Wear and Migration of Highly Cross-Linked and Conventional Cemented Polyethylene Cups with Cobalt Chrome or Oxinium Femoral Heads: A Randomized Radiostereometric Study of 150 Patients

Thomas Kadar,^{1,2} Geir Hallan,¹ Arild Aamodt,^{3,4} Kari Indrekvam,^{2,5} Mona Badawy,⁵ Arne Skredderstuen,¹ Leif Ivar Havelin,^{1,2} Terje Stokke,⁶ Kristin Haugan,³ Birgitte Espehaug,¹ Ove Furnes^{1,2}

¹Department of Orthopaedic Surgery, Haukeland University Hospital, N-5021 Bergen, Norway, ²Department of Surgical Science, University of Bergen, N-5021 Bergen, Norway, ³Department of Orthopaedic Surgery, Trondheim University Hospital, N-7006 Trondheim, Norway, ⁴Department of Neuroscience, Norwegian University of Science and Technology, N-7489 Trondheim, Norway, ⁵Hagevik Hospital, Haukeland University Hospital, N-5217 Hagavik, Norway, ⁶Department of Radiology, Haukeland University Hospital, N-5021 Bergen, Norway

Received 21 May 2010; accepted 25 January 2011

Published online in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.21389

ABSTRACT: This randomized study was performed to compare wear and migration of five different cemented total hip joint articulations in 150 patients. The patients received either a Charnley femoral stem with a 22.2 mm head or a Spectron EF femoral stem with a 28 mm head. The Charnley articulated with a γ -sterilized Charnley Ogee acetabular cup. The Spectron EF was used with either EtO-sterilized non-cross-linked polyethylene (Reflection All-Poly) or highly cross-linked (Reflection All-Poly XLPE) cups, combined with either cobalt chrome (CoCr) or Oxinium femoral heads. The patients were followed with repeated RSA measurements for 2 years. After 2 years, the EtO-sterilized non-cross-linked Reflection All-Poly cups had more than four times higher proximal penetration than its highly cross-linked counterpart. Use of Oxinium femoral heads did not affect penetration at 2 years compared to heads made of CoCr. Further follow-up is needed to evaluate the benefits, if any, of Oxinium femoral heads in the clinical setting. The Charnley Ogee was not outperformed by the more recently introduced implants in our study. We conclude that this prostheses still represents a standard against which new implants can be measured. © 2011 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

Keywords: highly cross-linked polyethylene; Oxinium; Charnley Ogee; radiostereometric analysis

Osteolysis induced by wear debris of ultra-high molecular weight polyethylene (UHMWPE) is considered the most common cause for failure of total hip arthroplasties (THA).¹ Sterilization technique and UHMWPE quality are related to wear.² Sterilization with gamma irradiation in air breaks the polymer chains and generates free radicals. Free radicals may combine with each other creating cross-links between adjacent molecules, which reduces abrasive wear. However, they entail the disadvantage of oxidative degradation of polyethylene (PE) when exposed to the body's oxidative environment, which may lead to deterioration of mechanical properties.³ To address the problem, sterilization methods in inert environments with ethylene oxide (EtO) or gas plasma were introduced. However, these methods do not have the benefits of cross-linking, and an earlier report showed increase in early in vivo wear after EtO sterilization.⁴

Highly cross-linked polyethylenes (HXLPE) provides a considerable reduction of wear compared to conventional polyethylene (PE).^{5,6} The common denominator of HXLPEs is an increased cross-linking by high dosage irradiation, and the reduction of oxidative degradation by eliminating the free radicals through thermal stabilization. The Reflection XLPE liner (Smith & Nephew, Memphis, TN) used in cementless THA has shown promising results in vitro⁷ and in vivo.⁸ The cemented version of this implant is the Reflection All-Poly XLPE cup. To our knowledge, no clinical studies exist on this implant.

Concerns of PE wear have also been addressed by introducing alternative femoral head materials. Oxidized zirconium (Oxinium, Smith & Nephew) was introduced in the last decade for use in THA.⁷ Oxinium has a metal core and an approximately 5 μ m thick zirconia ceramic surface. During the manufacturing process, heating causes oxygen to diffuse into the metallic zirconium alloy, thereby, transforming the original metal surface into zirconia. Laboratory tests of Oxinium femoral heads showed less risk of fracture than traditional ceramic heads and superior scratch resistance over metal heads.^{7,9} No randomized clinical studies exist evaluating its effect on PE wear in THA.

Radiostereometric analysis (RSA) enables in vivo measurement of relative 3D motion in the range of 0.1 mm and 0.05°. Due to its accuracy, few patients are needed to obtain satisfactory statistical power. With RSA the degree of migration during the first years after surgery correlates with the implant's longterm performance. We wanted to evaluate wear and migration patterns of the cemented highly cross-linked Reflection All-Poly XLPE cup and its non-irradiated counterpart, the cemented Reflection All-Poly cup, when articulating with either Oxinium or traditional cobalt chrome (CoCr) femoral heads (Smith & Nephew). Our null hypothesis was that wear and migration were equal to the Charnley Ogee prostheses (DePuy Intl.

Correspondence to: Thomas Kadar (T: +47-55978126; F: +47-55973749; E-mail: tkad@helse-bergen.no)

^{© 2011} Orthopaedic Research Society. Published by Wiley Periodicals, Inc.

Ltd, Leeds, United Kingdom), which is regarded by many as the gold standard for THA.¹⁰ The present study was an approach to a stepwise introduction of new implants used in THA.¹¹

MATERIALS AND METHODS

This prospective randomized controlled trial was registered with ClinicalTrials.gov (NCT00698672), and the trial was approved by the Regional Ethical Committee. 150 patients (59–80 year) with primary or secondary osteoarthritis of the hip were included in the study from November 2004 to June 2007. Each patient provided consent. In bilaterally operated patients, only one hip was included. Exclusion criteria were BMI > 35, incompensated cardio-pulmonary disease, malignant disease, dementia, rheumatoid arthritis, or other serious systemic diseases.

The patients were randomized into five groups. Eight consultant orthopaedic surgeons and one resident surgeon either performed or supervised the operations. To avoid the influence of surgeon, block randomization was used. The randomization process was conducted with sealed envelopes revealing study group. The patients were blinded.

Intervention

The five groups of patients received one of the following cemented THAs:

- (1) Charnley monoblock stainless steel femoral stem with a 22.2 mm head articulated with a cemented Charnley Ogee UHMWPE (GUR 1050) acetabular cup that was γ -sterilized with 2.5 Mrad in nitrogen.
- (2) Spectron EF femoral stem with a 28 mm CoCr femoral head and a Reflection All-Poly UHMWPE (GUR 1050) cup that was sterilized by EtO.
- (3) Spectron EF femoral stem with a 28 mm Oxinium femoral head and a Reflection All-Poly UHMWPE (GUR 1050) cup that was sterilized by EtO.
- (4) Spectron EF femoral stem with a 28 mm CoCr femoral head and a Reflection All-Poly XLPE (GUR 1050) cup irradiated with 10 Mrad, melted at 135°C, and EtO sterilized.
- (5) Spectron EF femoral stem with a 28 mm Oxinium femoral head and a Reflection All-Poly XLPE (GUR 1050) cup irradiated with 10 Mrad, melted at 135°C, and EtO sterilized.

Only patients suitable to receive both the Spectron EF stem size 2–5 with a standard offset and the Charnley Flanged 40 stem were included.

The manufacturer supplied the acetabular cups with spherical tantalum markers into the dome and periphery. The Charnley sockets had ten 0.8 mm markers and the Reflection sockets had six 1 mm markers. At surgery, 6-9 tantalum markers (diam. = 1 mm in the Charnley group and = 0.8 mm in the other groups) were inserted into the periprosthetic pelvic bone.

The surgical technique was standardized using a modified direct lateral approach¹² with the patient in the lateral decubitus position. All cases were performed in an operating theater with laminar airflow. Spinal anesthesia was used in all patients. The acetabulum was reamed to bleeding subchondral bone. In the Charnley group the smaller acetabuli received a 40 mm outer diameter (OD) cup,

and the larger acetabuli received a 43 mm OD cup. In the other groups the cup OD corresponded with the largest reamer used. 6–12 anchorage holes were drilled. The components were inserted with Palacos R with gentamicin cement (Schering-Plough, Labo N.V., Heist-Op-Den-Berg, Belgium) using third generation cementing technique. Femoral stem insertion was performed at 5 min after cement mixing; cup insertion at 6 min after mixing. Patients received tranexamic acid before surgery, perioperative systemic antibiotics (four doses of cefuroxime 2 g or two doses of clindamycin 0.6 g in the presence of penicillin allergy) and low molecular-weight heparin (Dalteparin 5000 IE sc). for 5 weeks. Patients were allowed partial weight bearing with crutches from the 1st post-operative day. Restrictions were discontinued 6 weeks post-operatively.

Outcomes

Harris Hip Score (HHS) was used to rate clinical outcome and was performed pre-op and at 3, 12, and 24 mos. The operating surgeon performed preoperative scoring, whereas, the first author did the subsequent rating.

The median time (range) for the index RSA examination was 11 (9-15) days after operation and RSA examinations were repeated at 3, 6, 12, and 24 months after surgery. All examinations were performed by one radiographer. A uniplanar technique with the calibration cage positioned under the examination table was used (cage 43, RSA Biomedical, Umeå, Sweden).¹³ The patient was supine during examination. A gantry-mounted and a portable X-ray tube were used to obtain simultaneous exposures. For imaging we used high definition digital plates (Agfa, Mortsel, Belgium CR MD 4.0) and for plate reading we used the ADC compact digitizer (Agfa). Point motion of the femoral head center, using the tantalum markers in the PE as a fixed reference segment, represented head penetration. Segment motion of the markers in the PE, using the markers in the periprosthetic pelvic bone as a fixed reference segment, represented cup migration. Penetration, migration, and rotational migration were calculated along and around the horizontal (X), longitudinal (Y), and sagittal axes (Z) on the basis of signed values and was computed using the UmRSA Digital measure version 5.0 software (RSA Biomedical). Maximum total point motion (MTPM) was calculated as the vector sum of the penetration. Our main outcome was proximal head penetration (proximal translation of the femoral head along the Y-axis).

Penetration measurements were only performed if ≥ 3 markers in the PE could be identified on repeated examinations. Migration measurements were only performed if ≥ 3 markers in the PE and the periprosthetic pelvic bone could be identified on repeated examinations. The upper limit for the mean error of body fitting was set at 0.35 and the condition number at 150.¹³ The median (range) condition numbers were 46 (22–107) and 33 (16–109) for the socket and acetabular markers, respectively. The corresponding mean errors of rigid body fitting were 0.07 (0.01–0.25) and 0.15 (0.03–0.28).

For determining precision, the difference between double measurements on 50 patients was computed. The standard deviation (SD) of the differences with respect to zero was calculated.¹⁴ The precision was then calculated using the formula:

$$P = 2.009 imes ext{SD} = 2.009 imes \sqrt{rac{\sum_{i=1}^{n} (x_i)^2}{n}}$$

Table 1. The Precision of RSA Obtained by 50 DoubleExaminations at 1 Year

Type of motion	Cup Migration (mm)	Cup Rotation (degrees)	Femoral head penetration (mm)
x-axis	0.16	0.48	0.11
<i>z</i> -axis	$0.09 \\ 0.21$	$\begin{array}{c} 0.48\\ 0.35\end{array}$	0.34
MTPM			0.22

where P is the precision, x the difference between double examinations, and 2.009 represented the critical value at two-sided 95 % *t*-distribution for a sample size of 50. The precision data are presented in Table 1.

Statistical Methods

In addition to an overall hypothesis test of differences among the groups, each prosthesis brand was compared against the Charnley prosthesis. The *p*-value considered statistically significant was therefore set to be smaller than the typically 5% using the Bonferroni method, which gave an adjusted significance level equal to 0.0125 (0.05 divided by 4). A power analysis for the student *t*-test for indepenent samples showed that group sizes of 24 would give a power of 80 % to detect a 0.1 mm difference in mean head penetration with a two-sided significance level of 0.0125 and an assumed SD of 0.1 mm. We anticipated some exclusions and, therefore, included 30 patients in each group.

Differences in baseline characteristics were analyzed using Chi-squared tests for proportions and one-way ANOVA for mean values. We compared mean HHS preoperatively and at 2 years post-op within each group using paired *t*-tests. One-way ANOVA and *t*-tests for independent samples were used to detect differences among the groups in mean values of HHS, head penetration and cup migration at 2 years. When comparing head penetration at 12 and 24 mos and cup migration at 6 and 24 mos, we used the paired *t*-test.

RESULTS

No differences in baseline characteristics were found among groups, except for the smaller cup size used with the Charnley Ogee (Table 2). Five patients were excluded for infection and dislocation and four were lost to follow-up at 24 mos (Fig. 1). Nine percent (n = 27) of the RSA examinations at 2 years were excluded due to missing RSA examinations, deficiency of a sufficient number of visible markers, or a transient problem with reading the digital plates. One examination was excluded due to a high condition number.

Clinical Outcome

We observed improvement in HHS in all groups (p < 0.005). At last follow-up mean (SD) HHS was 91 (10.8) in the Charnley Ogee and the Reflection All-Poly groups with CoCr (8.5) and Oxinium (11.1). In the Reflection All-Poly XLPE groups with CoCr and Oxinium, mean (SD) HHS was 93 (11.3) and 88 (9.5), respectively. We found no significant differences among the groups (p = 0.7).

Radiostereometric Analysis

In the Charnley Ogee cups, mean proximal head penetration at 2 years was 0.12 mm (Fig. 2). Higher values were observed in the Reflection All-Poly cups with CoCr heads, with a mean penetration of 0.34 mm and in the Reflection All-Poly cups with Oxinium heads, with a mean penetration of 0.37 mm (p < 0.001; Table 3).

In the Reflection All-Poly XLPE cups, the CoCr heads had a mean penetration at 2 years of 0.09 mm and Oxinium heads in the Reflection All-Poly XLPE cups had a mean penetration of 0.08 mm, which was lower compared to the Reflection All-Poly groups (p < 0.001; Table 3).

The penetration in the Reflection All-Poly XLPE groups with CoCr and Oxinium heads did not differ from the Charnley Ogee (p = 0.15 and p = 0.07, respectively).

We found no difference in proximal penetration at 2 years between heads made of CoCr and Oxinium when combined with either conventional UHMWPE (p = 0.4) or HXLPE (p = 0.8).

In the Reflection All-Poly groups with CoCr and Oxinium heads, the proximal penetration between 12 and 24 mos increased 0.18 mm (p < 0.001) and 0.17 mm (p < 0.001), respectively. The corresponding values for the Reflection All-Poly XLPE groups with CoCr and Oxinium heads were 0.03 mm (p = 0.03) and 0.02 mm (p = 0.12), respectively. In the Charnley Ogee group, the head penetration increased 0.04 mm (p = 0.001) between 12 and 24 mos.

At 6 mos, an initial proximal cup migration of 0.14 mm was observed in the Charnley Ogee group and between 0.04 and 0.07 mm in the groups with the Reflection cups (p = 0.2). At 2 years this migration reached 0.19 mm in the Charnley Ogee group and between 0.04 and 0.08 mm in the other groups (p = 0.03; Table 4). There were no differences in the medial/lateral (p = 0.1) or AP translations (p = 0.8) at 2 years among the groups. We found no differences in rotational migration of the different acetabular cups at 2 years (all p > 0.4; Table 4).

The difference in translation and rotational migration between 6 mos and 2 years did not reach significance in any of the groups.

DISCUSSION

Femoral head penetration is not solely attributed to the actual removal of substance. Creep, the non-elastic deformation of the PE, explains part of the penetration. The creep becomes negligible by the first 12 mos after implantation.^{15,16} A wear rate of >0.1 mm/year increases the risk of osteolysis,¹⁷ though a continuous dose–response relationship between wear and ostelolysis may exist.¹⁸ The head penetration of the Reflection All-Poly cups between 12 and 24 mos in our study is of great concern. Our results confirm results reported earlier.⁴ We found low femoral head penetration of Reflection All-Poly XLPE after the bedding-in period,

	Charnley Ogee $(n = 30)$					
		Reflection All-Poly		Reflection All-Poly XLPE		
		$\begin{array}{c} \text{CoCr} \\ (n=30) \end{array}$	Oxinium $(n = 30)$	$\begin{array}{c} \text{CoCr} \\ (n = 30) \end{array}$	Oxinium $(n = 30)$	$p ext{-Value}^*$
Female/male (n)	20/10	20/10	23/7	20/10	22/8	0.9
Mean age in years (SD)	70 (6.1)	69 (5.9)	69 (6.7)	70(5.3)	70(5.4)	0.8
Mean weight in kg (SD)	76 (14.9)	76 (11.1)	72 (13.9)	80 (14.8)	76 (14.6)	0.3
Mean HHS preop	45	41	47	47	40	0.2
Primary/secondary arthrosis (n) Median Cup size in mm (range)	28/2 43 (40–43)	26/4 52 (49–61)	26/4 52 (49–58)	$\begin{array}{c} 22/8 \\ 52 \; (46 58) \end{array}$	27/3 52 (43–58)	0.5 < 0.001

Table 2. Baseline Characteristics of Included Patients According to Allocated Treatment

*Chi-squared test and analysis of variance (*F*-test).

which is consistant with earlier reports with cemented HXLPE. 5,19

The Charnley prosthesis has a smaller femoral head than the other implants in our study. Smaller diameters in some studies on conventional UHMWPE were beneficial to wear,^{20,21} offering an explanation for the similar penetration results, despite the lower degree of PE cross-linking of the Charnley Ogee cup as compared to the Reflection All-Poly HXLPE cups. The low penetration of the Charnley may also be due to different materials (steel) and surface characteristics of the head compared to the heads in the other groups. Nevertheless, with similar penetration value, the expected total wear debris load is lower when a smaller femoral head is used, which consequently might result in less wear debris induced osteolysis.

We did not reveal any differences in femoral head penetration between CoCr and Oxinium heads. Our findings thus do not support the in vitro results showing reduced wear with Oxinium heads.⁷ Thus, caution should be used when transferring laboratory results to clinical performance. Our results might, however, be a consequence of the short follow-up; differences may become evident with a longer follow-up period.



Figure 1. Diagram showing the flow of participants through the trial.



Figure 2. Proximal head penetration (mean). Error bars represent 95 % Confidence Intervals of the Charnley Ogee and the Reflection All-Poly/CoCr.

Retrieval studies reported cracking, gouging, and delamination of Oxinium heads after dislocation.^{22,23} We used cemented acetabular sockets. The problem is presumably of greater concern when Oxinium is articulating with a metal backed cup, due to the risk of impingment of the head against the metal shell during dislocation and subsequent attempts at closed reduction.

In our study all groups of cups had a migration that was within the limits of what is considered safe with respect to long-term performance.²⁴ Our results regarding proximal migration for the Charnley Ogee and the cemented Reflection cups at 2 years were quite similar to those presented in earlier reports.^{25,26} There was no significant migration between 6 mos and 2 years in any group, indicating that fixation was stable, after an initial period of migration.

The Charnley Ogee cup had a numerically (but not significantly) higher proximal migration, when compared to the other cups. We regard this finding to be a consequence of different cup designs and cementing technique.

Table 3.	Femoral Head	Penetration	(mm) at 2	2-Years	Follow-	Up
----------	--------------	-------------	-----------	---------	---------	----

	n	Mean	$95\ensuremath{\%}$ CI of mean	Difference	$95\ \%$ CI of difference	p-Value ^a
X-axis						
Lateral(+)/medial(-)						$<\!0.001^{*}$
Charnley Ogee	27	0.01	-0.01 - 0.04	Reference		
Spectron EF Reflection						
All-Poly/CoCr	27	0.09	0.06 - 0.12	0.07	0.03 - 0.12	< 0.001
All-Poly/Oxinium	21	0.05	-0.02 - 0.11	0.03	-0.03 - 0.09	0.29
All-Poly XLPE/CoCr	29	0.002	-0.02 - 0.03	-0.01	-0.05 - 0.03	0.46
All-Poly XLPE/Oxinium	24	-0.02	-0.04 -0.005	-0.03	-0.06- (-0.01)	0.04
Y-axis						
Proximal(+)/distal(-)						$<\!\!0.001^{*}$
Charnley Ogee	27	0.12	0.09 - 0.15	Reference		
Spectron EF Reflection						
All-Poly/CoCr	27	0.34	0.28 - 0.40	0.21	0.15 - 0.28	< 0.001
All-Poly/Oxinium	21	0.37	0.30 - 0.44	0.25	0.18 - 0.31	< 0.001
All-Poly XLPE/CoCr	29	0.09	0.06 - 0.12	-0.03	-0.08 - 0.01	0.15
All-Poly XLPE/Oxinium	24	0.08	0.04 - 0.12	-0.04	-0.9 - 0.04	0.07
Z-Axis						
Anterior(+)/posterior(-)						0.2^{*}
Charnley Ogee	27	-0.02	-0.08 - 0.4	Reference		
Spectron EF Reflection						
All-Poly/CoCr	27	0.01	-0.07 - 0.08	0.03	-0.07 - 0.12	0.59
All-Poly/Oxinium	21	-0.05	-0.14 - 0.03	-0.04	-0.14 - 0.06	0.46
All-Poly XLPE/CoCr	29	0.06	0.002 - 0.12	0.08	-0.01 - 0.16	0.07
All-Poly XLPE/Oxinium	24	0.03	-0.04 - 0.10	0.05	-0.04 - 0.13	0.30
MTPM						$<\!\!0.001^{*}$
Charnley Ogee	27	0.19	0.16 - 0.23	Reference		
Spectron EF Reflection						
All-Poly/CoCr	27	0.40	0.33 - 0.46	0.20	0.13 - 0.27	< 0.001
All-Poly/Oxinium	21	0.44	0.37 - 0.51	0.25	0.17 - 0.32	< 0.001
All-Poly XLPE/CoCr	29	0.19	0.15 - 0.23	-0.002	-0.05 - 0.05	0.94
All-Poly XLPE/Oxinium	24	0.18	0.13-0.22	-0.02	-0.07 - 0.04	0.57

*p-value from analysis of variance. ^aAnalysis of variance and Students *t*-test.

6 KADAR ET AL.

Table 4. Migration at 2-Years Follow-Up

	n	Mean	95~% CI of mean	Difference	$95\ \%\ {\rm CI}$ of difference	<i>p</i> -Value ^a
Cup translations (mm)						
X-axis						
Lateral(+)/medial(-)						0.10^*
Charnley Ogee	27	-0.06	-0.17 - 0.6	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	0.09	0.03 - 0.15	0.15	0.02 - 0.28	0.03
All-Poly/Oxinium	21	0.06	-0.02 - 0.15	0.12	-0.03 -0.27	0.10
All-Poly XLPE/CoCr	29	0.01	-0.06 - 0.08	0.07	-0.06 - 0.20	0.30
All-Poly XLPE/Oxinium	24	0.04	-0.03 -0.10	0.09	-0.04 -0.22	0.17
Y-axis						
Proximal(+)/distal(-)						0.03^{*}
Charnley Ogee	27	0.19	0.09 - 0.30	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	0.06	-0.02 - 0.13	-0.13	-0.26-(-0.01)	0.04
All-Poly/Oxinium	21	0.08	0.02 - 0.14	-0.11	-0.24 - 0.01	0.08
All-Poly XLPE/CoCr	29	0.06	0.02 - 0.11	-0.13	-0.24- (-0.02)	0.02
All-Poly XLPE/Oxinium	24	0.04	-0.03 -0.12	-0.15	-0.28- (-0.02)	0.02
Z-axis						
Anterior(+)/posterior(-)						0.82^{*}
Charnley Ogee	27	0.02	-0.04 - 0.09	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	0.05	-0.05 - 0.15	0.03	-0.09 - 0.14	0.66
All-Poly/Oxinium	21	0.07	-0.04 - 0.19	0.05	-0.07 - 0.17	0.42
All-Poly XLPE/CoCr	29	0.01	-0.09 - 0.10	-0.02	-0.13 -0.10	0.76
All-Poly XLPE/Oxinium	24	0.06	-0.02 - 0.14	0.04	-0.07 - 0.14	0.49
Cup rotations (°)						
X-axis						
Ant. (+)/post. (-) tilt						0.63^*
Charnley Ogee	27	-0.14	-0.29-(-0.003)	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	-0.09	-0.31 - 0.13	0.06	-0.19 -0.30	0.65
All-Poly/Oxinium	21	-0.24	-0.56 - 0.07	-0.10	-0.41 -0.21	0.53
All-Poly XLPE/CoCr	29	-0.07	-0.24 -0.11	0.08	-0.15 - 0.30	0.50
All-Poly XLPE/Oxinium	24	-0.01	-0.25 - 0.22	0.13	-0.13 - 0.39	0.31
Y-axis						
Ant.(+)/retroversion(-)						0.42^{*}
Charnley Ogee	27	0.04	-0.14- 0.22	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	0.11	-0.14 - 0.37	0.07	-0.23 - 0.37	0.62
All-Poly/Oxinium	21	0.32	0.03 - 0.62	0.28	-0.04 - 0.60	0.09
All-Poly XLPE/CoCr	29	0.15	-0.03 -0.32	0.11	-0.14 - 0.35	0.40
All-Poly XLPE/Oxinium	24	0.05	-0.17 - 0.28	0.013	-0.27 - 0.29	0.93
Z-axis						
Increase $(-)$ /decrease $(+)$ of inclination						0.64^{*}
Charnley Ogee	26	0.07	-0.25 - 0.39	Reference		
Spectron EF Reflection						
All-Poly/CoCr	24	0.26	0.08 - 0.43	0.18	-0.19 - 0.55	0.33
All-Poly/Oxinium	21	0.29	-0.04 - 0.61	0.21	-0.24 - 0.66	0.34
All-Poly XLPE/CoCr	29	0.19	-0.004 - 0.39	0.12	-0.24 - 0.48	0.51
All-Poly XLPE/Oxinium	24	0.09	-0.03 -0.22	0.02	-0.33 -0.37	0.90

**p*-value from analysis of variance. ^aAnalysis of variance and Students *t*-test.

Interestingly, Charnley cups tended to migrate medially, while Reflection cups tended to migrate laterally. An earlier paper reported similar tendency of lateral migration of cemented Reflection cups.²⁶ Our findings are difficult to interpret because the diffe-

rence was not significant. Nevertheless, they imply that different migration directions might be expected with different designs and cement mantle thicknesses.

Cross-linking comes at the expense of mechanical properties. 27 An earlier study reported that HXLPE

mechanical properties did not alter the performance of cemented cups in terms of fixation.²⁸ We did not discern any differences in cup fixation of the two different cemented Reflection cups, thus supporting these earlier results.

Numerous studies showed higher wear rates with the use of metal-backed uncemented CUPS compared to all-polyethylene cups.^{29,30} The thinner polyethylene liner used for the same socket size with uncemented cups is one explanation.³¹ Thus, our results regarding polyethylene wear cannot directly be transferred to uncemented sockets.

We followed the proposed guidelines for standardization of RSA.¹³ The precision in our study was comparable with other reports.^{4,24} The examinations are technically difficult to perform, and we sized our study to allow for exclusions. However, 84 % of the RSA examinations were adequate at 2 years.

The cemented Reflection All-Poly XLPE and the Charnley Ogee cups performed better than the cemented Reflection All-Poly cups in terms of head penetration. The penetrations of the Reflection All-Poly XLPE and the Charnley Ogee were similar, but due to a larger head size the former might produce a higher total volume of wear debris. Longer follow-up is needed to evaluate steady state penetration rates. All three groups of cups had migrations within the limits considered to be safe with respect to long-term performance.

Care should be taken to generalize our results to other HXLPEs. Available implants differ in the manufacturing process and the PE resin used. Therefore, differences in wear, the degree of oxidation, and mechanical properties can be anticipated. Further follow-up is required to discern differences between CoCr and Oxinium heads with respect to wear, implant durability, and clinical benefits. Based on concerns of the mechanical properties and the lack of long-term clinical follow-up studies, we recommend the use of Oxinium to be restricted to clinical studies.

The Charnley Ogee has the longest follow-up and the largest volume of documentation of prostheses used in THA.¹⁰ Our results imply that this prosthesis still represents a standard against which new implants can be measured over time.

ACKNOWLEDGMENTS

The study was jointly financed by OrtoMedic AS, Smith & Nephew Norway AS, and the Regional Health Board of Western Norway. None of the funding sources played any role in the preparation, performance, or analysis of the results of this study. The author has received PhD grants form the Regional Health Board of Western Norway.

REFERENCES

1. Harris WH. 2004. Conquest of a worldwide human disease: particle-induced periprosthetic osteolysis. Clin Orthop Relat Res 429:39–42.

- McKellop H, Shen FW, Lu B, et al. 2000. Effect of sterilization method and other modifications on the wear resistance of acetabular cups made of ultra-high molecular weight polyethylene. A hip-simulator study. J Bone Joint Surg Am 82-A:1708-1725.
- 3. Premnath V, Harris WH, Jasty M, et al. 1996. Gamma sterilization of UHMWPE articular implants: an analysis of the oxidation problem. Ultra high molecular weight poly ethylene. Biomaterials 17:1741–1753.
- 4. Digas G, Thanner J, Nivbrant B, et al. 2003. Increase in early polyethylene wear after sterilization with ethylene oxide: radiostereometric analyses of 201 total hips. Acta Orthop Scand 74:531–541.
- 5. Digas G, Karrholm J, Thanner J, et al. 2007. 5-Year experience of highly cross-linked polyethylene in cemented and uncemented sockets: two randomized studies using radiostereometric analysis. Acta Orthop 78:746–754.
- Harris WH, Muratoglu OK. 2005. A review of current crosslinked polyethylenes used in total joint arthroplasty. Clin Orthop Relat Res 430:46–52.
- Good V, Ries M, Barrack RL, et al. 2003. Reduced wear with oxidized zirconium femoral heads. J Bone Joint Surg Am 85-A(Suppl 4): 105–110.
- Whittaker JP, Charron KD, McCalden RW, et al. 2010. Comparison of steady state femoral head penetration rates between 2 highly cross-linked polyethylenes in total hip arthroplasty. J Arthroplasty 25(5): 680–686.
- Sheth NP, Lementowski P, Hunter G, et al. 2008. Clinical applications of oxidized zirconium. J Surg Orthop Adv 17: 17–26.
- Aamodt A, Nordsletten L, Havelin LI, et al. 2004. Documentation of hip prostheses used in Norway: a critical review of the literature from 1996–2000. Acta Orthop Scand 75: 663–676.
- 11. Malchau H. 1995. On the importance of stepwise introduction of new hip implant technology. Thesis, Göteborg University.
- 12. Hardinge K. 1982. The direct lateral approach to the hip. J Bone Joint Surg Br 64:17–19.
- Valstar ER, Gill R, Ryd L, et al. 2005. Guidelines for standardization of radiostereometry (RSA) of implants. Acta Orthop 76:563–572.
- 14. Ranstam J, Ryd L, Onsten I. 2000. Accurate accuracy assessment: review of basic principles. Acta Orthop Scand 71:106-108.
- 15. Schmalzried TP, Callaghan JJ. 1999. Wear in total hip and knee replacements. J Bone Joint Surg Am 81:115–136.
- 16. Glyn-Jones S, McLardy-Smith P, Gill HS, et al. 2008. The creep and wear of highly cross-linked polyethylene: a three-year randomised, controlled trial using radiostereometric analysis. J Bone Joint Surg Br 90:556–561.
- 17. Dumbleton JH, Manley MT, Edidin AA. 2002. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. J Arthroplasty 17:649–661.
- Wilkinson JM, Hamer AJ, Stockley I, et al. 2005. Polyethylene wear rate and osteolysis: critical threshold versus continuous dose-response relationship. J Orthop Res 23: 520-525.
- Rohrl SM, Li MG, Nilsson KG, et al. 2007. Very low wear of non-remelted highly cross-linked polyethylene cups: an RSA study lasting up to 6 years. Acta Orthop 78:739–745.
- Devane PA, Horne JG. 1999. Assessment of polyethylene wear in total hip replacement. Clin Orthop Relat Res 369: 59–72.
- 21. Tarasevicius S, Robertsson O, Kesteris U, et al. 2008. Effect of femoral head size on polyethylene wear and synovitis

after total hip arthroplasty: a sonographic and radiographic study of 39 patients. Acta Orthop 79:489–493.

- 22. Evangelista GT, Fulkerson E, Kummer F, et al. 2007. Surface damage to an Oxinium femoral head prosthesis after dislocation. J Bone Joint Surg Br 89:535–537.
- Jaffe WL, Strauss EJ, Cardinale M, et al. 2009. Surface oxidized zirconium total hip arthroplasty head damage due to closed reduction effects on polyethylene wear. J Arthroplasty 24:898–902.
- 24. Karrholm J, Herberts P, Hultmark P, et al. 1997. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthop Relat Res 344:94–110.
- Onsten I, Carlsson AS, Besjakov J. 1998. Wear in uncemented porous and cemented polyethylene sockets: a randomised, radiostereometric study. J Bone Joint Surg Br 80:345–350.
- 26. Digas G, Thanner J, Anderberg C, et al. 2004. Bioactive cement or ceramic/porous coating vs. conventional cement to

obtain early stability of the acetabular cup. Randomised study of 96 hips followed with radiostereometry. J Orthop Res 22:1035-1043.

- 27. Bradford L, Baker D, Ries MD, et al. 2004. Fatigue crack propagation resistance of highly crosslinked polyethylene. Clin Orthop Relat Res 429:68–72.
- Digas G, Karrholm J, Thanner J, et al. 2003. Highly crosslinked polyethylene in cemented THA: randomized study of 61 hips. Clin Orthop Relat Res 417:126–138.
- Sychterz CJ, Moon KH, Hashimoto Y, et al. 1996. Wear of polyethylene cups in total hip arthroplasty. A study of specimens retrieved post mortem. J Bone Joint Surg Am 78: 1193-1200.
- Nashed RS, Becker DA, Gustilo RB. 1995. Are cementless acetabular components the cause of excess wear and osteolysis in total hip arthroplasty? Clin Orthop Relat Res 317:19–28.
- 31. Harris WH. 1994. Osteolysis and particle disease in hip replacement. A review. Acta Orthop Scand 65:113–123.