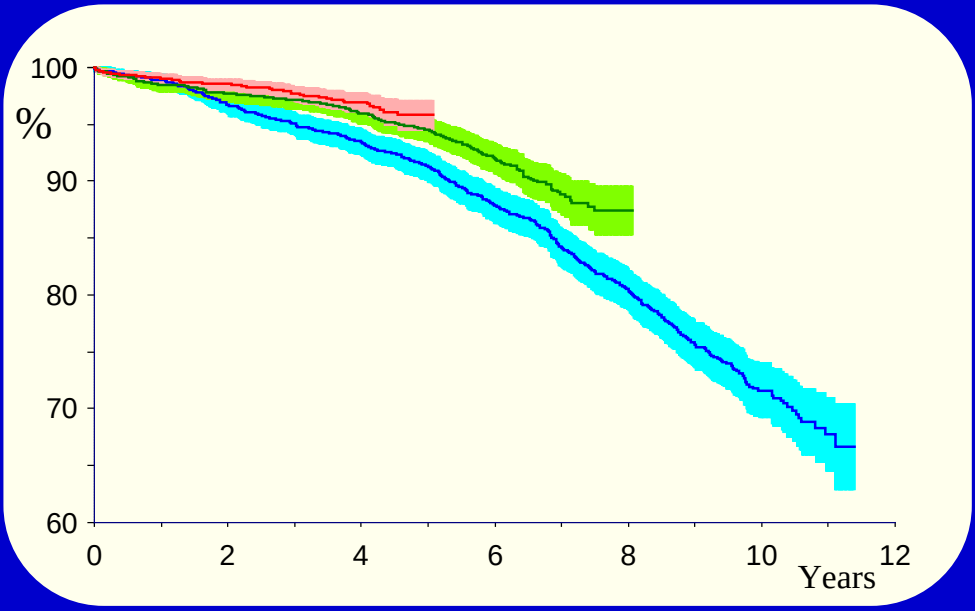
Prospective Studies of Hip Prostheses and Cements

A Presentation of the Norwegian Arthroplasty Register 1987-1999



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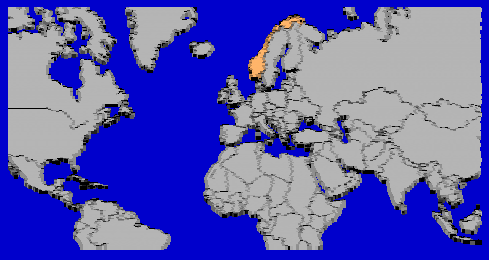


Scientific Exhibition presented at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons, March 15-19, 2000, Orlando, Florida, USA.

The Norwegian Arthroplasty Register

History

In 1987 the Norwegian Orthopaedic Association established the Norwegian Hip Register (Havelin et al.1993). In January 1994 it was extended to include all artificial joints. The main purpose of the register is to identify inferior implants as early as possible. The Register functions as a quality control system both at a national and a local level, as hospital-specific results are reported back to each participating hospital. The register is financed by the state and it is independent from the medical device industry. So far more than 64,000 primary and revision hip replacements have been registered.

Reports From the Surgeons

The orthopaedic surgeons provide information from all primary joint replacements, including an accurate description of the different parts of the implant. If the prosthesis is revised later, possibly at a different hospital, we receive a new report with information about the reason for and the type of revision. By using the patients' national social security numbers, the revisions are linked to their primary operations. From the Norwegian Population Registry, we receive information on dates of death of deceased patients.

Study Design and Statistical Methods

The ideal approach to evaluate the performance of implants would be to carry out randomized clinical trials. Properly conducted large randomized trials would eliminate any systematic differences between the different treatment groups that might lead to confounded results. However, prospective randomized studies are rarely performed in this field for several reasons. They are difficult to organize, are expensive, require a large workload and take a long time. Furthermore, a randomized trial can only address one or two primary research questions. As long as results from clinical trials are not mandatory before new implants can be freely marketed, the number of trials will remain limited. One alternative is to use national post-marketing registers. With this approach, results for practically all different implants used in a country can be assessed with minimal workload for the reporting surgeons. It must be kept in mind that these register-based studies are observational. Confounding issues must therefore be carefully scrutinized and accounted for. Analytic approaches to handle confounding include adjustment by multiple regression (the Cox model) or by limiting analyses to homogenous subgroups. Still, results from observational register-based studies are less conclusive than those of comparable randomized trials.

Epidemiology

Annually about 5,200 primary total hip replacements are performed in Norway (4.3 million inhabitants), which corresponds to 120 primary operations per 100,000 inhabitants. The average age at the primary operation is 69 years. 69 % of the operations are performed in women. The incidence of total hip replacement by age and gender is given in Figure 1.

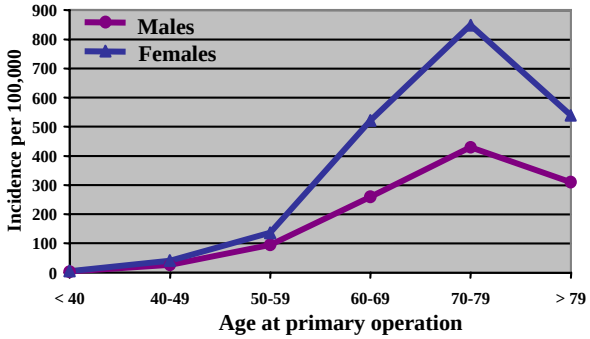


Figure 1: Incidence of THR by age and gender

Fixation of Prostheses

The proportion of uncemented primary prostheses was unchanged from 1988 to 1998 with 18 % of the cups and 13 % of the stems being uncemented. At revisions, the use of uncemented cups had declined. The use of the bone impaction grafting technique has increased, and in 1998 this technique was used in 23 % of the cup revisions and in 31 % of the stem revisions.

Choice of Prostheses

During the 12 years of the study 62 different types of cups and 67 different types of stems have been registered. Only 5 cups (all of which were cemented) and 7 femoral components (6 cemented and 1 uncemented) were used throughout the whole period. The 32 mm head was used on 73 % of the uncemented stems during 1987-1990, but 32 mm heads were only used at 5.6 % of the operations in 1998. The numbers of primary and revision hip prostheses are given in Figure 2.

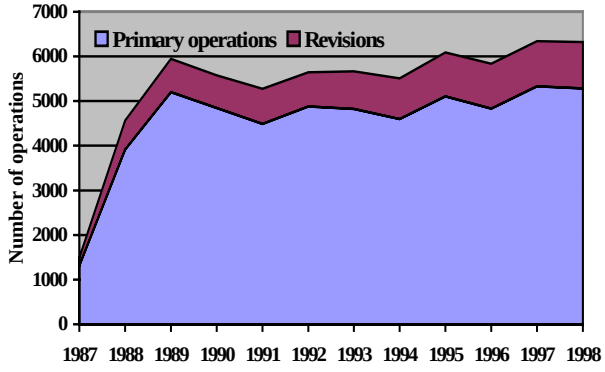


Figure 2: Annual number of primary operations and revisions

The 10 most common primary hip prostheses reported to the Norwegian Arthroplasty Register, 1987-1998.

Femoral components			Acetabular components		
Name (company)	Number	Fixation	Name (company)	Number	Fixation
Charnley (DePuy)	26915	cemented	Charnley (DePuy)	25886	cemented
Titan (DePuy)	5882	cemented	Exeter (Howmedica)	5139	cemented
Exeter (Howmedica)	5227	cemented	Titan (DePuy)	4737	cemented
Corail (DePuy)	3839	uncemented	Spectron (Smith & Nephew)	3381	cemented
ITH (Smith & Nephew)	2911	cemented	Tropic (DePuy)	2663	uncemented
Bio-Fit (Smith & Nephew)	1433	cemented	Modular hip system (Smith & Nephew)	2201	cemented
SP Lubinus (Link)	1335	cemented	Atoll (DePuy)	1376	uncemented
Profile (DePuy)	879	uncemented	Elite (DePuy)	1088	cemented
Fjord (DePuy)	519	cemented	SP Lubinus (Link)	1063	cemented
LMT (Biomet)	509	uncemented	Endler (AlloPro)	661	uncemented

Cement Type and Survival of Primary Total Hip Prostheses

Materials

Study I: The survival of 8,579 primary Charnley prostheses implanted due to primary coxarthrosis were studied according to the cement type used during 1987-93 (Havelin et al. 1995 a).

Study II: Comparison of 1,127 Boneloc and 8,266 high viscosity cemented Exeter and Charnley primary prostheses, 1991-94 (Furnes et al. 1997).

Study III: The effect on prosthesis survival of the high viscosity cements Palacos, Simplex, CMW1, and the low viscosity cement CMW3, was investigated in 15,536 primary Charnley prostheses implanted for primary coxarthrosis, 1987-98 (Espehaug et al., in preparation).

Results

Study I: Cox regression analysis with adjustment for antibiotic in cement, age, and gender showed that femoral components implanted with the low viscosity cement CMW3 (n=1,196; RR=2.4, p <0.0001) or the Boneloc cement (n=764; RR=8.7, p<0.0001) had an increased risk of revision due to aseptic loosening compared to high viscosity cemented implants (n=3,788) (Figure 1). Both cements were abandoned in Norway (Figure 2).

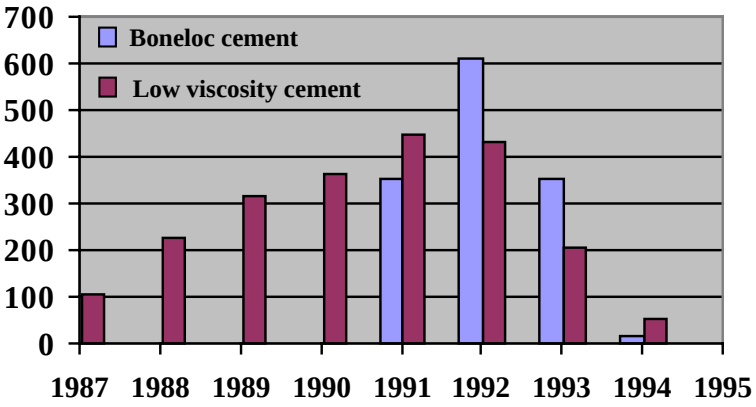


Figure 2: Annual number of hip prostheses with Boneloc or low viscosity cement

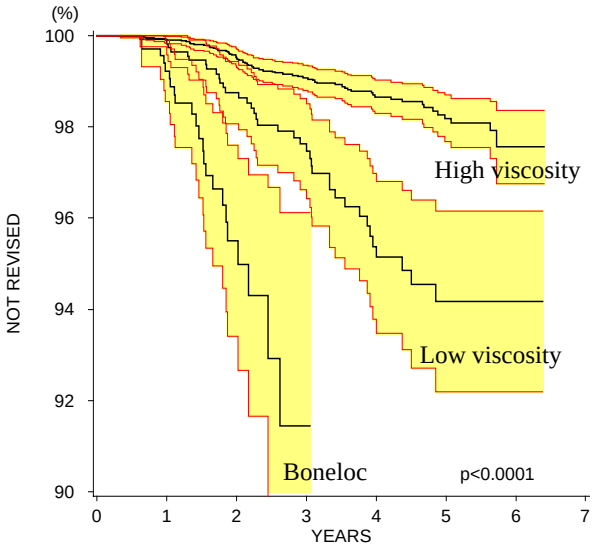


Figure 1: Kaplan-Meier survival curves of Charnley femoral prostheses with high viscosity, low viscosity, and Boneloc cement (Reproduced with permission from: Havelin et al. J Bone Joint Surg (Am) 1995; 77-A: 1543-1550)

Study II: In both Charnley and Exeter prostheses, the high viscosity cemented components had better survival than Boneloc cemented components (Table 1). The inferior results with the Boneloc cement was less pronounced with the Exeter prosthesis.

Table 1: Cox regression, adjusted for age, gender, diagnosis, and use of systemic antibiotic. Revision for aseptic loosening of the stem (follow-up 0–5 years).

Prosthesis/Cement	No.of hips	Risk Ratio	95% CI	p
Charnley/High-viscosity	6,621	1		
Charnley/Boneloc	955	14	11-19	<0.001
Exeter/High-viscosity	1,645	0.24	0.10-0.61	0.002
Exeter/Boneloc	172	1.8	0.64-4.9	0.3

Study III: Compared to Palacos cemented prostheses (n=9,830) in a multiple Cox regression, the revision risk due to aseptic loosening was similar with Simplex cement (n=754), but 2.6 (p<0.001) and 3.7 (p<0.001) times increased with CMW 1 (n=4,331) and CMW 3 (n=621) cement, respectively (Figure 3). Detailed information regarding cementing technique was not available in this study, however, it was common to use second and third generation techniques during the whole study period.

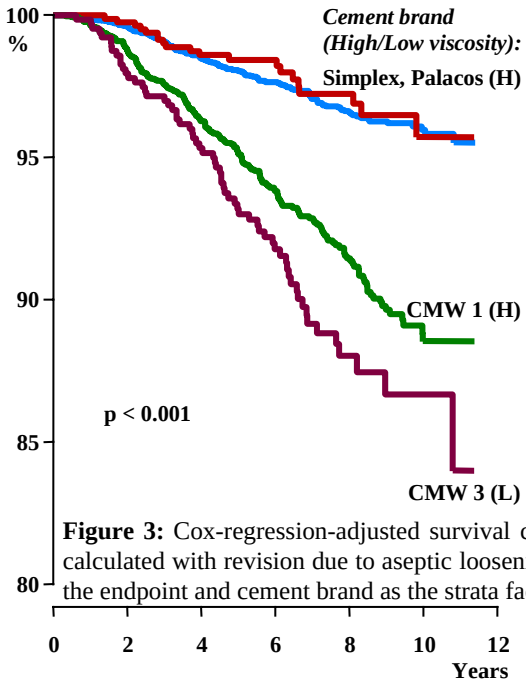


Figure 3: Cox-regression-adjusted survival curves calculated with revision due to aseptic loosening as the endpoint and cement brand as the strata factor.

Conclusions

After only three years of follow-up, Charnley prostheses with Boneloc cement or with low-viscosity cement (CMW 3), had inferior results compared to high viscosity cemented prostheses.

The Boneloc cement was also shown to be inferior to high viscosity cement brands with Exeter prostheses.

Exeter prostheses cemented with Boneloc cement performed better than Charnley prostheses with Boneloc cement.

Prosthesis survival also differed within the group of high viscosity cement brands, where the Palacos and the Simplex cement gave the best results.

Survival of Uncemented Primary Total Hip Prostheses

Short-term (0-5 years) Results

After about 3 years of observation, we found inferior results for uncemented implants compared to cemented implants (Havelin et al. 1994). These inferior results were mainly attributed to the first and second generations of uncemented stems and cups. We found good short-term results for uncemented prostheses with HA coating or porous coating (Havelin et al. 1994, Havelin et al. 1995 b and c).

Mid-term (0-11 years) Results

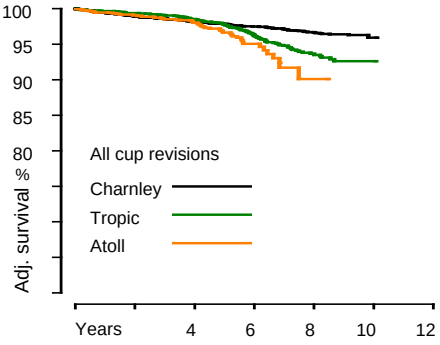
Charnley cups vs two uncemented HA-coated cups:

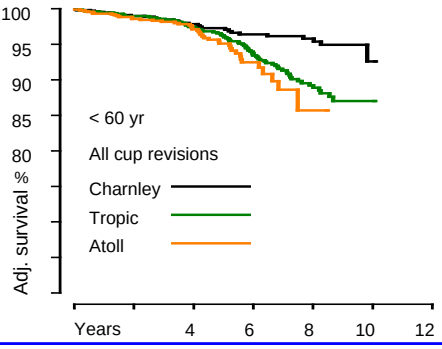
Two uncemented HA-coated cup brands were compared with cemented Charnley cups fixed with high viscosity Palacos cement.

Results: The risk for revision for the hemispheric Atoll (n=1,363) and the treaded Tropic cup (n=2,864) was increased in the total material compared to the Charnley cup (n=14,880) with follow-up longer than 4 years. This also applied for patients both over and under 60 years of age. Revision due to aseptic loosening was also increased for the HA-coated cups (Havelin et al. in preparation).

Cox regression, adjusted for age, gender, and diagnosis. Cup revision.

	% revised at 8 years	Follow-up<4 years Risk Ratio	95% CI	p-value	Follow-up ≥4years Risk Ratio	95% CI	p-value
Charnley	3.3	1			1		
Tropic	6.4	0.7	0.5-1.1	0.11	3.3	2.3-4.8	<0.001
Atoll	9.9	1.0	0.7-1.6	0.86	5.0	3.1-8.2	<0.001





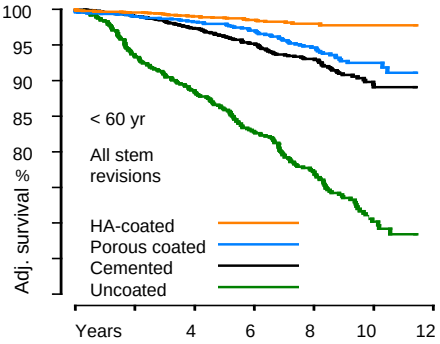
Mid-term (0-11 years) Results

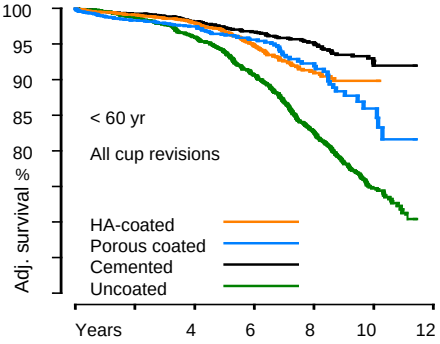
Cemented vs uncemented in young patients:

In patients under the age of 60 years, we compared the results of uncemented designs, with the overall result of the six most common high viscosity cemented stems and cups.

Cox regression, adjusted for age, gender, and diagnosis.

	All revisions Risk Ratio	95% CI	p-value	Revision for loosening Risk Ratio	95% CI	p-value
Stems:						
HA-coated	1			1		
Porous-coated	2.5	1.7-3.7	<0.001	2.1	1.2-3.9	0.01
Cemented	3.3	2.4-4.6	<0.001	6.8	4.2-11	<0.001
Uncoated	11	8.5-16	<0.001	26	16-41	<0.001
Cups:						
Cemented	1			1		
HA-coated	1.6	1.3-2.1	<0.001	1.3	0.9-1.9	0.14
Porous-coated	1.8	1.4-2.5	<0.001	0.5	0.3-0.9	0.05
Uncoated	3.4	3.8-6.8	<0.001	5.0	3.8-6.8	<0.001





Stems: Compared to HA-coated stems (n=4,648), the porous-coated (n=1,264), cemented (n=2,839), and smooth uncemented stems (n=740), had increased risks for revision, both for revisions due to any cause and for revisions due to aseptic stem loosening.

Cups: Compared to the cemented cups (n=2,839), the porous-coated (n=2,464) and the HA-coated cups (n=4,764) had increased overall risks for revision, mainly due to more wear problems. The uncoated threaded cups (n=1,885) had increased risk for revision compared to all other designs (Havelin et al. in preparation).

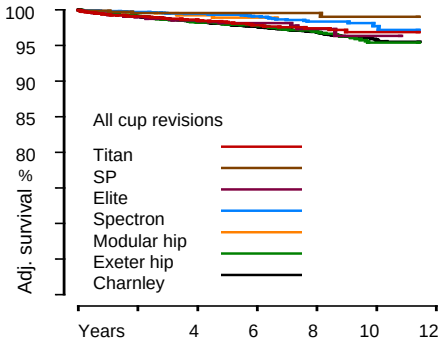
Conclusions

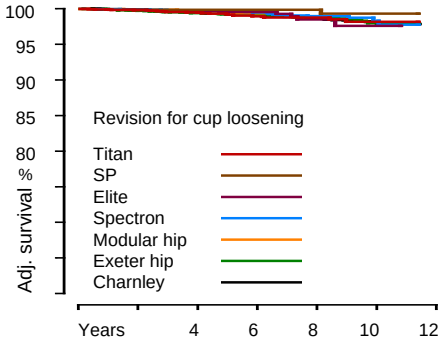
Uncemented stems with HA-coating or circumferential porous coating gave better or similar results, respectively, compared to cemented stems. The cemented cups had fewer revisions than the HA-coated cups and the porous-coated cups, mainly due to more wear problems among the uncemented cups. The HA-coated Tropic and Atoll cups had increased rates of revision due to aseptic loosening compared to Charnley cups. These findings do not support the common practice of implanting hybrids of cemented stems and uncemented cups.

Survival of Cemented Primary Total Hip Prostheses

Short-term (0-6 years) Results

We found good overall results with a 5-year revision probability of 2.5 %. The Elite/Charnley (cup/stem) combination and the Müller Type prostheses showed poorer results than the Charnley prosthesis, but differences were small (Espehaug et al. 1995).



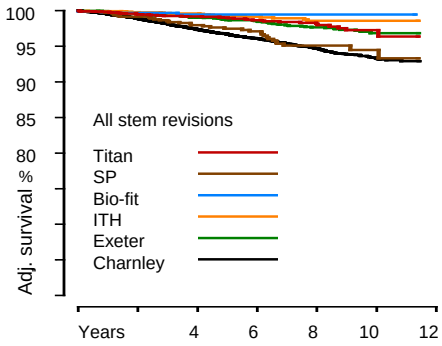


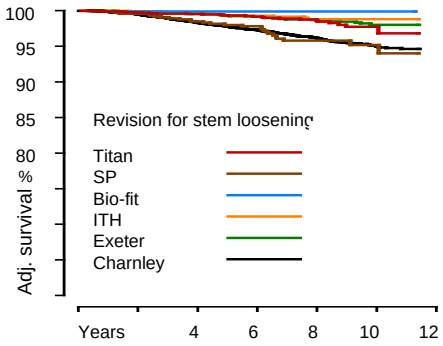
Mid-term (0-11 years) Results

We compared the results of the 6 most common cemented stems and the 7 most common cups inserted with high viscosity cement (CMW 1, Palacos, Simplex). The Cox model, with adjustment for age, gender, diagnosis, and cement brand was applied.

Cups: With revision due to aseptic cup loosening as end-point, there was virtually no difference among the brands. The revision probability due to aseptic loosening was less than 3 % at 10 years. With any cup revision as end-point, the Modular Cup System (n=2,153), SP (n=899), and Spectron cups (n=3,274) had significantly better results ($p<0.05$) than the Charnley (n=23,385) cups. The Titan (n=4,266), Exeter (n=4,838), and Elite (n=1,016) cups were not statistically significant different from the Charnley. Generally the results were good, with an over-all survival above 95 % at 10 years.

Stems: The results of Charnley (n=22,999) and SP (n=1,115) stems were inferior to ITH (n=2,758), Titan (n=4,629), Exeter (n=4,776), and Bio-Fit (n=1,246) stems ($p<0.001$). The result of the Charnley stem differed substantially among the hospitals, and all the revised SP stems were from one hospital. The cemented titanium stems, had results similar to stems made of chrome cobalt or stainless steel. We found better results for the polished stainless steel Exeter stem than the matt (Vaquasheen) Charnley stem. For titanium stems, we did not find any difference between implants with a matt or a polished surface.





Conclusions

Among the all-polyethylene cemented cups, we found good results and only small differences at mid-term (0-11 years). Also for the cemented stems, we found good mid-term results. Therefore, it seems justified to still use cemented implants in all age groups of patients, and the use of uncemented implants should still be regarded as experimental.

Of stainless steel stems, the one with a polished surface had slightly better results than the stem with a matt surface. However, each surface was associated with a particular stem design and it is still uncertain whether other design properties than the surface, might be responsible for the difference in result. Thus, our study gives no clear conclusion concerning material, or matt vs polished surface of cemented stems.

The differences we found among the cemented prosthesis brands should be interpreted cautiously, as the differences we found were small and the results were generally good. The brands with the best results had been used in small numbers and in few hospitals. For prosthesis brands, which are used at few hospitals, the individual surgeons' skill, the hospitals' follow-up of patients, policy for revision, and waiting lists, will have an impact on the observed results. For brands that are used in many hospitals, our results represent what the average surgeon achieves. With the large numbers of cases included in our material, even small differences will be statistically significant, but not always clinically relevant.

Antibiotic Prophylaxis and Survival of Primary Total Hip Prostheses

Materials

Study I: The survival of 10,905 primary cemented commonly used prosthesis brands in patients operated on due to primary coxarthrosis was studied in relation to use of systemic antibiotic prophylaxis only or systemic antibiotic in combination with antibiotic-containing cement, 1987-95 (Espehaug et al. 1997a).

Study II: Comparison of a 1-, 2-, or 3-day systemic antibiotic prophylaxis regimen in 7,682 Charnley prostheses with gentamicin-containing Palacos cement operated due to primary coxarthrosis. The effect of the number of times systemic antibiotic was administered the day of surgery (1, 2, 3 or 4 doses) was investigated within 5,017 patients receiving systemic antibiotics for 1 day only (Engesæter et al., in preparation).

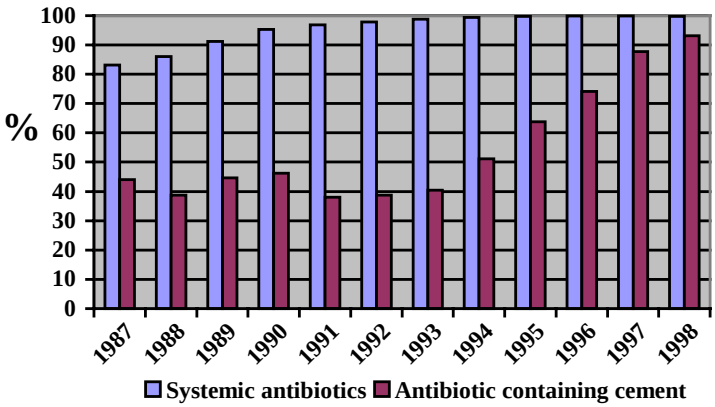


Figure 1: Antibiotic prophylaxis in Norway 1987-98.

Results: While the use of antibiotic-containing cement has been increasing, systemic antibiotic prophylaxis has been used in almost every operation since 1990 (Figure 1).

Study I: Best survival of primary total hip replacements was found when antibiotic prophylaxis was given both systemically and in the bone-cement (n=5,804) (Figure 2). With revisions due to infection as endpoint, the Cox-adjusted revision risk was 4.3 (95 % CI: 1.7-11, p=0.001) times increased if antibiotics were given systemically only (n=4,586).

Study II. For patients operated with primary Charnley prostheses and with Palacos gentamicin-containing cement, systemic antibiotic prophylaxis beyond the day of the operation did not give any further reduction in revision risk (Figure 3). For those who received systemic antibiotic prophylaxis for 1 day, the risk for revision was lowest if the antibiotic was given 4 times the day of surgery (Table 1).

Table 1: Cox regression, adjusted for age, gender, and type of systemic antibiotic, with any revision cause as endpoint among patients receiving a 1-day systemic antibiotic regime in combination with gentamicin-containing Palacos cement.

Systemic antibiotic Dosage	(mean total g)	No.of hips	No.of revisions	Risk ratio	95% CI	p
1 dose	(2.1 g)	703	28	1		
2 doses	(3.9 g)	1,371	42	1.3	0.79-2.1	0.31
3 doses	(4.8 g)	2,184	55	0.78	0.50-1.2	0.31
4 doses	(7.3 g)	759	2	0.08	0.02-0.36	<0.001

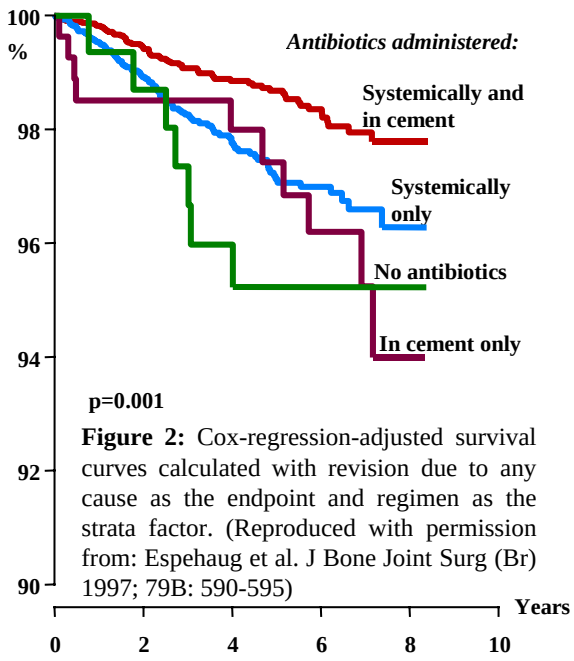


Figure 2: Cox-regression-adjusted survival curves calculated with revision due to any cause as the endpoint and regimen as the strata factor. (Reproduced with permission from: Espehaug et al. J Bone Joint Surg (Br) 1997; 79B: 590-595)

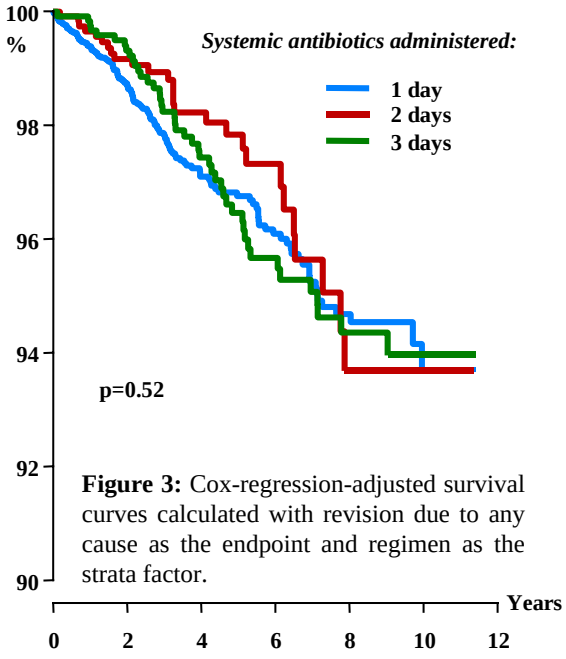


Figure 3: Cox-regression-adjusted survival curves calculated with revision due to any cause as the endpoint and regimen as the strata factor.

Conclusion

A combination of antibiotic prophylaxis administered both in the cement and systemically was associated with fewer revisions than other regimens.

Following a regime with antibiotic-containing cement, no difference was observed among patients receiving systemic antibiotics for 1, 2 or 3 days.

Systemic antibiotics administered 4 times the day of surgery was associated with a lower risk of revision compared to fewer doses.

Hospital and Patient Related Risk Factors. Patients Satisfaction, Function and Mortality

Hospital Category and Operating Volume

During 1988-1996, 53 % of the hip replacements in Norway were performed in 45 local hospitals, 32 % in 15 central and 16 % in 10 university hospitals (Espehaug et al. 1999). Primary hip replacements performed at university hospitals were revised more often than prostheses inserted at central and local hospitals (Figure 1). This difference was related to a more extensive use of uncemented prostheses with inferior design at university hospitals. However, revision rates were still consistently higher at university hospitals after adjustment for prosthesis brand, age, gender, diagnosis, and other confounding factors. Possible explanations for this result may include the centralization of high-risk patients to university hospitals, the lower annual number of operations per orthopaedic surgeon, and the high percentage of orthopaedic 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.

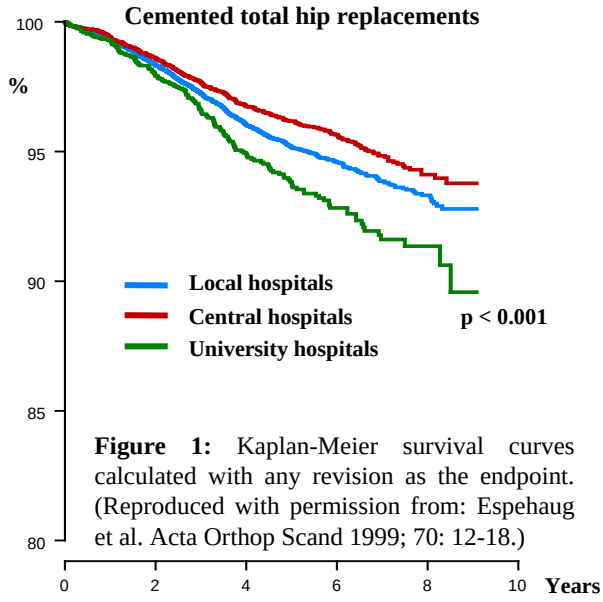


Figure 1: Kaplan-Meier survival curves calculated with any revision as the endpoint. (Reproduced with permission from: Espehaug et al. Acta Orthop Scand 1999; 70: 12-18.)

Patient Related Factors and Risk for Revision

We have found an increased risk for revision of hip prostheses in younger compared to older patients and in men compared to women (Havelin et al. 1994). Further, we found that increasing weight was associated with an increased risk for revision among old and tall male patients. Smoking had no over-all effect, but former heavy smokers had a 2.6 times increased risk compared to never smokers. Alcohol intake was associated with an increased risk for dislocation. Revision due to infection was increased among patients taking anti-diabetic drugs. We also found an increased risk for revision among patients using systemic or local pulmonary steroids, and in female patients of working age doing heavy work (Espehaug et al. 1997 b).

The Economical Impact of Inferior Implants

Furnes et al. (1996) and Engesæter et al. (1996) assessed the economical cost of using inferior implants and cements compared to a reference THR (the Charnley prosthesis with antibiotic containing high viscosity cement). The annual over-all extra cost of using other implants than the reference-THR was 1.7 million USD for the first 3-5 years postoperatively. By early detection of inferior implants, the register has reduced the number of revisions and thus the suffering of the patients and the expenses for the society.

Patient Satisfaction and Function

We found that 61 % of the patients who underwent revision surgery and 84 % of the persons who did not undergo revision, rated their overall satisfaction with their hip implant as good or very good (Espehaug et al. 1998 a).

Patient Mortality

The 8-year mortality for THR patients was 25 % compared to 30 % in the Norwegian population (with a corresponding composition of age, gender and year of birth) (Lie et al. in press) (Figure 2). The standardized mortality ratio (SMR) was 0.81. During the first 60 postoperative days we observed a statistically significant increased mortality for all patient categories (0.8 % mortality) (Figure 3).

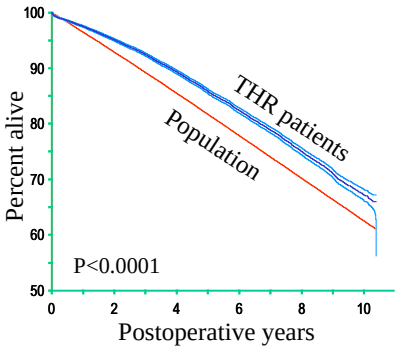


Figure 2: Survival of THR patients (with 95 % CI) compared with a corresponding Norwegian population (Reproduced with permission from: Lie et al. Acta Orthop Scand, in press)

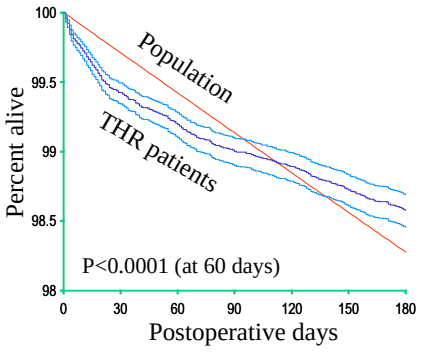


Figure 3: Survival of THR patients (with 95 % CI), the first 180 postoperative days, compared with a corresponding Norwegian population. (Reproduced with permission from: Lie et al. Acta Orthop Scand, in press)

Summary

The Norwegian Arthroplasty Register collected information on more than 64,000 primary and revision THRs performed between 1987 and 1999.

After three years of observation, we were able to document inferior results of the Boneloc cement and of the smooth surfaced uncemented implants used in the early 1990-ies.

Charnley prostheses had inferior results when fixed with the low-viscosity cement CMW 3 compared to high viscosity cements. The Palacos and Simplex cements gave the best results.

Antibiotic prophylaxis given as a combination of systemic antibiotic and antibiotic containing cement was associated with fewer revisions due to infection. We found no benefit of giving systemic antibiotic prophylaxis beyond the day of surgery.

Uncemented HA- or circumferentially porous-coated stems had better results than cemented stems at 10 years of follow-up.

Uncemented porous coated cups in young patients had a lower revision rate with aseptic loosening as end point than cemented cups, but higher revision risk over-all due to wear and osteolysis.

The uncemented HA-coated cups, Tropic and Atoll, had a higher revision risk due to aseptic loosing, wear and osteolysis than cemented cups.

Cemented hip prostheses fixed with high viscosity Palacos or Simplex cement had generally good results, with a 10-year survival of 95% or better.

Patients with intact primary prostheses had better function and less pain than patients with revised prostheses.

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