HIP ARTHROPLASTY
IN NORWAY
1987–1994

The Norwegian Arthroplasty Register

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CONTENTS

1 ACKNOWLEDGEMENTS

2 LIST OF PAPERS

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

I.   Havelin L I, Espehaug B, Vollset S E, Engesæter L B, Langeland N. The Norwegian Arthroplasty Register. A survey of 17,444 total hip replacements. Acta Orthop Scand 1993; 64: 245-251.

II. Havelin L I, Espehaug B, Vollset S E, Engesæter L B. Early failures among 14,009 cemented and 1,326 uncemented prostheses for primary coxarthrosis. The Norwegian Arthroplasty Register, 1987-1992. Acta Orthop Scand 1994; 65: 1-6.

III. Havelin L I, Espehaug B, Vollset S E, Engesæter L B. Early aseptic loosening of uncemented femoral components in primary total hip replacement. A review based on the Norwegian Arthroplasty Register. J Bone Joint Surg (Br) 1995; 77-B: 11-17.

IV. Havelin L I, Espehaug B, Vollset SE, Engesæter L B. The effect of cement type on early revision of Charnley total hip prostheses. A review of 8,579 primary arthroplasties from the Norwegian Arthroplasty Register. J Bone Joint Surg (Am) 1995; 77-A: 1543-1550. (Am).

V.   Havelin L I, Vollset S E, Engesæter L B. Revision for aseptic loosening of uncemented cups in 4,352 primary total hip prostheses. A report from the Norwegian Arthroplasty Register. Acta Orthop Scand 1995; 66: 494-500.

VI. Espehaug B, Havelin L I, Engesæter L B, Vollset SE, Langeland N. Early revision among 12,179 hip prostheses. A comparison of 10 different prosthesis brands reported to the Norwegian Arthroplasty Register 1987-1993. Acta Orthop Scand 1995; 66: 487-493.

3 BACKGROUND

3.1 Hip disease

The study of bones from prehistoric periods tells us that
arthritis and other hip diseases have represented a problem
for mankind since ancient times (Ackerknecht 1982).
Degenerative arthritis, most commonly called arthrosis, is the
end stage of many hip diseases. Most cases of arthrosis in the
hip (coxarthrosis) are, however, primary (without known
cause), and typically occurs above the age of 60 years, and
most often among women. The most common causes of secondary
coxarthrosis are sequelae after paediatric hip disease.
Patients with sequelae after proximal femoral fractures and
patients with inflammatory arthritis (i.e. rheumatoid
arthritis and ankylosing spondylitis) represent other large
groups with hip disease.

Arthritis, degenerative or inflammatory, usually gives
pain and stiffening of the joint. Conservative treatment with
analgesics, non-steroid anti-inflammatory drugs, and
physiotherapy is usually attempted. If this treatment does not
have a satisfactory effect, an operation with total
replacement of the hip, hip arthroplasty, has been the
treatment of choice for the last two decades.

3.2 Hip arthroplasty

The original meaning of the term hip arthroplasty was any
surgical formation or reformation of the hip joint. The first
known arthroplasty was done in the 1880s by Ollier who used
periarticular soft tissues (Amstutz 1991). During the last
decades, however, an arthroplasty of the hip has become
synonymous with a total hip replacement (THR), which is an
operation where the degenerated joint is replaced by an
artificial joint. In the acetabulum a cup (usually made of
polyethylene) is inserted, and on the femoral side, the
prosthesis replaces the femoral head (caput). The femoral head
is usually fixed by a stem which goes down into the femoral
canal. There are many types of prostheses made with different

designs, from different materials, and with different coatings. Most prostheses are fixed to the bone with bone-cement, of which there are many different brands, but the prostheses can also be fixed by bony ingrowth without the use of cement.

Generally the results of hip arthroplasty are very good. Most patients are pain-free and have a hip with a better range of movements than preoperatively. About 10-15% of the patients, however, get some problems, of which the most common are:

- Aseptic loosening of the components
- Infection
- Dislocation of the joint

The most important problem has been the fixation of the prostheses, as the prosthetic parts may loosen after some time (aseptic loosening). Aseptic loosening is treated by revision with replacement of the loose parts. If a hip arthroplasty becomes infected, the problem is serious. The prosthesis usually has to be removed or replaced in order to heal the infection. Other reasons for revision might be recurrent dislocations of the hip joint, fracture near the prosthesis or mechanical failure of the prosthetic parts.

3.3 Historic review of hip arthroplasty.

The first known joint replacement using foreign materials, was performed in 1890, when Thomas Gluck used ivory to replace hip joints (Amstutz 1991, Faro and Huiskes 1992).

In the years to follow, the cure of painful hip disease was a great challenge to many famous surgeons, like Smith-Peterson, Judet, Moore, McKee, Müller, Ring and Charnley. These and several other surgeons designed, constructed, tested, and clinically evaluated their prostheses. With their "trial and error" work, these surgeons contributed to the development of arthroplasty, but all of them were unsuccessful with at least some of their products. The developmental process, however, differed very much among these surgeons. The decision when to market a new device was crucial.

Unfortunately for many patients, some inventors marketed their devices before they knew how the prostheses performed clinically.

The reason for the success of John Charnley in the 1960s, was that, after laboratory testing, he tested his new prostheses in small groups of patients and then waited for the results. For example when he found problems with the teflon-like polytetrafluorethylene he stopped the use of it and alerted the orthopaedic community (Charnley 1963, Faro and Huiskes 1992). He did not market his prostheses before, after several failures, he had found the materials, head diameter, and the bone cement that performed well. He even went so far that only surgeons he had trained himself were allowed to use his prosthesis (Amstutz 1991). This is in contrast to the inventors of other prostheses, for example the Judet acrylic femoral head prosthesis, which has been considered a disaster in hip replacement surgery (Faro and Huiskes 1992).

During the period from about 1940 to 1960, orthopaedic surgeons learned that hip replacement surgery might give good results, but they also learned that some prostheses were disasters. A most important lesson that should have been learned from that period, but which still seems not to have been taken in, is that hip prostheses should be tested clinically before world-wide marketing and general use.

In the 1970s and early 1980s, several popular hip prostheses had very poor results. Moreover, these poor results were often not detected before the prostheses had been used for several years in thousands of patients. The surgeons had started to use the new prostheses, made after appealing new principles, before anything was documented about their clinical results.

3.4 Hip arthroplasty in Norway

The Norwegian surgeon Tor Christiansen constructed the Christiansen prosthesis (Christiansen 1969, Sundal 1974) with several new details in design. In the second generation of the prosthesis, the plastic material polyacetal (Delrin 150,

Dupont) was used. Laboratory tests had shown that the Christiansen prosthesis had very good friction properties (Benoist Girard, unpublished), and the trunnion bearing head seemed to be a good solution. This prosthesis became the most popular hip prosthesis in Norway in the 1970s. 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. Most prostheses at that time gave poorer results than the Charnley prostheses. It was, however, surprising and disappointing that Scandinavian surgeons had used this prosthesis for many years and in more than 10,000 patients before they were able to document its poor performance.

The Wagner prosthesis and other double-cup prostheses became popular in Norway shortly after the period with the Christiansen prosthesis. A double-cup prosthesis is a prostheses which, in addition to the acetabular cup, has a metal cup re-surfacing of the femoral head. It was later documented that the results of the double-cups were far inferior to those of the Christiansen prosthesis, with 30% revised after five years and 60% after eight years (Howie et al. 1990).

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

Based on the poor results with the Christiansen and the double-cup prostheses, Professor Einar Sudmann initiated a nation-wide registration system for THRs in Norway through the Norwegian Orthopaedic Association. In 1983, Professor Sudmann, Dr Lars B. Engesæter, Dr Tor Steinar Raugstad, and other orthopaedic surgeons in Norway started to work towards

establishing a national hip implant register. From 1986 Dr
Leif I. Havelin has been in charge of the day-to-day work, and
the registration started in September 1987.

4 THE NORWEGIAN ARTHROPLASTY REGISTER

The hip arthroplasty register was established in 1987 by the Norwegian Orthopaedic Association. It was located at the Haukeland University Hospital, with doctors only working spare time. From 1992, it has been a part of the Department of Orthopaedics and Traumatology, with a consultant orthopaedic surgeon as head of the Register.

Economical support from the Norwegian Medical Association's Fund for Quality Improvement has been received since 1993. During the last 3 years this support has represented the working capital for the hip register. It also made it possible to extend the register to include prostheses in all joints, from January 1994.

Cooperation with the Section for Medical Informatics and Statistics (SMIS) of the University of Bergen started in 1991. Investigations in the register have since been planned and conducted jointly with Professor Vollset from SMIS.

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 with this aim in mind.

The register is nation-wide so as to include as large a number of patients as possible and so as to be able to follow patients even when they were reoperated at other hospitals than where their primary operations had been performed.

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 revision with exchange or removal of one or more of the prosthetic parts were registered. Thus, no other reoperations such as reductions of dislocated prostheses were included.

5 AIMS OF THE PRESENT STUDY

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

1. Survey hip arthroplasty surgery in Norway.

2. Investigate the consequences of the introduction of
   uncemented hip arthroplasty in Norway.

3. Assess the results of the different types of cemented
   and uncemented hip implants.

4. Study the impact of the cement types on the results of hip
   prostheses.

6 MATERIAL: PATIENTS AND HIP PROSTHESES

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

Paper I surveys hip arthroplasty surgery. In this paper
we included all operations from September 1987 to December
1990, recorded in the Register before February 1991
(n=17,444).

In the next article (Paper II), comparing the cemented
and uncemented prostheses, patients operated with primary
prostheses for primary arthrosis, and where both components
were either cemented or not cemented, were selected
(n=15,335). These patients had been operated in the period
1987-1992, and had an observation period of 0-5.4 years.

In Paper III, different types of uncemented femoral
components were compared. We included primary uncemented
femoral prostheses in patients with stem types that had been
used in at least 100 operations each (n=2,907).

In paper IV, on cement types, only patients operated with
primary Charnley prostheses for primary coxarthrosis and
without any previous operation in the index hip were included
(n=8,579). The operations had been performed in the period
from September 1987 to February 1994.

Paper V, on uncemented cups, is based on primary
operations from the same period as in article IV. Cup types
which had been used in at least 100 primary operations each
were analyzed, and patients with all diagnoses were included
(n=4,352).

Paper VI, on different cemented prostheses, included
patients with primary arthrosis who had been operated with the
most common high viscosity cements and with THRs that had a
potential follow-up of 500 prosthesis-years (n=12,179).
The time period covered was from September 1987 to February
1994.

7 METHODS

7.1 Data Collection

The orthopaedic surgeons have filled in the hip register form after each operation where hip prostheses were inserted, exchanged, or removed. The form was mailed to the Arthroplasty Register where the data were coded and recorded on a computer.

The form is shown in Figure 1. An English translation can be found in article I. The form is simple to fill in (it takes less than 2 minutes), and it has space for free text comments.

In 1993, the form was simplified by removing the questions on pain, walking abilities and patient category.

7.2 Classification and code systems

When the data were recorded in the Register, the free text was transformed to code numbers. For example, when coding under Diagnoses of other (Figure 1), a list of the about 30 different other diagnoses reported were made. A similar system was made for previous operations in the index hip, reasons for revisions, and for complications.

Because it was common practice to combine components with one trade name (brand) with components with other trade names to make a THR, a more complex coding system had to be constructed for the prostheses. Moreover, the number of different designs within each trade name was large. Several designs, based on completely different principles, were often marketed under the same trade name. Thus, components made for uncemented and cemented use, with and without porous and/or hydroxy apatite-coating, could exist with the same trade name, and a vast number of combinations of head, cup, and stem were possible. Accordingly, we recorded each part of the THR separately, and each component was registered on catalogue number level. One code number was made for each trade name (brand) and subnumbers were made for each design within the trade name. The prosthesis trade name could thus be recorded even if we had incomplete information on which of its designs that had been applied. Several manufacturers of hip prostheses have provided stickers with catalogue numbers along with the

implants. Use of these stickers on the forms has improved the
accuracy of the coding.

Several different cements were used for fixation of the
prostheses, and a code list had to be made for the cement
types. The cement was recorded separately for the femoral and
acetabular components by trade name, viscosity, and addition
of antibiotic.

7.3 Quality control of data

The secretaries discussed forms with unclear or
incomplete information with the consultant, and these forms
often had to be returned to the hospitals for completion.
Checks were performed regularly in the data base, searching
for systematic errors which were corrected.

Once a year, the contact person at each hospital received
statistics for his/her hospital. They were asked to check the
numbers and to send forms from operations not reported. In
addition, similar statistics from the whole country were
supplied, making it possible to compare one's own hospital's
results with the nation-wide results.

7.4 Statistical methods

We used survival analyses (Kaplan & Meier, 1958) to estimate
the probability of the prostheses not being revised. The main
end-point in the analyses was revision of the prosthesis. Both
revision for different reasons and revision of different
components could be used as end-point. In survival analyses of
hip prostheses, patients are followed until the end-point
occurs (revision). If follow-up is terminated for other
reasons than revision (e.g. death or emigration) the
observation is censored. The survival time for patients who
died without having had a revision, were censored at the time
of death of the patient. Thus, the survival time from the
primary operation until the time of death was included in the
analyses and the prostheses of these patients were counted as
successes. The survival time of the prostheses that had been
revised for other reasons than the defined end-point, were

also censored. Thus, in analyses on survival until revision for <u>aseptic loosening</u>, THRs which had been revised because of <u>infection</u> were censored at the time of their revision.

Multivariate survival analyses (Cox regression) were performed to investigate the influence on the results of factors such as gender, age and diagnosis. The results of the different implants were compared, with adjustment for the above factors.

In addition, in all the articles on prosthesis survival, supplementary analyses (Kaplan-Meier and Cox analysis) were carried out restricted to smaller homogenous subgroups.

The two sided log-rank test was used to reveal statistically significant differences between groups in the Kaplan-Meier analyses. Score-tests were used in the Cox-analyses.

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

F. nr. [11 sifre] :

Navn:

Sykehus:

(Bruk blokkbokstaver)

ANAMNESE:

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

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

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

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

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

OPERASJONSOPPLYSNINGER:

                                    dag   mnd   år
6. OPERASJONSDATO: [__] [__] [__]

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

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

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

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

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

11. TILGANG (sett kryss):
    - [ ]¹ Fremre (Smith-Petersen).
    - [ ]² Anterolateral.
    - [ ]³ Lateral.
    - [ ]⁴ Posterolateral
    - [ ]⁵ Annet: ....

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

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

PROTESE. NAVN/TYPE (Spesifiser nøyaktig):
14. Acetabulum:
    Navn/Type: ....
    Evt. Kat. nr: ....
    - [ ]¹ Sement med antibiotika. Navn: ....
    - [ ]² Sement uten antibiotika. Navn: ....
    - [ ]³ Ikke sementert.

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

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

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

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

19. OPERASJONSTID (hud til hud): [_ _] min.

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

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

Figure 1. The hip register form.

8 SUMMARY OF RESULTS

Paper I.

This paper contains a survey of the hip arthroplasty in Norway
from September 1987 to the end of 1990. We found that 69% of
the patients were women. The mean age was 70 years (range: 12-
97) for primary operations and 71 years (range: 18-93) for
revisions. 13.5 % of the operations were revisions. Primary
arthrosis was the diagnosis in 68% of the primary operations,
sequelae after hip fracture in 13%, rheumatoid arthritis 4%,
sequelae after dysplasia 8%, and dysplasia with dislocation
2%. The most common reasons for the revisions were loosening
of the stem (64%) and loosening of the cup (56%). Dislocation,
infection and, fracture of the femur each accounted for 4% of
the reasons.

    The acetabular components were uncemented in 17% and the
stems in 12% of the primary operations and in 21 % and 17% of
the revisions. The Charnley was the dominant prosthesis type
with 49% of all implants. A total of 422 different designs and
sizes of cups and 398 different stems had been used in this
period. The annual incidences of THR in Norway were
124/100.000 and 114/100.000 inhabitants in 1989 and 1990
respectively.

Paper II.

In this paper, the nation-wide overall results of the cemented
primary THRs were compared to uncemented primary THRs in
patients with primary coxarthrosis. The Kaplan-Meier estimate
of the cumulative failure at 4.5 years was 2.7% for cemented
and 6.5% for uncemented THRs. In patients under 65 years, the
cumulative 4.5 years failure was 3.3% for cemented and 7.9%
for uncemented THRs. For the acetabular components the
cumulative 4.5 years failure was 0.6% for cemented and 1.7%
for uncemented, and corresponding figures for femoral
components were 1.7% and 3.9%. Two (2.0) times higher risk of
failure was found with the uncemented compared to cemented
THRs in Cox regression analyses, with adjustments for age and

sex. Cemented THRs in women had a better prognosis than in
men, but there was no difference in the results between the
sexes with uncemented THRs. The largest difference in results
between cemented and uncemented prostheses was seen among men
under 60 years.

Paper III.
The different types of uncemented femoral components were
compared in this paper. At 4.5 years, the Kaplan-Meier
estimate of the revision because of aseptic loosening of the
stem was 4.5% for all implants, 18.6 for the Bio-Fit
prosthesis, and 13.6% for the Femora stem. The PM-prostheses
and the Harris/Galante stems were revised in 5.6% and 3.6%
respectively. The Femora (a clockwise threaded stem) needed
revision in 20% of right hips but in only 4% of left hips. The
Corail, LMT, Profile, and Zweymüller stems all had
probabilities for revision of under 1% at 4.5 years. Cox
analyses with adjustment for age, gender and diagnosis
confirmed these results.

Paper IV
This paper addresses the impact of different cements on the
survival among primary Charnley prostheses. The end-point was
revision for aseptic loosening. For the femoral components,
the overall 5.5 years cumulative revision rate was 2.8%. The
femoral components with the low viscosity cement CMW 3 had an
estimated 5.5 years revision rate of 5.9%, whereas the
components with high viscosity cement had a 5.5 years revision
rate of 1.8% ($p < 0.001$). Boneloc cement had only been used for
3 years, and the femoral components with this cement had a
revision percentage for aseptic loosening of 4.5% after only 2
years ($p < 0.0001$ compared to each of the groups with high and
low viscosity cemented stems).

For acetabular components, there were only small
differences among the cements that had been used throughout
the period, with a cumulative survival better than 99% for all
types after 5.5 years. Cups with Boneloc cement had poorer

results than the others, with 1.2% revision already after 2 years, compared to 0.2% for the others at that stage (p<0.001).

Addition of antibiotic to the high viscosity cement gave a small improvement in survival, with statistically marginal significance in the survival of the stems and the cups.

Restricting the comparison to cements without antibiotics and with adjustments for age and gender in a Cox model, the femoral components with low viscosity cements had a 2.5 times (95% confidence interval (CI): 1.6 to 3.8) increased risk for revision compared to high viscosity cemented components. Those with Boneloc cement had an 8.7 times (95% CI: 5.1 to 14.8) increased rate of revision.

Paper V
In this paper, the results of the different types of uncemented cups were compared. The overall Kaplan-Meier estimate of the cumulative revision for aseptic loosening of the cups was 3.2% after 5 years and 7.1% after 6 years. None of the unthreaded porous-coated hemispheric cups (Harris/Galante (n=221) and Gemini (n=405)), and only one of the HA-coated cups (Atoll (n=772) and Tropic (n=1,171)) had been revised. The results differed among the threaded metal backed cups, from no revisions of the PM-cup (n=148) to a cumulative revision percentage of 20.6 for the Ti-Fit (n=300). The threaded all-polyethylene Endler cup (n=334) had a cumulative revision percentage of 13.9 after 6 years. Cox analyses with adjustment for age, gender and diagnosis confirmed the results.

Unlike the other papers, we found poorer results among women than among men. The threaded cups had an increased risk of revision in women compared to men, and these cups performed less well in patients with inflammatory arthritis (rheumatoid arthritis and ankylosing spondylitis) than in patients with arthrosis. The HA-coated and the hemispheric porous-coated cups, however, had good results in all groups of patients.

Paper VI

In this paper we compared the results of the 10 most common
cemented total hip prostheses. The Kaplan-Meier estimate of
the overall percentage revised at 5 years was 2.5, and the
corresponding figure for the Charnley prosthesis (n=6,694) was
2.9. The revision rate for the prosthesis types were compared
to the Charnley prosthesis using Cox regression, with
adjustment for gender, age, type of cement, and use of
systemic antibiotics. The revision rate for the Spectron/ITH
combination (n=1,034) was only 0.35 times of that of the
Charnley. The Elite/Charnley combination (Elite cup and
Charnley stem) (n=507) and the Müller Type prosthesis (n=116)
showed poorer results with failure rates of 2.3 and 2.7 times
that of the Charnley respectively. Among the other types there
were only minor differences in results.

The pattern of causes for revision was similar among the
different prostheses except for the Elite/Charnley combination
where 6 of 12 revisions were due to infections, compared to
20% of revisions for this reason in the total material.

Male patients had a failure rate ratio of 2.2 compared to
women.

9 DISCUSSION

9.1 METHODOLOGICAL CONSIDERATION

9.1.1. *Register studies versus randomized trials in total hip replacement surgery.*

A well performed randomized clinical trial provides the strongest evidence for conclusions about the results of different treatments, i.e. different total hip prostheses. Randomization provides an asymptotic guarantee that the groups are comparable both concerning known and unknown confounding factors.

Ideally randomized clinical trials should be carried out, with several years of follow-up, before new prostheses are marketed. However, in hip replacement surgery, randomized studies have not been required by the authorities and relatively few such studies have been published (Gross 1988, Faro and Huiskes 1992). As the results of hip arthroplasty are generally very good, large numbers of patients are needed to demonstrate differences, and the studies must continue for many years. To detect a difference in the probability of loosening between two prosthesis types with failure rates of 3% and 5% respectively, a total of 3,008 patients are required to obtain a significance level of 0.05 with a power of 80% (Rosner 1990). To detect a difference of 1%, with the same statistical significance level and power, 13,474 patients are required. The time needed in a randomized study with a smaller number of patients might be so long that the problem or the prosthesis studied may have lost its relevance before the study is finished.

As randomized trials are unpractical and few, it is important to evaluate the results of hip surgery in large register studies. An advantage in nation-wide register studies is their large numbers of patients, and that the results of many prostheses and many patient categories may be addressed in the same study. Register studies give a nation-wide overview of the results. This in contrast to randomized studies in which results are studied in smaller groups of

patients. As discussed in Paper IV, it is more of academic
interest to find good results of a prosthesis or of a cement
in a randomized study, where the operations are performed by
specially trained surgeons, if the nation-wide results are
poor.

A disadvantage of register studies is that known and
unknown confounding factors may be unevenly distributed in the
study groups. Young male patients with a known poor prognosis
might be given uncemented prostheses in a higher percentage
than old female patients with a known good prognosis. If
poorer results are found with uncemented prostheses, these
results might be caused by a greater number of patients with a
poor prognosis in the uncemented group. However, the uneven
distribution of risk factors in the comparison groups can be
dealt with, or adjusted for, in several ways in register
studies. One approach is to select a homogenous subgroup of
patients to study the effect of different treatments or
prostheses, and to perform additional tests within even more
homogenous strata of patients. Another approach is to perform
multivariate analyses, for example Cox regression, where the
simultaneous effect of several risk factors such as age,
gender, and diagnosis can be studied. These risk factors can
be adjusted for, when we compare the results of different
prostheses.

9.1.2. Completeness of data
All the orthopaedic surgeons and all the hospitals in Norway,
through the Norwegian Orthopaedic Association, have agreed
upon reporting to our register. The follow-up is complete in
the sense that revisions will be reported even if the patient
is revised at another hospital than where the primary
operation was performed. However, reporting to a large
register will never be absolutely complete. Note, however,
that only selective under-reporting of revisions of some types
of prostheses could affect the differences in results of
prosthesis survival.

An independent investigation on numbers of THRs in each

hospital was done for 1989 and is referred to in article I
(Solheim 1991). We have also been in regular contact with the
Norwegian Institute for Hospital Research (NIHR) in Trondheim,
comparing our numbers of operations. During the first years,
our numbers were larger than those registered in the NIHR. For
the years 1992 and 1993, our numbers were 5% lower. Four
smaller county hospitals did not report to us during these two
years, and this accounts for half of the discrepancy. As far
as we are able to check the data, the underreporting was not
associated with special implants or patients, and we are
assuming that at least 90% of the THRs performed in Norway are
reported to the Register. For these reasons, and in accordance
with Dorey and Amstutz (1989) who addressed the validity of
survival analyses, the under-reporting is assumed to be evenly
distributed among groups of patients and types of implants.
Thus it will not affect the relation between results of the
different prosthesis types.

9.1.3. Definition of failures
Failure was defined as a revision where the whole prosthesis
or a part of the prosthesis, was removed or exchanged. Other
end-points are possible. For example, a prosthesis may be
regarded a failure if it is radiographically loose, or if the
hip becomes painful or infected, even if the prosthesis has
not been revised. It would, however, be practically impossible
to use these definitions of failures in a nation-wide register
study such as the Norwegian Arthroplasty Register. The use of
the other end-points would demand that all THRs were followed
regularly in clinical and radiographic controls, which is not
common in Norwegian hospitals. We therefore found revision to
be an objective, and the only practical, end-point.

With revision as end-point, we have used the most strict
definition of failure. Thus all our failure rates are low
estimates compared to analyses with other end-points.

A disadvantage with this end-point is that there might be
differences between the surgeons' indications for revision.
The time interval between the moment the surgeon has found an

indication for revision and when the revision is done may also differ between hospitals. As each hospital usually only has a limited number of prosthesis types, the difference in waiting times and revision policy could therefore affect the results of some prosthesis types more than others.

Another issue is that patients with known inferior implants, for example those with Boneloc cement, are followed more closely by the surgeons and might have a lower threshold for revision than patients with other types of prostheses. In later investigations, results of these implants with already documented poor results may therefore show falsely high rates of revision compared to the other implants.

The revision is an undisputable event, but the reason for revision is not always completely clear. In our reporting system the surgeons give all the information immediately postoperatively. As we get no new report if peroperative cultures are positive, subclinical infections might be under-diagnosed. Furthermore, during revisions of one prosthetic component, loosening of the other component may be found peroperatively. The revision way therefore sometimes be carried out earlier than it would have been if the loosening had been diagnosed radiographically. These problems, however, apply to only small numbers of revisions.

These considerations mean that one should be especially careful about drawing conclusions from the results of prostheses with few revisions. However, as our numbers of revisions are minimum numbers, the problems above can never be used as an excuse or an explanation of poor results of a prosthesis. The results would have been even poorer if we had used end-points such as "planned revision" or "radiographic loosening".

9.1.4 Selection of study groups

In principle, comparing results of different treatments should only be done when the patients in the comparison groups are similar in all aspects apart from the treatment under study. In an observational study this cannot be achieved completely,

but the compared groups will be very similar if homogenous patient groups are selected. Supplementary analyses of this kind on homogenous subgroups were done in all the papers.

9.1.5 Statistical methods.

Survival analysis is a more appropriate method for evaluating data from the follow-up of THRs than failure percent analyses (Dorey and Amstutz 1986). The patients with prostheses have been followed for periods of different lengths, some patients have died or emigrated with their prostheses intact, and some prostheses have been revised. In contrast to analyses that only give the percentage of failed THRs, the survival analyses take care of all this information. As hip replacement surgery is mainly performed in old patients, it is important that the prostheses in patients who die without having had a revision are followed until the time of death, and then censored.

Multivariate analyses (Cox proportional-hazards model) had to be used to study the importance of prognostic factors such as age, diagnosis, and gender. In this model, several variables can be studied simultaneously. When one variable, such as prosthesis type, is studied, adjustments can be made for a set of potential confounders. The importance of these adjustments was clearly illustrated in Paper VI, where several of the differences in prosthesis survival after adjustment became reduced and no longer statistically significant.

The Cox model is based on the assumption that the hazard rates of the compared groups are proportional. This assumption was not tested for specifically in our study, which had a relatively short observation period, but the curves were examined. In future studies with longer follow-up, modifications of the Cox model, with different rate ratios for different time periods, should be considered.

9.2 DISCUSSION OF RESULTS

9.2.1 Epidemiology of hip arthroplasty surgery

As can be seen in Paper I, the annual incidence of primary THR in Norway was about 120/100,000 inhabitants. This number corresponded well to the numbers in Sweden in 1987, but the incidence was higher than in other countries (Harris and Sledge 1990, Overgaard et al. 1991, Paavolainen et al. 1991, Malchau et al. 1993). Several factors may contribute to the high incidence of hip replacement in Norway. In the Norwegian national health care system, the operations are free of charge. Similar access to operations in low and high income groups could give a higher operation incidence in the low-income groups than in some other countries. In the early 1980s, there were rather long waiting lists for THR, but the hospitals then received more resources for total hip replacement surgery.

The possibility could be considered that the high rate of hip surgery is caused by a high incidence of coxarthrosis in the Norwegian population, specially among women, but so far we have no such documentation.

The large number of different brands of prostheses and the vast number of different designs of these prostheses (about 400 of each of femoral and acetabular components, Paper I), can hardly be regarded as necessary from a surgical or a scientific point of view. The large number of implants is more a consequence of the weak control of medical implants in Norway and in most European countries. In Norway, each orthopaedic department (not the individual surgeon) makes the decision about which implant to use. The decision about which implant to market has been left to the distributors.

9.2.2 Uncemented prostheses

In Paper II, the conclusion is quite clear that <u>overall</u> the nation-wide result for the uncemented prostheses was poorer than for the cemented. From Paper II it can be seen that, especially in young patients, the uncemented prostheses had

poorer results than the cemented. Thus, we found the poorest results of uncemented prostheses in the patients who most commonly received uncemented implants.

Papers III and V show that although the overall results with uncemented implants were poorer than with cemented, several types of uncemented cups and stems had very good results. Thus, the results were more dependent on the design and surface of the prostheses than on the use or non-use of cement.

From articles III and V it can be concluded that uncemented implants with hydroxyapatite(HA)-coating generally gave good results during the first 5 years of follow-up. Moreover, good results were found for uncemented stems with circumferential porous coating, and for hemispheric cups with porous coating.

With the above designs, the problem of fixation of uncemented prostheses seems to be resolved, at least for the period up to 6 years. It is, however, still unknown to what extent these prostheses might loosen after a longer period of time, or whether osteolysis will become a more serious problem with the uncemented than with the cemented prostheses. During the study period, uncemented prostheses with a 32mm head diameter have been used in large numbers of patients in Norway. Caput prostheses made of titanium have also been common. Both these designs seem to be associated with increased polyethylene wear (Friedman et al. 1993). It is possible that these implants, and HA particles in the joint space (Bloenbaum & Dupont 1993), will constitute a serious wear and osteolysis problem in uncemented hip prostheses. What is the best prosthesis - cemented or uncemented ? To answer this question randomized studies with long follow-up and large numbers of patients should be performed, and the best cemented prostheses should be compared with the best uncemented. From data in the Norwegian Arthroplasty Register, we can still not answer this question.

9.2.3 Cement types

Low-viscosity cements have been used in Norway for several years without clinical data proving their superiority compared to high-viscosity cements. When surgeons also started to use Boneloc cement without documented clinical results, we found it important to investigate the results of the different cements used in Norway.

Because of the many THRs performed (about 5,000 a year in Norway), the 4% poorer 5.5 year survival for Charnley prostheses with low-viscosity cement compared to those with high viscosity cement represent large numbers of extra revisions. From our material we cannot see whether the inferior results were due to poorer properties of the cement, or whether the results were poorer because the low-viscosity cement was more technically demanding to use.

Boneloc cement, which was introduced in Norway in 1991, gave significantly poorer results than all the other types of cement (Paper IV) only after 2.5 years of use. At this stage, the cumulative revision was 4.5% for the femoral stems fixed with Boneloc cement compared to less than 2% for each of all the other cements. Poor results have also been published by others (Linder 1995). It remains to be seen whether this cement represents a new disaster in hip arthroplasty. The Norwegian Board of Health has sent out an international vigilance report on the Boneloc results from the Norwegian Arthroplasty Register. Partly because of this report the sale of the Boneloc cement was terminated, also abroad, in April 1995.

This example clearly showed the ability of the Register to reveal poor results of products as early as after about 3 years of use.

9.2.4 Cemented prostheses

Generally, the results of cemented implants were good and with less variation than the results of the uncemented implants. The Charnley prosthesis has dominated in Norway, and this prosthesis has by many been considered the "gold standard" in

THR surgery (Agins et al. 1988, Malchau et al. 1993, Wroblewski and Siney 1993). In the univariate survival analysis on prosthesis type in Paper VI, we found better results for several other prostheses. However, after adjustment for gender, age, cement type, and systemic antibiotic prophylaxis, only the result of the Spectron/ITH (cup/stem) combination remained statistically significantly better than the Charnley. It should be noted that the use of the Spectron/ITH has been limited to only a few hospitals, and that the good results of this THR could be due to better skilled surgeons than the average at these hospitals.

We found poorer results for the Müller Type and the Elite/Charnley combination. The Müller Type, with its curved stem, is no longer used in Norway. The poor result of the Elite/Charnley is difficult to explain. The Elite cups in our study had 22 mm inner diameter and larger outer diameters than the traditional Charnley cups. A higher percentage of men was seen among the patients with Elite cups than among patient with other THRs, and the cups may have been chosen during difficult operations in males with a known poor prognosis. Another possibility is bacterial contamination, as 6 revisions out of 12 were done because of infection. It must, however, be kept in mind that the number of the Elite/Charnley combination used was rather small (n=507).

Paper VI covered patients with primary arthrosis and with high viscosity cement. In univariate analyses, we found that the results for several prostheses were statistically significantly different from those of the Charnley prosthesis. For most prosthesis types, this statistical significance compared to Charnley disappeared after adjustments for age, gender, cement brand, antibiotics, and type of operating theatre. This fact clearly demonstrates the importance of the registration of, and adjustment for, other risk factors. These adjustments do not seem to have been done in other large register studies (Ahnfelt 1990, Malchau 1993) on hip prostheses.

Actually, for the cemented prostheses there were larger

differences among the cement types than among the prosthesis
types. Probably or hopefully, after many years of trial and
error, the poorest designs of cemented prostheses are now no
longer used, and with the new types, the design and the
results are only minimally different from previous types.

9.2.5 Diagnosis, gender, and age

The different diagnostic groups, except primary coxarthrosis,
were small, and the impact of diagnosis on the results of the
prostheses was not the primary subject of any of the papers.
However, the Cox model in Paper V showed that the risk for
revision of uncemented cups in patients with rheumatoid
arthritis was increased by 2.8 (p=0.01) compared to patients
with coxarthrosis. This result was, however, caused by the
great number of revisions of the threaded cups. The RA
patients, like the other patients, had very good results with
the porous or HA-coated cups. To study cemented THR, we
selected only patients with primary arthrosis. This thesis
does not give any information on the results for cemented
prostheses in patients with different diagnoses.

Women dominated in the total material and also in all the
larger diagnostic groups such as coxarthrosis, sequelae after
fracture, and rheumatoid arthritis. Earlier publications have
shown better results in women and old patients compared to men
and young patients (Gross 1988, Ahnfelt 1990), and we found
these results among patients with cemented THRs (Paper VI). In
patients with uncemented THRs, the results differed for the
femoral and acetabular components: The results with the
uncemented stems were best in the women, and the results with
uncemented cups were best in men. With the uncemented
prostheses, however, the difference in results between men and
women was only found for the components with poor results. No
difference between the sexes was found for the uncemented THRs
with good results,

It is possible and probable that young patients are
revised earlier, or with less symptoms, than older patients.
Surgeons will tend not to revise prostheses with loosening

among the very old patients, specially if they have heart- or lung disease. It seems possible that the good results of prosthesis surgery among old patients can partly be explained by the surgeons' stricter indications for revision of these patients. Similarly, it is possible that the lower revision rates for hip prostheses in women than in men are influenced by the surgeons having a lower threshold for revising loose prostheses in men than in women. Such gender differences in treatment have been reported in cardiovascular disease (Wenger et al. 1993). For these reasons, adjustments for age and gender have to be done in research on hip prostheses, and reservations have to be taken in the interpretation of the age and gender differences in the results of hip prostheses.

9.2.6. Marketing of hip implants.

New products must be tested in laboratories, in animal experiments, and then in pilot clinical studies. Although such testing is not required for medical devices, as opposed to drugs, new products should also be evaluated in randomized clinical trials before they are marketed. Of course, one has to wait for the results of the clinical trials before new products are marketed freely. Furthermore, to avoid future "disasters", new products should not be used in large numbers of patients during the first years. The Boneloc experience shows that there is still a need for national arthroplasty registers. Post marketing surveillance in national registers can, however, not replace clinical trials (Linder 1995).

10 CONCLUSIONS

1. The Norwegian Arthroplasty register has shown its ability
   to reveal poor results of hip prostheses as early as after
   3 years of follow-up.

2. About 40 different prosthesis brands, and about 400
   different designs and sizes of acetabular and femoral
   implants had been used. This is a larger number than seems
   necessary from a medical point of view.

3. The results for cemented implants were generally very good,
   with only small differences between the types.

4. The overall results for uncemented prostheses were poorer
   than for cemented THR. There were great differences in
   results among the uncemented THR. For cups, good results
   were found for those with HA-coating and for the
   hemispheric porous coated. For stems, good results were
   found for the HA-coated and for those with circumferential
   proximal porous coating.

5. The importance of the influence of the cement type on the
   results of THRs was demonstrated. Poorer results were found
   with low-viscosity cement and with Boneloc cement.

6. Cemented prostheses performed best in women and in old
   patients. For uncemented stems, best results were found in
   women, and for uncemented cups, best results were found in
   men. In patients with uncemented prostheses, there were no
   significant age differences in the results. Within the best
   designs of uncemented prostheses there were no age, gender,
   or diagnosis-related differences in results.

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PAPER 1

The Norwegian arthroplasty register

A survey of 17,444 hip replacements 1987–1990

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In Norway a national register for total hip replacements was established in September 1987. Up till February 1991, 17,444 total hip replacements (THR) were reported, i.e., 140 THR / 100,000 inhabitants / year. The median age of the patients was 70 years, and 69 percent were women. 87 percent were primary arthroplasties and 13 percent were revisions. Primary arthrosis was the diagnosis in 68 percent of the primary operations.

The acetabular implants were uncemented in 17 percent and the femoral implants in 12 percent of primary operations. In revisions, the implants were uncemented in 21 and 17 percent, respectively. The reasons for revision were loosening of components in 87 percent and deep infection in 4 percent.

The Charnley prosthesis dominated with 49 percent of all implants. A total of 422 different designs and sizes of acetabular implants, 398 femoral implants and 166 of caput designs and sizes were used. This large number of different types and designs seems unreasonable.

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In Norway a national register for total hip replacements (THR) was established in 1987 to record all prostheses in use and to compare the results of the different types of implants. We present the data from 17,444 hip replacements reported to the register during the first 3 years, giving a survey of the patients, the techniques used and the implants.

Patients and methods

The Norwegian registration of operations started September 15, 1987. The material presented here includes the operations registered before February 1, 1991, covering 3.5 months of 1987 and the full years 1988–1990. All 64 hospitals in Norway performing THR participated. The surgeons filled in the registration form (Figure 1) immediately after each operation. The patients were identified by their unique 11-digit social security number, including date of birth, assigned to all Norwegians. Preoperative pain, walking ability and functional level were classified according to Charnley's (1979) modification of the Merle d'Aubigné and Postel (1954) classification. The trade name of the prostheses with specifications of size, material, surface, etc., or catalogue number were given. Data on both primary total hip replacements and revisions were reported. Operations were classi-fied as primary, when no earlier THR had been performed in the index hip. Of reoperations, only those where prosthetic parts were either exchanged or removed were recorded. Primary operations and revisions were recorded in the same way, except that in the revisions the indications for surgery were also included, and in the primary operations the primary diagnoses were recorded. Statistical analyses were done by the program BMDP (Dixon et al. 1990).

Results

During the period of 3 years and 3.5 months, 17,444 operations were registered (Table 1), with 1,487, 4,502, 5,947 and 5,515 operations each year. Some of the hospitals did not participate from the start, and 1 hospital reported only a few of its operations. The number of THR in each hospital varied from 1 to 1068 during the registration period. Primary operations were performed in all hospitals, but revisions were not done in 4 of the smaller hospitals. 69 percent of the patients were women. The right hip was operated on in 54 percent. The revisions constituted 13.5 percent. The median age was 70 (12–97) years for primary operations and 71 (18–93) years for revisions (Table 2). The patients' symptoms, walking ability and functional group are given in Table 3. Primary operations were

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THE NORWEGIAN NATIONAL REGISTER FOR TOTAL HIP REPLACEMENTS

Pain:
1 Severe. Spontanous.
2 Severe on attempting to walk. Prevents activity.
3 Moderate. Permitting limited walking.
4 After some activity, disappears quickly with rest.
5 Slight or intermittent. Pain on starting.
6 No pain.

Walk:
1 Bedridden or few yards, two sticks or crutches.
2 Very limited with or without sticks.
3 Limited with one stick (less than one hour).
  Able to stand long periods.
4 Long distances with one stick.
5 No stick but a limp.
6 Normal.

Patient categories:
1 One hip affected, otherwise physically fit.
2 Both hips affected, otherwise physically fit.
3 Other conditions impairing walking ability.

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

Duration of symptoms (years):

OPERATION:

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 operations):
1 Idiopathic coxarthrosis.
2 Rheumatoid arthritis.
3 Seqv. after hip fracture.
4 Seqv. after dysplasia.
5 Dysplasia with dislocation.
6 Seqv. after slipped capital femoral epiphysis or Perthes
  disease
7 Ankylosing spondylitis.
8 Other:

Reason 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 Other:

Revision:
1 Change of femoral component.
2 Change of acetabular component.
3 Change of all components.
4 Other (e.g. Girdlestone op):

Approach:
1 Anterior.
2 Anterolateral.
3 Lateral.
4 Posterolateral.

Osteotomy of trochanter
1 Yes.
2 No.

Bone transplantation:
1 No
2 In acetabulum.
3 In femur.
4 In both.

Femur:
Name/Type:
Cat. no.:
1 Cement with antibiotic: Name:
2 Cement without antb.: Name:
3 Uncemented.

Caput:
1 Fixed caput.
2 Modular system: Type/Name:
  Cat. no.:
  Diameter (mm):

Systemic antibiotic prophylaxis:
1 No.
2 Yes: Name:

Operative theatre:
1 "Green house"
2 With laminar air flow.
3 Without laminar air flow.

Duration of operation:
Skin to skin, minutes:

Surgeon:
(Who has filled in the form)

Figure 1. English translation of the form filled in by the surgeon and sent to the hip register immediately after surgery.

Table 1. Reported total hip replacements September 1987–December 1990

	Men	Women	<65 years	≥65 years	Total	Percent
Primary THR	4607	10487	4223	10870	15094	87
Revisions	801	1549	624	1725	2350	13
Total	5408 31%	12036 69%	4847 28%	12595 72%	17444	100

Table 2. Age of the THR patients

Age	Primary operations		Revisions	
years	n	Percent	n	Percent
<20	15	0.1	2	0.1
20–29	52	0.4	13	1
30–39	191	1	40	2
40–49	541	4	101	4
50–59	1543	10	184	8
60–69	4866	32	675	29
70–79	6500	43	1012	43
>80	1374	9	322	14

Table 5. Types of removed prostheses at 2350 revisions

Prostheses	Number	Percent
Christiansen	535	23
Müller	449	19
Charnley	386	16
Wagner	200	9
Tharies	91	4
Exeter	53	2
ICLH	44	2
Others (33 different)	302	13
Hybrids (35 different)	123	5
Unknown	167	7
Total	2350	100

Table 3. Pain, walking ability and functional patient groups prior to index operation

	Percent of primary operations n 15094	Percent of revisions n 2350
Pain		
Severe, spontaneous	29	21
Severe on attempting to walk. Prevents all activity	16	22
Moderate, permitting limited activity	49	47
After some activity, disappears quickly with rest	4	4
Slight or intermittent, pain on starting	1	2
No pain	0.4	1
Walking ability		
Bedridden or few yards, two canes or crutches	12	21
Very limited with or without canes	46	43
Limited with one cane (less than one hour)	29	25
Able to stand long periods		
Long distances with one cane	4	3
No cane but a limp	7	4
Normal	0.3	1
Functional group		
1. One hip affected, otherwise physically fit	54	48
2. Both hips affected, otherwise physically fit	37	42
3. Other conditions impair walking ability	7	3

Table 4. Diagnoses at 15094 primary THR and indications for 2350 revisions, percent

Diagnosis (primary operations)		Indication for revisions*	
Primary arthrosis	68	Loosening of acetabular component	56
Rheumatoid arthritis	4	Loosening of femoral component	64
Sequelae after hip fracture	13	Dislocation	4
Sequelae after dysplasia	8	Infection	4
Dysplasia with dislocation	2	Fracture of femur	4
Other pediatric hip disease	1	Pain	11
Ankylosing spondylitis	0.4	Others	5
Others	2		

*Several indications possible for each revision.

Table 6. Systemic antibiotic prophylaxis given pr. operatively during total hip replacements

	Primary (15094)		Revisions (2350)	
	n	Percent	n	Percent
None	1450	10	117	5
Cephalosporins	8953	59	1387	59
Cloxacillin/dicloxacillin	3516	23	595	25
Others (11 different)	419	3	61	3
Combinations (27 different)	633	4	137	6
Unknown	99	0.7	32	1.4

done for primary arthrosis in 68 percent (Table 4). 17 percent of the index hips had undergone surgery preceding a primary THR; osteosynthesis of proximal femur fracture (11 percent), hemiprosthesis (1 percent), osteotomy (2 percent), and arthrodesis (0.5 percent). 14 other types of operations constituted 2 percent.

The most common of the revised prostheses was the Christiansen prosthesis (Table 5). 90 percent of the revised prostheses had been operated into the patients before the period of registration. The indication for revision was loosening of one or both components in 87 percent and infection in 4 percent (Table 4). 30 revisions were performed due to fracture of the femoral component. In 58 percent of the revisions all components were exchanged, in 14 percent only the acetabular component, in 23 percent only the femoral component. Removal of both components only (Girdlestone operation) was performed in 2 percent.

A lateral approach (Charnley 1979, Hardinge 1982) was used in 61 percent, and a posterolateral approach was used in 29 percent. A trochanteric osteotomy was performed in 24 percent of the operations. Some kind of bone transplant (not specified) was commonly used when uncemented prostheses were applied, in 53 percent of primary and 84 percent of revisions. Only 7 percent of the patients receiving a cemented prosthesis had any bone transplant.

Systemic antibiotic prophylaxis was given in 90 percent of the primary operations, and in 95 percent of revisions (Table 6). Use of prophylaxis increased from 84 percent in 1987 to 95 percent in 1990. Cephalosporins were used in 59 percent, and cloxacillin or dicloxacillin in 25 percent. The prophylaxis was given for only 1 day in 56 percent and in 17 percent for more than 3 days.

The median operative time for primary operations was 95 (30–430) minutes, and for revisions 135 (25–390) minutes; cemented prostheses and the operations with trochanteric osteotomy required some 10–20 minutes more than those without cement or osteotomy.

Cement with antibiotics was used in 50 percent of the cemented prostheses—45 percent of primary and 96 percent of revisions. 12 different types of cement were applied. Low viscosity cement was used in 7 percent of femoral and 3 percent of acetabular prostheses. 12 percent of the operations were performed in a "greenhouse", 25 percent in a theater with laminar airflow, and 60 percent in a conventional theater.

Peroperative complications were reported from 3 percent of the primary operations and 8 percent of the revisions. The revisions resulted in femoral fracture in 2 percent, while for primary operations this complication occurred in 0.2 percent of operations. When uncemented femoral prostheses were used at primary operations, a fissure in the proximal femur or fracture of the major trochanter was reported in 3 percent, but only in 0.7 percent when cemented femoral components were used. In revisions, these complications were seen in 3 percent, regardless of use or non-use of cement.

Implants

34 different types (or brands) of acetabular and 39 types of femoral implants (cemented and uncemented) were used. A total of more than 1,000 different component designs and sizes of these types of implants have been marketed in Norway, while 422 different acetabular and 398 femoral implants were actually used. Some of the types (brands) were only femoral, acetabular or caput components. All the types had components of many different designs and sizes. Within one single type of femoral or acetabular prosthesis, there were often designs both for cemented and uncemented use, and commonly, one single type had designs with different surfaces (coatings). Within each type of caput prostheses, designs of different diameters, neck lengths, and commonly also of different materials, had been used. The number of different designs used within each type (brand) of component, femoral, acetabular or caput, varied from 1 to 50.

Table 7. Types of cemented acetabular and femoral components used at primary THR and revisions in Norway, 1987-1990

| | Acetabulum (13475) | | | | Femur (14315) | | | |
| | Primary (12242) | | Revisions (1233) | | Primary (12790) | | Revisions (1528) | |
	n	Percent	n	Percent	n	Percent	n	Percent
Bio-fit	0	0	0	0	181	1	18	1
Biomet Watson Farrar	66	1	2	0	0	0	0	0
Charnley	7275	59	677	55	7361	58	850	56
Christiansen	5	0	111	9	0	0	12	1
Elite	179	1	68	6	9	0	16	1
Endler	16	0	6	0	0	0	0	0
European cup system	67	1	5	0	0	0	0	0
Exeter	1578	13	117	9	1585	12	148	10
Femora	0	0	0	0	6	0	15	1
ITH	0	0	0	0	614	5	44	3
Landos	952	8	84	7	1563	12	214	14
Link	275	2	21	2	561	4	74	5
LMT Biomet	193	12	3	0	370	3	10	1
Müller style	33	0	1	0	32	0	3	0
Müller THP	79	1	6	1	2	0	1	0
Müller type	222	2	15	1	195	2	28	2
Müller type V	1	0	0	0	124	1	17	1
Original M.E.Müller	33	0	1	0	33	0	5	0
Scan hip	51	0	9	1	62	0	31	2
Spectron	1142	9	82	7	48	0	3	0
Tharies	14	0	6	0	13	0	0	0
Others (13 different)	17	0	14	1	9	0	26	2
Unknown	23	0	5	0	21	0	12	1

The Charnley prosthesis was the most commonly used; 59 percent of the cemented acetabular and 57 percent of the cemented femoral prostheses (Table 7). Primary Christiansen acetabular components were used only in 5 operations, and these were on patients who previously had been given Christiansen hemiprostheses. In revisions of only 1 of the components, Christiansen acetabular or femoral components had been used in 107 and 8 patients, respectively. In 4 revisions a new Christiansen total prosthesis was used.

24 types (244 different designs and sizes) of cemented acetabular prostheses and 28 types (267 designs and sizes) of cemented femoral prostheses were used. Some of the prostheses designed for uncemented use, had been used with cement.

In the primary operations, 17 percent of the acetabular components and 12 percent of the femoral, were uncemented. In the revisions, the corresponding values were 21 and 17 percent. Uncemented components were more commonly used in patients under 65 years (42 percent in acetabulum) than in the elderly (7 percent in acetabulum), and also more commonly in men (24 percent) than in women (18 percent). A combination of cemented and uncemented components in the same hip was rather common. 25 percent of the uncemented acetabular prostheses were combined with a cemented femoral prosthesis. Concerning the unce-

mented prostheses, many hospitals changed the type during the period. 16 different types (238 designs and sizes) of uncemented acetabular and 18 different (179 designs and sizes) femoral prostheses were used (Table 8). Of the femoral prostheses the 4 most common types constituted 75 percent.

One third of the cemented prostheses had a modular caput and of the uncemented prostheses virtually all. 25 types (166 different designs and sizes) of modular caput prostheses were used with stainless steel 51 percent, chrome-cobolt and ceramics 17 percent each, and titanium 13 percent. 73 percent of the modular and 10 percent of the non-modular capita had a diameter of 32 mm. The most common diameter on non-modular prostheses was 22 mm (83 percent), whereas only 2 percent of the modular capita had this diameter. In 16 cases a bipolar endoprosthesis (Charnley/Hastings) was used, together with an acetabular component from a double-cup prosthesis (Tharies).

Discussion

National registers for total hip replacements have been in function in Sweden and Finland for some years. The

Table 8. Types of uncemented acetabular and femoral components used at primary THR and revisions in Norway, 1987–1990

| | Acetabulum (3059) | | | | Femur (2217) | | | |
| | Primary (2571) | | Revisions (488) | | Primary (1822) | | Revisions (395) | |
	n	Percent	n	Percent	n	Percent	n	Percent
Aesculap Parhofer	113	4	22	5	106	6	22	6
AML	0	0	0	0	15	1	3	1
Bio-M	0	0	0	0	186	10	34	9
Ceraver	30	1	3	1	0	0	0	0
Coxa	148	6	18	4	0	0	0	0
Endler	607	24	60	12	1	0	0	0
European Cup System	182	7	54	11	0	0	0	0
Harris/Galante	156	6	47	10	111	6	25	6
Femora	0	0	0	0	114	6	14	4
Landos	601	23	174	36	465	26	114	29
Link	107	4	6	1	22	1	0	0
LMT Biomet	244	10	63	13	400	22	110	28
PCA	21	1	0	0	22	1	2	1
Profile	0	0	0	0	44	2	3	1
Ti-Fit	267	10	29	6	32	2	2	1
Tri-Lock Plus	52	2	4	1	0	0	0	0
Zweimüller	8	0	0	0	285	16	59	15
Others (6 different)	11	0	5	1	14	1	5	1
Unknown	22	1	3	1	15	1	2	1

Norwegian register differs from the Swedish. In Sweden, so far, only reoperations have been reported individually (Ahnfelt 1986), and only the total numbers of primary operations have been obtained from each hospital. The system in Finland is more comparable to the Norwegian, but in Finland and Sweden, the prostheses have been registered only by trade names. A single trade name is often used for quite different designs, making comparisons among trade names of less value. In the Norwegian system information is obtained not only on trade names but on characteristics like size, shape, material, surface, and system for fixation, which makes assessments of these variables possible.

To have such detailed information reported, it was necessary to have a form that could be filled in and sent to the register immediately after the operation. Our simple system of reporting has been the key for the high degree of participation from the Norwegian orthopedic surgeons.

In a national register, under-reporting may be a problem, for primary operations as well as for revisions. Under-reporting of revisions would disturb analyses of prosthesis survival, as the failure of a prosthesis is recorded only through its revision or the removal of component parts. In an independent survey, however, the hospitals' reported total numbers of operations in 1989 differed only by 200 from ours (Solheim 1991), and of these about 100 were from 1 hospital.

The 1989 and 1990 numbers give the most complete annual numbers of THR in Norway; nearly 5,200 and 4,800 primary THR. This gives annual incidences

of primary THR of 124/100,000 and 114/100,000 inhabitants in Norway. These numbers are surprisingly high compared to 58/100,000 in Finland in 1988 (Paavolainen et al. 1991), and to 82/100,000 in the county of South Jutland in Denmark (Overgaard et al. 1991), but compare well to 117/100,000 primary THR reported from Sweden in 1987 (Ahnfelt et al. 1990). We have not made age-specific comparisons between the 4 countries.

When comparing the reasons for revisions to those in Sweden (Ahnfelt et al. 1990), fewer of the revisions in Norway were done because of infection and component fracture. However, the Swedish material on revisions dates from 1979–1986, and infections and component fractures were more common in that period. The percentage of bone fractures and dislocations compares well with those in Sweden, but the percentage of loosening was higher in Norway. Revisions of Christiansen prostheses and double cups, with high frequencies of aseptic loosening (Sudmann et al. 1983, Howie et al. 1990), constituted 37 percent of the revisions in the present study. These prostheses may have been more common in Norway than in Sweden, but it has not been possible to estimate the number of the different prostheses used in Norway before the register started in 1987. The Christiansen prosthesis, with its well documented inferior results (Sudmann et al. 1983, Ahnfelt et al. 1990), was used in 124 operations, but mostly in patients in need of only 1 new component. A new total Christiansen prosthesis was used only in 4 revisions.

The patients with THR in Norway, differ from those in Finland and in Sweden. The median age at the primary operation was 70 years in Norway, 67 years in Finland and 64–66 years (women–men) in Sweden. Remarkable is also the proportion of women in Norway (69 percent) compared to Sweden (51 percent). The reoperations constituted close to 13 percent in all 3 countries.

There are differences in the types of prostheses used in the Scandinavian countries, and there are also great differences among the 3 countries in the use of uncemented prostheses. In Finland more than 50 percent of primary prostheses were uncemented (National Agency for Welfare and Health 1991), in Sweden 4 percent (Ahnfelt et al. 1990) and in Norway 15 percent (both components). Initial analyses suggest poorer performance of uncemented prostheses (Engesæter et al. 1992). Only the future, and the follow-up, will show the consequences of the use of uncemented prostheses.

The number of different types of prostheses was surprisingly high. From a medical point of view, this seems unreasonable (Bauer 1992). Even within each hospital, several different prostheses and designs, based on fundamentally different principles, were often used. Every orthopedic surgeon seems to have had his own opinion about this matter. If the basis for having this great number of prostheses was research, it must be emphasized that evaluation of only 2 different prostheses requires large numbers of patients and long follow-up (Herberts et al. 1989). Introduction of new prostheses today should be part of multicenter studies, preferably randomized, with several hundreds, or thousands of patients. Standardization of procedures and reduction in numbers of types would make the search for the best prostheses an easier task.

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PAPER II

Early failures among 14,009 cemented and 1,326 uncemented prostheses for primary coxarthrosis

The Norwegian Arthroplasty Register, 1987–1992

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In the Norwegian Arthroplasty Register, 15,335 primary total hip replacements (THR) in patients with primary arthrosis were followed for 0–5.4 years.

The Kaplan-Meier estimate of cumulative failure (revision) after 4.5 years was 2.7 percent for cemented THR, compared to 6.5 percent for uncemented. In patients under 65 years the cumulative revisions for cemented and uncemented THR were 3.3 and 7.9 percent. For the acetabular components, the cumulative failures were 0.6 percent for cemented and 1.7 percent for uncemented, and for femoral components 1.7 and 3.9 percent after 4.5 years.

Adjusting for age and sex using a Cox regression model, 2 times higher rates of failure were found comparing uncemented to cemented THR. The results for uncemented prostheses were more unfavorable in young patients. In men and women under 60, the revision rates were increased 6 and 3 times, respectively, for patients with uncemented THR compared to those with cemented THR.

Restriction of the end-point to revision for aseptic loosening gave results similar to the over-all results. No difference between cemented and uncemented THR was seen for revisions due to infection, whereas the most unfavorable results for uncemented THR were seen when revisions due to causes other than infection and aseptic loosening were considered.

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Uncemented hip prostheses were introduced in Norway without any clinical evaluation of their advantages compared to cemented prostheses. They constitute about 15 percent of all hip replacements in Norway (Havelin et al. 1993). In many hospitals they are the standard treatment in patients under 65. Short-term analyses in the Norwegian Arthroplasty Register were clearly unfavorable for uncemented compared to cemented prostheses. Although it is not possible to rule out long-term advantages for uncemented THR, we present preliminary findings, comparing uncemented to cemented prostheses in primary arthrosis.

Patients and methods

All 64 hospitals performing THR in Norway (4.2 million inhabitants) reported their operations to the Norwegian Arthroplasty Register (Havelin et al. 1993). From September 1987 until February 1993, 24,408 patients with primary operations were registered. 37 patients who had emigrated were excluded. Only patients with primary arthrosis, and who had been operated on with both components, either cemented or uncemented, were selected (n 15,335). Many different prostheses were used; of the cemented THR, 27 acetabular and 22 femoral types were used, and of the uncemented, 19 acetabular and 18 femoral.

Survival times of the prostheses were defined as the time from the primary insertion to the revision. Revision was defined as reoperation with exchange or removal of one or more components. Revisions for different reasons, such as aseptic loosening, infection and others (pain, dislocation etc.) were selected as end-points in various analyses. Survival times for patients who died without having had a revision were censored. The observation period was 0–5.4 years.

Statistics

Survival of the prostheses was estimated by the Kaplan and Meier method (1958). A two-sided log-rank test was performed to determine if differences in survivorship between subgroups were significant (Mantel 1966).

The Cox proportional-hazards model (Cox 1972) was used to estimate the ratio of failure rate for uncemented THR compared to cemented THR with adjustment for age and sex. The failure ratios were also esti-

Table 1. Kaplan-Meier estimates of cumulative survival of prostheses in different groups of patients, operated with THR for arthrosis in Norway 1987–1992

	All				Under 65 years				65 years and over			
	A	B	C	D	A	B	C	D	A	B	C	D
All revisions												
Cemented	14009	1680	97.3	98.0	2170	289	96.7	97.7	11839	1391	97.4	98.1
Uncemented	1326	176	93.5	95.1	995	122	92.1	94.1	331	54	97.3	97.7
P-value			0.0001	0.0001			0.0001	0.0001			0.5	0.5
Women												
Cemented	9545	1194	98.1	98.7	1422	199	97.1	98.2	8123	995	98.2	98.8
Uncemented	824	105	93.7	95.2	608	67	92.5	94.2	216	38	96.9	97.6
P-value			0.0001	0.0001			0.0001	0.0001			0.08	0.03
Men												
Cemented	4464	486	95.5	96.6	748	90	95.9	96.7	3716	396	95.4	96.6
Uncemented	502	71	93.2	94.9	387	55	91.7	94.0	115	16	97.9	97.9
P-value			0.2	0.2			0.08	0.2			0.5	0.7

A   Number
B   At risk at 4.5 years
C   All revisions. Cumulative survival at 4.5 years
D   Aseptic loosening. Cumulative survival at 4.5 years

mated in subgroups of the patients and for different definitions of failure.

The analyses were performed using the BMDP statistical package (Dixon et al. 1990).

Results

During the period 1987–1992, 15,335 total hip replacements (THR) for primary arthrosis with both components cemented or uncemented were reported to the Norwegian Arthroplasty Register.

14,009 prostheses were cemented and 1,326 uncemented (Table 1, Figure 1). Patients with uncemented THR were younger, mean age 59 years, than those with cemented prostheses, mean age 71 years. Under 65 years, patients with uncemented prostheses constituted 31 percent, whereas over 65 years, only 3 percent had received an uncemented THR (Tables 1 and 2).

After 4.5 years, 6.5 percent of the uncemented THR had been revised, compared to only 2.7 percent of the cemented (Figure 2). For those under 65 years, the difference between uncemented and cemented prostheses was larger, with revision of 7.9 and 3.3 percent, respectively. The superiority of the cemented prostheses persisted also when analyses were done separately for men and women. The differences between cemented and uncemented in patients under 65 were 4.6 and 4.2 percent for women and men, respectively (Figure 3, Table 1).

For those over 65, however, there was no difference between cemented and uncemented prostheses.

Gender. Within the cemented group of prostheses, women had a better prosthesis-survival than men, with 98.1 percent at 4.5 years, compared to 95.5 percent in men. Within the uncemented group, there was no difference between the sexes.

Aseptic loosening. Analyses confined to revision because of aseptic loosening of one or both components as the end-point, gave the same pattern of survival as the overall analyses (Figure 2, Table 1).

Acetabular components. Survival analyses of the acetabular components (Figure 2) gave only a 1 per-
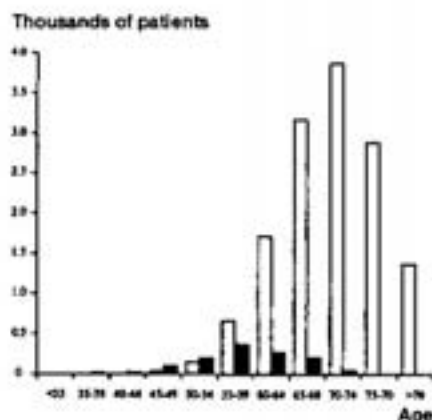
Thousands of patients

Figure 1. Age distribution of 15,335 patients operated using cemented (□) and uncemented (■) primary THR in Norway, 1987–1992.

Table 2. Cox regression estimates of ratio of revision rates comparing uncemented to cemented prostheses in patients operated in Norway 1987–1992. Results are given for all revisions and for revisions due to aseptic loosening, infection and other reasons

		Number	All revisions			Aseptic loosening			Infection			Other reasons		
			A	B	C	A	B	C	A	B	C	A	B	C
All ages														
All	Cemented	14009	211	2.02a	0.0001	141	2.28a	0.0001	42	0.51a	0.6	28	3.24a	0.0001
	Uncemented	1326	52			38			3			11		
Man	Cemented	4464	111	1.45b	0.2	82	1.47b	0.2	20	0.81b	0.8	9	2.75b	0.1
	Uncemented	502	19			14			2			3		
Women	Cemented	9545	100	2.71b	0.0001	59	3.49b	0.0001	22	0.30b	0.5	19	3.49b	0.0001
	Uncemented	824	33			24			1			8		
Under 60 years														
All	Cemented	655	11	2.90c	0.002	8	2.69c	0.02	2	1.54c	0.6	1	7.19c	0.04
	Uncemented	691	30			20			3			7		
Men	Cemented	216	2	6.00	0.01	2	4.29	0.06	0	2/0	0.2	0	2/0	0.2
	Uncemented	276	13			9			2			2		
Women	Cemented	439	9	2.16	0.06	6	2.13	0.1	2	0.57	0.7	1	5.46	0.06
	Uncemented	415	17			11			1			5		
60–64 years														
All	Cemented	1515	31	2.37c	0.004	19	3.06c	0.001	8	0	0.2	4	3.74c	0.07
	Uncemented	304	15			12			0			3		
Men	Cemented	532	17	1.07	0.9	12	1.11	0.9	4	0	0.4	1	4.67	0.2
	Uncemented	111	4			3			0			1		
Women	Cemented	983	14	4.00	0.0002	7	6.54	0.0001	4	0	0.4	3	3.40	0.2
	Uncemented	193	11			9			0			2		
65 years and over														
All	Cemented	11839	169	1.23c	0.5	114	1.51c	0.2	32	0	0.3	23	1.40c	0.7
	Uncemented	331	7			6			0			1		
Men	Cemented	3716	92	0.57	0.5	68	0.76	0.7	16	0	0.5	8	0	0.6
	Uncemented	115	2			2			0			0		
Women	Cemented	8123	77	2.20	0.08	46	2.92	0.03	16	0	0.5	15	2.29	0.4
	Uncemented	218	5			4			0			1		

A Number of revisions
B Failure ratio
C P-values
a Adjusted for sex and age
b Adjusted for age
c Adjusted for sex

cent difference in the result between uncemented and cemented components with a cumulative survival (until revision because of loosening) of 98.4 percent and 99.4 percent, respectively, after 4.5 years.

Femoral components. A larger difference was found between cemented and uncemented femoral components. The uncemented components had a cumulative survival (until revision because of loosening) of 96.1 percent and the cemented of 98.3 percent, after 4.5 years (Figure 2).

Cox regression

The Kaplan-Meier estimates showed that the results of the uncemented prostheses were most unfavorable among patients under 65. Cox regression was used to provide an overall age- and sex-adjusted estimate of the ratio of failure rates, comparing uncemented to cemented prostheses, as well as presenting results using a more exact age-grouping in patients under 65. In these analyses different indications for revisions were also considered.

With adjustment for sex and age in the total material, the failure rate for the uncemented prostheses was 2.0 times higher than for the cemented (Table 2). The risk for revision in the uncemented group was highest in the youngest patients, with a 2.9 times increased risk for revision in the patients under 60, compared to 2.4 and 1.2, respectively, in patients aged 60–64 and 65 and over.

For men in the age group under 60, the risk for revision of an uncemented prosthesis was increased 6 times compared to the cemented, but for men no increase in risk was found in the other age groups (Table 2). For women, the increase in risk for revision of uncemented prostheses was greatest in the 2 youngest age groups (Table 2).

Aseptic loosening was the indication for revision in 68 percent of the 263 failures. When only this endpoint was considered, the results were close to those reported over-all (Table 2).
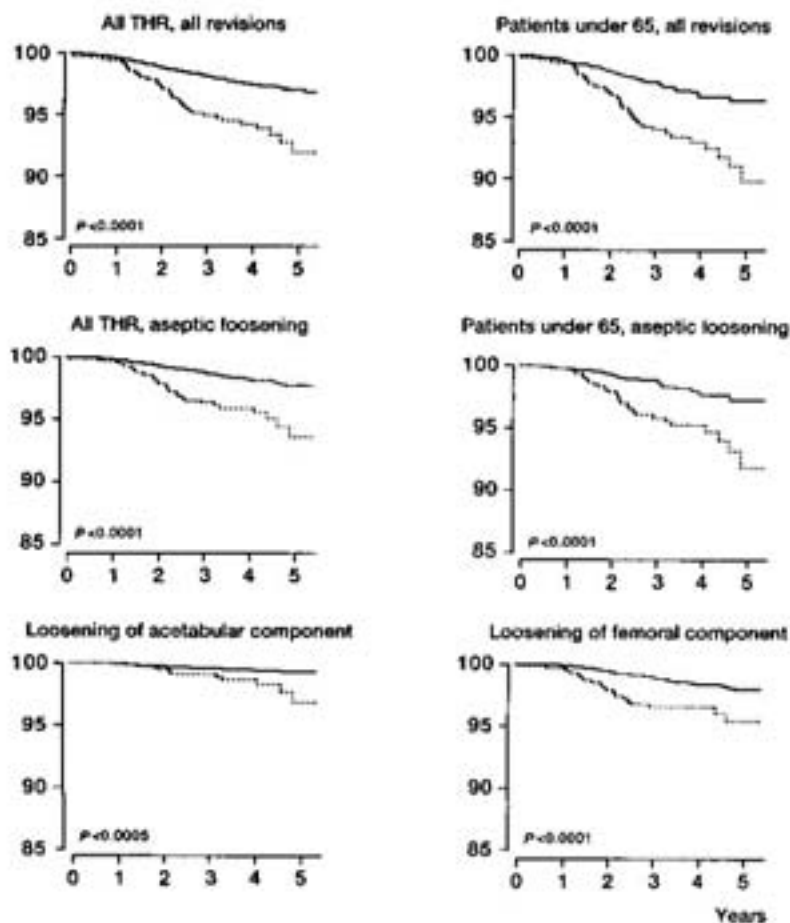
Figure 2. Percent survival until revision (for any reason, aseptic loosening, and aseptic loosening of acetabular and femoral components) of cemented (—) and uncemented (---) primary THR.

Infection caused revision in 17 percent of the failures with no difference in failure rates between cemented and uncemented cases.

Other reasons for revision. 15 percent of the revisions were done for other reasons than infection or aseptic loosening: fracture, dislocation, pain as only reason, technical error, etc. Here the results were most unfavorable for uncemented prostheses with an overall failure ratio of 3.2. For this endpoint also, the results were poorer for uncemented prostheses in young patients, with failure ratios of 7.2, 3.7, and 1.4 in the age groups under 60, 60-64, and 65 and over, respectively (Table 2).

Discussion

The over-all results for the uncemented hip prostheses were poorer than for the cemented prostheses in all groups of patients, except among men over 64. The difference in results between the cemented and the uncemented was most pronounced among young patients. Thus, the uncemented THR had the poorest results, compared to the cemented, in the group of patients who are usually selected for these prostheses.

Assumed negative prognostic factors (Gross 1988, Dorey and Amstutz 1989), as young age or male gender, were more common among patients with unce-
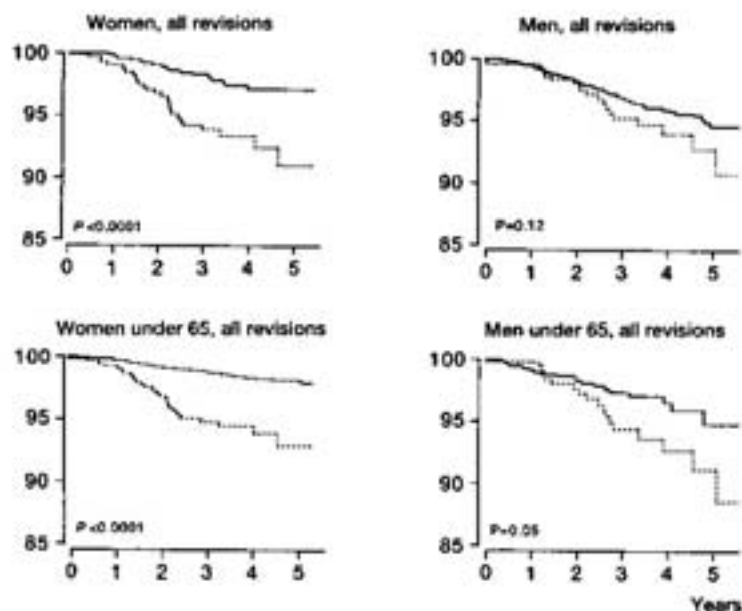
Figure 3. Percent survival until revision of cemented (—) and uncemented (----) THR in men and women in various age groups.

mented prostheses. However, also in the analyses of homogeneous subgroups, the inferior results with uncemented prostheses persisted.

Among the patients with cemented prostheses, we found poorer results for men than for women. However, among the patients with uncemented THR, there was no difference between men and women. Malchau et al. (1993) found a similar difference between the sexes, poorer results in men and in young patients, in survival analyses of patients with arthrosis. Cemented THR had been used in about 98 percent of the hips in their material.

The Charnley prosthesis was used in 50 percent of the patients in Norway (Havelin et al. 1993), and the results presented for cemented prostheses in the present study, were similar to those found for Charnley prostheses by others (Herberts et al. 1989, Ahnfelt et al. 1990, Hozack et al. 1990, Skeie et al. 1991, Malchau et al. 1993). Other cemented prostheses (i.e., Wagner resurfacing hip, Christiansen hip, Trapezoidal-28 and Müller) have been found to give poorer results in survival analyses (Ritter and Campbell 1987, Howie et al. 1990, Oblin 1990, Malchau et al. 1993).

The results of survival analyses of different systems of uncemented components have varied. Duparc and Massin (1992) found a 5-year cumulative survival (not revised) of 77 percent after use of a smooth, cemen-

tless femoral component. Engh and Massin (1989) analyzed results of stems with 80 percent of the surface porous-coated, and found a cumulative survival (no radiographic migration) of 94 percent at 5 years. A 5-year survival of approximately 90 percent was reported for the Ring prosthesis (Albrecht-Olsen et al. 1989, Bryant et al. 1991).

Several explanations for the poorer results of the uncemented prostheses, notably the uncemented femoral components, should be considered. The procedure of uncemented prostheses is new to many surgeons, and the current material may reflect the surgeons' learning process. It must also be remembered that the operations in this material were done by ordinary orthopedic surgeons from all over the country.

There is a tendency to choose uncemented prostheses for problem cases, but our analyses were adjusted for most of the known negative factors (Gross 1988), and were also confirmed in age- and sex- homogeneous subgroups, for patients with primary arthrosis only.

The uncemented prostheses in this study included many different systems (types): smooth-surfaced, porous-coated and hydroxyapatite-coated femoral components. It is therefore possible that a few of the uncemented systems (types) of prostheses are responsible for a substantial part of the revisions of the unce-

mented hip prostheses. The results of each system are now being evaluated in the Norwegian Arthroplasty Register. Furthermore, the assessment of survival was done after a maximum observation period of 5.4 years, and the difference in results between cemented and uncemented THR may change with time.

We have been through—and are still in—a period of evaluation of uncemented prostheses, and several types with confirmed poor results have now been taken off the market. Nationwide multi-center studies, as in the Swedish and Norwegian Arthroplasty Registers, with follow-up of all individual patients, have an important control function (Faro and Huiskes, 1992, Malchau et al. 1993). So far, new systems of uncemented THR should not be expected to give better results than cemented THR, and they should be used only as part of carefully planned research programs (Bauer 1992).

Acknowledgements

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PAPER III

EARLY ASEPTIC LOOSENING OF UNCEMENTED FEMORAL COMPONENTS IN PRIMARY TOTAL HIP REPLACEMENT

A REVIEW BASED ON THE NORWEGIAN ARTHROPLASTY REGISTER

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The Norwegian Arthroplasty Register recorded 24 408 primary total hip replacements from 1987 to 1993; 2907 of them (13%) were performed with uncemented femoral components. We have compared the results of eight different designs, each used in more than 100 patients.

Survivorship of the components was estimated by the Kaplan-Meier method using revision for aseptic loosening of the femoral component as the end-point.

At 4.5 years, the estimated probability of revision for aseptic loosening for all implants was 4.5%, for the Bio-Fit stem 18.6% (n = 210) and for the Femora stem 13.6% (n = 173). The PM-Prosthesis and the Harris/Galante stem prostheses needed revision in 5.6% and 3.6%, respectively. The clockwise threaded stem of the Femora implant needed revision in 20% of right hips, but in only 4% of left hips.

The short-term results of the four best uncemented femoral components (Corail, LMT, Profile and Zweimüller) were similar to those for cemented stems, with revision for loosening in less than 1% at 4.5 years. The importance of the control of innovative designs and the registration of early results is discussed.

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The Norwegian Arthroplasty Register has recorded 24 408 primary total hip replacements (THR) and 3824 revision operations from September 1987 to January 1993. An earlier report showed relatively poor results from uncemented THR in Norway from 1987 to 1992 (Havelin et al 1994), especially for femoral components. Many types of uncemented femoral component had been used, with major differences in design.

We now report the short-term results, at 0 to 5.4 years, for eight different types of uncemented femoral component used in Norway.

PATIENTS AND METHODS

Norway has 4.2 million inhabitants, and all THR operations are reported to the Norwegian Arthroplasty Register (Havelin et al 1993). From September 1987 to January 1993, 3141 uncemented femoral prostheses had been implanted in primary operations (13%). A total of 17 different types of femoral component had been used, but only eight designs had been implanted in more than 100 hips. The results for these eight types, in 2907 hips, have been studied and compared. The prostheses were the Bio-Fit (Richards, Memphis, Tennessee), the Corail (Landos, Chaumont, France), the Femora (Chas F Thackray, Leeds, UK), the Harris/Galante (Zimmer, Warsaw, Indiana), the LMT (Biomet, Warsaw, Indiana), the PM-Prosthesis (Aesculap, Tuttlingen, Germany), the Profile (DePuy, Warsaw, Indiana), and the Zweimüller (Allo Pro, Baar, Switzerland) (Table I). There was a total of 2421 patients, 486 of whom had bilateral operations. The distribution of age, gender and diagnosis in each group is shown in Table II.

All revision operations were reported to the Registry and linked to the primary operation by the patients' national social security number. The follow-up period was 0 to 5.4 years. Information on the revisions included details of components that had been changed or removed and the reasons for revision. In our survival analysis, only revision or removal of the femoral component for aseptic loosening of the stem was used as an end-point. Other reasons for revision, such as dislocation, infection and socket loosening, were excluded from this analysis.

Survival curves were constructed by the Kaplan-Meier method (Kaplan and Meier 1958), defining survival time as the time from the primary THR to revision due to aseptic
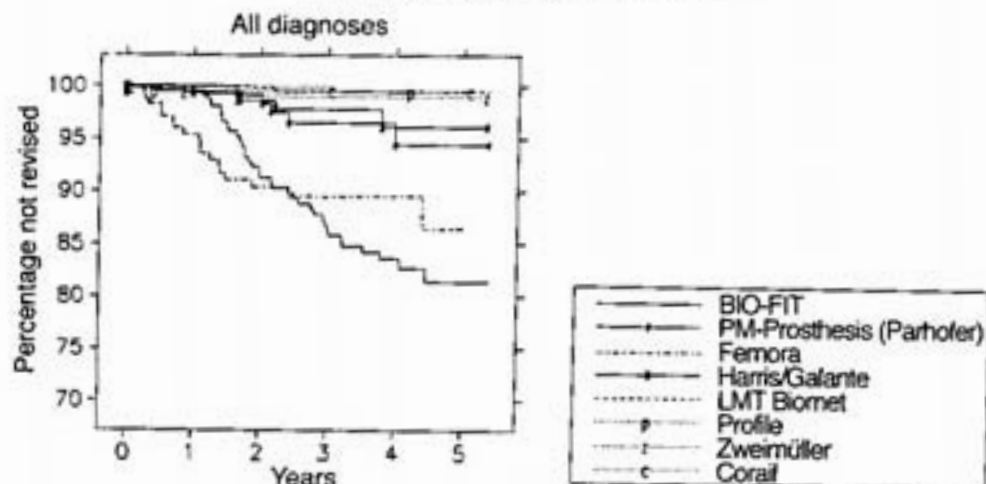
Fig. 1

Survival until revision (for aseptic loosening only) of eight designs of uncemented femoral component used in Norway from 1987 to 1993.

loosening of the stem. Survival times for patients who had died without revision were excluded. Patients who had emigrated (n = 36) were identified from the records of the Central Bureau of Statistics in Oslo and were also excluded. We used a two-sided log-rank test to determine the significance of differences in survival between the types of stem (Mantel 1966), and calculated confidence intervals by the Greenwood method.

We used the Cox proportional hazards model (Cox 1972) to compare the relative risk for revision, both with and without adjustment for gender, age group (< 40, 40 to 49, 50 to 59, 60 to 69, > 69 years) and diagnostic group. All analyses were performed using the BMDP statistical package (Dixon et al 1990).

RESULTS

Table II gives the number of each type of primary femoral component, with data for age, gender and diagnosis. As expected there were differences between the patients having different types of prosthesis: LMT patients were older and had a lower ratio of men, the Harris/Galante patients were the youngest, with a lower ratio of primary osteoarthritis. Table III shows the number of each type of component remaining at risk at 3 and 4.5 years, with the cumulative survival at 4.5 years. The total revision rate for aseptic loosening of femoral components after 4.5 years was 4.5%. Kaplan-Meier analysis showed some significant differences, with revision of 18.6% of the Bio-Fit prosthesis, 13.6% of the Femora, 3.6% of the Harris/Galante and 5.6% of the PM-Prosthesis. The other uncemented femoral components (Corail, LMT, Profile and Zweimüller) all had failure rates of less than 1% after 4.5 years (Fig. 1).

The differences between the Bio-Fit and the Femora, and the Harris/Galante and the PM-Prosthesis were not statistically significant, but the differences between each of these four prostheses and the group with low failure rates (Corail, LMT, Profile and Zweimüller) were statistically very significant (p < 0.0001). There were no statistically significant differences between the Corail, LMT, Profile and Zweimüller components.

We compared the two groups of components. Those with proximal circumferential porous coating, hydroxyapatite coating, or rough sandblasted surfaces (Corail, LMT, Profile and Zweimüller) had a cumulative survival of 99.5% at 4.5 years. The others (Bio-Fit, Femora, Harris/Galante and PM-Prosthesis) had a cumulative survival of 87.9% at 4.5 years (p < 0.0001).

Survival analyses for smaller groups, subdivided by primary osteoarthritis or other diagnoses, gender and age below or above 50 years, gave similar survival curves (Fig. 2).

All the analyses were carried out with an individual hip as the unit. This may be suspect, since failure of one hip in the 486 patients with bilateral THR may influence the outcome in the other hip. We therefore analysed the results for the first hip only in patients with bilateral THR: our results were virtually unchanged.

For each type of component we found no significant difference between results for the first two years of use compared with those done later.

The Femora prosthesis showed significantly better results on the left side than the right (p < 0.01), with cumulative survival after 4.5 years of 95.8% and 80.8% respectively (Fig. 3). We found no difference between the right and the left hip for the other seven prostheses taken together.

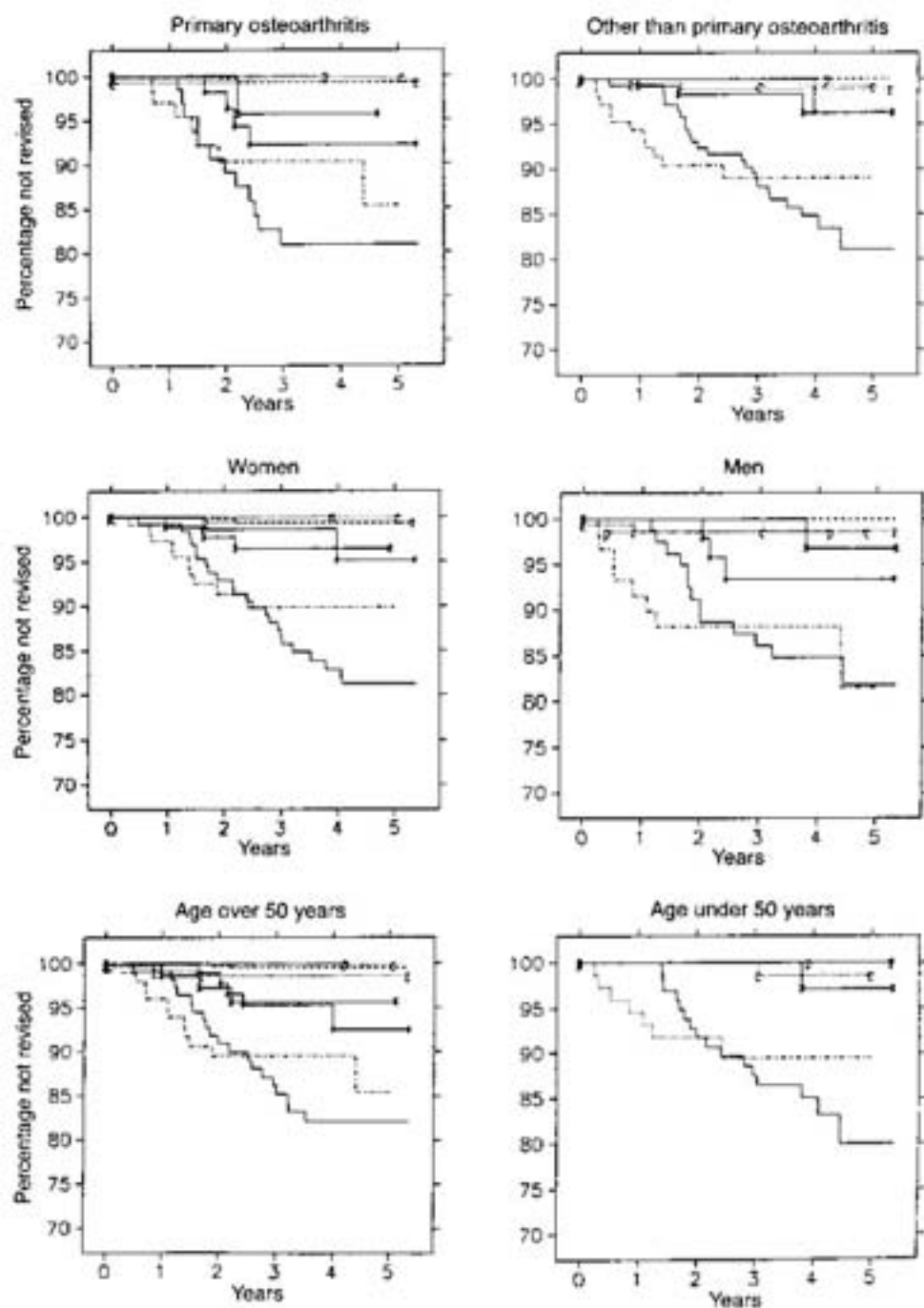The Cox model showed that patients having the Bio-Fit,

Fig. 2

Survival until revision (for aseptic loosening) of eight uncemented femoral components used in Norway from 1987 to 1993. Separate curves for primary osteoarthritis, other diagnoses, gender, and patients more than and less than 50 years old.
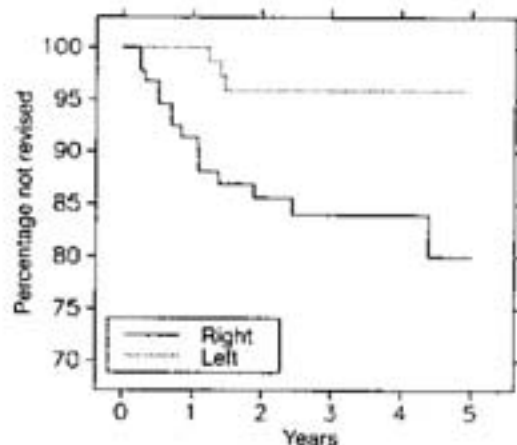
Fig. 3

Survival until revision (for aseptic loosening) of the femoral component of the Femora prosthesis in right hips (n = 93) and left hips (n = 80).

Femora, Harris/Galante or PM-Prosthesis had increased risks of failure (failure-rate ratios) by factors of 33, 26, 6 and 8 times respectively, compared with the other four prostheses. Adjustments for age and gender, and stratification for diagnoses, showed an even greater increase in failure-rate ratios for the worst group of four (Table IV). The effect of age on the risk for revision was inconclusive. Cox models restricted to the patients with primary osteo-arthritis, or those with the other diagnoses, gave similar results to those for all hips.

DISCUSSION

The overall results of the uncemented THR in Norway have been shown to be inferior to those for cemented THR (Havelin et al 1994). We have now shown that certain types of uncemented femoral component were responsible for most of the failures in the uncemented group. Despite the short period of observation, the results for Bio-Fit and Femora stems were significantly inferior to those for other uncemented femoral components. The early results for these two components are similar to or even worse than those reported for the Christiansen prosthesis, for which long-term results are known to be very poor with approximately 40% revised after ten years (Josefsson, Lindberg and Wiklander 1981; Sudmann et al 1983; Ahnfelt et al 1990; Ohlin 1990; Malchau, Herberts and Ahnfelt 1993).

Our analysis by hip and not by patient is a potential problem (Morris 1993), since strong interdependence of bilateral failures may compromise the analyses. However, our proportion of bilaterally operated patients (486 of 2421) was relatively low; less than 10% of the failures occurred in second hips and in no patient had both hips failed. We also found similar results in analyses with second hips excluded.

Our finding that results were similar early and late in the period under review, and the fact that all the implants were relatively new, indicates that learning curves cannot explain the inferior results.

The results in the better group (Corail, LMT, Profile and Zweimüller) with 99.5% survival after 4.5 years are similar to those reported for cemented femoral components (Havelin et al 1994). These are all of titanium with surfaces either rough sandblasted, porous-coated or hydroxyapatite-coated. The results for this group are promising although the mean follow-up for several of them was shorter than for others (Table III). The PM-Prosthesis ('Parhofer') was used in Norway without porous coating up to 1990, and the Harris/Galante, with only a small area of porous coating, had intermediate results as reported by others (Kim and Kim 1992), but they were still inferior to those of most cemented prostheses.

The relative failure of the Bio-Fit and Femora components may be due to their design. The Bio-Fit variant (Fig. 4) which was used is press-fit with a rather smooth surface
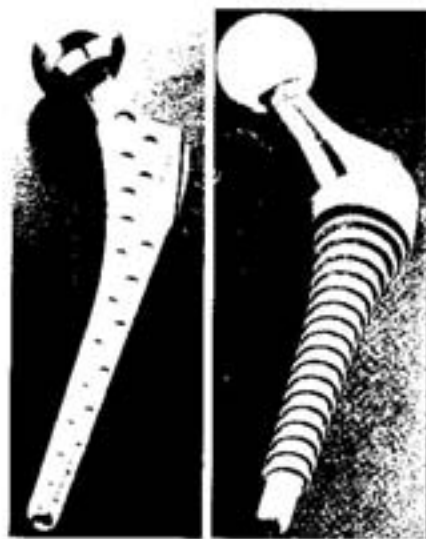
Fig. 4

The Bio-Fit component (left) and the Femora component (right).

of cobalt-chromium. Poor results have been found also for other smooth-surfaced press-fit prostheses (Duparc and Massin 1992).

The Femora prosthesis has a threaded screw stem (Fig. 4) of titanium. We could find no other report of the results for this component but good results have been reported for the SCL screw-in component with a screw which locks for rotation in the femur (Lang and Callea 1993). The inferior results of the Femora component in the right hip may be explained by the rotational forces produced by body-weight. Both left and right prostheses have a right-handed

Table 1. Characteristics of the eight most commonly used uncemented femoral components in Norway 1987 to 1993

	Material	Design	Surface
Bio-Fit	Cobalt-chromium	Straight stem	Smooth with buttressed scallops
Corail	Titanium alloy	Straight stem	Fully hydroxyapatite (HA)-coated
Femora	Titanium alloy	Threaded stem	Blasted
Harris/Galante	Titanium alloy	Straight stem	Proximally porous-coated, not circumferentially
LMT	Titanium alloy	Straight stem	Proximally porous-coated
PM-Prosthesis	Titanium alloy	Curved stem	Smooth with inverse scallops, porous-coated late in the period
Profile	Titanium alloy	Anatomic stem	Proximally porous- or HA-coated
Zweimüller	Titanium alloy	Straight stem with rectangular cross-section	Blasted surface

Table II. Age, gender and diagnosis of patients with eight different uncemented femoral components used in Norway 1987 to 1993

	Bio-Fit (n = 210)	Corail (n = 1117)	Femora (n = 173)	Harris/Galante (n = 157)	LMT (n = 500)	PM-Prosthesis (n = 151)	Profile (n = 266)	Zweimüller (n = 333)
Age (yr)								
Min	16	15	24	15	24	29	17	18
Mean	50	51	51	48	63	53	51	53
Max	82	84	75	83	87	78	75	71
Sex: percent men	38	37	34	41	30	43	38	47
Diagnoses (%)								
Primary osteoarthritis	31	39	38	20	71	42	42	43
Rheumatoid arthritis	8	6	2	6	0	3	7	4
Seq of fracture	8	6	7	6	10	5	9	6
CDH	30	20	33	24	12	28	21	26
CDH with dislocation	7	10	5	26	2	10	1	4
Other paediatric hip	8	6	3	8	1	8	9	6
Ankylosing spondylitis	1	2	3	1	0	1	2	1
Other diagnoses	7	12	6	10	3	3	9	12

Table III. Number of hips at risk and Kaplan-Meier estimates of cumulative survival (until revision because of aseptic loosening) of the different uncemented femoral components used in Norway 1987 to 1993

		Mean follow-up (yr)	Remain at risk				Revisions 0 to 5.4 years	Cumulative survival after 4.5 years (%)	95% confidence intervals at 4.5 years
	Number		3 years		4.5 years				
			Number	%	Number	%			
Bio-Fit	210	4.0	173	82	32	15	35	81.4	74.1 to 87.4
Corail	1117	1.8	239	21	16	1	2	99.5	98.5 to 100
Femora	173	3.1	92	53	28	16	18	86.4	78.7 to 92.0
Harris/Galante	157	3.3	96	61	21	13	4	96.2	91.4 to 100
LMT	500	3.2	278	56	93	19	2	99.5	98.8 to 100
PM-Prosthesis	151	3.2	83	55	29	19	5	94.4	89.0 to 99.8
Profile	266	0.9	22	8	0	0	0	-	
Zweimüller	333	3.9	247	74	89	27	3	99.1	97.9 to 100

Table IV. Cox model. Effect of type of femoral component, gender and age on the relative risk for revision (failure-rate ratio) of uncemented femoral components due to aseptic loosening. Failure-rate ratio is given unadjusted and adjusted for the other factors and for diagnoses

| | | | Unadjusted | | Adjusted | |
	Number	Revisions	Failure-rate ratio	p value	Failure-rate ratio	p value
Components						
Bio-Fit	210	35	32.8	< 0.0001	36.4	< 0.0001
Femora	173	18	26.3	< 0.0001	30.5	< 0.0001
Harris/Galante	157	4	5.8	< 0.005	8.0	< 0.001
PM-Prosthesis	151	5	8.0	< 0.0005	8.8	< 0.0005
Others*	2216	7	1		1	
Gender						
Female	1813	41	0.9	0.58	0.9	0.78
Male	1094	28	1		1	
Age (yrs)						
< 40	358	10	1		1	
40 to 49	633	14	0.77	0.52	0.80	0.67
50 to 59	1068	27	0.77	0.50	0.95	0.90
60 to 69	695	16	0.68	0.33	1.52	0.41
> 69	153	2	0.42	0.26	1.59	0.58
Trend test for age				0.24		0.26

* Curail, Profile, LMT, and Zweimüller

thread, so that the forces produced by standing up from a sitting position will tend to unscrew a prosthesis in the right hip, and tighten it in the left.

The Femora component was used only as part of a clinical trial in five Norwegian hospitals, in less than 200 patients. The Bio-Fit component was introduced before the Register was established, was freely available and has been used in approximately 1000 Norwegian patients. After a report from the Norwegian Arthroplasty Register (Havelin et al 1991), the manufacturer stopped the production of the Femora prosthesis, and the Bio-Fit prosthesis has since then only been used with cement in Norway. The Christiansen prosthesis was implanted in over 5000 Swedish patients (Ahnfelt et al 1990; Malchau et al 1993) and in over 6000 Norwegian patients before the findings from one hospital revealed the poor results (Sudmann et al 1983). The story

of these three prostheses clearly shows the importance and success of nationwide or multicentre quality control of implants (Herberts et al 1989; Faro and Huiskes 1992).

The use of uncemented prostheses should still be considered to be experimental (Bauer 1992). New types of prosthesis should be introduced by controlled multicentre trials, designed to confirm good clinical results before they are freely available. We conclude that several types of uncemented femoral component give poor results. The comparison of the best of the uncemented femoral components with cemented stems will require larger numbers and longer observation periods, or well-designed prospective randomised trials.

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Errata:

Page 11, second column, second paragraph, last sentence:
Other reasons for revision, such as dislocation, infection
and socket loosening, were excluded from this analysis.

Read:
Survival times for prostheses revised due to other reasons
than aseptic loosening of the femoral component were censored.

Page 12, line 2: excluded

Read: censored

Page 12, line 4: were also excluded.

Read: were excluded.

The Journal of Bone and Joint Surgery regrets this error.

PAPER IV

The Effect of the Type of Cement
on Early Revision of Charnley Total Hip Prostheses

A REVIEW OF EIGHT THOUSAND FIVE HUNDRED AND SEVENTY-NINE PRIMARY ARTHROPLASTIES
FROM THE NORWEGIAN ARTHROPLASTY REGISTER*

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ABSTRACT: We studied the survival of 8579 Charnley prostheses, in 7922 patients, according to the different types of cement that had been used. All of the patients had had a primary total hip replacement for primary coxarthrosis. The mean duration of follow-up was 3.2 years (range, zero to 6.4 years). The data were collected from the national Norwegian Arthroplasty Register.

The duration of survival was defined as the time to revision due to aseptic loosening. The Kaplan-Meier estimate of survival at 5.5 years for the 1226 femoral components that had been implanted with low-viscosity cement was 94.1 per cent (95 per cent confidence interval, 92.1 to 96.2 per cent), compared with 98.1 per cent (95 per cent confidence interval, 97.5 to 98.6 per cent) for the 6589 components that had been implanted with high-viscosity cement ($p < 0.0001$). The remaining 764 femoral components had been implanted with Boneloc cement, which was classified as neither high nor low-viscosity, and these components were considered as a separate group in the analyses. The Boneloc cement had been used for only three years, and the two-year survival rate of these prostheses was 95.5 per cent ($p < 0.0001$).

The cement contained an antibiotic in 2801 (42 per cent) of the hips in which the femoral component had been implanted with high-viscosity cement, compared with only thirty (2 per cent) of those in which it had been implanted with low-viscosity cement. With restriction of the comparison to cement without an antibiotic, and with adjustment for the age and sex of the patient, with use of the Cox proportional-hazards model the femoral components that had been implanted with low-viscosity cement had a rate of revision that was 2.5 times greater (95 per cent confidence interval, 1.6 to 3.8 times) than that for the components that had been implanted with high-viscosity cement, and those that had been implanted with Boneloc cement had a rate that was 8.7 times greater (95 per cent confidence interval, 5.1 to 14.8 times).

The addition of an antibiotic to the high-viscosity cement improved the Kaplan-Meier estimate of survival, at 5.5 years, from 97.7 to 98.7 per cent for the femoral components ($p = 0.06$) and from 99.2 to 99.6 per cent for the acetabular components ($p = 0.07$).

The rate of survival of the acetabular components at 5.5 years was higher than 99 per cent in association with all types of cement. There was no significant difference in the rates of failure between the low and high-viscosity cement. However, the acetabular components that had been implanted with Boneloc cement had a cumulative rate of revision of 1.2 per cent at two years, compared with 0.2 per cent for the other components ($p < 0.001$).

The nationwide Norwegian Arthroplasty Register was established in September 1987 by the Norwegian Orthopaedic Association. The purpose of the register is to aid in the assessment, and to help improve the quality of hip-replacement operations in Norway[4].

The register has shown the over-all results of total hip replacement to be better with use of cement than without its use[5]. Although many different types of cement have been introduced onto the market[6], there have been few reports on the clinical results associated with these various types of cement. The aim of the current study was to compare, with use of data from the national register, the results of total hip arthroplasty with respect to the different types of cement, to the viscosity of the cement, and to the addition of an antibiotic to the cement. We present the results for patients who received a Charnley prosthesis because of primary coxarthrosis.

Materials and Methods

Since the establishment of the Norwegian Arthroplasty Register, all members of the Norwegian Ortho

TABLE I

DATA ON THE SEX AND AGE OF THE PATIENTS AND THE DURATION OF FOLLOW-UP WITH RESPECT TO THE DIFFERENT TYPES OF CEMENT

	No. of Hips	Men (Per cent)	Age (Yrs.)			Median Durat. of Follow-up (Yrs.)	No. of Hips at Risk at 5.5 Yrs.
			Min.	Mean	Max.		
Femoral components							
All	8579	30	40	72	96	2.9	768
High-viscosity cement	6589	30	40	71	96	3.2	629
CMW 1	2309	30	40	71	96	3.3	321
CMW 2	7	14	60	69	75	3.2	2
CMW 1 with gentamicin	18	17	64	74	92	0.7	0
Palacos	1037	26	45	72	93	3.3	81
Palacos with gentamicin	2775	31	43	71	91	3.0	249
Simplex	435	29	56	72	89	3.3	66
Simplex with erythromycin	8	37	62	70	78	2.1	0
Low-viscosity cement	1226	32	48	71	93	3.1	139
CMW 3	1193	32	48	71	93	3.1	139
CMW 3 with gentamicin	30	43	59	73	85	1.9	0
Palacos E-Flow	3	33	59	68	77	2.8	0
Boneloc	764	29	47	72	94	1.4	0
Acetabular components							
All	8579	30	40	72	96	2.9	768
High-viscosity cement	7307	30	40	71	96	3.2	718
CMW 1	2786	31	40	71	96	3.3	305
CMW 2	7	29	60	69	77	4.9	2
CMW 1 with gentamicin	21	19	64	73	92	0.7	0
Palacos	1268	27	49	72	93	3.3	98
Palacos with gentamicin	2783	31	43	71	91	3.0	249
Simplex	434	29	56	72	89	3.3	63
Simplex with erythromycin	8	25	62	71	80	2.4	0
Low-viscosity cement	512	30	52	73	91	2.7	50
CMW 3	492	30	52	73	91	2.8	50
CMW 3 with gentamicin	18	39	59	73	85	1.4	0
Palacos E-Flow	2	50	47	72	77	2.4	0
Boneloc	760	29	47	72	94	1.4	0

...aedic Association have agreed to provide data on all primary total hip replacements and revisions to the register[a]. All sixty-four hospitals where total hip arthroplasties are performed in Norway (population, 4.3 million in 1994) have participated. The operations are reported individually, on a form filled out by the surgeon immediately after each procedure. For primary arthroplasties, the diagnosis, type of implant, and type of cement are recorded. The revision arthroplasties are classified on the basis of their type and the reason why they were performed. The collection of the data has been reported on previously[a].

The revisions were linked to the primary operations with use of the patient's national social security number. During the first six years, 29,068 primary total hip replacements and 4618 revisions were registered. The current investigation comprised 7922 patients (8579 hips) who had had implantation of a Charnley total hip prosthesis (Thackray, Leeds, England) for primary coxarthrosis and had not had any previous operations on the index hip (Table I). Of the 7922 patients, 6304 had had the operation on only one hip and 1618 patients (2275 prostheses) had been operated on bilaterally. For 661 of the patients who had had a bilateral operation, only one hip could be included in the study, as the other

hip had been operated on before 1987 or a type of implant other than the Charnley prosthesis had been used. Separate analyses were done to examine the impact of bilateral compared with unilateral replacement on the result.

The trade names of the cement were Boneloc (Polymers Reconstructive A/S, Farum, Denmark); CMW 1, CMW 2, and CMW 3, with and without gentamicin (CMW Laboratories Dentsply, Exeter, England); Palacos, with and without gentamicin (Schering-Plough International, Kenilworth, New Jersey); and Simplex, with and without erythromycin (Howmedica, London, England) (Tables I and II). Five brands had been used in less than 100 patients each; these brands were therefore excluded from the survival analyses based on the brands of cement, but they were included in the other analyses.

The brands of cement were classified into three main types[a] — low-viscosity, high-viscosity, or neither (Boneloc) — according to the information provided by the manufacturer. Boneloc cement, which was introduced in 1991, is produced with use of a new formulation based on methylmethacrylate/n-decyl-methacrylate/isobornyl methacrylate[a], and cannot be classified as high or low-viscosity. The high and low-viscosity groups

TABLE II

CUMULATIVE SURVIVAL (UNTIL REVISION DUE TO ASEPTIC LOOSENING) OF THE COMPONENTS WITH RESPECT TO
THE DIFFERENT TYPES AND BRANDS OF CEMENT, ACCORDING TO THE KAPLAN-MEIER ANALYSES

	Viscosity of Cement	No. of Hips	No. of Revisions	Cumulative Survival at 5.5 Yrs. (Per cent)	95 Per Cent Confidence Interval
All femoral components		8579	127	97.2	96.8 to 97.5
Types of cement					
High-viscosity with antibiotic		2801	19	98.7	98.1 to 99.4
High-viscosity without antibiotic		3788	47	97.7	96.9 to 98.5
Low-viscosity without antibiotic		1196	38	94.1	92.1 to 96.2
Brands of cement*					
CMW 1	High	2309	34	97.4	96.3 to 98.4
CMW 3	Low	1193	38	94.1	92.1 to 96.2
Palacos	High	1037	10	98.0	96.4 to 99.6
Palacos with gentamicin	High	2775	19	98.7	98.1 to 99.4
Simplex	High	435	3	98.3	96.2 to 100
Boneloc†		764	23	‡	
All acetabular components		8579	33	99.3	99.0 to 99.6
Types of cement					
High-viscosity with antibiotic		2812	5	99.6	99.2 to 100
High-viscosity without antibiotic		4495	21	99.2	98.8 to 99.6
Low-viscosity without antibiotic		494	1	99.7	99.1 to 100
Brands of cement*					
CMW 1	High	2786	15	99.0	98.4 to 99.6
CMW 3	Low	492	1	99.7	99.1 to 100
Palacos	High	1268	5	99.4	99.0 to 100
Palacos with gentamicin	High	2783	5	99.6	99.2 to 100
Simplex	High	434	1	99.7	99.2 to 100
Boneloc†		760	6	‡	

*Only brands that had been used in more than 100 hips were included in the survival analyses.
†Boneloc cement had been used for only three years.
‡Cumulative survival could not be estimated.

were subdivided according to whether or not they contained an antibiotic. The duration of follow-up ranged from zero to 6.4 years (mean, 3.2 years).

Survival analyses[15] were performed separately for the femoral and acetabular components. The duration of survival was defined as the time between the arthroplasty and the revision. Exchange or removal of the index component because of aseptic loosening was the end point because aseptic loosening was considered to be the reason for revision that was most closely related to the cement. The durations of survival of components that were revised for reasons other than aseptic loosening and of those in patients who had died or had emigrated from Norway were censored. (These data are presented in the Results section.) Patients who had died or had emigrated were identified from files provided by the Central Bureau of Statistics in Oslo.

Two-sided log-rank tests[17] were performed to determine if differences were significant.

The Cox proportional-hazards model[7] was used to assess the influence of an antibiotic in the cement, of the viscosity of the cement, and of the age and sex of the patient on the survival of the prosthesis. Age was considered according to four groups: less than sixty years, sixty to sixty-nine years, seventy to seventy-nine years, and more than seventy-nine years. The influence of age on revision was evaluated with a test for linear trend across the four age-groups. The trend test is sensitive to increasing or decreasing rates of revision with increasing age. The analyses were done with use of the BMDP statistical package (BMDP Statistical Software, Los Angeles, California) and S-PLUS (Statistical Sciences, Seattle, Washington).

Results

Only small differences related to the age and sex of the patient were found between the different types and brands of cement; however, the duration of follow-up for the patients in whom the prosthesis had been implanted with Boneloc cement was only zero to three years, compared with zero to 6.4 years for the other groups of patients (Table I). The operations had been done in forty-four different hospitals. The use of low-viscosity cement differed between the femoral and acetabular components. Low-viscosity cement had been used for the insertion of 1226 (14 per cent) of the femoral components and 512 (6 per cent) of the acetabular components. Of the eleven different brands of cement that had been used, only CMW 1, CMW 3, Palacos, Palacos with gentamicin, Boneloc, and Simplex had been employed in more than 100 patients each. These six brands were included in the survival analyses based on the brand of cement (Fig. 1). Of the low-viscosity cements, only CMW 3 without an antibiotic was used in more than 100 patients. Low-viscosity cement with an antibiotic had been used for only thirty femoral and

eighteen acetabular components; therefore, survival analyses were not done for this group.

Femoral Components

The over-all cumulative rate of survival of the femoral components at 5.5 years was 97.2 per cent, but there were significant differences according to the types of cement that had been used (p < 0.0001) (Fig. 1 and Table II).

The components that had been implanted with low-viscosity CMW 3 cement had an estimated probability of revision, at 5.5 years, of 5.9 per cent (95 per cent confidence interval, 3.8 to 7.9 per cent), compared with a rate of less than 3.0 per cent for the components that had been implanted with any brand of high-viscosity cement. The components that had been implanted with Boneloc cement had a revision rate of 4.5 per cent at only two years (Fig. 1).

The components that had been implanted with high-viscosity cement with or without an antibiotic had an estimated cumulative survival rate of 98.7 and 97.7 per cent, respectively, at 5.5 years, compared with 94.1 per cent for the components that had been implanted with low-viscosity cement (p < 0.0001) (Fig. 1 and Table II).

The pattern of results was the same when the analyses were done for the subgroups of men and women who were less than and more than sixty-five years old.

The survival rate, at 5.5 years, for the components that had been implanted with high-viscosity cement that contained an antibiotic was 1.0 per cent higher than that for the components that had been implanted with high-viscosity cement that did not contain an antibiotic, and the difference almost reached significance (p = 0.06) (Table II). With use of the Cox proportional-hazards model, with adjustment for the age and sex of the patient, the components that had been implanted with low-viscosity cement without an antibiotic had a rate of revision that was 2.4 times higher (95 per cent confidence interval, 1.6 to 3.8 times) than that for the components that had been implanted with high-viscosity cement without an antibiotic (Table III). The components that had been implanted with high-viscosity cement that contained an antibiotic had a rate of revision that was reduced to 59 per cent (95 per cent confidence
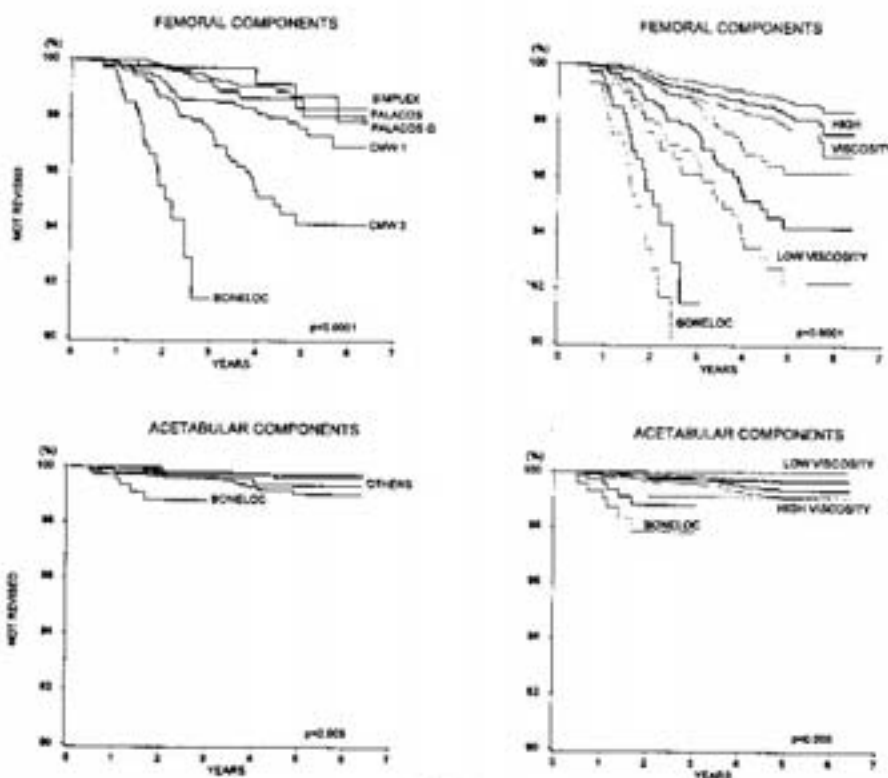

FIG. 1

Kaplan-Meier analyses of revision due to aseptic loosening in association with different types and viscosities of cement. The results for low-viscosity CMW 3 and Boneloc cement were significantly poorer (p < 0.0001) than those for the high-viscosity cement. (The area within the 95 per cent confidence limits is shaded.)

TABLE III

RELATIVE RATES OF REVISION (FAILURE RATE RATIO) DUE TO ASEPTIC LOOSENING, AS DETERMINED WITH USE OF THE COX PROPORTIONAL-HAZARDS MODEL

	No. of Hips	No. of Revisions	Unadjusted		Adjusted	
			Failure Rate Ratio	95 Per Cent Confidence Interval	Failure Rate Ratio	95 Per Cent Confidence Interval
Femoral components						
Type of cement*						
High-viscosity without antibiotic	3788	47	1		1	
Low-viscosity without antibiotic	1196	38	2.5	1.6 to 3.9	2.4	1.6 to 3.8
High-viscosity with antibiotic	2801	19	0.6	0.4 to 1.0	0.6	0.3 to 1.0
Boneloc	764	23	8.5	4.9 to 14.5	8.7	5.1 to 14.8
Sex						
Men	2575	64	1		1	
Women	5974	63	0.4	0.3 to 0.6	0.4	0.3 to 0.6
Age (yrs.)						
<60	449	11	3.1	1.2 to 7.9	2.7	1.1 to 7.1
60 to 69	2752	45	2.1	0.9 to 4.7	1.9	0.9 to 4.2
70 to 79	4230	64	2.2	1.0 to 4.9	2.1	0.9 to 4.5
>79	1118	7	1		1	
Acetabular components						
Type of cement*						
High-viscosity without antibiotic	4495	21	1		1	
Low-viscosity without antibiotic	494	1	0.5	0.1 to 3.6	0.5	0.1 to 3.6
High-viscosity with antibiotic	2812	5	0.4	0.2 to 1.1	0.4	0.2 to 1.1
Boneloc	760	6	3.9	1.5 to 10.2	4.0	1.5 to 10.6
Sex						
Men	2581	17	1		1	
Women	5980	16	0.4	0.2 to 0.8	0.4	0.2 to 0.8
Age† (yrs.)						
<70	3201	13	3.8	0.5 to 29.3	3.5	0.5 to 27.0
70 to 79	4241	19	4.7	0.6 to 35.3	4.5	0.6 to 33.5
>79	1119	1	1		1	

*Components that were implanted with low-viscosity cement containing an antibiotic were excluded from the analyses because of their small number (see Table II).

†Because no acetabular component failed in patients who were less than sixty years old, the age-groups were changed in the analyses of the acetabular components.

interval, 35 to 103 per cent) of that for the components that had been implanted with high-viscosity cement that did not contain an antibiotic (p = 0.05).

Because of the surprisingly poor results associated with the femoral components that had been implanted with Boneloc cement, some supplementary analyses were done. We thought that it was possible that these results were inferior because the surgeons in the hospitals where this cement had been used were less skilled. However, when the analyses were restricted to only those hospitals, the results remained significantly poorer than those for the components that had been implanted with high or low-viscosity cement (p < 0.0001). Because Boneloc cement and the new equipment for mixing it had been introduced onto the market during the study period, we wanted to correct for a possible problem with respect to the learning curve for this new technology. However, we found similarly poor results in association with the components that had been implanted with Boneloc cement after we had excluded the first twenty-five such components for each hospital (p < 0.0001). With use of the Cox proportional-hazards model, the components that had been implanted with Boneloc cement had a rate of revision that was 8.7 times higher (95

per cent confidence interval, 5.1 to 14.8 times) than that for the components that had been implanted with high-viscosity cement without an antibiotic.

With use of the Cox model, the rate of revision of the femoral components was reduced 41 per cent (95 per cent confidence interval, 29 to 59 per cent) in women compared with that in men. There was a tendency toward fewer revisions in the older age-groups, but this difference was not significant (p = 0.14, linear trend test) (Table III).

Acetabular Components

We found no significant difference in the results with respect to the different types of cement that had been used to implant the acetabular components. Each type of cement was associated with a revision rate of less than 1.0 per cent at 5.5 years (Fig. 1 and Table II). However, the components that had been implanted with Boneloc cement, and had been followed for a shorter duration (zero to three years), had a cumulative survival rate of only 98.8 per cent at two years, compared with a rate of 99.8 per cent for the other groups (p < 0.001). The difference in survival between the components that had been implanted with high-viscosity ce-
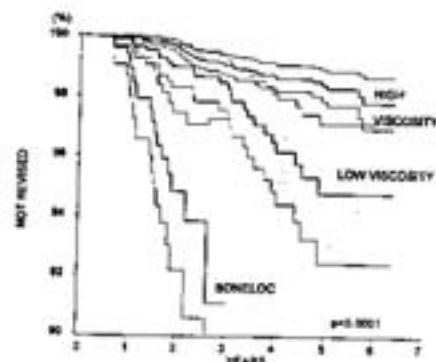
FIG. 2

Kaplan-Meier analysis of revision due to aseptic loosening of femoral components used in unilateral total hip replacements. The results were similar to those for the total patient population. (The area within the 95 per cent confidence limits is shaded.)

ment and those implanted with low-viscosity cement was negligible (Fig. 1 and Table II).

The results for the components that had been implanted with high-viscosity cement that contained an antibiotic were somewhat better than the results for the components implanted with high-viscosity cement that did not contain an antibiotic. These groups had rates of revision of 0.4 and 0.8 per cent, respectively, at 5.5 years; however, these differences were not significant.

With use of the Cox model, the viscosity of the cement had no significant effect on the survival of the acetabular components. The components that had been implanted with Boneloc cement had a rate of revision that was 4.0 times higher (95 per cent confidence interval, 1.5 to 10.6 times) than that of the components that had been implanted with high-viscosity cement (Table III). As was the case for the femoral components, the survival of the acetabular components in women was significantly better than that in men, with a rate of revision that was 40 per cent (95 per cent confidence interval, 20 to 79 per cent) that of the rate in men.

Unilateral Hip Replacement

The results for the patients who had had a unilateral operation were virtually the same as those for all patients who had had a total hip replacement (Fig. 2). The over-all results for patients who had had a unilateral operation were not significantly different from the over-all results for those who had had a bilateral operation (p = 0.37 for the femoral components and p = 0.35 for the acetabular components).

Revisions

Over-all, a total of 198 revisions were performed in this group of 8579 arthroplasties. Twenty-one revisions had been done for aseptic loosening of both components; 106, for aseptic loosening of only the femoral component; twelve, for aseptic loosening of only the acetabular component; thirty-seven, for infection; fourteen, for dislocation; and eight, for other reasons. The results of survival analyses with revision due to any cause as the end point were very similar to those of the analyses for revision due to aseptic loosening. The results associated with Boneloc and CMW 3 cement were poorer and significantly different from each other and from those associated with the other types of cement (p < 0.0001).

Discussion

As there had been few clinical studies on the types of cement that have been used in total hip operations, and as some surgeons had raised concerns about the results associated with use of the relatively new Boneloc cement, we investigated the effects of the brand and viscosity of the cement on the survival of hip prostheses. Although Boneloc cement had been in use for only three years at the time of our study, we considered it especially important to evaluate its clinical results, as it had been used in thousands of patients without those results being known.

The increased probability for revision of the femoral components implanted with Boneloc cement compared with the rate for the components implanted with low-viscosity CMW 3 cement, and the increased probability for the femoral components implanted with low-viscosity cement compared with that for the femoral components implanted with high-viscosity cement, cannot be explained by differences in the patient populations. The investigation comprised a homogeneous group of patients who had had only one type of prosthesis, one diagnosis, and no previous operations. As far as we know, no other large clinical study has addressed the impact of the cement on the results of hip arthroplasty. In a randomized clinical trial with five years of follow-up, Carlsson et al. found no difference in the results between femoral components that had been implanted with high-viscosity cement and those implanted with low-viscosity cement. However, the number of patients (226) in their study was small, and the power of the study to reveal differences of 4 per cent at a 5 per cent level of significance was less than 50 per cent. In addition, the operations in their study were performed during a period of only two years and only in hospitals where a so-called modern technique was used for application of the cement. Because the surgeons were experienced with this technique, better results could be expected with the low-viscosity cement although the technique is technically demanding. A study based on a nationwide register, such as the current one, can provide a more realistic picture of the over-all results with use of different types of cement because of the larger number of patients and the inclusion of many hospitals during a longer period of time.

The better results associated with the cement that contained an antibiotic are interesting, as revision because of aseptic loosening was the end point in the survival analyses. However, if some instances of aseptic loosening were actually due to subclinical infection, this may explain the better results. It is also possible that the addition of an antibiotic caused an alteration in the mechanical properties of the cement, such as an increase in the viscosity. However, for the femoral components inserted with high-viscosity cement, the difference in survival due to the addition of an antibiotic was only 1.0 per cent at 5.5 years. A larger number of patients or a longer duration of follow-up is needed to give more certainty about the clinical importance of this difference.

With respect to the acetabular components, no clinically important difference relative to the effect of the viscosity of the cement was found. This may be because, during cementing of the cup, it is easier (and probably common) to wait until the viscosity becomes high before the cup is inserted. Both the Kaplan-Meier analyses and the Cox proportional-hazards model demonstrated better results for the cups that had been implanted with cement containing an antibiotic. The rates of revision were less than 1.0 per cent for all groups of cups, and the clinical relevance of the positive effect of cement with an antibiotic is uncertain.

Boneloc cement was introduced in Norway in 1991. It became popular because of its lower toxicity, lower exothermic temperature, and closed system for application[11,12,19]. It had a new formula and a shorter handling time[13]. Problems related to learning to use the new equipment, and the shorter handling time of the cement, may have contributed to, but do not explain, the poorer results. However, a poor result is not surprising when a new product is introduced for hip operations. The impact of the Boneloc formula (50 per cent methylmethacrylate, 30 per cent n-decyl-methacrylate, and 20 per cent isobornyl methacrylate[11]), compared with that of the ordinary polymethylmethacrylate cements, should be further investigated. The manufacturer has since changed the formula, and Boneloc cement produced after December 1993 has a handling time more like that of the other types of cement[12].

The inclusion of patients who had had a bilateral operation might be questioned, as standard statistical methods assume independent observations[16]. Conceivably, failure in a patient who has had a bilateral operation is dependent. However, these patients constitute an important group who have hip prostheses. It should be noted that only negligible differences in the results were found between the total population of patients and the population who had had a unilateral procedure. The possible effect of a dependency within a patient who had a bilateral operation therefore seems to have been unimportant.

The present study was not randomized. Randomized trials of hip operations have generally been small, and the large number of patients in our study was an advantage. Because our study was not randomized, the possibility that certain types of cement were associated with other factors that affected the outcome cannot be excluded. For example, the surgeons who used low-viscosity cement or the new Boneloc cement might have been less experienced than the others. Such a bias is unlikely in Norway, however, as the choice of cement is generally made by the orthopaedic department and not by the individual surgeon.

Unfortunately, comparison of the different brands of low-viscosity cement was impossible, as only the low-viscosity CMW 3 cement was used in enough patients (Table 1). However, the most important difference between the CMW 3 cement and the other types of cement is its low viscosity. Low-viscosity cement has been shown to have greater penetration into cancellous bone[2,7], and this may explain the superiority of low-viscosity cement in experiments[8]. However, the experimental results have not been supported by the results of clinical trials. On the contrary, some clinical investigations have shown inferior results for prostheses implanted with low-viscosity cement[10], and a study based on stereophotogrammetry revealed a greater rate of migration of femoral components that had been implanted with low-viscosity cement compared with those implanted with high-viscosity cement[17].

There may be several explanations for the poorer results associated with the femoral components that were implanted with low-viscosity cement. The principles of so-called modern techniques of cement application[18,20,24] are well known throughout Norway, but the way that these principles are put into practice may differ. The technique for the application of low-viscosity cement is more demanding. The maintenance of pressure throughout the cementing process is critical, especially when low-viscosity cement is used. During polymerization, low-viscosity cement has been shown to be more easily displaced from the irregularities in the bone by blood[1] and to provide a lower shearing strength of the bone-cement interface[14] than high-viscosity cement. The strength of low-viscosity cement has been shown to be high in laboratory tests[6], but contamination of fat and blood has been shown to decrease the strength of low-viscosity cement more than it decreases the strength of high-viscosity cement[15].

In summary, this prospective clinical study, based on a nationwide register, demonstrated an increased rate of revision due to aseptic loosening of femoral components that had been implanted with low-viscosity cement compared with the rate for those that had been implanted with high-viscosity cement. The first generation of Boneloc cement was associated with poorer short-term results than the other types of cement. A randomized study with a sufficient number of patients should be performed to confirm our results.

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PAPER V

Revision for aseptic loosening of uncemented cups in 4,352 primary total hip prostheses

A report from the Norwegian Arthroplasty Register

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From September 1987 until January 1994 the Norwegian Arthroplasty Register recorded 5,021 primary total hip replacements performed with uncemented acetabular components. We compared the survival until revision for aseptic loosening of the cup, in the 11 commonest types (n 4,352).

The overall cumulative revision rate for the acetabular components was 3.2% after 5 years and 7.1% after 6 years, with large differences among the designs.

With the hydroxyapatite (HA)-coated cups and the hemispheric porous-coated cups, the failure rate was less than 0.1%. Of the unthreaded hemispheric porous-coated cups, Harris-Galante and Gemini (n 626), none had been revised, and of the HA-coated cups, Atoll and Tropic (n 1,943), only 1 had been revised.

For the threaded uncoated metal-backed cups, the results varied from no revisions of the PM cups (n 148) to a cumulative 6-year revision rate of 21% for the Ti-Fit (n 300). The all-polyethylene Endler cups (n 334) had a cumulative revision rate of 14%.

Women and patients with inflammatory arthritis had poorer results. However, the type and the design of the cups were of far greater importance for the results than patient-related factors.

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Uncemented total hip replacement (THR) has become the standard procedure in patients less than 60–65 years in many hospitals in Norway (Havelin et al. 1993). The nation-wide overall results of the uncemented THR from the period 1987–1992, however, have been shown to be inferior to those of cemented THR (Havelin et al. 1994). These poorer results could partly be explained by high revision rates of only a few of the uncemented femoral components (Havelin et al. 1995).

There were also many different designs and types of acetabular components. We analyzed the results for the 11 commonest uncemented acetabular components used in Norway.

Patients and methods

All 64 hospitals performing total hip replacements in Norway (4.3 million inhabitants in 1994) report their THR to the Norwegian Arthroplasty Register. From September 1987 until January 1994, 29,068 primary total hip replacements had been recorded. Uncemented acetabular components had been inserted in 17.3% (n 5,021) of the operations. For the present investigation we selected the designs that had been used in more than 100 patients (n 4,352). Thus, 11 different types of acetabular components were included: Atoll (Landos, Chaumont, France), Coxa (Thackray, Leeds, England), Endler all-polyethylene and Endler metal-backed (AlloPro, Baar, Switzerland), European Jensen ST (Biomet, Warsaw, Indiana, U.S.A.), Gemini (DePuy, Warsaw, Indiana, U.S.A.), Harris/Galante (Zimmer, Warsaw, Indiana, U.S.A.), LMT (Biomet, Warsaw, Indiana, U.S.A.), PM (Aesculap, Tuttlingen, Germany), Ti-Fit (Richards, Memphis, Tennessee, USA) and Tropic (Landos, Chaumont, France). The acetabular components were also grouped according to characteristics such as threaded, hemispheric, porous-coated, HA-coated, metal backing, or all-polyethylene.

All revisions with exchange or removal of one or more of the components were reported to the register. Detailed information about the operation, including the reasons for and type of revision, was given on a form filled in by the surgeons immediately after each operation. The revisions were linked to the primary operations with help of the patients' national social security numbers. Each THR was thus followed prospectively.

The estimated survival probabilities were obtained by the Kaplan-Meier method. Revision because of

Table 1. The 11 most commonly used uncemented acetabular components in Norway, 1987–1993

	Atoll	Coxa	Endler metal-backed	Endler all PE	Europ. Jensen ST	Gemini	Harris/ Galante	LMT	PM	TI-FIT	Tropic
Total number	772	200	285	334	250	405	221	266	148	300	1171
Gender (% men)	39	38	37	34	31	42	37	29	43	37	37
Age (%)											
<50	34	38	20	8	7	40	46	13	34	38	30
50–59	30	40	34	19	22	36	34	16	51	36	31
60–69	28	18	35	37	54	24	15	55	14	23	31
>69	9	5	11	35	16	1	6	16	1	3	8
Mean age	55	53	59	65	64	53	50	63	53	52	56
Diagnoses (%)											
Coxarthrosis	44	44	50	77	73	49	20	72	42	35	45
Rheumatoid arthritis	4	4	6	3	0	4	5	0	3	10	7
Sequelae after hip fracture	7	8	8	5	8	7	9	11	6	8	8
Sequelae after dysplasia	20	2	21	7	13	23	23	11	28	28	21
Dysplasia with dislocation	9	5	4	3	2	2	25	2	10	5	5
Other pediatric hip disease	5	4	5	2	0	7	7	2	7	7	4
Ankylosing spondylitis	2	3	1	0	0	2	1	0	1	1	2
Other	9	5	5	3	3	7	10	2	2	6	8

aseptic loosening of the cup was the end-point in this study. Survival times of the THRs, revised for reasons other than aseptic loosening of the cup and of THRs in patients who died or emigrated without having been revised, were censored. Deceased or emigrated patients were identified by the Central Bureau of Statistics, Oslo, Norway. Two-sided log-rank tests were performed to determine if differences were significant (Mantel 1966).

The Cox proportional-hazards model was used to assess the influence on the result of factors such as gender, age (<50, 50–59, 60–69, >69 years), diagnosis, type of implant and of the different characteristics in design. In this Cox analysis, the HA-coated cups and the hemispheric cups with porous coating were treated as one group and used as the basis. This group was chosen for this purpose because it was the largest group and also because these prostheses are made in accordance with the principles which are now the most accepted in Norway. We also analyzed whether the type of femoral component, cemented or uncemented, influenced the results. The importance of head diameter and head material could not be assessed, as each type of acetabular component, with few exceptions, was combined with only one type of head. The analyses were done by the BMDP statistical package (Dixon et al. 1990).

Results

Table 1 shows the characteristics of the patients regarding each type of acetabular component. The design characteristics of the cups are given in Table 2, along with the characteristics of the femoral compo-

nent associated with the different cups. In design, the European Jensen ST cup differed from the other metal-backed threaded cups because its central area over the dome was porous-coated. The Gemini and the HA-coated implants, Atoll and Tropic, had shorter median observation periods than the others (Table 3).

The overall estimate of cumulative survival was 97% (95% confidence interval (CI): 96–98) after 5 years and 93% (95% CI: 91–95) after 6 years, but the results varied for the different prostheses (Table 3). For the Endler all-polyethylene threaded cup and the Ti-Fit threaded cup, the cumulative survival decreased to 86% (95% CI: 80–91) and 79% (95% CI: 70–89), respectively, at 6 years, indicating that the revision rates increased after 5 years (Figure 1).

The overall 5-year cumulative survival of the metal-backed threaded cups without HA-coating was 97% (95% CI: 96–98) (Figure 1).

The two hemispheric porous-coated designs (n 626) required no revision for aseptic loosening. Of these cups, only the Harris/Galante cup (n 221) had been used throughout the whole period, whereas the Gemini (n 405) had been used only for 3 years. Of the two HA-coated prostheses (n 1,943), there had been only one revision of the Tropic (n 1,171).

The Kaplan-Meier analyses showed poorer results in women compared to men (p 0.01). In analyses restricted to women, to patients with arthrosis, and to the group of unilaterally operated patients, the results were similar to those in the total material. However, in analyses restricted to men, the over-all difference between the cups was marginally significant (p 0.03) (Figure 2).

We found no difference in the 5-year survival

Table 2. Design, surface and material characteristics of the uncemented acetabular components and of the femoral stems

	Atoll	Coxa	Endler metal-backed	Endler all PE	Europ.* Jensen ST	Gemini porous-coated	Harris/Galante	LMT TTAP	PM	TI-FIT	Tropic
Acetabular component											
Design											
Hemispheric, unthreaded	+					+	+				
partially threaded		+			+					+	+
Conic, fully threaded			+	+				+	+		
Surface											
No coating		+	+	+	+			+	+	+	
Porous-coated					+	+	+				
HA-coated	+										+
Material											
Titanium/PE	+	+	+		+	+	+	+	+	+	+
All polyethylene				+							
Stem (%)											
Cemented stem	15	25	40	64	3	18	16	12	0	27	27
Uncemented titanium stem	85	75	60	36	97	82	84	88	100	0	73
chrome cobalt stem	0	0	0	0	0	0	0	0	0	73	0
Head diameter (%)											
22 mm	1	46	0	0	0	14	12	1	0	0	1
26 mm	0	1	0	0	0	0	0	0	0	16	0
28 mm	57	0	0	0	0	86	8	0	0	1	3
32 mm	43	53	100	100	100	0	80	99	100	82	97
Head material (%)											
Chrome cobalt	0	48	1	1	0	100	85	0	0	83	0
Titanium	1	0	0	0	99	0	0	98	0	0	0
Ceramic	19	45	56	27	0	0	2	0	100	9	14
Stainless steel	80	7	43	72	1	0	13	2	0	8	86

* The threaded European Jensen ST cup was porous-coated centrally over the dome.

Table 3. Follow-up and survival analysis with Cox model of uncemented acetabular components. The hemispheric porous-coated and the HA-coated (hemispheric or threaded) were selected as the basis of this analysis

	No.	Median follow-up	Revisions no.	At risk 5 yrs	Cumul. survival 5 yrs	95% CI*	Cox unadjusted		Cox adjusted[b]		
							FRR[c]	P-value	FFR[c]	95% CI	P-value
Atoll	772	1.1	0	0[d]							
Gemini	405	1.1	0	0*			1				
Harris/Galante	221	3.4	0	55	100	99.7–100					
Tropic	1171	3.0	1	11	99.9	99.7–100					
Coxa	200	3.4	3	49	98.6	96.6–100	14.2	0.01	15.1	1.5–146	0.01
Endler metal-backed	285	5.0	4	222	99.0	97.6–100	8.5	0.03	8.6	0.9–78	0.03
Endler all PE	334	5.4	34	150	91.9	88.7–95.1	51.9	<0.0001	56.5	7.5–425	<0.0001
European Jensen	250	3.6	5	3	96.8	93.3–100	28.1	0.0002	30.7	3.5–267	0.0002
LMT	266	5.2	5	171	98.7	97.1–100	10.2	0.01	10.7	1.2–94	0.01
PM	148	4.0	0	39	100	–	0.0	0.57	0.0	–	0.6
TI-FIT	300	4.4	29	102	90.5	86.4–94.5	76.3	<0.0001	76.7	10.3–569	<0.0001

* CI confidence interval.
[b] Adjustments were made for age, sex and diagnosis.
[c] FRR failure rate ratio.
[d] Maximal follow-up of the Atoll: 3.5 years.
* Maximal follow-up of the Gemini: 3.0 years.

(p 0.78) for left- or right-sided cups.

From the patient characteristics given in Table 1 differences can be seen among the types. The patients with Endler, LMT and European cups were older than the others, whereas patients with the Harris/Galante cup were younger. The distribution of gender also varied; LMT was associated with the lowest percent-age of men, and the PM cup with the highest. The Harris/Galante had a very low percentage of primary coxarthrosis patients compared to the other types. Cox analyses were therefore done to study the impact on the results of the risk factors: sex, age and diagnosis, and to estimate the relative rate of revision in the groups, with adjustment for these risk factors (Table
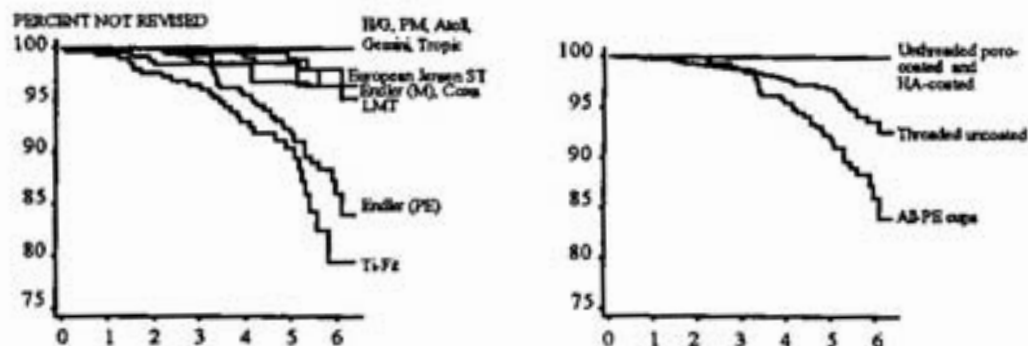
Figure 1. Prosthesis survival until revision for aseptic loosening of the cup. Total material of uncemented cups analyzed by type and by design characteristics.
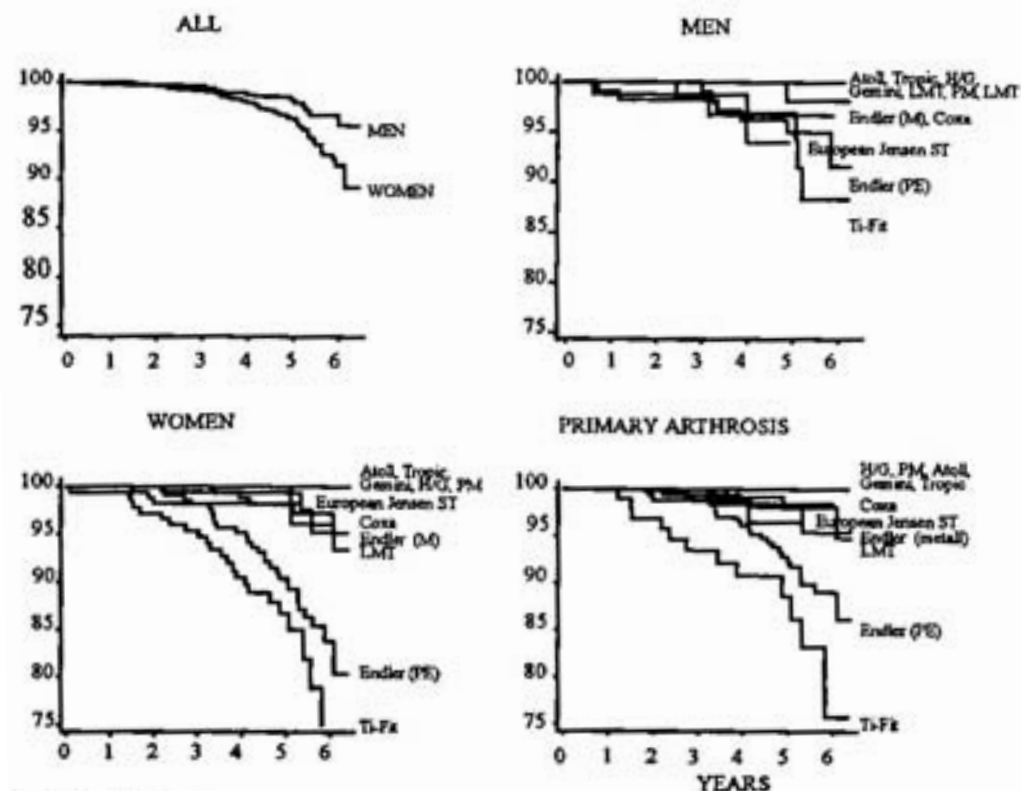

Figure 2. Prosthesis survival until revision for aseptic loosening of the cup, analyzed by gender in the total material, by type in the subgroup of all men (n 1,599), by type in the subgroup of all women (n 2,753), and analyzed by type in the subgroup of all patients with primary arthrosis (n 2,143).

). The Cox analyses gave an increased adjusted failure rate of 1.8 (p 0.03) in women. The failure rates were not different in any of the age groups. Inflammatory arthritis had an increased relative rate of revision (p 0.03).

The most important risk factor was design (Table 4). With adjustments for gender, age and diagnosis, the metal-backed threaded cups and the all-polyethy-

Table 4. Revision risk of uncemented acetabular components (Cox regression)

	No. of cups	No. of revisions	Unadjusted		Adjusted [a]		
			FRR [b]	95% CI [c]	FRR [b]	95% CI [c]	P-value
Cup design							
Metal-backed screw	1449	46	24.8	3.4–181	16.3	2.2–121	0.007
All polyethylene	334	34	54.3	7.3–401	62.2	8.2–469	0.0001
HA-coated or hemispheric	2569	1	1		1		
Stem characteristics							
Cemented stem	1033	27	1.7	1.0–2.9	0.7	0.4–1.4	0.36
Uncemented titanium stem	3148	34	1		1		
Uncemented chrome cobalt stem [d]	171	20	5.0	2.9–8.8	5.0	2.7–9.3	0.0001
Gender							
Men	1599	18	1		1		
Women	2753	63	1.9	1.1–3.3	1.8	1.1–3.2	0.03
Age							
< 50	1255	18	0.8	0.4–1.4	0.6	0.3–1.3	0.18
50–59	1331	19	0.7	0.4–1.2	0.6	0.3–1.2	0.13
60–69	1335	35	1		1		
> 69	431	9	0.9	0.5–1.7	0.7	0.4–1.4	0.33
Trend test for age							0.61
Diagnosis							
Coxarthrosis	2143	46	1		1		
Inflammatory arthritis	275	10	2.2	1.1–4.4	2.8	1.3–6.1	0.03
Sequelae after hip fracture	324	2	0.3	0.1–1.4	0.4	0.1–1.7	0.23
Sequelae after dysplasia	866	13	0.9	0.5–1.6	1.0	0.5–2.1	0.89
Dysplasia with dislocation	256	6	1.3	0.5–3.0	1.7	0.7–4.1	0.27
Other	488	4	0.5	0.2–1.4	0.8	0.3–2.4	0.7

[a] The model included gender, age, diagnosis, cup design and stem characteristics.
[b] FRR failure rate ratio
[c] CI confidence interval
[d] This group included only Ti-Fit cups combined with Bio-Fit (chrome cobalt stems).

Table 5. Reason for revision and total number of revisions for the THRs with different acetabular designs. More than one reason was possible for each hip. Each acetabular design could be combined with several different stems

Acetabular design	Number of THRs	Aseptic loosening acetabulum	Aseptic loosening femur	Infection	Dislocation	Fracture	Total
Atoll	772	0	0	1	7	0	9
Coxa	200	3	21	2	4	1	30
Endler metal	285	4	2	2	1	0	9
Endler all PE	334	34	3	1	0	0	38
European Jensen	250	5	0	1	1	1	8
Gemini	405	0	0	0	3	0	3
Harris/Galante	221	0	6	1	2	1	9
LMT	266	5	1	0	1	1	9
PM	148	0	5	0	0	0	6
Ti-fit	300	29	45	3	0	2	64
Tropic	1171	1	6	1	6	1	16
Total	4352	81	89	12	25	7	201

lene cups had increased risks of revision compared to the reference group, with failure rate ratios of 16 and 62, respectively. In the type-wise analyses, the risk for revision differed considerably between the threaded cups. The greatest increase in risk was found for the Ti-Fit cup which had a 76 times increased risk for revision compared to the cups in the reference group (Table 3).

The combination with cemented femoral compo-

nents gave a relative risk for revision of the cups of 0.7 compared to those combined with uncemented titanium implants, but the difference was not significant (Table 4).

The failure rate of the Ti-Fit cup did not differ, whether it was combined with the uncemented Bio-Fit (Richards, Memphis, Tennessee, U.S.A.) chrome cobalt stem or with cemented stems.

The numbers of THRs revised for reasons other

than aseptic loosening of the cup are given in Table 5. It should be noted that among THRs with Ti-Fit cups, a high number of revisions had been done because of loosening of the stem whereas, for the THRs with Endler cups, only a few revisions had been done because of stem loosening. In survival analyses on cup revision for any reason, the relations between the prosthesis types were practically unaltered.

Discussion

The surface coating seems to be the most important single factor for the survival of uncemented cups during the first 6 years. We found very low failure rates for porous-coated and for HA-coated cups. No difference could be demonstrated between these two groups, but the porous-coated cups had a longer follow-up. HA-coating was found to give good short-term results also on threaded cups. The results of the metal-backed threaded cups without HA-coating varied. Coxa, Endler metal-backed cup, PM, LMT and European Cup were far better than the Ti-Fit cups. The Ti-Fit and the Endler all-polyethylene cups gave poor results and they should be abandoned.

The literature gives results for only a few types of uncemented cups, but the results which have been reported are comparable to ours. For the Harris-Galante cup we found no revisions due to aseptic loosening, which is in accordance with Harris and Maloney (1989) in a study of 126 prostheses followed for 2–5 years. The same result was also reported by Schmalzried and Harris (1992) for 83 prostheses reviewed after a minimum of 5 years, and by Martell et al. (1993) for 110 patients after 5–7 years. With the Endler all-polyethylene cup, Gut et al. (1990) and Reigstad et al. (1994) found a high percentage of radiographic loosening. Fox et al. (1994) reported poorer results than ours with the LMT (TTAP) cup, but the follow-up was longer. No results could be found in the literature for the other types in our material.

The most important factors for good short-term results with uncemented implants seem to be immediate stability and possibilities for on-growth or in-growth of bone. The latter is the case in porous- and HA-coated surfaces (Bauer et al. 1993, Sumner et al. 1993). Threaded cups have been shown to have a smaller contact surface in apposition to bone (Huiskes 1987), and have been reported to give a poor immediate fixation (Tooke et al. 1988, Snorrason and Kärrholm 1990). However, in the present investigation, HA-coating on the threaded cups gave results comparable to those of hemispheric porous-coated cups.

The poorer results of the Ti-Fit cup, compared to the other metal-backed threaded cups, on the basis of our data, are difficult to explain. In contrast to the other cups, the Ti-Fit cups were mostly (73%) combined with the uncemented Bio-Fit stem which have poor results (Havelin et al. 1995). However, we found that the failure rate did not differ whether the Ti-Fit cups were combined with this stem or with cemented stems.

We observed better results in men than in women. This sex difference is the opposite of that by Malchau et al. (1993) and in most other reports on hip arthroplasties, but in accordance with Gut et al. (1990), Wilson-MacDonald (1990) and Morscher (1992). It seems possible that the quality of bone is different in women and that the immediate fixation of threaded cups therefore could be a greater problem in women than in men. This could also explain our somewhat poorer result in patients with inflammatory hip diseases. It must be emphasized that it cannot be concluded from our results that all uncemented cups are unsuitable for women and patients with inflammatory hip disease, as we found good results both with the hemispheric porous-coated cups and with the HA-coated cups in these patients. Our earlier experiences of increased risk for revision among younger patients was not confirmed (Havelin et al. 1994). One conclusion from this investigation can therefore be that the patient-related factors were of less importance than the type of prosthesis.

During the last few years, we have observed an evolution of uncemented acetabular components. Some inferior designs have to be abandoned, whereas the short-term results of the uncemented porous-coated and the HA-coated cups are good, and comparable to those of cemented cups. As demonstrated by Schmalzried et al. (1994) and Maloney et al. (1993), wear and osteolysis might influence the long-term results. It remains to be seen if the results with some uncemented cups, in some groups of patients, are better than for the best-cemented. Until more is known about their long-term results, uncemented acetabular components should be used as part of randomized trials.

Acknowledgements

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PAPER VI

Early revision among 12,179 hip prostheses

A comparison of 10 different brands reported to the Norwegian Arthroplasty Register, 1987–1993

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On the basis of data from the Norwegian Arthroplasty Register during the period 1987–1993, we have compared times to revision for 10 different cemented total hip prostheses. A total of 11,169 patients, with 12,179 primary total hip replacements (THRs), performed with high viscosity cement for primary arthrosis and followed for a maximum of 6.4 years, were included in this study.

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

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

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Large differences in revision due to aseptic loosening have been reported among various uncemented femoral prosthesis brands used in Norway (Havelin et al. 1995a). The purpose of the present study was to compare the survival of the most commonly used cemented total hip replacements (THRs) in Norway during the period 1987–1993. We decided to compare the prostheses in a homogeneous material and, because of poor results associated with the use of low viscosity cement (Havelin et al. 1995b), only operations performed with high-viscosity cement were selected. Furthermore, we restricted our analysis to patients with primary arthrosis. Thus, data are presented concerning revisions among 10 different hip prosthesis brands in 11,169 patients followed for a maximum of 6.4 years.

Patients and methods

All THRs performed in Norway (4.2 million inhabitants) since September 1987 have been reported to the Norwegian Arthroplasty Register (Havelin et al. 1993). Information was obtained from a form filled in by the surgeon after each operation at all the 64 hospitals performing THR. Revisions were linked to the primary operation, using the unique identification number assigned to each resident of Norway. As of February 1, 1994, data had been collected on 29,068 primary THRs in 25,957 patients.

In this study, we investigated possible differences among the prosthesis brands in high-viscosity cemented THRs (n 18,848). Restricting the analyses to operations performed because of primary arthrosis reduced the number of operations to 13,257. The material was further restricted to the most commonly used high-viscosity cement types: Palacos (Schering-Plough International Inc., Kenilworth, New Jersey, U.S.A.), Simplex (Howmedica International, London, U.K.) and CMW I (CMW Laboratories Dentsply, Exeter, U.K.). Operations performed with other cement types or with different cement types in the acetabulum and femur were excluded (n 399). Potential follow-up was defined as the longest pos-

Table 1. Number and percent of each prosthesis brand and distribution of gender and age for cemented primary total hip replacements in Norway 1987–1993

Prosthesis brand acetabulum/femur	No. (percent)		Percent males	Median age	Percent < 65 yrs	Percent 65–74 yrs
1. Charnley/Charnley	6694	(55)	30	72	17	48
2. Exeter/Exeter	1665	(14)	33	71	18	53
3. Titan/Titan	1333	(11)	31	74	5.3	48
4. Spectron/ITH	1034	(8.5)	34	72	17	50
5. Elite/Charnley	507	(4.2)	60	72	15	47
6. Spectron/Lubinus SP	302	(2.5)	40	73	14	51
7. Biomet/Biomet	247	(2.0)	21	76	0.0	28
8. Spectron/Bio-fit	152	(1.2)	18	76	1.3	44
9. Lubinus SP/Lubinus SP	129	(1.1)	28	73	3.9	55
10. Müller Type/Müller Type	116	(1.0)	25	71	12	57
All combinations	12179	(100)	32	72	15	49

sible follow-up for each implant, i.e., the time difference between the date of implantation and the latest possible censoring or revision date, namely February 1, 1994. Only prosthesis brands where the potential follow-up of the prostheses added up to 500 prosthesis-years or more were considered. Thus, data on 12,179 primary operations in 11,169 patients remained for analysis. A total of 2,433 patients underwent surgery on both hips, but only 1,010 patients were included in the analysis of both operations. One operation was included for bilaterally operated patients, if only one of the operations fulfilled the above inclusion criteria (737 patients) or if the first operation had been performed before registration of THRs started in Norway (686 patients).

In order to evaluate whether a prosthesis brand had been used throughout the whole period 1987–1993, or only during the first or last part of the period, the mean potential follow-up was calculated for each prosthesis brand. A large value would then indicate a more frequent use early in the period and the opposite would indicate a more frequent use in the latter part.

Different combinations of the following acetabular and femoral prosthesis brands were investigated (Table 1): Charnley stem and cup, Elite cup (Thackray, Leeds, U.K.); Exeter stem (polished) and cup (Howmedica International, Herouville, France); Titan stem and cup (Landos, Chaumont, France); SP HIP stem and cup, SP II Lubinus stem (Waldemar Link, Hamburg, Germany); ITH stem, Bio-fit stem, Spectron cup (Richards, Memphis, Tennessee, U.S.A.); LMT Biomet stem and cup, Biomet Watson Farrar cup, European Cup System (Biomet, Warsaw, Indiana, U.S.A.) and Müller Type stem and cup (Zimmer, Warsaw, Indiana, U.S.A.). As SP II Lubinus and SP HIP differed only by the modularity of the head in SP II, they were regarded as one group called Lubinus SP prostheses. The prostheses known

as Biomet Watson Farrar, LMT Biomet and European Cup System were also treated as one group called Biomet prostheses. Only Elite cups with inner diameters of 22 mm were included. From 1994, these cups were marketed as Charnley cups and the Elite name is now used only for cups with inner diameters other than 22 mm.

Kaplan-Meier survival curves were calculated with the endpoint defined as a revision for any cause in which a part or the whole primary prosthesis was exchanged or removed. Patients could be registered with different reasons for a revision and the effect of a specific cause was investigated by recognizing only revisions having this particular cause as endpoint and censoring revisions having other causes. When reported in combination with other causes, infection was always given priority. Furthermore, aseptic loosening had precedence over all causes other than infection. Thus, dislocation was accepted as the main cause of revision, except when given in combination with infection or aseptic loosening. The Central Bureau of Statistics, Oslo, Norway, provided information on deaths among the patients. The follow-up period was until the patient died or February 1, 1994. Two-sided log-rank tests (Mantel 1966) were performed to investigate whether any differences in survivorship among the prosthesis brands were significant. In the survival curves depicted, the percentage of revised hips was given only for times where more than 30 hips remained at risk.

Cox regression was used to establish effect estimates for prosthesis brand, with possible adjustment for type of cement (Palacos with antibiotics (i.e., gentamicin) and Palacos without antibiotics, Simplex without antibiotics, CMW I without antibiotics), use of systemic antibiotic prophylactics (yes, no), use of trochanteric osteotomy (yes, no), type of operating theater (greenhouse or laminar air ventilation, ordi-

Table 2. Number and percent of each prosthesis brand and distribution of hospitals, high viscosity cement types, use of antibiotic prophylaxis and type of operating theater for cemented primary total hip replacements in Norway 1987–1993

Prosthesis brand acetabulum/femur	No. (percent)		No. of hospitals	Types of cement in percent					Antibiotic prophylaxis		Op. theater
				Palacos with gentamicin	Without antibiotics				Percent systemic	Percent systemic and in cement	Percent greenhouse or laminar airflow
					Palacos	Simplex	CMW1				
1. Charnley/Charnley	6694	(55)	45	43	16	6.5	35		94	41	52
2. Exeter/Exeter	1665	(14)	9	1.5	0.2	98	0.0		100	1.4	63
3. Titan/Titan	1333	(11)	15	68	18	6.1	8.5		95	64	34
4. Spectron/ITH	1034	(8.5)	5	50	9.7	40	0.0		86	50	10
5. Elite/Charnley	507	(4.2)	18	72	24	0.6	3.7		97	70	39
6. Spectron/Lubinus SP	302	(2.5)	1	1.0	5.6	93	0.0		99	1.0	0.0
7. Biomet/Biomet	247	(2.0)	2	98	2.0	0.0	0.0		14	14	0.4
8. Spectron/Bio-fit	152	(1.2)	3	3.9	96	0.0	0.0		100	3.9	0.7
9. Lubinus SP/Lubinus SP	129	(1.1)	2	53	7.8	40	0.0		100	53	0.0
10. Müller Type/Müller Type	116	(1.0)	6	6.9	3.4	90	0.0		64	6.0	3.5
All combinations	12179	(100)	62	41	14	25	20		93	38	43

nary ventilation), gender and age (< 65, 65–74, > 74 years). Variables with more than two levels were represented by indicator variables to avoid assumptions of linear relationships. Score tests were used to calculate p-values for the Cox regression. Furthermore, to investigate whether the Cox estimated prosthesis brand differences applied to subgroups of the material, prosthesis brand-specific Kaplan-Meier survival curves were created within patient subgroups.

The statistical packages S-PLUS (Statistical Sciences 1991) and BMDP (Dixon 1992) were used for statistical analyses.

Results

The Charnley prosthesis was used in 55% of the operations. The gender and age distribution varied among the prosthesis brands (Table 1). For example, the Elite/Charnley combination was associated with male patients, and the Charnley, Exeter and Spectron/ITH prostheses with patients younger than 65 years. Other characteristics of the procedure were also unevenly distributed (Table 2). Use of the cement containing antibiotics varied from 1.0% (Spectron/Lubinus SP) to 98% (Biomet). Overall, 93% of the operations were performed with systemic antibiotic prophylaxis. Only for the Biomet prosthesis was the use of systemic antibiotics the exception rather than the rule. Combined use of antibiotics both in the cement and systemically varied from 1.0% to 70%. Overall, a 'greenhouse' or a laminar airflow environment was used in 43% of the operations, and almost exclusively with the 5 most commonly used prosthesis brands. Of the 2,740 trochanteric osteotomies registered,

98% were performed with Charnley THRs.

Survival analyses of prosthesis brand

The estimated 5-year failure rate was 2.5% for all prostheses and 2.9% for Charnley THRs (Figure 1, Table 3). The performance of the Spectron/ITH combination was superior to Charnley, while the Müller Type and Elite/Charnley prostheses were associated with poorer results. These results were corroborated in a Cox model with adjustment for gender, age, type of cement and use of systemic antibiotic prophylaxis.
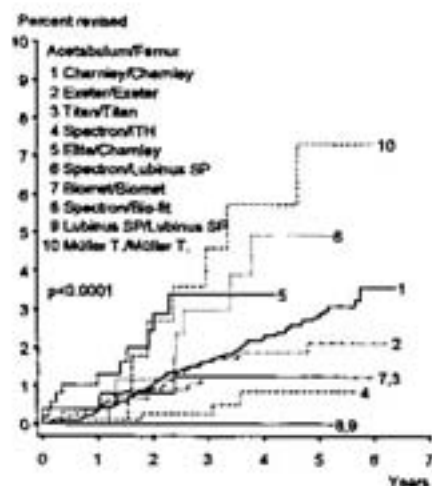

Figure 1. Kaplan-Meier estimated survival curves until revision for any cause for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands.

Table 3. Kaplan-Meier 3- and 5-year failure rates and Cox regression failure rate ratios (FRR) estimated with all causes of revision as endpoint. Cemented primary total hip replacements in Norway 1987–1993

Prosthesis brand acetabulum/femur	No.	No. (%) of revisions	Mean pot. follow-up in yrs [a]	Kaplan-Meier failure rates			Cox regression failure rate ratios (FRR)			
				3-year rate	5-year rate	(95% CI)	Unadjusted FRR	p-value	Adjusted [b] FRR (95% CI)	p-value
1. Charnley/Charnley	6694	115 (1.7)	3.3	1.63	2.86	(2.27–3.45)	1.0		1.0	
2. Exeter/Exeter	1665	23 (1.4)	3.3	1.63	2.15	(1.19–3.11)	0.80	0.34	1.04	(0.49–2.23)	0.90
3. Titan/Titan	1333	12 (0.9)	2.8	1.23	1.23	(0.50–1.06)	0.60	0.09	0.83	(0.45–1.54)	0.55
4. Spectron/ITH	1034	4 (0.4)	2.7	0.25	0.85	(0.00–1.77)	0.27	0.01	0.35	(0.12-1.00)	0.04
5. Elite/Charnley	507	12 (2.4)	2.1	3.40	9.84	(0.00–22.2)	2.19	0.01	2.34	(1.25–4.38)	0.01
6. Spectron/Lubinus SP[c]	302	8 (2.6)	3.1	2.98	4.96	(1.37–8.55)	1.65	0.16	1.96	(0.78–4.92)	0.15
7. Biomet/Biomet[d]	247	3 (1.2)	4.5	1.25	1.25	(0.00–2.66)	0.51	0.24	0.65	(0.19–2.23)	0.49
8. Spectron/Bio-fit	152	0 (0.0)	3.7	0.0[f]	0.0[f]	[f]	0.0[f]	0.08	0.0[f]	[f]	0.11
9. Lubinus SP/Lubinus SP[e]	129	0 (0.0)	4.4	0.0[f]	0.0[f]	[f]	0.0[f]	0.08	0.0[f]	[f]	0.16
10. Müller T/Müller Type	116	7 (6.0)	5.0	4.59	7.33	(1.96–12.7)	2.38	0.02	2.69	(1.02–7.05)	0.04
All combinations	12179	184 (1.5)	3.2	1.56	2.54	(2.13–2.95)				

[a] Mean time difference from date of implantation to February 1, 1994.
[b] Adjusted for gender, age, type of cement and systemic antibiotic prophylaxis.
[c] Spectron/SP II Lubinus (n 180, 4 revisions); Spectron/SP HIP (n 122, 4 revisions).
[d] Biomet Watson Farrar/LMT Biomet (n 65, 0 revisions); LMT Biomet/LMT Biomet (n 131, 1 revision); European Cup System/LMT Biomet (n 51, 2 revisions).
[e] SP HIP/SP II Lubinus (n 1, 0 revisions); SP HIP/SP HIP (n 128, 0 revisions).
[f] No revisions.

where the Spectron/ITH combination had a failure rate of 0.35 that of Charnley (failure rate ratio 0.35, p 0.04). The Müller Type and Elite/Charnley prostheses had failure rate ratios of 2.7 (p 0.04) and 2.3 (p 0.01), respectively. Further adjustment for use of trochanteric osteotomy and type of operating theater gave only negligible differences in results.

For all prostheses, gender was strongly related to their survival, with poorest results among male patients. Overall, the failure rate ratio comparing men to women was 2.2 (p < 0.0001). Figure 2 shows survival curves separately for male and female patients aged less than 75 years and 75 years or more. While the results were quite similar in young and older patients, the variability among prostheses' performance was more pronounced among male patients than among female patients.

Different causes of revision

The overall 5-year failure rate due to aseptic loosening of one or both components was 1.8% (95% Confidence Interval: 1.4–2.1), to dislocation 0.2% (CI: 0.1–0.3) and to infection 0.5% (CI: 0.3–0.6). Of the 184 revisions, 116 (63%) were performed because of aseptic loosening of one or both components (Table 4). Of these, 76 were due to isolated loosening of the femoral component and 22 revisions were due to isolated loosening of the acetabular component (Figure 3). Overall, 42 (23%) of the revisions were performed because of infection, and 20 (11%) prostheses had been revised because of dislocation. The

patterns of the cause of revision were similar among the different prostheses, with the exception of the Elite/Charnley combination where 6 out of 12 revisions were due to infection.

Bilateral operations

It is possible that survival results might be different in bilaterally operated patients (n 1,747) compared to patients having only one artificial hip. To investigate this possibility we performed all analyses among unilaterally operated patients. The results were similar in this subgroup.

Discussion

The brand-specific survival analyses in our study showed significant differences among the cemented prosthesis brands used in Norway during the period 1987–1993. The Spectron/ITH combination had a better survival than the Charnley prosthesis. The results found for the titanium femoral implants ITH, Titan and LMT Biomet seem to be promising, but little is yet known about their long-term failure rates. Concern about debris of titanium particles has been expressed (Friedman et al. 1993, Haynes et al. 1993, Bischoff et al. 1994).

The Elite cup was introduced in Norway in 1988 by the Charnley manufacturers in order to have cups with larger outer diameters available in the Charnley system. Because of the obvious similarity between
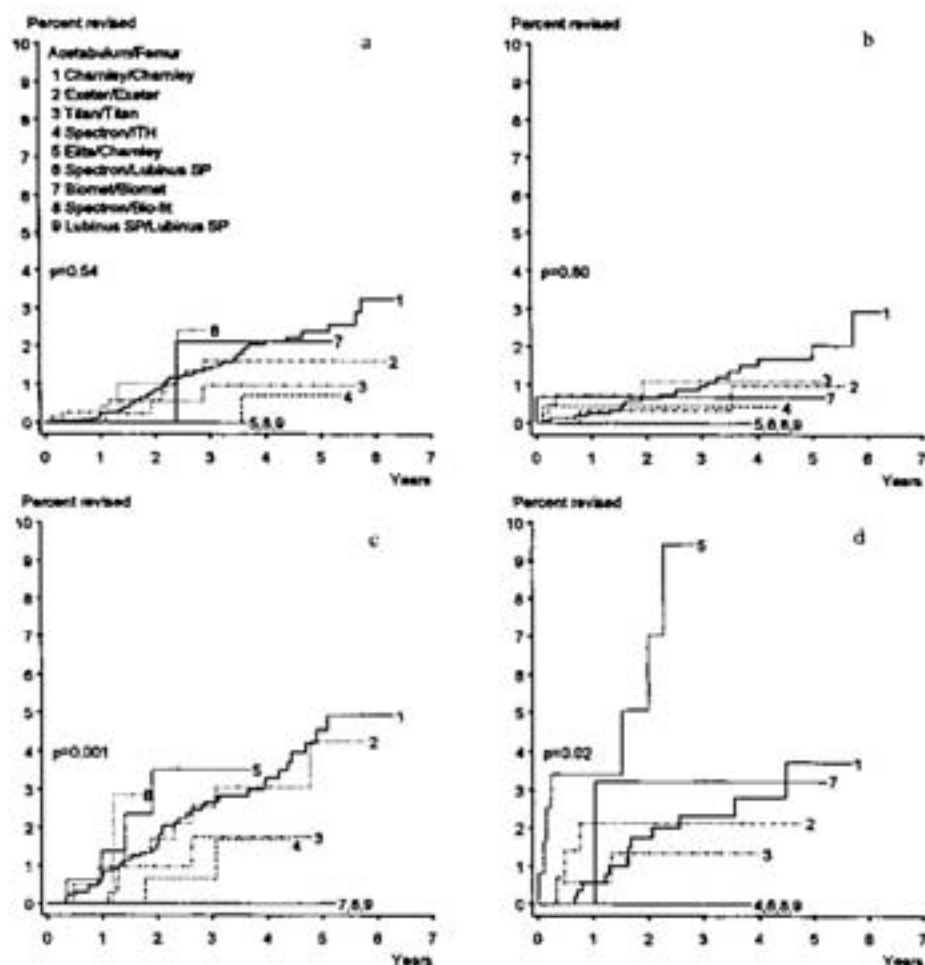
Figure 2. Kaplan-Meier estimated survival curves until revision for any cause for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993 in patient subgroups. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands. a) Women younger than 75 years at primary operation. b) Women 75 years or more at primary operation. c) Men younger than 75 years at primary operation. d) Men 75 years or more at primary operation.

the Elite/Charnley combination and the original Charnley prosthesis, it is difficult to explain the inferiority of the Elite/Charnley. The fact that 50% (6 out of 12) of the revisions were performed because of infection might indicate that factors other than the design of the prosthesis influenced the result. The use of the Elite/Charnley combination was commoner in male patients, who are known to be a high-risk group (Skeie et al. 1991, Malchau et al. 1993), but the results persisted after adjustment for gender, age, type of cement and use of systemic antibiotic prophylaxis. Additional adjustment for type of operating theater did not alter the results. Furthermore, the pri-

mary operations of the 6 infected Elite/Charnley hip were performed at 5 different hospitals.

In addition to the Elite/Charnley combination, th Müller Type prosthesis had inferior results whe compared to the Charnley THR. For the Müller Typ similar results have been reported previousl (Krismer et al. 1991, Malchau et al. 1993), and th prosthesis has not been in use in Norway since 199(The high failure rate of the Müller Type prosthesi might be linked to the curved form of the femor: stem.

Other prosthesis brands considered in this stud were reported to have both higher and lower failur
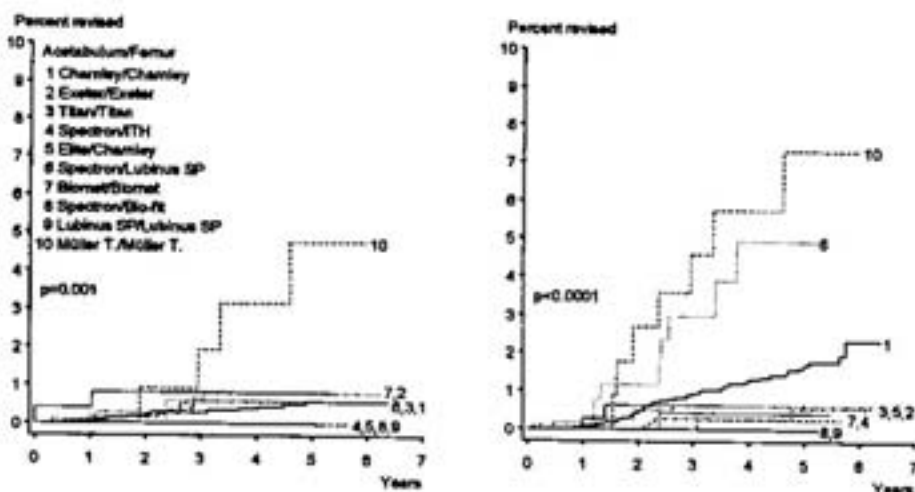
Figure 3. Kaplan-Meier estimated survival curves for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993 with aseptic loosening as the cause of revision. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands. Aseptic loosening of the acetabular component (left) and the femoral component (right) as a cause of revision.

Table 4. Cause-specific revisions, percentages by prosthesis brand. Cemented primary total hip replacements in Norway 1987–1993

Prosthesis brand acetabulum/femur	No.	No. of revisions	Percent aseptic loosening	Percent dislocation	Percent infections	Percent other causes
1. Charnley/Charnley	6694	115	63	8.7	25	2.6
2. Exeter/Exeter	1665	23	48	22	22	8.7
3. Titan/Titan	1333	12	83	8.3	8.3	0.0
4. Spectron/ITH	1034	4	25	50	25	0.0
5. Elite/Charnley	507	12	25	17	50	8.3
Other combinations	946	18	100			
All combinations	12179	184	63	11	23	3.3

rates than the Charnley prosthesis (Table 3). Several of these prostheses were used in relatively low numbers and the tests performed therefore lacked the statistical power to show small differences that might be present.

The data in a national register come from many hospitals with many surgeons performing the operations. This fact must be taken into account when comparing these results with data from one hospital or surgeon having a special interest in a prospective project or a particular prosthesis brand. Our results concerning Charnley prostheses, however, were comparable to those reported for Charnley prostheses implanted during the 1970s (Skeie et al. 1991, Schulte et al. 1993).

The Charnley, Exeter, Luhinus SP and Müller Type prostheses have also been used in Sweden, where

they were reported to a similar register. For these brands, the survival results could be compared in the two countries, and our results were similar to those in Sweden (Malchau et al. 1993).

Aseptic loosening was the main cause of revision in our material, with an estimated 5-year failure rate of 1.8%. As might be expected after only 6 years of follow-up, aseptic loosening of the acetabular component played a minor role compared to aseptic loosening of the femoral component (Sutherland et al. 1982, García-Cimbrelo and Munuera 1992). Infection was the second most important reason for revision. At 5 years, the estimated failure rate due to infection was 0.5%, which is comparable to other studies (Ahnfelt et al. 1990). No specific prosthesis brands dislocated more often than others and the revision percentage ascribed to dislocation was very low.

The explanation for this low number might be that the Norwegian Arthroplasty Register records only revisions where a part of or the whole prosthesis is exchanged or removed. Thus, closed or open reductions or other types of reoperations for dislocation are not reported. Moreover, as only patients with arthrosis and not diagnoses commonly associated with dislocation were included in our study, the number of dislocations would be expected to be low.

The differences between the unadjusted and adjusted prosthesis brand estimates in the Cox analysis show the importance of adjusting for known risk factors when comparing the results of different prostheses (Gross 1988). Our analyses were carried out with adjustment for gender, age, type of cement and use of systemic antibiotic prophylaxis. There may also be important factors not considered in this study, either because they have not yet been recognized as such or they were not available in the data material reported to the Register.

We have observed good overall results of cemented hip prostheses. However, clinically important differences in revision rates were demonstrated among the various cemented total hip prosthesis brands.

Acknowledgements

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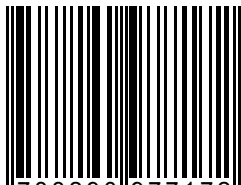
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