Metal-backed acetabular components with conventional polyethylene

A REVIEW OF 9113 PRIMARY COMPONENTS WITH A FOLLOW-UP OF 20 YEARS

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The Norwegian Arthroplasty Register has shown that several designs of uncemented femoral stems give good or excellent survivorship. The overall findings for uncemented total hip replacement however, have been disappointing because of poor results with the use of metal-backed acetabular components. In this study, we exclusively investigated the medium-to long-term performance of primary uncemented metal-backed acetabular components.

A total of 9113 primary uncemented acetabular components were implanted in 7937 patients between 1987 and 2007. These were included in a prospective, population-based observational study. All the implants were modular and metal-backed with ultra-high-molecular-weight polyethylene liners. The femoral heads were made of stainless steel, cobalt-chrome (CoCr) alloy or alumina ceramic. In all, seven different designs of acetabular component were evaluated by the Kaplan-Meier survivorship method and Cox regression analysis.

Most acetabular components performed well up to seven years. When the endpoint was revision of the acetabular component because of aseptic loosening, the survival ranged between 87% and 100% at ten years. However, when the endpoint was revision for any reason, the survival estimates were 81% to 92% for the same implants at ten years. Aseptic loosening, wear, osteolysis and dislocation were the main reasons for the relatively poor overall performance of the acetabular components. Prostheses with alumina heads performed slightly better than those with stainless steel or CoCr alloy in subgroups.

Whereas most acetabular components performed well at seven years, the survivorship declined with longer follow-up. Fixation was generally good. None of the metal-backed uncemented acetabular components with ultra-high-molecular-weight polyethylene liners in our study had satisfactory long-term results because of high rates of wear, osteolysis, aseptic loosening and dislocation.

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Earlier reports from the Norwegian Arthroplasty Register found that the results of uncemented total hip replacement (THR) have been relatively poor,[1,2] and the findings from other national registers were similar.[3,4] More recent reports from the Norwegian Arthroplasty Register[5] and from other sources,[6,7] however, have shown that contemporary uncemented femoral stems have, with some exceptions, performed well up to 15 years. However, metal-backed acetabular components have performed less well than cemented all-polyethylene designs in register reports.[8-10] In non-register reports, both threaded and press-fit designs of uncemented metal-backed acetabular components have had good results in some studies,[11-13] but a poorer outcome in others.[10,14-17] Favourable results with follow-up longer than ten years have been reported in only a few studies.[13,18,19] Wear of polyethylene and osteolysis have been the main problems in the medium and long-term in metal-backed acetabular components with standard ultra-high-molecular-weight polyethylene (UHMWPE) inserts.[20-22]

In this study we evaluated the performance of primary uncemented metal-backed acetabular components.

Patients and Methods

The Norwegian Association of Orthopaedic Surgeons founded the Norwegian Arthroplasty Register in 1987.[1] Patients gave their written consent to the collection of data, and individual data on nearly all hip and knee joint replacements were registered.[23] By 31 December 2007, a total of 110 991 primary THRs had been registered, of which uncemented acetabular components

Table I. Details of the patients grouped according to the type of implant

	Number of hips	Number of hospitals	Mean age (yrs)	% < 60 years	% males	Diagnosis (%)* OA	RA/ankylosing spondylitis	Sequelae after hip fracture	DDH	High DDH	Perthes only	Others†
Tropic	3417	31	59	*51*	*35*	*51.0*	*7.6*	*8.4*	*18.3*	*3.0*	*3.7*	*7.2*
Trilogy	1977	26	57	*60*	39	*56.0*	*3.6*	*5.1*	*16.7*	*4.0*	*4.9*	*8.9*
Igloo	414	12	69	*21*	*32*	*61.0*	*7.5*	*11.8*	*13.0*	*0.0*	*1.2*	*5.1*
Duraloc	902	20	54	*73*	*42*	*49.0*	*5.2*	*3.8*	*28.6*	*0.6*	*6.0*	*5.4*
Reflection	645	12	57	*60*	*42*	*58.0*	*3.6*	*5.6*	*20.2*	*2.0*	*6.7*	*3.7*
Atoll	1344	21	55	*64*	*39*	*44.0*	*7.6*	*7.7*	*19.4*	*6.8*	*4.7*	*8.6*
Gemini	414	10	53	*74*	*41*	*50.0*	*7.7*	*6.0*	*21.3*	*1.7*	*6.5*	*6.3*
Total	9113	56	58	*57*	*38*	*52.0*	*6.2*	*7.0*	*19.2*	*3.3*	*4.6*	*7.2*

* OA, osteoarthritis; RA, rheumatoid arthritis; DDH, sequelae of developmental dysplasia of the hip with normal hip centre; High DDH, sequelae of developmental dysplasia of the hip with a high hip centre

† includes avascular necrosis, acute fracture of the proximal femur

Table II. Details of the acetabular components

	Period	Number of hospitals	Femoral head material: Stainless steel	CoCr	Alumina	Femoral head (mm): 32/28/22/missing	Surface†	Polyethylene sterilisation‡	Company
Tropic	1988-*	31	1622	199	1596	1062/2307/40/8	Blasted, HA	a) or b) (1992 to 97)	DePuy
Trilogy	1994-*	26	588	378	1011	27/1491/453/6	PC fibre mesh	c)	Zimmer
Duraloc	1993 to 2006	20	173	371	358	70/659/172/1	PC (Porocoat)	a)	DePuy
Reflection	1995-*	12	24	242	379	0/637/8/0	PC (rough coat)	d)	Smith and Nephew
Atoll	1990 to 1999	21	723	19	602	387/951/4/2	Blasted, HA	a) or b) (1992 to 97)	DePuy
Gemini	1991 to 1995	10	71	343	0	0/301/111/2	PC	a) or b) (1992 to 95)	DePuy
Igloo	1998-*	12	5	84	325	25/382/5/2	HA	e)	Biotechni

* still used at the end of the study

† HA, hydroxyapatite; PC, porous coating

‡ a) gamma irradiation in air; b) beta irradiation in air; c) gamma irradiation in inert atmosphere (nitrogen); d) ethylene oxide; e) gamma irradiation in vacuum

were used in 19 255 (17%). Of these, 14 622 (76%) were all-uncemented THRs and 4492 (23%) were hybrids with cemented stems. A total of 66 different acetabular designs had been used in the study period. We included only modular metal-backed acetabular components with standard UHMWPE and femoral heads made of either stainless steel, CoCr alloy or alumina ceramic which had been used in 400 hips or more. These parameters identified seven different acetabular component designs implanted in 9113 hips in 7937 patients. Their details are shown in Table I.

The acetabular components included were the Tropic (DePuy, Warsaw, Indiana), the Trilogy (Zimmer, Warsaw, Indiana), the Duraloc (DePuy), the Reflection (Smith and Nephew, Memphis, Tennessee), the Atoll (Landanger, Chaumont, France), the Igloo (Biotechni, La Ciotat, France) and the Gemini (DePuy). All these components were modular with the metal-backing made of titanium alloy. The Tropic and Igloo components were threaded; the others were hemispherical and intended for press-fit and/or screw fixation. Other characteristics of the components, the materials used for the femoral head, its size and the number of hospitals using the implants are given in Table II. The sterilisation methods of the polyethylene liners varied among and within the groups during the study period.

Statistical analysis. The Kaplan-Meier method[24] was used to calculate survival probabilities with the 95% confidence interval (CI). The results were presented at seven, ten and 12 years. The survival analyses were terminated when less than 20 patients remained at risk. The reversed Kaplan-Meier method was used to calculate the median follow-up.[25] Cox multiple regression analyses[26] were used with adjustments made for age (stratified age groups below 40, 40 to 49, 50 to 59, 60 to 69, 79 to 79, and over 80 years), gender, diagnosis, the material and size of the femoral head. This allowed presentation of adjusted mean survival curves for study of covariates and the relative risk of revision among the implants. In order to evaluate the impact of differences in the length of follow-up, we performed Cox analyses with follow-up stratified into zero to seven and seven or more years. The Tropic (DePuy) acetabular implant was chosen as the reference device in the Cox analyses since this implant was the most frequently used. In the analyses, revi-

Table III. Kaplan-Meier survival (yrs; 95% confidence interval (CI)) and relative risk (RR; 95% CI) of acetabular revision from Cox analyses with adjustments for age and gender with the endpoint of aseptic loosening

			Survival (yrs, 95% CI)				
	Number	Number of revisions	7	10	12	RR	p-value
Tropic	3417	159	99 (99 to 99)	97 (96 to 98)	94 (93 to 95)	1 (reference component)	
Trilogy	1977	13	99 (99 to 100)	98 (98 to 99)	98 (98 to 99)	0.4 (0.3 to 1.0)	0.003
Igloo	414	0	100	*	*	No estimate	
Duraloc	902	4	100 (99 to 100)	100 (99 to 100)	100 (99 to 100)	0.1 (0.0 to 0.3)	< 0.001
Reflection	645	6	99 (98 to 100)	98 (95 to 100)	*	0.4 (0.2 to 0.9)	0.03
Atoll	1344	234	94 (93 to 96)	87 (85 to 89)	81 (79 to 83)	3.0 (2.4 to 3.7)	< 0.001
Gemini	414	17	100 (98 to 100)	98 (97 to 100)	97 (95 to 99)	0.3 (0.3 to 0.9)	0.008

* less than 20 hips at risk

sion of the acetabular component because of aseptic loosening and for any cause, were the primary endpoints. Sub-analyses with different endpoints such as acetabular revisions as a result of polyethylene-related failures and according to the material of the femoral head were also undertaken. The length of follow-up was from 0 to 20 years. Hips which had not been revised were censored at the end of the study on 31 December 2007. We used the statistical software packages SPSS Version 15.0 (SPSS Inc., Chicago, Illinois) and S-Plus version 7.0 (MathSoft Inc., Seattle, Washington). A p-value ≤ 0.05 was considered as statistically significant.

Results

The patients were fairly uniform in regard to age, gender and diagnoses (Table I), but because of the large number of hips, some differences among the study groups were statistically significant. This was exemplified in the Igloo (Biotechni) group in which the mean age was greater and there was a larger number of patients with osteoarthritis. When evaluated in the regression analyses however, the impact of these factors was minute.

With the endpoint for the survival analysis of aseptic loosening, most acetabular components performed well up to ten years with a survival of 97% to 100%. However, the grit-blasted and hydroxyapatite (HA)-coated Atoll (Landanger) acetabular component did less well than the others, and had a three times higher (95% CI 2.4 to 3.7) risk of revision because of aseptic loosening than that of the Tropic (DePuy) component which is a HA-coated, threaded implant. Among the other acetabular components there were some smaller differences (Table III, Fig. 1).

When the endpoint was revision of the acetabular component or liner for any cause, the results were poorer (Table IV, Fig. 2). At seven years, the overall survival of the acetabular component was 95% (95% CI 95 to 96), but decreased to 88% (95% CI 88 to 89) at ten and 83% (95% CI 82 to 84) at 12 years. We found differences among the acetabular components, and the contemporary components generally performed better than the earlier implants.

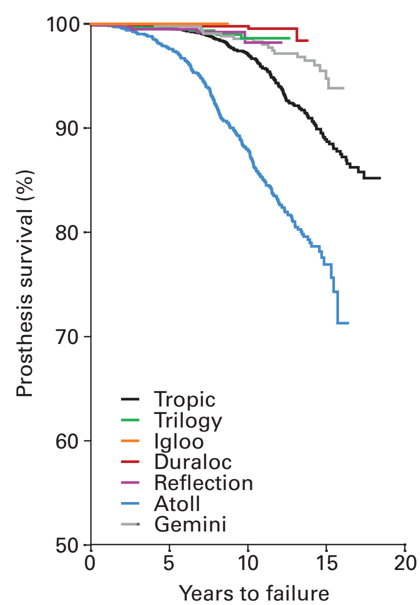

Fig. 1

Survival curves (Cox) adjusted for age and gender with the endpoint as revision of the acetabular component for aseptic loosening.

The most common reasons for revision of the acetabular components with the longest follow-up time (Tropic, Atoll, Gemini, Duraloc) were wear of the polyethylene and acetabular osteolysis in well-fixed metal shells. The acetabular components with a shorter follow-up (Reflection, Trilogy, Igloo) were revised most often because of dislocation, infection or aseptic loosening (Table IV). The times when the various causes for revision occurred are shown in Figure 3.

When grouping the hips according to the material of the femoral head we found smaller yet statistically significant differences. Adjustments were made for age, gender, diagnosis and brand of component. Alumina heads performed better than those made of stainless steel and CoCr alloy. The relative risks for revision of the acetabular component

Table IV. Kaplan-Meier survival (years; 95% confidence interval (CI)) and relative risk (95% CI) of revision of the acetabular component from Cox analyses with adjustments for age and gender and the endpoint of revision for any reason with the frequency of the different causes of revision

				Survival (yrs; 95% CI)					Reasons for revision† (number of revision cases)				
	Number	Number of revisions	Median follow-up (yrs)	7	10	12	Relative risk	p-value	Aseptic loosening	Dislocation	Infection	PE‡ wear	Osteolysis
Tropic	3417	452	10.0	96 (95 to 96)	90 (88 to 91)	84 (82 to 86)	1 (ref)		159	56	22	141	48
Trilogy	1977	75	5.6	96 (95 to 97)	92 (90 to 94)	90 (86 to 93)	0.7 (0.5 to 0.9)	0.007	13	27	9	6	3
Igloo	414	6	5.6	98 (96 to 100)	*	*	0.3 (0.1 to 0.9)	0.028	0	1	2	0	1
Duraloc	902	65	8.9	96 (94 to 97)	92 (90 to 94)	88 (85 to 91)	0.6 (0.5 to 0.9)	0.003	4	16	7	16	10
Reflection	645	31	7.5	96 (94 to 98)	93 (90 to 95)	*	0.6 (0.4 to 1.0)	0.033	6	9	3	5	1
Atoll	1343	335	12.6	91 (89 to 92)	81 (79 to 83)	74 (72 to 77)	1.6 (1.4 to 1.8)	< 0.001	234	25	9	51	21
Gemini	414	111	14.7	92 (89 to 94)	85 (82 to 89)	78 (74 to 82)	1.2 (1.0 to 1.5)	0.096	17	22	3	40	25

* less than 20 hips at risk
† more than one reason is possible for each revision
‡ PE, polyethylene

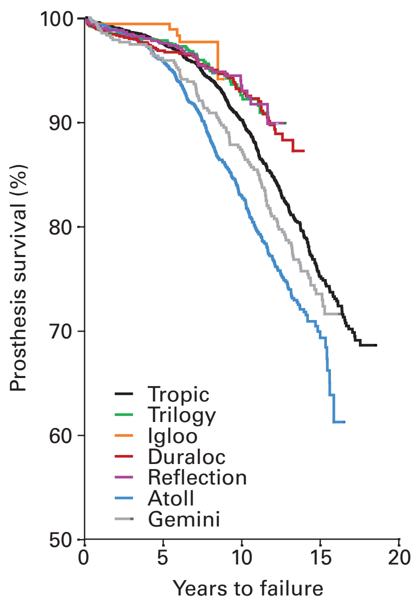

Fig. 2

Survival curves (Cox) adjusted for age and gender with the endpoint as revision of the acetabular component or liner for any reason.

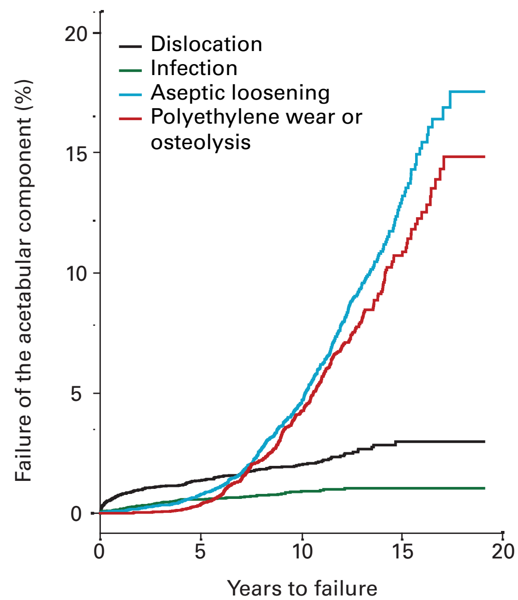

Fig. 3

Graph showing the frequency of different reasons for revision of the acetabular component according to time.

for the latter two compared with that of alumina were 1.9 (95% CI 1.6 to 2.2) and 1.8 (95% CI 1.4 to 2.3) respectively (Fig. 4).

Discussion

We found that the fixation of most of the acetabular components investigated was good or excellent. However, revision of the acetabular component or liner for reasons other than aseptic loosening suppressed medium-term performance. Thus, the overall performance of these uncemented metal-backed acetabular components with UHMWPE liners was unsatisfactory. Most acetabular components performed well up to seven years, but the revision rate increased afterwards. The main causes for this were wear of polyethylene, aseptic loosening of the acetabular component and acetabular osteolysis. We hope that the current wear-resistant articulations in use will give an improved outcome. Highly cross-linked polyethylenes (XLPE) have been shown to reduce the rate of penetration of the femoral head into the polyethylene in short- and medium-term studies and offer encouraging clinical results.[27-32] The problems of polyethylene wear encountered in our study may be addressed by the use of XLPE inserts, which in the presence of durable bony fixation could offer an extremely

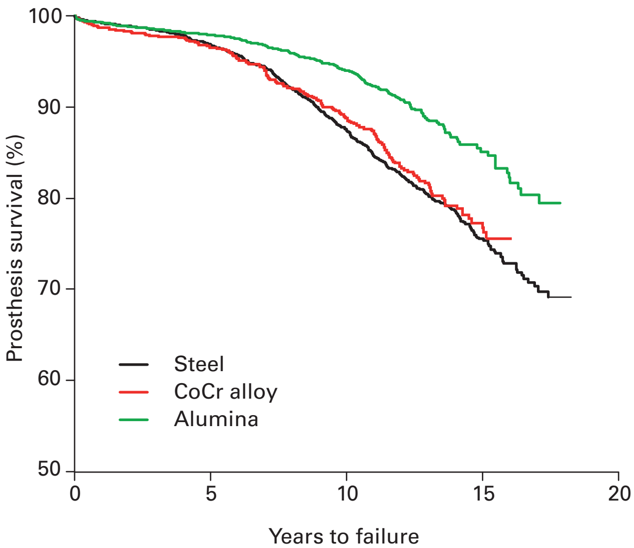

Fig. 4

Survival curves (Cox) of the hips groups according to the material of the femoral head adjusted for age, gender, diagnosis and of acetabular component brand and with the endpoint as revision of the acetabular component for any reason.

good reconstruction. However, the follow-up available for modern XLPE is not yet sufficient to evaluate fully its effect on osteolysis and long-term performance.

It is known that polyethylene wear is influenced by the method of sterilisation.[33] In our study, these differed according to the type of component and the time of production. Irradiation in air is no longer used because of oxidation of the polyethylene which provides resistance to wear. Contemporary sterilisation methods offer the potential for improved survivorship of the prosthesis.

We have no quantitative data on wear rates for our patients. Some studies indicate that the rate of polyethylene wear is higher in metal-backed uncemented components than in cemented implants.[34,35] Several factors may contribute to this, including backside wear, the reduced thickness of the polyethylene, and higher stresses on the polyethylene because of the stiffer construct. All these factors relate to the metal backing of the implants rather than because they are uncemented.

Our study is a population-based prospective observational study of a large number of hips registered with the Norwegian Arthroplasty Register which has a high level of compliance.[23] The results therefore represent a national mean and should be achievable by the average surgeon.

Some of the implants were used in relatively large numbers, in many hospitals and in a reasonably high annual volume, while others were used in smaller numbers and in only a few hospitals. With an increasing number of observations, the power to detect small differences between study groups increases. Because of the high numbers investigated in our study relatively discrete differences between the acetabular components were statistically significant. However, the study was not a randomised trial, but an observational study. Therefore, small differences should be interpreted with caution since variables other than the implants themselves may have biased the results. Among the possible confounders were the skill of the surgeon, the revision threshold, the waiting time for revision and follow-up routines. Details of the operative technique and whether the acetabular component was fixed by press-fit or screws or both were not taken into account. Radiological and clinical evaluation were not performed. Accordingly, smaller differences found in our study, although statistically significant, should not dictate clinical practice.

The acetabular components used were quite dissimilar, and the somewhat poor results in terms of bony fixation for a few designs should not distract from the finding that most of the included components had excellent fixation. Moreover, the acetabular components with the poorest results are no longer used in Norway.

Newer articulations such as metal-on-metal, ceramic-on-ceramic, and XLPEs were not included in our study to avoid introducing a confounding variable and because of the short follow-up of these articulations. These materials will be analysed in the future.

Late loosening of the acetabular component was most often seen with the smooth HA-coated implants (Atoll and Tropic). Loosening was seen less often with porous-coated implants. Our findings support the view that the metal-backed acetabular component should have a rough outer surface to allow secure secondary bony fixation, as found with most contemporary implants. HA may be released from the implant surface with time. Therefore the substrate should allow bony interlocking between the host bone and surface of the implant. Grit-blasting alone may not be able to provide this type of interlocking.[8,36] Acetabular components with a porous-coated metal surface beneath the HA coating have been used for some time. The primary fixation seems to be excellent,[36] but the long-term performance of this double coating is not yet well documented. According to our survival data, porous coating alone may be adequate without the need for the HA coating to obtain secure fixation.

A large proportion of the revisions performed in our study were liner-exchange procedures, with or without concomitant grafting of the osteolytic lesions of the acetabulum or femur. In some studies the complication rates after these procedures have been high,[37,38] with recent data from the register suggesting that the results after isolated liner exchanges are worse than those after exchanges of the whole acetabular component.[39] In our opinion, a liner exchange should be considered as a failure of the acetabular component implant. We believe that survival analysis with revision for any cause as the endpoint reflects more adequately the outcome than that with revision for aseptic loosening as the endpoint.

Polyethylene wear and wear-related osteolysis generally appear after several years of clinical success. In our study, the reason for revision of the components with the longest follow-up (Atoll, Gemini, Tropic, Duraloc) was wear or osteolysis (without loosening) in about 30% to 40% of cases (Table III). Those with a shorter follow-up (Reflection, Trilogy, Igloo) were more often revised because of early complications such as infection and dislocation. The time-dependent frequencies of the different causes of revision are shown in Figure 3. It is hoped that those designs with the shortest follow-up will perform better than the older implants with regard to the later complications of wear, osteolysis and loosening.

We conclude that the metal-backed uncemented acetabular components in our study generally performed well with regard to fixation. When the endpoint was revision of the acetabular component for any reason the results were poorer, primarily due to UHMWPE wear and osteolysis. Components in current use generally performed better than the earlier implants. Alumina femoral heads performed slightly better than heads made of stainless steel or CoCr alloy in subgroups. The modular metal-backed acetabular components with UHMWPE liners performed unsatisfactorily. It is hoped that the newer bearing surfaces will perform better.

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