Early revision among 12,179 hip prostheses

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

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

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

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

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

Patients and methods

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

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

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

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

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

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

Different combinations of the following acetabular and femoral prosthesis brands were investigated (Table 1): Charnley stem and cup, Elite cup (Thackray, Leeds, U.K.); Exeter stem (polished) and cup (Howmedica International, Herouville, France); Titan stem and cup (Landos, Chaumont, France); SP HIP stem and cup, SP II Lubinus stem (Waldemar Link, Hamburg, Germany); ITH stem, Bio-fit stem, Spectron cup (Richards, Memphis, Tennessee, U.S.A.); LMT Biomet stem and cup, Biomet Watson Farrar cup, European Cup System (Biomet, Warsaw, Indiana, U.S.A.) and Müller Type stem and cup (Zimmer, Warsaw, Indiana, U.S.A.). As SP II Lubinus and SP HIP differed only by the modularity of the head in SP II, they were regarded as one group called Lubinus SP prostheses. The prostheses known as Biomet Watson Farrar, LMT Biomet and European Cup System were also treated as one group called Biomet prostheses. Only Elite cups with inner diameters of 22 mm were included. From 1994, these cups were marketed as Charnley cups and the Elite name is now used only for cups with inner diameters other than 22 mm.

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

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

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

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

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

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

Results

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

Survival analyses of prosthesis brand

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

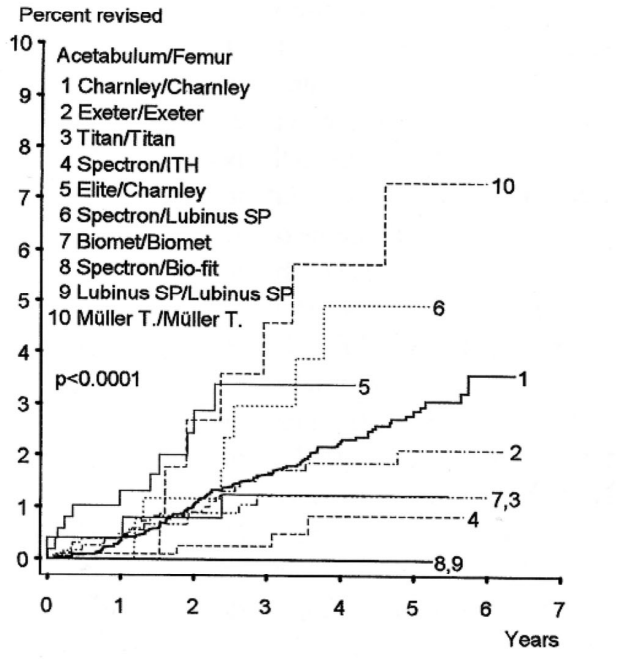

Figure 1. Kaplan-Meier estimated survival curves until revision for any cause for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands.

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

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

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

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

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

Different causes of revision

The overall 5-year failure rate due to aseptic loosening of one or both components was 1.8% (95% Confidence Interval: 1.4–2.1), to dislocation 0.2% (CI: 0.1–0.3) and to infection 0.5% (CI: 0.3–0.6). Of the 184 revisions, 116 (63%) were performed because of aseptic loosening of one or both components (Table 4). Of these, 76 were due to isolated loosening of the femoral component and 22 revisions were due to isolated loosening of the acetabular component (Figure 3). Overall, 42 (23%) of the revisions were performed because of infection, and 20 (11%) prostheses had been revised because of dislocation. The patterns of the cause of revision were similar among the different prostheses, with the exception of the Elite/Charnley combination where 6 out of 12 revisions were due to infection.

Bilateral operations

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

Discussion

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

The Elite cup was introduced in Norway in 1988 by the Charnley manufacturers in order to have cups with larger outer diameters available in the Charnley system. Because of the obvious similarity between

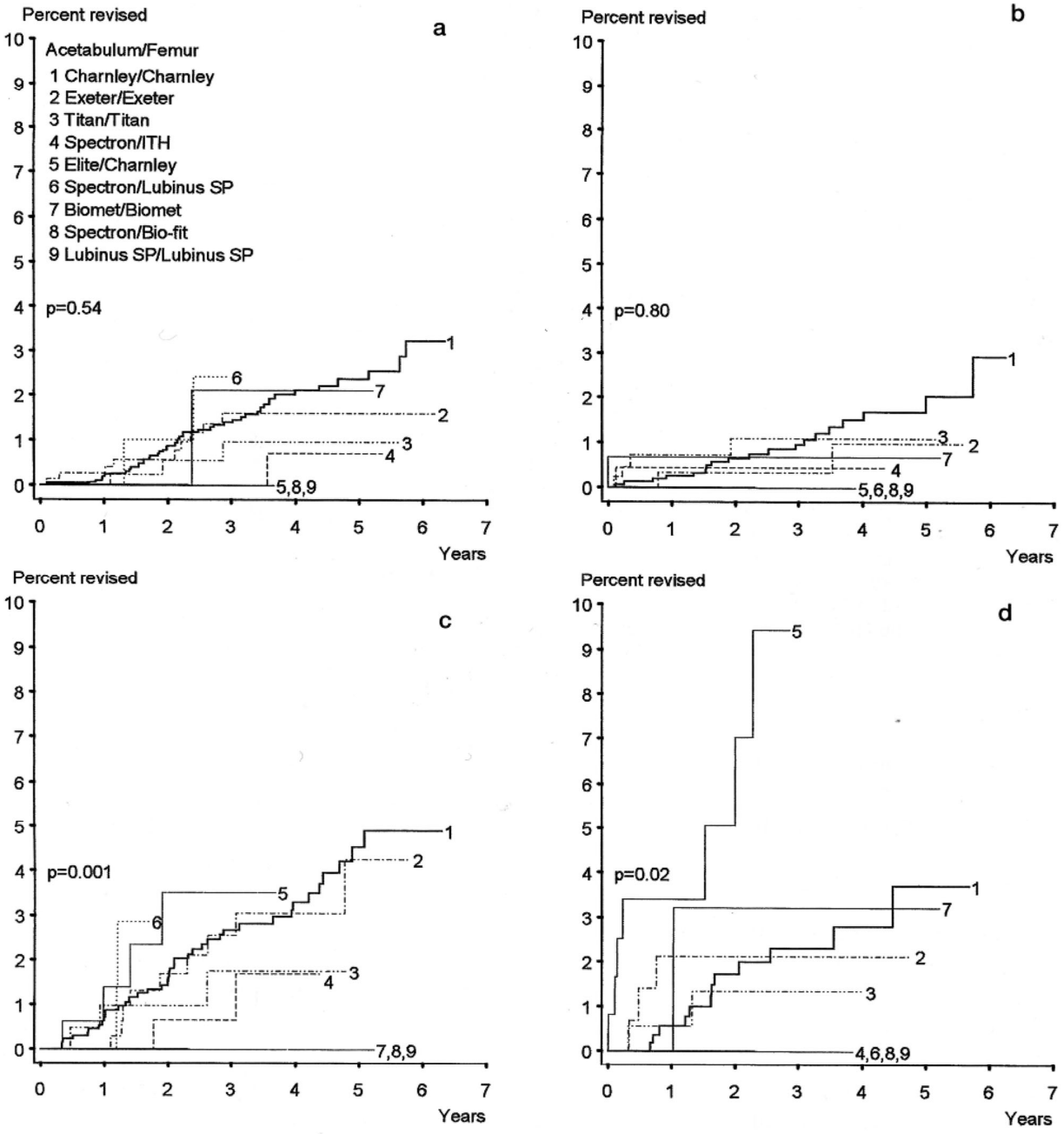

Figure 2. Kaplan-Meier estimated survival curves until revision for any cause for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993 in patient subgroups. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands. a) Women younger than 75 years at primary operation. b) Women 75 years or more at primary operation. c) Men younger than 75 years at primary operation. d) Men 75 years or more at primary operation.

the Elite/Charnley combination and the original Charnley prosthesis, it is difficult to explain the inferiority of the Elite/Charnley. The fact that 50% (6 out of 12) of the revisions were performed because of infection might indicate that factors other than the design of the prosthesis influenced the result. The use of the Elite/Charnley combination was commoner in male patients, who are known to be a high-risk group (Skeie et al. 1991, Malchau et al. 1993), but the results persisted after adjustment for gender, age, type of cement and use of systemic antibiotic prophylaxis. Additional adjustment for type of operating theater did not alter the results. Furthermore, the primary operations of the 6 infected Elite/Charnley hips were performed at 5 different hospitals.

In addition to the Elite/Charnley combination, the Müller Type prosthesis had inferior results when compared to the Charnley THR. For the Müller Type, similar results have been reported previously (Krismer et al. 1991, Malchau et al. 1993), and the prosthesis has not been in use in Norway since 1990. The high failure rate of the Müller Type prosthesis might be linked to the curved form of the femoral stem.

Other prosthesis brands considered in this study were reported to have both higher and lower failure

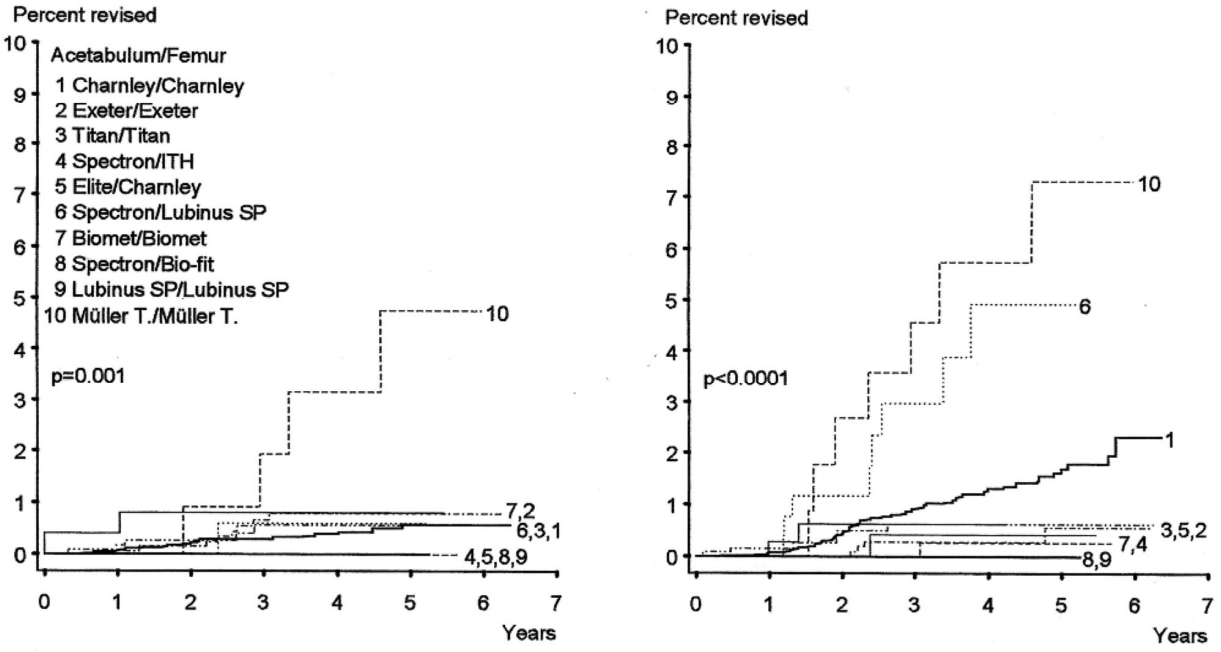

Figure 3. Kaplan-Meier estimated survival curves for prosthesis brands used in primary cemented total hip replacements in Norway 1987–1993 with aseptic loosening as the cause of revision. The p-value refers to a log-rank test of differences in survivorship among the prosthesis brands. Aseptic loosening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

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

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

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

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

The Charnley, Exeter, Lubinus SP and Müller Type prostheses have also been used in Sweden, where they were reported to a similar register. For these brands, the survival results could be compared in the two countries, and our results were similar to those in Sweden (Malchau et al. 1993).

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

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

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

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

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