

Wear Rates of XLPE Nearly 50% Lower Than Previously Thought After Adjusting for Initial Creep

An RCT Comparing 4 Bearing Combinations

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Background: The ideal bearing combination for total hip arthroplasty (THA) remains debatable. Highly cross-linked polyethylene (XLPE) is widely used, but long-term wear rates are not fully known, nor is how much the initial “creep,” if any, affects overall wear. Additionally, the use of oxidized zirconium (OxZir) is purported to lower polyethylene wear rates, but this has not been proven. We present the 10-year data of a cohort of patients who underwent THA. Patients were prospectively randomized to 1 of 4 bearing combinations: a conventional ultra-high molecular weight polyethylene (UHMWPE) or XLPE acetabular liner coupled with either a cobalt-chromium (CoCr) or OxZir femoral head. The aims of the study were to (1) assess the extent to which creep affected overall wear rates and (2) assess wear rates between OxZir and CoCr with polyethylene.

Methods: A total of 92 hips (92 patients) between the ages of 22 and 65 years (mean, 52.2 ± 9.3 years) were randomized to 4 groups. At 10 years, 70 (76%) of the hips were available for analysis; patients who had undergone revision, had died, or were lost to follow-up were excluded from final analysis. Radiographic analysis was performed using a validated digital assessment program to determine linear, volumetric, and directional wear of the polyethylene for all 4 bearing couples. Radiographic assessments were performed immediately postoperatively, at 6 and 12 weeks, and then annually for a minimum of 10 years.

Results: XLPE had significantly lower wear rates than UHMWPE. Once creep was eliminated, annual and overall wear rates were nearly 50% lower than have been previously reported. This was proportionally more important in the XLPE group than in the UHMWPE group. There was a nonsignificant trend toward a lower wear rate with OxZir heads.

Conclusions: Creep plays a notably more important role than first thought. Once creep was eliminated, the overall wear rate was even lower than previously assumed. This has important implications for the overall survivorship of hip arthroplasty implants.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Total hip arthroplasty (THA) is a common elective orthopaedic procedure and is associated with highly favorable patient-reported outcomes¹. It is a successful treatment option for patients with advanced symptomatic arthritis. Recent advances have led to improved implant survivorship. Notably, the advent of highly cross-linked polyethylene (XLPE) has greatly decreased the rate of wear-related osteolysis compared

with previously used ultra-high molecular weight polyethylene (UHMWPE)².

Creep

Wear debris is an inevitable result of any articulation of the hip^{3,4}. It is the particulate debris that is postulated to be a major contributing factor to the development of osteolysis

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A **data-sharing statement** is provided with the online version of the article (<http://links.lww.com/JBJSOA/A185>).

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around orthopaedic implants, and hence, XLPE was developed to minimize wear². Creep is technically distinct from wear, as it is a result of plastic deformation rather than true particulate loss. While wear produces particles of debris, creep does not⁵. More recently, it is thought that the initial “loss” period may be even shorter and estimated to be 3 to 6 months^{6,7}.

The term *creep* was first applied to the initial polyethylene loss period⁸. Rather than being a detrimental event, creep actually decreases the contact surface pressures by increasing the head-liner contact areas⁷, also known as “bedding-in.” The evidence for the duration over which creep has occurred varies between 1 million⁹ and 2.5 million hip cycles¹⁰. Finite element analysis (FEA) demonstrated that creep generally occurs after the first million cycles, increasing the predicted contact area by 56%⁹. While creep results in early head penetration, after the “bedding-in” phase, it has little further effect on long-term volumetric wear. Computed tomography (CT) scan assessment of hip replacements has demonstrated creep occurring as early as 5 days following implantation¹¹.

Results of wear analysis have consistently shown that the annual wear rate of XLPE is well below the 0.1 mm/yr threshold thought to be associated with the development of osteolysis¹².

Polyethylene Wear Rates with Oxidized Zirconium Versus Cobalt-Chromium Heads

Previous radiostereometric analysis and randomized controlled trials (RCTs) comparing overall wear rates between XLPE and UHMWPE have shown a better mid-term wear profile for XLPE¹³⁻¹⁵. Two RCTs found similar superiority of XLPE results over 10 years^{16,17}, and the use of UHMWPE has decreased steadily in recent years, as reported by multiple international joint registries^{18,19}. The focus has now shifted to improving the other half of the bearing couple, the femoral head, so as to further increase the survivorship of THA bearing couples.

The most commonly used materials for femoral heads are cobalt chromium (CoCr) and ceramic¹⁹. The former is most frequently used by surgeons because of its lower price, modularity, and good wear resistance when matched with XLPE. Recent data from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man¹⁹ showed that, at 14 years, there was a significantly lower revision rate with CoP (ceramic-on-polyethylene) compared with MoP (metal-on-polyethylene).

Previous studies comparing polyethylene wear rates when paired with either ceramic or metal heads have been largely inconclusive and may potentially be outdated because of their use of older-generation ceramics and polyethylene²⁰⁻²². Although ceramic heads have been shown to have even better scratch resistance and a better scratch profile than CoCr heads, head-fracture risk remains a concern²³. Recently, oxidized zirconium (OxZir) was introduced and is purported to have improved wettability, scratch resistance, and scratch profile when compared with CoCr, while eliminating the fracture risk associated with ceramic heads^{24,25}.

The aims of the current study were to (1) assess the contribution of creep to overall observed polyethylene wear rates and, once creep was adjusted for, to determine whether the annual wear rate of XLPE was even lower than previously reported^{12,13,14}; and (2) assess whether polyethylene wear differed when paired with either OxZir or CoCr femoral heads.

Materials and Methods

This prospective RCT was performed at St. Michael's Hospital, Toronto, Ontario, Canada, and was approved by our institutional research ethics board. Patients were enrolled between 2003 and 2007. The study was registered at clinicaltrials.gov (NCT03900039). The project protocol was an adaptation of a previously published follow-up report¹², which is further described ahead.

Inclusion criteria consisted of adult patients (18 to 65 years of age) who were undergoing THA for primary or secondary osteoarthritis. Exclusion criteria included a history of hip joint sepsis, primary or secondary malignancy in the involved hip, acute fracture of the femoral head or neck, and bone deficiency requiring the use of autologous or allograft bone for either acetabular or femoral reconstruction.

A total of 92 patients (92 hips) with a mean age (and standard deviation) of 52.2 ± 9.3 years (range, 22.5 to 65.4 years) who were undergoing THA at a single high-volume center were enrolled for the study and randomized to receive 1 of the 4 bearing couples, after providing informed written consent. A standard posterior approach to the hip was used for all patients. Eighty-two hips (89%) were diagnosed with osteoarthritis, while 9 had an inflammatory arthropathy (10%) and 1 had osteonecrosis. Fifty-six (61%) of the patients were female.

After giving informed consent, the patients were randomized using opaque envelopes and a computer-generated block randomization scheme to 1 of 4 bearing surfaces: (1) CoCr and UHMWPE, (2) CoCr and XLPE, (3) OxZir and UHMWPE, or (4) OxZir and XLPE.

All patients received a porous-coated cementless acetabular shell (Reflection; Smith & Nephew) and a metaphyseal fit, proximally coated stem (Synergy; Smith & Nephew) with a 28-mm femoral head. The trunnion taper was 12/14 with a small anteroposterior polished neck to minimize impingement and maximize stability. Screw usage with the acetabular shell was left at the discretion of the treating physician.

Strict adherence to the protocol was followed at each follow-up visit to ensure that standardized anteroposterior and cross-table lateral radiographs were made. Linear and volumetric wear were measured on radiographs using a computer software package (PolyWare Rev. 5; Draftware Developers) as previously described and validated^{12,15}. We have also previously described this technique (which uses an anteroposterior and a lateral plain radiograph to calibrate the wear)¹². This process has been validated, with an intraobserver error at 95% estimated to be ±0.0077 mm and previously reported to be more reliable than 2-dimensional and stereoisometric analysis²⁶.

All patients received standardized postoperative instructions, which included posterior hip precautions for 6 weeks, and were encouraged to fully weight-bear and mobilize from the time of surgery. All patients received the same anticoagulation and postoperative antibiotics and physiotherapy regimen.

Each patient was reviewed clinically and radiographically at 6 weeks, 3 and 12 months, and annually up to 10 years postoperatively. Gruen zones²⁷ on the femoral side and DeLee and Charnley zones²⁸ on the acetabular side were assessed for any signs of osteolysis or radiolucent lines.

As stated above, the project protocol was an adaptation of a previously published follow-up report¹². That study included patients who had undergone THA using a CoCr femoral head and 1 of 3 bearing surfaces (XLPE, UHMWPE, and ceramic-on-ceramic [CoC]). In the prior study, we evaluated XLPE compared with UHMWPE over a 10-year period and compared the wear rates on an annual basis and determined an annual wear rate and overall wear at 10 years (implant survivorship). The exclusion criteria were the same between the prior study and the current study. However, the patient cohorts were not the same, with the current study including both different patients as well as a fourth arm (use of OxZir with both types of polyethylene). Because radiographs were made immediately postoperatively and at 6 and 12 weeks, we were able to measure how long and to what extent creep/viscoelastic deformation occurs.

Statistical Analysis

Analysis of variance (ANOVA) was used to compare linear and volumetric wear rates between groups, and a Kruskal-Wallis (KW) nonparametric test was performed to assess differences at 6 weeks, 3 months, and then annually up to 10-year follow-up using SPSS (2019; IBM). A p value of <0.05 was considered significant for all analyses.

Results

Of the 92 hips enrolled in the study, a total of 70 (76.1%) of the hips were available for review at 10 years of follow-up (Fig. 1): Group 1 (UHMWPE + CoCr) had 17 hips (24%), Group 2 (UHMWPE + OxZir) had 13 hips (19%), Group 3 (XLPE + CoCr) had 22 hips (31%), and Group 4 (XLPE + OxZir) had 18 hips (26%). See also Table I for patient characteristics by UHMWPE and XLPE groups.

Of the 23 initially treated in the UHMWPE + CoCr group, 1 had been lost to follow-up, and 5 (21.7%) had undergone revision: 1 for infection and 4 for aseptic loosening of the cup. Of the 21 initially treated in the UHMWPE + OxZir group, 1 was lost to follow-up, 3 had died, and 4 (19.0%) had undergone revision, for aseptic loosening of the cup. The cases that were revised for aseptic loosening were all associated with excess polyethylene wear. Of the 24 initially treated in the XLPE + CoCr group, 1 was lost to follow-up and 1 had died; there were no revisions. Of the 24 initially treated in the XLPE +

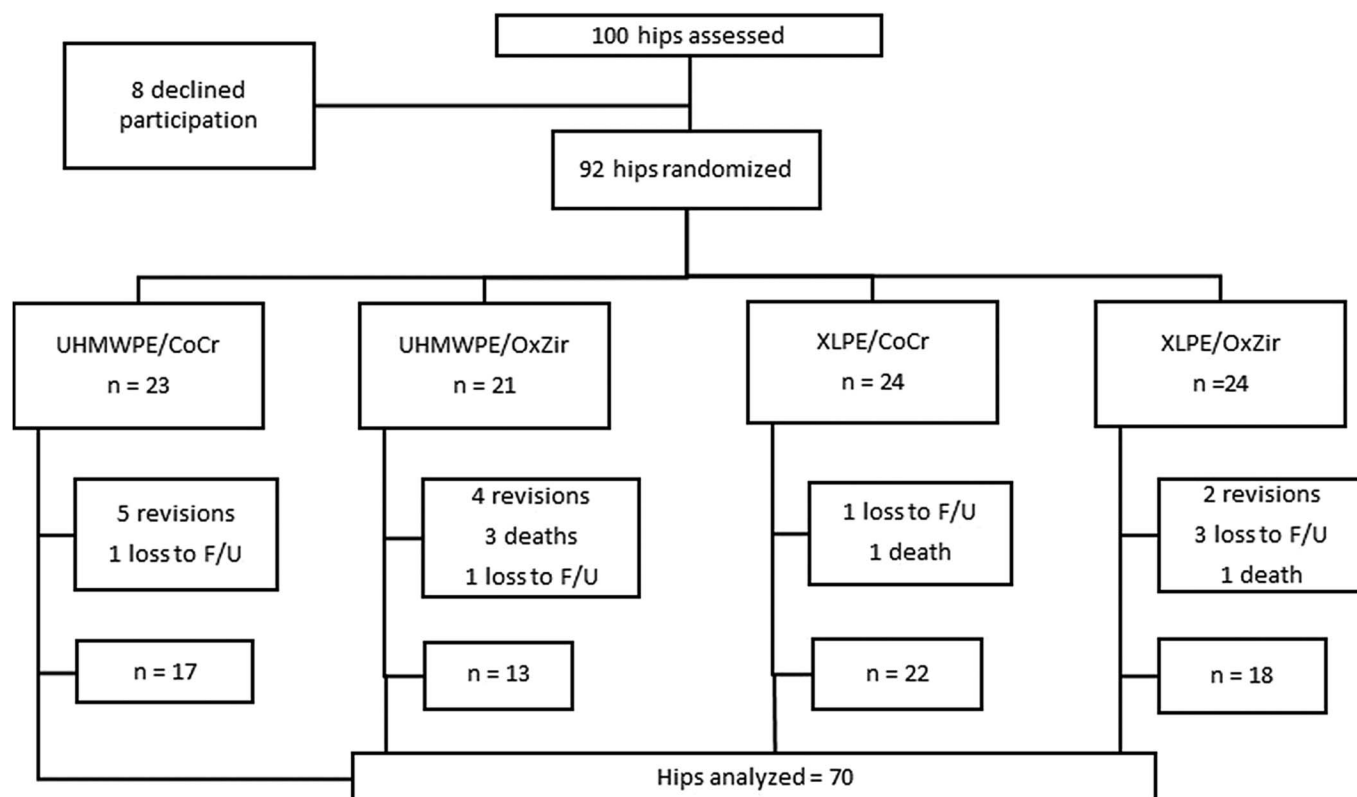


Fig. 1

Flow diagram of enrolled patients. F/U = follow-up.

TABLE I Baseline Demographic and Operative Characteristics and 10-Year Wear Rates of UHMWPE and XLPE Groups (Pooled Head Types)*

	UHMWPE	XLPE	P Value
No. of hips available for analysis	30	40	
Sex (no.)			
Male	16	21	
Female	14	19	
Age (yr)	52.7 ± 7.9	51.6 ± 10.8	0.325
Operative side (no.)			
Left	16	20	
Right	14	20	
Body mass index (kg/m ²)	27.4	26.9	0.34
Acetabular cup size (mm)	55.3 ± 3.5	54.5 ± 3.1	0.179
Cup abduction angle (°)	44.2 ± 7.7	46.4 ± 6.2	0.100
Cup anteversion angle (°)	12.5 ± 9.0	13.1 ± 8.5	0.166
Total linear wear at 10 yr (mm)	2.44 ± 1.14	0.620 ± 0.523	<0.00001†
Linear wear rate at 10 yr (mm/yr)	0.242 ± 0.12	0.062 ± 0.052	<0.00001†
Adjusted linear wear rate at 10 yr (mm/yr)	0.177 ± 0.095	0.0315 ± 0.0371	<0.00001†
Total volumetric wear at 10 yr (mm ³)	542.1 ± 310.3	185.9 ± 110.1	<0.00001†
% of measured wear at 10 yr due to creep	30.7 ± 18.6	55.0 ± 28.5	0.000133†

*The values are given as the mean and standard deviation, except where otherwise indicated. †Significant difference between groups.

OxZir group, 3 were lost to follow-up, 1 had died, and 2 (8.3%) had undergone revision: 1 for deep infection and 1 for dislocation. No hips had a dislocation necessitating a closed reduction.

Summary of Wear Findings

Group analysis indicated that patient age, sex, and operative side as well as acetabular cup size and acetabular component anteversion and abduction angle did not affect the rate of wear in any group.

For the 3 measurements of total linear wear, annual linear wear rate, and total volumetric wear at 10 years, there was significant difference only when comparing UHMWPE (pooled analysis of UHMWPE + CoCr and UHMWPE + OxZir groups) and XLPE (pooled analysis of XLPE + CoCr and XLPE + OxZir groups) as seen in Table I; there was no significant difference when comparing CoCr (pooled analysis of UHMWPE + CoCr and XLPE + CoCr groups) and OxZir (pooled analysis of UHMWPE + OxZir and XLPE + OxZir groups), although there was a nonsignificant trend in favor of OxZir.

Additional details of our results are presented below.

Overall Linear Wear at 10 Years

UHMWPE

The mean total linear wear at 10 years for UHMWPE coupled with a CoCr head was 2.49 ± 1.13 mm and, coupled with an OxZir head, was 2.38 ± 1.19 mm. When pooled to include both

head types with UHMWPE, the overall linear wear was 2.44 ± 1.14 mm (Table I).

XLPE

For XLPE, the total linear wear at 10 years was 0.71 ± 0.55 mm when articulating with a CoCr head and was 0.52 ± 0.49 mm with an OxZir head. This difference was not significant. When pooled to include both head types with XLPE, the overall linear wear was 0.62 ± 0.52 mm.

Mean Annual Linear Wear Rate

UHMWPE

The mean annual linear wear rate over the whole 10 years was 0.25 ± 0.11 mm/yr for UHMWPE + CoCr and was 0.23 ± 0.11 mm/yr for UHMWPE + OxZir. When pooled to include both head types with UHMWPE, the overall mean annual linear wear rate was 0.24 ± 0.12 mm/yr.

XLPE

The mean annual linear wear rate over the whole 10 years was 0.07 ± 0.06 mm/yr for XLPE + CoCr and was 0.05 ± 0.05 mm/yr for XLPE + OxZir. Again, while trending toward a better wear pattern for OxZir, this was not a significant difference. Figure 2 demonstrates how linear wear rates continued to be level up to 10 years for the XLPE bearing combinations, whereas they steadily increased for UHMWPE. When pooled to include both head types with XLPE, the overall mean annual linear wear rate was 0.06 ± 0.05 mm/yr. When comparing this

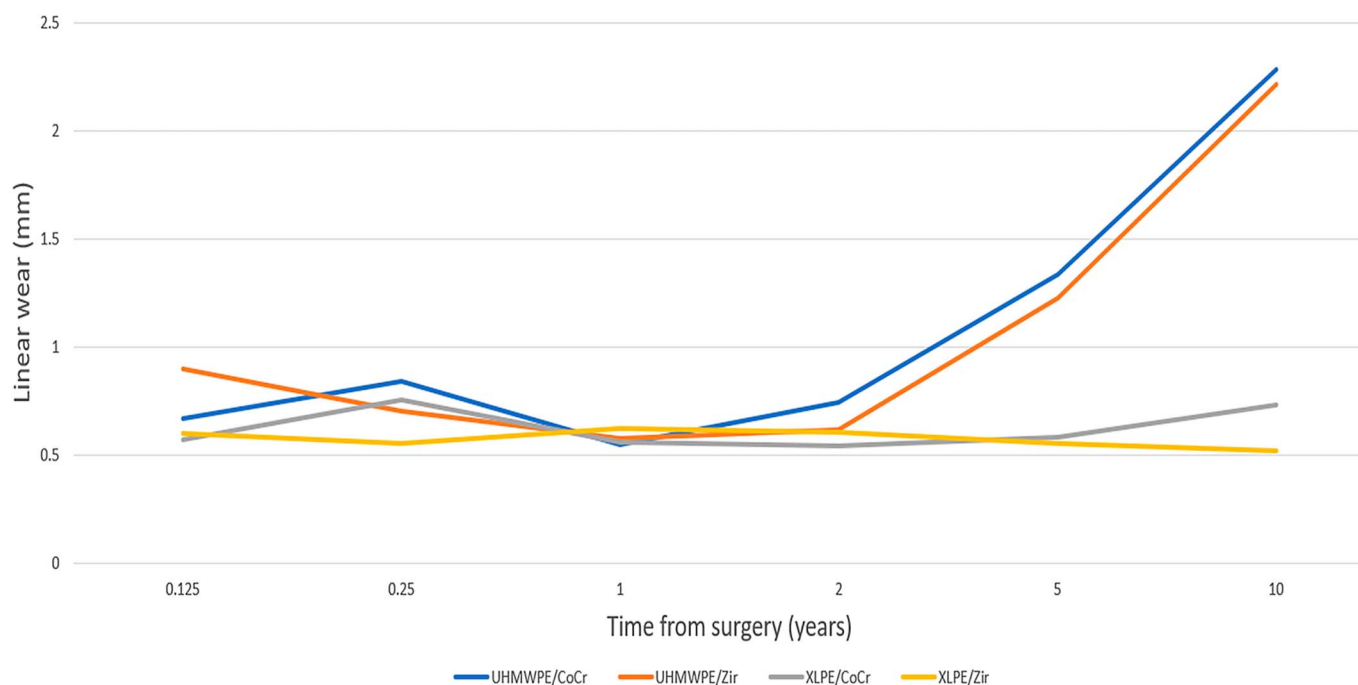


Fig. 2
The annual linear rates of wear for the 4 bearing surfaces (mm/yr). UHMWPE = ultra-high molecular weight polyethylene, CoCr = cobalt-chromium, Zir = oxidized zirconium, and XLPE = highly cross-linked polyethylene.

rate with that of UHMWPE with both head types pooled (0.24 mm/yr), the difference was significant ($p < 0.00001$).

Overall Volumetric Wear Rate

UHMWPE

The mean total volumetric wear at 10 years for UHMWPE + CoCr was $535.5 \pm 260.3 \text{ mm}^3$ and, for UHMWPE + OxZir, was $550.6 \pm 377.1 \text{ mm}^3$.

XLPE

The mean total volumetric wear for XLPE + CoCr was $196.5 \pm 118.6 \text{ mm}^3$ and, for XLPE + OxZir, was $174.2 \pm 102.0 \text{ mm}^3$.

Elimination of Creep

The length of time we assumed for creep to occur was given an arbitrary value of 3 months; our routine follow-up protocol and radiographs were routinely at this point. This arbitrary

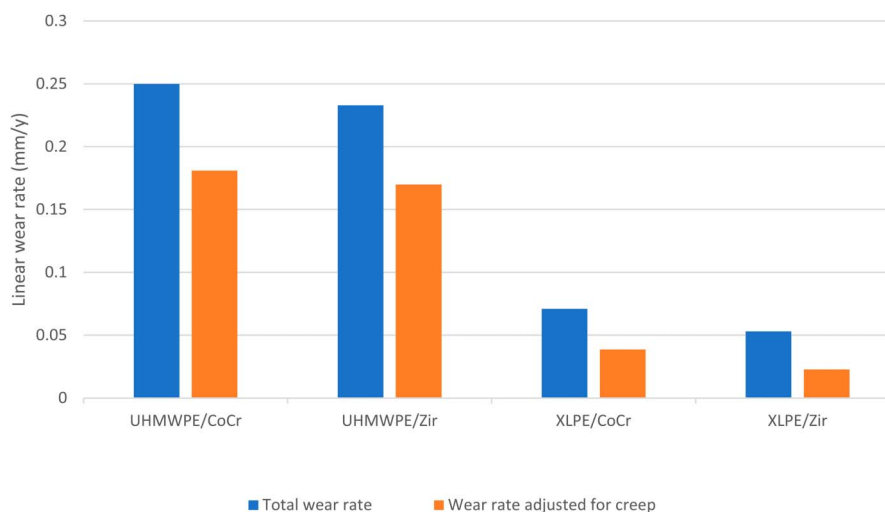


Fig. 3
Bar graph showing the comparative linear wear rates (mm/yr) without adjustment for creep and with adjustment (the first 3 months eliminated). UHMWPE = ultra-high molecular weight polyethylene, CoCr = cobalt-chromium, Zir = oxidized zirconium, and XLPE = highly cross-linked polyethylene.

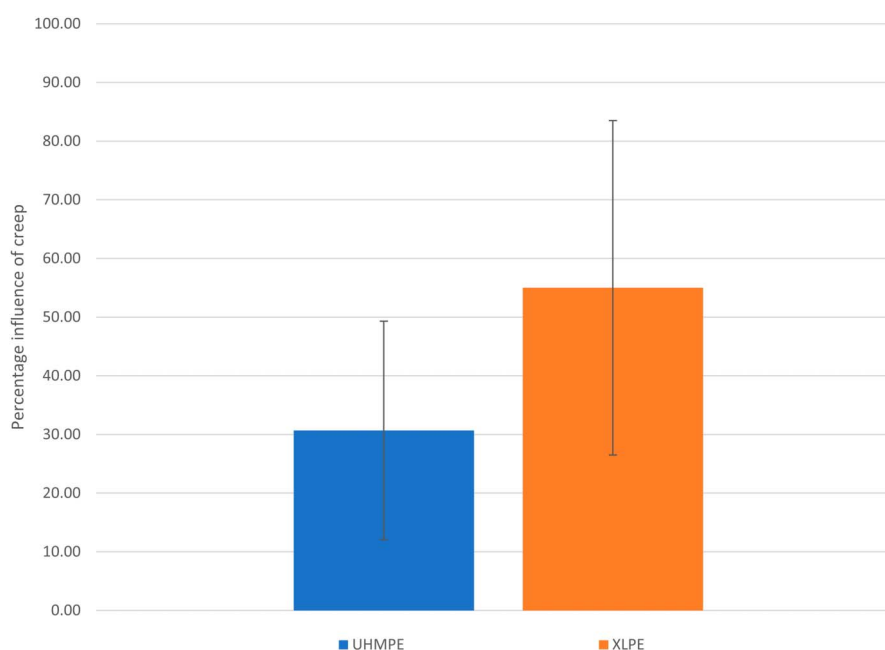


Fig. 4

The percentage influence of creep relative to total linear wear for pooled UHMPE (ultra-high molecular weight polyethylene) and XLPE (highly cross-linked polyethylene) (mean and standard deviation).

3-month mark was chosen on the basis of the FEA analysis that creep and predicted contact areas were increased by 56% after 1 million cycles⁹.

UHMWPE

The mean adjusted annual linear wear rate at 10 years was 0.18 ± 0.10 mm/yr for UHMWPE + CoCr and 0.17 ± 0.10 mm/yr for UHMWPE + OxZir.

XLPE

Once the values for the first 3 months were eliminated from the total, the mean adjusted linear wear rate was 0.039 ± 0.044 mm/yr for XLPE + CoCr and was 0.02 ± 0.03 mm/yr for XLPE + OxZir.

Unadjusted Versus Adjusted Results

For all 4 groups, the mean adjusted annual wear rate was significantly less when compared with the unadjusted annual wear rate

($p < 0.00001$) (Figs. 3 and 4, Table II). With creep eliminated, the mean XLPE + CoCr wear rate decreased from 0.07 to 0.04 mm/yr. The XLPE + OxZir wear rate decreased from 0.05 to 0.02 mm/yr.

Furthermore, we calculated the proportion of wear at 10 years that was due to creep by dividing the first 12 weeks of wear by the total linear wear at 10 years. For this, we pooled the bearing couples that contained UHMWPE and those with XLPE.

The proportions of measured wear due to creep in the individual groups were $29.5\% \pm 18.2\%$ (UHMWPE + CoCr), $32.3\% \pm 19.9\%$ (UHMWPE + OxZir), $58.3\% \pm 26.0\%$ (XLPE + CoCr), and $50.9\% \pm 31.8\%$ (XLPE + OxZir).

There was no difference in creep with respect to the femoral head component. However, there was a significant difference in creep ($p = 0.000133$) with respect to the type of polyethylene component (Fig. 4). As such, creep accounted for proportionally more of the measured wear at 10 years in XLPE than in UHMWPE.

TABLE II Comparative Wear Rates Among the 4 Groups*					
	UHMWPE + CoCr	UHMWPE + OxZir	XLPE + CoCr	XLPE + OxZir	P Value
Total linear wear at 10 yr (mm)	2.49 ± 1.13	2.38 ± 1.19	0.710 ± 0.552	0.520 ± 0.485	<0.00001 †
Linear wear rate at 10 yr (mm/yr)	0.250 ± 0.112	0.233 ± 0.112	0.071 ± 0.055	0.053 ± 0.050	<0.00001 †
Adjusted linear wear rate at 10 yr (mm/yr)	0.181 ± 0.096	0.170 ± 0.099	0.0387 ± 0.0435	0.0227 ± 0.0262	<0.00001 †
Total volumetric wear at 10 yr (mm ³)	535.5 ± 260.3	550.6 ± 377.1	196.5 ± 118.6	174.2 ± 102.0	<0.00001 †
% of measured wear at 10 yr due to creep	29.5 ± 18.2	32.3 ± 19.9	58.3 ± 26.0	50.9 ± 31.8	0.00941 †

*The values are given as the mean and standard deviation. †Significant for overall comparisons.

Discussion

One of the primary goals of hip arthroplasty is maximizing implant survivorship, and the optimal choice of bearing surfaces is integral to that. There are numerous factors that will govern which bearing surfaces are chosen, including cost, availability, and various patient factors (such as age, function, and potential stability issues).

Limiting the amount of wear particles produced is paramount to optimizing the longevity of implants. All bearing combinations have their pros and cons. Hard-on-hard combinations produce the least amount of particulate debris. Although the use of metal-on-metal has now been virtually discontinued because of the incidence of adverse reaction to metal debris (ARMD)²⁹, CoC remains a popular choice of bearing combination (especially for the younger population)³⁰. As well as being associated with low wear rates, CoC implants allow for relatively larger head sizes and the potential for increased stability. However, there are negatives for this bearing combination, such as squeaking, edge loading, and brittleness. More recently, there have been concerns about the survivorship of this combination as demonstrated by registry data. A review of patients in the Danish registry³¹ comparing >11,000 hips treated with CoC or MoP (mostly UHMWPE) demonstrated a 33% higher revision rate with CoC (although not significant).

A further study using data from a joint registry in the U.S.³² analyzed multiple bearing combinations and identified that revision rates of CoC versus metal-on-XLPE were higher by 87% for aseptic loosening. This confirms a similar finding in the joint registries¹⁹ of a higher failure rate for aseptic loosening. One possible explanation for this is the occurrence of a greater transfer of torque of the hard-on-hard bearings to the acetabular prosthesis-bone interface and a predisposition to more aseptic loosening³³.

As a result of this, many surgeons will prefer a hard-on-soft combination for their patients when trying to maximize survivorship. One of the concerns with this bearing combination is polyethylene debris. Several RCTs^{12,34,35} have found that the wear rates of XLPE are significantly lower than those of UHMWPE. That is not in contention now. However, the amount of that XLPE wear has been thought to be between 0.04 and 0.07 mm/yr. The amount of that overall loss that was attributable to creep, or the initial “bedding-in” period, has not been fully known.

Our findings show that, once creep was eliminated from what was perceived to be “total wear,” actual wear (adjusted for creep) was nearly 50% less than previously reported¹²⁻¹⁷, which has implications for overall osteolysis and, ultimately, survivorship.

The exact length of time for the creep period to be complete is unknown^{5,12,34}, but previous work including FEA show that it is complete by 1 million cycles (which usually occurs within 3 months in vivo)⁹. The distinct creep period is difficult to accurately measure in vivo, as it would potentially have required serial (potentially weekly) radiographs to find out when the rate of wear changed. What we discovered by

having initial, 6-week, and then 12-week images was that linear wear rates were at a steeper steady state up to the 3-month mark. Subsequently, the rates for XLPE remained much lower for the duration of the trial. It is therefore safe to assume that the distinct “creep” period ends somewhere between the sixth and twelfth week.

While we did find that the use of OxZir heads when coupled with XLPE demonstrated lower polyethylene wear rates than when paired with CoCr heads, this difference was not significant.

The limitation of the study is the relatively small sample size, compounded by losses to follow-up and death. A post-hoc analysis confirmed there was sufficient power for an assessment of wear differences between the 2 polyethylene types (with or without creep), but there was a lack of sufficient power to differentiate between the OxZir and CoCr heads.

It was, however, a prospective RCT and used a validated method of analysis of wear, which previously has been found to be accurate¹⁵. The current study showed significant differences in the primary outcome measure of linear and volumetric wear rates after creep elimination.

Creep plays a notably more important role than first thought. Once creep was eliminated, the overall wear rate was even lower than previously assumed. This has important implications for the overall survivorship of hip arthroplasty implants. ■

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