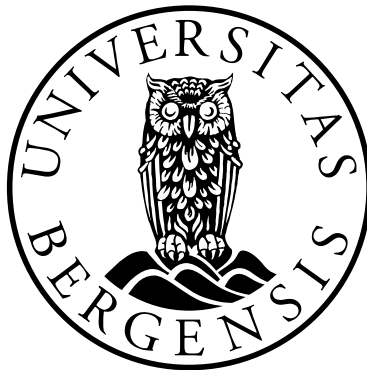


Treatment of trochanteric and subtrochanteric hip fractures

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	Arbeitsgemeinschaft für Osteosynthesefragen / 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 comorbidities
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 Kjellevoid** 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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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 Høvdig**, 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 Kjellevoid**, 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.

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Finally, I am grateful to **Annette**, my best companion and beloved wife for 23 years, for her continuous support through out my career, and for taking good care of me and our two wonderful daughters **Marianne and Kathrine**. The three of you are the spirit in my life and remind me that there are more important things in life than hip fracture science.

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 Kjellevoid, 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.

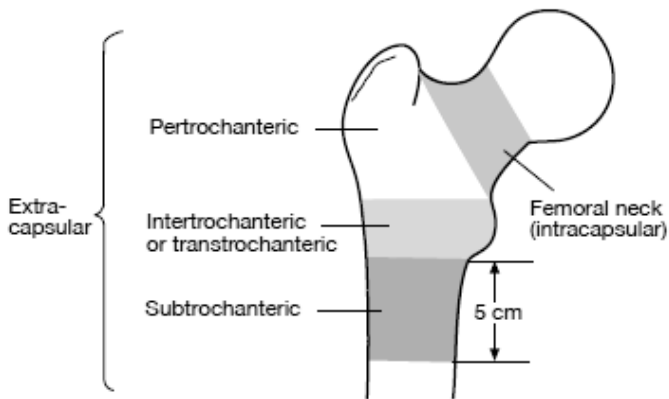


Fig 1a: Classification of hip fractures. Intracapsular = femoral neck fractures. Extracapsular = pertrochanteric, intertrochanteric, and subtrochanteric fractures.

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**).

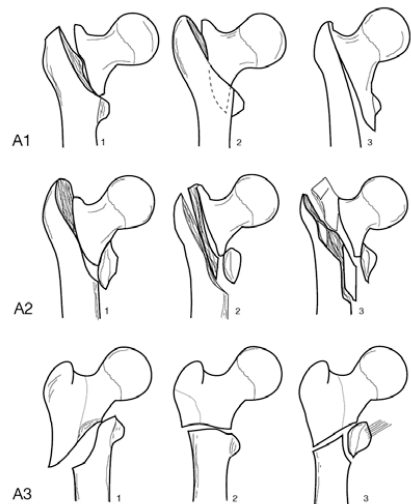


Fig 1b: AO/OTA classification of trochanteric hip fractures.

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.

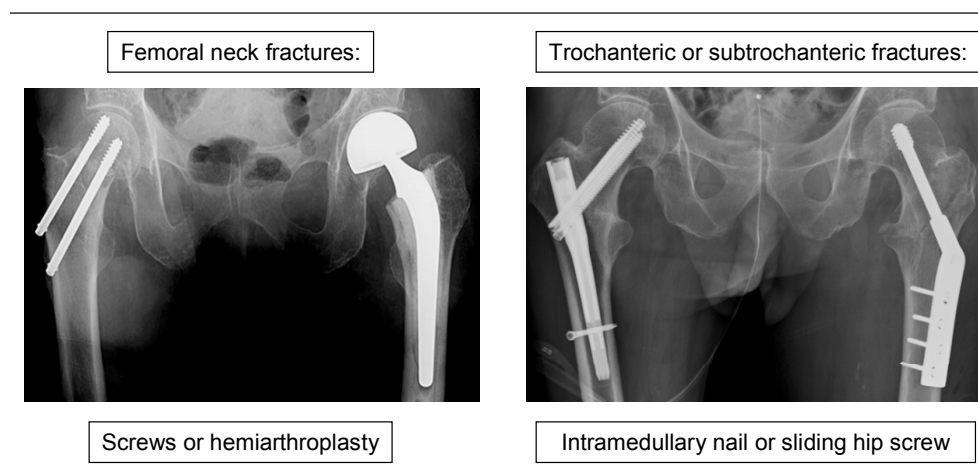


Fig 2: Common treatment options in hip fracture surgery

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 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 of 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**).

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,



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

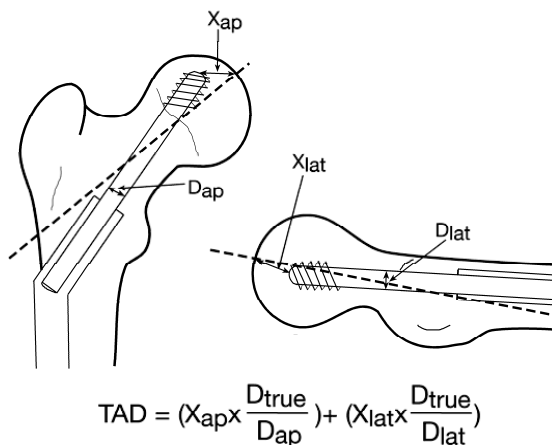


Fig 8: The tip-apex distance (TAD) according to Baumgaertner; The sum of the distance between the tip of the nail/screw and the apex of the femoral head in the frontal and the lateral plane (adjusted for magnification).

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 95° 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**.

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

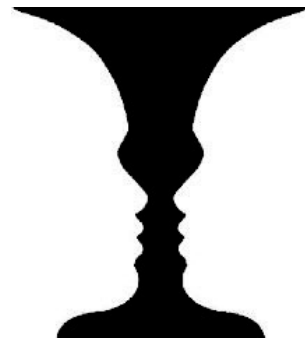


Fig 9: *Rubin's vase.*

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 multifactorial, 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 market, 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 regularly, 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:

Absence of deformity points are given if the patient demonstrates none of the listed deformities	4
- Less than 30 ⁰ fixed flexion contracture	
- Less than 10 ⁰ fixed adduction	
- Less than 10 ⁰ fixed internal rotation in extension	
- Limb-length discrepancy exceeding 3,2 cm	
Feilstillinger i <i>en</i> 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 ercm 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 NÅ:

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
-
-

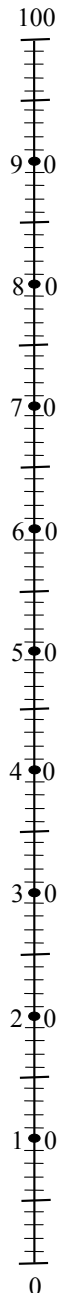
8. Din helsetilstand i dag.

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**

Best tenkelige
helsetilstand



Verst tenkelige
helsetilstand

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 trekantære brudd:

A1	A 1.1 <input type="checkbox"/> ¹	A1.2 <input type="checkbox"/> ²	A1.3 <input type="checkbox"/> ³
A2	A 2.1 <input type="checkbox"/> ⁴	A2.2 <input type="checkbox"/> ⁵	A2.3 <input type="checkbox"/> ⁶
A3	A 3.1 <input type="checkbox"/> ⁷	A3.2 <input type="checkbox"/> ⁸	A3.3 <input type="checkbox"/> 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

Retrokruvasjon: 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 Posteriert ³

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

			Superiort (AP –plan)					
Posteriert (sideplan)	1	2	3	4	5	6	Anteriort (sideplan)	
	7	8	9					

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 ”Cut-out” av skruen: Gjennom caput ¹
Bevegelse av skruen i caput ²mm

Ledd-penetrasjon/migrasjon ³

Teleskopering av skruen i collum/caput ⁴

.....mm

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

AKTUELLE OPERASJON Primæroperasjon Reoperasjon**SIDE (ett kryss)** (Bilateral opr.= 2 skjema) Høyre 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 0-6 >6-12 >12-24 >24-48 >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

ÅRSÅK 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 trochantært 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.....

ÅRSÅK 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 prominente 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.....døgnMekanisk 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 Universitetspsykiatri
 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 hemiprotese. 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 (ÅRSÅK 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 trochantært 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.....

ÅRSÅK TIL REOPERASJON (Flere enn ett kryss kan brukes)

- 1 Osteosyntesevikt/havari
 2 Ikke tilhelet brudd (non-union/pseudartrose)
 3 Caputnekrose (segmentalt kollaps)
 4 Lokal smerte pga prominierende 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, hvilken(n).....

OPERASJONSTID (hud til hud).....minutter.**SYSTEMISK ANTIBIOTIKAPROFYLAKSE**

- 0 Nei 1 Ja, Hvilken (A).....

Dose (A).....Totallt antall doser.....Varighettimer

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

Dose (B).....Totallt antall doser.....Varighettimer

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 varighetdøgnMekanisk 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 hofteprotese-registeret.

Ett skjema fylles ut for hver operasjon. Originalen sendes Haukeland universitetssjuehus 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 samtykkeklæringen 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.

DEIENS

Demens kan eventuelt testes ved å be pasienten tegne klokken når den er 10 over 11. En demens 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/doende pasient



GARDENS KLASSIFISERING AV LÅRHALSBRUDD

Garden 1: Ikke komplett brudd av lårhalsen (såkalt innkilt)

Garden 2: Komplette lårhalsbrudd uten dislokasjon

Garden 3: Komplette lårhalsbrudd med delvis dislokasjon. Fragmentene er fortsatt i kontakt, men det er feilstilling av lårhalsens trabekler. Caputfragmentet ligger uanatomisk i acetabulum.

Garden 4: Komplette 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.

REOPERASJONSÅRSÅK

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

IMPLANTAT

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

TROMBOSEPROFYLAKSE

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

FIBRINOLYSEHEMMER

Her fores det på om en benytter blodningsreducerende legemidler i forbindelse med operasjonen (f.eks. Cyklokapron).

Kontaktpersoner vedrørende registreringsskjema er:

Overlege Jan-Erik Gjertsen, Ortopedisk klinikk, Haukeland universitetssjuehus. Tlf. 55 97 56 72 (email: jan-erik.gjertsen@helse-bergen.no)

Professor Lasse Engesaeter, Ortopedisk klinikk, Haukeland universitetssjuehus. 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 Incapacitating 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)
- 6 Intertrochanteric (AO class A3)
- 7 Subtrochanteric
- 8 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 Durationdays

Mechanical pump 0 No 1 Foot 2 Leg Durationdays

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

