Hemiarthroplasty for Femoral Neck Fracture

Results of surgical approach, fixation method, and stem design reported to the Norwegian Hip Fracture Register

Torbjørn Berge Kristensen

Thesis for the Degree of Philosophiae Doctor (PhD)
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Sammendrag på norsk

Det forekommer ca. 9000 hoftebrudd hos eldre i Norge årlig. Dette er den hyppigste årsaken til akutt innleggelse i kirurgiske avdelinger i norske sykehus. Det er sannsynligvis den mest alvorlige bruddtypen som ortopeder behandler. Hoftebrudd pasienter blir innlagt hele døgnet, blir operert av både ferske og erfarne leger og representerer en høyrisiko pasient-gruppe med mange tilleggs sykdommer og gjennomsnitts alder rundt 80 år. En av fire pasienter dør innen ett år, og flesteparten oppnår ikke funksjonsnivået som de hadde før bruddet. Det er også et stort behov for rehabilitering og hjemmesykepleie etter behandling og derav høye kostnader for samfunnet. Pasienter som får komplikasjoner etter kirurgi har enda dårligere prognose og høyere dødelighet.

Hoftebrudd involverer flere typer hoftenære brudd. Denne avhandlingen konsentrerer seg om lårhalsbrudd, og spesielt de 3500 pasientene som hvert år blir operert med en delprotese etter lårhalsbrudd.

I Norge registrerer kirurgen hver hoftebruddoperasjon på et skjema som sendes til Nasjonalt Hoftebruddregister (NHBR). Dersom pasienten får en komplikasjon og må gjennomgå ny operasjon blir denne registrert på et tilsvarende skjema og koblet til den første operasjonen ved hjelp av pasientens personnummer. Hoftebruddpasientene får også tilsendt spørreskjema etter operasjonen for å svare på hvordan de har det. Dødsfall registrert i Norge kan også kobles til hofteoperasjonen.

En delprotese operasjon involverer å erstatte lårhals og lårhode med en protese. Det er i dag ikke enighet om hvilken operasjonstilgang som er best når man opererer halvproteser. Det er heller ikke enighet om man skal bruke en protese som festes med bensement eller en protese som gror fast i benet. Hvis man velger å feste protesen med bensement finnes det forskjellige design på de protesene som er på markedet i dag. Man vet ikke hvilke protesedesign som gir best resultat hos pasientene.

I denne doktoravhandlingen har vi brukt NHBR til å gi svar på problemstillingene over. Den består av tre publiserte artikler.

I første artikkel viser vi at de som er operert med en bakre kirurgisk tilgang til hoften (og svart på spørreskjema etter operasjon) har tendens til mindre smerte, mer tilfredshet, bedre livskvalitet og mindre rapporterte gangproblemer enn en kirurgisk tilgang rett fra siden. Når man skal velge kirurgisk tilgang ved halvprotese må våre resultater sees i sammenheng med andre studier som viser at den bakre tilgangen har større risiko for en fryktet komplikasjon hvor protesen går ut av ledd.

I andre artikkel finner vi at halvproteser som er festet med bensement har mindre risiko for en ny operasjon enn halvproteser som skal gro fast. Vi finner ikke forskjell i risiko for dødsfall det første året mellom metodene. Vi finner heller ikke forskjell i smerte eller livskvalitet mellom metodene for de som har svart på spørreskjema. Vi anbefaler bruk av bensement når man skal feste halvprotese etter lårhalsbrudd for å redusere fare for ny operasjon.

I tredje artikkel ser vi på forskjellig design ved de halvprotesene som er festet med bensement. Dersom man bruker en protese som er rett eller formet som lårbenet, finner vi en tendens til mindre risiko for ny operasjon sammenlignet med en glatt kileformet protese. Den glatte kileformede protesen er nesten den eneste som er registrert med ny påfølgende operasjon som følge av brudd rundt protesen. Vi anbefaler å bruke en rett eller lårbensformet sementert protese ved lårhalsbrudd for å redusere fare for ny operasjon.

Denne avhandlingen har, ved hjelp av informasjon fra pasienter operert i hele Norge, funnet ny og viktig informasjon som kan bidra til bedre operasjonsresultater ved lårhalsbrudd kirurgi i fremtiden.

Scientific environment

This PhD project was initiated in 2014 and completed while working as a resident and later as a consultant orthopaedic surgeon at the Department of Orthopaedic Surgery, Haukeland University Hospital. The project is a part of the PhD programme at the Department of Clinical Medicine, Faculty of Medicine, University of Bergen. I received a two-month scholarship from the Norwegian Arthroplasty Register in autumn 2018 to complete the last paper and finish courses in statistics.

My main supervisor for this PhD was Jan-Erik Gjertsen, MD, PhD, head of the Norwegian Hip Fracture Register and Associate Professor in Orthopaedic Surgery at the Department of Clinical Medicine, University of Bergen.

My co-supervisors were Eva Dybvik, MSc, PhD, statistician at the Norwegian Hip Fracture Register and Lars B. Engesæter, MD, PhD, Professor Emeritus in Orthopaedic Surgery.

Nasjonalt Hoftebruddregister

Nasjonalt Register for Leddproteser

HELSE BERGEN
Haukeland universitetssjukehus

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First of all, I would like to thank my colleagues and the hospital director at the Coastal Hospital in Hagevik, Kari Indrekvam, who gave me the opportunity to work at the Coastal Hospital in my final year as a medical student, and later as a resident doctor in the field of orthopaedic surgery.
After two years of work at the Coastal Hospital, I started work as a doctor in the Department of Orthopaedic Surgery at Haukeland University Hospital, and there I had the fortune to be introduced to Jan-Erik Gjertsen. At the Coastal Hospital, I had learned hip surgery using a posterior approach, and when starting as a resident at Haukeland I was introduced to the direct lateral approach to the hip, which inspired me to delve into the field of surgical approaches. This resulted in an invitation from Jan-Erik to conduct a study on surgical approaches in the Norwegian Hip Fracture Register, which soon evolved into this PhD project.

I could not have done this work on my own and would like to thank all the people who made this possible. In particular, I would like to thank:

My main supervisor, Jan-Erik Gjertsen, your academic wisdom and friendly and positive attitude made you a role model for me. Your offer to take me with you to conferences to present our work, your fast and excellent feedback on my written material and your belief in me are the main reasons why this thesis has been completed.

My co-supervisor Eva Dybvik deserves a special thank you for help with the statistics work. Your helpfulness, friendly attitude and expertise have contributed to making this possible. Thanks for your patience and for introducing me to SPSS and Cox regression analysis.

My co-supervisor Lars Birger Engesæter is a great role model, and has recently received the Order of St. Olav for his lifetime work as a researcher and one of the pioneers in the Norwegian Arthroplasty Register. I am most grateful for his advice, supervision and discussions during the entire thesis.

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A special thank you for the support from my closest family, my wife and best friend Linn-Marie, who is always the first to listen to my oral presentations. I am grateful every day for our children, Ulrik and Amalie, for reminding me of what is more important in life than work.

Contents

List of abbreviations

AA	Anterior Approaches
ASA	American Society of Anaesthesiologists
BCIS	Bone Cement Implantation Syndrome
BMD	Bone Mineral Density
BMI	Body Mass Index
CB	Composite Beam
CI	Confidence Interval
DLA	Direct Lateral Approach
EQ-5D	the five-dimensional scale of EuroQol
EQ-VAS	the Visual Analogue Scale of EuroQol
FNF	Femoral Neck Fracture
GLM	General Linear Model
HA(s)	Hemiarthroplasty(ies)
HHS	Harris Hip Score
HRR	Hazard Risk Ratio
ISAR	International Society of Arthroplasty Registers
MCID	Minimal Clinically Important Difference
N	Number
NAR	Norwegian Arthroplasty Register

NHFR	Norwegian Hip Fracture Register
NPR	Norwegian Patient Registry
PA	Posterior Approach
PASS	Patient Acceptable Symptomatic State
PJI	Periprosthetic Joint Infection
PPF	Peri Prosthetic Fracture
PROMs	Patient Reported Outcome Measures
RCT	Randomized Controlled Trial
THA(s)	Total Hip Arthroplasty(ies)
TS	Taper Slip
VAS	Visual Analogue Scale

List of publications

I Kristensen TB, Vinje T, Havelin LI, Engesaeter LB, Gjertsen JE. **Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture.** *Acta Orthop 2017; 88 (1): 29-34.*

II Kristensen TB, Dybvik E, Kristoffersen M, Dale H, Furnes O, Engesaeter LB, Gjertsen JE. **Cemented or uncemented hemiarthroplasty for femoral neck fracture? Data from the Norwegian Hip Fracture Register** *Clin Orthop Relat Res (2019). June 06, 2019 - Volume Published Ahead of Print - Issue - p doi: 10.1097/CORR.0000000000000826*

III Kristensen TB, Dybvik E, Furnes O, Engesaeter LB, Gjertsen JE. **More reoperations for periprosthetic fracture after cemented hemiarthroplasty with polished taper-slip stems than after anatomical and straight stems in the treatment of hip fractures.** *Bone Joint J. 2018 Dec;100-B(12):1565-1571.*

Abstract

Every year, more than 9000 patients undergo hip fracture surgery in Norway, and about 3500 of these receive a hemiarthroplasty (HA) for a femoral neck fracture (FNF). Despite the high number of patients and extensive research, there is still no consensus on which surgical approach, fixation method, and cemented stem design to use. Several national and international guidelines on treatment options exist, but recommendations are not consistently followed. A FNF patient in Norway has an average age of 80 years and one-year mortality is reported to be 25%. Efforts should be made to optimize treatment for this high-risk patient group. Based on data from the Norwegian Hip Fracture Register (NHFR), we have investigated whether surgical approach, method of stem fixation or type of femoral stem influenced the risk of reoperation, mortality, and patient-reported outcome measures (PROMs) in patients treated with HA.

In **Paper I**, we included patients aged 60 years and older with FNF treated from 2005 to 2014. In all, 18,918 HA procedures were reported with direct lateral approach (DLA) and 1,990 with posterior approach (PA). There were statistically significant differences in PROMs with less pain, better satisfaction, better quality of life and fewer patients having walking problems after surgery with PA than with DLA. However, using a Cox regression model adjusted for confounding variables, we found no difference in risk of reoperation between DLA and PA (HRR 1.2; 95% CI 0.9-1.4; $p = 0.2$) with DLA as reference.

In **Paper II**, a total of 7,539 uncemented HAs and 22,639 cemented HAs for FNF in patients 70 years or older treated in 2005-2017 were compared for risk of reoperation, mortality rate, and PROMs. Uncemented HAs had a higher overall risk of reoperation for any reason (HRR 1.5; 95% CI 1.4-1.7; $p < 0.001$). Although higher early mortality was found for those receiving cemented implants, no differences were found in the overall one-year mortality rate (HRR 1.0; 95% CI 0.9-1.0; $p = 0.12$). HA fixation type was not associated with differences in patients' pain (19 versus 20 for uncemented and

cemented HAs respectively, p = 0.052) or quality of life (EQ-VAS score 64 versus 64, p = 0.43, EQ-5D index score 0.64 versus 0.63, p = 0.061), one year after surgery.

In **Paper III**, the different types of cemented stems were studied. A total of 20,529 primary cemented hemiarthroplasties for FNF in patients aged 70 years or older treated in 2005-2016 were included. Polished tapered stems (n=12,064) (the Exeter and CPT prostheses), straight stems (n=5,543) (the Charnley, Charnley Modular, and Spectron EF prostheses), and anatomic stems (n=2,922) (the Lubinus SP2 prosthesis) were compared. When dividing the stems according to design, better survival for the stems with a straight design (HRR 0.66; 95% CI 0.55 to 0.79; p < 0.001) and with an anatomic design (HRR 0.74; 95% CI 0.59 to 0.93; p = 0.010) was found compared to the polished tapered stem design. Reoperation due to periprosthetic fracture (PPF) occurred almost exclusively after surgery with polished tapered stems.

In conclusion, patients operated for FNF with HA performed with a PA reported less pain, better patient satisfaction, better quality of life and fewer walking problems compared to DLA. No differences in risk of reoperation between the surgical approaches were found. Uncemented HAs had a greater reoperation risk than cemented. The fixation method did not influence pain, quality of life, or the one-year mortality rate after HA. In cemented HAs, differences in reoperation rates seemed to favour anatomic and straight stems over polished tapered stems, which had a higher risk of PPF.

1. Introduction

1.1. Importance of topic and epidemiology

Hip fractures in elderly patients are probably the most common serious fracture that orthopaedic surgeons treat (1). Hip fracture patients arrive at all hours and surgery is performed by both residents and consultant surgeons (2), involving a high-risk population that benefits from urgent surgical care (3, 4). In a general perspective, when comparing with other diseases, a woman's risk of sustaining a hip fracture is equal to her combined risk of developing breast, uterine, and ovarian cancer (1). About one out of four patients with hip fracture will not survive the first year after surgery (5-8), most patients do not regain their pre-fracture level of physical functioning, and many need to receive increased home care or be admitted to a nursing home (9, 10). These patients cost society great expense (11). Patients who fail primary surgery and need reoperation have even worse outcome and mortality rates (12-17).

In 2000, around 1.6 million hip fractures occurred worldwide, and this number has been estimated to rise to 6.3 million in 2050 (18).

In Norway, with 5.3 million inhabitants, approximately 9,000 hip fractures occur annually, which is one of the highest incidences in the world (19). Low energy hip fractures occur among older persons (Fig 1), the average age of hip fracture patients is 80 years and 70% are women (20).

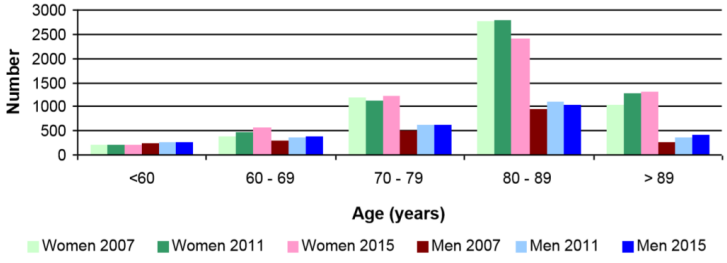

Fig. 1: Age and gender at primary operation (in 2007, 2011 and 2015). Figure from the annual report of the Norwegian Hip Fracture Register, June 2016.

Hip fractures are divided into femoral neck fractures (60%), trochanteric fractures (35%) and sub-trochanteric fractures (5%). While trochanteric and sub-trochanteric fractures have treatment options such as a sliding hip screw and intertrochanteric nails, this thesis focuses on the treatment of femoral neck fractures (FNFs) and especially the 3500 patients receiving a hemiarthroplasty for their FNF in Norway annually (8).

1.2. Pathophysiology and classification

Bone mineral density (BMD) decreases with increasing age in both genders, with an accelerated loss in women after menopause (21). Low BMD increases the risk of fracture (22). High age, female gender, increased disability, use of walking aids, and polypharmacy are factors associated with increased risk of falling (23). In the population above 65 years, every third person experiences at least one fall yearly (24). Hip fractures most commonly occur due to a simple fall from a standing position as a result of the hip and the greater trochanter hitting the floor (25-27). A fracture occurs where the greatest forces appear in the weakest part of the bone (Fig 2.). This is typically in the femoral neck (about 60% of all hip fractures).

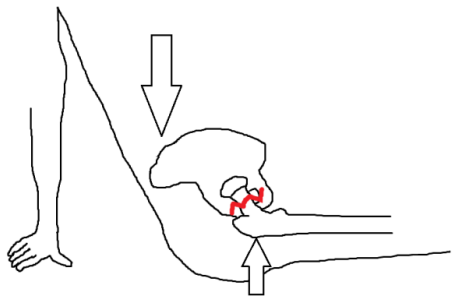

Fig. 2: Illustration of trauma mechanism for a hip fracture

A fracture of the femoral neck may reduce the blood supply to the femoral head, which is mainly provided by an anastomosis of vessels around the femoral neck (28). This complicates the healing process and increases the risk of complications such as avascular necrosis of the femoral head, non-union of the fracture, and shortening of the femoral neck with loss of offset. High risk of reoperation, ranging from 10 to 49%, is

the reason why, especially for displaced femoral neck fractures, replacing the femoral neck with a prosthesis has become the most common treatment (29-33).

The FNF is most often defined as a fracture through the intracapsular part of the femoral neck. The most commonly used classification system is still the Garden classification (34), which divides fractures into undisplaced (Garden 1 and 2) and displaced (Garden 3 and 4) (34, 35). Problems with inter-observer reliability of the Garden classification (36, 37) have led to a simplification of the classification in daily practice, dividing the fractures only into undisplaced or displaced (38-40). A weakness of the Garden classification is that it is based solely on anterior-posterior radiographs. Palm et al. (41) suggested a new measurement for posterior tilt in 2009 as reliable and able to predict reoperations after undisplaced (Garden 1-2) fractures. Dolatowski et al. reproduced these results in 2016 and found that preoperative posterior tilt of $\geq 20^{o}$ in Garden 1 and 2 fractures increased the risk of fixation failure (42). For this reason, measuring posterior tilt could be valuable in clinical practice.

The Pauwels (43) and AO classifications (44) are also described in current literature, but Pauwels classification has been found unreliable (45) and the AO classification is too complicated and has poor intra- and inter-observer accuracy (46). These classifications are not frequently used.

1.3. Treatment of femoral neck fractures

In general, all intracapsular fractures of the proximal femur in older persons should be treated surgically. In a single-centre retrospective study, patients with hip fracture who were treated non-operatively had a fourfold risk of death at one year, compared to patients who underwent surgery (33, 47). Fractures left untreated will either have an increased risk of secondary displacement, or if primarily displaced, will cause unacceptable pain, and appropriate nursing or mobilization of the patient will be difficult or impossible (48, 49). Some exceptions could be considered where patients might not survive surgery (50).

1.3.1. Undisplaced femoral neck fractures

Undisplaced FNFs can be treated with internal fixation with percutaneous screws with good results (51-54). However, a recent multicentre randomized controlled trial (RCT) suggests that patients with these fractures could achieve improved mobility and reduced risk of reoperation if treated with HA instead of screw fixation (55).

1.3.2. Displaced femoral neck fractures

Young patients with a displaced FNF may be treated with reduction and screw fixation, because of their good bone quality (54). The age at which patients cease to be "young" is usually suggested to be 60-70 years, but is still debated. One study from the Norwegian Hip Fracture Register (NHFR) reported a high failure rate of 27% after internal fixation for displaced FNFs in patients aged 55-70 (56), and one recent study from Taiwan reported 84.1% complications in displaced FNFs in patients aged 50-60 years (57), suggesting that more patients should receive an arthroplasty.

The past decade has seen a change in the treatment of FNFs from internal fixation towards more use of HA in many countries (38, 39, 58-61). HA surgery has shown superior results compared to closed reduction and screw fixation in several trials (29, 62, 63). Treatment with HA involves replacement of the femoral neck and head with a prosthesis, while keeping the acetabulum intact. The HA can be bipolar or unipolar (Fig. 3). In a unipolar HA, the head is attached to the stem by a taper locking mechanism, permitting movement only in the hip joint or in a monoblock construct. In a bipolar HA, the bipolar head is attached to a smaller prosthesis head, permitting movements in both the hip joint and between the bipolar and prosthesis heads. In Norway there has been a tradition of using bipolar HA (20).

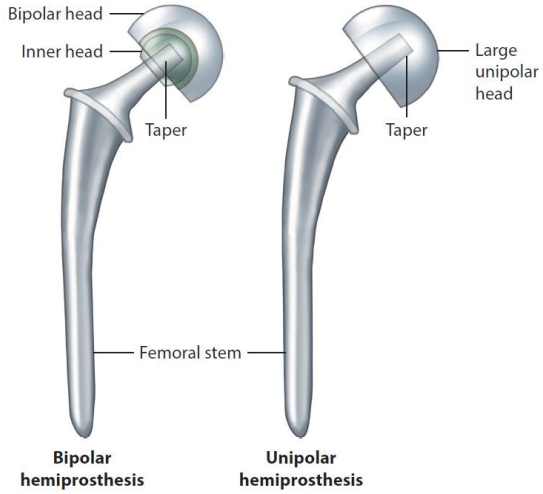

Fig. 3: Illustration of the concepts of bipolar and unipolar HA. Reprinted from Musculoskeletal Trauma in the Elderly (50) with permission from the author.

An increasing number of patients with FNF receive a total hip arthroplasty (THA) (64-66). A THA consists of replacing both the acetabulum and the femoral neck and head. This trend is supported by the literature suggesting that THA is less painful and provides better mobility and function than HA in patients who were reasonably independent and functional prior to the injury (58, 67-71). A recent propensity score-matched population-based study imply lower revision rates and lower health costs after THA than HA (72). A large, randomized trial comparing THA with HA in 1,500 patients with displaced FNF is currently ongoing, and may provide more evidence of this (73). Patients with cognitive impairment and those with reduced walking ability prior to injury are generally not included in randomized trials. This fact, combined with studies indicating higher risk of dislocation after THA (68, 71), suggests that the faster and less invasive HA is still a good option for many patients (1).

1.4. History of the hemiarthroplasty

Charles Scott Venable (1877-1963), a medical doctor specializing in surgery and gynaecology, was the first researcher who showed that electrolysis and corrosion were the principal causes of failure of metal appliances in bone. While conducting experiments, he found only one alloy among all those tested that was completely

passive (electrically inert) in the presence of body fluids, that caused no pathological changes in bone, and that was not itself corroded. This alloy, vitallium, composed of cobalt, chromium, and molybdenum, seemed so inert that he recommended its use in orthopaedic surgery (74). The most important progress for the introduction of HA in orthopaedic surgery was obtained when Austin Moore conceived a mega metal prosthesis with Bohlmann in 1940 for a patient with an FNF after a bone tumour. This prosthesis had a vitallium head. Although the patient had a fracture after the surgery, he finally recovered and after nine months was able to walk without support. The patient died two years later of heart failure and the autopsy showed a hip joint with a capsule and lining of almost normal appearance, no evidence of recurrence of the tumour, and the vitallium head appeared unaffected with no sign of corrosion. They reported the use of this HA in 1943 (74). They then refined their implant, which led to the first uncemented hip arthroplasty that was widely used (75, 76). Later, in 1950, Fredrick Röeck Thompson developed a cemented vitallium prosthesis (77). The cemented Thompson HA and the uncemented Austin Moore HA began to gain popularity in the treatment of various hip conditions, including fractures. However, the number of poor results with the Thompson and Austin Moore arthroplasties ranged from 30 to 48% (78).

The first step towards the modern bipolar HA was made by Tor Christiansen in the late 1960s (79), with a built-in trunnion bearing that allowed some movement between the stem and the head of the prosthesis. The Christiansen prosthesis was the most frequently used prosthesis in Scandinavia in the 1970s. However, acetabular protrusion (80) and poor results occurred with the Christiansen stem compared with the Charnley stem in THAs (81). The first bipolar HA was the Bateman prosthesis, introduced in 1974 (82). In a five- to ten-year follow-up study, the Bateman prosthesis for FNF reported promising results with 10% late revision, less pain and decreased protrusion compared with the Austin Moore and Thomson prostheses (83). Most implant manufacturers nowadays produce HAs with different designs and fixation methods to offer surgeons and patients around the world.

1.5. Contemporary hemiarthroplasty surgery

1.5.1 Surgical approaches

When treating patients with HA, the type of surgical approach is important. An ideal approach should prevent unnecessary devascularization and be safe and simple. It should provide satisfactory exposure to the joint and not result in unnecessary bone and soft-tissue damage in order to restore function and contribute to operative success (84). The direct lateral approach (DLA) and the posterior approach (PA) have dominated in HA surgery (85, 86). Anterior and anterolateral approaches are less frequently used, but have gained some popularity lately (20). In the transgluteal DLA, as described by Hardinge in 1982 (87), a skin incision is made directly laterally over the greater trochanter, further splitting the fascia latae, and then the anterior portion of the gluteus medius and gluteus minimus muscles is divided to give exposure to the lateral hip capsule (Fig. 4). The PA, as described by Moore in 1957 (76), after splitting the fascia latae, involves splitting the gluteus maximus in line with its fibres, followed by division of the piriformis tendon, obturator internus muscle, and gemelli tendons to give exposure to the posterior part of the joint capsule (Fig. 4). In Norway, the DLA has been the most common surgical approach (77% in 2018) when treating older patients with femoral neck fractures (20).

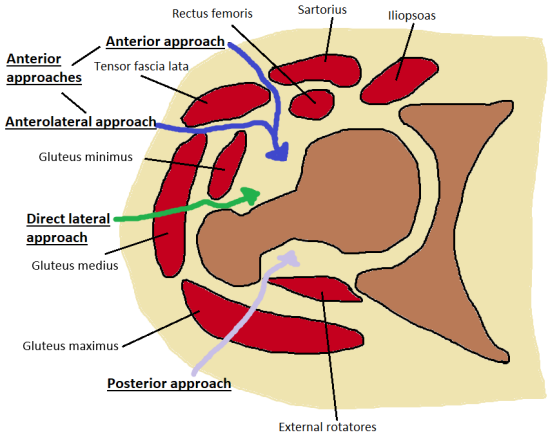

Fig. 4: Illustration of surgical approaches to the hip

One study by Parker (2015) found no difference in pain or functional outcomes among 216 patients randomized to DLA or PA (88). Rogmark and Leonardsson published a review of RCTs and register studies reporting an increased risk of dislocation with PA, and given the seriousness of dislocations they suggest that DLA is preferable (89). A recent review article by Fulham (2019) on DLA versus PA described observational studies (85, 90-92) recommending the DLA based on higher risk of posterior dislocation, but concluded that the evidence is limited and that the topic needs further investigation (93). On the other hand, Sayed-Noor reported more cases of Trendelenburg sign and limping with DLA (94), and Hongisto reported 22% of patients using crutches one year after surgery with DLA versus 12 % after PA (95), implying better walking function after PA. Further, a study by Amlie et al. on THAs reported worse PROMs after DLA than after PA (96).

Anterior approaches (AAs) in arthroplasty surgery most often refer to muscle sparing approaches like the Smith-Petersen approach (97) between the sartorius and tensor fasciae latae muscles and the Watson-Jones approach (98) between the tensor fasciae latae and gluteus medius muscles. Several articles (99, 100) and reviews (101, 102) of the AAs to the hip suggest that these are safe procedures with comparable outcome and superior early functional mobility, when compared to the DLA and PA in HA surgery. The AAs could potentially have the advantage of sparing the gluteus medius muscle, important for postoperative mobilization and walking ability, and avoiding the greater risk of dislocation of the PA. However, in studies of THA surgery, an increased risk of intraoperative fracture and femoral cutaneous nerve neuropraxia has been reported (103-105). High-quality comparative studies are needed. The AAs is probably less used due to its learning curve and surgeons' choice (106).

1.5.2. Fixation of the femoral stem

Uncemented stems have developed since Austin-Moore introduced his prosthesis and are today widely used in THA patients. Most FNF patients represent an old, osteoporotic, and fragile population. Several recently published studies have shown that stem fixation with cement has a lower risk of reoperation, especially due to fewer PPFs, compared to uncemented stems (85, 107-109). This is supported by a recently published biomechanical study on ten femurs from cadaveric specimens, showing that implanting a cemented version of the stem increases the load-to-failure force by 25% compared to implanting an uncemented stem (110). National guidelines (111-113) and a Cochrane review (114) recommend the use of cemented fixation when performing arthroplasties for hip fractures in old patients. These recommendations are not consistently followed (65, 115). Reasons could be the surgeons' or hospitals' preferred choice, shorter surgical duration with uncemented fixation or awareness of avoiding the risk of bone cement implementation syndrome (BCIS) and early death. BCIS will be further discussed in Chapter 6.6.4.

1.5.3. Cementation principles and stem design

Shen, an engineer, suggested in the late 90s (116) that cemented femoral stems could be divided into two different cementation principles. Polished stems with a wedge design using the taper-slip (TS) principle have been designed to subside inside the cement mantle to achieve an even load bearing. Anatomic and straight stems with a matt finish have been designed to become fixed in the cement mantle using the composite-beam (CB) principle (Fig. 5 and Fig. 6) (116).

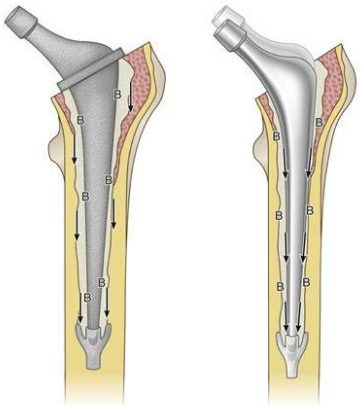

Fig. 5: Illustration of the taper-slip (TS) (left) and the composite-beam (CB) principle (right). Figure reprinted with kind permission from musculoskeletalkey.com.

Small observational studies including both HAs and THAs (117-119) and one large register study on THAs (120) have reported a higher risk of PPF with a polished TS stem than with an anatomic CB stem. A large review study by Carli et al. published in 2017 (121) investigated 596 studies on PPF in THAs. The authors defined the TS fixation as loaded taper design compared to composite beam design. They found four studies reporting higher incidence of PPF with the Exeter stem in THAs, and concluded that there is a need for register studies.

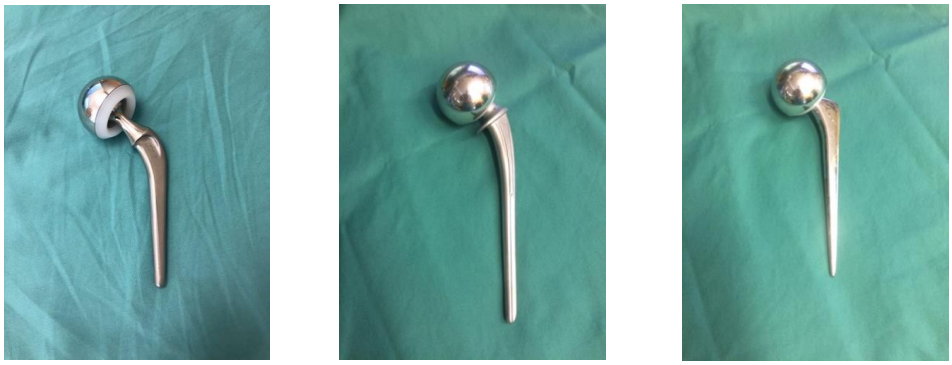

Fig. 6: Left, the matt finish, straight Charnley stem with CB principle. Middle, the matt finish, anatomic Lubinus SPII stem with CB principle. Right, the polished wedge Exeter stem with TS principle. Photo: T. Kristensen

Patients treated with HA for FNF represent an older and more comorbid population with more osteoporotic bone structure than THA patients (10), and the risk of PPF could therefore potentially be higher than for THA patients.

1.6. Complications after hemiarthroplasty surgery

The goals of HA surgery are to provide pain relief and early mobilization, and to reduce morbidity and mortality, in an old, frail population. Complications for these patients are potentially devastating and should be avoided. However, one recently performed study reported a 12% complication rate after HA surgery (122). The main reasons for reoperation are listed below:

1.6.1. Periprosthetic joint infection

Periprosthetic joint infection (PJI) after HA ranges from 1.7-7.3% (123). A PJI usually requires secondary surgery, which affects patients' pain and quality of life. One prospective study found 30-day mortality after PJI to be as high as 19%. This was significantly higher than in patients without infection (124). Guren et al. investigated 37 patients with a PJI after HA for FNF. They described very poor results for these patients with the need for new surgery. Only 15 patients became free of infection and the one-year mortality rate was 41% (125). In this high-risk patient group, low grade PJIs may also be treated only with antibiotic suppression without reoperation. However, even if the prosthesis is retained, pain and dissatisfaction could still be present.

1.6.2. Dislocation

Dislocation after HA is often serious. Blewitt et al. reported mortality after dislocation to be 65% after six months (17). Many factors can influence stability and dislocation risk after surgery. Component malposition and decreased femoral offset can result in impingement and muscular imbalance, negating the stabilizing effect of the periarticular muscles (126, 127). PA has been considered as a risk factor for posterior dislocation (85, 90-92). Medical conditions like Parkinson's disease or stroke, resulting in muscular imbalance in the hip, have been found to predispose to

instability (128). Patients unable to follow any postoperative restrictions, such as those with cognitive impairment, are also at increased risk of dislocation (126). Enocson et al. found a persistent deterioration of quality of life in patients with recurrent dislocation of their hip arthroplasty for FNF (129).

1.6.3. Periprosthetic fracture (PPF)

A PPF is a feared complication and is commonly characterized by the Vancouver classification (130). Type A fractures occur around the greater or lesser trochanter and can in most cases be treated with cerclage, a grip plate or non-operatively. Type B fractures occur around the stem and the goal of treatment is revision of loose components, accurate fracture reduction, and stable fixation with a plate, or revision arthroplasty with or without allograft. Type C fractures occur below the femoral stem and are usually treated with plate fixation (130). A higher risk of fractures with uncemented stem fixation has been described in the literature (107, 131). A recent large register study on THAs from the Swedish Hip Arthroplasty Register found 10 times higher risk of Vancouver B fractures but no statistical difference for Vancouver C fractures between an anatomic stem (Lubinus SP2) and a polished taper stem (Exeter) (132). The literature on how patients are affected following PPFs is sparse. One observational retrospective study from Spain (16) stated that only five of seventeen patients recovered to preoperative functional level following a PPF. Mortality after PPF is probably high because of extensive surgery, blood loss and immobilization.

1.6.4. Bone cement implantation syndrome (BCIS)

Bone cement implantation syndrome (BCIS), a complication during and after cementation of the femoral stem, has been thoroughly described in the literature (133, 134). The aetiology and pathophysiology are not completely understood. The main substance of bone cement is methyl methacrylate (MMA). Earlier studies have demonstrated that circulating MMA monomers cause vasodilation (135-137). However, animal studies have shown that the plasma MMA concentration after cemented hip arthroplasties is much lower than the concentration needed to cause

pulmonary or cardiovascular effects (133, 138). Other research has focused on the embolic model in BCIS. This describes both a mechanical effect and mediator release including fat, marrow, cement, air, bone particles, and aggregates of platelets and fibrin, which provokes increased pulmonary vascular tone (133). Three degrees of severity (grades 1, 2 and 3) have been described by Donaldson et al. (133); these depend on the degree of hypoxia, hypotension and the occurrence of loss of consciousness and, in severe cases, cardiac arrest. In one retrospective study of 1,016 patients, the incidence of grade 1 BCIS was found to be 21%, grade 2, 5.1% and grade 3, 1.7% (134). One recent randomized trial on cemented vs. uncemented THAs found that cemented components were associated with pulmonary hypertension with right heart negative effects, and the need for more circulatory support (139). Studies have indicated increased perioperative and early postoperative mortality after cemented fixation (140-142), which may be due to BCIS. In a large register study from the NHFR, there was one fatality due to cementation for every 116 patients treated with a cemented prosthesis, while in the most comorbid group (ASA 4 and 5) the figure was one in 33 (143). In THAs, intra-operative death is quite rare and has been reported to occur in 0.11% of patients (133). In a study including patients with and without hip fractures, it was shown that intraoperative mortality for cemented hemiarthroplasty in patients with hip fractures was 0.2-4.3%, depending on the type of fracture (141).

1.6.5. Acetabular erosion

In HA surgery, the acetabulum is not replaced, and there is accordingly a risk of acetabular erosion, especially in younger, active patients (144-146). The bipolar prosthesis design was made to prevent this complication. However, the preventive effect of a bipolar prosthesis has not been sufficiently proven in the literature (147, 148). One recent randomized controlled radiostereometric study of 19 fit older patients showed higher cartilage wear and lower EQ-5D VAS score in patients treated with a unipolar prosthesis than in those treated with a bipolar prosthesis (149).

1.6.6. Aseptic loosening

Aseptic loosening of the femoral stem may present with localized thigh pain and is often described as start-up pain, occurring in the first several steps of walking (150). In large studies of THAs, aseptic loosening often correlates with the release of micro particles which can lead to osteolysis and present itself after many years (151). Hip fracture patients are older and five-year mortality has been reported to be 63% (152). Accordingly, aseptic loosening is probably not such a problem for most hip fracture patients, with short life expectancy.

2. Aims of the study

The overall objective of this thesis was to identify surgical factors and implants associated with an unsatisfactory result in patients with femoral neck fracture receiving hemiarthroplasty in Norway by using data from the Norwegian Hip Fracture Register.

The specific aims of the three studies included in the thesis were:

Paper I: To compare patient reported outcome measures, walking ability, and reoperations after direct lateral approach and posterior approach in hemiarthroplasty for femoral neck fracture.

Paper II: To compare reoperations, mortality, and patient reported outcome measures for uncemented and cemented hemiarthroplasty for femoral neck fracture.

Paper III: To investigate whether different femoral stem designs influence risk for reoperation after cemented hemiarthroplasty for femoral neck fracture.

3. Methods

3.1. The Norwegian Hip Fracture Register (NHFR)

At the general meeting of the Norwegian Orthopaedic Association in October 2004, it was decided to establish the Norwegian Hip Fracture Register (NHFR) (8). The register is owned by the Norwegian Orthopaedic Association. Nationwide registration of hip fractures started in January 2005, where the intention was to collect epidemiological data to evaluate the results of different treatment methods for different types of hip fractures in the Norwegian population and to enable identification of implant failure after a short time. The register provides data on incidences of fracture types, treatment methods, and trends over time. The information is obtained from a paper form (Appendix I) filled in by the surgeon immediately after surgery. The form contains detailed patient information, such as the unique 11-digit Norwegian personal identification number, age, gender, comorbidity according to the classification of the American Society of Anesthesiologists (ASA), presence of cognitive impairment, time of fracture, and type of fracture. Information on time of start of surgery, type of surgery, fixation of HA, duration of surgery, surgical approach, and type of implant (identified by catalogue numbers) is also recorded.

Data collection is approved by the Norwegian Data Protection Authority based on written consent from the patients. The NHFR has high registration completeness (93%) when compared to the compulsory Norwegian Patient Registry (NPR) and the coverage of hospitals in the NHFR is 100% (153).

The NHFR presents interactive results on the following website: (https://www.kvalitetsregistre.no/registers/525/resultater). On this website, each hospital can compare its results with other hospitals on quality indicators. The NHFR also publishes an annual report on the website of the Norwegian Advisory Unit on Arthroplasty and Hip Fractures (http://nrlweb.ihelse.net/eng/). A detailed yearly report presenting individual hospital results is sent to all reporting hospitals.

3.2. Reoperation as endpoint

A reoperation in the included studies was defined as any secondary procedure performed after the primary HA operation. All reoperations are reported to the NHFR in the same way as primary operations, including closed reduction for dislocation, osteosynthesis for PPF or soft tissue debridement for infection. Reoperations are linked to the primary operation using the Norwegian personal identification number and side of operation regardless of which hospital performed the primary operation.

3.3. Patient reported outcome measures (PROMs)

PROMs paper questionnaires are sent to patients 4, 12, and 36 months postoperatively to assess pain from the operated hip using the VAS 0-100 scale (0 means no pain, 100 means unbearable pain), along with VAS satisfaction 0-100 (0 means very satisfied, 100 means very dissatisfied), EQ-VAS 0-100 (0 means poor subjective quality of life, 100 means best subjective quality of life), and EQ-5D-3L (Appendix II). The EQ-5D questionnaires comprise five dimensions (walking ability, ability of self-care, ability to perform usual activities, pain/discomfort, and anxiety/depression). An EQ-5D index score is calculated based on the 5 dimensions, and 1 indicates the best possible health state, and a score of 0 indicates a health state similar to death (154). Preoperative EQ-5D was collected retrospectively in the questionnaire sent to the patients four months postoperatively.

In **Paper I,** we evaluated particularly self-reported walking ability according to the first dimension of the EQ-5D questionnaire. We examined the percentages of patients in each surgical approach group who responded “I have no walking problems”.

3.4. Mortality

Data on death and emigration were provided by the Norwegian National Registry (155) with approval from the Norwegian Data Protection Authority. Pedersen et al. found the information on deaths in Norway to be near 100% (156).

3.5. Statistics

The Pearson chi-square test was used for comparison of categorical variables and the independent t-test (Student's test) was used to compare mean values in continuous variables in independent groups in all articles. In **Paper I**, when measuring PROMs data, p-values were calculated with general linear models (GLM) adjusted for comorbidity (ASA class), cognitive function, and fixation of prosthesis. To evaluate the patients' walking ability, the first dimension of EQ-5D-3L, describing mobility problems, was explored. Adjustments for differences in fixation technique between the two approaches could not be performed, as walking ability was a categorical variable. Therefore, separate analyses were performed for uncemented and cemented prostheses.

In **Papers I and III**, prosthesis survival and mortality were calculated with the Kaplan-Meier method. In all papers, the Cox regression model was used to calculate hazard risk ratios (HRRs) for reoperation and mortality with adjustments for age, gender, comorbidity (ASA class), cognitive function, surgical approach, and duration of surgery. Patients without reoperations were censored at time of death, time of emigration, or at end of inclusion. As death was a potential competing risk that may have influenced the accumulated probability for reoperation, regression analyses for competing risk were performed in all papers. The Fine and Gray regression model for the sub-hazard was applied (157). These results were compared with the results of the Cox proportional hazards regression model, and no important differences between the analyses were identified. Accordingly, we present results from the Cox model in our studies. Data were presented using a Cox model in line with a recently published recommendation on estimating relative revision risk from arthroplasty register data (158).

Additional analyses for patients operated bilaterally were not performed, due to a previous study that showed that adjusting for bilateral surgery would only have a negligible influence on the results (159).

The significance level was set to 0.05. The statistical analyses were performed in the statistical package IBM SPSS Statistics Version 21 in **Paper I** and 24 in **Papers II and III** (IBM Corp., Armonk, NY, USA) and the statistical package R (http://CRAN.R-project.org).

4. Summary of Papers I-III

4.1. Paper I:

Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture

Kristensen TB, Vinje T, Havelin LI, Engesaeter LB, Gjertsen JE. *Acta Orthop 2017; 88 (1): 29-34.*

Background The direct lateral approach (DLA) and the posterior approach (PA) are the most commonly used surgical approaches in Norway. Based on data from the Norwegian Hip Fracture Register (NHFR), we compared the results in terms of patient reported outcome measures (PROMs) and reoperation rate after hemiarthroplasty (HA) with DLA and PA.

Patients and methods HAs due to femoral neck fracture (FNF) in patients aged 60 years and older from the NHFR (2005-2014) were included. A total of 18,918 procedures were reported with DLA and 1,990 with PA. PROMs data (patient satisfaction, pain, quality of life (EQ-VAS and EQ-5D with walking ability)) were reported 4, 12, and 36 months postoperatively. The Cox regression model was used to calculate the hazard risk ratio (HRR) of reoperation.

Results There were statistically significant differences in PROMs data with less pain, better satisfaction, and better quality of life after surgery with PA than after surgery with DLA (Table 1). There was no difference in risk of reoperation between DLA and PA (HRR 1.2; 95% CI 0.9-1.4; P = 0.2).

Conclusion Patients operated with HA for hip fracture using a PA reported less pain, better patient satisfaction, better quality of life and fewer walking problems than patients undergoing surgery with a DLA. No difference in the risk of reoperation between the approaches was found.

Scores	Unadj. mean values DLA	PA	Adj. mean values [a] DLA	PA	Direct lateral vs. Posterior Adj. mean difference [a]	95% CI	p-value [a]
4 months							
Pain	22	20	25	23	2.2	0.53 to 3.8	0.01
Satisfaction	25	20	31	28	2.1	0.39 to 3.7	0.02
EQ-5D index score	0.55	0.57	0.45	0.47	–0.014	–0.034 to 0.008	0.2
EQ-VAS	60	61	52	53	–0.29	–2.1 to 1.5	0.8
12 months							
Pain	20	17	21	18	3.1	1.3 to 4.9	0.001
Satisfaction	25	21	27	22	4.7	2.7 to 6.7	< 0.001
EQ-5D index score	0.61	0.64	0.55	0.58	–0.030	–0.055 to –0.006	0.01
EQ-VAS	62	64	59	61	–2.1	–4.2 to –0.0	0.05
36 months							
Pain	20	16	20	17	3.1	0.41 to 5.9	0.02
Satisfaction	26	22	27	24	3.7	0.57 to 6.8	0.02
EQ-5D index score	0.61	0.66	0.56	0.60	–0.033	–0.070 to 0.004	0.08
EQ-VAS	61	65	60	63	–2.4	–5.6 to 0.80	0.1

DLA: direct lateral approach; PA: posterior approach.
[a] GLM (adjusted for differences in ASA, class, cognitive impairment, and fixation of prosthesis).

Table 1: Patient reported outcome measures. Results are presented as mean values and as mean differences between direct lateral approach (DLA) and posterior approach (PA) at the different follow-ups. Table from the original article in Acta Orthopaedica.

4.2. Paper II:

Cemented or uncemented hemiarthroplasty for femoral neck fracture? Data from the Norwegian hip fracture register

Kristensen TB, Dybvik E, Kristoffersen M, Dale H, Furnes O, Engesaeter LB, Gjertsen JE. *Clin Orthop and Relat Res (2019) June 06, 2019 - Volume Published Ahead of Print - Issue - p doi: 10.1097/CORR.0000000000000826*

Background Previous literature and national guidelines have recommended cemented fixation in arthroplasty for hip fracture in older patients, but these guidelines are inconsistently followed.

The purpose of this study was to compare the results of cemented and uncemented hemiarthroplasties (HAs) using the data in the Norwegian Hip Fracture Register (NHFR) regarding the risk of reoperation, the mortality rate, and patient reported outcome measures (PROMs).

Patients and methods Data from the NHFR with high completeness (93%) and near 100% information on deaths were used. From 2005 to 2017, 104,993 hip fractures were reported to the register. Fractures other than intracapsular femoral neck fractures and operative methods other than bipolar HA, such as osteosynthesis or total hip arthroplasty, were excluded. A total of 7,539 uncemented HAs (70% women, mean age 84 years [SD 6 years]) and 22,639 cemented HAs (72% women, mean age 84 years [SD 6 years]) were eligible for analysis. Hazard risk ratios (HRRs) on reoperation and mortality were calculated in a Cox regression model adjusted for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery. At 12 months postoperatively, 65% of patients answered questionnaires regarding pain and quality of life, the results of which were compared between the fixation groups.

Results A higher overall risk of reoperation for any reason was found after uncemented HA (HRR 1.5; 95% CI 1.4-1.7; $p < 0.001$) compared to cemented HA (Fig. 7). When assessing reoperations for specific causes, higher risks of reoperation because of PPF (HRR 5.1; 95% CI 3.5-7.5; $p < 0.001$) and infection (HRR 1.2; 95%

CI 1.0-1.5; p = 0.037) were found for uncemented HA than cemented HA. No differences were found in the overall mortality rate after one year (HRR 1.0; 95% CI 0.9-1.0; p = 0.12). The type of fixation was not associated with differences in patients' pain (19 versus 20 for uncemented and cemented HAs respectively, p = 0.052) or quality of life (EQ-VAS score 64 versus 64, p = 0.43, EQ5D index score 0.64 versus 0.63, p = 0.061) one year after surgery.

Conclusion Our study found a higher overall risk of reoperation for uncemented than cemented HA, but no differences in pain, quality of life, or one-year mortality rate. Uncemented HAs are not recommended in the treatment of elderly patients with hip fractures because of the increased risk of reoperation.

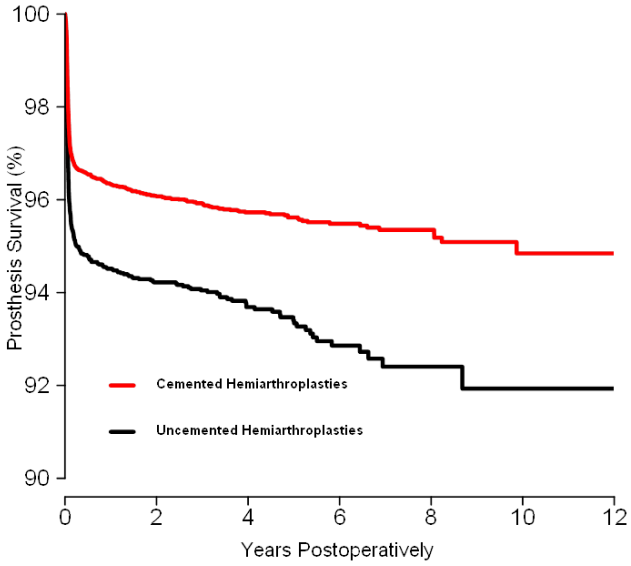

Fig. 7: Cox regression curve for prosthesis survival after uncemented and cemented HAs, with adjustments for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery.

4.3. Paper III:

More reoperations for periprosthetic fracture after cemented hemiarthroplasty with polished taper-slip stems than after anatomical and straight stems in the treatment of hip fractures

Kristensen TB, Dybvik E, Furnes O, Engesaeter LB, Gjertsen JE. *Bone Joint J. 2018 Dec;100-B(12):1565-1571.*

Background Different designs of implant are used in cemented hemiarthroplasty (HA) operations. Polished taper-slip (TS) wedge-shaped implants have been designed to subside inside the cement mantle to achieve an even load bearing while anatomical and straight stems with matt finish have been designed to be fixed in the cement mantle based on the composite-beam (CB) principle. The aim of this large register-based observational study was to compare mid-term survival rates of cemented femoral stems of different designs used in HAs for femoral neck fracture (FNF) in older patients.

Patients and methods From the Norwegian Hip Fracture Register (NHFR) 20,529 primary cemented HAs for FNF in patients aged 70 years or older treated in 2005-2016 were included in this prospective observational study. Polished TS stems (n=12,064) (the Exeter and CPT prostheses), straight CB stems (n=5,543) (the Charnley, Charnley Modular, and Spectron EF prostheses), and anatomic CB stems (n=2,922) (the Lubinus SP2 prosthesis) were included. Prosthesis survival was calculated using the Kaplan-Meier (KM) method and hazard risk ratios (HRRs) for reoperation risk were calculated with Cox regression analysis.

Results Better survival for the straight CB stems (HRR 0.7; 95% CI 0.6-0.8; $p < 0.001$) and anatomic CB stems (HRR 0.7; 95% CI 0.6-0.9; $p = 0.010$) than for the polished TS stems was found (Fig. 8). When analysing stem brands, HRR for reoperation after one year was statistically significantly lower for the Lubinus SPII (HRR 0.8; 95% CI 0.6-1.0), Charnley (HRR 0.6; 95% CI 0.5-0.9), and Spectron EF stems (HRR 0.4; 95% CI 0.3-0.7) than for the Exeter stem. Reoperation due to

periprosthetic fracture (PPF) occurred almost exclusively after surgery with polished TS stems.

Conclusion Prosthesis survival after cemented HAs for hip fractures is high. Differences in reoperation rates seem to favour anatomic and straight CB stems over polished TS stems, which had a higher risk of PPF.

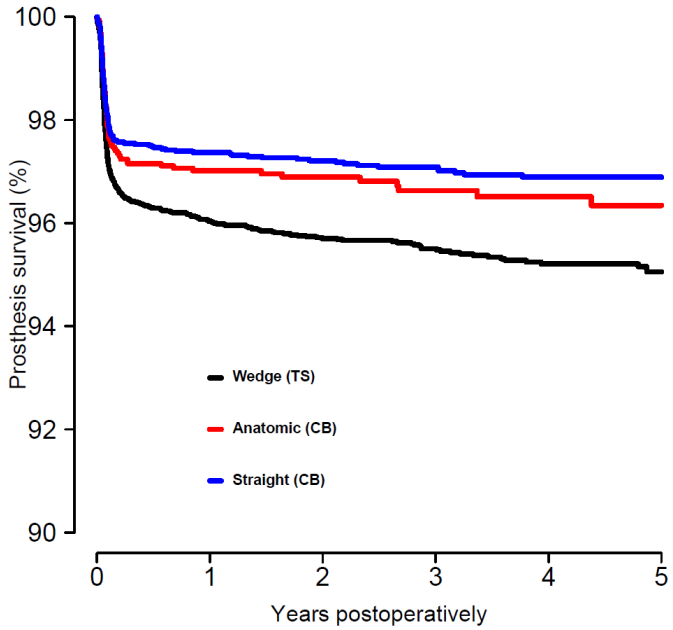

Fig. 8: Cox regression curves by design of stem. TS: taper-slip, CB: composite-beam, with adjustments for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery.

4.4. Combination of Papers II and III

The results from **Paper II** and **Paper III** can be combined to better illustrate which prosthesis stem yields less risk of reoperation. Figure 9 shows a curve with the uncemented stems from **Paper II**, combined with cemented stems from **Paper III**. The Cox regression curve is adjusted for the same factors as in **Paper III**. In the figure, the cemented straight and anatomic stems performed best, the cemented polished tapered stem had a medium performance, while the uncemented stems performed worst. The curves clearly show the superior results of all cemented stems, irrespective of design, compared to uncemented stems.

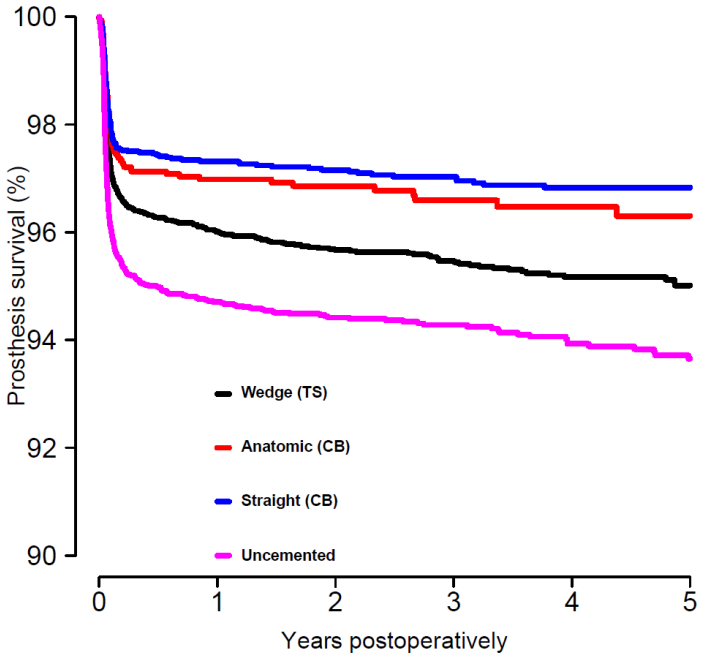

Fig. 9: Cox regression curves for reoperations for uncemented stems and different cemented stem designs, with adjustments for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery.

5. Discussion

5.1. Methodological considerations in register studies

Register research in the form of prospective observational studies is valuable in orthopaedic surgery (160). Observational studies are crucial when rare outcomes are evaluated and can be used to supplement the literature when performing an RCT is unethical or unfeasible. Understanding the strengths and limitations of register studies is, however, important.

5.1.1. Strengths of register studies

Register-based research has several strengths. First, register-based studies often have a large sample size and, accordingly, high statistical power. This enables studies of rare exposure and several outcomes. A large sample size also facilitates finding significant results earlier than in an RCT (161).

Second, in register-based studies data already exist, which makes data collection faster and less expensive to conduct (162, 163).

Third, registers are typically complete as far as the persons in the target population are concerned (162, 163) which ensures representativeness and studies of associations in the real world. As an example, a national register study reflects a broad sample of practice across an entire country, which gives the study high generalizability (external validity). The results are also likely to generalize well to practice in other countries. Since HA surgery is performed in 54 hospitals in Norway, a national register reflects the results from an average surgeon at an average hospital.

Fourth, the completeness of a register minimizes the effect of selection bias due to non-response and loss to follow up, as the oldest and frailest hip fracture patients would be at risk of not volunteering for a randomized study.

Fifth, it is a strength that the data have been collected independently of a study. As the use of an HA implant is usually regulated by tender processes in Norway, in each

hospital or ward, and not by the individual surgeon, this reduces the risk of selection bias. The fact that the information is collected prospectively, often before the project, reduces recall bias and influence of the diagnostic process determined by the study.

Sixth, in a prospective cohort, valuable time has passed; some complications after surgery manifest themselves many years after exposure and registers are especially valuable when studying complications with a long latency period.

A seventh strength in registers is the possibility to adjust for some possible confounders available in the register in risk analysis, such as age, gender, comorbidity, surgical approach and presence of cognitive impairment (162, 163).

5.1.2. Limitations of register studies

Register-based research has several important limitations that have to be taken into account when results are interpreted. First, data selection and quality in a register study are defined by the register and not controlled by the researcher, which could lead to a risk of selection bias and unrecognized confounders (164). Potential confounders not registered in the NHFR, such as smoking, drug abuse, medications, BMI, social and economic status, rehabilitation, surgeon's preferred choice of treatment and hospital routines could possibly affect bone quality, surgical method, implant choice, and complications after surgery. The possibility to adjust for these confounders is limited by the data available in the database. Not adjusting for important confounders could affect the results. This limitation, together with the fact that register-based studies often have great statistical power to detect small effect sizes, makes register-based studies prone to confounding and results must be interpreted with caution (165). When significant relationships are identified in observational studies, these are sometimes assumed to indicate causality. Because of the potential risk of confounders in observational studies, they cannot prove that an association reflects cause and effect (166). Results in observational studies are usually described as associations between the aim and the outcome. Advanced analytical techniques such as propensity score methods, introduced by Rosenbaum and Rubin (167) are one suggested way to control for treatment selection and

confounding in observational studies and have recently gained popularity in orthopaedic research (168). However, these methods do not control for unobserved variables, and accordingly, unmeasured confounding may still be present and cannot be equated with the quality of an RCT (169, 170).

Second, outcome measures in register studies are limited to the endpoints available in the database. One typical endpoint in HA studies is reoperation linked to primary surgery, using the patient's identification number. However, as an example, low-grade infections in old and frail patients may be treated with antibiotic suppression only, without reoperation, and still have an unsatisfactory pain outcome.

Third, collecting PROMs could require many reminders for patients to maintain a good response rate in trials. In a register, due to many patients and lack of resources, it may be difficult to get as high a response rate as in many randomized trials. An earlier study from the Norwegian register found that non-responders were older, more cognitively impaired, and had a higher degree of comorbidity (31).

Fourth, evaluation and validation of data quality is often difficult and a gold standard is difficult to establish (162). Data in the NHFR have been validated against the NPR (153). High registration completeness of 94% was found for primary hemiarthroplasties in 2015-2016. However, one Norwegian study has reported that re-hospitalizations due to sequelae after hip fractures might be registered in the NPR as acute hip fractures (171). In that study, an overestimation of 14% was found when comparing with electronic patient records from three hospitals. A study from the Public Health Common Dataset in the UK found a similar overestimation for hip fractures (172). Registration completeness for reoperations after HA surgery, validated against the NPR, has been found to be 66%, which is worse than for primary surgery. Imprecise coding and coding errors are more challenging in reoperations reported to the NPR and might explain this. However, there is no reason to believe there is selected underreporting of reoperations following one type of prosthesis or one surgical approach. Validation studies on reoperations reported to the NHFR against medical records are ongoing.

Fifth, the large number of available data may lead to dredging and a misleading post hoc analysis (163). This can be avoided with good planning.

Finally, in register studies with a high number of patients, even small differences may become statistically significant, without necessarily being clinically significant. This is important to be aware of when interpreting results regarding reoperations, mortality and PROMs from register-based studies.

The use of standard reporting guidelines for observational studies, such as the statements of "STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)" (173) and the "REporting of studies Conducted using Observational Routinely-collected health Data (RECORD)" (174) have been proposed to provide researchers with the minimum reporting requirements needed to adequately convey the methods and results of their research. Our studies were performed in accordance with the STROBE statement.

5.1.3. Register-based studies compared with RCTs

Randomized controlled trials (RCTs) are the gold standard and represent the strongest level of evidence when evaluating clinical research (175). In hip fracture surgery, the differences between treatment modalities may be considerable and RCTs may provide significant results favouring one surgical approach or implant. This is especially because the randomization process in these studies allows for reducing the chances of bias and confounding. As an example, Frihagen et al. published a randomized controlled study in 2007 (38) on 222 patients with FNF treated with either internal fixation or bipolar HA which changed practice, especially in Norway, to more use of HAs instead of internal fixation for FNF. However, it has been shown that observational studies can give results similar to those of RCTs if potential selection bias and confounding factors are adjusted for (175, 176).

RCTs have also some limitations. They are time-consuming, require extensive work by the researchers, and are expensive to conduct. In the field of hip fracture surgery there is a high number of implants and treatment methods available. Since an RCT can only address one or two primary outcomes, a very large number of studies would

be necessary. Randomized studies may also fail to detect even large (and clinically important) between-group differences owing to limited power, especially those pertaining to less common but still important complications. Since hip fracture patients are usually old and frail, there is a risk that only the healthiest patients would volunteer for a randomized study, and they would not be generalizable to the typical hip fracture population.

In our view, large register studies should not compete with, but supplement, the literature in addition to RCTs when evidence is sought to give hip fracture patients optimal treatment.

5.1.4. Patient reported outcome measures (PROMs) in registers

Measuring patient-reported outcomes has provided important information about outcomes that matter to patients. One example is the change from DLA to PA in THAs in Norway. DLA was until recently the most frequently used surgical approach in Norway (20). One explanation for this was the fear of dislocation when using PA. Then, an article by Amlie et al. (2014) showed better PROMs after PA in THAs than after DLA (96). These results, combined with the development and introduction of highly cross-linked polyethylene, which enables an increase in the head size of the prostheses and thereby a decrease in dislocation rates, have led to a change of practice in Norway. The annual report from the NAR describes more use of PA at the expense of DLA in recent years. The use of PROMs is therefore an important supplement to the more common endpoint of reoperation.
The International Society of Arthroplasty Registries (ISAR) Patient-Reported Outcome Measures (PROMs) Working Group was established to convene, evaluate, and advise on best practice when using PROMs (177). They published their first report in 2016 (177). This report had not been published when **Paper I** was written, but was used as a guideline in **Paper II**. When evaluating PROMs, the issues of minimal clinically important difference (MCID) and patient acceptable symptomatic state (PASS) should be taken into consideration to give PROMs a more clinically relevant meaning. MCID is defined as the smallest change in a treatment outcome that a patient would identify as important (178). PASS is defined as the highest level

of symptom beyond which patients consider themselves well (179). Thus, there is no standard MCID or PASS because these issues are specific to different PROMs, conditions, and populations (177). As far as we know, MCID or PASS criteria for patients operated for hip fractures have not been established for the PROMs we used. In **Paper 2,** instead of using an unknown PASS value, we compared the proportion of patients in each group reaching the preoperative EQ-5D score one year postoperatively as a threshold for a good surgical outcome.

5.2. Discussion of results

5.2.1. Paper I

In **Paper I,** patients operated with PA had better patient-reported outcomes after HA for FNF, when compared to DLA.

The results of PROMs data in Paper I are in line with two earlier register-based studies (96, 180) and a recent RCT (181) on THAs showing inferior PROMs with DLA (181) than with PA. In contrast, Mukka et al. found no difference in Harris hip score (HHS) or pain between DLA and PA in an observational study on 185 HAs for FNF (91). In a letter to the editor of Acta Orthopaedica, Rogmark (182) (Appendix III) questioned our conclusions on patient-reported outcomes based on the fact that the response rate of 50% in our study was rather low. At the time of this study, no guidelines on how to present PROMs from registers existed. Our results may represent the replies from a relatively healthy and cognitively fit group of patients. These patients probably also have higher functional demands and, accordingly, they will profit most from a PA. The estimated healthy and cognitively fit group of patients that were able to respond to the questionnaires at postoperative follow-up examinations may also not be the ones at risk of dislocation. When interpreting PROMs, it is also important to take MCID and PASS into consideration. Dr Söderlund wrote a letter to Acta Orthopaedica with comments on these issues (183) (Appendix IV). The MCID or PASS criteria in PROMs for patients operated for hip

fracture have, to our knowledge, not yet been established. This could be an important research task for the future.

Our data showed no statistically significant difference in risk of reoperation between the DLA and the PA. However, it is important to have possible underreporting of reoperations in mind when interpreting our results. The two groups compared were different with respect to the number of patients (1:10). This increases the risk of type II error (i.e. failure to reject a false null hypothesis). The skewed distribution in surgical approaches and fixation techniques is difficult to correct for because there was no randomization of the patients to one of the two approaches. Accordingly, if the posterior group had been larger there might have been a greater risk of dislocation and an increased reoperation rate in that group, as reported in several other studies (90, 92, 184). The phrase “seems like a safe procedure” in our conclusion could probably have been toned down.

To conclude, the decision on which surgical approach to use is not straightforward. Our data represent the average nationwide results for both reoperations and functional outcome and must of course also be balanced with other available studies to determine the true risk of reoperation and dislocation after different surgical approaches.

On the other hand, evidence today supports the use of THA in femoral neck fractures to reduce pain, and to give better function and mobility in patients who were reasonably independent and functional prior to surgery (67-69, 71, 185). One recent study using the PA shows better HHS and less dislocation after one and three years for older patients operated for FNF treated with THA with dual mobility cups compared with HA (185). Our study could lend support to the decision to use THA in patients with good function prior to injury, through a PA, and by using a dual-mobility cup to reduce the risk of dislocation (67, 185).

5.2.2. Paper II

In **Paper II**, after controlling for relevant confounding variables, our large register-based study showed a higher risk of reoperation, no differences in overall one-year mortality and similar PROMs for uncemented HA compared to cemented HA.

Our results for reoperations are supported by previous literature. Two meta-analyses of RCTs comparing cemented and uncemented HAs (186, 187) and several observational studies (107, 140, 188, 189) have reported more reoperations due to mechanical issues such as PPF and dislocation after uncemented HAs. However, in our study we found a total HRR of 1.5 for reoperations with uncemented HAs, which is lower than in an earlier study from the NHFR which showed an HRR of 2.1 (107). In **Paper III**, we compared different stem designs and found more reoperations after HAs with polished tapered stems than with matt straight and anatomic stems. The increased proportion of polished tapered stems used in later years in our material could explain why HRR was lower in **Paper II**. We also found a higher risk of infection after uncemented HA than after cemented HA. One possible explanation for more infections in the uncemented group could be that antibiotic-loaded bone cement, which protects against postoperative infection, is used in nearly all cemented HAs in Norway (20).

Even though overall mortality after one year is similar, our results concur with other studies, suggesting increased perioperative and early postoperative mortality after cemented fixation (107, 140-142). The BCIS could be a possible explanation (133, 134). A paper by Pripp et al. concluded that about half of deaths within the first day of surgery could be associated with the use of bone cement (190). Although the overall one-year mortality was not associated with any difference in mortality, we believe that increased mortality within one day of surgery should be addressed. HA surgery is performed on a large scale, by both residents and consultant surgeons, at all hours (2), in a very high number of hospitals around the world. Since uncemented stems clearly have increased reoperation rates, and the existing literature describes one-year mortality of up to 50% for the most important reasons for reoperation (16, 17, 125), an uncemented stem is probably not the solution. Also, if inexperienced

surgeons should perform HAs with uncemented stems on the patients with the highest risks, and probably the most osteoporotic bone structure, this would probably lead to even higher rates of intraoperative and postoperative PPFs. Cementing techniques to decrease the rate of fat embolism have been described, such as cleaning the femoral canal with high-pressure lavage before cementation (191), using a suction catheter, and retrograde cementation (141). The recently published safety guidelines of the Association of Anaesthetists of Great Britain and Ireland (192) should be followed when using cemented HA for hip fracture. If a high-risk patient is frail during anaesthesia, with a chance that he or she will not survive cementation, other treatment options could be possible. In these settings, good clinical judgement should be used, and there could be a place for an uncemented fixation or osteosynthesis, in a life-saving setting, for some very few patients.

In our large group of patients, similar results in PROMs could be found when comparing uncemented and cemented HAs, suggesting that the type of fixation does not affect patients' quality of life when contemporary HAs are used. One systematic review and one Cochrane review have reported less pain and better function after cemented HA than uncemented HA (193, 194). Most uncemented implants in these reviews are, however, no longer in use, and the results may not be valid for the prostheses in use today. One RCT study from 2014 with five-year follow-up comparing cemented and uncemented HAs found better Harris hip score after uncemented HA (195), but no difference in the EQ-5D index score.

Our study, with large numbers, strong methods, and high generalizability, adds important information to existing knowledge (107, 108, 140, 186-188) and national guidelines (66, 111-113), and might be used in decision- making processes to convince more surgeons to choose cemented stems.

5.2.3. Paper III

In **Paper III**, the results showed that design of the stem significantly influenced the surgical outcome. The polished tapered stems with the TS principle had a higher risk of reoperation than straight and anatomic stems with the CB principle. The most

common reason for reoperation was infection followed by luxation and PPF. PPF occurred almost exclusively after HA with polished TS stems.

A large review study by Carli et al. published in 2017 (121) investigated 596 studies on PPF after THAs. They found four studies reporting higher incidence of PPF with the Exeter stem and concluded that there was a need for register studies to enhance knowledge.

In that context, our register study on HAs supported these findings with an almost tenfold increased risk of PPF with the polished TS stems than with the straight and anatomic CB stems. Yet in our material PPFs occurred after only 0.2% of the operations. Is this rather rare complication of clinical interest? It probably is. HA surgery is performed on a large scale around the world. Other studies have reported the incidence of PPF to be 0-4%. Clinical observational studies (117, 196, 197) have a tendency to report higher incidence of rare complications than register studies (85, 118, 198). An underreporting of reoperations due to PPFs may be present in this register-based study, maybe especially in those cases where the prosthesis is retained and the fracture is treated with osteosynthesis, as are most of the Vancouver C fractures. A recent large register study from the Swedish Hip Arthroplasty Register on THAs found a ten times higher risk of Vancouver B fractures but no statistical difference for Vancouver C fractures between the anatomic Lubinus SP2 and polished tapered Exeter stem (132). This study supports the notion that underreporting of Vancouver C fractures would probably not affect the results in **Paper III**. If there is underreporting, a selected underreporting of reoperations after only one prosthesis type is unlikely, and the problem of PPF may be even greater in real life. The PPF incidence in the NHFR should be validated by evaluating medical records at representative hospitals.

Even though our paper focused on the rare PPFs, the most common reason for reoperation was infection followed by luxation. We have no good explanation as to why polished TS stems had a higher incidence of infection. Each stem was used in several hospitals, which decreases the risk that local procedures or environmental

factors influenced the results significantly. Some stems were, however, used in few hospitals and small differences in the rate of infection could be attributed to the environment of these units. Further investigation on this area is needed.

In Norway, each hospital decides which implant to use during a tender process. Consequently, many hospitals started to use the CPT implant with TS design in the last year of the study period of **Paper III**. This implant seems to perform alarmingly worse than the others. When introducing a new implant there will always be a learning curve, which could explain a higher reoperation rate at first. However, we believe that the poor results call for a discussion of the role of the tender process in forcing hospitals to use an implant that is indicated to be inferior in **Paper III**.

6. Conclusions

Paper I:

- A posterior approach in HA patients was associated with better patient reported outcome measures, including less pain, higher satisfaction and better quality of life, when compared with a direct lateral approach.

- A greater proportion of patients reported “no walking problems” after surgery with a posterior approach than with a direct lateral approach.

- No difference in reoperation rate was found between direct lateral and posterior approaches to the hip.

Paper II:

- A higher risk of reoperation was found after uncemented hemiarthroplasty compared with cemented hemiarthroplasty for femoral neck fracture.

- No difference was found in overall one-year mortality between uncemented and cemented fixation, but a higher risk of early mortality on the day of surgery and the day after surgery was found with cemented fixation.

- No difference in patient reported outcome measures between uncemented and cemented hemiarthroplasties was found.

Paper III:

- A polished taper-slip stem was associated with a higher risk of reoperation than a straight or anatomic composite-beam stem in cemented hemiarthroplasty for femoral neck fracture.

- Periprosthetic fracture occurred almost exclusively after polished taper-slip stems.

7. Future research

7.1. Anterior versus direct lateral versus posterior approach

Several articles suggest that the anterior approaches (AAs) to the hip are a safe procedure with comparable outcome and superior early functional mobility compared to the direct lateral approach (DLA) and posterior approach (PA) (99-101, 199). A future study from the NHFR could compare the DLA and PA with the AAs. This study would include more patients than **Paper I**, and add more power to the results. Probably there would also be a skewed distribution of patients with most in the DLA group. To counteract the skewness, the anterior and anterolateral approaches could be combined in one muscle-sparing group, and a propensity score matching of patients could be performed before comparing PROMs results.

7.2. Reduce risk of bone cement implantation syndrome (BCIS)

In 1984, Engesæter et al. (200) found reduced intramedullary pressure when drilling a distal venting hole in the femur prior to cementation. A German article from 1995 has also described this procedure (201). These studies have, to our knowledge, not been reproduced and could encourage further investigations on preventing the BCIS.

Our hip fracture register does not yet include information on suggested procedures to decrease the pressure when cementing, such as cleaning the femoral canal with high pressure lavage, reducing the size of the final implant to that of the last reamer, good communication with anaesthetists, and retrograde cementation. If this happens, it would provide an opportunity to assess whether these procedures prevent this rare complication.

7.3. Mechanical studies comparing the taper-slip and composite-beam principles

Few studies have investigated biomechanical failure modes. No studies, to our knowledge, have compared the TS and CB principles. One study by Ginsel et al.

compared TS-designed Exeter stems with identical length and offset, but with different cross-section size (202), and found large stems to be more resistant to torque forces for fracture. The wedge polished TS design facilitates a thicker cement mantle around the tip of the stem than the straight and anatomic CB-designed stems. Osteoporotic bone structure is generally accepted as a risk factor for PFF (203-205). A thick cement mantle and more osteoporotic bone structure in hip fracture patients could be an unfortunate combination. The CB principle with anatomic and straight stems may be more resistant to torque forces. This could be one explanation for fewer PPFs in **Paper III**. A biomechanical fracture model study comparing TS and CB principles could be interesting and might provide new knowledge.

The NHFR does not allow for the examination of x-rays. Investigating x-rays of TS stems reoperated for fracture, to look for factors like malposition or thick/thin cement mantle, could also be valuable and encourage further biomechanical studies.

7.4. Hemiarthroplasty versus total hip arthroplasty

Several articles suggest the use of THA instead of HA in displaced FNF patients, to reduce pain and enhance function and mobility (67-69, 71, 185). If dislocation can be prevented by using a dual-mobility cup (67, 185), why should not more hip fracture patients receive a THA? Observational or register studies on this research question would probably involve selection bias, where the healthiest, most active patients received a THA and the frailest patients received an HA, which would lead to the results being questioned. In an RCT, there is a risk that the healthiest patients would volunteer for the study, and they would not be generalizable to the typical hip fracture population.

To provide a solution to this, the best method could be to perform a register-based RCT (206). By using randomization in the framework of an existing clinical register to allocate treatment, it would be possible to follow the included patients within the collected register endpoints. This would result in low-cost and pragmatic prospective randomized trials that could prove causality with strong external validity.

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9. Appendices

Appendix I: Operation form from the Norwegian Hip Fracture Register (in Norwegian)

Appendix II: PROMS questionnaire (in Norwegian)

Appendix III: Correspondence in Acta Orthopaedica: Letter from Dr. Rogmark regarding Paper I

Appendix IV: Correspondence in Acta Orthopaedica: Letter from Dr. Söderlund regarding Paper I

Appendix I: Operation form from the Norwegian Hip Fracture Register (in Norwegian)

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

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

Navn:.....

(Skriv tydelig ev. pasientklistrelapp – **spesifiser sykehus**.)

Sykehus:.....

HOFTEBRUDD

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

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

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

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

BRUDD TIDSPUNKT (dd.mm.åå) |__|__| |__|__| |__|__| kl |__|__|
Dersom det er usikkerhet om bruddtidspunkt, 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

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

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

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

TYPE PRIMÆROPERASJON (Kun ett kryss)
(Fylles ut bare ved primæroperasjon - eget skjema for totalproteser)
(Fest produktklistrelapp på baksiden eller spesifiser nøyaktig produkt)
☐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 trokantær 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 og katalognummer.....

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

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

Navn / størrelse og 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 Fremre (mellom sartorius og tensor)
☐2 Anterolateral (mellom gluteus medius og tensor)
☐3 Direkte lateral (transgluteal)
☐4 Bakre (bak gluteus medius)
☐5 Annet, spesifiser.....

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

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

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

ANTIBIOTIKAPROFYLAKSE ☐0 Nei ☐1 Ja

	Navn	Dosering	Varighet i timer
Medikament 1			……timer
Medikament 2			……timer
Medikament 3			……timer

TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja: Første dose ☐1 Preoperativt ☐2 Postoperativt

Medikament 1 ..... Dosering opr.dag.....
Dosering videre ..... Varighet ..... døgn

Medikament 2 ..... Dosering ..... Varighet ..... døgn

FAST TROMBOSEPROFYLAKSE
☐0 Nei ☐1 Ja, type: .....

FIBRINOLYSEHEMMER
☐0 Nei ☐1 Ja, medikament : ..... Dosering .....

OPERATØRERFARING
Har en av operatørene mer enn 3 års erfaring i hoftebruddkirurgi? ☐0 Nei ☐1 Ja

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

Appendix II: PROMS questionnaire (in Norwegian)

NASJONALT HOFTEBRUDDREGISTER
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PASIENTSPØRRESKJEMA NASJONALT HOFTEBRUDDREGISTER

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:_____

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I de neste 5 spørsmålene ønsker vi å vite hvordan livssituasjonen din var FØR du fikk hofte/lårhalsbruddet som du ble operert for.

3. Hvordan opplevde du gangevnen din?

- ☐ [1] Jeg hadde ingen problemer med å gå omkring
- ☐ [2] Jeg hadde litt problemer med å gå omkring
- ☐ [3] Jeg var sengeliggende

4. Hvordan klarte du personlig stell?

- ☐ [1] Jeg hadde ingen problemer med personlig stell
- ☐ [2] Jeg hadde litt problemer med å vaske meg eller kle meg
- ☐ [3] Jeg klarte ikke å vaske meg eller kle meg

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

- ☐ [1] Jeg hadde ingen problemer med å utføre mine vanlige gjøremål
- ☐ [2] Jeg hadde litt problemer med å utføre mine vanlige gjøremål
- ☐ [3] Jeg var ute av stand til å utføre mine vanlige gjøremål

6. Smerter eller ubehag?

- ☐ [1] Jeg hadde verken smerte eller ubehag
- ☐ [2] Jeg hadde moderat smerte eller ubehag
- ☐ [3] Jeg hadde sterk smerte eller ubehag

7. Angst eller depresjon?

- ☐ [1] Jeg var verken engstelig eller deprimert
- ☐ [2] Jeg var noe engstelig eller deprimert
- ☐ [3] Jeg var svært engstelig eller deprimert

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Haukeland Universitetssykehus
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5021 BERGEN

I de 5 neste spørsmålene ønsker vi å vite hvordan livssituasjonen din er NÅ:

8. 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

9. 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

10. 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

11. Smerter eller ubehag?

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

12. Angst eller depresjon?

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

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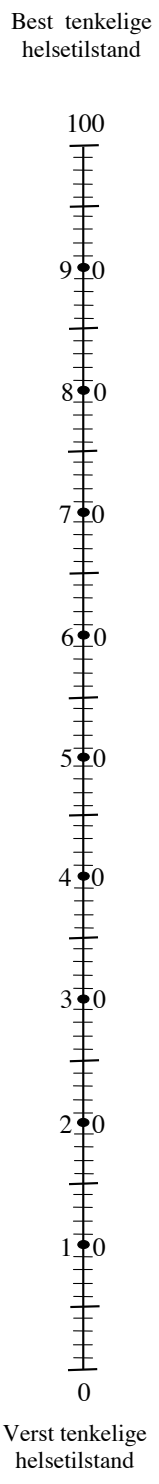
13. Din helsetilstand i dag.

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



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SMERTE

14. Sett ett kryss på den streken som du synes tilsvarer din gjennomsnittlige smerteopplevelse fra den opererte hoften den siste måneden:

Ingen smerte — Maksimal smerte

lett | moderat | middels | sterk | uutholdelig

TILFREDSHET

15. Sett ett kryss på den streken som du synes tilsvarer hvor fornøyd du er med operasjonsresultatet:

Fornøyd — Misfornøyd

svært fornøyd | fornøyd | middels fornøyd | misfornøyd | svært misfornøyd

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16. Har du besvær fra den andre hoften?

☐ 1 Ja ☐ 2 Nei

17. Er det andre årsaker til at du har problemer med å gå?
(For eksempel smerter fra andre ledd, ryggsmerter, hjerte-karsykdom eller andre sykdommer som påvirker gangevnen din)

☐ 1 Ja ☐ 2 Nei

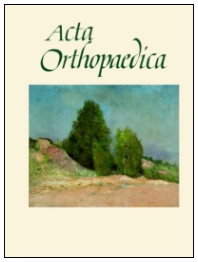
18. Har du hatt nye operasjoner i den samme hoften som ble operert for hoftebrudd?

☐ 1 Ja ☐ 2 Nei

Takk for at du tok deg tid til å svare på spørsmålene. Dine svar er svært nyttige for oss. Vennligst send spørreskjemaet i retur til oss i den ferdig frankerte svarkonvolutten.

Appendix III: Correspondence in Acta Orthopaedica:
Letter from Dr. Rogmark

regarding Paper I



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Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture

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Correspondence

Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture

Sir,—The efforts of the Norwegian Hip Fracture Register (NHFR) to track hip fractures and gain patient-reported outcome data from a national cohort is praiseworthy. The current study (Kristensen et al. 2016) adds new and interesting knowledge on patient-reported outcome related to surgical approach in hemiarthroplasty cases.

Nevertheless, two aspects may be discussed: That the reoperation risk is said to be similar with both approaches and that the conclusions on patient reported outcome is drawn from half of the patients answering.

Dislocation is more frequent after posterior approach in fracture cases compared to after direct lateral approach (Enocson et al. 2008, Abram and Murray 2015), which the authors avoid to elaborate on. These clinical studies have read hospital records to note the true incidence of dislocations. It is not clear how the study by Kristensen et al. defines "reoperation". They use the terms reoperation, revision, and implant survival interchangeable. According to the Annual Report of the NHFR (http://nrlweb.ihelse.net/Rapporter/Rapport2016.pdf), 356 reoperations due to dislocation were reported after approximately 31,000 primary fracture arthroplasties, i.e. a dislocation rate of 1.1%. Of these 129 were closed reductions. The completeness of reoperation reporting must be questioned. Hence, Kristensen et al. underestimate the dislocation risk. In addition they found "more reoperations after the posterior approach than after the direct lateral approach", but conclude that posterior approach is a "safe procedure".

Dislocation is painful and stressful for an elderly individual. Furthermore, only half of the hemiarthroplasty patients remains stable after the first dislocation (Enocson et al. 2008, Abram and Murray 2015) and recurrent dislocations lead to a permanent loss of health-related quality of life (Enocson et al. 2009). It is, together with infection, the most common complication in fracture-arthroplasty cases and should be prevented.

Better function and less pain favor the posterior approach. However, this is true only for the 50% of the patients in the study that managed to answer the PROM questionnaires. An analysis of non-responders in the current study is lacking, but referring to an earlier study these are said to be older, with more cognitive impairment and comorbidity. Hence, the result of the Kristensen et al. study is assumingly applicable to the healthier segment of fracture patients but cannot guide us regarding the functionally not so demanding, "old old" and frail individuals. For them, the increased risk of dislocation may outweigh any subtle patient-reported benefits.

To summarize, the article does not tell the whole story about outcome related to surgical approach in hip fracture patients, and should therefore be interpreted with much caution.

Cecilia Rogmark

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The Swedish Hip Arthroplasty Register, Gothenburg, Sweden
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Sir,—We thank dr Rogmark for her response to our article (Kristensen et al. 2016). Dr Rogmark questions two important aspects of our conclusions which we aim to address below.

Firstly, regarding risk for reoperation, we were not able to find any statistically significant difference in risk for reoperation between the direct lateral and the posterior approach in our data. All reoperations, also closed reduction of dislocated hemiarthroplasties and soft tissue debridement for infections, should be reported to the Norwegian Hip Fracture Register (NHFR). We are aware that reoperations are probably underreported to the NHFR, but we have no indications that differences in the reporting of reoperations between the two treatment groups exist. Accordingly, the relative difference should be the same. It is of course important to have the possible underreporting of reoperations in mind when interpreting our results. We do agree that the "reoperation" term could have been defined more exact in our article and that the terms "prosthesis survival" and "hemiarthroplasty survival" are somewhat misleading and should have been replaced by "percent not reoperated".

The increased risk of dislocation after the posterior approach found in other studies was discussed in our study by referring to the study by Rogmark et al. (2014) reporting a doubled risk of dislocations after posterior approach compared to direct lateral approach. Other studies have also reported more dislocations after posterior approach (Enocson et al. 2008, Abram and Murray 2015). These results are alarming, as dislocation

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of a hemiarthroplasty clearly is a feared and devastating complication. Our conclusion that the posterior approach seems to be a safe procedure was based on our data. However, our data must of course also be balanced with other available studies to determine the true risk for reoperation and dislocation after different surgical approaches.

Secondly, regarding patient reported outcome, taking the patients' age and comorbidity into account our completion rate of 50% is as expected. We agree with dr Rogmark that our results may represent the answers from a relative healthy and cognitive fit group of patients. These patients probably also have higher functional demands and, accordingly, they will profit most on a posterior approach. Patients that are able to respond to the questionnaires at postoperative follow-up examinations may also be able to follow restrictions after surgery. This may reduce their risk of prosthesis dislocation. For these patients a posterior approach could be an option.

To conclude, the decision on which surgical approach that should be used is not straight forward. Our data represent the average nationwide results regarding both reoperations and functional outcome. For the individual patient both risk for complications and the expected functional outcome must be taken into consideration. Our results may contribute in this demanding decision-making process.

Torbjørn Kristensen, Tarjei Vinje, Leif I Havelin, Lars B. Engesæter, Jan-Erik Gjertsen

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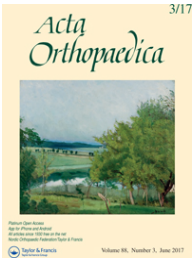
Rogmark C, Fenstad A M, Leonardsson O, Engesaeter L B, Karrholm J, Furnes O, et al. Posterior approach and uncemented stems increases the risk of reoperation after hemiarthroplasties in elderly hip fracture patients. Acta Orthop 2014; 85 (1): 18-25.

Appendix IV: Correspondence in Acta Orthopaedica:
Letter from Dr. Söderlund

regarding Paper I



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Correspondence

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Correspondence

Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture

Sir,—With interest I read the article ”Posterior approach compared to direct lateral approachresulted in better patient-reported outcome after hemiarthoplasty for femoral neck fracture” by Kristensen et al. (Acta Orthop 2017; 88(1): 29-34). As I use direct lateral approach in hemiarthroplasty I was interested whether it is time to begin using posterior approach instead. The title and abstract suggest a major difference between the two approaches. However, the data shown does not support the conclusions.

The reported differences in the article between the approaches in the pain (VAS, 100 mm-scale) at any time are between 2.2 and 3.1 mm. This difference reached statistical significance even after adjustment for ASA, cognitive impairment and fixation of protheses. The reported minimal clinically important difference (MCID) for VAS is estimated to be 14 mm (Tashjian et al. 2009), thus the difference is clinically insignificant. Patient acceptable symptomatic state (PASS) score for VAS (100 mm-scale) is 30 mm (Paulsen et al. 2014). The patients having VAS below 30 mm consider themselves well. Thus, there was no clinically significant difference between the two approaches.

The MCID and PASS values are 0.31 and 0.92 for EQ-5D and 23 and 85 for EQ-VAS (Paulsen et al. 2014). The EQ-5D scores in both groups were (at any postoperative time point) below 0.92 and the adjusted difference between the groups was less than 0.31. For EQ-VAS the values were below 85 mm and the difference between groups less than 3 mm. Thus, the difference between two approaches was clinically insignificant.

When analysing large dataset, such as in the study by Kristensen et al., even small differences reach statistical significance. It is therefore important to estimate whether the difference is also clinically significant. In light of the above, I feel that the title as well as the conclusions of the study are incorrect and misleading.

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Another Correspondence regarding this article was published in Acta’s April issue: Rogmark C. Acta Orthop 2017; 88 (2): 234-5

Sir,—We thank dr Söderlund for his response to our article (Kristensen et al. 2017). Dr Söderlund comments on the issues of minimal clinically important difference (MCID) and patient acceptable symptomatic state (PASS). In light of his comments we want to clarify some important aspects of MCID and PASS.

Firstly, MCID has, in orthopedic literature, most commonly been used to determine the clinical importance of treatment for conditions with chronic pain (rheumatic disease, osteoarthritis, shoulder- or back pain) by analyzing changes in patient reported outcome measures (PROMs) based on pre- and postoperative collected data (Dworkin et al. 2008, Tashjian et al. 2009, Paulsen et al. 2014, Katz et al. 2015). Our study is not evaluating changes in PROMs over time as a result of the hip fracture, but compares the outcome after surgery for hip fracture patients treated with two different surgical approaches.

Secondly, when analyzing differences in PROMs between groups, like in our study, the MCID for individuals cannot be directly applied to the evaluation of clinically important group differences (Dworkin et al. 2008, Glassman et al. 2008, Katz et al. 2015). “*It should not be inferred that the difference between the 2 groups must be larger than the MCID before the treatment benefit in one group can be considered clinically important. Even if the difference between the 2 groups is smaller than the MCID, there could be a sizable percentage of patients in one of the groups who reports a clinically important better outcome”* (Dworkin et al. 2008).

One recommended way to determine treatment effectiveness to compare the effectiveness of two treatments in clinical trials by using MCID is to calculate the proportion of patients in each treatment group that meet the MCID, defined as individual patients for whom the difference between pre- versus post-treatment pain score is equal to or greater to the MCID threshold. Then, the treatment groups can be compared for the proportion of patients who meet the MCID using a standard statistical method (Katz et al. 2015). In our material we unfortunately don’t have pre-treatment PROM score to do these calculations for all outcomes. One alternative way could be to calculate the proportion of patients in each group who has reached a PASS (Fekete et al. 2016). However, as hip fracture patients are old and frail, very few patients will report PROMs higher than the PASS values mentioned by Dr Söderlund. These values were calculated after elective total hip arthroplasty surgery (Paulsen et al. 2014). Hip fracture patients, representing an older and frailer patient group, may be inclined to

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accept a lower functional state than these PASS values. Katz et al. (2015) do clearly recommend to use benchmarks for clinical improvement derived from the same patient group as they are applied on. As long as we know, PASS- criterion for patients operated for hip fractures are not determined.

We are aware of the small differences in our study between the surgical approaches. Still, all PROMs after 4, 12, and 36 months including walking ability, were consistently better for the posterior approach, and is reason for the abstract and title. The walking ability is a dichotomous variable and can accordingly not be evaluated by MCID and PASS.

The aim of our article was not to give an absolute recommendation on which surgical approach to use, but our results may contribute in the decision making process.

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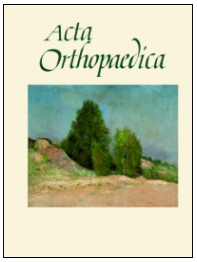
Paper I



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Posterior approach compared to direct lateral approach resulted in better patient-reported outcome after hemiarthroplasty for femoral neck fracture

20,908 patients from the Norwegian Hip Fracture Register

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Background and purpose — Hemiarthroplasty (HA) is the most common treatment for displaced femoral neck fractures in many countries. In Norway, there has been a tradition of using the direct lateral surgical approach, but worldwide a posterior approach is more often used. Based on data from the Norwegian Hip Fracture Register, we compared the results of HA operated through the posterior and direct lateral approaches regarding patient-reported outcome measures (PROMs) and reoperation rate.

Patients and methods — HAs due to femoral neck fracture in patients aged 60 years and older were included from the Norwegian Hip Fracture Register (2005–2014). 18,918 procedures were reported with direct lateral approach and 1,990 with posterior approach. PROM data (satisfaction, pain, quality of life (EQ-5D), and walking ability) were reported 4, 12, and 36 months postoperatively. The Cox regression model was used to calculate relative risk (RR) of reoperation.

Results — There were statistically significant differences in PROM data with less pain, better satisfaction, and better quality of life after surgery using the posterior approach than using the direct lateral approach. The risk of reoperation was similar between the approaches.

Interpretation — Hemiarthroplasty for hip fracture performed through a posterior approach rather than a direct lateral approach results in less pain, with better patient satisfaction and better quality of life. The risk of reoperation was similar with both approaches.

During the past decade, there has been a change in the treatment of femoral neck fractures from internal fixation to more use of hemiarthroplasty (HA) in many countries (Parker et al. 2002, Keating et al. 2006, Frihagen et al. 2007, Gjertsen et al. 2010, Stoen et al. 2014). One important issue when treating patients with HA is the type of surgical approach. Two different surgical approaches have predominated. In the transgluteal direct lateral approach, as described by Hardinge (1982), the anterior portion of the gluteus medius and minimus muscles is divided. The posterior approach, as described by Moore (1957), involves division of the piriformis, obturator internus muscle, and gemelli tendons. In Norway, the direct lateral approach has been the most common surgical approach when treating elderly patients with femoral neck fractures (Havelin et al. 2016).

For total hip arthroplasty (THA) in osteoarthritis patients, one recent study by Amlie et al. (2014) found worse patient-reported outcome with lower quality of life, more pain, and more limping after the direct lateral approach compared to the posterior approach. To our knowledge, patient-reported outcome measures (PROMs) for the different surgical approaches when treating hip fracture patients with hemiarthroplasty has not been thoroughly investigated. However, in a recently published study by Parker (2015), no significant difference in pain or functional outcomes could be found in 216 patients who were randomized to the lateral or posterior approach.

With this background, we compared the results of the posterior surgical approach and the direct lateral approach regarding patient-reported outcome and reoperation rate in a national setting using data from the Norwegian Hip Fracture Register (NHFR).

Patients and methods

Study design

The NHFR has registered hip fractures on a national basis

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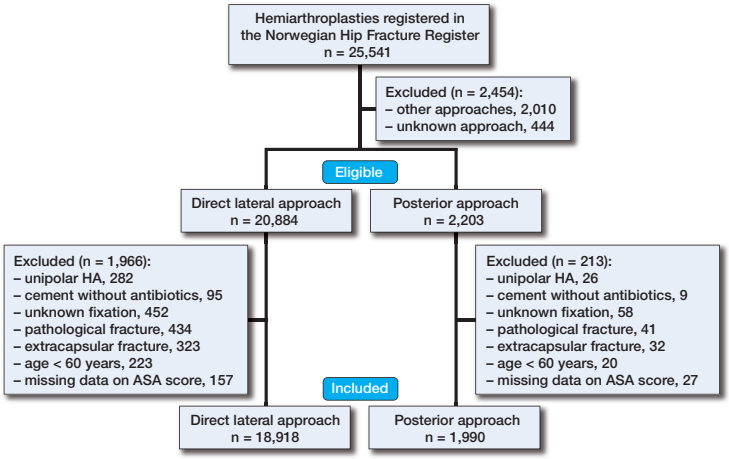

Figure 1. Flow chart of study.

since 2005. After each primary operation or reoperation, the surgeon fills out a paper form that is sent to the registry. The completeness for primary hemiarthroplasty operations in the NHFR was found to be 91% (Havelin et al. 2016). Comorbidity was classified according to the ASA classification. Cognitive impairment was classified as present, not present, or uncertain status. Follow-up questionnaires used for assessing VAS pain from the operated hip (0–100 with 0 meaning no pain and 100 meaning unbearable pain), VAS satisfaction (0–100 with 0 meaning very satisfied and 100 meaning very dissatisfied), EQ-VAS, and EQ-5D-3L were distributed to the patients 4, 12, and 36 months after surgery. The EQ-5D questionnaire has 5 dimensions (walking ability, ability regarding self-care, ability to perform usual activities, pain/discomfort, and anxiety/depression). Preoperative EQ-5D scores were collected retrospectively 4 months postoperatively. We evaluated self-reported walking ability according to the first dimension of the EQ-5D questionnaire in particular. To calculate the EQ-5D index score, a European VAS-based value set was used (Greiner et al. 2003).

Patients

On December 31, 2014, a total of 25,541 hemiarthroplasties performed for a hip fracture had been registered in the NHFR. All patients who had undergone hemiarthroplasty surgery through a direct lateral or posterior surgical approach were selected. To have a homogenous group, patients with unipolar prostheses, with cemented prostheses fixed with non-antibiotic-loaded cement, with pathological fractures, with extracapsular fractures, operated with surgical approaches other than posterior or direct lateral, and patients who were < 60 years old were excluded (Figure 1). After exclusion, 20,908 patients remained for analysis. The direct lateral approach group had 18,918 patients and the posterior approach group had 1,990 patients. The patients included had been operated in 52 different hospitals. 36 of these hospitals used one specific approach (direct lateral or posterior) in more than 90% of the operations.

Statistics

PROM data (satisfaction, pain, and quality of life (EQ-5D)) were analyzed and compared between the 2 groups 4, 12, and 36 months postoperatively. The p-values were calculated with general linear models (GLMs) adjusted for cormobidity (ASA class), cognitive function, and fixation of prosthesis.

To evaluate the patients' walking ability, the first dimension of EQ-5D-3L, describing mobility problems, was explored. Adjustments for differences in fixation technique between the 2 approaches were not possible to perform, as walking ability was a categorical variable. Separate analyses were therefore performed for uncemented and cemented prostheses.The Pearson chi-square test was used for comparison of categorical variables and Student's t-test was used for continuous variables in independent groups. Patients were followed until time of death, time of emigration, or until the end of the study.

Prostheses survival was calculated using the Kaplan-Meier method. The Cox regression model was used to calculate relative risk (RR) of reoperation with adjustment for age, sex, comorbidity (ASA class), cognitive function, fixation of the prosthesis, and operation time in the 2 treatment groups. Furthermore, the Cox model was used to construct adjusted survival curves. Also, for risk of reoperation, subanalyses were performed for cemented and uncemented prostheses separately. The proportional hazards assumption was fulfilled when investigated visually using a log-minus-log plot. However, the survival curves crossed each other for prosthesis survival after 8.5 years. The Cox survival analysis was therefore terminated at 8 years of follow-up. A competing risks analysis was also performed using the Fine and Gray (1999) model. The mortality in the study period was set as the competing risk for revision of the prosthesis, and adjustments were done for possible influence of age, sex, cognitive function, ASA class, operation time, and type of fixation. Adjustment for patients who were operated bilaterally was not performed—in line with the results of a previously study that showed that this would not alter the conclusions (Lie et al. 2004). The significance level was set to 0.05. The statistical analyses were performed with the statistical package IBM SPSS Statistics version 21 and the statistical package R (Gray RJ (2010) Cmprsk: Subdistribution Analysis of Competing Risks. https://cran.r-project.org).

Table 1. Baseline characteristics of patients

	Lateral n = 18,918	Posterior n = 1,990	p-value
Mean age (SD) at fracture	83 (7)	83 (8)	0.6
Women, n (%)	13,770 (73)	1,424 (72)	0.2 [a]
ASA class, n (%)			< 0.001 [a]
1	510 (2.7)	90 (4.5)	
2	6,438 (34)	658 (33)	
3	10,747 (57)	1,130 (57)	
4	1,213 (6.4)	110 (5.5)	
5	10 (0.1)	2 (0.1)	
Uncemented prostheses, n (%)	4,635 (25)	1,139 (57)	< 0.001 [a]
Cognitive impairment, n (%)	4,809 (25)	582 (29)	< 0.001 [a]
Mean duration of surgery (SD), min	76 (25)	67 (21)	< 0.001 [b]

[a] Pearson's chi-squared test. [b] Student's t-test.

Table 2. Types of implants

Name [a]	n	(%)
Lateral approach	18,918	(100)
Exeter/V40 (Stryker)	6,994	(37)
Corail (DePuy Synthes)	3,936	(21)
Charnley (DePuy Synthes)	2,277	(12)
Lubinus SP II (LINK)	1,706	(9.0)
Charnley Modular (DePuy Synthes)	1,361	(7.2)
Spectron (Smith and Nephew)	881	(4.7)
Titan (DePuy Synthes)	784	(4.1)
Other	979	(5.2)
Posterior approach	1,990	(100)
Corail (DePuy Synthes)	854	(43)
Exeter/V40 (Stryker)	477	(24)
Spectron (Smith and Nephew)	199	(10)
Polar (Smith and Nephew)	137	(6.9)
Filler (Biotechni)	109	(5.5)
Charnley Modular (DePuy Synthes)	58	(2.9)
Charnley (DePuy Synthes)	49	(2.5)
Other	107	(5.4)

[a] DePuy Synthes located in Leeds, UK; Stryker, in Kalamazoo, MI; Biotechni, in La Ciotat, France; Smith and Nephew, in Memphis, TN; and LINK, in Hamburg, Germany.

Table 3. Response rates for patient questionnaires. The number of posted and returned questionnaires at each follow-up

	Posted	Returned (%)	Completed (%) [a]
Lateral approach			
4 months	11,233	6,369 (57)	5,459 (49)
1 year	9,100	5,140 (57)	4,350 (48)
3 years	4,577	2,475 (54)	2,475 (46)
Posterior approach			
4 months	1,254	731 (58)	624 (50)
1 year	1,010	584 (58)	506 (50)
3 years	547	299 (55)	247 (45)

[a] Completed questionnaires included in the PROM data analyses.

Results

Table 1 shows the baseline characteristics of the patients. There were more uncemented prostheses (57% vs. 25%) and there was shorter duration of surgery (67 min vs. 76 min) in the posterior group than in the lateral group. These differences were statistically significant.

Table 2 shows the implants used in the 2 groups. Table 3 presents the response rates to the patients' questionnaires. The overall response rate varied from 54% to 58%. Only completed forms were included in the final analysis.

PROM data

Table 4 shows that patients reported more pain from and less satisfaction with the operated hip after the direct lateral approach than after the posterior approach. The results were statistically significantly different after 4, 12, and 36 months. Better quality of life (EQ-VAS and EQ-5D index score) was found with the posterior approach, but with statistically significant differences only after 12 months. The patients' walking ability was similar between the groups preoperatively. At all postoperative follow-ups, patients reported having statistically significantly more walking problems in the direct lateral group than in the posterior group (Figure 2A). Subanalyses for cemented and uncemented prostheses separately showed statistically significantly better walking ability for patients who were operated with the posterior approach in the uncemented group, after 4 and 12 months. Patients operated with an uncemented prosthesis through the posterior approach also reported better walking ability preoperatively (Figure 2B and C).

Reoperations

There were more reoperations after the posterior approach than after the direct lateral approach. 1-year prostheses survival was 96% for the direct lateral approach and 95% for the posterior approach. After 8 years, the prostheses survival was 96% after the direct lateral approach and 93% after the posterior approach. Figure 3 is a plot of implant survival, with adjustment for age, sex, cognitive function, ASA class, fixation of the prosthesis, and operation time. The risk of reoperation was similar in the first 8 years irrespective of which approach was originally used (RR = 1.2, 95% CI: 0.92–1.4; p = 0.2). Additional analyses with adjustment also for stem fixation gave similar results (RR = 1.2, 95% CI: 0.99–1.5; p = 0.07). The analyses using the Fine and Gray competing risk model gave a subhazard rate ratio (subHRR) of 1.16 (95% CI: 0.94–1.4; p = 0.2). Hence, the competing risk approach did not alter the results that had already been obtained using the Cox regression model. Subanalyses showed similar results for the approaches when cemented prostheses (RR = 1.0, 95% CI: 0.8–1.5) and uncemented prostheses (RR = 1.2, 95% CI: 0.9–1.6) were analyzed separately.

Table 4. Patient-reported outcome measures. Results are presented as mean values and as mean differences between direct lateral approach (DLA) and posterior approach (PA) at the different follow-ups

Scores	Unadj. mean values DLA	PA	Adj. mean values [a] DLA	PA	Direct lateral vs. Posterior Adj. mean difference [a]	95% CI	p-value [a]
4 months							
Pain	22	20	25	23	2.2	0.53 to 3.8	0.01
Satisfaction	25	20	31	28	2.1	0.39 to 3.7	0.02
EQ-5D index score	0.55	0.57	0.45	0.47	−0.014	−0.034 to 0.008	0.2
EQ-VAS	60	61	52	53	−0.29	−2.1 to 1.5	0.8
12 months							
Pain	20	17	21	18	3.1	1.3 to 4.9	0.001
Satisfaction	25	21	27	22	4.7	2.7 to 6.7	< 0.001
EQ-5D index score	0.61	0.64	0.55	0.58	−0.030	−0.055 to −0.006	0.01
EQ-VAS	62	64	59	61	−2.1	−4.2 to −0.0	0.05
36 months							
Pain	20	16	20	17	3.1	0.41 to 5.9	0.02
Satisfaction	26	22	27	24	3.7	0.57 to 6.8	0.02
EQ-5D index score	0.61	0.66	0.56	0.60	−0.033	−0.070 to 0.004	0.08
EQ-VAS	61	65	60	63	−2.4	−5.6 to 0.80	0.1

DLA: direct lateral approach; PA: posterior approach.
[a] GLM (adjusted for differences in ASA, class, cognitive impairment, and fixation of prosthesis).

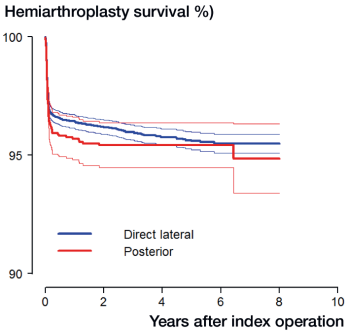

Figure 3. Prosthesis survival curves with 95% confidence interval for surgical approach adjusted for age, sex, cognitive function, ASA class, fixation of the prosthesis, and operation time (ASA-5 patients were excluded to make confidence interval curves smaller).

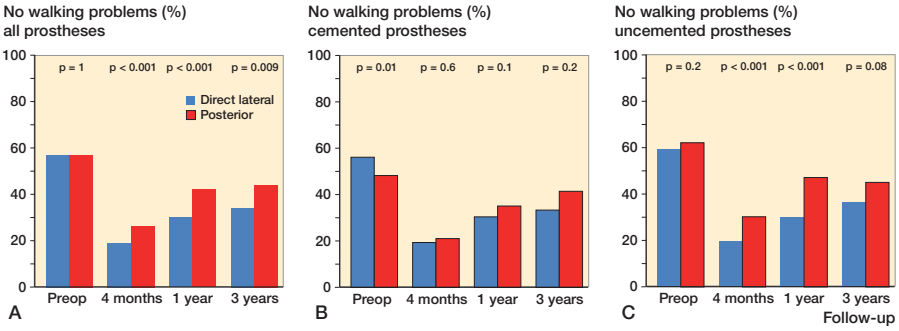

Figure 2. Walking ability. The bars show the percentage of patients in each treatment group who reported no problems with walking in the first dimension of EQ-5D at different follow-ups.

Discussion

Patients operated with hemiarthroplasty using the posterior approach had less pain, were more satisfied, and had a better quality of life than those operated with direct lateral approach. In addition, a larger group of those operated with the posterior approach had fewer walking problems postoperatively.

A study performed by Amlie et al. (2014) found more pain, less satisfaction, poorer life quality, and twice the risk of limping after primary total hip arthroplasty (THA) performed with the direct lateral approach rather than the posterior approach (Amlie et al. 2014). These findings are supported by another registry-based study that found less residual pain and greater satisfaction after elective THAs performed with the posterior approach than after elective THAs performed with direct lateral approach (Lindgren et al. 2014). The results of the present study on hemiarthroplasty support the findings of these 2 studies regarding pain, satisfaction, and walking ability.

In an observational study with a 1-year follow-up, Leonardsson et al. (2016) reported better patient-reported outcome after the posterior approach than after the direct lateral approach. After adjusting for age, sex, cognitive impairment, and ASA grade, however, no statistically significant results were found. The lower number of patients in that study compared to our study may explain the lack of statistically significant differences.

Parker et al. performed meta-analyses to find a preferred approach for hemiarthroplasties since the 1990s, without being able to come to any firm conclusions (Keene and Parker 1993, Parker and Pervez 2002). In a recently pub-

lished randomized, controlled trial involving 216 patients with hip fractures treated with HA, performed either with a lateral or a posterior approach, no differences could be found regarding residual pain or regain of walking ability (Parker 2015). Biber et al. (2012) conducted a retrospective study on 704 patients in 2012 and concluded that there was no difference between the posterior approach and the direct lateral approach regarding early surgical complications. However, the posterior approach predisposed to dislocation whereas the direct lateral approach predisposed to hematoma. Rogmark et al. (2014) found that the posterior approach clearly increased the risk of reoperation due to dislocation. Rogmark's study included patients from both the Norwegian and the Swedish national registries. Although there was a similar tendency, no statistically significant difference was found in the present study involving only patients from the Norwegian Register, probably due to the lower number of patients in the posterior approach group.

Other studies have found a greater risk of reoperation with uncemented prostheses (Langslet et al. 2014, Rogmark et al. 2014). Langslet et al. showed better 5-year results for uncemented prostheses regarding Harris hip score. In the present study, there was more use of uncemented implants in the posterior group than in the direct lateral group (57% vs. 25%). There is a possibility that patients treated with uncemented stems are a selected extra-fit group. To minimize the risk of confounding, we adjusted the p-values for PROM data for differences in stem fixation. Subanalyses on walking ability, performed for uncemented and cemented prostheses, showed a greater difference in favor of the posterior approach with uncemented stems. Furthermore, a similar risk of reoperation was found for the 2 approaches with cemented and uncemented stems.

In Norway, most hospitals have one standard procedure for hemiarthroplasty, including only 1 approach and 1 fixation technique. 36 out of 52 hospitals had more than 90% of the operations performed with only one of the surgical approaches. This finding supports the assumption that 1 standard approach was used for HAs in most hospitals. Accordingly, the risk of surgical selection bias was low.

The strength of our study was the high number of patients included, and the fact that there was a nationwide result showing the outcome that could be expected in an average orthopedic department.

A registry study compares the actual number of patients operated. The 2 groups that we compared were different regarding the numbers of patients (1:10). This increases the risk of type-II error (i.e. failure to reject a false null hypothesis). The skewed distribution in surgical approaches and fixation techniques is difficult to correct for, because this was no randomized study where the patients could be randomized to 1 of the 2 approaches. Our study shows the actual distribution of approaches used for hemiarthroplasty in our country, and one should have this in mind when discussing the results.

It was a weakness that the preoperative PROM (EQ-5D) data were collected retrospectively 4 months postoperatively, but there is no reason to believe that recall bias should be different for the 2 groups. 1 study comparing recalled data and prospective data found only moderate agreement concerning preoperative status of the patients (Lingard et al. 2001). In contrast, Howell et al. (2008) found that the correlation between recalled data and prospective data was good. The response rates to the patient questionnaires were low, probably due to high age, considerable comorbidity, and cognitive dysfunction. An earlier study from the registry found that the non-responders were older, were more cognitively impaired, and had a higher degree of comorbidity. The type of operation did not, however, influence the response rate, so there is no reason to suspect a systematic underreporting in 1 of the 2 treatment groups (Gjertsen et al. 2008).

In summary, hemiarthroplasty for hip fracture performed through a posterior approach appears to be a safe procedure with less pain, better patient satisfaction, and better quality of life than with the direct lateral approach.

No competing interests declared.

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Cemented or Uncemented Hemiarthroplasty for Femoral Neck Fracture? Data from the Norwegian Hip Fracture Register

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Abstract

Background A displaced femoral neck fracture in patients older than 70 years is a serious injury that influences the patient's quality of life and can cause serious complications or death. Previous national guidelines and a Cochrane review have recommended cemented fixation for arthroplasty to treat hip fractures in older patients, but data suggest that these guidelines are inconsistently followed in many parts of the world; the effects of that must be better characterized.

Questions/purposes The purpose of this study was to evaluate a large group of patients in the Norwegian Hip Fracture Register to investigate whether the fixation method in hemiarthroplasty is associated with (1) the risk of reoperation; (2) the mortality rate; and (3) patient-reported outcome measures (PROMs).

Methods Longitudinally maintained registry data from the Norwegian Hip Fracture Register with high completeness (93%) and near 100% followup of deaths were used for this report. From 2005 to 2017, 104,993 hip fractures were registered in the Norwegian Hip Fracture Register. Fractures other than intracapsular femoral neck fractures and operative methods other than bipolar hemiarthroplasty, such as osteosynthesis or THA, were excluded. The selection bias risk on using cemented or uncemented hemiarthroplasty is small in Norway because the decision is usually regulated by tender processes at each hospital and not by surgeon. A total of 7539 uncemented hemiarthroplasties (70% women, mean age, 84 years [SD 6] years) and 22,639 cemented hemiarthroplasties (72% women, mean age, 84 years [SD 6] years) were eligible for analysis. Hazard risk ratio (HRR) on reoperation and mortality was calculated in a Cox regression model adjusted for age, sex, comorbidities (according to the American Society of Anesthesiologists classification), cognitive function, surgical approach, and duration of surgery. At 12 months postoperatively, 65% of patients answered questionnaires regarding pain and quality of life, the results of which were compared between the fixation groups.

Results A higher overall risk of reoperation for any reason was found after uncemented hemiarthroplasty (HRR, 1.5; 95% CI, 1.4–1.7; $p < 0.001$) than after cemented hemiarthroplasty. When assessing reoperations for specific

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Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.
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causes, higher risks of reoperation because of periprosthetic fracture (HRR, 5.1; 95% CI, 3.5–7.5; p < 0.001) and infection (HRR, 1.2; 95% CI, 1.0–1.5; p = 0.037) were found for uncemented hemiarthroplasty than for cemented procedures. No differences were found in the overall mortality rate after 1 year (HRR, 1.0; 95% CI, 0.9–1.0; p = 0.12). Hemiarthroplasty fixation type was not associated with differences in patients' pain (19 versus 20 for uncemented and cemented hemiarthroplasties respectively, p = 0.052) or quality of life (EuroQol [EQ]-VAS score 64 versus 64, p = 0.43, EQ5D index score 0.64 versus 0.63, p = 0.061) 1 year after surgery.
Conclusions Our study found that the fixation method was not associated with differences in pain, quality of life, or the 1-year mortality rate after hemiarthroplasty. Uncemented hemiarthroplasties should not be used when treating elderly patients with hip fractures because there is an increased reoperation risk.
Level of Evidence Level III, therapeutic study.

Introduction

Displaced femoral neck fractures in elderly patients are serious injuries that influence quality of life [14] and are associated with morbidity and an increased risk of death [38]. In Western countries, hemiarthroplasty is now the most common treatment for displaced femoral neck fractures [5]. Several recently published studies have shown that stem fixation with cement is associated with a lower reoperation risk than fixation with uncemented stems [16, 28, 39]. In addition, a review study and a Cochrane review have described less pain and better function after cemented hemiarthroplasty than after uncemented hemiarthroplasty [21, 34]. An earlier randomized controlled trial with 5 years of followup indicated better long-term Harris Hip scores in patients with uncemented hemiarthroplasty than in those with cemented hemiarthroplasty [23]. However, bone-cement implantation syndrome has been described previously [9, 33], and the risk of serious harm associated with cementing in older patients who may have cardiovascular comorbidities remains a concern.

The National Institute for Health and Care Excellence guidelines in the UK [29] and the American Academy of Orthopaedic Surgeons recommendations [6], as well as a Cochrane review [34], support the use of cemented fixation when performing arthroplasties for hip fractures in elderly patients. But data suggest that these guidelines are inconsistently followed in many parts of the world [1, 3, 30], and the effects of that need to be better characterized. Minimizing the risk of reoperation and death and determining which approach is most likely to provide the patient with pain relief and a good quality of life are important goals when choosing the hemiarthroplasty fixation method for femoral neck fractures. Investigating uncommon endpoints (in particular fracture and death) in a randomized study is difficult, and to our knowledge, no large register study has been done that evaluated those endpoints. Our national (Norway) register has the benefit of providing all these endpoints in the same population with more than 12 years of followup.

Therefore, we thought to use the Norwegian Hip Fracture Register to determine whether the hemiarthroplasty fixation method is associated with (1) the risk of reoperation; (2) the mortality rate; and (3) PROMs.

Patients and Methods

This nationwide (Norway) observational study was based on longitudinally maintained data in the Norwegian Hip Fracture Register from 2005 to 2017 [15]. The Norwegian Hip Fracture Register has high registration completeness (93%), and 100% of hospitals are covered by it [2]. Data on death and emigration were provided by the National Registry in Norway [42]. The Norwegian Hip Fracture Register has approval from the Norwegian Data Inspectorate to process health data. The followup rate of deaths is nearly 100% [36]. After each primary operation and reoperation for femoral neck fracture, surgeons complete a paper form that is sent to the register. This form includes detailed patient information such as the unique 11-digit Norwegian personal identification number, age, sex, comorbidities (according to the American Society of Anesthesiologists [ASA] classification), time of fracture, time of the start of surgery, type of fracture, type of surgery, fixation of hemiarthroplasty, duration of surgery, surgical approach, and type of implant (identified by catalog numbers). In Norway, the choice of implant and fixation is mainly regulated by a tender process that occurs every fourth year in the hospital or health region. Factors influencing this decision are clinical documentation, implant costs, and service from manufacturer. Based on our annual hospital reports, most hospitals have used either an uncemented or a cemented stem for all patients in a given time period. The fact that a hospital has used only one fixation technique for a time period mitigates this selection bias. Therefore, we performed a subanalysis on these patients including only these hospitals to compare with our main findings. From the register's inception in January 2005 to the end of 2017, 104,993 primary operations for hip fractures were reported to the Norwegian Hip Fracture Register. We excluded patients with pathologic fractures (n = 1356), fractures other than intracapsular femoral neck fractures (n = 46,764), operation methods other than bipolar hemiarthroplasty such as THAs and osteosyntheses (n = 22,948 (unipolar hemiarthroplasties are used in fewer than 1% [n =

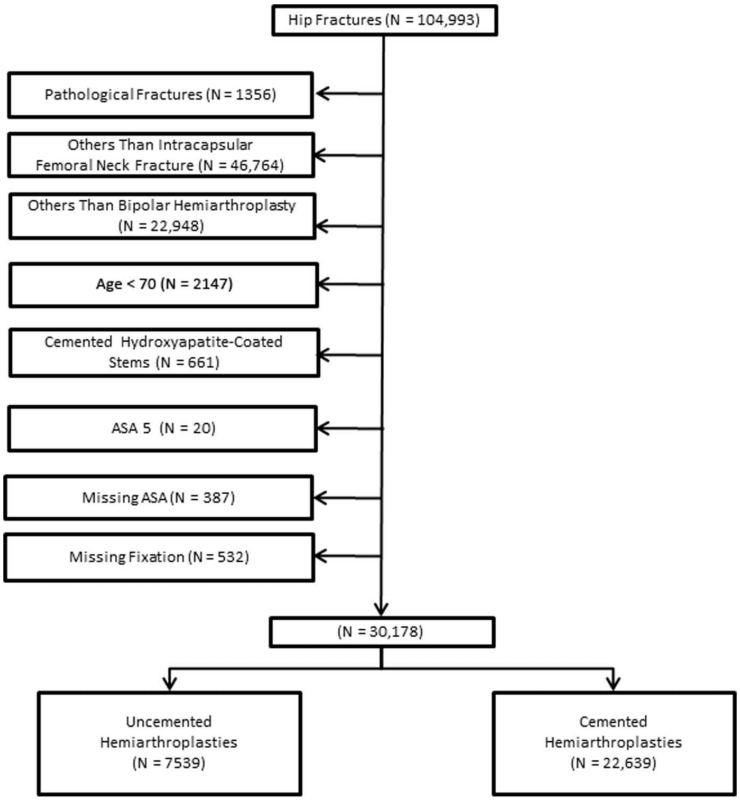

Fig. 1 A flowchart of the inclusion and exclusion process is shown.

317] of patients with hip fractures in Norway), patients younger than 70 years (n = 2147), patients with uncemented stems that had been fixed with cement (n = 661), patients with ASA Grade 5 physical status (n = 20), and patients with incomplete information in the Norwegian Hip Fracture Register dataset regarding the ASA grade or fixation method (n = 919) (Fig. 1). A total of 30,178 bipolar hemiarthroplasties (7539 uncemented and 22,639 cemented) were eligible for the final analyses regarding reoperations and mortality. All patients were observed for reoperation for any reason until death, emigration, or until December 31, 2017.

The mean age was 84 years (range, 70-104 years), and 71% of the patients were women. The median followup duration was 2 years (interquartile range, 0.5–4.2 years). The duration of surgery was shorter for uncemented fixation than for cemented fixation (61 versus 80 minutes). There were more women in the uncemented group than in the cemented group (72% versus 70%). The posterior approach was used more frequently in uncemented hemiarthroplasties (17%) than in cemented hemiarthroplasties (8%) (Table 1). Other than the differences identified above, the groups were not different in terms of any parameters apart from the intervention in question.

PROM questionnaires were distributed to patients from 2005 to 2016. Patients receiving questionnaires in 2017 (n = 2366) were excluded because their 1-year results were not ready for analysis at the time we prepared this manuscript. Because of a lack of resources from 2007 to 2009, only a randomly selected group of patients were asked to answer the questionnaires, and most patients (n = 4520) did not receive questionnaires in this period. We excluded patients with cognitive impairment (mainly dementia; n = 3147) to improve the quality of information; we believe this did not likely have a differential between-group effect. In addition, we excluded those who died within the first year postoperatively (n = 7459). There were no differences between the uncemented and cemented groups in terms of the proportion of patients who returned PROMs questionnaires (66% (n = 2299 of 3499) versus 65% (n = 5930 of 9087); p = 0.64) (Fig. 2).

Table 1. Baseline

Patient-related factors	Baseline reoperations and mortality			Baseline PROMs		
	Uncemented hemiarthroplasties	Cemented hemiarthroplasties	p value	Uncemented hemiarthroplasties	Cemented hemiarthroplasties	p value
Total number, n	7539	22,639		3499	9087	
Age (years, SD)	84 (6)	84 (6)	0.55†	83 (6)	83 (6)	0.77†
Women	70%	72%	0.007*	73%	75%	0.005*
Duration of surgery (min)	61	80	< 0.001†	61	81	< 0.001†
ASA class			< 0.001*			< 0.001*
ASA 1, n (%)	150 (2)	517 (2)		97 (3)	269 (3)	
ASA 2, n (%)	2581 (34)	7237 (32)		1542 (44)	3670 (40)	
ASA 3, n (%)	4236 (56)	13,358 (59)		1707 (49)	4819 (53)	
ASA 4, n (%)	572 (8)	1527 (7)		153 (4)	329 (4)	
Cognitive impairment, n (%)	2123 (28)	6001 (27)	< 0.001*			
Approach			< 0.001*			< 0.001*
Anterior, n (%)	516 (7)	1748 (8)		291 (8)	707 (8)	
Lateral, n (%)	5663 (75)	18,741 (83)		2642 (76)	7485 (82)	
Posterior, n (%)	1280 (17)	1805 (8)		525 (15)	720 (8)	
Missing approach, n (%)	80 (1)	345 (2)		41 (1)	175 (2)	
Frequency of response (PROMs), n (%)				2299 (66)	5930 (65)	0.64*

*Chi-square.
†Student's t-test.
PROMs = patient-reported outcome measures; ASA = American Society of Anesthesiologists.

PROM paper questionnaires were sent to patients at 4, 12, and 36 months after primary surgery to collect VAS scores for pain in the operated hip (range, 0-100; 0 means no pain, 100 means unbearable pain), EuroQol (EQ)-VAS scores, and EQ-5D-3L scores. The EQ-5D-3L questionnaire comprises five dimensions (walking ability, ability for self-care, ability to perform usual activities, pain or discomfort, and anxiety or depression) [12]. Preoperative EQ-5D-3L questionnaires were collected retrospectively along with the questionnaire sent to the patients 4 months postoperatively, and these questionnaires were sent to patients who underwent reoperation, as well. In this report, we chose to present the PROM data 12 months after surgery, in line with published recommendations for PROM data in registries [40].

Patients who returned the PROMs questionnaires were younger than the overall group of patients at baseline (median age, 83 versus 84 years) and healthier (according to ASA classification) (Table 1). Among the PROM questionnaire responders, the cemented hemiarthroplasty group had more women, longer surgical times, and the posterior approach was used less often compared with the uncemented group.

The surgical approach, stem fixation, and other details when performing hemiarthroplasty were selected according to each hospital's routine protocol; more than 99% of cemented hemiarthroplasties in Norway are implanted with antibiotic-loaded cement [32]. In Norway, the decision about which implant type should be used in hospitals is driven by a tender process at the regional level. The hemiarthroplasties included in the analyses were performed at 54 hospitals, of which one only used uncemented hemiarthroplasties, 14 only used cemented hemiarthroplasties, and 39 used both types of hemiarthroplasties. Mainly contemporary implants were used (Table 2). Bipolar heads were usually (about 85% of the time) from the same manufacturer as the stem. Accordingly, we did not consider the brand of the bipolar head when analyzing the results.

A reoperation was defined as any secondary procedure performed after primary hemiarthroplasty. The surgeons report reoperations, including closed reduction for dislocation, osteosynthesis for periprosthetic fracture, or soft-tissue débridement for infection. Reoperations were linked to the primary operation using the unique 11-digit Norwegian personal identification number and side that was

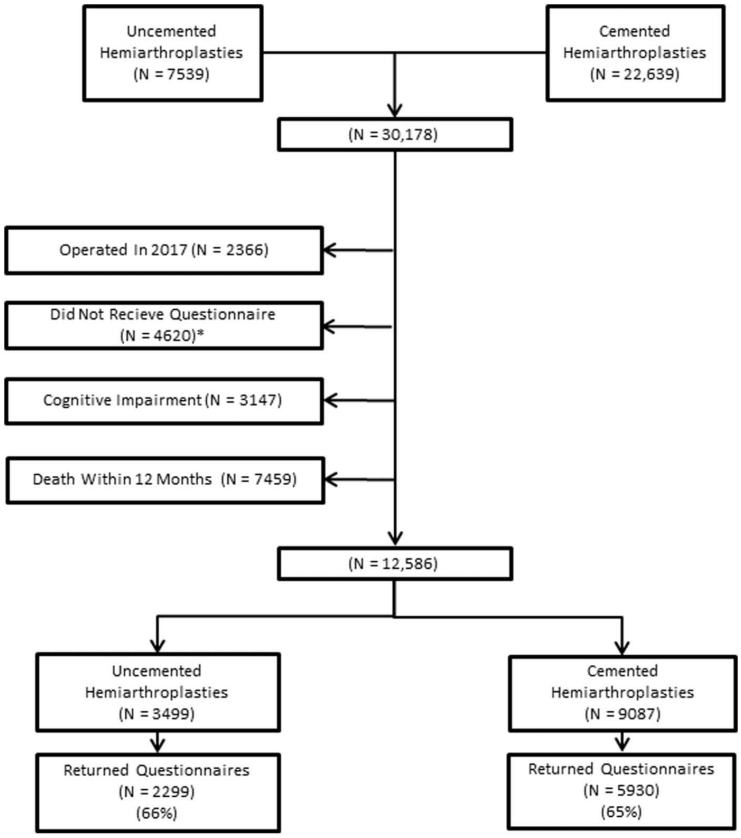

Fig. 2 This figure shows a flowchart of patients with patient-reported outcome measures 1 year after surgery. *From 2007 to 2009, because of a lack of resources, only a randomly selected group of patients were asked to answer the questionnaires

operated on, regardless of the hospital at which the primary operation was performed.

Statistical Analysis

We used the Pearson chi-square test to compare categorical variables, and we used an independent t-test for continuous variables in independent groups. Data is presented in a Cox model in line with a recent published recommendation when estimating relative revision risk from arthroplasty register data [37]. The Cox regression model was used to calculate hazard rate ratios (HRRs) for any reoperation, reoperations for specific causes and mortality, with adjustments for age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery. Patients without reoperations were censored at the time of death or emigration, or on December 31, 2017. Because death is a potential competing risk that may influence the accumulated probability of reoperation, regression analyses for competing risk were performed. We applied the Fine and Gray regression model for subhazards [13]. These results were compared with the results of the Cox proportional hazards regression model, and no important differences between the analyses were identified, so we present herein results from our Cox model. Additional analyses of patients who underwent bilateral operations were not performed; a previous study showed that adjusting for bilateralism would have a negligible influence on the results [25]. The significance level was set at 0.05. The statistical analyses were performed using the statistical package IBM SPSS Statistics, version 24 (IBM

Table 2. Type of implants

Uncemented hemiarthroplasty			Cemented hemiarthroplasty		
Name	Number (%)		Name	Number (%)	
Total number	7539	(100)	Total number	22,639	(100)
Corail® (DePuy Synthes)	5979	(79)	Exeter™ (Stryker)	11,604	(51)
Filler® (Biotechni)	854	(11)	Lubinus® SP II® (Link)	3003	(13)
Polarstem™ (Smith and Nephew)	252	(3)	Charnley® (DePuy Synthes)	2445	(11)
SL-PLUS™ (Smith and Nephew)	164	(2)	Charnley Modular® (DePuy Synthes)	1896	(8)
HACTIV® (Evolutis)	111	(2)	Spectron™ (Smith and Nephew)	1385	(6)
Furlong® (JRI Orthopaedics)	109	(1)	CPT® (Zimmer Biomet)	841	(4)
Other	70	(0.9)	Titan™ (DePuy Synthes)	817	(4)
			C-Stem® (DePuy Synthes)	356	(2)
			MS-30® (Zimmer Biomet)	223	(1)
			Other	69	(0.3)

DePuy Synthes is located in Leeds, UK; Stryker is located in Kalamazoo, MI, USA; Biotechni is located in La Ciotat, France; Smith & Nephew is located in Memphis, TN, USA; LINK is located in Hamburg, Germany; JRI Orthopaedics is located in Sheffield, UK; Evolutis, in Briennon, France; Zimmer Biomet is located in Warsaw, IN, USA.

Corp, Armonk, NY, USA) and the statistical package R (http://CRAN.R-project.org). This study was performed in accordance with the Reporting of Studies Conducted using Observational Routinely-collected Data (RECORD) statement and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [4].

Results

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach, and duration of surgery, there was a higher overall risk of reoperation for any reoperation in patients with uncemented hemiarthroplasties (HRR, 1.5; 95% CI, 1.4–1.7; $p < 0.001$) than for those with cemented hemiarthroplasties (Fig. 3). When assessing reoperations for specific causes, we found there were higher risks of reoperation because of periprosthetic fracture (HRR, 5.1; 95% CI, 3.5–7.5; $p < 0.001$), infection (HRR, 1.2; CI, 1.0–1.5; $p = 0.037$), aseptic loosening (HRR, 3.9; 95% CI, 1.4–10.9; $p = 0.008$), and reoperation for other reasons (HRR, 1.9; 95% CI, 1.3–2.6; $p < 0.001$) for uncemented hemiarthroplasties than for cemented hemiarthroplasties (Table 3).

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach, and duration of surgery, there was no difference in the 1-year mortality rate between the fixation groups (HRR, 1.0; 95% CI, 0.9–1.0; $p = 0.12$). Patients with uncemented hemiarthroplasty, however, had lower mortality at days 0 and 1 than patients with cemented hemiarthroplasty (HRR, 0.4; CI, 0.3–0.5; $p < 0.001$) (Table 4). For the remainder of the patients' lifetimes, as well as in aggregate, there were no differences in mortality (Fig 4).

No differences between uncemented and cemented hemiarthroplasties were found regarding pain (19 versus 20, $p = 0.052$) in the operated hip, and quality of life (EQ-VAS score 64 versus 64, $p = 0.43$, EQ5D index score 0.64 versus 0.63, $p = 0.061$) 1 year after surgery (Table 5). Additionally, no differences were found between the groups when measuring the

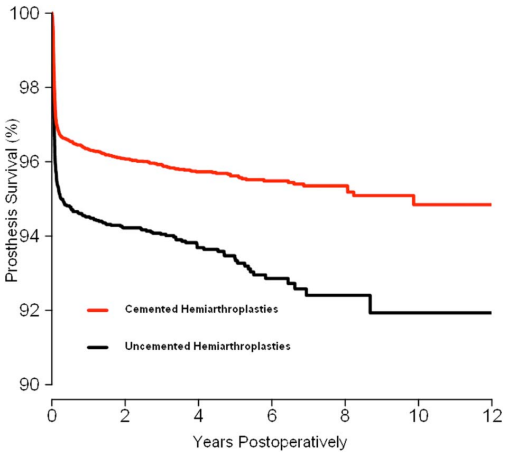

Fig. 3 In this figure, a Cox regression curve for reoperations after uncemented and cemented Hemiarthroplasties is shown, with adjustments for age, sex, comorbidities (American Society of Anesthesiologists [ASA] class), cognitive function, surgical approach, and duration of surgery.

Table 3. Reoperations

Reasons for reoperations	Uncemented hemiarthroplasty		Cemented hemiarthroplasty		HRR*	95% CI	p value
	Number	Percent	Number	Percent			
Total	433	6	834	4	1.5	1.4-1.7	< 0.001
Infection	179	2	425	2	1.2	1.0-1.5	0.037
Fracture	88	1	53	0.2	5.1	3.5-7.5	< 0.001
Dislocation	95	1	237	1	1.1	0.8-1.4	0.55
Aseptic loosening	9	0.1	8	0.04	3.9	1.4-10.9	0.008
Other	62	0.8	111	0.5	1.9	1.3-2.6	< 0.001

*Cox regression analysis adjustments for age, gender, comorbidity (ASA class), cognitive function, surgical approach, and duration of surgery; ASA = American Society of Anesthesiologists.

change in the index EQ-5D-3L score from preoperatively to 1 year postoperatively (-12.9 versus -12.7 ; p = 0.75), or when comparing the proportion of patients in each group whose EQ-5D-3L score at 1 year postoperatively reached the preoperative EQ-5D-3L score (37% versus 36%; p = 0.81).

Subanalyses on reoperations and mortality, adjusted for same variables as the main results, were performed on patients from hospitals that used either an uncemented (n = 3286 of 7539) or a cemented stem (n = 12,644 of 22,639) for all patients in a given time period. A higher overall risk of reoperation for any reoperation was found with uncemented hemiarthroplasties (HRR, 1.7; 95% CI, 1.4–2.1; p < 0.001) than for those with cemented hemiarthroplasties. Patients with uncemented hemiarthroplasties, however, had lower mortality at days 0 and 1 (HRR, 0.4; CI, 0.2–0.7; p = 0.001) and from day 2 to 7 (HRR, 0.7; CI, 0.5–0.9; p = 0.003) than patients with cemented hemiarthroplasty. For the remainder of the patients' lifetimes there were no differences in mortality.

Discussion

Reoperation is a devastating complication for an elderly and frail patient with a hip fracture. Therefore, efforts should be made to improve treatment to minimize the likelihood of this event. Many recommendations suggest cement, though these suggestions are inconsistently followed. Based on data reported in the Norwegian Hip Fracture Register, with its high completeness and generalizability, we have studied the rate of reoperations, mortality, and PROMs. We found a lower risk of reoperation after cemented hemiarthroplasty than after uncemented hemiarthroplasty, mainly because of fewer periprosthetic fractures and infections. One year postoperatively, the type of hemiarthroplasty fixation was not associated with differences in mortality, pain scores, or quality of life.

This study had some limitations. First, in a register study, the patients, methods, and surgeons are not randomized, leading to a risk of confounding factors and possible selection bias. From our annual hospital reports, we have seen that most hospitals have used either an uncemented or a cemented stem for all patients in a given time period. Therefore, we performed subanalyses that we compared with our main findings to mitigate selection bias. We adjusted for possible registered confounders such as age, sex, comorbidities (ASA class), cognitive function, surgical approach, and duration of surgery. Because this study reflects a broad sample of practice across an entire

Table 4. Mortality

Time from surgery to death	Uncemented hemiarthroplasty		Cemented hemiarthroplasty		HRR*	95% CI	p value
	Nunber of deaths	%	Number of deaths	%			
Total	4830	64	13,903	61	1.0	1.0-1.0	0.64
0-1 days	38	0.5	272	1	0.4	0.3-0.5	< 0.001
2-7 days	195	3	571	3	0.9	0.8-1.1	0.21
8-30 days	384	5	1142	5	1.0	0.9-1.1	0.51
31-365 days	1281	19	3587	17	1.0	0.9-1.1	0.75
> 1 year	2932	55	8331	56	1.0	1.0-1.1	0.61

*Cox regression analysis adjustments for age, gender, comorbidity (ASA class), cognitive function, surgical approach, and duration of surgery; ASA = American Society of Anesthesiologists.

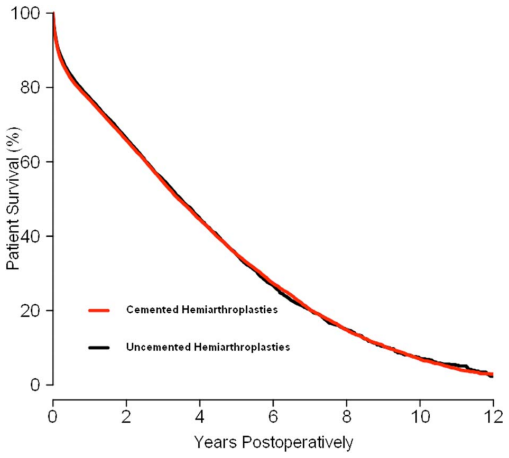

Fig. 4 A Cox regression curve for mortality after uncemented and cemented Hemiarthroplasties is shown, with adjustments for age, sex, comorbidities (American Society of Anesthesiologists [ASA] class), cognitive function, surgical approach, and duration of surgery.

country, we believe that the study has high generalizability (external validity), and that the results also likely would generalize well to practice in other countries. Second, a large study like this may identify statistical differences that are not necessarily clinically important (such as the small difference in the risk of death identified in the first few days after surgery, which was not observed at subsequent time points when we observed no between-group differences). Readers must use good judgment when interpreting findings with very small effect sizes in large, observational trials; we believe this is a shortcoming worth tolerating, since randomized studies—which almost inevitably are much smaller—may fail to detect even larger (and clinically important) between-group differences owing to limited power, especially those pertaining to less common but still important complications. Additionally, since patients who undergo hemiarthroplasty sometimes are frailer, there would be a risk that only the healthiest patients would volunteer for a randomized study, and they would not be generalizable to the typical population.

Third, the difference in volume between the cemented hemiarthroplasty and uncemented might represent a confounding variable; Norwegian surgeons may have greater expertise with the cemented stem. We do not believe this affected results to any great degree because hospitals using uncemented hemiarthroplasties also use uncemented stems for planned THAs and have done this for many years, and thus have more-than-sufficient experience with this procedure.

There were additional limitations, as well. For example, low-grade infection is often difficult to diagnose and may present only as prolonged wound drainage or later aseptic loosening, and may, therefore, have been misreported in the register on the day of reoperation. In addition, such low-grade infections in elderly and frail patients may be treated only with antibiotic suppression without reoperation. Hence, the infection burden may be even higher than reported. There is, however, no reason why the treatment strategy was different for cemented and uncemented hemiarthroplasties. Moreover, different bipolar heads used in combination with different stems might affect the rate of reoperation, especially in procedures performed for dislocation. The different stems were usually used with a bipolar head from the same manufacturer, and we could not adjust for bipolar heads in the Cox regression analyses. The stem and bipolar head must be seen as one unit. In addition, comparisons of many brands of cemented and uncemented hemiarthroplasties should be interpreted with caution. Differences in reoperations after cemented hemiarthroplasties with an increased risk of periprosthetic fracture for polished taper-slip stems have been reported [22]. One study [18] found inferior survivorship with the Titan™ (DePuy Synthes, Leeds, UK) stem. When survivorship is lower with one particular device, it reduces the aggregate survivorship for the group in which it is reported. Still, most of the stems in our study had well-

Table 5. Comparison of patient-reported outcome 1 year after surgery

Patient-reported outcome measures	Uncemented Mean	Cemented Mean	Mean difference (95% CI)	p value*
Pain	19	20	-0.9 (-1.9-0.01)	0.052
EQ-VAS	64	64	0.5 (-0.7-1.6)	0.43
EQ-5D index	0.64	0.63	0.01 (-0.005-0.03)	0.061
ΔEQ-5D	-12.9	-12.7	-0.2 (-1.6-1.1)	0.75
Percent reached preop EQ-5D	37%	36%		0.81†

*Students t-test.
†Chi-square test.
EQ = EuroQol.

documented excellent long-term results in register studies on THAs [11, 19]. The way the data were collected may have influenced results; for example, the preoperative EQ-5D-3L data were retrospectively collected 4 months after surgery, but there is no reason to believe that recall bias would be different between the two groups. One study comparing recalled data and prospective data found only moderate agreement concerning the patients' preoperative status [26]. In contrast, Howell et al. [20] found that the correlation between recalled data and prospective data was good. Finally, the patient response rate to the questionnaires was rather low (64%), probably because of old age and its associated comorbidities. Still, a response rate higher than 60% was considered acceptable by recent published recommendations for PROM data in registries [40].

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach and duration of surgery, our large register-based study showed that the risk of reoperation was much higher for the uncemented hemiarthroplasties. These findings were strengthened by our subanalyses on patients from hospitals that only operated uncemented or cemented hemiarthroplasties for a time period, which mitigated selection bias. Our study with large numbers, strong methods, and high generalizability adds important information to existing evidence [8, 16, 27, 28, 43, 44] and national guidelines [6, 29-31] in the decision-making process. Our results are similar to previous studies and support those findings. Still, in our study, we found a total HRR of 1.5 for reoperations with uncemented hemiarthroplasties, which is lower than the HRR reported in an earlier study using data from the Norwegian Hip Fracture Register (2.1) [16]. One study [22] compared different stem designs and found more reoperations after hemiarthroplasties with polished taper-slip stems than with matte straight and anatomic composite beam stems. The increased proportion of taper-slip stems, used in the later years in our study, could explain why the HRR was lower in the present study than that in previous research. We also found a higher infection risk after uncemented hemiarthroplasty than after cemented hemiarthroplasty. Yli-Kyyny et al. [44] found a nonimportant tendency towards more infection after uncemented hemiarthroplasty than after cemented hemiarthroplasty in their large observational study in Finland. An earlier study, based on patients with data in the Norwegian Hip Fracture Register [16], found more reoperations for superficial infections after uncemented hemiarthroplasty than after cemented hemiarthroplasty. One possible explanation for more infections in uncemented hemiarthroplasty could be that antibiotic-loaded bone cement, which protects against postoperative infection, is used in nearly all cemented hemiarthroplasties in Norway [32].

After controlling for relevant confounding variables like age, sex, comorbidities, cognitive function, surgical approach and duration of surgery our large register study found no differences in overall mortality after 1 year. This is in line with a recent review [43] and earlier observational studies [8, 16]. This is, however, in contrast to a study from the National Hip Fracture Database in the UK, which reported a lower mortality rate for cemented hemiarthroplasty than for uncemented hemiarthroplasty [7]. Even if the overall mortality after 1 year is no different, our results are in concordance with other studies suggesting increased peri- and early postoperative mortality after cemented fixation [8, 16, 35, 41]. Bone-cement implantation syndrome could be an explanation for this [9, 33]. We recommend following the recently published safety guidelines from the Association of Anaesthetists of Great Britain and Ireland [17] to reduce the mortality risk when using cemented hemiarthroplasty for hip fracture. Engesæter et al. [10] found reduced intramedullary pressure when drilling a distal venting hole in the femur before cementation; this study, to our knowledge, has not been reproduced and could stimulate further investigations in this area.

In our large group of patients, we found similar PROMs between patients undergoing uncemented hemiarthroplasty and those undergoing cemented hemiarthroplasty, suggesting that fixation type does not affect the patients' quality of life when contemporary hemiarthroplasties are used. The mean values for EQ-5D-3L and pain scores in our study were comparable with those in a Swedish register-based study [24]. A systematic review and a Cochrane review have reported less pain and better function after cemented hemiarthroplasty than after uncemented hemiarthroplasty [21, 34]. However, most uncemented implants in these reviews are no longer in use. A randomized controlled trial comparing cemented and uncemented hemiarthroplasties with 5 years of followup found better Harris hip scores after uncemented hemiarthroplasty than after cemented hemiarthroplasty [23], but there was no difference in the index EQ-5D-3L score.

In summary, our study supports the use of cemented hemiarthroplasty to decrease the risk of reoperation, a potentially devastating complication for elderly and frail patients. The fixation method was not associated with differences in pain, quality of life, or the overall mortality rate 1 year after surgery. Uncemented hemiarthroplasty should not be used when treating elderly patients with hip fractures.

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Paper III

More reoperations for periprosthetic fracture after cemented hemiarthroplasty with polished taper-slip stems than after anatomical and straight stems in the treatment of hip fractures: a study from the Norwegian Hip Fracture Register 2005 to 2016.

Kristensen TB, Dybvik E, Furnes O, Engesaeter LB, Gjertsen JE. More reoperations for periprosthetic fracture after cemented hemiarthroplasty with polished taper-slip stems than after anatomical and straight stems in the treatment of hip fractures: a study from the Norwegian Hip Fracture Register 2005 to 2016. *Bone Joint J* 2018;100-B:1600-1608.

Abstract

Aims

The aim of this large register-based observational study was to compare mid-term survival-rates of cemented femoral stems of different designs used in hemiarthroplasties for femoral neck fracture in elderly patients.

Patients and Methods

From the Norwegian Hip Fracture Register (NHFR) 20529 primary cemented bipolar hemiarthroplasties for femoral neck fracture in patients aged 70 years or older treated in 2005-2016 were included in this prospective observational study. Polished tapered stems (n=12064) (the Exeter and CPT prostheses), straight stems (n=5543) (the Charnley, Charnley Modular and Spectron EF prostheses), and anatomic stems (n=2922) (the Lubinus SP2 prosthesis) were included. Prosthesis survival was calculated using the Kaplan-Meier (KM) method and Hazard rate ratios (HRRs) for reoperation risk were calculated with Cox regression analysis.

Results

1-and 5 year KM prosthesis survival was 96.0% (CI: 95.6-96.4) and 95.0% (CI: 94.6-95.4) for the Exeter stem, 97.0% (CI: 96.4-97.6) and 96.3%(CI: 95.5-97.1) for the Lubinus SP2 stem, 97.6% (CI: 97.0-98.2) and 97.0% (CI: 96.2-97.8) for the Charnley stem, 98.1% (CI: 97.3-98.9) and 98.0% (CI: 97.2-98.8) for the Spectron EF stem, 96.4% (CI: 95.6-97.2) and 95.9 (CI: 0.67-1.15) for the Charnley Modular stem. The CPT stem had only been used in the NHFR the last year and follow-up was too short to calculate KM survival. HRR for reoperation after 1 year was statistically significant lower for the Lubinus SPII (HRR 0.77

(95% CI 0.60 - 0.97)), Charnley (HRR 0.64 (95%CI 0.48 - 0.86)) and Spectron EF stems (HRR 0.44 (95%CI 0.29 -0.67)) compared to the Exeter stem. Reoperation due to periprosthetic fracture occurred almost exclusively after operation with polished tapered stems.

Conclusion

This study shows that prosthesis survival after cemented hemiarthroplasties for hip fractures is high. Differences in reoperation rates seem to favor anatomic and straight designed stems compared to polished tapered stems, which had higher risk of periprosthetic fracture.

Bullet points; “Hemiarthroplasty, Reoperation, Periprosthetic fracture”

Introduction

Hemiarthroplasty has become the most common treatment for displaced femoral neck fractures in elderly patients in western countries. It is well known that stem fixation with cement has superior outcome regarding reoperations compared to uncemented fixation in these patients (1-4). Different prosthesis designs and two different cementation principles are used in hemiarthroplasty operations. The polished wedge designed stems with the taper-slip (TS) principle has been designed to subside inside the cement mantle to achieve an even load bearing while the anatomic and straight designed stems with matt finish has been designed to become fixed in the cement mantle after the composite-beam (CB) principle (5). Small observational studies including both hemiarthroplasties and total hip arthroplasties (6-8) and one large register study on total hip arthroplasties (9) has reported higher risk of periprosthetic fracture (PPF) with a polished taper-slip (TS) stem compared to an anatomic stem. Patients treated with hemiarthroplasty for femoral neck fracture represent an older and more comorbid population than the total hip arthroplasty patients (10). No large register study has so far investigated stem survival for cemented hemiarthroplasties. On this background we have studied a large group of patients with femoral neck fractures in The Norwegian Hip Fracture Register (NHFR). We wanted to investigate whether the stem design and brand influences the risk of reoperation and in particular whether the risk of periprosthetic fracture is higher with wedge polished TS stems compared to other stem designs.

Patients and Methods

Data sources

The NHFR has prospectively registered hip fractures in Norway since 2005 (11). After each primary operation and reoperation the surgeons fill in a paper form that is sent to the register. This form includes detailed patient information like age, gender and comorbidity according to the American Society of Anesthesiologists (ASA) classification, time from fracture until surgery, surgical approach, and type of implants using catalogue numbers. For periprosthetic fractures both reoperations that involve removal/exchange of the stem and reoperations with open reduction and internal fixation (ORIF) should be reported. Reoperations are linked to the primary operation using the unique 11-digit Norwegian personal identification number. The coverage of hospitals in the NHFR is 100% and the completeness of reporting of primary hemiarthroplasties in the NHFR has been found to be 93 % compared to the compulsory administrative database of the Norwegian Patient Registry (10,12). Patients were included from the NHFR from 2005 to 2016. As of December 31, 2016 there were 104980 primary operations for hip fractures registered. Pathological fractures (n=1356), other fractures than intracapsular femoral neck fractures (n=42990), other operation methods than bipolar hemiarthroplasty such as osteosyntheses (n=26363), uncemented stems (n=8226), uncemented stems that were cemented (n=725), patients <70 years (n=1557), operations with stems used in <500 cases in the whole study period (n=622), ASA 5 patients (n=13) and patients with incomplete necessary information in the NHFR dataset were excluded (n=1758) (Fig 1). Further, operations with the Titan stem (n=835) were excluded because this stem was not in use during the last years of the studied period (10), and because this stem has shown inferior outcome in an earlier study (13). 20529 cemented bipolar hemiarthroplasties remained for analyses: The Exeter V40 stem (n=11244) (Stryker, Mahwah, New Jersey) and the CPT stem (n=820) (Zimmer, Warsaw, Indiana) has a wedge, polished TS stem design. The Charnley

(n=2389) and Charnley Modular stems(n=1842) (DePuy Synthes, Leeds, United Kingdom.) and Spectron EF stem(n=1312) (Smith & Nephew, Memphis, TN) have matt finish straight design with composite beam stems (CB). The Lubinus SP2 stem (n=2922) (Link, Hamburg, Germany) was the only matt finish anatomic designed CB stem. The stems were mainly used with one particular bipolar head from the same manufacturer as the stem. Accordingly, we did not take the bipolar head brand into account when analyzing the results of the different stems.

Statistical analyses

The Pearson chi-square test was used for comparison of categorical variables and the independent t-test (Student's test) was used for continuous variables in independent groups. 1- and 5-year prosthesis survival was calculated with the Kaplan-Meier method. The Cox regression model was used to calculate hazard rate ratio (HRR) after 1 and 5 years for reoperation with adjustments for age, gender, comorbidity (ASA-class), cognitive function and surgical approach between the groups. Patients without reoperations were censored at time of death, time of emigration, or at December 31. 2016. Data on death and emigration was provided by the Statistics Norway. Further, the Cox model was used to construct adjusted survival curves and to compare risk of reoperation due to all causes and due to periprosthetic fracture between the different stems. The proportional hazards assumption was not fulfilled when investigated visually by use of log-minus-log plots. The curves crossed each other at 40 days for prostheses survival. We therefore performed separate Cox regression analyses with the follow-up divided into two periods; first period from surgery to 40 days postoperative and second period from 40 days postoperative and until December 31. 2016. The proportional hazard assumption was fulfilled within these two time-periods. Since curves only

crossed each other short time after surgery we chose to present HRR after 1 and 5 years. Death is a competing risk and may influence the accumulated probability for revision. Therefore regression analyses for competing risk were performed. The Fine and Gray (1979) regression model for the sub-hazard was applied. These results were compared with the results from the Cox proportional hazards regression model. Additional analyses excluding patients who were operated bilaterally (N=904) were performed. These analyses gave similar results. This is in line with the results of a previous study that showed that adjusting for bilaterally will not alter the conclusions (14). The significance level was set to 0.05. The statistical analyses were performed in the statistical package IBM SPSS statistics version 22 (IBM Corp., Armonk, NY, USA) and the cmprsk Library in the statistical package R (http://CRAN.R-project.org/Package=cmprsk<http://cran.r-project.org/Package=cmprsk>). This study is done using the RECORD and STROBE statement (15).

Results

Overall, 72% of patients were women, and the mean age was 83 years. The median follow-up was 2.1 years, but varied from 0.4 years (CPT stem) to 3.2 years (Charnley stem) when calculated by the reverse Kaplan-Meier method of Schemper and Smith (16). Fewer women were operated with the CPT stem. Patients operated with the Charnley Modular stem had higher comorbidity. There were more patients with cognitive impairment in the Spectron EF group. Further, there were variations between all stems regarding surgical approach (Table I).

When dividing the stems after design, better survival for the straight (HRR 0.66 (CI 0.55 to 0.79), p<0.001) and anatomic designed stems (HRR 0.74 (CI 0.59 to 0.93), p=0.010) were found compared to the wedge designed stems (Fig 2). When analyzing stem brands, the anatomic designed Lubinus SP2 stem and the straight designed Charnley, Charnley modular and Spectron stems with CB cement fixation showed better implant survival compared to the wedge designed Exeter and CPT stems with TS cement fixation (Fig 3). 1-and 5-year KM prosthesis survival was 96.0% (CI 95.6 to 96.4) and 95.0% (CI 94.6 to 95.4) for the Exeter stem, 97.0% (CI 96.4 to 97.6) and 96.3% (CI 95.5 to 97.1) for the Lubinus SP2 stem, 97.6% (CI 97.0 to 98.2) and 97.0% (CI 96.2 to 97.8) for the Charnley stem, 96.4% (CI 95.6 to 97.2) and 95.9 (CI 94.9 to 96.9) for the Charnley Modular stem, and 98.1% (CI 97.3 to 98.9) and 98.0% (CI 97.2 to 98.8) for the Spectron EF stem (Table II). The CPT stem had only been used in the NHFR the last year and follow-up was too short to calculate KM survival. HRR for reoperation after 1 year was statistically significant lower for the Lubinus SPII (HRR 0.77 (CI 0.60 to 0.97)), Charnley (HRR 0.64 (CI 0.48 to 0.86)) and Spectron EF stems (HRR 0.44 (CI 0.29 to 0.67)) compared to the Exeter stem. HRR for reoperation after 5 years was 0.75 (CI 0.60 to 0.95) for the Lubinus SP2 stem, 0.64 (CI 0.49 to 0.84) for the Charnley stem and 0.41 (CI 0.27 to 0.62) for the Spectron EF stem compared to the Exeter stem (Table II). When performing competing risk analyses similar results were found as in the Cox regression analyses. The three most common reasons for reoperation were infection, dislocation and periprosthetic fracture where infection was the most decisive (Table III). Overall, fracture rates were rare, still they were dominating in the wedge designed TS principle stems (n=44). Only 4 periprosthetic fractures were reported as reason for reoperation with the anatomic (n=1) and the straight (n=3) designed stems. For the Exeter stem the periprosthetic fractures (n=40) were evenly distributed between the different stem sizes.

Table IV shows the types of reoperations performed for each stem type. For all stem types, the majority of reoperations occurred during the first months. Few reoperations occurred later than 12 months postoperatively (Table IV).

Using the Exeter stem as reference the risk of reoperation due to periprosthetic fracture was lower for Lubinus SP2 (HRR 0.10 (CI 0.01 to 0.74)), Charnley (HRR 0.09 (CI 0.01 to 0.67)) and Charnley Modular stems (HRR 0.14 (CI 0.02 to 0.99)) (Table V). The CPT stem had higher risk of periprosthetic fracture (HRR 3.19 (CI 1.06 to 9.56)) compared to the Exeter stem. Table VI shows the types of reoperations due to periprosthetic fracture performed for each stem type. More than 50% of these reoperations with the wedge designed TS principle stems occurred during the first 12 months postoperatively. On the contrary, all reoperations for fracture occurred later than 12 months postoperatively for the straight and anatomic designed CB principle stems (Table VI).

As a comparator we also counted reoperations for stems used less than 500 times (see Table III). The 3 periprosthetic fractures reported had all polished wedge design with TS principle (2 MS30 (Zimmer, Warsaw, Indiana) and 1 C-Stem (Depuy International)).

Complications during surgery are also registered in the NHFR and the intra-operative fractures for different stems varied from 0.3 to 1.3%. (Exeter stem; 1.0%, Lubinus sp2; 0.5%, Charnley; 0.3%, Charnley Modular; 0.5%, Spectron EF; 1.3% and CPT; 1.3%).

Discussion

Our results showed that stem design significantly influenced the outcome. The wedge designed stems with TS principle indicates higher risk for reoperation when compared to straight and anatomic stems with composite-beam principle. The most common reason for

reoperation was infection followed by luxation and periprosthetic fracture. Periprosthetic fractures occurred almost exclusively with wedged polished stems.

The Exeter and CPT stems with wedge polished TS design had inferior outcome with higher risk of reoperation compared to the other stems. In our study the Spectron EF stem with straight design had a high implant survival. A RSA study by Kadar et al 2011(17) also showed great 2-year results with the Spectron EF stem with more stability than the Charnley flanged 40 stem in total hip arthroplasties (THAs). These findings are in contrast to an earlier study by Espehaug et al. 2009(18) from the Norwegian Arthroplasty Register on THAs for osteoarthritis, showing better results with the Exeter stem compared to the Spectron EF stem with endpoint aseptic loosening. In Espehaugs study, the Cox regression analyses showed that the inferior results of the Spectron EF stem was due to more reoperations after 7-10 years of follow up especially in the combination with the Reflection non-crosslinked All-Poly cup. Patients operated with a THA are usually more active with healthier bone than the average hip fracture patient. More activity over time will release more micro particles which can lead to osteolysis and aseptic loosening using a proximally rough stem as the Spectron EF. The mean age in Espehaugs study was 73 year. Hip fracture patients are older and frailer than THA patients. Van den Bekerom has reported that hemiarthroplasty patients have 5 years mortality at 63% (19). This could be one explanation why the Spectron EF stem had better outcome in our study including an older population with higher mortality and without the combination with the Reflection non-crosslinked All-Poly cup.

In Norway each hospital decides which implant to use during a tender process. As a consequence of this many hospitals have started using the CPT stem the last year in the study period. When introducing a new implant there will always be a learning curve with a higher reoperation rate at first. This could be one explanation for the higher reoperation rate found for the CPT stem.

Periprosthetic fractures (PPFs) occurred rarely in our study. The Exeter and CPT stems were almost the only stems reoperated due to PPF. In accordance with our study, other studies have also shown an association between wedged polished TS-designed stems and PPFs. In our study, PPFs occurred after 0.2% of the operations. Other studies have reported the incidence of PPF to be 0-4 %. Clinical observational studies (6, 20, 21) have a tendency of reporting higher incidence of this rare complication compared to register studies. Our incidence of PPF is, however, in line with other register studies (2,7,22). An observational study by Mukka et al from 2016 (6), comparing the CPT and Lubinus SP2 stems used in both hemiarthroplasties and total hip arthroplasties for femoral neck fracture, described increased risk of PPF when operating with the TS designed CPT stem and presented several possible mechanisms for this rear complication. Our larger register study supports these findings.

A large register study by Palan from the National Joint Registry in England (22) investigated revisions from periprosthetic fractures after 257 202 primary total hip arthroplasties. They found statistically significant higher risk of revision with the CPT stem and lower risk with the Charnley stem compared to the Exeter stem. They reported that reoperations due to PPF occurred earlier for wedge designed stems (C-Stem, CPT and Exeter) than for the straight Charnley stem. This is in good accordance with our results.

A large review study by Carli et al. published in 2017(23), investigated 596 studies regarding periprosthetic fractures in THAs. In that review they defined the TS fixation as loaded taper design compared to composite beam design. They found 4 studies reporting higher incidence of periprosthetic fractures with the Exeter stem and concluded with the need for registry studies.

Few studies have investigated biomechanical failure modes. None were comparing TS and CB principles. One study by Ginsel et al compared TS-designed, Exeter stem with identical

length and offset with different cross-section size (24) finding large stems were more resistance to torque forces for fracture. The wedge TS design facilitates a thicker cement mantle around the tip of the stem than the straight and anatomic CB designed stems. Osteoporotic bone structure is generally accepted as a risk factor for PFF (25-27). Thick cement mantle and more osteoporotic bone structure on hip fracture patients could be an unfortunate combination. The composite beam principle with anatomic and straight design stems may be more resistant to torque forces. This could be one explanation for fewer periprosthetic fractures. Future biomechanical investigations comparing TS and CB principles are needed.

There were some limitations of our study. Firstly, our primary endpoint was reoperations. Pain and discomfort could be present without reoperation and the result of the operation may accordingly not be good. Further, low grade infections are difficult to detect and could be present as aseptic loosening. Different bipolar heads used in combination with the stems might affect the reoperation rate, especially reoperation for dislocation. The different stems were nearly exclusively used with a bipolar head from the same manufacturer, accordingly we could not adjust for the bipolar head in the Cox regression analyses. The stem with the bipolar head must thus be seen as one unit.

There is a risk of underreporting of reoperations to the NHFR. An underreporting of reoperations due to periprosthetic fractures is possible, maybe in particular in cases where the prosthesis is retained and the fracture is treated with osteosynthesis. However, all reoperations, including osteosyntheses, are registered in the NHFR. If underreporting exists, a selected underreporting of reoperations after only one prosthesis type is unlikely. The burden of periprosthetic fractures may be even larger in real life and make the findings in this study even more clinicaly important.

In a register study no randomization is present for patients or surgeons leading to a risk of possible confounders. Adjustments were done for possible registered confounders such as ASA classification, age, gender, comorbidity, cognitive function, surgical approach, and duration. The results in this study represent the average result that can be achieved on a national level. Each stem was used at multiple hospitals, which decrease the risk that local routines or environmental factors could have influenced the results significantly. Still, some stems were used in fewer units than other stems and small differences in infection rate could be attributed to unit environment.

The strength of the present study is the high number of patients and high external validity. In observational studies, with high number of patients, even small differences may become statistically significant, but they are not necessary of clinical importance. However, in Norway, with approximately 3000 hemiarthroplasties for hip fractures performed annually a small 1.0% difference in risk for reoperation will lead to 30 extra reoperations, or even a 0.2% difference for reoperation due to periprosthetic fracture will lead to 6 extra reoperations in this old and frail group of patients. We therefore believe that the differences found in our study also are of clinical importance. On the contrary, randomized studies may fail to detect small differences due to limited number of patients.

In conclusion, prosthesis survival after femoral neck fracture is relative high. Differences in the results for distinct stem designs are however important, because reoperation of old, fragile patients could result in a devastating outcome for these patients, leading to increased morbidity and mortality. Our results seem to favour matt finished straight and anatomic hemiarthroplasty stems with composite-beam fixation, compared to polished tapered stems which had higher risk for periprosthetic fracture.

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Table I. Baseline demographics

	Exeter	Lubinus SP2	Charnley	Charnley Modular	Spectron EF	CPT	P-Value
Total N	**11 244**	**2922**	**2389**	**1842**	**1312**	**820**	
Age	**83.8**	**83.9**	**83.6**	**84.1**	**84.0**	**84.1**	**0.03***
Women	**71.9%**	**71.3%**	**74.5%**	**71.2%**	**74.4%**	**64.3%**	**<0.005†**
Follow-up, median (years)	**2.1**	**1.9**	**3.3**	**2.9**	**3.0**	**0.4**	
ASA class							**<0.005†**
ASA 1	**1.7%**	**2.4%**	**4.7%**	**1.6%**	**4.6%**	**1.2%**	
ASA 2	**33.0%**	**32.3%**	**34.7%**	**23.0%**	**35.4%**	**29.5%**	
ASA 3	**59.1%**	**58.4%**	**54.7%**	**64.3%**	**53.4%**	**62.7%**	
ASA 4	**6.1%**	**6.8%**	**5.8%**	**11.2%**	**6.7%**	**6.6%**	
Cognitive impairment	**26.7%**	**28.1%**	**24.7%**	**27.6%**	**32.2%**	**28.3%**	**<0.005†**
Approach							**<0.005†**
Anterior	**5.0%**	**11.6%**	**8.0%**	**9.5%**	**20.4%**	**1.5%**	
Lateral	**86.4%**	**81.5%**	**90.1%**	**81.9%**	**64.7%**	**81.1%**	
Posterior	**8.6%**	**6.9%**	**1.8%**	**8.6%**	**14.9%**	**17.4%**	
Hospitals N	**30**	**10**	**22**	**6**	**15**	**15**	
Stem design	**Wedge**	**Anatomic**	**Straight**	**Straight**	**Straight**	**Wedge**	
Stem finish	**Polished**	**Matt**	**Matt**	**Matt**	**Matt, proximally rough**	**Polished**	
Classification	**Taper-Slip**	**Composite-Beam**	**Composite-Beam**	**Composite-Beam**	**Composite-Beam**	**Taper-Slip**	

* Students' t-test †Chi square test

Table II. Survival analysis by Kaplan-Meier and Cox regression for reoperation after hemiarthroplasty

Stem	Total (n)	Reoperation (n)	1-Year survival (95% CI)	5-Year survival (95% CI)	HRR 1 Year (95% CI) *	P-value	HRR 5 Year (95% CI) *	P-value	Left at risk after 5 years (N)
Exeter	11 244	461	96.0 (95.6 to 96.4)	95.0 (94.6 to 95.4)	1 (reference)		1 (reference)		1784
Lubinus SP2	2922	89	97.0 (96.4 to 97.6)	96.3 (95.5 to 97.1)	0.77 (0.60 to 0.97)	0.029	0.75 (0.60 to 0.95)	0.014	476
Charnley	2389	62	97.6 (97.0 to 98.2)	97.0 (96.2 to 97.8)	0.64 (0.48 to 0.86)	<0.005	0.64 (0.49 to 0.84)	0.001	809
Charnley Modular	1843	70	96.4 (95.6 to 97.2)	95.9 (94.9 to 96.9)	0.88 (0.67 to 1.15)	0.35	0.86 (0.67 to 1.11)	0.253	410
Spectron EF	1312	25	98.1 (97.3 to 98.9)	98.0 (97.2 to 98.8)	0.44 (0.29 to 0.67)	<0.005	0.41 (0.27 to 0.62)	<0.005	404
CPT†	820	36	-	-	1.21 (0.86 to 1.70)	0.28	-	-	0

*Cox regression model adjusted for age, gender, comorbidity (ASA-class), cognitive function, surgical approach, and operating time

† Too few patients were left for 1 and 5 year calculation

Table III. Number and causes of reoperations for the different femoral stems

	Total (n)	Reoperations n (%)	Infection n (%)	Luxation n (%)	Fracture n (%)	Aseptic loosening n (%)	Other reasons n (%)
Totalt	20 532	743 (3.6)	373 (1.8)	217 (1.1)	48 (0.2)	7 (0.03)	98 (0.5)
Exeter	11 244	461 (4.1)	230 (2.0)	123 (1.1)	40 (0.4)	4 (0.04)	64 (0.6)
Lubinus SP2	2922	89 (3.0)	42(1.4)	36 (1.2)	1(0.03)	0 (0)	10 (0.3)
Charnley	2389	62 (2.6)	34 (1.4)	15 (0.6)	1 (0.04)	2 (0.08)	10 (0.4)
Charnley Modular	1843	70 (3.8)	44 (2.4)	17 (0.9)	1 (0.05)	0 (0)	8 (0.4)
Spectron EF	1312	25 (1.9)	9 (0.7)	10 (0.8)	1 (0.08)	1 (0.08)	4 (0.3)
CPT	820	36 (4.4)	14 (1.7)	16 (2.0)	4 (0.5)	0 (0)	2 (0.2)
<500*	622	28 (4.5)	16 (2.5)	6 (1.0)	3 (0.5)	0 (0)	3 (0.5)

* Cemented stems excluded from other analyses because of limited use (used less than 500 times during the study period).

Table IV. Type and timing of reoperation, all causes

		Exeter	Lubinus SP2	Charnley	Charnley Modular	Spectron EF	CPT
	Tot N	461	89	62	70	25	36
Type of reoperation	**New THA**	105	27	7	20	7	11
	New HA	36	3	3	-	2	6
	ORIF	20	-	1	1	-	4
	ORIF+ HA/THA	6	-	-	-	-	-
	Debridement for infection	193	38	28	35	8	10
	Reduction of dislocated prosthesis	50	17	13	9	5	2
	Girdlestone	32	2	8	4	2	3
	Other	19	2	2	1	1	-
Timing of reoperation	**0-1 month**	263 (57%)	49 (55%)	37 (60%)	44 (63%)	14 (56%)	26 (72%)
	1-12 months	148 (32%)	32 (36%)	16 (26%)	17 (14%)	8 (32%)	10 (28%)
	>12 months	50 (11%)	8 (9%)	9 (15%)	9 (13%)	3 (12%)	-

HA, hemiarthroplasty, THA, total hip arthroplasty, ORIF, open reduction and internal fixation

Table V. Risk for reoperation due to periprosthetic fracture. Cox regression analysis with adjustments for gender, age group, ASA class, cognitive impairment, and surgical approach.

Stem	Number	Reoperation	HRR (95% CI)	P-value
Exeter	**11244**	**40**	**1 (reference)**	
Lubinus SP2	**2922**	**1**	**0.10(0.01-0.74)**	**0.024**
Charnley	**2486**	**1**	**0.09 (0.01-0.67)**	**0.019**
Charnley Modular	**1890**	**1**	**0.14 (0.02-0.99)**	**0.049**
Spectron EF	**1399**	**1**	**0.17 (0.02-1.25)**	**0.082**
CPT	**820**	**4**	**3.19 (1.06-9.56)**	**0.039**

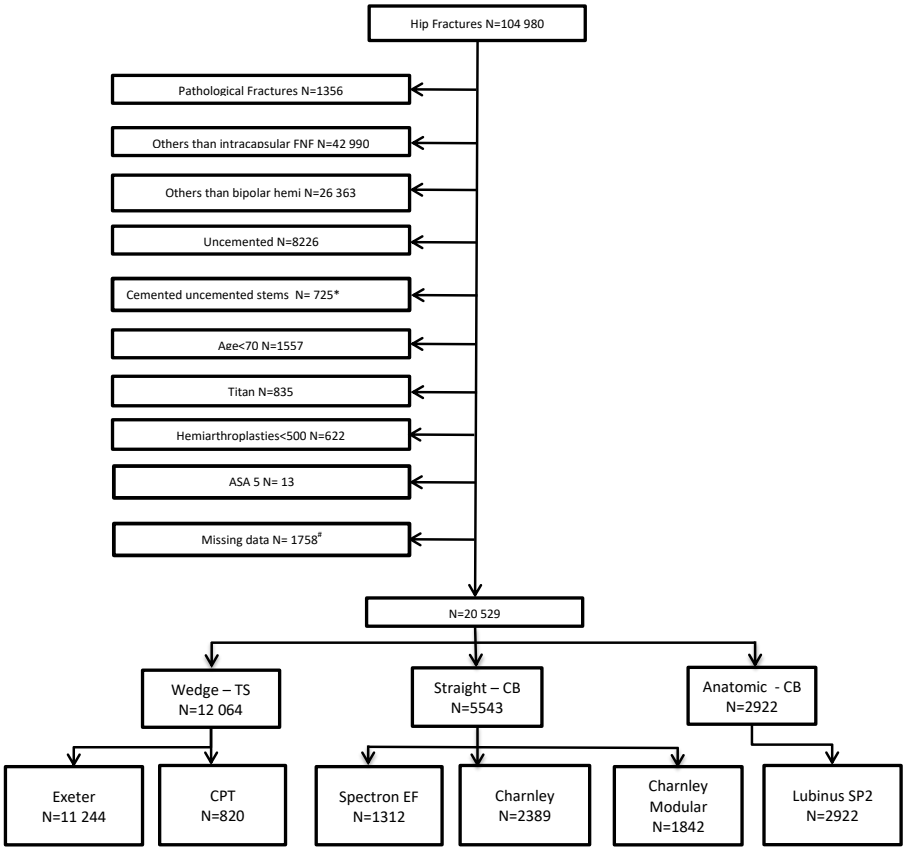
HRR, hazard risk ratio

Table VI. Type and timing of reoperation for periprosthetic fracture

		Exeter	Lubinus SP2	Charnley	Charnley Modular	Spectron EF	CPT
	Tot N	40	1	1	1	1	4
Type of reoperation	**New HA**	12	1	-	-	1	-
	ORIF	19	-	1	1	-	4
	ORIF+ HA/THA	6	-	-	-	-	-
	Other	3	-	-	-	-	-
Timing of reoperation	**0-1 month**	3	-	-	-	-	1
	1-12 months	18	-	-	-	-	3
	>12 months	19	1	1	1	1	-

HA, hemiarthroplasty, THA, total hip arthroplasty, ORIF, open reduction and internal fixation

Fig. 1. Flowchart



FNF=Femoral Neck Fracture TS=Taper-Slip CB= Composite-Beam

*Hydroxyapatite-coated stems fixated with cement

Missing data (incomplete information in NHFR) Exeter: 5.6%; Lubinus SP2: 5.1%; Charnley: 4.6%; Charnley Modular: 4.6%; Spectron EF: 9.2%; CPT: 3.8%

Fig. 2. Kaplan–Meier survival curve by design of stem. TS, taper-slip; CB, composite-beam.

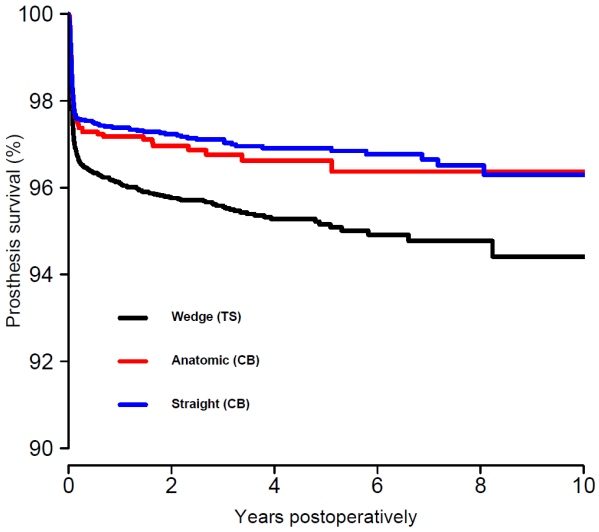
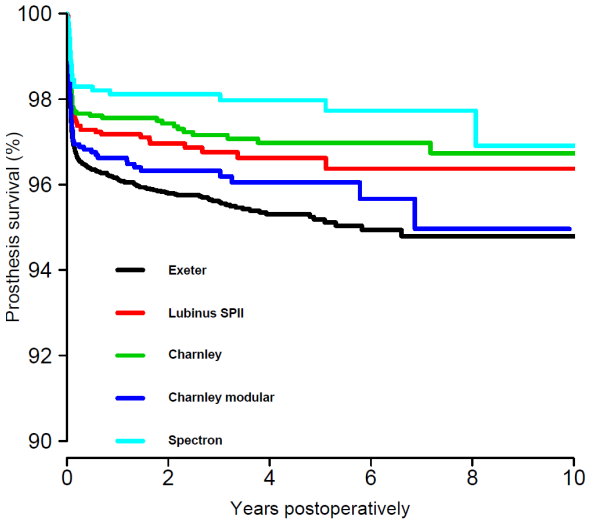


Fig 3. Kaplan–Meier survival curve by brand of stem.



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