A commentary by Harry A. McKellop, PhD, is linked to the online version of this article at jbjs.org.

Highly Cross-Linked Polyethylene Reduces Wear and Revision Rates in Total Hip Arthroplasty

A 10-Year Double-Blinded Randomized Controlled Trial

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Background: Highly cross-linked polyethylene (XLPE) was developed to address the problem of wear and osteolysis associated with metal-on-conventional ultra-high molecular weight polyethylene (UHMWPE) bearing surfaces. The purpose of this study was to compare in vivo wear rates and clinical and radiographic outcomes between XLPE and UHMWPE in a prospective double-blinded randomized controlled trial with a minimum of 10 years of follow-up.

Methods: We randomized 122 patients to receive either a conventional UHMWPE liner (Enduron; DePuy) or an XLPE liner (Marathon; DePuy). Ninety-one patients were assessed clinically and radiographically at a minimum of 10 years (range, 10.08 to 12.17 years). Oxford Hip Scores and Short Form-12 Health Survey scores were collected. The radiographs were analyzed for osteolysis and for 2-dimensional (2-D), 3-dimensional (3-D), and volumetric wear using validated software.

Results: All 122 patients were accounted for at the 10-year follow-up evaluation. Twelve patients had undergone revision surgery, 21 patients had died (1 of whom had previously undergone revision surgery), and 2 patients were unable to return for follow-up, leaving 91 patients available for clinical and radiographic evaluation. At a minimum of 10 years, 3-D wear rates were significantly lower ($p < 0.001$) in the XLPE group (mean, 0.03 mm/yr) than in the conventional UHMWPE group (mean, 0.27 mm/yr). The prevalence of osteolysis was also significantly lower in the XLPE group (38% versus 8%, $p < 0.005$), as was the revision rate (14.6% versus 1.9%, $p = 0.012$), with 10 of the 12 revisions being in the Enduron group. There was no significant difference between the clinical scores of the 2 groups.

Conclusions: XLPE liners have significantly reduced wear and are associated with a greater implant survival rate at 10 years compared with conventional UHMWPE liners.

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

Wear debris-induced osteolysis and loosening are the most common causes of late failure of total hip arthroplasty[1,2]. While using hard bearing articulations may reduce wear, ceramic-on-ceramic bearings have the potential disadvantages of a squeak[3] and catastrophic fracture[4] as well as higher cost. Metal-on-metal articulations have been associated with pseudotumor formation[5], increased metal-ion release, and potential DNA changes[6]. Cross-linking by gamma sterilization of ultra-high molecular weight polyethylene (UHMWPE) to form highly cross-linked polyethylene (XLPE) is one potential solution to this problem[7]. In vitro testing has shown a reduction in wear[8], and XLPE has been in clinical use for nearly 15 years. Whether this reduced wear correlates with improved clinical outcomes has not yet been resolved. Increased cross-linking by higher exposure to radiation could adversely affect the mechanical properties of XLPE[9], and the smaller wear particles associated with XLPE have been

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reported to cause a greater inflammatory response compared with that seen with conventional UHMWPE[10]. Reduced in vivo wear rates at 10 years have been reported with XLPE[11-14], but it has not been convincingly demonstrated that this translates into improved clinical outcomes. A recent randomized study failed to establish that XLPE improves clinical outcomes, as there was no reduction in the aseptic loosening rate of cemented total hip replacements at 10 years[15]. As previous failures of bearing surfaces including Hylamer have shown[16,17], only long-term follow-up can demonstrate the success of a bearing.

The purpose of this study was to compare, in a double-blinded randomized controlled trial with a minimum of 10 years of follow-up, the wear rates and clinical results of standard UHMWPE and XLPE using identical implant designs and fixation methods. We hypothesized that XLPE would be associated with less in vivo wear than conventional UHMWPE at 10 years following primary hip arthroplasty and that this would be associated with lower rates of osteolysis and improved prosthetic survival.

Materials and Methods

A prospective double-blinded randomized controlled trial was initiated to compare conventional UHMWPE (Enduron; DePuy) and XLPE (Marathon; DePuy) acetabular liners. Regional ethics committee approval was obtained prior to the study, and the study was registered at ClinicalTrials.gov (CT 99/31). Power calculation for this study has been described previously[18]. Between June 2001 and September 2003, 122 patients were recruited into the study. Inclusion criteria were an age between 45 and 75 years at the time of

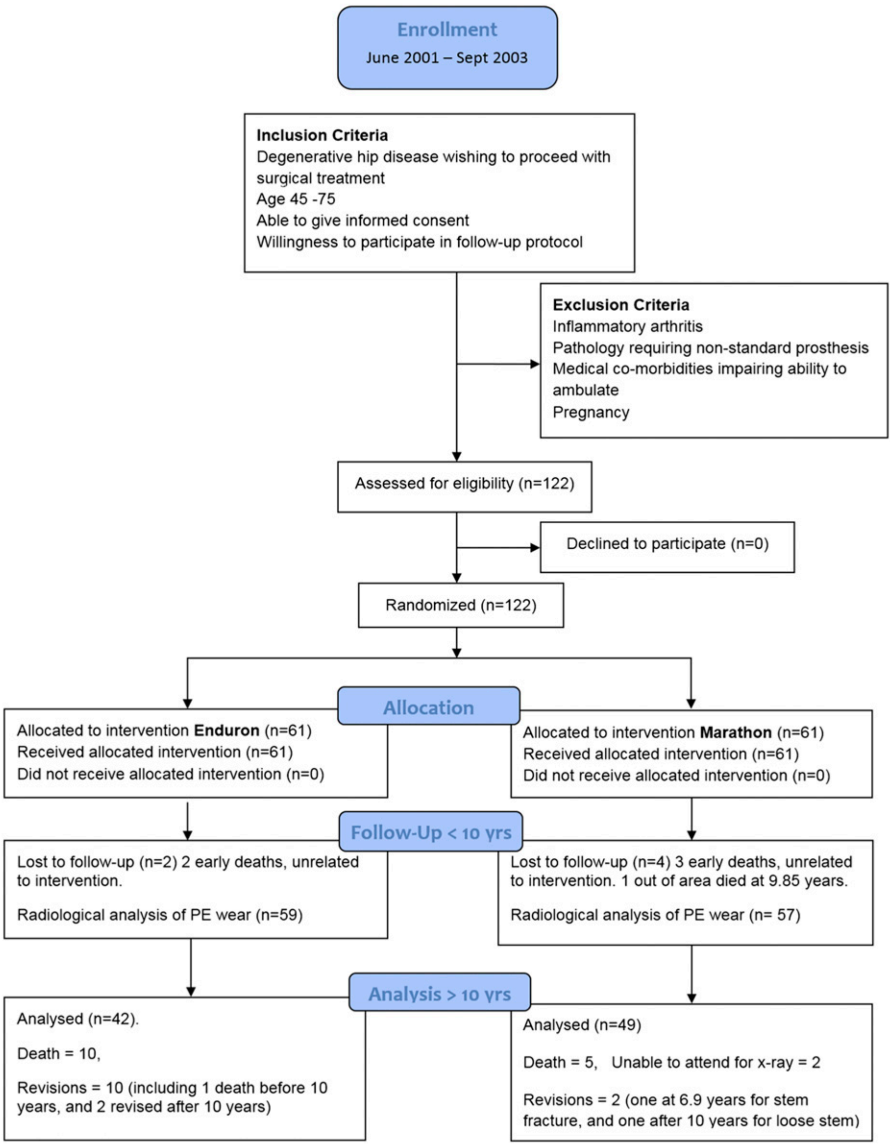

Fig. 1

CONSORT 2010 flow diagram depicting the passage of patients through the randomized controlled trial with details of enrollment, intervention, follow-up, and analysis.

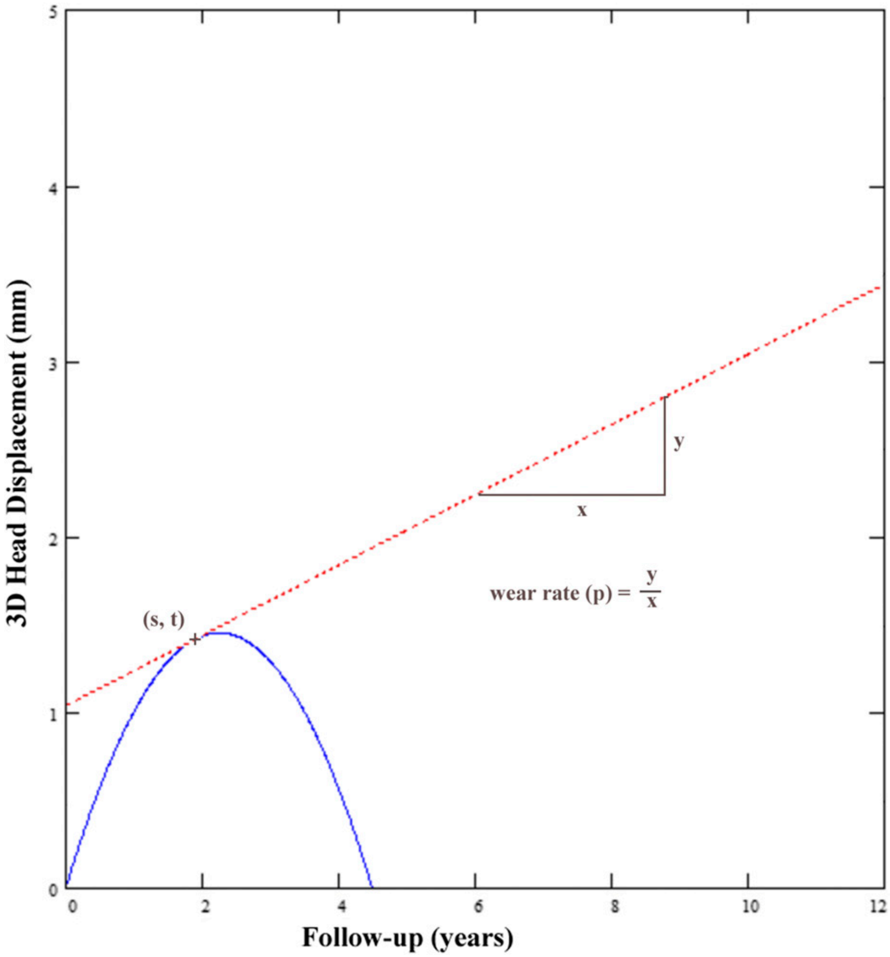

Fig. 2
Two functions representing 3-D femoral head displacement. An inverted parabola with its left side passing through point 0, 0 represents "bedding in" of the femoral head. A straight line represents polyethylene wear. The slope of these 2 functions is identical at their intersection point, which represents the bedding-in period (s) and nonlinear value of head displacement (t) made up of creep and wear. The slope of the straight line represents the rate of polyethylene wear (p). The intersection of the straight line with the y axis indicates the true polyethylene creep for this patient (see Appendix).

the operation, non-inflammatory arthritis, the ability to give informed consent, and willingness to participate in the follow-up protocol. Exclusion criteria were pregnancy and medical comorbidities that impaired the ability to walk (Charnley C classification).

Patients were randomized on entry into the study with use of a computer-generated random numbers list (Fig. 1). A sealed envelope opened by the circulating nurse at the time of surgery determined the type of polyethylene to be used. The liners were packaged such that the operating surgeon could confirm the size but not the type of polyethylene. Blinding was maintained for the patients, surgeons, and clinical and radiographic assessors. The code for the treatment group allocation was kept solely by a research nurse available only in case of adverse postoperative events and was forwarded directly to the statistician for data analysis.

TABLE I Demographic, Clinical, and Radiographic Data (N = 116)

	Enduron	Marathon
No. of patients	59	57
Age* *(yr)*	61 (49-75)	61 (46-75)
Male:female *(no.)*	31:28	36:21
Left:right *(no.)*	30:29	19:38
Surgeon (J.G.H.:P.A.D.) *(no.)*	39:20	34:23
Cup size* *(mm)*	54 (48-60)	54 (48-60)
Abduction angle* *(deg)*	47.7 (29.4-61)	48.8 (31-66.7)
Anteversion* *(deg)*	12.8 (−15.2-32)	13.8 (−14.9-35.2)

*The values are given as the mean with the range in parentheses.

All operations were carried out by 1 of the 2 senior surgeons involved in the study, one of whom used a posterior approach and the other of whom used a direct lateral approach. An uncemented shell (Duraloc Sector; DePuy) augmented with two 6.5-mm cancellous screws was used after underreaming by 1 mm to achieve initial press-fit. All patients received a Charnley Elite size-2 roundback cemented femoral stem (DePuy), a 28-mm cobalt-chromium femoral head (Articul/eze; DePuy), and a 28-mm inner-diameter polyethylene liner.

Follow-up was at 6 weeks, 6 months, 1 year, 2 years, 5 years, and 10 years with clinical and radiographic assessment. Standard anteroposterior pelvic and cross-table lateral hip radiographs were obtained at each visit[19]. All radiographs were examined for loosening of the components, wear, and osteolysis. Radiographs were scanned using a ScanMaker 9800XL scanner (Microtek) or obtained in high-quality tagged image file format (TIFF) from a picture archiving and communications system (PACS; Kodak), ensuring a resolution of 300 dots per inch (dpi). Patient-reported outcome measures were obtained with the Short Form-12 Health Survey (SF-12) and Oxford Hip Score at the latest review (at a minimum of 10 years postoperatively).

Polyethylene wear was measured using validated software, PolyWare Rev 7 (Draftware); 2-dimensional (2-D) wear was measured from the anteroposterior radiograph only, 3-dimensional (3-D) wear was measured from both the anteroposterior and the lateral radiograph, and volumetric wear was calculated using formulas that assume a cylindrical loss of polyethylene along the path of femoral head penetration. Varying projections of different radiographs were automatically accounted for.

Differences in linear, 3-D, and volumetric wear between the 2 groups were determined with mixed linear models, using the MIXED procedure (PROC MIXED) in SAS 9.1. Parameters were fit to estimate the mean difference in wear between liner types, the linear slope of wear across time, and an interaction term to explicitly examine whether the slope of wear over time was substantially different between the 2 liner types. Follow-up time was entered into the equation as a continuous variable, as follow-up radiographs did not always exactly coincide with annual scheduling.

A new regression plot was developed for each of the patients with a minimum of 10 years of follow-up. The plot starts at point 0, 0 (zero wear at zero time) and is initially the shape of an inverted parabola. At some point in time (s), a state of constant polyethylene wear (t) is reached and after that time the regression plot becomes a straight line. The slope of both the inverted parabola and the straight line are equal at point s, t on the regression plot (Fig. 2). Formulas used in calculating point s, t and the rate of polyethylene wear are shown in the Appendix. For each patient with a minimum of 10 years of follow-up, we were able to calculate the polyethylene wear rate, the time taken to bed in, and the amount of bedding in. The presence or absence of osteolysis was determined from the anteroposterior and lateral radiographs and characterized according to the zones described by Gruen et al.[20]. Complications such as death, dislocation, repeat surgery on the involved hip for any reason, infection, deep venous thrombosis, and pulmonary embolus were reviewed as non-continuous variables. Analysis of time to revision was conducted with the "survival" package in R 3.1.2[21] using Kaplan-Meier graphs and the log-rank test to test for differences by liner type.

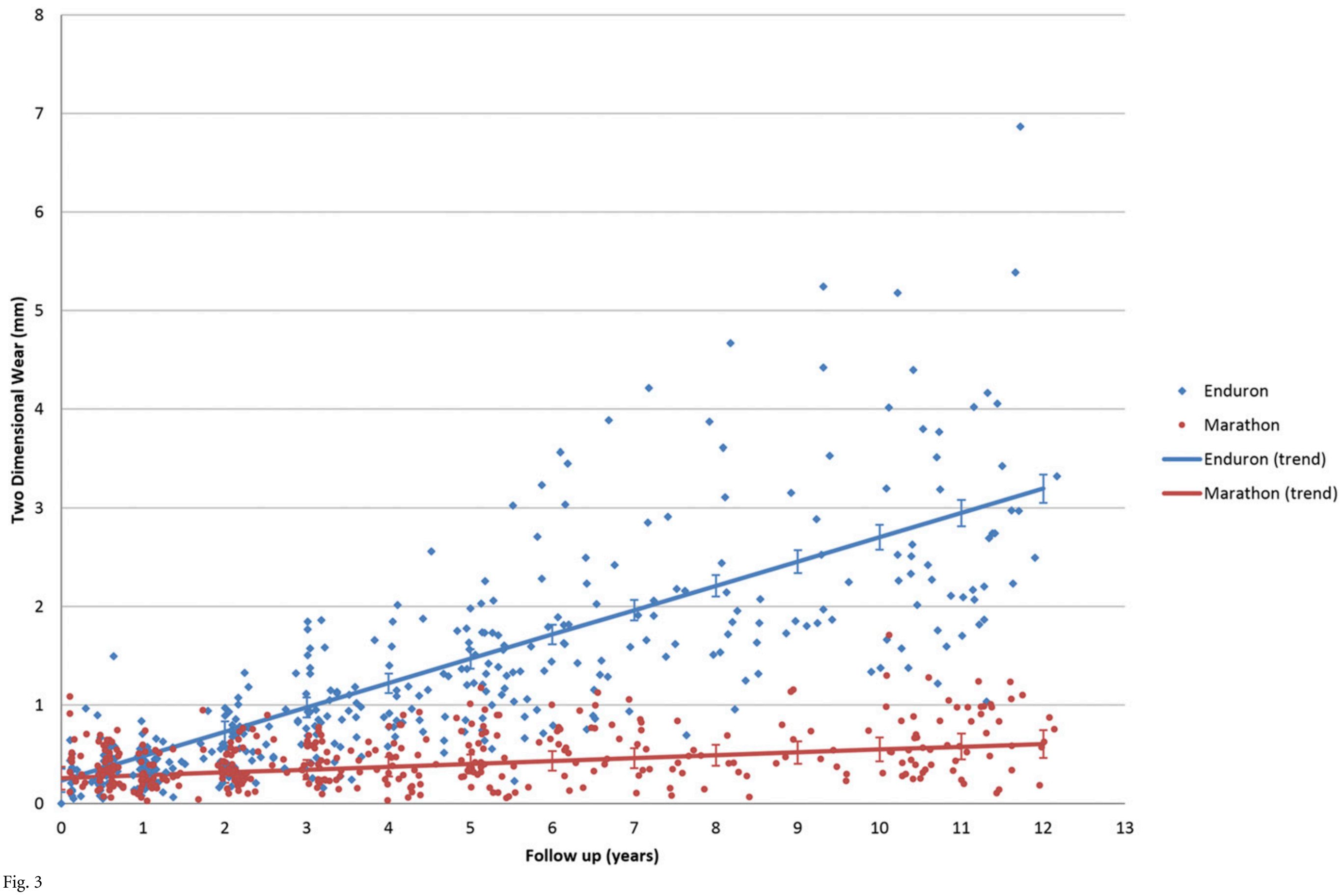

Fig. 3

Two-dimensional polyethylene wear (measured using only the anteroposterior radiograph) for 116 patients. Error bars represent the 95% confidence intervals.

Results

All of the initial 122 patients were accounted for at 10 years. Six patients had insufficient radiographic data (<4 anteroposterior and lateral radiographs available for analysis) because they had died of causes unrelated to the index surgery (5 patients) or moved out of the area (1 patient) within 2 years postoperatively. This left 116 patients available for radiographic analysis (mean duration of follow-up, 10.03 years; range, 3.2 to 12.17 years). We observed no significant difference between the Marathon (XLPE) and Enduron (UHMWPE) groups with respect to age, sex, operative side, surgeon, cup size, or cup positioning (anteversion or abduction angle) as analyzed with the chi-square test for ratios and the Mann-Whitney U test for continuous data (Table I). Of these 116 patients, those with a Marathon liner had significantly reduced 2-D (Fig. 3), 3-D (Fig. 4), and volumetric (Fig. 5) polyethylene wear compared with those with an Enduron liner (Table II).

Ninety-one patients (42 in the Enduron group and 49 in the Marathon group) were available for clinical and radiographic examination at a minimum of 10 years (mean, 10.97 years; range, 10.08 to 12.17 years) postoperatively. Of the patients who were not available, 9 had undergone revision surgery <10 years postoperatively (Table III), 21 had died (including 1 who had previously undergone revision surgery), and 2 (1 with severe dementia and 1 who was housebound because of severe inclusion-body myositis) were unable to return for follow-up radiographs and declined to complete the Oxford Hip Score and SF-12 forms. A mean of 8 pairs of anteroposterior and lateral radiographs (range, 4 to 13) were reviewed for the 91 patients.

The 91 patients with radiographs obtained at a minimum of 10 years were individually analyzed using the regression technique to obtain the time required for the implant to bed in, the amount of bedding in, and the steady state rate of polyethylene wear. The mean wear rate was 0.03 mm/yr (standard deviation [SD], 0.03 mm/yr; range, 0.0 to 0.13 mm/yr) for the 49 patients with a Marathon liner and 0.27 mm/yr (SD, 0.136 mm/yr; range, 0.12 to 0.65 mm/yr) for the 42 patients with an Enduron liner (Fig. 6). There was no significant difference between the 2 liner types with regard to bedding-in time or creep (Table IV). The regression plots of 2 representative patients, 1 with an Enduron liner and 1 with a Marathon liner, are shown in Figure 7. Liner thickness had no effect on the wear rate of either the Enduron or the Marathon liner (Table V). The expected wear-through time of the polyethylene liner was calculated on the basis of the liner thickness, creep, and wear rate.

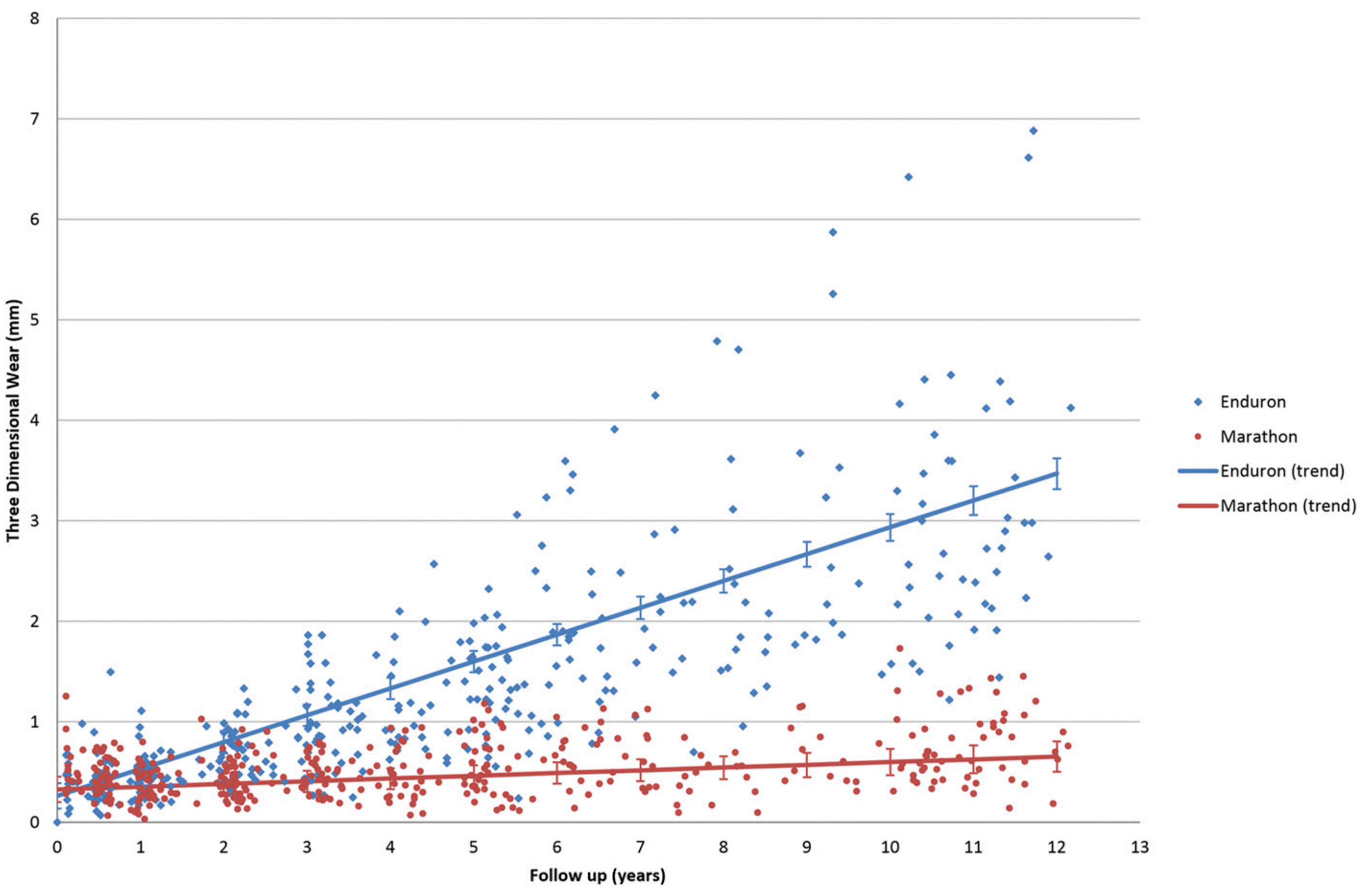

Fig. 4
Three-dimensional polyethylene wear for all 116 patients. Error bars represent the 95% confidence intervals.

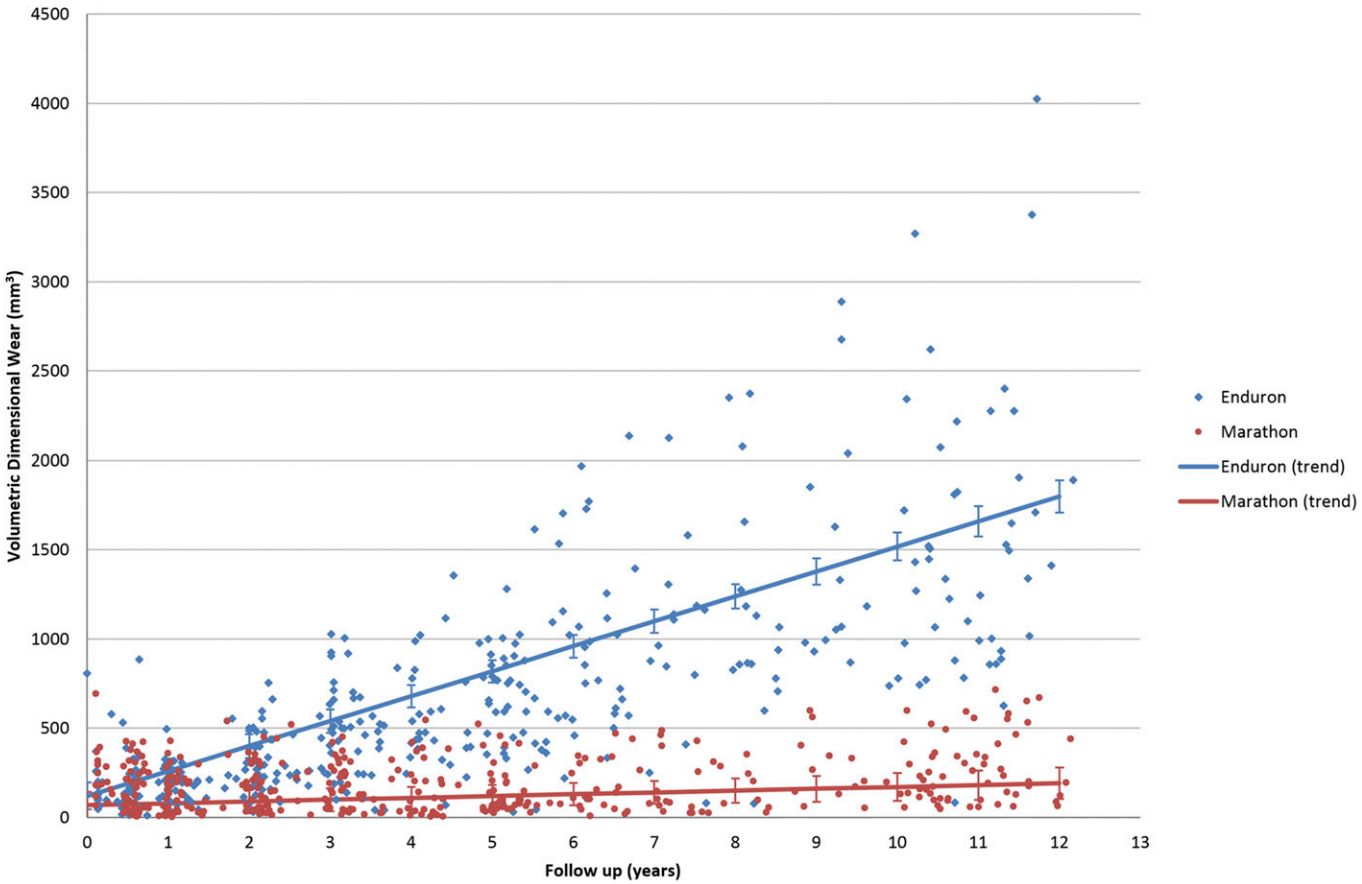

Fig. 5

Volumetric polyethylene wear, calculated from 3-D movement of the femoral head, for all 116 patients. Error bars represent the 95% confidence intervals.

Osteolysis was defined as localized bone resorption or endosteal erosions and was classified as minor (<1 cm^2) or major (≥1 cm^2). The distribution of osteolytic areas was assessed according to the zones defined by Gruen et al.[20] and DeLee and Charnley[22] (Fig. 8). Osteolysis was observed in 20 hips, and there was a significant difference in the prevalence between the 2 groups (16 [38%] of 42 in the Enduron group and 4 [8%] of 49 in the Marathon group, $p < 0.005$). There were no significant differences in the Oxford Hip Score or SF-12 mental or physical well-being scores between the Enduron and Marathon groups (Table VI).

Postoperative complications included a nonfatal pulmonary embolus secondary to a deep venous thrombosis in 1 patient (Marathon group) and a deep infection at 4 weeks treated with irrigation and debridement without exchange of the Enduron liner in another. There were 6 dislocations (Table VII), all occurring in patients in whom the posterior approach had been used. At the time of the latest follow-up, 21 patients had died (mean age at surgery, 67.2 years; range, 52 to 75 years); 12 of these patients had an Enduron liner and 9, a Marathon liner. All deaths, which occurred at a mean of 6.2 years (range, 0.7 to 10.3 years) postoperatively, were considered to be unrelated to the index surgery.

TABLE II Wear Rates (N = 116)

	Mean (95% CI)		
	Enduron (N = 59)	Marathon (N = 57)	P Value
2-D wear *(mm/yr)*	0.27 (0.23-0.29)	0.03 (0.01-0.04)	<0.001
3-D wear *(mm/yr)*	0.28 (0.25-0.30)	0.03 (0.01-0.04)	<0.001
Volumetric wear *(mm^3/yr)*	139.9 (130.9-148.9)	10.25 (1.5-18.9)	<0.001

TABLE III Revisions (N = 12)

Sex	Age *(yr)*	Liner	Time to Revision *(yr)*	Reason for Revision	Wear *(mm/yr)*
F	53	Enduron	5.3	Osteolysis of greater trochanter	
M	73	Enduron	6.4	Stem loosening, osteolysis	
M	65	Marathon	6.9	Stem fracture	
M	56	Enduron	7.7	Osteolysis of greater trochanter	
M	59	Enduron	8.1	Liner wear	
M	70	Enduron	8.6	Stem loosening, osteolysis	
M	53	Enduron	9.0	Stem fracture	
F	57	Enduron	9.3	Stem loosening, osteolysis	
F	52	Enduron	9.6	Liner wear	
M	71	Marathon	10.4	Stem loosening	0.07
M	51	Enduron	10.5	Stem fracture	0.17
F	49	Enduron	12.0	Liner wear	0.59

There were 12 revisions, including 3 of the liner and femoral head because of excessive polyethylene wear, 6 due to femoral osteolysis or aseptic loosening of the stem, and 3 due to stem fracture (Table III). Ten of the revisions were performed in the Enduron group and the other 2 (due to stem loosening caused by stem fracture in 1 and by cement mantle

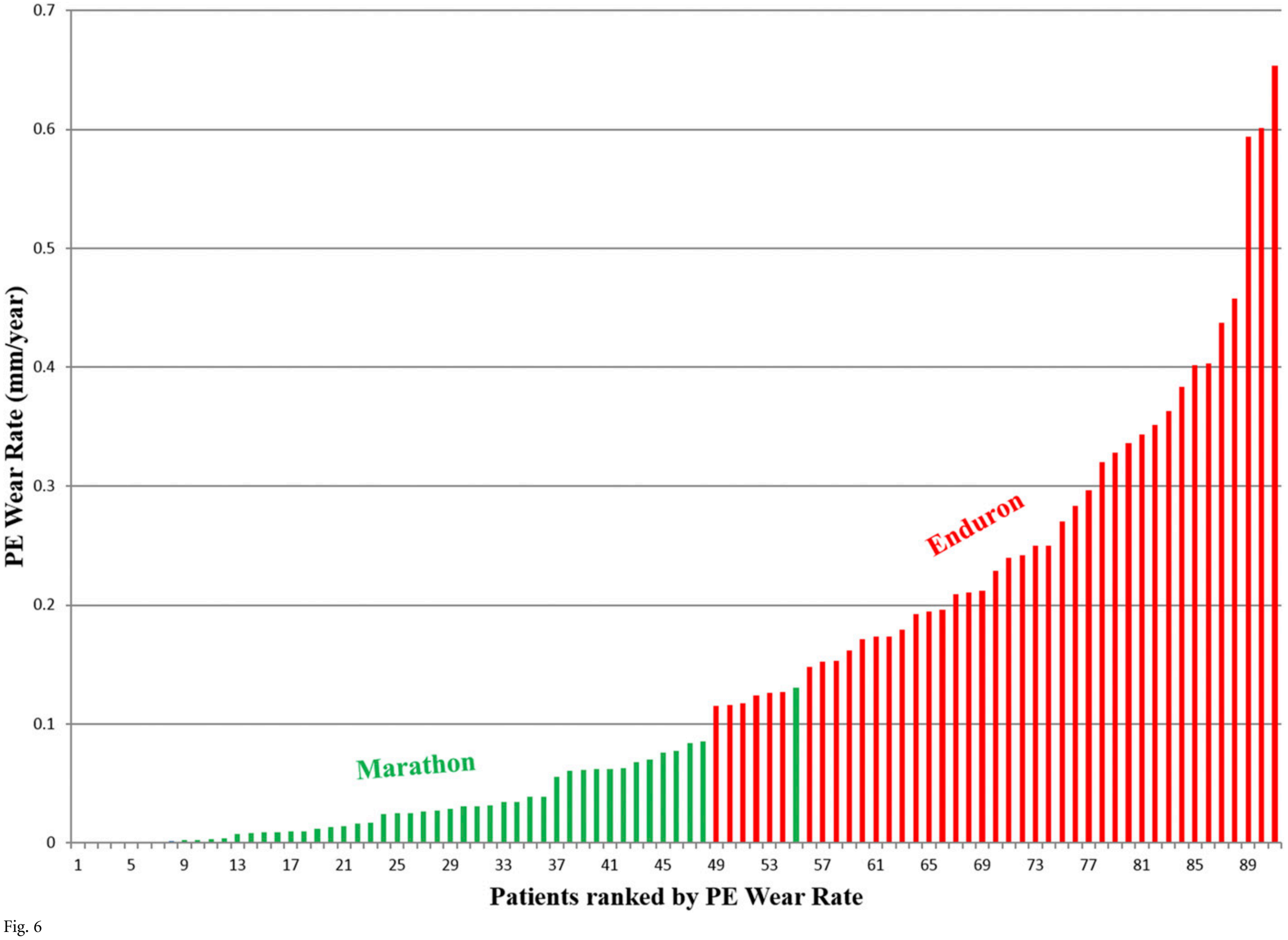

Fig. 6
Rate of polyethylene (PE) wear for the 91 patients with a minimum 10-year follow-up.

TABLE IV Regression Values of Individual Patients (N = 91)

	Enduron	Marathon
No.	42	49
Follow-up* *(yr)*	11.0 (10.1-12.2)	11.0 (10.1-12.1)
Wear rate* *(mm/yr)*	0.27 (0.12-0.65)	0.03 (0.0-0.13)
Bedding-in time* *(yr)*	1.7 (0.1-3.0)	0.7 (0.0-3.0)
Creep + wear* *(mm)*	0.62 (0.02-1.65)	0.42 (0.03-0.82)
Creep* *(mm)*	0.2 (0.0-0.75)	0.4 (0.01-0.82)

*The values are given as the mean with the range in parentheses.

failure in 1), in the Marathon group. Three patients underwent the revision after they had been followed for 10 years, and their data are included in the analysis (Table III). No revisions were undertaken as a result of loosening of the acetabular shell. Patients with an Enduron liner had a significantly higher revision rate than those with a Marathon liner (Fig. 9; log-rank chi-square test (1 degree of freedom [df]) = 6.3; p = 0.012), with the first revisions seen after just 5 years.

Discussion

Cross-linking of polyethylene has been shown to improve wear in multiple studies, but there is little evidence to date that this improves prosthetic longevity[23]. In 2 studies, radiostereometric analysis (RSA) showed XLPE to have improved results with respect to wear at 10 years, but both included a small number of patients and only 1 was randomized[15,24]. In another study, in which 95 patients (105 hips) were followed for a minimum of 10 years after total hip arthroplasty with an XLPE liner from a different manufacturer (Longevity; Zimmer), Garvin et al. found a low wear rate of 0.022 mm/yr after bedding in[25]. Another clinical study, with

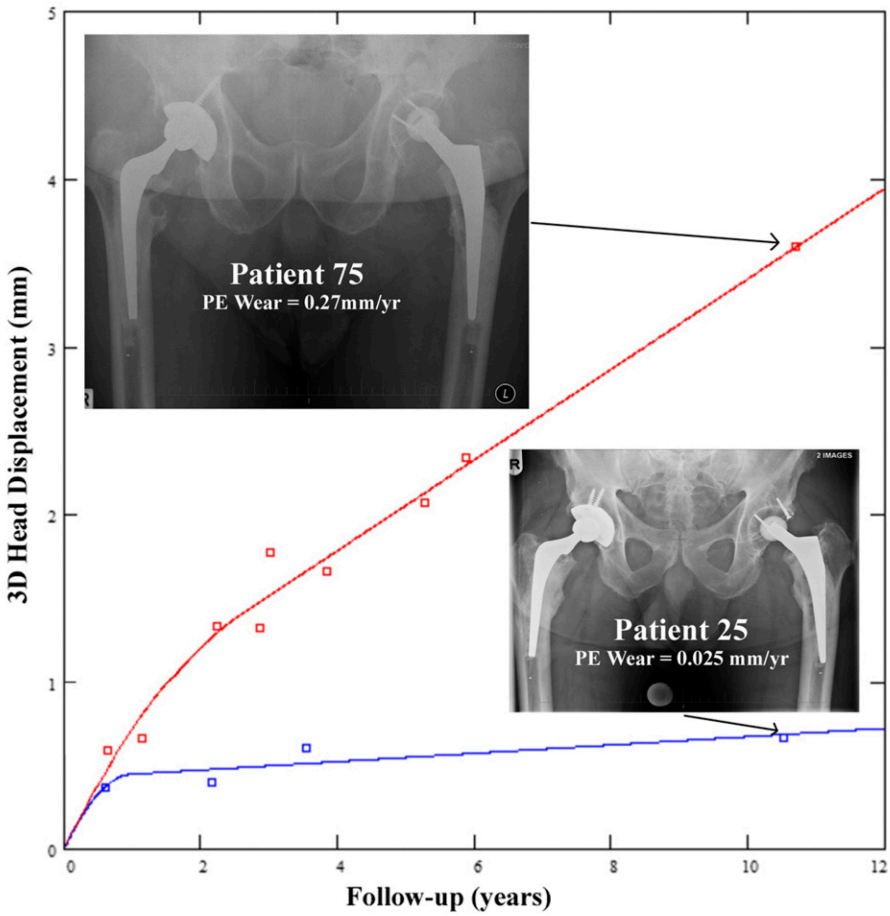

Fig. 7

Representative parabola/line regression plot of fitted data of a 61-year-old man (Patient 75) with a right total hip replacement performed with an Enduron liner (red line) and a 56-year-old man (Patient 25) with a right total hip replacement performed with a Marathon liner (blue line).The Enduron liner had a polyethylene (PE) wear rate of 0.27 mm/yr, a bedding-in time of 2.6 years, 0.7 mm of creep, and 1.41 mm of creep plus wear. The Marathon liner had a wear rate of 0.03 mm/yr, a bedding-in time of 1.0 year, 0.42 mm of creep, and 0.45 mm of creep plus wear.

TABLE V Liner Thickness Versus Wear for Patients with Minimum 10-Year Follow-up (N = 91)

	<8 mm Thick	8-10 mm Thick	>10 mm Thick	All Liners
Enduron				
No. of implants	20	17	5	42
Wear rate* *(mm/yr)*	0.26	0.26	0.32	0.27 (0.12-0.65)
Time until wear-through* *(yr)*	36	43	43.6	39.7 (13.5-85.4)
Marathon				
No. of implants	18	24	7	49
Wear rate* *(mm/yr)*	0.03	0.03	0.04	0.03 (0-0.13)
Time until wear-through* *(yr)*	762	657	1,329	791 (81.4-5,479)

*The values are given as the mean and, in the last column, as the mean with the range in parentheses.

10 to 14-year follow-up of the same material, showed a similar low wear rate of 0.024 mm/yr[13]. A randomized controlled trial with a minimum 10-year follow-up of the same polyethylene reported on in our paper showed that the Marathon liner had a lower wear rate (0.04 mm/yr) compared with the Enduron liner (0.22 mm/yr)[26].

We believe that our study is the first randomized double-blinded trial assessing polyethylene wear rates of individual patients with the use of multiple measurements and a regression formula that models femoral head penetration during the first 2 years. With 1 exception (Patient 55; Fig. 6), all patients with a Marathon liner had a wear rate of

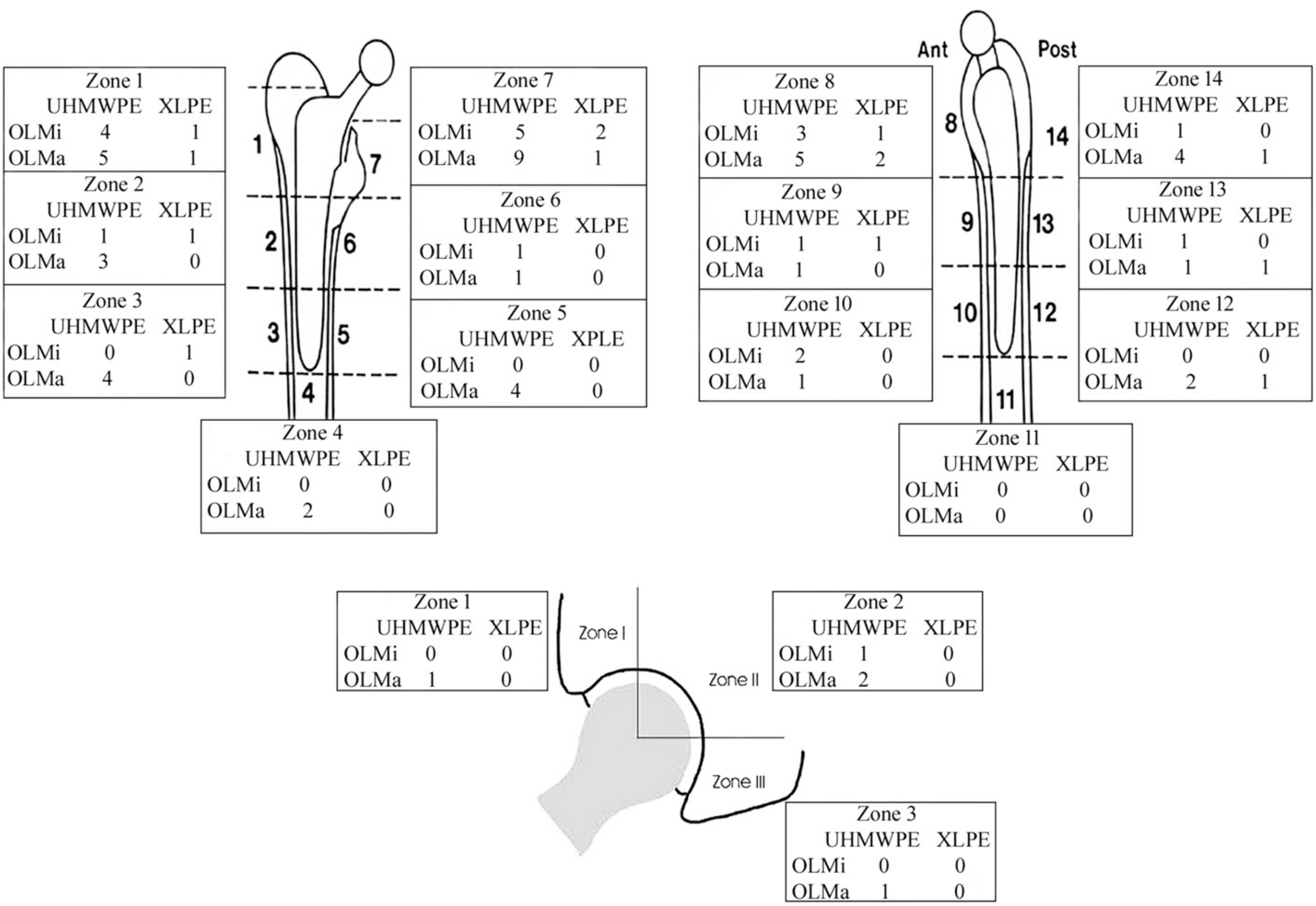

Fig. 8

Distribution of observed osteolysis by zone. OLMi = minor osteolysis, and OLMa = major osteolysis.

TABLE VI Clinical Scores

	Mean (Range)		
	Enduron (N = 42)	Marathon (N = 49)	P Value
Oxford Hip Score	41 (14-48)	44 (30-48)	0.06
SF-12 mental well-being	45.4 (27.4-67.3)	44.3 (31.7-71.3)	0.66
SF-12 physical well-being	52.4 (16.4-62.1)	54.9 (14-59.3)	0.24

TABLE VII Dislocations (N = 6)

Sex	Age *(yr)*	Liner	Dislocation Details	Wear Rate *(mm/yr)*
M	62	Marathon	1 early, at 2 wk	0.04
F	57	Enduron	2 late, at 16 mo	0.12
M	67	Marathon	2 early, in 1st wk; 3 late	0.13
F	64	Enduron	2 early, at 4 wk	0.17
M	70	Enduron	1 late, at 10.5 yr	0.38
M	59	Enduron	3 early, in 1st yr	Revised at 8 yr for osteolysis

<0.08 mm/yr and all patients with an Enduron liner had a wear rate of >0.12 mm/yr. Patient 55, a 67-year-old man with a Marathon liner, had a wear rate of 0.13 mm/yr. He had 2 dislocations of the hip in the first week after surgery followed by 3 additional dislocations, 2 at 7 years and 1 at 11 years. We assume that he had surface damage of the femoral head that caused a higher wear rate of the Marathon liner, but to date he has refused revision surgery.

Measurement of polyethylene creep from clinical radiographs assumes a constant bedding-in period[27], but this may not be the case. In our study, individual patient data points were fitted to the parabola/straight line model and this demonstrated that, although the finding was not statistically significant, XLPE tended to bed in more quickly (in 0.7 versus 1.7 years) and had higher initial creep (0.4 versus 0.2 mm). Higher creep of XLPE was reported in a simulator study[28], but we believe that we are the first to quantify bedding-in time in individual patients. Our calculation of the time needed for the polyethylene liners to wear through (Table V) indicated that no Marathon liner would require revision but 6 Enduron liners would wear through within 20 years. The liner that was expected to wear through the most quickly (in 13.5 years in a woman who was 49 years of age at surgery) was revised at 12 years (Table III).

As was found in previous studies[29,30], patient-reported outcome scores did not differ significantly between the 2 types of polyethylene (Table VI). However, the patients treated with the Enduron liner had a significantly higher prevalence of osteolysis (38% versus 8%, $p < 0.005$). Lachiewicz et al. reported that 8.2% (12) of 146 hips treated with a Longevity implant (Zimmer) had osteolysis after a similar duration of follow-up[13]. The longer-term implications of these findings are unclear. In our study, the reasons for revision were liner wear (3 cases), stem fracture (3), and stem loosening or osteolysis (6), but there were no revisions of the acetabular shell (Table III). The Marathon group had 2

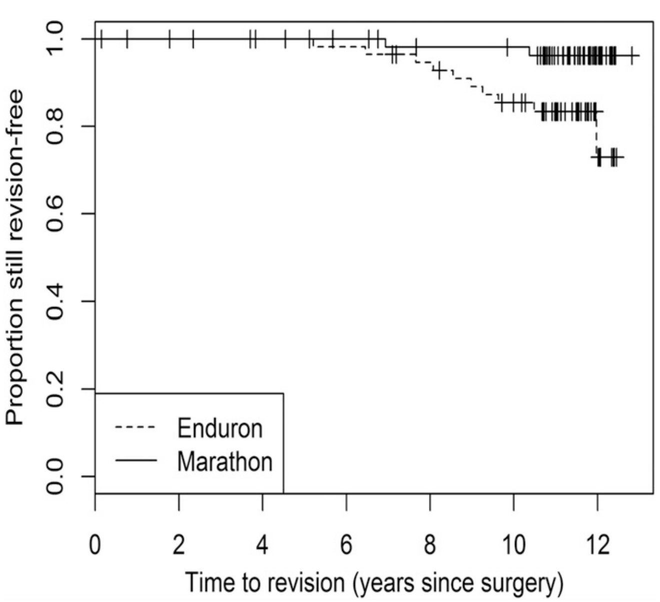

Fig. 9

Kaplan-Meier survival curve for the Enduron and Marathon groups. At 10 years postsurgery, the revision rate was 14.6% (95% confidence interval [CI] = 4.7%, 23.4%) in the Enduron group and 1.9% (95% CI = 0.0%, 5.4%) in the Marathon group. At 12 years postsurgery, the revision rate was 27.0% (95% CI = 2.7%, 45.3%) in the Enduron group and 3.8% (95% CI = 0.0%, 8.8%) in the Marathon group.

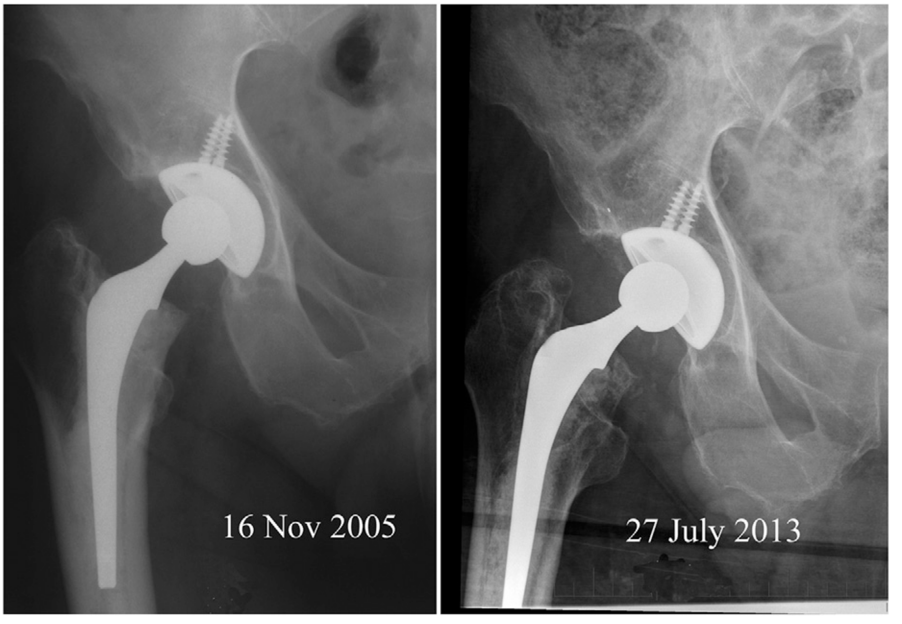

Fig. 10

Radiographs made at 2.5 and 10 years after total hip arthroplasty with a Marathon liner was performed in a 71-year-old man. He required revision at 10.4 years because of pain. The stem had subsided, with multiple fractures of the cement mantle. The cup was well fixed. There was no osteolysis.

revisions, 1 due to stem fracture at 6.9 years and the other due to cement mantle failure without osteolysis at 10.4 years (Fig. 10). Despite stem loosening, the wear rate for this patient was 0.07 mm/yr. The 3 stem fractures were a fault of the study design, with the use of a Charnley Elite size 2 for all patients leading to undersizing in some patients and causing the stem to fracture. Our radiographic and clinical results for this stem are similar to those reported by Ollivere et al., who showed an 88% revision-free survival rate at 12 years but a 37% rate of either radiographically evident failure or revision[31].

This study has several limitations. It was a single-center study in which polyethylene from a single manufacturer was analyzed. Our recording of osteolysis from only anteroposterior and lateral radiographs instead of computed tomography (CT) or magnetic resonance imaging (MRI) almost certainly led to underreporting of the prevalence[32]. Study strengths are that the prostheses were standardized as much as possible, the follow-up rate was 100%, and polyethylene wear was measured at multiple time points for each patient.

In conclusion, XLPE (Marathon) liners had less wear than standard UHMWPE (Enduron) liners at 10 years as well as lower osteolysis and revision rates. It should be noted that our data were derived from a group with hybrid fixation, and while they may apply to other forms of fixation, such as all-cemented or all-cementless, the osteolysis and revision rates may differ with different fixation methods. The 2 revisions in the Marathon group were due to stem failure, showing that a less than optimal stem design cannot fully protect a patient with a Marathon liner from revision. The longevity of hip replacements with a Marathon liner needs to be assessed with longer-term studies, and the use of CT or MRI to better quantify osteolysis should be considered, although this would require additional ethical considerations and patient consent.

Appendix

eA The formulas used to calculate creep and the polyethylene wear rate are available with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/E293). ■

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