON (Flere enn ett kryss kan brukes)
☐1 Osteosyntesesvikt/havari
☐2 Ikke tilhelet brudd (non-union/pseudartrose)
☐3 Caputnekrose (segmentalt kollaps)
☐4 Lokal smerte pga prominerende osteosyntesemateriale
☐5 Brudd tilhelet med feilstilling
☐6 Sårinfeksjon – overfladisk
☐7 Sårinfeksjon – dyp
☐8 Hematom
☐9 Luksasjon av hemiprotese
☐10 Osteosyntesematerialet skåret gjennom caput
☐11 Nytt brudd rundt implantat
☐12 Løsning av hemiprotese
☐13 Annet, spesifiser……

TYPE REOPERASJON (Flere enn ett kryss kan brukes)
(Spesifiser nøyaktig produkt eller fest evt produktklistrelapp på baksiden)
☐1 Fjerning av implantat (Brukes når dette er eneste prosedyre)
☐2 Girdlestone
(= fjerning av osteosyntesemateriale/hemiprot. og caputresten)
☐3 Bipolar hemiprotese
☐4 Unipolar hemiprotese
☐5 Re-osteosyntese
☐6 Drenasje av hematom eller infeksjon
☐7 Lukket reposisjon av luksert hemiprotese
☐8 Åpen reposisjon av luksert hemiprotese
☐9 Annet, spesifiser……

Navn / størrelse ev. katalognummer……

FIKSASJON AV HEMIPROTESE
(For totalprotese sendes eget skjema til hofteproteseregisteret)
☐1 Usementert
☐1 med HA ☐2 uten HA
☐2 Sement med antibiotika Navn……
☐3 Sement uten antibiotika Navn……

PATOLOGISK BRUDD (Annen patologi enn osteoporose)
☐0 Nei
☐1 Ja, type……

TILGANG TIL HOFTELEDDET VED HEMIPROTESE (Kun ett kryss)
☐1 Anterolateral
☐2 Lateral
☐3 Posterolateral
☐4 Annet, spesifiser……

ANESTESITYPE
☐1 Narkose ☐2 Spinal ☐3 Annet, spesifiser……

PEROPERATIVE KOMPLIKASJONER
☐0 Nei
☐1 Ja, hvilke(n).....

OPERASJONSTID (hud til hud).....minutter.

SYSTEMISK ANTIBIOTIKAPROFYLAKSE
☐0 Nei ☐1 Ja, Hvilken (A).....

Dose (A).....Totalt antall doser.....Varighet .....timer

Ev. i kombinasjon med (B).....

Dose (B).....Totalt antall doser.....Varighet .....timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, hvilken type……

Dosering opr.dag……Første dose gitt preopr ☐0 Nei ☐1 Ja

Senere dosering……Antatt varighet……døgn

Ev. i kombinasjon med ……

Dosering……Antatt varighet……døgn

Strømpe ☐0 Nei ☐1 Legg ☐2 Legg + Lår Antatt varighet ……døgn

Mekanisk pumpe ☐0 Nei ☐1 Fot ☐2 Legg Antatt varighet……døgn

Lege.....
Legen som har fylt ut skjemaet (navnet registreres ikke i databasen).

Norwegian Hip Fracture Register form 2008 – 2011, back side

RETTLEDNING

Registreringen gjelder alle operasjoner for hoftebrudd (lårhals, pertrokantære og subtrokantære) og alle reoperasjoner, også reposisjoner, på pasienter som er primæroperert og reoperert for hoftebrudd. **Ved primæroperasjon med totalprotese og ved reoperasjon til totalprotese sendes bare skjema til hofteproteseregisteret.**
Ett skjema fylles ut for hver operasjon. Originalen sendes Haukeland universitetssjukehus og kopien lagres i pasientens journal. Pasientens fødselsnummer (11 sifre) og sykehuset må være påført. Aktuelle ruter markeres med kryss. Pasienten skal på eget skjema gi samtykke til registrering i Nasjonalt hoftebruddregister og samtykkeerklæringen lagres i pasientens journal på sykehuset.

Kommentarer til enkelte punkt:

OPERASJONS- OG BRUDDTIDSPUNKT
Operasjonstidspunkt (dato og klokkeslett) må føres opp på alle primæroperasjoner. Det er også sterkt ønskelig at dato og klokkeslett for *bruddtidspunkt* føres opp. Dette bl.a. for å se om tid til operasjon har effekt på prognose. (Hvis en ikke kjenner klokkeslettet for bruddtidspunkt lar en feltet stå åpent. En må da prøve å angi omtrentlig tidsrom fra brudd til operasjon på neste punkt).
Ved reoperasjon er ikke klokkeslett nødvendig.

DEMENS
Demens kan eventuelt testes ved å be pasienten tegne klokken når den er 10 over 11. En dement pasient vil ha problemer med denne oppgaven.

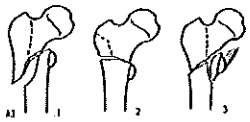
ASA-KLASSE (ASA=American Society of Anesthesiologists)
ASA-klasse 1: Friske pasienter som røyker mindre enn 5 sigaretter daglig.
ASA-klasse 2: Pasienter med en asymptomatisk tilstand som behandles medikamentelt (f.eks hypertensjon) eller med kost (f.eks diabetes mellitus type 2) og ellers friske pasienter som røyker 5 sigaretter eller mer daglig.
ASA-klasse 3: Pasienter med en tilstand som kan gi symptomer, men som holdes under kontroll medikamentelt (f.eks moderat angina pectoris og mild astma).
ASA-klasse 4: Pasienter med en tilstand som ikke er under kontroll (f.eks hjertesvikt og astma).
ASA-klasse 5: Moribund/døende pasient

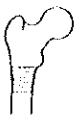
GARDENS KLASSIFISERING AV LÅRHALSBRUDD
Garden 1: Ikke komplett brudd av lårhalsen (såkalt innkilt)
Garden 2: Komplett lårhalsbrudd uten dislokasjon
Garden 3: Komplett lårhalsbrudd med delvis dislokasjon. Fragmentene er fortsatt i kontakt, men det er feilstilling av lårhalsens trabekler. Caputfragmentet ligger uanatomisk i acetabulum.
Garden 4: Komplett lårhalsbrudd med full dislokasjon. Caputfragmentet er fritt og ligger korrekt i acetabulum slik at trabeklene er normalt orientert.

AO KLASSIFIKASJON AV TROKANTÆRE BRUDD


A1: Pertrokantært tofragment brudd


A2: Pertrokantært flerfragment brudd


A3: Intertrokantært brudd


Subtrokantært brudd*

*Subtrokantært brudd: Bruddsentrum er mellom nedre kant av trokanter minor og 5 cm distalt for denne.

REOPERASJONSÅRSAK
Dyp infeksjon defineres som infeksjon som involverer fascie, protese, ledd eller periprotetisk vev.

IMPLANTAT
Implantattype må angis entydig. Produktklistrelapp er ønskelig for å angi katalognummer for osteosyntesematerialet eller protesen som er brukt.

PEROPERATIVE KOMPLIKASJONER
Vi ønsker også å få meldt dødsfall på operasjonsbordet og peroperativ transfusjonstrengende blødning.

SYSTEMISK ANTIBIOTIKA
Her føres det på hvilket antibiotikum som er blitt benyttet i forbindelse med operasjonen. Det anføres dose, antall doser og profylaksens varighet. F.eks. Medkament 1: Keflin 2g x 4, med varighet 12 timer.

TROMBOSEPROFYLAKSE
Medikament, dose og antatt varighet av profylaksen skal angis separat for oprerasjonsdagen og senere. Det skal også oppgis om pasienten står fast på antikoagulantia (AlbylE, Marevan, Plavix ol).

FIBRINOLYSEHEMMER
Her føres det på om en benytter blødningsreduserende legemidler i forbindelse med operasjonen (f.eks. Cyklokapron).

Kontaktpersoner vedrørende registreringsskjema er:
Overlege Jan-Erik Gjertsen, Ortopedisk klinikk, Haukeland universitetssjukehus. Tlf. 55 97 56 72 (email: jan-erik.gjertsen@helse-bergen.no)
Professor Lasse Engesæter, Ortopedisk klinikk, Haukeland universitetssjukehus. Tlf. 55 97 56 84
Prosjektkoordinator Nasjonalt Hoftebruddregister: Lise B. Kvamsdal. Tlf. 55 97 64 52 (email: nrl@helse-bergen.no)
Internett: http://www.haukeland.no/nrl/

PRODUKTKLISTRELAPPER:

Norwegian Hip Fracture Register form 2008 – 2011, English version

NORWEGIAN HIP FRACTURE REGISTER
Norwegian Arthroplasty Register
Helse Bergen HF, Department of Orthopaedic surgery
Haukeland University Hospital
Møllendalsbakken 11
5021 BERGEN
Phone: (+47)55976452

Birth number:.....

Name:.....

(Write distinct ev. patient sticker – **specify hospital**.)

Hospital:.....

HIP FRACTURES

PRIMARY OPERATIONS ON PROXIMAL FEMORAL FRACTURES and ALL REVISIONS, included closed reduction of hemiprosthesis.

When primary operation with total hip arthroplasty and revision with total hip arthroplasty use form to the arthroplasty register only. All stickers are to be put in marked area on back of form.

CURRENT OPERATION
☐1 Primary operation ☐ 2 Revision

SIDE (one mark) (Bilateral op.= 2 forms)
☐1 Right ☐2 Left

TIME OF OPERATION |__|__| |__|__| |__|__| hrs |__|__|

TIME OF FRACTURE |__|__| |__|__| |__|__| hrs |__|__|

If uncertainty on time of fracture, fill in next section.

TIME FROM FRACTURE TO OPERATION IN HOURS
☐1 0-6 ☐2 >6-12 ☐3 >12-24 ☐4 >24-48 ☐5 >48

COGNITIVE IMPAIRMENT
☐0 No ☐1 Yes (See text on the back of form) ☐2 Uncertain

ASA-CLASSIFICATION (see text on the back of form for definition)
☐1 Healthy
☐2 Mild systemic disease
☐3 Severe systemic disease
☐4 Incapasitating disease
☐5 Moribund

REASON FOR PRIMARY OPERATION (TYPE OF FRACTURE)
(One mark only)
☐1 Undislocated intracapsular fracture (Garden 1 og 2)
☐2 Dislocated intracapsular fracture (Garden 3 og 4)
☐3 Basocervical fracture
☐4 Trochanteric 2 fragment (AO class A1)
☐5 Trochanteric multifragment (AO class A2)
☐9 Intertrochanteric (AO class A3)
☐6 Subtrochanteric
☐7 Other ……

TYPE OF PRIMARY OPERATION (One mark only)
(Fill in only when primary operation – separate form for THAs)
(Specify product exactly or use stickers with catalogue number supplied by the manufacturers on the back of form)
☐1 Two screws or pins
☐2 Three screws or pins
☐3 Bipolar hemiarthroplasty
☐4 Unipolar hemiarthroplasty
☐5 Hip compression screw and plate
☐6 Hip compression screw with lateral support plate
☐7 AO-plate
☐8 Short intramedullary nail without distal locking
☐9 Short intramedullary nail with distal locking
☐10 Long intramedullary nail without distal locking
☐11 Long intramedullary nail with distal locking
☐12 Other, specify……..
Name / size, if possible Catalogue number……

REASON FOR REVISION (More than one mark can be used)
☐1 Osteosynthesis failure
☐2 Nonunion
☐3 Avascular necrosis (segmental collapse)
☐4 Local pain due to osteosynthesis material
☐5 Fracture healed in wrong position
☐6 Wound infection - superficial
☐7 Wound infection - deep
☐8 Haematoma
☐9 Dislocated hemiarthroplasty
☐10 Penetration of osteosynthesis material through caput
☐11 New fracture around implant
☐12 Loosening of hemiarthroplasty
☐13 Other, specify……..……

TYPE OF REOPERATION (More than one mark can be used)
(Specify product exactly or use stickers with catalogue number supplied by the manufacturers on the back of form)
☐1 Removal of implant (when only procedure)
☐2 Girdlestone
(= Removal of implant/hemiarthroplasty and caput)
☐3 Bipolar hemiarthroplasty
☐4 Unipolar hemiarthroplasty
☐5 Re-osteosynthesis
☐6 Drainage of hematoma or infection
☐7 Closed reduction of dislocated hemiarthroplasty
☐8 Open reduction of dislocated hemiarthroplasty
☐9 Other, specify……..……

Name / size, if possible Catalogue number……

FIXATION OF HEMIPROSTHESIS
(For total hip arthroplasty a separate form is sent to the arthroplasty register)
☐1 Uncemented
☐ with HA ☐ without HA
☐2 Cement with antibiotics Name……..…
☐3 Cement without antibiotics Name…….……

PATHOLOGICAL FRACTURE (Other pathology than osteoporosis)
☐0 No
☐1 Yes, type……..

APPROACH TO HIP JOINT WHEN HEMIARTHROPLASTY (One mark only)
☐1 Anterolateral
☐2 Lateral
☐3 Posterolateral
☐4 Other, specify……..……..

TYPE OF ANESTHESIA
☐1 Narcosis ☐2 Spinal ☐3 Other, specify……..

PEROPERATIVE COMPLICATIONS
☐0 No
☐1 Yes, Which.....……

DURATION OF OPERATION (skin to skin).....minutes

SYSTEMIC ANTIBIOTIC PROPHYLAXIS
☐0 No ☐1 Yes, Which (A).....

Dosis (A)..... Total number of dosis:.....……..Duration: .....…...hours

Ev. in combination with (B).....

Dosis (B).....Total Number of dosis:.....…...Duration: .....…...hours

THROMBOSIS PROPHYLAXIS
☐0 No ☐1 Yes, which type……

Dosis day of surgery…… First dosis given preoperatively ☐0 No ☐1 Yes

Later dosis…….. Duration..……days

Evt. in combination with ……..……..……..

Dosis..……..Duration..……days

Stockings ☐0 No ☐1 Leg ☐2 Thigh Duration ……days
Mechanical pump ☐0 No ☐1 Foot ☐2 Leg Duration……...days

Surgeon.....
Surgeon who has filled in form (name is not registered).

14. Papers I-IV

Paper I

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TRIGEN INTERTAN Intramedullary Nail Versus Sliding Hip Screw

A Prospective, Randomized Multicenter Study on Pain, Function, and Complications in 684 Patients with an Intertrochanteric or Subtrochanteric Fracture and One Year of Follow-up

Kjell Matre, MD, Tarjei Vinje, MD, Leif Ivar Havelin, MD, PhD, Jan-Erik Gjertsen, MD, PhD, Ove Furnes, MD, PhD, Birgitte Espehaug, MSc, PhD, Stein-Harald Kjellevold, MD, and Jonas Meling Fevang, MD, PhD

Investigation performed at the Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, and the Department of Surgical Sciences, University of Bergen, Bergen, Norway

Background: Both intramedullary nails and sliding hip screws are used with good results in the treatment of intertrochanteric and subtrochanteric fractures. The aim of our study was to assess whether use of the TRIGEN INTERTAN nail, as compared with a sliding hip screw, resulted in less postoperative pain, improved functional mobility, and reduced surgical complication rates for patients with an intertrochanteric or subtrochanteric fracture.

Methods: In a prospective, randomized multicenter study, 684 elderly patients were treated with the INTERTAN nail or with a sliding hip screw with or without a trochanteric stabilizing plate. The patients were assessed during their hospital stay and at three and twelve months postoperatively. A visual analogue scale (VAS) pain score was recorded at all time points, and functional mobility was assessed with use of the timed Up & Go test. The Harris hip score (HHS) was used to assess hip function more specifically. Quality of life was measured with the EuroQol-5D (EQ-5D). Radiographic findings as well as intraoperative and postoperative complications were recorded and analyzed.

Results: Patients treated with an INTERTAN nail had slightly less pain at the time of early postoperative mobilization (VAS score, 48 versus 52; $p = 0.042$), although this did not influence the length of the hospital stay and there was no difference at three or twelve months. Regardless of the fracture and implant type, functional mobility, hip function, patient satisfaction, and quality-of-life assessments were comparable between the groups at three and twelve months. The numbers of patients with surgical complications were similar for the two groups (twenty-nine in the sliding-hip-screw group and thirty-two in the INTERTAN group, $p = 0.67$).

Conclusions: INTERTAN nails and sliding hip screws are similar in terms of pain, function, and reoperation rates twelve months after treatment of intertrochanteric and subtrochanteric fractures.

Level of Evidence: Therapeutic Level I. See Instruction for Authors for a complete description of levels of evidence.

Both intramedullary and extramedullary implants are currently used in the treatment of intertrochanteric and subtrochanteric fractures. The sliding hip screw remains the best documented implant, and in several randomized trials it has been associated with lower complication and reoperation rates compared with intramedullary nails[1-3]. In addition, the

Disclosure: One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by authors are always provided with the online version of the article.

A commentary by Hans J. Kreder, MD, FRCSC, is linked to the online version of this article at jbjs.org.

sliding hip screw is a less expensive implant. Nevertheless, there has been a recent trend toward more widespread use of intramedullary nails for these fractures[4,5], even though documentation to support this change is lacking[4-6].

The TRIGEN INTERTAN nail (Smith & Nephew, Memphis, Tennessee) was recently introduced, and according to the manufacturer the shape of the nail should enhance stability and offer greater resistance to implant cutout[7]. Ruecker et al.[8] reported good clinical results in a study on their first 100 patients treated with an INTERTAN nail. However, we are not aware of any study comparing the INTERTAN nail with a sliding hip screw. The aim of the present randomized controlled trial was to compare the INTERTAN nail with the sliding hip screw, with or without a trochanteric stabilizing plate, to determine if use of the nail decreased postoperative pain, improved function, and lowered the surgical complication rate in elderly patients with a trochanteric or subtrochanteric fracture.

Materials and Methods

Patients and Fractures

Patients over sixty years of age in whom a trochanteric or subtrochanteric fracture had been treated surgically at one of five hospitals from February 2008 to February 2009 were included in the study. Prior to the study, the sliding hip screw was the favored implant for both intertrochanteric and subtrochanteric fractures in the participating hospitals; therefore, patients with a subtrochanteric fracture were included. We also included cognitively impaired patients, even if they were unable to give informed consent, a decision that was supported by our ethical committee. Cognitive impairment was categorized by the surgeons as "no," "yes," or "uncertain." If there was any doubt, the clock-drawing test[9] was used to determine the cognitive status of the patient. Patients with a pathologic fracture were excluded. Fractures were classified by an independent radiologist according to the AO/OTA classification[10]. Fractures distal to, but with the main fracture line within 5 cm from, the lesser trochanter were classified as subtrochanteric.

The inclusion of 684 patients (341 treated with an INTERTAN nail and 343, with a sliding hip screw) is described in the CONSORT flow diagram[11] (Fig. 1). Two patients received the incorrect implant after allocation in error, in four patients the stabilization choice was changed during surgery, and six patients were not operated on according to the randomization code for unknown reasons. According to the intention-to-treat principle, these twelve patients remained in the group to which they had been originally allocated.

Implants

A short or long version of the INTERTAN nail with distal locking was used with two integrated screws inserted into the femoral head-neck fragment (see Appendix). The nail design was described in detail by Ruecker et al.[8]. Two different sliding hip screw implants were used (see Appendix): the Compression Hip Screw (Smith & Nephew), and the Dynamic Hip Screw (Synthes, Basel, Switzerland). A trochanteric stabilizing plate, either as an integrated part of the sliding hip screw or added as a separate device onto the sliding hip screw, was used when indicated (see Appendix). A trochanteric stabilizing plate is indicated for all transverse or reverse oblique (A3) fractures to prevent excessive medialization of the femoral shaft. A trochanteric stabilizing plate can be considered for A1 or A2 fractures in osteoporotic bone, where it supports a weak lateral trochanteric wall susceptible to breakage after weight-bearing. A pilot study was performed in each hospital before patients were enrolled in the study, and the surgeons participated in at least five operations involving use of the INTERTAN nail before they could participate in the study.

Follow-up

All general and fracture-related intraoperative and postoperative complications were recorded, as were the surgeons' level of experience, the duration of the surgery, the patient's hemoglobin level, the number of blood transfusions, and the length of the hospital stay. Whenever possible, the patients were examined on the fifth postoperative day. However, some patients left the hospital before day 5, and performing day-5 examinations during weekends was not always possible. The time distribution of the postoperative examinations is presented in the Appendix. Clinical examination, radiographs, and completion of a EuroQol-5D (EQ-5D) questionnaire[12] were scheduled at three and twelve months. If patients were too frail or sick to return for follow-up, the EQ-5D questionnaire was sent to them. A returned questionnaire, radiographs, or attendance at the outpatient clinics was each considered acceptable follow-up. Depending on local preferences, the clinical examination of the patients was carried out through collaboration among a physician, a physiotherapist, and a study nurse.

Postoperative pain was our primary outcome measure. The results of the timed Up & Go test[13], the length of the hospital stay, the complication and reoperation rates, and all other variables were defined as secondary outcomes. On day 5 and later follow-up intervals, the patients indicated the pain from the treated hip on a visual analogue scale (VAS) ranging from 0 to 100, with 0 meaning no pain and 100 meaning unbearable pain. Pain at rest and at mobilization was recorded in the hospital, whereas the average pain from the operatively treated hip during the previous month was recorded at three and twelve months. In the timed Up & Go test, the patient rises from a chair with armrests, walks 3 m, turns around, walks back, and sits down again. Walking aids are allowed while the patient performs the test, but active assistance is not. The time needed for this exercise (the score for the timed Up & Go test) is the outcome. VAS pain scores and timed Up & Go test results were measured at all follow-up visits.

Additional secondary outcomes were the patients' residence, walking ability, Harris hip score (HHS), quality of life (EQ-5D score), and mortality. Failure of the osteosynthesis, including poor initial reduction and implant positioning, deep infection or postoperative hematoma requiring surgical intervention, cutout, femoral fracture, and removal or planned removal of whole implants were considered "major" complications and reoperations. Locking screws missing the nail or removal of a single locking or lag screw were classified as "minor" complications and reoperations in the INTERTAN group. In the sliding-hip-screw group, surgical removal of a drain was considered a minor reoperation and all other reoperations were considered major.

As described by Baumgaertner et al., all postoperative radiographs were assessed for the quality of the fracture reduction (good, acceptable, or poor)[14] and the implant position in the femoral head (tip-apex distance [TAD])[15]. In addition, shortening and medialization of the femoral shaft, changes in the femoral neck-shaft angle, and fracture-healing were recorded.

Sample Size

A difference in VAS scores of ≥10 points was considered a clinically relevant difference[16]. Sixty-three patients were required in each group to have an 80% chance of detecting such a difference in VAS scores with a 5% significance level with an assumed standard deviation (SD) of 20. To detect a reduction in the length of stay of one day (SD, 3), 142 patients would be needed in each group. A difference in reoperation rates of 5% versus 7% would require 2313 patients in each group to detect a significant difference (with 80% power and $p < 0.05$). Accordingly, although reoperation rates are of major interest in hip fracture surgery, it was not realistic to design this trial with this as a primary outcome. A high mortality rate, a high number of cognitively impaired patients, and an expected high dropout rate were considered when the sample size for the study was determined. Thus, assuming a one-year attrition rate of up to 40%, we aimed to recruit at least 500 patients.

Randomization Procedure

Sealed, opaque, and consecutively numbered envelopes were used to randomly allocate the patients to receive one of the two implants. Block randomization

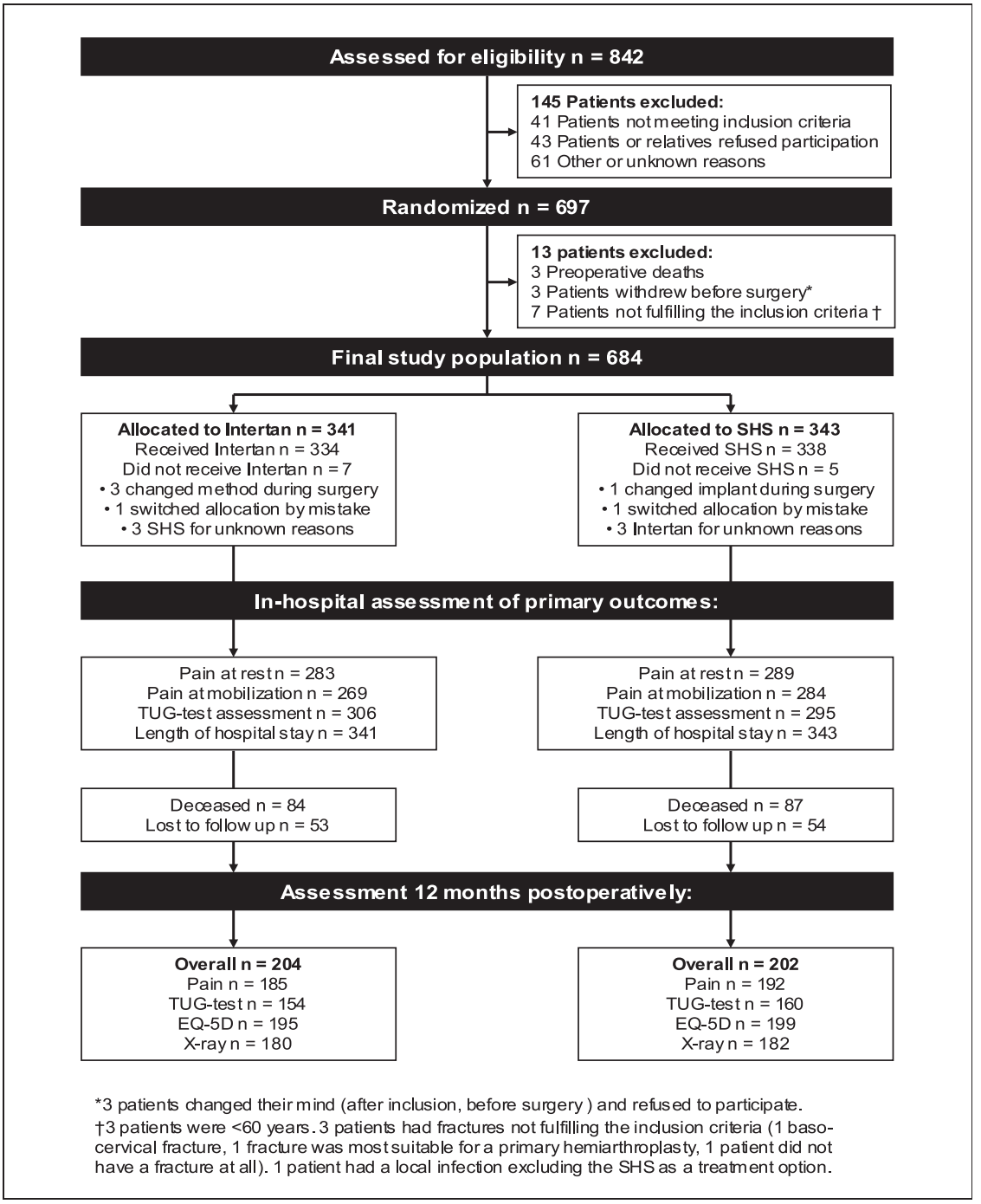

Fig. 1

CONSORT flow diagram of patients and outcome analyses[11]. SHS = sliding hip screw. TUG = timed Up & Go.

with varying block sizes unknown to the surgeon was used to ensure nearly equal treatment numbers within each hospital.

Statistical Analysis

To test for group differences, the chi-square test was used for categorical variables and the independent t test, for continuous variables. P values of <0.05 were considered significant (two-sided tests). The results were analyzed according to the intention-to-treat principle. Linear regression analyses of pain and timed Up & Go test results were performed with adjustment for the rate of cognitive impairment and the surgeons' experience, and we also analyzed these outcomes after excluding the cognitively impaired patients. The in-hospital pain and timed Up & Go test results were also analyzed with adjustment for differences in the time of examination.

The Regional Committee of Ethics in Western Norway (203.07) approved the study, and the ClinicalTrials.gov registration number is NCT00621088.

Source of Funding

Smith & Nephew supported the study, but otherwise the company had no influence on the study protocol, performance of the study, data analysis, or

TABLE I Baseline Characteristics

	INTERTAN*	Sliding Hip Screw*	P Value†
No. of patients			
Total (n = 684)	341	343	
Diakonhjemmet Hospital (n = 182)	92	90	
Levanger Hospital (n = 36)	18	18	
Akershus University Hospital (n = 171)	83	88	
Vestfold Hospital (n = 133)	68	65	
Haukeland University Hospital (n = 162)	80	82	
Mean age *(yr)* (n = 684)	84.1	84.1	0.98‡
Female (n = 684)	258 (75.7%)	255 (74.3%)	0.69§
ASA class# (n = 670)			0.56§
1	22 (6.6%)	15 (4.5%)	
2	138 (41.2%)	143 (42.7%)	
3	164 (49.0%)	162 (48.4%)	
4	11 (3.3%)	15 (4.5%)	
Cognitive impairment (n = 665)			**0.002**§
Yes	105 (31.3%)	68 (20.6%)	
No	192 (57.3%)	231 (70.0%)	
Uncertain	38 (11.3%)	31 (9.4%)	
Preoperative residential status (n = 669)			**0.02**§
Home	208 (62.1%)	230 (68.9%)	
Nursing home	94 (28.1%)	62 (18.6%)	
Other	33 (9.9%)	42 (12.6%)	
Mean preop. HHS** (n = 646)	68	69	0.44‡
Fracture AO/OTA type (n = 684)			0.93§
A1	150	140	
A2	113	122	
A3	71	68	
Subtrochanteric	7	13	0.22§
Fracture on right side (n = 684)	186 (54.5%)	174 (50.7%)	0.32§
Preop. mobility (n = 650)			0.41§
Walking outdoors alone	186 (58.1%)	198 (60.0%)	
Walking outdoors with living support	24 (7.5%)	31 (9.4%)	
Walking indoors alone, not outdoors	79 (24.7%)	77 (23.3%)	
Walking indoors with living support	26 (8.1%)	23 (7.0%)	
No walking ability	5 (1.6%)	1 (0.3%)	

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡Independent samples t test. §Pearson chi-square test. #American Society of Anesthesiologists classification of comorbidities. **Harris hip score (modified, with no value for range of movement [maximum, 5 points]).

presentation of the results. The first author (K.M.) received a research grant from the Regional Health Board of Western Norway.

Results

The baseline characteristics of the two treatment groups are presented in Table I. More patients in the INTERTAN group were rated as cognitively impaired (31% versus 21%, p = 0.002) and accordingly more lived in nursing homes (p = 0.02). There was also a tendency toward more experienced surgeons implanting INTERTAN nails (p = 0.02).

The pain scores and timed Up & Go test results are presented in Table II. During the initial hospitalization, there was a minor but significant difference in pain at the time of postoperative mobilization in favor of the INTERTAN group (VAS score, 48 versus 52, p = 0.042). However, this difference was no longer evident at later follow-up times: at three and twelve months, both groups had pain scores of 25 and 17,

TABLE II Primary Outcomes

	INTERTAN	Sliding Hip Screw	Mean Difference (95% Confidence Interval)	P Value*
Mean VAS score for pain				
Postop.				
At rest	22 (n = 283)	21 (n = 289)	1.1 (−2.3-4.5)	0.54†
At mobilization	48 (n = 269)	52 (n = 284)	−3.7 (−7.4-0.04)	**0.042**†
3 mo	25 (n = 226)	25 (n = 206)	−0.5 (−4.6-3.6)	0.82
12 mo	17 (n = 185)	17 (n = 192)	0.05 (−4.0-4.1)	0.98
Timed Up & Go test				
Postop. *(no. [%] of patients)*				
Total no. assessed	306/341	295/343		0.14
Unable to perform test	167 (55%)	163 (55%)		0.87
Test performed, not passed‡	7 (2%)	6 (2%)		0.83
Test performed and passed‡	132 (43%)	126 (43%)		0.92
Mean score *(sec)*				
Postop.	74 (n = 132)	69 (n = 126)	5.1 (−3.5-14.3)	0.20†
3 mo	29 (n = 177)	29 (n = 164)	0.04 (−4.3-4.4)	0.99
12 mo	27 (n = 154)	25 (n = 160)	1.3 (−3.6-6.2)	0.60

*Significant p value is in bold. †Adjusted p values; adjustments were made because of differences in the time distribution of patient examinations. The unadjusted p value for pain at mobilization was 0.053. ‡A timed Up & Go test of more than three minutes and thirty seconds was considered to be a test not passed.

respectively. We found no significant difference in the timed Up & Go test score between the groups postoperatively or at three or twelve months, and the rate of patients who were able to perform the test was the same in the two groups. The lengths of the hospital stays were also similar (see Appendix). In the linear regression analyses, with adjustment for cognitive impairment and surgeons' experience, the results regarding pain, the timed Up & Go test, and the length of stay remained unchanged. These results also persisted in the analyses based on the actual implants that the patients received as well as after exclusion of the twelve patients who, according to the allocation at baseline, received the "incorrect" treatment. No significant differences in pain or the timed Up & Go test results between the two treatment groups were found in separate analyses of the A3 and subtrochanteric fractures.

Operative details and early postoperative results are summarized in the Appendix. There was no significant difference in the operating time between the groups. The mean estimated blood loss was greater in the sliding-hip-screw group (263 mL versus 183 mL, $p < 0.001$), and more patients treated with a sliding hip screw had a blood transfusion (171 [52%] versus 143 [43%], $p = 0.02$). However, the lowest measured hemoglobin value during the hospital stay was almost identical in the two groups.

At three and twelve months, we found no significant difference in the HHS or quality of life (EQ-5D score). These results were also reflected by similar rates of patients regaining their prefracture mobility and residential status.

Surgical complications and reoperations are presented in Table III. More intraoperative technical or implant-related problems were reported in the INTERTAN group compared with the sliding-hip-screw group (sixty-two [19%] of 328 versus twenty-one [7%] of 315, $p < 0.001$). However, the majority were minor problems without consequence for the patients. We found no difference regarding in-hospital general medical complications. At twelve months, twenty-eight and twenty-seven patients had had a reoperation in the INTERTAN and sliding-hip-screw groups, respectively. Five postoperative femoral fractures occurred in the INTERTAN group, all during the first three months; one fracture was at the distal tip of a long nail, and the other fractures appeared around the tips of short nails. One fracture occurred through the distal screw hole in a four-hole sliding hip screw-plate (see Appendix). The difference between the groups was not significant ($p = 0.10$). Cutouts of implants were observed in twenty-four patients (3.5%), eleven in the sliding-hip-screw group and thirteen in the INTERTAN group ($p = 0.67$) (see Appendix). However, not all cutouts led to revision surgery, which was performed for nine of the eleven sliding-hip-screw cutouts and six of the thirteen INTERTAN-nail cutouts. Subgroup analyses of A3 and subtrochanteric fractures showed no significant difference in complication and reoperation rates between the groups.

Details of the radiographic assessments are described in the Appendix. The quality of the reduction was similar for the two groups, but the postoperative femoral neck-shaft angle demonstrated more varus in the INTERTAN group (131° versus 138°, $p < 0.001$). Accordingly, lag screws for INTERTAN nails were more frequently positioned in the superior part of the femoral head. Furthermore, the intramedullary nails were

TABLE III Intraoperative, Early, and Late Postoperative Complications and Reoperations in the Two Treatment Groups

	INTERTAN* (N = 341)	Sliding Hip Screw* (N = 343)	P Value†
Intraop. complications			
Technical or implant-related (n = 643)‡	62/328 (18.9%)	21/315 (6.7%)	<**0.001**
Requiring surgical intervention§	4	2	0.41
Other in-hospital complications			
General medical	104	110	0.79
Early postop. death	8	14	0.20
Postop. surgical complications (including those with nonop. treatment)#	32 (9.4%)	29 (8.5%)	0.67
Major	26 (7.6%)	27 (7.9%)	0.90
Minor	7 (2.1%)	2 (0.6%)	0.09
Reoperation in 1st 12 mo	28 (8.2%)	27 (7.9%)	0.87
Indications for reoperations			
Major reoperations**	23 (6.7%)	28 (8.2%)	0.48
Cutout	6 (1.8%)	9 (2.6%)	
Infection	2 (0.6%)	3 (0.9%)	
Fracture around implant	5 (1.5%)	1 (0.3%)	
Mechanical failure/nonunion	3 (0.9%)	10 (2.9%)	
Poor reduction/implant position	4 (1.2%)	3 (0.9%)	
Other	3 (0.9%)	2 (0.6%)	
Minor reoperations	5 (1.5%)	1 (0.3%)	0.10
Removal of drain		1	
Adding distal locking screw	3		
Removal of distal locking screw	1		
Removal of separate lag screw	1		
1-yr mortality††	24.6%	25.4%	0.83

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Pearson chi-square test. The significant p value is in bold. ‡Technical or implant-related problems were mainly minor problems without any crucial influence on the surgical procedure or the outcome of the operation. Exceptions are listed in the row below. §One femoral fracture after nailing was treated with a long INTERTAN nail as planned. One long nail was converted to a short nail because of distal anterior cortex penetration. Two planned long nails were converted to a short nail because of a short femur in one case and a narrow femur in the other. One intraoperative fissure with a sliding hip screw was treated with a longer plate. Another intraoperative fracture/fissure with a sliding hip screw was not detected initially and was treated with a reoperation eleven days later. #More than one complication per patient is possible. Seven patients in the INTERTAN group and two patients in the sliding-hip-screw group with a cutout left surgically untreated are included. **More than one reason per patient possible. ††Kaplan-Meier survival analyses.

associated with more initial shortening than the sliding hip screws, and this difference persisted at one year. Femoral shaft medialization of >5 mm at one year was more frequent in the sliding-hip-screw group. The number of patients with medialization of >5 mm at twelve months also depended on the fracture type (5.2% for A1, 11.4% for A2, and 22.3% for A3), and patients with >5 mm of medialization had more postoperative pain compared with those with <5 mm of medialization (VAS score, 23 and 16, respectively). The timed Up & Go test results, however, were independent of medialization. Within the sliding-hip-screw group, twelve of the fourteen fractures with >10 mm of medialization had been treated with a trochanteric stabilizing plate. The average TAD was shorter and more favorable in the INTERTAN group (18 mm versus 21 mm, $p < 0.001$). The average TAD for all patients who had an implant cutout was 26 mm, whereas the average for those without a cutout was 20 mm ($p < 0.001$). Similarly, a poor reduction and a lower femoral neck-shaft angle were associated with more surgical complications. Poorly reduced fractures were associated with an 18% complication rate, whereas those with a good reduction were associated with a 7% complication rate ($p = 0.007$). Patients with complications also had a lower postoperative femoral neck-shaft angle compared with those without surgical complications (132° and 135°, respectively; $p = 0.038$).

Mortality

The one-year mortality rate was approximately 25% for the INTERTAN and sliding-hip-screw groups (24.6% and 25.4%, respectively; $p = 0.83$).

Discussion

Overall, we found comparable results between patients treated with the INTERTAN intramedullary nail and those

treated with the sliding hip screw. The INTERTAN group had less pain at the time of early postoperative mobilization, but this difference was not reflected in better functional mobility or a shorter hospital stay and may not be clinically important. No differences in pain, function, quality of life, or complication rates were evident at three or twelve months postoperatively. This finding is in agreement with those of most recent studies and meta-analyses[1,6,17-19].

For an individual patient, a VAS pain-score difference of 10 points is considered clinically relevant[16]. Although this may be interpreted differently at a group level, a difference of 4 points in the early postoperative phase, as was found in the present study, is probably of minor clinical relevance. The mean estimated blood loss was 80 mL higher in the sliding-hip-screw group, but assessing "internal" blood loss after nailing is difficult. More patients in the sliding-hip-screw group received a blood transfusion, but we had no protocol for when to perform transfusions, and the hemoglobin level at the time of transfusion was not known. The differences in blood loss and in the number of blood transfusions did not seem to influence the length of hospital stay or in-hospital complication rates. Therefore, the clinical relevance of these differences is unclear.

The timed Up & Go test[13] and the HHS[20] are outcome measures commonly used to assess function after hip fractures[21]. Regardless of the functional outcome measure used in the present study, we did not detect any significant difference between the two implant groups during follow-up, which is in agreement with the findings of recent meta-analyses[1,2,22].

Since the introduction of nailing for intertrochanteric fractures, peri-implant femoral fractures have been well-known complications[23-26]. According to Bhandari et al.[19], this should no longer be an issue with modern nail designs and more experience; however, the authors of a Cochrane review[1] came to a different conclusion. In our study, two intraoperative and five postoperative femoral fractures occurred in the INTERTAN group, all within the first three months. In another recent study using INTERTAN nails, a 6% rate of postoperative femoral fractures was reported[27]. This implies that the problem with fractures around the tips of intramedullary nails has not been completely solved.

To date, no consistent difference in implant-cutout rates has been found between intramedullary nails and sliding hip screws in randomized trials[1]. In a prospective study on patients treated with the INTERTAN nail, Ruecker et al.[8] reported two implant cutouts in forty-eight patients with one year of follow-up. In the present study, implant cutout was the most common cause of failure of the osteosynthesis, but we found no significant difference between the treatment groups.

Treating unstable reverse oblique and subtrochanteric fractures with a sliding hip screw is controversial, and is not recommended by many authors[6,28-30]. However, in our view, the scientific evidence from well-designed clinical studies supporting the exclusive use of intramedullary nails in this subgroup of fractures is lacking. Recent meta-analyses also demonstrated that more high-quality studies are required before definitive conclusions regarding implant selection for these fractures can be drawn[1,29,31]. We have continued to favor the use of the sliding hip screw for these fractures, but we are using an additional trochanteric stabilizing plate to prevent excessive medialization of the femoral shaft.

It is well known that poor reduction and implant position result in a poor prognosis in hip fracture treatment[16,32-35]. In the present study, implant cutout and other surgical complications were associated with a higher TAD, poor reduction, or reduction more into varus but were independent of the type of implant. Therefore, an increased focus on surgical perfection, rather than implant selection, is probably the best way to address this problem. Fewer patients in the INTERTAN group had medialization exceeding 5 mm, probably because of the intramedullary position of the nail providing solid resistance to excessive sliding along the axis of the lag screw. The increased medialization in the sliding-hip-screw group could not be prevented by the trochanteric stabilizing plate, and our data do not allow us to quantify the extent to which a trochanteric stabilizing plate may have helped. Despite radiographic differences in femoral neck-shaft angle, shortening, TAD, and medialization, no difference in pain, function, or surgical complication rate between the two groups was evident. Similarly, no significant differences in these outcomes were found in subgroup analyses of A3 and subtrochanteric fractures. We are not aware of any randomized controlled trial comparing the use of a sliding hip screw (including a trochanteric stabilizing plate) with intramedullary nailing in this specific group of patients. Two randomized controlled trials[36,37] comparing an intramedullary nail with other extramedullary implants in the treatment of A3 fractures were, however, reported in the Cochrane Database Review[1]. One study demonstrated a higher reoperation rate for patients treated with a Dynamic Condylar Screw (DCS) compared with the Proximal Femoral Nail (PFN)[36], whereas one study comparing a blade plate with a gamma nail revealed no difference in reoperation rates[37]. These studies, however, included only small numbers of patients (thirty-nine and twenty-six, respectively). Contradictory findings were also reported for patients with subtrochanteric fractures when either a 95° blade plate[38] or the Medoff sliding plate[39,40] was compared with an intramedullary nail. In our trial, the sliding hip screw (including a trochanteric stabilizing plate) appeared to be a valid option for treatment of these fractures.

A major strength of the present study is the number of patients included. To our knowledge, this is the largest published series of its kind. In addition, due to its multicenter design, many different surgeons and several hospitals participated in the study, closely resembling a real-life setting.

There are some limitations to our study. Preoperatively, some potential risk factors for a poor outcome could have been assessed with more detail. Still, American Society of Anesthesiologists (ASA) class, preoperative mobility, quality of life (EQ-5D score), preoperative health status, and HHS were recorded as baseline characteristics. In addition, the randomization and large number of patients included should reduce the risk of any selection bias and the risk of baseline differences between the two groups.

Cognitively impaired patients were included in our study. It might be difficult to obtain accurate information regarding pain from such patients, who may also find it difficult to perform functional tests. Nevertheless, many patients with a hip fracture are cognitively impaired, and we found it important to include this group of patients. Despite the randomization, rates of dementia differed slightly between the groups. We sought to minimize this problem by adjusting for differences between the groups. Analyses performed with the cognitively impaired patients excluded provided similar results.

We were not able to examine all patients on the same postoperative day, and this could potentially have biased our results. However, for this reason, a linear regression analysis with adjustment for differences in the time distribution of postoperative examinations was performed, and the timing of the postoperative evaluations did not influence our results significantly.

The higher number of experienced surgeons performing the operations with the INTERTAN nails was a concern, but the overall percentage of consultants operating on patients in our study was low (11%). In addition, regression analyses adjusting for the surgeons' formal qualifications did not influence our results. Finally, the lack of blinding of patients and examiners may have potentially influenced our findings. However, in this multicenter study involving large numbers of patients, physicians, and other research personnel in five hospitals with a duration of follow-up of one year, we considered blinding the patients (and examiners) with respect to the treatment to be too ambitious, if possible at all.

Our long-term follow-up rate was 79% of those still alive at one year, which is less than desirable. Still, with the large number of patients included and with no difference in follow-up rates between the groups, we believe that our main findings are valid.

In conclusion, we found similar results regarding pain, function, complications, and reoperation rates at one year in this randomized controlled trial comparing the INTERTAN nail and the sliding hip screw for the treatment of intertrochanteric and subtrochanteric fractures. Patients treated with the INTERTAN nail had slightly less pain at the time of initial postoperative mobilization and received fewer blood transfusions. However, this did not influence the length of the hospital stay, function, or complication rate.

Improving outcomes and reducing complication rates after treatment of these fractures remain a challenge, but to achieve a good outcome, optimizing hip fracture reduction and implant position is probably more important than the choice of implant.

Appendix

eA Tables showing operative and postoperative data and radiographic findings as well as figures demonstrating INTERTAN nails, sliding hip screws, the trochanteric stabilizing plate, the time distribution of the evaluations for early postoperative pain and performance of the timed Up & Go test, postoperative femoral fractures, and cutout are available with the online version of this article as a data supplement at jbjs.org. ■

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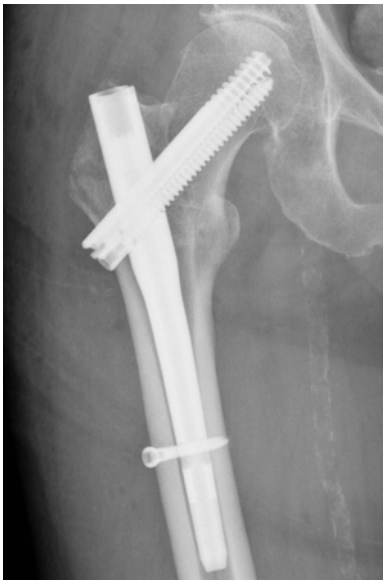

Fig. E1-A
The INTERTAN nail was short or long.

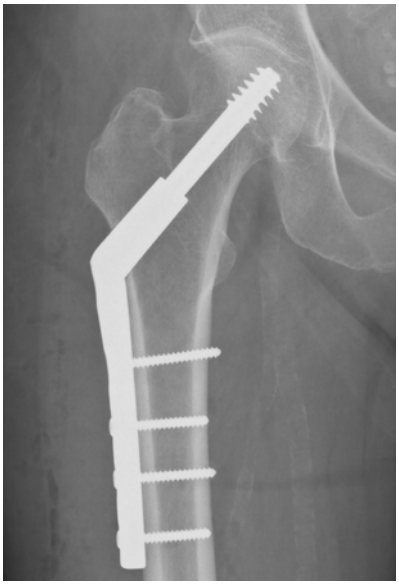

Fig. E1-B
The sliding hip screw comes in different lengths, and is used with or without a trochanteric stabilizing plate.

http://dx.doi.org/10.2106/JBJS.K.01497

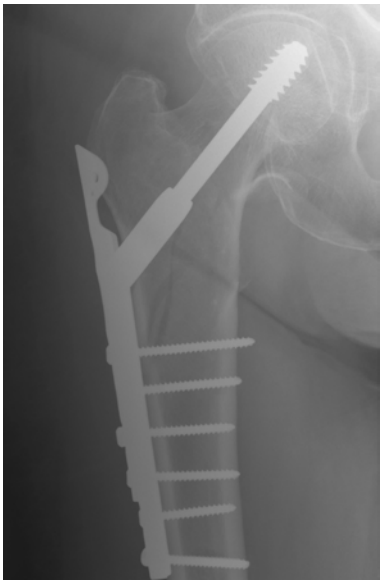

Fig. E1-C
The trochanteric stabilizing plate was either an integrated part of the sliding hip screw or a separate plate added onto the sliding hip screw.

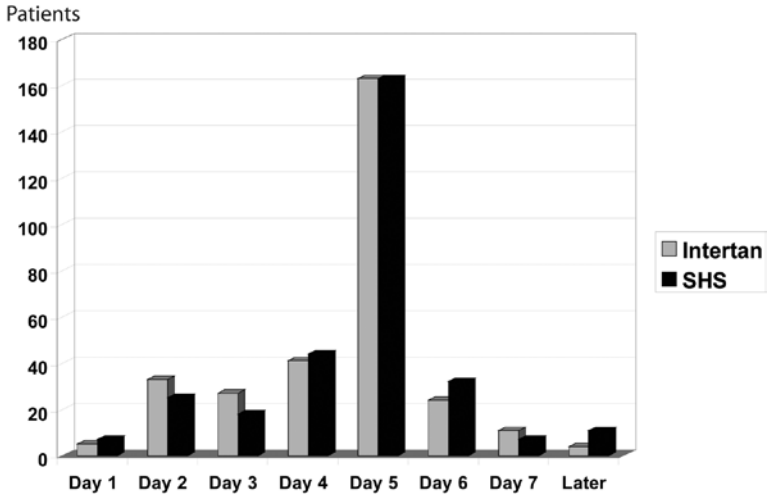

Fig. E2
Time distribution of the evaluations for early postoperative pain and performance of the timed Up & Go test. Sixty-nine patients were not evaluated either with the timed Up and Go test or with the VAS pain scores. SHS = sliding-hip-screw group.

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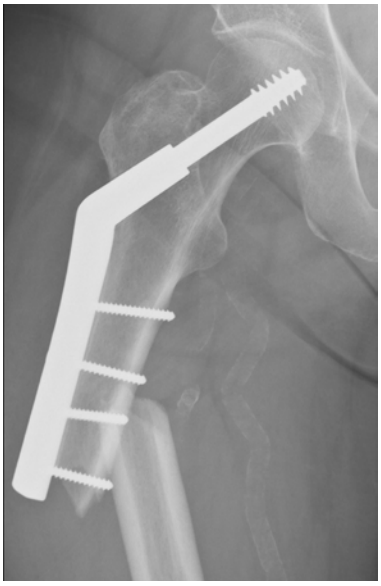
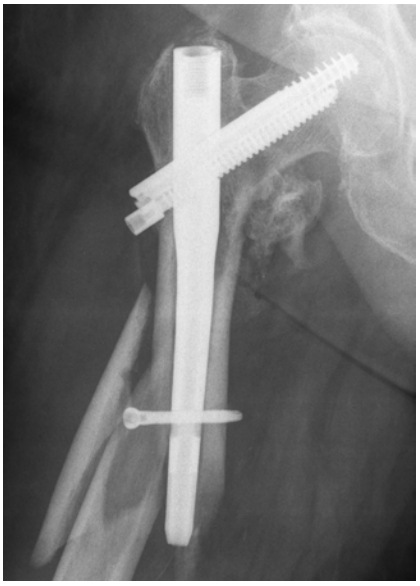

Fig. E3-A Fig. E3-B

Figs. E3-A and E3-B Postoperative femoral fractures included one femoral fracture in the sliding-hip-screw group and five fractures in the INTERTAN group (four associated with short nails and one associated with a long nail). **Fig. E3-A** A sliding hip screw with a periprosthetic fracture at the level of the distal screw. **Fig. E3-B** A short INTERTAN nail with a periprosthetic fracture at the tip of the nail.

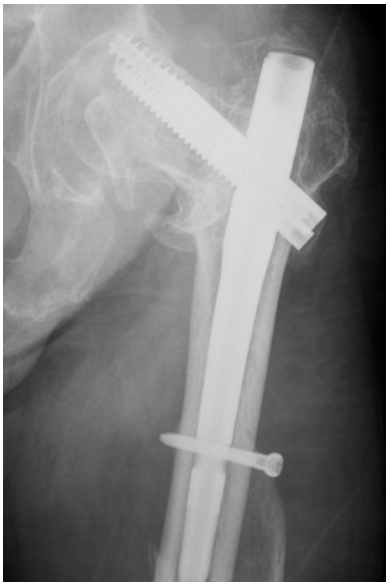
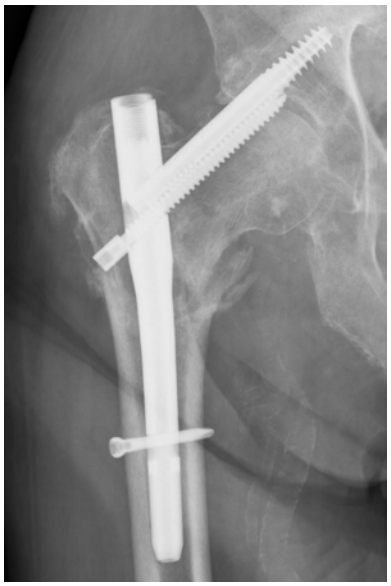
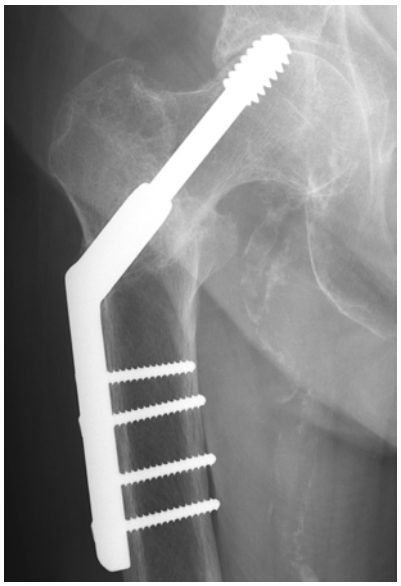

Fig. E4-A Fig. E4-B Fig. E4-C

Figs. E4-A, E4-B, and E4-C There were thirteen cases of cutout/cut-through in the INTERTAN group and eleven cases of cutout in the sliding-hip-screw group. **Fig. E4-A** A short INTERTAN nail with cutout in the femoral head. **Fig. E4-B** A short INTERTAN nail with cutout in the femoral head and migration of the proximal lag screw into the acetabulum. **Fig. E4-C** A sliding hip screw with a cutout in the femoral head.

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TABLE E-1 Operative and Postoperative Data in the Two Treatment Groups*

	INTERTAN* (N = 341)	Sliding Hip Screw* (N = 343)	P Value†
Op. data			
Preop. delay (n = 666)			0.65‡
<24 hr	181 (54.0%)	167 (50.5%)	
24-48 hr	109 (32.5%)	116 (35.0%)	
>48 hr	45 (13.4%)	48 (14.5%)	
Anesthesia (n = 667)			0.82‡
Spinal	304 (90.7%)	303 (91.3%)	
General	31 (9.3%)	29 (8.7%)	
Surgeon's experience (n = 664)			**0.02‡**
Resident <2 yr	70 (21.4%)	101 (30.0%)	
Resident >2 yr	183 (56.0%)	184 (54.6%)	
Resident assisted by consultant	34 (10.4%)	20 (5.9%)	
Consultant	40 (12.2%)	32 (9.5%)	
Duration of surgery (n = 661) *(min)*			
All fractures	54.7 (n = 331)	55.6 (n = 330)	0.69§
AO/OTA type A1	46.1 (n = 145)	44.0 (n = 133)	0.39§
AO/OTA type A2	57.1 (n = 112)	54.4 (n = 118)	0.44§
AO/OTA type A3 and subtrochanteric	67.8 (n = 74)	76.5 (n = 79)	0.10§
Long nail or sliding hip screw w/trochanteric stabilizing plate#			
AO/OTA type A1	8/149 (5%)	9/141 (6%)	
AO/OTA type A2	38/113 (34%)	39/122 (32%)	
AO/OTA type A3	44/70 (63%)	51/69 (74%)	
Subtrochanteric	7/7 (100%)	6/13 (46%)	
Total**	97/339 (29%)	105/345 (30%)	
Postop. data			
Transfusion (n = 663)	143 (43.1%)	171 (51.7%)	**0.02‡**
Mean est. external blood loss (n = 650) *(mL)*	183	263	**<0.001§**
Mean hemoglobin value (g/dL)			
Preop. (n = 660)	12.1	12.0	0.81§
Lowest postop. (n = 650)	9.2	9.1	0.26§
Mean length of postop. hospital stay (n = 684) *(days)*	8.5	8.4	0.85§
Residence after discharge (n = 650)			0.81‡
Home	39 (11.9%)	47 (14.6%)	
Nursing home	190 (57.9%)	168 (52.2%)	
Rehab.	47 (14.3%)	47 (14.6%)	
Other	52 (15.9%)	60 (18.6%)	

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡Pearson chi-square test. §Independent samples t test. #The use of different implants was based on the fracture classification and degree of osteoporosis. All hospitals received a guide describing when to use long nails or an additional trochanteric stabilizing plate, but this decision was finally left to the surgeon. **The actual implants used were not identical with the randomization code for twelve of the 684 patients (Fig. 1). Therefore, the numbers are slightly different compared with other (intention-to-treat) analyses.

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TABLE E-2 Radiographic Findings

	INTERTAN*	Sliding Hip Screw*	P Value†
Postop. fracture reduction‡			0.25§
Good	147 (44%)	164 (48%)	
Acceptable	141 (43%)	143 (42%)	
Poor	44 (13%)	32 (9%)	
Total	332 (100%)	339 (100%)	
Shortening at 12 mo			**0.007§**
None	88 (49%)	111 (61%)	
<10 mm	71 (39%)	47 (26%)	
10-20 mm	11 (6%)	19 (11%)	
>20 mm	10 (6%)	4 (2%)	
Total	180 (100%)	181 (100%)	
Medialization at 12 mo			**0.002§**
<5 mm	153 (85%)	127 (71%)	
5-10 mm	18 (10%)	23 (13%)	
10 mm	9 (5%)	28 (16%)	
Total	180 (100%)	178 (100%)	
Radiographic fracture-healing at 12 mo			0.80§
Yes	154 (86%)	158 (87%)	
No	13 (7%)	14 (8%)	
Uncertain	13 (7%)	10 (6%)	
Mean postop. tip-apex distance (TAD)# (n = 655) *(mm)*	18	21	**<0.001****
Mean femoral neck-shaft angle *(deg)*			
Postop. (n = 678)	131	138	**<0.001****
12 mo (n = 361)	126	132	**<0.001****

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡The postoperative reduction was considered "good" with no more than 4 mm of displacement of any fracture fragment and normal or slight valgus alignment on the anteroposterior radiograph, and <20° of angulation on the lateral radiograph. Fractures that had either good alignment or no more than 4 mm of displacement, but not both, were rated as "acceptable." Fractures that fulfilled neither criterion were categorized as "poor." §Pearson chi-square test. #TAD = the sum of the distance from the (superior) lag screw to the apex of the femoral head on the frontal and lateral view, adjusted for magnification. **Independent samples t test.

Paper II

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CLINICAL RESEARCH

Intramedullary Nails Result in More Reoperations Than Sliding Hip Screws in Two-part Intertrochanteric Fractures

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Abstract

Background Sliding hip screws (SHSs) and intramedullary (IM) nails are well-documented implants for simple two-part intertrochanteric fractures; however, there is no consensus regarding which type of implant is better.

Questions/purposes We asked whether patients with simple two-part intertrochanteric fractures treated with IM nailing had (1) a lower reoperation rate and (2) less pain and better quality of life than patients treated with SHSs.

Methods We used data from the Norwegian Hip Fracture Register on 7643 operations for simple two-part intertrochanteric fractures (AO/OTA Type A1) treated with an SHS (n = 6355) or an IM nail (n = 1288) between 2005 and 2010. Kaplan-Meier analysis was used to assess reoperation percentages and a Cox regression model was used to assess the risk of reoperation. Questionnaires regarding pain and quality of life were answered by the patients at 4, 12, and 36 months postoperatively.

Results We found an increased risk of reoperation after IM nailing within 1 postoperative year: 2.4% and 4.2% for SHS and IM nails, respectively. The difference persisted with time: 4.5% and 7.1% at 3 years. We also found minor differences for pain and quality of life which we judged clinically unimportant.

Conclusions Based on our findings and a critical review of the literature, we suggest an SHS is likely the preferred implant for simple two-part intertrochanteric fractures.

Level of Evidence Level III, therapeutic study. See the Instructions for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the Haukeland University Hospital (Bergen, Norway) and University of Bergen (Bergen, Norway).

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Introduction

Implant selection for intertrochanteric fractures remains controversial, and whether intertrochanteric fractures are best treated with a sliding hip screw (SHS) or an intramedullary (IM) nail has not been conclusively answered in the literature [17, 24]. Most randomized clinical trials (RCTs) [5, 23, 27, 29–31] found no major difference in long-term functional outcome between the two groups of implants. However, a meta-analysis [16] concluded higher fracture fixation failure and reoperation rates occurred after

IM nailing. Jones et al. [16] concluded an IM nail should not be recommended for stable intertrochanteric fractures. Even for unstable fractures, they found no advantage in using an IM nail. Their findings, however, might have been skewed by the inclusion of studies on the earliest commercially available trochanteric nails and a learning curve among surgeons beginning to use trochanteric nailing. Some of the earlier nails were associated with higher failure rates, postoperative femoral fractures in particular, and are no longer in use [4, 8, 10, 25]. Bhandari et al. assessed the effects of time and different generations of implants (Gamma™ nails, Stryker, Kalamazoo, MI, USA) on femoral shaft fractures after nailing [6]. They found the differences in femoral fracture risk between the SHS and the Gamma™ nail lessened and eventually disappeared and therefore recommended the findings from earlier RCTs and meta-analyses should be interpreted with caution.

Thus, despite numerous publications on this topic, firm conclusions regarding the best implant for intertrochanteric fractures cannot be drawn and recommendations have diverged. In addition, a consistent fracture classification has not always been used, making the interpretation of data more difficult. Nevertheless, there has been a trend toward more IM nailing in intertrochanteric fractures, even though evidence supporting its increased use is missing [2, 26]. We have seen a similar but less pronounced trend in our country, but we still treat nearly 80% of all intertrochanteric fractures with an SHS [21].

To clarify the distinctions between these two implants, we studied a large group of patients with simple two-part fractures and specifically asked whether patients with simple two-part intertrochanteric fractures treated with IM nailing had (1) lower risks of reoperation and (2) less pain and better quality of life than patients treated with SHSs.

Patients and Methods

Since January 1, 2005, hip fracture operations in our country have been recorded prospectively in the Norwegian Hip Fracture Register (NHFR) [12]. Seventeen thousand one hundred forty-eight primary operations for intertrochanteric and subtrochanteric fractures were recorded until December 31, 2010. For the current study, we selected patients with two-part intertrochanteric fractures (AO/OTA Type A1 [19]) treated with an SHS or an IM nail (n = 7724). Operations performed with other implants (n = 22) and operations for pathologic fractures (n = 59) were excluded, leaving 7643 operations (6355 operations with SHSs and 1288 with IM nails) for final analyses (Fig. 1). The surgeons classified the fractures according to the AO/OTA classification and also reported the patients' baseline characteristics (age, sex, cognitive function, American Society of Anesthesiologists [ASA] classification of morbidities) and details from the primary operations (surgical time, type of anesthesia, antibiotic and thrombotic prophylaxis). Overall, 71% of the patients were female, and the mean age for both groups was 82 years. We found no differences in the mean ASA scores, cognitive functions, or preoperative quality of life (EQ-5D™ index score; EuroQol Group, Rotterdam, The Netherlands) between the two treatment groups (Table 1).

Power calculations, including the number of patients in the SHS and IM nail groups (6355 and 1288, respectively), were performed. We considered a difference in reoperation percentages of 1% to 2% to be clinically relevant, and detecting a significant difference in reoperations of 2% could be obtained with a power of 85% by using our numbers of patients. Accordingly, our study had sufficient power to detect a clinically important difference of this size.

The SHS has remained the most commonly used implant in Norway for treatment of all intertrochanteric and subtrochanteric fractures [21]. In our study, compression hip screws (AMBI®/CLASSIC Hip Screw System; Smith & Nephew, London, UK) and dynamic hip screws (Dynamic Hip System screw/blade; Synthes GmbH, Basel, Switzerland) were the two most frequently used SHSs. A trochanteric stabilizing plate was added in 8% of these operations, possibly to prevent fracture of a small and osteoporotic lateral spike of the trochanter at mobilization. The second and third generations of the Gamma3™ Locking Nail (Stryker Corp) and the Trigen™ Intertan™ Trochanteric Antegrade Nail (Smith & Nephew) were the most commonly used IM nails. Long nails were used in 4% of the nailing procedures (Table 2).

Operating surgeons from 55 hospitals nationwide reported primary operations and reoperations, with causes and type of reoperation, to the NHFR. Failure of the fixation, nonunions or malunions, femoral head necroses, local pain from protruding hardware, infections, hematomas, cutouts, periimplant fractures, and other occurrences were the options for reporting causes of reoperation. Removal of the implants, resection arthroplasties, unipolar or bipolar hemiarthroplasties, refixation, débridement for infections, and other occurrences were the options for reporting type of reoperations. More than one cause of reoperation and more than one type of reoperation were recorded for some patients. Patients whose reoperations were THAs (n = 81), however, were reported to the Norwegian Arthroplasty Register. The NHFR obtained these data and linked them to the primary operations, but we had no detailed information regarding the causes of reoperations for these patients.

Questionnaires regarding quality of life (EQ-5D™ health questionnaire) [28] and pain were sent to the patients at 4, 12, and 36 months postoperatively. A preoperative

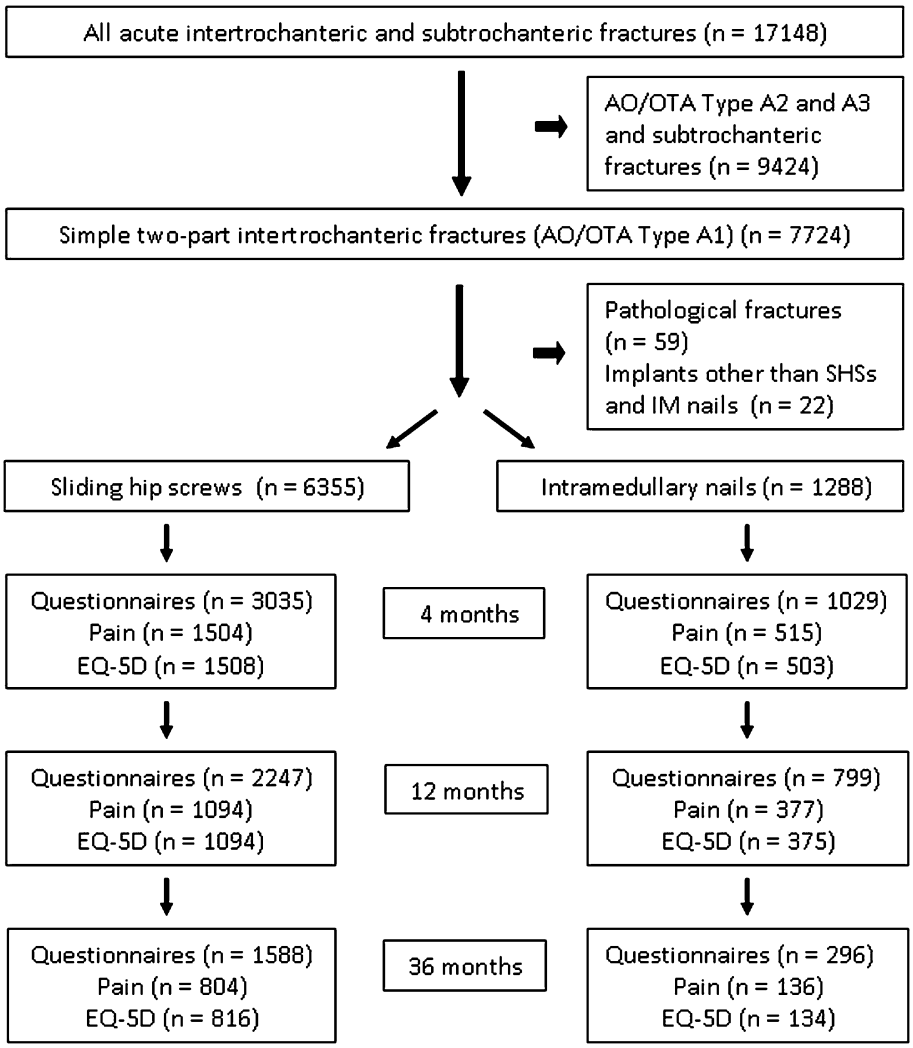

Fig. 1 A flowchart of the patients and followup assessments is shown.

quality-of-life status was recorded in retrospect together with the 4-month questionnaire. At 4 months, 1029 patients with an IM nail received the questionnaires, and 515 and 503 answered the questionnaires regarding pain and EQ-5D™, respectively, giving a response rate of approximately 50% (Fig. 1). In the questionnaires, the patients were asked to report pain from the surgically treated hip, using a VAS (0 indicating no pain, 100 indicating unbearable pain). The EQ-5D™ questionnaire contains five factors (mobility, degree of self-care, ability to perform usual activities, pain/discomfort, and anxiety/depression) rated at three levels (no problems, some problems, severe problems). Derived from these questions, the EQ-5D™ index score gives a value, with a maximum score of 1.0 indicating a very good quality of life and a score of 0 being equivalent to death.

All patients were observed for any reason for reoperation until December 31, 2010 (mean followup, 1 year 10 months; range, 0–6 years). The questionnaires regarding pain and quality of life were sent to all living patients with IM nails or SHSs with a trochanteric stabilizing plate during followup from 2005 to 2010. Similarly, all patients with simple SHS operations in 2005, 2006, and 2010 received this questionnaire. Of the patients treated with a simple SHS in 2007 to 2009, however, owing to lack of resources, only a randomly selected subgroup of patients was asked to answer the questionnaires.

We estimated the cumulative 1- and 3-year reoperation risks for the two treatment groups using a Kaplan-Meier survival analysis. The log-rank test was used to detect differences. Patients without reoperations were censored at their dates of death or emigration or at the end of followup (December 31, 2010). The National Population Register provided death and emigration information. In addition, relative differences in reoperation rates (relative risk [RR]) between the implant types were estimated in a multiple Cox regression model with adjustments for possible confounding factors (age, sex, ASA class, cognitive impairment).

Table 1. Baseline characteristics of the two groups

Characteristic	Sliding hip screw	Intramedullary nail	p value
Total number of hips (n = 7643)	6355 (83%)	1288 (17%)	
Age (years) (n = 7643)*	82 (10)	82 (10)	0.22†
Sex (number of hips) (n = 7643)			0.24‡
Female	4515 (71%)	936 (73%)	
ASA type (number of hips) (n = 7520)	6252	1268	0.007‡
1	463 (7%)	66 (5%)	
2	2224 (36%)	506 (40%)	
3	3216 (51%)	629 (50%)	
4	337 (5%)	66 (5%)	
5	12 (0.2%)	1 (0.1%)	
ASA score*	2.55 (0.7)	2.55 (0.7)	0.88†
Cognitive impairment (number of hips) (n = 7453)	6198	1255	0.10‡
Yes	1522 (25%)	288 (23%)	
No	4009 (65%)	808 (64%)	
Uncertain	667 (11%)	159 (13%)	
Preoperative EQ-5D™ index score* (n = 2038)	0.69 (0.28)	0.69 (0.29)	0.71†
Surgical time (minutes)* (n = 7643)	52 (25)	51 (23)	0.029†
Anesthesia (n = 7643)			0.67‡
Spinal	90%	90%	
General	6%	6%	
Other or missing	4%	4%	
Antibiotic prophylaxis (n = 7643)			< 0.001‡
Yes	95%	86%	
No	5%	13%	
Missing value	0.6%	0.8%	
Thrombosis prophylaxis	99%	99%	0.63‡

* Values are expressed as mean, with SD in parentheses; †Student's t-test; ‡Pearson chi-square test; ASA = American Society of Anesthesiologists.

Patients without complete information regarding their ASA classes and cognitive impairments (n = 290) were excluded from the regression analysis. The mortality during followup was determined with Kaplan-Meier analyses. Differences in mean pain and quality of life (EQ-5D™ index score) scores were analyzed using Student's t-test, while categorical outcome variables (EQ-5D™ mobility and usual activity) were analyzed using the Pearson chi-square test. We used PASW® Statistics Software (Version 18.0; SPSS Inc, Chicago, IL, USA) for all statistical analyses.

Table 2. Implants used

Implant	Number of hips
Sliding hip screws	
Compression hip screw (AMBI®/CLASSIC Hip Screw System)*	3887 (61%)
Dynamic hip screw (Dynamic Hip System)†	1929 (30%)
Locking compression plate (Dynamic Hip System)†	492 (8%)
Omega Plus™‡	43 (0.7%)
Other/missing data	4 (0%)
Total	6355 (100%)
Intramedullary nails	
Gamma3™ Locking Nail‡	699 (54%)
Trigen™ Intertan™*	355 (28%)
Trochanteric-Gamma™‡	154 (12%)
Proximal femoral nail-antirotation†	51 (4%)
Proximal femoral nail†	11 (0.9%)
Intramedullary hip screw*	10 (0.8%)
Other nails/missing data	8 (0.6%
Total	1288 (100%)

* Smith & Nephew, London, UK; †Synthes, Basel, Switzerland; ‡Stryker Corp, Kalamazoo, MI, USA.

Results

We found a higher (p = 0.001) 1-year reoperation rate for patients treated with IM nails than for those treated with SHSs (4.2% and 2.4%, respectively). Two-hundred forty-nine reoperations were identified. At 3 years, the reoperation rates were 7.1% for IM nails and 4.5% for SHSs ($p < 0.001$) (Fig. 2). There was an overall 61% increased (p = 0.002) risk of reoperation after IM nailing, compared with that after using an SHS (RR, 1.61; 95% CI, 1.19–2.17). Comorbidity (ASA class) and sex did not influence the reoperation rates, whereas cognitively impaired patients had a lower ($p < 0.001$) reoperation risk than those who were cognitively lucid (RR, 0.44; 95% CI, 0.28–0.68). In addition, older (p = 0.049) age reduced the reoperation risk (Table 3). Failure of the fixation was the most common reason for reoperation in both groups (0.8%), and we found no differences between the two groups for most reasons for reoperations. However, the rates of periimplant fractures (p = 0.027) and reoperations attributable to implant-related pain (p = 0.043) were higher in the IM nail group. Accordingly, implant removal was more frequent (p = 0.028) in that group. Otherwise, the distribution of types of reoperations was similar for the two groups, but reoperations in the SHS group more frequently were recorded with a combination of reasons for reoperation (not just one reason) (Table 4). We found a higher (p = 0.016) reoperation rate for the 52 patients with a long nail in our study (six of 52 versus 54 of 1236).

The average scores for pain were similar for the two implant groups at all times during the followup (Table 5). Four months postoperatively, the mean VAS pain scores were 28 and 29 for the IM nail and SHS, respectively (p = 0.332); they then decreased to 22 and 23, respectively, 3 years postoperatively (p = 0.845). We found no major differences between the two treatment groups in the quality-of-life assessments (Table 5). After analyzing the five factors of the EQ-5D™ questionnaire separately, however, we found, after 1 postoperative year, patients in the SHS group reported more problems regarding their mobility and performing usual activities.

We also found the average surgical times for the two operative methods were almost identical: 52 minutes for the SHS group and 51 minutes for the IM nail group (p = 0.029). Mortality rates after 1 postoperative year were 25% for the SHS group and 23% for the IM nail group (p = 0.224).

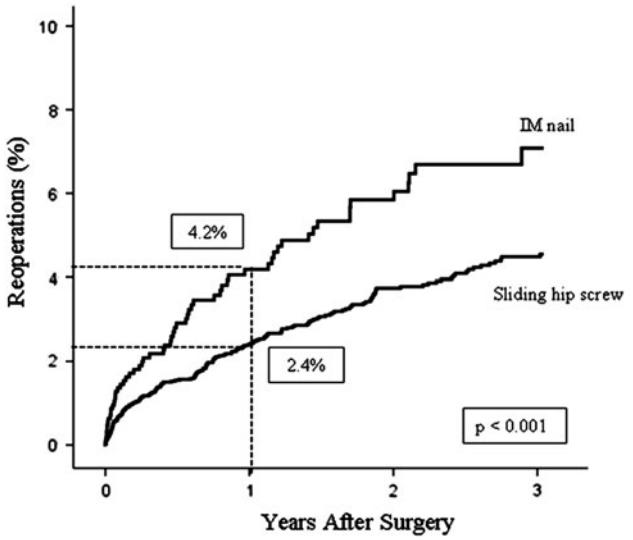

Fig. 2 Kaplan-Meier analysis found cumulative reoperation rates of 4.2% and 2.4% at 1 year and 7.1% and 4.5% at 3 years for IM nails and SHSs, respectively.

Table 3. Cox regression analysis of factors with possible influences on the risk of reoperation

Factor	Relative risk	95% CI	p value
Type of implant			
Sliding hip screw	1		
Intramedullary nail	1.61	1.19–2.17	0.002
Sex			
Male	1		
Female	1.11	0.82–1.49	0.51
Age*	0.99	0.98–1.00	0.049
ASA type			
1	1		
2	1.07	0.69–1.67	0.76
3	0.93	0.59–1.45	0.74
4	1.12	0.52–2.42	0.77
Cognitive impairment			
No	1		
Uncertain	0.79	0.50–1.24	0.31
Yes	0.44	0.29–0.69	< 0.001

Patients were followed until reoperation, end of study inclusion, time of emigration, time of patient's death; * risk reduction for each year of older age; ASA = American Society of Anesthesiologists.

Discussion

There has been a trend toward more IM nailing in intertrochanteric fractures, but this trend has not been based on current evidence [2, 26]. Historically, higher failure rates

Table 4. Reason for and type of reoperation versus type of implant in 249 hips with reoperations

Reoperations	Number of hips		p value*
	Sliding hip screw	Intramedullary nail	
Reoperated hips (overall 249/7643 [3.3%])	189/6355 (3.0%)	60/1288 (4.7%)	0.002
Reported reasons†			
Failure of osteosynthesis	54 (0.8%)	10 (0.8%)	0.79
Nonunion	18 (0.3%)	2 (0.2%)	0.41
Local pain from implant	17 (0.3%)	8 (0.6%)	0.043
Infection (deep and superficial)	14 (0.2%)	2 (0.2%)	0.64
Cutout	17 (0.3%)	7 (0.5%)	0.11
Fracture around implant	10 (0.2%)	6 (0.5%)	0.027
Other reasons	31 (0.5%)	12 (0.9%)	0.05
Unknown reasons (THAs‡)	63 (1.0%)	18 (1.4%)	0.19
Types of reoperations§			
Implant removal	25 (0.4%)	11 (0.9%)	0.028
New osteosynthesis	35 (0.6%)	10 (0.8%)	0.33
Bipolar hemiarthroplasty	50 (0.8%)	16 (1.2%)	0.11
THA	63 (1.0%)	18 (1.4%)	0.19
Debridement for infection	17 (0.3%)	3 (0.2%)	0.83
Others	8 (0.1%)	3 (0.2%)	0.36

* Pearson chi-square test; †more than one reason per reoperation possible; 208 reasons for reoperations were reported in 249 hips; ‡for the 81 patients whose reoperation was a THA, no detailed descriptions of reasons for the reoperations were given; §reporting more than one type of procedure was possible for each reoperation.

Table 5. Pain and quality of life (with selected subcategories) in the two groups

Variable	Sliding hip screw	Intramedullary nail	Mean difference (95% CI)	p value
Mean VAS score for pain (points)				
4 months	29 (n = 1504)	29 (n = 515)	0.9 (−1.2 to 3.1)	0.40
1 year	26 (n = 1097)	24 (n = 378)	1.7 (−0.8 to 4.1)	0.19
3 years	23 (n = 804)	22 (n = 136)	0.4 (−3.3 to 4.0)	0.85
Mean EQ-5D™ index score*				
Preoperative	0.69 (n = 1519)	0.69 (n = 519)	0.005 (−0.023 to 0.034)	0.71
4 months	0.49 (n = 1508)	0.51 (n = 503)	−0.017 (−0.045 to 0.009)	0.20
1 year	0.55 (n = 1097)	0.58 (n = 376)	−0.030 (−0.061 to 0.001)	0.06
3 years	0.59 (n = 816)	0.59 (n = 134)	−0.008 (−0.061 to 0.044)	0.76
EQ-5D™: mobility at 12 months†				0.006
No problems	24%	32%		
Some problems	72%	65%		
Severe problems	4%	4%		
EQ-5D™: usual activities at 12 months†				0.014
No problems	26%	33%		
Some problems	47%	43%		
Severe problems	27%	24%		

* EQ-5D™ index score scale: 0 indicates a situation similar to death and 1 indicates the best possible quality of life; †no significant differences were found at 4 months or 3 years or for other EQ-5D™ dimensions at any time.

have been observed after IM nailing compared with operations using SHSs [6, 16, 24]. To what extent modern nails reduce complication rates or improve function (if at all) remains to be shown. Currently, there is no consensus regarding which implant, an SHS or an IM nail, is the best for different intertrochanteric fractures. We therefore asked whether patients with simple two-part intertrochanteric fractures treated with IM nailing had (1) lower reoperation rates and (2) less pain and better quality of life than patients treated with SHSs.

There were some limitations to our study. First, as there had been no randomization of the treatment allocation, patient- and surgeon-related confounders may have been present. With comparable baseline characteristics for the groups, however, we believe the risk of any important bias is less likely. In addition, data representing a national average of hospitals and surgeons and the fact that the implant selection usually reflects the policy in each hospital rather than the choice of each surgeon should have reduced the chance of bias. Second, our responder rate was low, partly because of high mortality rates and the elderly study population, but the large number of included patients may have, to some extent, compensated for this. Underreporting of complications and reoperations might be anticipated. Even so, this probably should have affected both treatment groups equally, and most likely, the difference in the reoperation rates was real. Third, different IM nails and SHSs were used in our study, and we did not examine pain, function, or reoperation rates for each implant brand. Therefore, our results may not be generalized to any nail or SHS. Fourth, as the fracture classification is performed by the operating surgeons, and we have no radiographs available in our register, this is also a source of uncertainty. Finally, in a register study including thousands of patients, even minor and clinically irrelevant differences might become statistically significant. Accordingly, our data should be interpreted with caution. Nevertheless, where RCTs may fail to detect small differences owing to limited numbers of patients in rare events like reoperations in particular, we believe the large number of patients in a register study can add valuable information [14].

We found a higher rate of complications and reoperations after IM nailing than after SHS operations for simple two-part trochanteric fractures. Reoperation percentages of 2.4% and 4.2% for the SHS and IM nail groups at 1 year were comparable to rates in other reports [1, 3, 16] on intertrochanteric fractures. In line with our results, one meta-analysis of RCTs [16] concluded the failure rate were higher after IM nailing of stable intertrochanteric fractures than after using an SHS, and nailing of these fractures was not recommended. Our reoperation rates were slightly higher than those reported for stable fractures in that review but were lower than those reported in other studies [1, 3, 22] where stable and unstable fractures were not separated. Even though absolute numbers of reoperations vary among studies, the consistent overall difference in favor of the SHS

seems to have remained. The severity of the complications and reasons for reoperation may vary among implant groups. In our study we found more patients had reoperations because of fracture around the implant and local pain from the implant in the IM nail group. Otherwise we found no differences in reasons for reoperation between the groups, indicating a similar rate of minor or major complications in both groups. Most types of reoperations were more frequent in the IM nail group, however, only "removal of implants" was significant. Postoperative femoral fracture rates were high when using the first few generations of IM nails [4, 8, 10, 25]. Therefore, reported failure rates after IM nailing, including nails no longer in use, may distort the results in updated reviews [15, 18, 24]. This problem was addressed in a meta-analysis by Bhandari et al. [6] who assessed the change of postoperative femoral fracture rates after Gamma™ nailing with time. They found less femoral fractures and no differences compared with the SHS in the most recent studies. However, no studies published after 2005 or studies on other types of IM nails were included in that review. In addition, others did not find a similar time-dependent change in the postoperative femoral fracture and failure rates for IM nailing [7, 24]. We suspect some underreporting of femoral fractures and subsequent reoperations in our study, as only six reoperations (0.5%) in the IM nail group were caused by fractures around the implants. These findings contrast with those in another study [11], where a 6% rate of postoperative femoral fractures was reported after IM nailing, clearly indicating this problem has not been solved. Our data included only recent generations of implants and indicated reoperation rates have continued to be higher after IM nailing of simple two-part intertrochanteric fractures. In our study, 96% of the nailing procedures were performed with short nails, and to what extent a shift toward more long nails even in stable intertrochanteric fractures would reduce the number of periimplant fractures remains unknown. However, despite a higher rate of reoperations for long nails, periimplant fractures were not the cause of reoperation in patients who were treated with long nails. We found the reoperation rate among cognitively impaired patients to be lower than that for cognitively lucid patients. This is consistent with another report [13] from our hip fracture register and might be caused by these patients' poorer abilities to express complaints and/or differences in the indications for surgical interventions.

We also found no difference in pain or quality of life between the two implant groups during followup. The assessment of pain for patients with hip fractures has not been standardized, and several outcomes for pain have been reported [9, 24]. Therefore, comparing results is difficult. Nevertheless, regardless of the implant and outcome measure used and in accordance with our results, two meta-analyses [9, 24] reported no major differences in pain between implants and operative methods in trochanteric fractures. Our finding of no difference in the reported quality of life between the implants, using the EQ-5D™ index score, indicated the difference in reoperation rates was not enough to influence the patients' perception of quality of life. After 1 postoperative year, however, more patients in the IM nail group rated their mobility and ability to perform usual activities with the best score. The differences were minor and temporary, but these EQ-5D™ dimensions describe important factors related to a patient's ability to maintain his or her independence. Quality-of-life measures have been reported inconsistently in trials comparing the SHS and IM nail in intertrochanteric fractures [9]. We were not aware of any other study assessing quality of life using the EQ-5D™ questionnaire in cases of simple two-part intertrochanteric fractures. In a RCT comparing the Gamma™ nail with the Medoff sliding plate (Swemac, Linköping, Sweden) in unstable intertrochanteric and subtrochanteric fractures [20], the authors reported no difference in EQ-5D™ index scores between the groups. Overall, the most updated and thorough review of RCTs [24] comparing SHSs and IM nails in intertrochanteric fractures concluded there was no difference in terms of quality-of-life issues, such as pain, walking ability, or the number of patients regaining their prefracture levels of independence after intertrochanteric fractures.

We found a higher rate of reoperations after IM nailing than after use of the SHS in simple two-part intertrochanteric fractures, but we also found no clinically relevant differences in pain or overall quality of life during the followup assessments. Our study had several limitations, but the findings seemed to be in accordance with meta-analyses of RCTs. Despite modern trends suggesting otherwise, in our opinion, the SHS still seems to be the better treatment for simple two-part intertrochanteric fractures compared with short IM nails.

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Paper III

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Sliding hip screw versus IM nail in reverse oblique trochanteric and subtrochanteric fractures. A study of 2716 patients in the Norwegian Hip Fracture Register

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ABSTRACT

Background: Intramedullary nailing is commonly recommended as the treatment of choice for transverse/reverse oblique trochanteric (AO/OTA type A3 = intertrochanteric) and subtrochanteric fractures. However, only to a limited extent is this approach supported by superior results in well designed clinical trials, and the sliding hip screw (SHS) is still a frequently used implant for these fractures. The aim of the present study was to compare IM nails and SHS in the treatment of transverse/reverse oblique trochanteric and subtrochanteric fractures using data from the Norwegian Hip Fracture Register (NHFR).

Methods: Data on 2716 operations for acute transverse/reverse oblique trochanteric or subtrochanteric fractures were collected from the NHFR from 2005 to 2010. Surgeons reported patient characteristics and details from initial surgery and reoperations, and patients answered questionnaires about pain, satisfaction, and quality of life (EQ-5D) 4, 12, and 36 months postoperatively. Reoperation rates were calculated using Kaplan–Meier analyses. Primary outcome measures were pain (Visual Analogue Scale (VAS)), satisfaction (VAS), quality of life (EQ-5D), and reoperation rates at one year.

Results: The treatment groups were similar regarding age, gender, ASA-class, cognitive impairment, and preoperative EQ-5Dindex score. At one year reoperation rates were 6.4% and 3.8% for SHS and IM nails, respectively ($p = 0.011$). Patients treated with SHS also had slightly more pain (VAS 30 vs. 27, $p = 0.037$) and were less satisfied (VAS 31 vs. 36, $p = 0.003$) compared to patients treated with IM nail. There was no statistically significant difference in the EQ-5Dindex score, but the mobility was significantly better for the IM nail group.

Conclusion: 12 months postoperatively patients with transverse/reverse oblique trochanteric and subtrochanteric fractures operated with a SHS had a higher reoperation rate compared to those operated with an IM nail. Small differences regarding pain, satisfaction, quality of life, and mobility were also in favour of IM nailing. Consequently, a change in our treatment strategy for these fractures could be considered.

Introduction

The management of transverse/reverse oblique trochanteric (AO/OTA type A3 = intertrochanteric) and subtrochanteric fractures is still a subject to debate, and different intra- or extramedullary implants may be used. In Scandinavia, these fractures are usually treated with either an IM nail or a SHS, whereas an IM nail might be considered the only option in other countries. The scientific evidence supporting either treatment is scarce and to some extent conflicting. Therefore, a final consensus has not been reached. Better biomechanical properties and lower failure rates are highlighted by several authors to recommend IM nailing as the treatment of choice for these fractures.[1–4] Still, results are not unambiguous, and good results with more favourable reoperation rates for the SHS have been reported in other series.[5–7] Blade plates and the dynamic condylar screw (DCS) may be used, and good results have been reported in selected

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groups of fractures and patients.[8,9] However, in more recent studies these implants have been associated with poor outcome and high failure rates in this particular group of hip fractures.[1,10,11]

To enhance fracture stability and prevent medialization of the femoral shaft, an additional trochanteric stabilizing plate (TSP) may be added to the SHS. Several clinical studies have reported favourable results using this construct.[12–14] The ability of the TSP to resist dislocating forces causing excessive lag screw sliding and medialization of the femoral shaft has also been confirmed in biomechanical studies.[15,16] Nevertheless, despite the ability to retain acceptable fracture reduction, produce satisfactory functional results, and low complication rates, the use of the TSP has not gained any widespread popularity. In our country, however, the SHS including a TSP has remained the implant of choice for the majority of transverse/reverse oblique trochanteric and subtrochanteric fractures.[17]

In the present study, the aim was to assess any implant dependent difference in pain, patient satisfaction, quality of life, or reoperation rates in these fracture types.

Materials and methods

The NHFR has been described in detail by Gjertsen et al.[17] 17,148 primary operations for trochanteric and subtrochanteric fractures were registered in the NHFR from January 1, 2005 until December 31, 2010. Patient characteristics, fracture classification, and details from the primary operations were reported by the surgeons. Trochanteric fractures were classified as transverse/reverse oblique trochanteric (intertrochanteric) according to the AO/OTA classification,[18] whereas fractures between the lower border of the lesser trochanter, and 5 cm distal to this, were defined as subtrochanteric (Fig. 1). For the present study we selected patients of all ages with these unstable transverse/reverse oblique trochanteric or subtrochanteric fractures ($n = 2841$). Fractures operated with other implants than a SHS or a nail ($n = 24$) and pathological fractures ($n = 101$) were excluded. This left 2716 fractures treated with a SHS ($n = 1792$) or an IM nail ($n = 924$) for final analysis. The Norwegian Data Inspectorate has approved the recording of data in the NHFR, and the patients sign an informed consent form which is kept in their medical records.

Any type of secondary surgery during follow-up was considered a reoperation and these were reported to the register by the surgeons who performed the reoperations. Reoperations were categorised according to reason for reoperation and type of reoperation performed. In some patients more than one reason for reoperation or more than one type of reoperation were recorded. The patients, or their relatives/care-givers, answered questionnaires containing questions about pain from the operated hip (VAS with 0 indicating no pain and 100 indicating unbearable pain), satisfaction with the result of the operation (VAS with 0 indicating very satisfied and 100 indicating very dissatisfied), and quality of life (EQ-5D) 4, 12, and 36 months postoperatively. The EQ-5D questionnaire assesses mobility, degree of self care, ability to perform usual activities, pain/discomfort, and anxiety/depression. 3 levels are registered for each of these dimensions (no problems, some problems, severe problems). The EQ-5Dindex score is calculated from these answers and gives a value with a maximum score of 1.0, indicating a very good quality of life, and 0 being equivalent to death.[19] Preoperative information was given in retrospect at 4 months follow-up. A detailed flow chart for inclusion, patient-reported outcome, and follow-up is presented in Fig. 2.

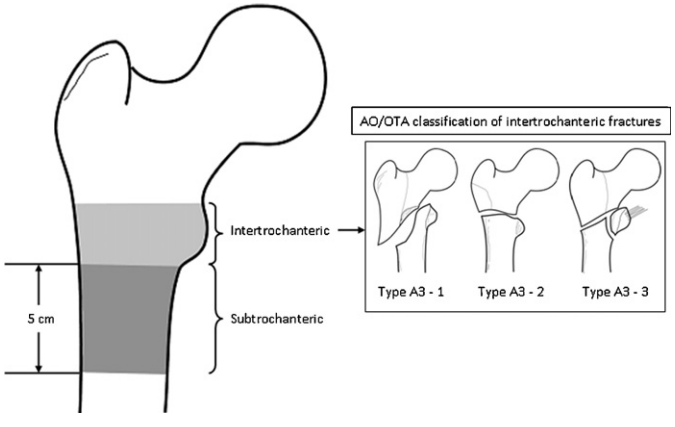

Fig. 1. Classification of intertrochanteric (transverse/reverse oblique trochanteric or AO/OTA type A3) and subtrochanteric fractures.

The SHS was the most common implant and comprised 1792 out of 2716 operations (66%). Overall, an additional TSP was used in 1120 out of the1792 fractures treated with a SHS (63%). The TSP was most frequently used in transverse/reverse oblique trochanteric fractures (240 out of 294 fractures (82%)), whereas 880 out of 1498 subtrochanteric fractures (59%) were operated with a TSP. Patients treated with a nail ($n = 924$) received a long nail in 688 out of 924 cases (74%), and 98% (902 out of 924) of all nails were locked distally.

Statistical analyses

For the categorical outcome variables; reason for reoperation, type of reoperation, and walking ability, we used the Pearson chi-square test. Student's *t*-test was used for analyzing continuous variables like pain, patient satisfaction and EQ-5Dindex score.

In the survival analyses, the endpoint was any reoperation. For implants without reoperation survival times were censored at their dates of death or emigration, or at the end of study inclusion (December 31, 2010). Information on deaths or emigrations was retrieved from the National Population Register. All patients were included in the Kaplan–Meier analyses applied to determine the proportion of reoperations after 1 and 3 years follow-up. The log rank test was used for testing the statistical significance of overall differences in survival. A multiple Cox regression model was used to assess the relative reoperation risk for the two treatment groups and for the potential confounding factors: age, gender, ASA-class, cognitive impairment, and fracture type. Only patients with complete information regarding these factors were included in this analysis ($n = 2611$). To adjust for potential differences in baseline characteristics between the two groups, additional analyses using the propensity score method[20] were performed. p values less than 0.05 were considered statistically significant (two-sided tests).

Source of funding

No external funding has been received for this specific study, but the NHFR is funded by the regional Health Board of Western Norway. The first author has also received a grant for hip fracture research from the same regional health board.

Results

At inclusion, baseline characteristics regarding age, gender, ASA-classification, cognitive impairment, and preoperative quality of life (EQ-5Dindex score) were similar for the two groups (Table 1). However, a larger proportion of fractures were transverse/reverse oblique in the SHS group. An overview of type implants is presented in Table 2. The surgical time was similar for

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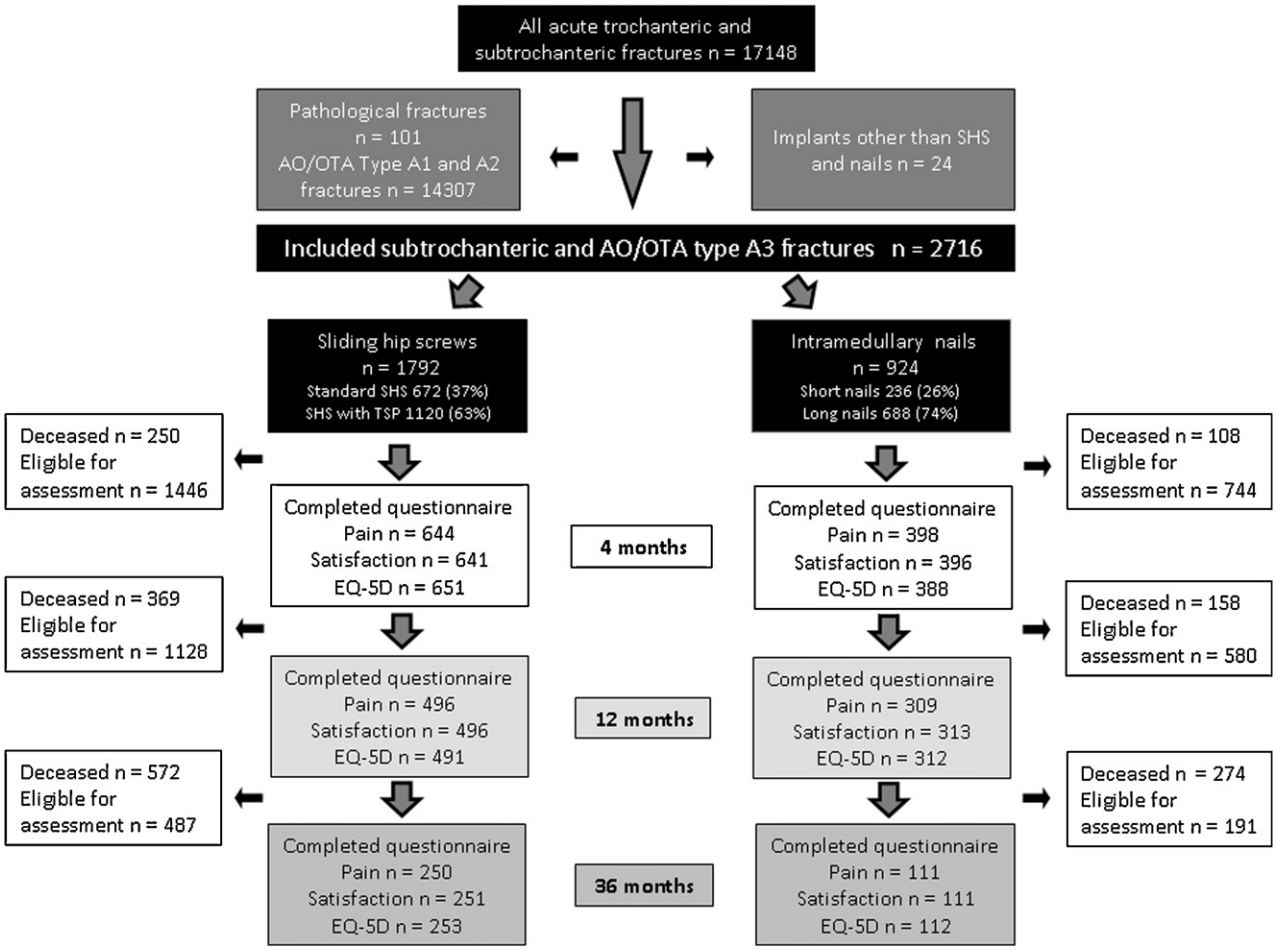

Fig. 2. Flow chart of patients and follow-up assessments. Kaplan–Meier analyses were used to assess mortality rates and number of patients under observation at follow-up (eligible for assessment).

Table 1
Baseline characteristics.

Patients and fractures	Sliding hip screws	IM nails	*p* value
Total number (*n* = 2716)	1792	924	
Mean age, years (*n* = 2716) (SEM[a])	79.1 (0.309)	79.6 (0.419)	0.35[b]
Gender (*n* = 2716)			0.35[c]
Female (%)	1358 (75.8)	685 (74.1)	
ASA-class[d] (*n* = 2677)	1769	908	0.15[c]
ASA 1 (%)	176 (9.9)	73 (8.0)	
ASA 2 (%)	590 (33.4)	328 (36.1)	
ASA 3 (%)	889 (50.3)	452 (49.8)	
ASA 4 (%)	108 (6.1)	55 (6.1)	
ASA 5 (%)	6 (0.3)	0	
Cognitive impairment (*n* = 2650)	1754	896	0.42[c]
Yes (%)	367 (20.9)	168 (18.8)	
No (%)	1211 (69.0)	637 (71.1)	
Uncertain (%)	176 (10.0)	91 (10.2)	
Injured right side (%) (*n* = 1375)	465 (50.3)	910 (50.8)	0.37[c]
Mean preoperative EQ-5Dindex score (*n* = 1048) (SEM[a])	0.71 (0.014)	0.71 (0.011)	0.76[b]
Fracture type			
Intertrochanteric[e]	294	96	<0.001[c]
Subtrochanteric	1498	828	
Total (% TSP/long nails)	1792 (63%)	924 (74%)	

[a] Standard error of the mean.
[b] Student's *t*-test.
[c] Pearson chi-square test.
[d] American Society of Anesthesiologists classification of comorbidities.
[e] Intertrochanteric (AO/OTA type 31-A3) fractures were not classified as such before 2008.

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Table 2
Used implants.

Implants	Numbers (%)
Sliding hip screws	
Richards CHS (Smith & Nephew)[a]	1127 (62.9)
Omega Plus (Stryker)[b]	7 (0.4)
Dynamic Hip Screw (DHS) (Synthes)[c]	521 (29.1)
Locking Compression Plate DHS (Synthes)	137 (7.6)
Total	1792 (100)
Intramedullary nails	
Gamma 3 (Stryker)	431 (46.6)
T-Gamma (Stryker)	122 (13.2)
T2 recon (Stryker)	16 (1.7)
TriGen (Smith & Nephew)	96 (10.4)
Trigen Intertan (Smith & Nephew)	129 (14.0)
Intramedullary Hip Screw (IMHS, Smith & Nephew)	7 (0.8)
Proximal Femoral Nail (PFN, Synthes)	8 (0.9)
Proximal Femoral Nail Antirotation (PFNA, Synthes)	54 (5.8)
Lateral Femoral Nail (LFN, Synthes)	16 (1.7)
ACE (DePuy)[d]	36 (3.9)
Other nails/data missing	9 (1.0)
Total	924 (100)

[a] Smith & Nephew, Memphis, Tennessee (US).
[b] Stryker, Selzach, Switzerland.
[c] Synthes, Basel, Switzerland.
[d] DePuy, Leeds, UK.

Table 3
Cox regression analysis of factors with possible influence on the risk of reoperation.

Variable	RR	95% CI	*p* value
Type of implant			
IM nails	1		
SHS	1.43	1.01–2.03	0.044
Gender			
Men	1		
Women	1.02	0.70–1.49	0.91
Age	0.985	0.973–0.997	0.017
ASA-class			
ASA 1	1		
ASA 2	1.87	1.06–3.33	0.032
ASA 3	1.37	0.76–2.49	0.30
ASA 4	1.41	0.53–3.73	0.49
Cognitive impairment			
No	1		
Uncertain	0.89	0.49–1.59	0.68
Yes	0.73	0.44–1.21	0.22
Fracture type			
Subtrochanteric	1		
Transverse/revere oblique	1.41	0.92–2.18	0.12

Patients were followed until reoperation, end of study inclusion, or the time of emigration or death.

the two groups, 91 and 92 min for IM nail and SHS, respectively ($p = 0.33$), and we found no difference in preoperative waiting time for the groups ($p = 0.386$).

Reoperations

A higher proportion of reoperations were found in the SHS group as compared to the IM nail group (log rank test, $p = 0.011$) (Fig. 3). The percentage of reoperations at one year was 6.4% ($n = 96$) for the SHS group and 3.8% ($n = 30$) for patients treated with IM nails. At three years the percentage of reoperations was 10.2% ($n = 128$) and 6.7% ($n = 43$), respectively. In an unadjusted Cox regression analyses there was a 56% increased risk of reoperation in the SHS group compared to the IM nail group (RR 1.56, 95% CI 1.1–2.2, $p = 0.012$). Adjusted for age, gender, ASA-class, cognitive impairment, and fracture type there was a 43% increased risk of having a reoperation after operation with a SHS (RR 1.43, 95% CI 1.01–2.03, $p = 0.044$). As presented in Table 3, the reoperation risk was not statistically significantly affected by gender, cognitively impairment, or fracture type. The probability of being reoperated was, however, influenced by age and ASA-classification. In subgroup analyses for the two fracture types (Kaplan–Meier analyses) we found three years reoperation rates of 6.7% and 9.8% for IM nail and SHS in subtrochanteric fractures ($p = 0.041$), and 5.6% and 10.3% in transverse/reverse oblique fractures ($p = 0.18$), respectively. Within the two treatment groups there was no significant difference in reoperation rates between a SHS with or without a TSP ($p = 0.55$), or between short and long nails ($p = 0.67$) using unadjusted Cox regression analyses.

A detailed description of reasons for reoperation and type of reoperations performed is presented in Table 4. For the overall category "failure of osteosynthesis", significantly more reoperations were encountered in the SHS group (3.3% vs. 1.1%, $p = 0.001$). There was, however, no statistical significant difference in percentage of reoperations between the two implant groups for any single reason such as non-union, local pain from the implant, infections, cutout, or peri-implant fractures.

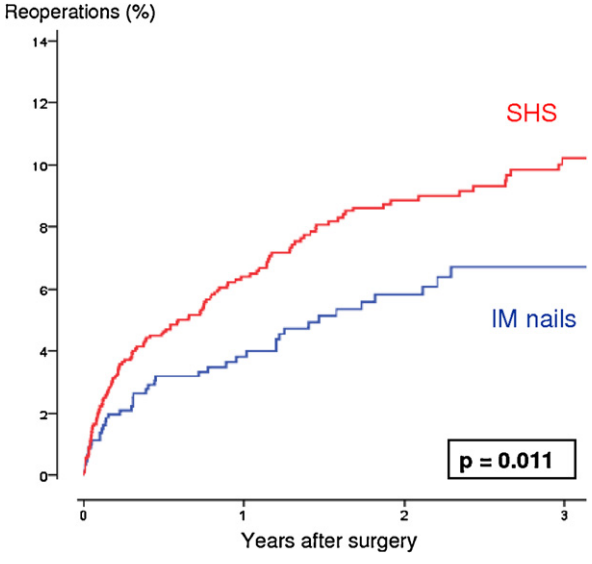

Fig. 3. Cumulative reoperation rates the first 3 years after surgery (Kaplan–Meier analysis).

Functional outcome data

Patient-reported outcome data are presented in Table 5. At 4 and 12 months there were small, but statistically significant, differences in terms of pain and patient satisfaction in favour of patients treated with IM nails. At 36 months, no statistically significant differences were found. The quality of life assessments (EQ-5Dindex score) were also slightly in favour of IM nailing, but statistically significant only at 4 months (0.51 vs. 0.47, $p = 0.012$). However, separately assessing the different dimensions of the EQ-5D-questionnaire, the mobility (walking ability) was clearly in favour of the IM nail group the first postoperative year (Table 6). Patients operated with a SHS reported more frequently "I have some problems in walking about", and at 1 year the difference was close to 10% in disfavour of the SHS (77.9% vs. 68.0% for the SHS and IM nail group, respectively, $p = 0.003$).

The observed differences between implants were independent of fracture type, and whether operations were performed with long or short nails did not influence pain, patient satisfaction, or quality of life significantly. Patients with a standard SHS, however, reported slightly better quality of life at 4 and 12 months, compared to those treated with an additional

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Table 4
Different *reasons* for reoperation and *types of* reoperations vs. type of implant in 172 reoperated hips.

	Sliding hip screws, *n* (%)	IM nails, *n* (%)	*p* value[a]
Reoperated hips			
Overall 172/2716 (6.3%)	129/1792 (7.2%)	43/924 (4.7%)	0.010
Reported reasons[b]			
Failure of osteosynthesis	59 (3.3)	10 (1.1)	0.001
Nonunion	17 (0.9)	8 (0.9)	0.83
Local pain from implant	16 (0.9)	5 (0.5)	0.32
Infection (deep and superficial)	14 (0.8)	4 (0.4)	0.29
Cutout	6 (0.3)	3 (0.3)	0.97
Fracture around implant	5 (0.3)	2 (0.2)	0.76
Other reasons	14 (0.8)	7 (0.8)	0.95
All reported reasons	131 (7.3)	39 (4.2)	0.002
Reported reoperations[c]			
Implant removal	19 (1.1)	7 (0.8)	0.44
New osteosynthesis	52 (2.9)	14 (1.5)	0.026
Bipolar hemi arthroplasties	23 (1.3)	3 (0.3)	0.015
Total hip arthroplasties[d]	25 (1.4)	13 (1.4)	0.98
Drainage	11 (0.6)	4 (0.4)	0.55
Other	12 (0.7)	7 (0.8)	0.80
All reported reoperations	142 (7.9)	48 (5.2)	0.008

[a] Pearsons chi-square test.
[b] More than one reason per reoperation possible. 170 reasons for reoperations were reported in 134 hips.
[c] More than one type of reoperation possible for each patient. 190 types of reoperations were reported in 172 hips.
[d] 38 hips were reported to the Norwegian Arthroplasty Register as they were reoperated with a total hip replacement. For these patients no specific reason for reoperation was recorded.

Table 5
Pain, satisfaction, and quality of life.

Patient reported outcome	Sliding hip screws	IM nails	Mean difference (95% CI)	*p* value
Pain (mean VAS)[a]				
4 months	33 (*n* = 644)	29 (*n* = 398)	3.9 (1.3–6.6)	0.004
1 year	30 (*n* = 496)	27 (*n* = 309)	3.2 (0.2–6.3)	0.037
3 years	25 (*n* = 250)	22 (*n* = 111)	2.8 (−1.8 to 7.4)	0.23
Satisfaction (mean VAS)[b]				
4 months	35 (*n* = 641)	30 (*n* = 396)	4.7 (2.0–7.5)	0.001
1 year	36 (*n* = 496)	31 (*n* = 313)	5.0 (1.7–8.3)	0.003
3 years	31 (*n* = 251)	28 (*n* = 111)	2.7 (−2.4 to 7.8)	0.29
EQ-5Dindex score[c] (mean)				
Preoperative	0.71 (*n* = 661)	0.71 (*n* = 387)	0.01 (−0.03 to 0.04)	0.76
4 months	0.47 (*n* = 651)	0.51 (*n* = 388)	−0.04 (−0.07 to −0.01)	0.012
1 year	0.55 (*n* = 491)	0.57 (*n* = 312)	−0.02 (−0.06 to 0.01)	0.23
3 years	0.60 (*n* = 253)	0.60 (*n* = 112)	−0.01 (−0.07 to 0.06)	0.79

[a] VAS (Visual Analogue Scale) for pain. 0 indicating no pain, 100 indicating unbearable pain.
[b] VAS for satisfaction. 0 the best score, indicating very satisfied, 100 the worst score, indicating very dissatisfied.
[c] EQ-5Dindex score. 0 indicating the worst possible quality of life, 1 indicating the best possible quality of life.

TSP (EQ-5Dindex score 0.52 vs. 45, $p = 0.002$ and 0.60 vs. 0.53, $p = 0.007$, respectively). Otherwise, no significant difference in patient outcome was evident for the subgroups of implants up to 3 years postoperatively.

Performing analyses for our main outcome measures using the propensity score method gave practically the same estimated average treatment effects and test results as those reported.

Discussion

In the present study, comparing SHS and IM nail for transverse/reverse oblique trochanteric and subtrochanteric fractures, we found significantly more reoperations for patients operated with a SHS. In addition, results regarding pain, patient satisfaction, quality of life, and mobility were all slightly in favour of IM nailing.

Table 6
Patient reported walking ability (EQ-5D questionnaire = "mobility").

Time	Implant	No problems (%)	Some problems (%)	Bedridden (%)	Total (%)	*p* value[a]
Pre-operative	IM nail (*n* = 403)	57.1	40.9	2.0	100	0.81
	SHS (*n* = 678)	57.1	41.4	1.5	100	
4 months	IM nail (*n* = 407)	15.5	80.3	4.2	100	<0.001
	SHS (*n* = 674)	6.5	87.1	6.4	100	
1 year	IM nail (*n* = 325)	28.0	68.0	4.0	100	0.003
	SHS (*n* = 524)	17.9	77.9	4.2	100	
3 years	IM nail (*n* = 117)	36.8	58.1	5.1	100	0.39
	SHS (*n* = 266)	29.7	64.3	6.0	100	

[a] Pearson chi-square test.

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Treating transverse/reverse oblique trochanteric and subtrochanteric fractures with a SHS is by some authors considered inappropriate, in particular due to biomechanical considerations.[2,4,21] However, the evidence in the literature is sparse and conflicting, and the debate whether to use a SHS or a nail in these fractures has not come to a final or indisputable conclusion. To the best of our knowledge, no randomised clinical trial comparing the SHS with a nail in these unstable fracture types has been published. In the present study 2/3 of the patients were operated with a SHS, however, a TSP working as a buttress to the greater trochanter was frequently added. The aim of the TSP is to reduce medialization and shortening of the femoral shaft, while at the same time to provide sufficient stability to allow full postoperative weight bearing. Favourable outcome using a TSP has been published in several clinical series,[12–14] and the ability of a TSP to resist dislocating forces causing excessive lag screw sliding and medialization of the femoral shaft in unstable fracture patterns has been confirmed in biomechanical studies.[15,16] However, as we had no radiographs available for initial fracture classification or later follow-up, assessing the exact significance of a TSP in this register study was not possible. In addition, clinical data in our register-based study are limited, and a randomised controlled study design would be the best way to assess any usefulness of the TSP.

Our reoperation rates of 3.8% and 6.4% at one year for IM nails and SHS, respectively, are in the lower range compared to most other studies on transverse/reverse oblique trochanteric and subtrochanteric fractures,[5,22–28] and significantly higher failure rates, for the SHS in particular, have been reported for reverse oblique- and subtrochanteric fractures in some studies.[1,11,29] In a retrospective review of 55 patients with reverse oblique fractures operated with different types of implants over a 10 year period, Haidukewych et al.[1] reported a failure for 9 out of 16 patients operated with a SHS (56%). However, what we consider mandatory for the reverse oblique fractures, no TSP was used in their operations. Other implants were also associated with high failure rates in the same study, but due to a retrospective study design and a small number of patients, conclusions on failure rates and implant selection based on that study alone should be drawn with caution. Brammar and colleagues found a considerably lower overall fracture healing complication rate of 9% in a review of 101 reverse oblique and transverse trochanteric fractures, and no statistically significant difference in reoperation rates between SHS and IM nails was found in that study.[6] More favourable complication rates for the SHS have also been reported in other studies.[5,13,25] A few randomised clinical trials assessing extramedullary implants other than the SHS in subtrochanteric fractures (frequently including AO/OTA type A3 trochanteric fractures) exist. Two studies comparing the Medoff sliding plate (MSP) with a nail had inconsistent findings regarding reoperations and failure rates.[28,30] Ekstrøm et al. reported a significantly higher reoperation rate in the nailing group (9% vs. 1% reoperations, $p < 0.02$),[30] whereas Miedel et al. found a non-significant trend towards a higher reoperation rate in the MSP group, 3 out of 12 (25%) compared to 0 out of 16 in the nailing group ($p = 0.067$).[28] However, in studies by Sadowski and Rahme, comparing a nail to a DCS or a blade plate, reoperation rates were clearly in favour of IM nailing.[10,11] Lunsjö et al. compared the MSP to 3 other extramedullary screw-plate devices, a SHS with or without a TSP included, and they found fewer fixation failures with the MSP (1 vs. 8, $p = 0.01$).[31]

The additional use of a TSP, for the reverse oblique fracture type in particular, may to some extent account for the lower rate of reoperations in our study. Recent improvements in implant design and surgeons becoming more aware of surgical pitfalls in treating these fractures may also have had a positive impact on failure rates. Incomplete reporting is another possible explanation for our rather low reoperation rates. In addition, as some elderly, demented, or frail patients may have been considered unsuitable candidates for further surgery, we might suspect the actual failure rates to be higher than our reoperation rates indicate. Therefore, the difference in reoperation rate between the two implants is probably more important than the absolute numbers. We may have underestimated the reoperation rates, but any under-reporting of reoperations is most likely similar for the two groups. The number of primary operations reported to the register was validated in 2006, and at that time 79% of the operations were reported.[17] However, reoperations have not been validated in a similar way.

Historically, a high rate of peri-implant fractures has been a major concern after IM nailing for trochanteric fractures. In the present series of 924 patients treated with IM nails only two patients were reported with a second femoral fracture around the implant during a follow-up of 12 months. This is also in line with the findings by Bhandari et al., where the rate of subsequent femoral fractures after Gamma nailing was low and comparable to sliding hip screws in more recently published studies.[32] Still, such a low rate of peri-implant fractures might represent an under-reporting of these injuries to the register, but, as suggested by Bhandari and co-workers, improvements in operative technique and implant design could be other reasonable explanations. Finally, the frequent use of long IM nails (74%) in the present study may also have prevented some peri-implant fractures.

Data on pain and functional outcome in comparative trials for inter- and subtrochanteric fractures are to a variable extent reported in the existing literature, and no standardised criteria for assessments have been used. To the best of our knowledge, no consistent or major difference in such outcome parameters has been published,[33,34] and this is also in accordance with our findings. However, due to a large number of patients in the present study, also small differences in pain, patient satisfaction, and EQ-5Dindex score reached statistical significance. The clinical relevance of these minor differences, though, is debatable. In addition, at 3 years no statistically significant difference in clinical outcome was evident. A difference of 10 points in VAS-pain has been considered a clinically significant difference for an individual patient,[35] but at no time during follow up we were close to such a difference between the two implant groups. Nevertheless, at a group level, a difference in VAS pain score of 3–4 points should not be neglected. Similar, statistically significant differences regarding patient satisfaction within the first year cannot be ignored. A minimally clinical relevant difference in the EQ-5Dindex score has been suggested to be in the range of 0.06–0.08.[36,37] Accordingly, the importance of a statistically non-significant difference of 0.02 at one year should not be over-emphasised in our study. However, with a similar level of mobility at baseline, the patients' self-assessment of significantly better mobility in the IM nail group at 4 and 12 months postoperatively is an important finding and very relevant for this group of patients.

Less pain in the IM nail group may be a result of mini invasive surgery and/or better stability of the implant in the initial postoperative phase, whereas long term differences could be due to more local pain from protruding hardware or more secondary fracture displacement and malunions in the SHS group. Detailed information on such issues is, however, not retrievable from our register data. Pain is most probably influential on patient satisfaction and quality of life measures, and may to some extent explain the slightly superior results in favour of the IM nail for these outcomes. Even though the differences were small, we found that patients one year postoperatively had less pain and were more satisfied after operation with an IM nail compared to a SHS.

Strengths and limitations

The major strength of this study is the large number of patients with these rather uncommon fractures. To achieve results with

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sufficient statistical power comparing treatment groups with small differences in outcome is a challenge. In such instances register data assessing patient reported outcome and complication rates may provide valuable information.

Still, there are several limitations to our study. Since this is a register study and no RCT, we cannot exclude possible selection bias. For instance, in our register the clinically relevant information regarding each patient is limited, and we have no information regarding the surgeons' level of experience. In addition, differences in implant preferences/surgical indications, and rehab programmes might represent important bias in the interpretation of our results. However, as patient characteristics regarding age, gender, ASA-class, and cognitive function at baseline were similar for the two groups, a selection bias is less likely. A selection bias is also less probable as treatment policy and implant selection in our country usually is a matter of administrative decisions in each hospital, and less based on the surgeons' individual preference.

Patients with hip fractures in this age group have a high one year mortality rate, and in the present study also a large number of patients were cognitively impaired. These facts not only influence the response rate, but also the quality of the patient reported outcome. Further, we rely on the fracture classification done by the operating surgeons, and even though there are pictures and guidelines for classification on the report form, the accuracy of the fracture classification might also be an uncertainty. Finally, we have compared two main surgical principles and groups of implants in our study, and no single implants. Consequently, our findings should be interpreted with caution.

In our health care system, implant costs are usually not considered an argument to select one implant to another for the individual patient. However, when hospitals establish routines regarding implant selection for certain fracture types, in particular if results are otherwise considered equivalent, costs may play an important role and should be considered.

Performing a large randomised controlled trial (RCT) would have been the best solution to provide a more definitive answer regarding any possible implant superiority. However, performing RCTs in these rather uncommon fractures is a major challenge. To prove small differences between implants large numbers of patients need to be included, and to the best of our knowledge no such study exists in the current literature.

Conclusions

Patients with transverse/reverse oblique trochanteric or subtrochanteric fractures operated with a SHS had a significantly higher reoperation rate compared to those treated with an IM nail. 4 and 12 months postoperatively we also found a small difference in pain, patient satisfaction, walking ability, and quality of life in favour of the nail. The clinical significance of these differences, however, is uncertain. Further, at 3 years no statistically significant difference in functional outcome was evident.

Based on the present study, and as opposed to our current practice, a change in our treatment algorithm for these unstable fracture types could be considered. For colleagues already treating these patients with an IM nail, the current study provides scientific evidence to support such an approach.

Conflict of interest

Leif Ivar Havelin, Jan-Erik Gjertsen, Tarjei Vinje, Birgitte Espehaug, and Jonas M. Fevang have no personal or financial conflict of interest to disclose related to the current study.

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Paper IV

Is the sliding hip screw still an option in the treatment of transverse or reverse oblique intertrochanteric and subtrochanteric fractures?

A PROSPECTIVE RANDOMISED MULTICENTRE TRIAL COMPARING THE TRIGEN INTERTAN INTRAMEDULLARY NAIL WITH THE SLIDING HIP SCREW IN 159 PATIENTS

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Abstract

Transverse or reverse oblique intertrochanteric (AO/OTA type A3) and subtrochanteric fractures are considered highly unstable, and treating them with a sliding hip screw (SHS) is controversial. However, adding a trochanteric stabilizing plate (TSP) may prevent medialization of the femoral shaft and thus justify the SHS also in these fractures. In a recent randomised controlled trial (RCT) we compared the TRIGEN INTERTAN intramedullary nail (Smith & Nephew, Memphis, Tennessee, US) with the SHS in 684 patients with trochanteric and subtrochanteric fractures. In the present study only the subgroup of patients

with transverse or reverse oblique intertrochanteric (n = 139) and subtrochanteric fractures (n = 20) from that study were included.

We found no significant difference regarding VAS pain scores, function (Harris hip score and timed Up & Go-test), quality of life (EQ-5D), or complication and reoperation rates between the two treatment groups. However, estimated blood loss and number of patients receiving blood transfusions were slightly higher in the SHS group. In conclusion, the SHS, including a TSP, still seems to be an acceptable option in the treatment of transverse and reverse oblique inter- and subtrochanteric fractures.

Introduction

The treatment of transverse and reverse oblique intertrochanteric (AO/OTA type A3) and subtrochanteric fractures remains controversial. In Norway the sliding hip screw (SHS) is the most commonly used implant even for this subgroup of trochanteric fractures. According to the Norwegian Hip Fracture Register 61 % of these fractures were treated with a SHS in 2010, but to improve fracture stability and prevent medialization of the femoral shaft, a trochanteric stabilizing plate (TSP) was frequently added (71% of the cases).[1] The use of a SHS in these fractures, however, is in contrast to opinions expressed in some recent literature.[2-4] Because of its sliding parallel to a reverse oblique fracture line and no proximal lateral support, the SHS has been considered inappropriate for these fractures in particular, and high failure rates have been reported.[5,6] Other extramedullary implants like blade plates and the 95 degree dynamic condylar screw (DCS) have also been associated with poor outcome and unacceptable failure rates in this group of fractures.[5,7] Favorable results using mini-invasive plating techniques have been reported in some studies, but this has not been established as a generally accepted standard of care.[8,9] Kregor and colleagues from the Evidence-Based Orthopaedic Trauma Working Group recommended in their review that

intramedullary (IM) nailing should be the preferred treatment for unstable pertrochanteric (AO/OTA type A3) fractures.[2] Kuzyk and co-workers compared intra- and extramedullary implants for subtrochanteric fractures in another review and came to a similar conclusion.[3] However, both reviews acknowledged limitations in the scientific documentation and stated that larger comparative trials were needed to give clear recommendations. To our knowledge, no RCT comparing IM nail and SHS (with a frequent use of a TSP) in these particular fractures has been published to date.

Recently we conducted a RCT comparing the Intertan nail to the SHS in 684 patients with trochanteric or subtrochanteric fractures.[10] In the present study, we selected the subgroup of patients with transverse and reverse oblique intertrochanteric and subtrochanteric fractures (n = 159) from that trial for separate analyses. Our aim was to compare the Intertan nail to the SHS in patients with these unstable fractures in terms of pain, function, quality of life, complications and reoperations.

Patients and Methods

Patients and fractures. For the present study we selected patients with transverse and reverse oblique intertrochanteric (n = 139) or subtrochanteric (n = 20) fractures from the 684 patients included in a prospective, randomised, multicenter study comparing the Intertan nail to the SHS for any type of trochanteric or subtrochanteric fracture.[10] Between February 2008 and February 2009 patients above the age of 60 were recruited from 5 different hospitals. Cognitively impaired patients were also included in the study. All patients signed an informed consent form, and for cognitively impaired patients consent was provided by relatives when required. If this was not obtainable in an acute setting, the attending physician was also allowed to include the patient. Patients with pathological fractures were excluded, and patients sustaining a contralateral trochanteric or subtrochanteric fracture during follow-up

were not included a second time. An independent radiologist classified fractures as intertrochanteric according to the AO/OTA-classification (type A3, with subgroups 1-3).[11] Subtrochanteric fractures were defined as fractures below, but within 5 cm from the lesser trochanter (Fig. 1).

One patient in the Intertan group (n = 78) was converted intraoperatively to receive a SHS because of problems with the closed reduction, and one patient in the SHS group (n = 81) received an Intertan nail due to the fracture morphology. In addition, one patient allocated to treatment with an Intertan nail was operated with a SHS for unknown reasons. A detailed flow chart of the included patients, fractures, and implants is presented in Figure 2.

Implants. The CHS (Compression Hip Screw, Smith & Nephew, Memphis, TN, US) and the DHS (Dynamic Hip Screw, Synthes, Basel, Switzerland) were used as SHSs in the present study. Due to similarities in design and biomechanics they were considered as one group. The TSP for the CHS was either an integrated part of the SHS or added as a separate support plate onto the SHS. The two different versions of the TSP for the DHS both had to be mounted separately onto the SHS (Fig. 3). As the same biomechanical principles apply for all trochanteric stabilizing plates, we considered also the patients operated with different types of TSPs as one group.

The Intertan nail (Smith & Nephew, Memphis, Tennessee, US) was launched in 2006, and the implant and the surgical technique have been described by Rücker et al.[12] In the present study we used short or long Intertan nails with distal locking and two integrated screws in the femoral head and neck fragment.

The study protocol recommended the use of a SHS with an additional TSP and long IM nails in transverse or reverse oblique intertrochanteric and subtrochanteric fractures, but these guidelines where not consistently followed by the surgeons. Consequently, 70% (57 out

of 82) of the patients operated with a SHS had an additional TSP, and 66% (51 out of 77) of the patients operated with a nail, received a long nail. Both treatment groups should have the same type of antibiotic- and antithrombotic prophylactics according to their hospital routines. 6 patients in the Intertan group, however, did not receive any peri-operative prophylactic antibiotics. Immediate postoperative weight-bearing as tolerated was allowed for all patients.

Before the study was initiated, the SHS with a TSP was the standard treatment for all trochanteric and subtrochanteric fractures at the participating hospitals. A training program for the use of the Intertan nail was therefore carried out before patients were enrolled in the study. The surgeons had to take part in at least 5 operations with each implant before they were qualified to participate in the study.

Outcome measures and follow-up. Assessment of pain using a visual analogue scale (VAS) was the primary outcome variable in the study (0 representing no pain, 100 representing unbearable pain). Functional mobility (timed "Up & Go" (TUG-test),[13] length of postoperative hospital stay, complications, and all other variables were defined as secondary outcomes. The TUG-test measures the time it takes to rise from a chair with armrests, walk 3 meters, turn around, walk back, and sit down again. Active assistance is not permitted when performing the test, while walking aids are. The time needed for this exercise (TUG-test score) is the test outcome. In addition, we recorded the number of patients within each group able to perform the test or not. If patients were not able to perform the test independently, or the TUG-test score exceeded 3 min 30 seconds, the TUG-test was considered as not passed. A physiotherapist or a study nurse most frequently recorded the pain and the TUG-test results.

As secondary in-hospital outcomes we recorded length of surgery, estimated intra operative blood loss, the lowest haemoglobin level measured after surgery, number of blood transfusions, and any postoperative complication. Further, during follow-up we recorded the

quality of life ($EQ\text{-}5D_{index}$ score),[14] hip function (Harris hip score (HHS),[15] living conditions, walking ability, surgical complications, reoperations, and mortality.

Data on postoperative pain and functional mobility (TUG-test) were recorded the 5^{th} postoperative day whenever possible. Pain, functional mobility, and other outcome measures were also assessed at follow-up visits 3 and 12 months postoperatively. Radiographs were examined for postoperative fracture reduction and implant position, including the tip-apex distance (TAD) as described by Baumgaertner.[16] At follow-up until one year postoperatively we also recorded medialization of the femoral shaft, shortening, changes in the neck-shaft angle, and fracture healing.

Randomisation procedure and statistical analyses. A random allocation to one of the two treatment options was performed using sealed, opaque, and consecutively numbered envelopes for each hospital. To ensure similar treatment numbers within the hospitals, block randomization with varying block sizes unknown to the surgeon was used. During follow-up, patients and examiners were not blinded to the treatment.

The three patients who did not receive the correct implant in accordance with the randomization code were analysed according to the intention-to-treat principle and remained in the group to which they were allocated at baseline. To test for group differences, the Pearson chi-square test was used for categorical variables, and the independent samples t test was used for continuous variables. P-values < 0.05 were considered statistically significant (two-sided tests). Because of a slightly uneven distribution of cognitively impairment and surgeons' level of experience between the groups, linear regression analyses with adjustment for these risk factors were performed when analysing early postoperative pain and TUG-test results. As not all patients were examined the same postoperative day, we also adjusted for this in a linear regression analysis.

Sample size and power calculated for the main study[10] did not apply for the current study, and statistical power was therefore considered based on sample sizes from this subset of fractures. With postoperative information on pain at mobilization (VAS) available for 131 patients, there was an 81 % chance of detecting a clinically relevant difference of 10 points or more with an assumed standard deviation of 20 points and a 5 % significance level. At 12 months follow-up, information was available for 94 patients and the corresponding statistical power 62 %.

Source of funding. The study was supported by Smith & Nephew, but the company had no influence on the study protocol, study performance, data analyses, or how to present the results. In addition, the first author received a research grant from the Regional Health Board of Western Norway to complete the work on this multicenter trial.

The study was approved by The Regional Committee of Ethics in Western Norway, and the ClinicalTrials.gov registration number was NCT00621088.

Results

The two treatment groups are presented with baseline characteristics in Table I. No significant differences regarding age, gender, comorbidities (ASA-class), cognitive impairment, preoperative HHS and quality of life ($EQ\text{-}5D_{index}$ score), subgroup of fracture type, or preoperative mobility were found. However, more patients in the Intertan group lived in nursing homes preoperatively, and this corresponded with a tendency towards more patients being cognitively impaired in that group.

Primary and secondary outcomes. Results regarding pain, function (TUG-test and HHS), and quality of life are presented in Table II. We found no statistically significant difference between the groups in pain at rest or pain at mobilization during the first stay in hospital (VAS pain score 19 vs. 20 at rest ($p = 0.96$), and 47 vs. 52 at mobilization ($p = 0.31$), for Intertan and SHS, respectively). At 3 and 12 months the pain was also comparable for the two groups. Whether a short or a long nail was used did not influence the pain significantly, but at 12 months patients operated with an additional TSP had more pain than patients operated with a simple SHS (VAS 23 vs. VAS 11 respectively, $p = 0.05$). Practically the same rate of patients in both groups passed the TUG-test the 5^{th} postoperative day, and at 3 and 12 months, and no statistically significant difference in the TUG-test score (time needed to perform the test) was found at any time point during follow-up. Pain and TUG-test analyses adjusted for differences in the timely distribution of in-hospital examinations revealed similar results. The patients' own assessment of health related quality of life was close to equal for the two groups. At 12 months, however, the results were slightly in favour of the SHS group (EQ-$5D_{index}$ score 0.59 and 0.50, for SHS and Intertan, respectively, $p = 0.15$). Minor differences between the groups in walking ability and numbers of patients living independently at baseline remained practically unchanged one year postoperatively.

Surgical details and early postoperative results are summarized in Table III. 6 patients in the Intertan group did not receive antibiotic prophylaxis, but this had no consequence for the later course. Intertan patients had significantly less estimated blood loss (238ml vs. 374ml, $p = 0.027$) and required less blood transfusions (37 (49%) out of 75 vs. 51 (67%) out of 76, $p < 0.001$), compared to those operated with a SHS. There was also a tendency towards a shorter surgical time for the Intertan group. No statistically significant difference in length of postoperative hospital stay was found between the groups (7.8 vs. 9.0 days, $p = 0.37$).

Overall, surgical complication and mortality rates were comparable for the two groups. In each group 2 patients had major reoperations during the first stay in hospital because of poor initial fracture reduction and implant position. In addition, one of the SHS patients had to be operated to remove a drain. Cutout or other mechanical failures required later reoperations in 3 Intertan patients and in 4 SHS patients, in addition one primary cutout in the Intertan group was left untreated. Overall, including also two cutouts secondarily to other reoperations, cutout was more frequent in the Intertan group (Intertan 6 vs. SHS 1, $p = 0.047$), but three of these were not reoperated. One SHS patient was put on a pending list at the 12 months follow-up visit for removal of the implant because of lateral thigh pain. Table IV gives a detailed description of all surgical complications and reoperations.

Radiological results. Radiological details are presented in Table V. We found no difference in the quality of the fracture reduction between the two groups, but the postoperative TAD was shorter in the Intertan group. More Intertan patients had a fracture reduction in varus, whereas medialization of the femoral shaft > 10mm at 12 months was more frequent in the SHS group. 12 of the 14 SHS patients with a medialization > 10mm had been operated with an additional TSP.

We found no correlation between complications or reoperations in the SHS group to any aspect of our radiological assessments. However, for Intertan patients with cutout the average TAD was 25mm vs. 19mm for those without a cutout ($p = 0.009$), and the postoperative femoral neck-shaft angle was more into varus for those having a cutout, though not statistically significant (125º vs. 130º respectively, $p = 0.11$).

Discussion

We found no significant differences in pain, function, or overall complication and reoperation rates between the two treatment groups up to 12 months postoperatively, but patients operated with an Intertan nail had less estimated blood loss, and required less blood transfusions compared to those operated with a SHS. These results are somewhat in contrast to some other studies and views advocated in the literature.[2-6]

Pain is measured differently in several studies on trochanteric hip fractures, thereby complicating the comparison of results. Nevertheless, our results seem to be in line with those from other studies. In general, no consistent or major difference in long term pain between implant groups has been found,[17,18] but for the subgroup of transverse or reverse oblique intertrochanteric fractures specifically, comparable pain scores from randomized trials are lacking. With the numbers available in this study, and the small differences in VAS pain scores, we think it is fair to state that there was no clinically relevant difference in pain between the groups. The only long term difference was found between a SHS with and without a TSP, VAS 23 and 11, respectively ($p = 0.05$). This could be explained by local pain from more protruding hardware, but a selection bias based on different fracture types within the SHS group for those receiving a TSP compared to those operated with a plain SHS, is another explanation. No significant difference in pain between the Intertan nail and the SHS including a TSP was found.

The patients' functional mobility was measured using the TUG-test, and in addition the Harris hip score was used to assess hip-function specifically. These tests showed no significant difference between the groups at any time point during follow-up. Even though the number of patients followed for 12 months was limited, and limitations to our statistical power should be considered, almost identical TUG-test and HHS results suggest that there is probably no major difference in functional outcome between the two groups. Accordingly, we could not verify that assumed differences regarding biomechanical stability between the

Intertan nail and the SHS influenced patients' mobility or hip function. No standardized assessment of hip function or patients' overall mobility has been used in the literature on trochanteric and subtrochanteric fractures, but even so, and consistent with our results, in most studies no long term difference in functional outcome has been reported, regardless of fracture type, type of outcome measure, and implant used.[17,18]

We found similar complication and reoperation rates in the two treatment groups. The numbers of patients with surgical complications were 6 and 7 for the Intertan and SHS groups, respectively, and with one exception, all of these were reoperated. There is a wide range of complication and reoperation rates reported in the literature for transverse and reverse oblique intertrochanteric and subtrochanteric fractures (0 - 56%), and our complication and reoperation rates in the range of 6 - 9% are in line with, or in the lower range of most other reports on reverse oblique intertrochanteric fractures as summarized by Chou et al.[19] Our results might indicate that modern treatment of these fractures actually gives a lower complication rate than previously reported, for the SHS operations in particular, and that no major difference between the two implants exists. Overall, this could be explained by better surgical technique, implant improvements, or the frequent use of a TSP in the SHS group. However, with 159 patients included, this study was not designed to detect differences in complication or reoperation rates. For that purpose, far more patients would have to be included. Therefore, these results should be interpreted with caution.

The association between cutout rate and the TAD has been recognized in several studies,[16,20] but despite a larger mean TAD in the SHS group in the present study, fewer cutouts occurred in that group. Still, the importance of paying attention to surgical details was confirmed also in our study. A significantly higher mean TAD was found for patients in the Intertan group with cutouts (25mm), as compared to those without a cutout (19mm). In addition, the postoperative femoral neck-shaft angle was significantly more in varus for

Intertan patients having a cutout. Probably no implant can compensate for poor fracture reduction and poor implant position.

The importance of the TSP has been questioned,[21] and its use varies in different parts of the world. However, both biomechanical testing and clinical studies have confirmed its ability to withstand dislocating forces and prevent excessive fracture impaction and medialization of the femoral shaft in unstable trochanteric fractures.[22-26] In our study, we found more patients with a femoral medialization > 10mm in the SHS group, and interestingly, the majority of the SHS patients with a medialization > 10mm (12 out of 14) were operated with an additional TSP. This, however, does not mean that the TSP is not working, but it illustrates that not all medialization can be prevented. The difference also confirms that the intramedullary position of the nail better limits the femoral shaft medialization than the laterally positioned TSP. Still, a limited number of patients and complications within the SHS group, and no randomization between SHS with or without a TSP, prevent us from drawing firm conclusions regarding the value of the TSP in the present study.

The estimated intraoperative blood loss was less in the Intertan group, and this is in accordance with several other RCTs comparing SHS and IM nails, but not all.[17] Accordingly, more patients in the SHS group received a blood transfusion (67% vs. 49%, $p = 0.027$). However, the accuracy and clinical relevance of these findings is unclear. The estimated blood loss was measured in suction and compresses, and performing a mini-invasive nailing procedure makes it difficult to assess any internal bleeding due to the surgical procedure or the fracture itself. In addition, there were no standardized criteria for when to transfuse a patient. Accordingly, our results should be interpreted with caution.

The major strength of the current study was its randomised multicenter design and the inclusion of a relatively large number of patients with these rather uncommon fractures. To

our knowledge, this is not only the first RCT comparing an IM nail and SHS for this subgroup of fractures, but also the largest number of transverse or reverse oblique intertrochanteric fractures reported in any clinical series.[19] Nevertheless, the study did not have the statistical power to draw valid conclusions regarding any potential difference in complication or reoperation rates and some other clinical outcome parameters. A more stringent adherence to the study protocol regarding implant selection would also have been desirable, and still questions regarding the usefulness of the TSP remains unanswered. Further, as no consistent fracture classification has been used in the literature, comparing our results with others' remains a challenge. Finally, this study compares the Intertan nail to the SHS, and our results do not automatically apply to other IM nails.

In conclusion, the Intertan nail and the sliding hip screw, with or without a lateral support plate, both proved to be reliable implants with favourable results in transverse and reverse oblique intertrochanteric and subtrochanteric fractures in this RCT. However, our patient numbers were too small, and the statistical power too weak, to draw definitive conclusions for this subgroup of trochanteric fractures. Accordingly, more randomised trials or register based studies are necessary to verify or challenge our findings.

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Table I. Baseline characteristics.

Patients and fractures (n = 159)	**Intertan (n = 78)**	**Sliding hip screw (n = 81)**	**p-value**
Diakonhjemmet Hospital (n = 38)	15	23	
Levanger Hospital (n = 9)	6	3	
Akershus University Hospital (n = 34)	21	13	
Vestfold Hospital (n = 30)	13	17	
Haukeland University Hospital (n = 48)	23	25	
Mean age (n = 159)	83.7	83.5	0.91*
Gender (n = 159)			0.52†
Female (%)	63 (80.8)	62 (76.5)	
ASA –class ‡ (n = 156) (%)			0.91†
ASA 1	4 (5.2)	4 (5.1)	
ASA 2	32(41.6)	37(46.8)	
ASA 3	37 (48.1)	35 (44.3)	
ASA 4	4 (5.2)	3(3.8)	
Cognitive impairment (n = 155, %)			0.18†
No	44(57.9)	57 (72.2)	
Yes	25 (32.9)	17 (21.5)	
Uncertain	7 (9.2)	5 (6.3)	
Preoperative residential status (n = 154, %)			**0.037**†
Home	48 (63.2)	58 (74.4)	
Nursing home	21 (27.6)	9(11.5)	
Other	7 (9.2)	11 (14.1)	
Mean preoperative HHS§ (n = 147)	66	69	0.31*
Mean preoperative EQ-5D$_{index}$ score (n = 142)	61	61	0.94*
Fracture type (n = 159)			0.84†
AO/OTA A3-1	19	16	
AO/OTA A3-2	21	19	
AO/OTA A3-3	31	33	
Subtrochanteric	7	13	0.22†
Preoperative mobility (n = 150, %)			0.82†
Walking outdoor alone	42 (58.3)	50 (64.1)	
Walking outdoor with living support	8 (11.1)	8 (10.3)	
Walking indoor alone, not outdoor	14 (19.4)	14 (17.9)	
Walking indoor with living support	7 (9.7)	6 (7.7)	
No walking ability	1 (1.4)	0 (0)	

* Independent samples t test. †Pearson chi-squared test. ‡American Society of Anesthesiologists classification of comorbidities. §Harris hip score (modified; no value for range of movement (max 5 points)). Statistically significant p-values in **bold.**

Table II. Primary outcomes and clinical results.

		Intertan	Sliding Hip Screw	Mean Difference (95% CI)	p-value
Pain (VAS), mean(n)					
Postoperatively	at rest	19 (61)	20 (71)	-0.2(-7.4 - 7.0)	0.96*
	at mobilization	47 (61)	52 (70)	-4.4(-13.0 - 4.1)	0.31*
3 months		24 (49)	24 (47)	-0.5(-9.4 - 8.5)	0.92*
12 months		21 (46)	19 (48)	1.6(-6.9 - 10.2)	0.71*
TUG - test postoperatively					0.98†
No of patients assessed		72/78	77/81		
Unable to perform the TUG-test, n (%)		42 (58)	46 (60)		
TUG-test performed, not passed‡, n (%)		2 (3)	2 (3)		
TUG-test performed and passed‡, n (%)		28 (39)	31 (40)		
TUG - test score, seconds (n)					
Postoperatively (TUG passed)		77 (28)	73 (31)	3.6(-22.2 - 29.4)	0.78*
3 months		31 (40)	28 (40)	3.2(-5.3 - 11.6)	0.59*
12 months		26 (34)	22 (39)	3.6(-4.5 - 11.7)	0.37*
Harris hip score§ (n)					
3 months		58 (42)	57 (31)	0.9(-7.7 - 9.5)	0.84*
12 months		63 (35)	64 (35)	-1.2(-10.9 - 8.4)	0.80*
$EQ\text{-}5D_{index}$ score# (n)					
3 months		47 (49)	49 (49)	-2.0(12.7 - 8.6)	0.71*
12 months		50 (42)	59 (47)	-8.8(-20.6 - 3.1)	0.15*
Length of postoperative hospital stay (n = 159)		7.8 days	9.0 days	-1.1(-3.6 - 1.3)	0.37*

VAS = Visual Analogue Scale. TUG - test = Timed Up and Go - test.
*Independent samples t test †Pearson chi-squared test. ‡A TUG - test of more than 3 minutes 30 seconds was considered as test not passed. §Modified Harris hip score, no value for range of movement encountered (max 5 points). 0 is the worst score, 100 the best. # EuroQol- 5Dimensions, 0 is the worst score, 100 the best possible score.

Table III. Intra- and postoperative data in the two treatment groups

	Intertan (n = 78)	**Sliding hip screw (n = 81)**	**p-value**
Intraoperative data			
Anesthesia (n, %)	n = 76	n = 81	0.52*
Spinal	66 (87)	73 (90)	
General	10 (13)	8 (10)	
Prophylactic antibiotics (n, %)	70/76 (92	80/80 (100)	**0.010***
Surgeons experience (n, %)	n = 77	n = 78	0.11*
Resident < 2 years	14 (18)	26 (33)	
Resident > 2 years	41 (53)	39 (50)	
Resident assisted by consultant	12 (16)	7 (9)	
Consultant	**10 (13)**	6 (8)	
Length of surgery (min, n)	n = 74	n = 79	
AO/OTA type A3-1	68.0 (19)	78.7 (15)	0.34†
AO/OTA type A3-2	52.1 (18)	70.3 (18)	0.09†
AO/OTA type A3-3	71.3 (30)	73.6 (33)	0.78†
All AO/OTA type A3	65.2 (67)	73.9 (66)	0.11†
Subtrochanteric	92.9 (7)	90.4 (13)	0.89†
All fractures	67.8 (74)	76.6 (79)	0.10†
Estimated external blood loss (n = 150)	238 ml	374 ml	**<0.001**†
Postoperative data			
Patients needing transfusions (n, %)	37/75 (49)	51/76 (67)	**0.027***
Hemoglobin (g/dl)			
Preoperative (n = 153)	12.2	12.0	0.34†
Lowest postoperative (n = 149)	8.9	8.6	0.12†
Length of hospital stay (n = 159)	7.8 days	9.0 days	0.37†
In-hospital postoperative deaths	4	3	0.66*
Residence after discharge (n = 147)	n = 71	n = 76	0.40*
Other hospital	9 (13%)	13 (17%)	
Rehab	13 (18%)	10 (13%)	
Home	5 (7%)	11 (15%)	
Nursing home	37 (52%)	38 (50%)	
Other	7 (10%)	4 (5%)	

*Pearson chi-squared test. †Independent samples t test. Statistically significant p-values in **bold**

Table IV. Complications and reoperations

			Intertan	**Sliding hip screw**	**p-value**
Major complication rate[*] (n, %)			6/78(8)	7/81(9)	0.83[†]
Major reoperation rate[*] (n, %)			5/78(6)	7/81(9)	0.59[†]
1 year mortality [‡] (n, %)			19/78(24.4)	23/81(28.4)	0.20 [‡]
Complications and reoperations in detail					
Patient number /implant	Fracture type	Complication	Treatment	Comments	
22 Intertan	A3-3	Nail breakage / non union	Exchange nailing (long Trigen)	Late cutout left untreated	
251 Intertan	A3-2	Cutout	Reoperated with a SHS w/TSP	Uneventful fracture healing	
264 Intertan[§]	A3-2	Poor reduction / implant position	Reoperated with a SHS w/TSP	Late cutout left untreated	
410 Intertan	A3-2	Cutout	No treatment		
647 Intertan[§]	A3-3	Poor reduction / implant position	Reoperated with long Intertan	Late cutout left untreated	
850 Intertan	A3-3	Cutout	Total hip arthroplasty		
186 SHS[§]	A3-2	"Wrong" implant, no TSP used	TSP added	Late failure and total hip arthroplasty	
215 SHS	A3-2	Failure of osteosynthesis	Reoperated with SHS w/TSP	Late failure, infection and total hip arthroplasty	
271 SHS	A3-1	Cutout	Reoperated with SHS w/TSP	Uneventful at last follow-up (3 months)	
336 SHS	Subtroch	Non-union, mechanical failure	Total hip arthroplasty		
341 SHS	A3-1	Lateral pain from TSP	Scheduled for implant removal	Uneventful fracture healing	
520 SHS[§]	A3-2	Mechanical failure / femoral fracture	Long SHS with TSP	Uneventful at last follow-up (3 months)	
527 SHS	A3-3	Non-union, failure of osteosynthesis	Hemi arthroplasty		
958 SHS[§]	Subtroch	Drain sutured	Drain removed	Uneventful fracture healing	

[*]Removal of a drain was considered a minor complication and reoperation, all other complications and reoperations were considered "major". Number of patients with complications or reoperations were counted, not total number of complications/reoperations (some patients had several).
[†]Pearson chi-square test. [‡]Kaplan-Meier analysis and log rank test. [§]Patients operated during the initial stay in hospital.

Table V. Radiographic analyses

		Intertan n (%)	**Sliding Hip Screw n (%)**	**p-value**
Postoperative fracture reduction[*]	Good	21 (28)	30 (38)	0.49[†]
	Acceptable	40 (54)	38 (48)	
	Poor	13 (18)	12 (15)	
	Total	74 (100)	80 (100)	
Shortening at 12 months	No shortening	15 (38)	22 (49)	0.53[†]
	< 10mm	18 (45)	17 (38)	
	10- 20mm	5 (13)	6 (13)	
	> 20 mm	1 (2.5)	0 (0)	
	> 30 mm	1 (2.5)	0 (0)	
		40 (100)	45 (100)	
Medialization at 12 months	<5 mm	26 (67)	23 (54)	**0.017**[†]
	5-10mm	10 (26)	6 (14)	
	>10mm	3 (8)	14 (33)	
	Total	39 (100)	43 (100)	
Postoperative tip-apex distance (TAD)[§] (n)		19mm (73)	22mm (79)	**0.001**[‡]
Femoral neck-shaft angle (n)	Postoperative	130º (75)	139º (82)	**<0.001**[‡]
	At 12 months	126º (40)	134º (44)	**0.050**[‡]

[*]The postoperative reduction was considered "good" with no more than 4 mm displacement of any fracture fragment and normal or slight valgus alignment on the AP radiograph, and less than 20 degrees of angulation on the lateral x-ray. Fractures that had either a good alignment or less than 4 mm of displacement, but not both, were rated as "acceptable". Fractures with neither criterion fulfilled were categorized as "poor". [†]Pearson chi-squared test. [‡]Independent samples t test. [§]TAD: The sum of the distance from the (superior) lag screw to the apex of the femoral head in the frontal and lateral view adjusted for magnification. Statistically significant p-values in **bold**

Figure 1

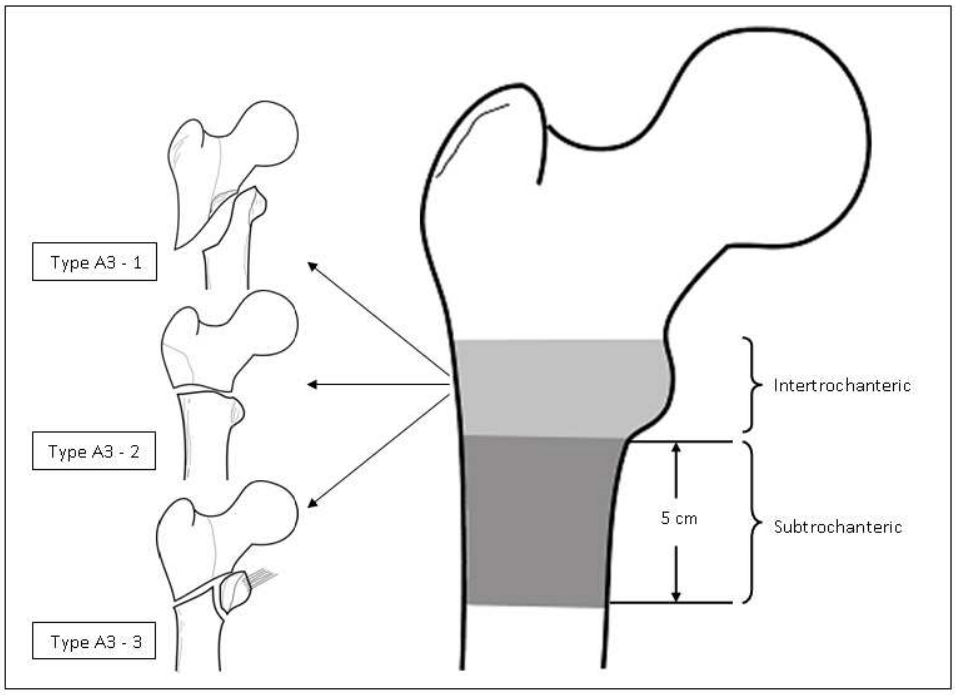


Fig. 1

Classification of intertrochanteric (AO/OTA type 31-A3) and subtrochanteric fractures.

Figure 2. Flow Chart

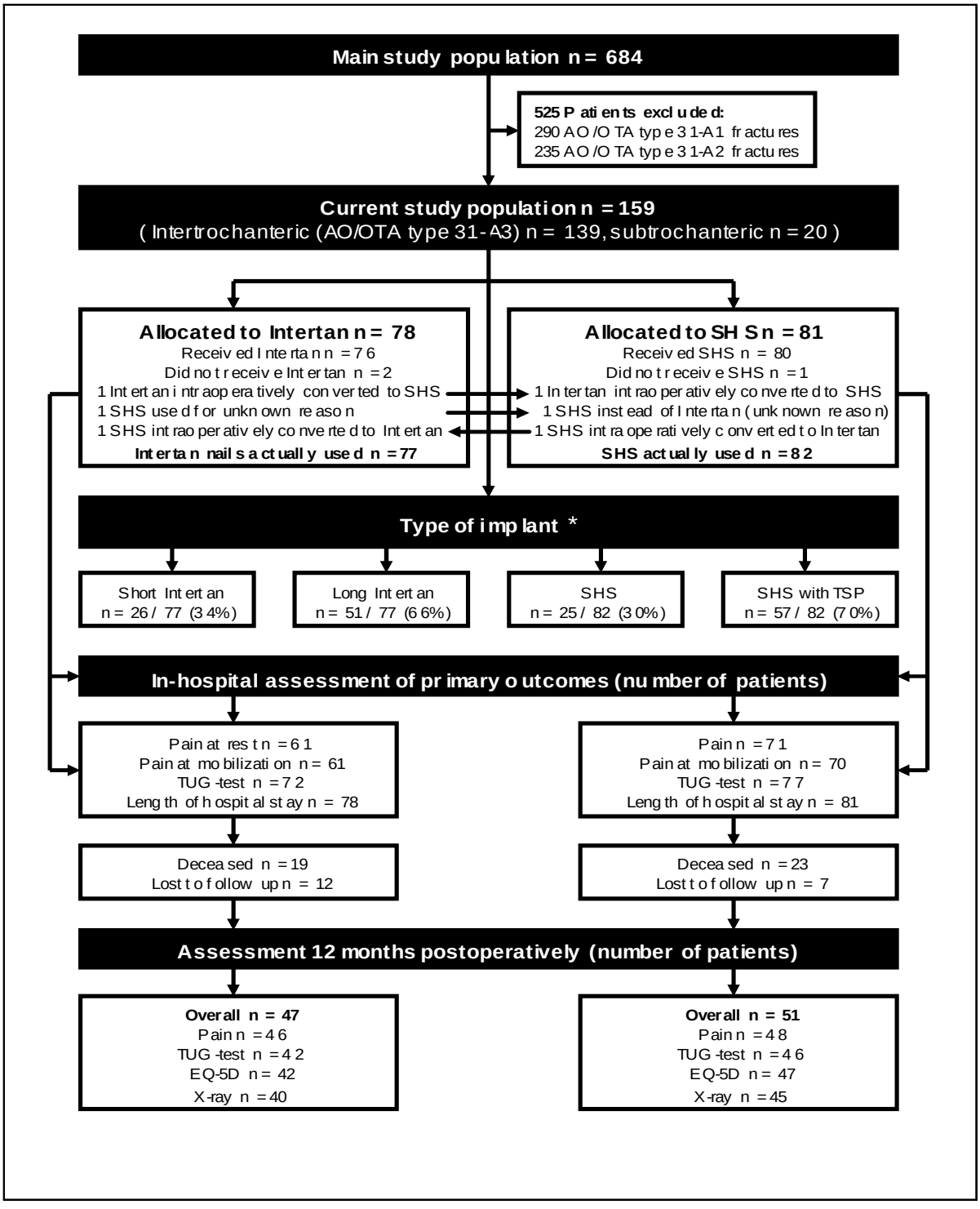
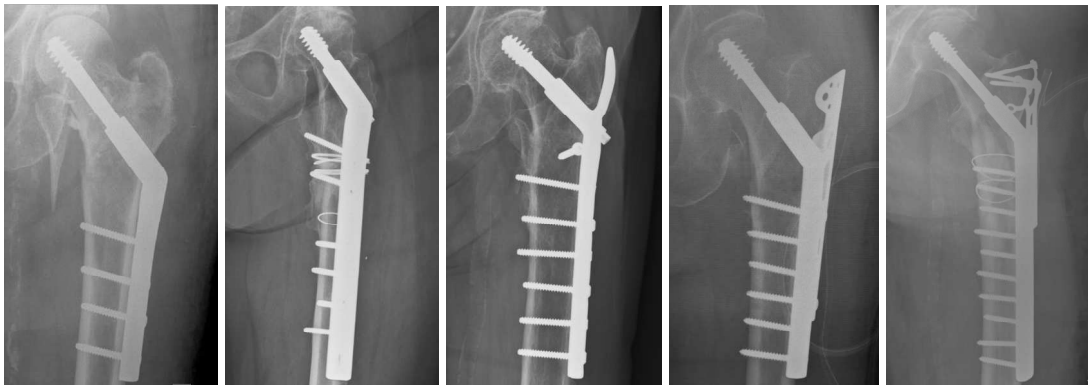


Fig. 2

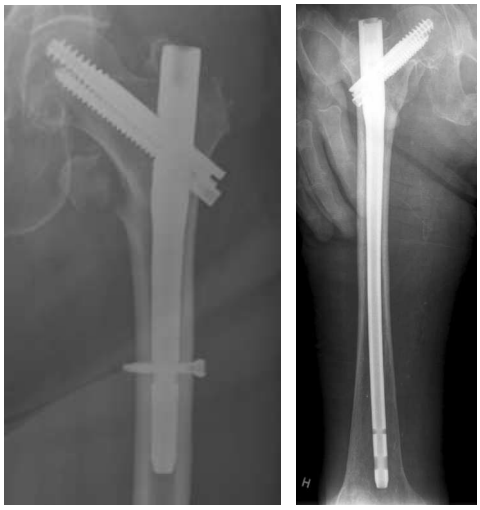
Flow chart of patients and outcome analyses according to Consort guidelines. *The distribution of type of implants is based on the actual implants used, not on the allocation of patients.

Figure 3



a) b) c) d) e)

Sliding hip screws (SHS) were used in different lengths (a, b) and with or without a trochanteric support plate (TSP). The TSP could be an integrated part of the SHS (c) or in different versions be added onto the SHS (d, e).



f) g)

Intertan nails were used in a short (f) or a long (g) version.

Fig. 3

Different implants used in the present study.