Surgical treatment of hip fractures in Norway

The Norwegian Hip Fracture Register

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Scientific environment

This study was initiated in 2004 and the work was carried out while working as a registrar, and later as a consultant surgeon at the Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen. Supervision has been given by the staff at the Norwegian Arthroplasty Register at the same department. During the last three months financial support was given by the Centre for Clinical Research at Haukeland University Hospital.

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Contents

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2. List of abbreviations

ADL	activities of daily living
ANOVA	analysis of variance
AO	Arbeitsgemeinschaft für Osteosynthesefragen (Eng: ASIS)
ASA	American Society of Anaesthesiologists
CI	confidence interval
cm	centimetre
EQ-5D	the five-dimensional scale of EuroQol
EQ-VAS	the visual analogue scale of EuroQol
GLM	general linear model
HA(s)	hemiarthroplasty (ies)
IF	internal fixation
MID	minimal important difference
n	number
NAR	Norwegian Arthroplasty Register
NHFR	Norwegian Hip Fracture Register
NPR	Norwegian Patient Registry
OA	osteoarthritis
RCT	randomised controlled trial
RR	relative risk
THA(s)	total hip arthroplasty (ies)
UK	United Kingdom
VAS	visual analogue scale

3. List of publications

This thesis is based on the following papers, referred to in the text by their roman numerals:

I Gjertsen JE, Engesæter LB, Furnes O, Havelin LI, Steindal K, Vinje T, and Fevang JM. **The Norwegian Hip Fracture Register.** Experiences after the first 2 years and 15,576 reported operations. *Acta Ortop 2008;79(5):583-593.*

II Gjertsen JE, Vinje T, Lie SA, Engesæter LB, Havelin LI, Furnes O, and Fevang JM. **Patient satisfaction, pain, and quality of life 4 months after displaced femoral neck fractures.** A comparison of 663 fractures treated with internal fixation and 906 with bipolar hemiarthroplasty reported to the Norwegian Hip Fracture Register. *Acta Ortop 2008;79(5):594-601.*

III Gjertsen JE, Vinje T, Engesæter LB, Lie SA, Havelin LI, Furnes O, and Fevang JM. **Internal screw fixation versus bipolar hemiarthroplasty as treatment for displaced femoral neck fractures in elderly patients.** A national register based study on 1,031 patients. *Submitted.*

IV Gjertsen JE, Lie SA, Fevang JM, Havelin LI, Engesæter LB, Vinje T, and Furnes O. **Total hip replacement after femoral neck fractures in elderly patients.** Results of 8,577 fractures reported to the Norwegian Arthroplasty Register. *Acta Ortop 2007;78 (4):491-497.*

4. Abstract

Each year in Norway, approximately 9,000 patients are hospitalised and operated on due to hip fractures (femoral neck fractures, trochanteric fractures, and subtrochanteric fractures). There are several treatment methods available for the different types of fractures. Despite the high number of patients, and extensive research on hip fractures, there has so far been no consensus on the treatment. To evaluate the results of different treatment methods for different types of hip fractures, and to investigate the epidemiology of these fractures, the Norwegian Hip Fracture Register (NHFR) was established, and a nation-wide registration initiated, in 2005. The findings of this thesis were based on data from this new hip fracture register and from the Norwegian Arthroplasty Register. The overall intention was to evaluate the treatment of hip fractures in Norway, with special emphasis on dislocated, intracapsular femoral neck fractures in elderly patients.

In the first paper, the completeness of the registration in the NHFR was evaluated using data from the Norwegian Patient Registry. The completeness of operation form registration was 64 % in 2005 and 79 % in 2006. All hospitals performing hip fracture surgery reported to the register at the end of 2006. The response rate of the questionnaire sent to the patients 4 months postoperatively was 58 %. After 2 years of registration, the data in the register confirmed that disagreement on which treatment methods should be used for different hip fractures, and in particular for the dislocated femoral neck fractures, existed between orthopaedic surgeons.

In the second paper, we investigated the outcome of dislocated femoral neck fractures in elderly patients. The results of internal fixation with 2 screws/pins and bipolar hemiarthroplasty (HA) were compared. The functional outcome was assessed from questionnaires sent to patients 4 months postoperatively. This study showed that the patients operated with a hemiarthroplasty had less pain, were more satisfied with the result of the operation, and had a higher health-related quality of life according to EQ-5D.

In the next study, we used the data from the questionnaires sent to elderly patients operated due to dislocated femoral neck fractures 4 and 12 months postoperatively to compare the results of internal fixation with 2 screws/pins and bipolar HA. Statistically significant differences were found after both 4 and 12 months. HA provided less pain, higher patient satisfaction, higher quality of life, and fewer re-operations compared with internal fixation.

The differences were present also in patients with cognitive impairment and in groups of patients with different walking abilities.

In the last study, we used data from the Norwegian Arthroplasty Register to investigate the results of total hip replacement (THA) as treatment for acute femoral neck fractures and sequelae after femoral neck fractures. The results of these particular THAs were compared to the results of THA in patients with osteoarthritis (OA). The results showed that THA in fracture patients showed good results, but with an increased risk of revision, especially due to early infections, early dislocations, and of peri-prosthetic fractures, compared to OA patients.

The overall conclusion of this thesis is that we have established a well-functioning national register for hip fractures. Our findings suggest that elderly patients with dislocated femoral neck fracture should be treated with hemiarthroplasty in preference to internal fixation irrespectively of cognitive function and walking ability. THAs have also showed good results concerning the number of revisions.

5. Background

5.1 Definition of hip fractures

The term hip fracture refers to fractures in the upper femur, including femoral neck fractures, trochanteric fractures, and subtrochanteric fractures. Different studies have revealed a great variation in the fracture type distribution. The femoral neck fractures can be divided into intracapsular fractures and extracapsular, or basocervical, fractures. The intracapsular fractures can further be divided into undisplaced (Garden 1 or 2) and displaced (Garden 3 or 4)[1]. In most studies, the femoral neck fracture is the most frequent fracture type. Approximately 55-60 % of the hip fractures are intracapsular femoral neck fractures, and 2/3 of these fractures are displaced[2-6]. The trochanteric fractures include intertrochanteric and pertrochanteric fractures[7], and constitutes approximately 30-52 % of all hip fractures[2;5;6]. The subtrochanteric fractures are fractures where the centre of the fracture line is between the distal limit of the lesser trochanter and the proximal 5 cm of the femoral shaft. The subtrochanteric fractures and the basocervical fractures constitutes each approximately 5% of all hip fractures[2;5;6].

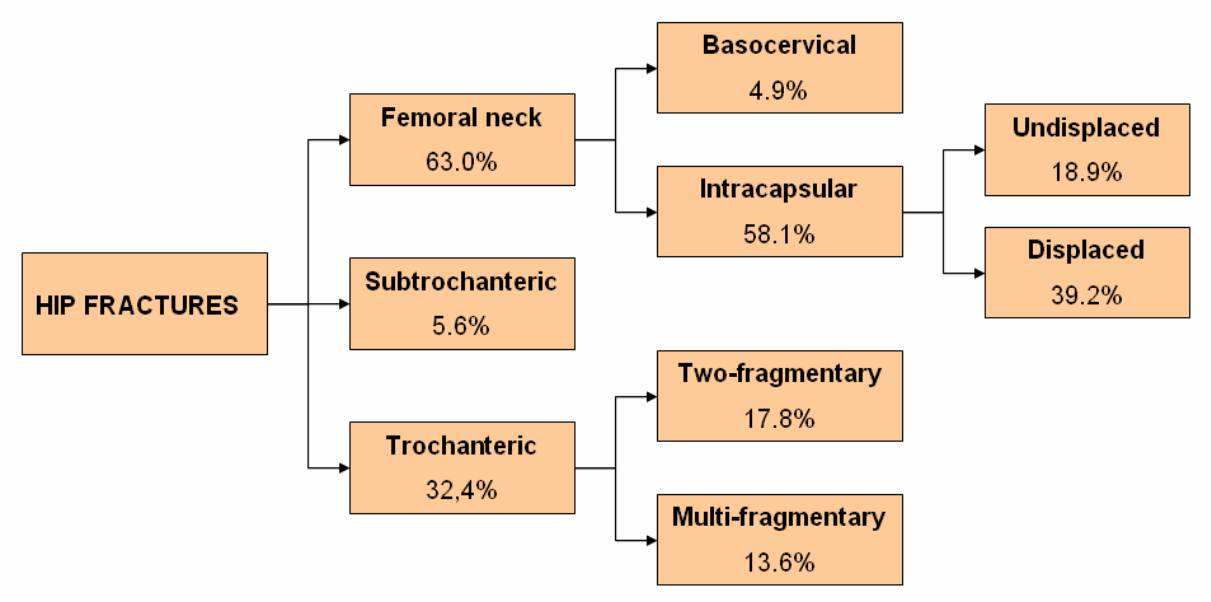

Figure 1. Classification of hip fractures, with distribution in percent according to The Norwegian Hip Fracture Register. Annual Report 2008[8].

5.2 Epidemiology of hip fractures

World-wide approximately 1.7 million hip fractures occur every year[9]. The highest rates are seen in North America and Europe[10;11]. In Norway (with 4.7 million inhabitants), approximately 9,000 patients are hospitalised and operated due to hip fractures annualy[12]. The incidence of hip fractures in Norway is high compared to other countries[4;13;14]. There are also geographical differences in incidence between the different counties[13-16], and even differences in incidence within a single city[17]. During the last decades, the incidence has been increasing both in Norway and other parts of the world[3;13-15;18]. However, several recent studies have suggested a reversal of this trend[19-24]. The mean age of patients at fracture varies in the literature from 74 to 82 years[2-4;6;23]. Only 2 % of the total number of hip fractures occurs in patients younger than 50 years of age[25]. In younger patients, hip fractures usually result from a large trauma, while in the elderly, most hip fractures occur due to low-energy trauma, i.e. fall from standing height. Women constitute from 68 to 78 % of the patients[2-4;6;23]. The high number of women can be explained by the predominance of women over men as age increases, and the higher incidence of osteoporosis among postmenopausal women.

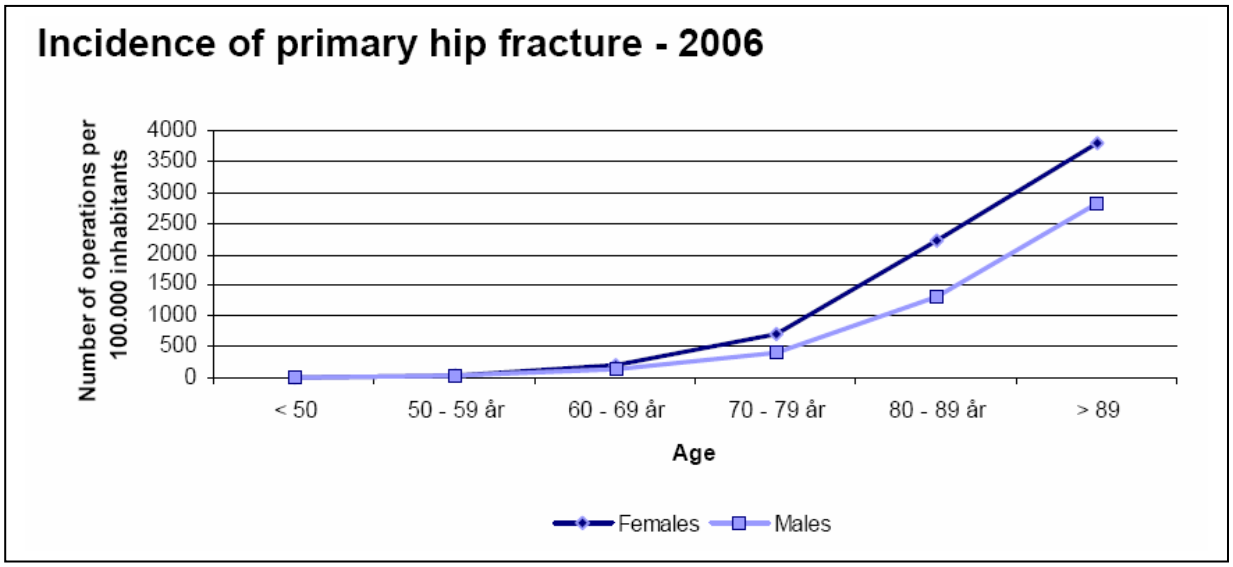

Figure 2. Incidence of hip fractures in Norway. The figure does not show the true incidence as only approximately 80 % of fractures are reported to the register. From: The Norwegian Arthroplasty Register. Report 2007[26].

It has been reported that the incidence of hip fractures increases exponentially with age[4;13;15;18-21;23;26-28]. Around the world the number of elderly is rising. Thus, the advancing age of the population has led to a higher number of hip fractures[27], and increased demands on health service[6;29-32]. Even if assuming an unchanged age- and sex-specific incidence of hip fractures, the projected number of hip fractures world-wide in the near future is escalating. In 2050, there will be between 7 and 21 million hip fractures in the world annually, depending on secular trends[33]. Accordingly, there is a need to develop preventive strategies, and to optimise treatment and rehabilitation[6;33].

5.3 Treatment of hip fractures

5.3.1 Historic perspective

The era of "modern" operative orthopaedics started in 1846 after the introduction of anaesthesia. However, orthopaedic surgery was not without considerable risk for the patients. The invention of asepsis by Joseph Lister in 1867 improved the results concerning infections[34]. Even after Wilhelm Konrad Röntgen discovered X-rays in 1895, the first X-ray machines were not good enough to take satisfactory radiographs of the hip. Accordingly, it was difficult to separate trochanteric fractures from femoral neck fractures. Most patients with hip fractures were treated by bed rest, by traction, with huge splints, or with plaster cast. Most intracapsular fractures did not unite, and the mortality was high[35]. Bernhard Rudolf Konrad von Langenbeck was probably the first surgeon to perform an internal fixation of a non-united fracture in the femoral neck during the 1850-ies using a gimlet, but unfortunately his patient died of sepsis [36]. He was followed by Franz König in 1875, who also used a gimlet to treat a femoral neck fracture in a young patient. This fracture healed, and accordingly, König became the first surgeon to perform a successful internal fixation of femoral neck fracture[36;37]. In Norway, Professor Julius Nicolaysen already in 1897 described an operation method used for femoral neck fractures; after closed reduction, and without general anaesthesia or radiographs, a triangular steel nail was carefully introduced percutaneously, parallel to the assumed axis of the femoral neck. By listening to the sound of the nail being introduced trough the femoral neck, it was possible to identify the time when the nail reached the acetabulum. The nail was then wrapped in a sterile bandage, and the hip was immobilised in a plaster cast. The nail was extracted after 4 weeks and the cast was removed 8 to 10 weeks postoperatively[38].

In 1931, Marius Nygaard Smith-Petersen invented a special nail that on cross section had three flanges, used for stabilising femoral neck fractures by preventing rotation of the

neck of the femur[39]. The nail was originally made from stainless steel, later changed to cobalt-chrome (Vitallium). Sven Christian Johansson introduced a thin metal wire as guide for the Smith-Petersen nail, which now became cannulated[40]. In the trochanteric fractures, a lateral offset plate could be used in addition to the Smith-Petersen nail.

Guy Whitman Leadbetter reported good results with the use of his reduction manoeuvre in 1933. In this manoeuvre, the injured hip was flexed 90 degrees, and while manual traction was applied, the hip was internally rotated and circumducted into abduction. Also in the days before operative treatment with nailing was common he used this method with relatively good results. In patients with intracapsular fractures treated with plaster cast after reduction, approximately 70 % of the fractures united[41].

In 1940 Austin T. Moore constructed a Vitallium model of the proximal femur in a patient with a tumor. The model was made from calculations on radiograms, and had side plates that were bolted to the femur[42]. Later, the idea of an intramedullary stem was introduced; first, the acrylic femoral head prosthesis designed by the Judet-brothers[43;44], later the self-locking metal hemiprosthesis designed by Austin Moore[45]. Frederick R. Thompson invented his hemiprosthesis in 1950[46]. The indications, however, were non-union, avascular necrosis after femoral neck fracture, and bilateral arthritis. From the 1950-ies John Charnley started to develop hip replacements, and his work led to the modern principles of low-friction arthroplasty used today[47]. The Charnley total hip prosthesis and the Norwegian Christiansen prosthesis were the most commonly used prostheses brands in Norway in the 70-ties[48]. The Christiansen prosthesis had, however, inferior results[49].

5.3.2 Modern treatment

General principles

A hip fracture is associated with increased morbidity and mortality. Half of the patients die within 5 years after the operation[50-52]. The increased mortality is in particular prominent in patients with cognitive impairment, comorbidity, and low physical abilities. These patients must be paid special attention during treatment and rehabilitation[53]. Several complications are associated with prolonged bed rest, including infections, thrombo-embolic disease, and pressure-sores. These complications are particularly pronounced in the elderly. Accordingly, it is essential to achieve a good functional outcome as soon as possible. Surgical management which will allow early mobilisation is therefore the treatment of choice for most hip fractures. The aim of the treatment is to return the patients to their pre-fracture functional ability[6;54].

Several newer studies have concluded that the treatment should be based on the patient's age, functional demands, and individual risk profile[55-59]. Many different types of implants exists, each of the implants has its advantages and disadvantages.

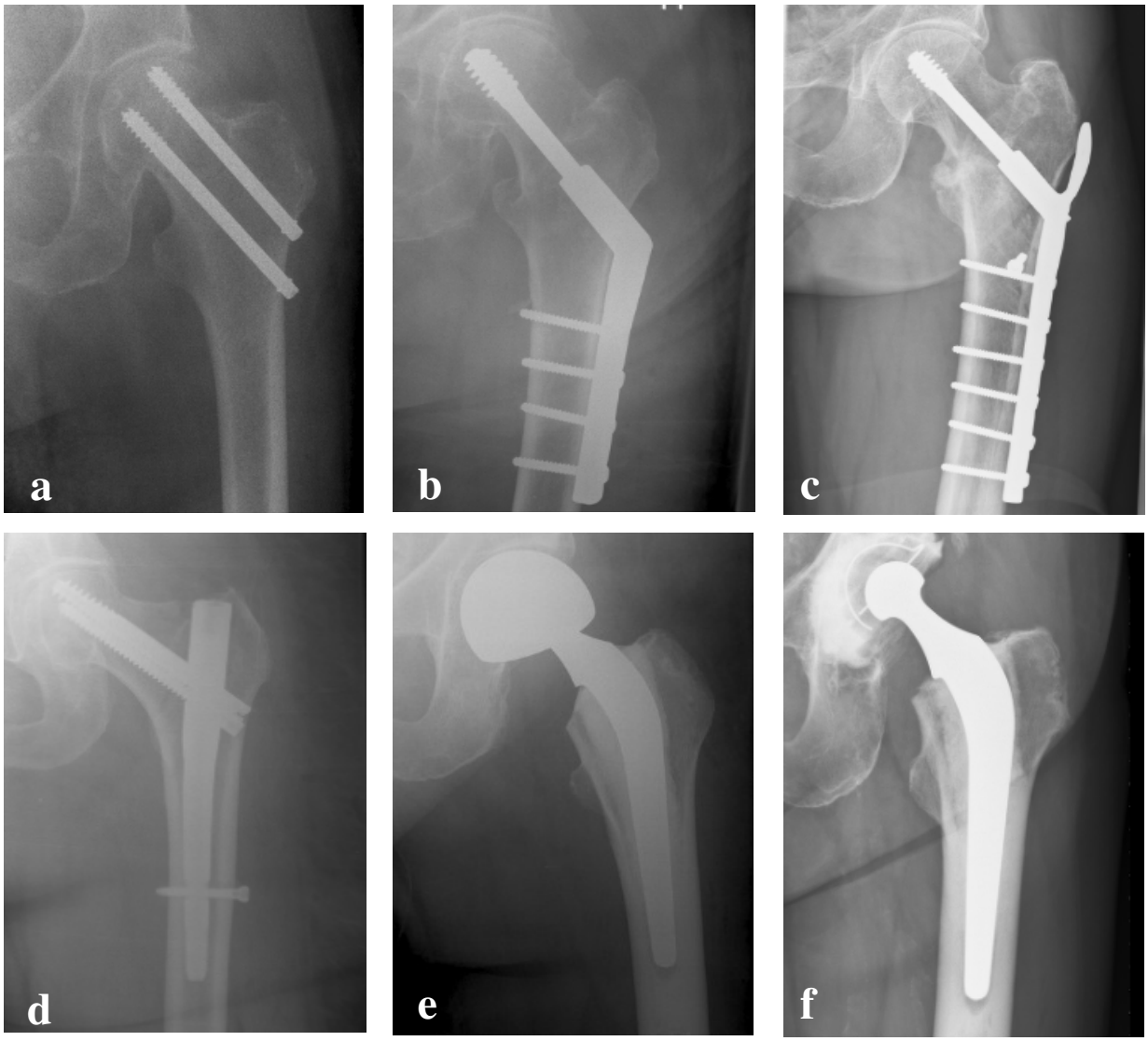

Figure 3. Operation methods for hip fractures. Radiograms of different type of implants:

a. Osteosynthesis with 2 screws
b. Osteosynthesis with hip compression screw
c. Osteosynthesis with hip compression screw with lateral support plate
d. Osteosynthesis with intramedullary nail
e. Hemiarthroplasty
f. Total hip arthroplasty

Screws and pins

Screws and pins have been used for both displaced and undisplaced femoral neck fractures. Several different implants exist. They are introduced in the femoral neck over guide pins through small incisions. The screws have only proximal threads, which secures compression, and consequently, a good contact face in the fracture, even when the femoral neck is shortened during fracture healing. Complications after internal fixation with screws or pins include avascular necrosis of the femoral head, non-union, malunion, osteosynthesis failure, and local pain due to the osteosynthesis-material. For the displaced fractures, reoperation rates from 10 to 49 percents have been found in the literature[60]. For the undisplaced fractures, however, the reoperation rate is low[61]. Screws or pins have been the most common treatment used in younger patients with femoral neck fractures, and for the undisplaced femoral neck fractures in the elderly[62].

Compression Hip Screw

The compression hip screw system has been the most frequently used implant for the trochanteric and subtrochanteric fractures in Norway[5]. It consists of a lag screw inserted into the femoral neck and a hip plate with a proximal barrel. In order to secure compression of the fracture during healing, the lag screw can slide through the barrel. The hip plate can have an integrated or additional lateral support-plate to prevent medial dislocation of the femur. The support plate is especially applicable in the multifragmentary trochanteric fractures, intertrochanteric fractures, and in subtrochanteric fractures. The complications include infection, malunion, fracture of femur, and osteosynthesis failure[63-65].

Intramedullary nail

The intramedullary nails are most frequently used for the trochanteric and subtrochanteric fractures. They are mini-invasively introduced proximal to the greater trochanter, and inserted through the tip of the trochanter or through the piriform fossa. There are several designs of nails available; the preferable design for hip fractures is the reconstruction design. The nails typically have one lag screw that with a guiding instrument can be introduced through the nail and into the femoral neck. Some nails have two lag screws in order to give rotational stability. The recently introduced Trigen Intertan Intertrochanteric Antegrade Nail (Smith & Nephew, Memphis) has one lag screw and one compression screw, which facilitates both rotational stability and intraoperative compression of the fracture. Some nails are equipped with a set

screw used to lock the lag screw in fractures where compression is not required. The characteristics of the fracture determine whether to use a short or a long nail. In order to increase the stability of the fracture, both the short and long nails have distal locking screws. One of the most frequently occurring complications has been the peri-implant fracture[63;66]. Other complications include infection, malunion and osteosynthesis failure[63-65].

Hemiarthroplasty

The hemiarthroplasty (HA) can be used for both femoral neck fractures and basocervical fractures, and are more uncommonly used for trochanteric fractures. A HA is also frequently used as a salvage operation for the non-healed femoral neck fractures in elderly patients. The hemiprosthesis can be of a bipolar or a unipolar design. A bipolar hemiprosthesis consists of a femoral stem, a femoral head and a bipolar head. The femoral head can be in one piece together with the stem, or it can be attached to the stem through a taper locking mechanism, the latter giving the possibility of adjusting tension by choosing between different sizes of the head. The bipolar head is attached to the femoral head, permitting movements both in the hip joint and between the bipolar head and the femoral head. The bearing surface between the femoral head and the bipolar head is typically metal on polyethylene. In the unipolar prosthesis, a hemi-head is attached directly to the stem through the taper locking mechanism, permitting movement only in the hip joint. The monoblock hemiprosthesis consists of only one piece, and is therefore also considered to be unipolar. The hemiprosthesis can be fixated to the femur with or without cement. Modern uncemented stems have a structured surface, and can be hydroxy-apatite coated, to facilitate bony anchoring of the prosthesis. By operating a patient with a HA, the problems with avascular necrosis of the femoral head, malunion, and non-union can be avoided. However, complications after hemiarthroplasty include infections, dislocations, and peri-prosthetic fractures[55;58;67-70]. Also, there is a risk of acetabular erosion, specially in younger, active patients[71-73].

Total hip arthroplasty

An increasing number of patients are operated with a total hip arthroplasty (THA) as primary treatment for acute femoral neck fractures[74;75]. The components of a THA can be of cemented or uncemented design. The THA consists of a femoral stem, a femoral head and an acetabular cup. Both the femoral stem and the acetabular component can be of monoblock or modular design. Modern uncemented implants have a structured surface, and may have hydroxy-

apatite coating, to facilitate bony anchoring of the prosthesis. The femoral head is typically made from metal or ceramic, while the bearing surface of the acetabular component is normally made from polyethylene (plastic), ceramic, or metal. Complications include infections, dislocations, peri-prosthetic fractures, and aseptic loosening[76-78].

Controversies

Primary arthroplasty and internal fixation with screws or pins have been the two main options for treating the dislocated femoral neck fracture in elderly patients. In several randomised, controlled studies, arthroplasty has provided better functional outcome than internal fixation, as assessed by Harris hip score[79] and EQ-5D[80-82]. In two randomised, control studies, hemiarthroplasty showed better results than internal fixation as treatment for dislocated femoral neck fractures[70;83], while other randomised, controlled studies have shown poor results for the hemiarthroplasty compared to internal fixation as treatment for these fractures[55;57]. A Cochrane review comparing arthroplasty and internal fixation found no definite differences in pain and residual capacity[84]. There has, so far, been no consensus in Norway on the treatment of the dislocated femoral neck fractures[5]. This controversy has been the main focus of interest in this thesis. Also, for the trochanteric and subtrochanteric fractures, there has been no consensus on which operation method to be preferred. While some authors advocate intramedullary nailing for the unstable trochanteric fractures[65], other studies recommend hip compression screw as standard treatment[63;85].

The need for a registry

Despite extensive research on hip fractures, the treatment of the dislocated femoral neck fractures in the elderly is still controversial. Several surveys in the past have shown lack of agreement among orthopaedic surgeons on the treatment of these fractures[25;62;86-90]. Further, there has been no consensus on the treatment of trochanteric and subtrochanteric fractures[25;63;65;85]. Increased age in the population has led to a higher number of hip fractures[27]. Due to continued increasing of age, the number of hip fractures requiring treatment accordingly will increase in the future. Consequently hip fracture patients will have an increased demand for the health service[29]. To reduce this already heavy workload for the health system in Norway, it is therefore essential to optimise the treatment of this important group of patients. The lack of consensus states that there is a need for a national register to monitor the treatment of the hip fractures.

National registers for hip fractures already exist in several countries. In Sweden, the RIKSHÖFT was initiated in 1988. With operation forms from the different hospitals, and patient questionnaires 4 months postoperatively, a nationally registration of hip fracture treatment in the elderly has been performed[6]. In the Swedish registry it is possible both to compare different treatment methods for the different fracture types, and to compare different ways of rehabilitating the patients. In 1993 the Scottish Hip Fracture Audit was established to improve hip fracture care, and they now provide nationally comparable data[91]. The Standardised Audit of Hip Fractures in Europe (SAHFE) is a national audit encompassing the Swedish and the Scottish registries as well as datasets from other European countries[92]. Through these datasets it is possible to study background and outcome factors such as rehabilitation methods of hip fractures on a Europe-wide basis and in a standardised manner.

There has been agreement in the Norwegian Orthopaedic Association that a hip fracture register also was needed in Norway. Therefore, The Norwegian Hip Fracture Register was established, and a nation-wide registration of hip fractures was initiated in January 2005[5]. This registry will be thorough described later in this thesis.

6. The Norwegian Hip Fracture Register

Under the initiative of Kristian Bjørgul, the Quality Improvement Committee of the Norwegian Orthopaedic Association started a pilot project from 2001 to 2002 called "Hofte fraktur prosjektet". This project was derived from the Swedish RIKSHÖFT and the SAHFE project. The project was based in 3 hospitals: Haugesund sjukehus, Sykehuset Østfold (Fredrikstad), and St. Olavs Hospital (Trondheim). There were 3 patient forms following the patients through the hospital system, and information was added along the way. Information included final reports from the hospital stay, consultations in outpatient clinics, and reoperations. Data on return to home and functional scores was to be collected by the surgeons. There was a large workload on the contact surgeons, and they only worked part time with the project. Consequently, the hospital reports did not work.

Based on the experience with the pilot project, the committee contacted the Norwegian Arthroplasty Register (NAR) with a suggestion to start a national register of hip fractures. The leader of the NAR, Professor Ove Furnes, consequently became a member of the committee in the end of the project. It was of paramount importance to secure money for the register. After securing the finances from Helse Vest in 2004, the NAR with Professor Ove Furnes, Professor Lars B Engesæter, Professor Leif Ivar Havelin, Dr Jonas Fevang, Dr Jan-Erik Gjertsen, Mrs Kjersti Steindal, and Mrs Lise Kvamsdal started the process of reworking the report forms and writing research protocols. It was decided that the register should be based on the same principles as the well-established Norwegian Arthroplasty Register with regard to only gathering information that the surgeons are able to fill in directly after surgery. Thus, the report form was made simple and consisted of only one page. In order to diminish workload and to increase the compliance, the information on patient-reported pain, patient satisfaction, and quality of life was decided to be collected by mail administrated from the register's central office, and no longer by the hospitals.

At the request of the general meeting of the Norwegian Orthopaedic Association 23, October 2004, The Norwegian Hip Fracture Register (NHFR) was established[5]. The register is owned by the Norwegian Orthopaedic Association, and receives funding from Helse-Vest. In January 2005, the register started a nation-wide registration of hip fractures. The main aims of the NHFR are to collect epidemiological data, to evaluate the results of different treatment methods for the different types of hip fractures in various populations, and to identify inferior implants early on. The register provides data on incidence of fracture types, treatment

methods, and trends over time. Information about the patient, fracture, and operation is obtained from a form that is filled in by the surgeon immediately after surgery (Appendix 1-3). The patient questionnaire is described in more detail in Chapter 9.3 (Appendix 4-7). The register receives records from the Norwegian Register of Vital Statistics with information on dates of death and emigration. The data collection has concession from the Data Inspectorate based on consent from the patients.

Professor Lars B Engesæter has the position as head of the register and Dr Jonas M. Fevang has a 20 % position as orthopaedic surgeon in the NHFR. The orthopaedic surgeons Dr Jan-Erik Gjertsen, Dr Tarjei Vinje, and Dr Kjell Matre are all performing research in the register. Project co-ordinator for the NHFR is Mrs Lise Kvamsdal. Informatics specialist Kjersti Steindal is responsible for the database, and for preparing the annual reports. Mrs Kari Alver Vågstøl and Mrs Marianne Wiese are responsible for the registration of data from the operation forms. Ms Kaia Furnes and Ms Ronja Furnes register data from the patient's questionnaires. Dr Jan-Erik Gjertsen supervises the registration of the operation forms.

The registration completeness has been approximately 80 %, and the response rate of the 4-months patient questionnaires has been 59 %[5]. The annual report is sent to all members of the Norwegian Orthopaedic Association, to all hospitals performing hip fracture surgery, and to the health authorities. Hospital-specific reports are reported back to the participating hospitals to facilitate improvement in treatment.

7. The Norwegian Arthroplasty Register

The Norwegian Arthroplasty Register (NAR) was established in September 1987[93;94]. The register is owned by the Norwegian Orthopaedic Association, and receives funding from Helse-Vest and Helse-Bergen. The register contains prospective data on more than 110,000 primary hip arthroplasties and 18,000 revisions[74]. From 1994 the register was extended to include registration of all joint replacements[95]. The main aim of the NAR is to identify inferior implants as early as possible. The register also provides hospital-specific results, which are reported back to the participating hospitals to facilitate local improvement in treatment. Thus, the NAR functions as a quality register, both locally and nationally[95].

Information is collected through a 1-page form that is filled in by the surgeon after each operation (Appendix 8-10). The same form is used for both primary operations and revisions. Using the patients' national personal identification number, the revisions can be linked to their primary operation. Only operations involving removal or change of one or more prosthesis components are defined as a revision. Small re-operations, such as closed reduction of a dislocated prosthesis or soft tissue revision are not reported. To obtain accurate information on the implants, stickers with catalogue numbers of the implants, supplied by the manufacturers, are used.

The register receives records from the Norwegian Register of Vital Statistics with information on dates of death and emigration. The data collection is approved by the Data Inspectorate. All patients give a written consent to be entered into the register. The completeness of registration in the NAR has been close to 100%, both for primary operations and revisions[96;97]. The register staff includes orthopaedic surgeons, statisticians, informatics specialists, and secretaries.

The annual report is sent to all members of the Norwegian Orthopaedic Association, to all hospitals performing joint replacements, and to the health authorities. Hospital-specific reports are reported back to the participating hospitals to facilitate improvement in treatment.

8. Aims of the study

The overall objective of this thesis was to investigate the treatment of hip fractures, and in particular the displaced femoral neck fractures, in Norway.

The specific aims of the four papers included in the thesis were:

I To describe and evaluate the completeness of the Norwegian Hip Fracture Register, and to describe epidemiological data of hip fractures, and the treatment of these fractures in Norway.

II To compare the functional outcomes 4 months postoperatively of hemiarthroplasty and internal screw fixation as treatment for displaced femoral neck fractures in elderly patients.

III To investigate whether the functional outcomes found in Paper II could be found also after 12 months follow-up, and in particular if similar differences between the treatment groups could be found in subgroups of patients with cognitive impairment and in patients with various degrees of walking ability. Further, to investigate the short-term functional outcomes in patients treated with a secondary hemiarthroplasty. Finally, to assess reoperation rates after hemiarthroplasty and internal screw fixation as treatment for the displaced femoral neck fractures.

IV To investigate the survival of total hip arthroplasty after acute femoral neck fractures and sequelae after these fractures, in particular the short-term time dependent revision rates.

9. Methods

The methods described in Chapter 9.1 to 9.6 refer to the Norwegian Hip Fracture Register, and accordingly to Papers I, II, and III. The methods used in Paper IV were in accordance with the methods described in Chapter 7.

9.1 Collection of data

The collection of data in the NHFR is performed as a prospective observational study. Before initiating the register, we worked out an operation form, to be filled in by the surgeon, and a patient questionnaire. To be able to include the correct questions in the forms, the main problems of interest were defined during this process. Even though some new problems of interest have turned up after the registration of patients started, the research is limited by the specific questions available on the original forms. The data collection has been approved by the Data Inspectorate.

Contact persons (surgeons or medical secretaries) have been established at all hospitals where hip fracture surgery is performed. They are responsible for the local registration of operation forms, which is described in more detail in Chapter 9.3. Each patient has to give a written consent to be entered into the register, and consent from the patient's family is sought if the patient is not able to give or withhold consent. The consent form is entered into the patient record at the hospital. Both primary operations and re-operations are registered. Using the patients' national personal identification number, revisions can be linked to their primary operation. All re-operations should be reported to the register. Hip fractures treated primarily with a total hip arthroplasty (THA), and hips reoperated with THAs due to sequelae after hip fractures, are reported on separate forms and registered in the NAR (Appendix 8-10). These THAs can be added to the analysis files before analyses are performed. Hip fractures treated without surgery are not reported to the register.

9.2 Coding list

Dr Jan-Erik Gjertsen did the coding of the implants, and all other variables on the operation form. For the implants, all main components are registered. Since some hemiprostheses can consist of components from different prostheses brands, and since the implants may consist of different numbers of components, a system where up to 5 different implants could be registered separately was made. The implants were categorised into 5 main groups describing which method of operation that was used (hemiarthroplasty, screws/pins, hip compression screw system, intramedullary nail, angular plate). Further, they were categorised into subgroups to describe the different component in each implant type (e.g. for hemiarthroplasty: femur stem, prosthesis head, bipolar head). Each component was registered with a catalogue number supplied by the manufacturers. Accordingly, all implants were registered as accurately as possible. If only the implant brand, and not the specific type of implant, was known, the implant could still be registered as an unspecified implant of a certain brand. Also, for the other variables on the operation form, code lists were made. The code lists for cement, antibiotic prophylaxis, and thrombosis prophylaxis were the same as the lists in the NAR. Together with project co-ordinator for the NHFR, Mrs Lise Kvamsdal, Dr Jan-Erik Gjertsen has regularly updated the coding lists. New implants have been included in the code lists as soon as they have been reported to the register.

All information was registered in an Oracle 9i database. Once a year, during preparations of survival files and annual reports, data on THAs due to acute hip fractures or sequelae after hip fractures, registered in the database of the NAR, were duplicated into the NHFR database. In order to send questionnaires to the patients at proper times, the two databases were connected monthly to get data also on the acute hip fractures operated primarily with a THA. Further, the registers were monthly updated with information on dates of death and emigration from the records of the Norwegian Register of Vital Statistics. Mrs Kjersti Steindal was responsible for the database, and for making analysis files and annual reports. The Department of Information Technology at Haukeland University Hospital was responsible for the technical- and data safety system.

9.3 Operation form

The operation form to the NHFR has been made as simple as possible (Appendix 1-3). It is a one-page form. And it takes only about one minute to fill it in. To achieve as correct and complete reporting as possible, the surgeons were encouraged to fill in the operation form immediately after surgery. To obtain accurate information on the implants, stickers with catalogue numbers of the implants supplied by the manufacturers were used. If no stickers were available, the surgeon described the implant as accurately as possible.

Time of operation and time of fracture were recorded. If the exact time of fracture was unknown, an estimate of the time from fracture until surgery should be made. The classification of fracture type is described in Chapter 9.4.1. The patient's co-morbidity was estimated using the American Society of Anaesthesiologists score (ASA-score)[98], which is described in Chapter 9.4.2. To define the presence of cognitive impairment, the surgeon - if in doubt – could use the clock-drawing test[99]. The clock-drawing test is described in detail in Chapter 9.4.3. Further, the operation form contained information on type of operation and cause of operation. If a hemiarthroplasty is used, information on fixation and the surgical approach was filled in. In addition, the following information was included:

- Presence of a pathological fracture
- Type of anaesthesia
- Peroperative complications
- Duration of surgery
- Systemic antibiotic prophylaxis
- Thrombosis prophylaxis

In order to send out the 4-months questionnaires to the patients at the proper time, we encouraged monthly delivery of operation forms to the register. Forms lacking information were returned to the hospitals for completion of the data that was missing. One hospital registers the operation forms electronically. Guidance to the operation form has been made and has been to all contact persons.

9.4 Classification

9.4.1 Fracture classification

We defined hip fractures as femoral neck fractures, trochanteric fractures, and subtrochanteric fractures. The femoral neck fractures were further divided into intracapsular fractures and basocervical fractures. For the intracapsular fractures, the Garden classification was used[1]. The Garden classification is one of the most commonly used classification systems available and is preferred by most orthopaedic surgeons[100]. Garden classified femoral neck fractures into 4 types based on displacement on the anterior-posterior radiograph:

Garden I: undisplaced incomplete, including valgus impacted fractures
Garden II: undisplaced complete
Garden III: complete fracture, incompletely displaced
Garden IV: complete fracture, completely displaced

While most surgeons have problems with distinguishing all four Garden fracture types it has been shown that the inter- and intraobserver variation in distinguishing between undisplaced and displaced fractures is acceptable[101]. Therefore, in this thesis, Garden I and II fractures were defined as undisplaced femoral neck fractures and Garden III and IV fractures as displaced femoral neck fractures. The basocervical fractures are extra capsular fractures with the fracture plane running along the capsular insertion, just proximal to the lesser and greater trochanter. During the first 3 years of registration, the trochanteric fractures were divided into two-fragmentary fractures and multi-fragmentary fractures. This was also the classification used in this thesis. In order to investigate the intertrochanteric fractures as a separate group, the AO-classification has been used for the classification of trochanteric fractures since 13. May 2008[7]. The subtrochanteric fractures were defined as fractures where the centre of the fracture line was between the distal limit of the lesser trochanter and the proximal 5 cm of the femoral shaft.

9.4.2 Co-morbidity

The score of the American Society of Anaesthesiologists (ASA-score) was used to assess comorbidity[98]. A patient that smokes more than 5 cigarettes daily was defined as at least ASA 2.

ASA 1: A normal, healthy patient

ASA 2: A patient with mild systemic disease

ASA 3: A patient with severe systemic disease

ASA 4: A patient with incapacitating disease

ASA 5: A moribund patient

9.4.3 Cognitive function

To define the presence of cognitive impairment, the surgeon - if in doubt – could use the clock-drawing test[99]. In this test the patient gets a paper with a circle and the following instruction: "This circle represents a clock face. Please put the numbers so that it looks like a clock and then set the time to 10 minutes past 10". This test has been reported to have good correlation with the Mini-Mental State Examination, and is quick and easy to administer[99].

9.4.4 Charnley category

The Charnley category was used in the patient questionnaire to describe functional ability of the patients[102].

Charnley category A: Involvement of only the ipsilateral hip

Charnley category B: Also involvement of the contra lateral hip

Charnley category C: Also involvement of other joints or systemic problems limiting activity

9.5 Patient questionnaire

A pilot investigation was performed at Haukeland University Hospital in 2004 to test whether elderly patients were able to fill in the patient questionnaires properly. After 4, 12, and 36 months the questionnaires were sent directly from the register to all the patients operated on in 2005 and 2006 (Appendix 4). For scientific- and economic reasons, and in order to reduce the workload at the register, the questionnaires from 2007 were only sent to selected subgroups of patients. The patient questionnaire is described in detail in Paper I[5]. If an operation form was delivered to the register later than 7 months after the primary operation, the 4-months questionnaire was not sent to the patient. However, these patients will still receive the 12-months and 36-months questionnaires.

9.6 Quality of life (EQ-5D)

To assess quality of life, we used the EuroQol, which is a standardised non-disease-specific instrument for describing and evaluating health-related quality of life[103]. It consists of a health status part (EQ-5D) which has five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each item has 3 different responses (no problem, some problems, and major problems) (Appendix 5). The preference scores (EQ-5D index scores) generated from a large European population were used[104]. An EQ-5D index score of 1 indicates best possible health state, and a score of 0 indicates a health state similar to death. Some health states are given negative index score, which indicates a health state worse than death. Further, we used the EQ-VAS, which is a 20-cm visual analogue scale ranging from 0 (signifying worst possible health) to 100 (signifying best possible health) (Appendix 6).

9.7 Quality of data

All operation forms that were difficult to interpret were discussed with Dr Jan-Erik Gjertsen before they were registered in the database. Forms lacking information were returned to the hospitals for completion of the data that were missing. Since all forms from a specific period from a specific hospital were registered consecutively, a form with incorrect information about implants, or other variables, might be more easily discovered. Before the yearly reports were made, the staff of the NHFR critically reviewed the manuscript, and illogical information was corrected. Because hospital-specific reports were sent to the contact persons, they had the possibility to check their own data, and to report back to the register if any operations were missing, or if incorrect information was discovered. To validate the data in the NHFR, our data have been compared to data from the Norwegian Patient Registry (NPR). Compared to the NPR, the completeness of registration was 64 % in 2005 and 79 % in 2006[5].

9.8 Statistics

The Pearsons chi-square test was used for comparison of categorical variables in independent groups. Student's t-test and analysis of variance (ANOVA) were used for continuous variables. All data were considered to be independent. A logistic regression analysis was done to describe each variable's influence on the response rate (Paper I). We used general linear models (GLMs) to adjust for potential confounders in Paper II (age, sex, cognitive impairment, ASA-score, and preoperative delay of surgery) and Paper III (age, sex, ASA-

score). In Paper IV, the Cox model was used to adjust for differences in sex, age, and cement type, to calculate cumulative survival of the prostheses at given times, to make adjusted survival curves, and to calculate differences in revision risk with different reasons for revision as endpoint in the various diagnosis groups[105]. Patients who died or emigrated during the follow-up period were identified from files provided by Statistics Norway, and the follow-up for implants in these patients was censored at the date of death or emigration or at the date of which the annual analysis-files were made. Non-parametric (time-dependent) relative risks in Paper IV were calculated using smoothed scaled Schoenfeld residuals[106]. Continuous variables were normally presented with 95 % CI. The significance levels were set to 0.05; except in Paper I where it was set to 0.01. Patients younger than 70 years were excluded in Papers II and III and patients younger than 60 years were excluded in Paper IV. In Paper II, sub-analyses were performed for patients in different age groups, patients with cognitive impairment, patients with no problems in walking prior to the fracture, and patients in Charnley category A. In Paper III, separate analyses were performed for patients with cognitive impairment and patients with different preoperative walking ability. Both in Papers II and III analyses were performed according to the intention-to-treat principle: i.e. the patients remained in the same treatment group (IF or HA) whether or not a reoperation was performed. Also, analyses without reoperated patients were performed in Paper II and III. In Paper IV separate analyses were performed for patients operated before and after 1995. The statistical analyses were performed with SPSS software for MS-Windows, versions 13.0 (Papers II and IV), 14.0 (Paper I) and 15.0 (Paper III) (SPSS Inc., Chicago, IL) and S-Plus version 7.0 for MS-Windows (Insightful Corp., USA).

10. Summary of Papers I – IV

Paper I

Gjertsen JE, Engesæter LB, Furnes O, Havelin LI, Steindal K, Vinje T, and Fevang JM. **The Norwegian Hip Fracture Register.** Experiences after the first 2 years and 15,576 reported operations. *Acta Ortop 2008; 79 (5):583-593.*

Background: The Norwegian Hip Fracture Register was established in January 2005 to collect nation-wide information as a basis for improved management of patients with hip fractures. This paper reported our experience after the first two years.

Methods: After both primary operations and re-operations, the surgeons filled in a standardised, one-page form with information about the patient, the fracture, and the operation. Fractures treated with a total hip arthroplasty were reported to the national arthroplasty register, but were added to the hip fracture register before analyses were performed. 4, 12, and 36 months postoperatively a standardised questionnaire including health-related quality of life (EQ-5D), visual analogue scales concerning pain and patient satisfaction, and Charnley category for functional assessment was sent directly from the register to the patients. To validate the registration completeness, our data were compared with data from the Norwegian Patient Registry (NPR).

Results: During the first year of registration all 55 hospitals treating hip fractures in Norway started to report their hip fracture operations. During 2005, the monthly reporting increased and it was stabilised in 2006. 13,251 primary operated hips (mean age of patients 80 years, 72 % females) and 2,325 reoperations were reported during 2005 and 2006. Compared to NPR, the registration completeness was 64% in 2005 and 79% in 2006. 58 % of the patients alive answered the 4-months questionnaire. The non-responders were older, more often cognitively impaired, and had a higher degree of co-morbidity compared to the responders. Undisplaced femoral neck fractures (19 % of all fractures) were almost exclusively operated with screw osteosynthesis (95 %). Dislocated femoral neck fractures (38 % of all fractures) were in 52 % of the cases operated with a hemiarthroplasty. Osteosynthesis with a hip compression screw was the dominating operation method (81 %) for trochanteric fractures.

Conclusion: Already after two years, our nation-wide system for surveillance of demographics, treatment, and outcome for hip fractures was functioning well. The response rate on the 4-months questionnaires was as expected relatively low due to an old population with high co-morbidity and cognitive impairment. The different treatment methods used for patients within the same fracture type groups revealed that there was no consensus in Norway regarding the treatment of hip fractures.

Paper II

Gjertsen JE, Vinje T, Lie SA, Engesæter LB, Havelin LI, Furnes O, and Fevang JM. **Patient satisfaction, pain, and quality of life 4 months after displaced femoral neck fractures.** A comparison of 663 fractures treated with internal fixation and 906 with bipolar hemi-arthroplasty reported to the Norwegian Hip Fracture Register. *Acta Ortop 2008; 79 (5):594-601.*

Background: Primary arthroplasty and internal fixation are the two main options for treatment of displaced femoral neck fractures. Despite several randomised studies, the optimal treatment in the elderly is still controversial. Based on data from the Norwegian Hip Fracture Register, we compared satisfaction, pain, and quality of life 4 months after surgery in patients over 70 years of age with a displaced femoral neck fracture operated with internal fixation or with a bipolar hemiarthroplasty.

Patients and methods: Data on 1,569 fractures in patients over 70 years of age operated with internal fixation (n=663) or hemiarthroplasty (n=906) had been registered in the hip fracture register. The register also provided data on patient satisfaction, pain, and quality of life (EQ-5D) assessed 4 months after surgery using VAS scales and EQ-5D health questionnaires.

Results: Patients operated with hemiarthroplasty had less pain (VAS 27 vs. 41), were more satisfied with the result of the operation (VAS 33 vs. 48), and had better EQ-5D index score 4 months postoperatively (0.51 vs. 0.42) than patients operated with internal fixation.

Conclusion: Our findings suggested that a hemiarthroplasty gave better results than internal fixation 4 months after surgery in elderly patients with displaced femoral neck fracture.

Paper III

Gjertsen JE, Vinje T, Engesæter LB, Lie SA, Havelin LI, Furnes O, and Fevang JM. **Internal screw fixation versus bipolar hemiarthroplasty as treatment for displaced femoral neck fractures in elderly patients.** A national register-based study on 1,031 patients. *Submitted.*

Background: Internal fixation and arthroplasty are the two main options in the treatment of displaced femoral neck fractures in the elderly. The optimal treatment remains controversial. Using data from the Norwegian Hip Fracture Register, we compared the results of hemiarthroplasty and internal screw fixation in displaced femoral neck fractures.

Patients and Methods: Data from 1,031 patients over 70 years of age operated due to a displaced femoral neck fracture with internal fixation (n = 428) or hemiarthroplasty (n = 603) were compared. The evaluation was based on the patients' own assessment (visual analogue scales concerning pain (0-100) and patient satisfaction (0-100), and quality of life (EQ-5D)) at 4 and 12 months follow-up. Subanalyses on patients with cognitive impairment were done. The risk of reoperations was also analysed.

Results: After 12 months the HA group reported less pain (19.2 vs. 29.9), higher satisfaction with the operation result (25.7 vs. 38.9), and a higher EQ-5D index score (0.60 vs. 0.51) compared to the IF group. All results were statistically significant ($p<0.001$). Virtually the same statistically significant differences were found at 4 months follow-up. Also for patients with cognitive impairment the HA provided the best functional outcome at 12 months follow-up (less pain, higher satisfaction with the operation result, and higher EQ-VAS) ($p<0.001$). There were 118 reoperations (29 %) performed in the IF group and 10 (1.6 %) in the HA group.

Conclusion: Hemiarthroplasty provided less pain, higher patient satisfaction, and higher quality of life both at 4 and 12 months follow-up compared with internal fixation as treatment for dislocated femoral neck fractures in elderly patients. Also for the cognitively impaired patients the best functional outcome was provided by HA. There were more reoperations in the IF group.

Paper IV

Gjertsen JE, Lie SA, Fevang JM, Havelin LI, Engesæter LB, Vinje T, and Furnes O. **Total hip replacement after femoral neck fractures in elderly patients.** Results of 8,577 fractures reported to the Norwegian Arthroplasty Register. *Acta Ortop 2007; 78 (4):491-497.*

Background: A total hip arthroplasty (THA) is often used as treatment for failed osteosynthesis of femoral neck fractures and increasingly also for acute femoral neck fractures. To investigate the results of THA after femoral neck fractures, we used data from the Norwegian Arthroplasty Register (NAR).

Patients and methods: The results of primary total hip replacements in patients with acute femoral neck fractures (n = 487) and sequelae after femoral neck fractures (n = 8,090) were compared to those of total hip replacements in patients with osteoarthrosis (OA) (n = 55,109). The hips were followed 0 - 18 years. The Cox multiple regression model was used to construct adjusted survival curves and to adjust for differences in sex, age, and type of cement among the diagnostic groups. Separate analyses were done on the subgroups of patients who were operated with Charnley prostheses.

Results: The survival rate of the implants after 5 years was 95 % for the patients with acute fractures, 96 % for the patients with sequelae after fracture, and 97 % for the OA-patients. With adjustment for age, sex, and type of cement, the patients with acute fractures had an increased risk of revision compared to the OA patients (RR 1.6, 95 % CI: 1.0-2.6; p=0.05) and the sequelae patients had an increased risk of revision (RR 1.3, 95% CI: 1.2-1.5; p<0.001). The increased risk of revision was most apparent for the first 6 months after primary operation. Sequelae hips had higher risk of revision due to dislocation (RR 2.0, 95 % CI: 1.6-2.4; p<0.001) and periprosthetic fracture (RR 2.2, 95 % CI: 1.5-3.3; p<0.001) and lower risk of revision due to loosening of the acetabular component (RR 0.72, 95 % CI: 0.57-0.93; p=0.01) compared to the OA patients. There was a marked increase in risk of revision due to deep infection during the first 2 weeks.

Conclusion: THA in fracture patients showed good results, but there was an increased risk of early dislocations, early infections, and periprosthetic fractures compared to OA patients.

11. General discussion

11.1 Register studies as a method

11.1.1 Register studies and randomised, controlled trials

Randomised, controlled trials (RCTs) represent the strongest level of evidence in medical research[107]. These studies should therefore be the gold standard when evaluating clinical evidence in orthopaedic patients. In the field of hip fractures, several randomised studies have been published, and the results of these studies are of great importance when different treatments are compared. However, the randomised studies have, unfortunately, some limitations. First of all, conducting a RCT is difficult, requires large work loads for the researchers, and is time demanding. Accordingly, conducting these studies may be very expensive. In hip arthroplasty surgery, the results are generally very good, and the differences between the different study groups may be small. Consequently, a large number of patients and a very long follow-up are needed to detect differences. In hip fracture surgery, on the other hand, the differences between the different treatment modalities can be large, and RCTs may give highly significant results favouring one particular implant. However, there are several different treatment methods and a great number of different implants available today. Many of the complications that have been reported occur very infrequently, and a very high number of implants and patients must be investigated to detect any statistically significant differences. Since RCTs only can address one or two primary research questions, a very high number of these studies would be necessary. Consequently, it is not possible to conduct randomised studies on all possible hypotheses that ideally should be investigated.

Register studies are less conclusive than RCTs and they have a lower level of evidence. The fundamental criticism of observational studies has been that the results may be distorted by unrecognised confounding factors. It has, however, been shown that observational studies can give results similar to those of RCTs if potential confounders are controlled for[108]. Small differences between treatments may still be due to unknown confounders, and the differences must therefore not be overestimated. To minimise the possibility for confounding of the results, adjusted analyses, such as Cox regression analyses or logistic regression analyses can be performed, in where the simultaneous effect of several risk factors can be studied, and the analyses may be adjusted for skewnesses in the distribution for background variables. On the other hand, register-based studies have several

advantages over the randomised, controlled studies, including lower cost, greater timeliness, and a broader range of patients. Register studies can address several implant brands and patient categories in the same study. Further, a register-based study can collect epidemiological data to give information on incidence of fracture types, treatment methods, and trends over time.

There are some advantages of a national register study. Firstly, the large number of patients makes it possible to find significant results earlier than in a RCT. Secondly, a national register provides the results from the average surgeon at the average hospital. Since hip fracture surgery is performed at more than 50 hospitals in Norway, the results from the large university hospitals, specialised into orthopaedic trauma, generally do not dominate the results. However, a national register study also has disadvantages. If implants are used only in a few hospitals and by a few surgeons, factors such as surgical skills and the particular hospitals' routines and revision policy may influence the results of these particular implants. Further, an eventual specialised rehabilitation program available after the discharge from some particular hospitals may influence the functional outcome of the surgery in these patients.

Some treatments may routinely be selected for the sickest patients by the physicians, and an observational study may in these cases give invalid results[109]. There may be similar differences in the indications for some of the treatment modalities for hip fracture patients; i.e. the sickest patients are operated with one particular treatment method. However, so far it seems to be no consensus on the treatment of hip fractures in Norway[5;89]. The results provided by this national registry reflect the outcomes that can be achieved for the average patients. Further, adjustments for confounders, such as ASA-score and cognitive dysfunction, can be done. Thus, there is reason to believe that the results from the Norwegian Hip Fracture Register may be trusted.

Even if the randomised, controlled trials represent the gold standard when seeking evidence in medical research, it seems clear that it is not always possible, or appropriate, to conduct this type of studies. Observational studies can often give useful and valid data, also when investigating problems that can not easily be clarified with randomised, controlled studies, in particular for rare adverse outcomes. Consequently, it is more accurate to say that observational and randomised studies complement each other, rather than competing in the field of clinical research. Results from both types of studies should therefore be included when searching the literature.

11.1.2 Completeness and quality of data

Completeness of the operation forms

The registration completeness in the Norwegian Arthroplasty Register (NAR) has been high both for primary operations and revisions. Espehaug and colleagues found a registration completeness of 97 % for all primary THAs when comparing the results in the NAR with the data from the Norwegian Patient Registry (NPR)[97]. Arthursson and colleagues found that only 0.4% of the THAs performed at one large local hospital had not been reported to the NAR[96]. In order to obtain a high registration completeness from the surgeons, a one-page operation form, similar to that of the NAR, has been used in the Norwegian Hip Fracture Register (NHFR).

Also for the NHFR, data from the Norwegian Patient Registry (NPR) were used to evaluate the completeness of the registration. The completeness, according to the NPR, was 64 % in 2005 and 79 % in 2006[5]. There was an increase in the reporting to the NHFR during 2005 due to the fact that some of the larger hospitals started registration late that year. A stable reporting rate to the register was observed throughout 2006.

One Norwegian study has reported that re-hospitalisations due to sequelae after hip fractures might be registered in the NPR as acute hip fractures[110]. Accordingly, they found an overestimation of 14 % in the NPR when compared to local electronic databases at 3 hospitals, and therefore questioned the validity of the NPR electronic database. An overestimation was also reported on hip fractures in the English Public Health Common Data Set[111]. These findings may explain some of the difference between the data in the NHFR and the NPR. From 2008, the NPR data will be personally identifiable and consequently, the comparing of data from the NPR and the NHFR will probably be more valid. Validation studies of the registration of both primary operations and re-operations in the hip fracture register should be performed.

The main reason why there was a lower completeness in the NHFR compared to the NAR was probably that it takes time to establish good routines for reporting to a recently established register. Also, while elective hip arthroplasties are performed at daytime by surgeons dedicated to prosthesis surgery, hip fracture surgery is also performed during weekends and at night time by the surgeons on call, usually registrars in training and with a high turnover in their positions. Since both the NAR and the NHFR are dependent on reporting from a large group of surgeons, feedback is important to maintain the surgeons'

interest. Therefore, all participating hospitals receive their hospital-specific report in addition to the annual report.

Completeness of the patient questionnaires

In the NAR, two studies have reported a response rate of 81 % from patients who had undergone primary or revision hip arthroplasties[112;113]. Those patients were younger than, and had probably less co-morbidity than the average hip fracture patient, and they received a reminder if they did not respond to the questionnaire. Thus, the relatively low response rate in the NHFR can be explained by high age, considerable co-morbidity, cognitive impairment, and many patients moving temporarily or permanently into nursing homes. Probably, a better response rate could have been achieved if reminders were sent to the non-responders. The patients who responded to the 4-months questionnaires were younger, less cognitively impaired, and had a lower ASA-score compared to the non-responders. Consequently, the responders represented a selected subgroup of patients. Also, patients with an inferior clinical outcome may be more likely to respond to the questionnaire. However, the results showed that the response rate was not influenced by fracture type and operation method. We therefore believe that data from the 4-months and 12-months questionnaire can be trusted.

11.1.3 Outcome measures

Outcome in the Norwegian Arthroplasty Register

The common outcome measure in the NAR is revision of the prosthesis. The definition of a revision is an operation involving removal or change of one or more prosthesis components. Accordingly, patients with dislocated hip prosthesis treated with closed reduction of the prosthesis should not be reported as a revision to the register. Normally, only patients with recurrent dislocations undergo surgical revision of the prosthesis. The rate of surgical treatment for recurrent dislocations has been reported to be about 40 %[114]. This means that our endpoint was very strict and that the results found in Paper IV could have been more evident if all dislocations were included as an endpoint. Further, patients with prosthesis infection operated with soft tissue revision without a change or removal of prosthesis components were not registered in the NAR, and consequently not included in Paper IV. Again, the endpoint was very strict. Therefore, the risk of deep infection is probably greater than the findings of that study. However, the comparison of the relative risk estimates between OA patients and fracture patients should not be affected unless one of the patient

groups more often was treated non-operatively, i.e. with soft tissue debridement and long-term suppression antibiotic treatment. The use of clinical endpoints, such as functional outcome, would demand that the patients had to be followed regularly with radiographic and clinical controls, which is not practically possible in a national register.

Outcome in the Norwegian Hip Fracture Register

A re-operation is the primary outcome measure in the NHFR. In contrast to the NAR, the NHFR has defined all secondary procedures as re-operations, including removal of implant, soft tissue revisions, and closed reduction of dislocated hemiprosthesis. Since some of the re-operations are performed as day-surgery or in outpatient clinics, there could be a lower reporting rate for these re-operations, especially for the minor re-operations. The results found in Paper IV were, however, in good accordance with the literature. Other studies have reported reoperation rates from 24 to 42 % for internal fixation and from 2 to 13 % for arthroplasties[55;67;83].

In addition to re-operations, clinical outcome measures such as pain, satisfaction with the result of the operation, and quality of life (EQ-5D) can be assessed with the patient questionnaires. One weakness of the clinical outcome variables is that they are patient reported. Information from eventual clinical examinations and / or radiographic controls at the different operating hospitals was not reported to the register. Such data would certainly have strengthened the validity of the results and conclusions of Papers II and III. However, to maintain a good completeness of the registration, it is important to keep the workload for the surgeons as small as possible.

The results from both the VAS scales concerning pain, patient satisfaction, and quality of life (EQ-VAS), and from the EQ-5D index score must be interpreted with some care. Due to the high number of patients in the NHFR, small differences between treatment groups can be statistically significant. However, when the differences are small, they could be of no clinical relevance. This is important to keep in mind when analysing data from the register. Ehrich and colleagues found that, on a 10 cm visual analogue scale, the minimal perceptible clinical improvement was determined to be 9.7 mm[115]. Another study found that changes larger than 12 % of the baseline score, or 6 % of the maximum score, can be detected as minimal important differences (MID)[116]. Two studies found that the lower bounds of MID for EQ-5D index score was between 0.06-0.08[117;118], whereas for the EQ-VAS the lower bound of MID was 7[117]. Consequently, in our studies, a difference of 10 on the VAS concerning pain,

satisfaction, and quality of life (EQ-VAS) could indicate a difference of clinical importance. Similary, a difference of 0.1 on the EQ-5D index score may indicate a significantly clinical difference.

Quality of life

The EQ-5D has been widely used in patients with hip fractures, also when the patients have been cognitively impaired. Several studies have validated the EQ-5D, and it has been recommended to be used also in elderly patients with hip fractures[119-123]. Some studies, however, found some disadvantages for use on the cognitively impaired patients, where differences could be found between the patients' and their relatives' assessments[124;125]. Tidermark and colleagues found that there was a good correlation between the EQ-5D index scores and other outcome measures such as pain, mobility, independence in ADL, and independent living status [119]. One weakness in the design is that the preoperative EQ-5D is assessed retrospectively at 4 months postoperatively. The patients, or the relatives, may have problems remembering the exact situation before the fracture. Consequently, the answers in EQ-5D may be inaccurate. Lingard et al found only moderate agreement between recalled data and prospective data concerning preoperative status[126]. In contrast, Howell et al found the correlation between prospective data and recalled data to be good[127]. However, the preoperative EQ-5D index score reported by the patients in study II and III showed good correlation with an age-matched Swedish reference population[128].

11.2 Results

11.2.1 Epidemiology and treatment of hip fractures

In Paper I, we found that the mean age of patients was 80 years, and that 72 % of the patients were women. These findings corresponded well with the results of the Swedish National Hip Fracture Register, RIKSHÖFT (mean age 81 years, 71 % females)[6] and the Scottish Hip Fracture Audit (mean age 81 years, 76 % females)[91]. Other epidemiological studies of hip fractures in Northern Europe found a mean age between 78 and 82 years[2-4;23;25;129;130]. In these studies, between 70 % and 79 % of the patients were women. In Paper I we found that the femoral neck fractures constituted 57 % and the trochanteric fractures constituted 30 % of all fractures. Also the distribution of fractures was similar to that presented by the Swedish register[6]. Furthermore, other studies found that the femoral neck fracture was the most

frequent fracture type (41-61 %), and that the trochanteric fractures constituted between 35 % and 52 % of all hip fractures[2-4;23].

The results in Paper I showed that there was no national consensus on the treatment of dislocated femoral neck fractures. However, compared to earlier studies from the NHFR, a greater part of the patients has recently been operated with a hemiarthroplasty, which now has become the most frequent operation method used when treating these fractures[131;132]. This may indicate a shift in the treatment from primary osteosynthesis to hemiarthroplasty in patients with dislocated femoral neck fractures. Also in Denmark a similar shift in the treatment of these fractures has been found[62]. One explanation to this shift is probably the results of several studies concluding that the outcome after arthroplasty is superior to that after internal fixation[67-70;80-83;133-135]. Another explanation, however, may be that treatment of hip fractures nowadays are performed more frequently by trained orthopaedic surgeons, instead of general surgeons with less competence in arthroplasty surgery.

In a recent Norwegian national survey, Figwed and colleagues found great variance in the hospitals' preferences on the treatment methods of dislocated femoral neck fractures in the elderly. Written directions on the treatment of hip fractures only existed at 55 % of the hospitals[89]. Other surveys have found the same lack of consensus in Denmark, UK, Canada, and USA[62;86;87;90]. Results from the Scottish Hip Fracture Audit, showed no consensus on the treatment of both undisplaced and displaced femoral neck fractures in patients over 80 years of age, although the majority of patients with displaced fractures was operated with arthroplasty. In addition, there was great variance in the policy of using uncemented prostheses between the different hospitals[91]. In two prospective multicenter studies, a heterogeneous treatment of femoral neck fractures and trochanteric fractures between hospitals in Sweden, Finland, and the Netherlands were found. There were also differences between the two Swedish hospitals[25;136].

In Paper I, no consensus on the treatment of trochanteric and subtrochanteric fractures were found. Other studies from other European countries have also indicated that the treatment of trochanteric fractures varied between different countries, and also between hospitals within the same country[25;136]. In Norway, the compression hip screw has been the dominating operation method used for these fractures, although the trochanteric multifragmentary fractures, and in particular the subtrochanteric fractures, frequently were operated with intramedullary nailing [5;131]. The Gamma nail (Stryker Howmedica) has been used as treatment for trochanteric and subtrochanteric fractures in several hospitals, and is the

most popular intramedullary nail used when treating hip fractures in Norway[5]. This implant has been associated with an increased risk of femoral shaft fractures[63;64;66]. So far, there seems to be no agreement in the literature on the treatment of the trochanteric and subtrochanteric fractures, even though the Cochrane collaboration recommend compression hip screw for the trochanteric fractures[65;85;137-139].

11.2.2 Treatment of displaced femoral neck fractures in elderly patients

The main findings in Papers II and III were that hemiarthroplasty (HA) provided less pain, more satisfied patients, better quality of life according to the EQ-5D, and fewer re-operations in elderly patients with displaced femoral neck fractures compared to internal screw fixation (IF). The superior outcome was present both at 4 and 12 months follow-up.

Already in 1979, Søreide and colleagues found that hemiarthroplasty provided better results than internal fixation in patients with femoral neck fractures[135]. However, the treatment of the dislocated femoral neck fractures in the elderly is still controversial[25;62;86-90]. Our findings were in good accordance with the results of a recent randomised, controlled study from Frihagen et al comparing hemiarthroplasty (HA) with internal fixation (IF) using Harris hip score, EQ-5D, and Barthel index as functional outcome[83]. The patients in that study were also Norwegian, and they were about the same age. However, they had more patients with cognitive impairment. They found virtually the same differences in EQ-5D index score and EQ-VAS between IF and HA as in our study at both 4 and 12 months follow-up. However, in the randomised study, all mean values were generally higher than in the present study for both treatment groups. One reason can be that the EQ-5D in the two studies was assessed differently. In the randomised study, a research assistant registered the EQ-5D, and the patients might be eager to please the department that performed the surgery. In our study, the EQ-5D was filled in by the patients or the relatives in their homes and sent to an independent national register by airmail. One other reason can be that our study represents the results from a whole country with a large cohort of patients, and from the average surgeon, and not only the results from one specialised clinic with special interest for these fractures. Our results were also in good accordance with another recent randomised, controlled study that used pain and walking ability as functional outcome[70].

Other studies in which the uncemented Austin Moore uncoated hemiprostheses were used, found no difference in functional outcome compared to IF[55;57;133;140]. One reason could be the use of hemiprostheses documented to have inferior results[141]. In our study, most

prostheses were cemented, and the majority of the uncemented prostheses had modern, hydroxy-apatite coated stems. The results of cemented prostheses have previously been reported to be better than the results of uncemented, uncoated hemiprostheses, concerning pain, walking ability, use of walk aids and ADL[142]. Other studies reported better results after arthroplasty compared to IF at early follow-up, but with less differences at later follow-ups[68;70;79;80]. According to these studies and the present study, the patients in the arthroplasty group might have a faster rehabilitation period with less pain and better quality of life. A hip fracture is associated with an increased mortality, and half of the patients are dead within 5 years[50;51]. Therefore, it is important to achieve a good outcome as soon as possible.

Furthermore, sub-analyses in paper III showed that the bipolar HA performed well also in the cognitively impaired patients. This is in contrast to an earlier study that found no difference in functional outcome between IF and HA in this subgroup of patients[55]. The cognitively impaired patients were older and had a higher degree of comorbidity. The probability for these patients to be reoperated may therefore be less than for other patients. Consequently, to avoid a final inferior outcome it is important that these patients are operated initially with the best available treatment. According to the results of this study, the cognitively impaired patients should be operated with a modern well-documented hemiprosthesis. The sub-analyses of patients with minimal and moderate problems in walking showed similar differences as those found for all patients, favouring HA as the treatment of choice independent of the patient's walking ability. For ambulatory healthy elderly patients with high functional demands, several studies have found better results after THA compared to IF as treatment for dislocated femoral neck fractures[57;79-81;143]. In order to find the optimal treatment modalities for the different patient groups, comparison of the results of THA and HA will be performed in future studies from our register. The results from Paper III showed that the secondary HAs provided the same functional outcome as the primary HAs at follow-up 12 months after the index operation, although there was a non-significant tendency towards poorer results for the secondary HAs. All these salvage arthroplasties had a follow-up of more than 4 months, and this could indicate that the rehabilitation period also for these secondary procedures was rapid. These results must however, be interpreted with some care. Other studies have reported more pain one year postoperatively[144] and a higher risk of reoperation after secondary HA compared to primary HA[144;145].

In Paper III, few minor reoperations, such as removal of screws or pins, were reported. Our results were in good accordance with other studies that have reported a reoperation rate

from 24 to 42 % for internal fixation and from 2 to 13 % for arthroplasties[55;67;83]. A meta-analysis found reoperation rates from 10 to 49 % for internal fixation and from 0 to 24% for arthroplasties[60]. According to our data, only 2 hemiprostheses (0.3 %) were re-operated due to dislocation. Only one closed reduction (0.2 %) of a dislocated hemiprosthesis was reported to the register. This is in contrast to a recent study finding that dislocation occurred in 4 % of hemiarthroplasties, and that the dislocations most frequently were interprosthetic, i.e. separation of the prosthesis head and the bipolar head[146]. This result indicates that an under-reporting of re-operations to the NHFR, and especially closed reduction of dislocated hemiarthroplasties, exists. One of the long-term complications associated with hemiarthroplasty is acetabular erosion[71-73]. The follow-up for the patients included in Papers II and III is, so far, too short to assess this problem. The rate of re-operations after hemiarthroplasty will therefore probably increase.

Several RCTs have found that total hip arthroplasty provided better functional outcome than internal fixation when assessed by Harris hip score[79] and EQ-5D[80-82]. In a Cochrane review comparing IF and arthroplasty, Parker and Gurusamy found no definite differences in pain and residual disability[84].

Several more recent studies have concluded that the treatment of the displaced femoral neck fractures should be based on the patient's age, functional demands, and individual risk profile[55;56;58;59]. With today's knowledge, arthroplasty surgery seems to give superior results compared to internal fixation in the elderly, provided that well-documented, good prosthesis brands are used. Our register-based study in a large cohort confirmed that the hemiarthroplasty gave satisfactory outcome[147]. THA may, according to other studies, give better outcome than a HA both in the short and long term, in particular in the relatively healthy, active, and lucid patients. However, a THA has also some disadvantages that will be discussed in Chapter 11.2.3.

11.2.3 Total hip arthroplasty as treatment of hip fractures

Total hip arthroplasty (THA) is known to be a highly cost-effective operation for patients with osteoarthrosis (OA) [148]. Every year approximately 6,500 patients receive a THA in Norway. Primary osteoarthrosis was the cause for of the THAs in 78 % while 7.1 % were performed due to sequelae after previous fractures in the proximal femur[8]. An increasing number of patients are operated with primary THA after acute fractures in the femoral neck[8;75]. This may

reflect an indication shift from primary internal fixation to THAs in patients with displaced femoral neck fractures.

In Paper IV we found that total hip arthroplasties (THAs) as treatment for primary osteoarthritis (OA) provided good results when the main outcome measure was revision. Similarly, THAs after acute femoral neck fractures and sequelae after these fractures had good results. The results were, however, inferior to those of the OA patients mainly due to more infections during the first 2 weeks and dislocations during the first year after surgery, and due to more periprosthetic fractures. This is in accordance with the findings of Johnsen and colleagues who found that patients with sequelae after trauma had an adjusted RR of implant failure of 2.8 between 31 days and 6 months after primary THA, when compared to OA patients[149]. After 6 months they found no statistically significant difference.

We found that one of the most important risk factor for revision of the prostheses in the patients with acute femoral neck fractures or sequelae after such fractures was dislocation. Other studies have also confirmed these results[76;78;150-153]. Bystrøm and colleagues found that femoral head size was an important risk factor for dislocations of THAs[151]. Studies have reported that increasing age, and especially the presence of cerebral dysfunction is associated with a higher dislocation rate[151;154]. However, in Paper IV the patients with acute femoral neck fractures and sequelae after fractures had a lower average age than usually seen in studies of femoral neck fracture patients[5;80;119;155]. Consequently, these patients represented a selected group of femoral neck fracture patients. Other plausible explanations to dislocation can be an increased tendency to fall, less muscular control, abnormal local anatomy with limb shortening and scar tissue after the previous operation. Only patients with recurrent dislocations undergo surgical revision, and as mentioned in Chapter 11.1.3, our results might have been even more significant if we had used dislocation alone as the end-point.

In the time dependence study in Paper IV the sequelae group had a significantly increased risk of revision due to infection during the first 2 weeks postoperatively compared to OA patients. Our study only included patients who underwent surgical revision with a new prosthesis or with an exchange or removal of one or more of the components. Patients operated only with a soft tissue revision were not registered, and thus we believe that the risk of deep infection is larger than the results presented in Paper IV. However, the relative risk estimates comparing OA patients and fracture patients should not be influenced unless the fracture patients more often are treated with soft tissue debridement and long time suppression antibiotic treatment than OA patients. A previous study from our register found no statistically significant difference in infection risk when comparing sequelae patients with OA

patients[78] but this study did not present time dependent analyses. The risk of a deep infection is still small. More use of antibiotics, both systemically and in cement, may be one possible explanation to these good results[156;157].

Patients with sequelae after femoral neck fractures have been reported to have an increased risk of peri-prosthetic fractures[76;78;158]. Our study confirmed these results. In a nation-wide observational study, minor trauma, including a fall to the floor, and a spontaneous fracture was reported to be the main aetiologies for peri-prosthetic femoral fractures[159]. Patients with previous femoral neck fractures may have a higher tendency to fall. They are also osteoporotic and thus more prone to fractures. Also, holes after osteosynthesis material in the proximal femur may cause a weakness in the bone and may lead to peri-prosthetic fractures. In Paper IV only patients who have had a surgical revision with a new prosthesis component were included. The patients treated with wire and/or plate fixation were not reported to the Arthroplasty Register and were therefore not included. The true number of peri-prosthetic fractures is therefore probably higher.

In several, recent randomised controlled studies THA has provided superior functional outcome than IF as treatment of dislocated femoral neck fractures[57;70;79;81;82;143]. In other studies THA gave superior results compared to HA as treatment of femoral neck fractures[56;57;71]. Blomfeldt and colleagues found that secondary THAs performed as salvage operations after failed IF provided inferior hip function according to Charnley score and EQ-5D when compared to primary THA for displaced femoral neck fractures[160]. The results of these randomised studies suggest that THAs could be recommended as a treatment of femoral neck fractures in the relatively healthy, lucid, elderly patients with high functional demands. The long-term results of these particular THAs should be addressed in future studies.

12. Conclusions

Paper I:

- All hospitals performing hip fracture surgery reported to the NHFR.
- The registration of data in the register was satisfactory after two years of registration.
- 59% of the patients answered the 4-months questionnaire. Considering high age and considerable co-morbidity, this result is as expected.
- There was no consensus in Norway regarding the treatment of hip fractures.

Paper II:

- Patients with a dislocated femoral neck fracture treated with a HA had less pain, were more satisfied with the result of the operation, and had a higher quality of life 4 months after surgery compared to patients treated with IF.

Paper III:

- The differences in functional outcome found in Paper II persisted 12 months postoperatively.
- HA provided a superior functional outcome than IF also in patients with cognitive impairment, and in subgroups of patients with different walking ability.
- No significant difference between primary and secondary HA was found twelve months after the index operation, although there was a non-significant tendency towards poorer results for the secondary HAs.
- There were more re-operations in the IF group compared to the HA group.

Paper IV:

- THA had good results, not only for OA, but also for acute femoral neck fractures and for sequelae after femoral neck fractures.
- The patients with an acute fracture had a 1.6 times higher risk of revision compared to OA patients. The sequelae patients had 1.3 times higher risk of revision.
- We found an increased relative risk of revision for the fracture patients due to early dislocation and infection, and due to peri-prosthetic fractures compared to the OA patients.

13. Future research

13.1 Surgical outcome after hip fractures

The reoperation rates for the dislocated femoral neck fractures have, so far, only been investigated briefly and we still have a short follow-up of the implants [147]. Even though we know that most complications following osteosynthesis occur during the first two years, the problems with loosening or wear of the prosthesis, or acetabular wear in the hemiarthroplasties may occur later. The higher risk of reoperation for the secondary hemiarthroplasties found in other studies must be further investigated also in the hip fracture register[144;145]. The hemiarthroplasty has become the most frequently used operation method for the dislocated femoral neck fractures[5]. Several types of hemiprosthesis designs exist. Future studies should focus on the results of different types of prostheses. The results of cemented and uncemented prostheses should be compared. Further, the results of the monoblock-prostheses should be investigated. Finally, since an earlier study has shown a risk of interprosthetic dislocation in prostheses with snap-fit bipolar heads, the results of these prostheses should be compared to the results of bipolar hemiprostheses with locked bipolar heads[146].

13.2 Functional outcome after hip fractures

The results of Papers II and III showed superior outcome in patients operated with HA compared to those operated with IF. The follow-up was, however, only 12 months. The patients included in the studies above all had their primary operation in 2005 and 2006. All patients still alive at 36 months follow-up will receive a new questionnaire and the results from these questionnaires will be investigated, and compared to the 4- and 12-months results. The comparison of primary and secondary HAs in Paper III must be further investigated. Before conclusions can be made, a longer follow-up and a higher number of patients are needed. Total hip arthroplasties performed due to acute hip fractures, and registered in the NAR, are also included in the files of the NHFR. Consequently it will be possible to compare the functional outcome of HA and THA. Earlier studies have shown that THA gives superior outcome compared to HA as treatment of dislocated femoral neck fractures[56;57;71]. Since also patients operated with a primary THA due to a femoral neck fracture receive questionnaires 4, 12, and 36 months after surgery, the results of these particular THAs should be compared to the results of both IF and HA. Further, the outcome after IF in younger patients should be investigated. For all the different treatment modalities, sub-analyses should be done in

different age groups. As a result of this thesis and several recent studies it seems likely that most dislocated femoral neck fractures in the elderly should be treated with an arthroplasty. Further research should concentrate on which type of arthroplasty that gives the best outcome for different patient categories.

13.3 Economic outcome after hip fractures

One important issue that has not been discussed in this thesis is the economic outcome after the different treatment modalities for patients with displaced femoral neck fractures. The initial cost of treating a patient with screw osteosynthesis is lower than treatment with a bipolar HA. However, the patients in the IF group have more re-admissions due to hip-related problems, and they undergo more reoperations than patients operated with HA. Keating and colleagues found, accordingly, that the total hip-related costs was higher in the IF group compared to the HA group[81]. A study from Rogmark and colleagues found similar results, favouring the HA group as the most cost efficient treatment[161]. Another study found that THA was the most cost-effective treatment for the elderly patients with displaced femoral neck fractures[162]. Using data from NHFR and NAR it is possible to examine the cost-effectiveness of IF, HA and THA as treatment for the dislocated femoral neck fractures.

13.4 Mortality rates after hip fractures

Postoperative mortality is one important factor to consider when choosing between different surgical procedures. The mortality rates have only been briefly investigated in this thesis. However, in order to complete the comparison of IF and HA as treatment for the dislocated femoral neck fractures, a study assessing mortality rates has been initiated[163].

14. Source of data

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15. Appendix

Appendix 1 Operation form The Norwegian Hip Fracture Register 2005-2008 (Norwegian)

Appendix 2 Operation form The Norwegian Hip Fracture Register 2008- (Norwegian)

Appendix 3 Operation form The Norwegian Hip Fracture Register 2008- (English)

Appendix 4 Patient questionnaire (Norwegian)

Appendix 5 EQ-5D (English)

Appendix 6 EQ-VAS (English)

Appendix 7 Visual analogue scales (English)

Appendix 8 Operation form The Norwegian Arthroplasty Register 1987-1992 (Norwegian)

Appendix 9 Operation form The Norwegian Arthroplasty Register 1993-2004 (Norwegian)

Appendix 10 Operation form The Norwegian Arthroplasty Register 2005- (Norwegian)

Appendix I

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

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

Navn:.....

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

Sykehus:.....

HOFTEBRUDD

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

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

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

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

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

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

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

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

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

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

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

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

Navn / størrelse ev. katalognummer.....

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

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

Navn / størrelse ev. katalognummer.....

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

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

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

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

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

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

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

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

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

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

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

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

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

Ev. i kombinasjon med .....

Dosering.....Antatt varighet.....døgn

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

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

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

Appendix II

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

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

Navn:.....

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

Sykehus:.....

HOFTEBRUDD

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

AKTUELLE OPERASJON
☐1 Primæroperasjon ☐ 2 Reoperasjon

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

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

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

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

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

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

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

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

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

Navn / størrelse ev. katalognummer……

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

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

Navn / størrelse ev. katalognummer……

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

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

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

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

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

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

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

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

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

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

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

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

Senere dosering……Antatt varighet……døgn

Ev. i kombinasjon med ……

Dosering……Antatt varighet……døgn

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

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

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

Appendix III

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

Birth number:.....

Name:.....

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

Hospital:.....

HIP FRACTURES

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

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

CURRENT OPERATION
☐1 Primary operation ☐ 2 Revision

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

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

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

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

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

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

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

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

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

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

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

Name / size, if possible Catalogue number……

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

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

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

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

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

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

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

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

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

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

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

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

Later dosis…….. Duration..……days

Evt. in combination with ……..……..……..

Dosis..……..Duration..……days

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

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

Appendix IV

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

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:_____

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

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

NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
Møllendalsbakken 11
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

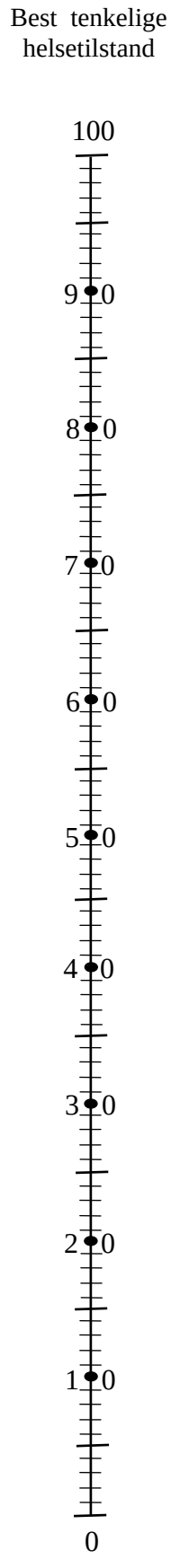
NASJONALT HOFTEBRUDDREGISTER
Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
Møllendalsbakken 11
5021 BERGEN

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



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

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

IıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııI

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

IıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııIıııııııııI

svært fornøyd — fornøyd — middels fornøyd — misfornøyd — svært misfornøyd

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

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

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 V

By placing a tick in one box in each group below, please indicate which statements best describe own health state today

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual activities *(e.g. work, study, homework, family or leisure activities).*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

I am moderately anxious or depressed ❑

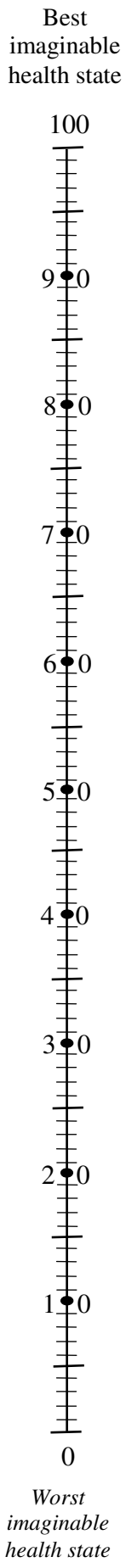
I am extremely anxious or depressed ❑

Appendix VI

To help people say how good or bad health state is, we have drawn a scale (rather like thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the bow below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Appendix VII

PAIN

Place a mark on the line which represents the average pain from the operated hip the last month:

No pain — Maximal pain

mild moderate medium strong unbearable

SATISFACTION

Place a mark on the line which represents the degree of satisfaction with the result of the operation:

Satisfied — Dissatisfied

Very satisfied satisfied medium satisfied dissatisfied very dissatisfied

Appendix VIII

NASJONALT REGISTER FOR TOTALPROTESER I HOFTELEDD

Ortopedisk avdeling
Haukeland sykehus,
5021 BERGEN

F. nr. (11 sifre):

Navn:

Sykehus:

(Bruk blokkbokstaver)

ANAMNESE:

1. SMERTER (ett kryss):
- ☐[1] Sterke spontane i hvile og om natten.
- ☐[2] Sterke som hindrer all gangaktivitet.
- ☐[3] Moderate, tillater begrenset gange.
- ☐[4] Etter noe aktivitet, forsvinner i hvile.
- ☐[5] Lette eller periodevise. Startsmerter.
- ☐[6] Ingen smerter.

2. GANGEVNE (ett kryss):
- ☐[1] Få meter med 2 krykker/stokker/sengeliggende.
- ☐[2] Sterkt begrenset med eller uten stokker.
- ☐[3] Begrenset med stokk (under en time). Kan stå lenge.
- ☐[4] Kan gå lange avstander med en stokk.
- ☐[5] Ingen stokk, men halter.
- ☐[6] Normal gangevne.

3. FUNKSJONSGRUPPE (ett kryss):
- ☐[1] Aktuelle hofte syk ellers frisk.
- ☐[2] Begge hofter syke ellers frisk.
- ☐[3] Annet som reduserer gangevnen.

4. TIDLIGERE OPERASJON(ER) I AKTUELLE HOFTE:
- ☐[0] Nei (evt. flere kryss)
- ☐[1] Osteosyntese pga. fraktur i prox.femurende.
- ☐[2] Hemiprotese pga. fraktur
- ☐[3] Osteotomi.
- ☐[4] Artrodese.
- ☐[5] Totalprotese(r) Type(r): .....
  Årstall siste protese: ☐☐
- ☐[6] Annet: .....

5. VARIGHET AV SYMPT. I AKT. HOFTE: ☐☐ år
(under 1 år = 0).

OPERASJONSOPPLYSNINGER:

6. OPERASJONSDATO: dag ☐☐ mnd ☐☐ år ☐☐

7. AKTUELLE OPERASJON ER (ett kryss).
- ☐[1] Primær totalproteseoperasjon.
- ☐[2] Reoperasjon.

8. AKTUELLE SIDE (ett kryss).
- ☐[1] Høyre
- ☐[2] Venstre
- ☐[3] Høyre - venstre allerede protese.
- ☐[4] Venstre - høyre allerede protese.

9. AKTUELLE HOFTEOPERASJON ER (ett kryss).
a) Primæroperasjon pga.:
- ☐[1] Idiopatisk coxartrose
- ☐[2] Rheumatoid artritt.
- ☐[3] Seq.fr. colli fem.
- ☐[4] Seq.dysplasi.
- ☐[5] Seq.dysplasi med luksasjon.
- ☐[6] Seq.Perthes/epifys.
- ☐[7] Bechterew.
- ☐[8] Annet: .....

b) Reoperasjon pga. (evt. flere kryss):
- ☐[1] Løsning av acetabulardel.
- ☐[2] Løsning av femurdel.
- ☐[3] Luksasjon.
- ☐[4] Dyp infeksjon.
- ☐[5] Fraktur av femur.
- ☐[6] Smerter.
- ☐[7] Annet: .....

10. HVIS reoperasjon (ett kryss):
- ☐[1] Reop. - bytte av femurdelen.
- ☐[2] Reop. - bytte av acetabulardelen.
- ☐[3] Reop. - bytte av hele protesen.
- ☐[4] Reop. - annet: (f.eks. Girdlestone). .....

11. TILGANG (ett kryss):
- ☐[1] Fremre (Smith-Pettersen).
- ☐[2] Anterolateral.
- ☐[3] Lateral.
- ☐[4] Posterolateral
- ☐[5] Annen: .....

12. TROCHANTEROSTEOTOMI:
- ☐[0] Nei
- ☐[1] Ja

13. BENTRANSPLANTASJON:
- ☐[0] Nei
- ☐[1] I acetabulum.
- ☐[2] I femur.
- ☐[3] I acetabulum og femur.

PROTESE. NAVN/TYPE (**Spesifiser nøyaktig**):

14. **Acetabulum:**
Navn/Type: .....
Evt. Kat. nr: .....
- ☐[1] Sement med antibiotika. Navn: .....
- ☐[2] Sement uten antibiotika. Navn: .....
- ☐[3] Ikke sementert.

15. **Femur:**
Navn/Type: .....
Evt. Kat. nr. .....
- ☐[1] Sement med antibiotika. Navn: .....
- ☐[2] Sement uten antibiotika. Navn: .....
- ☐[3] Ikke sementert.

16. **Caput:**
- ☐[1] Fastsittende caput.
- ☐[2] Separat caput. Navn/Type: .....
  Evt. Kat. nr. ..... Diam.: .....

17. SYSTEMISK ANTIBIOTIKAPROFYLAKSE:
- ☐[0] Nei
- ☐[1] Ja. Hvilken: .....
  Dose: .....
  Varighet: .....

18. OPERASJONSSTUE:
- ☐[1] "Green house"
- ☐[2] Operasjonsstue med laminær luftstrøm.
- ☐[3] Vanlig operasjonsstue.

19. OPERASJONSTID (hud til hud): ☐☐☐ min.

20. PEROPERATIVE KOMPLIKASJONER:
- ☐[0] Nei.
- ☐[1] Ja. Hvilken: .....

Lege: .....
(Legen som har fylt ut skjemaet)

Appendix IX

NASJONALT REGISTER FOR LEDDPROTESER
Ortopedisk klinikk, Helse Bergen
Besøksadresse: Haukeland Universitetssykehus
Postadresse: 5021 BERGEN
Tlf.: 55 97 37 42 / 55 97 37 43

1. F.nr. (11 sifre) .....
   Navn: .....
2. Sykehus: .....
   (Skriv tydelig!)

HOFTEPROTESER

ALLE TOTALPROTESER I HOFTELEDD REGISTRERES (ikke hemiproteser)
Innsetting, skifting eller fjerning av protese eller protesedeler.

4. TIDLIGERE OPERASJON I AKTUELLE HOFTE (evt. flere kryss)
- ☐ 0 Nei
- ☐ 1 Osteosyntese for fraktur i prox. femurende
- ☐ 2 Hemiprotese pga fraktur
- ☐ 3 Osteotomi
- ☐ 4 Artrodese
- ☐ 5 Totalprotese(r)
- ☐ 6 Annen operasjon .....

5. Hvis protese tidligere, TYPE(R): .....
Årstall siste protese: |_|_|
Antall proteser tidligere i aktuelle hofte: |_|_|

6. OPERASJONSDATO: dag |_|_| mnd |_|_| år |_|_|

7. AKTUELLE OPERASJON ER (ett kryss):
- ☐ 1 Primæroperasjon (Også hvis hemiprotese tidl.)
- ☐ 2 Reoperasjon (totalprotese tidligere)

8. AKTUELLE SIDE (ett kryss):
(Bilateral opr.= 2 skjema)
- ☐ 1 Hø
- ☐ 2 Ve
- ☐ 3 Hø - Venstre allerede protese
- ☐ 4 Ve - Høyre allerede protese

9. AKTUELLE OPERASJON ER:
(kryss av enten i 9A eller 9B)

A. Primæroperasjon pga. (ett kryss):
- ☐ 1 Idiopatisk coxartrose
- ☐ 2 Rheumatoid artritt
- ☐ 3 Seqvele etter frakt. colli fem.
- ☐ 4 Seqv. dysplasi
- ☐ 5 Seqv. dysplasi med total luksasjon
- ☐ 6 Seqv. Perthes/Epifysiolyse
- ☐ 7 Mb. Bechterew
- ☐ 8 Annet: .....
  (f.eks. caputnekrose, tidl. artrodese o.l.)
- ☐ Akutt fraktura colli femoris

B. Reoperasjon. pga. (evt. flere kryss):
- ☐ 1 Løs acetabular komponent
- ☐ 2 Løs femur komponent
- ☐ 3 Luksasjon
- ☐ 4 Dyp infeksjon
- ☐ 5 Fraktur (ved protesen)
- ☐ 6 Smerter
- ☐ 7 Annet .....
  (f.eks Girdlestone etter tidl. infisert protese, protesefraktur, utslitt plastforing osv.)
- ☐ Osteolyse i acetab. uten løsning
- ☐ Osteolyse i femur uten løsning

10. REOPERASJONSTYPE (evt. flere kryss):
- ☐ 1 Bytte av femur komponent
- ☐ 2 Bytte av acetabularkomponent
- ☐ 3 Bytte av hele protesen
- ☐ 4 Andre operasjoner:
- ☐ Fjernet protese (f.eks Girdlestone).
  Angi hvilke deler som ble fjernet .....
  .....
- ☐ Bytte av plastforing
- ☐ Bytte av caput
- ☐ Annet: .....
  .....

Hustrykkeriet HU - 12.11.02 - 1/2

11. TILGANG
- ☐ 1 Fremre (Smith-Petersen)
- ☐ 2 Anterolateral
- ☐ 3 Lateral
- ☐ 4 Posterolateral
- ☐ 5 Annen: .....

12. TROCHANTEROSTEOTOMI
- ☐ 0 Nei
- ☐ 1 Ja

13. BENTRANSPLANTASJON
- ☐ 0 Nei
- ☐ 1 I acetabulum
- ☐ 2 I femur
- ☐ 3 I acetabulum og femur
- ☐ 4 Benpakking i acetabulum (impaksjon)
- ☐ 5 Benpakking i femur (impaksjon a. m. Ling/Gie)

PROTESE: NAVN/DESIGN/"COATING"
Spesifiser nøyaktig eller bruk klistrelapp på baksida

14. Acetabulum
Navn/Type: .....
Evt. katalognummer: .....
- ☐ Med hydroksylapatitt ☐ Uten HA
- ☐ 1 Sement med antibiotika - Navn: .....
- ☐ 2 Sement uten antibiotika - Navn: .....
- ☐ 3 Usementert

15. Femur
Navn/Type: .....
Evt. katalognummer: .....
- ☐ Med hydroksylapatitt ☐ Uten HA
- ☐ 1 Sement med antibiotika - Navn: .....
- ☐ 2 Sement uten antibiotika - Navn: .....
- ☐ 3 Usementert

16. Caput
- ☐ 1 Fastsittende caput
- ☐ 2 Separat caput - NavnType: .....
  Evt. katalognummer: .....
  Diameter: |_|_| millimeter

17. SYSTEMISK ANTIBIOTIKAPROFYLAKSE:
- ☐ 0 Nei
- ☐ 1 Ja, hvilken .....
  Dose: .....
  Varighet (antall døgn): |_|_|

18. OPERASJONSSTUE
- ☐ 1 "Green house"
- ☐ 2 Operasjonsstue med laminær luftstrøm
- ☐ 3 Vanlig operasjonsstue

19. OPERASJONSTID (HUD TIL HUD): |_|_|_| MINUTTER

20. PEROPERATIV KOMPLIKASJON
- ☐ 0 Nei
- ☐ 1 Ja, hvilken: .....
  .....

Lege: .....
Legen som har fylt ut skjemaet, (navnet registreres ikke)

Appendix X

H Nasjonalt Register for Leddproteser
Ortopedisk klinikk, Helse Bergen HF
Haukeland Universitetssykehus
Møllendalsbakken 11
5021 BERGEN
tlf 55973742/55973743

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

Navn:.....

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

Sykehus:.....

HOFTEPROTESER

ALLE TOTALPROTESER I HOFTELEDD REGISTRERES (ved hemiproteser etter hoftebrudd sendes hoftebruddskjema til Hoftebruddregisteret). Innsetting, skifting eller fjerning av protese eller protesedeler.

TIDLIGERE OPERASJON I AKTUELLE HOFTE (ev. flere kryss)
- ☐0 Nei
- ☐1 Osteosyntese for fraktur i prox. femurende
- ☐2 Hemiprotese pga. fraktur
- ☐3 Osteotomi
- ☐4 Artrodese
- ☐5 Totalprotese(r)
- ☐6 Annen operasjon ……

OPERASJONSDATO (dd.mm.åå) |__|__| |__|__| |__|__|

AKTUELLE OPERASJON (ett kryss)
- ☐1 Primæroperasjon (også hvis hemiprotese tidligere)
- ☐ 2 Reoperasjon (totalprotese tidligere)

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

AKTUELLE OPERASJON (KRYSS AV ENTEN I A ELLER B)

A . Primæroperasjon pga. (ev. flere kryss)
- ☐1 Idiopatisk coxartrose
- ☐2 Rheumatoid artritt
- ☐3 Sekvele etter frakt. colli. fem.
- ☐4 Sekv. dysplasi
- ☐5 Sekv. dysplasi med total luksasjon
- ☐6 Sekv. Perthes/Epifysiolyse
- ☐7 Mb. Bechterew
- ☐8 Akutt fraktura colli femoris
- ☐ Annet ……
  (f.eks caputnekrose, tidl. artrodese o.l)

B . Reoperasjon pga. (ev. flere kryss)
- ☐1 Løs acetabularkomponent
- ☐2 Løs femurkomponent
- ☐3 Luksasjon
- ☐4 Dyp infeksjon
- ☐5 Fraktur (ved protesen)
- ☐6 Smerter
- ☐7 Osteolyse i acetab. uten løsning
- ☐8 Osteolyse i femur uten løsning
- ☐ Annet ……
  (f.eks Girdlestone etter tidl. infisert protese)

REOPERASJONSTYPE (ev. flere kryss)
- ☐1 Bytte av femurkomponent
- ☐2 Bytte av acetabularkomponent
- ☐3 Bytte av hele protesen
- ☐4 Fjernet protese (f.eks Girdlestone)
  Angi hvilke deler som ble fjernet ……
- ☐5 Bytte av plastforing
- ☐6 Bytte av caput
- ☐ Andre operasjoner ……

TILGANG (ett kryss)
- ☐1 Fremre (Smith-Petersen)
- ☐2 Anterolateral
- ☐3 Lateral
- ☐4 Posterolateral
- ☐5 Annen ……

LEIE ☐0 Sideleie ☐1 Rygg

TROCHANTEROSTEOTOMI ☐0 Nei ☐1 Ja

BENTRANSPLANTASJON (ev. flere kryss)

Acetabulum	☐0 Nei	☐1 Ja	☐2 Benpakking
Femur	☐0 Nei	☐1 Ja	☐2 Benpakking a.m. Ling/Gie

BENTAP VED REVISJON (Paprosky's klassifikasjon se baksiden)

Acetabulum		Femur	
☐1 Type I	☐4 Type II C	☐1 Type I	☐4 Type III B
☐2 Type II A	☐5 Type III A	☐2 Type II	☐5 Type IV
☐3 Type II B	☐6 Type III B	☐3 Type III A	

PROTESE NAVN / DESIGN / "COATING"
(spesifiser nøyaktig eller bruk klistrelapp på baksiden)

Acetabulum
- Navn/Type ……
- ev. katalognummer ……
- ☐ Med hydroksylapatitt ☐ Uten hydroksylapatitt
- ☐1 Sement med antibiotika – Navn ……
- ☐2 Sement uten antibiotika – Navn ……
- ☐3 Usementert

Femur
- Navn/Type ……
- ev. katalognummer ……
- ☐ Med hydroksylapatitt ☐ Uten hydroksylapatitt
- ☐1 Sement med antibiotika – Navn ……
- ☐2 Sement uten antibiotika – Navn ……
- ☐3 Usementert

Caput
- ☐1 Fastsittende caput
- ☐2 Separat caput - Navn/Type ……
- ev. katalognummer ……
- Diameter ……

MINI INVASIV KIRURGI (MIS) ☐0 Nei ☐1 Ja

COMPUTERNAVIGERING (CAOS) ☐0 Nei ☐1 Ja
Type navigering ……

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

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

Senere dosering……Antatt varighet……døgn

Ev. i kombinasjon med ……

Dosering…… Antatt varighet……døgn

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

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

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

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

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

OPERASJONSSTUE
- ☐1 "Green house"
- ☐2 Operasjonsstue med laminær luftstrøm
- ☐3 Vanlig operasjonsstue

OPERASJONSTID (hud til hud) ……min

PEROPERATIV KOMPLIKASJON
- ☐0 Nei
- ☐1 Ja,hvilke(n) .....

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

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

Paper I

The Norwegian Hip Fracture Register

Experiences after the first 2 years and 15,576 reported operations

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Background and purpose The Norwegian Hip Fracture Register was established in January 2005 to collect nationwide information as a basis for improved management of patients with hip fractures. We now report our experience after the first 2 years.

Methods After both primary operations and reoperations, the surgeons fill in a standardized 1-page form with information about the patient, the fracture, and the operation. Fractures treated with a total hip arthroplasty are reported to the national arthroplasty register, but are added to the hip fracture register before analyses are performed. 4, 12, and 36 months postoperatively, a standardized questionnaire including health-related quality of life (EQ-5D), visual analog scales concerning pain and patient satisfaction, and Charnley class for functional assessment is sent directly from the register to the patients. To evaluate the completeness of registration, our data were compared with data from the Norwegian Patient Registry (NPR).

Results During the first year of registration, all 55 hospitals treating hip fractures in Norway started to report their hip fracture operations. During 2005, the monthly reporting increased and it stabilized in 2006. 13,251 primary-operated hips (mean age of patients: 80 years; 72% females) and 2,325 reoperations were reported during 2005 and 2006. Compared to the NPR, the completeness of registration was 64% in 2005 and 79% in 2006. 58% of the patients who were alive answered the 4-month questionnaire. The non-responders were older, were more often cognitively impaired, and had a higher degree of comorbidity than the responders. Undisplaced femoral neck fractures (19% of all fractures) were almost exclusively operated with screw osteosynthesis (95%). Dislocated femoral neck fractures (38% of all fractures) were operated with a hemiarthroplasty in 52% of the cases. Osteosynthesis with a hip compression screw was the predominant operation method for trochanteric fractures (81%).

Interpretation After only 2 years, our nationwide system for surveillance of demographics, treatment, and outcome of hip fractures is functioning well. As expected, the response rate for the 4-month questionnaires was relatively low due to the old population with high comorbidity and cognitive impairment. The different treatment methods used for patients in the same groups of fracture types show that there is still no consensus in Norway regarding the treatment of hip fractures.

Each year in Norway (with 4.7 million inhabitants), approximately 9,000 patients are hospitalized and operated due to hip fractures (femoral neck fracture, trochanteric fracture, and subtrochanteric fracture) (Directorate for Health and Social Affairs, 2005). The incidence of hip fractures in Norway is higher than in other countries (Falch et al. 1985, 1993, Lofthus et al. 2001) and increases exponentially with age (Falch et al. 1985, Lofthus et al. 2001, Mirchandani et al. 2005). Thus, the advancing age of the population has led to a higher number of hip fractures (Larsson et al. 1989), and increased demands on the health service (Engesaeter and Soreide 1985). An increase

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in the incidence of hip fractures has been shown in previous studies (Finsen and Benum 1987, Falch et al. 1985, 1993, Lonnroos et al. 2006). However, some recently published studies have suggested a reversal of this trend (Rogmark et al. 1999, Finsen et al. 2004, Nymark et al. 2006, Chevalley et al. 2007). There are several operative treatment methods available, and there is no consensus on which methods should be preferred (Jalovaara et al. 1992, Berglund-Roden et al. 1994, Cserhati et al. 2002, Bhandari et al. 2005, Figwed et al. 2006, Gjertsen et al. 2006, Frihagen et al. 2007).

With the support of the Norwegian Orthopaedic Association, the Norwegian Hip Fracture Register initiated a nationwide registration of hip fractures in January 2005. The register cooperates with—and shares facilities with—the Norwegian Arthroplasty Register. The main aims of the hip fracture register are to collect epidemiological data, to evaluate the results of different treatment methods for the different types of hip fractures in various patient populations, and to identify inferior methods early on. The register also provides data on incidence of fracture types, treatment methods, and trends over time. Finally, hospital-specific results are reported back to the participating hospitals to facilitate improvement in treatment.

Methods

Recording of data

At each of the 55 hospitals where hip fracture surgery is performed, a contact surgeon is responsible for the monthly reporting to the register. Information about the patient, the fracture, and the treatment is obtained from a form that is filled in by the surgeon immediately after surgery (Figure). To ensure that reporting is complete as possible, the form has been made as simple as possible. The same form is used both for primary operations and reoperations. Informed consent is obtained from each patient or a relative and the form is kept in the hospitals.

Hip fractures treated primarily with a total hip arthroplasty (THA) and hips reoperated with THAs due to sequelae after hip fractures are registered on separate forms from the Norwegian Arthroplasty Register. These particular THAs are added to the hip fracture register before analyses are performed. Hip fractures treated without surgery should not be reported to the register.

Using patients' national personal identification numbers, reoperations can be linked to the primary operations. All types of reoperations must be reported to the hip fracture register, including removal of implants, soft tissue revisions, and closed reduction of dislocated hemiprostheses. This is different from the reporting to the hip arthroplasty register, where only reoperations that include removal or exchange of implant components are registered. All reoperations are registered regardless of year of fracture. Consequently, for primary operations from before 2005, the reoperations would not have an index operation registered.

In order to send out 4-month questionnaires to patients at the correct time, the register encourages monthly delivery of forms to the register. Forms lacking information are returned to the hospitals for completion of the data that are missing. We receive records from the Norwegian Register of Vital Statistics with information on dates of death and emigration. To assess the completeness of the data on primary operations in the hip fracture register, data files, including all hospitalizations in 2005 and 2006 with the ICD-10 codes S72.0 (fracture of neck of femur), S72.1 (trochanteric fracture), and S72.2 (subtrochanteric fracture), and the procedure codes NFJ and NFB according to the NOMESKO Classification of Surgical Procedures (NCSP), were obtained from the obligatory administrative Norwegian Patient Registry (NPR). These data were compared to the data in the hip fracture register.

Operation form

The orthopedic surgeons in Norway are familiar with the registration form used in the Norwegian Arthroplasty Register for reporting of joint arthroplasties (Havelin 1999), and a comparable form was prepared for hip fracture operations (Figure). The form contains information about the patient, including the ASA score (American Society of Anaesthesiologists 1963) and cognitive function. To define the presence of cognitive impairment, the surgeons—if in doubt—may use the clock-draw-

ing test (Shulman 2000). Information about time of fracture, time of surgery, type of fracture, operation technique, thrombosis prophylaxis, and infection prophylaxis is also given in the form.

We use a modification of Garden's classification of femoral neck fractures (Garden 1961) where Garden 1 and 2 fractures were defined as undisplaced and Garden 3 and 4 fractures as displaced. Basocervical fractures were defined as extracapsular femoral neck fractures. Trochanteric fractures were defined as fractures involving the trochanter region, including both pertrochanteric and intertrochanteric fractures. Subtrochanteric fractures were defined as fractures with a main fracture line between the distal limit of the lesser trochanter and the proximal 5 cm of the femoral shaft.

To obtain accurate information on the implants, stickers with catalog numbers of the implants, supplied by the manufacturers, are used.

Patient questionnaire

The patients receive a questionnaire directly from the register after 4, 12, and 36 months. The questionnaire contains the EuroQol, which is a standardized non-disease-specific instrument for describing and evaluating health-related quality of life (Brooks 1996). Both the health status part (EQ-5D) and the visual analog scale (EQ-VAS) are included in the questionnaire. The EQ-5D has 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each item has 3 different responses (no problem, some problems, major problems). The preference scores ($EQ\text{-}5D_{index}$ scores) generated from a large European population (Greiner et al. 2003) were used. The EQ-VAS is a 20-cm visual analog scale ranging from 0 (signifying worst possible health) to 100 (signifying best possible health).

In addition to the EuroQol, the questionnaire contains visual analog scales (VAS) concerning the average pain from the operated hip during the previous month (0 = no pain, 100 = unbearable pain) and patient satisfaction (0 = very satisfied, 100 = very dissatisfied). Finally, we use the Charnley class (Charnley 1979) to describe functional ability. If the questionnaire is filled in with assistance from others, this is indicated. So far, no reminders have been sent out to patients who did not return the questionnaire. Data from the patient questionnaires are not presented in this paper, but will appear in subsequent papers.

Statistics

The Pearson chi-square test was used for comparison of categorical variables in independent groups. Student's t-test and analysis of variance (ANOVA) were used for continuous variables. All data were considered to be independent, and we did not adjust for patients who were operated for hip fractures on both sides. To describe the influence of each variable on the response rate of the 4-month questionnaire, we performed a logistic regression analysis. All p-values are two-tailed, and the significance level was set to 0.01. All continuous variables are presented with 95% confidence intervals (CIs). In the hip fracture register a reoperation is defined as any surgical procedure that has been performed due to a complication after hip fracture surgery, whereas in the arthroplasty register a reoperation is defined as the removal or exchange of part of an implant, or the whole implant. The analyses were performed using SPSS 14.0 for Windows.

Reports to surgeons and hospitals

The annual reports are sent to all members of the Norwegian Orthopaedic Association, to all hospitals performing treatment of hip fractures, and to the health authorities. Each participating hospital receives specific descriptive statistics for that particular hospital on an annual basis, and also survival analyses of osteosyntheses and arthroplasties for hip fractures performed at the hospital.

Ethics

Each patient has to give written consent to be entered into the register, and consent from the patient's family is sought if the patient is not able to give or withhold consent. The consent form is entered into the patient journal at the hospital. Accordingly, the register has no information on patients who refused to give consent, and also no information on the number of patients who were not reported to the register due to the fact that they withheld their consent.

The registration is approved by the Norwegian Data Inspectorate.

Table 1. Monthly registrations of primary operations

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2005	398	434	473	398	462	428	463	494	503	517	542	703
2006	699	624	681	581	586	518	604	566	596	601	653	727

Table 2. Baseline data for all patients according to fracture types. Fractures operated with a THA, and reported to the arthroplasty register, were classified as femoral neck fractures or trochanteric fractures without further subclassification. The p-values relate to statistically significant differences between fracture types

Fracture type	n	Age mean (95% CI)	Female %	Cognitive impairment % (yes / no / uncertain)	ASA mean (95% CI)
Undisplaced femoral neck (Garden 1 + 2)	2,452	79 (78–79)	69	20 / 68 / 12	2.5 (2.4–2.5)
Displaced femoral neck (Garden 3 + 4)	5,051	81 (80–81)	73	24 / 63 / 13	2.6 (2.6–2.7)
Basocervical	612	79 (78–80)	63	21 / 69 / 10	2.6 (2.5–2.7)
Femoral neck, unspecified [d]	244	71 (70–73)	74		2.6 (2.4–2.9)
Trochanteric, 2-fragment [c]	2,292	82 (81–82)	72	24 / 63 / 13	2.6 (2.5–2.6)
Trochanteric, multifragment [c]	1,738	82 (81–82)	74	25 / 62 / 13	2.6 (2.6–2.7)
Trochanteric, unspecified [d]	27	76 (71–80)	59		2.3 (2.0–2.6)
Subtrochanteric	713	78 (77–79)	73	18 / 69 / 13	2.5 (2.5–2.6)
Others or combined fractures	103	75 (71–79)	69	18 / 70 / 12	2.6 (2.3–2.9)
Unknown	19	83 (79–88)	84	21 / 42 / 37	3.4 (2.4–4.4)
All fractures	13,251	80 (80–80)	72	24 / 63 / 12	2.6 (2.6–2.6)
p-values		< 0.001 [a]	< 0.001 [b]	< 0.001 [b]	< 0.001 [a]

[a] ANOVA.
[b] Pearson chi-square test.
[c] Including intertrochanteric fractures.
[d] Patients reported to the Norwegian Arthroplasty Register.

Results

Completeness of registration

An increase in the numbers of reported hip fractures and reporting hospitals was found during the second half of 2005, and by December 2005 all 55 hospitals operating hip fractures were reporting to the register. During 2006, the number of monthly registrations stabilized (Table 1).

When we included all data reported until October 23, 2007, 13,251 primary operations for hip fractures (2005: n = 5,815, 2006: n = 7,436) had been registered, including 271 THAs that had been reported to the hip arthroplasty register. According to the Norwegian Patient Registry (NPR), 9,150 patients had been operated due to a hip fracture in 2005, and 9,376 in 2006. Thus, comparing our data with those from the NPR, we had a completeness of registration of 64% in 2005 and 79% in 2006.

In addition to the primary operations, 2,325 reoperations were registered, including 1,084 THAs reported to the arthroplasty register. The register thus contained data on 15,576 operations.

Primary operations

The mean age of all patients was 80 years (Table 2). There were significant differences in average age between the different fracture groups ($p < 0.001$). As expected, patients operated with THAs were generally younger than the other patients, and they had the lowest ASA scores. Women constituted 72% of all patients, and there were statistically significant differences in sex distribution between the different fracture groups ($p < 0.001$). Furthermore, there was a difference in cognitive function between the fracture groups with less cognitive impairment in patients with undisplaced femoral neck fractures, basocervical fractures, and sub-

Table 3. Reporting completeness for different subgroups of the 11,038 patients who received the 4-month questionnaire

	n	Responders (%)	p-value [a]
All patients	11,038	6,399 (58)	
Age			< 0.001
< 60 years	690	436 (63)	
60–69 years	950	649 (68)	
70–79 years	2,655	1,662 (63)	
80–89 years	5,188	2,892 (56)	
> 90 years	1,555	760 (49)	
Sex			0.5
Female	8,109	4,698 (58)	
Male	2,929	1,701 (58)	
Cognitive impairment			< 0.001
yes	2,219	846 (38)	
no	7,502	4,807 (64)	
uncertain	1,090	550 (50)	
missing	227	116 (51)	
ASA score: [b]			< 0.001
1	1,308	917 (70)	
2	4,332	2,649 (61)	
3	4,794	2,520 (53)	
4	403	188(47)	
5	9	4 (44)	
Missing	192	121 (63)	
Fracture type:			0.005
femoral neck	6,449	3,833 (59)	
basocervical	511	292 (57)	
trochanteric	3,353	1,882 (56)	
subtrochanteric	618	333 (54)	
other or combined/unknown	107	59 (55)	

[a] Pearson chi-square test.
[b] ASA score
1: Healthy
2: Mild, systemic disease
3: Severe, systemic disease
4: Incapacitating disease
5: Moribund

trochanteric fractures ($p < 0.001$). However, these patient groups were younger. Finally, there were statistically significant differences in ASA class for the different fracture types ($p < 0.001$).

After 4 months (120 days), 11,494 patients were still alive. The 4-month questionnaire was sent to 11,038 patients (96% completeness). Of these questionnaires, 6,399 (58%) were returned to the register (responders). The non-responders were 2.2 years older on average (CI: 1.7–2.6), they were more cognitively impaired (30% vs. 13%), and had a higher degree of comorbidity (ASA class) compared to the responders ($p < 0.001$). There was no significant difference in response rate for the 4-month questionnaire in female and male patients ($p = 0.5$, Table 3). There were minor differences in reporting rate for the different fracture types, which were statistically significant. However, when doing a logistic regression analysis we found that age, ASA class, cognitive impairment, and hospital influenced the response rate, whereas sex, fracture type, and method of operation did not.

Femoral neck fractures constituted 57% of all fractures and 67% of the femoral neck fractures were displaced (Table 4). Trochanteric fractures represented 30% of all fractures. Screw osteosynthesis was the predominant operation method used to treat undisplaced femoral neck fractures (95%), while a bipolar hemiarthroplasty (HA) was used more often if the femoral neck fracture was displaced (52%). Basocervical fractures were operated with a hip compression screw (HCS) in 83% of cases; however, the osteosynthesis was stabilized with an additional anti-rotation screw (registered as "Other implant or combination") in 24% of these operations. Osteosynthesis with an HCS was the predominant operation method used to treat trochanteric fractures (84%). Intramedullary nails were used in 11% of all trochanteric fractures. When the fracture was multifragmented, it was more likely to be operated with an additional HCS lateral support plate (37%) or with an intramedullary nail (14%).

Most of the HAs performed were cemented, and the most commonly used implant was the Charnley-Hastings combination (Table 5). The most frequently used uncemented hemiprosthesis was the hydroxyapatite-coated Corail stem. No Austin Moore uncemented prostheses were used.

Reoperations

The commonest reason for reoperation was sequelae after femoral neck fracture (reported to the Hip Arthroplasty Register) (44%), osteosynthesis failure (25%), nonunion (10%), and local pain due to osteosynthesis material (8%) (Table 6). The most commonly performed reoperations were insertion of a THA (47%) or a bipolar HA (29%) (Table 7). In the arthroplasty register, only procedures that include removal or exchange of a prosthesis component are defined as a reoperation of a THA, and other reoperations of THAs are not registered.

Table 4. Frequencies of fracture type and operation method in the 13,251 hips primarily operated for hip fractures. Fractures operated with a THA, and reported to the NAR, were classified as femoral neck fractures or trochanteric fractures without further subclassification

A	B	C	D	E	F	G	H	I	J	K
Undisplaced femoral neck (Garden 1 + 2)	2,452 (19)	2,300	30	54	2		49	4	4	9
Displaced femoral neck (Garden 3 + 4)	5,051 (38)	2,196	79	2,622	52		53	3	10	36
Basocervical	612 (4.6)	55	2	17	7		374	11	20	126
Femoral neck, unspecified [b]	244 (1.8)					244				
Trochanteric, 2-fragment [a]	2,292 (17)	1	0	4	0		1,879	131	205	71
Trochanteric, multifragment [a]	1,738 (13)	0	1	6	0		754	642	243	92
Trochanteric, unspecified [b]	27 (0.2)					27				
Subtrochanteric	713 (5.4)	0	0	4	0		223	278	185	23
Other or combined fractures	103 (0.8)	0	0	8	0		25	28	21	21
Unknown	19 (0.1)	5	0	7	0		4	0	1	2

[a] Including intertrochanteric fractures.
[b] Hips reported to the Norwegian Arthroplasty Register.
A Fracture type
B Total n (%)
C 2 screws or pins
D 3 screws or pins
E Bipolar HA
F Unipolar HA
G THA
H Hip compression screw (HCS)
I HCS with lateral support plate
J Intramedullary nail
K Other implant or combination including HCS with additional antirotation screw

Discussion

After 2 years of registration, all hospitals operating hip fractures were reporting to the Norwegian Hip Fracture Register (NHFR). During 2005 the monthly reporting increased, and it was stable in 2006 with a completeness of registration of 79% relative to the NPR. The response rate for the 4-month questionnaires was 58%. The different treatments used among the different fracture types show that there is still no consensus in Norway about the treatment of displaced femoral neck fractures.

Completeness of registration

There was an increase in reporting during 2005 due to the fact that some of the larger hospitals started registration late that year. There was a stable reporting rate to the register throughout 2006.

The completeness of registration in the Norwegian Arthroplasty Register (NAR) has been high, both for primary operations and revisions. Espehaug et al. (2006) found a completeness of registration of 97% for all primary THAs when comparing the results in the NAR with the data from the NPR. Arthursson et al. (2005) found that only 0.4% of the THAs performed at one large local hospital had not been reported to the NAR. Elective hip arthroplasties are performed during daytime by surgeons dedicated to prosthesis surgery. Hip fracture surgery is also performed during weekends and at night by the surgeon on call—usually registrars in training and with a high turnover in their positions. This may explain some of the differences in registration completeness between the hip fracture register and the arthroplasty register. However, one might expect that it would take some time to establish good routines for reporting to a recently established register.

One Norwegian study reported that rehospitalizations due to sequelae after hip fractures might be registered in the NPR as acute hip fractures (Lofthus et al. 2005). In accordance with this, they found an overestimation of 14% in the NPR compared to local electronic databases at 3 hospitals,

Table 5. Distribution of implants used in primary operated hip fractures

Implant	n (%)	n (%)
2 screws or pins		4,669 (100)
Olmed (DePuy)	2,710 (58)	
Richards CHP (S&N) [a]	1,050 (23)	
LIH nail (Orthovita)	686 (15)	
Asnis III (Stryker)	214 (4.6)	
Unknown implant	9 (0.3)	
Hemiarthroplasty [b]		2,783 (100)
Charnley – C B (DePuy)	847 (30)	
Exeter/V40 – C B (Stryker)	560 (20)	
Corail – U B HA (DePuy)	428 (15)	
Spectron – C B (S&N) [a]	304 (11)	
Titan – C B (DePuy)	296 (11)	
Other / unknown implant	348 (13)	
Hip compression screw		4,458 (100)
CHS (S&N) [a]	2,794 (63)	
DHS (Stratec)	1,575 (35)	
Omega plus (Stryker)	87 (2.0)	
Other implant	2 (0.04)	
Intramedullary nail		689 (100)
Gamma (Stryker)	358 (52)	
Gamma 3 (Stryker)	184 (27)	
Trigen (S&N) [a]	48 (7.0)	
PFNA (Stratec)	27 (3.9)	
PFN (Stratec)	24 (3.5)	
Other / unknown implant	48 (7.0)	

[a] Smith & Nephew
[b] HA Hydroxyapatite-coated; C Cemented; U Uncemented; B Bipolar

Table 6. Reason for reoperation. All reoperations after hip fracture surgery registered in the hip fracture register in 2005 and 2006, including reoperations with THAs reported to the arthroplasty register. The numbers also include reoperations with no registered index operation. Note that each reoperation may have more than one indication. The total number of reasons (2,619) is therefore higher than the total number of reoperated hips (2,325)

Reason for reoperation	n	(%) [b]
Sequelae of femoral neck fracture (unspecified) [a]	1,028	(44)
Osteosynthesis failure	590	(25)
Nonunion	231	(9.9)
Local pain due to osteosynthesis material	174	(7.5)
Avascular necrosis (segmental collapse)	134	(5.8)
Deep wound infection	122	(5.2)
New fracture around implant	65	(2.8)
Penetration of osteosynthesis material through caput	58	(2.5)
Dislocated hemiprosthesis	55	(2.4)
Hematoma	37	(1.6)
Superficial wound infection	20	(0.9)
Fracture healed in wrong position	16	(0.7)
Sequelae of proximal femoral fracture (except femoral neck fracture)	10	(0.4)
Loosening of hemiarthroplasty	9	(0.4)
Pain after hemiarthroplasty	3	(0.1)
Other reasons	3	(0.1)
Unknown	64	(2.8)
Total number of reasons	2,619	(113)

[a] Total hip replacements reported to the Norwegian Arthroplasty Register, include avascular necrosis, nonunion, and osteosynthesis failure.
[b] Percentages of reoperated hips.

and they therefore questioned the validity of the NPR electronic database. An overestimation has also been reported for hip fractures in the English Public Health Common Data Set (McColl et al. 1998). These 2 studies may explain some of the difference between the data in the NHFR and those in the NPR.

From 2008, the NPR data will be identifiable at the level of the patient, and with such information comparisons of data from the NPR and the hip fracture register will probably be more valid. Validation studies should be performed on the registration of both primary operations and reoperations in the hip fracture register.

To date, 58% of the patients who are alive have answered the 4-month questionnaire. Two studies from the NAR have reported a response rate of 81% from patients who had undergone primary or revision hip arthroplasties (Espehaug et al. 1997, 1998). These patients did, however, have a mean age of 67 years, they had probably less comorbidity than the average hip fracture patient, and they received a reminder if they did not respond to the questionnaire. Thus, the relatively low response rate in our study group can be explained by high age, considerable comorbidity, cognitive impairment, and by many patients moving into nursing homes on a temporary or permanent basis. A better response rate might also be achieved if reminders are sent to the non-responders. One weakness in the design of the study is that the preoperative EQ-5D is assessed retrospectively, at 4 months postoperatively. The patients or the relatives may have difficulty in remembering the exact situation before fracture. Consequently, the answers in the EQ-5D may be inaccurate. The patients who responded to

Table 7. Type of reoperation. The numbers also include reoperations with no registered index operation. Note that each reoperation could consist of more than one procedure. The total number of types of reoperations (2,421) is therefore higher than the total number of reoperated hips (2,325)

	n	(%) [b]
Total hip arthroplasty [a]	1,084	(47)
Bipolar hemiarthroplasty	681	(29)
Removal of implant (when the only procedure)	202	(8.7)
Re-osteosynthesis	125	(5.4)
Drainage of hematoma or infection	115	(4.9)
Girdlestone (removal of implant/ hemiprosthesis and caput femoris)	61	(2.6)
Unipolar hemiarthroplasty	40	(1.7)
Closed reduction of dislocated hemiarthroplasty	17	(0.7)
Open reduction of dislocated hemiarthroplasty	11	(0.5)
Other	85	(3.7)
Total no. of types of reoperations	2,421	(104)

[a] Reported to the Norwegian Arthroplasty Register.
[b] Percentages of reoperated hips.

the 4-month questionnaire were generally younger, were less cognitively impaired, and had a lower ASA class compared to the non-responders. Consequently, the responders represent a selected subgroup of patients. Also, patients with an inferior clinical outcome may be more likely to respond to the questionnaire. However, the results have shown that the response rate was not influenced by fracture type or method of operation. We therefore believe that the data from the 4-month questionnaire can be relied upon.

We did not adjust for patients who were operated on both sides, as this was considered to be of little relevance to the results presented. According to an earlier study from the NAR, this adjustment will not necessarily have any effect on the results (Lie et al. 2004). However, this adjustment may be of more importance in future studies. Such adjustment will be possible whenever relevant because the primary registration is based on the patient's personal identification number.

Primary operations

We found that the mean age of patients was 80 years, and that 72% of all patients were women. These findings agree well with the results of the Swedish National Hip Fracture Register (RIKSHÖFT-SAHFE) (mean age 81 years, 71% females) (Thorngren et al. 2002) and to the results of other studies (mean age 79–80 years, 70–80% females) (Rogmark et al. 1999, Osnes et al. 2004, Moran et al. 2005, Lonnroos et al. 2006). Also, the distribution of fractures was similar to that presented for the RIKSHÖFT-SAHFE (Thorngren et al. 2002).

No national consensus on the treatment of dislocated femoral neck fractures or on the treatment of trochanteric and subtrochanteric fractures can be reached from the results of this study. Several studies from other countries have indicated that no consensus can be reached regarding the method of operative treatment for proximal femoral fractures (Jalovaara et al. 1992, Berglund-Roden et al. 1994, Cserhati et al. 2002, Bhandari et al. 2005).

Reoperations

A high number of the reoperations were prosthesis surgery. 76% of patients who underwent a reoperation were operated with a THA or an HA. Few minor complications, such as removal of an implant, were reported (9%). These operations are often performed as day surgery or in outpatient clinics. We suspect that there is a lower rate of reporting of these reoperations. The reporting rate of reoperations should be addressed in future studies.

Further research

Due to the link between the Norwegian Arthroplasty Register and the Norwegian Hip Fracture Register, the latter has a unique opportunity to perform complete analysis of all hip fracture surgery performed in an entire country. The register may also provide data on incidence of fracture types, and information on changes of treatment over time. We aim to conduct studies on pain, patient satisfaction, and quality of life in individuals who have undergone different methods of treatment, and who belong to different patient populations. We will also assess mortality after hip fractures. With further research, we hope to be able to identify inferior methods and to improve the quality of treatment in this large patient group.

Contributions of authors

This paper represents close teamwork by the orthopedic surgeons JEG, LBE, OF, LIH, TV, and JMF, and informatics specialist KS. All authors participated in the planning of the Norwegian Hip Fracture Register, the design of this study, interpretation of the results, and in preparation of the manuscript. JEG was mainly responsible for performing the statistical analyses and for writing the manuscript.

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NORWEGIAN HIP FRACTURE REGISTER
Norwegian Arthroplasty Register
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Haukeland University Hospital
Møllendalsbakken 11
5021 BERGEN
Phone: (+47)55976452

Birth number:.....

Name:.....

(Write distinct or use patient sticker – **specify hospital**.)

Hospital:.....

HIP FRACTURES

PRIMARY OPERATIONS ON PROXIMAL FEMORAL FRACTURES and ALL REVISIONS, included closed reduction of hemiprosthesis. When primary operation with total hip arthroplasty and revision with total hip arthroplasty use form to the arthroplasty register only. All stickers are to be put in marked area on back of form.

CURRENT OPERATION
☐1 Primary operation ☐ 2 Revision

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

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

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

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

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

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

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

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

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

Name / size, if possible Catalogue number……

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

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

Name / size, if possible Catalogue number……

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

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

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

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

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

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

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

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

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

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

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

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

Later dosis…… Duration.....days

Evt. in combination with ……

Dosis……Duration.....days

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

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

English translation of the operation form used by surgeons postoperatively.

Paper II

Patient satisfaction, pain, and quality of life 4 months after displaced femoral neck fractures

A comparison of 663 fractures treated with internal fixation and 906 with bipolar hemiarthroplasty reported to the Norwegian Hip Fracture Register

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Background **Primary arthroplasty and internal fixation are the two main options for treatment of displaced femoral neck fractures. Despite the fact that there have been several randomized studies, the optimal treatment in the elderly is still controversial. In the present study, based on data from the Norwegian Hip Fracture Register, we compared satisfaction, pain, and quality of life 4 months after surgery in patients over 70 years of age with a displaced femoral neck fracture operated with internal fixation or with a bipolar hemiarthroplasty.**

Patients and methods **Data on 1,569 fractures in patients over 70 years of age operated with internal fixation (n = 663) or hemiarthroplasty (n = 906) were registered in the hip fracture register. The register also included data on patient satisfaction, pain, and quality of life (EQ-5D) assessed 4 months after surgery using VAS scales and EQ-5D health questionnaires.**

Results **Patients operated with hemiarthroplasty had less pain (VAS 27 vs. 41), were more satisfied with the result of the operation (VAS 33 vs. 48), and had better EQ-5D index score 4 months postoperatively (0.51 vs. 0.42) than patients who were operated with internal fixation.**

Interpretation **Our findings suggest that elderly patients with displaced femoral neck fracture should be treated with arthroplasty.**

Every year in Norway, approximately 9,000 patients are hospitalized and operated on due to hip fractures (Directorate for Health and Social Affairs, 2005). Femoral neck fractures constitute 53–60% of the hip fractures and two-thirds of these fractures are displaced (Rogmark et al. 2002, Thorngren et al. 2002, Gjertsen et al. 2008). While most authors advocate osteosynthesis for younger patients and for those with undisplaced fractures, there is still controversy as to how to treat displaced femoral neck fractures in elderly patients (Chua et al. 1997, Bhandari et al. 2005, Iorio et al. 2006). There seems, however, to be a growing opinion that treatment should be based on the patient's age, functional demands, and individual risk profile (Tidermark 2003, Blomfeldt et al. 2005a, Rogmark and Johnell 2005).

Primary arthroplasty and internal fixation (IF) with nails or screws are the two main options for treatment of displaced femoral neck fractures. In recent randomized, controlled trials total hip arthroplasties (THAs) have been shown to provide superior functional outcome to IF—as assessed by Harris hip score (Johansson et al. 2000) and EQ-5D (Tidermark et al. 2003a, Blomfeldt et al. 2005a, Keating et al. 2006).

Another study found that hemiarthroplasty (HA) provided a superior outcome than IF as treatment

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for displaced fractures in the elderly (Rogmark et al. 2002). In elderly patients with severe cognitive impairment randomized, controlled studies showed poor results for HA when compared to IF as treatment for displaced femoral neck fractures (Ravikumar and Marsh 2000, Blomfeldt et al. 2005b). A Cochrane review comparing IF and arthroplasty found no definite differences in pain and residual disability (Parker and Gurusamy 2006).

A hip fracture is associated with increased mortality; half of the patients may die within 5 years (Ohman et al. 1969, Jensen and Tondevold 1979). It is therefore important to achieve a good outcome as soon as possible. Thus, we believe that evaluation of different treatment modalities during the first postoperative months is important. We compared IF and bipolar HA as treatment for dislocated femoral neck fractures in patients over 70 years of age using patient satisfaction, pain, and quality of life 4 months after surgery as outcome.

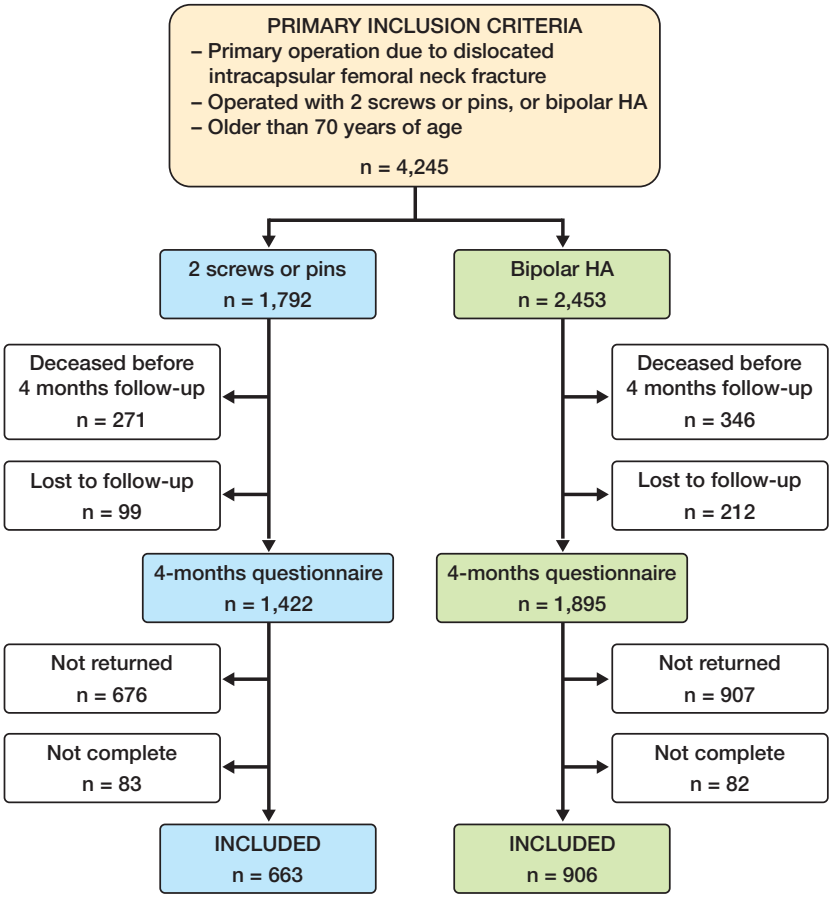

Figure 1. Flow chart of the study.

Patients and methods

The Norwegian Hip Fracture Register (NHFR) started registration of hip fractures in January 2005 (Gjertsen et al. 2008), and the aim of this national prospective study is to improve the quality of care. National recommendations on treating dislocated femoral neck fractures with prostheses exist in Norway (Directorate for Health and Social Affairs, 2005); however, the decision on whether to use screws/pins or HA is based on the preference of individual hospitals.

From January 2005 through December 2006, 13,104 proximal femur fractures were registered in the NHFR. Of these, 5,224 patients were registered as having a primary operation due to a dislocated femoral neck fracture. Our primary inclusion criteria were patients over 70 years old who were operated due to a dislocated femoral neck fracture (Garden III and IV) with 2 screws/pins or a bipolar HA. 4,245 patients fulfilled these criteria (Figure 1). Patients who died during the first 4 postoperative months were excluded. We also excluded patients who emigrated during this period, and patients with an unknown address (Figure 1). The remaining 3,317 patients received a questionnaire from the registry 4 months after surgery. No reminders were sent to patients who did not answer the questionnaire. 1,583 patients who did not return the questionnaire, and 165 patients whose questionnaire was not filled in a satisfactory way were excluded from further analysis. These two groups of patients were older (mean age 82, SD 6.2), had higher ASA scores (American Society of Anaesthesiologists, 1963), and were more often cognitively impaired (32%) than the patients who returned the questionnaire. The differences were statistically significant for all three variables ($p < 0.001$). Finally, 1,569 fractures operated with IF (n = 663) and HA (n = 906) remained for further analyses.

Patient and operative data were obtained from a form filled in by the surgeon immediately after the operation. To determine the presence of cognitive impairment, the surgeons, if in doubt, used the clock-drawing test (Shulman 2000). Both primary operations and reoperations were registered at all 55 hospitals performing hip fracture surgery in Norway (Gjertsen et al. 2008).

Any reoperations were linked to the primary operations using the patient's national social security number. The definition of a reoperation was any operation performed due to complications after the primary operation, including removal of osteosynthesis material, closed reduction of dislocated hemiprostheses, revision to an HA or a THA, and soft tissue revisions.

The 4-months questionnaire included the Norwegian translation of the EuroQol (EQ-5D) (Brooks, 1996). An EQ-5D index score of 1 indicated the best possible health state and a score of 0 indicated a health state similar to death. Some health states were given a negative score, which indicated a health state worse than death. The patients were also asked to assess their preoperative EQ-5D.

Furthermore, the patients were asked to fill in a visual analog scale (VAS) concerning average pain from the operated hip during the previous month. A value of 0 indicated no pain and a value of 100 represented unbearable pain. The patients also filled in a VAS to describe how satisfied they were with the result of the operation. The value 0 represented very satisfied while the value 100 represented very dissatisfied. Finally, we used the Charnley classification for functional assessment (Charnley 1979).

In the analysis, all patients included in the study remained in the same group (IF or HA) according to the intention-to-treat principle, whether or not a reoperation was performed. 65 of the patients in the IF group had already been reoperated with an HA at the time of the 4-month evaluation. Since the reoperated patients could not be expected to demonstrate good clinical outcome (pain, satisfaction, and quality of life) in a very short time after reoperation, we also performed additional analyses without the reoperated patients in both treatment groups. Separate analyses for patients with cognitive impairment, and for patients in different age groups (70–79 years, 80–89 years, and 90–99 years), were also done. We also performed subanalyses on patients in Charnley class A, i.e. patients with involvement of the ipsilateral hip only and no involvement of other joints or systemic problems limiting activity.

Records with information on dates of death and emigration were obtained from the Norwegian Register of Vital Statistics. The Norwegian Data Inspectorate approved the recording of data, and all patients signed an informed consent form.

Statistics

The Pearson chi-square test was used for comparison of categorical variables in independent groups. The independent samples t-test (Student's t-test) was used for parametric scale variables in independent groups. All tests were two-sided. The p-values in Table 3 were adjusted for potential confounders (age, sex, cognitive impairment, ASA-class, and preoperative delay of surgery) with general linear models (GLMs). In the figures, mean values with standard error of the mean are presented. All results were considered statistically significant at the 5% level. The analyses were performed using SPSS software version 13.0.

Results

Patients operated with an HA were older, were more often female, and had a higher preoperative delay compared to patients operated with IF. There were no statistically significant differences in the preoperative ASA score, cognitive impairment, and EQ-5D index score (Table 1).

In the HA group, uncemented prostheses accounted for 22% of the total. Only contemporary uncemented implants were used. No Austin Moore or Thompson prostheses were reported (Table 2). After 4 months, 110 patients had been reoperated, 92 in the IF group and 18 in the HA group.

Patients in the IF group had more pain than patients in the HA group 4 months after surgery ($p < 0.001$). More patients in the HA group were satisfied with the result of the operation than those in the IF group ($p < 0.001$) (Table 3A). Even after reoperated patients had been excluded, patients in the IF group had more pain and were less satisfied 4 months after surgery than patients in the HA group ($p < 0.001$) (Table 3B).

Table 1. Baseline characteristics of patients

	Internal fixation	Hemiarthroplasty	P-value
Total no.	663	906	
Mean age (min–max)(SD)	82.0 (70–99) (6.5)	82.6 (70–100) (5.9)	< 0.001[a]
Sex (% female)	75	81	0.004 [b]
ASA score			
ASA 1 Healthy	64 (9.9%)	84 (9.5%)	
ASA 2 Mild, systemic disease	266 (41%)	398 (45%)	
ASA 3 Severe, systemic disease	284 (44%)	373 (42%)	
ASA 4 Incapacitating disease	34 (5.2%)	30 (3.4 %)	
ASA 5 Moribund	2 (0.3%)	1 (0.1%)	0.35 [b]
Cognitive impairment (%)	16	14	0.2 b[b]
Preoperative delay (h) (min–max)(SD) [c]	18.2 (3–225) (17.7)	27.9 (2–556) (36.1)	< 0.001[a]
Preoperative EQ-5D index score	0.68	0.69	0.45 [a]

[a] Independent samples t-test.
[b] Pearson chi-square test.
[c] 1 patient in the hemiarthroplasty group with a preoperative delay of 5 months is excluded.

Table 2. Types of implants

Internal fixation		Hemiarthroplasty	
Name	n (%)	Name	n (%)
Olmed	391 (59)	Charnley – cemented bipolar	279 (31)
Richards CHP	141 (21)	Exeter/V40 – cemented bipolar	195 (22)
LIH nail	99 (15)	Corail – uncemented bipolar [a]	148 (16)
Asnis III	32 (4.8)	Titan – cemented bipolar	108 (12)
		Spectron – cemented bipolar	85 (9.4)
		Other/missing	91 (10)

[a] Hydroxyapatite-coated.

Table 3. Pain and satisfaction with the result of the operation, derived 4 months postoperatively from visual analog scales (VAS)

	Internal fixation		Hemiarthroplasty		P-value [c]
	Mean (SE)	95% CI	Mean (SE)	95% CI	GLM
A. All patients (intention-to-treat analysis)					
Pain [a]	41 (2.5)	36–46	27 (2.6)	22–32	< 0.001
Satisfaction with the result [b]	48 (2.7)	42–53	33 (2.7)	27–38	< 0.001
B. Reoperated patients excluded					
Pain [a]	40 (2.5)	35–45	28 (2.5)	23–33	< 0.001
Satisfaction with the result [b]	47 (2.6)	42–52	33 (2.6)	28–38	< 0.001

[a] Pain: the value 0 means no pain and the value 100 means unbearable pain.
[b] Satisfaction: the value 0 means satisfied and the value 100 means dissatisfied.
[c] p-value is the probability of no difference between the two treatment groups (general linear models (GLMs) adjusted for differences in age, sex, cognitive impairment, ASA class, and preoperative delay of surgery between the groups).

Most of the patients with unbearable pain were found in the IF group and most patients with minimal pain were found in the HA group (Figure 2). Most of the satisfied patients were found in the HA

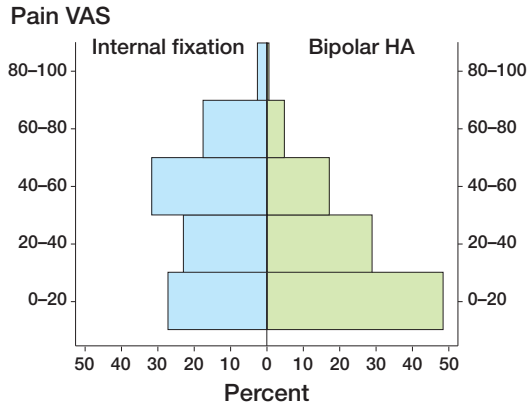

Figure 2. The degree of pain derived from a visual analog scale (VAS) 4 months postoperatively. The figure shows the distribution of pain for the 2 different treatment groups. 0 indicates no pain and 100 indicates unbearable pain.

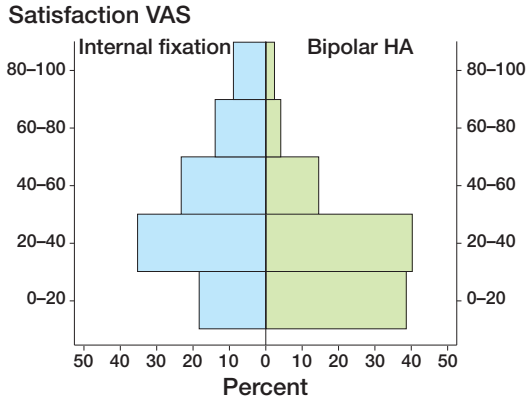

Figure 3. The degree of satisfaction with the result of the operation, derived from a visual analog scale (VAS) 4 months postoperatively. The figure shows the distribution of patient satisfaction for the 2 different treatment groups. 0 indicates very satisfied and 100 indicates very dissatisfied.

group while most of the dissatisfied patients were found in the IF group (Figure 3).

Only 625 IF patients and 862 HA patients had filled in both the preoperative EQ-5D and the 4-month EQ-5D questionnaire correctly. The preoperative EQ-5D index scores were equal in the IF and the HA groups: 0.68 and 0.69, respectively (Table 1). 4 months postoperatively, an inferior EQ-5D index score was found for the IF group (0.42) compared to the HA group (0.51) ($p < 0.001$). The decline in EQ-5D index score was 0.26 for the IF group and 0.19 for the HA group ($p < 0.001$) (Figure 4). When separate analyses were performed excluding all reoperated patients in both treatment groups, the EQ-5D index score was 0.43 for the IF

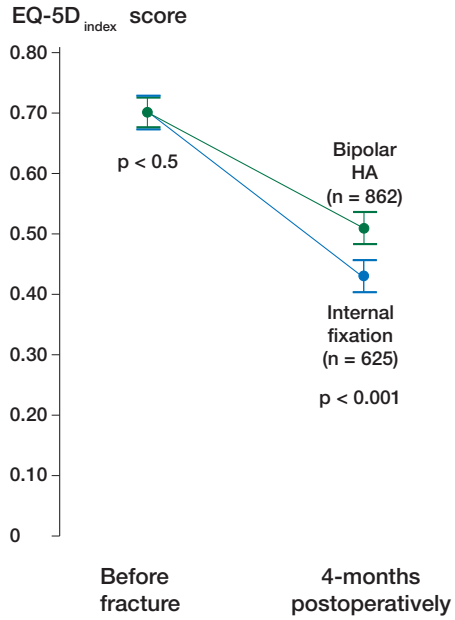

Figure 4. Health-related quality of life (EQ-5D index score) for patients at 0 and 4 months. 0 indicates the worst possible health state and 1.0 indicates full health. The p-values are given for differences between the treatment groups (general linear model).

group (n = 488) and 0.51 for the HA group (n = 843) ($p < 0.001$).

Preoperatively, no differences between the two groups in any of the 5 dimensions of the EQ-5D could be detected (Table 4). 4 months after surgery, the HA group was more mobile than the IF group ($p < 0.001$). Moreover, they had less problems with self-care ($p = 0.001$) and in performing their usual activities ($p < 0.001$) than the IF group. Finally, the HA group had less pain or discomfort than the patients operated with IF ($p < 0.001$) (Table 4). No difference in anxiety/depression was found between the two groups.

Separate analyses on patients suffering from dementia, patients in different age groups, and patients who had been walking without problems prior to the fracture showed practically the same differences regarding pain, satisfaction, and EQ-5D index score. Also, separate analyses on patients in Charnley class A showed similar differences regarding these outcomes. Finally, there were no statistically significant differences in pain, satisfaction, and EQ-5D index score between uncemented and cemented hemiprostheses.

Table 4. Quality of life (EQ-5D) for patients operated with internal fixation or bipolar hemiarthroplasty

	Before operation			4 months postoperatively		
	Internal fixation	Hemi-arthroplasty	P-value [a]	Internal fixation	Hemi-arthroplasty	P-value [a]
Mobility						
No problems in walking about	333 (52%)	464 (52%)		54 (8.4%)	162 (18%)	
Some problems in walking about	308 (48%)	418 (47%)		525 (81%)	669 (75%)	
Confined to bed	4 (0.6%)	6 (0.7%)	0.96	66 (10%)	57 (6.4%)	< 0.001
Self-care						
No problems with self-care	418 (65%)	608 (68%)		200 (31%)	358 (40%)	
Some problems with self-care	171 (27%)	218 (24%)		293 (46%)	380 (43%)	
Unable to wash or dress	52 (8.1%)	68 (7.6%)	0.51	148 (23%)	156 (17%)	0.001
Usual activities						
No problems in performing usual activities	300 (46%)	407 (46%)		77 (12%)	163 (18%)	
Some problems in performing usual activities	240 (37%)	347 (40%)		314 (49%)	449 (51%)	
Unable to perform usual activities	106 (16%)	132 (15%)	0.62	255 (40%)	274 (31%)	< 0.001
Pain/discomfort						
No pain or discomfort	368 (57%)	514 (58%)		106 (16%)	284 (32%)	
Moderate pain or discomfort	239 (37%)	331 (37%)		422 (65%)	530 (60%)	
Extreme pain or discomfort	41 (6.3%)	40 (4.5%)	0.29	120 (19%)	71 (8.0%)	< 0.001
Anxiety/depression						
Not anxious or depressed	413 (64%)	568 (64%)		317 (49%)	456 (51%)	
Moderately anxious or depressed	198 (31%)	272 (31%)		282 (44%)	364 (41%)	
Extremely anxious or depressed	33 (5.1%)	51 (5.7%)	0.88	45 (7.0%)	71 (8.0%)	0.47

[a] Pearson chi-square test.

Discussion

We found that patients operated with a bipolar hemiarthroplasty due to a dislocated femoral neck fracture had less pain, were more satisfied with the result of the operation, and had a better quality of life 4 months postoperatively than patients operated with internal fixation.

Quality of life

We found a marked reduction in EQ-5D index score postoperatively in both treatment groups. The patients treated with a bipolar HA did, however, have a better EQ-5D index score at 4 months than the IF group. Tidermark et al. (2003b) found a reduction in EQ-5D index scores at 4, 12, and 24 months in patients with displaced femoral neck fractures treated with IF, even when the fracture had healed uneventfully. In elderly patients with severe cognitive impairment, Blomfeldt et al. (2005b) found a lower quality of life for uncemented HA according to the EQ-5D at 2-year follow-up compared to IF. We found that HA was also superior to IF for the patients with cognitive impairment. One reason for this difference in results between studies could be that different implants were used. While Blomfeldt et al. used the unipolar Austin Moore uncoated uncemented hemiprosthesis—which is documented to be inferior (Australian Orthopaedic Association 2007)—most of the prostheses used in our study were cemented, and the uncemented prostheses used were all modern, hydroxyapatite-coated implants. The results of cemented HAs have been reported to be better than the results of uncemented, uncoated HAs concerning pain, walking ability, use of walk aids, and ADL (Khan et al. 2002). Keating et al. (2006) found that there were no statistically significant differences between IF and bipolar HA when the EQ-5D was used 4, 12, and 24 months postoperatively. Our study had more patients, however, and therefore higher power.

We found a good correlation between the EQ-5D index scores and the other outcome variables at 4 months; i.e. patients reported similar pain and satisfaction scores. This is in accordance with an earlier study that showed a good agreement between the EQ-5D index scores and other outcome variables

such as pain, mobility, independence in ADL, and independent living status (Tidermark et al. 2002).

Pain

Patients treated with an IF had more pain 4 months after surgery than patients treated with a primary HA (VAS scores: 41 and 27, respectively). This is in accordance with one study from Sweden (Rogmark et al. 2002). Other studies have, however, reported no statistically significant difference in pain between IF and HA (Parker and Pryor 2000, Keating et al. 2006). In the study by Parker and Pryor, uncemented, uncoated Austin Moore hemiprostheses were used.

Strengths and limitations of the study

Results from observational, register-based studies (cohort studies) are less conclusive than those from randomized clinical trials. If potential confounders are controlled for, however, observational studies may give results that are similar to those of controlled, randomized trials (Benson and Hartz 2000). Only known and measured confounders can, of course, be adjusted for in observational studies, whereas randomized studies take account of all confounders—both known and unknown. On the other hand, observational studies have several advantages over controlled, randomized studies, including lower cost, greater timeliness, and a wider range of patients. Our study represents the results from the whole country, and of the average surgeon, and not only the results from one specialized clinic, as in many randomized studies. Considering the high age and considerable comorbidity of the patients, the 60% response to the patient questionnaire was as expected, but a higher compliance would have strengthened our results. The patients who did not return the questionnaire were generally older, more cognitively impaired, and had a higher ASA class than the patients who responded. Since we had no EQ-5D scores for the patients who failed to respond, we can of course not be sure of any differences in quality of life in the two groups. However, preoperative age, cognitive impairment, and ASA class were similar for the non-responders in the 2 treatment groups. Consequently, the comparison of the treatment groups was reliable. The relatively high number of patients lost to follow-up may also reflect the fact that many of these frail patients are transferred to nursing homes when discharged from hospital; thus, they cannot be contacted at their permanent address.

In summary, 4 months after surgery, a bipolar hemiarthroplasty showed good results—better than those after screw or pin fixation—in dislocated femoral neck fractures in patients over 70 years of age. A longer follow-up will be necessary to determine whether the superior outcomes of hemiarthroplasty persist in the long term.

Contributions of authors

This study represents close teamwork by the orthopedic surgeons JEG, TV, LBE, LIH, OF, and JMF, and statistician SAL. All authors participated in the interpretation of the results and in preparation of the manuscript. JEG, SAL, and JMF performed the statistical analyses. JEG was mainly responsible for writing the manuscript.

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No competing interests declared.

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Paper III

Internal screw fixation versus bipolar hemiarthroplasty as treatment for displaced femoral neck fractures in elderly patients. A national register-based study on 1,031 patients.

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ABSTRACT

Background: Internal fixation and arthroplasty are the two main options in the treatment of displaced femoral neck fractures in the elderly. The optimal treatment remains controversial. Using data from the Norwegian Hip Fracture Register, we compared the results of hemiarthroplasty and internal screw fixation in displaced femoral neck fractures.

Methods: Data from 1,031 patients over seventy years of age operated due to a displaced femoral neck fracture with internal fixation (IF) (n = 428) or hemiarthroplasty (HA) (n = 603) were compared. The evaluation was based on the patients' own assessment (visual analogue scales concerning pain (0-100) and patient satisfaction (0-100), and quality of life (EQ-5D)) at four and twelve months follow-up. Sub-analyses on patients with cognitive impairment were done. The risk for reoperation was also analysed.

Results: After twelve months the HA group reported less pain (19.2 vs. 29.9), higher satisfaction with the operation result (25.7 vs. 38.9), and a higher EQ-5D index score (0.60 vs. 0.51) compared to the IF group. All differences were statistically significant ($p<0.001$). Virtually the same statistically significant differences were found at four months follow-up. Also for patients with cognitive impairment, the HA provided the best functional outcome at twelve months follow-up (less pain, higher satisfaction with the operation result, and higher EQ-VAS) ($p<0.001$). There were 118 reoperations (29 %) performed in the IF group and 10 (1.6 %) in the HA group.

Conclusions: Hemiarthroplasty provided less pain, higher patient satisfaction, and higher quality of life both at four and at twelve months follow-up compared to internal fixation as treatment for dislocated femoral neck fracture in elderly patients. Also for

the cognitively impaired patients, the best functional outcome was provided by HA. There were also less reoperations in the HA group than in the IF group.

Level of Evidence: Therapeutic Level II. See instructions to Authors for a complete description of levels of evidence.

Introduction

The incidence of hip fractures in the US and Europe, and in particular in the Scandinavian countries, are high[1-5]. Every year approximately 9,000 patients in Norway (4.7 million inhabitants) and 1.7 million patients worldwide are hospitalised and treated due to hip fractures[6;7]. Thus, large resources are used to treat these fractures[8]. In a meta-analysis, Bandhari et al found no difference between internal fixation and arthroplasty with regard to provision of pain relief and good function[9]. Another meta-analysis by Rogmark et al, however, found better function and less pain after arthroplasty compared to internal fixation[10]. In several randomised, controlled studies, total hip arthroplasty has provided better functional outcome than internal fixation, as assessed by Harris hip score[11] and EQ-5D[12-14]. In two randomised controlled studies, hemiarthroplasty (HA) showed better results than internal fixation (IF) as treatment for dislocated femoral neck fractures[15;16], while other randomised controlled studies have shown poor results for HA as treatment for such fractures[17;18]. The Cochrane collaboration have not been able to give any definitive conclusion[19]. The treatment of the dislocated femoral neck fractures in the elderly is thus still controversial[17;18;20-28].

The Norwegian Hip Fracture Register (NHFR) initiated a nationwide registration of hip fractures in 2005[29]. A study from this register, assessing patients over seventy years of age with dislocated femoral neck fractures four months postoperatively, showed that a bipolar HA provided less pain, better patient satisfaction, and a higher quality of life (EQ-5D) compared to IF[30]. In the present study, we wanted to investigate whether these results could also be found twelve months postoperatively. In addition, the risk for reoperations was assessed.

Materials and Methods

Since January 1, 2005, The Norwegian Hip Fracture Register (NFHR) has recorded fractures of the proximal femur as a prospective observational study. Compared with the Norwegian Patient Registry, the completeness of the registration has been approximately 80 percent[29]. After each operation, patient- and operative data were filled in by the surgeon on a standard one-page form and sent to the register[29]. The presence of cognitive impairment could, if in doubt, be determined by the use of the clock-drawing test[31]. Both primary operations and reoperations were registered, and reoperations were linked to the index operation using the national identification number assigned to each inhabitant of Norway. The definition of a reoperation was any operation performed due to complications after the index operation, including closed reduction of dislocated hemiprostheses, removal of osteosynthesis material, soft tissue revisions, and revision to a HA or a total hip arthroplasty (THA). Hip fractures treated primarily with a THA and hips reoperated with a THA due to sequelae after hip fracture, were registered on separate forms to the Norwegian Arthroplasty Register. These particular THAs were added to the NHFR before analyses were performed. Records with information on dates of death and emigration were obtained from the Norwegian Register of Vital Statistics. The Norwegian Data Inspectorate approved the recording of data. All patients signed an informed consent form that was entered into the patient journal in the hospitals.

Four and twelve months postoperatively, the patients received a questionnaire from the register. This included visual analogue scales (VAS) concerning average pain from the operated hip during the previous month (0 indicated no pain, 100 indicated unbearable pain) and satisfaction with the result of the operation (0 indicated very satisfied, 100 indicated very unsatisfied). Furthermore, the patients filled in the

Norwegian translation of the EuroQol (EQ-5D)[32]. The preference scores (EQ-5D $_{index}$ scores) generated from a large European population were used[33]. An EQ-5D index score of 1 represented the best possible health state, and a score of 0 represented a health state similar to death. The preoperative EQ-5D was retrospectively filled in by the patients 4 months postoperatively. The EQ-VAS should also be filled in (0 signifying worst possible health, 100 signifying best possible health). For the cognitively impaired patients, the questionnaires could be filled in by the relatives.

At May 21st 2008 there were 21,210 primary operations registered in the NHFR with fractures of the proximal femur. In order to have more than twelve months follow-up of the patients, only patients operated in 2005 and 2006 were selected (n = 13,403). Of these, 7,585 operations were performed due to femoral neck fractures. The primary inclusion criteria for this study were patients older than seventy years of age, operated, due to a displaced fracture (Garden 3 and 4)[34] with two screws or a bipolar HA. 4,335 patients fulfilled these criteria (Fig 1). Patients who died were excluded. The response rate of the four-months questionnaire was 55 % for both the IF group (819 of 1,495 patients) and the HA group (1,157 of 2,087 patients). For the twelve-months questionnaire, the response rate was 71 % for the IF group (455 of 640 patients) and 75 % for the HA group (711 of 946 patients). Patients who did not respond and patients who returned the questionnaires incompletely filled in, were excluded. No reminders were sent to patients not answering the questionnaires. In this way, 1,031 patients were included for further analyses, 403 patients were operated with internal fixation with two screws or pins (IF-group) and 628 patients operated with a bipolar hemiarthroplasty (HA-group) (Fig 1). In the outcome analyses, all patients remained in the same treatment group according to the intention-to-treat principle. Sub-analyses excluding reoperated patients were done. We also performed sub-analyses including only

cognitively impaired patients. Furthermore, we did sub-analyses on patients in the three different response groups of the first dimension of the preoperative EQ-5D concerning walking ability. Finally, we compared the results of patients treated with a HA as a primary procedure with patients operated with a HA as a secondary procedure. This comparison included only patients re-operated during the first 240 days after the index operation in order to assure there were more than four months delay between the secondary procedure and the twelve months follow-up. Accordingly, none of the patients were in the early postoperative period when the questionnaire was filled in.

Statistical Analysis

The Pearson chi-square test was used for comparison of categorical variables in independent groups. The independent samples t-test (Student's t-test) was used for continuous variables in independent groups. The p-values of preoperative EQ-5D index scores in table I and VI and the patient assessed outcomes presented in Table III, IV, V, and VII were adjusted for potential confounders (age, sex, and ASA-score) using general linear models (GLMs). All continuous variables were presented with 95 % confidence intervals (CIs). All tests were two-sided. All results were considered statistically significant at a 5 % level. The analyses were performed with use of SPSS software, version 15.0 (SPSS Inc., Chigaco, IL).

Results

Perioperative results

There were no differences in mean age, sex, ASA-score, presence of cognitive impairment, side of fracture, and mean preoperative EQ-5D index score between the two treatment groups (Table I). Compared to the HA group, the IF group had a shorter preoperative delay (19 vs 26 hrs, $p<0.001$) and a shorter duration of the surgery (mean

time 23 vs 72 minutes, p<0.001). Almost all patients had spinal anaesthesia (IF group: 369 of 403 patients (91.6 %), HA group: 578 of 628 patients (92.0 %), p=0.4). Systemic thrombotic prophylaxis was administered to 388 patients (96.3 %) in the IF group and 627 patients (99.8 %) in the HA group (p<0.001). 97 patients (24.1 %) in the IF group and 625 patients (99.5 %) in the HA group received systemic infection prophylaxis (p<0.001). There was no difference in the number of intraoperative complications (10 patients (2.5 %) in the IF group and 18 patients (2.9 %) in the HA group (p= 0.9)). Table II shows the distribution of implants used. In the HA group, uncemented prostheses accounted for 19.4 % (n = 122). Only contemporary bipolar prostheses were used. No Austin Moore or Thompson prostheses were reported.

Functional outcome

In the intention-to-treat analyses, patients operated with HA were more satisfied with the result of the operation, had less pain, and reported a higher quality of life according to EQ5D when compared with patients operated with IF both at 4 and 12 months follow-up. All differences were statistically significant (p<0.001)(Table III). After patients who were reoperated had been excluded, virtually the same statistically significant differences were found between the two treatment groups (Table IV). Also, when sub-analyses on patients with no preoperative problems in walking (IF: n = 233, HA: n = 353) and moderate preoperative problems of walking (IF: n = 163, HA: n = 266) were performed, similar statistically significant differences were found in both groups after four and twelve months follow-up. The group of patients confined to bed preoperatively was too small to perform meaningful statistical analyses on.

When comparing HA performed as a primary procedure with HA as a secondary procedure after failure of IF, there were no statistically significant differences twelve months after the index operation. However, at four months follow up after the index

operation, the patients who underwent a secondary HA-procedure were more dissatisfied, had more pain, and reported a lower quality of life compared to the patients operated primarily with a HA (Table V).

Patients with cognitive impairment

There were 48 patients in the IF group and 62 patients in the HA group with cognitive impairment, and the baseline characteristics of these patients are presented in Table VI. The cognitively impaired patients were older (mean age: 84.2 vs 81.5, $p<0.001$) and had more comorbidity (mean ASA score: 2.76 vs 2.29, $p<0.001$) compared to non-cognitively impaired patients. Among the cognitively impaired, patients in the IF group was older and had a higher ASA score compared to patients in the HA group (Table VI). All outcome variables favoured the HA group, although some differences were not statistically significant (Table VII). At twelve months follow-up, the cognitively impaired patients operated with HA were more satisfied and reported less pain and better quality of life according to the EQ-VAS compared to the IF patients (Table VII). Relatives or other persons filled in the four-months questionnaire in 99 of 110 patients (90 %) and the twelve-months questionnaire in 95 of 110 patients (86 %).

Reoperations

118 reoperations (29 %) were performed in the IF group and 10 reoperations (1.6 %) in the HA group during the follow-up. The most common reported causes of reoperation in the IF group were unspecified sequelae reoperated with a THA (n = 43), osteosynthesis failure (n = 41), local pain due to protruding screws, and non-union (n = 13). In the HA group the most common cause of reoperation was deep infection (n = 5). In the IF group arthroplasty was the most commonly performed reoperation (THA: n = 43, HA: n = 60). The osteosynthesis material was removed in 12 patients. In the HA group the most commonly performed reoperation was drainage of haematoma or infection (n = 6). One

patient was reoperated with an excision arthroplasty (Girdlestone procedure), one with a secondary HA, and one patient received a secondary THA.

Discussion

In elderly patients with displaced femoral neck fractures, this study shows that hemiarthroplasty gives less pain, better patient satisfaction, better quality of life, and fewer reoperations than internal screw fixation. The superior functional results that we previously reported at four months follow-up persist at twelve months follow up[30].

Our findings are in good accordance with the results of a recent randomised, controlled study from Frihagen and colleagues, comparing hemiarthroplasty (HA) with internal fixation (IF)[15]. The patients in that study were also Norwegian, and they were about the same age. However, they had more patients with cognitive impairment. All their patients were operated during a time-period ahead of the start of NHFR, and accordingly they are not included in the present study. They found virtually the same differences in EQ-5D index score and EQ-VAS between IF and HA as we found in our study at both four and twelve months follow-up. However, in the randomised study, the patients in both treatment groups generally reported better quality of life according to the EQ-5D compared to patients in the present study. One reason can be that the EQ-5D in the two studies was assessed differently. In the randomised study, a research assistant registered the EQ-5D, and the patients might be eager to please the department that performed the surgery. In our study, the EQ-5D was filled in by the patients or the relatives in their homes and sent to an independent national registry by ordinary mail. Another reason could be that our study gives the results from a whole country, with a large cohort of patients, and from the average surgeon and not only the results from one specialised clinic with special interest for these fractures.

Other studies, in which the uncemented Austin Moore uncoated hemiprostheses were used, found no difference in functional outcome compared to IF[17;18;35;36]. Most probably the reason is that the type of hemiprosthesis used has inferior results[37]. In our study, most prostheses were cemented, and of the uncemented prostheses used, the majority had modern, hydroxy-apatite-coated stems. Some studies, however, reported better results after arthroplasty compared to IF at early follow-up, but with smaller differences twenty-four and forty-eight months postoperatively[11;12;16]. According to these studies and the present study, the patients in the arthroplasty group might have a faster rehabilitation period with less pain and better quality of life. A hip fracture is associated with increased mortality, and up to fifty percent of the patients may die within the first five years[38;39]. Consequently, it is important to achieve a good clinical outcome as soon as possible. The differences found at early follow-ups, such as four and twelve months postoperatively, are therefore of great relevance when deciding the treatment for the elderly patients. Several recent studies have reported better functional outcome in elderly patients with femoral neck fractures operated with a total hip arthroplasty (THA) compared to patients operated with a HA[13;18;21;40]. A comparison of the results of THA versus HA will be addressed in future studies from our register.

Subgroup analyses

Sub-analyses of patients without any reoperation revealed that the HA provided superior results compared to IF for all functional outcome variables. One important weakness with the present study is the lack of clinical examination and radiographs at follow-up. Consequently, we have no information on whether the fractures not reoperated were healed or not. Frihagen et al, however, found that HA provided superior results over IF even when the fracture healed uneventfully[15].

Furthermore, sub-analyses showed that the bipolar HA performed well also in the cognitively impaired patients. This is in contrast to a previous study, in which no difference in functional outcome was found between IF and HA in this subgroup of patients[17]. The cognitively impaired patients were older and had a higher degree of comorbidity. The probability for these patients to be reoperated may therefore be less than for other patients. Consequently, to avoid a final inferior outcome, it is important that these patients are operated initially with the best available treatment. According to the results of this study the cognitively impaired patients should be operated with a modern well-documented hemiprosthesis.

Analyses of patients with minimal and moderate problems in walking showed similar findings as for all patients, favouring HA as the treatment of choice independently of the patient's walking ability. For ambulatory, healthy, elderly patients, with high functional demands, several studies have found better results after THA compared to IF as treatment for dislocated femoral neck fractures[11-13;18;41].

Reoperations

In our study, few minor reoperations, such as removal of screws or pins, were reported. These operations are often performed as day surgery or in outpatient clinics. Consequently, there could be a lower reporting rate for these operations. Our results were, however, in good accordance with the literature. Other studies have reported reoperation rates from 24 to 42 % for internal fixation and from 2 to 13 % for arthroplasties[15;17;42]. One meta-analysis found reoperation rates from 10 to 49 % for internal fixation and from 0 to 24% for arthroplasties[9].

Compared to patients operated with a primary HA, the patients operated with a secondary HA had poorer functional outcome four months postoperatively. However, no significant difference between the two groups was found twelve months after the

index operation, although there was a non-significant tendency towards poorer results for the secondary HAs. The reason for the poor results at four months follow-up could be complications after the index operation (IF), such as malunion or osteosynthesis failure. In addition, some patients had already been reoperated with a secondary HA and were suffering the immediate postoperative phase at this time. Our findings are in good accordance with the results from Frihagen et al[15]. Since these salvage arthroplasties had a follow-up of minimum four months, this could indicate that the rehabilitation, also for these secondary procedures was rapid. These results must, however, be interpreted with some care. Other studies have reported more pain[43] and a higher risk of reoperation after secondary HA compared to primary HA[43;44].

Strengths and weaknesses

A major strength of this study is the high number of patients, and that results from a whole country were analysed. The response rates to the patient questionnaire at four and twelve months were as must be expected, considering the high age, considerable comorbidity, and cognitive dysfunction in the population. According to an earlier study from the register, the non-responders were older, more cognitively impaired, and had a higher degree of comorbidity. The type of operation did not influence the response rate, and consequently there is no reason to suspect a systematic underreporting in one of the treatment groups[29].

One weakness of the study was that the preoperative EQ-5D index score was retrospectively filled in four months after surgery. Lingard et al found only moderate agreement between recalled data and prospective data concerning preoperative status[45]. In contrast, Howell et al, found the correlation between prospective data and recalled data to be good[46]. However, there was no difference in the preoperative EQ-5D index

score, and we found no reason to expect a systematic difference in one of the treatment groups.

Differences of clinical importance

The results from both the VAS scales concerning pain, patient satisfaction, and quality of life (EQ-5D), and from the EQ-5D index score must be interpreted with some care. Due to the high number of patients in this study, most differences between the treatment groups were statistically significant. However, the differences could still be small, and of no clinical relevance. Ehrich et al found that, on a 10 cm visual analogue scale, the minimal perceptible clinical improvement was determined to be 9.7 mm[47]. Two studies found that the minimal important difference (MID) for the EQ-5D index score was between 0.06-0.08[48;49], whereas for the EQ-VAS the MID was 7[48]. Consequently, in our study, a difference of 10 on the visual analogue scales concerning pain, satisfaction, and quality of life (EQ-VAS) could indicate a difference of clinical importance. Similarly, a difference of 0.07 on the EQ-5D index score could indicate a significant clinical difference. When considering the MID of our results, most statistically significant differences, with exception of the EQ-VAS, were of clinical importance.

In conclusion, with a lower number of reoperations, less pain, higher satisfaction with the result of the operation, and a higher quality of life, the patients operated with a bipolar hemiarthroplasty performed better than patients operated with internal screw fixation both after four and twelve months postoperatively. The superior results of hemiarthroplasty were present for all patients, irrespective of preoperative walking ability and cognitive function. Our results suggest that dislocated femoral neck fractures in the elderly should be treated with arthroplasty. Further research should focus on the controversy between total hip arthroplasty and hemiarthroplasty as treatment for these fractures.

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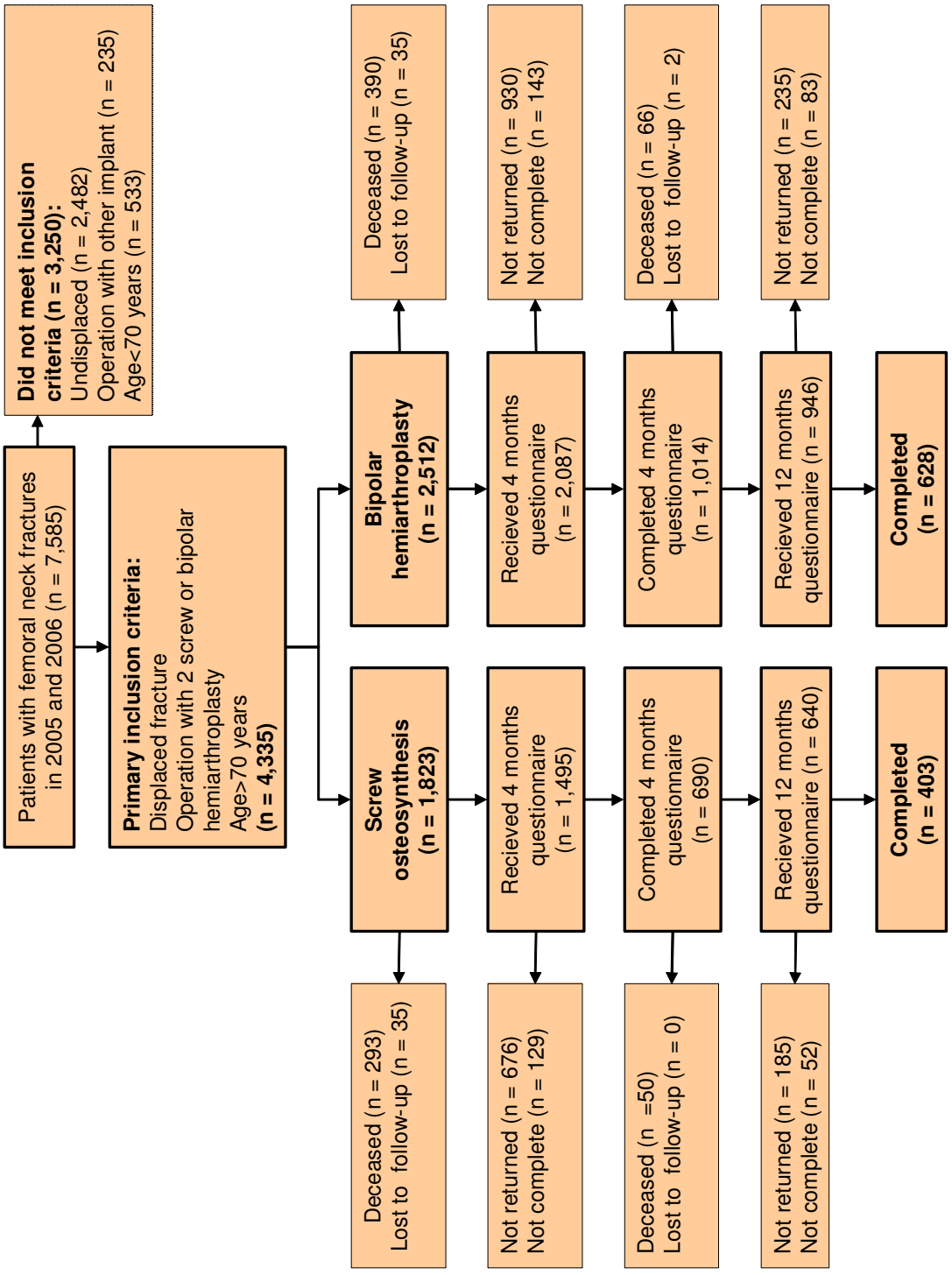

Fig 1 Flow chart of patients

TABLE I Baseline Characteristics of Patients According to Type of Treatment

	Internal fixation	Hemiarthroplasty	p-value
Number	403	628	
Mean age (95% CI) at fracture (years)	81.6 (81.0, 82.3)	82.2 (81.8, 82.7)	0.102 *
Women (%)	304 (75.4)	500 (79.6)	0.114 †
ASA group 1 or 2 (%)	215 (53.3)	341 (54.3)	0.117 †
Cognitive impairment (%)	48 (11.9)	62 (9.9)	0.410 †
Injured left hip (%)	222 (44.9)	334 (53.2)	0.550†
Mean preoperative EQ-5D $_{index}$ score (95% CI) ‡	0.73 (0.71, 0.76)	0.76 (0.74, 0.78)	0.131§

* Independent samples t-test. † Pearson chi-square test. ‡ IF group: n = 386 HA group: n = 610. EQ-5D $_{index}$ score: 0 = worst, 1 = best. § GLM with adjustments for age, sex, and ASA group.

TABLE II Types of Implants Used as Primary Treatment

2 screws or pins		Hemiarthroplasty	
Name	N (%)	Name	N (%)
Olmed (DePuy)	231 (57.3)	Charnley - Hastings (DePuy) *	188 (29.9)
Richards CHP (S&N)†	89 (22.1)	Exeter/V40 - UHR (Stryker) *	138 (22.0)
LIH nail (Orthovita)	60 (14.9)	Corail - Cupule mobile (DePuy) ‡§	92 (14.6)
Asnis III (Stryker)	23 (5.7)	Titan - Cupule mobile (DePuy) *	72 (11.5)
		Spectron - Tandem (S&N)* †	40 (6.4)
		Spectron - Cupule Mobile (S&N)* †	23 (3.7)
		Lubinus SP II - Vario-cup (Link) *	19 (3.0)
		SL Plus - Bipolar head (S&N) † ‡	17 (2.7)
		Other combination / unknown implant	39 (6.2)
Total	403 (100)	Total	628(100)

* cemented implant. † Smith & Nephew. ‡ uncemented implant. § Hydroxy-apatite-coated

TABLE III Comparison of Patient-Assessed Outcomes in Patients with Hip Fractures According to Type of Treatment. Intention-To-Treat Analysis

	Internal fixation	Hemiarthroplasty	Mean difference (95% CI)	p-value
Total n	403	628		
Mean (95% CI) patient satisfaction (VAS) *				
At 4 months	40.6 (38.3, 42.9)	25.2 (23.3, 27.2)	15.4 (12.6, 18.1)	<0.001 †
At 12 months	38.9 (36.6, 41.3)	25.7 (23.7, 27.8)	13.2 (10.4, 16.1)	<0.001 †
Mean (95% CI) pain (VAS) *				
At 4 months	36.8 (34.7, 39.0)	22.3 (20.4, 24.1)	14.5 (12.0, 17.1)	<0.001 †
At 12 months	29.9 (27.8, 32.0)	19.2 (17.4, 21.0)	10.7 (8.2, 13.3)	<0.001 †
Mean (95% CI) EQ-5D$_{index}$ score and EQ-VAS‡				
Index score:				
At 4 months§	0.46 (0.43, 0.48)	0.56 (0.54, 0.59)	-0.11 (-0.14, -0.07)	<0.001 †
At 12 months‖	0.51(0.48, 0.54)	0.60 (0.58, 0.63)	-0.10 (-0.13, -0.06)	<0.001 †
VAS				
At 4 months	52.9 (50.6, 55.2)	60.4 (58.4, 62.4)	-7.5 (-10.3, -4.7)	<0.001 †
At 12 months	56.7 (54.2, 59.1)	62.1 (60.1, 64.2)	-5.5 (-8.3, -2.6)	<0.001 †

* VAS: 0 = best, 100 = worst. † GLM with adjustments for age, sex, and ASA group. ‡ EQ-5D index score: 0 = worst, 1 = best. EQ-VAS: 0 = worst, 100 = best. § IF group: n = 378, HA group: n = 598. ‖ IF group: n = 372, HA group: n = 604.

TABLE IV Comparison of Patient-Assessed Outcomes in Patients with Hip Fractures According to Type of Treatment. Only Patients Without Reoperation Included

	Internal fixation	Hemiarthroplasty	Mean difference (95% CI)	p-value
Total n	285	618		
Mean (95% CI) patient satisfaction (VAS) *				
At 4 months	37.7 (35.1, 40.2)	25.1 (23.2, 27.0)	12.6 (9.7, 15.5)	<0.001 †
At 12 months	37.4 (34.8, 40.0)	25.3 (23.4, 27.3)	12.1 (9.0, 15.1)	<0.001 †
Mean (95% CI) pain (VAS) *				
At 4 months	34.4 (31.9, 36.8)	22.4 (20.6, 24.2)	12.0 (9.2, 14.8)	<0.001 †
At 12 months	28.7 (26.3, 31.1)	19.2 (17.4, 21.0)	9.5 (6.8, 12.3)	<0.001 †
Mean (95% CI) EQ-5D $_{index}$ score and EQ-VAS‡				
Index score:				
At 4 months§	0.48 (0.45, 0.52)	0.56 (0.54, 0.59)	-0.08 (-0.11, -0.04)	<0.001 †
At 12 months ‖	0.53 (0.49, 0.56)	0.60 (0.58, 0.63)	-0.08 (-0.12, -0.04)	<0.001 †
VAS				
At 4 months	54.8 (52.1, 57.4)	60.1 (58.1, 62.1)	-5.4 (-8.4, -2.3)	0.001 †
At 12 months	57.7 (54.9, 60.5)	62.1 (60.0, 64.2)	-4.4 (-7.6, -1.2)	0.007 †

* VAS: 0 = best, 100 = worst. † GLM with adjustments for age, sex, and ASA group. ‡ EQ-5D index score: 0 = worst, 1 = best. EQ-VAS: 0 = worst, 100 = best. § IF group: n = 266, HA group: n = 588. ‖ IF group: n = 261, HA group: n = 595.

TABLE V Comparison of Patient-Assessed Outcomes in Patients Operated with Hemiarthroplasty (HA) as Primary or Secondary Procedure

	Secondary HA*	Primary HA	Mean difference (95% CI)	p-value
Total n	47	628		
Mean (95%CI) patient satisfaction (VAS) †				
At 4 months	39.2 (33.4, 44.9)	25.0 (23.1, 26.9)	14.2 (8.3, 20.1)	<0.001 ‡
At 12 months	29.6 (23.5, 35.6)	24.9 (22.9, 27.0)	4.6 (-1.6, 10.8)	0.145 ‡
Mean (95% CI) pain (VAS) †				
At 4 months	34.4 (28.8, 40.1)	22.0 (20.1, 23.9)	12.5 (6.7, 18.2)	<0.001 ‡
At 12 months	20.9 (15.5, 26.3)	18.6 (16.8, 20.4)	2.4 (-3.2, 7.9)	0.404 ‡
Mean (95%CI) EQ-5D $_{index}$ score and EQ-VAS §				
Index score:				
At 4 months ‖	0.41 (0.33, 0.48)	0.56 (0.54, 0.59)	-0.15 (-0.23, -0.07)	<0.001 ‡
At 12 months ¶	0.53 (0.45, 0.61)	0.60 (0.58, 0.63)	-0.07 (-0.16, 0.01)	0.083 ‡
VAS				
At 4 months	51.4 (45.0, 57.9)	60.6 (58.4, 62.7)	-9.1 (-15.7, -2.5)	0.007 ‡
At 12 months	58.2 (51.5, 64.8)	62.8 (60.6, 65.0)	-4.7 (-11.5, 2.1)	0.177 ‡

* Patients in the IF group reoperated with HA during the first 240 days postoperatively. † VAS: 0 = best, 100 = worst. ‡ GLM with adjustments for age, sex, and ASA group. § EQ-5D index score: 0 = worst, 1 = best. EQ-VAS: 0 = worst, 100 = best. ‖ Primary HA group: n = 598, secondary HA group: n = 43. ¶ Primary HA group: n = 604, secondary HA group: n = 43.

TABLE VI Baseline Characteristics of Patients with Cognitive Impairment According to Type of Treatment

	Internal fixation	Hemiarthroplasty	p-value
Number	48	62	
Mean age (95% CI) at fracture (years)	85.5 (83.9, 87.2)	83.1 (81.8, 84.4)	0.019 *
Women (%)	41 (85.4)	46 (74.2)	0.151 †
ASA group 1 or 2 (%)	9 (18.8)	24 (38.7)	0.023 †
Injured left hip (%)	23 (47.9)	36 (58.1)	0.290 †
Mean preoperative EQ-5D $_{index}$ score (95% CI) ‡	0.53 (0.42, 0.63)	0.54 (0.46, 0.63)	0.844 §

* Independent samples t-test. † Pearson chi-square test. ‡ IF group: n = 46, HA group: n = 60. ‡ EQ-5D $_{index}$ score: 0 = worst, 1 = best. § GLM with adjustments for age, sex, and ASA group.

TABLE VII Comparison of Patient-Assessed Outcomes in Patients with Hip Fractures According to Type of Treatment. Only Patients with Cognitive Impairment Included

	Internal fixation	Hemiarthroplasty	Mean difference (95% CI)	p-value
Total n	48	62		
Mean (95% CI) patient satisfaction (VAS) *				
At 4 months	42.7 (33.8, 51.5)	32.0 (24.8, 39.2)	10.7 (0.6, 20.7)	0.037 †
At 12 months	41.9 (33.5, 50.4)	27.6 (20.7, 34.5)	14.3 (4.8, 23.9)	0.004 †
Mean (95% CI) pain (VAS) *				
At 4 months	34.3 (26.3, 42.4)	27.0 (20.4, 33.5)	7.36 (-1.7, 16.5)	0.112 †
At 12 months	34.0 (26.6, 41.3)	22.7 (16.7, 28.7)	11.3 (3.0, 19.6)	0.008 †
Mean (95% CI) EQ-5D $_{index}$ score and EQ-VAS ‡				
Index score:				
At 4 months §	0.24 (0.14, 0.33)	0.32 (0.24, 0.39)	-0.08 (-0.18, -0.03)	0.136 †
At 12 months ‖	0.32 (0.23, 0.42)	0.41 (0.33, 0.49)	-0.09 (-0.20, 0.02)	0.112 †
VAS				
At 4 months	41.4 (32.9, 50.0)	43.5 (36.5, 50.4)	-2.1 (-11.7, 7.6)	0.673 †
At 12 months	42.8 (34.5, 51.0)	53.8 (47.0, 60.5)	-11.0 (-20.3, -1.6)	0.022 †

* VAS: 0 = best, 100 = worst. † GLM with adjustments for age, sex, and ASA group. ‡ EQ-5D index score: 0 = worst, 1 = best. EQ-VAS: 0 = worst, 100 = best. § IF group: n = 44, HA group: n = 59. ‖ IF group: n = 46, HA group: n = 58.

Paper IV

Total hip replacement after femoral neck fractures in elderly patients

Results of 8,577 fractures reported to the Norwegian Arthroplasty Register

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Background A total hip arthroplasty (THA) is often used as treatment for failed osteosynthesis of femoral neck fractures and is now also used for acute femoral neck fractures. To investigate the results of THA after femoral neck fractures, we used data from the Norwegian Arthroplasty Register (NAR).

Patients and methods The results of primary total hip replacements in patients with acute femoral neck fractures (n = 487) and sequelae after femoral neck fractures (n = 8,090) were compared to those of total hip replacements in patients with osteoarthrosis (OA) (n = 55,109). The hips were followed for 0–18 years. The Cox multiple regression model was used to construct adjusted survival curves and to adjust for differences in sex, age, and type of cement among the diagnostic groups. Separate analyses were done on the subgroups of patients who were operated with Charnley prostheses.

Results The survival rate of the implants after 5 years was 95% for the patients with acute fractures, 96% for the patients with sequelae after fracture, and 97% for the OA patients. With adjustment for age, sex, and type of cement, the patients with acute fractures had an increased risk of revision compared to the OA patients (RR 1.6, 95% CI: 1.0–2.6; p = 0.05) and the sequelae patients had an increased risk of revision (RR 1.3, 95% CI: 1.2–1.5; p < 0.001). Sequelae hips had higher risk of revision due to dislocation (RR 2.0, 95% CI: 1.6–2.4; p < 0.001) and periprosthetic fracture (RR 2.2, 95% CI: 1.5–3.3; p < 0.001), and lower risk of revision due to loosening of the acetabular component (RR 0.72, 95% CI; 0.57–0.93; p = 0.01) compared to the OA patients. The increased risk of revision was most apparent for the first 6 months after primary operation.

Interpretation THA in fracture patients showed good results, but there was an increased risk of early dislocations and periprosthetic fractures compared to OA patients.

Background

Every year, approximately 7,000 patients receive a total hip arthroplasty (THA) in Norway (4.7 million inhabitants). Primary osteoarthrosis was the reason for the THAs in 71% of cases, and 11% were performed due to sequelae after proximal femur fractures (The Norwegian Arthroplasty Register 2005). An increasing number of patients are being operated with THA as primary treatment for acute fractures of the femoral neck (Malchau et al. 2002, The Norwegian Arthroplasty Register 2005). This may reflect a shift of indication from primary osteosynthesis to THA in patients with displaced femoral neck fractures.

Previous studies from the Norwegian Arthroplasty Register (NAR) have found that patients with sequelae after femoral neck fracture had a higher risk of revision compared to primary osteoarthrosis

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patients (Skeide et al. 1996, Furnes et al. 2001). These studies did not, however, include patients with acute femoral neck fractures. Randomized studies have shown that THA is a good treatment for acute fractures (Tidermark et al. 2002, 2003, Abboud et al. 2004, Blomfeldt et al. 2005). To investigate whether these results could be demonstrated on a national basis, we assessed the results of THA after acute femoral neck fractures, and sequelae after these fractures, by using data from the ongoing prospective study of THA in Norway.

Patients and methods

Patients

Approximately 98% of all primary hip prostheses and revisions in Norway have been registered in the NAR since 1987 (Engesaeter et al. 1992, Havelin et al. 1993, Arthursson et al. 2005, Espehaug et al. 2006). The register contains prospective data on more than 97,000 primary total hip arthroplasties (from September 1987 to the end of December 2005) and thus provides excellent data for the study of factors affecting outcome after THA. Information is collected using a questionnaire that is filled in by the surgeon (Havelin 1999).

In this study we included patients operated with a primary THA due to acute femoral neck fracture, or sequelae after this fracture, and compared the results with those from patients with OA. Of the 97,773 primary THAs registered in the NAR from September 1987 to December 2005, 81,221 patients were operated because of acute femoral neck fracture, sequelae after femoral neck fractures, or OA. In order to obtain more comparable age groups, patients younger than 60 years of age were excluded. Patients reported as sequelae after femoral neck fractures, without an earlier operation for the fracture, were also excluded. With these criteria for inclusion, only 8.8% of the prostheses turned out to be uncemented, and thus there were too few for meaningful analyses in the different diagnostic groups. Consequently, we only included patients operated with cemented prostheses (both femoral and acetabular component). After exclusion, there were 63,686 THAs registered with the diagnoses acute femoral neck fracture (n = 487), sequelae after femoral neck fracture (n = 8,090), or OA (n = 55,109). To investigate whether the brand of prosthesis affected the results, separate analyses of the patients operated with Charnley prostheses were performed.

Due to an increase in the number of THAs resulting from acute femoral neck fractures during the last years of the study period, we performed separate analyses on patients operated in the period 1987–1995 and on patients operated after 1995. All patients were followed until time of revision, until their death, or up to December 31, 2005. A revision was defined as an operation involving removal or change of one or more prosthesis components. Time of death was obtained from Statistics Norway.

Statistics

We used the Cox model to calculate the percentage survival. Cox regression models were used to adjust for differences in sex, age, and cement type in the different diagnostic groups with follow-up from 0 to 17 years. Furthermore, the Cox model was used to construct adjusted survival curves at mean values of the covariates. The percentage survival was given at 5 years due to short follow-up for the hips of patients with acute fracture.We used the Cox regression model to calculate differences in revision risk with different reasons for revision as endpoint in the different diagnosis groups. Non-parametric (time-dependent) relative risks were calculated using scaled Schoenfeld residuals (Therneau and Grambsch 2000). Two-sided p-values less than 0.05 were considered significant. Relative risks are presented with 95% CI.

Results

The fracture and sequelae patients were generally older than the OA patients, and there was a higher proportion of women in the fracture and sequelae groups (Table 1).

The Cox adjusted prosthesis survival after 5 years using all causes of revision as endpoint was 95.1% (95% CI: 92.3–97.6) for the patients with acute fracture of the femoral neck, 95.9% (95% CI: 95.4–96.4) for the patients with sequelae after femoral neck fracture, and 97.1% (95% CI: 97.0–97.3) for the OA patients (Figure 1). After adjustments

Table 1. Descriptive statistics for the different patient groups

	n	Mean age (range) [SD]	Women	Earlier operation
Acute fracture	487	76 (60–97) [7.7]	82%	0%
Sequelae after fracture	8,090	77 (60–100) [7.3]	81%	100%
OA	55,109	74 (60–97) [6.5]	71%	1.7%

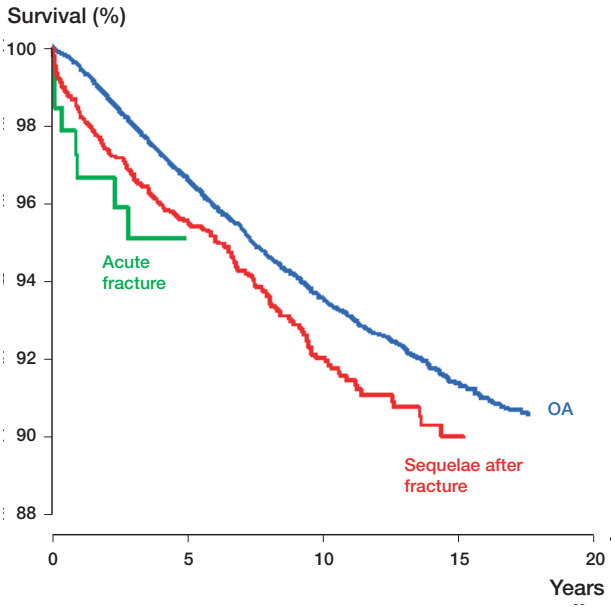

Figure 1. Adjusted prosthesis survival curves for the different diagnoses.

for differences in sex, age, and cement in the Cox regression model, the patients with an acute fracture had 1.6-times higher risk of revision (p = 0.05) compared to OA patients. The sequelae patients had 1.3 times higher risk of revision (p < 0.001) (Table 2). The sequelae patients had a lower risk of revision due to loosening of the acetabular component when compared to OA patients (RR 0.71, p = 0.01), and they had an increased risk of revision due to loosening of the femoral component (RR 1.2, p = 0.005), dislocation of the prosthesis (RR 2.0, p < 0.001), and revision due to periprosthetic fractures (RR 2.2, p < 0001) (Table 2). We found nearly the same risk estimates in the patients with acute fracture, but these results were not statistically significant due to lower numbers of patients (Table 2). In a separate analysis of the patients operated with Charnley prostheses, we found an increased risk of revision due to dislocation in patients operated due to acute fracture as compared to OA patients (RR 4.5, 95% CI: 1.9–11; p = 0.001). In the Charnley group, there were more revisions in the sequelae group than in OA patients due to all causes of revision (RR 1.3, 95% CI: 1.1–1.5; p = 0.001), dislocation (RR 2.2, 95% CI: 1.6–2.9; p < 0.001), and periprosthetic fracture (RR 1.9, 95% CI: 1.0–3.3; p = 0.04) (Table 3). The time-dependent relative

Table 2. Number of revisions after diagnosis. Several reasons may exist for each revision. The table also shows relative risk (RR) of revision for the different diagnoses. RR was adjusted for differences in sex, age, and type of cement in a Cox model

Reason for revision	OA (n 55,109)		Acute fracture (n 487)			Sequelae after fracture (n 8,090)		
	n	Reference	n	RR (95%CI)	P-value	n	RR (95%CI)	P-value
All revisions	2,904	1	16	1.6 (1.0–2.6)	0.05	375	1.3 (1.2–1.5)	< 0.001
Loose acetabular component	993	1	0			68	0.72 (0.57–0.93)	0.01
Loose femoral component	1,765	1	7	1.6 (0.76–3.4)	0.2	187	1.2 (1.1–1.5)	0.005
Dislocation	412	1	5	2.0 (0.81–4.7)	0.1	112	2.0 (1.6–2.4)	< 0.001
Deep infection	315	1	4	2.5 (0.93–6.7)	0.07	46	1.3 (0.97–1.8)	0.08
Periprosthetic fracture	127	1	1	2.4 (0.33–17)	0.4	32	2.2 (1.5–3.3)	< 0.001
Pain	162	1	2	4.0 (0.99–10)	0.05	14	0.93 (0.53–1.6)	0.8

Table 3. Subanalyses of Charnley prostheses. Number of revisions after diagnosis. Several reasons may exist for each revision. The table also shows relative risk (RR) of revision for the different diagnoses. RR was adjusted for differences in sex, age and type of cement in a COX model

Reason for revision	OA (n 26,790)		Acute fracture (n 221)			Sequelae after fracture (n 4,414)		
	n	Reference	n	RR (95%CI)	P-value	n	RR (95%CI)	P-value
All revisions	1,916	1	9	1.6 (0.82–3.0)	0.2	242	1.3 (1.1–1.5)	0.001
Loose acetabular component	203	1	0			36	0.76 (0.53–1.1)	0.1
Loose femoral component	1,395	1	4	1.2 (0.45–3.2)	0.7	142	1.2 (0.98–1.4)	0.08
Dislocation	203	1	5	4.5 (1.9–11)	0.001	69	2.2 (1.6–2.9)	< 0.001
Deep infection	199	1	1	1.1 (0.15–7.7)	1.0	30	1.3 (0.87–1.9)	0.2
Periprosthetic fracture	72	1	1	5.3 (0.73–39)	0.1	15	1.9 (1.0–3.3)	0.04
Pain	92	1	0			7	0.82 (0.38–1.8)	0.6

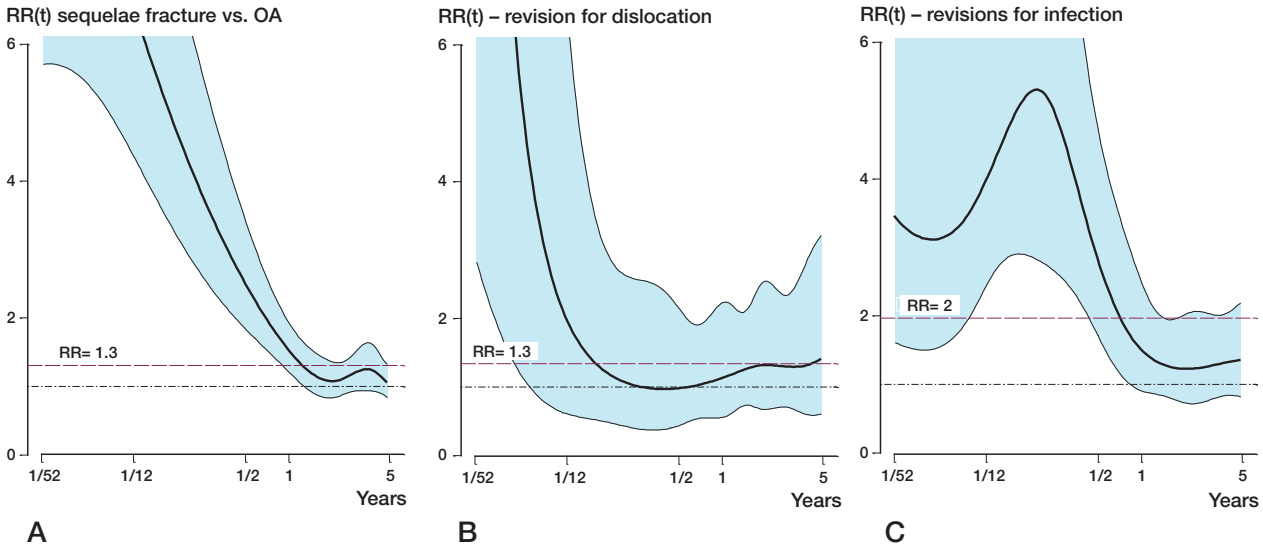

Figure 2. Time-dependent relative risks (RRs) of revision, with 95% confidence intervals, for prostheses in patients with sequelae after femoral neck fractures compared to prostheses in OA patients. The horizontal red dotted line indicates overall RR. The horizontal black line represents the risk of revision in OA patients. The x-axis is logarithmic. The curves show an increased overall RR of revision due to any cause during the first year (A), an increased RR of revision due to dislocation during the first 2 weeks (B), and an increased RR of revision due to infection during the first year (C)

risks of revision in the sequelae patients are presented in Figure 2. For the sequelae patients, the relative risk of revision was increased due to dislocations during the first 2 weeks, and due to infection during the first year postoperatively, as compared to OA patients.

For the subanalyses on patients operated before 1995, we found no difference in the results in comparison to patients operated after 1995. However, there were relatively few patients (n = 72) with acute fractures registered before 1995.

Discussion

Our study shows that THAs carried out because of primary OA had good outcome (with 2.9% revised after 5 years). Similarly, THAs after acute femoral neck fractures and sequelae after these fractures had good outcome. The outcomes were, however, inferior to those in the OA patients—mainly due to more dislocations in the first 2 weeks and more infections in the first year after surgery, and due to more periprosthetic fractures. This is in accordance with the findings of Pedersen et al. (2006) who

found that patients with sequelae after trauma had an adjusted RR of implant failure of 2.8 between 31 days and 6 months after primary THA, when compared to OA patients. After 6 months, there was no statistically significant difference.

One of the most important risk factors for revision of prostheses in patients with acute femoral neck fractures and patients with sequelae was dislocation. Other studies have shown similar results (Lindberg et al. 1982, Skeide et al. 1996, Furnes et al. 2001, Bystrøm et al. 2003, Mishra et al. 2004, Berry et al. 2005). Bystrøm et al. found that femoral head size was an important risk factor for dislocations of THAs. It has been reported that increasing age and especially the presence of cerebral dysfunction is associated with a higher dislocation rate (Woolson and Rahimtoola 1999, Bystrøm et al. 2003). The patients with acute femoral neck fractures and sequelae after fractures in our study did, however, have a lower average age than normally presented in studies of femoral neck fracture patients (Tidermark et al. 2002, 2003, Blomfeldt et al. 2005, Gjertsen et al. 2006). The average age of patients with hip fractures in Norway is 80 years (Gjertsen et al. 2006), but those selected for THA are younger. The patients treated with a THA after femoral neck fractures in this study thus represent a selected group of femoral neck fracture patients. Other plausible explanations for the increased dislocation rate in these patients might be an increased tendency to fall, less muscular control, or abnormal local anatomy with limb shortening and scar tissue after the previous operation (Furnes et al. 2001). Only patients with recurrent dislocations undergo surgical revision. The rate of surgical treatment for recurrent dislocations has been reported to be about 40% (Daly and Morrey 1992). This means that our endpoint—including only revisions for dislocation—is very strict and our results would probably have been even more evident if we had included all dislocations as the endpoint.

In the time-dependence study, we found a statistically significantly increased risk of revision due to infection during the first year in the sequelae group relative to OA patients. Again, our study only included patients who underwent surgical revision with a new prosthesis, or with a change or removal of one or more of the components. Patients operated with soft tissue revision only are not registered; thus, we believe that the risk of deep infection is greater than what we found in this study. However, comparison of the relative risk estimates between OA patients and fracture patients should not be affected unless fracture patients are more often treated with soft tissue debridement and long-term suppression antibiotic treatment than OA patients. A previous study based on our register found no statistically significant difference in infection risk when sequelae patients and OA patients were compared (Skeide et al. 1996), but time-dependent analyses were not used. The risk of a deep infection is still low. More use of antibiotics, both systemically and in cement, may be one possible explanation for these good results (Espehaug et al. 1997, Engesaeter et al. 2003).

Patients with sequelae after femoral neck fractures have been reported to have an increased risk of periprosthetic fractures (Skeide et al. 1996, Furnes et al. 2001, Sarvilinna et al. 2004, The Swedish National Hip Arthroplasty Register 2005). Our study confirms these results. In a nationwide observational study, minor trauma—including a fall to the floor—and a spontaneous fracture are reported to be the main etiologies of periprosthetic femoral fractures (Lindahl et al. 2006). Patients with previous femoral neck fractures may have a greater tendency to fall. They are also osteoporotic, and thus more prone to fractures. Also, holes after the use of osteosynthesis material in the proximal femur may cause a weakness of the bone and may lead to periprosthetic fractures. Again, our study only included patients who had a surgical revision with a new prosthesis component. Patients treated with wire and/or plate fixation are not reported to the Arthroplasty Register, and were therefore not included in this study. The true number of periprosthetic fractures is therefore higher.

One important weakness of our study is the lack of information on minor complications and procedures. Also, this study has no results on the functional outcome and quality of life of patients in the different diagnostic groups. We plan to address these issues in further studies from the new Norwegian Hip Fracture Register, which was started in 2005 (Gjertsen et al. 2006).

An observational register-based study reflects the outcome for the average surgeon rather than for specialized centers, and it therefore reflects what

one can expect with this procedure in a general setting. Results from observational register-based studies (cohort studies) may be less conclusive than those of randomized clinical trials. It has, however, been shown that if potential confounders are controlled, observational studies give results similar to those of controlled randomized trials (Benson and Hartz 2000). On the other hand, observational studies have several advantages over controlled randomized studies, such as lower cost, greater timeliness, and a broader range of patients.

Our study shows that THA is a good treatment not only for OA, but also for acute femoral neck fractures and for sequelae after femoral neck fractures. Even though we found an increase in relative risk of revision for the fracture patients, due to early dislocation and infection, and due to periprosthetic fractures compared to OA patients, the increased risk was small.

Contributions of authors

JEG: planning, conducting and first writer. SAL: planning (statistics) and reviewing the writing process. OF: idea, planning, and reviewing the writing process. JMF, LIH, LBE and TV: participated in the interpretation of the results, and reviewing the writing process.

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Erratum

In the article "Total hip replacement after femoral neck fractures in elderly patients: Results of 8,577 fractures reported to the Norwegian Arthroplasty Register" published in Acta Orthopaedica 2007; 78 (4): 491-497 by Gjertsen J-E et al. errors have occurred in the article text and in the headings and text to Figure 2.

Correct article text

In Results, page 494, first paragraph, the last sentence should be changed to:

For the sequelae patients, the relative risk of revision was increased due to **infection** during the first 2 weeks, and due to **dislocations** during the first year postoperatively, as compared to OA patients.

In Discussion, page 494, first paragraph, sentence 3 should be changed to:

The outcomes were, however, inferior to those in the OA patients-mainly due to more **infections** in the first two weeks and more **dislocations** in the first year after surgery, and due to more periprosthetic fractures.

In Discussion, page 495, third paragraph, the first sentence should be changed to:

In the time-dependence study, we found a statistically increased risk of revision due to infection during the first **2 weeks** in the sequelae group relative to OA patients.

Correct Figure 2:

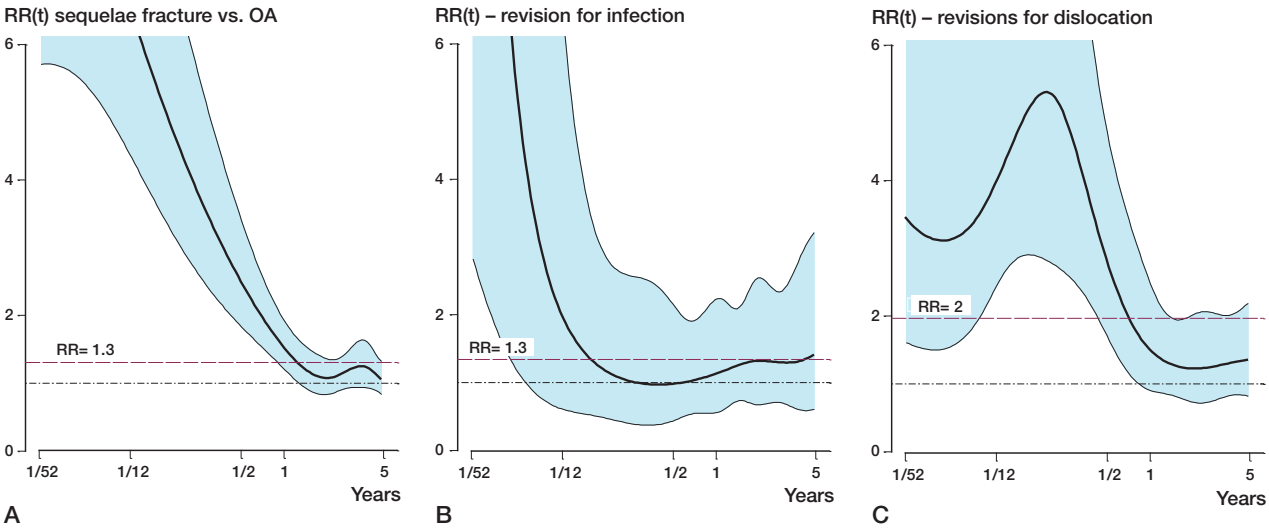

Figure 2. Time dependent relative risks (RRs) of revision, with 95% confidence intervals, for prostheses in patients with sequelae after femoral neck fractures compared to prostheses in OA patients. The horizontal red dotted line indicates overall RR. The horizontal black line represents the risk of revision in OA patients. The x-axis is logarithmic. The curves show an increased overall RR of revison due to any cause during the first year (A), an increased RR for revision due to infection during the first 2 weeks (B), and an increased RR for revision due to dislocation during the first year (C).

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