Surgical approach and muscle strength in total hip arthroplasty

Results of total hip arthroplasty, with a focus on surgical approach and validation of a national register

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Scientific environment

The study was initiated while working as a consultant surgeon at the Department of Orthopaedic Surgery, Stavanger University Hospital, with scientific supervision from the staff of The Norwegian Arthroplasty Register at the Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen. During the first three months financial support was given by the Centre for Clinical Research at Haukeland University Hospital and later a full finance PhD grant for three years from The Authorities of Western Norway (Helse Vest RHF) from research grant no. 911159 and a research grant from OrtoMedic from The OrtoMedic Charnley Award 2002.

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Contents

1. Acknowledgements

In Iceland clinical research is a part of medical training. This was my first introduction to medical research. In 1997 I started my work at Stavanger University Hospital at the Department of Orthopaedic Surgery; I later continued my interest in research. The head of the department Dr Kjell Harbo gave me the challenge of taking care of the surgical history and clinical information on hip arthroplasty.

This study was performed at the Department of Orthopaedic Surgery, Stavanger University Hospital and at the Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway.

I would first like to thank my three supervisors: Professor Ove Furnes, Professor Leif Ivar Havelin and Professor Jon Arne Søreide. This team has made this thesis possible. Their great influence and effort have guided me along this difficult road. I am deeply grateful for their support through the whole process, not only for the scientific part involving planning and writing the papers and this thesis, but also for their personal support through all the unexpected problems.

Thanks for the helpful attitude and kindness of my co-author, Birgitte Espehaug MSc, PhD. Her help during statistical analyses and practical database work has been invaluable. Thanks to the staff at the Norwegian Arthroplasty Register for the good atmosphere and kindness they showed me, and the high quality of both their secretarial work and data recording, which has been a source of great inspiration. I have always looked forward to the regular visits to Bergen during these years.

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I also wish to thank Dr Haukur Árnason, who, while working at Borgarspítalinn University Hospital Reykjavik, Iceland, lured me into the field of orthopaedic surgery, and Dr. J.C. Brügger Anderson in Stavanger University Hospital for always helping and teaching me the techniques and tricks in orthopaedic surgery.

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Financial support for this study was received from the Centre for Clinical Research at Haukeland University Hospital, Bergen, and The Authorities of Western Norway research funding (Helse-Vest RHF).

I must express my thanks and deepest gratitude to my mother Lára Karlsdóttir. You are a true role model.

Last, but not least, I thank my wife Elín for her kind and caring support, and for doing her best to correct and put up with me during times of distress and the many long working days of this busy period. Our three princesses, Ásdís Ósk, and twins Sara Rún and Signý Rut are wonderful, invaluable and a source of happiness.

This thesis is dedicated to my father – Arthur Sigurbergsson.

You tried to teach me to work, to never give up and to believe that everything is possible if you work hard on it. If a thing looks impossible or difficult you always said: “No problem. It is possible. This has been done before”. Now I believe you.

2. List of abbreviations

ASA	American Society of Anaesthesiologists score
BMI	body mass index
BW	body weight
CI	confidence interval
DRG	Diagnosis Related Groups
EMG	Electromyelogram
g	grams
HHS	Harris hip score
LA	lateral approach
m	metres
n	number(s)
NAR	Norwegian Arthroplasty Register
NIS	Norwegian Institute of Hospital Research
NPR	Norwegian Patient Register
OA	osteoarthritis
PA	posterior approach
PhD	philosophiae doctor
PMMA	polymethyl-metacrylate
REK	Regional Ethics Committee

RCT(s)	randomised controlled trial(s)
RR	failure (revision) rate ratio (risk ratio)
se	standard error
SUH	Stavanger University Hospital
THA(s)	total hip arthroplasty(ies)
TO+	Lateral approach with trochanteric osteotomy
TO-	Lateral approach without trochanteric osteotomy
UHMWPE	ultra high molecular weight polyethylene
VAS	visual analogue scale

3. List of papers

This thesis is based on the following papers, which will be referred to by their Roman numbers in the text.

Paper I

Arthursson AJ, Furnes O, Espehaug B, Havelin LI, Søreide JA. **Validation of data in the Norwegian Arthroplasty Register and the Norwegian Patient Register:** 5,134 primary total hip arthroplasties and revisions operated at a single hospital between 1987 and 2003.

Acta Orthop. 2005;76(6):823-8

Paper II

Arthursson AJ, Furnes O, Espehaug B, Havelin LI, Søreide JA. **Prosthesis survival after total hip arthroplasty – does surgical approach matter?** Analysis of 19,304 Charnley and 6,002 Exeter primary total hip arthroplasties reported to the Norwegian Arthroplasty Register.

Acta Orthop. 2007;78(6):719-29

Paper III

Arthursson AJ, Espehaug B, Havelin LI, Meling T, Søreide JA, Furnes O. **Restoration of hip abductor strength after primary total hip arthroplasty.** A prospective randomized trial comparing the lateral approach with or without trochanteric osteotomy.

Submitted, 2008.

4. Introduction

The Department of Orthopaedic Surgery at Stavanger University Hospital (SUH) is one of the largest orthopaedic departments in Norway, carrying out a relatively high number of elective orthopaedic surgical procedures. The head of the department, Dr. Sverre Skeie MD, introduced the low friction Charnley hip arthroplasty to SUH, as the second hospital in Norway to perform such an operation. The first Charnley hip prosthesis operation was done on the 20th of November 1972 and the department subsequently played an important role in the education and instruction of the "Charnley methods" in Norway. Thus, total hip arthroplasty has a long tradition at our orthopaedic department, and various clinical efforts have translated into good long-term results[1].

Faced with significantly increased revision rates in 230 patients operated on with primary hip arthroplasty using Boneloc® cement (Figure 1) between January 1991 and May 1993, Dr. Kjell Harbo MD, then head of the department, suggested that a clinical database should be established locally to monitor the quality and outcome after hip arthroplasty. The survival rate at 9 years for prostheses cemented with Boneloc was 55 % compared to 95 %

Figure 1.

with conventional bone cement.

While working with the database the idea of the “Stavanger study” came up, a prospective randomised study comparing the lateral approach, either with or without trochanteric osteotomy. At our department in Stavanger, there was a unique possibility to conduct that type of research, with several experienced orthopaedic surgeons who regularly used both surgical approaches.

5. Background

a. Hip arthroplasty. Basic concept

The original meaning of the term hip arthroplasty was any surgical formation or reformation of the hip joint, with the first known arthroplasty performed by Ollier in the 1880s using periarticular soft tissues. However, during the last few decades, the term hip arthroplasty has become synonymous with total hip replacement.

Hip diseases have occurred since early times. The most common degenerative hip disorder is coxarthrosis. Prostheses are generally accepted as an excellent treatment of pain and stiffening of the joint due to destruction caused by chronic disease, injury or congenital deformities. A total hip arthroplasty consists of two main components, the femoral stem with a head and the acetabular cup. The majority of the stems are made of stainless steel, titanium or cobalt-chromium. The femoral stem is either a modular or a monoblock design. The monoblock prostheses come as one piece or block, but in the modular form the femoral head is separate and is attached to the stem through a taper-locking mechanism, giving the possibility of adjusting tension (length and lateralisation) and abductor strength. Fixation of total hip arthroplasty is achieved either with or without bone cement. Both concepts have considerable support in the literature with good long-term survival[2,3]. Similarly, the acetabular component (cup) is monoblock or modular, the modular cup consisting of a metal shell that is fixed to the pelvic bone (acetabulum), either with or without cement, and an insert (liner), which is attached inside the shell. The bearing surface of the

artificial joint is either steel, cobalt-chrome or ceramic on the femoral head and either polyethylene (plastic), ceramic, or cobalt-chrome (metal) on the inner surface of the cup. There is an ongoing debate about the bearing surface and fixation, but cemented polyethylene cups have predictable results, while uncemented cups with conventional polyethylene have had poorer results[3].

b. Incidence and prevalence of total hip arthroplasty

The prevalence of coxarthrosis increases with age. While the disease may affect less than 1 % of the population under 55 years, it affects around 3.5 % of the population over 55 years and between 6–20 % of the population 75 years or older[4,5]. Recently,

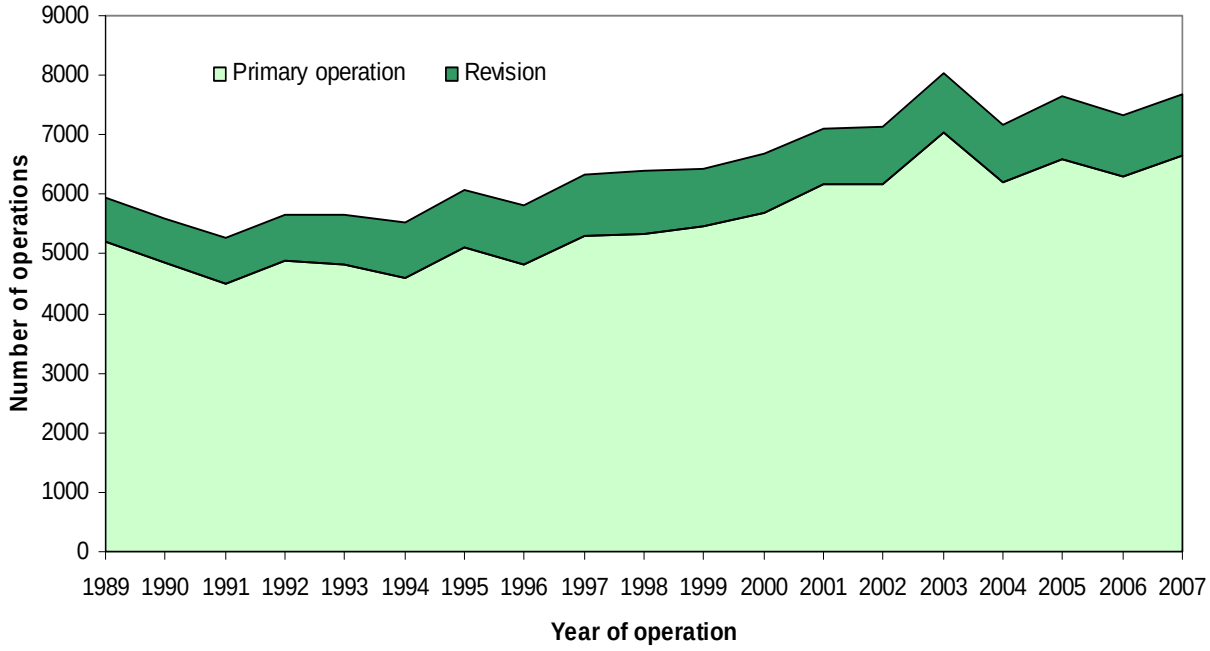


Figure 2. *Report Norwegian Arthroplasty Register.*

several reports have supported the use of prostheses after dislocated femoral neck fracture to achieve better outcome for these patients. Since the proportion of elderly in the general population is increasing, the need for total hip arthroplasty is also increasing.

The incidence of total hip arthroplasty is slightly different with regard to gender and is highest for females in Norway and Iceland[6,7]. In Norway the number of primary hip arthroplasties has increased, particularly since 1995 (Figure 2).

Total incidence has increased from 119 per 100,000 inhabitants in 1989 to 140 in 2007 (Figure 3).

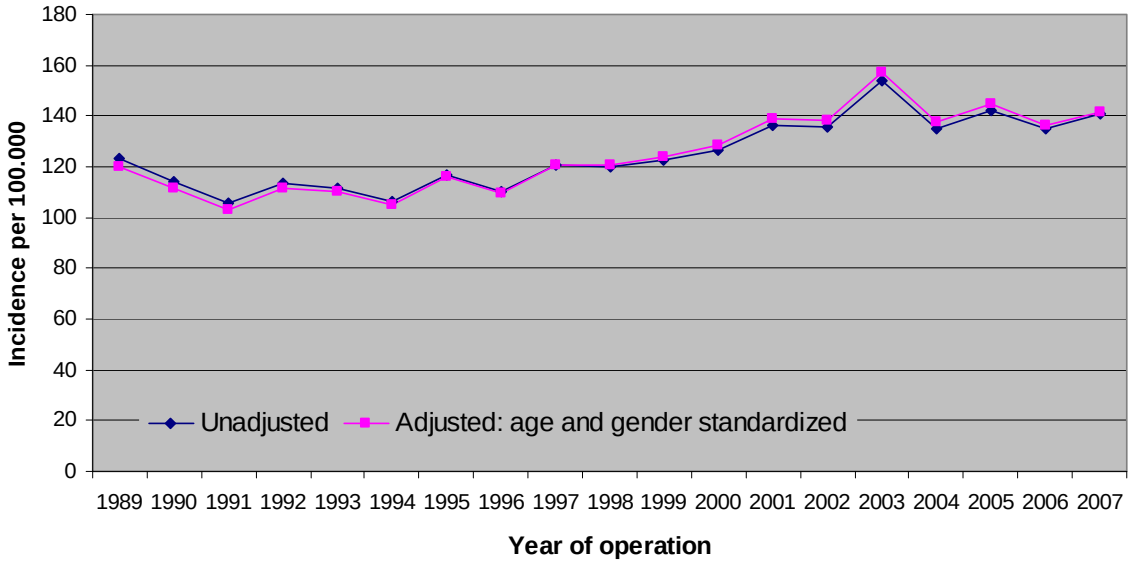


Figure 3. *Lecture Espehaug B. 20 years anniversary symposium Norwegian Arthroplasty Register; 2007*

As shown in Figure 4, the increase in incidence is most prominent in the 70–79 years and 80 years or over age groups. In Norway, the proportion of hip arthroplasties due to primary osteoarthritis has been fairly stable at around 70 %[8], which is similar to that recorded in other Nordic countries[6,9,10].

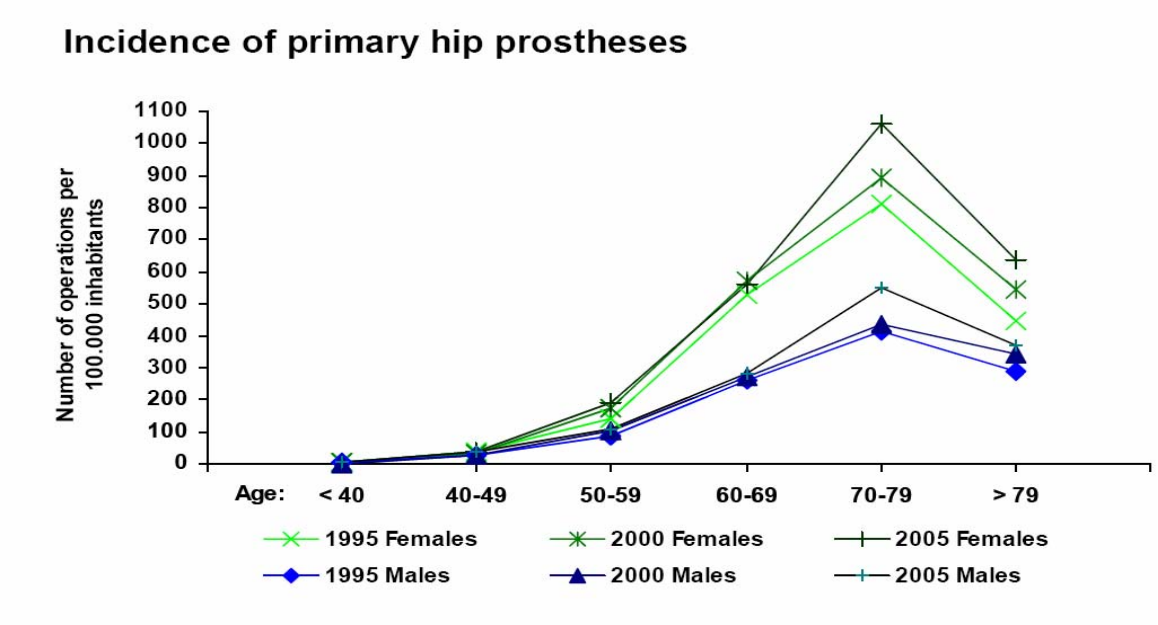


Figure 4. *Yearly report Norwegian Arthroplasty Register;2007*

c. Surgical approach

The success of total hip arthroplasty is well documented in terms of low revision rates, with 20-year revision rates ranging from 10 to 16 %[11]. A correctly performed surgical exposure is fundamental to an excellent functional result after hip arthroplasty, and the choice of approach has been recognised as an important factor for stability and long-term survival[12]. In the last 10–15 years operation techniques and surgical approaches have changed. Use of different surgical approaches also varies among countries and according to prosthesis type and prosthesis design. The

choice of surgical approach is usually based on the surgeon's experience during training, rather than on documented studies[13].

i. Lateral approach

The lateral approach has many derivations and many synonyms. The most commonly used are: direct lateral, Hardinge, trans-gluteal, trans-lateral and abductor split. The lateral approach was described by McFarland and Osborne in 1954 and was based on their anatomical observation that the gluteus medius and vastus lateralis are in direct functional continuity through the thick tendinous periosteum covering the trochanter major[14]. They also included de-attachment of the gluteus medius tendon in its entirety while maintaining its continuity with the vastus lateralis. The functional continuity between the gluteus medius and the vastus lateralis has, however been disputed by others. In 1970 Müller used the same intermuscular plane to perform total hip arthroplasty without osteotomy of the trochanter major[15]. In his approach, a transverse incision was used to separate the anterior third of the distal attachment of the gluteus medius, and the tendon of the gluteus minimus was divided 1 cm from its attachment to the bone. Bauer et al. in 1979[16] and Hardinge in 1982[17] modified the approach again by detaching only the anterior ½ of the medius tendon. Frndak et al. described an additional modification involving elevating only the anterior third of the gluteus medius and minimus tendons in continuity with the vastus lateralis[18]. The last modification was done by Learmonth and Allen in 1996 and Soni 1997, when they recommended the release of the anterior third of the

gluteus medius, and the gluteus minimus was released separately from the anterior aspect of the trochanter major in a way that facilitates reattachment. The vastus lateralis muscle was left undisturbed[19,20]. The Hardinge modification was used in paper III.

Closure: The important principle of closure is a strong reattachment of the capsule and transosseous reattachment of the gluteal muscles. The gluteus minimus is reattached separately.

ii. Trochanteric osteotomy

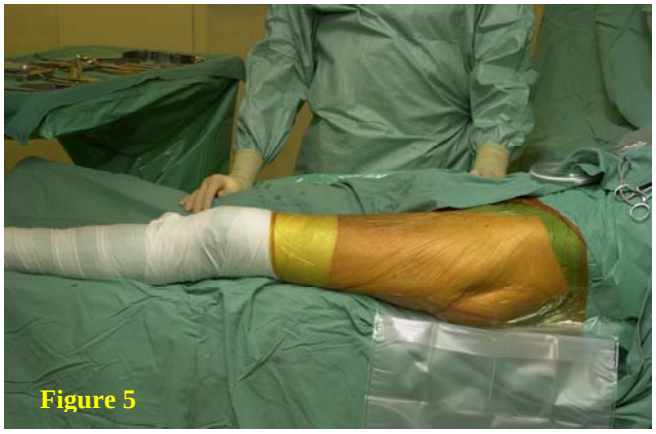


Figure 5

This approach is also often called the transtrochanteric approach and was originally a modification of the anterolateral approach. A biplanar trochanteric osteotomy was probably first used by Debeyre and Duliveux in 1954[21]. Weber and Stühmer described a self-stabilising trochanteric osteotomy designed to resist rotation of the trochanter after reattachment but the approach was popularised by Charnley[22]. The patient lies in a supine position (Figure 5). The pelvis and the leg length are easy to measure. The skin incision is centered over the trochanter major and runs along the femur axes or posteriorly[23]. The trochanteric and femoral neck osteotomy is done with a Gigli saw (Figures 6 and 7). Successful

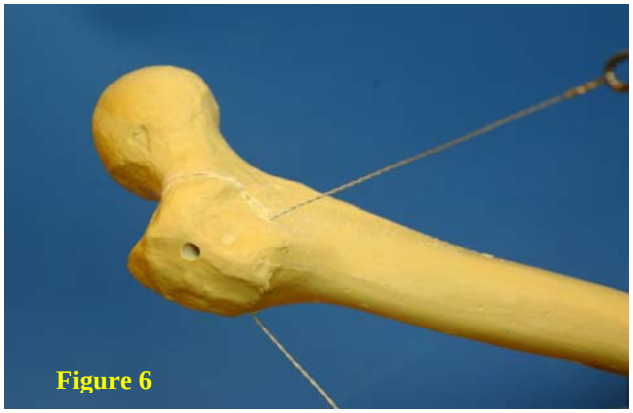


Figure 6


Figure 7

reattachment of a trochanter demands that the trochanter be of the correct size and shape (neither too large nor too small).

Closure: The challenge for this operation technique is closure, for which various methods of trochanteric reattachment have been described and tested[23-26]. Charnley introduced his method using two single wires and one double wire. We used one

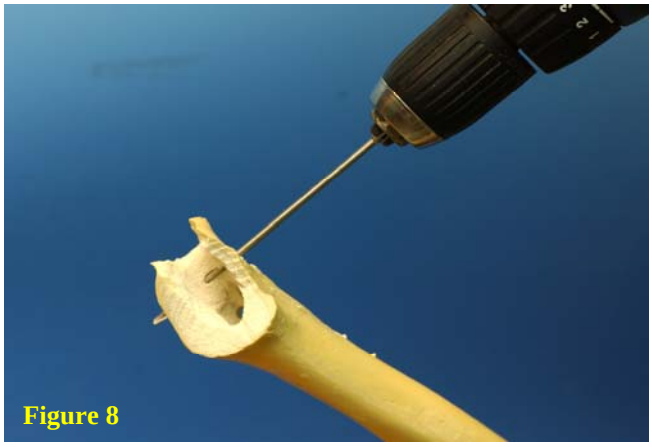


Figure 8


Figure 9

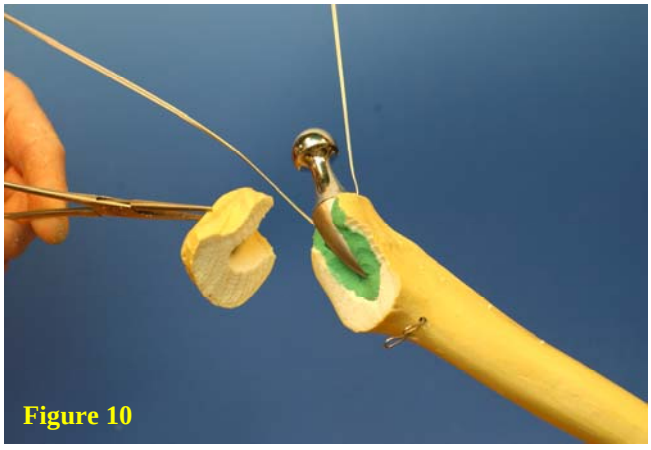
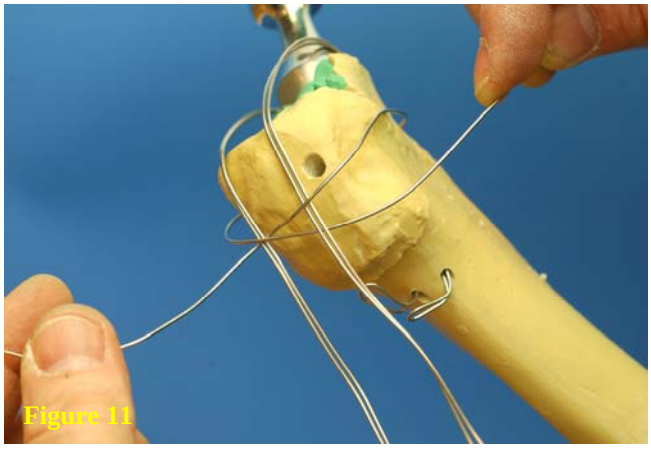


Figure 10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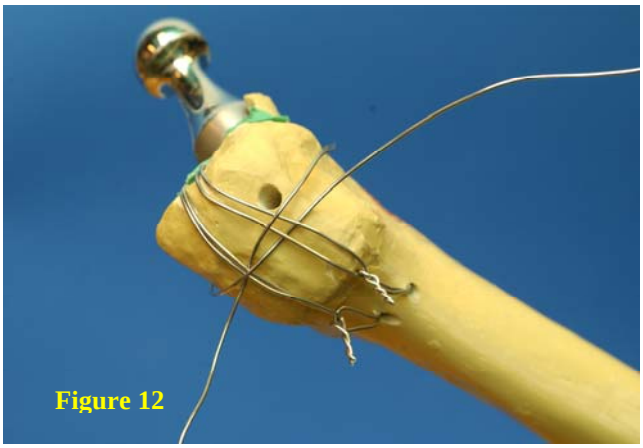
Figure 12

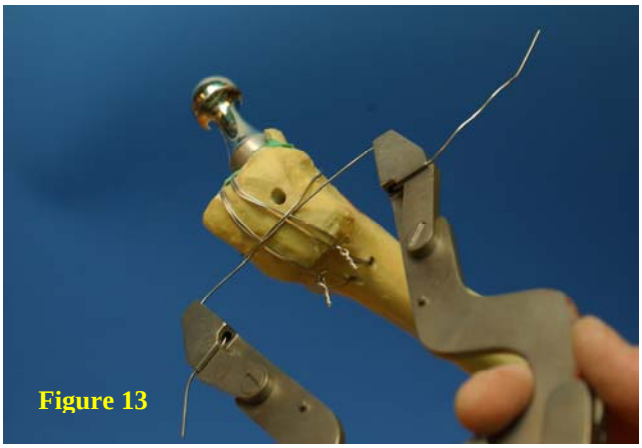
Figure 13


Figure 14


Figure 15

single and two double wires in paper III (Figures 8–11). It is important to take care that the vertical double wires do not slip forwards or backwards by twisting the horizontal wire between both doubles wires (Figures 11–15).

iii. Posterior approach

The first description of a posterior approach to the hip joint was by von Langenbeck in 1874, but there have since been many modifications to the procedure. The most popular current approach was described by Moore in 1957. Although the preferred choice worldwide, it is less common in Norway[27].

The incision is made at the posterior rim of the greater trochanter and follows the axis of the femur. The sciatic nerve is usually not seen directly, and can be injured by the posterior retractors, so care must be taken to avoid vigorous posterior retraction.

Closure: The capsule is usually closed at the rim of the acetabulum. To prevent posterior dislocation it is recommended to reattach the external rotators by passing the suture through drill holes in the trochanter major (osteosutures).

d. Contemporary problems

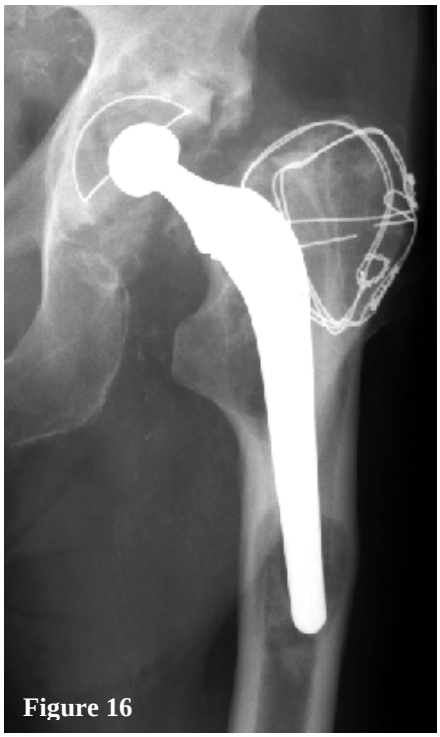

Figure 16

i. Osteolysis and loosening

Osteolysis is a change of state in the bone around the prosthesis implant with reduction of spongious or cortical bone. It is usually a radiological diagnosis based on comparisons of sequential x-rays during a time period (Figure 16). The prevalence and type of osteolysis varies between type of implant and bone cement[28,29]. The reasons for this and the changes in bone formation are unclear, but are most likely multifactorial, including infection, foreign-body inflammatory reaction, particle production and activity, defect in the cement mantle or increased pressure of the hip fluid[30]. Mechanical factors also probably contribute to osteolysis. Osteolysis often develops slowly and without pain, but it can also be progressive and a triggering

factor for femoral or leg pain. It is not clear whether the triggering factor for loosening is osteolysis or vice versa. Aseptic loosening of the prosthesis implant (cup or stem) is the most frequent reason for revision[31].

ii. Infection

Charnley stated that "Postoperative infection is the saddest of all complications"[32]. Several factors, including earlier operation of the same joint, increasing age and various diagnoses like mental dementia, adipositas, diabetes mellitus, and immune suppressive diseases increase the risk of infection. Increased infection rates have also been reported in association with increased operation times[33]. Tsukayama et al. (1996) defined a useful four group classification of infections[34] that is used today:

Type I: Infection diagnosed only by positive culture growing in the biopsy taken under revision.

Type II: Infection diagnosed earlier than four weeks postoperatively.

Type III: Acute haematogenous infection of the prosthesis.

Type IV: Infection diagnosed later than four weeks postoperatively.

The treatment of infections varies between countries and clinics, from treatment with oral antibiotics to the most dramatic therapy that includes a Girdlestone revision (i.e. removal of the total implant without a new insertion). Several efforts have been made to reduce the infection rate. In 2007, 14 % of all hip arthroplasty revisions in Norway were due to deep infection[8]. The most common action to prevent infection is

the application of a strict aseptic regime and field during the operation, with the operation done in specially designed operating theatres with laminar airflow and increased air pressure, body-exhaust systems, and antibiotic prophylaxis. Infection rates have decreased over time from 7 % in 1972[23] to 1–3 % today[35]. Infection rates as low as 0.3 % have been reported in low-risk patients[36].

iii. Dislocation and instability

Dislocation of the prosthesis is one of the most frequent complications that cause re-hospitalisation after total hip arthroplasty surgery. Dislocations can be divided into early (earlier than four weeks postoperatively) or late (later than four weeks postoperatively) dislocation. There are four main reasons for dislocation:

1. Malposition of prosthesis components (femoral stem and/or acetabular cup).
2. Muscles function or muscle strength insufficiency.
3. Wear of the polyethylene.
4. Unexpected reasons (such as trauma and the patient's compliance).

The reasons for dislocation must be considered in every case to ensure appropriate treatment. In Norway, dislocations were the cause of approximately 7–8 % of all revisions performed in 2007[8]. The incidence of dislocation also depends on the patient's age, mental and clinical condition, and diagnosis, and on the surgical approach, quality of surgery, the design of the stem, neck and cup, and the size of the femoral head[12,37].

iv. Material failure and bone cement

Fracture of the metal stem is exceptionally rare among prostheses in use today. New materials and modular combinations of ceramics in the cup or femoral head were initially subject to failure due to ceramic fractures. New designs, improved manufacturing processes, and proof testing have however improved these materials. Despite this progress, relatively high rates of fractures have been reported with contemporary ceramics[38,39]. The bone cement for fixation of hip implants is as important as the implant itself to enable the best possible survival of the prosthesis. Cement provides a mechanical connection between the implant and bone and does not act as glue to adhere the implant to the bone. It acts as an elastic zone between a stiff material (the prosthesis implant) and the elastic bone. Several studies on bone cement and prosthesis survival have been reported based on data in the Norwegian Arthroplasty Register. Results from these studies have reduced Norwegian

Figure 17

Government expenditure and saved many patients from revision surgery[40-42]. The best known example is Boneloc cement (Figure 17), the inferior results of which were discovered after just three years of use[43,44]. In Norway the use of cement types has changed over the registration period, most likely due to reports from the register. In paper II we investigated revision rates among prostheses fixated with Palacos or Simplex cement, both of which have shown good long-term results. In paper III, the same bone cement (Palacos with Gentamycin – Shering, Plough) was used for all patients. The quality of the cement-bone mantle is dependent on factors such as the cementing technique, especially pressurisation and cleaning of the bone bed, and the viscosity of the cement[43-47].

v. Limping and gluteal insufficiency

Biomechanics in the hip before and after total hip arthroplasty play a major role in postoperative function and probably also in loosening of the prostheses. The most interesting and important factor for pelvic stability and limping is the muscle strength in the abductor muscle group. This group contains the gluteal muscles (m. Gluteus Medius, m. Gluteus Maximus and m. Gluteus Minimus).

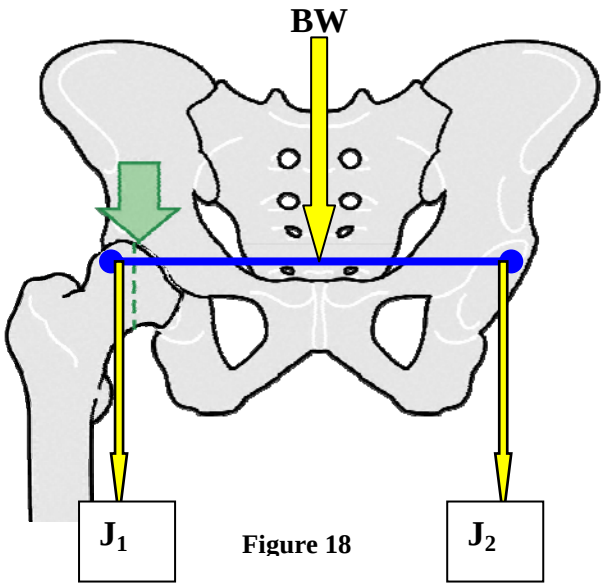

Figure 18

Balance in the hip and the pelvis when we are standing still, with equal weight on both legs, is achieved with minimal use of the gluteal muscles. It is possible to

calculate these resultant forces for one leg by the formulation ***J1(J2) = (4/6xBW)/2 = 1/3BW*** (Figure 18). This means that the force is just a third of the body weight. The situation is different when the patient is standing with the weight on one leg. The axes for the body weight lie medial to the centre of rotation in the hip, and make an adduction moment force on the centre of the rotation in the hip. To achieve balance in the centre of the rotation it is necessary to bring in the abductor force on the standing leg. This compensation will mainly come from the gluteal muscles, of which m. Gluteus Medius is the strongest[48]. These forces are larger than body weight. The reason is that the abductor weight arm (the weight arm that is lateral to the hip rotational centre **(a)**) is shorter than the weight arm for the weight of the body **(b)**. This ratio **(b/a)** is about 1.8[49]. With this information it is possible to calculate the necessary force for the abductor muscles to stand on one leg using the mathematical formula ***m x a = BW x b***. For the normal pelvis the distance (b) is approximately 10 cm and thus (a) is 5.5 cm (10/1.8=5.5). The force needed to stand with weight on one leg only thus increases substantially with increasing patient weight.

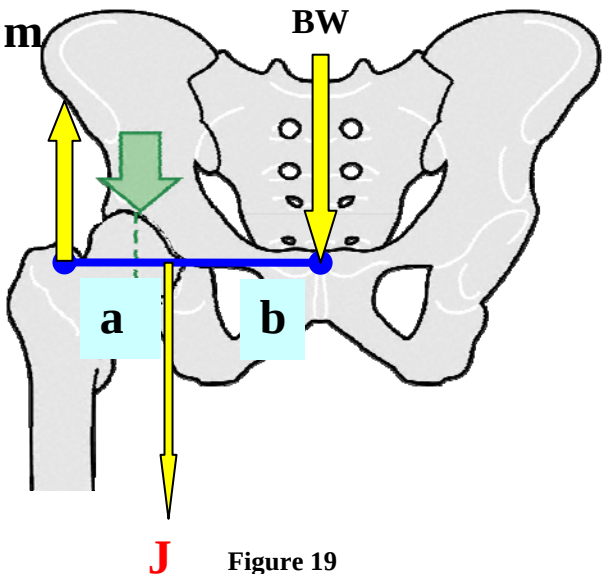

Figure 19

This situation can be changed and the necessary abductor force reduced by shortening the body-weight weight arm (weight arm b in Figure 19) by leaning the body over the rotational centre of the standing hip (Figure 20). This is the mechanism in limping or

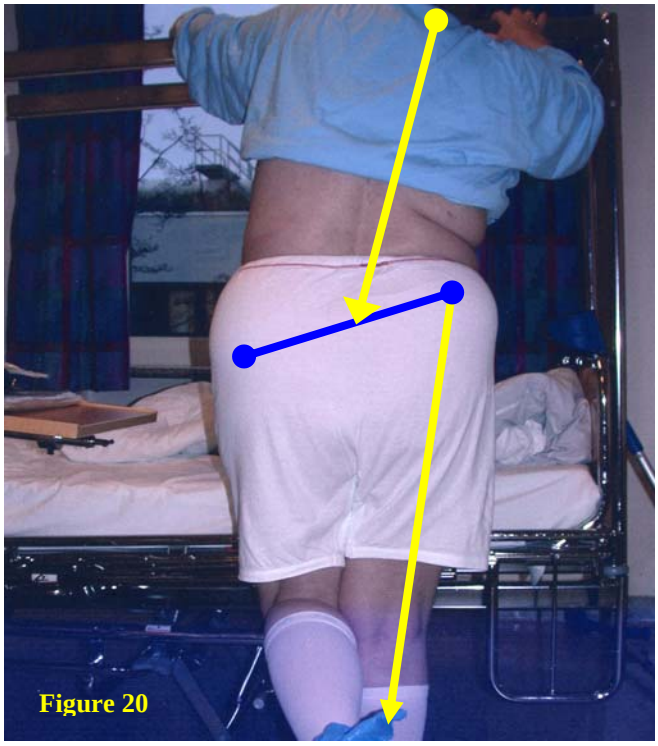
Figure 20

the positive Trendelenburg test[50]. During the operation it is also possible to influence the abductor muscle strength by changing the offset of the rotational centre or the leg length. Studies have shown that by reducing the lateral offset by 5 mm compared to the preoperative anatomical offset one needs about 10 % more force to maintain the balance in the resultant force. In this way, increasing the lateral offset by 1 cm gives a reduction of about 20 % in abductor force needed to balance the pelvis. Lengthening and shortening of the leg length also have a negative influence on the abductor strength[51-53]. This is possible to avoid by extremely precise preoperative planning[53].

Gluteal insufficiency is one part of the limping problem. There are three possible explanations for postoperative gluteal insufficiency:

1. Damage to the innervations of the abductor muscles.
2. Unsuccessful attachment of the abductor muscles.
3. Change in medial offset or leg length.

Many studies show that these explanations vary depending on the surgical approach. For the lateral approach there is a risk of damaging the superior gluteal nerve. This

nerve innervates m. Gluteus Medius and lies about 4 cm proximal to the trochanter major. Injury to the nerve by splitting and dissection of this muscles, when preparing the acetabulum and when the caput of the femur is dislocated out of the socket, has been reported[54]. This might be possible to avoid with the lateral approach with trochanteric osteotomy.

Unsuccessful attachment of the abductor muscles is well known but the reason is not always clear. The reduced force of the abductors in the condition "naked trochanter" (Figure 21), where the gluteus medius has not attached to the trochanter major, influences the abductor strength, the hip dislocation rate, limping and pain. Patient factors such as immunosuppressant medication, NSAID-use, rheumatism, nutrition state and degree of loading of the operated hip are factors that are thought to influence the reattachment of the gluteus medius. Technical factors for reattachment with closure after surgery are also discussed in the literature. Use of slow or non-absorbable suture is not common in Norway and many orthopaedic departments use a fast absorbable suture (Vicryl®) to reattach the abductors. In vivo studies of closure of abdominal facia have shown that Vicryl® has just 50 % of its original strength after three weeks and that it becomes weaker than the facia between the third and fourth week after operation, with just 25 % of the original strength after four weeks. In our study we used a slow absorbable suture, Panacryl®, to reattach the

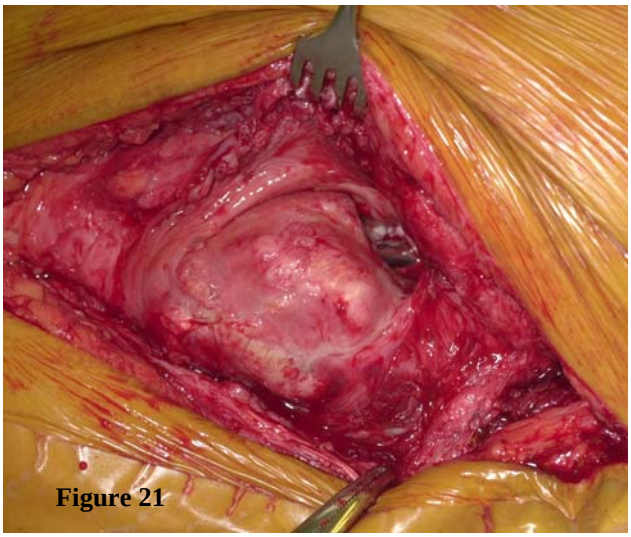

Figure 21

abductor muscles groups. This suture retains more than 80 % of its original strength after three months (Data from ETHICON, Inc).

For the direct lateral approach with trochanter osteotomy the method of reattachment is different. The ingrowths of the adductor muscle group are probably more reliable with the possibility for bone-bone reattachment instead of bone-tendon. Failure in reattachment of the trochanter (Figure 22) and wire breakage (Figure 23) have however been reported, with differences in incidence dependent on the method used for wire attachment[55].

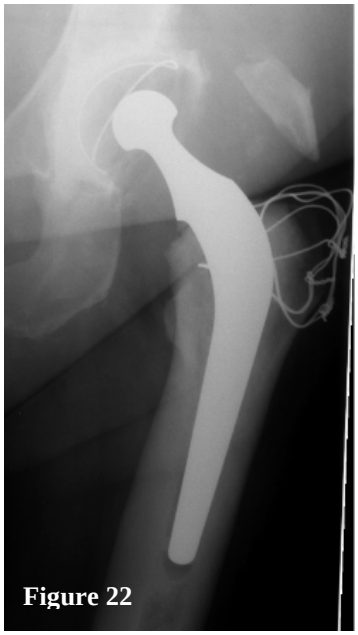

Figure 22

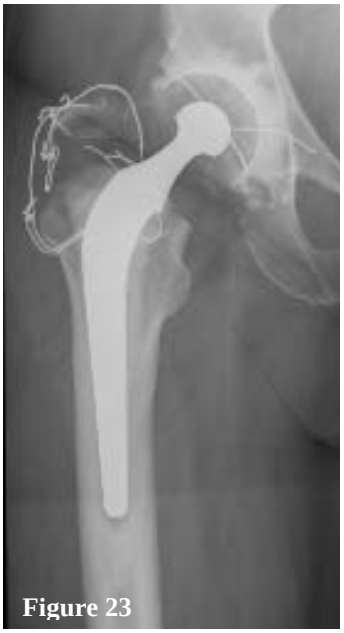

Figure 23

e. Revision of hip prostheses

Revision is the end stage of the prosthesis (implant) "life". Since 1987, the annual revision incidence in Norway has been relatively constant at around 13 %[8]. In the Norwegian Arthroplasty Register, a reoperation is defined as a revision with exchange or removal of one or more of the prosthetic parts (components). Re-operations not covered by this definition are not reported to the register, such as reduction of dislocated prostheses, attachment of the acetabular rim with repeated dislocations, reattachment of the gluteal muscle groups, reattachment of the

trochanter after trochanter malunion and removal of the trochanteric wire with trochanteric pain.

6. Aims of the present study

1. Investigate the differences and completeness of registration in the Norwegian Arthroplasty Register and the national Norwegian Patient Register compared to patient records and operating protocols from a local hospital.

2. Validate the quality of selected data recorded in the Norwegian Arthroplasty Register.

3. Investigate the effect of missing data in the Norwegian Arthroplasty Register on the results of prosthesis survival analyses.

4. Investigate the differences in long term survival of total hip prostheses inserted with the three most commonly used surgical approaches in Norway (i.e. the lateral approach with and without trochanteric osteotomy, and the posterolateral approach).

5. Investigate differences in two surgical approaches to the hip with regard to the restoration of abductor strength and functional outcome.

7. Materials

a. The Norwegian Arthroplasty Register

The incentive to establish The Norwegian Arthroplasty Register was the discovery of the poor results with Christiansen prostheses[56]. In 1983, Professor Sudmann, Dr. Lars B. Engesæter, Dr. Tor Steinar Raugstad, and other orthopaedic surgeons in Norway started to work towards establishing a national hip implant register. The hip arthroplasty register was then officially established in 1987 and data collection started on 15th of September 1987. Thanks to the head of the orthopaedic department, Norvald Langeland, the register was located at the Haukeland University Hospital and from 1992 it has been part of the Department of Orthopaedic Surgery, with a consultant orthopaedic surgeon as head of the register. Dr. Ove Furnes started developing the registration forms for knee and other joints in 1992 in co-operation with Dr. Asgeir Furnes, Dr. Leif Ivar Havelin, statistician Atle Lie and Professor Lars B. Engesæter. The hip register was extended to include prostheses in all joints, from 1st January 1994. From 1985 Dr. Leif Havelin worked systematically to implement the nationwide registration system for THA. From 1987 he was in charge of the day-to-day work as head of the Norwegian Arthroplasty Register until September 2002 when Dr. Ove Furnes took over. Lasse Engesæter has been involved in the day-to-day work from the beginning and he is now chairman of the board.

The register is primarily intended to function as a quality control system. The aim of the register is to detect inferior results of prosthetic implants, bone cements,

routines and procedures as early as possible, and the register was designed with this aim in mind. The register is nationwide to include the largest possible number of patients and to be able to follow the patients across the country and be able to capture all revisions even when performed at other hospitals. The data is collected and reported through paper forms, together with the patient's unique national identification number. The form is usually completed by the operating surgeon just after surgery. The registration form was therefore made as simple as possible to fill in and is less than one page. This principal rule has been followed over the years. Information on the diagnosis, operated side, earlier surgery to that particular joint, operating technique, every detail on the prosthetic components used, use of antibiotics, and operating time, complications, etc. are recorded. In 2005, information on computer navigation, bone loss, thrombosis prophylaxis and ASA classification was added to the form. The forms are listed in the APPENDIX (see Appendix 1 - 3). Of re-operations, only revisions with exchange or removal of one or more of the prosthetic parts are registered. Thus, other re-operations such as reductions due to dislocated prostheses are not reported.

b. Stavanger Hip Register

The Stavanger Hip Register was established at the request of Dr. Kjell Harbo, the head of the Department of Orthopaedic Surgery in 1998. Dr. Harbo initiated this local database to be used as a quality control system after the discovery of inferior results with Boneloc® cement. With excellent support from Dr. Normann Lichtenberg the database was designed and programmed in Access97 and later updated to Access2002. The database included all the information reported to the Norwegian

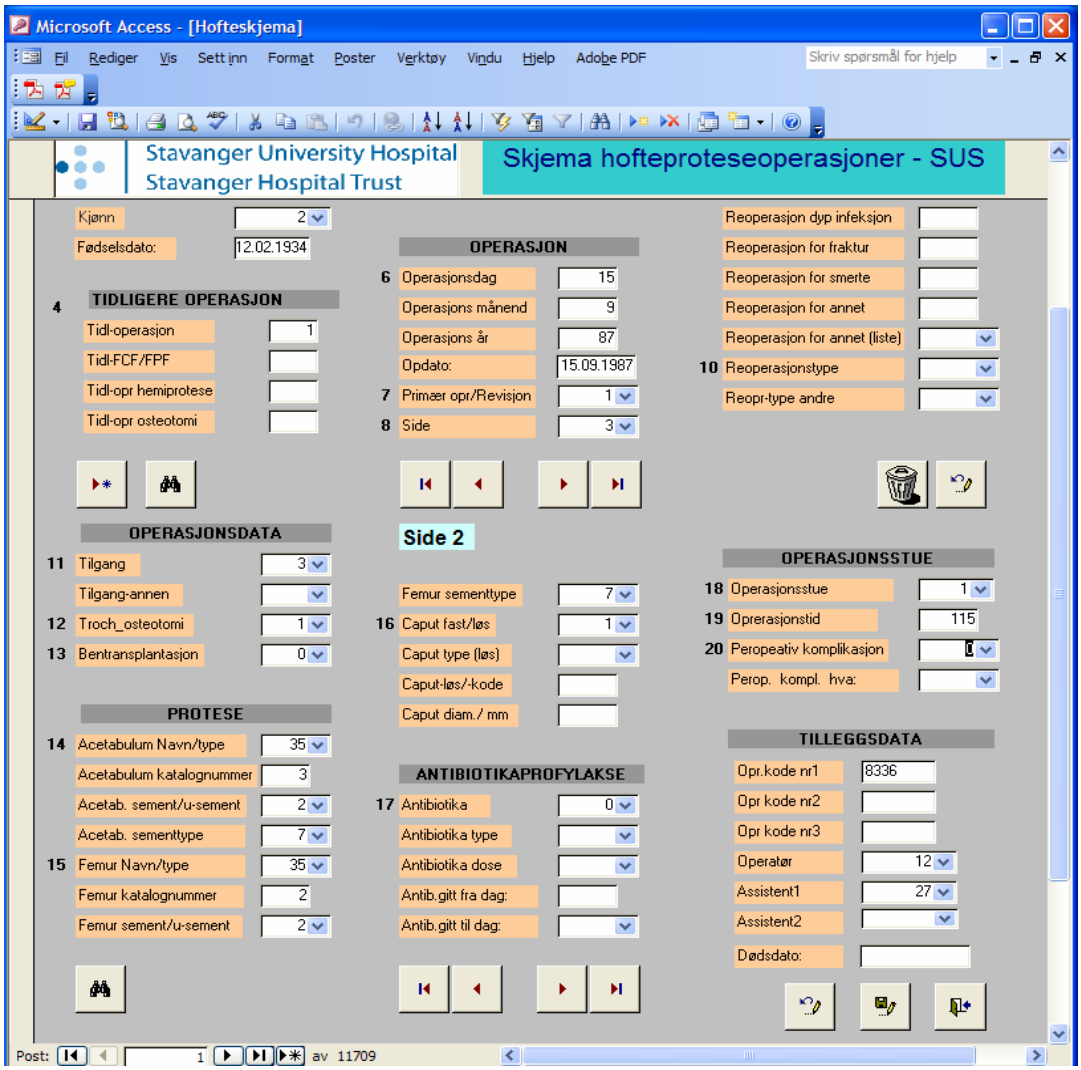

Figure 24

Arthroplasty Register, along with the specific surgical procedure as classified according to the Norwegian NOMESCO Classification of Surgical Procedures (N-NCSP), and the name of the surgeon and the assistant surgeon (Figure 24). All patients operated on with hemi-arthroplasty and primary total hip arthroplasty were recorded, as well as all surgical procedures that followed, or those that could be related to the implanted hip prostheses as follow-up data. By searching through and reading surgical log books, paper versions of the patients' medical records, and digitalised medical records and hospital administrative systems, the patients were retrospectively picked out and recorded in the database. The database goes back to the first Charnley hip prosthesis inserted in Stavanger University hospital on the 20th of November 1972. The database is continually updated and now contains 11,709 procedures. This database is the foundation for future research and the basis for paper I.

c. Norwegian Patient Register

The Norwegian Patient Register (NPR) was established in March 1997 and covers inpatient and outpatient hospital care in Norway. Before establishment of the NPR almost the same information was collected by the Norwegian Institute for Hospital Research (NIS), which is now incorporated into the NPR. For inpatient surgical procedures the data is complete for inpatients from 1990 and from 1999 for outpatient surgery. Each year around 1,000,000 inpatient and 3,000,000 outpatient consultations are reported from Norwegian hospitals[57]. The register is owned and

funded by the Government and run by SINTEF Health Research, a non-profit research organisation. Data on the patient's age, gender, hospital and department, diagnosis(es) and surgical procedure(s), dates of admission and discharge and date of procedure are included in the registry. The unique personal identification number that each Norwegian citizen has was included from 2007. The financial funding of Norwegian hospitals is partly based on the activity at each institution, with reimbursements to the hospital dependent on activity that utilises ICD-10 and Diagnosis Related Groups (DRG). The Norwegian Patient Registry was established mainly for administrative purposes. Data from the registry are also used in research on availability, quality and utilisation of health service resources, and epidemiological research. Validation of the completeness of the data reported and recorded in the Norwegian Patient Register has shown that it varies depending on the diagnosis, with the simplest procedures and shortest treatments showing the most complete reporting[58]. Later the Norwegian Arthroplasty Register was validated by comparing it to the NPR on a national level for primary total arthroplasty and revision arthroplasty, with the findings being consistent[59]. In paper I we validated reporting from a single hospital using the hip database from Stavanger and compared it to reporting to the Norwegian Arthroplasty Register and Norwegian Patient Register.

d. Randomised study

Randomised controlled studies (RCS) are comparative, prospective studies in which patients are randomly assigned to the treatment groups. This is the ideal approach to evaluate the performance of implants and techniques. Randomised controlled studies allow investigators to control factors with known and unknown influence on the measures that are studied. Large randomised studies would eliminate any systematic differences between the different treatment groups that might lead to confounded results. Such studies are generally considered to have the strongest level of evidence for comparison of treatment modalities but can only address one or two primary research questions. However, randomised controlled studies are too rarely performed in orthopaedic surgery. They are difficult to design, difficult to organise, are expensive, require a large workload and take a long time. This is especially true in treatment of diseases where there are generally good results with small differences between the treatment groups. To evaluate the design of randomised controlled studies and reporting of these studies for level of evidence it is common to use a specialised scoring system. The three most commonly used are:

1. The Oxford Level of Evidence[60].

2. A modified Coleman Methodology Score[61,62].

3. Revised CONSORT (Consolidated Standards of Reporting Trials) score[63].

With the Oxford Level of Evidence system, Level-I therapeutic studies are defined as high-quality randomised controlled trials demonstrating a significant difference or no

significant difference but with narrow confidence intervals. Level-II are lower-quality randomised controlled studies (<80 % follow-up, no blinding or improper randomisation).

The Coleman Methodology Score system includes many factors such as: inclusion criteria, power, alpha error, sample size, number of patients to treat, randomisation, follow-up, patient analysis, blinding and group comparability. The score is scaled to result in a value between 0 and 100. The categorical rating is considered to be excellent if the score is more than 85 points, good if it is 70 to 84 points, fair if it is 55 to 69 and poor if it is less than 54 points.

The revised CONSORT statement consists of a twenty-two-item checklist. The purpose of the CONSORT checklist is to compare the conduct of trials and the validity of their results. For each of the twenty-two items on the checklist, a trial is given 1 point if it meets the criteria of the CONSORT statement and 0 points if it does not. Thus, the maximum possible score is 22 points. The rating is excellent if the score is 18 to 22 points, good if it is 13 to 17 points, fair if it is 8 to 12 points and poor if it is less than 7. We believe that our randomised study in paper III scores 18 points by the CONSORT statement and is of good quality, while in the Oxford Level of Evidence system our study is a Level-I study.

8. Methods

a. Validation of data

Population-based quality registers have become important tools in quality assessment during the past decade. The validity of such data is however crucial if it is to be used in answering clinical and administrative research questions[64]. Completeness of registration may be defined as the proportion of all cases in the target populations that also appear in the registry database[64]. In paper I we investigated the completeness of registration in the national registers NAR and NPR, with the number of operations reported to these registers as numerators and the number of operations registered in the SUH database as the denominator. Registration completeness was studied for primary THA and revisions (removal or exchange of prosthetic parts), respectively, and specifically for Girdlestone revisions (removal of an implant without insertion of a new implant). The validity of a specific variable may be defined as the percentage of agreement between registry data and an independent source objectively measuring the same variable[64]. In paper I we validated registration in the NAR of date of operation and of index hip (left or right), the most important factors when calculating survival time, based on the accurate information in the SUH database.

b. Statistical methods

Statistical analyses were performed using the statistical software packages S-PLUS 2000 (papers I, II and III) (MathSoft Inc., Seattle, WA) and SPSS version 12.01 (paper II) and 14.0 (paper III) (SPSS Inc., Chicago, IL). A p-value of less than 0.05 was considered statistically significant in the analyses.

i. Survival analyses: Kaplan-Meier method and Cox regression

Survival analyses describe the distribution of life times until a defined event. In papers I and II, prosthesis survival was defined as the time period from insertion of an implant until at least one prosthetic component was revised (removed or exchanged). If not revised, survival was until death or emigration of the patient, or at study closure. Information on death and emigration was obtained from Statistics Norway. For calculation of survival in medical registers there are two methods that have become the basis of survival analysis and play an important role in medical research[65]. The Kaplan-Meier method (Kaplan and Meier, 1958) has become a standard for calculating survival probabilities and graphical presentation of follow-up data[66]. The Kaplan-Meier method was used in paper I to construct survival curves with 95 % confidence limits with Girdlestone revision as the endpoint. With the Cox multiple regression model[67,68], relative risks (incidence rate ratios) can be assessed with adjustment for differences in potential confounders in the compared groups. In paper II, relative revision risk estimates were established for the surgical approaches

with adjustment for differences in gender, age, diagnosis, cement and systemic antibiotic prophylaxis. Varying endpoints were used: revision for any cause, for deep infection, dislocation, and aseptic loosening. Estimates from the Cox regression analyses (stratified by approach) were further used to construct survival curves for mean values of the covariates. Median follow-up estimates in paper II were established by the method described by Schemper et al. (1996).

ii. Mixed-effects model

In paper III, hip abductor strength was measured in 130 patients preoperatively, and at 3, 6, 12 and 24 months following surgery. A linear mixed-effects model[69] was applied to handle possible dependencies introduced due to the repeated measurements of abductor strength. The model was fitted with common slopes and randomly distributed intercepts. Since the results of models fitted with common slopes and with randomly distributed slopes were very similar, the simpler model was chosen. In the model we included hip abductor strength as the outcome variable, and operative approach, time, and interaction terms between the two, as covariates. Since few patients were examined at exactly 3, 6, 12 and 24 months following surgery, time was also modelled as a continuous covariate including a linear and a quadratic term to describe the relationship between abductor strength and time.

c. Clinical Outcome

i. Muscle strength measurement


Figure 25

Measurement of the muscle strength in the hip has great interest from a clinical point of view. Limping and joint stability depend on the strength of the abductor muscle. Caldwell et al.[70] described a standardised procedure to carry out isometric measurements including standardised instructions to the patient. In our study these principles were generally followed. A custom-made table was constructed to optimise measures to make it possible to stabilise and adjust position to fit the variable size of the patients. The patient was tested in the supine position with the arm on the chest. To avoid influence of strength from the upper body and to enable maximal stabilisation the pelvis was stabilised by an adjustable clamp arch against the ala ossis ilei (Figures 25 and 26).


Figure 26

A standardised protocol for positioning and measurement was used in all patients. The measured hips were tested in the

Figure 27

anatomically neutral position of rotation, flexion, and extension (0 degrees), with the knee fully extended. The contra-lateral hip was in 20 degrees of flexion with the leg elevated and placed in a Therapy Master® to avoid repulsive power from the contra-lateral side. The measurement instrument strap (Figure 27) (Kinedyne S1 Kinetec®, Smith & Nephew Kinetec S.A.) was strapped around the femur 2 cm above the apex of the patella. We chose to place it above the knee joint to prevent possible influence from a painful knee joint. The patient was asked to perform a maximal isometric contraction, and to maintain it for four seconds. Each patient did four test contractions (to make sure the patient provided maximum strength). All contractions lasted four seconds, with 20 seconds relaxation between each contraction. Maximum effort isometric abductor strength in both hips was tested in the same manner (Figure 28).


Figure 28

ii. Harris hip score

The Harris hip score was introduced in 1969 for evaluation of clinical results after pelvic fracture[71] and has become the most commonly used surgeon-based scoring system after hip arthroplasty[72]. The score is not a continuous scale from 0 to100; it is more similar to a ranking scale, where pain or pain relief is the most important item with 44 points (see Appendix 4). Harris defined 90 to 100 points as excellent, 80 to 90 as good, 70 to 80 as fair and below 70 as poor.

iii. Oxford score

The Oxford hip score was developed by the Oxford group and first published by Dawson et al. in 1996[73]. The Oxford score is a patient administrated and self reported score system that is used to evaluate clinical results from the patient's point of view. This scoring system contains twelve questions with five possible categories for answers. Six of the twelve questions regard pain and six questions regard function (see Appendix 5). Each answer gives 1 to 5 points where 1 is no pain or problems and 5 is the worst score. The minimal score is thus 12 points and 60 points is the worst possible score.

9. Summary of papers I–III

Paper I

Background. The usefulness of a national medical register relies on the completeness and quality of reported data. Therefore, the recorded data need to be validated to prevent systematic errors, which can cause biased reports and study conclusions.

Patients and methods. We compared the number of hip replacements reported to the Norwegian Arthroplasty Register (NAR), 1987-2003, and the Norwegian Patient Register (NPR), 1999-2002, with data recorded at a local hospital. The date of operation and index hip was further validated to find inaccurately recorded data in the NAR. Kaplan-Meier estimated survival curves were compared to evaluate possible influences of missing data.

Results. Of 5134 operations performed at a local hospital, 19 (0.4 %) were not reported to the NAR. Registration completeness was poorer for revisions (1.2 %) than for primary operations (0.2 %). Among 86 Girdlestone revisions (removal only of the prosthesis), 9 (11 %) were not reported to the NAR. Missing data on revisions had, however, only minor influence on survival analyses. The date of the operation had been incorrectly recorded in 56 cases (1.1 %), and the index hip in 12 operations (0.2 %). The surgeon was responsible for 85 % of these errors. Comparisons with data reported to the NPR, 1999 to 2002, showed that 3.4 % of the operations at the local hospital had not been reported to the NPR.

Interpretations. Only 0.4 % of the data from a local hospital was missing in the NAR, as compared to the NPR were 3.4 % were missing. The recorded information in the NAR seems valid and reliable during the whole period, and provides an excellent basis for clinically relevant information regarding total hip arthroplasty.

Paper II

Background Controversies still exist about the effect of operative approach. The purpose of this study was to compare long-time survival of primary total hip arthroplasties in a well-defined study population from a national prospective population-based registry with regard to the three most commonly used surgical approaches.

Methods We assessed prosthesis survival according to surgical approach (the lateral with or without trochanteric osteotomy, and the posterolateral) for 19,304 Charnley and 6,002 Exeter total hip arthroplasties from 1987 to 2004.

Results For Charnley total hip arthroplasties, lateral approach with trochanteric osteotomy had a lower probability of revision than lateral approach without trochanteric osteotomy (RR=0.6, 95% CI: 0.5-0.8). The lower revision rate was due to fewer revisions for aseptic loosening and dislocation. The differences had declined in the latest time period. We observed no differences between lateral approach without trochanteric osteotomy and posterolateral approach, except for more revisions due to dislocation in the posterolateral approach group (RR=1.9, 1.1-3.2).

For Exeter total hip arthroplasties, no statistically significant differences were observed.

Interpretation For the Charnley prostheses, the lateral approach with trochanteric osteotomy gave a reduced revision risk compared to the other

approaches, due to fewer revisions for dislocation, and in the first time period also fewer revisions for aseptic loosening.

Paper III

Aim The aim was to compare the direct lateral operative approach with trochanteric osteotomy (TO+) and without trochanteric osteotomy (TO-) with respect to restoration of abductor strength and function following total hip arthroplasty.

Patients and methods Patients (n=130) aged 75 or less, operated on due to osteoarthritis during 2002–2003, were randomised to TO+ (n=65) or TO- (n=65). Abductor strength (measured in grams), Harris hip score (HHS), and the Oxford 12-item score, were recorded preoperatively and at 3, 6, 12, and 24 months following surgery. The effect on improvement according to surgical approach and time since operation was investigated in a mixed-effects regression model.

Results We observed similar levels of improvement in abductor strength in the two groups at all check-ups, with the maximal level reaching 5226 g (95 % CI: 4140–6312) in the TO- group and 5987 g (95 % CI: 4904–7069) in the TO+ group (p=0.3) at 12 months. In the TO- group, improvement was statistically significant until 6 months after surgery, and in the TO+ group until 12 months. The improvement in the operated hip increased by 549 g per month (95 % CI: 435–658; p<0.001). Preoperative abduction strength in the unoperated hip was 3040 g higher (95 % CI: 2358–3723; p< 0.001) than in the operated hip. However, we also observed improvement in the unoperated hip, although this was less than in the operated hip. In contrast to findings in the operated hip, there was a tendency for greater improvement in the TO- group than in the TO+ group in the unoperated

hips. Results for the operated hip were consistent across Charnley classification groups, even for patients with multiple joint disease and other diseases limiting mobility. The clinical scores (HHS and Oxford 12) were the same for both approaches up to 24 months.

Conclusion There was no difference in abductor strength restoration and function when operating with a lateral approach with or without trochanteric osteotomy. The improvement in abductor strength was largest during the first 6 months after surgery, and continued for 12 months.

10. Discussion

a. Methods

i. Validation of data

In prosthesis surgery, arthroplasty registers have been used as a tool to monitor and improve treatment options[74,75]. Several outcome measures are of interest, depending on the type of operation, but the most commonly used are those related to complications and function following arthroplasty. Registration of serious and definite complications have been shown to be more valid and complete than that of less serious and diffuse complications[76]. This is one of the reasons why NAR evaluates prosthesis quality based on a well-defined end-point (revision). In such a population-based registry, all cases of the disease (total hip prosthesis operations) should be included, and more importantly all subsequent failures. All results derived from quality registers should therefore be published together with a declaration of the validity of key variables. Registrations with an error frequency of below 5 per cent for each variable are often considered valid[77,78]. However, even with a very low error frequency for a specific parameter, false conclusions may be drawn[78]. This may occur when a significant proportion of uncommon occurrences are not registered. As risk factors are established based on information in national registers, invalid data may lead to wrongly based clinical decisions, which in turn may subject the patient to a hazardous operation that would not have been undertaken if the true values had been known[79].

Registration errors can be divided into systematic and random errors. It is highly unlikely that random errors will influence the results of a large national register. The most frequent causes of random errors are typing errors and illegible handwriting. In a central registry database, one can expect 5 % inaccuracy and 5 % incomplete data after transcription of data from paper forms[77,78]. Presently, hand-written paper forms are used by the NAR. Systematic errors may however affect results to a larger degree. The most common reason for systematic errors is unclear definition of data items or violation of the data collection protocol. In NAR the definition of revision surgery is clear (removal or exchange of prosthetic parts), but for specific revision procedures where the implant is removed without insertion of a new implant, e.g. Girdlestone operations, it has been shown that some surgeons may have interpreted "revision" as meaning "exchange of implant"[59].

ii. Register studies versus randomised studies

Papers I and II are based on information from a register study, while paper III is based on information from a randomised clinical trial. A well-performed and sufficiently large randomised clinical trial is generally recognised to have the highest level of evidence, as randomisation will ensure an even distribution of factors that may otherwise confound the results. Ideally, randomised clinical trials should be carried out to examine the quality of different prostheses and surgical techniques, but they are impractical, expensive, require a large workload and take a long time. In hip arthroplasty, results from relatively few such studies have thus been published[80,81]. As

results in hip arthroplasty are, in general, good, with small differences among treatment groups, large numbers of patients are required and studies must continue for many years to detect clinically and statistically significant differences. With a revision rate of 5 % after 10 years, one would need more than 13,000 patients to detect a difference in revision rates of 1 % with a statistical power of 80 % and a significance level of 0.05. National and regional quality registers have therefore become a common method for assessing the results of surgical procedures[75]. In addition many hospitals have their own quality register. The main point of these registers is to detect any differences in treatment as soon as possible. The time needed to perform a randomised study might be so long that the problem or the prosthesis studied may have lost its relevance before the study is finished. Based on arthroplasty registers, it has been possible to identify inferior results as early as after three years of follow-up[44]. Register studies give a nationwide overview of results and reflect the outcome for the average surgeon rather than for specialised centres. This is in contrast to randomised studies in which results are from smaller groups of patients and often one or a few surgeons.

Population-based, prospective observational studies, such as register studies, have generally been thought to overestimate the effect of treatment, and have therefore been seen as unsuitable in comparative clinical studies[82-84]. Others have challenged this statement, and have concluded that the results of well designed observational studies usually provide valid information that is not qualitatively different from that obtained from randomised trials[85,86]. Confounding may be dealt with in several ways in register studies. One may select a homogenous subgroup of patients and in this

way limit differences among treatment groups. One may also perform multiple regression analyses, for example Cox regression, to investigate and adjust for further differences. In paper II, the effect on survival of operative approach was studied in a homogenous subgroup of patients with the same type of prostheses and the same type of bone-cement. Cox regression analyses were used to adjust for known confounders.

The end-point in the survival analyses was revision, but it is clear that for revision causes such as dislocation and infection, as used in paper II, this may not be the optimal choice. Complications like this are often dealt with by closed manipulation and soft tissue debridement, respectively, which are not reported to the NAR. The register has no information on radiographic or clinical measures undertaken in the patients, or on re-operations not defined as revisions. Probably only about half the patients with clinical and radiographic failure are revised[87-89]. Survival analyses with end-points such as clinical and radiographic failure are of course of great value, but are not readily achievable on a large scale, are difficult to finance, and are less reliable in a register setting[90].

iii. Clinical outcomes

There have been changes in the surgical approach to the hip over the last 15 years with little documentation of better long-term survival or better clinical outcome. The choice of surgical approach has been made by the individual surgeons or by the heads

of orthopaedic departments. Over the last 10 years the survival of primary hip arthroplasty has generally improved in Norway. However, this is not the case if revision due to dislocation is used as the endpoint. Whether this is connected with new surgical instruments or implants, cementing techniques or the change in surgical approach could not be addressed in this study. In paper III we addressed this problem by investigating the development of muscle strength measured before the operation and following patients subjected to two different surgical approaches for 24 months; we found only minor differences between the two groups. In paper II we assessed long-term survival according to surgical approach by using revision as the endpoint. In paper III we included clinical parameters such as the Harris hip score and Oxford 12 item score to gather abductor strength measurements. In national register studies these clinical parameters are not normally available. The Harris hip score is the most commonly used physician-based hip scoring system but it may be influenced by the surgeon. In paper III, an independent blinded surgeon performed the Harris hip score. The Oxford score is patient administrated and gives a more reliable indication of the patient's perception of the results. This is especially true when the patient meets individual investigators, as in our study.

Several methods to measure abductor strength have been used. Hip muscle strength measurement when standing or supine with simultaneous bilateral measurements as performed by May [91] and Murray et al.[92] were used. In these procedures, however, the pelvis was not fixed sufficiently to avoid the trunk muscles having an effect on the movements and forces being tested (Figure 25). Jensen et al.[93] pointed out the importance of fixation of the trunk and pelvis and described a method for

measurement of the hip joint muscles. This method was however, rather complicated and not suitable for clinical use. They also found that higher values were as a rule recorded at the retest, probably because of the learning effect and fear of pain in the operated hip at the first attempt. Similar observations have been made by other investigators[94,95]. Williams and Stutzman investigated the relationship between the agonist-antagonist muscle groups of several joints[96]. They found that the strength ratios depend on the position of the joint, and at only one angle in the range were forces equal. The forces of the two muscle groups in the present study were equal when the lower limb was in the anatomical position (0°). The measurements and the maximal value for abductor muscle strength are difficult to determine and are dependent on several factors. One of these factors is the performance of the patient.

b. Results

i. Validation of data

In paper I we found that in the Stavanger University Hospital there was extremely good reporting of revision surgery with just one revision missing. This missing revision was performed at SUH two months after initiating the Norwegian Arthroplasty Register. Overall 0.4 % of the operative procedures at the Stavanger University Hospital were missing. These findings indicate that the data in the local database and the Norwegian Arthroplasty Register are complete and valid. Our data is more complete than what is generally accepted as a complete and valid data set.

The strength of this study is that we have complete observations for the whole functional period of the Norwegian Arthroplasty Register for one large teaching hospital that performs one of the largest numbers of elective hip operations in Norway. On the other hand it is not possible to generalise this reporting result for the whole country, although the data are consistent with a study from another large teaching hospital, St. Olavs Hospital in Trondheim[87] and the completeness study of the NAR[59]. Most of the missing procedures were those from Girdlestone operations, when removing the whole implant without insertion of a new implant. More than 20 % of these operations were not found in the Norwegian Arthroplasty Register. The inferior result for reporting the Girdlestone operations was possibly a systematic error. As a consequences of these findings surgeons are reminded yearly of the importance of reporting these procedures. The missing Girdlestone operations had just a minor influence on the long-term prosthesis survival with an endpoint of revision due to infections, when compared to analyses that included the missing Girdlestone revisions. We also showed that the excellent voluntary reporting by the orthopaedic surgeons to the Norwegian Arthroplasty Register contrasted with an eight times higher rate of missed reporting to the Norwegian Patient Register by the hospital's administrative system. This finding was surprising since hospitals' reimbursement is dependent on reporting to the Norwegian Patient Register. The system that used paper form reporting and individual secretary registration into a database also showed the excellent quality of the secretarial work in the register. The reported errors (85 %) were mainly attributed to the surgeons, due to poor handwriting, or recording the wrong date or index side. Such errors may be reduced

by changing the paper form so that there are numbers to underline or cross out. However, changes to a system may add unexpected negative effects. In paper I we found that such errors (of operation date and index hip) were just a minor problem and that the registration form did not need to be changed. One of the main reasons for the good quality of data in the Norwegian Arthroplasty Register database is the well-qualified and stable secretarial support. Systematic and continuous efforts have been made to minimise the occurrence of missing erroneous data in the Norwegian Arthroplasty Register database. When errors or missing data are identified on the form, the form is returned to the local hospital for further information. These controls seem to work well.

ii. Surgical approach

The effect of operative approach on long-term survival has not been published or investigated adequately. In the literature there are just a few reports on long-term survival that compare surgical approach. This theme is difficult to examine and study by a randomised study due to the relatively small differences in revision rates and good long-term results after primary total hip arthroplasty. Complications such as dislocations and infections are so rarely seen that it is practically impossible to perform a sufficiently large randomised study to investigate two different surgical approaches. The strength of our study in paper II was that we had over 20,000 primary hip arthroplasties using the same hip implant and bone cement. The weakness of this observational method is that it was only possible to examine the

"hard end-point" of surgical revision, defined as changing or removing one or more prosthesis components. Clinical parameters (function and pain) and X-ray findings and patient information were not reported. We also know that some types of "re-operation", such as removing the cerclage after trochanteric osteotomy, closed manipulation of a dislocated prosthesis and augmentation of a stabilising rim as a solution for the recurrent dislocating hip are not reported to the Norwegian Arthroplasty Register. Morbidity for the patient is almost the same regardless of which type of re-operation is performed. These missing procedures may influence the results. We recorded these procedures in paper III and there were nearly the same number of complications that needed a repeated surgical procedure in the two approaches compared, but different types of "re-operation". The power to detect a statistically significant difference using re-operation as the endpoint was however too small since the study was powered to detect differences in muscle strength and muscle function. The clinical parameters (Oxford and Harris hip scores) showed no significant differences between the groups, which is consistent with the two groups having the same muscle strength after operation. Pain is multidimensional and a personal experience, and is therefore difficult to define and not easily measured. In the Harris hip score the pain is described categorically by using adjectives such as severe, moderate, mild, or none and some authors have shown that this way of measuring pain can be an inaccurate method compared with a visual analogue scale[97]. Activities of daily living and walking ability (variables that are not always related to the operated hip) are also given a great deal of weight with a total of 47 points. These

two groups constitute more than 90 % of the points in the Harris hip score. Joint movement accounts for just 5 %.

In paper II we found significant increased long-term survival for the lateral approach with trochanteric osteotomy compared to the other approaches for the whole period when using revision due to reason of dislocation as the endpoint. These findings suggest that postoperative muscle strength that is dependent on the surgical approach can influence the stability of the primary total hip arthroplasty. However, in paper III we found similar muscle strength in these two approaches and this hypothesis could not be verified. Another interesting finding was the inferior result from the cups due to aseptic loosening when inserted with a lateral approach without trochanteric osteotomy compared to with a lateral approach with trochanteric osteotomy. To our knowledge this has not been reported previously and must be addressed with further studies. A possible explanation is an inferior overview of the surgical field that leads to inferior positioning and inferior cementing. Some authors claim that trochanteric osteotomy provides a better overview to the proximal femur and acetabulum and thus greater avoidance of varus-positioning of the femur and wrong positioning of the cup[98-100]. With exact preoperative planning these problems should be able to be solved.

In paper III (randomised study) we showed that there were more revisions due to wire breakage and pseudarthrosis in the trochanteric osteotomy group. These complications were not detected in the register study indicating that the revision rate for the trochanteric osteotomy group in the register study (paper II) was

underestimated for these complications, and also probably the dislocation rate in the group without trochanteric osteotomy.

We showed in paper II that the largest difference between the lateral approach with and without trochanteric osteotomy was the problem with dislocation. In paper III we also showed a tendency for increased dislocation in the group without trochanteric osteotomy but the power was not strong enough to give statistically significant differences. The only patient with dislocation in the trochanteric osteotomy group had a dislocated trochanter and non-union with wire breakage and reduced abductor strength.

There was no re-operation due to insufficient reattachment of the abductor muscle group in the group without trochanteric osteotomy in paper III. The possible reason is our use of the strong slow-absorbable Panacryl® suture that gave the muscle a chance to grow before the strength of the suture decreased.

iii. Abductor strength

Abductor muscle strength is probably one of the most important factors for stabilising the hip prosthesis and preventing dislocation. In paper III we showed large individual differences in the abductor muscle strength in the operated hip for the patients operated on with primary total hip arthroplasty. The abductor muscle strength is also an important factor for good clinical results and had a strong influence on the Oxford and Harris hip score where it influences over a third of the total score. With poor

abductor strength it is impossible to get a good clinical result for hip arthroplasty. In paper III we found that there was no difference in abductor strength restoration between patients operated on with the lateral approach with and without trochanteric osteotomy. We also observed a tendency for decreases in abductor strength after 12 months. This probably represents the aging of the patient, but there is no evidence about how much abductor muscle strength is expected in the hip in a normal population due to aging. If these reduced muscle strength is real, it may explain the late dislocation after total hip arthroplasty. We found that the non-operated hip also showed increased abductor strength after operation but not to the same extent, and that this was also dependent on Charnley categories. This may have influenced the results of earlier studies where the strength was compared with the non-operated hip[101,102].

Strength of our study is that it is randomised and the confounders are almost equal in both groups. We used only one prosthesis brand, and both surgical approaches were familiar to all the surgeons who used both approaches routinely. The postoperative routine and rehabilitation was also the same for both approaches. A weakness of our study is connected to the use of patients with bilateral operations and the exclusion of one patient with the Girdlestone procedure. In our analysis we tested the results without these patients and found no alterations to the results.

11. Conclusion

1. We observed minor differences in registration completeness for primary hip arthroplasty (0.4 %) between the Norwegian Arthroplasty Register and the operations registered in the database at Stavanger University Hospital. This is also true for the revisions (1.2 %) except for the Girdlestone revisions that showed missing data in 11 % (9/86) of the cases. Just one "ordinary" revision was missing (1/742, 0.1 %). The differences in reporting to the Norwegian Patient Register during the years 1999–2002 and the operations performed at Stavanger University Hospital were only minor for the primary hip arthroplasty (0.4 %), but reporting of the revisions was inferior with 16 % missing.

2. We found that the Norwegian Arthroplasty Register consisted of valid data concerning date of the operation and index side, throughout the entire period. The surgeons were responsible for 85 % of the errors.

3. The effect of missing data and reporting errors had a minimal effect on long-term prosthesis survival.

4. The long-term survival varied according to surgical approach. This was especially true for revisions due to aseptic loosening and dislocation. The lateral approach with trochanteric osteotomy showed superior long-term survival compared to the lateral approach without trochanteric osteotomy and the posterior approach. The posterior approach showed inferior long-term survival with revision due to dislocation compared to the other approaches.

5. There was no significant difference in restoration of the hip abductor strength and functional outcome after primary total hip arthroplasty between the lateral approach with and without trochanteric osteotomy. The improvement in abductor strength was largest during the first 6 months after surgery, and continued for 12 months.

12. Future research

By initiating and validating our local database at Stavanger University Hospital we are able to address different research questions by supplementing the data in the Norwegian Arthroplasty Register. In particular, questions regarding dislocation and infections can be addressed in the future by combining data from Stavanger and the nationwide register. To treat these complications, re-operations such as removing the trochanter wire, re-attachment of the dislocated trochanter, failure in reattachment of the abductor muscle group, dislocation of the prostheses without revision, operation with augmention of a rim on the posterior side of the acetabular cup to prevent new dislocation and soft tissue debridment are performed but not reported to the Norwegian Arthroplasty Register. The occurrence of these complications and re-operations should be investigated more thoroughly in the future.

The influence of the surgeons and the surgeons' experience on the long-term survival and dislocation rate after primary hip arthroplasty should be investigated; the Stavanger database identifies surgeons, unlike the national register.

We have shown that restoration of hip abductor strength after primary total hip arthroplasty continues for up to 12 months after operation. To our knowledge there has been no publication reporting more than 12 months postoperative strength measurements after primary total hip arthroplasty. In our study we found that during the next 12 months (op to 24 months after operation) the strength showed a tendency to decrease. This decrease was not statistically significant. If this decrease were real

and continuous it may contribute to the problem of late dislocation. This finding needs further investigation by longer follow-up with abductor strength measurements.

The optimal location of the stem and the cup are essential for excellent long-term results after hip arthroplasty and to prevent dislocations. Different surgical approaches give different overviews of the operative field for calculating the position and assisting in the implantation of the femoral stem and cup. In paper II we found that the lowest risk for revision due to aseptic loosening and dislocation was with use of the lateral approach with trochanteric osteotomy. One of the possible explanations is that this surgical approach gives a better overview and thereby better positioning of the cup and stem. In our study we used the same surgeons who were experienced with both approaches. We need to investigate the cement mantle and positioning of the cup and the femoral stem by X-ray measurement to further address this aspect.

The influence of timing and intensity of different physical exercise programmes preoperatively and postoperatively after primary hip arthroplasty and the optimal length of these programmes require further investigation combined with EMG.

We investigated and compared the restoration of muscle strength for the two lateral approaches with or without trochanteric osteotomy and did not find any differences. A similar investigation needs to be done for the posterior approach which is the most commonly used approach in most other countries.

13. References

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14. Papers I-III

15. Appendix