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

A report from the Norwegian Arthroplasty Register

Leif I Havelin[1], Stein E Vollset[2] and Lars B Engesæter[1]

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

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

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

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

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

[1]Department of Orthopedics, Haukeland University Hospital, N-5021 Bergen, Norway, and [2]Section for Medical Informatics and Statistics, University of Bergen, Norway. Tel +47 55-298060. Fax -972761
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Uncemented total hip replacement (THR) has become the standard procedure in patients less than 60–65 years in many hospitals in Norway (Havelin et al. 1993). The nation-wide overall results of the uncemented THR from the period 1987–1992, however, have been shown to be inferior to those of cemented THR (Havelin et al. 1994). These poorer results could partly be explained by high revision rates of only a few of the uncemented femoral components (Havelin et al. 1995).

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

Patients and methods

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

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

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

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

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

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

Results

Table 1 shows the characteristics of the patients regarding each type of acetabular component. The design characteristics of the cups are given in Table 2, along with the characteristics of the femoral component associated with the different cups. In design, the European Jensen ST cup differed from the other metal-backed threaded cups because its central area over the dome was porous-coated. The Gemini and the HA-coated implants, Atoll and Tropic, had shorter median observation periods than the others (Table 3).

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

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

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

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

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

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

[a] The threaded European Jensen ST cup was porous-coated centrally over the dome.

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

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

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

We found no difference in the 5-year survival (p 0.78) for left- or right-sided cups.

From the patient characteristics given in Table 1 differences can be seen among the types. The patients with Endler, LMT and European cups were older than the others, whereas patients with the Harris/Galante cup were younger. The distribution of gender also varied; LMT was associated with the lowest percentage of men, and the PM cup with the highest. The Harris/Galante had a very low percentage of primary coxarthrosis patients compared to the other types. Cox analyses were therefore done to study the impact on the results of the risk factors: sex, age and diagnosis, and to estimate the relative rate of revision in the

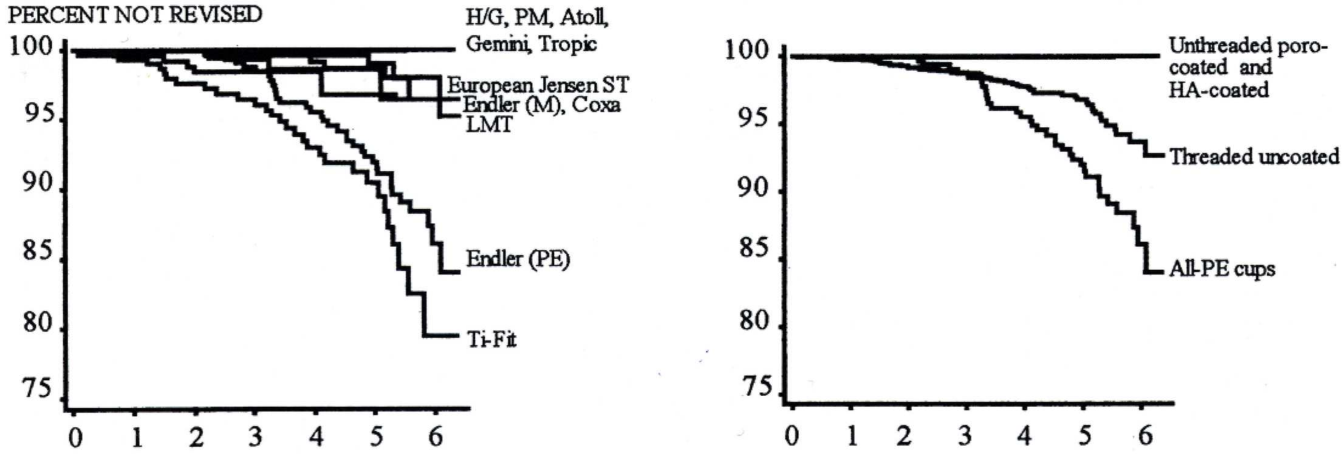

Figure 1. Prosthesis survival until revision for aseptic loosening of the cup. Total material of uncemented cups analyzed by type and by design characteristics.

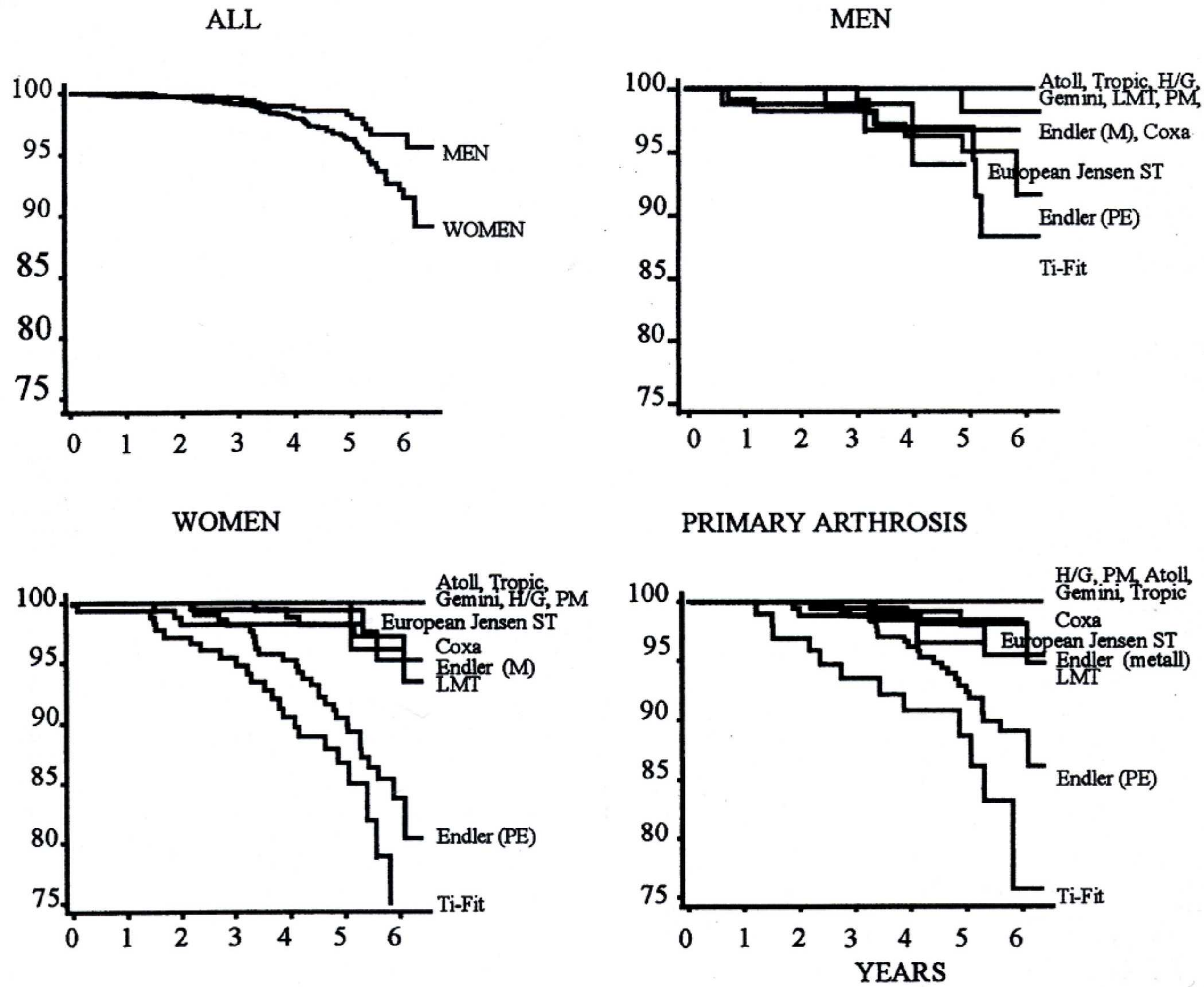

Figure 2. Prosthesis survival until revision for aseptic loosening of the cup, analyzed by gender in the total material, by type in the subgroup of all men (n 1,599), by type in the subgroup of all women (n 2,753), and analyzed by type in the subgroup of all patients with primary arthrosis (n 2,143).

groups, with adjustment for these risk factors (Table 4). The Cox analyses gave an increased adjusted failure rate of 1.8 (p 0.03) in women. The failure rates were not different in any of the age groups. Inflammatory arthritis had an increased relative rate of revision (p 0.03).

The most important risk factor was design (Table 4). With adjustments for gender, age and diagnosis,

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

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

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

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

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

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

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

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

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

Discussion

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

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

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

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

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

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

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