QUALITY OF TOTAL HIP REPLACEMENTS IN NORWAY 1987-1996

The Norwegian Arthroplasty Register

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1 List of papers

Paper I

Havelin LI, Espehaug B, Vollset SE, Engesæter LB, Langeland N. The Norwegian arthroplasty register. A survey of 17,444 total hip replacements 1987-1990. *Acta Orthop Scand* 1993; 64: 245-51.

Paper II

Espehaug B, Havelin LI, Engesæter LB, Vollset SE, Langeland N. Early revision among 12,179 hip prostheses. A comparison of 10 different brands reported to the Norwegian Arthroplasty Register, 1987-1993. *Acta Orthop Scand* 1995;66:487-93.

Paper III

Espehaug B, Engesæter LB, Vollset SE, Havelin LI, Langeland N. Antibiotic prophylaxis in total hip arthroplasty. Review of 10,905 primary cemented total hip replacements reported to the Norwegian Arthroplasty Register, 1987 to 1995. *J Bone Joint Surg* 1997; 79-B:590-5.

Paper IV

Espehaug B, Havelin LI, Engesæter LB, Langeland N, Vollset SE. Patient-related risk factors for early revision of total hip replacements. A population register-based case-control study of 674 revised hips. *Acta Orthop Scand* 1997;68:207-15.

Paper V

Espehaug B, Havelin LI, Engesæter LB, Vollset SE. The effect of hospital-type and volume on the survival of total hip replacements. A review of 39,505 primary total hip replacements reported to the Norwegian Arthroplasty Register, 1988-1996. Submitted for publication in *Acta Orthop Scand*.

Paper VI

Espehaug B, Havelin LI, Engesæter LB, Langeland N, Vollset SE. Patient satisfaction and function after primary and revision total hip replacement. *Clin Orthop* 1998;351:135-48.

2 Background

2.1 Introduction

The most striking feature of total hip replacement is the instant and almost complete relief of pain after surgery, which has been shown to last for decades after the operation (Schulte et al. 1993, Kavanagh et al. 1994). The success of total hip replacement is also well documented in terms of low revision rates, with 20-year revision probabilities ranging from 10-16 % (Schulte et al. 1993, Kavanagh et al. 1994). With these excellent clinical results, total hip replacement is considered as one of the most cost-effective surgical procedures (Williams 1985).

With an estimated 800,000 total hip replacements performed world-wide each year (Malchau et al. 1993), even low failure rates implicate a large number of patients. It is also evident that some prostheses and patients may be associated with a much higher revision risk (Harris and Sledge 1990). As the prognosis after revision is considerably poorer than after primary surgery (Kavanagh et al. 1985), it is important to ensure the best possible outcome of the primary hip replacement.

2.2 Hip disease and hip arthroplasty

Hip disease

Osteoarthritis of the hip, also called coxarthrosis, is a common degenerative hip disorder which causes pain, stiffening of the joint and diminished range of motion. These patients suffer a decreased quality of life often with reduced ability to carry out tasks related to their occupational work and everyday life. The prevalence of coxarthrosis increases with age. While the disease may affect less than 1 % of the population under 55 years, it affects from 6-20 % of the population 75 years or older (Danielsson et al. 1984, Heliövaara et al. 1993). For most patients with coxarthrosis no specific etiology has yet been established (idiophatic or primary coxarthrosis). A secondary form of coxarthrosis is usually a consequence of sequelae after paediatric hip disease, sequelae after proximal femoral fractures or due to inflammatory arthritis (rheumatoid arthritis and ankylosing spondylitis).

A conservative treatment of coxarthrosis will include use of analgesics, non-steroid antiinflammatory drugs, physiotherapy, and possibly also weight reduction and limitations of physical activities (Hochberg et al. 1995). Surgical treatment with total replacement of the hip is to be considered if the conservative treatment does not have a satisfactory effect.

Hip arthroplasty

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 (Ollier 1885). However, during the last decades, the term hip arthroplasty has become synonymous with total hip replacement.

About 100 years ago the first known joint replacements were performed using foreign materials, with Gluck replacing the hip joint with ivory components using nickel-plated steel screws for fixation (Gluck 1891). Further significant advances were made during the next years, but it was not until the 1960s that important progress was seen in joint arthroplasty. Sir John Charnley played a leading role in the introduction of new materials and designs, including use of cement for the fixation of the prosthesis. A reduction of postoperative infections was also seen after the introduction of antibiotic prophylaxis and specially designed operating environments (Charnley 1972a, Eftekhar et al. 1976).

Several new designs similar to the Charnley prosthesis were introduced throughout the 1970s (Amstutz and Clarke 1991). However, although some new hip replacements performed satisfactory in older patients, high failure rates prevailed among young and active patients. Different types of prostheses were proposed to enhance prosthesis survival also among these patients. One approach was to use resurfacing arthroplasty in order to prolong the time before a conventional total hip replacement would be needed. Due to high rates of loosening, this method was soon abandoned by most orthopaedic surgeons (Amstutz and Clarke 1991). A second approach was to use uncemented prostheses with porous- or hydroxyiapatite-coating to ensure 'biological fixation', or to use uncemented press-fit prostheses. Uncemented prostheses have since been widely applied in several countries, in particular in young patients.

In 1980, an estimated 300,000 to 400,000 total hip arthroplasties were performed worldwide (Levy et al. 1985). A steady increase in the utilisation of total hip replacements has been reported from most Western countries (Raugstad et al. 1984, Johnsson and Lidgren 1987, Rajaratnam et al. 1990, Paavolainen et al. 1991, Madhok et al. 1993), and the current annual figure exceeds 800,000 (Malchau et al. 1993).

2.3 Quality control of hip arthroplasty

In the earliest days of hip arthroplasty, progress was based on the 'trial-and-error' work of many surgeons. Many of these attempts proved to be failures, and unfortunately, some of the inferior prostheses were widely used without sufficient knowledge on clinical performance. The Judet prosthesis for instance was applied to a large number of patients before its poor results were recognised (Faro and Huiskes 1992). Sir John Charnley secured that marketing of his prostheses was stalled until convincing results were attained from laboratory testing and clinical trials involving only a small number of patients. If the prosthesis was a failure, it was abandoned and the orthopaedic community alerted (Charnley 1963). Previous experiences have shown that also relatively small alterations in the design of prostheses with stable results, may have large negative implications (Fowler et al. 1988, Dall et al. 1993).

Faro and Huiskes (1992) have described 'three stages of failure prevention' that will help evaluate the quality of new products:

(1) Preclinical testing
(2) Clinical trials
(3) Continuous surveillance (national registers)

The first stage involves *preclinical testing* which is important to uncover potential problems with the product before it is implanted in humans. Preclinical tests include methods based on laboratory tests, animal experiments and computer simulations. However, test results cannot guarantee that the implant will perform well in the patient. *Clinical trials* with randomisation are therefore needed as a second stage of failure prevention before the product becomes freely available on the market. Firstly, randomised trials should be performed to detect early signs of poor prosthesis behaviour involving only a small number of patients. At this stage, techniques like roentgen stereophotogrammetric analysis (Nilsson and Kärrholm 1996) represent new investigative tools of short-term performance (Malchau 1995). Problems may, however, arise when the new prosthesis design is applied by 'average' surgeons not so experienced with the introduced procedure (Rothman and Cohn 1990). A prospective multicenter study would reveal whether the product performs well also when used by a large number of surgeons at different hospitals (Malchau 1995). It may

also be that problems will not turn out before after the trial is closed. Thus, as a third stage of failure prevention, a *continuous surveillance* of implants might prevent that an inferior product, already on the market, is used to a large number of patients. This demonstrates the need for a central registration of all total hip replacements which will be monitored until revision. National arthroplasty registers have been in function in the Nordic countries for a number of years, except for Denmark where a national register was started up only recently. A regional register covering the Trent region in England was started in 1990 (Gregg et al. 1997), and a start-up has also been discussed for parts of the USA (Fitzgerald et al. 1995).

Although the hazards concerning early marketing of new products are well known, there are many examples of new products marketed and used on large patient populations without adequate testing of the product. In Norway, there have been several examples of such incidences. The Christiansen prosthesis was widely used throughout the 1970s. A Norwegian follow-up study published in 1983 (Sudman et al. 1983) showed that the 5-8 year revision rate was 31 % among the Christiansen prostheses compared to 4 % among the Charnley prostheses. At this time, the orthopaedic surgeons had used the Christiansen prosthesis in more than 10,000 patients throughout the Nordic countries. Shortly thereafter, the Wagner prosthesis and other double-cup prostheses, became popular in Norway, especially in young patients. The double-cup prostheses was later reported with even worse results than the Christiansen prosthesis, with a 5-year revision rate of 30 % and a 8-year revision rate of 60 % (Howie et al. 1990). Even after these experiences, the new uncemented prostheses of different types gained great popularity, again without any convincing documentation of performance from clinical trials. Based on data in the Norwegian arthroplasty register, some types of uncemented prostheses were reported with revision rates around 15-20 % after only 4.5 years of follow-up (Havelin et al. 1995ab). The most recent example has been the Boneloc cement which was in use in Norway from 1991 through 1993, also without any prior clinical testing. Based on data in the Norwegian arthroplasty register, the Boneloc cement was shown to give highly inferior results (Havelin et al. 1995c). The Boneloc cement was also marketed in most other European countries.

2.4 The Norwegian Arthroplasty Register

A nation-wide registration system of primary and revision total hip replacements was initiated in Norway by Professor Einar Sudmann through the Norwegian Orthopaedic Association. In 1983, Professor Einar Sudmann, Dr. Lars Birger Engesæter, Dr. Tor Steinar Raugstad, and other orthopaedic surgeons in Norway, started to work towards establishing a national hip implant register. The motivation for this work was the recent experiences with the wide spread use of the Christiansen prosthesis and the double-cup prostheses. The increasing popularity of different types of uncemented prostheses with more or less undocumented results, was also a major source of concern. Registration of total hip replacements started in September 1987, with Dr. Leif Ivar Havelin as head of the register.

2.5 Risk factors for revision - a review

The most common problem with hip arthroplasty has been the *fixation* of the prostheses, as the prosthetic parts may loosen after some time (aseptic loosening). The common treatment for aseptic loosening is revision with replacement of the loose parts. Another very serious problem is *infection*, which affects about 1 % of all patients with total hip replacement during the life time of the implant (Nasser 1991). If the hip implant is infected, the whole prosthesis usually has to be removed or replaced in order to heal the infection. Other reasons for revision might be recurrent *dislocations* of the hip joint, *fracture* near the prosthesis or *mechanical failures* of the prosthetic parts. The uncemented prostheses seem to be associated with increasing problems related to osteolysis and wear (Sychterz et al. 1996, Devane et al. 1997).

There are several established or postulated risk factors for revision of hip implants which can be classified as procedure-related, patient-related or hospital-related. Status for research on associations between these factors and the *survival of total hip replacements*, is given below for the time when the present study was started.

2.5.1 Procedure-related factors

Many factors related to the surgical procedure, including surgical technique, prosthesis type, cement type and antibiotic prophylaxis regimen, may influence the survival of total hip replacements. In the present study, the focus was on the *survival of cemented prostheses*, with a special attention to possible associations with prosthesis brand and antibiotic prophylaxis regimen.

Prosthesis brands

Havelin et al. (1994) had shown that the overall revision rate for cemented prostheses was 3 % after 4.5 years with any revision as endpoint, and 2 % with revisions performed due to aseptic loosening as endpoint. For the majority of cemented prosthesis brands in use, results were largely unknown (Murray et al. 1995). Best documentation had been presented for the Charnley prosthesis, with a failure rate of 4 % at 5 years of follow-up, 6-9 % at 10 years, 12 % at 15 years, and 10-16 % at 20 years (Skeie et al. 1991, Malchau et al. 1993, Schulte et al. 1993, Kavanagh et al. 1994). The Exeter prosthesis had a 4-year failure rate of 2 % (Fowler et al. 1988, Malchau et al. 1993). Among cemented prostheses, the Charnley prosthesis had been held as the 'gold standard' towards which other prostheses were compared (Agins et al. 1988, Malchau et al. 1993, Wroblewski and Siney 1993). However, a study based on data in the Swedish arthroplasty register had shown inferior survival results for the Charnley prosthesis compared with other cemented prosthesis brands (Malchau et al. 1993). The reported differences in the Swedish study may have been compromised as the influence of other important risk factors had not been considered.

Antibiotic prophylaxis

Historically, the percentage of sepsis after total hip replacement was very high, from 7 to 11 % (Charnley 1972a, Wilson et al. 1972). But after the introduction of clean air operating environment and antibiotic prophylaxis the high rate of infection was reduced. At present, the revision rate due to infection is considered to be under 1 % (Ahnfelt et al. 1990). With the large number of hip arthroplasties performed world-wide, this seemingly small percentage will affect a large number of patients. Deep infection is associated with substantial morbidity and also mortality for the individual patient (Antti-Poika et al. 1990). In addition to patient concern, a reduced number of revisions would also cut medical expenses.

The effect of systemic antibiotic prophylaxis on total hip replacement survival had been confirmed by several large randomised studies (Pavel et al. 1977, Hill et al. 1981, Doyon et al. 1987), and in Norway, most total hip replacements were performed with systemic antibiotic prophylaxis (Havelin et al. 1993). Although indicating an effect of antibiotic-loaded cement, previous studies comparing revision rates among total hip replacements performed with plain cement, had not been convincing (Buchholz and Engelbrecht 1970, Buchholz et al. 1977, Thierse 1978). However, no study had reported superiority of either method when compared against each other in randomised trials (McQueen et al. 1990, Josefsson and Kolmert 1993). A combined use of systemic antibiotics and antibiotic-loaded cement had been suggested (Trippel 1986, Josefsson and Kolmert 1993), but so far no study had investigated whether a combined use would lead to a further reduction of revision rates.

2.5.2 Patient-related factors

When the present study was started, little was known about any associations between patient characteristics and revision risk after total hip replacement (NIH Consensus Conference 1995). One exception was the effect of gender and age, where several studies had shown that males and young patients with cemented prostheses had an increased risk for revision (Ahnfelt et al. 1990, Malchau et al. 1993, Havelin et al. 1994).

Many studies had investigated patient-related factors as risk factors for coxarthrosis, and reported an increased risk for coxarthrosis related to patient weight (Rissanen et al. 1990, Vingård 1991a, Heliövaara et al. 1993) and to physical demands in relation to occupation (Vingård et al. 1991bc, Axmacher and Lindberg 1993, Roach et al. 1994) and recreation (Lindberg et al. 1993, Vingård et al. 1993).

Previous reports had shown that increasing weight (Surin and Sundholm 1983, Schurman et al. 1989, Hozack et al. 1990, Karachalios et al. 1993) and physical demands (White 1988, Kilgus et al. 1991), also increase the risk for prosthesis failure. An association between alcohol use and luxation of the hip had been indicated (Hedlundh and Fredin 1995), but so far no studies had investigated smoking in relation to revision risk. There were reports indicating that non-steroidal anti-inflammatory drugs inhibited bone-repair (Keller et al. 1987, Ahrengart et al. 1988, McLaren 1990, Høgevold et al. 1992), but the possible influence on revision rates had not been investigated. Patients with diabetes had been shown to have an increased risk of total hip replacement revision due to infection (Vannini et al. 1984, Wymenga et al. 1992), but less was reported on other diseases or on the possible effect of different types of medication.

2.5.3 Hospital-related factors

Various studies had focused on the possible relationship between the number of surgical procedures performed per hospital, including total hip replacements, and clinical outcome as assessed by mortality rates. Low-volume hospitals were associated with increased in-hospital mortality (Luft et al. 1979, Flood et al. 1984ab, Maerki et al. 1986, Hughes et al. 1987, Fowles et al. 1987, Taylor et al. 1997, Kreder et al. 1997) and also with increased mortality after discharge (Fowles et al. 1987, Taylor et al. 1997). Only a few studies had reached different conclusions regarding in-hospital mortality (Farley and Ozminkowski 1992) and later mortality (Riley and Lubitz 1985). Low volume hospitals had also been associated with longer hospital stay (Kreder et al. 1997) and higher hospital cost (Fowles et al. 1987, Kreder et al. 1987, Kreder et al. 1997). Thus, the common view was that better quality of care was provided in large regionalised hospitals (Luft et al. 1979, Maerki et al. 1986).

Few studies had considered these issues in relation to total hip replacement survival (Fowles et al. 1987, Kreder et al. 1997). The most recent study reported no effect of hospital volume, whereas Fowles et al. (1987) reported higher revision rates for low operating volumes. Information on cutpoint values for low and high volumes were not given by Fowles et al. (1987), and apparently there was no adjustment for other risk factors in this study.

There had been no studies of total hip replacement survival at different types of hospitals. In the Nordic countries, hospitals are classified as local, central or regional. Another classification may be based on training versus non-training hospitals.

2.6 Patient evaluated outcome

While the assessment of total hip replacement surgery often is based on radiological evaluations and survival analyses of prosthesis failure, the patients own assessment is an important measure of outcome (Gartland 1988). Clinical evaluations made by the orthopaedic surgeon has been shown to differ from evaluations made by the patient, in particular when the patient was dissatisfied with the outcome (Lieberman et al. 1996).

When the present study started, several studies had demonstrated considerable improvement after total hip replacement surgery regarding self reported function and quality of life (Wiklund and Romanus 1991, O'Boyle et al. 1992, Rorabeck et al. 1994, Rissanen et al. 1995, Chan and Villar 1996, Norman-Taylor et al. 1996, Rissanen et al. 1996). However, as most of these studies included few or no patients with revised hip implants, it was largely unknown whether an improvement was experienced also among patients who had undergone revision surgery, and how these patients would assess their situation as compared with patients who had undergone primary surgery only.

3 Aims of the study

The main objective of the study was to disclose possible associations between factors that are either procedure-related, patient-related or hospital-related, and the survival of total hip replacements. While these studies focused on time to revision as outcome measure, we also wanted to gain information on the patients' own evaluation of success.

Specifically the following aims of the study were formulated:

- 1. Give a survey of total hip replacement surgery in Norway.
- 2. To assess revision rates among the most commonly used types of cemented hip implants in Norway.
- 3. Investigate the influence on revision rates of different antibiotic prophylaxis regimens used for cemented hip implants in Norway.
- 4. Identify patient-related risk factors for revision of total hip replacements.
- 5. Identify hospital-related risk factors for revision of total hip replacements.
- 6. Assess patient satisfaction and function before and after total hip replacement, among patients with revision surgery and patients with primary surgery only.

4 Materials and Methods

4.1 The Norwegian Arthroplasty Register

4.1.1 Follow-up of patient cohort

The papers I, II, III and V were all based on data from the Norwegian arthroplasty register, which comprises information on approximately all total hip replacements performed in Norway since 1987. Each primary hip replacement is followed prospectively until the implant is revised, or until the patient dies or emigrates. Detailed information concerning primary and revision surgery is obtained through a standard form filled in by the orthopaedic surgeons and sent to the register. Information on revisions in the register are linked to data already assembled on the primary operation using the unique person number assigned to each inhabitant of Norway.

The Norwegian arthroplasty register form is given in the appendix. In addition to information on gender, age and primary diagnosis, the register obtains detailed information on prosthesis type, cement type and use of antibiotic prophylaxis. The register also receives information on previous operations, operating approach, type of operating theatre, operating time, whether osteotomy of the trochanter or bone transplant has been performed, and on perioperative complications. For revisions, information is also provided on the reason for revision and on which components have been revised. Furthermore, the data base is updated annually with information on deaths and emigrations provided by The Central Bureau of Statistics in Oslo, Norway.

Definition of primary total hip replacement:

An operation where the hip joint is replaced by an artificial acetabular and femoral component.

Insertion of hemiprostheses, e.g. for hip fractures, are not reported to the register.

Definition of hip replacement revision:

A surgical removal or exchange of a part of or the whole implant.

Following the definition of revision, other reoperations where no parts of the implant is removed or replaced, such as reductions of dislocated hips, do not count as revisions although they may indicate a malfunctional prosthesis.

Reasons for revision

On the Norwegian arthroplasty register form it is possible to report multiple causes for a revision, with the following alternatives given:

- Aseptic loosening of the acetabular component
- Aseptic loosening of the femoral component
- Dislocation
- Deep infection
- Fracture near the prosthesis
- Pain
- Osteolysis, without loosening of the acetabular component
- Osteolysis, without loosening of the femoral component
- Other reasons (e.g. reinsertion of prosthesis after former Girdlestone operation, fracture of the prosthesis, wear)

Hierarchical definition of revision causes

As patients could be registered with different reasons for a revision, a hierarchical arrangement of the different revision causes were defined. If reported in combination with other causes, infection was always given first priority, aseptic loosening second, dislocation of the hip third, fracture of the femur fourth, pain fifth and other causes sixth.

Time to revision was analysed in papers II, III and V, with different endpoints. In paper II, separate analyses were performed with revisions due to aseptic loosening, and revisions due to any cause, as endpoint, respectively. In paper III, separate analyses were performed with revisions due to infection, revisions due to aseptic loosening, and revisions due to any cause, as endpoint, respectively. In paper V, endpoint was defined as revisions performed due to any cause.

As of today, the Norwegian arthroplasty register includes information on more than 50,000 primary total hip replacements representing different groups of patients and different surgical procedures. In order to perform the studies in patients with a relatively homogenous background, several of the papers were based on subgroups of patients. A detailed description of the design of each study is given below:

Survey of patients and surgical procedures (paper I)

The survey in paper I was based on information on 17,444 operations reported to the Norwegian arthroplasty register during the years 1987 through 1990, comprising all primary and revision total hip replacements performed in Norway during this period.

Cemented prosthesis brands and early revision risk (paper II)

Time to revision was compared for the 10 most commonly used primary cemented total hip prostheses. The study was based on 12,179 primary operations performed in 11,169 patients operated on during the period 1987 through 1993. The material was restricted to operations performed with high viscosity cement (Palacos, Simplex, CMW I) for primary arthrosis. Furthermore, only prosthesis brands where the potential follow-up of the prostheses added up to 500 prosthesis-years or more were considered in the study.

Definition of potential follow-up:

The longest possible follow-up for each implant, i.e. the time difference between the date of implantation and February 1, 1994 (date of study closure).

Antibiotic prophylaxis regimens and revision risk (paper III)

10,905 primary cemented total hip replacements, performed for primary arthrosis in patients who had not had a previous operation in the index hip, were included in the study. These were operations reported to the Norwegian arthroplasty register during the period 1987 through 1995, with a restriction in included operations due to a selection of the most common prosthesis brands (Charnley, Exeter, Titan, Spectron/ITH (cup/stem)), all cemented with high viscosity cement (Palacos, Simplex). If the operation had been performed with the use of systemic antibiotic prophylaxis, we included only operations performed with the most common systemic antibiotic types, namely cephalothin, cefuroxime, dicloxacillin and cloxacillin. The effect of the following antibiotic prophylaxis regimens on total hip implant survival was assessed: antibiotics administered both systemically and in the bone cement (n=5,804), systemically only (n=4,586), in the bone cement only (n=239) and no antibiotics given (n=276).

Hospital-type and volume as risk factors for revision (paper V)

During the period 1988 through 1996, a total of 42,413 primary total hip replacements were performed in Norway. As information was incomplete for 1987, all operations performed this year were excluded from the study. Also, due to few operations and short follow-up, 240 operations performed at two private clinics were excluded from the study. Furthermore,

total hip replacements with unknown cement use or hybrid cement use were excluded from the study. The present study thus included 39,505 total hip replacements performed at 70 different departments in 64 hospitals performing orthopaedic surgery.

Definition of annual hospital volume:

The annual number of total hip replacements performed at each hospital. In analyses performed among cemented and uncemented prostheses, the annual hospital volume referred to the annual number of cemented and uncemented prostheses, respectively.

4.2 Additional data collection

4.2.1 Register-based matched case-control study

Except for gender, age and primary diagnosis, the Norwegian arthroplasty register does not contain information related to the patient.^{*} Information on patient-related factors was therefore obtained through a mail survey among a subgroup of the patients reported to the register. The study was conducted as a matched case-control study based on patients reported to the Norwegian arthroplasty register during the years 1987 through 1993. Each patient included in the study received a questionnaire (appendix) from the register with questions detailing other aspects than the medical information rendered by the orthopaedic surgeon on the standard form.

The case-control study form had, among other inquiries, questions regarding occupation, employment status, weight and height, type of medication, smoking habits, use of alcohol, exercise habits, need of help, pain and walking ability. Information on employment status, need of help, pain and walking ability was retrieved for the time period just before the primary operation and at follow-up, i.e. when the form was filled in. Regarding exercise habits, information was retrieved for the time period before the first symptoms from the hip, and at follow-up. Patients with revised implants received additional questions regarding their function prior to the second operation.

Papers IV and VI were based on the data reported by the patient on the case-control questionnaire and on data reported by the orthopaedic surgeon on the standard register form. As in the papers based on information from the standard form only (papers I, II, III and V), the unit of study was the hip.

Definition of case:

Hip with primary and revision total hip replacement surgery performed in the years 1987 through 1993.

Definition of control:

Hip with primary total hip replacement surgery only performed in the years 1987 through 1993.

^{*} Information on pain, walking ability and functional group, based on the modified Merle d'Aubigné and Postel scores (Merle d'Aubigné and Postel 1954, Charnley 1972b), was reported on the standard register form during the years 1987 through 1992. The information was often based on the evaluation of the orthopaedic surgeon.

Matching criteria:

Gender, age at primary operation (± 5 years), date of primary operation (± 30 days) and bilaterality (whether the patient had had total hip replacement surgery in one or both hips).

By the end of 1993, 683 hips were registered as having primary and revision surgery, and 26,486 hips had had primary surgery only. For each patient who had undergone revision surgery, two matched patients were selected randomly among patients at risk for revision following the density sampling procedure (Wacholder et al. 1992). The matching criteria were given above. Only 1 control was found for 5 of the cases and none for 9 cases. This left 2,017 hips, of which 674 were cases and 1,343 controls.

The number of patients, however, was 1,896. Among these were 1,353 operated on unilaterally, 437 bilaterally and 106 patients bilaterally but with the first operation performed before registration started in September 1987. Among the 437 patients operated on bilaterally, 9 patients were included with both hips as cases, 7 patients with both hips as controls and 6 patients with one hip as case and the other as control. All other patients were included with one hip only. The discrepancy between the number of observation units and the number of patients was also due to the density sampling procedure used when selecting controls. Following the density sampling procedure, controls were selected from all unrevised hips at the time of the case revision. This means that a control hip may appear as a case at a later time. Here, 38 patients were selected as both case and control. Two patients were selected as case and twice as control and 2 patients were selected three times as control (4 additional observations).

Patient-related risk factors for early revision (paper IV)

Complete questionnaires were received from 81 % of the 2,017 individual cases and controls selected for the study. Thus, the study included 536 hips that had experienced both primary and revision surgery and 1,092 hips with primary surgery only.

Patient satisfaction and function before and after total hip replacement (paper VI) Two matching hips with unrevised hip prostheses were found for 669 of the cases. These case-control triplets were selected for the study. Complete questionnaires were received from 1,618 (81 %) of the 2,007 cases and controls, and a total of 531 hips with primary and revision surgery and 1,087 hips with primary surgery only, were included in the study.

4.2.2 Hospital profiles

As individual information on the surgeon was not reported to the Norwegian arthroplasty register, the annual number of total hip replacements per orthopaedic surgeon could not be calculated (paper V). The annual number of surgeons performing total hip arthroplasty was therefore obtained from each hospital through an additional questionnaire. In this questionnaire, we inquired about the number of consultants and registrars (residents in training) who performed hip arthroplasty during 1996, and the yearly average of surgeons who operated during the period 1988 through 1995.

Definition of mean annual surgeon volume:

The mean annual surgeon volume was calculated for each hospital as the ratio between the annual number of operations and the number of orthopaedic surgeons participating in total hip replacement surgery. In analyses performed among cemented and uncemented prostheses, the mean annual surgeon volume referred to the annual number of cemented and uncemented prosthesis operations per surgeon, respectively.

4.3 Statistical analyses

Descriptive statistics

As paper I mainly gave an overview of the data collected in the Norwegian arthroplasty register, descriptive statistics only were produced for this paper.

4.3.1 Unadjusted survival analyses

In papers II, III and V, the survival time was defined as the time from the primary operation until revision, or until the patient died or the study was closed. The survival times for hips in patients who did not undergo revision were censored at the time of death or when the study was closed.

Kaplan-Meier estimated revision probabilities and log-rank tests

The Kaplan-Meier (product-limit) method (Kaplan and Meier 1958) was used to estimate revision probabilities. In paper II, survival curves were constructed where the percentage of revised hips was given only for times where more than 30 hips remained at risk. Log-rank tests (Mantel 1966) were used to test whether survival was statistically significant different among subgroups in the material.

4.3.2 Multiple regression

Cochran (1965) defined an observational study as an empirical investigation in which:

... the objective is to elucidate cause-and-effect relationships ... [in which] it is not feasible to use controlled experimentation, in the sense of being able to impose the procedures or treatments whose effects it is desired to discover, or to assign subjects at random to different procedures.

An observational study thus resembles an experiment, as it concerns the effect of treatments or interventions. However, in an experiment, the assignment of treatments is controlled by the experimenter, which ensures that subjects receiving different treatments are comparable. In an observational study, this control is absent.

In an observational study, bias may be introduced if the treated and untreated groups differ prior to treatment in ways that matter for the outcome under study (confounding). In such cases it is necessary to adjust for bias by confounding. In this study we have used multiple regression analyses in all papers investigating an association between a potential risk factor and revision risk.

Cox regression analyses

In papers II, III and V, Cox regression analyses (Cox 1972) provided effect estimates of differences in survival among patient subgroups with adjustment for possible confounding by other factors. Variables with more than two levels were represented by indicator variables to avoid assumptions of linear relationships and score tests were used to calculate the p-values. In paper III, estimates from the Cox analyses were used to construct adjusted survival curves at mean values of the risk factors. Also in paper III, tests of the proportional hazards assumption were performed for the risk factors included in the Cox regression models (Grambsch and Therneau 1994).

Conditional logistic regression

In analyses of data from the matched case-control study (paper IV), relative risks (incidence density ratios) were estimated as odds ratios obtained from conditional logistic regression analyses (Breslow and Day 1980, Hosmer and Lemeshow 1989).

Generalized additive models for survival data

In paper V, the relationship between annual hospital volume and revision rate was studied based on generalized additive models for survival data (Hastie and Tibshirani 1990). These are models that extend the traditional linear statistical model, and in this case allowed for an identification of non-linear trends and threshold effects of annual hospital volume on revision rate. The analyses provided graphical displays of the relationship between volume and revision rate, and were used as a supplement to Cox analyses performed with indicator variables.

Generalized estimating equations

In paper VI, multiple regression analyses were conducted by Gaussian regression with pain score and walk score as response variables, and by logistic regression with satisfaction, need of help, employment status, and weekly exercise as binary response variables. Because of the matched study design and repeated measures for each individual, results from standard regression models might be questionable. Therefore, a procedure based on the generalized estimating equations method for generalized linear modelling of clustered data, was used to account for dependencies introduced by the design (Zeger and Liang 1986, Liang and Zeger 1993). All matching factors were represented in the regression models, although with a coarser categorisation than in the matching procedure.

4.3.3 Statistical software

Statistical analyses were performed using the statistical software BMDP (Dixon 1992) in papers I, II and III, SPSS (SPSS Inc. 1993) in papers III, IV, V and VI and S-PLUS (Statistical Sciences 1995) in papers II, III, V and VI.

The conditional logistic regression analyses in paper IV were performed using the program SPSS. The SPSS does not include a conditional logistic regression procedure for analyses of matched case-control data as such, but the Cox proportional hazards regression module of SPSS, will give conditional logistic regression results when performed with risk sets restricted by the matching factors and time set to a constant value. The partial likelihood of the Cox module is thus equivalent to the conditional logistic regression likelihood (Walker 1982, Le and Lindgren 1988). It should be noted that such use of SPSS will work only with one case per matched set, as approximations used by SPSS for multiple cases per set deviate from standard implementation of conditional logistic regression.

The statistical software Gamfit, written by Trevor Hastie (Stanford University, CA) and Robert Tibshirani (University of Toronto, Ontario, Canada), is available in the General archive of StatLib (Carnegie Mellon University, Pittsburgh, PA). Gamfit, which fits Gaussian, Binomial, Poisson, Gamma and Cox models using cubic smoothing splines (Hastie and Tibshirani 1990), was applied in paper V. In paper VI, we used the statistical software GEE by Vincent Carey (Harvard University, Boston, MA) in which the generalized estimating equations method was implemented. The program is made available in the S archive of StatLib (Carnegie Mellon University, Pittsburgh, PA) and was used in connection with the statistical program package S-PLUS.

5 Review of papers

Paper I **The Norwegian arthroplasty register. A survey of 17,444 total hip replacements 1987-1990**. Havelin LI, Espehaug B, Vollset SE, Engesæter LB, Langeland N

Background. A national register for total hip replacements was established in Norway in September 1987 to record all prostheses in use and to compare results of the different types of implants. This paper contains a survey of the patients, the techniques and implants used in Norway as described by data reported to the Norwegian arthroplasty register during the three first years of registration.

Material and methods. The study was based on information on 17,444 total hip replacements reported to the Norwegian arthroplasty register until February 1, 1991.

Results. For the period 1987 through 1990, the annual incidence of primary and revision total hip replacements in Norway was 140/100,000 inhabitants. The median age of the patients was 70 years. 69 % were women. Primary coxarthrosis was the diagnosis in 68 % of the primary operations. The acetabular implants were uncemented in 17 % and the femoral implants in 12 % of the primary operations. In revisions, the implants were uncemented in 21 and 17 %, respectively. 13 % of all operations were revisions, with aseptic loosening of one or both components as reason for the revision in 87 % and deep infection in 4 %. The Charnley prosthesis dominated with 49 % of all implants. However, a total of 422 different designs and sizes of acetabular implants were used, 398 of femoral and 166 of caput.

Conclusion. The large number of different types and designs of prosthesis components seems unreasonable and cannot be justified as means in the search for the best prostheses. A standardisation of procedures and a reduction in numbers of types would more so facilitate research. Introduction of new prostheses should be part of large multicenter randomised studies.

Paper II Early revision among 12,179 hip prostheses. A comparison of 10 different brands reported to the Norwegian Arthroplasty Register, 1987-1993. Espehaug B, Havelin LI, Engesæter LB, Vollset SE, Langeland N

Background. The purpose of the present study was to compare the survival of different cemented total hip replacements used in Norway. Based on data reported to the Norwegian Arthroplasty Register during the years 1987 through 1993, we have compared times to revision for the 10 most commonly used cemented prosthesis brands.

Material and methods. A total of 11,169 patients, with 12,179 primary total hip replacements performed with high viscosity cement for primary arthrosis were included in this study. The maximum follow-up was 6.4 years.

Results. The Kaplan-Meier estimate of the overall percentage revised after 5 years was 2.5 (95% Confidence Interval: 2.1-3.0). For the Charnley prosthesis (n = 6,694), 2.9 % were revised after 5 years (95% CI: 2.3-3.4). Using Cox regression to adjust for gender, age, type of cement and use of systemic antibiotic prophylaxis, the Charnley prosthesis was compared with the 9 other prosthesis brands. The revision rate for the Spectron/ITH combination (Spectron acetabulum, ITH femur) (n = 1,034) was only 0.35 (p = 0.04) times that of the Charnley prostheses. The Elite/Charnley combination (Elite acetabulum, Charnley femur) (n = 507) and the Müller Type prosthesis (n = 116) showed poorer results with failure rates 2.3 (p = 0.01) and 2.7 times (p = 0.04) that of Charnley, respectively.

Conclusion. Although the overall results for cemented total hip replacements were good, clinically important differences in revision rates were demonstrated among the cemented prosthesis brands. Our findings underline the need for careful and continuous evaluation of the different total hip replacements.

Paper III

Antibiotic prophylaxis in total hip arthroplasty. Review of 10,905 primary cemented total hip replacements reported to the Norwegian Arthroplasty Register, 1987 to 1995. *Espehaug B, Engesæter LB, Vollset SE, Havelin LI, Langeland N*

Background. We have assessed the effect on total hip implant survival of different antibiotic prophylaxis regimens used in Norway, comparing antibiotics administered both systemically and in the bone cement, systemically only, in the bone cement only and no antibiotics given.

Material and methods. The study was based on data on 10,905 primary cemented total hip replacements performed because of coxarthrosis and reported to the Norwegian arthroplasty register during the period 1987 through 1995. Cox estimated failure rate ratios (FRR) are presented with adjustment for gender, age, cement- and prosthesis brand, type of operating theatre and operating time.

Results. With revisions performed because of infection as endpoint (39 revisions), the lowest revision rate was found among patients receiving antibiotic-containing cement plus systemic antibiotics (n=5,804). Compared with this regimen, a 4.3 (95% CI: 1.7 - 11.0, p=0.001) times higher revision rate was found among patients receiving systemic antibiotics only (n=4,586), a 6.3 (CI: 1.6 - 25.0, p=0.003) times higher revision rate among patients with antibiotics in the bone cement only (n=239) and a 11.5 (CI: 2.1 - 63.0, p=0.002) times higher revision rate among patients receiving no antibiotics (n=276). Further adjustment for the total amount of systemic antibiotics administered did not change the results. We also observed an increased revision rate of aseptic loosening (109 revisions) comparing the systemic only regimen (FRR=1.8, CI: 1.1 - 2.9, p=0.01) and the cement only regimen (FRR=2.6, CI: 1.2 - 5.9, p=0.02) to the combined regimen.

Conclusion. Our study demonstrated that systemic antibiotics used in combination with antibiotic-containing bone cement give fewer revisions than the other alternatives.

Paper IV

Patient-related risk factors for early revision of total hip replacements. A population register-based case-control study of 674 revised hips.

Espehaug B, Havelin LI, Engesæter LB, Langeland N, Vollset SE

Background. In this population register-based matched case-control study, we investigated the effect of various patient-related factors on early risk of revision after total hip replacement.

Material and methods. Information was obtained through a mail survey among patients reported to the Norwegian Arthroplasty Register during the period 1987 through 1993. The study included 674 revised hips as cases and 1,343 hips with a primary operation only as controls. Complete questionnaires were received from 81 % of the 2,017 individual cases and controls.

Results. We identified a set of patient-related factors associated with poor total hip replacement prognosis. Increasing weight was a risk factor among male patients older than 67 years with height over 1.77m (p = 0.01). There was no overall effect of smoking, but former heavy smokers had an increased risk of 2.6 compared to never-smokers. Alcohol use was associated with an increased risk for dislocation. Revision due to infection was more frequent among patients taking anti-diabetic drugs (OR=14) than among patients not taking any medication. An increased overall revision risk was found among patients using systemic steroids (OR=2.8) or local pulmonary steroids (OR=6.0). The risk was also increased in male patients performing regular exercise before the primary operation (OR=2.6), and in working-age female patients with a heavy occupation (OR=1.9).

Conclusion. While the strongest risk factors for revision may be directly related to the surgical procedure, we have identified a set of patient-related factors defining patients with poor prognosis after total hip replacement.

Paper V

The effect of hospital-type and volume on the survival of total hip replacements. A review of 39,505 primary total hip replacements reported to the Norwegian Arthroplasty Register, 1988-1996.

Espehaug B, Havelin LI, Engesæter LB, Vollset SE

Background. We investigated associations between the survival of total hip replacements, type of hospital and annual number of total hip replacements performed per hospital.

Material and Methods. The study was based on 39,505 primary total hip replacements reported to the Norwegian Arthroplasty Register from 45 local hospitals (n = 20,756), 15 central hospitals (n = 12,455), and 10 university hospitals (n = 6,294), during the period 1988 through 1996. Multiple Cox regression analyses provided estimates of differences in revision rates. The relationship between volume and revision rate was also considered through generalized additive proportional hazards models.

Results. For cemented total hip replacements, the adjusted revision rates at central and university hospitals were 0.8 (95% Confidence Interval: 0.67 - 0.95) and 1.2 (95% CI: 1.02 - 1.47) times that of local hospitals, respectively. A high annual number of cemented total hip replacements per hospital was not associated with lower revision rates. For uncemented total hip replacements, survival results were similar for central and local hospitals, whereas the adjusted revision rate at university hospitals was 1.6 (95% CI: 1.13 - 2.19) times that of local hospitals. The adjusted 6.5 year revision probability was 12% in hospitals performing \leq 10 uncemented total hip replacements per year (n 606), 8% in hospitals performing from 18 - 28 operations (n 1,378), and 5% in hospitals performing > 84 operations (n 526). The lowest mean annual number of total hip replacements per surgeon was observed at university hospitals.

Conclusion. The poorer survival results observed at university hospitals could not be explained by differences in gender, age, primary diagnosis, procedure characteristics, and annual number of total hip replacements performed per hospital. Other possible explanations may relate to the lower mean annual number of total hip replacements per surgeon at university hospitals.

Paper VI **Patient satisfaction and function after primary and revision total hip replacement.** *Espehaug B, Havelin LI, Engesæter LB, Langeland N, Vollset SE*

Background. The study objective was to assess satisfaction and function before and after total hip replacement, with a particular reference to differences between patients with both primary and revision surgery and patients with primary surgery only.

Material and methods. The study was based on a population register-based case-control study among patients reported with total hip replacement to the Norwegian Arthroplasty Register during the years 1987 through 1993. Information was obtained through a mail survey. Complete questionnaires were received from 531 patients with primary and revision surgery, and 1,087 patients with primary surgery only. Time from last surgery to follow-up ranged from 0.6 to 6.4 years. The data was analysed using generalized estimating equations to account for dependencies introduced by the study design.

Results. 61 % of the patients who underwent revision surgery and 84 % of the patients who did not undergo revision surgery rated their overall satisfaction with the hip implant as good or very good. With adjustment for primary diagnosis, gender, age, bilaterality, and time since the primary operation, a substantial benefit of total hip replacement was observed in both groups concerning pain, walking ability, and need of help. The improvement, however, was considerably poorer among patients with revision surgery. As opposed to patients with primary surgery only, fewer patients with revision surgery held salaried positions or exercised regularly at follow-up, as compared to before the primary operation.

Conclusion. An improved situation was reported regarding pain, walking ability and need of help also among patients with revision surgery. The improvement, however, was poorer than for patients with primary surgery only. Our findings underline the importance of a successful primary operation.

6 General discussion

6.1 Methodological considerations

6.1.1 Study designs

Randomised versus observational studies

The first randomised clinical trial was conducted by Bradford Hill in 1947 investigating the effect of streptomycin as treatment of pulmonary tuberculosis (A Medical Research Council Investigation 1948). Today, it is common practice that no new drug is marketed before its usefulness has been confirmed in rigorous trials. In non-drug treatment, including orthopaedic surgery, this has not been the standard approach. Concern has been raised in relation to the small number of randomised clinical studies within orthopaedic research (Rudicel and Esdail 1985, Laupacis et al. 1989, Goodfellow 1993, Clark 1997), and efforts have been made to outline a system for a controlled introduction of new techniques and procedures (Faro and Huiskes 1992, Gross 1993, Malchau 1995). These involve different stages or phases of investigation, in which laboratory studies should precede clinical trials which should be followed by continuous surveillance studies.

There are several reasons for the lack of properly conducted randomised trials in orthopaedic surgery. Blinding of the operator is usually difficult or impossible. The most important reason, however, relates to the size and duration of such studies. The generally good long-term results of total hip replacements, implies that very large studies have to run for a long period of time to detect differences between treatments. To detect a difference in revision risk between two prosthesis types with 5-year failure rates of 2 % and 5 %, an accrual rate of 518 patients per year are required to obtain a significance level of 5 % with a power of 80 %, meaning enlisting of 2,590 patients (George and Desu 1974). To detect a difference of 1 % (failure rates of 2 % and 3 %) under the same conditions, 15,543 patients would be required. The time needed in a randomised study with less patients included, might be so long that the investigation may have lost its relevance before the study is finished.

Arthroplasty registers provide long-term follow-up of large patient populations, and may represent a more practical investigative approach. Furthermore, results from register-based studies will reflect the performance among many surgeons not necessarily equally skilled. Whereas a procedure may attain satisfactory results when applied by specially trained surgeons (Carlsson et al. 1972), a nation-wide study may show poorer and perhaps more realistic results (Havelin et al. 1995c).

A disadvantage of observational studies is the lack of control regarding treatment assignment. This may lead to differences in the distribution of covariates between treatment groups, and possibly produce results biased by confounding. Randomisation will secure that any imbalances between treatment groups are introduced by chance, and asymptotically secure complete equivalence. Common statistical methods will therefore suffice to address the uncertainty introduced. In observational studies it is necessary to adjust for possible confounding, either through stratified analyses or through adjustment by regression methods. At present, observational studies represent the main source of information regarding the efficacy of different treatments in orthopaedic surgery. It is therefore important that the results presented are based on adequate statistical methods (Dorey et al. 1994).

Case-control studies

Cohort studies and case-control studies are the two primary types of observational, or nonexperimental studies. The Norwegian arthroplasty register represents an observational study in which a patient (or implant) cohort is followed from insertion of the implant to revision, or until the patient dies or emigrates. As the proportion of patients with revised total hip replacements is small, a large population is needed to establish effect estimates with sufficient precision. This is provided through the Norwegian arthroplasty register. However, if exposures not reported to the register are to be investigated, a case-control study within the register (*nested case-control study*) will represent an economic and efficient alternative. In our study, a case-control study was performed with cases defined as patients who had undergone revision surgery and controls as patients who had not. Information on factors related to the patient was obtained through a questionnaire.

Selection bias may arise if the procedures used to select participants to the study lead to an effect estimate among those included that is different from the estimate based on the entire study population (Rothman 1986). As both patients with revised hips and random controls came from the same well-defined population, selection bias was not an important issue in our study. Only very serious under-reporting to the register for specific patient groups, may have introduced severe selection bias. This is, however, not likely in connection with the patient-related risk factors investigated.

As information in case-control studies is retrieved in retrospect, there is always the possibility of *differential information bias* in classifying exposure (Rothman 1986). The concern is that cases recall previous exposures different than do controls. Although we were unable to rule out the possibility of *recall bias*, the likely direction of it was difficult to ascertain. Both an inflation and a deflation of any true association between patient-related factors and revision risk was possible. However, empirical work suggest that differential accuracy does not cause serious distortion of results (Preston-Martin et al. 1985, Linet et al. 1989, Mackenzie and Lippman 1989, Werler et al. 1989, Drews et al. 1990, Friedenreich et al. 1991).

We were concerned that some patients would find it difficult to render accurate retrospective information regarding weight, medication, smoking habits and alcohol use. In order to facilitate completion of the form, we asked for current information only. All analyses involving these factors, were thus based on an assumption of stability in exposure status. A study by Woolf et al. (1994) concluded that there was no evidence of a trend towards weight loss after total hip replacement. To assume stable medication since the primary operation, is, however, not possible. Regarding alcohol and tobacco consumption, we believe that few patients would dramatically alter their smoking and drinking habits during the brief time period, notably as the study population mainly consisted of older patients. However, methods of exposure measurement were equal for both cases and controls.

6.1.2 Definition of outcome

Different measures have been used to evaluate the quality of total hip replacement. Common for most techniques is that they are based on imprecise and subjective evaluations.

Clinical evaluation

A physical examination of the patient will give the surgeon information on how well the implant is functioning in the patient. Although there are several tests available to assess gait, movement and mobility (Thomas and Amstutz 1991), the interpretation of these tests are largely subjective. Similarly, the notion and response to pain and disability will differ from patient to patient. An infected hip may be diagnosed preoperatively through different

means including haematological studies, roentgenography, aspiration, imaging techniques and isotope studies.

Radiological findings

Roentgenographic evaluation of total hip arthroplasty is based on changes in the marginal zones and in the position of the implant, and specific criteria for the definition of loosening have been developed (DeLee and Charnley 1976, Gruen et al. 1979). There are, however, various definitions of radiographic 'loosening' and variations in technique may also make comparison of roentgenograms difficult.

New investigative tools have been developed to give more precise signs of poor prosthesis behaviour at an early stage. These methods include dual-energy X-ray absorption (Engh et al. 1992, Kiratli et al. 1996), which allows for precise measurements of bone apposition and resorption around the prosthesis, and use of digitisation of radiograms (Dooley et al. 1992) and roentgen stereophotogrammetric analyses (Kärrholm 1989, Ryd et al. 1995) to give more accurate longitudinal analyses of prosthetic migration and relative motions.

Assessment by the patient

In addition to evaluations based on the surgeon, the patients' own assessment of outcome is recognised as an important measure of success (Gartland 1988). Studies have also shown that the surgeons' and the patients' opinion of success may not always coincide (Lieberman et al. 1996). Several questionnaires have therefore been designed for this purpose and evaluated against each other (Liang et al. 1985, Callaghan et al. 1990, Johanson et al. 1992, Katz et al. 1992, O'Boyle et al. 1992, Borstlap et al. 1995, Stucki et al. 1995, Dawson et al. 1996). Most of the questionnaires, however, are very extensive and therefore probably not applicable in mail survey studies comprising large numbers of mostly elderly patients.

Revision of the implant

The decision to revise an implant is made by the orthopaedic surgeon, based on clinical and radiological findings, and on the patients' view of the situation. These are mostly subjective evaluations and may lead to differences among surgeons as to the indications for revision. With little variation within each hospital regarding procedure-related factors, differences in revision policies may affect the results of some surgical procedures more than others. One should therefore be especially careful about making conclusions from analyses based on few revisions.

An advantage of revision is that it is an indisputable event, which provides a clear indication of the time of the failure. This is important in relation to analyses based on time to failure. Furthermore, as revision is the most strict definition of failure, failure rates given in the present study are low estimates compared to analyses with other endpoints.

The other possible definitions of failure, like radiographic loosening or clinical evidence of malfunction, indicate that a revision may be needed. These endpoints can therefore be considered as *surrogate endpoints* (Editorial 1990, Ellenberg 1991) for revision. An earlier detection of failure means that smaller groups of patients are needed to establish treatment effects. However, patients would have to be followed at regular intervals which is not current practise in Norway, and almost impossible with large patient populations. Revision may therefore be considered as the most practical and useful definition of failure.

6.1.3 Quality and completeness of data

The classification and code system of prostheses and procedures in the Norwegian arthroplasty register allows for very detailed information on surgical procedures. The quality control of data performed at the register has been described by Havelin (1995). The

control includes annual hospital-specific reports, where each hospital receives information on operations performed at their hospital and report back on discrepancies with their own registration. Additional information is received from representatives of manufacturers if the total numbers on products do not compare with internal sales numbers.

Notification of total hip replacements to the Norwegian arthroplasty register is not compulsory. The orthopaedic surgeons at all hospitals in Norway performing total hip replacements have agreed, through the Norwegian Orthopaedic Association, to report all primary and revision surgery to the register. An independent investigation on numbers of total hip replacements performed at each hospital (Solheim 1991), and regular comparisons of our numbers with numbers from the Norwegian Institute for Hospital Research, Trondheim, Norway, have shown that at least 90 % of the total hip replacements performed in Norway are reported to the register.

It is crucial for the study that any under-reporting is unrelated to revisions of particular procedures or patient groups. A selective under-reporting of revisions could affect conclusions drawn with respect to differences in effects. Although not verified, this seems unlikely as the known underreporting is associated with a few small hospitals that underreport both primary and revision surgery.

6.1.4 Statistical methods

Confounding

The present study was based on observational data reported to the Norwegian arthroplasty register or data collected through the register-based matched case-control study. Confounding factors may therefore be unevenly distributed among treatment groups. As an example, if a larger proportion of young male patients with a poor prognosis receives uncemented prostheses as compared to older female patients, inferior failure rates for uncemented prostheses may be caused by the greater number of patients with a poor prognosis.

A formal definition of confounding is given by Rothman (1986):

- (1)A confounding variable must be a risk factor for the disease
- (2) A confounding variable must be associated with the exposure under study in the population from which the cases derive
- (3) A confounding variable must not be an intermediate step in the causal path between the exposure and the disease

Prevention of confounding

In experimental studies, confounding bias can be prevented through *randomisation* of the treatment. The effectiveness of the randomisation procedure will, however, be influenced by the number of subjects enrolled in the study. In nonexperimental studies, we can use *restriction* and *matching* of subjects. Randomisation of treatment will also secure random distribution of unknown confounders and of confounders for which information has not been collected. Apparently, this cannot be achieved in non-randomised studies. Another problem relates to categorisation of confounders with continuous measurements, if misclassified neither restriction nor matching will perform as expected.

In papers II, III and V, subgroups of patients were selected from the complete database in order to investigate the effect of different treatments in a relatively homogenous population. For instance, in paper II we compared the survival of different cemented prosthesis brands based on patients operated on due to primary coxarthrosis and where the operations were performed with high viscosity cement. Whether primary diagnosis may be considered a potential confounder is unclear, but type of cement has been shown to be an important predictor of revision risk (Havelin et al. 1995c).

Analyses in papers IV and VI were based on the matched case-control study where controls were selected to match patients with revised prostheses regarding gender, age, bilaterality and the date of the primary operation. In particular gender and age were considered as strong potential confounders. Matching was also performed to secure a sufficient number of controls to estimate an effect in particular subgroups of patients. Matching on the date of operation ensured time comparability between patients with revised hip implants and controls.

Control of confounding

In the present study, the procedures described above could not completely secure absence of bias due to confounding. Again referring to paper II, the distribution of the high viscosity cement types, Palacos, Simplex and CMW I, differed among the prosthesis brands. Dissimilar revision rates have further been reported among the cement types (Havelin et al. 1995c).

Control of confounding can be achieved through *stratification* or *multiple regression analyses*. Both approaches were used in the present study. Multiple regression analyses were applied in all papers to adjust for the possible influence of confounding factors. Cox regression analyses (Cox 1972) were applied in studies were outcome was defined as time until revision or censoring. Unadjusted and adjusted effect estimates were provided in these papers, demonstrating the influence of confounders. Furthermore, supplementary analyses were carried out within strata of the data selected for study.

Regression analyses for correlated data

In paper IV, the matched case-control data set implicated clusters of data with correlated observations. Relative risks were therefore estimated by odds ratios obtained from conditional logistic regression (Breslow and Day 1980). The analyses thus allowed both for removal of confounding introduced by the matching factors and for the control of additional unmatched confounding factors.

In paper V, also based on the matched case-control data, additional correlation was introduced as preoperative and postoperative scores were compared for each patient. Since both binary and continuous outcome measures were applied, the generalized estimating equation method was used to account for dependencies introduced by the design (Liang and Zeger 1993). With this approach, the marginal rather than the conditional distribution was modelled.

In all papers, the analytic unit was the hip and not the patient. This may represent a potential problem (Morris 1993), since strong interdependence of bilateral failures may compromise the results. Analyses performed within strata defined by unilaterally and bilaterally operated patients did not indicate such dependencies.

6.2 Discussion of results

6.2.1 Epidemiology of total hip replacements

Differences in incidence

The survey in paper I showed that the annual incidence of primary total hip replacement in Norway was 124/100,000 inhabitants in 1989 and 114/100,000 in 1990. The number reported for 1990 was representative also for the period 1991 through 1996. There are large variations in reported incidence rates among countries. In 1988, according to Malchau et al. (1993) the incidence rate per 100,000 inhabitants was equal to 116 in Belgium, 108 in France, 101 in Sweden and 54 in the United Kingdom. Other figures for 1988 include reported incidence rates of 82/100,000 inhabitants in the county of South Jutland in Denmark (Overgaard et al. 1991), 58 in Finland (Paavolainen et al. 1991) and 56 in the USA (Madhok et al. 1993). Compared to most countries, the incidence of total hip replacements was higher in Norway. This may suggest that total hip replacement surgery has high priority in Norway. Total hip replacement procedures are also fully covered by social security, and access to treatment equal for all inhabitants.

The high incidence of total hip replacement in Norway may have been caused by a high prevalence of coxarthrosis. We have, however, not been able to find any information on coxarthrosis prevalence in Norway, and reports in general have been inconclusive due to differences in study designs and in the methodology for identifying coxarthrosis (Felson 1988). A Danish study reported a coxarthrosis prevalence of 4.7 % (Jörring 1980), a Swedish study of 2.1 % (Danielsson et al. 1984) and a Finnish study of 5.1 % (Heliövaara et al. 1993). Altogether, these figures did not correspond with reported incidence rates of total hip replacements, or with reported proportions of total hip replacements performed due to primary coxarthrosis, 68 % in Norway (paper I), 78 % in Sweden (Malchau et al. 1993) and 56 % in Finland (Paavolainen et al. 1991).

At present we cannot say why the use of total hip replacement surgery is so high in Norway. Furthermore, as long as a precise knowledge on the prevalence of pathologic conditions that indicate total hip replacement is largely unknown, it is also impossible to say whether the actual need of total hip replacements is met.

Demographic variables

Regarding gender and age, patients in Norway were comparable with patients in other countries (Madhok et al. 1993, Malchau et al. 1993). However, in Finland, more young patients were operated, seemingly at the expense of older patients (Paavolainen et al. 1991). More females than males receive total hip replacements, but again we were unable to find an association with reported prevalence on coxarthrosis. An increasing prevalence with increasing age were reported by most studies, but reports on gender were confusing (Kellgren 1961, Lawrence et al. 1966, Zinn 1970, Jörring 1980, Pogrund et al. 1982, Danielsson et al. 1984, Heliövaara et al. 1993). Perhaps the high proportion of females among total hip replacement patients rather relate to a longer life expectancy among women.

An unwarranted large number of prosthesis types?

Counting both cemented and uncemented prosthesis brands, a total of 34 acetabular and 39 femoral prosthesis brands were in use in Norway during the years 1987 through 1990. Additionally, all brands had components available with different designs and sizes, resulting in 422 different acetabular and 398 different femoral components that had been used during the study period. Comparing reports from Finland, Sweden and Norway (Paavolainen et al. 1991, Malchau et al. 1993, paper I), we find that the selection of prosthesis brands differ among countries and thus accounting for a very large total number

of different prosthesis brands. The differentiation of prosthesis brands may be attributed to the weak control of medical implants (Faro and Huiskes 1992) and possibly reflects that the decision about which implant to market has been left to the distributors. This state of affairs cannot be justified from a medical point of view and will certainly not make quality control easier.

6.2.2 Procedure-related factors

Cemented prosthesis brands and early revision risk

The Charnley prosthesis has been held as the 'gold standard' among prostheses during the last decades (Agins et al. 1988, Malchau et al. 1993, Wroblewski and Siney 1993). In Norway, about 50 % of all cemented total hip replacements are performed using a Charnley prosthesis. However, reports from the Swedish national hip arthroplasty register showed that several prosthesis brands had lower revision rates than the Charnley prosthesis, including the Exeter polished, the Scan Hip with collar, the Spectron with all-polyethylene cups and the Lubinus SP (Malchau et al. 1993). These results originated from unadjusted statistical analyses, i.e. the results were unadjusted for possible confounding by other factors, like cement type, patient age and gender. It was therefore important to compare the survival of the Charnley prosthesis with the survival of other cemented prostheses in adjusted analyses.

As reported from Sweden, we observed several prosthesis brands with lower failure rates than the Charnley prosthesis. However, after adjustment for gender, age, cement type and use or non-use of systemic antibiotic prophylaxis, only the Spectron/ITH (cup/stem) combination remained statistically significant better than the Charnley prosthesis. As use of the Spectron/ITH combination was limited to only a few hospitals, the effect may be caused by particularly skilled orthopaedic surgeons. Low failure rates were indicated for the titanium femoral prostheses Titan and ITH, but little is yet known about their long-term failure rates. These prostheses should be followed with particular interest due to concerns regarding debris of titanium particles (Friedman et al. 1993).

Compared to the Charnley prosthesis, we found statistically significant inferior revision rates for the Müller Type prosthesis and the Elite/Charnley (cup/stem) combination. Poor results of the curved stem Müller Type prosthesis has been reported by other authors (Krismer et al. 1991, Malchau et al. 1993), and the prosthesis is no longer used in Norway. Regarding the Elite/Charnley combination, 6 out of 12 revisions were performed due to infection. It is therefore unlikely that the high revision rate should be associated with the design of the prosthesis. The primary operations of the 6 infected hips were performed at 5 different hospitals. The Elite cups with a 22 mm inner diameter and larger outer diameter were used as an alternative to the traditional Charnley cup. The prosthesis combination may therefore have been used in difficult operations in male patients with a particular poor prognosis.

Other prosthesis brands considered in this study was shown to have both higher and lower failure rates than the Charnley prosthesis. However, as several of the prostheses were used in low numbers, the tests lacked the statistical power to show differences that might be present. Many prosthesis brands were not included in the study due to even lower numbers. This demonstrates that there are many prosthesis brands currently in use in Norway which cannot be controlled for their quality.

Previous analyses of uncemented prostheses have identified specific prosthesis characteristics associated with poor prognosis (Havelin et al. 1995ab). Analyses of this kind are also appropriate for cemented prostheses, e.g. in relation to femoral head size. These issues were not addressed in paper II, due to the close link between characteristics of the prosthesis, like femoral head size, and prosthesis brand. However, later analyses should address these questions. A longer follow-up may also be important to show differences among cemented prostheses.

Antibiotic prophylaxis and revision risk

The protective effect of antibiotic prophylaxis administered systemically and in the bone cement was better compared with antibiotics given systemically only, in the cement only, or no antibiotics given. The revision rate with infection as endpoint was 4 (95% CI: 1.7-11) times higher for total hip replacements performed with systemic antibiotics only compared with total hip replacements performed with the combined regimen.

Similar conclusions were drawn based on analyses performed with aseptic loosening as endpoint. The most likely explanation is that antibiotic prophylaxis prevent low-grade infections which are unrecognised and possibly misclassified as aseptic loosenings. Usually, the register form is completed right after surgery. Thus, if peroperative cultures are positive, subclinical infections will possibly be reported to the register as aseptic loosenings.

The present study showed that with revisions performed because of infection as endpoint, the benefit of systemic antibiotics administered in combination with antibiotic-containing bone cement was highest during the first and the second year after surgery. With any revision as endpoint, the effect was upheld throughout the first 5 years of follow-up. This finding may indicate that late infections are misclassified more frequently.

The data set was restricted to total hip replacements performed with cement types and prosthesis brands with a good prognosis. It is unlikely that the revision rate due to infection should be influenced by the selection of prosthesis brands (Ahnfelt et al. 1990), but an association with cement type cannot be ruled out. However, the proportion of revisions performed due to infection was similar to that previously found for all cemented prostheses combined (Havelin et al. 1994).

Concern was raised early as to whether antibiotics added to the cement would cause more revisions due to less mechanical strength of the cement (Buchholz and Engelbrect 1970). While some experimental studies with mechanical tests have reported inferior results for antibiotic-containing cement as compared to plain cement (Buchholz and Engelbrect 1970, Ger et al. 1977, Moran et al. 1979, Bargar et al. 1986), others report only negligible differences (Marks et al. 1976, Wright et al. 1984, Gerhart et al. 1988, Langlais et al. 1988). The effect on mechanical strength of adding antibiotics (De Palma et al. 1982). The clinical significance of a reduction of strength is not clear. In accordance with other clinical studies (Garvin et al. 1988, McQueen et al. 1990, Josefsson and Kolmert 1993), we did not find higher failure rates due to aseptic loosening among total hip replacements with antibiotic-containing cement. Palacos cement with gentamicin was used in 98 % of all operations performed with antibiotics and cements may not be appropriate (Trippel 1986).

We found similar result patterns for antibiotic prophylaxis use among operations performed in ordinary operating theatres and in special operating theatres designed to lower airborne contamination. This result was in accordance with some studies (Lidwell et al. 1984, Lidwell 1988), but opposing other studies reporting an effect of systemic antibiotics in ordinary operating theatres only (Hill et al. 1981). Overall, we did not find lower revision rates due to infection for operations performed in operating theatres with laminar airflow or in a 'greenhouse' (enclosed operating area with laminar airflow and surgeons using body exhaust systems). It should be noted that relatively few operations were performed in 'greenhouse'. A convincing beneficiary effect of ultra-clean air technology has yet to be established (Hanssen and Osmon 1994).

6.2.3 Patient-related factors

The case-control study was designed to investigate the effect on revision risk of different patient characteristics, such as factors associated with co-morbidity or medication, lifestyle (smoking, alcohol use, weight, exercise habits) and occupation.

Many studies have shown that males and young patients with cemented prostheses are at high risk for revision (Ahnfelt et al. 1990, Malchau et al. 1993). Other studies, however, report that the gender difference may be confounded by patient weight (Surin and Sundholm 1983). This issue was not investigated in the present study, as patients who had undergone revision surgery (cases) and controls were matched with respect to gender.

Increasing weight has been associated with prosthesis failure by many authors (Surin and Sundholm 1983, Schurman et al. 1989, Hozack et al. 1990, Karachalios et al. 1993). It is interesting that the effect of weight has been found to be limited to or strongest in male patients (Hierton et al. 1983, Amstutz et al. 1990) and older patients (Schurman et al. 1989). Our findings indicate that increasing weight is a risk factor among older male patients above average male height. In accordance with other authors, we did not observe an association between revision risk and relative weight as measured by the body mass index (kg/m^2) (Surin and Sundholm 1983).

Although not shown in all studies (Ritter and Meding 1987), there is reason to believe that a high activity level after the primary operation will increase the risk for revision (White 1988, Kilgus et al. 1991, McGrory et al. 1995). In our paper we observed the opposite effect of returning to salaried work or engaging in regular exercise after the primary operation. These were patients in working age at follow-up. A similar effect was noted by Dubs et al. (1983). It is reasonable to assume that only patients with an initially successful prosthesis may work after the operation, and that a longer exposure is needed to evaluate an association with revision risk.

Exposure to physically heavy work increased the revision risk among females, in particular among women who reported domestic work in addition to other occupation. The estimated effect was consistent whether the women were salaried or not salaried at the primary operation, and among women not salaried after the primary operation. Few women with hard physical work were salaried after the primary operation. Among male patients, an effect of physical strain prior to the operation was only seen in connection with regular exercise.

Alcohol abuse has been associated with an increased risk of revision (Dorr et al. 1983), and in particular in relation to dislocation (Paterno et al. 1997). In the present study, few patients had an alcohol intake of more than 4 units per week. However, compared to nondrinkers there was an increased risk of revision due to dislocation irrespective of the amount of alcohol reported. Otherwise, the association of alcohol intake with revision risk was Jshaped.

We could not find previous studies investigating smoking in relation to revision risk. In the present study, the revision risk was similar between smokers, former or current, and non-smokers. Considering amount of smoking, compared to non-smokers, we observed an

increased risk among former smokers who had smoked more than 8 cigarettes per day in 30 years or more. Adjustment for a number of potential confounders gave only negligible differences in estimates. This finding may indicate a patient group at high risk for revision due to smoke-related health problems, most likely circulatory and pulmonary problems.

Compared to patients not using medication, we observed an increased revision risk among patients using systemic and pulmonary steroids, non-steroidal inflammatory drugs, female sex hormones, and drugs for diabetes. Both *the medication and the medicated disease* might represent the increased revision risk. With the above concern in mind, one may speculate whether the increased risk among patients taking estrogen substitution may be osteoporosis related. Estrogen substitution is otherwise associated with a lowered risk for receiving total hip replacement for osteoarthritis (Vingård et al. 1997). Non-steroidal anti-inflammatory drugs (NSAIDs) have been claimed to inhibit bone-repair (Keller et al. 1987, Ahrengart et al. 1988, McLaren 1990, Høgevold et al. 1992), but NSAID use in the present study cannot be regarded as a risk factor as we do not know whether patients received NSAIDs as an analgesic. In general, use of analgesics is most likely an indication of a poorly functioning implant, and patients using analgesics were therefore investigated as a separate group.

The effect of different risk factors may vary among the different primary diagnoses. Investigating such effects was difficult in the present study, as 67 % of the patients were operated on due to primary coxarthrosis and the other diagnoses were reported in small numbers only. This issue should, however, be subject to further research.

6.2.4 Hospital-related factors

The poorest prognosis was observed among total hip replacements performed in university hospitals and the best among those performed in central hospitals, with unadjusted revision rates 1.5 (p < 0.001) and 0.8 (p = 0.01) times that of local hospitals. It was an imperative of the study to investigate whether these differences possibly related to differences among hospital types regarding patient characteristics, procedure characteristics or other hospital characteristics.

Usually, patients in Norway are treated at the nearest hospital. Our findings indicated that the proportion of young patients and patients with other diagnoses than coxarthrosis, was highest in university hospitals and lowest in local hospitals. Regarding factors related to the surgical procedure, use of uncemented prostheses with a design associated with poor outcome (Havelin et al. 1995ab) was more frequent in university hospitals (8.7 %) than in local (4.7 %) and central hospitals (3.1 %). Our findings indicated that a part of the observed differences in *overall* revision rates were related to an unequal use of uncemented prostheses.

However, a less pronounced but still higher revision rate was observed at university hospitals irrespective of cement use. This finding was upheld also after adjustment for gender, age, diagnosis, and more detailed information with respect to the surgical procedure. Further adjustment for number of total hip replacements performed per hospital did not alter these results.

Although adjustment was performed for gender, age and primary diagnosis, the above results may have been confounded by other patient-related factors. Previous studies have identified patients with a high alcohol intake, and patients taking anti-diabetic or steroid medication as patients with an increased risk for revision (paper IV).

Furthermore, the experience of the surgeon has been associated with total hip replacement outcome (Buchholz et al. 1985, Courtois et al. 1985), and a low annual number of total hip

replacements per surgeon has been identified as a risk factor for revision (Fowles et al. 1987, Kreder et al. 1997). Individual information on the number of total hip replacements performed per surgeon was not available in this study. However, the mean annual surgeon volume was calculated based on information on number of orthopaedic surgeons and annual number of operations performed per hospital. The lowest mean number of operations per surgeon was observed at university hospitals where 50 % of the surgeons operated 11 or less total hip replacements a year. The highest mean number of operations per surgeon was observed in local hospitals. Thus, a possible explanation for the poorer results in university hospitals may be related to the lower operating volume per surgeon.

Further studies are needed to evaluate the importance of individual operating volume per orthopaedic surgeon. It should be noted that operating volume per surgeon seems to be high in Norway compared with other countries. In a study by Kreder et al. (1997), only 20 % of total hip replacements performed in the State of Washington, was performed by surgeons who operated more than 10 total hip replacements per year.

Fowles et al. (1987) reported a higher revision rate at hospitals performing few total hip replacements a year, but did not provide information on the definition of low volume. This finding was not supported in a more recent study reporting no differences among hospitals performing less than 16 procedure a year, from 16 to 65 procedures, and more than 65 procedures (Kreder et al. 1997). Our findings indicated a 'learning curve' on hospital level for uncemented total hip replacements, with an increased risk in hospitals performing 10 or less uncemented prostheses a year. A similar finding was not observed among cemented prostheses, suggesting that practice is more important in relation to uncemented prostheses. The general acquaintance with uncemented prostheses may also be poorer than for cemented prostheses.

6.2.5 Patient satisfaction and function

Total hip replacement is considered a highly successful surgical procedure (Harris and Sledge 1990), with low overall revision rates. Several studies have also provided evidence for the success of hip implants as assessed by the patient (Wiklund and Romanus 1991, O'Boyle et al. 1992, Rorabeck et al. 1994, Rissanen et al. 1995, Chan and Villar 1996, Norman-Taylor et al. 1996, Rissanen et al. 1996). These studies were primarily conducted among patients with initially successful implants. An important strength of this study is the large number of patients with prosthesis failure who were studied. This made it possible to assess and compare satisfaction and improvement in function among patients with revised prostheses and patients with primary prostheses only.

A substantial improvement was observed regarding pain, walking ability and need of help. The improvement, however, was poorer among patients who had undergone revision surgery than among patients with primary surgery only. Furthermore, as opposed to patients with unrevised prostheses, there had been a decrease in the proportion of patients performing weekly exercise and patients holding salaried positions among patients with revised prostheses.

Function before the primary operation was compared with function at follow-up (when the questionnaire was completed). As patients with revision surgery and patients without revision surgery were matched with respect to the date of the primary operation, time since last surgery was shorter for patients with revised prostheses. The median time interval between revision surgery and follow-up was 2.3 years ranging from 0.6 to 6.4 years. The follow-up in the present study seems to be sufficient, also for revised patients, as several studies have reported that most of the improvement occur within 3 or 6 months postoperatively (Laupacis et al. 1993, Rissanen et al. 1996).

Previous studies have asserted that it is more cost effective to treat patients with lower preoperative health scores, as postoperative scores are effectively identical (Liang et al. 1986). This was not supported by the present study, where patients with the poorest preoperative scores also tended to have the lowest postoperative scores. Poor preoperative walking ability has also been associated with inferior postoperative occupational capacity (Jensen et al. 1985).

It has been argued that a possible cost benefit of total hip replacement surgery would relate to a reduced number of patients needing help from health and welfare services after surgery (Wilcock 1978, Rissanen et al. 1996). In the current study, comparing preoperative and postoperative information, the proportion of patients needing help from a home help or a home nurse had increased in all except the youngest age group. This finding was supported by Jacobsson et al. (1991), which reported no reduction in community expenses for welfare services after total hip replacement surgery among elderly patients.

In conclusion, although improvement was less among patients who had undergone revision surgery than among patients who had not, this study demonstrated that also patients with revision surgery had experienced considerable improvement regarding important factors like pain and walking ability.

7 Conclusions

Survey of patients and surgical procedures

The median age of patients was 70 years, and 69 % of the patients were women. The study documented an unreasonably high number of different designs and sizes of acetabular and femoral prostheses in use in Norway during the period 1987 through 1990.

Cemented prosthesis brands and revision risk

The overall short-term survival results for cemented total hip replacements were very good. However, the prosthesis-specific analyses demonstrated differences which underline the need for continuous monitoring of prosthesis survival.

Antibiotic prophylaxis regimens and revision risk among cemented hip implants We investigated the effect on total hip replacement survival of antibiotic prophylaxis administered both systemically and in the bone cement, systemically only, in the cement only or no antibiotics given. The study demonstrated that systemic antibiotics combined with antibiotic-containing cement led to fewer revisions than the other methods.

Patient-related risk factors for revision

While the strongest risk factors for revision may be related to the surgical procedure, we identified a set of patient characteristics associated with poor prognosis after total hip replacement. These factors were related to medication use, occupation, and patient lifestyle.

Hospital-related risk factors for revision

Total hip replacements performed at university hospitals were more often revised than total hip replacements performed at central and local hospitals. An inverse association between revision rate and annual number of total hip replacements per hospital was observed among uncemented prostheses only.

Patient evaluated outcome

A total of 61 % of patients with revision surgery and 84 % of patients with primary surgery only, rated their satisfaction with the implant as good or very good. Improvement after surgery was less pronounced among patients with revision surgery. This finding emphasise the importance of a successful primary operation.

In conclusion, although overall results of total hip replacement surgery are good, there are important differences in outcome relative to characteristics of the surgical procedure, the patient and the hospital. Intensified quality control measures are needed to reduce these differences.

8 Future research

The effect on total hip replacement survival of operating volume per surgeon has been quantified by one study only (Kreder et al. 1997). Further investigations of this issue may be based on data in the Norwegian arthroplasty register with additional collection of individual data on orthopaedic surgeon.

Current controversies regarding systemic antibiotic prophylaxis include identification of the optimum antibiotic, and the appropriate timing and duration of antimicrobial prophylaxis (Hanssen and Osmon 1996). Based on data in the Norwegian arthroplasty register, Engesæter et al. (1997) is currently investigating the effect on total hip replacement survival of dosage and duration of systemic prophylaxis. Randomised clinical trials should be initiated to further substantiate findings based on data in the Norwegian arthroplasty register.

An association of total hip replacement survival and primary diagnosis is currently being investigated by Furnes et al. (1997), using data reported to the Norwegian arthroplasty register.

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10 Appendix

The Norwegian Arthroplasty Register form

The Norwegian arthroplasty register form used in the period 1987 through 1992 The Norwegian arthroplasty register form used from 1993

The Norwegian arthroplasty register form used from 1993 (English translation)

Case-control study form

Case version of the case-control study form

Case version of the case-control study form (English translation)

The Norwegian arthroplasty register form used in the period 1987 through 1992

	NASJONALT REGISTER FOR TOTALPROTESER I HOFTELEDD Ortopedisk avdeling Haukeland sykehus, 5021 BERGEN		F. nr. (11 sifre) : Navn: Sykehus: (Bruk blokkbokstaver)
ANA	MNESE:		
		3.	FUNKSJONSGRUPPE (ett kryss): Aktuelle hofte syk ellers frisk.
1.	SMERTER (ett kryss):		Begge hofter syke ellers frisk.
	Sterke spontane i hvile og om natten. Sterke som hindrer all gangaktivitet.		Annet som reduserer gangevnen.
1 3	Moderate, tillater begrenset gange.	4.	TIDLIGERE OPERASJON(ER) I AKTUELLE HOFTE:
	Etter noe aktivitet, forsvinner i hvile.	D ⁰	Nei (evt. flere kryss)
	Lette eller periodevise. Startsmerter. Ingen smerter.		
	the second s		Hemiprotese pga. fraktur Osteotomi.
2.	GANGEVNE (ett kryss):		Artrodese
	Få meter med 2 krykker/stokker/sengeliggende. Sterkt begrenset med eller uten stokker.		Totalprotese(r) Type(r):
	Begrenset med stokk (under en time). Kan stå lenge.	□ ⁶	Annet:
	Kan gå lange avstander med en stokk. Ingen stokk, men halter.	5.	
Ľ.	Normal gangevne.	5.	(under 1 år = 0).
•			
OPE	RASJONSOPPLYSNINGER:		
	dag mnd år	13.	BENTRANSPLANTASJON:
6.	OPERASJONSDATO:		Nei I acetabulum.
7.	AKTUELLE OPERASJON ER (ett kryss).		I femur.
	Primær totalproteseoperasjon. Reoperasjon.	□3	l acetabulum og femur.
8.	AKTUELLE SIDE (ett kryss).		OTESE. NAVN/TYPE (Spesifiser nøyaktig): Acetabulum:
	Høyre	14.	Navn/Type:
	Venstre	-	Evt. Kat. nr:
□4	Høyre - venstre allerede protese. Venstre - høyre allerede protese.		Sement med antibiotika. Navn:
9.	AKTUELLE HOFTEOPERASJON ER (ett kryss).		
	a) Primæroperasjon pga.: Idiopatisk coxartrose	15.	Femur: Navn/Type:
	Rheumatoid artritt.		Evt. Kat. nr
	Seq.fr. colli fem.		Sement med antibiotika. Navn:
15	Seq.dysplasi. Seq.dysplasi med luksasjon.		Sement uten antibiotika. Navn:
	Seq.Perthes/epifys.	_	
	Bechterew.	16.	Caput:
-	Annet:		
-	b) Reoperasjon pga. (evt. flere kryss):	-	Evt. Kat. nr Diam.:
	Løsning av acetabulardel. Løsning av femurdel.	17.	SYSTEMISK ANTIBIOTIKAPROFYLAKSE:
	Løsning av femurdel. Luksasjon	D°	Nei
	Dyp infeksjon.		Ja. Hvilken:
	Fraktur av femur.		Dose:
67	Smerter. Annet:		Varighet:
10.		18.	OPERASJONSSTUE:
	HVIS reoperasjon (ett kryss): Reop bytte av femurdelen.		"Green house"
	Reop bytte av acetabulardelen.		Operasjonsstue med laminær luftstrøm. Vanlig operasjonsstue.
	Reop bytte av hele protesen. Reop annet: (fjeks. Girdlestone),		
	V	19.	OPERASJONSTID (hud til hud):
	TILGANG (ett kryss):	20.	PEROPERATIVE KOMPLIKASJONER:
	Fremre (Smith-Pettersen). Anterolateral.		Nei. Ja. Hvilken:
	Lateral.	U .	Ja. mviiken:
	Posterolateral		
0-	Annen:	-	a service and a service and a service and a
12.	TROCHANTEROSTEOTOMI:		
D°	Nei		Lege :
D'	Ja		(Legen som har fylt ut skjemaet)

The Norwegian arthroplasty register form used from 1993

NASJONALT REGISTER FOR LEDDPROTESER Ortopedisk klinikk, Helse Bergen Besøksadresse: Haukeland Universitetssykehus Postadresse: 5021 BERGEN Tift: 55 97 37 42 / 55 97 37 43 HOFTEPROTESER ALLE TOTALPROTESER I HOFTELEDD REGIST	1. F.nr. (11 sifre) Navn: 2. Sykehus:
ALLE TOTALPROTESER THOFTELEDD REGIST Innsetting, skifting eller fjerning av protese eller pr 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 Artodese 5 Totalprotese(r) 6 Annen operasjon 5. Hvis protese tidligere, TYPE(R): Årstall siste protese: Antall proteser tidligere i aktuelle hofte: dag mnd år 6. OPERASJONSDATO: 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)	IHERES (ikke nemiproteser) otesedeler. 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 Ja acetabulum 2 I femur 3 Lacetabulum 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 hydroksylapatit 1 Sement med antibiotika - Navn: 2 Sement uten antibiotika - Navn: 3 Usementert
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 8, Reoperasjon. pga. (evt. flere kryss): 1 I die sectebulge komponent	15. Femur Navn/Type: Evt. katalognummer: Wed hydroksylapatitt 1 Sement med antibiotika - Navn: 2 Sement uten antibiotika - Navn: 3 Usementert 16. Caput 1 Fastsittende caput 2 Separat caput - NavnType: Evt. katalognummer: Diameter:
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Annet:	Lege: Legen som har fylt ut skjemaet, (navnet registreres ikke)

The Norwegian arthroplasty register form used from 1993 (English translation)

Patient: Hospital: Previous operation in index hip: 0 No Approach: 1 Anteroior 0 No 3 Lateral 1 Anteroior 3 Lateral 2 Memiprosthesis 3 Lateral 3 Oxteotomy of trochanter: 1 Yes 2 Meriopateral 4 Posterolateral 4 Arthrodesis 5 Total hip prosthesis 5 Total hip prosthesis 1 Yes 2 Meriopateral 9 Oxteotomy of trochanter: 1 Yes 1 Ne 2 Meriopateral 1 Ne 6 Other operation: 1 Ne 1 Right 1 Atterior 1 Right 1 Atterior 2 Revision 1 Ne Hip: 1 Right 1 Right 1 Atterior 2 Let 2 Rementation: 3 Right, prosthesis in left hip 2 Rement with antibiotic. Name: 2 Requelae after dysplasia sit dislocation 3 Uncernented 5 Sequelae after dysplasia with dislocation 3 Uncernented 2 Sequelae after dysplasia with dislocation 3 Uncernented 3 Despineticion 3 Uncernented 2 Maneering of femoral component 2 Modular system. 3 Discoation 3 Uncernented 2 Maneering of femoral component 2 Noneering 3 Oxtolysis of femoral component 2 Noneer	THE NORWEGIAN ARTHROPLASTY REGIST	'ER (TOTAL HIP REPLACEMENTS)
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 5 Fracture of femur 6 Pain 7 Other:	4 Deep infection	Systemic antibiotic prophylaxis:
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 8 Osteolysis of acetabular component, no loosening 9 Osteolysis of femoral component, no loosening Revision: Change of femoral component Change of acetabular component Change of all components Other: Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other: Perioperative complication: No Yes. Name: Surgeon (who has filled in the form): 	7 Other:	Dosage:
 9 Osteolysis of femoral component, no loosening Revision: Change of femoral component Change of acetabular component Change of all components Operating theatre: 'Green house' With laminar air flow Without laminar airflow Duration of operation: Exchange of caput only Exchange of caput only Other: Perioperative complication: Yes. Name: Surgeon (who has filled in the form): 	8 Osteolysis of acetabular component, no loosening	Duration (days):
Revision: 1 'Green house' 1 Change of femoral component 2 With laminar air flow 2 Change of acetabular component 3 Without laminar airflow 3 Change of all components 4 Other: - Removal of component (e.g. Girdlestone) Duration of operation: - Kexchange of PE liner only Skin to skin (min.): - Exchange of caput only 1 No - Other: 2 Yes. Name: Surgeon (who has filled in the form):	9 Osteolysis of femoral component, no loosening	
 1 Change of femoral component 2 Change of acetabular component 3 Change of all components 4 Other: Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other: Perioperative complication: 1 No 2 Yes. Name: Surgeon (who has filled in the form): 		
 2 Change of acetabular component 3 Change of all components 4 Other: Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other: 2 Without laminar airflow 3 Without laminar airflow Duration of operation: Skin to skin (min.): Perioperative complication: 1 No 2 Yes. Name: Surgeon (who has filled in the form): 		
 3 Change of all components 4 Other: Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other: Perioperative complication: 1 No 2 Yes. Name: Surgeon (who has filled in the form): 	1 Change of femoral component	
 4 Other: Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other: Other: Buration of operation: Skin to skin (min.): Perioperative complication: 1 No 2 Yes. Name: Surgeon (who has filled in the form): 		3 Without laminar airflow
 Removal of component (e.g. Girdlestone) Which parts: Exchange of PE liner only Exchange of caput only Other:		
Which parts:		
 Exchange of PE liner only Exchange of caput only Other: Mathematical Surgeon (who has filled in the form): 		Skin to skin (min.):
- Exchange of caput only - Other:	Which parts:	
- Other:		
Surgeon (who has filled in the form):	- Exchange of caput only	
	- Other:	2 Yes. Name:
		Surgeon (who has filled in the form):
(Surgeon name is not registered)		(Surgeon name is not registered)

Case version of the case-control study form

SKJEMA 2

NASJONALT REGISTER FOR LEDDPROTESER Ortopedisk avdeling, Haukeland Sykehus

Ved Nasjonalt register for leddproteser arbeider vi med et forskningsprosjekt for å kartlegge holdbarheten til kunstige hofteledd. I denne sammenheng ønsker vi å innhente opplysninger om forhold i dagliglivet til proteseopererte.

Vi ber deg derfor være vennlig å besvare spørsmålene nedenfor så nøyaktig som mulig, og returnere skjemaet i svarkonvolutten. Porto er betalt. Alle opplysninger du gir vil bli behandlet strengt fortrolig etter de regler Datatilsynet gir. Etter en tid vil vi sende ut en påminnelse til dem som ikke har returnert skjemaet. Dersom du ikke ønsker å besvare skjemaet ber vi deg derfor likevel om å returnere skjemaet ubesvart.

Det er viktig at du leser brevet som følger med før du fyller ut skjemaet. Har du spørsmål i forbindelse med utfyllingen, kan du kontakte Birgitte Espehaug, stipendiat ved Nasjonalt register for leddproteser, tlf 55 97 46 70. På forhånd takk for hjelpen!

Med vennlig hilsen fra

Leif I. Havelin Overlege Ortopedisk avdeling Haukeland Sykehus

Birg itte Espehany

Birgitte Espehaug NFR-Stipendiat Universitetet i Bergen Haukeland Sykehus

Navn	
Adresse	
Postadresse	
Kommune	

YRKESBAKGRUNN	UTDANNELSE	
Kryss av for det yrket du har. Dersom du ikke lenger er yrkesaktiv så kryss av for det yrket du hadde tidligere. (Sett eventuelt flere kryss	Hvilken utdannelse har du? (Sett eventu flere kryss).	elt
Industri/verksted/anlegg/bygningsarbeid Jordbruk/skogbruksarbeid Fisker/sjømann Kontor/handel/hotell/servicearbeid Helsearbeid Lærer/undervisning/forskning Landtransport, f.eks. sjåfør Administrativt arbeid (offentlig/privat) Husarbeid i hjemmet Annet Ikke aktuelt	Grunnskole Videregående (gymnas, realskole) Videregående fagskole (yrkesskole) Høyskole (teknisk, distriktshøyskole, lærer, sykepleie) Universitet (også NTH, NHH) TIDLIGERE AKTIV INNEN IDRE Har du vært tidligere aktiv innen konkurranseidrett? Ja Hvis ja, angi i hvor mange år du var aktiv	Nei
Kryss av for hvor fysisk anstrengende du vurderer yrket du har angitt ovenfor. (Sett kun <u>ett</u> kryss).	Hvis du har vært aktiv innen konkurrans idrett, angi hvilken idrett du holdt på me	
Tungt fysisk arbeid Lett, men med mye bevegelse Stillesittende Ikke aktuelt	SIVIL STATUS Bor du alene? Ja	 Nei
Kryss av for hvor lenge du har hatt tungt fysisk arbeid. (Sett kun <u>ett</u> kryss).	Kryss av for sivil status. (Sett kun <u>ett</u> kry	vss).
Sjelden/Aldri < 20 år 20-30 år > 30 år	Gift Ugift Skilt Enke eller enkemann Samboer	

ALKOHOLFORBRUK	VEKT OG HØYDE
Er du totalavholdende? Ja Nei	Oppgi vekt i kg. └─└──┘ kg Oppgi høyde i cm. └─└──┘ cm
Hvis nei, angi hvor ofte du drikker øl, vin eller brennevin. (Sett kun <u>ett</u> kryss for hver alkoholtype). Omtrent Ukentlig Månedlig Sjeld-	
daglignereØIIVinIBrennevinI	HØYRE- ELLER VENSTREHENDT? Er du høyre- eller venstrehendt? Høyre Venstre
Hvis vi regner at en alkoholenhet er : 1 liten flaske pils = 1 glass vin = 1 drink (brennevin), hvor mange alkoholenheter drikker du pr. uke?	NÅVÆRENDE BRUK AV MEDISINER
Angi antall alkoholenheter.	Bruker du medisiner? Ja Nei
RØYKEVANER	
Røyker du, eller har du røykt tidligere? Ja Nei	Hvis ja, angi hvilke medisintyper du bruker.
Hvis ja, angi i hvor mange år du har røykt.	
L år	
Hvis du røyker nå eller har røykt tidligere, angi hvor mye. i sigaretter pr dag i pakker tobakk pr uke Hvis du har røykt tidligere, angi hvor lenge det er siden du sluttet. i år	Hadde du i tiden mellom første og andre operasjonen, en kur mot infeksjon (pencillin el. lignende) som varte i mer enn en måned? Ja Nei

VENTETID FØR FØRSTE OPERASJON	BEHOV FOR HJELP FØR OG ETTER OPERASJON
Den første gangen du ble operert, hvor lang tid gikk det fra du var hos legen (privatlegen) til du hadde time på sykehuset hos spesialist?	Kryss av for behov for hjelp i tiden like før den første operasjonen. (Sett kun <u>ett</u> kryss).
└──└── år └──└── mnd Den første gangen du ble operert, hvor lang tid gikk det fra du var hos legen på sykehuset (spesialisten) til	Bodde privat, klarte meg selv Bodde privat, fikk hjelp av ektefelle/samboer/slektninger Bodde privat, fikk hjelp av
selve operasjonen ble utført?	hjemmehjelp/hjemmesykepleier
VARIGHET AV PLAGER FØR FØRSTE OPERASJON	Kryss av for behov for hjelp i tiden like før den andre operasjonen. (Sett kun <u>ett</u> kryss).
Angi hvor lenge du hadde plager med hoften som f.eks. smerter og gangvansker, før du ble operert første gang.	Bodde privat, klarte meg selv Bodde privat, fikk hjelp av ektefelle/samboer/slektninger Bodde privat, fikk hjelp av
L_L_l år L_L_l mnd	hjemmehjelp/hjemmesykepleier
BEDØVELSE UNDER FØRSTE OPERASJON	Annet
Kryss av for type bedøvelse som ble gitt under operasjonen den første gangen du ble operert. (Sett kun <u>ett</u> kryss).	Kryss av for behov for hjelp nå. (Sett kun <u>ett</u> kryss).
	Bor privat, klarer meg selv
Full narkose (sov)	Bor privat, får hjelp av
Spinal/Epidural (våken,	ektefelle/samboer/slektninger
bedøvet fra midjen og ned)	Bor privat, får hjelp av
Vet ikke, husker ikke	hjemmehjelp/hjemmesykepleier
	Bor på aldershjem
	Bor på sykehjem

SMERTER FØR OG ETTER OPERASJON	GANGEVNE FØR OG ETTER OPERASJON
Angi hvor sterke smerter du hadde like før den første operasjonen. (Sett kun <u>ett</u> kryss).	Kryss av for gangevne like før den første operasjonen. (Sett kun <u>ett</u> kryss).
Sterke spontane, i hvile og om natten Sterke, ved all gangaktivitet Moderate, ved gange Etter noe aktivitet, forsvant i hvile Lette eller i perioder. Startsmerter Ingen smerter Angi hvor sterke smerter du hadde like før den andre	Få meter med 2 krykker/stokker eller sengeliggende Sterkt begrenset med eller uten stokker Inntil 1 time med stokk. Kunne stå lenge Kunne gå lange avstander med stokk Ingen stokk, men haltet Normal gangevne
operasjonen. (Sett kun <u>ett</u> kryss). Sterke spontane, i hvile og om natten	Kryss av for gangevne like før den andre operasjonen. (Sett kun <u>ett</u> kryss).
Sterke, ved all gangaktivitet	Få meter med 2 krykker/stokker eller
Etter noe aktivitet, forsvant i hvile	Sterkt begrenset med eller uten stokker
Angi hvor sterke smerter du har nå. (Sett kun <u>ett</u> kryss).	Kunne gå lange avstander med stokk Ingen stokk Ingen stokk, men haltet Ingen stokk Normal gangevne Ingen stokk
Sterke spontane, i hvile og om natten	Kryss av for gangevne nå. (Sett kun <u>ett</u> kryss).
Etter noe aktivitet, forsvinner i hvile	Få meter med 2 krykker/stokker eller sengeliggende
Ingen smerter	Sterkt begrenset med eller uten stokker Inntil 1 time med stokk. Kan stå lenge
Hadde du i perioden mellom operasjonene smerter som varte i mer enn 6 måneder? Ja Nei	Kan gå lange avstander med stokk Ingen stokk, men halter Normal gangevne



FRITIDSAKTIVITET FØR OG ETTER OPERASJON		ARBEIDSSITUASJON FØR OG ETTEI OPERASJON	R
Kryss av for aktuelle fritidsaktiviteter i tiden før du fikk problemer med hoften. (Sett eventuelt flere kryss).		Kryss av for den arbeidssituasjon du var i l før den første operasjonen. (Sett eventuelt flere kryss).	
Mosjonerte sjelden/aldri		Fulltid lønnsarbeid	
Hagearbeid/vedlikeholdsarbeid		Deltid lønnsarbeid	
Gikk tur langs vei		Ulønnet arbeid, f.eks. husarbeid	
Gikk tur i ulendt terreng		Sykemeldt	
Løping		Uføretrygdet	
Sykling		Alderspensjonert	
Skigåing		Arbeidsløs	
Jakt/fiske		Annet	
Annet Kryss av for aktuelle fritidsaktiviteter nå. (Sett eventuelt flere kryss).		Kryss av for den arbeidssituasjon du var i l før den andre operasjonen. (Sett eventuelt flere kryss).	ike
Mosjonerer sjelden/aldri		Fulltid lønnsarbeid	
Hagearbeid/vedlikeholdsarbeid		Deltid lønnsarbeid	
Går tur langs vei		Ulønnet arbeid, f.eks. husarbeid	
Går tur i ulendt terreng		Sykemeldt	
Løper		Uføretrygdet	
Sykler		Alderspensjonert	
Skigåing		Arbeidsløs	
Jakt/fiske		Annet	
Annet		Kryss av for den arbeidssituasjon du er i na (Sett eventuelt flere kryss).	à.
		Fulltid lønnsarbeid	
Mosjonerte eller trente du jevnlig (minst en gang i uken) før du fikk problemer med hoften?		Deltid lønnsarbeid	
Ja	Nei	Ulønnet arbeid, f.eks. husarbeid	
Mosjonerte eller trente du jevnlig i tiden mellom		Sykemeldt	
operasjonene? Ja	Nei	Uføretrygdet	
		Alderspensjonert	
Mosjonerer eller trener du jevnlig nå?		Arbeidsløs	
Ja	Nei	Annet	

ARBEIDSSITU/ OF	ASJON F PERASJO		TER	
Dersom du var sykemeldt før du ble operert første eller andre gang, angi varighet av sykemelding.				
Før første operasjon Før andre operasjon				
Har du vært i lønnet arbe første og andre operasjo		mellom		
	lkke aktuelf	Ja t	Nei	
NY	PROTE	SE		
Er det søkt om eller planl protesen du har nå (dvs.				Nei
Er protese nummer to all	erede ski	iftet?	Ja	Nei
Hvis ja, angi operasjonsd	lato			
		1 1 1		
NY	TTEVER	DI		
Kryss av for hvordan du i dag vurderer nytten av proteseoperasjonene.				
Meget god				
God				
Hverken god eller dårlig				
Dårlig				
Meget dårlig				

Case version of the case-control study form (English translation)

Name:	Address:
OCCUPATION	EDUCATION
Put a mark against current occupation. If you are not working now, put a mark against former occupation (If needed use more than one alternative).	Put a mark against the alternative that describe your education. (If needed use more than one alternative).
Industry/engineering/construction Industry/engineering/construction Agriculture/forestry Industry/engineering/construction At sea Industry/engineering/construction Office/trade/hotel/service Industry/engineering/construction Health-service Industry/engineering/construction	Primary school
Education/research Transport, e.g. road transport	SPORT
Administrative work (public/private)	Have you ever participated in competitive sports?
How do you define your occupation. (Only <u>one</u> mark).	If yes, for how many years? years If yes, please note types of activity.
Physically heavy Easy, but with much movement Sedentary	
Not relevant	MARITAL STATUS
For how long have you held a physically heavy occupation. (Only <u>one</u> mark).	Do you live alone? Yes No
Seldom/Never< 20 years	Put a mark against marital status. (Only one mark). Married Single Divorced Widow, widower Cohabitant

ALCOHOL	WEIGHT AND HEIGHT
Are you a tectotaller? Yes No	Weight └─└─┘ kg Height └─└─┘ cm
If no, please mark how often you drink beer, wine or spirits. (Only one mark at each type of alcohol). About daily Weekly Monthly More seldom Beer Image: Imag	RIGHT- OR LEFT-HANDED? Are you right-handed or left-handed? Right Left
	MEDICATION
If no, how many units of alcohol do you drink per week? (1 unit of alcohol = 1 small bottle of beer = 1 glass of wine = 1 drink). Units of alcohol:	Do you use any kind of medication? Yes No
	If yes, please note types of medication
SMOKING Do you smoke, or did you smoke previously? Yes No If yes, how many years have you been smoking? years	
If yes, please note how much you smoke or smoked.	Did you between operations receive treatment against infection (e.g. penicillin) where the treatment lasted for longer than one month? Yes No

physician until your appointment at the hospital (with a specialist)?	WAITING TIME BEFORE THE PRIMARY OPERATION	NEED OF HELP		
(with a specialist)? Lived at home with no help	you wait after your consultation with your	Put a mark against your need for help just before your second operation. (Only <u>one</u> mark).		
		Lived at home with no help		
The first time you were operated, how long did you wait for your operation after your consultation at the hospital (with the specialist)? Lived in home for the aged Lived in nursing home DURATION OF SYMPTOMS BEFORE THE PRIMARY OPERATION Put a mark against your need for help just before your second operation. (Only <u>one</u> mark) Before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home. Help from spouse/cohabitant/ relatives Lived at home. Help from home help/home nurse Lived in nursing home Lived in nursing home ANAESTHESIA DURING THE PRIMARY OPERATION Other Put a mark against type of anaesthesia during your first operation. (Only <u>one</u> mark). Put a mark against your current need for help Living at home with no help Lived in nursing home Other	years in months	Lived at home. Help from spouse/cohabitant/		
you wait for your operation after your consultation at the hospital (with the specialist)? Lived in home for the aged Lived in nursing home Other DURATION OF SYMPTOMS BEFORE THE PRIMARY OPERATION Before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). uight a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against type of anaesthesia during your first operation. (Only one mark). Curved with no help Lived at home. Help from spouse/cohabitant/ In a mark against type of anaesthesia during your first operation. (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/	The first time you were operated how long did	Lived at home. Help from home help/home nurse		
Lived in hussing nome DURATION OF SYMPTOMS BEFORE THE Put a mark against your need for help just before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home. Help from spouse/cohabitant/ relatives Lived at home for the aged Lived in home for the aged Lived in nursing home Other Put a mark against type of anaesthesia during your first operation. (Only <u>one</u> mark). Living at home with no help Living at home. Help from spouse/cohabitant/	you wait for your operation after your	Lived in home for the aged		
DURATION OF SYMPTOMS BEFORE THE PRIMARY OPERATION Put a mark against your need for help just before your second operation. (Only one mark before your second operation. (Only one mark). Before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home with no help Lived at home. Help from spouse/cohabitant/ relatives Lived at home. Help from home help/home nurse Lived at home. Help from home help/home nurse Lived in nursing home ANAESTHESIA DURING THE PRIMARY OPERATION Other Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help just before your second operation. (Only one mark). Current height the hip (e.g. pain and difficulties with walking). Lived at home. Help from home help/home nurse Lived at home. Help from home help/home nurse Lived in nursing home Other Other	consultation at the hospital (with the specialist)?	Lived in nursing home		
DURATION OF SYMPTOMS BEFORE THE PRIMARY OPERATION before your second operation. (Only one mark) Before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home with no help Lived at home. Help from spouse/cohabitant/ relatives Lived at home. Help from home help/home nurse Lived in home for the aged Lived in nursing home ANAESTHESIA DURING THE PRIMARY OPERATION Other Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/	years in months	Other		
Before the first operation, please note how long you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home. Help from spouse/cohabitant/ relatives Lived at home. Help from home help/home nurse Lived at home. Help from home help/home nurse Lived at home. Help from home help/home nurse Lived in home for the aged Lived in nursing home Other Put a mark against type of anaesthesia during your first operation. (Only <u>one</u> mark). Put a mark against your current need for help (Only <u>one</u> mark). Living at home with no help Living at home. Help from spouse/cohabitant/		Put a mark against your need for help just before your second operation. (Only <u>one</u> mark).		
you had had trouble with the hip (e.g. pain and difficulties with walking). Lived at home. Help from spouse/cohabitant/ relatives Lived at home. Help from home help/home nurse Lived at home. Help from home help/home nurse Lived in home for the aged Lived in nursing home OPERATION Put a mark against type of anaesthesia during your first operation. (Only <u>one</u> mark). Put a mark against type of anaesthesia during your first operation. (Only <u>one</u> mark). Living at home. Help from spouse/cohabitant/	you had had trouble with the hip (e.g. pain and difficulties with walking).	Lived at home with no help		
ANAESTHESIA DURING THE PRIMARY ANAESTHESIA DURING THE PRIMARY Other Other Put a mark against type of anaesthesia during your first operation. (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/				
ANAESTHESIA DURING THE PRIMARY OPERATION Lived in home for the aged Lived in nursing home Lived in nursing home Other Other Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/		Lived at home. Help from home help/home nurse		
ANAESTHESIA DURING THE PRIMARY OPERATION Other Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/		Lived in home for the aged		
Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help (Only one mark). Living at home with no help				
Put a mark against type of anaesthesia during your first operation. (Only one mark). Put a mark against your current need for help (Only one mark). Living at home with no help Living at home. Help from spouse/cohabitant/		Other		
Spinal anaesthesia (awake, anaesthetised from the waist) Image: Constraint (artep) Do not know, or do not remember Image: Constraint (artep) Image: Constraint (artep) Image: Constraint	your first operation. (Only <u>one</u> mark). General anaesthesia (sleep) Spinal anaesthesia (awake, anaesthetised from the waist)	Living at home with no help		

PAIN	WALKING ABILITY		
Put a mark to describe your pain just before the first operation. (Only <u>one</u> mark).	Put a mark to describe your walking ability just before the first operation. (Only <u>one</u> mark).		
Severe and spontaneous, in rest and at night Severe on attempting to walk. Prevented all activity Tolerable, permitted limited activity Only after some activity. Disappeared quickly with rest Slight or intermittent. Pain on starting. No pain Put a mark to describe your pain just before the second operation. (Only one mark). Severe and spontaneous, in rest and at night Severe on attempting to walk. Prevented all activity Tolerable, permitted limited activity Only after some activity. Disappeared quickly with rest	Few yards or bedridden. Two sticks or crutches Very limited with or without sticks Limited with one stick (less than one hour). Able to stand long periods. Long distances with one stick. No stick but a limp Normal Put a mark to describe your walking ability just before the second operation. (Only one mark). Few yards or bedridden. Two sticks or crutches Very limited with or without sticks Limited with one stick (less than one hour). Able to stand long periods. Long distances with one stick. No stick but a limp		
Slight or intermittent. Pain on starting.	Normal		
mark). Severe and spontaneous, in rest and at night Severe on attempting to walk. Prevents all activity Tolerable, permits limited activity Only after some activity. Disappears quickly with rest Slight or intermittent. Pain on starting to walk. Getting less with normal activity No pain Did you between operations have pain that lasted for more than 6 months?	(Only one mark). Few yards or bedridden. Two sticks or crutches Very limited with or without sticks Limited with one stick (less than one hour). Able to stand long periods. Long distances with one stick. No stick but a limp Normal		

RECREATIONAL ACTIVITIES	EMPLOYMENT	
Put a mark against recreational activities before the first symptoms from the hip. (If needed use more than one alternative).	Put a mark against occupational status just before the first operation. (If needed use more than one alternative).	
Exercised seldom or never		
Gardening/Maintenance	Full time salaried work	
Walked at roads	Part time salaried work	
Walked in terrain	Unsalaried work, e.g. domestic work	
Running	Sick leave	
Cycling	Disability pension	
Skiing	Age retirement pension	
Hunting/fishing	Unemployed	
Other	Other	
Put a mark against current recreational activities. (If needed use more than one alternative).	Put a mark against occupational status just before the second operation. (If needed use more than one alternative).	
Exercise seldom or never	Full time salaried work	
Gardening/Maintenance	Part time salaried work	
Walks at roads	Unsalaried work, e.g. domestic work	
Walks in terrain	Sick leave	
Running	Disability pension	
Cycling	Age retirement pension	
Skiing	Unemployed	
Hunting/fishing	Other	
Other	Put a mark against occupational status now. (If needed use more than one alternative).	
Did you exercise or train regularly (at least once		
a week) before the first symptoms from the hip? Yes No	Full time salaried work	
	Part time salaried work	
	Unsalaried work, e.g. domestic work	
Did you exercise or train regularly (at least once a week) between operations?	Sick leave	
Yes No	Disability pension	
	Age retirement pension	
Do you exercise or train regularly (at least once	Unemployed	
a week) now? Yes No	Other	

1EMPLOYMENT					
If you were on sick-leave before the first or the second operation, please note for how long.					
Before the first ope Before the second	eration operation		☐ months ☐ months		
Were you in salaried employment between					
	Vot elevant	Yes	No		
SECOND REVISION					
Is a second revisio		prosthesi Yes	s) planned? No		
Has prosthesis nu already?		been repl	No		
If yes, please note the date of the operation					
SATISFACTION					
Put a mark against how you today evaluate the usefulness of your prosthesis operations.					
Very good Good Neither Poor Very poor					

70 Birgitte Espehaug 1998

11 Papers I to VI