HIP AND KNEE REPLACEMENT IN NORWAY

1987-2000

The Norwegian Arthroplasty Register

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1. ACKNOWLEDGEMENTS

2. LIST OF PAPERS

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

I.   Furnes O, Lie SA, Vollset SE, Engesæter LB, Havelin LI: Exeter and Charnley arthroplasties with Boneloc or high viscosity cement. Comparison of 1127 arthroplasties followed for 5 years in the Norwegian Arthroplasty Register**.** Acta Orthop Scand 1997; 68 (6): 515-20.

II.   Espehaug B, Furnes O, Havelin LI, Engesæter LB, Vollset SE. Cement type and failure of total hip replacements. J Bone Joint Surg Br 2002; (84): Accepted for publication.

III.   Furnes O, Lie SA, Espehaug B, Vollset SE, Engesæter LB, Havelin LI. Hip disease and the prognosis of total hip replacements. A review of 53698 primary total hip replacements reported to the Norwegian Arthroplasty Register 1987-1999. J Bone Joint Surg Br 2001; (83): 579-586.

IV.   Furnes O, Espehaug B, Lie SA, Vollset SE, Engesæter LB, Havelin LI. Early failures among 7174 primary total knee replacements. A follow-up study from The Norwegian Arthroplasty Register 1994-2000. Acta Orthop Scand 2002; 73 (2): 117-129.

3. BACKGROUND

3.1. HIP REPLACEMENT

3.1.1. Hip disease

Studies of the Tyrolian Iceman tell us that arthritis must have represented a problem for man even in prehistoric times (Dorfer et al. 1999).

The American Rheumatism Association has developed a set of criteria for osteoarthritis (osteoarthrosis) (Altman et al. 1986). This classification system separates patients with osteoarthritis into two categories: 1) those with no presently known prior event or disease related to the osteoarthritis (idiopathic or primary), and 2) those with known events or disease associated with osteoarthritis (secondary). Most cases of osteoarthritis of the hip (coxarthrosis) are primary (without known cause), and typically occur above the age of 60 years. The prevalence of osteoarthritis increases with age (Danielsson and Lindberg 1997), and although there is little difference between men and women regarding radiographic changes in the hip (Danielsson and Lindberg 1997), total hip replacements in Norway are, however, more prevalent in women (Havelin et al. 2000a). The Norwegian numbers are supported by a Canadian study showing that women had a higher prevalence of arthritis of the hip and knee, worse symptoms and greater disability, but the women were less likely to have undergone arthroplasty adjusted for the severity of symptoms and willingness to undergo hip or knee replacement (Hawker et al. 2000). The most common causes of secondary osteoarthritis of the hip (coxarthrosis) are paediatric hip diseases, patients with sequela after proximal femoral fractures and patients with inflammatory arthritis (i.e. rheumatoid arthritis and ankylosing spondylitis).

Radiographic primary osteoarthritis of the hip affects less than 1 % (prevalence) of the Swedish population (Malmø) under the age of 55 years, and 10 % of the population over 85 years (Danielsson and Lindberg 1997). Danielsson applied joint space narrowing as a criteria for osteoarthritis, reports from North America regard presence of ostephytes alone as radiological criteria and the reported prevalences from these countries are therefore higher than in Sweden. The incidence and prevalence of osteoarthritis in Norway is not known, although the prevalence of rheumatoid arthritis is known for Oslo County (Kvien et al. 1997).

In Norway primary osteoarthritis of the hip constitutes 69 % of the patients receiving hip prostheses, fracture of the femoral neck 13 %, childhood diseases like congenital dysplasia 7.6 %, congenital dysplasia with total dislocation 1.1 %, epiphysiolysis/Perthes' disease 1.3 %, rheumatoid arthritis 3.7 %, ankylosing spondylitis 0.5 %, and other diseases 3.3 % of the patients. These figures are based on what, in their opinion, the operating surgeons report to the Norwegian Arthroplasty Register as being the hip disease.

Osteoarthritis is a complex disease whose etiology bridges biomechanics and biochemistry. Evidence is growing for the role of systemic factors, such as genetics, diet, oestrogen use, bone density, and local biomechanical factors such as muscle weakness, obesity, and joint laxity. These risk factors are particularly important in the weight-bearing joints, and modifying them may help prevent osteoarthritis-related pain and disability (Felson et al. 2000a).

3.1.2. Treatments

Hip disease usually gives pain and stiffness of the joint. Conservative treatment should be attempted with analgesics such as paracetamol, or non-steroid anti-inflammatory drugs. Use of a cane and physiotherapy should also be attempted. Operative treatment includes osteotomies of the acetabulum or the femur in malalignments, especially after childhood hip diseases. Arthrodesis of the hip joint in young patients may still be considered in selected cases. Bone-grafting (autografts or vascularised grafts) in osteonecrosis should be considered. If these treatments do not have a satisfactory effect or the destruction of the joint is so severe that further attempts are not justified, the treatment of choice is, as it has been for the last three decades, total hip replacement (THR) (Felson et al. 2000b). In Danielssons prevalence study 55 % of the patients with radiographic osteoarthritis had undergone a total hip replacement (Danielsson and Lindberg 1997).

3.1.3. History

The term arthroplasty was originally used to mean any surgical formation or reformation of a joint. During recent decades, however, an arthroplasty has become synonymous with a joint replacement, which is an operation where the degenerated joint is replaced by an artificial joint. Joint arthroplasty dates back to 1827 when Barton used an osteotomy to produce a false joint to restore movement to a painful stiff joint (Rang 2000). Later, interposition of various

tissues such as facias was tried, starting with Verneuil and Ollier in the 1860's (Rang 2000).
Joint replacements started in the early 1890's with Gluck and Pean (Friedman 1994, Pean
1894, Rang 2000). Gluck used an ivory replacement for the upper tibia in knee replacement,
and an ivory ball for the hip. Pean constructed a shoulder prosthesis with a boiled rubber head
and a platinum tube anchored to the humeral shaft. The success of these early attempts was
limited because of infections and limitations in the materials used. In 1923 Smith-Petersen
developed mould arthroplasty of the hip, first using glass (Smith-Petersen 1948) and later in
1938 using cobalt chromium (Vitallium [RT]) to cover the head of the femur (Smith-Petersen
1939). The Smith-Petersen resurfacing was the hip arthroplasty of the 1940's and 50,s. Other
replacement prostheses such as the Judet prostheses, first inserted in 1946, became popular in
the early 1950's but did not last. The acrylic material in the Judet prosthesis soon started to
wear, break and loosen, and the prosthesis became a disaster (Faro and Huiskes 1992).
Experience with the Smith-Petersen arthroplasty showed also that an unresurfaced acetabulum
could wear out with an artificial femoral head (Aufranc 1957). John Charnley's work in the
50's and 60's marked the start of the era of modern hip arthoplasty with the development of
cemented low friction arthroplasty (Charnley 1961 and 1979). This method, that has stood the
test of time, uses a cemented polyethylene acetabular component. A stainless steel
monoblock cemented component with a small stainless steel head (22-mm) is used on the
femoral side. His low friction arthroplasty is still regarded as the "gold standard" of hip
arthroplasty.

3.1.4. Hip implants

Total hip replacement is one of the most successful surgical procedures, both in terms of
function and pain relief (Rorabeck et al. 1994), and is cost effective in improving quality-
adjusted years of life (Williams 1985, Chang et al. 1996). To ensure success, surgeons need
to use hip implants and modes of fixation of the implants that have been documented over the
years. The success of cemented Charnley low friction arthroplasty with respect to preserved
function and pain relief has been documented over more than 30 years of observation, with a
20 year revision probability of 10-16% (Schulte et al. 1993), and 30 year revision probability
of 30 % (Sochart and Porter 1997).

With an estimated 1 million total hip replacements performed each year world-wide
(Söderman 2000), even low failure rates result in large numbers of patients needing

reoperations. The most important concerns for patients and surgeons are the pain and suffering of a failed prosthesis, the increased morbidity and mortality during and after revision operations (Lie et al. 2000), and the facts that the longevity of the second prosthesis is reduced (Kavanagh et al. 1985), and that the patient satisfaction and function are poorer compared to after primary operation (Espehaug et al. 1998). The extra cost for society (Furnes et al. 1996) is also a good argument for those who are interested in the financial side of not using inferior implants and fixation methods.

In the 1970's and 1980's several popular hip prostheses had very poor results. Moreover, these poor results were often not detected until the prostheses had been used for several years and in thousands of patients. Surgeons had started to use the new prostheses, made along appealing new principles, before their clinical results were documented in controlled clinical trials.

In Norway, the surgeon Tor Christiansen constructed a prosthesis with several new details in design (Christiansen 1969). This Christiansen prosthesis became the most popular hip in Norway in the 1970's. The first Norwegian follow up study of the Christiansen prosthesis was published in 1983 (Sudmann et al. 1983). The study showed that after 5-8 years of follow up, 31 % of the Christiansen prostheses had been revised, compared to 4 % of the Charnley prostheses. It took over 10000 Christiansen prostheses and 14 years of use to prove the Christiansen inferior to the Charnley prosthesis.

The Wagner and other double cup prostheses became popular in Norway shortly after the Christiansen period. It was later documented that the results of the double cup prostheses were inferior to the Christiansen prostheses, with 30 % revised after five years and 60 % after eight years (Howie et al. 1990).

Following the double cup prostheses, uncemented hip prostheses gained popularity in Norway in the eighties. In the 1970's and early 1980's bone cement was suspected to play a major role in bone resorption and aseptic loosening of prostheses. This led to the introduction of prostheses for cementless use (Harris et al. 1976). The cementless technique relies on biological fixation provided by initial press fit insertion or screw fixation followed by bone ingrowth into a textured or porous implant surface (Galante et al. 1971). Later calcium phosphate (Ca-P) coatings like hydroxyapatite were introduced for the purpose of enhancing the bone implant ingrowth (Geesink et al. 1987, Söballe 1993).

The belief that the cement itself caused the loosening of the prostheses explains their popularity, even though no good long-term results of uncemented prostheses had been demonstrated so far. Once again new hip prostheses were riding on a wave of popularity, and surgeons used these prostheses in great numbers without any knowledge of their clinical results.

Because of the poor results with the Christiansen and the double-cup prostheses, Professor Einar Sudmann and Professor Lars B. Engesæter initiated through the Norwegian Orthopaedic Association a nation-wide registration system for total hip replacement in Norway. The Swedish knee and hip registers established in 1975 and 1979 (Knutson et al. 1986, Ahnfelt et al. 1990), together with the Finnish implant register established in 1980 (Paavolainen et al. 1991) were used as models.

It took only a short time (3-5 years) before the register indicated that inferior results were obtained with uncemented implants compared to cemented implants. This difference was largest in younger patients (Havelin et al. 1994). The inferior results were mainly attributed to the uncemented Bio-fit stem (Smith and Nephew) with a smooth surface, and the threaded uncemented Femora stem (Thackray) (Havelin et al. 1995a). Furthermore, the uncoated cementless threaded cups, metal backed or all-polyethylene, had inferior results compared to the cemented all-polyethylene cups and the uncemented cups with a porous or hydroxyapatite coating (Havelin et al. 1995c). When these results became known, use of these inferior designs was abandoned in Norway.

There were 34 different brands of acetabular components and 39 types of femoral components on the Norwegian market during the years 1987-1991. While over 1000 different component designs and sizes of these implants were marketed, 422 different acetabular and 398 femoral designs were actually used (Havelin et al. 1993). Many of these have turned out to be catastrophes.

3.1.5. Cemented fixation of hip implants

Cement provides a mechanical connection between implant and the human bone. Cement also acts as an elastic zone between implant and bone. All bone cements currently on the market are chemically based on the same basic substance: methyl methacrylate (MMA). Chemically, MMA is an ester of methacrylic acid, a substance scientists have studied intensively since the beginning of the twentieth century. Otto Röhm wrote his thesis entitled:

"Polymerization Products of Acrylic Acid" in the 1920's, (Kühn 2000). By 1928 he had already established a large-scale technical synthesis for MMA. This led to the birth of dentures using MMA, and this technique was patented in 1935. When the problems regarding technical production had been solved, the questions of how and where to use these new substances arose. By 1936 the company Kulzer had already found that a dough could be produced, by mixing ground polymethylmethacrylate (PMMA) powder and liquid monomer, that hardened when benzoyl peroxide was added and the mixture heated to $100\,^0$C. Kulzer is today's producer of the Palacos cement. The first clinical use of this PMMA cement (Paladon 65) was in an attempt to close cranial defects in monkeys in 1938. Later, chemists discovered that the polymerisation of MMA would occur by itself at room temperature if a co-initiator of tertiary aromatic amines were added. The company, Degussa and Kulzer, patented this chemical protocol in 1943 and the process is still valid to this day (patent DRP 973 590:Germany). After World War II many German patents in the field of methacrylates were handed over to the victors of the war and the use of PMMA bone cements developed independently in several countries. Kiær and co-workers in Denmark first used PMMA in 1951 as anchoring material to fix acrylic glass caps on the femoral head after removing the cartilage (Kiær 1952). Later John Charnley used bone cement to fix his low friction arthroplasty prostheses (Charnley 1961, Charnley 1972). PMMA cement soon proved to have good biocompatibility (Henrichsen et al. 1953).

At the end of the 1960's, Buchholz at the Endo-Klinik in Hamburg and the company Kulzer, were the first to add antibiotic to bone cements. This resulted in the development of the Refobacin-Palacos R cement (Buchholz and Engelbrecht 1970).

Several different cement types have been used in Norway (Havelin et al.1995b). Although each cement is mainly based upon a PMMA polymer or MMA copolymer with an MMA monomer, all cements have a distinctive formulation leading to different handling and mechanical properties. A list of the components of commercially available cements is given in Harper and Bonfields 2000.

From 1991 to 1994, Boneloc cement (Polymers Reconstructive, Denmark) was used in many European countries. It became popular because it could be mixed in a closed system, and it had a new chemical composition, which was said to be less toxic than other cements (Jensen et al. 1991, Nimb et al., 1993, Kindt-Larsen et al. 1995). In 1994, the Norwegian Arthroplasty Register found that after 3 years, Charnley prostheses fixed with the Boneloc

cement had significantly worse results than Charnley prostheses fixed with other cements (Havelin et al. 1995b). These findings contributed to the withdrawal of the cement from the international market in 1995.

A different cement, the low viscosity cement CMW3 (DePuy, England), had poor results with 5 years of follow up (Havelin et al. 1995b), although laboratory tests had shown good results. The CMW3 cement was therefore also abandoned in Norway. The high viscosity cements Palacos (Schering-Plough, US), Simplex (Howmedica, France) and CMW1 (DePuy, UK) all performed well after 5 years of observation although there was a tendency for inferior performance with the CMW1 cement (p=0.06) (Havelin et al. 1995b).

3.1.6. Hip disease and hip replacement

It has been believed that hip prostheses in patients with some hip diseases have a higher revision risk than others (Unger et al. 1987, Ahnfelt et al. 1990, Joshi et al. 1993, Malchau et al. 1993, Dorr et al. 1994) and that the type of failure may be specific to certain hip diseases (Poss et al. 1984, Unger et al. 1987, Ahnfelt et al. 1990). These beliefs were based on results from small studies (Unger et al. 1987, Joshi et al. 1993, Dorr et al. 1994) or studies where the type of prosthesis had not been taken into account (Ahnfelt et al. 1990, Malchau et al. 1993).

In Norway, as in most other countries, uncemented prostheses are most commonly used in young patients (<60 years) (Havelin et al. 1993). Thus, in many clinical materials the common combination of known negative prognostic factors such as young age, male gender and the use of "first and second generation" of uncemented prostheses, has given inferior results. This may have led to the conclusion that the primary hip diseases in these young male patients were responsible for the higher revision rate.

3.2. KNEE REPLACEMENT

3.2.1. Knee disease

The American Rheumatism Association has developed a set of criteria for osteoarthritis (Altman et al. 1986). This classification system separates patients with osteoarthritis into two categories: 1) those with no presently known prior event or disease related to the osteoarthritis (idiopathic or primary); and 2) those with known events or disease associated with osteoarthritis (secondary). Most cases of osteoarthritis of the knee (gonarthrosis) are primary

(without known cause), and typically occur above the age of 60 years as in the hip. The prevalence of osteoarthritis of the knee increases with age (Lawrence et al. 1998). In the knee, radiographic evidence of disease is slightly higher in women (Felson et al. 1987, Lawrence et al. 1998), and there is a significantly higher proportion of women with symptomatic disease (Felson et al. 1987). Among U.S. adults 30 years of age or older, symptomatic disease in the knee occurs in approximately 6 % and symptomatic hip osteoarthritis in 3 % (Felson et al. 2000a). There is also a greater number of total knee replacements in Norway in women than in men. The most common causes of secondary gonarthritis are sequela after fractures, ligament and meniscal injuries and osteoarthritis on the basis of inflammatory arthritis (i.e. rheumatoid arthritis and ankylosing spondylitis).

In Norway, patients with primary osteoarthritis of the knee constitute 76 % of the patients receiving knee prostheses, rheumatoid arthritis 15 %, fracture sequela 4.1%, meniscal sequela 3.4 %, ligament injury sequela 1.4%, psoriatic arthritis 0.7%, ankylosing spondylitis 0.5 % and other diseases 3.4 % of the patients. These figures are based on what the operating surgeons report to the Norwegian Arthroplasty Register.

Osteoarthritis is a complex disease whose etiology bridges biomechanics and biochemistry. Evidence is growing for the role of systemic factors, such as genetics, diet, oestrogen use, and bone density, and local biomechanical factors, such as muscle weakness, obesity, and joint laxity. These risk factors are particularly important in the weight-bearing joints, and modifying these factors may help prevent osteoarthritis-related pain and disability (Felson et al. 2000a).

3.2.2. Treatments

Knee disease usually gives pain and stiffness of the joint. Conservative treatment comprises weight reduction, health education, analgesics like paracetamol and non-steroid anti-inflammatory drugs, use of a cane, physiotherapy and change of physical activity to a tolerable level. Operative treatment includes arthroscopic debridement, osteotomy, arthrodesis and arthroplasty (Buckwalter and Lohmander 1994). Biological approaches to the surgical treatment of osteoarthritis have been explored. However, the repair of articular cartilage remains elusive, and the statement by Hunter in 1743 that "ulcerated cartilage is a troublesome thing, once destroyed is not repaired" remains true today. Biological restoration of articular cartilage loss can be approached using two different treatment strategies. In the

first approach, the resident hyaline cartilage is stimulated to repair the defects by mechanical means, such as osteotomy, or by biological enhancement of bone marrow cells or growth factors. In the second approach, cartilage transplantation, the articular cartilage is replaced with adult's tissue or cells. Three types of cartilage transplantation are available: osteochondral autografting, osteochondral allografting and use of tissue engineering to transplant differentiated or undifferentiated chondrocytes (Brittberg et al. 1994, Felson et al. 2000b). Tissue engineering is still in its infancy, and only preliminary experimental and clinical studies are available.

If knee replacement is warranted, the treatment of choice in most cases for the last two decades has been total knee replacement (Buly and Sculco 1995, Robertsson 2000a)

3.2.3. History

In 1940, Campbell reported the use of an interposition arthroplasty made of cobalt chromium (Vitallium^{RT}) in the knee (Campbell 1988). He was inspired by Smith-Peterson's good results from the hip (Smith-Petersen 1939) and his own experience with fascia lata interposition of the knee (Campbell 1931). The cobalt chromium was well tolerated, but the prosthesis did not produce sufficient pain relief (Guyton 1998). Shiers and Waldius constructed hinged prostheses in the 1950's. The results of the cemented hinged Waldius knee were reported in 1973 (Bain 1973) with functional improvement, but the problems at 3 years follow up of 100 patients were 7 deep infections, 5 aseptic loosening and one fracture. The hinged prostheses were abandoned and condylar prostheses were developed. In 1971, Gunston (Gunston 1971) reported his early results with the polycentric knee, in which he incorporated many of the concepts of Charnley's low friction arthroplasty of the hip. The components were fixed with PMMA cement. The polycentric knee enjoyed early success with its improved kinematics over hinged implants, but it tended to fail because of inadequate fixation of the prosthesis to bone (Guyton 1998).

Other attempts were the Duo Condylar developed by Walker (Ranawat and Shine 1973), the Oxford knee by Goodfellow and O'Connor (Goodfellow and O'Connor 1978) (Biomet, Warzaw, IN) and the Modular knee (Smith and Nephew, Memphis, TN) developed by Marmor (Marmor 1973). These designs used two separate unicondylar prostheses operated in as a total knee prosthesis. Poor fixation and deformation of the tibial component was observed. The same designs showed relatively better results when implanted in the medial or

the lateral compartment only and are still used with small design modifications as unicondylar prostheses (Marmor 1988, Cartier et al. 1996, Lewold et al. 1998, Murray et al. 1998).

In 1974, Insall and associates introduced the total condylar prosthesis (Johnson and Johnson, New Brunswick, NJ and Howmedica, Rutherford, NJ) at the Hospital for Special Surgery in New York. This prosthesis has set the standard for knee replacements with 94% survival at 15 years (Ranawat et al. 1993).

3.2.4. Knee implants

Total knee replacement is a successful surgical procedure, both in terms of pain relief (Hawker et al. 1998) and in cost effectiveness (Zicat et al. 1993, Callahan et al. 1994, Lavernia et al. 1997, Rissanen et al. 1997). To ensure success, surgeons need to use knee implants and modes of fixation of the implant that have been documented over a number of years.

Two of the early criticisms of the total condylar prosthesis were its tendency to subluxate posteriorly in flexion if the flexion gap was not balanced perfectly with the extension gap and a smaller range of flexion compared with prosthetic designs that allow femoral roll-back to occur. To correct these problems the Insall-Burstein posterior-stabilised knee or posterior cruciate-substituting knee was introduced (Zimmer, Warsaw, IN). This was a modification of the total condylar knee with a central tower on the tibial component and a corresponding "box" or indentation on the femoral component. The idea was to simulate the function of the posterior cruciate ligament (PCL) and facilitate femoral rollback. This should increase flexion and decrease the risk of dislocation. The mid-term report of this prosthesis has been good (Aglietti et al. 1999).

In the late 1970's and early 80's implant fixation and wear of the tibial polyethylene were recognised as problems for long term survival of knee prostheses. Buechel introduced the LCS (Low Contact Stress) knee in 1977 (DePuy, Johnson and Johnson, Warsaw, In) (Buechel and Pappas 1990). This prosthesis could be used with one moveable polyethylene platform or two meniscal bearings. It had some similarities to the Oxford design, but the meniscus/menisci were supported by a central stud or separate grooves on the tibial component to reduce the risk of dislocation. These design features were intended to decrease the fatigue wear associated with failure of the polyethylene in knee replacement. The

prosthesis has gained widespread interest, and now nearly all manufacturers of knee prostheses offer a mobile bearing solution (Callaghan et al. 2001).

Knee joint replacement with total condylar knee prostheses fixed with methyl methacrylate bone cement has been established as a successful procedure (Ranawat et al. 1993, Ritter et al. 1995). Some new designs, which were introduced on the market without clinical documentation, have performed poorly (Bauer 1992, Goodfellow 1992). The poor results were probably caused by the use of uncemented implants, thin or poor quality polyethylene and metal backing of the patellar components (Engh 1988, Goodfellow 1992, Goodman and Lidgren 1992, Toksvig-Larsen et al. 1996).

Large scale comparative studies of knee prostheses are few (Knutson et al. 1986, Rand and Ilstrup 1991, Knutson et al. 1994, Robertsson et al. 2001), and future studies are needed to guide surgeons in their choice of implant type (Liow and Murray 1997). In a large study by the Mayo Clinic total condylar knee replacements of the resurfacing type with metal backed tibial components had good results compared to other designs (Rand and Ilstrup 1991), and most of the knee prostheses used in Norway today are of this design.

Still there are extensive discussions regarding whether the patella should be resurfaced or not, whether to use a rotating tibial insert or not, and finally whether to use uncemented or cemented fixation (Bourne et al., 1995, Vince 1996, Whiteside 1996, Callaghan et al. 2001).

When our national registration of knee implants started in 1994, only 3 of the 6 prostheses brands used on the Norwegian market, the AGC, LCS and Tricon prostheses, had published mid term (6-10 years) results (Buechel and Pappas 1990, Knutson et al. 1994).

3.2.5. Fixation of knee implants

Due to supposed negative effects of bone cement (PMMA), such as third body wear, thermal necrosis and toxicity, cementless total knee replacement was reintroduced in the late 1970's. The Primary Porous-Coated Anatomic (PCA) total knee prosthesis (Howmedica, Rutherford, NJ) was the first of the porous-coated prostheses aimed at bony ingrowth that was commercially available (Hungerford and Kenna 1983). Short and intermediate results were promising, but during the late 1980's it became evident that both the PCA total knee prosthesis and PCA unicondylar knee prosthesis gave poor results (Bauer 1992, Goodfellow 1992).

Galante studied porous titanium fiber-metal mesh surfaces in the 1970's (Galante et al. 1971). Several clinical studies have since been conducted with this type of implant (Rosenberg et al. 1990). Recently Gallant and co-workers concluded that, based on their 11 years clinical results, they have abandoned cementless fixation in total knee arthroplasty (Berger et al. 2001).

Freeman developed an uncemented polyethylene interlocking prosthesis (ICLH), but the clinical results were discouraging (Albrektsson and Herberts 1988).

Hydroxyapatite (HA) has been introduced in knee replacement surgery. A HA-coating has been shown to enhance bone ingrowth and stability of implants compared to non-coated titanium implants, especially in the early phase of fixation. Önsten and co-workers compared hydroxyapatite porous coated tibial components with porous coated and cemented components in a RSA study. After 2 years no significant difference in migration between HA coated and porous coated implants were found; both these components migrated more than the cemented group (Önsten et al. 1998). In general, cementless fixation of tibial components has so far not proved to be superior compared to cemented fixation, but new ceramic coatings, additional fixation with screws and stem seem to display a good clinical outcome in the short-term (5 years) (Regner 1998). However, since the results of the original cemented total condylar prostheses were published (Ranawat et al. 1993) and other cemented prostheses reported excellent results (Rand and Ilstrup 1991), cemented fixation has become the gold standard of knee fixation.

3.3. INTRODUCTION OF NEW IMPLANTS AND CEMENTS IN IMPLANT SURGERY

3.3.1. Regulations for introduction of new implants and cements

Our knowledge of the clinical effectiveness and safety of implanted medical devices is generally weaker than for drugs (Bright 1999, Ramsey et al. 1998). Marketing regulations both in the United States and Western Europe have been less strict for medical devices than for drugs (Reigstad 1993 and 1996). The Norwegian laws are conformed to EU regulations by "Lov om medisinsk utstyr 1995, 12. januar nr.6" and by "Forskrift om medisinsk utstyr av 12. januar 1995". Implants and cements have to follow directive 90/385 from the EU about

active implantable medical devices. Companies wishing to market an orthopaedic implant need to provide documentation that the implant meets the standards outlined for that implant.

The standardization process for cements started in the US, where "the Standard Specifications for Acrylic Bone cements" was developed in 1978 by the American Society for Testing and Materials (ASTM). On its basis, the protocol International Organisation for Standardisation (ISO) 5833/1 (1979) was developed. Today, all bone cements must comply with the present standards ISO 5833/2 (1992) and ASTM F451-99a (ASTM 1999).

In Europe bone cements were considered to be drugs until June 1998, but are now looked upon as medical devices according to the medical device law. Thus registration of new products can be obtained through Notified Bodies. The Notified Bodies use documentation produced by the companies to ascertain that the product complies with the ISO standards. Recently bone cements were reclassified also in the US and in the future a pre-market approval (PMA) by the food and drug administration (FDA) may no longer be necessary before placement on the market. Registration of bone cement can now be attained via a pre-market notification process (510 (k)) (Ramsey et al. 1998). In the USA, to obtain FDA approval of a medical device through the 510 (k) program, manufacturers must demonstrate that their product is substantially equivalent to a device marketed before the 1976 Medical Device Amendments. The amendments do not define substantial equivalence, and it is not clear whether this term refers to safety and efficacy or to the physical characteristics of the device. New devices that are not equivalent to any pre 1976 device have to be approved through the PMA program. There is substantial difference in review time and expense between the 510 (k) and PMA programs. The average time of review and expenditure for a 510 (k) application is about 178 days and 13 million US$, respectively, versus 357 days and 36 million US$ for PMA applications. In contrast, new drug applications cost as much as 231 million US$ and take from 4 to 12 years from first submission to approval for marketing. To acquire safety and performance data for 510 (k) and PMA evaluations, the FDA allows manufacturers to introduce experimental devices into clinical use under the Investigational Device Exemption (IDE) program. An IDE-approved device can be used only in the context of a clinical study. The studies do not necessarily have to be randomised or have a control population, although the FDA encourages controlled clinical investigations. In practice, most device evaluations are neither randomised nor controlled studies. Manufacturers have responded to FDA device regulations largely by developing products that can be approved

through the 510 (k) process. Nearly 98% of devices entering the US market each year have been reviewed through the 510 (k) submission process (Ramsey et al. 1998). The consequences this will have, especially on the quality of new bone cements introduced onto the market, remain to be seen.

For orthopaedic implants there are at least 17 ISO orthopaedic standards and in addition there are ISO standards for the different metals, polyethylene and ceramics. The two standards: Non-active surgical implants: general requirements (ISO 14630:1997) and Non-active surgical implants, joint replacements, particular requirements (EN 12010:1998 by CEN) outline the general requirements in the EU market. These standards do not absolutely demand clinical testing of new implants before they are permitted CE-marking, the so-called permission to sell the product. The producer is obliged to report poor performance and adverse effects through Vigilance Secretariats set up by the health authorities in each country. Since it can take 5-10 years to reveal poor performance, thousands of prostheses could be sold on the market before the product is stopped by this control system. The problem with today's regulations can be illustrated by the fact that a product with the same biochemical and biomechanical test results as the Boneloc cement would still be allowed to be marketed.

Another side effect of this process is that products that have a proven clinical record but no CE marking, like the "Norway elbow prostheses" (Risung 1997), disappeare from the market. The Norway elbow prostheses were used in a small number of rheumatoid arthritis patients and produced by a small company that did not have the financial means of putting the product through the CE and FDA approval process.

3.3.2. Recommendation for new implants and cements for joint replacement
Since some good implants and cements already exist (Ranawat et al. 1993, Murray et al. 1995, Ritter et al. 1995, Baxter and Bevan 1999, Havelin et al. 2000a, Herberts and Malchau 2000, Puolakka et al. 2001), there must be very good reasons and documentation for using new products. However, this is not always the case. Due to the negative consequences of poor implants and cements on patients and society (Kavanagh et al. 1985, Furnes et al. 1996, Espehaug et al. 1998, Lie et al. 2000a) a surgeon should demand the following before using a new implant or cement in patients: Laboratory testing of the implant/cement, including testing of biomechanical, metallurgical and biochemical properties. Randomised studies comparing the new product to a proven implant using RSA technique. The follow up in RSA

studies should be at least two years (Faro and Huiskes 1992, Malchau 1995, Nilsson and Kärrholm 1996).

New implants or cements should only be used in clinical trials. After this the implants and cements should be followed in registers and every country should probably have its own implant register.

4. THE NORWEGIAN ARTHROPLASTY REGISTER

4.1. The Hip Register

Because of the poor results with the Christiansen and the double-cup prostheses, Professor Einar Sudmann, Dr. Lars B. Engesæter and Dr. Tor Steinar Raugstad started to work towards establishing a national hip implant register via the Norwegian Orthopaedic Association in 1983. Dr. Leif Ivar Havelin has been in charge of the day to day work of the register since 1987, and registration started the 15th September in 1987. It became located at the Haukeland University Hospital, with doctors only working on it in their spare time. Co-operation with the Section for Medical Statistics (SMIS), Department of Public Health and Primary Health Care, University of Bergen was started in 1991. Investigations in the register have since been planned and conducted jointly with Professor Stein Emil Vollset from SMIS. From 1992 to date, the register has been part of the Department of Orthopaedics with a consultant orthopaedic surgeon as head of the Register.

It was decided that the main aim of the Hip Register should be to detect inferior results of hip implants as early as possible, and the register was designed according to this aim. It was expected that a major long-term problem would be the participation of the surgeons, and the registration forms were therefore made as simple as possible to fill in. Of reoperations, only revisions with a surgical insertion, removal or exchange of a part of or of the whole implant were to be registered. Thus, no other reoperations such as closed reductions of dislocated prostheses were included. The register is nation-wide so as to include as large a number of patients as possible and to follow patients even when they were reoperated at other hospitals than that at which their primary operation had been performed.

Two doctoral theses have been produced so far with data from the Norwegian hip register (Havelin 1995 and Espehaug 1998).

4.2. The establishment of the Knee and Other Joints Register

Encouraged by the initial results of the hip register (Engesaeter et al. 1992) and the results of the Swedish knee arthroplasty register (Knutson et al. 1986), Norwegian orthopaedic surgeons wished to follow the quality of implants in other joints than the hip. The expansion of the register was further justified by setbacks in knee prosthesis surgery from the 1980's (Bauer 1992, Goodfellow 1992). Dr. Ove Furnes started developing the registration forms for knee

and other joints in 1992 (Appendix 3 and 4) in co-operation with Dr. Leif Ivar Havelin and Professor Lars B. Engesæter. Financial support from the Norwegian Medical Association's fund for Quality Improvement was received from 1993 to 1996. This made it possible to extend the register to knee and other joints in 1994, and registration started 1st January 1994.

Statistician Stein Atle Lie was employed in august 1993 and created the database for knee and other joints. He worked until 1st October 1997, when statistician Birgitte Espehaug, PhD, took over his work. Stein Atle Lie then started working as a research fellow in the register. Later Dr. Asgeir Furnes temporarily took over the work of Ove Furnes while he worked as a registrar at the Department of Surgery, Diakonissehjemmets University Hospital, Haraldsplass and Hagavik Orthopaedic Hospital, University of Bergen during the years 1993-1996. Dr. Ove Furnes restarted register work and became responsible for the registration of knee and other joints in 1995 when Dr. Asgeir Furnes left for a position as a consultant orthopaedic surgeon at the Central Hospital in Skien in 1995.

The main aim of the register for knee and other joints was to detect inferior results of knee and other joint implants as early as possible and to survey implant surgery in Norway, and the register was designed with this aim in mind.

4.3. Staff

At the present time the staff consists of 1½ secretaries, Mrs. Inger Skar and Mrs. Adriana Opazo. Mrs. Kari Tollefsen Strømme worked as a secretary in our staff from 1991-1997. The register has one position for an orthopaedic surgeon and this position is split between 3 doctors: Dr. Leif Ivar Havelin in a 60% position as head of the register, Professor Lars B. Engesæter in a 20% position, and Dr. Ove Furnes in a 20% position as head of knees and other joints. Birgitte Espehaug, PhD, works as a statistician in a full position and prepares annual reports and scientific publications in collaboration with the orthopaedic surgeons. The register also has one research fellow, Stein Atle Lie, MSc, who is financed externally. There are weekly meetings with Professor Stein Emil Vollset at the Section for Medical Statistics at the University of Bergen.

4.4. Funding

Funding has been a problem from the beginning. The health authorities usually have a great interest in register studies, but experience shows that it takes time to get financial support

from that source. At the present time (2001) the Government covers practically all expenses for the Norwegian Arthroplasty Register, about 1.4 million NOK or 175 000 Euro, annually. The cost per registered joint replacement is approximately 22 Euro. In comparison, the register in Trent, England, costs roughly £50 (80 Euro) per total hip replacement (Fender et al. 1996). Norway has 4.4 million inhabitants. Reports are received from about 9000 operations annually, and the register now (2001) contains approximately 90000 operations.

The register has been supported by grants from the Norwegian Medical Association's Fund for Quality Improvement, the Norwegian Research Council, the University of Bergen, Dr. Trygve Gythfeldt og frues forskningsfond, Norske Kvinners Sanitetsforenings forskningsfond, Aslaug Andersens fond for revmatologisk forskning and the Norsk Revmatikerforbund.

The Norwegian Arthroplasty Register assesses results of implants or treatment systems made by industrial companies, and we believe that it is preferable that we are financially independent from the industry.

4.5. Governmental involvement

In recent years we have seen a growing interest from the Government for co-operation and use of material from our register. The office of the Auditor General (Riksrevisjonen) has requested data about operations and would like to use this to investigate effectiveness in Norwegian Hospitals. SINTEF-UNIMED Health Services Research has produced a report on county differences in primary and revision hip replacement surgery in co-operation with the register (Hansen 2000).

The Norwegian Parliament has recently passed a new law on health registers (Lov 2001-05-18 nr.24: Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)) that will be effective as of 01.01.2002. This law protects patients and ensures that health related information will be used in the health service and ensures that the Government is provided with knowledge for implementing better administration, quality assurance, planning and guidance of resources. Lately, the Norwegian Board of Health (Statens Helsetilsyn) has produced a report : "National Medical Quality Registers: Framework and guidelines for establishment and operation, March 2001" (Nasjonale Medisinske Kvalitetsregistere: rammeverk og retningslinjer for etablering og drift). The guidelines have

not yet been approved and implemented, but will probably influence the work of the Norwegian Arthroplasty Register.

The future funding and ownership of medical quality registers is not solved. The Government would like to own the quality registers. The view of our register and the Norwegian Orthopaedic Association is that the Norwegian Arthroplasty Register should be owned by the Norwegian Medical Association through the Norwegian Orthopaedic Association and funded by the Government. The daily running of the register should be handled through a clinical or university department with a clinical doctor as head of the register. This is to ensure good quality handling of data and that results are communicated back to the operating surgeons and used in daily clinical work.

5. AIMS OF THE PRESENT STUDY

Based on data from the Norwegian Arthroplasty register the aims of the study were to

1. Assess the short-term (5 years) results of Boneloc cement used with different hip prostheses brands.
2. Assess the impact of cement types on the mid term (0-12 years) results of hip replacement surgery.
3. Assess the influence of various hip diseases on the results of hip replacement surgery.
4. Establish a register and survey total knee replacement surgery in Norway.
5. Compare the results of cemented knee prostheses brands.
6. Assess the results of bicompartmental and tricompartmental total knee replacements.
7. Compare the results of cemented and uncemented total knee replacements.

6. MATERIALS

All the papers in this thesis are based on data from the Norwegian Arthroplasty Register.

In *Paper I*, on Boneloc cement and hip prostheses, all patients in the register operated with Boneloc cement were included and compared with patients operated with high viscosity cemented prostheses. The following cement and prostheses brands combinations were analysed: Boneloc/Charnley (n=955), Boneloc/Exeter (n=172), high viscosity/Charnley (n=6621), high viscosity/Exeter (n=1645). Boneloc with other prostheses brands (n=69) were excluded from further analyses. We included only cases where the same type of cement and prosthesis were used in both acetabulum and femur. The patients, operated between 1991-1994, were followed until 31st January 1996, a follow-up of 0-5 years.

In *Paper II*, on high and low viscosity cement types, only patients with primary coxarthrosis and without any previous operation in the index hip and who had been given a primary Charnley prosthesis were included (n=17323). The operations were performed between 15th September 1987 and 1st May 2000, a follow-up of 0-12 years. We included only cases where the same cement type was used in acetabulum and femur. Only cases with the most common cement types, Palacos with (n=9186) and without (n=2115) gentamicin, Simplex (n=736), and CMW 1 with (n=1394) and without (n=3306) gentamicin and CMW3 (n=586), were included.

In *Paper III*, on hip disease, all hip prostheses in the register (n=53698) between 15th September 1987 and 1st February 1999 were studied, a follow-up of 0-11.5 years. Separate analyses were made on a more homogenous subgroup of patients operated with Charnley prostheses cemented with Palacos cement with and without gentamicin or Simplex cement (n=16217).

Paper IV surveys knee prosthesis surgery in Norway. All primary total knee replacements (TKRs) (n=7174) reported between 1st January 1994 and 1st May 2000, a follow-up of 0-6.3 years, were analysed.

7. METHODS

7.1. Data collection

Surgeons report the patient's national personal identification (ID) number to identify the patient (Havelin 1999). The surgeon therefore needs the patient's consent to be allowed to send data to the register. A consent form was formulated in 1998. By using ID numbers, information on outcomes (revisions) can be linked to the baseline information (primary operation) even if the revision is performed at another hospital than that of the primary operation. With such a system, and when all hospitals and all surgeons are participating and where data on patients' deaths or emigration are available, the follow-up of patients can be nearly complete.

To ensure nearly complete and accurate reporting we followed a few important principles when the register was established. The surgeon performs reporting immediately after the operation. Short and simple forms were used (Appendix 1-4), since the level of dedication may vary among the participants. As cases with incomplete information usually cannot be included in the statistical analyses, only information that is essential and easily available for the reporting surgeons, was asked for.

We followed the same procedure for knee and other joints as for hip implants (Havelin 1999, Havelin et al. 2000a).

7.2. Classification, coding and data systems

The date of the operation (primary or revision) and information such as diagnosis or reasons for re-operation, type of revision, approach, use of bone transplant, prostheses, cement, and antibiotic prophylaxis, are necessary information. The Norwegian Arthroplasty Register collects separate data on the proximal (e.g. cup in hip, and femur in knee), distal (e.g. stem in hip and tibia in knee), and intermediate (e.g. head in hip and patella in knee) prosthesis components and on catalogue number level. In this way, results for the different implant designs, can be calculated separately, both for proximal and distal components. To ensure accurate information on the implant, the surgeons use stickers with the catalogue numbers of the implants supplied by the manufacturers.

Arild Berger at the Department of Information Technology, Haukeland University Hospital, developed the hip register database. Dr. Leif Ivar Havelin coded the implants in the hip register.

Coding of the implants in the knee and other joints register was done by Dr. Asgeir Furnes and Dr. Ove Furnes. Ove Furnes has updated the database since 1995 with codes for new prostheses as soon as new implants have been reported to the register. Coding lists for prosthesis components, cement, antibiotic, diagnosis, and all the other groups have been updated continually. For the first two years a separate PC unit using Paradox (Borland) was set up for the knee and other joints. Statistician Stein Atle Lie developed the database. A similar system was planned for the hip register. However, Haukeland University Hospital then updated its old mainframe (Norwegian Data-ND) system to a MS-Windows NT Environment with PC units and MS-Windows Office Professional as a standard. It was therefore sensible to convert the hip register from the mainframe system to MS-Access database; this was done in 1995. The old text files with the hip prostheses catalogue with more than 6000 lines of hip prostheses was manually converted to an MS-Access database and connected to the hip register. This connection also gave the possibility to use the prostheses database as look-up menus. Furthermore, application for look-up tables (hospitals, diagnosis etc), tools for making reports, checking of the data-quality within the database and a design for the register's annual report was constructed. The established register for knee and other joints was then converted to the same system in 1996. The data system for the Norwegian Arthroplasty Register thus consists of two databases for the joint replacements (hips and other joints), two databases for the look-up and control tables, two databases with the applications, two databases for the prostheses components and finally a database with the main menu for the system.

The responsibility for the technical and data safety system for the register is now under the Department of Information Technology at Haukeland University Hospital. This ensures a higher level of security than the more vulnerable set-up with the separate PCs. The responsibilities for the software solutions are still that of the register staff.

The Data Inspectorate (Datatilsynet) has given the Norwegian Arthroplasty Register a permanent concession, as of 1998, to collect data on joint replacements in Norway. This concession demands consent from all patients included in the register. The Data Inspectorate has inspected the data-security, with the latest inspection in March 1999.

7.3. Quality control of data

The secretaries consulted Dr. Ove Furnes for knee and other joints and Dr. Leif Havelin for hips if the written forms from the surgeons were difficult to interpret. Forms that had incomplete information were returned to the hospital of source. When the yearly reports were made, illogical information was corrected. In 1995-1997, the Norwegian Arthroplasty Register compared its data with information from the Norwegian Patient Register (NPR). This is the official hospital discharge register in Norway, located at SINTEF-Unimed in Trondheim. In this period 18269 hip replacements were reported to the Norwegian Arthroplasty Register and 17857 to NPR. Thus the hip register had 2.3 % more reported hips than NPR. In the same period 3726 knees were reported to the Norwegian Arthroplasty Register and 3687 to NPR, representing 1% more reported knee prostheses to the knee register than to NPR. Reporting to the Norwegian Arthroplasty Register was lower than to NPR for other joints, especially for shoulder and toe joints. After this and earlier surveys, all hospitals were given an overview of the discrepancies between the reports to NPR and the Norwegian Arthroplasty Register and were asked to report the missing cases. A summary of the study was given in Norsk Ortoped Post 1999; (3) and at the annual spring meeting of the Norwegian Orthopaedic Association, Haugesund 1999. We plan to continue the regular comparisons with NPR in the future. We also co-operate with hospitals when they are doing retrospective or prospective studies on their operated patients (Frøen and Lund-Larsen 1998). In this way, we reveal differences between the register and the hospitals' records, which are then used to update our database.

7.4. Statistical methods

Prosthesis survival was calculated by the Kaplan-Meier method (Kaplan and Meier 1958) in all the papers. The median follow-up was calculated by the reverse Kaplan-Meier method (Schemper and Smith, 1996). The log-rank test (Mantel 1966) was used to reveal statistically significant differences between groups in the Kaplan-Meier analyses. Patients who died or emigrated during follow-up were identified from files provided by Statistics Norway, and the follow-up time for the prostheses in these patients was censored at the date of death or emigration. A Cox multiple regression model (Cox 1972) was used to study relative risks

(incidence rate ratios) among the prosthesis brands and to adjust for potential confounding by age (usually <60, 60-70, >70 years), gender, and diagnosis in all the papers. Other confounders were also studied. Separate analyses in the age group under 60 years were undertaken in Papers III and IV.

Estimates from Cox analyses with type of prosthesis or cement as the stratification factor were used to construct adjusted survival curves at mean values of the risk factors in Papers II, III and IV. The statistical analyses were performed using the software SPSS (SPSS Inc. 1999) and S-PLUS (Statistical Sciences Inc. 1995).

8. REVIEW OF PAPERS

Exeter and Charnley arthroplasties with Boneloc or high viscosity cement. Comparison of 1127 arthroplasties followed for 5 years in the Norwegian Arthroplasty Register.
Ove Furnes, Stein Atle Lie, Leif Ivar Havelin, Stein Emil Vollset, Lars Birger Engesæter

During the years 1991-1994 the Norwegian Arthroplasty Register recorded 1324 primary hip arthroplasties implanted with the Boneloc cement. We compared survival until revision due to aseptic loosening for Charnley (n 955) and Exeter (n 172) prostheses. The Boneloc cemented hips were also compared with high viscosity cemented hips implanted during the same period.

In the Boneloc cemented group the estimated probability of survival at 4.5 years of a Charnley femoral component was 74.1% and for an Exeter femoral component 97.0% (p<0.0001). Using a Cox regression model with adjustment for age, gender, type of cement, systemic antibiotic and stratified for diagnosis, an 8 times higher risk of revision was found for Boneloc cemented Charnley femoral components compared to Exeter femoral components (p<0.0001). For the acetabular components the difference between the Charnley and Exeter components with Boneloc cement was not significant.

For both the Charnley and the Exeter prostheses, the high viscosity cemented components had significantly better survival than the Boneloc cemented components. The Cox regression model showed that a Boneloc cemented Charnley femoral component had a 14 times higher risk of revision than a high viscosity cemented component (p<0.0001), and for Exeter femoral components a 7 times higher revision risk was found for the Boneloc cemented components (p=0.003).

Our results confirm the previously reported inferior results of Charnley prostheses implanted with Boneloc cement, and establish inferior results for Boneloc cemented Exeter prostheses as well, but less pronounced than for Charnley prostheses.

PAPER II

Cement type and failure of total hip replacements.

Birgitte Espehaug, Ove Furnes, Leif Ivar Havelin, Lars Birger Engesæter, Stein Emil Vollset

We assessed the survival of 17323 primary Charnley hip prostheses in coxarthrosis patients according to the cement type used for fixation of the implant.

Overall, 9.2 % of the implants had been revised (failed) after 10 years of follow-up, and 71 % of the failures involved aseptic loosening of the femoral component. We observed important and highly significant increased failure rates for prostheses inserted with the CMW1 and CMW3 cements. Using implants fixed with gentamicin-containing Palacos cement as the reference, the adjusted Cox-regression failure rate ratios were 1.1 (95 % CI: 0.9 – 1.4) for implants cemented with plain Palacos, 1.1 (CI: 0.7 – 1.6) with Simplex, 2.1 (CI: 1.5 – 2.9) with gentamicin-containing CMW1, 2.0 (CI: 1.6 – 2.4) with plain CMW1, and 3.0 (CI: 2.3 – 3.9) for implants fixed with the CMW3 cement. The adjusted 10-year failure rate varied from 5.9 % for implants with gentamicin containing Palacos cement to 17 % for those with CMW3 cement.

PAPER III

Hip disease and prognosis of total hip replacement.

A review of 53698 primary total hip replacements reported to the Norwegian Arthroplasty Register 1987-1999.

Ove Furnes, Stein Atle Lie, Birgitte Espehaug, Stein Emil Vollset, Lars Birger Engesæter, Leif Ivar Havelin

We studied the revision rates for primary total hip replacements (THR) (n=53698) in 9 different hip disease groups.

The distribution of factors that have previously been shown to be associated with increased revision risk, such as male gender, young age, and certain types of uncemented prostheses, showed important differences across the diagnostic groups. Without adjustment for these factors we observed an increased revision risk for THR in patients with paediatric hip diseases and in a small heterogeneous patient group "others" compared to patients with primary coxarthrosis. However, most differences were reduced or disappeared when adjustments for the prognostic factors were made. After adjustment, an increased relative revision risk (RR) compared to primary coxarthrosis was seen in hips with a sequela after fracture of the femoral neck (RR=1.3, p=0.0005), in hips with congenital dislocation (RR=1.3, p=0.03), and in the heterogeneous rest group "others". The analyses were also performed in a more homogenous subgroup of patients that had been given a Charnley prosthesis with high viscosity cement (n=16217). The only difference that remained in this group was an increased risk for revision in hips with sequela after fracture of the femoral neck (RR=1.5, p=0.0005).

In conclusion, THR for diagnoses mainly seen among young patients had a good prognosis per se, but these patients had more often received inferior uncemented implants. If a cemented Charnley prosthesis is used, the type of hip disease leading to THR seems in most cases to have only a minor influence on the survival of the prosthesis.

PAPER IV

Early failures among 7174 primary total knee replacements. A follow-up study from The Norwegian Arthroplasty Register 1994-2000.

Ove Furnes, Birgitte Espehaug, Stein Atle Lie, Stein Emil Vollset, Lars Birger Engesæter, Leif Ivar Havelin

Primary total knee replacements (TKRs), reported to the Norwegian Arthroplasty Register, operated between 1994 and 2000 were investigated.

A Cox multiple regression model was applied to study differences in survival among the prosthesis brands, the types of fixation, and whether the patella was resurfaced or not.

In Norway, in 1999, the incidence of use of knee prosthesis operations was 35 per 100 000 inhabitants. Cement was used as fixation in 87 % of the knees, 10 % were hybrid and 2 % were uncemented implants. Bicompartmental (nonresurfaced patella) prostheses were used in 65 % of the knees. With all revisions as endpoint, no statistically significant differences in the 5 year survival was found among the cemented tricompartmental prostheses brands: AGC 97.4 % (n=279), Duracon 98.6 % (n=101), Genesis I 95.2 % (n=654), Kinemax 97.5 % (n=213) and Tricon 96.0 % (n=454). The bicompartmental LCS prostheses had a 5 year survival of 97.2 % (n=476). The type of meniscal bearing in LCS knees did not influence the survival.

Survival with revision due to all causes as endpoint, did not reveal differences among types of fixation, or among bi- or tricompartmental prostheses. Pain alone was the most common reason for revision in cemented bicompartmental prostheses. The revision risk due to pain was 5.7 times higher (p<0.001) in cemented bicompartmental prostheses compared with cemented tricompartmental prostheses, but the revisions were mainly insertion of a patellar component. In tricompartmental prostheses the risk for revision due to infection was 2.5 times higher than in bicompartmental prostheses (p=0.03). Young age (<60) and the diagnosis sequela after fracture gave increased risk for revision.

The 5 years survival of the six most used cemented tricompartmental knee prostheses brands varied between 95.2 % and 98.6 %, but the differences were not statistically significant. There were more revisions due to pain in bicompartmental than in tricompartmental knees. In tricompartmental knees, however, there were more revisions due

to infection. The relatively low numbers of uncemented and hybrid implants did not indicate any improvements of results compared to cemented knee prostheses.

9. DISCUSSION

9.1. METHODS

9.1.1. Register studies versus randomised trials in total hip and knee replacement surgery

The ideal approach to evaluate the performance of implants and techniques would be to carry out randomised clinical trials. Properly conducted large randomised trials would eliminate any systematic differences between the different treatment groups that might lead to confounded results. However, randomised studies are rarely performed in orthopaedic surgery for several reasons. They are difficult to organise, are expensive, require a large workload and take a long time. This applies especially to fields such as arthroplasty surgery where the results in general are good, and since differences among treatments are small, large numbers of patients and long follow-up are therefore needed to be able to detect statistically significant differences. Acceptable long-term results for good prostheses are 5 % revisions at 10 years and 2-3 % at 5 years. To detect a difference in risk of revision between two prostheses with 5 year failure rates of 2 and 5 % requires 518 prostheses per year if the level of significance is 5 % and the power 80 %. If recruitment of patients continues for the whole study period of 5 years an accumulated 2590 prostheses would be needed for such a study (George and Desu 1974). If the 5 year failure rates were 2 and 3 %, a total of 15543 prostheses would be needed.

Furthermore, a randomised trial can only address one or two primary research questions. As long as results from clinical trials are not mandatory before new implants or treatments can be freely used, the number of trials will remain limited.

As results from clinical trials with satisfactory long follow-up periods do not exist for the majority of joint replacement devices or for many other orthopaedic treatments as well, one alternative is to use register studies. With this approach, results for practically all different implant- or treatment modifications reported to the register can be assessed with minimal workload for the reporting surgeons. Because of the large numbers in a national register, it is commonly possible to find significant results earlier than in randomised studies. The results from register studies will also reflect the outcome for the average surgeon rather than for specialised centres. Using arthroplasty registers, it has been possible to identify inferior results of some implants as early as after three years when the differences were large.

To find and document small differences, however, larger numbers of patients and longer observation is usually needed. It must be kept in mind that register-based studies are observational.

As confounding by unknown risk factors is possible in register studies, small differences among treatments with good results must not be overestimated and changes in clinical practice should not be based on marginal results. If procedures or implants are used at only a few or single hospitals, and by probably a few or single surgeons, results for these procedures or implants may reflect the skill of the surgeon rather than characteristics of the implants. There can also be a surgeon bias on the view of early revision, and the experience and technique of each surgeon will influence the results to a great extent. Some surgeons may have great faith in their prosthesis and thus be inclined to delay revision, even if the prosthesis obviously is radiographically loose. The Norwegian Arthroplasty Register is not able to control cementing techniques, but generally Norwegian surgeons have used the so-called third generation cementing technique during the study period (Ranawat et al. 1997). We also know that the introduction of vacuum mixing has not changed the results of cemented Charnley prostheses (Eikrem et al. 2001). In Paper II on the different low and high viscosity cements we, in addition, analysed the results from hospitals that had used Palacos and CMW1 or CMW3 cement at different stages in the study period. These analyses supported our finding that Palacos cement was better than the latter cements and that this finding was not a result of an association of inferior surgeon technique or skill with CMW1 or CMW3 cement. Differing skill and techniques by surgeons are unavoidable. By comparing implants and cements where many surgeons are involved the objection against register studies is only valid if there is an association between skill/technique and implant brand or cement brand. This association is not likely.

Results from observational register-based studies (cohort studies) may be less conclusive than those of randomised clinical trials. However, newer studies have compared the results of observational studies with those of randomised trials, and these authors found little evidence for the results of well designed observational studies being qualitatively different from those of randomised trials (Benson and Hartz 2000, Concato et al. 2000).

9.1.2. Quality and completeness of data

The Norwegian Arthroplasty Register validates its data by comparing reports with the official hospital discharge register, the Norwegian Patient Register (NPR) in Trondheim. Our latest survey revealed that approximately 95% of the hip and knee replacements at the 68 different hospitals operating hip and knee prostheses in Norway, were reported to the Norwegian Arthroplasty Register (Havelin et al. 2000a). This good compliance is partly due to the high level of motivation among the orthopaedic surgeons because of the prosthetic catastrophes seen in the years before the register was established. Continuous feedback to the surgeons and a simple reporting system are other important factors for the compliance not declining. Any under-reporting is assumed to be evenly distributed among groups of patients and types of implants. Thus it would not affect the relationship between results of the different prosthesis types.

There are a few surgeons who do not report operations to the register; we know what type of prostheses they use and if these prostheses are used only at one or two other hospitals the results for these prostheses must be interpreted with caution. It would be more problematic if some surgeons under-reported re-operations. The results of implants and cements operated at more than a few hospitals can obviously be expected to be more reliable than implants and cements used in only two or three hospitals.

Reporting each case on a paper form is probably at present the simplest system for the surgeons contributing to the register, but computer-based reporting systems may be considered.

The register is dependent on participation from large groups of orthopaedic surgeons, including those that normally are not dedicated to scientific work. Feedback is therefore important to maintain the surgeons' interest in the project and thereby good compliance. All contributors receive an annual report, and each orthopaedic department is given their own production statistics and survival results, which they can compare with the national result and with the results of all other hospitals (given anonymously). Production numbers in the hospitals can be compared with the corresponding numbers in the register, and missing cases can be reported to the register. Furthermore, the co-workers of the register give updates on results at meetings, conferences, courses, and in scientific articles.

9.1.3. Definition of outcome

Revision surgery was chosen as endpoint (outcome) in survival analyses. With baseline data on the primary operations and data from the revisions, the survival of different implant components can be assessed and the possible causes for revisions established. Furthermore, if sufficient data are registered on age, gender, diagnosis, operative techniques, use of antibiotic prophylaxis, and other patient-, surgeon- or hospital related risk factors, the impact of these risk factors on the revision rates can also be investigated.

Revision surgery is a most convenient end-point measure, but quality of life measures, mortality, level of pain, satisfaction and function, or x-ray findings after different time intervals could also be chosen as outcomes. The decision to revise the patient may depend on many factors and it can be questioned whether revision is an adequate outcome variable. The proportion of patients who have their prostheses still in place gives little information on clinical and radiographic outcome or the patient's satisfaction (Fender et al. 1999). However, parameters like quality of life measures, pain, function and x-ray findings are only suitable in smaller studies that are going on for limited time periods. It is probably impossible to get all the surgeons in a country to check every one of their patients and report the clinical and radiographic findings to the register. In addition, if revision surgery is not used as outcome, the choice of level for the definition of a clinical failure is a problem. Södermann (Söderman 2000) evaluated revision as end-point in the Swedish hip register by analysing the clinical and radiographic outcome of 1113 randomly selected patients from the register. They concluded that the failure end-point in the register (revision) was valid and exact. In short, general experience indicates that in large permanent register studies on joint arthroplasty, revision surgery is the only practical end-point.

9.1.4. Statistical methods

Survival analyses are based on observations of time from a starting point to a response (e.g. failure, death). The possibility to include data from patients in which the response has not yet occurred distinguishes survival analyses from other statistical methods (Altman 1995). Such data are called incomplete, or censored. They may arise from loss to follow-up, death, or no response (no failure) before the end of the study. The survival is the probability that, for any specific survival time, a subject will survive at least for that long or longer. Data on patients who died are needed in register studies. In survival analyses, intact implants in patients who

died or emigrated are followed from the primary operation until the date of death (or emigration) when the follow-up of these patients is stopped, and their follow-up times are included as censored observations. The patients' dates of death were obtained from Statistics Norway.

Three methods for estimating the survivor curves are commonly used. First, in the actuarial life table method (Cutler and Ederer 1958) the time-to-response is grouped into time intervals. For each time interval, the life table records the number of patients still in the study at the beginning of the interval, and the number of responses and censored observations during the interval. From these numbers the probability of survival at the beginning of each interval is estimated. This method has been applied in orthopaedic surgery as described by Dobbs (Dobbs 1980), and is suitable for tabular presentation of the results. Secondly, a more computing intensive method is the product-limit or Kaplan-Meier method (Kaplan and Meier 1958). Its advantage is to provide results that are independent of the choice of time intervals, as the survival is estimated at every response (failure) time. The Kaplan-Meier method is most commonly applied to estimate the prosthesis survival and to construct survival curves, with different end-points as described above. This method was used in Paper I, III and IV. Thirdly, the Cox model, which is a multiple regression analysis of survival times (Cox 1972). Both unadjusted and adjusted survival curves can be constructed with the Cox-model; the unadjusted curves are similar to the Kaplan-Meier curves. The method of constructing Cox adjusted survival curves was applied in paper II, III and IV.

By linking information on the revisions (response) to the primary operations by use of the patient ID numbers, the time to response is found, and survival of the implants or treatments can be assessed. If sufficient data are collected, survival of the different prosthesis components (stem, polyethylene insert, head, and cup) with end-points such as all revisions or revision because of aseptic loosening, dislocation, infection, fracture, osteolysis, or pain can be estimated.

Our results are based on observational data. Confounding factors may therefore be unevenly distributed among treatment groups. To be confounding a variable must have the following three characteristics (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.

In experimental studies confounding bias can be prevented through randomisation of the treatment.

The log-rank test (Mantel 1966) is used to analyse if there are statistically significant differences between the compared groups when using the Kaplan-Meir method. But the log-rank test gives no possibilities for adjustment for confounding factors.

When using the Cox regression it is possible to estimate relative failure risks with adjustment for multiple variables. With the Cox multiple regression model, relative risks of revision (hazard rate ratios, failure rate ratios), (RR) can be assessed with adjustment for differences in the compared treatment groups with respect to age, gender, diagnosis, and other confounding factors. The Cox regression was used in all papers to estimate hazard rate ratios. The impact on the results of the confounding factors can be assessed, and corresponding Cox-adjusted survival curves can be constructed. The Cox model is based on the assumption that the hazard rates of the compared groups are proportional. A modification of the Cox model with different rate ratios for different time periods was used in the 11 years survey of the hip register (Havelin et al. 2000d). This paper showed that the revision rates for certain uncemented acetabular cups accelerated during the last years of the period studied. In the Cox model different tests such as the Wald and Score test are used to test statistical significance.

Another way to handle prognostic differences in subgroups of patient materials, is to restrict the inclusion of patients in the analyses to certain patient groups (e.g. to only one gender, or most commonly, to certain age groups within a diagnostic group) (Rothman 1986). A combination, where the Cox model is applied on a restricted homogenous group of patients, is often the best solution. In paper III an illustrative example of the importance of the adjustment for confounding by multiple-regression and restriction to a homogenous subgroup is given. The group of patients with femoral neck fracture had the lowest revision rate in the unadjusted total material (Kaplan-Meier method), but this group was the only one with a statistically significant higher risk for revision compared to primary osteoarthrosis when full adjustment for confounders (Cox model) was made in the restricted homogenous Charnley subgroup. Analysis of homogenous subgroups was used in papers II, III and IV.

9.2. RESULTS

9.2.1. Boneloc cement with different hip prostheses brands

It was demonstrated in Paper I that Boneloc cement gives inferior results compared with high viscosity cement, both for Charnley prostheses and Exeter prostheses after 4.5 years. The 4.5 years survival with aseptic loosening as endpoint in Charnley/high viscosity cemented femoral stems was 98.2% compared to 74.1% in Boneloc cemented Charnley stems. The results confirm the sensitivity of the register, since the inferior properties of the Boneloc cement had been demonstrated after only 2.5 years use (Havelin et al.1995b).

Boneloc cement was introduced in Norway 1991 without any clinical documentation, and in 1992 had 14% of the market for bone cement in Norway.

Boneloc cement with the formula 50 % methylmethacrylate, 30 % n-decyl-methacrylate, and 20 % isobornyl methacrylate (Jensen et al. 1991, Thanner et al. 1995) was tested in the laboratory by the manufacturer (Kindt-Larsen et al. 1995) and by an independent group (Thanner et al. 1995). The results of their studies were contradictory with those of the manufacturer being the best, while Thanner concluded that the new cold-curing cement provided an inferior fixation of both the acetabular and femoral components compared with standard high viscosity cement. In the femur Thanner attributed this to both mechanical failure of the cement and failure at the prosthesis/bone interface as demonstrated by radiostereometry (RSA) and by laboratory findings. Since there is no general consensus on the relationship between laboratory test results of cements and clinical performance (Lewis 1997) clinicians should wait for clinical results before using new cements. The results further underline the importance of making clinical testing mandatory before general marketing of medical devices is allowed.

In the present study a difference was found between the survival rates of Charnley and Exeter femoral components implanted with Boneloc cement, which can probably be explained by the difference in prosthesis design. The Exeter femoral component has a double tapering section and a polished surface (Fowler et al. 1988). It is possible that this design better tolerates a bone cement with poorer mechanical performance than the design of the Charnley prosthesis. This finding is an argument for that, in the future, the design and material of the prostheses should be tested with different types of cement.

Boneloc cement has been used in 33 countries and in approximately 14000-21000 hips, depending on whether 2 or 3 portions of cement have been used in each hip (Polymers Reconstructive AS. Personal communication 1996). The annual extra revision cost of using this cement in Norway (1324 hips in a 4 year period) is estimated to 0.9 million US$ (Engesaeter et al. 1996, Furnes et al. 1996). Boneloc cement was introduced on the Norwegian market and on the international market with only laboratory tests as documentation. There were no clinical or randomised studies to support the laboratory tests. The Boneloc case illustrates the importance of new prosthesis designs and new cements having documentation including laboratory tests and randomised clinical studies with RSA techniques, before they are introduced to the market (Malchau 1995).

9.2.2. Cement types in hip replacement

In Paper II we demonstrated important differences in failure rates for Charnley total hip prostheses when different types of cement were used for fixation. The low viscosity cement CMW3 and the high viscosity cement CMW1 showed increased long-term failure risks compared with the high viscosity cements Palacos and Simplex.

The novel finding of this study was the variation in failure rates observed among high viscosity cement types. At 10 years, we observed a 12 % failure probability in Charnley hip prostheses fixed with CMW1 cement without antibiotics compared to 7 % with Palacos cement without antibiotics. Furthermore, the present study extends our previous observation of increased failure rates associated with the low viscosity CMW3 cement (Havelin et al. 1995b).

The mechanical properties of bone cements have been assessed by numerous investigations using a large number of testing methods (Lewis 1997). However, no consensus has been achieved on the relationship between laboratory test results and clinical performance. However, stress controlled fatigue testing has been recommended by several authors (Lewis 1997, Harper and Bonfield 2000, Kühn 2000). The findings of Harper and Bonfield (Harper and Bonfield 2000) show agreement with our clinical results and findings by the Swedish National Hip Register (Herberts and Malchau 2000). At present, fatigue testing is not included in standards set by the International Organisation for Standardisation (ISO) and the American Society for Testing and Materials (ASTM). Fatique testing has been recommended by the Food and Drug Administration (FDA) in their "Class II Special Controls Guidance

Document: Polymethylmethacrylate (PMMA) Bone Cement 510 (k)s; Final Guidance for Industry", issued 2nd August 2001.

While laboratory testing has demonstrated that the addition of an antibiotic to the bone cement may compromise the mechanical strength of the cement (Kühn 2000), data on the clinical relevance of this finding has been sparse. In Norway, the use of antibiotic-containing cement in either component has increased from 40 % in 1989 to 94 % in 1999. We observed no difference in failure rates for prostheses inserted with Palacos cement with and without added gentamicin. The same was observed for CMW1 cemented prostheses with any failure as the endpoint, but with failure due to aseptic loosening as the endpoint there was a tendency towards worse results with gentamicin-containing CMW1 cement. It has been argued that weaker cements might be more adversely affected by the addition of an antibiotic (Kühn 2000). In an earlier study with shorter follow-up we found statistically significant better results with antibiotic containing cement combined with systemic antibiotic prophylaxis compared to other combinations where endpoint was revision due to infection and due to any cause (Espehaug et al. 1997). In the present study, the use or not of systemic antibiotic was adjusted for.

The present study demonstrated that the choice of cement used for fixation has important consequences for the long-term durability of an implant. These differences in failure risk were also observed among high viscosity cement types in common use. The study highlights the importance of reporting the type of cement when reporting results of hip prostheses surgery. The report further represents an argument for a greater awareness regarding current marketing regulations for medical devices.

9.2.3. Hip disease in hip replacement

Paper III demonstrated that several hip disease groups, mainly found among younger patients, seemed to give inferior survival of THR compared to primary osteoarthrosis, but these patients had often been given inferior uncemented implants. When we applied the Cox multiple-regression model and adjusted for confounding factors only THRs in patients with congenital dislocated hips and THRs in patients with hip fracture, had inferior results compared to patients with primary osteoarthrosis. The relative revision risk due to all causes of revision for hips in patients with sequela after femoral neck fracture and congenital dislocation was increased only 30 % compared to primary osteoarthrosis. The reason for this

increased revision risk was due to an increased risk of revision due to dislocation in these two hip disease groups. The increased risk of revision due to dislocation was respectively 2.8 and 5.6 times higher. Further studies are warranted among patients with these two hip diseases regarding use of different prosthesis designs and femoral head-sizes to prevent dislocation.

This paper also illustrates that surgeons have experimented with undocumented prostheses in young patients under 60 years of age. In some of the hip disease groups, up to 80 % percent of the prostheses were uncemented in young patients, a procedure that still might be regarded as experimental. Even worse is the fact that in some hip disease groups in young patients up to 28 % of the uncemented prostheses could be classified as inferior, i.e. smooth press-fit stem, threaded cups with smooth surface, or porous-coated stems without circumferential coating. The general finding in our study is that young patients in all hip disease groups have good mid-term results (0-10 years) using a cemented implant. This is in accordance with Wroblewski's study of patients 50 years and younger operated with cemented Charnley prostheses (Wroblewski and Siney 1992). We also recommend using cemented implants even in young patients, and that undocumented implants should be used only in randomised studies using RSA technique.

9.2.4. Epidemiology of total knee replacement surgery

In Paper IV we showed that the incidence of primary knee prosthesis surgery in Norway was 35 operations per 100 000 inhabitants in 1999, compared to Sweden's 63 operations per 100 000 inhabitants in 1996 (Robertsson et al. 2000c). Thirty-one percent of the Norwegian population was 50 years or older in 1999 compared to 36% of the Swedish population in year 2000 (Statistics Sweden and Statistics Norway). However, this difference in age distribution probably does not fully explain the nearly double incidence of knee prosthesis surgery in Sweden. The population of Norway is most likely under-treated with regard to knee prosthesis surgery. Because of this, we can expect an increased demand for knee prosthesis operations not solely due to an expected increase in the elderly population (Robertsson et al. 2000c). This is further underlined by the finding that the average age of the patients in Norway was 70 years while the mean age in Sweden was 2 years higher. Operations are performed on older patients in Sweden and this trend can be expected in Norway.

Uncemented prostheses were used in younger patients than those in which cemented and hybrid implants were used; this is the same tendency as for hip replacements in Norway.

Cemented prostheses are regarded as being the gold standard for knee prosthesis surgery (Robertsson 2000a). In our study 87 % of the prostheses were cemented. This is a higher percentage than in Sweden where 80 % of the primary knee prostheses were cemented during the years 1988-97 (Robertsson 2000a). In total hip replacement, the situation is the opposite, with 85% cemented hips in Norway and 93 % in Sweden. Ten percent of the knee prostheses in Norway were hybrid prostheses with uncemented porous-coated femoral components and cemented tibial components.

Which implants are marketed is left up to the distributors. In Norway, each orthopaedic department (not the individual surgeon) then decides which implant to use. Nine different knee prostheses brands were reported to the register as being used, as opposed to 39 different hip implants (Havelin 1993). For some of these 9 implants, the surgeon could choose between cemented, uncemented and hybrid fixation, rotating tibial insert, posterior stabilised or constrained condylar or deep dish designs, and whether to use a patellar component or not, or whether the patellar component should be with metal backing or all polyethylene.

During the study period 93 % of the cemented knee prostheses were inserted with antibiotic containing cement. The reason for the high use of antibiotic-loaded cement was probably partly because of the good results reported for antibiotic-loaded cements in combination with systemic antibiotic prophylaxis in hip surgery (Espehaug et al. 1997) and the problems with infections in knee arthroplasty in the past (Bengtson et al. 1986, Bengtson and Knutson 1991).

9.2.5. Cemented knee prosthesis brands

In Paper IV we showed that the results of the 6 most used cemented knee prosthesis brands were generally good. This is in accordance with results from the Swedish Knee Arthroplasty register (Robertsson et al. 2001) and results from the large study from the Mayo clinic where total condylar knee replacements of the resurfacing type with metal backed tibial components had good results compared to other designs (Rand and Ilstrup 1991). Surgeons should be aware of the lack of long-term clinical documentation for some of the knee prostheses currently in use. However, both patients and surgeons can hope for the positive trend demonstrated in Sweden, where the new implants performed better than the old implants (Robertsson et al. 2001).

9.2.6. Bicompartmental and tricompartmental total knee replacements

In Paper IV we showed that of the primary total knee prostheses used during the study period, 65 % were bicompartmental. This percentage increased from 59 % in 1994 to 77 % in 1999. There was a tendency in our data for more revisions due to all causes in cemented bicompartmental TKRs compared to cemented tricompartmental TKRs but the difference was not statistically significant (p=0.2). However, there were distinct differences between the reason for revision in these two groups of prostheses. There was a 2.5 times higher revision rate for infection in knees with tricompartmental prostheses than with bicompartmental prostheses. A possible explanation may be that insertion of tricompartmental prostheses is a more extensive procedure that may compromise the circulation of the patella, traumatise the soft tissue of the patella and possibly overstuff the patellofemoral joint.

There were statistically significantly more revisions for pain in bicompartmental prostheses compared to tricompartmental prostheses, and most of the revisions in bicompartmental prostheses were insertion of a patellar component. We do not, however, know if patients with the bicompartmental knees really have more pain than those with tricompartmental knees. Robertsson (Robertsson et al. 2000b) has shown that nearly 20 % of the patients with TKRs have some pain in their knee after knee surgery. If the patient presents a painful knee with a bicompartmental prosthesis, the surgeon will have the option for an operation he would not have in a tricompartmental knee. This may explain the increased revision rate in bicompartmental knees even if the level of pain is the same in the two types of prostheses. However, randomised studies have shown that there is a tendency to more anterior knee pain in bicompartmental knees (Partio and Wirta 1995). This has been claimed to be dependent on the design of the prostheses (Matsuda et al. 2000). The Swedish Register found that patients with bicompartmental prostheses were slightly less satisfied than patients with tricompartmental prostheses. Whereas the satisfaction of patients with tricompartmental prostheses decreased with time, it was not so for patients with bicompartmental prostheses (Robertsson et al. 2000b). The increased risk of infection in patellar resurfaced prostheses and the increased risk of aseptic loosening of the patellar component must be weighed against the possible increased risk of reoperation with insertion of a patellar component, because of pain in bicompartmental prostheses.

9.2.7. Fixation of total knee replacements

In Paper IV we showed that uncemented prostheses were used in younger patients than cemented and hybrid implant patients; this is the same tendency as in hip replacements in Norway. We could not detect any statistically significant difference in survival after 5 years among prostheses with cemented, uncemented and hybrid fixation. With the increasingly poor results of the uncemented acetabular components after 6-7 years of follow-up in mind (Havelin et al. 2000a), and recent reports on inferior results of uncemented knee implants at mid-term (11 years) follow-up (Berger et al. 2001), the results of the uncemented and hybrid prostheses must be followed closely. The results of the uncemented and hybrid implants were not better than the results of the all-cemented prostheses, which applies also for patients younger than 60 years. This finding does not support the use of the more expensive uncemented implants, with uncertain long-term results, even in young patients.

10. CONCLUSION

1. Inferior results were observed for Boneloc cement compared with high viscosity cement both with Charnley prostheses and Exeter prostheses. The femoral prosthesis design caused important differences when using a poorly performing cement (Boneloc). The polished and tapered Exeter femoral stem showed better results with the Boneloc cement than did the matt surfaced (Vaquasheen) Charnley stem.

2. The choice of cement used for fixation of hip prostheses had important consequences for the mid-term (0-12 years) durability of the implant. Poor results were found for the low viscosity CMW3 cement and the high viscosity CMW1 cement.

3. The type of hip diseases had little influence on the result of hip replacement surgery, compared to the age of the patient and implant choice. Patients with sequela after fracture of the femoral neck and congenital dislocation had an increased risk of revision due to dislocation. Some Norwegian surgeons have been using undocumented prosthesis designs in young patients.

4. Annually only half the number of knee prosthesis operations per 100 000 inhabitants are performed in Norway compared to Sweden. In Norway 87 % of knee implants were fixed with cement, 10 % were hybrid implants and 2 % were uncemented. The use of uncemented implants decreased during the study period, and the use of cemented bicompartmental prostheses increased.

5. The results of cemented primary total knee prostheses were generally good and comparable with cemented hip prostheses after 5 years. No statistically significant difference could be detected between the knee prosthesis brands.

6. When the endpoint was infection, tricompartmental knee prostheses had higher risk of revision compared to bicompartmental prostheses. Bicompartmental prostheses had, however, higher risk of revision for pain compared to tricompartmental prostheses, but the revisions were mainly insertion of a patellar component.

7. There was a tendency for more revisions in uncemented knee prostheses compared to cemented and hybrid prostheses, but the difference was not statistically significant. The same results were found in young patients (under 60 years of age). The results support the use of cemented implants in all age groups, since the uncemented implants are more expensive and future results of uncemented implants are unknown.

11. FUTURE STUDIES

11.1. Future need for the register

Most orthopaedic surgeons are aware that the former catastrophes in joint replacement surgery were caused by the common practice of using implants without documented good long-term results. Unfortunately, this practice is still common in most countries, including Norway.

For example after 15 years of use, there is no good documentation of long term results from clinical studies of patients operated on with prostheses based on the metal-on-metal principle, although 70 000 of these prostheses have been used in several European countries. Copy prostheses with so called old designs, have been introduced on the market and are in large scale use because of their low price; this practice has led to catastrophic results (Massoud et al. 1997). There is still uncertainty about which metal (cobalt chromium, stainless steel, or titanium) is best in joint prostheses, and about the surface and geometry of cemented hip prostheses (polished, matt, tapered, collar). Of the uncemented implants that are presently used, very few have reported good long-term results. The problem with polyethylene wear of uncemented cups has still not been solved. The long-term consequences of different types of sterilization of polyethylene are not known. Many orthopaedic surgeons consider the new highly crosslinked polyethylene to be the best solution to the wear problems. Tests of these products in laboratory situations are promising, but they have now been marketed before clinical results are available. New ceramic surfaces have been introduced like Alumina (Al_3O_2) and later Zirconium (ZrO_2). Vigilance reports have recently been sent out, because of the breakage of ZrO_2 heads. New cements, without documentation of good clinical results were introduced to the market in 1999, even though it was well known that changes in the cement formulae might give unexpected problems. It is not agreed which prophylactic antibiotic regimens are the best, and it is uncertain whether there is a life-saving effect of thromboprophylaxis in hip replacement surgery (Bulstrode 1998).

Norwegian orthopaedic surgeons have followed our recommendations, since they have abandoned inferior uncemented prostheses and cements when results became known. However, instead of changing to well documented implants, some surgeons have changed to another new and still undocumented product.

Norwegian and Scandinavian populations are stable and have a well functioning national personal identification (ID) number system. People are willing to be registered in central

registers and surgeons are not reluctant to enter their cases and complications into a register. Similar national registers have been established in Sweden, Finland and Denmark (Herberts and Malchau 2000, Lucht 2000, Puolakka et al. 2001, Robertsson et al. 2001). Other countries where most of the prostheses are produced and used such as France, Germany, UK and USA will probably not be able to organise national registers covering all patients. The independent information that the Scandinavian countries provide is thus of great international importance for ensuring the quality of orthopaedic implants.

There is therefore, and will continue to be, a need for the register to assess new products and, as the results of the CMW1 cement showed, implants and cements will have to be followed for long periods of 10-20 years.

In knee prosthesis surgery new implants are constantly being introduced on the market with new design concepts like PMMA precoating, new polyethylene designs, new sterilization procedures of the polyethylene, new materials like ceramics, and new highly crosslinked polyethylene. New designs of the patellofemoral articulation have been introduced lately, and new instrumentation and operating techniques have also been introduced. All of these new concepts lack long-term clinical follow-up.

11.2. Ongoing studies in the register

A study of head diameter and revision due to luxation, based on data in the register, is in manuscript.

Surgical procedures such as the vacuum mixing system for cements have been studied (Eikrem et al. 2001). Thromboprophylaxis and death in hip replacement surgery has been studied (Lie et al. 2000b).

Different antibiotic prophylactic regimens (type, dosage and duration of prophylaxis) for infection prophylaxis have been studied (Engesaeter et al. 1999, Havelin et al. 2000b), and will be studied further in more depth. Investigations into whether there are different rates of infections in cemented and uncemented implants have also been planned.

11.3. Future studies in hip replacement

Mid- and long- term follow-up of uncemented stems and cups will be necessary, as well as long term follow-up of different types of existing cements. The relationship between cement type and design of cemented prostheses needs to be investigated further. Long-term (15-20

years) follow-up of cemented stems and cups with reference to type of metal, design, modularity and head diameter has yet to be completed. Special studies on head diameter, head material, surface roughness and wear should be made.

Pain and function in different hip implant designs should be studied by patient self-administered postal surveys for a limited time period. Special studies are needed for young age groups since these patients traditionally have been reported to have a poorer prognosis.

Revision surgery with different techniques using cemented prostheses, uncemented prostheses with porous coating or HA coating, or bone-grafting techniques are other important studies that have been planned.

11.4. Future studies in knee and other joint replacement

Results of unicondylar prostheses have been investigated (Furnes et al. 2000), and publication is planned. Cement types in knee prosthesis surgery should be investigated. Validation and translation to Norwegian of a patient administrated score system and a knee specific score system ought to be performed to enable future randomised studies and to carry out postal surveys of the currently used knee prostheses in Norway.

Thromboprophylaxis and death following knee prosthesis surgery has yet to be studied; information on thromboprophylaxis could be collected using the registration form for a short time. Special studies on knee disease, age, gender and previous operations also need to be carried out.

Results from shoulder, elbow, hand, finger, ankle and toe joint replacements have been reported (Havelin et al. 2000a), but longer follow-up warrants more in-depth analyses.

11.5. Co-operation with other institutions

Co-operation with other institutions will probably increase in the future (Flugsrud et al. 2002). We will continue our validation studies into reporting compliance in co-operation with the Norwegian Patient Register (NPR).

In Norway there are few epidemiology data on prevalence of joint diseases; such investigations should be carried out to estimate the need for treatment in the future. Regional differences in incidence and prevalence linked to regional differences in treatment volume corrected for population structure (age and gender) would give valuable data for planning treatment resources. It could also maybe explain regional differences in risk factors for

developing osteoarthritis and other joint diseases. Such studies will also make it possible to compare and explain differences in incidence of disease and differences in treatment volume in different countries (Ingvarsson 2000).

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13. APPENDIX

The Norwegian Arthroplasty Register forms

      1. Total hip replacements form used from 1987 (Norwegian)

      2. Total hip replacements form used from 1993 (English translation)

      3. Knees and other joints form used from 1994 (Norwegian)

      4. Knees and other joints form used from 1994 (English translation)

Total hip replacements form used from 1987 (Norwegian)

NASJONALT REGISTER FOR TOTALPROTESER I HOFTELEDD
Ortopedisk avdeling
Haukeland sykehus,
5021 BERGEN

F.nr.:

Navn:

Sykehus:

ANAMNESE:

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

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

3. FUNKSJONSGRUPPE (ett kryss):
- $\square^1$ Aktuelle hofte syk ellers frisk.
- $\square^2$ Begge hofter syke ellers frisk.
- $\square^3$ Annet som reduserer gangevnen.

4. TIDLIGERE OPERASJON(ER) I AKTUELLE HOFTE:
- $\square^0$ Nei
- $\square^1$ Osteosyntese pga. fraktur i prox.femurende.
- $\square^2$ Hemiprotese pga. fraktur
- $\square^3$ Osteotomi.
- $\square^4$ Artrodese.
- $\square^5$ Totalprotese(r) Type(r):. . . . .
  Årstall siste protese: |__|__|
- $\square^6$ Annet: . . . .

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

OPERASJONSOPPLYSNINGER:

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

7. AKTUELLE OPERASJON ER (ett kryss):
- $\square^1$ Primær totalproteseoperasjon.
- $\square^2$ Reoperasjon.

8. AKTUELLE SIDE (ett kryss).
- $\square^1$ Høyre
- $\square^2$ Venstre
- $\square^3$ Høyre - venstre allerede protese.
- $\square^4$ Venstre - høyre allerede protese.

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

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

10. HVIS reoperasjon (ett kryss):
- $\square^1$ Reop. - bytte av femurdelen.
- $\square^2$ Reop. - bytte av acetabulardelen.
- $\square^3$ Reop. - bytte av hele protesen.
- $\square^4$ Reop. - annet: . . . .

11. TILGANG (ett kryss):
- $\square^1$ Fremre (Smith-Pettersen).
- $\square^2$ Anterolateral.
- $\square^3$ Lateral.
- $\square^4$ Posterolateral
- $\square^5$ Annen: . . . .

12. TROCHANTEROSTEOTOMI:
- $\square^0$ Nei
- $\square^1$ Ja

13. BENTRANSPLANTASJON:
- $\square^0$ Nei
- $\square^1$ I acetabulum.
- $\square^2$ I femur.

PROTESE. NAVN/TYPE (Spesifiser nøyaktig):
14. Acetabulum:
Navn/Type: . . . .
. . . .
- $\square^1$ Sement med antibiotika. Navn: . . . .
- $\square^2$ Sement uten antibiotika. Navn: . . . .
- $\square^3$ Ikke sementert.

15. Femur:
Navn/Type: . . . .
. . . .
- $\square^1$ Sement med antibiotika. Navn: . . . .
- $\square^2$ Sement uten antibiotika. Navn: . . . .
- $\square^3$ Ikke sementert.

16. Caput:
- $\square^1$ Fastsittende caput.
- $\square^2$ Separat caput. Navn/Type: . . . .
. . . . Diam.: . . . .

17. SYSTEMISK ANTIBIOTIKAPROFYLAKSE:
- $\square^0$ Nei
- $\square^1$ Ja. Hvilken: . . . .
  Dose: . . . .
  Varighet: . . . .

18. OPERASJONSSTUE:
- $\square^1$ "Green House"
- $\square^2$ Operasjonsstue med Allandertak.
- $\square^3$ Vanlig operasjonsstue.

19. OPERASJONSTID (hud til hud): |__|__|__| min.

20. PEROPERATIVE KOMPLIKASJONER:
- $\square^0$ Nei.
- $\square^1$ Ja. Hvilken: . . . .

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

Total hip replacements form used from 1993 (English translation)

THE NORWEGIAN ARTHROPLASTY REGISTER   TOTAL HIP REPLACEMENTS

Patient ID and date of birth: ....   **Hospital:**.....................................

Previous operation in index hip:
0 No
1 Osteosynthesis for prox. femur fracture
2 Hemiprosthesis
3 Osteotomy
4 Arthrodesis
5 Total hip prosthesis
Type:...
Year:............
Number of prostheses in index hip: ....
6 Other operations: ....
....

Date of operation: ....

Index operation is:
1 Primary operation
2 Revision

Hip:
1 Right
2 Left
3 Right, prosthesis in left hip
4 Left, prosthesis in right hip

Diagnosis (primary operation):
1 Idiophatic coxarthrosis
2 Rheumatoid arthritis
3 Sequelae after hip fracture
4 Sequelae after dysplasia
5 Sequelae after dysplasia with dislocation
6 Sequelae after slipped capital femoral epiphysis or Perthes disease
7 Ankylosing spondylitis
8 Other: ....

Reasons for revision (one or more):
1 Loosening of acetabular component
2 Loosening of femoral component
3 Dislocation
4 Deep infection
5 Fracture of femur
6 Pain
7 Osteolysis in acetabulum
8 Osteolysis in proximal femur
9 Other: ....

Type of revision (one or more):
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
- Exchange of caput
- Other:
....

Approach:
1 Anterior
2 Anterolateral
3 Lateral
4 Posterolateral

Osteotomy of greater trochanter:
0 No   1 Yes

Bone transplantation:
0 No
1 In acetabulum
2 In femur
3 Bone impaction in acetabulum
4 Bone impaction in femur (a.m. Ling/Gie)

Acetabulum:
Name/type:.......................................
Catalogue number: ....
Hydroxyapatite coated: 0 No   1 Yes
1 Cement with antibiotic. Name: ....
2 Cement without antibiotic. Name: ....
3 Uncemented

Femur:
Name/type: ....
Catalogue number: ....
Hydroxyapatite coated: 0 No   1 Yes
1 Cement with antibiotic. Name:..............
2 Cement without antibiotic. Name: ....
3 Uncemented

Caput:
1 Fixed caput
2 Modular system.
  Name/type: ....
  Catalogue number:............................
Diameter (mm): ......

Systemic antibiotic prophylaxis:
0 No   1 Yes Name:.............................
Dosage:..
Duration (days): ....

Operating theatre:
1 'Green house'
2 With laminar air flow
3 Without laminar airflow

Duration of operation:
Skin to skin (min.):

Peroperative complication:
0 No
1 Yes.
Type:..

Surgeon (who has filled in the form):

....
(Surgeon's name is not registered)

Knees and other joints form used from 1994 (Norwegian)

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

   Navn: ....

2. Sykehus: ....

   (Skriv tydelig!)

KNEPROTESER og andre leddproteser (Hofteproteser på annet skjema)
Innsetting, skifting eller fjerning av protese eller protesedeler.

3. Vekt: .... kg

4. LOKALISASJON, AKTUELL OPERASJON
- ❑ 1 Kne
- ❑ 2 Ankel
- ❑ 3 Tær (angi ledd) ....
- ❑ 4 Skulder
- ❑ 5 Albue
- ❑ 6 Håndledd
- ❑ 7 Fingre (angi ledd) ....
- ❑ 8 Annet: ....

5. AKTUELLE SIDE (ett kryss):
Hvis samtidig bilateral operasjon - bruk to skjema.
- ❑ 1 Høyre
- ❑ 2 Venstre

6. TIDLIGERE OPERASJON I AKTUELLE LEDD (evt. flere kryss):
- ❑ 0 Nei
- ❑ 1 Osteosyntese for intraartikulær/leddnær fraktur
- ❑ 2 Osteotomi
- ❑ 3 Artrodese
- ❑ 4 Protese
- ❑ 5 Synovectomi
- ❑ 6 Annet (f.eks. menisk- og leddbåndsop.) ....

7. HVIS PROTESE TIDLIGERE I AKTUELLE LEDD:
Antall tidligere proteser i leddet: |__|
Type siste protese: ....
Årstall siste protese: |__|__|

8. OPERASJONSDATO: |__|__| |__|__| |__|__|

9. AKTUELLE OPERASJON ER (ett kryss):
- ❑ 1 Primæroperasjon
- ❑ 2 Reoperasjon (protese tidligere)

10. AKTUELLE OPERASJON ER:

A. Primæropr. pga. (evt. flere kryss)
- ❑ 1 Idiopatisk artrose
- ❑ 2 Rheumatoid artritt
- ❑ 3 Fraktursequele ....
- ❑ 4 Mb. Bechterew
- ❑ 5 Sequele ligamentskade
- ❑ 6 Sequele meniskskade
- ❑ 7 Akutt fraktur
- ❑ 8 Infeksjonssequele
- ❑ 9 Annet: ....
....
....
....
....

B. Reoper. pga. (evt. flere kryss)
- ❑ 1 Løs prox. protesedel
- ❑ 2 Løs distal protesedel
- ❑ 3 Løs patellaprotese
- ❑ 4 Luksasjon av patella
- ❑ 5 Luksasjon (ikke patella)
- ❑ 6 Instabilitet
- ❑ 7 Aksefeil
- ❑ 8 Dyp infeksjon
- ❑ 9 Fraktur (nær protesen)
- ❑ 10 Smerter
- ❑ 11 Defekt plastforing
   Hvilken: ....
- ❑ 12 Annet (f.eks tidl. fjernet prot.)

11. REOPERASJONSTYPE (evt. flere kryss)
- ❑ 1 Bytte av distal protesedel
- ❑ 2 Bytte av proximal protesedel
- ❑ 3 Bytte av hele protesen
- ❑ 4 Bytte av patellaprotese
- ❑ 5 Bytte av plastforing (f.eks. tibia, ulna, humerus)
- ❑ 6 Fjernet protesedeler
   Angi hvilke deler ....
- ❑ 7 Annet ....
- ❑ Innsetting av patellakomponent

12. BENTRANSPLANTASJON
- ❑ 0 Nei
- ❑ 1 Autograft
- ❑ 2 Allograft
- ❑ 3 Annet ....
- ❑ Benpakking proksimalt
- ❑ Benpakking distalt

13. SYSTEMISK ANTIBIOTIKAPROFYLAKSE:
- ❑ 0 Nei
- ❑ 1 Ja. Hvilken type? A: ....
   Evt. kombinasjon med B: ....
Dosering A: .... Antall døgn A: ....
Dosering B .... Antall døgn B: ....

14. OPERASJONSTID (hud til hud): .... minutter

15. PEROPERATIV KOMPLIKASJON
- ❑ 0 Nei
- ❑ 1 Ja. Hvilken type: ....

PROTESE, NAVN, TYPE
(Spesifiser nøyaktig eller bruk evt. klistrelapp på baksida)

KNE

16. PROTESETYPE
- ❑ 1 Totalprot. m/patella ❑ 3 Unicondylær prot. ❑ 4 Patellofemoralledd prot.
- ❑ 2 Totalprot. u/patella ❑ Medial
   ❑ Lateral

17. FEMUR KOMPONENT
Navn/type/størrelse ....
Evt. katalognummer: ....

Sentral stamme	❑ 0 Nei	❑ 1 Ja, evt. lengde: .... mm	
Metallforing	❑ 0 Nei	❑ 1 Ja	
Stabilisering	❑ 0 Nei	❑ 1 Ja, bakre	❑ 2 Ja, annen

- ❑ 1 Sement med antibiotika - navn: ....
- ❑ 2 Sement uten antibiotika - navn: ....
- ❑ 3 Usementert

18. TIBIAKOMPONENT (metallplatå)
Navn/type/størrelse ....
Evt. katalognummer: ....
Stabiliseringsplugger: ❑ 0 Nei ❑ 1 Ja, plast ❑ 2 Ja, metall ❑ 3 Ja, 1+2
Forlenget sentral stamme: ❑ 0 Nei ❑ 1 Ja Evt. lengde .... mm
Metallforing: ❑ 0 Nei ❑ 1 Ja

- ❑ 1 Sement med antibiotika - navn: ....
- ❑ 2 Sement uten antibiotika - navn: ....
- ❑ 3 Usementert

19. TIBIAKOMPONENT (plastkomponent)
Navn/type/størrelse ....
Evt. katalognummer: ....
Tykkelse: .... mm
Stabilisering ❑ 0 Nei ❑ 1 Ja, bakre ❑ 2 Ja, annen

20. PATELLAKOMPONENT
Navn/type/størrelse ....
Evt. katalognummer: ....
Metallrygg: ❑ 0 Nei ❑ 1 Ja

- ❑ 1 Sement med antibiotika - navn: ....
- ❑ 2 Sement uten antibiotika - navn: ....
- ❑ 3 Usementert

KORSBÅND
21.	Intakt fremre korsbånd før operasjon	❑ 0 Nei	❑ 1 Ja
22.	Intakt fremre korsbånd etter operasjon	❑ 0 Nei	❑ 1 Ja
23.	Intakt bakre korsbånd før operasjon	❑ 0 Nei	❑ 1 Ja
24.	Intakt bakre korsbånd etter operasjon	❑ 0 Nei	❑ 1 Ja

ANDRE LEDD

25. PROTESETYPE
- ❑ 1 Totalprotese ❑ 2 Hemiprotese ❑ 3 Enkomponentprotese

26. PROKSIMAL KOMPONENT
Navn/type/størrelse ....
Evt. katalognummer: ....
- ❑ 1 Sement med antibiotika - navn: ....
- ❑ 2 Sement uten antibiotika - navn: ....
- ❑ 3 Usementert

27. DISTAL KOMPONENT
Navn/type/størrelse ....
Evt. katalognummer: ....
- ❑ 1 Sement med antibiotika - navn: ....
- ❑ 2 Sement uten antibiotika - navn: ....
- ❑ 3 Usementert

28. INTERMEDIÆR KOMPONENT (f.eks. caput humeri)
Navn/type/størrelse/diameter ....
Evt. katalognummer: ....

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

Knees and other joints form used from 1994 (English translation)

THE NORWEGIAN ARTHROPLASTY REGISTER   KNEES AND OTHER JOINTS (than hips)

Patient ID and date of birth:.........................   Hospital:..

Patient's weight:..................	<u>KNEE</u>
Localization:	**Prosthesis type:**
1 Knee 5 Elbow	1 Tricompartmental.....2 Bicompartmental......
2 Ankle 6 Wrist	3 Unicondylar......4 Patellofemoral......
3 Toe Joints:.......... 7 Finger joints:.............	**Femoral component:**
4 Shoulder 8 Others....................	Name/size.......................................
	Catalogue number:..
1 Right 2 Left	Stem/Stabilized/Wedge:...............................
	1 Cement with antibiotic. Name: ....
Previous operation in index joint:	2 Cement without antibiotic. Name: ....
0 No 4 Arthodesis	3 Uncemented
1 Osteosynthesis 5 Synovectomy	**Tibial component(metal):**
2 Osteotomy 6 Other:......................	Name/size: ....
3 Prosthesis.Type..........................Year..........	Catalogue number: ....
	Stem/Stabilized/Wedge:...............................
Date of operation:	1 Cement with antibiotic. Name: ....
	2 Cement without antibiotic. Name: ....
Index operation is: 1 Primary op. 2 Revision	3 Uncemented
	Tibial component (polyethylene):
Diagnosis (primary operation):	Name/size:..
1 Idiophatic arthrosis	Catalogue number:..
2 Rheumatoid arthritis	Thichness:......mm
3 Sequelae after fracture	Stabilized:.......................................
4 Ankylosing spondylitis	**Patella component:**
5 Sequelae, ligament tear	Name/type: ....
6 Sequelae, menisceal tear	Catalogue number:.................................
7 Acute fracture	Metal-back 0 No 1 Yes
8 Sequela, infection	1 Cement with antibiotic. Name: ....
9 Other	2 Cement without antibiotic. Name: ....
	3 Uncemented

Reasons for revision (one or more):
1 Loose prox. comp.   7 Mal-alignment
2 Loose distal comp.   8 Deep infection
3 Loose patella comp. 9 Fracture
4 Dislocated patella 10 Pain
5 Dislocation   11 Defect polyethylene......
6 Instability   12 Other......................

Cruciate ligaments
1 Anterior, intact before operation		0 no	1 yes
2 Anterior, intact after operation		0 no	1 yes
3 Posterior, intact before operation	0 no	1 yes
4 Posterior, intact after operation		0 no	1 yes

....

OTHER JOINTS:
Prosthesis type:
1 Total   2 Hemi   3 One-component prosthesis

Type of revision (one or more):
1 Change of distal component
2 Change of proximal component
3 Change of all components
4 Change of patella component
5 Change of polyethylene:............................
6 Removal. Components:...............................
7 Insert of patella component
8 Other: ....

Proximal component:
Name/size: ....
Catalogue number: ....
1 Cement with antibiotic. Name: ....
2 Cement without antibiotic. Name: ....
3 Uncemented

Structural bone transplant: 0 No
1 Autograft   2 Allograft   3 Bone impaction prox.
4 Bone impaction distal   5 Other:..........

Distal component:
Name/size: ....
Catalogue number: ....
1 Cement with antibiotic. Name: ....
2 Cement without antibiotic. Name: ....
3 Uncemented

Systemic Antibiotic prophylaxis:
0 No
1 Yes: Type..............Combinations.............
   Dosage.................Duration, days............

Intermediate component (e.g. caput humeri):
Name/size: ....
Catalogue number: ....

Duration of operation: ....

Surgeon (who has filled in the form):

Peroperative complication:
0 No
1 Yes. Type:...

....
(Surgeon's name is not registered)

14. PAPERS I-IV