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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Submitted 93-01-23. Accepted 93-11-01

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-

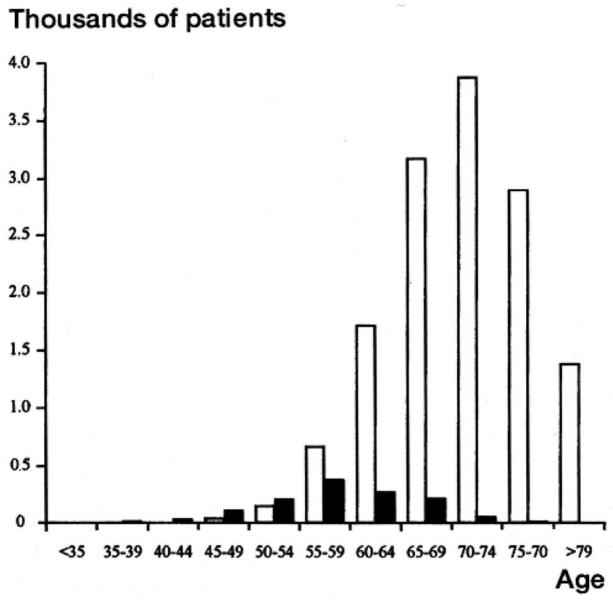

Figure 1. Age distribution of 15,335 patients operated using cemented (□) and uncemented (■) primary THR in Norway, 1987–1992.

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	2.02[a]	0.0001	141	2.28[a]	0.0001	42	0.51[a]	0.6	28	3.24[a]	0.0001
	Uncemented	1326	52			38			3			11		
Men	Cemented	4464	111	1.45[b]	0.2	82	1.47[b]	0.2	20	0.81[b]	0.8	9	2.75[b]	0.1
	Uncemented	502	19			14			2			3		
Women	Cemented	9545	100	2.71[b]	0.0001	59	3.49[b]	0.0001	22	0.30[b]	0.5	19	3.49[b]	0.0001
	Uncemented	824	33			24			1			8		
Under 60 years														
All	Cemented	655	11	2.90[c]	0.002	8	2.69[c]	0.02	2	1.54[c]	0.6	1	7.19[c]	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	0.08
	Uncemented	415	17			11			1			5		
60–64 years														
All	Cemented	1515	31	2.37[c]	0.004	19	3.06[c]	0.001	8	0	0.2	4	3.74[c]	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	1.23[c]	0.5	114	1.51[c]	0.2	32	0	0.3	23	1.40[c]	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	216	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).

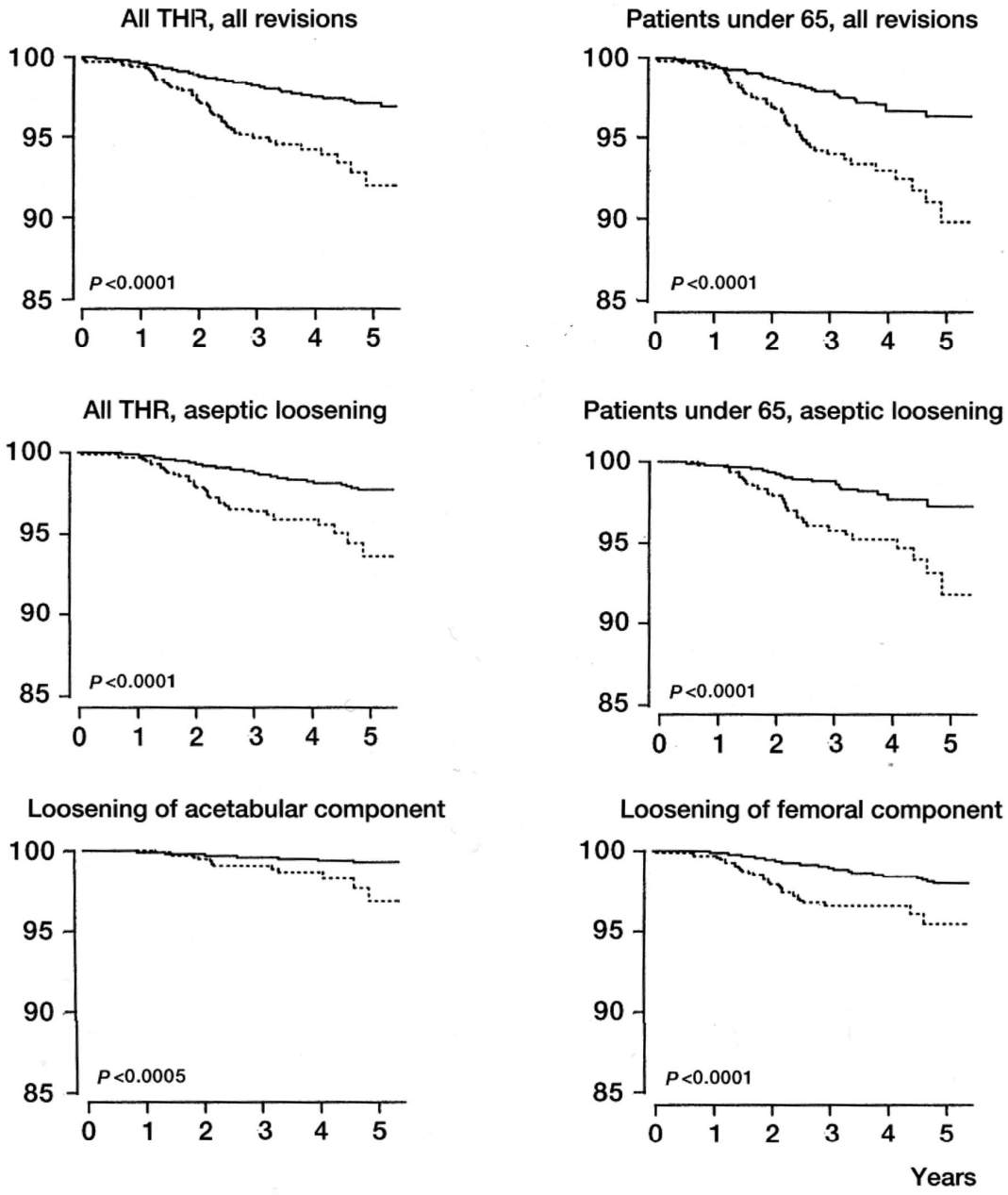

Figure 2. Percent survival until revision (for any reason, aseptic loosening, and aseptic loosening of acetabular and femoral components) of cemented (—) and uncemented (·····) primary THR.

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-

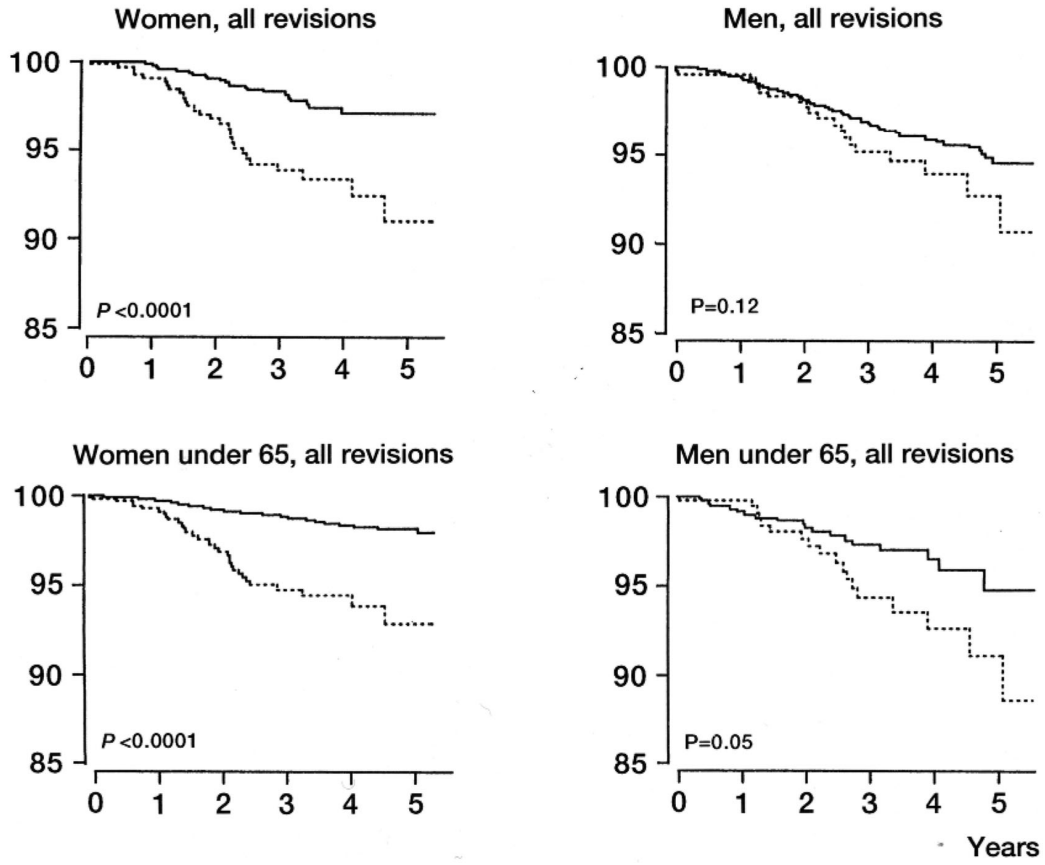

Figure 3. Percent survival until revision of cemented (—) and uncemented (.....) THR in men and women in various age groups.

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, Ohlin 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, cementless 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

The authors are grateful to the Norwegian orthopedic surgeons who have reported their cases to the register. The present study was supported by grants from Dr. Trygve Gythfeldt og frues forskningsfond and Norske kvinners sanitetsforenings forskningsfond.

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