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Head Material Influences Survival of a Cemented Total Hip Prosthesis in the Norwegian Arthroplasty Register

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Abstract

Background High prosthesis survival is reported for total hip prostheses with metal and alumina heads, but direct comparisons of a single prosthesis design with one of two different head materials has seldom been studied. Prostheses with zirconia heads are less commonly used than metal and alumina heads, and the few reports suggest variable results with zirconia heads.

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L. I. Havelin (🖂) Department of Surgical Sciences, University of Bergen, Bergen, Norway e-mail: livh@helse-bergen.no; leif.havelin@helse.bergen.no *Questions/Purposes* We therefore asked: (1) Would metal heads provide better survival of a cemented total hip arthroplasty (THA) than alumina heads? (2) Would metal heads provide better survival of a cemented THA than zirconia heads?

Methods We searched in the Norwegian Arthroplasty Register for cemented primary THA cup/stem combinations that simultaneously had been used with different head materials. The only THA that fulfilled these inclusion criteria was the cemented Reflection All-Poly/ Spectron EF (cup/stem) that had during 2001 to 2006 been used both with alumina (n = 448) and cobaltchromium (n = 5229) heads; that implant had also been used with zirconia (n = 275) and cobalt-chromium heads (n = 3195) during 1997 to 2003, and we included patients with this THA from these two time intervals in the study. All cups were conventional polyethylene. We estimated prosthesis survival and relative revision risks adjusting for age, sex, and diagnosis. The followup in the two study materials was until December 2010.

Results The survival at 8 years of the Spectron EF/ Reflection THAs, inserted with alumina and cobaltchromium heads during 2001 to 2006, was 92.3% and 94.0%, respectively. The Reflection/Spectron EF THA had inferior survival with zirconia heads compared with cobaltchromium heads (relative risk, 1.7). At 12 years, the survival rate was 88.1% with cobalt-chromium heads and 74.8% with zirconia heads.

Conclusions Alumina femoral heads provided no advantage over cobalt-chromium heads on midterm prosthesis survival. THAs with zirconia heads had inferior survival. *Level of Evidence* Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Wear debris-induced osteolysis and loosening has in the course of time been recognized as major reasons for failure and revision in THA [15]. To reduce wear debris-induced osteolysis and loosening, alternative femoral head materials made of ceramics such as alumina and zirconia were introduced and refined to improve the longevity of THA. Nonetheless, the primary long-term problem of cemented THA remains aseptic loosening as shown in a previous study from our register [8].

The problems with polyethylene wear have been addressed by the introduction of highly crosslinked polyethylene cups (HXLPEs). However, the long-term survival of implants with this increasingly used material is not known [2, 7, 22, 28].

Ceramic femoral heads, eg, alumina (Al₂O₃/aluminium oxide) and zirconia (ZrO₂/zirconium oxide), were introduced with the belief that PE wear would be reduced with these heads compared with metal femoral heads. Ceramic femoral heads might be smoother and more scratch-resistant than metal heads. However, ceramics are brittle and susceptible to fracture [1, 29]. According to previous studies from the Norwegian Arthroplasty Register (NAR) on uncemented metal-backed acetabular components, certain prosthesis brands had higher survival with alumina ceramic femoral heads than with heads made of stainless steel or cobalt-chromium (CoCr) [13, 17]. However, it remains unclear whether ceramic heads in general provide better long-term survival than metal heads in THAs with conventional cemented all-poly UHMWPE sockets.

We therefore determined: (1) if survival of cemented THAs with metal heads would be higher than survival of the same THAs with alumina heads; and (2) if survival of a cemented prosthesis with metal heads would be higher than with zirconia femoral heads.

Patients and Methods

The NAR was founded in 1987 [16]. Patients give their written consent to the collection of data and the arthroplasty register receives data on almost all hip arthroplasties [9]. By December 31, 2010, the register contained information on 132,000 cases of THA. To exclude other time-dependent factors that could affect the outcome, we searched in the register for cemented THAs (cup/stem combinations) that had been used with at least two different head materials simultaneously. As a result of short followup and small numbers in our registry of sockets made of HXLPE, we included only sockets made of conventional PE. Using these inclusion criteria, we identified

only one cup/stem combination, the all-polyethylene Reflection socket in combination with the Spectron EF stem (Smith & Nephew, Memphis, TN, USA) with sufficient numbers, and only patients with this cup/stem combination were included in the study. The Reflection/ Spectron EF THA had been used with CoCr (Smith & Nephew) heads continuously since 1997. However, during 1997 to 2003, Richards Zirconia heads (Smith & Nephew) (n = 275) were also used, and we therefore included these in the study to be compared with Reflection/Spectron EF THAs with CoCr heads (n = 3195) from the same time interval. Similarly, Biolox alumina (Smith & Nephew) (n = 448) heads had been used during 2001 to 2006 and THAs with these heads were included to be compared with Reflection/Spectron EF prostheses with CoCr heads (n = 5229) from the same time period.

The Spectron EF stem is made of CoCr, and it is a distally satin, proximally roughened, collared tapered stem relying on the composite-beam fixation model [26]. It has a Ra of 2.8 μ m on the proximal one-third and a Ra of 0.7 μ m on the distal two-thirds of the stem. The cemented Reflection All-Poly UHMWPE cup (Smith & Nephew) is not irradiated but sterilized by EtO. The patients receiving zirconia heads were an average 10 years younger than patients receiving other femoral heads (Table 1). The majority of patients received 28-mm femoral heads.

The Kaplan-Meier method was used to calculate survival probabilities. The survival percentages were presented at 3, 5, and 8 years. For the material of Reflection/Spectron EF prostheses with zirconia and CoCr heads from 1997 to 2003, 12-year survival was also assessed. Survival percentages were not presented when fewer than 20 hips remained at risk. Cox regression analyses were used with adjustment for age (stratified age groups < 50, 50-60, 60-70, 70-80, and > 80 years), sex, and diagnosis (osteoarthritis, rheumatoid arthritis/inflammatory disease, other) to make adjusted survival curves at a mean of covariates and to present the relative risk of revision among the different femoral head materials. In a Cox analysis on a subgroup of patients younger than 65 years of age, we adjusted for sex, diagnoses, and the age groups < 50, 50 to 60, and 60 to 65 years. We censored the survival times of patients who had died or emigrated without revision surgery at the time of death or emigration. Hips, which had not been revised at the end of the study on December 31, 2010, were censored at that date. We chose the most frequently used head material in each time period as the reference in the Cox analyses. Different end points were used in the survival analyses such as revision for any cause and revision because of aseptic loosening of the stem or the cup. For all analyses, we used the statistical software package SPSS Version 17.0 (SPSS Inc, Chicago, IL, USA).

Fable 1 .	Details of th	Table 1. Details of the patients grouped according to type of implant	cording to type of ir	nplant								
Type of	Type of Period	Femoral	Femoral head	Number	Median	Mean age	Percent	Percent	Median Mean age Percent Percent Approach ⁺ A/AL/L/P/O/M Diagnosis	Diagno	osis	
implant		head material	size (mm) 32/28/22/missing	of hospitals followup (years) (years)	followup (years)		< 60 years males	males		OA	OA RA/inflamatory [‡] Others	Others
S/R*	2001-2006	2001–2006 CoCr (n = 5232)	397/4821/4/9	25	6.2	73	6	27	3/498/2305/2377/7/42	4148 111	111	973
		Alumina $(n = 448)$ 0/446/0/1	0/446/0/1	8	6.3	74	5	30	0/5/433/8/0/2	369	5	74
S/R*	1997-2003	1997–2003 CoCr ($n = 3195$)	49/3135/2/9	19	7.9	73	6	26	4/190/1750/1242/1/8	2457	76	662
		Zirconia (n = 275) 0/273/2/0	0/273/2/0	6	10.1	63	31	35	0/11/238/25/0/1	189	4	82
* Spectr spondyli	on EF/ Reflec tis, psoriatic a	* Spectron EF/ Reflection All-Poly; ^{\dagger} Approach: A = anterior, AL = anterolateral, L = lateral, P = spondylitis, psoriatic arthritis, sclerodermitis, systemic lupus erythematosus; CoCr = cobalt-chromium.	ach: A = anterior, systemic lupus ery	AL = anterols thematosus; C	ateral, L = oCr = coba	lateral, P = lt-chromium	posterolatera 	1, 0 = ot	AL = anterolateral, L = lateral, P = posterolateral, O = other, M = missing; [‡] including rheumatoid arthritis, ankylosing thematosus; CoCr = cobalt-chromium.	g rheum	atoid arthritis, anl	cylosin

Results

The survival rate of the Spectron EF/Reflection THAs with any revision as the end point was not affected (p = 0.84) by the choice of alumina or CoCr heads (Fig. 1). At 8 years, the survival rates with alumina and CoCr were 92.3% and 94.0%, respectively (Table 2). The most common reason for revision was aseptic cup loosening (Table 3). When the end point was revision for aseptic cup loosening, prostheses with alumina heads had higher risk (relative risk, 2.4; p = 0.003) of revision compared with prostheses with CoCr heads (Table 4), but the difference in survival between alumina and CoCr was only 4% at 8 years (Fig. 2). With revision resulting from aseptic stem loosening as the end point, the risk of revision of the Spectron EF stem was increased 2.4 times (p = 0.009)when used with an alumina head compared with a CoCr head, although the difference in stem survival at 8 years was only 3%. In our material, no revisions were caused by fracture of the femoral head.

The Spectron EF/Reflection THAs had close to double the risk (relative risk, 1.7; p = 0.002) of any revision when used with zirconia heads compared with CoCr heads (Fig. 3). At 12 years, the survival rate was 88.1% with CoCr heads and 74.8% with zirconia heads (Table 2). When we limited the analyses to include only patients younger than 65 years, we found the risk for revision was greater for THAs with zirconia heads (relative risk, 1.6;

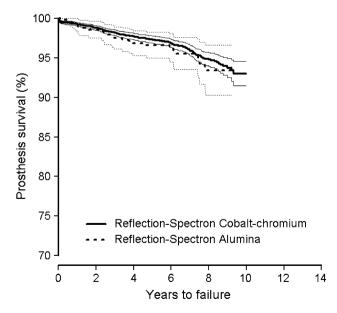


Fig. 1 Survival curves (Cox) are shown of Spectron EF/Reflection THAs according to femoral head material (CoCr or alumina) adjusted for age, sex, and diagnosis with any revision as the end point. The survival with this end point was not affected by the choice of alumina or CoCr heads. Prosthesis survival with alumina and CoCr heads at 8 years was 94% and 92% (p = 0.84), respectively.

Type of	Number	Number of	Survival (year	rs; 95% CI)			Relative risk	p value
implant		revisions	3	5	8	12	(95% CI)	
S/R								
CoCr	5232	219	98 (98–99)	97 (97–98)	94 (93–95)		1 (reference)	
Alumina	448	22	97 (96–99)	96 (95–98)	92 (87–96)		1.2 (0.8–1.9)	0.84
S/R								
CoCr	3195	178		98 (97–98)	95 (94–96)	88 (86–91)	1 (reference)	
Zirconia	275	55		97 (95–99)	87 (83–91)	75 (68-81)	1.7 (1.2–2.3)	0.002

Table 2. Kaplan-Meier survival (years; 95% CI) and relative risk of revision from Cox analyses with adjustments for age, sex, and diagnosis with the end point of any revision

CoCr = cobalt-chromium.

Table 3. Number (percent of revisions) of different reasons for revision by prosthesis/head material combination*

Type of	Number	Number	Loose cu	р	Loose ste	em	Dislocation	on	Infection		Other [†]	
implant	of THAs	of revisions	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
R/S												
CoCr	5232	219	73	33	58	26	72	33	36	16	41	19
Alumina	448	22	14	63	12	55	4	18	3	14	2	9
R/S												
CoCr	3195	178	92	51	70	39	44	25	13	7	22	12
Zirconia	275	55	49	89	22	40	2	4	1	2	11	20

* More than one reason is possible for each revision; [†]other includes fracture, pain, osteolysis cup without loosening, osteolysis femur without loosening, and other reasons; CoCr = cobalt-chromium.

Table 4. Kaplan-Meier survival (years; 95% CI) and relative risk from Cox analyses with adjustment for age, sex, and diagnosis with the end points revision resulting from aseptic loosening of the cup or stem

Type of implant	Number	Number of cup	Survival cup (years; 95%		Relative risk (95% CI)	Number of stem revisions	Survival stem (years; 95% CI)		Relative risk (95% CI) value
		revisions	8	12	p value		8	12	
S/R									
CoCr	5232	63	98 (97–98)		1 (reference)	55	98 (98–99)		1 (reference)
Alumina	448	13	94 (91–98)		2.4 (1.4–4.5) 0.003	11	95 (92–98)		2.4 (1.2–4.6) 0.009
S/R									
CoCr	3195	90	98 (94–96)	92 (86–91)	1(reference)	67	98 (98–99)	94 (92–97)	1 (reference)
Zirconia	275	49	89 (83–91)	77 (68–81)	2.5(1.7–3.6) < 0.001	22	95 (92–98)	89 (84–94)	1.6 (1.0–2.7) 0.07

CoCr = cobalt-chromium.

p = 0.02) compared with THAs with CoCr heads. When performing the analysis in a subgroup with only 28-mm femoral heads, we found an increased risk for revision (relative risk, 1.7; p = 0.002) with zirconia heads. Different sizes of the CoCr femoral heads (32 mm versus 28 mm) did not influence the survival. When the end point was revision for aseptic cup loosening, prostheses with zirconia femoral heads had more than twice the risk (relative risk, 2.4; p = 0.003) of revision compared with prostheses with CoCr heads (Table 4), and the difference in survival was 9% at 8 years and 15% at 12 years (Fig. 4).

Discussion

Because it remains unclear whether ceramic heads provide better long-term survival than metal heads in THA, and many different ceramics and metal alloys are used, we asked

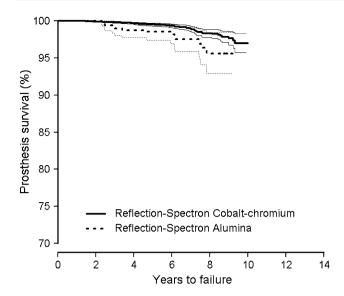


Fig. 2 With aseptic cup loosening as the end point, survival curves (Cox) are shown of Spectron EF/Reflection THAs according to femoral head material (CoCr or alumina) adjusted for age, sex, and diagnosis. Prosthesis survival with alumina and CoCr heads at 8 years was 94% and 98% (p = 0.003), respectively.



Fig. 3 Survival curves (Cox) are shown of Spectron EF/Reflection THAs according to femoral head material (CoCr or zirconia) adjusted for age, sex, and diagnosis with any revision as the end point. Prosthesis survival with zirconia heads was inferior to the survival with CoCr heads. At 12 years, the survival rates were 88% and 75% (p = 0.002) with CoCr and zirconia heads, respectively.

(1) if the survival of cemented THAs with metal heads would be superior to the survival with alumina heads; and(2) if survival of a cemented prosthesis with metal heads would be higher than with zirconia femoral heads.

Our study is subject to certain limitations. First, small differences in a register study, although statistically



Fig. 4 With aseptic cup loosening as the end point, survival curves (Cox) are shown of Spectron EF/Reflection THAs according to femoral head material (CoCr or zirconia) adjusted for age, sex, and diagnosis. Prosthesis survival with zirconia heads was inferior to the survival with CoCr heads. At 12 years, the survival was 92% and 75% (p = 0.003) with CoCr and zirconia heads, respectively.

significant, must be interpreted with caution, especially when the numbers of revisions are small, because variables such as patient activity, skill of the surgeon, and indication for revision surgery usually cannot be controlled for and may introduce bias. However, register studies may also have strengths, because the numbers of patients usually are higher than in other study models, and the results represent a national mean. Second, we do not know to what degree the heads and the THA in our study are representative and if our results can be generalized. The cemented All-Poly Reflection cup, made of EtO-sterilized conventional PE, reportedly has greater wear and higher loosening rates than some other cemented conventional all-PE cups [8]. The cemented Spectron EF stem was reported from a radiostereometric analysis study to have better stability at 2 years than the Charnley stem with retroversion of 2.3° and 0.7° and a posterior translation of 0.44 mm and 0.17 mm, respectively, for the Charnley and the Spectron EF stems [19]. However, it is reported that if the Spectron EF stem with time debonds, it might, as a result of its rough surface, be a source of abrasive wear particles from the stem/cement interface [6, 10, 12]. This may subsequently lead to third-body wear that could damage the femoral heads or PE. However, ceramic femoral heads have greater scratch resistance than metal heads [4, 23]. For these reasons, the cemented Reflection/Spectron EF combination might be more vulnerable than some other THAs, and potential differences could theoretically show earlier and be larger. Also for the heads in the present study, it might be uncertain if the results can be generalized because it has been reported that the monoclinic phase transformation seen on yttria-stabilized zirconia heads was not found on magnesia-stabilized zirconia [25], that different brands of zirconia might behave differently [24, 30], and that prostheses with heads with old versions of alumina had lower survival compared with current alumina [21]. Furthermore, wear results of zirconia heads compared with CoCr heads vary [27].

The answer to our first question was that the cemented Reflection All-Poly/Spectron EF THA with alumina heads had similar survival as the same THA with CoCr heads when any revision was the end point. We found no studies on survival of cemented conventional THAs comparing survival with CoCr and alumina heads. The finding of a higher risk for revision resulting from aseptic loosening with alumina heads than with CoCr heads is inconsistent with reports on higher survival for certain uncemented prosthesis brands with alumina compared with metal heads [13, 17]. One radiostereometry study reported approximately 50% wear reduction with alumina heads compared with CoCr heads after 10 years followup of THAs with conventional PE cups [5]. The finding of increased revision resulting from aseptic loosening of THAs with alumina heads must be interpreted with caution because the number of THAs with alumina heads was relatively small, the difference in revision at 8 years was only 4%, the confidence intervals on the survival curves were overlapping, and the numbers of revised cups and stems in the alumina group were only 13 and 11, respectively.

Our second answer was that with zirconia heads, the risk for revision of cemented Spectron EF/Reflection All-Poly THAs was close to double compared with CoCr heads. Zirconia was introduced as a more fracture-resistant alternative to alumina femoral heads [3], and it was argued that the wear characteristics were the same as for alumina. However, with time zirconia may deteriorate with increased surface roughness as a result of phase transformation [14, 18]. Hernigou and Bahrami [18] reported increased wear with yttria-stabilized zirconia heads, and one systematic review with a meta-analysis suggested THAs with zirconia on PE had more revision surgery than nonzirconia on PE [30]. These reports are consistent with our findings. Further developments of ceramics, based partly on zirconia, have been introduced in arthroplasty. Biolox Delta (CeramTec, Plochingen, Germany) is a zirconia-toughened alumina composite that was developed to increase the fracture resistance of alumina. Oxinium (oxidized zirconium; Smith & Nephew) has a metal zirconium core and a thin zirconia ceramic surface. This material is reportedly advantageous regarding wear, scratch resistance, and fracture toughness in vitro [11]. However, in a randomized radiostereometric study, the cemented Spectron EF/Reflection All-Poly THAs with Oxinium heads had practically the same wear at 2 years as with CoCr heads with maximum total point motions of 0.44 and 0.40 mm, respectively [20]. Compared with metal heads, most ceramic heads have some disadvantages: higher cost, reduced neck-length options, and a risk of head fracture. We believe long-term followup in clinical trials, preferably large randomized studies, is essential before widespread clinical use of new materials can be supported.

When we asked if a cemented THA with metal heads would have better survival than with alumina heads, we found no overall difference. Our study has limitations by being a register study, but we found no reports in the literature of better survival of cemented THAs with one of these two heads compared with the other. Our finding of more revisions resulting from aseptic loosening for prostheses with alumina heads must be interpreted with caution as a result of the small difference in survival, the small numbers of revisions, and the lack of similar findings in the literature. Our second finding of inferior survival for THAs with zirconia heads compared with CoCr heads we consider solid. The limitations of the study model are still valid, but here the difference in survival at 12 years was 13%, the numbers of revisions were larger, and this finding was similar both with revision for any reason and revision resulting from aseptic loosening as end point. The finding of inferior results with zirconia heads seems to be consistent with the literature.

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