A commentary by Rémy Simon Nizard, MD, PhD, is linked to the online version of this article at jbjs.org.

Conventional Versus Highly Cross-Linked Polyethylene in Primary Total Knee Replacement

A Comparison of Revision Rates Using Data from the National Joint Registry for England, Wales, and Northern Ireland

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Background: There is evidence to support the use of highly cross-linked polyethylene (HXLPE) in patients undergoing total hip arthroplasty. However, the benefits for those undergoing total knee arthroplasty are uncertain, with conflicting reports based on previous cohort analyses. The purpose of the present study was to compare the revision rates following primary total knee arthroplasty with use of HXLPE as compared with conventional polyethylene (CPE) using data from the National Joint Registry (NJR) for England, Wales and Northern Ireland.

Methods: We performed a retrospective analysis of primary total knee arthroplasties recorded in the NJR from 2003 to 2014. Cobalt-chromium (CoCr)-CPE and CoCr-HXLPE bearing surfaces were compared using all-cause revision, aseptic revision, and septic revision as end points. Survival analyses were conducted using rates per 100 years observed, Kaplan-Meier survival estimates, and Cox regression hazard ratios (HRs) adjusted for age, sex, American Society of Anesthesiologists (ASA) classification, body mass index (BMI), lead surgeon grade, and implant constraint. Secondary analyses compared the most commonly used HXLPEs (Zimmer Prolong, DePuy XLK, and Stryker X3) against CPE for the 3 most common total knee arthroplasty systems (NexGen, PFC Sigma, and Triathlon).

Results: In the present study of 550,658 total knee arthroplasties, the unadjusted aseptic revision rates were significantly lower following procedures performed with CPE (n = 513,744) as compared with those performed with HXLPE total knee replacements (n = 36,914) (0.29 [95% confidence interval (CI), 0.28 to 0.30] compared to 0.38 [95% CI, 0.35 to 0.42], $p < 0.01$). The 10-year HR associated with CPE was 0.4 (95% CI, 0.1 to 0.8, $p = 0.03$). There were no significant differences between the adjusted revision rates of HXPLE compared with CPE in individual analyses of the most common total knee arthroplasty systems. However, for the subset of patients who were both <60 years of age and had a BMI of >35 kg/m^2, the “second-generation” Stryker X3 HXLPE demonstrated significantly better survival than its respective CPE, with CPE having an HR of 2.6 (95% CI, 1.2 to 5.9) ($p = 0.02$).

Conclusions: Alternative bearings are marketed as having improved wear properties over traditional CoCr-CPE. This registry-based analysis demonstrated no overall survival benefit of HXLPE after a maximum duration of follow-up of 12

continued

Disclosure: The authors indicated that no external funding was received for any aspect of this work. On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article*, one or more of the authors checked “yes” to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work (http://links.lww.com/JBJS/F598).

years. Because of their increased cost, the routine use of HXLPE bearings may not be justified. However, they may have a role in specific "higher demand" groups such as patients <60 years of age and/or those with a BMI of >35 kg/m^2.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete list of levels of evidence.

The demand for total knee arthroplasty is increasing and is predicted to rise further over the next decade[1]. The most common indication for revision is aseptic loosening associated with polyethylene wear and osteolysis[2]. With growing demand and heightened patient expectations, it is essential to investigate and aid strategies that maximize implant longevity and address modifiable factors associated with implant failure.

Highly cross-linked polyethylene (HXLPE) was introduced in the late 1990s with the intention of reducing wear and debris-induced osteolysis following joint arthroplasty[3]. HXLPE is developed by exposing ultra-high molecular weight polyethylene (UHMWPE) to gamma radiation[3]. Radiation breaks up intramolecular bonds and produces free radicals that promote cross-linking across multiple polymer chains, increasing overall density and improving wear characteristics. Excess free radicals produced during this process cause oxidative instability; therefore, in order to preserve mechanical properties, further thermal treatments are required to help eliminate them[4]. The inferred improvement in wear properties has been demonstrated in vitro, prompting the introduction of HXLPE for total hip arthroplasty in the 1990s[5-8]. HXLPE has been clinically shown to have improved survival in comparison with conventional UHMWPE polyethylene (CPE) and has started to become the preferred choice for patients undergoing total hip arthroplasty[9-12].

The introduction of HXLPE for total knee arthroplasty has been much more gradual because of the concerns about reduced ductility and fatigue resistance[3,13,14]. In contrast to the congruent "ball and socket" hip joint, the mechanics of the knee include rolling, sliding, and rotational motion that potentially put the polyethylene insert at greater risk of wear by delamination, pitting, and fatigue failure[15]. In an attempt to address these demands and improve wear behavior, different manufacturers have used their own unique methods of annealing and remelting when processing HXLPEs[3]. "Second-generation" HXLPEs were introduced in 2005 in an attempt to reduce free radicals further by means of sequential irradiation and annealing (X3 [Stryker]) or antioxidant stabilization (AOX [DePuy], E1 [Biomet], Vivacit-E [Zimmer])[3]. Knee replacement data from the Australian Orthopaedic Association National Joint Registry suggest an overall survival benefit of HXLPE when compared with CPE with follow-up beyond 10 years[16]. However, there is still no consensus[15] about the use of HXLPE in total knee arthroplasty, and there is little evidence about the performance of different types of HXLPE used in individual total knee arthroplasty systems.

The purposes of this National Joint Registry (NJR) study were (1) to establish the usage of HXLPE in England, Wales, and Northern Ireland; (2) to provide further information about the rates of revision for total knee arthroplasties performed with use of HXLPE versus CPE; and (3) to present evidence pertaining to the differential performance of HXLPE and CPE within the most frequently used total knee arthroplasty systems.

Materials and Methods

Design

In this retrospective cohort study, data from the NJR for England, Wales and Northern Ireland were used to compare the rates of revision (including all-cause revision, septic revision, and aseptic revision) of CoCr implants on CPE bearings against those of CoCr implants on HXLPE bearings in patients undergoing primary total knee arthroplasty.

Data

NJR data were used to analyze patients who had had a total knee arthroplasty recorded within the NJR data set between 2003 and 2014. Overall, 669,411 total knee arthroplasties were recorded in the NJR during this period. From this cohort, 118,753 patients were excluded because either the bearing type could not be ascertained or it was not a CoCr-on-CPE or CoCr-on-HXLPE bearing (Fig. 1). Of the remaining 550,658 total knee arthroplasties, 513,744 involved a CoCr-on-CPE bearing and 36,914 involved a CoCr-on-HXLPE bearing.

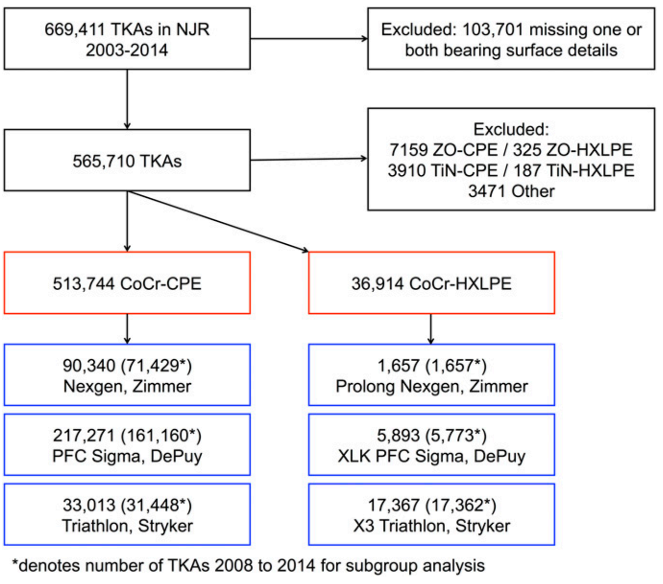


Fig. 1

Flowchart of inclusion and exclusion criteria. TKA = total knee arthroplasty, ZO = zirconium oxide, and TiN = titanium nitride.

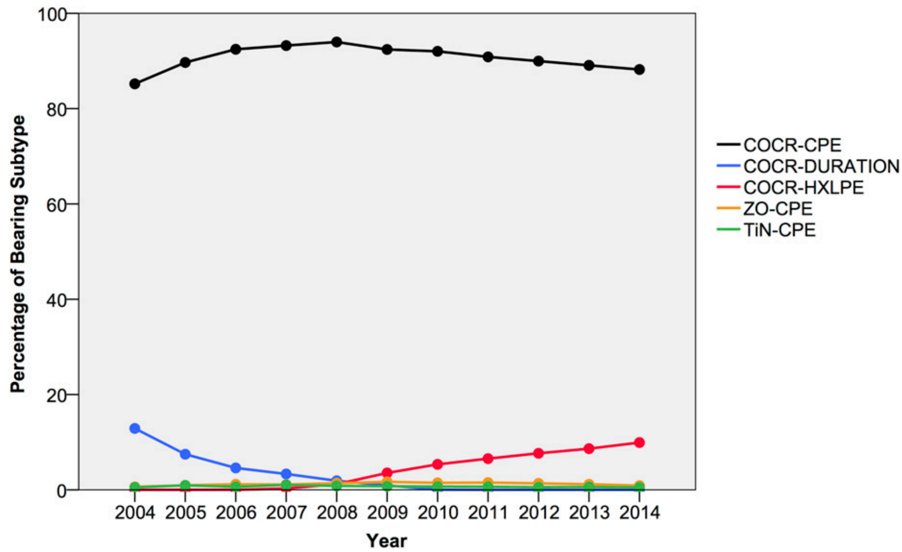


Fig. 2
Line graph showing alternative bearing usage in the NJR between 2003 and 2014. ZO = zirconium oxide, and TiN = titanium nitride.

Age, sex, American Society of Anesthesiologists (ASA) physical status classification, body mass index (BMI), lead surgeon grade, and implant constraint were recorded for each patient. Implant manufacturer, brand, component details, and catalog numbers were used to establish bearing type and the use of CPE or HXLPE. These data also were used to identify the most frequently used total knee arthroplasty brands and the relative usage of CPE and HXLPE bearings within these implant systems (NexGen [Zimmer], PFC Sigma [DePuy], and Triathlon [Stryker]).

The preliminary analysis focused on the unadjusted overall rates of revision (all-cause) for total knee arthroplasties performed with use of CPE compared with HXLPE inserts. With use of the reported reason for revision within the NJR, further subanalyses were undertaken for septic revision (revision for the treatment of infection) and aseptic revision (revision for any other reason). The rate of septic revision was not expected to demonstrate inferiority or superiority of HXLPE as the meniscal insert material is unlikely to be a risk factor for infection; therefore, subsequent analyses focused on aseptic revision.

To account for different total knee replacement designs and the evolution of implants, further analysis included a within-brand examination of CPE versus HXPLE for the 3 most common knee implants recorded within the NJR as listed above. Additional subgroup analyses were conducted

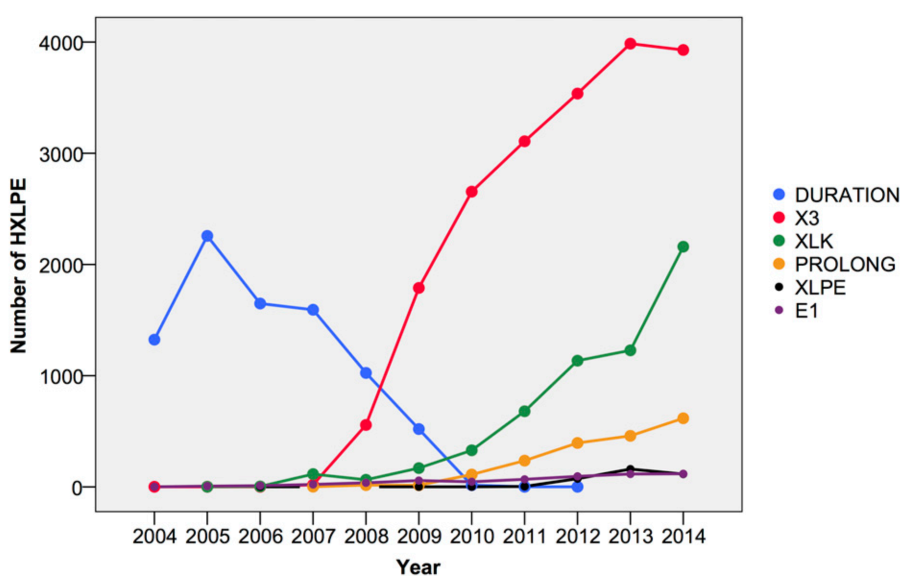


Fig. 3
Line graph showing HXLPE usage in the NJR between 2003 and 2014.

TABLE I Revision Rates per 100 Component-Years

		All-Cause Revision		Aseptic Revision		Septic Revision	
	Component-Years	No. of Revisions	No. of Revisions per 100 Component Years*	No. of Revisions	No. of Revisions per 100 Component Years*	No. of Revisions	No. of Revisions per 100 Component Years*
CoCr-CPE (n = 513,744)	2,203,461	8,786	0.40 (0.39-0.41)	6,386	0.29 (0.28-0.30)	2,400	0.11 (0.10-0.11)
CoCr-HXLPE (n = 36,914)	141,726.6	698	0.49 (0.46-0.53)	542	0.38 (0.35-0.42)	156	0.11 (0.09-0.13)
CoCr-HXLPE without Kinemax Duration (n = 27,418)	68,376.1	325	0.48 (0.43-0.53)	239	0.35 (0.31-0.40)	86	0.13 (0.10-0.16)

*The 95% CI is given in parentheses.

on patients <60 years of age at time of primary total knee arthroplasty and those with a BMI of >35 kg/m² as these factors were consistent predictors of the risk of aseptic revision.

Statistical Analysis

Survival analyses were conducted with use of revision rates per 100 component-years observed, and 95% confidence intervals (CIs) were estimated using Poisson distributions. Secondary

TABLE II Adjusted Cox Regression Estimates for CoCr-on-CPE Versus CoCr-on-HXLPE*

	CPE (N = 513,744)†	HXLPE (N = 36,914)†	Adjusted HRs with Aseptic Revision as End Point‡
Female (ref., male)	295,916 (57.6%)	21,066 (57.1%)	1.0 (1.0-1.0)
ASA classification			
1	60,327 (11.7%)	4,640 (12.6%)	Ref.
2	371,770 (72.4%)	26,387 (71.5%)	1.0 (1.0-1.1)
≥3	81,647 (15.9%)	5,887 (15.9%)	1.0 (0.9-1.1)
BMI			
<30 kg/m²	127,305 (24.8%)	8,109 (22.0%)	1.0 (0.9-1.0)
30-35 kg/m²	89,146 (17.4%)	6,005 (16.3%)	1.0 (0.9-1.1)
>35 kg/m²	63,752 (12.4%)	4,724 (12.8%)	1.1# (1.1-1.2)
NA§	233,541 (45.5%)	18,076 (49.0%)	Ref.
Non-consultant as primary surgeon (ref., consultant as primary surgeon)	107,285 (20.9%)	7,391 (20.0%)	1.0 (0.9-1.1)
Posterior-stabilized (ref., cruciate-retaining)	157,761 (30.7%)	5,406 (14.6%)	1.2# (1.1-1.2)
Age			
<60 yr	72,956 (14.2%)	6,898 (18.7%)	
1-yr HR			1.8# (1.5-2.2)
3-yr HR			2.1# (1.7-2.7)
5-yr HR			2.5# (1.9-3.3)
10-yr HR			6.9 (0.9-53)
60-75 yr	280,895 (54.7%)	19,649 (53.2%)	
1-yr HR			1.8# (1.5-2.2)
3-yr HR			1.9# (1.6-2.4)
5-yr HR			2.0# (1.6-2.7)
10-yr HR			4.6 (0.6-35)
>75 yr	159,893 (31.1%)	10,367 (28.1%)	Ref.
CPE HR (ref., HXLPE)			
1-yr HR	-	-	0.8 (0.6-1.0)
3-yr HR			0.8 (0.6-1.1)
5-yr HR			0.5# (0.4-0.7)
10-yr HR			0.4# (0.1-0.8)

*Ref. denotes reference group for multivariable analysis. †The values are given as the number of patients, with the percentage in parentheses. ‡The 95% CI is given in parentheses. §NA = not available. #P < 0.05.

TABLE III Subgroup Analysis of Most Commonly Used Total Knee Arthroplasty Brands: CoCr-on-CPE Versus CoCr-on-HXLPE*†

	NexGen			PFC Sigma			Triathlon		
	CPE (N = 71,429)	Prolong First-Generation HXLPE‡ (N = 1,657)	Adjusted Aseptic Revision HR§	CPE (N = 161,160)	XLK First-Generation HXLPE# (N = 5,773)	Adjusted Aseptic Revision HR§	CPE (N = 31,448)	X3 Second-Generation HXLPE** (N = 17,362)	Adjusted Aseptic Revision HR§
Female (ref., male)	41,679 (58.4%)	887 (53.5%)	0.9 (0.8-1.0)	92,295 (57.3%)	3,464 (60.0%)	1.0 (0.9-1.1)	18,293 (58.2%)	9,855 (56.8%)	1.2 (1.0-1.4)
Age									
<60 yr	10,606 (14.8%)	277 (16.7%)		24,315 (15.1%)	1,365 (23.6%)		4,767 (15.2%)	3,458 (19.9%)	2.9†† (2.2-3.8)
1-yr HR			1.0 (0.5-1.8)			1.8†† (1.2-2.7)			
5-yr HR			4.1†† (2.3-7.2)			2.8†† (1.9-3.9)			
60-75 yr	39,301 (55.0%)	868 (52.4%)		88,747 (55.1%)	2,977 (51.6%)		16,873 (53.7%)	9,281 (53.5%)	1.5†† (1.1-1.9)
1-yr HR			0.9 (0.5-1.7)			1.8†† (1.2-2.7)			
5-yr HR			2.0†† (1.2-3.4)			1.3 (1.0-1.8)			
>75 yr	21,522 (30.1%)	512 (30.9%)	Ref.	48,098 (29.8%)	1,431 (24.8%)	Ref.	9,808 (31.2%)	4,623 (26.6%)	Ref.
ASA classification									
1	7,239 (10.1%)	119 (7.2%)	Ref.	16,887 (10.5%)	542 (9.4%)	Ref.	3,070 (9.8%)	1,898 (10.9%)	Ref.
2	52,444 (73.4%)	1,266 (76.4%)	1.0 (0.8-1.3)	117,422 (72.9%)	4,411 (76.4%)	1.1 (0.9-1.3)	23,075 (73.4%)	12,351 (71.1%)	1.0 (0.8-1.4)
≥3	11,746 (16.4%)	272 (16.4%)	0.9 (0.6-1.2)	26,851 (16.7%)	820 (14.2%)	1.1 (0.9-1.4)	5,303 (16.9%)	3,113 (17.9%)	1.1 (0.8-1.6)
BMI									
<30 kg/m²	21,081 (29.5%)	388 (23.4%)	0.8 (0.7-1.0)	45,724 (28.4%)	1,455 (25.2%)	1.0 (0.9-1.2)	10,335 (32.9%)	4,653 (26.8%)	1.1 (0.9-1.5)
30-35 kg/m²	15,346 (21.5%)	298 (18.0%)	0.9 (0.7-1.1)	32,957 (20.4%)	1,158 (20.1%)	1.0 (0.9-1.2)	7,231 (23.0%)	3,500 (20.2%)	1.1 (0.8-1.4)
>35 kg/m²	11,157 (15.6%)	260 (15.7%)	1.1 (0.9-1.4)	24,546 (15.2%)	987 (17.1%)	1.2†† (1.0-1.3)	5,451 (17.3%)	2,695 (15.5%)	1.4†† (1.0-1.8)
NA§§	23,845 (33.4%)	711 (42.9%)	Ref.	57,933 (35.9%)	2,173 (37.6%)	Ref.	8,431 (26.8%)	6,514 (37.5%)	Ref.
Non-consultant as primary surgeon (ref., consultant as primary surgeon)	16,932 (23.7%)	434 (26.2%)	1.0 (0.8-1.2)	30,110 (18.7%)	1,413 (24.5%)	1.0 (0.9-1.2)	7,283 (23.2%)	3,164 (18.2%)	1.0 (0.8-1.2)
Posterior-stabilized (ref., cruciate-retaining)	36,186 (50.7%)	374 (22.6%)	1.6†† (1.3-1.8)	49,752 (30.9%)	867 (15.0%)	1.1 (1.0-1.2)	7,797 (24.8%)	2,460 (14.2%)	1.0 (0.8-1.2)

*Ref. denotes reference group for multivariable analysis. †Unless otherwise specified (i.e., with the exception of the "Adjusted Aseptic Revision HR" columns), the values are given as the number of patients, with the percentage in parentheses. ‡Irradiated at 65 kGy and remelted at 135°C. §The 95% CI is given in parentheses. #Irradiated at 50 kGy, remelted at 155°C and annealed at 120°C. **Irradiated at 90 kGy (3 × 30) and sequentially annealed at 130°C. ††P < 0.05. §§Not available.

analyses compared the most commonly used HXLPEs (Prolong [Zimmer], XLK [DePuy], and X3 [Stryker]) within that manufacturer's specific total knee arthroplasty brand with use of Kaplan-Meier survival estimates and Cox regression hazard ratios (HRs); the predictors were age at the time of the primary procedure (<60, 60 to 75, >75 years), sex (male,

TABLE IV Revision Rates and Adjusted Cox Regression Estimates of Most Commonly Used Total Knee Arthroplasty Brands: CoCr-on-CPE Versus CoCr-on-HXLPE*

	NexGen		PFC Sigma		Triathlon	
	CPE (N = 71,429)	Prolong First-Generation HXLPE† (N = 1,657)	CPE (N = 161,160)	XLK First-Generation HXLPE‡ (N = 5,773)	CPE (N = 31,448)	X3 Second-Generation HXLPE§ (N = 17,362)
No. of revisions per 100 component-years						
All-cause revision	0.42 (0.40-0.45)	0.54 (0.31-0.87)	0.41 (0.39-0.42)	0.53 (0.40-0.69)	0.49 (0.45-0.54)	0.46 (0.40-0.53)
Aseptic revision	0.30 (0.28-0.32)	0.37 (0.18-0.66)	0.28 (0.27-0.30)	0.36 (0.26-0.50)	0.34 (0.30-0.38)	0.34 (0.28-0.40)
Septic revision	0.13 (0.11-0.14)	0.17 (0.05-0.39)	0.12 (0.11-0.13)	0.17 (0.10-0.27)	0.15 (0.13-0.18)	0.13 (0.09-0.16)
Adjusted CPE HR						
All-cause revision	0.8 (0.5-1.2) [p = 0.3]		0.9 (0.7-1.2) [p = 0.5]		1.2 (1.0-1.4) [p = 0.1]	
Aseptic revision	0.7 (0.4-1.3) [p = 0.3]		0.9 (0.7-1.3) [p = 0.7]		1.1 (0.9-1.3) [p = 0.5]	
Septic revision	0.8 (0.3-2.0) [p = 0.6]		0.8 (0.5-1.4) [p = 0.6]		1.3 (0.9-1.8) [p = 0.1]	

*The 95% CI is given in parentheses. †Irradiated at 65 kGy and remelted at 135°C. ‡Irradiated at 50 kGy, remelted at 155°C, and annealed at 120°C. §Irradiated at 90 kGy (3×30) and sequentially annealed at 130°C.

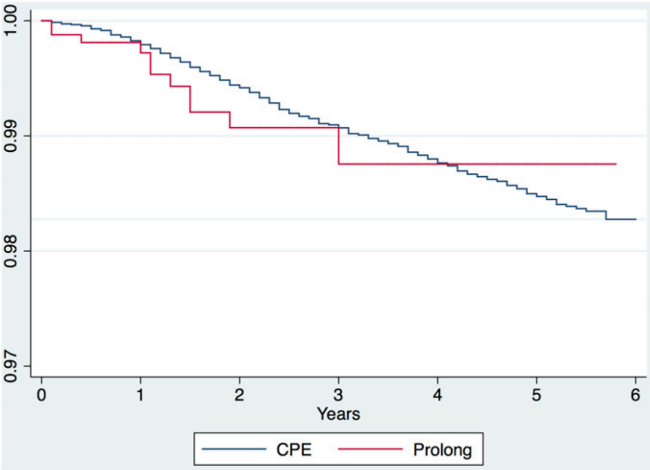
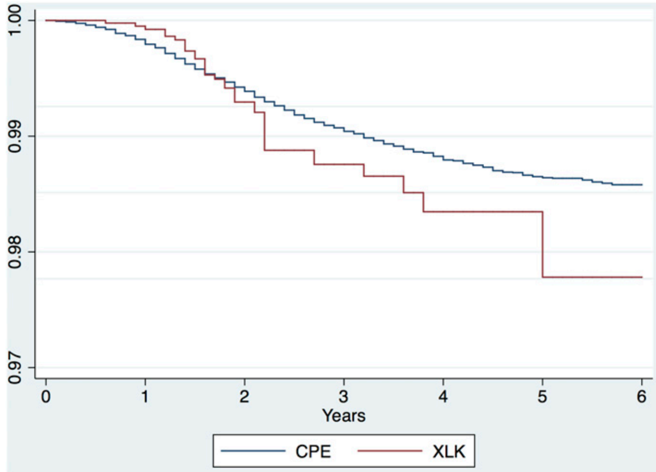


Fig. 4



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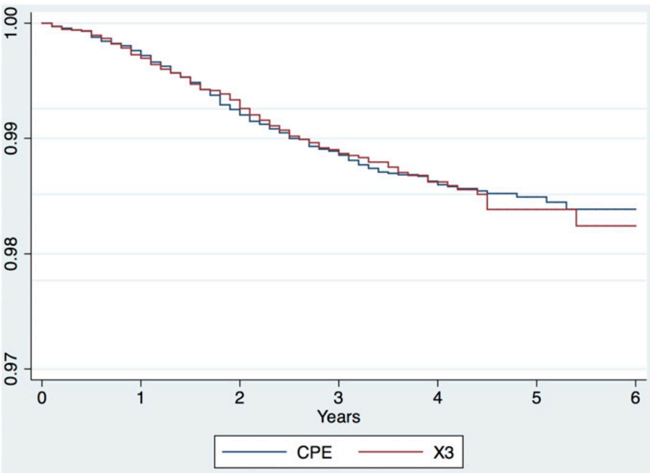

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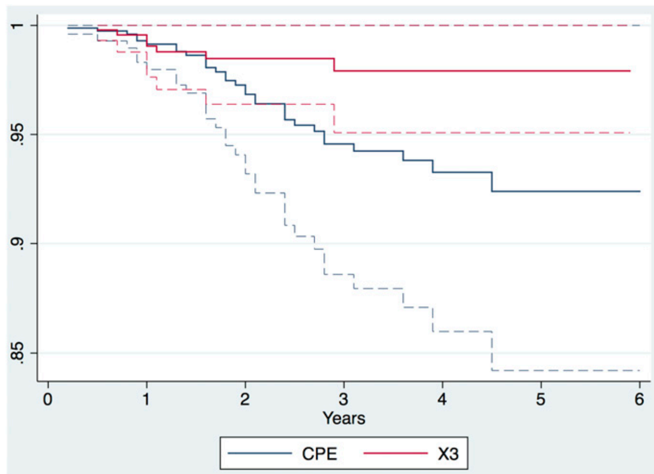

Fig. 7

Fig. 4 Unadjusted Kaplan-Meier survival curve for Zimmer NexGen with aseptic revision as the primary end point. CPE = blue line, and HXLPE = red line. **Fig. 5** Unadjusted Kaplan-Meier survival curve for DePuy PFC Sigma, with aseptic revision as the primary end point. CPE = blue line, and HXLPE = red line. **Fig. 6** Unadjusted Kaplan-Meier survival curve for Stryker Triathlon, with aseptic revision as the primary end point. CPE = blue line, and HXLPE = red line. **Fig. 7** Adjusted Cox regression survival curve for Stryker Triathlon in patients <60 years of age and with a BMI of >35 kg/m^2 with aseptic revision as the primary end point. CPE = blue line, HXLPE = red line, dashed lines = 95% CIs.

female), ASA classification (1, 2, 3, or 4), body mass index (<30, 30 to 35, >35 kg/m^2), lead surgeon grade (consultant as primary surgeon, non-consultant as primary surgeon), and constraint (cruciate-retaining, posterior-stabilized). The assumption of proportionality was checked for each model on the basis of Schoenfeld residuals. Any predictors violating the proportional hazards assumption were refitted into the model as time-varying coefficients. Time frame split points were sequentially chosen until the Schoenfeld global test was nonsignificant ($p > 0.05$). To control for HXLPE availability and length of follow-up, the within-brand secondary analyses were restricted to procedures performed from 2008 to 2014. The present study was exploratory in nature, using the complete data set of a national registry; as such, no formal power calculation was performed.

Analyses were performed with use of SPSS statistical software (version 20.0; IBM) and STATA/IC (version 13.1; StataCorp).

Results

The usage of HXLPE bearings during the period of observation is shown in Figures 2 and 3.

Primary Analysis

Table I demonstrates that the unadjusted all-cause revision rates (0.40 compared with 0.49 revision per 100 component-years) and aseptic revision rates (0.29 compared with 0.38 revision per 100 component-years) were significantly lower for traditional CoCr-on-CPE total knee arthroplasties when compared with the CoCr-on-HXLPE total knee arthroplasties ($p < 0.01$ for both). This finding remained even after removing

9,496 Kinemax Plus total knee arthroplasties with the first annealed cross-linked Duration (unadjusted aseptic revision rate, 0.35 per 100 component-years). Septic revision rates were the same for the CPE and HXLPE groups (0.11 revisions per 100 component-years for both).

Table II demonstrates the results of the survival analysis comparing CoCr-on-CPE versus CoCr-on-HXLPE with aseptic revision as the end point. CPE had a superior aseptic survival rate at 10 years (HR = 0.4 [95% CI, 0.1 to 0.8], p = 0.03).

Polyethylene Brand Analysis

The survival analyses of the 3 most commonly used HXLPE brands (Zimmer Prolong, DePuy XLK, and Stryker X3) are shown in Tables III and IV. There were no significant differences in aseptic revision rates per 100 component-years for CoCr-on-CPE and CoCr-on-HXLPE bearings for each of the 3 total knee arthroplasty systems. Figures 4, 5, and 6 show unadjusted Kaplan-Meier survival curves comparing CPE with its respective HXLPE for each total knee arthroplasty system. No significant difference was demonstrated between CPE and HXLPE for any of these systems with use of the log-rank test (Zimmer NexGen, p = 0.41; DePuy PFC Sigma, p = 0.27; Stryker Triathlon, p = 0.98).

After adjustment for age, sex, BMI, ASA classification, lead surgeon grade, and constraint, Cox regression analysis demonstrated no significant differences in the rate of aseptic revision between HXPLE and CPE for any of the 3 total knee arthroplasty systems (Table IV). Sex, ASA classification, and lead surgeon grade were not significant risk factors for aseptic revision (p > 0.05 for all) (Table III).

Age, BMI, and Constraint Subgroup Analysis

Within the regression models, younger age (<60 years) and high BMI (>35 kg/m^2) were consistent predictors of the risk of aseptic revision (Table III). Therefore, further analyses were conducted on patients <60 years of age and/or with a BMI of >35 kg/m^2. Because of the limited numbers of HXLPE cases available for analysis, the Zimmer Prolong HXLPE and DePuy XLK HXLPE did not demonstrate a significant difference in aseptic revision rates compared with their respective CPEs in unadjusted or adjusted analyses. However, for patients <60 years of age, the Stryker X3 HXLPE had a significantly better survival rate than its respective CPE (HR = 1.5 [95% CI, 1.0 to 2.1]; p = 0.03). In addition, for patients with a BMI of >35 kg/m^2, the Stryker X3 HXLPE had a significantly better survival rate than its respective CPE (HR = 2.0 [95% CI, 1.2 to 3.3]; p < 0.01). For the subset of patients who were both <60 years of age and had a BMI of >35 kg/m^2, the Stryker X3 HXLPE had a significantly better survival rate than its respective CPE (HR = 2.6 [95% CI, 1.2 to 5.9], p = 0.02) (Fig. 7).

Posterior cruciate-substituting total knee replacements were a risk factor for aseptic revision in the Zimmer NexGen subgroup (HR = 1.6 [95% CI, 1.3 to 1.8], p < 0.001). There were significantly fewer posterior cruciate-substituting total knee replacements in the HXLPE group than in the CPE group (22.6% compared with 50.7%, p < 0.001). Further analysis restricted to posterior cruciate-substituting total knee replacements demonstrated no significant difference in the rate of aseptic revision with CPE compared with HXLPE (HR = 2.7 [95% CI, 0.4 to 20.0], p = 0.3). Posterior cruciate-substituting total knee replacements were not identified as a significant risk factor for aseptic revision in the PFC Sigma or Stryker Triathlon subgroups.

Discussion

HXLPEs are marketed as having improved wear properties over conventional polyethylene CPEs[17-19] and have been shown to reduce wear and improve implant survival in patients undergoing total hip arthroplasty[9-12]. The present registry study demonstrated that these benefits are not generally translatable to the total knee arthroplasty population in the intermediate term. Overall, HXLPE demonstrated no survival benefit after a maximum duration of follow-up of 12 years. This preliminary analysis compared CPE and HXLPE for all total knee replacements in the NJR and as a result did not account for different total knee replacement designs or the evolution of implants. Therefore, individual brand analysis was conducted for the 3 most commonly used knee arthroplasty systems in England, Wales, and Northern Ireland; this analysis demonstrated no overall benefit. However, further subgroup analysis suggested that HXLPE may have a role in specific “higher-demand” patient groups (patients with an age of <60 years and/or a BMI of >35 kg/m^2).

The limitations of the present study include the use of revision within the registry as the end point, without consideration of other potentially relevant outcomes such as patient-reported outcomes, radiographic measures of wear, or retrieval analysis of revised explanted implants. Missing information on 1 or both bearing surfaces occurred in 15.5% of the data set and was excluded. We were unable to control for clinical or departmental decision-making and possible selection bias for the use of HXLPE. The present study represents an intermediate-term review of HXLPE performance, and greater follow-up is needed in order to identify if HXLPE behavior changes over longer-term follow-up.

The findings of the present study are consistent with data from the Kaiser Permanente registry, with no difference in revision rates between CPE and HXLPE[20]. While the overall proportion of total knee arthroplasties with HXLPE in the Kaiser Permanente registry is greater, the longer duration of follow-up and the greater number of total knee arthroplasties in the current study provide further insight into the behavior of these implants.

The preliminary analysis included the Duration HXLPE used with the Kinemax Plus total knee replacement. Duration was the first annealed cross-linked polyethylene and was gamma-sterilized to 30 kGy and heated at 50°C[3]. It has been suggested that poor survival rates were seen with the Kinemax Plus because of defective batches of polyethylene, with poor wear characteristics and pitting noted in retrieval studies[21]. This observation highlights the importance of differentiating between the different processes used by implant companies to manufacture their HXLPEs. The first HXLPEs were irradiated at much lower doses and had less refined thermal treatments; remelting reduced mechanical and fatigue properties and annealing was associated with higher free radical content. Concerns about the first HXLPE's wear properties and risk of fatigue cracking limited its use in knee replacement[13,22]. On removing the first HXLPE Duration from the analysis, there was still no overall benefit demonstrated with the newer HXLPEs over CPE.

The Stryker X3 HXLPE succeeded the Duration and Crossfire HXLPEs, creating a "second-generation" HXLPE with fewer free radicals, achieved by sequential irradiation and an alternative annealing process[3,23]. Its time-zero mechanical superiority and improved oxidative resistance made it a more suitable and durable option for total knee arthroplasty. This change occurred around the same time that Stryker replaced the Kinemax total knee replacement with the Triathlon total knee replacement[24]. Our results demonstrated a superior survival rate in association with the X3 HXLPE in patients aged <60 years and those with a BMI of >35 kg/m^2. Arguably, greater prosthesis loading in younger patients (who are associated with a higher level of activity) and heavier patients will cause CPE to wear faster[25]. This finding is comparable with results from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). de Steiger et al. demonstrated a reduced failure rate for HXLPE in younger patients, which was most pronounced for Zimmer NexGen Prolong total knee arthroplasties[16].

Prolong HXLPE, manufactured by Zimmer Biomet, is a first-generation HXLPE that is irradiated at a dose of 65 kGy and remelted at 135°C. We were unable to replicate the AOANJRR's findings with the Zimmer Prolong HXLPE in the present study, possibly because there are substantially fewer Prolong total knee arthroplasties in the NJR. Paxton et al. found no significant difference in survival in a study in which 6,473 NexGen total knee replacements with Prolong were compared with 25,320 NexGen total knee replacements with CPE at 5 years[26], similar to the current study. The XLK HXLPE, manufactured by DePuy Synthes, is another first-generation HXLPE, which is irradiated at 50 kGy, remelted at 155°C, and annealed at 120°C. The Kaiser Permanente Registry demonstrated no significant difference in survival when 2,291 PFC total knee arthroplasties with XLK were compared with 35,166 PFC total knee arthroplasties with CPE[26]. The relatively small numbers of Prolong and XLK in our study are a further limitation; these subgroup analyses should therefore be regarded as exploratory.

Recent 10-year survival analyses, presented in the Australian registry annual report, suggested a benefit for HXLPE over CPE following >100,000 total knee arthroplasties performed with use of HXLPE inserts[16]. At 2.5 years of follow-up, the hazard ratio for all-cause revision was 1.73 (95% CI, 1.60 to 1.86; $p < 0.001$). Currently, only 10% of total knee arthroplasties in England, Wales, and Northern Ireland are performed with use of HXLPE inserts, compared with >50% in the Australian registry. It is difficult to reconcile the differing findings between these 2 registries. The difference may relate to "selective" use within the NJR, with HXLPE being reserved for patients in whom excessive wear is predicted, such as the younger, higher-demand patients, who are known to have a higher rate of revision when compared with more elderly, sedentary patients. While the current analysis adjusted for patient-related factors, including age, we could not adjust for patient function, preoperative expectation, disease severity, and other factors that may confound comparison when 1 implant is used "selectively."

The use of HXLPEs as the bearing interface for total knee arthroplasty is increasing in the NJR. The present study suggests that there is no survival benefit in association with first-generation HXLPEs (Duration, Prolong XLK) after a maximum duration of follow-up of 12 years. As such, the extra costs associated with these bearings may not be justified in the intermediate term. Second-generation HXLPEs (X3) may be beneficial for patients who are young (<60 years) and/or obese (BMI >35 kg/m^2). Additional follow-up is required to assess whether HXLPEs become a cost-effective alternative to CPE in the longer term. ■

Note: We thank the patients and staff of all the hospitals in England, Wales, and Northern Ireland who have contributed data to the National Joint Registry. We are grateful to the Healthcare Quality Improvement Partnership (HQIP), the NJR Research Sub-committee, and staff at the NJR Centre for facilitating this work. The authors have conformed to the NJR's standard protocol for data access and publication. The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Registry Steering Committee or the Health Quality Improvement Partnership (HQIP), who do not vouch for how the information is presented.

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