

■ HIP

Oxinium modular femoral heads do not reduce polyethylene wear in cemented total hip arthroplasty at five years

A RANDOMISED TRIAL OF 120 HIPS USING RADIOSTEREOMETRIC ANALYSIS

B. A. Jonsson,
T. Kadar,
L. I. Havelin,
K. Haugan,
B. Espehaug,
K. Indrekvam,
O. Furnes,
G. Hallan

From Haukeland
University Hospital,
Bergen, Norway

■ B. A. Jonsson, MD, Orthopaedic Surgeon,
■ T. Kadar, MD, PhD, Senior Consultant,
■ L. I. Havelin, MD, PhD, Orthopaedic Surgeon, Professor
■ B. Espehaug, PhD, Professor,
■ K. Indrekvam, MD, PhD, Clinical Director/Chief Surgeon, Orthopedic Clinic
■ O. Furnes, MD, PhD, Orthopaedic Surgeon, Professor,
■ G. Hallan, MD, PhD, Orthopaedic Surgeon, Department of Orthopaedic Surgery Haukeland University Hospital, Bergen, Norway.
■ K. Haugan, MA, Senior Adviser, Orthopaedic Research Centre Trondheim University Hospital, Trondheim, Norway.

Correspondence should be sent to Mr B. A. Jonsson; e-mail: benedikt.arni.jonsson@helse-bergen.no

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We report the five-year outcome of a randomised controlled trial which used radiostereometric analysis (RSA) to assess the influence of surface oxidised zirconium (OxZr, Oxinium) on polyethylene wear *in vivo*.

A total of 120 patients, 85 women and 35 men with a mean age of 70 years (59 to 80) who were scheduled for primary cemented total hip arthroplasty were randomly allocated to four study groups. Patients were blinded to their group assignment and received either a conventional polyethylene (CPE) or a highly cross-linked (HXL) acetabular component of identical design. On the femoral side patients received a 28 mm head made of either cobalt-chromium (CoCr) or OxZr.

The proximal head penetration (wear) was measured with repeated RSA examinations over five years. Clinical outcome was measured using the Harris hip score.

There was no difference in polyethylene wear between the two head materials when used with either of the two types of acetabular component ($p = 0.3$ to 0.6). When comparing the two types of polyethylene there was a significant difference in favour of HXLPE, regardless of the head material used ($p < 0.001$).

In conclusion, we found no advantage of OxZr over CoCr in terms of polyethylene wear after five years of follow-up. Our findings do not support laboratory results which have shown a reduced rate of wear with OxZr. They do however add to the evidence on the better resistance to wear of HXLPE over CPE.

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Aseptic loosening resulting from periprosthetic osteolysis is the principal limiting factor for the long-term survivorship of total hip arthroplasty (THA).^{1,2} Wear debris generated by the articulation is a key element in the multifactorial pathogenesis of osteolysis.^{3,4} Consequently, the focus of new developments in THA has been on improving the wear characteristics of the bearing surfaces.

The first generation of highly cross-linked polyethylene (HXLPE) was introduced into clinical practice in the late 1990s and is now commonly used as a bearing material in THA. It has shown better wear properties than non-cross-linked conventional polyethylene (CPE) both in hip simulator studies⁵⁻⁷ and clinically at medium-term follow-up (five to ten years).⁸⁻¹³

On the femoral side, new bearing materials have been developed in an attempt to improve the wear characteristics. Heads made of oxidised zirconium (OxZr) alloy (OxZr, Oxinium, Smith and Nephew, Memphis, Tennessee) are believed to combine the strength of a metal

head with the smoothness of ceramic, which should result in improved wear characteristics and a reduced risk of abrasive roughening and femoral head fracture.¹⁴ Although pre-clinical hip simulator studies reported that OxZr heads have better wear properties than conventional cobalt-chromium (CoCr),^{15,16} it remains to be clinically proven.

As an approach to the stepwise introduction of new implants,¹⁷ we undertook a randomised controlled trial (RCT) to evaluate the influence of this new femoral head material on polyethylene wear *in vivo*. We compared the wear of two cemented acetabular components of identical design, one made of CPE and the other of HXLPE, in articulations which had either an OxZr or a conventional CoCr head. Radiostereometric analysis (RSA) was used to measure wear. Owing to its high precision, only a small number of patients were needed in each study group.¹⁸

We hypothesised that there would be no difference in the rate of polyethylene wear with

$$P = 2.009 \times SD = 2.009 \times \sqrt{\frac{\sum_{i=1}^n (x_i)^2}{n}}$$

Fig. 1

The formula used for calculating the precision of radiostereometric analysis measurements obtained from 50 double examinations.

the two femoral heads. Furthermore, we expected less wear of the HXLPE than the CPE acetabular components. The two-year results from this study have previously been published,¹⁹ which revealed that the CPE had a rate of wear that was four-times higher than that of HXLPE but there was no statistical difference in terms of polyethylene wear between the OxZr and CoCr femoral heads when combined with either CPE or HXLPE. We now report the results after a minimum of five years of follow-up.

Patients and Methods

This prospective randomised controlled trial was registered with ClinicalTrials.gov (NCT00698672), and the trial was approved by the Regional Ethical Committee. Between November 2004 and June 2007 120 patients with primary or secondary osteoarthritis of the hip who were scheduled for THA were recruited to the study. There were 35 men and 85 women with a mean age of 70 years (59 to 80). Each patient provided informed consent to participation in the study. In patients who underwent bilateral operations, only one hip was included in the analysis. Exclusion criteria were body mass index > 35 kg/m²; uncompensated cardiopulmonary disease; malignant disease; dementia; rheumatoid arthritis and any other serious systemic disease.

We used a computer-generated randomisation sequence (R statistical software package, R foundation, Vienna, Austria). The randomisation process was conducted with sealed envelopes which revealed the study group. The patients were blinded to their group assignment.

The operations were undertaken or supervised by eight consultant orthopaedic surgeons and one resident surgeon. To avoid the influence of the surgeon, block randomisation was used to ensure that all surgeons operated on an equal number of patients in each study group.

Implants. The four groups of patients were randomised to receive one of four different types of articulation:

- CPE acetabular component/CoCr head
- CPE acetabular component/OxZr head
- HXLPE acetabular component/CoCr head
- HXLPE acetabular component/OxZr head

All implants were manufactured by Smith and Nephew, which supplied the acetabular components with spherical tantalum markers in the dome and at the edge. The CPE acetabular component used was the cemented Reflection All-Poly, which is made of ultra-high molecular weight polyethylene (GUR 1050) and sterilised in ethylene oxide (EtO). The HXLPE acetabular component used was the cemented Reflection XLPE (GUR 1050), irradiated

with 10 Mrad, melted at 135°C and EtO sterilised. All femoral heads were 28 mm in diameter. Each patient received a Spectron EF Primary cemented femoral stem. Only patients suitable to receive stem sizes 2 to 5 with standard offset were included, with those not suitable excluded. At surgery, 6 mm to 9 mm tantalum markers (0.8 mm) were inserted into the periprosthetic pelvic and femoral bone.

The surgical procedure and post-operative treatment was standardised, and has previously been described in detail.¹⁹ **Outcomes.** The Harris hip score²⁰ (HHS) was used to rate clinical outcome and was undertaken pre-operatively and at three, 12, 24 and 60 months post-operatively. The operating surgeon performed the pre-operative scoring, and the second author (TK) all subsequent scoring.

The median time for the index RSA examination was 11 days (9 to 15) post-operatively; it was repeated at three, six, 12, 24 and 60 months. All examinations were performed by one experienced radiographer (TS). A uniplanar technique was used with the patient supine and a calibration cage positioned under the examination table (cage 43, RSA Biomedical, Umeå, Sweden).²¹ Gantry-mounted and portable x-ray tubes were used to obtain simultaneous exposures. We used high definition digital plates (CR MD 4.0 Agfa, Mortsel, Belgium) for imaging and an ADC compact digitiser (Agfa) for plate reading. Head penetration was represented by point movement of the centre of the femoral head, using tantalum markers in the polyethylene as a fixed reference segment. Penetration was 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, Umeå, Sweden). Our main outcome measure was proximal head penetration (proximal translation of the femoral head along the Y-axis).

Wear measurements could only be performed if ≥ three markers in the polyethylene were identified on repeated examinations. The upper limit for the mean error of body fitting was set at 0.35 and the condition number at 150.²¹ To determine precision, the difference between double measurements on 50 patients was computed. The standard deviation (SD) of the differences with respect to zero was calculated.²² The precision was then calculated using the formula shown in Figure 1, where P is the precision, x the difference between double examinations, and 2.009 the critical value at two-sided 95% t-distribution for a sample size of 50. The precision for femoral head penetration measurements was 0.11 mm for the X-axis, 0.11 mm for the Y-axis and 0.34 for the Z-axis.

Statistical analysis. A small number of patients, 15 to 25 in each study group, can be used in RSA studies owing to the high precision of the measurement technique.²¹ For the current study, a power analysis using the Student's *t*-test for independent samples showed that group sizes of 16 would give a power of 80% to detect a 0.1 mm difference in mean proximal head penetration with a two-sided significance level of 0.05 and an assumed SD of 0.1 mm. Our patient

Table I. Patient demographics by study group

	Conventional PE		Highly cross-linked PE	
	CoCr (n = 30)	OxZr (n = 30)	CoCr (n = 30)	OxZr (n = 30)
Male/female (n)	10/20	7/23	10/20	8/22
Mean (yrs) (SD)	69 (5.9)	69 (5.8)	70 (5.3)	70 (5.4)
Mean weight (kg) (SD)	76 (11)	72 (13)	80 (15)	76 (15)
Mean BMI (kg/m ²) (SD)	27 (3)	26 (4)	27 (4)	27 (4)
Primary/secondary OA (n)	26/4	26/4	22/8	27/3
Side (right/left) (n)	15/15	12/18	16/14	18/12
Charnley ²³ class A/B/C (n)	14/15/1	16/13/1	18/10/2	16/14/0
Mean HHS pre-operatively (SD)	41 (14)	47 (16)	47 (16)	40 (12)
Median cup size (mm) (range)	52 (49 to 61)	52 (49 to 58)	52 (46 to 58)	52 (43 to 58)

PE; polyethylene, CoCr; cobalt-chromium, OxZr; oxidised zirconium; standard deviation (SD); BMI, body mass index; OA, osteoarthritis; HHS, Harris hip score

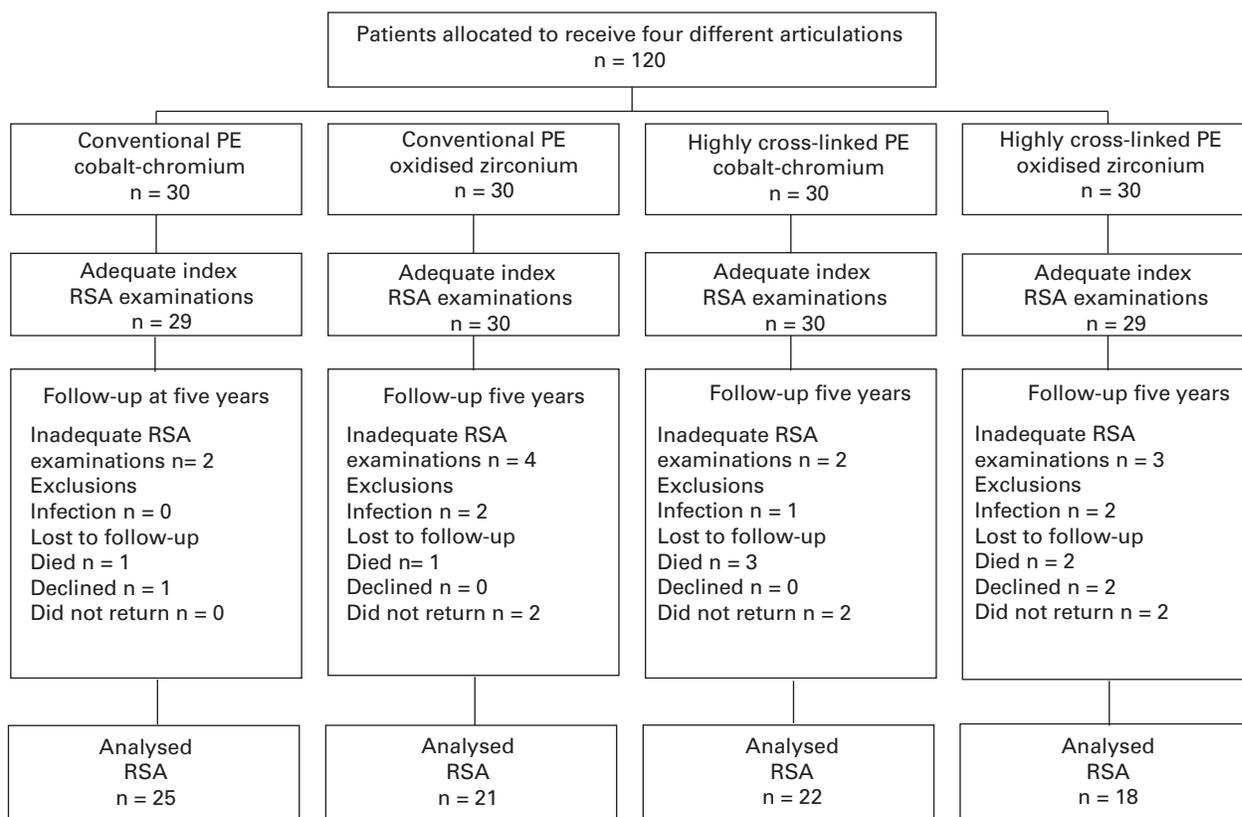


Fig. 2

Flowchart showing the flow of participants through the trial (RSA, radiostereometric analysis; PE, polyethylene).

material was drawn from a larger RCT which included 30 patients in each group.¹⁹

We compared the HHS pre-operatively and at five years post-operatively within each group using paired *t*-tests. One-way analysis of variance (ANOVA) was used to detect differences among the groups in mean values of HHS at five years. Independent samples *t*-tests were used to detect differences in the mean values of proximal head penetration at five years. We used paired *t*-tests to calculate annual wear rates between one and five years post-operatively. Differences were regarded as being statistically significant if the *p*-value (two-sided) was < 0.05. In addition, a mixed effects model analysis was carried out to determine further the

wear rate at steady-state. Statistical analyses were performed with IBM SPSS Statistics version 21 (IBM Corp, Armonk, New York).

Results

The demographic details of the patients are listed in Table I.²³

In all, seven patients died during the study period; five were excluded owing to deep infection which required debridement or revision of the implant; three withdrew from the study and six did not return for follow-up. At five years, 11 (9%) patients were excluded from RSA analysis because of missing examinations, insufficient number of visible markers or problems related to the digital plates.

Table II. Mean proximal penetration (along the longitudinal y-axis) and annual wear rates by study group

Articulation		Proximal head penetration (mm)*			Annual wear rate (mm/year) [†]
		At 1 year	At 2 years	At 5 years	
CPE/CoCr	Mean	0.17	0.34	0.84	0.18
	sd	0.12	0.15	0.41	0.10
	n	23	27	25	21
CPE/OxZr	Mean	0.18	0.37	0.99	0.20
	SD	0.08	0.15	0.45	0.09
	n	15	21	21	12
HXLPE/CoCr	Mean	0.06	0.09	0.12	0.02
	SD	0.08	0.09	0.16	0.03
	n	27	29	22	20
HXLPE/OxZr	Mean	0.06	0.08	0.10	0.01
	SD	0.07	0.09	0.10	0.01
	n	24	24	18	17
Total	n	89	101	86	70

* Positive migration of the femoral head along the y-axis

† Between one and five years post-operatively

CPE, conventional polyethylene; CoCr; cobalt-chromium; OxZr; oxidised zirconium; HXLPE, highly cross-linked polyethylene; n, number of patients within each group available for wear analysis; sd, standard deviation

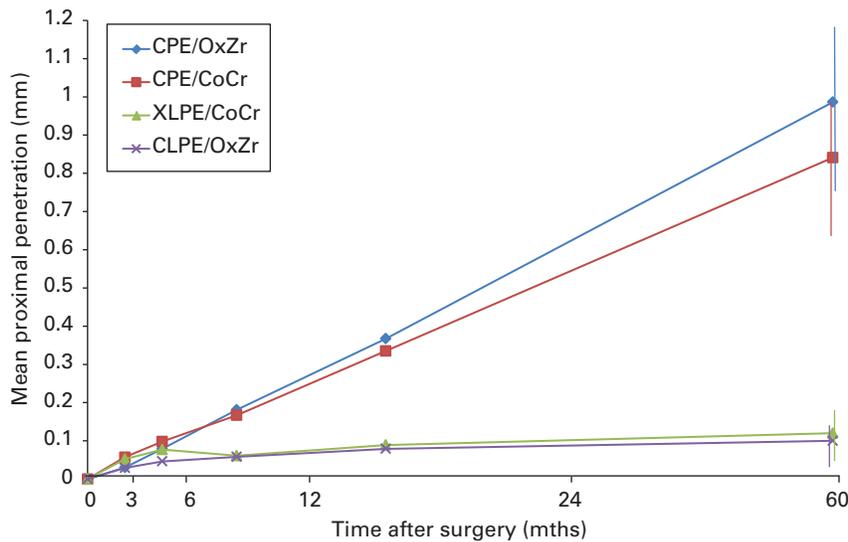


Fig. 3

Graph showing the mean total proximal penetration over five years for all study groups with 95% confidence interval at five years (CPE, conventional polyethylene; OxZr; oxidised zirconium; CoCr; cobalt-chromium; HXLPE, highly cross-linked polyethylene).

Two patients had inadequate index examinations. Figure 2 shows the flow of patients through the study.

Clinical outcome. We observed a significant improvement in HHS for all study groups, from a mean value of 44 (SD 15) pre-operatively to 89 (SD 12) at five years post-operatively ($p < 0.001$, paired t -test). The mean HHS at five years in the CPE groups were 87 with CoCr (SD 12) and 92 with OxZr (SD 10). In the HXLPE groups with CoCr and OxZr, the mean HHS were 90 (SD 11) and 86 (SD 14), respectively. There were no significant differences in HHS between groups at five years ($p = 0.3$, one-way ANOVA).

Wear analysis. We found no difference in polyethylene wear after five years when comparing the two head materials

(CoCr and OxZr), in combination with either the CPE ($p = 0.3$) or the HXLPE acetabular component ($p = 0.6$). When comparing the wear results of the two polyethylenes, there was a significant difference in favour of HXLPE, regardless of the head material used ($p < 0.001$): the HXLPE acetabular components had an approximately eight- to ten-fold reduction in wear. The data on proximal head penetration and annual wear rates are listed in Table II.

Figure 3 shows the mean total proximal penetration over five years for all study groups and Figure 4 shows the median proximal penetration for all groups at five years in a Tukey box plot, illustrating the individual distribution and allowing the identification of outliers.

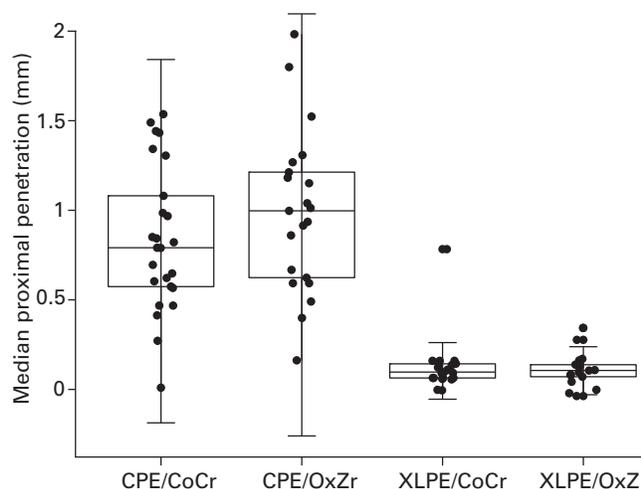


Fig. 4

Tukey box plot showing median proximal penetration at five years for all patients in the four study groups. The top and bottom of each rectangular box represent the 75th and 25th percentiles respectively, with the median indicated with a solid line inside the box. Horizontal bars extending from each box represent more extreme values defined as 1.5-times the interquartile range (25th percentile subtracted from the 75th percentile) above the 75th percentile or below 25th percentile. Circles represent outliers (CPE, conventional polyethylene; CoCr; cobalt-chromium; OxZr; oxidised zirconium; HXLPE, highly cross-linked polyethylene).

Discussion

Radiostereometric analysis was used to measure polyethylene wear. This is considered to be the reference standard for the measurement of implant migration *in vivo* and can resolve differences with high precision and a small number of patients in each study group.^{18,21} Early wear and implant migration as measured with RSA serves as a surrogate endpoint for later clinical failure.²⁴

We present wear as proximal femoral head penetration, i.e. the translation of the centre of the femoral head into the acetabular polyethylene component along the longitudinal Y-axis, using markers in the polyethylene as a fixed reference segment. Measurements along the longitudinal axis were found to be the most precise in a phantom study which evaluated the accuracy and precision of RSA.²⁵ This accords with our calculations of precision which were derived from double examinations. Other studies with which we compare our results, also report wear in a similar manner.²⁶

A substantial proportion of the total femoral head penetration during the first post-operative months is due to creep or bedding-in, a non-elastic deformation of the polyethylene, whereas the steady-state penetration after this period almost exclusively indicates true wear, i.e. the removal of substance.^{10,27}

The bedding-in process is included in our results for the mean proximal penetration at five years for both acetabular components. According to our measurements, creep was similar for both and was largely completed within the first three months of implantation. To eliminate creep from our

annual wear rate estimations, the calculations were based on penetration differences between the first and fifth post-operative year as creep diminishes with time and becomes negligible after the first post-operative year.^{27,28}

RSA studies are technically challenging and difficult to execute in large populations. A total of 13 patients had inadequate examinations initially or at five years and therefore had to be excluded from the wear calculations. We also had some deaths, exclusions because of infection and drop-outs. However, we managed to gather wear data for 86 patients (72%).

The CPE acetabular component demonstrated a mean annual wear rate of 0.21 mm/year in combination with OxZr and 0.18 mm/year with CoCr: this exceeds the proposed 0.1 mm/year threshold for the generation of osteolysis.^{3,29} Therefore, any reduction in wear afforded by the OxZr heads could be expected to show more clearly in articulation with this less wear-resistant polyethylene. However, we found no difference when comparing the two heads articulating with CPE ($p = 0.3$).

During the study period (2004 to 2007), the CPE Reflection All-Poly acetabular component was the second most frequently used cemented acetabular component in Norway.³⁰ However, the absence of radiation in the manufacturing process and subsequent lack of irradiation-induced cross-linking of the polyethylene, proved to be detrimental to wear resistance. As a result, the popularity of this implant plummeted following reports on inferior wear characteristics and, later, high revision rates for both the cemented and uncemented versions.³¹⁻³³ Although it is still commercially available, there is no record of either component being used in Norway after 2010, according to data from the Norwegian Arthroplasty Register.³⁰

By contrast, the Reflection XLPE liner has given favourable results in both the laboratory¹⁵ and clinical setting.³⁴ According to our results for the cemented version of this implant, there was no detectable wear between one and five years after surgery. To our knowledge, no clinical studies exist on the wear properties of this implant except for the previously published two-year results of the present study.¹⁹

XLPEs, which differ in terms of polyethylene resins and manufacturing process, can be expected to behave differently in terms of wear characteristics. Consequently, it is important that wear results for each different type of HXLPE acetabular component are reviewed separately to avoid extrapolating results from one material to another. Equally, care should be taken when extrapolating wear results from studies on uncemented implants to cemented implants, and vice versa.

In a systematic review of the published literature on uncemented THA, first-generation HXLPE liners had significantly lower rates of wear than CPE liners and, consequently, a reduced risk of producing osteolysis.¹² In contrast, a recently published RCT on wear and osteolysis in cemented THA found no reduction in the incidence of

osteolysis or aseptic loosening with HXLPE acetabular components when compared with CPE at ten years, despite the former having significantly less wear.³⁵ However, as the authors themselves pointed out, the study was most likely underpowered to detect any differences between study groups for variables other than polyethylene wear.

The relationship between the wear of HXLPE and its influence on osteolysis is somewhat unclear: a longer follow-up with clinical end-points is needed to see the actual impact of HXLPE on the long-term survival of THA.

OxZr was introduced in 2003 as a bearing material for the femoral head. Clinical research on this new material is still limited: recent studies have not found that it significantly reduces polyethylene wear.^{36,37}

Retrieval studies have reported damage and compromised wear properties of OxZr femoral heads after dislocation and subsequent closed reduction with uncemented THA, where the head has sustained damage from contact with the metal shell.³⁸⁻⁴⁰ This is probably of less concern with cemented acetabular components because of the absence of a solid metal backing.

In conclusion, we found no advantage in terms of polyethylene wear of using an OxZr femoral head rather than a conventional CoCr head in cemented THA at five years. Further follow-up is needed to establish whether this new head material provides any long-term benefits in terms of wear and survivorship. This trial adds further evidence for the enhanced wear characteristics of HXLPE, supporting its further use in THA.

Author contributions:

B. A. Jonsson: Data collection, analyses and writing.
 T. Kadar: Planning, performed surgeries, data collection, analyses and writing.
 L. I. Havelin: Planning and writing.
 K. Haugan: Data collection and analysis.
 V. B. Espehaug: Data analysis.
 K. Indrekvam: Data collection and writing.
 O. Furnes: Planning, performed surgeries, data collection and writing.
 G. Hallan: Planning, performed surgeries, data collection and writing.

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