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SYMPOSIUM: ADVANCES IN UHMWPE BIOMATERIALS

Metal-on-conventional Polyethylene Total Hip Arthroplasty Bearing Surfaces Have a Higher Risk of Revision Than Metal-on-highly Crosslinked Polyethylene: Results From a US Registry

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Abstract
Background Although studies have reported lower radiological wear in highly crosslinked polyethylene (HXLPE) versus conventional polyethylene in total hip arthroplasty (THA), there is limited clinical evidence on the risk of revision of these polyethylene THA bearing surfaces.

Questions/purposes We asked: (1) Do primary THAs with a metal-on-conventional polyethylene bearing surface have a higher risk of revision (all-cause or aseptic) than metal-on-HXLPE? (2) Is the risk of revision (all-cause or aseptic) higher for conventional polyethylene versus HXLPE when the effect of femoral and acetabular components is controlled for in prosthesis-specific analyses?
Methods The Kaiser Permanente's Total Joint Replacement Registry was used to identify metal-on-conventional polyethylene and metal-on-HXLPE primary THAs (N = 26,823) performed between April 2001 and December 2011. The registry has 95% voluntary participation and 8% were lost to followup during the 10-year study period. Endpoints of interest were all-cause and aseptic revisions. Descriptive statistics and marginal Cox regression models with propensity score adjustments were applied to compare risk of revision for metal-on-conventional polyethylene versus metal-on-HXLPE THAs and to evaluate two specific manufacturers' hip implant designs while controlling for femoral and acetabular components. Of the 26,823 THAs included in the study, 1815 (7%) were metal-on-conventional polyethylene and 25,008 (93%) were metal-on-HXLPE.
Results At 7 years followup, the cumulative incidence of revision was 5.4% (95% confidence interval [CI], 4.4%–6.7%) for metal-on-conventional and 2.8% (95% CI, 2.6%–3.2%) for metal-on-HXLPE. There was a higher adjusted risk of all-cause (hazard ratio [HR], 1.75; 95% CI, 1.37–

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
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2.24; $p < 0.001$) and aseptic (HR, 1.91; 95% CI, 1.46–2.50; $p < 0.001$) revisions among metal-on-conventional polyethylene bearing surface hips compared with metal-on-HXLPE. Results were similar within manufacturer hip designs with the same femoral and acetabular components.
Conclusions Metal-on-conventional polyethylene THA bearing surfaces have a higher risk of revision compared with metal-on-HXLPE bearing surfaces. Clinicians should consider the use of HXLPE when using a polyethylene bearing in THA.
Level of Evidence Level II, cohort study.

Introduction

Ultrahigh-molecular-weight polyethylene wear and associated aseptic loosening and osteolysis are leading causes of long-term THA revision [26]. The rates of loosening and osteolysis in metal-on-conventional polyethylene THAs have been reported to range from 9% to 47% [3, 5, 6]. Highly crosslinked polyethylene (HXLPE) was introduced to reduce wear and THA revision rates; however, there is limited information about the reduced risk of revision associated with HXLPE compared with conventional polyethylene in THA.

Several hip simulator and randomized clinical trials (RCTs) have evaluated HXLPE versus conventional polyethylene wear. Simulator studies report decreased femoral penetration and wear in HXLPE compared with conventional polyethylene [13, 15]. Radiological evaluations of in vivo liner wear in RCTs have also found lower wear of HXLPE versus conventional polyethylene [2, 5, 12, 16, 27]. Meta-analyses and systematic reviews also suggest that HXLPE has lower femoral penetration and wear than conventional polyethylene [8, 10, 14]. Although these findings suggest decreased wear of HXLPE liners, these studies have not evaluated reduction in risk of THA revision rates.

Findings from studies that have examined THA revision rates in relationship to polyethylene formulation are conflicting. Although some studies report a reduction in risk of revision rate for metal-on-HXLPE versus metal-on-conventional [17], others did not find an increased risk or did not investigate reduction in risk of THA revision [3, 7]. These prior study findings are limited by the small sample sizes from single-center and academic institutions, loss to followup, and limited length of followup. Methodological differences and investigation of a variety of implant designs also limit the use of current findings.

Larger, registry-based studies have reported a higher risk of revision for conventional polyethylene versus HXLPE [1, 22]. These studies are important in that they provide large samples on a wide range of patients across multiple settings by surgeons with various experience levels. However, as a result of the limited availability of data from US registries, there is currently a reliance on information about THA bearing surface performance from other countries.

Therefore, the purpose of this study was to compare risk of revision of metal-on-HXLPE compared with a metal-on-conventional polyethylene bearing surface in primary THAs using a large US registry. Specifically: (1) Do primary THAs with a metal-on-conventional polyethylene bearing surface have a higher risk of revision (all-cause or aseptic) than metal-on-HXLPE? (2) Is the risk of revision (all-cause or aseptic) higher for conventional polyethylene versus metal-on-HXLPE when the effects of femoral and acetabular components are controlled for in prosthesis-specific analyses?

Patients and Methods

A retrospective cohort study was conducted. Kaiser Permanente's Total Joint Replacement Registry (TJRR) was used to identify cases during the study period. Data collection procedures, participation, and coverage of this TJRR have been published [19, 21]. In brief, the TJRR covers over 9 million members of an integrated healthcare system in seven geographical regions in the United States and enrolls over 20,000 joint arthroplasties a year. The registry has 95% voluntary participation and only 8% were lost to followup during the 10-year study period [20]. All elective nonbilateral primary THAs, in which patients were at least 18 years old at the time of their procedure and had metal-on-conventional polyethylene or metal-on-HXLPE bearing surfaces registered between April 1, 2001, and December 31, 2011, were included in the sample. Revision procedures, bilateral (same-day) primary procedures, and conversion procedures were not included. The overall study sample ($N = 26{,}823$) included all metal-on-conventional polyethylene and metal-on-HXLPE hips; cohorts for prosthesis-specific analysis to control for the femoral and acetabular components consisted of Duraloc (DePuy Inc, Warsaw, IN, USA) ($N = 1146$) and Reflection (Smith & Nephew Inc, Memphis, TN, USA) ($N = 5202$) THA cohorts. The cohort included cases from 51 medical centers and 333 surgeons were included.

The majority of the 26,823 primary THAs included in the study were women ($n = 16{,}170$ [60%]), white ($n = 20{,}559$ [77%]), had a body mass index < 30 kg/m^2 ($n = 16{,}233$ [61%]), and had an American Society of Anesthesiologists (ASA) score of 1 or 2 ($n = 15{,}374$ [57%]) at the time of their surgery. The mean age of the total THA cohort was 70 years (SD = 10), and the prevalence of diabetes was 23% ($n = 6239$) (Table 1). Of the 26,823 THAs included in the study, 1815 (7%) had metal-

Table 1. Patient, surgeon, implant, and hospital characteristics for the total THA cohort, 2001–2011

Variables		All		Bearing surface			
				Conventional polyethylene		HXLPE	
		Number	Percent	Number	Percent	Number	Percent
		26,823		1815	7	25,008	93
Sex	Male	10,649	40	653	36	9996	40
	Female	16,170	60	1160	64	15,010	60
	Missing	4	<0.01	2	0.1	2	<0.01
ASA category	1 or 2	15,374	57	1028	57	14,346	57
	≥ 3	10,704	40	706	39	9998	40
	Unknown	745	3	81	5	664	3
BMI category (kg/m^2)	< 30	16,233	61	1088	60	15,145	61
	≥ 30 and < 35	6263	23	370	20	5893	24
	≥ 35	3857	14	214	12	3643	15
	Unknown	470	2	143	8	327	1
Race	Asian/Pacific Islander	886	3	94	5	792	3
	Black	1882	7	61	3	1821	7
	Native American	41	0.2	4	0.2	37	0.1
	White	20,559	77	1232	68	19,327	77
	Hispanic	1804	7	114	6	1690	7
	Other	358	1	46	3	312	1
	Unknown	1293	5	264	15	1029	4
Diabetes	Yes	6239	23	468	26	5771	23
Surgeon fellowship	Yes	10,893	41	718	40	10,175	41
	Missing	45	0.2	0	<0.1	45	0.2
Surgeon average annual volume category	< 10	1448	5	71	4	1377	6
	10 to < 50	16,097	60	1145	63	14,952	60
	≥ 50	9276	35	599	33	8677	35
	Missing	2	<0.01	0	<0.1	2	<0.01
Site average annual volume category	< 100	4436	17	395	22	4041	16
	100 to < 200	13,703	51	889	49	12,814	51
	≥ 200	8682	32	531	29	8151	33
	Missing	2	<0.01	0	0.1	2	<0.01
Fixation	Uncemented	20,991	78	727	40	20,264	81
	Hybrid	3871	14	914	50	2957	12
	Cemented	181	1	26	1	155	1
	Missing	1780	7	148	8	1632	7
Head size	≤ 28 mm			1420	78	3773	15
	32 mm			341	19	10,420	42
	36 mm			54	3	9620	38
	> 36 mm			0	0.2	1195	5
Cup Type	Converge (Zimmer, Warsaw, IN, USA)			0	<0.1	463	2
	Duraloc (DePuy Synthes, Warsaw, IN, USA)			382	21	764	3
	Other			101	6	732	3
	Pinnacle (DePuy Synthes)			9	1	12,877	52
	Reflection (Smith & Nephew, Memphis, TN, USA)			753	42	4449	18
	S-Rom (DePuy Synthes)			133	7	14	<0.01
	Sector (DePuy Synthes)			49	3	523	2
	Trabecular Metal (Zimmer)			1	<0.1	3160	13
	Trident (Stryker, Kalamazoo, MI, USA)			369	21	353	1
	Trilogy Ace (Zimmer)			1	0.1	1624	7

Table 1. continued

	Mean	SD	Mean	SD	Mean	SD
Membership termination						
Yes	2159	8	284	16	1875	8
Operative time (minutes)	93	34	98	33	93	34
Age (years)	70	10	72	10	69	10
BMI (kg/m^2)	29	6	29	6	29	6
Days of followup	1286	973	2361	970	1208	926

HXLPE = highly crosslinked polyethylene; ASA = American Society of Anesthesiologists; BMI = body mass index.

on-conventional polyethylene bearing surfaces, and 25,008 (93.2%) had metal-on-HXLPE bearing surfaces. The median followup for this cohort was 2.9 years (interquartile range [IQR] 1.3–5.5 years). There were 1146 THAs in the Duraloc cohort, of which 382 (33%) had metal-on-conventional polyethylene and 764 (67%) had metal-on-HXLPE (Table 2). The median followup for this cohort was 8.2 years (IQR 5.8–9.2 years). There were 5202 THAs in the Reflection cohort, of which 753 (15%) had metal-on-conventional polyethylene and 4449 (86%) had metal-on-HXLPE (Table 3). The median followup for this cohort was 5.1 years (IQR 3.4–7.0 years). The conventional polyethylene cohorts included liners that were only gas-sterilized (uncrosslinked) or were gamma radiation-sterilized, corresponding to a dose of 25 to 40 kGy. The HXLPE cohorts included eight individual formulations with varying technical characteristics (Table 4).

Revision was the outcome of interest. All-cause revision included procedures for any reason in which removal and reimplantation of a component occurred at any time after the original index procedure. Aseptic revision was defined as a revision for which infection was not a reason performed any time after the original index procedure. The TJRR prospectively monitors all registered hips for subsequent revisions. After identification of a possible revision by the TJRR through electronic algorithms or surgeon reporting, the hip in question was reviewed by trained clinical research experts (see Acknowledgments), who adjudicated the event and confirmed the reason for revision.

Exposure and Covariates

The type of bearing surface used was the exposure of interest (metal-on-conventional polyethylene versus metal-on-HXLPE). Variables thought to be related to both bearing surface and revision-free survival time were included in a propensity score model to adjust for observed confounding. The variables included continuous covariates for age, operative time, body mass index, surgeon average annual volume, and hospital average annual volume as well as categorical covariates for gender, ASA score [18], diabetes diagnosis, race (six categories), and surgeon total joint arthroplasty fellowship training status.

Statistical Analysis

Frequencies, proportions, means and SDs as well as medians and IQRs were used to describe the total THA cohort and the Duraloc and Reflection cohorts within the two bearing surface groups. Cumulative incidence of revision was calculated. Crude cumulative incidence of all-cause and aseptic revision rate/100 years of observation (revision density) and reasons for revision were calculated for the total THA and the Duraloc and Reflection cohorts.

Revision rate/100 years of observation was compared using a Poisson regression. Because bearing surface material was not randomly assigned, we addressed observed confounding using a propensity score approach [4, 25]. The objective for using propensity scores was to remove or reduce confounding so that the magnitude of bias in the estimated treatment effect was negligible. Propensity score methods can minimize confounding by making the treatment groups equal (or approximately so) on a collection of measured variables. The fundamental theoretical property of propensity score methods is that hips with the same correctly estimated propensity scores will be comparable with respect to all covariates used to calculate the propensity scores so that it is only a matter of chance as to whether each actually receives one treatment or the other. In the specific approach used, the following steps were taken: (1) the propensity score was estimated in the conventional way by fitting a logistic regression model and estimating the conditional probability of treatment assignment for each record; (2) we checked that cases in one bearing group had comparable counterparts with respect to their covariate distribution in the other bearing group and those that did not were excluded based on a

Table 2. Patient, surgeon, implant, and hospital characteristics for the Duraloc cohort, 2001–2011

Variables		Bearing surface					
		All		Conventional polyethylene		HXLPE	
		Number	Percent	Number	Percent	Number	Percent
	All	1146		382	33	764	68
Sex	Male	472	41	130	34	342	45
	Female	673	59	251	66	422	55
	Missing	1	0.1	1	0.3	0	0
ASA category	1 or 2	713	62	248	65	465	61
	≥ 3	384	34	99	26	285	37
	Unknown	49	4	35	9	14	2
BMI category (kg/m^2)	< 30	617	54	220	58	397	52
	≥ 30 and < 35	241	21	71	19	170	22
	≥ 35	169	15	36	9	133	17
	Unknown	119	10	55	14	64	8
Race	Asian/Pacific Islander	24	2	12	3	12	2
	Black	60	5	15	4	45	6
	Native American	0	0	0	0	0	0
	White	785	69	257	67	528	69
	Hispanic	67	6	20	5	47	6
	Other	12	1	4	1	8	1
	Unknown	198	17	74	19	124	16
Diabetes	Yes	257	22	83	22	174	23
Surgeon fellowship	Yes	286	25	66	17	220	29
	Missing	0	0	0	0	0	0
Surgeon average annual volume category	< 10	64	6	14	4	50	7
	10 to < 50	551	48	154	40	397	52
	≥ 50	531	46	214	56	317	42
	Missing	0	0	0	0	0	0
Site average annual volume category	< 100	9	1	5	1	4	1
	100 to < 200	437	38	94	25	343	45
	≥ 200	700	61	283	74	417	55
	Missing	0	0	0	0	0	0
Fixation	Uncemented	527	46	59	15	468	61
	Hybrid	471	41	268	70	203	27
	Cemented	15	1	2	1	13	2
	Missing	133	12	53	14	80	11
Head Size	≤ 28 mm			322	84	387	51
	32 mm			60	16	344	45
	36 mm			0	0	33	4
	> 36 mm			0	0	0	0

	Mean	SD	Mean	SD	Mean	SD	
Membership termination							
Yes		214	19	76	20	138	18
Operative time (minutes)	97	35	101	33	95	36	< 0.001 (NP)
Age (years)	68	12	70	11	66	12	< 0.001
BMI (kg/m^2)	30	6	28	6	30	6	< 0.001
Days of followup	2582	1021	2697	1051	2525	1002	< 0.001 (NP)

HXLPE = highly crosslinked polyethylene; ASA = American Society of Anesthesiologists; BMI = body mass index; NP = nonparametric.

Table 3. Patient, surgeon, implant, and hospital characteristics for the Reflection cohort, 2001–2011

Variables		Bearing surface					
		All		Conventional polyethylene		HXLPE	
		Number	Percent	Number	Percent	Number	Percent
	All	5202		753	15	4449	86
Sex	Male	1899	37	273	36	1626	37
	Female	3302	64	479	64	2823	64
	Missing	1	0.1	1	0.1	0	0
ASA category	1 or 2	2937	57	376	50	2561	58
	≥ 3	2188	42	358	48	1830	41
	Unknown	77	2	19	3	58	1
BMI category (kg/m^2)	< 30	3161	61	455	60	2706	61
	≥ 30 and < 35	1162	22	144	19	1018	23
	≥ 35	734	14	95	13	639	14
	Unknown	145	3	59	8	86	2
Race	Asian/Pacific Islander	200	4	21	3	179	4
	Black	392	8	34	5	358	8
	Native American	9	0.2	3	0.4	6	0.1
	White	3721	72	501	67	3220	72
	Hispanic	449	9	73	10	376	9
	Other	71	1	9	1	62	1
	Unknown	360	7	112	15	248	6
Diabetes	Yes	1307	25	195	26	1112	25
Surgeon fellowship	Yes	1948	37	334	44	1614	36
	Missing	0	0.1	0	1	0	0
Surgeon average annual volume category	< 10	336	7	41	5	295	7
	10 to < 50	3569	69	614	82	2955	66
	≥ 50	1297	25	98	13	1199	27
	Missing	0	0.2	0	0.1	0	0
Site average annual volume category	< 100	756	15	54	7	702	16
	100 to < 200	3592	69	570	76	3022	68
	≥ 200	854	16	129	17	725	16
	Missing	0	0.1	0	0.4	0	0
Fixation	Uncemented	3315	64	256	34	3059	69
	Hybrid	1549	30	446	59	1103	25
	Cemented	56	1	6	1	50	1
	Missing	282	5	45	6	237	5
Head size	≤ 28 mm			685	91	1719	39
	32 mm			68	9	2065	46
	36 mm			0	0.1	665	15
	> 36 mm			0	0.4	0	0

	Mean	SD	Mean	SD	Mean	SD
Membership termination						
Yes	534	10	128	17	406	9
Operative time (minutes)	90	31	94	31	90	31
Age (years)	72	9	73	8	71	9
BMI (kg/m^2)	29	6	29	6	29	6
Days of followup	1899	869	2412	1029	1812	808

HXLPE = highly crosslinked polyethylene; ASA = American Society of Anesthesiologists; BMI = body mass index.

Table 4. Summary of highly crosslinked polyethylene formulations in the present study and their technical characteristics

Number of patients undergoing THA	HXLPE brand name	Manufacturer (city, state)	Total (cumulative) radiation crosslinking dose (kGy)	HXLPE stabilization technology
11,510	Marathon	DePuy Synthes (Warsaw, IN, USA)	50	Thermal treatment (remelting)
4,979	XLPE	Smith & Nephew (Memphis, TN, USA)	100	Thermal treatment (remelting)
4,802	Longevity	Zimmer (Warsaw, IN, USA)	100	Thermal treatment (remelting)
2,693	ALTRX	DePuy Synthes	75	Thermal treatment (remelting)
466	Durasul	Zimmer	95	Thermal treatment (remelting)
402	X3	Stryker Orthopaedics (Mahwah, NJ, USA)	90	Thermal treatment (sequential annealing)
54	E1	Biomet (Warsaw, IN, USA)	130	Vitamin E
31	ArCom XL	Biomet	50	Mechanical annealing

HXLPE = highly crosslinked polyethylene.

caliper width of 0.2 SD of the logit propensity score; (3) we stratified the sample into six strata based on the estimated logit propensity score; and finally (4) we calculated the weight for each record based on the number of units in a stratum multiplied by the proportion of units assigned to the treatment group of interest in the data and divided by the number of records assigned to the treatment group of interest in that particular stratum. Missing data were handled using multiple imputation. Ten imputed data sets were created and Rubin's rules for aggregating parameter estimates and variances were used [23]. Logistic regression models were used to generate propensity scores.

Marginal multivariate Cox regression models accounting for surgeon clustering using robust variance estimation were fit with stratification (five strata) by propensity score for each imputed data set and results were subsequently aggregated across data sets [11]. Additionally, some of the analytic models also used regression adjustment for surgeon volume, site volume, and hybrid fixation to address imbalance remaining in these variables after stratification by propensity score. All analyses used metal-on-HXLPE as the reference group. Hazard ratios (HRs) with 95% confidence intervals (CIs) and Wald p values are provided. For the primary analysis models, individuals not experiencing a revision were treated as censored as of whichever date came first: the study end date (December 31, 2011), a membership termination date, or date of death. Data were analyzed using SAS (Version 9.2; SAS Institute, Cary, NC, USA) and $p < 0.05$ was used as the threshold for statistical significance. In this study, hypothesis testing was focused on the adjusted HR for the comparison of the bearings for three groups (total THA cohort, Duraloc cohort, Reflection cohort) for each of two outcomes (all-cause and aseptic revision), leading to six tests and an increased chance of committing a Type I error. Under a conservative approach of assuming these tests are independent, the Bonferroni-adjusted alpha is 0.0056.

Sensitivity Analysis

Based on the distribution of head size, the two bearings surfaces were not comparable for head size with metal-on-HXLPE containing head sizes > 36 mm, whereas conventional PE did not. Conventional PE also contained very few 36-mm heads. To address this issue we conducted a sensitivity analysis removing head sizes ≥ 36 mm and only included two categories: head size ≤28 mm and head size 32 mm. We included this head size variable in the propensity score model as well. We also examined whether the effect of the bearing was moderated by cup type. To do this we compared the bearing surface effect estimate for Duraloc versus Reflection for each of the outcomes using Wald chi square tests.

Results

Risk of Revision, All THA: Conventional Polyethylene versus HXLPE

The adjusted risks of all-cause (HR, 1.75; 95% CI, 1.37–2.24; $p < 0.001$) and aseptic (HR, 1.91; 95% CI, 1.46–2.50; $p < 0.001$) were higher in patients with metal-on-conventional polyethylene bearing surfaces compared with metal-on-HXLPE (Table 5). At 7 years followup, the cumulative incidence of revision was 5.4% (95% CI, 4.4%–6.7%) for metal-on-conventional and 2.8% (95% CI, 2.6%–3.2%) for metal-on-XLPE. The all-cause revision density for metal-on-conventional hips was 0.76 (95% CI, 0.68–0.84) revisions/

100 years of followup and 0.60 (95% CI, 0.57–0.63) for metal-on-HXLPE hips (Table 6). The main reasons for revision in the metal-on-conventional polyethylene group were instability (49%), aseptic loosening (20%), infection (15%), and other (22%) (Table 6). The main reasons for revision in the metal-on-HXLPE group were instability (40%), infection (25%), periprosthetic fracture (13%), and other (14%). When accounting for differences in femoral head size distribution, the results were not substantively different from those previously reported for the overall effect (ie, without any cup restriction) (HR, 1.69; 95% CI, 1.19–2.40; p = 0.003 [all-cause]; HR, 1.73; 95% CI, 1.22–2.44; p = 0002 [aseptic]). Therefore, it appears that the size of the femoral head is not able to explain most of the differences observed in the performance of the bearings.

Risk of Revision, THA Design-specific: Conventional Polyethylene versus HXLPE

Within the Duraloc cohort, the adjusted risks of all-cause (HR, 3.15; 95% CI, 1.65–6.02; p < 0.001) and aseptic (HR, 2.87; 95% CI, 1.43–5.78; p = 0.003) revision were higher in patients with metal-on-conventional polyethylene compared with those with metal-on-HXLPE bearing surfaces (Table 5). The 7-year cumulative incidence of revision was 8.3% (95% CI, 5.8%–11%) for metal-on-conventional polyethylene versus 2.6% (95% CI, 1.7%–4.2%) for metal-on-HXLPE polyethylene (Table 7). The all-cause revision density for metal-on-conventional polyethylene hips was 1.06 (95% CI, 0.87–1.26) revisions/100 years of followup and 0.42 (95% CI, 0.33–0.51) for metal-on-HXLPE hips (Table 6). The main reasons for revision in the metal-on-conventional polyethylene group were instability (43%), aseptic loosening (27%), infection (20%), and other (33% each). The main reasons for revision in the metal-on-HXLPE group were instability (68%), aseptic loosening (14%), pain (14%), infection (9%), and periprosthetic fracture (9%).

Within the Reflection cohort, the adjusted risks of all-cause (HR, 1.93; 95% CI, 1.23–3.01; p = 0.004) and aseptic (HR, 2.44; 95% CI, 1.49–3.48; p < 0.001) were higher in patients with metal-on-conventional polyethylene compared with those with metal-on-HXLPE bearing surfaces (Table 5). The 7-year cumulative incidence of revision was 4.6% (95% CI, 3.2%–6.6%) for metal-on-conventional polyethylene versus 2.2% (95% CI, 1.7%–2.7%) for metal-on-HXLPE (Table 7). The all-cause revision density for metal-on-conventional polyethylene hips was 0.63 (95% CI, 0.51–0.74) revisions/100 years of followup and 0.39 (95% CI, 0.35–0.44) for metal-on-HXLPE (Table 6). The main reasons for revision in the metal-on-conventional polyethylene group were instability (65%),

Table 5. Propensity score-weighted regression results for risk of all-cause and aseptic revision in conventional bearings compared with HXLPE bearings for the overall THA, Duraloc, and Reflection cohorts

	All (N = 26,823)			Duraloc cohort (N = 1146)			Reflection cohort (N = 5202)		
	Crude HR (95% CI)	Adjusted* HR (95% CI)	p value (adjusted model)	Crude HR (95% CI)	Adjusted* HR (95% CI)	p value (adjusted model)	Crude HR (95% CI)	Adjusted* HR (95% CI)	p value (adjusted model)
All-cause	1.73 (1.38–2.18)	1.75 (1.37–2.24)	< 0.001	2.67 (1.54–4.64)	3.15 (1.65–6.02)	< 0.001	1.83 (1.21–2.77)	1.93 (1.23–3.01)	0.004
Aseptic	1.91 (1.48–2.45)	1.91 (1.46–2.50)	< 0.001	2.35 (1.30–4.25)	2.87 (1.43–5.78)	0.003	2.14 (1.36–3.37)	2.44 (1.49–3.48)	< 0.001

* Cox regression stratified by propensity score and also using surgeon volume, site volume, and hybrid fixation versus other as covariates; propensity score model includes body mass index (continuous), age (continuous), gender, race, diabetes, diagnosis, surgeon average volume, fellowship status, site average volume, American Society of Anesthesiologists, and operative time. HXLPE = highly crosslinked polyethylene; HR = hazard ratio; CI = confidence interval.

Table 6. Crude all-cause and aseptic cumulative incidence of revision, revision rate per 100 years of followup, and reasons for revision for the overall THA, Duraloc, and Reflection cohorts

Revision type and reason		All		Duraloc		Reflection	
		Conventional polyethylene	HXLPE	Conventional polyethylene	HXLPE	Conventional polyethylene	HXLPE
	Number	1815	25008	382	764	753	4449
All-cause	Number of revisions (%)	89 (4.9)	495 (2.0)	30 (7.9)	22 (2.9)	31 (4.1)	87 (2.0)
	Rate/100 years observation time (95% CI)	0.8 (0.7–0.8)	0.6 (0.6–0.6)	1.1 (0.9–1.3)	0.4 (0.3–0.5)	0.6 (0.5–0.7)	0.4 (0.4–0.4)
Aseptic	Number of revisions (%)	76 (4.2)	371 (1.5)	24 (6.3)	20 (2.6)	27 (3.6)	64 (1.4)
	Rate/100 years observation time (95% CI)	0.7 (0.6–0.7)	0.5 (0.4–0.6)	0.9 (0.7–1.0)	0.4 (0.3–0.5)	0.5 (0.4–0.7)	0.3 (0.3–0.3)
Reasons for revision[a]	Instability	44 (49.4)	200 (40.4)	13 (43.3)	15 (68.2)	20 (64.5)	35 (40.2)
	Infection	13 (14.6)	124 (25.1)	6 (20.0)	2 (9.1)	4 (12.9)	23 (26.4)
	Periprosthetic fracture	7 (7.9)	62 (12.5)	0 (0.0)	2 (9.1)	3 (9.7)	10 (11.5)
	Aseptic loosening	18 (20.2)	51 (10.3)	8 (26.7)	3 (13.6)	3 (9.7)	7 (8.0)
	Pain	8 (9.0)	43 (8.7)	3 (10.0)	3 (13.6)	2 (6.5)	6 (6.9)
	Femoral fracture	3 (3.4)	23 (4.6)	0 (0.0)	1 (4.5)	1 (3.2)	6 (6.9)
	Hematoma/seroma	1 (1.1)	19 (3.8)	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)
	Hematoma	1 (1.1)	14 (2.8)	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)
	Linear wear	5 (5.6)	13 (2.6)	3 (10.0)	0 (0.0)	2 (6.5)	3 (3.4)
	Wound drain	1 (1.1)	12 (2.4)	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)
	Compound fracture	1 (1.1)	5 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)
	Failed ORIF	1 (1.1)	2 (0.4)	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)
	Rheumatoid arthritis	0 (0.0)	1 (0.2)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)
	Other	19 (21.4)	67 (13.5)	10 (33.4)	2 (9.0)	8 (25.9)	15 (17.2)

[a] Number (%), percents are based on the total number of revisions in the specific cohort

HXLPE = highly crosslinked polyethylene; CI = confidence interval; ORIF = open reduction and internal fixation.

other (26%), infection (13%), periprosthetic fracture (10%), and aseptic loosening (10%). The main reasons for revision in the metal-on-HXLPE group were instability (40%), infection (26%), other (17%), and periprosthetic fracture (12%).

The hypothesis testing, assuming tests for the outcomes by cohort are independent, found that all tests that would be significant under an alpha of 0.05 would still be significant with this stricter threshold (Table 5). Despite apparent differences in the magnitude of the HR when examining the effect of the bearing moderated by cup type, none of these tests achieved statistical significance: chi square (1) = 1.48, p = 0.223 (all-cause), chi square (1) = 0.14, p = 0.709 (aseptic).

Discussion

Osteolysis associated with polyethylene wear is a long established cause of THA revision of surgery [3, 9, 24, 26]. A reduction in polyethylene liner wear therefore should reduce THA revision. Although prior studies suggest differences in radiologically measured wear in metal-on-HXLPE versus metal-on-conventional polyethylene bearing surfaces, findings regarding reduction in risk of revision are conflicting [7, 17] and limited based on sample sizes, single-center and academic studies, limited length of followup, methodological differences, and investigation of a variety of implant designs. Larger population-based registry studies have primarily focused on countries outside of the United States [11]. Our study provides the risk of THA revision associated with conventional versus HXLPE-polyethylene in a large US representative sample. The strengths of our study include the large, representative US sample, the ability to evaluate different implant designs with different HXLPE formulations, and the inclusion of revision as the study endpoint, which has been reviewed and adjudicated by trained clinical content experts. In our study, the risk of all-cause and aseptic revision in primary THA was higher for metal-on-conventional polyethylene bearings compared with metal-on-HXLPE bearing surfaces.

Table 7. Yearly number of procedures at risk and cumulative incidence of revision by bearing surface for the overall THA, Duraloc, and Reflection cohorts

Bearing surface	Number at risk, Year 0	Cumulative incidence of revision, Year 1 (%, CI)	Number at risk, Year 1	Cumulative incidence of revision, Year 5 (%, CI)	Number at risk, Year 5	Cumulative incidence of revision, Year 7 (%, CI)	Number at risk, Year 7	Cumulative incidence of revision, Year 10 (%, CI)	Number at risk, Year 10
HXLPE	25,008	1.4 (1.3–1.6)	19,361	2.4 (2.2–2.7)	6289	2.8 (2.6–3.2)	2672	3.9 (2.9–5.2)	62
Conventional polyethylene	1815	2 (1.5–2.8)	1706	4 (3.2–5.1)	1289	5.4 (4.4–6.7)	816	6.4 (5.1–7.9)	74
Duraloc HXLPE	764	1.3 (0.7–2.4)	725	2.1 (1.3–3.5)	583	2.6 (1.7–4.2)	480	4.9 (2.5–9.5)	19
Duraloc conventional polyethylene	382	2.4 (1.3–4.6)	357	6.9 (4.7–10.1)	283	8.3 (5.8–11.8)	245	9.1 (6.4–12.8)	37
Reflection HXLPE	4449	1.2 (0.9–1.6)	4244	2 (1.6–2.5)	2086	2.2 (1.7–2.7)	844	2.7 (2–3.7)	16
Reflection conventional polyethylene	753	2.2 (1.3–3.5)	703	3.1 (2–4.6)	530	4.6 (3.2–6.6)	385	5.2 (3.6–7.4)	33

CI = confidence interval; HXLPE = highly crosslinked polyethylene.

This study had a number of limitations. First, this study is observational and it is possible that we did not address every potential confounding variable in our analyses. In our study, we addressed confounding using propensity score-matching techniques to address differences in the conventional and HXLPE groups. Second, to control for femoral and acetabular components, we included only two cohorts (Duraloc and Reflection) with sufficient samples in the subgroup prosthesis-specific analyses. Third, lack of radiological, functional, or patient-reported outcomes may be perceived as limitations. However, revision is the definitive endpoint of wear, which HXLPE was designed to address. Finally, followup for greater than 10 years is necessary to evaluate longer-term results. Despite this limitation, the benefits of HXLPE are already observed within our study.

Our study findings confirm the results of in vitro hip simulator and other clinical studies that compared HXLPE with conventional polyethylene liners. Similar to Nakashima et al [17], we found an increased risk of revision for conventional polyethylene versus HXLPE. Our results differ from Howard et al's [7] study, which did not report a higher risk of revision in conventional polyethylene versus HXLPE. Most likely this difference is related to limitation in statistical power associated with sample size because rates were similar to our study but did not reach statistical significance. The higher risk of revision in metal-on-conventional polyethylene bearing surfaces in our US sample is consistent with results reported by the Australian Orthopedic Association National Joint Replacement Registry [1]. Similar to the Australian Registry results, the difference between HXLPE and conventional polyethylene is evident in less than 10 years followup. These findings suggest that metal-on-conventional bearing surfaces have a higher risk of revision in both populations.

Within the Duraloc and Reflection cohorts, metal-on-conventional polyethylene also had a higher risk of revision than metal-on-HXLPE bearings. This finding confirms findings from registries from other countries [1] in a US sample of THA and emphasizes that higher risk of revision for conventional polyethylene is consistent when controlling for femoral and acetabular components.

In conclusion, in a large US population-based study, metal-on-conventional polyethylene THA bearing surfaces had a higher risk of revision compared with metal-on-HXLPE bearing surfaces. Clinicians should consider the use of HXLPE when using a polyethylene bearing in THA.

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