The Norwegian Arthroplasty Register

11 years and 73,000 arthroplasties

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ABSTRACT – In 1985, the Norwegian Orthopaedic Association decided to establish a national hip register, and the Norwegian Arthroplasty Register was started in 1987. In January 1994, it was extended to include all artificial joints. The main purpose of the register is to detect inferior results of implants as early as possible. All hospitals participate, and the orthopedic surgeons are supposed to report all primary operations and all revisions. Using the patient's unique national social security number, the revision can be linked to the primary operation, and survival analyses of the implants are done. In general, the survival analyses are performed with the Kaplan-Meier method or using Cox multiple regression analysis with adjustment for possible confounding factors such as age, gender, and diagnosis. Survival probabilities can be calculated for each of the prosthetic components. The end-point in the analyses is revision surgery, and we can assess the rate of revision due to specific causes like aseptic loosening, infection, or dislocation. Not only survival, but also pain, function, and satisfaction have been registered for subgroups of patients.

We receive reports about more than 95% of the prosthesis operations. The register has detected inferior implants 3 years after their introduction, and several uncemented prostheses were abandoned during the early 1990s due to our documentation of poor performance. Further, our results also contributed to withdrawal of the Boneloc cement. The register has published papers on economy, prophylactic use of antibiotics, patients' satisfaction and function, mortality, and results for different hospital categories.

In the analyses presented here, we have compared the results of primary cemented and uncemented hip prostheses in patients less than 60 years of age, with 0–11 years' follow-up. The uncemented circumferentially porous- or hydroxyapatite (HA)-coated femoral stems had better survival rates than the cemented ones. In young patients, we found that cemented cups had better survival than uncemented porous-coated cups, mainly because of higher rates of revision from wear and osteolysis among the latter. The uncemented HA-coated cups with more than 6 years of follow-up had an increased revision rate, compared to cemented cups due to aseptic loosening as well as wear and osteolysis.

We now present new findings about the six commonest cemented acetabular and femoral components. Generally, the results were good, with a prosthesis survival of 95% or better at 10 years, and the differences among the prosthesis brands were small.

Since the practice of using undocumented implants has not changed, the register will continue to survey these implants. We plan to assess the mid- and long-term results of implants that have so far had good short-term results.

It is common to market and use undocumented joint prostheses, and consequently we have had several disasters. In Scandinavia, the best known is the Christiansen prosthesis, although the Judet acrylic prosthesis and the resurfacing prostheses had worse results (Judet et al. 1954, Scales 1967, Sudmann et al. 1983, Howie et al. 1990).

In Finland and Sweden, excellent joint replacement registers were already available (Ahnfelt et

al. 1990, Paavolainen et al. 1991, Knutson et al. 1994).

To detect inferior implants early, the Norwegian Orthopaedic Association established a national quality control system, a national hip register, also in Norway. The Norwegian Arthroplasty Register, started in 1987, and in January 1994, it was extended to include information on all artificial joints (Engesaeter et al. 1992, Havelin et al. 1993, 1995d, Furnes et al. 1996a, Espehaug et al. 1998b).

This Register is owned by the Norwegian Orthopaedic Association, which is represented on its board by the chairman and 3 members. The Register is located in the Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway. 80% of its financial support comes from the Norwegian Ministry of Health and Social Affairs. Apart from this, the Register is independent of the health authorities and is also of the medical industry. When this register was established in 1987, 1 part-time secretary formed the staff, and much of the work was voluntary. At present, the Register has 3 orthopedic surgeons on its staff, doing part-time work, 1 statistician, 2 secretaries, and 1 research fellow in the Division for Medical Statistics at the University of Bergen.

The main purpose of the Register is to identify inferior implants as soon as possible. Further, with longer follow-up, smaller differences in results can be detected. The Register functions as a quality control both nationally and locally, since hospital-specific results are reported to each participating hospital.

In this article, we present descriptive statistics, review previously published results on short-term survival, and give new results on hip prostheses with 0–11 years' follow-up.

Methods

Recording of data

The following procedure has been used since September 1987 for hip replacements, and since January 1994 for all other joint replacements. After each primary joint replacement, the orthopedic surgeon fills in a one-page form, with information about the operation technique, including a description about implant parts (Havelin et al. 1999). If the prosthesis is revised later, we receive a report with information about the reason for and the type of revision. To obtain accurate information on the prosthetic components, it is recommended that the surgeons fill in the form immediately after the operation, and that they report the catalogue number of each component by using stickers delivered by the manufacturers.

With the patient's national social security number, the revisions are linked to their primary operations. We also receive records from the Norwegian Population Register with information on dates of death and emigration.

Our system needs a near-to-complete reporting of operations. It is therefore made simple for the surgeons. It takes about one minute to fill in the form and, by using the stickers, we get correct and accurate information on the prosthetic components. Most hospitals mail the paper forms, but a few hospitals send us the information on disks or on print-outs.

Statistical methods

Survival analyses are usually performed by the Kaplan-Meier method or the Cox regression analysis (Kaplan and Meier 1958, Cox 1972). When comparing the survival of different types of implants, we commonly select subgroups of patients who are homogeneous as regards gender, age, and diagnosis, or we adjust for these and other confounding factors in a Cox regression model.

The end-point (failure) in the survival analyses is revision. The information gathered allows us to study revision of individual components, such as the cup or the femoral stem, and to use different types of end-points such as revision due to aseptic loosening of one specific component, revision due to dislocation or revision due to infection. Intact prosthetic components in deceased or emigrated patients are followed until the time of death or emigration.

Reports to surgeons and hospitals

The annual report is sent to all members of the Norwegian Orthopaedic Association, to all hospitals performing joint replacement surgery, and to the health authorities. To motivate the orthopedic surgeons to cooperate, we report to each hospital

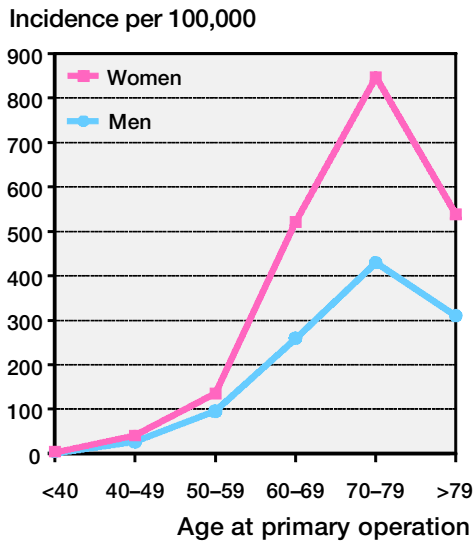

Figure 1. Incidence of primary total hip replacement, by age and gender in Norway in 1997. The calculations are based on data from the Norwegian Arthroplasty Register and the Norwegian Population Register.

its own specific descriptive statistics and survival analyses of prostheses inserted at the hospital.

The results on performance of prosthesis brands and cement types are published in international orthopedic journals and presented at orthopedic meetings.

Validation

To validate our data, the number of primary operations and revision joint replacements for each hospital are compared with the data registered in the National Institute for Hospital Research (NIHR), Trondheim, Norway. If there is a discrepancy between the number of cases reported from the NIHR and our figures, the hospitals are contacted. To evaluate for underreporting of revision, in particular, 2,007 patients in a case-control study were asked about the number of hip revisions.

Compared to the National Institute of Hospital Research, the Register receives reports about more than 95% of the knee and hip replacements (Espehaug et al. 1999b). We found that most of the missing 5% of cases were due to one local hospital that had not reported at all for about 5 years. Of the remaining hospitals, approximately 97% of the primary operations and revisions have been reported.

Results

Hip replacements, epidemiology:

Annually, about 5,200 primary total hip replacements are performed in Norway (4.3 million inhabitants), which corresponds to about 120 primary operations per 100,000 inhabitants. Most (69%) of the primary operations were performed in women, and the average age at the primary operation was 69 years. The incidence of total hip replacements by age and gender is given in Figure 1. The annual number of revisions has increased from 650 in 1988 to 1,042 in 1998. The overall number of revisions was 15% of the number of primary operations, which is more than in Sweden, but less than in most other countries (Malchau and Herberts 1998). Diagnoses and reasons for revisions are given in Table 1. Revision due to cup loosening and stem loosening had declined from 59% and 63% in 1988 to 44% and 49%, respectively, in 1998. On the other hand, revisions due to dislocation increased from 2.8% to 12.5% during the same period. Hardly any revisions due to wear and osteolysis without loosening were reported in 1988, but in 1998, these reasons constituted 5.2% and 6.1% of the revisions (Table 1). Of the cups that had been revised due to wear and other polyethylene (PE) problems, 94% were uncemented, and of those revised due to osteolysis, 65% were uncemented.

Fixation. The proportion of uncemented primary replacements was the same in 1988 and 1998, with 18% of the acetabular components and 13% of the femoral components being uncemented. At revisions, the use of uncemented acetabular components had declined during the last 4–5 years from about 50% of cup revisions in 1994 to 36% in 1998 (Table 1). Uncemented stems were used in 40% of the stem revisions in 1994 and in 33% in 1998. The use of bone impaction grafting has become increasingly popular, and in 1998, it was used in 23% of the cup revisions and 31% of the stem revisions.

During recent years, the use of antibiotic-containing cement has increased, and in 1998, such cement was applied in 93% of the cemented primary operations.

The Boneloc cement was used in Norway from 1991 to 1993. When the poor results of the Bone-

Table 1. Primary total hip replacements and revisions[a] reported to the Norwegian Arthroplasty Register in 1988 and 1998

	1988 %	1998 %
Approach		
Lateral	61.4	68.6
Posterior	29.1	21.3
Trochanteric osteotomy	23.8	6.5
Primary operations		
Diagnosis		
Idiopathic coxarthrosis	68.7	70.6
Rheumatoid arthritis	4.2	3.1
Sequela after fracture	13.1	12.2
Sequela after dysplasia	8.2	6.8
Dislocated dysplastic hip	1.7	0.5
Other pediatric hip disease	1.2	1.3
Ankylosing spondylitis	0.4	0.5
Others	3.5	5.0
Antibiotic prophylaxis		
Systemic	90.3	99.8
In cement (if cemented)	44.6	92.9
Uncemented		
Uncemented cup	17.7	17.5
Uncemented stem	13.0	12.8
Revisions		
Reasons for revision		
Loose cup	58.8	44.3
Loose stem	63.0	48.9
Dislocation	2.8	12.5
Deep infection	4.9	6.1
Fracture of femur	3.6	3.9
Girdlestone situation	1.5	4.3
Pain	10.8	6.9
Osteolysis without loosening	0	6.1
Wear	0.2	5.2
Others	2	2.7
Type of revision		
Change of total prosthesis	62.4	36.7
Change of cup only, or cup and head	12.0	25.3
Change of stem only	20.5	20.4
Girdlestone	2.0	3.6
Total prosthesis after Girdlestone	1.4	4.3
Change of polyethylene liner at revision	0	4.6
Fixation (percent of changed components)		
Bone impaction grafting in femur	0	30.5
Recemented stem	81	36.3
Uncemented stem	19	33.2
Bone impaction grafting in acetabulum	0	22.6
Recemented cup	76.5	41.9
Uncemented cup	23.5	35.5
Antibiotic prophylaxis		
Systemic	94.7	99.4
In cement (if cemented)	95.7	99.1

[a] Revisions with exchange or removal of prosthetic components.

Table 2. Numbers of cemented and uncemented prosthesis brands used in the femur and acetabulum at primary total hip replacement in Norway in 1988, in 1998, and throughout the period of 1988–1998 [a]

Prosthesis brands	1988	1998	1988 -1998
Femur			
Cemented	20	16	32
Cemented, used in < 50 patients	9	5	11
Uncemented	13	16	35
Uncemented, used in < 50 patients	10	15	21
Acetabulum			
Cemented	17	13	29
Cemented, used in < 50 patients	8	4	11
Uncemented	15	12	33
Uncemented, used in < 50 patients	9	7	11

[a] In addition, some designs intended for uncemented use had been used with cement. Only 5 brands of cemented cups and 7 brands of stems (6 cemented and 1 uncemented) had been in continuous use in the total period.

loc cement were published, its use was abandoned (Havelin et al 1994a, 1995a, Thanner et al. 1995, Nilsen and Wiig 1996, Furnes et al. 1997). Due to inferior results in our register, the low-viscosity cement CMW 3 was also discontinued in Norway (Havelin et al 1994a, 1995a).

Prostheses. Among the cemented prostheses, the Charnley (DePuy) totalled 49% of the primary total hip prostheses used in Norway during the last 10 years. The Exeter prosthesis (Howmedica) constituted 9% and the Titan (DePuy) 11%. Furthermore, cups from the Modular Hip System (Smith + Nephew) were used in 4%, the Spectron cup (Smith + Nephew) in 6% and the uncemented acetabular cup Tropic (DePuy) in 5%. On the femoral side, the International Total Hip (ITH) stem (Smith + Nephew) was used in 6%, and the Corail (DePuy) uncemented HA-coated stem in 8% of the primary operations.

A large number of different prosthesis brands had been used, and 21 of 35 uncemented femoral brands, and 11 of 33 uncemented acetabular brands had been used in less than 50 patients each (Table 2). Only 5 cups (all of which were cemented) and 7 femoral components (6 cemented and 1 uncemented) had been in continuous use from September 1987 till January 1999.

On uncemented stems, the 32 mm femoral head diameter was used in 73% during 1987–1990, but was only used at 5.6 % of the operations in 1998, whereas the use of 28 mm heads constituted 0.5% during 1987–1990 and 27% in 1998. Regarding

cemented prostheses, the monobloc Charnley stem, with a 22 mm head, has been the commonest stem in Norway throughout 1987–1999. On other cemented stems, the use of 32 mm heads has declined.

Survival of uncemented primary total hip prostheses

Short-term (0–5 years) results. In 1987, several uncoated or partly-coated cementless hip replacements were still in use (Havelin et al. 1993). After about 3 years, we observed inferior results with uncemented implants, compared to cemented implants. This difference was largest in younger patients (Havelin et al. 1994b). These inferior results were mainly attributed to the uncemented Bio-Fit stem (Smith + Nephew) with a smooth surface, and the threaded uncemented Femora stem (Thackray) (Havelin et al. 1992, 1995b). Furthermore, the uncoated cementless threaded cups, metal backed or all-polyethylene, had worse results than the cemented all-polyethylene cups and the uncemented cups with a porous or HA-coating (Havelin et al. 1992, 1995c). When these results became known, the use of these inferior designs was abandoned in Norway.

However, we found good short-term results for uncemented stems with HA coating or circumferential porous coating, and of uncemented cups with HA-coating, and hemispheric porous-coated cups.

Mid-term (0–11 years) results. We have recently compared the mid-term results of uncemented components with cemented components, used at primary total hip replacement, in patients under 60 years of age (Havelin et al. 2000). The 6 commonest cemented stems fixed with high viscosity cement, and Charnley cups fixed with the same type of cement, were chosen as controls. The analyses were performed using the Kaplan-Meier method and the Cox regression model with adjustment for differences in age, gender, and diagnosis.

With a follow-up of 0–11 years, the results of the uncemented HA-coated stem designs were still good (Figure 2). The uncemented stems with circumpherential porous coating had inferior results compared to stems with HA-coating, but they were slightly better than the cemented stems (Havelin et al. 2000) (Figure 2).

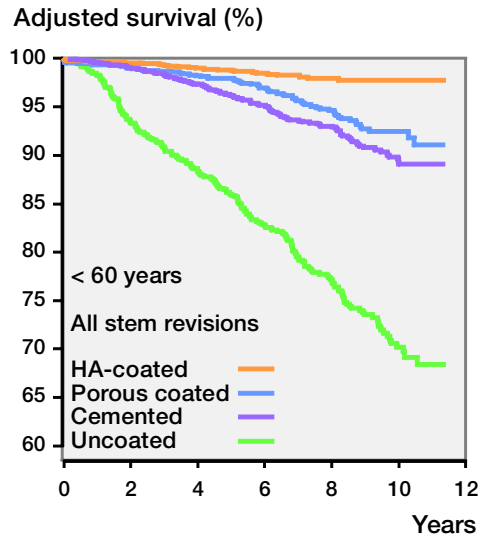

Figure 2. Cox regression-adjusted survival curves of HA-coated (n 4,648), circumferentially porous-coated (n 1,264), and uncoated (n 740) uncemented stems, compared with the 6 most commonly used cemented stems inserted with high viscosity cement (n 2,849), used in Norway from September 1987 to January 1999. Only prostheses in patients younger than 60 years of age were included. The end-point was stem revision, and adjustment was made for age, gender, and diagnosis. Compared to HA-coated stems, the porous coated stems had a 2.5 (95% CI: 1.7–3.7, $p < 0.0001$, Wald test) times increased risk, the cemented stems had a 3.3 (95% CI: 2.4–4.6, $p < 0.0001$) times increased risk for revision, and the uncoated uncemented stems had a 11.6 (95% CI: 8.5–16.1, $p < 0.0001$) times increased risk for revision. (Concerning revision due to aseptic stem loosening, the porous-coated stems had a 2.1 (95% CI: 1.2–3.9, $p = 0.01$) times increased risk, the cemented stems a 6.8 (95% CI: 4.2–11, $p < 0.0001$) times increased risk, and the uncoated uncemented stems a 26 (95% CI: 16–41, $p < 0.0001$) times increased risk for revision, compared to the HA-coated stems).

For the uncemented cups with a hemispheric porous-coated design, the revision rate due to aseptic loosening was about the same as in cemented Charnley cups, but the overall revision rate (mainly due to wear) was higher (Figure 3). The HA-coated uncemented cups had a higher revision rate due to aseptic loosening than the Charnley cups, and they also had wear problems like the porous-coated metal-backed cups (Havelin and Engesæter 1999, Havelin et al. 2000). Since the uncoated uncemented designs were abandoned in the early 1990s, there has been a clear improvement in the overall results of the uncemented implants.

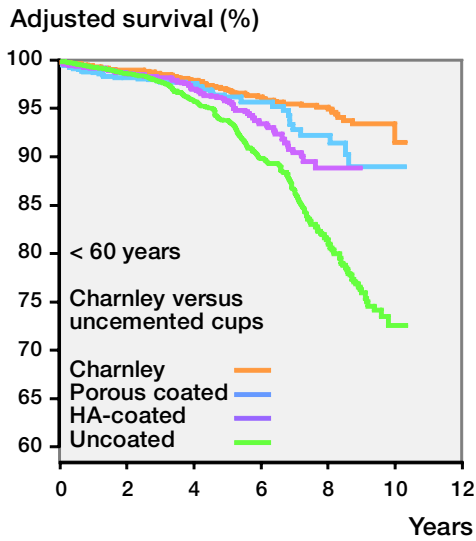

Figure 3. Kaplan-Meier survival curves of different uncemented cup designs and cemented Charnley all-polyethylene cups, used in Norway from September 1987 to January 1997 in patients younger than 60 years of age. The end-point was revision with exchange of the cup or polyethylene liner. The HA-coated cups (n 2,144) had statistically significant worse results than the Charnley cups ($p< 0.001$, log rank test) as did the porous-coated cups (n 1,197) ($p = 0.06$). The uncoated threaded cups were inferior to all the other design groups ($p < 0.001$). Cox regression analyses with adjustment for age, gender and diagnosis confirmed these findings (from Havelin and Engesæter, 1999).

Survival of cemented primary total hip prostheses

Short-term (0–6 years) results. When the short-term results of the commonest cemented total hip prostheses were assessed, we found good overall results with a 5-year revision probability of 2.5% (Espehaug et al. 1995). The combination Spectron cup/ITH stem had a lower revision rate than the Charnley prosthesis. The combination of Elite cup/Charnley stem and the Müller Type prostheses showed worse results than the Charnley prosthesis, but the differences were small (Espehaug et al. 1995).

Mid-term (0–11 years) results. In the analyses presented here, we have included the 6 commonest cemented stems and the 7 commonest cemented cups, inserted with high viscosity cement (Havelin et al. 2000). The follow-up was 0–11.4 years. Implant brands and numbers are given in Figures 4 and 5. The Charnley prosthesis had been used in more than 50 patients at 43 hospitals, whereas the corresponding figures for the other designs was 2–10 hospitals. Survival of the implants was assessed by Cox regression, with adjustment for age, gender, diagnosis, and cement brand (Palacos (Schering-Plough), Simplex (Howmedica) and CMW 1 (DePuy)).

The results of the cemented femoral stems were generally good (Figure 4). The cemented titanium femoral stems, Titan (DePuy, France) and ITH (Smith + Nephew, USA), had results similar to, or better than, the chrome cobalt stems, Lubinus SP (Link, Germany) and Bio-Fit (Smith + Nephew, USA), and the stainless steel Charnley (DePuy, England) and Exeter (Howmedica, England) stems. We found somewhat better results for the polished, stainless steel Exeter stem, compared to the Charnley stem, which has a matt surface (Vaquasheen surface finish, according to the manufacturer). For the cemented titanium stems, we found no difference between implants with a matt (ITH) or a polished surface (Titan). As seen in Figure 6, the results with the femoral component of the Charnley prosthesis differed among the hospitals. The Lubinus SP prosthesis had been used in three hospitals. All 34 reported revisions of the Lubinus SP femoral prosthesis were from only one hospital where 821 of the 1,081 reported primary operations had been performed.

For the 6 commonest cemented all-polyethylene cups also the results at mid-term, were good (Figure 5). We found only small differences between the designs, with an overall survival above 95% at 10 years, and a probability for revision due to aseptic loosening of less than 3% at 10 years.

Results of various cement types

From 1991 to 1994, the Boneloc cement (Polymers Reconstructive, Denmark) was used in many European countries. It became popular because it could be mixed in a closed system, and it had a new chemical composition, which was said to be less toxic than other cements (Jensen et al. 1995). In 1994, we found that after 3 years, Charnley prostheses fixed with the Boneloc cement had significantly worse results than to Charnley prostheses fixed with other cements (Figure 7) (Havelin et al. 1994a, 1995a). Our findings contributed to the withdrawal of the cement from the internation-

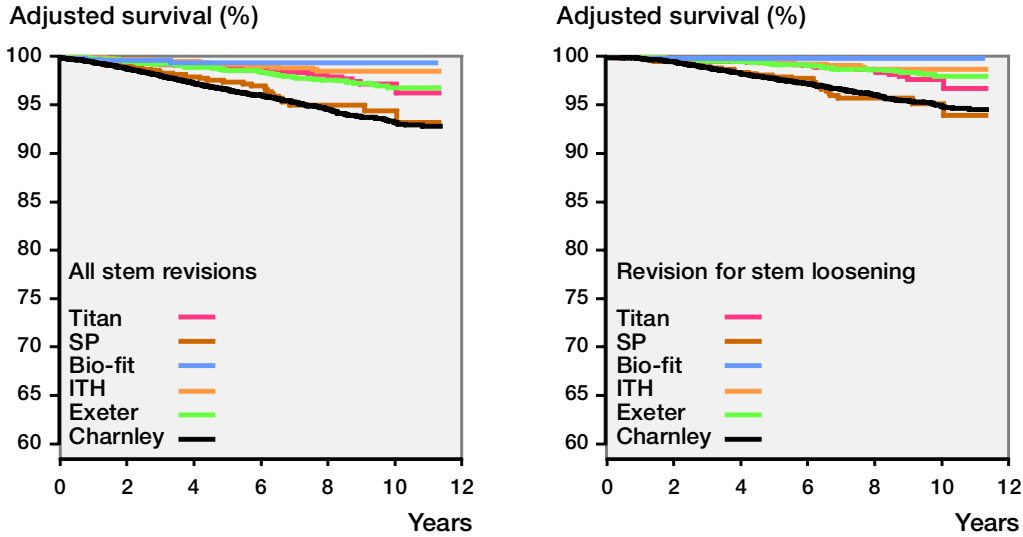

Figure 4. Cox regression-adjusted survival curves of the 6 most commonly used cemented stems, inserted with high viscosity cement (CMW 1, Palacos, Simplex), in Norway from September 1987 to January 1999. Adjustment was done for age, gender, diagnosis and cement brand. The end-points were stem revision for any cause (left) and revision of the stem due to aseptic loosening (right). The results of the Charnley (n 22,999) and the SP (n 1,115) stems were statistically significant ($p < 0.001$, Wald test) worse than those with the ITH (n 2,758), Titan (n 4,629), Exeter (n 4,776), and Bio-Fit (n 1,246) stems. The Charnley prosthesis had been used in more than 50 patients in 43 hospitals, whereas the other designs had been used in more than 50 patients in 2–10 hospitals. All the revised SP prostheses had been inserted in the same hospital.

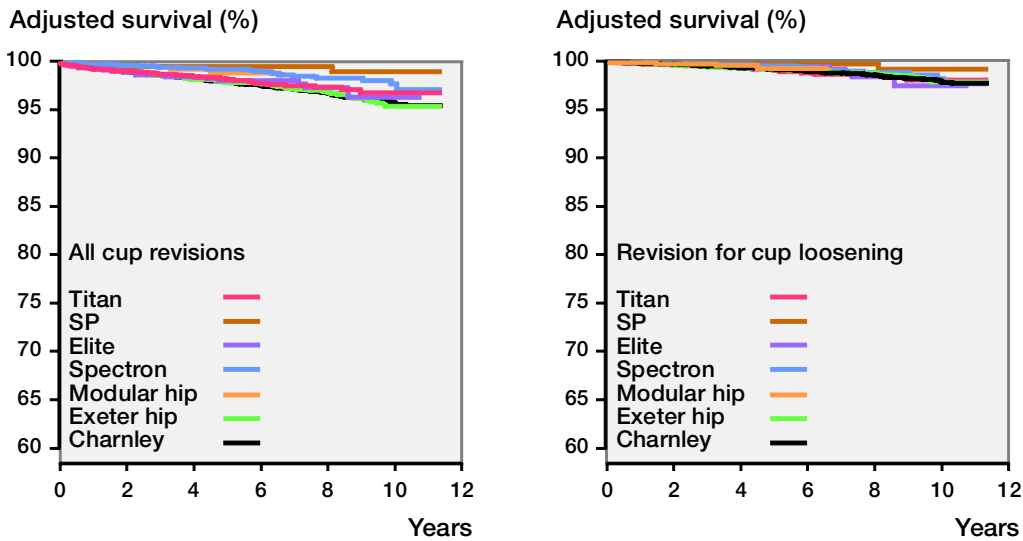

Figure 5. Cox regression-adjusted survival curves of the 7 most commonly used cemented cups, inserted with high-viscosity cement (CMW 1, Palacos, Simplex), in Norway from September 1987 to January 1999: Charnley (n 23,385), Titan (n 4,266), Exeter (n 4,838), Elite (n 1,016), Modular Cup System (n 2,153), SP (n 899), and the Spectron (n 3,274) cups. Adjustment was done for age, gender, diagnosis, and cement brand. With any revision as end-point (left), the results with the Charnley cups were significantly ($p < 0.05$, Wald test) worse than with the Modular Cup system, the SP, and the Spectron cups. With revision due to aseptic cup loosening as the end-point (right), there were virtually no differences among the brands. The Charnley prosthesis had been used in more than 50 patients at 43 hospitals, whereas the SP, the Modular Cup System, and the Spectron cups had been used in more than 50 patients in fewer hospitals (3–7).

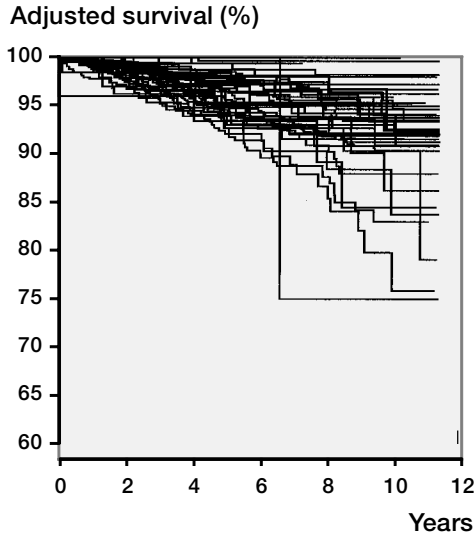

Figure 6. Kaplan-Meier survival curves of the hospital results for primary Charnley femoral stems using high-viscosity cement (Palacos, Simplex, CMW 1), in Norway from September 1987 to January 1999. End-point: stem revision. Each curve represents the overall prosthesis survival for Charnley stems from one hospital.

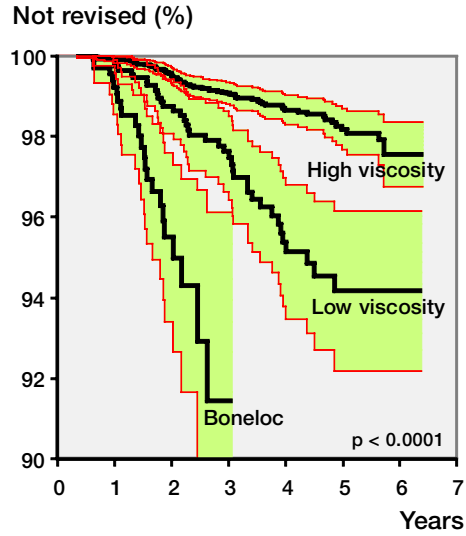

Figure 7. Kaplan-Meier survival curves with revision due to aseptic stem loosening as the end-point among primary Charnley prostheses by type and viscosity of cement. The results for the implants inserted with the low-viscosity cement, CMW 3 and the Boneloc cement, were significantly poorer ($p < 0.0001$, two-sided log-rank test) than for those with high-viscosity cement. The area within the 95% confidence limits is shaded. The figure is reproduced from Havelin et al. 1995 a, with permission from the Journal of Bone and Joint Surgery (Am).

al market in 1995, but others have also found worse performance of prostheses fixed with this cement (Thanner et al. 1995, Nilsen and Wiig 1996). Furnes et al. (1997) showed that when cemented with the Boneloc cement, the results with the polished Exeter femoral prostheses were better than with the matt (Vaquasheen surface) Charnley stem. However, Exeter stems cemented with Boneloc cement had worse results, compared to Exeter stems fixed with high viscosity cement.

Havelin et al. (1995a) reported poor results with the low-viscosity cement CMW 3 (DePuy, England). Although laboratory tests had shown good results, the clinical findings were inferior. The CMW 3 cement was also abandoned in Norway after that.

Antibiotic prophylaxis in hip replacement surgery

Espehaug et al. (1997a) found that a combination of antibiotic in the cement and antibiotic given systemically was associated with a 5-year estimated revision probability due to infection of 0.2%. The revision probability due to infection was 0.8% when antibiotic was given systemically only, 0.9% when given in the cement only, and 1.2% when no antibiotic was given. We found a similar pattern when revision due to aseptic loosening was assessed (Figure 8). The explanation for the latter result was probably that some revisions reported as aseptic, in fact were undiagnosed low-grade infections.

No improvement in survival was observed if antibiotics were given systemically for more than one day, compared to one day only (Engesæter et al. 1999).

Associations between hospital category and operating volume and the survival of hip replacements

During 1988–1996, 53% of the primary total hip replacements were performed in 45 local hospitals, 32% in 15 central and 16% in 10 university hospitals (Espehaug et al. 1999a). The mean annual number of primary total hip replacements per hospital was highest in central and university hospitals, whereas the mean annual number of primary operations per surgeon was lowest at university

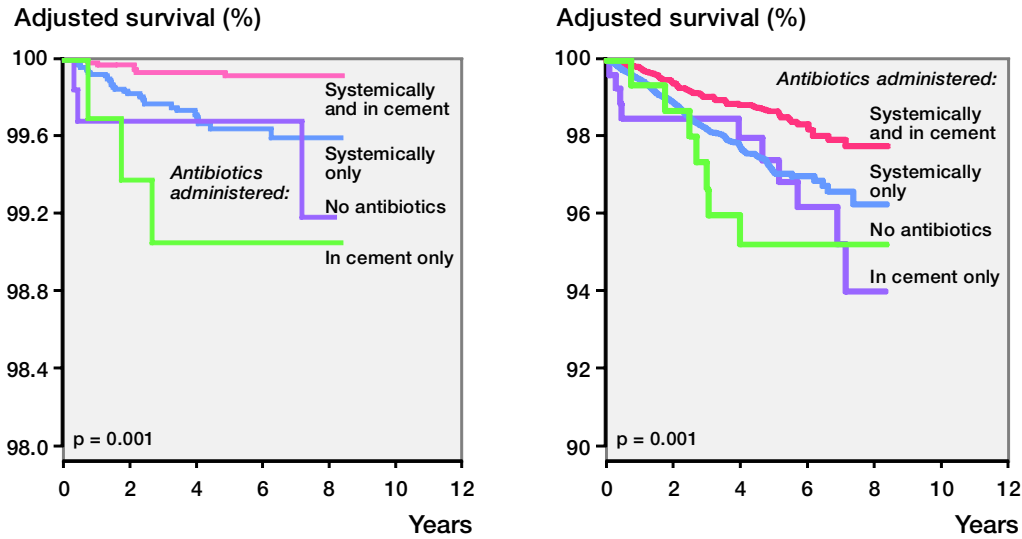

Figure 8. Cox regression-adjusted survival curves of THRs performed in Norway from 1987 to 1995. The probabilities of survival were calculated with revisions due to infection (left) and revision due to any cause (right) as end-points for patients receiving various antibiotic regimens for prophylaxis. The p-values refer to a test for homogeneity showing statistical significant differences in survival among the regimens. The figure is reproduced from Espehaug et al. 1997a, with permission from the Journal of Bone and Joint Surgery (Br).

hospitals. Primary total hip replacements performed at university hospitals were revised more often than prostheses at central and local hospitals. This difference was in part related to a more extensive experimental use of uncemented prostheses with inferior design at university hospitals. However, revision rates were consistently higher at university hospitals also within subgroups of total hip replacements performed with or without cement, and after adjustment for gender, age, diagnosis, and procedure-related factors such as cement type, prosthesis brand and antibiotic prophylaxis regimen. Possible explanations for this result may include the centralization of high-risk patients with additional medical conditions to university hospitals, the low annual number of operations per orthopedic surgeon, and the high percentage of surgeons in training at university hospitals. The study also showed that for uncemented implants, the highest revision rate was in hospitals performing few (≤ 10) uncemented hip replacements per year.

Patient-related factors and risk for reoperation of hip prostheses

We found a higher risk for revision of hip prostheses in younger compared to older patients and in men than in women (Havelin et al. 1994b). We did a matched case-control study based on patients from the Norwegian Arthroplasty Register, and evaluated patient-related factors and risk of early revision (Espehaug et. al 1997b). We found that heavy weight was a risk for male patients older than 67 years and above median height. Smoking had no overall effect, but former heavy smokers had a 2.6 times higher risk than those who had never smoked. Alcohol intake was associated with a higher risk of dislocation. Revision due to infection was commoner among patients taking anti-diabetic drugs than among those taking no medication. We also found an increased overall risk of revision among patients using systemic steroids or local pulmonary steroids. Further, the risk was higher in male patients performing regular exercise before the primary operation, and in female patients with heavy work.

The influence of diagnosis on the risk of revision has also been assessed (Furnes et al. 1998a). Several diagnoses, mainly found among younger patients, seemed to give worse results, compared to primary coxarthrosis. However, when we applied the Cox model and adjusted for the use of inferior implants and the effect of age and gender, only patients with a totally dislocated dysplastic

hip and patients with sequelae after hip fracture had inferior results, compared to the patients with primary coxarthrosis. Diagnoses mainly seen among young patients had a good prognosis per se, but they were operated on with inferior uncemented implants.

Skeide et al. (1996) observed a higher overall revision risk (relative risk 1.35) in patients with a total hip prosthesis due to a previous femoral neck fracture compared to patients with coxarthrosis. Revision for recurrent dislocation and because of fracture of the femoral shaft was commoner in patients with a previous neck fracture, while revision due to cup loosening was less frequent.

The economic impact of inferior implants in total hip replacement

Furnes et al. (1996b) assessed the cost of using inferior implants and cements, compared to the Charnley prosthesis with an antibiotic containing high viscosity cement. The annual extra cost during the first 5 postoperative years for the use of the Boneloc cement was 0.6 million USD, whereas the annual extra cost for the use of the Christiansen prosthesis was calculated at 2.2 million USD (Engesæter et al. 1996).

Satisfaction and function after total hip replacements

In a matched case-control study, 2,007 registered patients were sent questionnaires about their satisfaction and function (Espehaug et al. 1998). We compared patients who had been operated on with a primary prosthesis only (controls), to patients who had been revised (cases). 61% of the revised patients and 84% of the patients not revised rated their overall satisfaction with their hip implant as good or very good. A substantial benefit was observed in both groups with regard to pain, walking ability and need for help. However, the improvement was less among patients who were revised.

Mortality after total hip replacement

The 8-year mortality of THR patients was 25%, compared to 30% in the Norwegian population matched for age and gender (Lie et al. 2000). The overall standardized mortality ratio (SMR = Observed patient mortality divided by the mortality in the corresponding population) was 0.81 (95% confidence interval: 0.79–0.83). The lower mortality for patients may be due to a selection of healthy patients. There was an increased standardized mortality ratio in patients under 50 years (SMR = 2.50), patients 50–59 years (SMR = 1.16), patients with rheumatoid arthritis (SMR = 1.48), and patients with femoral neck fracture (SMR = 1.11). The higher mortality in these patient categories is probably due to the underlying disease and not the operation. During the first postoperative period, we observed a significantly increased mortality for all patient categories (Lie et al. 2000).

Prostheses in other joints

As implants in joints other than the hip have been registered only from January 1994, most publications have been on total hip replacement, but now we have data on more than 6,000 total knee prostheses. Preliminary results concerning knee prostheses and prostheses in the elbow, ankle, shoulder and finger joints are presented below.

Arthroplasty in the knee

The annual number of primary knee prosthesis operations was 1,409 in 1998, which corresponds to 34 knee replacements per 100,000 inhabitants, which is considerably less than in Sweden, Finland, and the USA. In 1998, 125 revisions were performed which constituted 8.1% of the total number of knee replacements. 2/3 of the total number of knee replacements were performed without resurfacing of the patella, 9% were inserted without the use of cement on the femoral component, and 1% without cement on the tibial component. 12 different brands of knee prostheses have been used, of which the Genesis I prosthesis (Smith + Nephew, USA) was used in 36% of the cases, but the LCS knee (DePuy, USA), with a mobile tibial plastic insert, has become increasingly popular and was used in 18% of the knees in 1998, compared to 1% in 1994. A unicondylar prosthesis was used in 8% of the primary replacements.

Survival of knee prostheses. The overall survival probability at 5 years was 96% (Furnes et al. 1999). The survival result was virtually the same

in men and women, but patients 60 years or older had better results than patients under 60 years. With the short follow-up, we were not able to show any significant difference among designs or between cemented or uncemented fixation. We found no significant difference between knees with or without resurfacing of the patella. However, preliminary analyses showed that reoperation because of pain was commoner in knees without a patellar component. The commonest reoperation in this group was insertion of a patellar component. On the other hand, knee prostheses with a patellar component had a significantly higher risk of revision due to deep infection (Furnes et al. 1999).

The unicondylar prostheses had a 4-year survival of 90%, which was significantly poorer than the result of the total knee replacements.

Replacement of the shoulder joint

After 5 years, we had registered 132 total shoulder replacements and 553 hemiarthroplasties. We found significantly more revisions due to dislocation during the first postoperative year in patients with a total shoulder replacement than in those with a hemiprosthesis (Furnes et al. 1998b).

Elbow prostheses

Replacement of the elbow has mainly been used in patients with rheumatoid arthritis. 287 primary total elbow replacements have been registered 1994–1998. We found no significant difference between the 2 prosthesis types (Kudo, Biomet, USA and Norway, Brødrene Johnsen, Norway) that had been used (Furnes et al. 1998c).

Prostheses in hand and finger joints

1,318 metacarpophalangeal (MCP) prostheses had been registered, 1,198 primary operations and 120 revisions. 99% of the prostheses were a one-component silicone prosthesis, the Avanta (DePuy, England) in 30% and the Swanson Silastic HP 100 (Wright Medical Technology Inc, USA) in 70%.

Most of the 120 reoperations were revisions of implants that had been inserted prior to 1994, when our registration started. The reasons for the revisions were pain (31%), instability or ulnar drift (15%), fracture of the bone (8%), fracture of the implant (6%) and infection 1%. Only 18 prostheses were registered as inserted in interphalangeal joints, and 21 carporadial prostheses had been used (Hove et al. 1998).

Ankle and toe prostheses

55 ankle prostheses (Link S.T.A.R., Link, Germany, 29%, and Norwegian TPR, Smith + Nephew, USA, 71%) were registered from 1994 to 1998. 416 toe prostheses had been inserted, of which the Swanson Silastic HP100 constituted 93%.

Discussion

Identifying inferior implants

In accordance with the aims of the register to be used for quality control, we found inferior results with some prostheses and with the Boneloc cement, as early as after 3 years of use (Havelin et al. 1992, 1994a, 1995a, b, c). Thus, several hip implants have been abandoned due to our results. To be able to detect inferior implants so early, their performance must very clearly be inferior. With larger numbers of patients and longer follow-up, we can assess smaller differences among the implants.

Uncemented hip prostheses versus cemented

Inferior results of uncoated uncemented designs with a smooth surface have been found in our register (Havelin et al. 1995b, c). In Norway, the results of uncemented stems with HA-coating, circumferential porous coating or rough, blasted surface, seem to give about the same or better results as cemented stems in young patients. Further, in the same age group, cemented cups had fewer revisions due to aseptic loosening than HA-coated cups, and both porous-coated cups and HA-coated cups had an increased rate of revision compared to cemented cups, mostly due to more wear and osteolysis. These findings do not support the common practice in many countries, or the recommendation by the National Institute of Health in the USA (1995), to implant hybrids of cemented stems and uncemented cups. There is documentation of good long-term results of cemented cups available in the literature (Schulte et al. 1993, Garellick et al. 1994, Ranawat et al. 1997), supporting our findings. We have found no long-term

results of comparative studies in young patients showing better results with uncemented cups than with cemented cups. The practice of using hybrids of an uncemented cup/cemented stem is probably based on some long-term studies of cemented cups, where a high rate of radiographic loosening was found, on good short-term results of uncemented cups and on the poor results of uncoated or not circumferentially coated uncemented stems.

New bearing materials, such as the highly cross-linked polyethylenes, seem promising and might solve the wear and osteolysis problems of uncemented cups, and we are looking forward to the results of clinical trials with these materials. Meanwhile, based on our findings, it may perhaps be justified to perform randomized studies with hybrids of cemented cups, inserted with modern cementing technique, combined with uncemented HA- or porous-coated stems in young patients.

Cements

The inferior results of the Boneloc cement are now well documented (Havelin et al. 1994a, 1995a, Thanner et al. 1995, Nilsen et al. 1996, Furnes et al. 1997). The Boneloc experience should remind surgeons of the dangers of using products without proper clinical documentation.

We also found poor results with hip prostheses fixed with the low-viscosity cement CMW 3 (Havelin et al. 1995a). It has been argued that the results of low-viscosity cement in laboratory situations are good, and that the poor clinical results with the CMW3, compared to high-viscosity cement, may have occurred due to bad cementing technique among the Norwegian surgeons. The low viscosity makes this cement vulnerable to poor technique in a clinical situation, as the cement easily might "float away" early during the cementing. Low viscosity cement is difficult to use correctly, and the argument for its use is not based on documented better clinical results than with the high viscosity cements.

Cemented hip prostheses

Among the cemented cup designs, we found only small differences. The results of the cemented all-polyethylene cups are, in general, very good at mid-term, a finding which is supported by many authors (Schulte et al. 1993, Garellick et al. 1994, Ranawat et al. 1997, Malchau and Herberts 1998). We found very good mid-term results with the cemented stems, 95% survival or better. With the above results in mind, it still seems justified to use cemented implants in all age groups of patients. The use of uncemented implants should be regarded as experimental.

Concerning the stems made of stainless steel, the results with Exeter stem having a polished surface were slightly better than with the Charnley stem having a matt (Vaquasheen) surface. As each surface was associated with a particular stem design, it is still uncertain if differences other than in design of the surface, might be responsible for the difference in the results.

Neither of the two titanium stems designs in our material had been used with titanium heads. Both titanium stems, the matt ITH stem and the polished Titan stem, had results comparable to the polished stainless steel Exeter stem, and we found no difference between the two. However, there have been serious concerns about cemented titanium prostheses, and poor results with cemented ITH titanium stems, compared to stems made of chrome cobalt have been reported by Jacobson et al. (1995). We are looking forward to the results of an ongoing study in the three Norwegian hospitals using the ITH prosthesis, where the rate of radiographic loosening of this implant will be assessed.

Thus, our study gives no clear conclusion concerning material or the question about matt or polished surface on cemented stems.

The differences among the brands of cemented prostheses must be interpreted with caution because the differences we found were small and the results generally good. Results from our register represent a best case situation, as we have only assessed the different revision rates of the implants (Fender et al. 1999). Further, the brands with the best results were generally used in smaller numbers of patients and in fewer hospitals than, for example, the Charnley prosthesis. For prosthesis brands which are used at few hospitals, the individual surgeons' ability, the hospitals' policy concerning operative technique, follow-up of patients, policy for revision, and waiting list for revisions, will affect the results with the prosthesis brands used in these hospitals. Whereas for brands

that are used in many hospitals, such as the Charnley, our results represent what the average surgeon achieve with this prosthesis. Thus, with this type of potential bias concerning the results of cemented implants, the small differences we found should be interpreted with caution. With the large numbers of cases included in our materials, even small differences will be statistically significant, but not always clinically relevant.

With this in mind, however, for prostheses and cements that are used both in Sweden and Norway, our findings are generally in good accordance with the results in the Swedish hip register (Malchau and Herberts 1998). The results of the Charnley prosthesis are virtually the same in the 2 registers, whereas for the Lubinus SP stem, the Norwegian results were poorer than those in the Swedish register. The Lubinus SP stem had been used in three hospitals in Norway, but as all the revised Lubinus SP stems had been inserted in only one of these hospitals, it is uncertain whether these revisions can be related to the implant or to special circumstances in that hospital.

Methods and statistics

Our experience is that to succeed in running an implant register, there must be a continuous close working relationship between orthopedic surgeons and medical statisticians. Rather than have orthopedic surgeons planning the study and statisticians performing the analyses, orthopedic surgeons and statisticians should plan and run the study together. Orthopedic surgeons and statisticians should participate at the statistical analysis stage and in the writing. The statisticians are needed for the quality of the data management and the statistical analysis. The knowledge the orthopedic surgeons have about the recorded data and about prosthesis surgery is needed for statistical analysis.

Concerning the study design, it is sometimes argued that randomized clinical trials are better than national registers in assessing the performance of implants. However, prospective randomized studies are rarely performed in this field because they are difficult to organize, take a long time, are expensive, and require a large work-load. With national registers, we can assess results of practically all the different implants in the country, with a minimal work-load for the reporting surgeons. However, as the national studies are not randomized, confounding factors must be adjusted for, either by selection of homogeneous subgroups, or by use of a multiple regression model.

It would probably be useful to test all new implants with radiostereometric analyses (RSA) before they are released on the market (Kärrholm et al. 1997). Results of RSA studies are available only for relatively few cement brands and implant designs so far. For some prosthesis designs, such as those with a polished surface, there is still some uncertainty about the clinical relevance of the early migration detected in RSA studies. Even if RSA studies and/or randomized clinical trials were performed, a longer term follow-up study on a larger scale outside specialized centers would still be necessary. Since the implants used in the different countries are not the same, it might be better if each country had its own register.

Reporting system

The very good cooperation with the Norwegian orthopedic surgeons has permitted the functioning of the register. After the Christiansen experience, the Norwegian orthopedic surgeons were keen to participate in a national register. In our register, there should be no fear of reporting failures, as we do not record the name of the surgeons and the hospitals' findings are kept confidential to all but the hospital in question. We believe that our simple reporting system and our continuous feedback to the surgeons are the main reasons why the compliance rate of nearly 100% has not declined during the 12 years while the register has been operative.

Publication of results

We have decided to report results of prostheses and cement brands in scientific journals and conferences. We feel that this type of result should be presented, together with a description of the material and methods, and with a discussion of the strength and weakness of the study model. Publication of results in independent scientific journals is a guarantee for quality, but the price might be the delay due to the printing process, before the results become public.

Research and joint replacement surgery

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

For example, after 15 years of use, there is no good documentation of long-term results from clinical studies of patients operated on with prostheses based on the metal-on-metal principle, although 60,000 of these prostheses have been used in central Europe. There is still uncertainty about which metal (chrome cobalt, stainless steel, or titanium) is better in joint prostheses, and about the surface and geometry of cemented hip prostheses (polished, matt, precoated, taper, collar). Of the uncemented implants that are presently used, very few have reportedly good long-term results. The problems with polyethylene wear of the uncemented cups has still not been solved. Many orthopedic surgeons consider the new highly cross-linked polyethylenes to be the solution of the wear problems. Testing of these products in laboratory situations is promising, but they have now been marketed before clinical results became available. To complicate the situation further, many of the manufacturers of prostheses change their products before the long-term results are known. New cements, without documentation on good clinical results, were introduced on the market in 1999, even though it was well known that changes in the cement formulae might give unexpected problems. It is not agreed which prophylactic antibiotic regimens are the best, and it is uncertain whether there is a life-saving effect of thromboprophylaxis in hip replacement surgery (Bulstrode 1998).

The Norwegian orthopedic surgeons have followed our recommendations, since they have abandoned inferior uncemented prostheses and cements when the results became known. But instead of changing to well documented implants, some surgeons change to another new and still undocumented product. Thus, as undocumented implants are still used, the register will continue its function to survey the new implants. We will also assess the mid- and long-term results of implants which have had good short-term results.

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Table 3. Hospitals reporting to the Norwegian Arthroplasty Register

Hospital	Contact persons, hip prostheses	Contact persons, other joints
Aker sykehus	Unni Stensrud	Unni Stensrud
Aust-Agder Sentralsykehus	Tor Rundén, MD	Tor Rundén, MD
Askim Sykehus	Jan Roar Orlin, MD	Jan Roar Orlin, MD
Betanien Hospital		Finn Risung, MD
Buskerud Sentralsykehus	Finnur Snorrason, MD	Finnur Snorrason, MD
Bærum Sykehus	Gudleik Dale, MD	Gudleik Dale, MD
Det Norske Diakonshjems Sykehus	Tore Heier, MD	Tore Heier, MD
Det Norske Radiumhospital	Gunnar Follerås, MD	Gunnar Follerås, MD
Diakonissehjemmets sykehus	Rune Muri, MD	Knut Rokstad, MD
Farsund Sykhus	E. Bjering, MD	E. Bjering, MD
Flekkefjord Sykehus	Thore Hinderaker, MD	Thore Hinderaker, MD
Fylkessjukehuset i Haugesund	Birger Valen, MD	Birger Valen, MD
Fylkessjukehuset i Kr.sund N.	Kamel Farran, MD	Kamel Farran, MD
Fylkessjukehuset i Lærdal	Fritjof Lund-Larsen, MD	Fritjof Lund-Larsen, MD
Fylkessjukehuset i Molde	Hans Kleven, MD	Hans Kleven, MD
Fylkessjukehuset i Nordfjordeid	Hartmut Lange, MD	Hartmut Lange, MD
Fylkessjukehuset i Odda	Terje Hansen, MD	Terje Hansen, MD
Fylkessjukehuset i Volda	Yngve Norderval, MD	Yngve Norderval, MD
Fylkessjukehuset i Ålesund	Kjersti Rønnestad	Kjersti Rønnestad
Fylkessjukehuset på Stord	Olav Stray, MD	Olav Stray, MD
Fylkessjukehuset på Voss	Åsta Syslak	Åsta Syslak
Gjøvik Fylkessykehus	Arne Skoglund, MD	Arne Skoglund, MD
Gravdal sykehus	Bjørn Bergsdal, MD	Bjørn Bergsdal, MD
Halden sykehus	Sven T.Andersen, MD	Sven T.Andersen, MD
Hammerfest sykehus	Arvid Småbrekke, MD	Arvid Småbrekke, MD
Harstad sykehus	Asle Vebostad, MD	Asle Vebostad, MD
Haugesund San.for.Rev.sykehus	Ivar Eskill, MD	Ivar Eskill, MD

Haukeland sykehus	Leif Ivar Havelin, MD	Ove Furnes, MD
Horten sykehus	Vidar Berg, MD	Vidar Berg, MD
Innherred sykehus	Paul Fuglesang, MD	Paul Fuglesang, MD
Kirkenes sykehus	Lennart Wählby, MD	Lennart Wählby, MD
Kongsberg sykehus	H.Chr.Blom, MD	H.Chr. Blom, MD
Kongsvinger sykehus	O.J. Fretheim, MD	O.J. Fretheim, MD
Kysthospitalet i Hagevik	Stein Hellesnes, MD	Stein Hellesnes, MD
Larvik sykehus	Tore Ottesen, MD	Tore Ottesen, MD
Lillehammer Fylkessykehus	Tor Finn Denstad, MD	Tor Finn Denstad, MD
Lovisenberg Diak.Sykehus	Gisle Uppheim, MD	Gisle Uppheim, MD
Mandal sykehus	Arne Reinertsen, MD	Arne Reinertsen, MD
Martina Hansens Hospital	Arne Ekeland, MD	Arne Ekeland, MD
Moss sykehus	Rolf Grøntvedt, MD	Rolf Grøntvedt, MD
Namdal sykehus	K. Grigel, MD	K. Grigel, MD
Narvik sykehus	Ole Edvard B.Gabrielsen, MD	Ole Edvard B.Gabrielsen, MD
Nordland sentralsykehus	Hans H. Wasmuth, MD	Hans H. Wasmuth, MD
Notodden sykehus	Ola Aarseth, MD	Ola Aarseth, MD
Orkdal San.forening sykehus	Randi S.Ø.Oddli	Randi S.Ø.Oddli
Oslo Kommunale Legevakt	Lars Nordsletten, MD	Lars Nordsletten, MD
Oslo San.for.Revmatismesykehus	Lasse Kvarnes, MD	Lasse Kvarnes, MD
Rana sykehus	Dag Johansen, MD	Dag Johansen, MD
Regionsykehuset i Tromsø	Johan Fr.Winge, MD	Johan Fr. Winge, MD
Regionssykehuset i Trondheim	Leif Persen, MD	Leif Persen, MD
Rikshosp.senter for ortopedi, KMI	Magne Røkkum, MD	Magne Røkkum, MD
Rikshosp.senter for ortopedi, SM	Paul Lereim, MD	Paul Lereim, MD
Ringerike sykehus	Arvid Lager, MD	Arvid Lager, MD
Rjukan sykehus	Knut G. Grønneberg, MD	Knut G.Grønneberg, MD
Røde Kors Klinikken	Lars Vasli, MD	Lars Vasli, MD
Røros sykehus	Leif Persen, MD	Leif Persen, MD
Sentralsykehuset i Akershus	Odd G.Granlund, MD	Odd G.Granlund, MD
Sentr.sykehuset i Hedmark, Elverum	Ola Gjøa, MD	Ola Gjøa, MD
Sentralsykehuset i Hedmark, Hamar	Holm Holmsen, MD	Holm Holmsen, MD
Sentr.sykehuset i Rogaland	Helge Træland, MD	Helge Træland, MD
Sentr.sykehuset i Sogn og Fjordane	Svenning I.Lida, MD	Svenning I. Lida, MD
Stensby Sykehus	Lasse Efskind, MD	Lasse Efskind, MD
Stokmarknes sykehus	Jan Grøtan, MD	Jan Grøtan, MD
Telemark Sentralsykehus	Tore Grønmark, MD	Tore Grønmark, MD
Tynset Sjukehus	Bjørn Nordbye, MD	Bjørn Nordbye, MD
Ullevål Sykehus	Lars Nordsletten, MD	Lars Nordsletten, MD
Vest-Agder Sentralsykehus	Roald Sætermo, MD	Helge Svensen, MD
Vestfold Sentralsykehus	Odd Warholm, MD	Odd Warholm, MD
Volvat Medisinske Senter	Erik A. Rosenlund, MD	Erik A. Rosenlund, MD
Østfold Sentr.sykehus, Fredrikstad	Arne Nilsen, MD	Arne Nilsen, MD