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Long-Term Results of Total Hip Arthroplasty with 28 millimeter Cobalt-Chromium Femoral Heads on Highly Cross-linked Polyethylene in Patients 50 years and Less

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Abstract

Highly cross-linked polyethylene (HXLPE) is the most commonly used bearing surface in total hip arthroplasty (THA) because of its superior wear properties, but long-term results in young patients are limited. We report on the clinical outcome, radiographic wear patterns and survivorship of 72 patients 50 years old who had a 28-millimeter cobalt-chromium femoral head on HXLPE acetabular liner. Mean and median true linear wear rates at average ten-year follow-up were 0.0104 and 0.016 mm per year $\pm$ 0.07 mm. Mean and median two-dimensional volumetric wear rates were 12.79 mm³ and 5.834 mm³ per year $\pm$ 26.1mm³ as determined by Martell analysis. As a result of the minimal wear profile, there was no evidence of radiographic osteolysis and no wear-related revisions.

Introduction

Polyethylene wear is a well-defined mechanism that can directly lead to osteolysis and subsequent total hip arthroplasty (THA) failure [14]. Furthermore, previous research has established that linear polyethylene wear exceeding 0.2 mm per year or volumetric wear surpassing 150 mm³ per year predisposes the hip to periprosthetic osteolysis [51]. Highly

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cross-linked polyethylene (HXLPE) after electron-beam radiation and re-melting is a specific type of alternative bearing that has been championed over the past 15 years because of laboratory findings of reduced wear rates and particle formation [7, 37, 39]. Mid and long-term *in vivo* results have corroborated simulated findings of decreased wear rates [23, 33, 43], but concerns still exist regarding the longevity of the bearing surface due to fatigue fracture risk [5] and potentially increased biologic activity of wear particles [25].

Young patients present a unique dilemma for bearing survivorship in that they not only live longer, but commonly pursue more physically demanding activities that place significantly more stresses across the articulation surfaces [12, 42]. Currently, few reports in the literature focus on long-term results of HXLPE in younger cohorts [3], which is an important issue to clarify due to recent problems with hip resurfacing, metal-on-metal, and primary modular implants. The purpose of this study is to evaluate the linear and volumetric wear patterns, survivorship and functional activity scores at average ten-year follow-up of a specific cohort of patients under the age of 50 years at the time they underwent THA utilizing 28-mm cobalt-chromium femoral heads on modern HXLPE liners.

Materials and Methods

After the ethical review committee granted approval, we performed a retrospective review of our institutional database for all patients 50 years of age or less who underwent THA with the bearing combination of a 28-millimeter cobalt-chromium (CoCr) femoral head on HXLPE acetabular liner. All surgeries were performed by one of two senior authors. All patients received the combination of cementless acetabular shell augmented with screw fixation (Trilogy®, Zimmer, Warsaw, IN) and a CoCr femoral head (VerSys™, Zimmer, Warsaw, IN). The HXLPE acetabular liner (Longevity®: Zimmer) was fabricated by a process that included electron-beam irradiation to 9 mRad and gas plasma-sterilized, remelting, and annealing. Ninety-six percent (n=96) of patients had cementless femoral stem fixation. All patients had a posterolateral approach. Only those patients with greater than eight-year follow-up were included. Patients were excluded if they had undergone previous THA or received any combination of components other than listed above. We did not discriminate based on preoperative diagnosis. The primary study endpoint was defined as all-cause revision, with secondary outcomes including reoperation or death.

We identified 99 consecutive hips (95 patients) that had received a HXLPE acetabular bearing from July 2001-February 2004. Eight patients (nine hips, 9%) were lost to follow-up despite extensive efforts to contact them to return for clinical evaluation. Fifteen patients (16 hips, 16%) had an average follow-up of 5.25 years (SD 2.1 years) and were excluded due to insufficient long-term follow-up duration. It is important to state, however, that none of these 16 patients required a revision for any reason at the time of their most recent follow-up. After these exclusions, 75 hips (72 patients, 75%) with an average 10-year follow-up (range 98 to 143 months, SD 10.8 months) who received the 28-mm CoCr head on HXLPE liner combination remained. No other alternative bearing surfaces were utilized by the surgeons at our institution during the time period of this study.

Prospective institutional joint registry data entry has been accomplished for all patients undergoing total hip arthroplasty at our institution, including preoperative evaluations and postoperative assessments at recommended six-week, one-year, two-year, five-year, and ten-years, unless otherwise specified by the treating surgeon. Retrospective data review was performed by two individuals who were neither directly involved in surgical treatment or patient management.

The study group was comprised of 43 females (59%) and 29 males (41%). The mean patient age was 41.2 years (SD 8.5, range 17-50 years) and mean BMI was 28.8 kg/m² (SD 5.6, range 17.7- 46.2 kg/m²). Eighty percent of cohort members self-identified as Caucasian (n=58), while the remainder of subjects identified themselves as either African-American (15%, n=11) or Asian (1%, n=1). The two most common preoperative diagnoses included osteoarthritis (53%, n=38) and osteonecrosis (39%, n=28), while post-traumatic arthritis and other causes comprised 4% each (n=3). Comorbidities included inflammatory arthritis, hypertension and smoking (each 16%, n=12), gastrointestinal (14% n=10), respiratory (8%, n=6), and alcohol, neuropathy, obesity (each 7% n=5), and others (12%, n=14).

Preoperative and postoperative patient-reported outcome measures included the modified Harris hip score (mHHS) [22], the Western Ontario and McMaster Universities (WOMAC) Index [29] and the UCLA activity scale. The HHS and WOMAC have been validated as a reliable measures of overall function after hip replacement [49]. The UCLA scoring system is a patient reported self-assessment scale, with '1' indicating inactivity and '10' representing participation in high impact sports [2].

A standard radiographic series including low anteroposterior (AP) pelvis and cross-table lateral views of the affected hip were obtained and digitally assessed for all patients. Acetabular component inclination and version were determined using techniques previously described [32]. Osteolysis surrounding the acetabular and femoral components were determined using the DeLee and Charnley and Gruen methods, respectively [13, 20]. Definite acetabular component loosening was defined by either component migration >4 mm from initial component placement or complete, contiguous radiolucency 2 mm wide present in all three DeLee and Charnley zones. Criteria described by Engh et al. were utilized to determine femoral implant stability [16]. Post-operative heterotopic ossification was quantified according to the Brooker classification system [8].

The Martell computerized, semi-automated, edge-detection method was used to determine the two-dimensional vector wear by one author who was trained and validated in the use and function of the program (Martell Hip Analysis Suite, version 8.0.4.3; University of Chicago, Chicago IL). Calculation of linear wear was performed with this validated computer algorithm for all AP radiographs taken at two, five and ten years postoperatively against a baseline radiograph taken at the first postoperative visit and a subsequent radiograph taken one year after THA [36]. A radiograph taken between 12-18 months after surgery was used as a baseline for the measurement of steady-wear rate to account for bedding-in of the liner within the acetabular shell [50]. The resultant data was processed using the two measurements approach as described by Shia et al [46]. Volumetric wear is calculated from

the magnitude of the wear vector on the two-dimensional projection on AP radiograph and the direction of the wear with respect to the cup face and the femoral head size [24, 36].

Statistical analysis included the use of the Wilcoxon signed rank sum test, which does not require a normality assumption, to examine the difference between the pre and post-operative clinical assessment measures as a non-parametric alternative of a paired t-test. Revision free survival probability was estimated by the Kaplan-Meier survival curve. Pearson correlation coefficients were calculated among cup angles and wear data.

Results

The modified Harris Hip score improved from mean of 46.3 to 81.9 ($p<0.001$) at final follow-up (Table 1). The mean postoperative WOMAC scores were 82.7 for pain (range 10-100, SD 23.8), 78.4 for stiffness (range 0-100, SD 26.9), and 81.9 for function (range 7-100, SD 22.3) and all demonstrated significant improvements from preoperative values ($p<0.001$). UCLA activity score also improved from a mean of 4.07 to 6.36 ($p<0.001$) at average ten-year follow-up, signifying a change from regular participation in mild (i.e. walking or shopping) to moderate activity (i.e. heavy housework or moderate distance walking) participation. In a subgroup analysis examining the relationship of polyethylene wear and relative postoperative activity levels, no statistical difference was appreciated in linear or volumetric wear rates when comparing those patients considered highly active (UCLA 8-10) versus lower demand individuals (UCLA score 1-7) (Table 2).

Radiographic analysis demonstrated no evidence of periprosthetic osteolysis in any of the surviving subjects. All cups were placed in an anteverted position with an average cup-rotation angle of 20.4° (range $3-39^\circ$, SD 7.7). The average cup inclination angle was 42.5° (range $25.4^\circ-59.9^\circ$, SD 7.5). Twenty-three patients had cup angles outside the traditional Lewinnek safe zone[34], but subgroup analysis did not demonstrate any significant differences in linear or volumetric wear when compared to those subjects whose cups were placed between $5-25^\circ$ of anteversion (linear wear $p=0.4$; volumetric wear $p=0.17$). Furthermore, no differences in pre or postoperative UCLA activity scores were found based on variations in cup angle (pre-THA $p=0.23$, post-THA $p=0.17$).

We observed a true steady-state linear wear rate of 0.0104 mm/year after accounting for the one-year bedding-in period (median 0.016, range -0.133 to 0.307, SD 0.07). This low rate demonstrates a nearly undetectable wear at average ten-year follow-up (Figure 1). Using three-dimensional Martell analysis software, the volumetric wear was found to be 12.79 mm^3 per year (median 5.83, range .007-175.2, SD 26.1). This too is clinically undetectable, as illustrated by the graphical representation of wear points over ten-years in Figure 2. A Pearson correlation analysis of cup position and wear demonstrated an increase in 10-year volumetric wear with decreasing anteversion (volumetric wear rate: $r^2 = -0.44$, $p=0.001$) (Table 3).

At ten years, our cohort experienced an overall implant survivorship of 92%, which can be visualized by the Kaplan-Meier survival curve (Figure 3). Five of the 72 patients (6.9%) underwent revision hip arthroplasty before the ten-year mark while one experienced an

unscheduled reoperation (Table 4). Three of the five failures were due to aseptic loosening because of a failure to achieve initial osseointegration of the bone onto the component surface (2 femoral, 1 acetabular). All cases of failed osseointegration occurred in patients with a pre-operative diagnosis of osteonecrosis (ON) and who had a history of chronic steroid use. It is important to note that there was no radiographic evidence of osteolysis around the bone-implant interface in any of these three instances. The first subject was a 44 year-old male with ON and co-morbid conditions including alcohol, tobacco use, chronic steroids and GI disease whose femoral stem never osseointegrated and subsided at the one-year visit. The second case was a 43-year old male with ON from alcohol use who demonstrated progressive femoral subsidence and hip pain, again indicating that his component never fully osseointegrated. Finally, a case of late acetabular aseptic loosening occurred in an 18-year old African-American female with dermatofibromyositis and chronic steroid use.

Two other patients were revised for issues other than aseptic loosening. The first of these cases was due to repeated anterior instability episodes within two-months of index surgery. Like the aseptic loosening cases, this subject presented with osteonecrosis due to chronic prednisone use for lupus. The final case was due to a late presenting infection (113 months) in a 33-year old obese female caused by *Corynebacterium striatum*. The infection was treated by a standard explant and two-stage revision with a six-week course of intravenous Vancomycin and Cefepime.

There was one case of aseptic acetabular loosening due to lack of osseointegration in a patient whose cup assumed a more vertical position in the early post-op period and remained in the same position at the ten-year follow-up roentgenogram. She has not been revised, however, because of her deteriorating functional status and multiple surgical risk factors. This particular patient has an underlying glycogen storage disease and has had bilateral lung transplants, a mitral valve replacement and is on lifelong Warfarin all since her index procedure. Given these multiple comorbidities and adequate hip function, the patient declined further hip surgery.

When considering preoperative diagnosis, it is worth noting that no patients with a preoperative diagnosis of osteoarthritis experienced a failure due to osteolysis or aseptic loosening (Figure 4). Yet, a preoperative diagnosis of osteonecrosis was not a statistically significant predictor of subsequent failure ($p=0.129$). Revision rates between genders did not differ significantly ($p=0.957$, Figure 5).

Finally, there was one case of progressive heterotopic ossification (Brooker stage IV) that caused pain and restricted range of motion and necessitated a reoperation at 64 months for excision of heterotopic bone. An acetabular liner and femoral head exchange was performed in this scenario only to fully access the excessive bone anteriorly. None of the five revisions were directly due to polyethylene wear and/or osteolysis in either the femoral or acetabular region. Furthermore, there were no male patients with a pre-operative diagnosis of osteoarthritis who went on to revision THA.

Discussion

Multiple studies have demonstrated superior HXLPE wear rates *in vivo* at ten years, but the majority of such reports are limited due to the varying femoral head sizes and/or acetabular components as well as older patient populations [3, 6, 17]. Our investigation determined that young patients who received a THA with a 28-mm cobalt-chrome femoral head coupled with a HXLPE liner in a cementless, titanium fiber metal mesh shell (Longevity®, Zimmer) maintained superior wear properties, clinical improvement and survivorship at average ten-year follow-up.

Our results demonstrate excellent wear properties, with linear penetration rates less than the 0.038 mm/year weighted average cited in the systematic review of mid-term outcomes of first-generation HXLPE use by Kurtz et al [31] and others [17, 43, 45]. When comparing to only subjects less than fifty years of age, our results are comparable to those recently reported in the literature. In patients less than 30 years of age, Kim et al found a mean HXLPE wear rate of 0.031 ± 0.004 mm when coupled with alumina femoral heads and no failures due to osteolysis [28]. Babovic and Trousdale [3] reported mean femoral head penetration rates of 0.004 ± 0.0047 mm/year using the Roman method in patients <50 years of age. Their results should be cautiously interpreted, however, due to the varying femoral head sizes used (22, 28, 32 or 50mm).

Limitations of our study include the incomplete follow-up of 28% of our patients who underwent initial THA. We made a concerted effort to communicate with patients via mail, phone calls and online communication, but were unable to contact and obtain follow-up on these patients. As previously reported by our group, patient compliance with clinical follow-up after THA remains challenging [10]. Secondly, the Martell method has its own limitation in that it may calculate a negative wear rate when the true HXPLE wear is below a detectable threshold, thus reporting an impossible value into the equation. And while the reliability and reproducibility of such a system may be called into question, a phantom study by Kraay et al reported accuracy of the Martell method of 8 microns $\pm$ 12 microns [30]. Our study is also inherently weakened due to the lack of a control group. However, there are historical controls with which to compare wear results and THA survivorship. Although there is a current attraction to use 32 and 36 mm femoral heads to increase hip stability, it is important to analyze the alternative bearing options with the longer-utilized smaller heads, especially in a young cohort with increased activity and functional demands. The early results of larger heads on HXPLE show similar linear properties but higher volumetric wear rates [32], which could affect osteolysis rates at longer-term time points. It has been posited that an increase in volumetric wear by 40mm^3 per year raises the osteolysis risk threefold [41]. We calculated four high volumetric wear points (seen in Figure 2) in two patients over the duration of the study. On second look, these outliers were likely caused by slight alterations in the Martell software's calculation of the femoral head center. We evaluated the individual x-rays in question and did not find any osteolysis or shifting of the cup over time. We decided against re-running calculations for all subjects as manual alterations in hip center referencing would change the reliability of the Martell system. The strength of our study lies in its uniformity and long-term follow-up – all patients were prospectively identified and received a 28-mm CoCr femoral head on the same HXPLE liner.

Specifically for young patients under the age of 50, the wear and survivorship findings brought forward in this study provide a stark contrast when compared with the earlier bearing surfaces. The results of first generation Charnley low-friction arthroplasty in young patients demonstrated that polyethylene wear rates above 0.19-0.21 mm/year were associated with a higher incidence of revision for osteolysis. A total of 19% of hips in the series required revision for osteolysis and/or cup migration at an average 13.8 years from index procedure [48]. Maloney et al reported a 22% acetabular osteolysis rate (15/68 subjects) and a 10.2% (7/68) revision rate at ten-years for patients under 50 years of age for metal heads on conventional polyethylene (CPE) liners [35]. Furthermore, young patients in the CPE cohort exhibited a mean 0.22 mm/yr linear wear rate, far exceeding the noted osteolysis threshold of 0.1 mm/year established by Dumbleton [15]. When considering volumetric wear rates and associated osteolysis in young patients, previous studies regarding conventional polyethylene have suggested that rates above 40-62 mm³ per year predict osteolysis and subsequent revision [21, 41, 51].

It is important to note that there were no failures due to polyethylene wear, osteolysis or aseptic loosening in the subgroup of patients with a primary diagnosis of osteoarthritis. Furthermore, no male patients with osteoarthritis demonstrated problems with femoral or acetabular-sided osseointegration. Alternative bearings such as metal-on-metal and resurfacing arthroplasty (RSA) have been endorsed in cases of osteoarthritis and have shown variable success [1, 9, 18, 27]. Additionally, recent registry data indicates increased failure rates of RSA at 10-year follow-up [11, 40, 47]. Specifically in young males with osteoarthritis, resurfacing has shown excellent early and mid-term survival [19, 44], but increased problems at greater than eight years follow-up, with failures due to loosening or head collapse between 9-11% [38, 52]. Although failure rates of those with a preoperative diagnosis of ON in our study population approached statistical significance ($p=0.129$), we believe our results suggest a more predictable long-term survivorship of contemporary THA with a HXLPE bearing surface in this specific at-risk subgroup. With larger numbers in our future datasets, we will be able to analyze this question with increased statistical power.

The finding of increased volumetric wear as anteversion approaches 0° (neutral) goes against the conventional thought that there is no difference in wear when placed in the safe zone of 5-35° [4, 26, 34]. This phenomenon could be due to a combination of increased activity levels in our specific young cohort, but more likely is due to marginal differences in extremely small volumetric wear patterns at differing anteversion angles that reaches statistical but not clinical significance. Yet, this association warrants further investigation to consider if younger patients with large head sizes and varying cup placement experience clinical differences in outcomes or complications from altered wear patterns.

The introduction of highly cross-linked polyethylene in total hip arthroplasty for young patients has been associated with reductions in linear and volumetric wear. Our study demonstrates linear and volumetric wear rates below the historic threshold of 0.1-0.2 mm/yr. and 40-150 mm³/yr. with 28-mm CoCr femoral heads [15, 41]. At long-term follow-up young patients with 28-mm CoCr femoral heads on HXLPE experienced significant functional and activity improvements, no failures related to osteolysis or polyethylene wear and nearly undetectable linear (0.0104 mm/yr., SD 0.07) and volumetric (12.79 mm³ per

year, SD 26.1) wear rates. There were no failures in male patients with osteoarthritis at a minimum of eight-year follow-up, indicating outstanding survivorship in this subgroup of patients.

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Figure 1.

The true linear wear rate for HXLPE liners calculated from the 1-year AP pelvis compared with the longest available follow-up film available for each subject yielded a mean wear rate of 0.0003 mm (SD 0.04) per year excluding the first year bedding-in period.

Figure 2.

The true volumetric wear rate for HXLPE liners calculated from the 1-year AP pelvis compared with the longest available follow-up film available for each subject yielded a mean wear rate of 0.0009 mm (SD 7.6) per year excluding the bedding-in period over the first postoperative year.

Figure 3.

Kaplan-Meier estimates of revision-free survival time (in months), as determined by the time between the date of last follow-up and the date of index arthroplasty. Three survival curves shown are 1) Revision Free Survival (RFS) of all causes (i.e., 5 revisions); 2) RFS for aseptic loosening (ASL)/osteolysis/wear (i.e., 3 revisions); and 3) RFS of other causes (i.e., 2 revisions).

Figure 4.
Survival Log-rank Test of Revision by Pre-operative Diagnosis.

Figure 5.
Survival Log-rank Test of Revision by Gender.

Table 1

Summary of preoperative and >10 year follow-up patient reported outcomes (PROs)

PRO	Pre-operative (SD)	Post-operative (SD)	P-value
mHHS	46.3 (14.7)	81.9 (19)	p<0.001
UCLA Activity	4.1 (2)	6.3 (2)	p<0.001
WOMAC Pain	38.7 (18.9)	82.6 (23.7)	p<0.001
WOMAC Stiffness	40.2 (23.6)	78.3 (26.8)	p<0.001
WOMAC Function	41.8 (17.1)	81.8 (22.3)	p<0.001

PRO = patient-reported outcome, mHHS = modified Harris Hip score, WOMAC = Western Ontario and McMaster Universities Index, SD = standard deviation.

Table 2

Subgroup analysis comparing linear and volumetric wear rates based on low (UCLA score 1-7) versus high (UCLA score 8-10) postoperative activity levels.

UCLA 1-7 vs. 8-10				
<u>Linear (mm)</u>	Low	High	<u>P-values:</u>	
			t-test	Mann-Whitney
<u>Mean linear rate</u>	0.010	0.002	0.360	0.266
<u>Median linear rate</u>	0.015	0.016		
<u>Std. dev. Linear</u>	0.043	0.056		
<u>Volumetric (mm³)</u>	Low	High	0.879	0.694
<u>Mean vol. rate</u>	9.453	9.991		
<u>Median vol. rate</u>	4.700	5.921		
<u>Std. dev. Vol.</u>	10.785	15.118		

Table 3

Pearson correlation coefficient (r) matrix among cup angles and wear data. A negative r demonstrates an inverse relationship, such that this analysis represents less acetabular component anteversion correlates with a higher volumetric wear rate. Furthermore, a positive *r*-value closer to one suggests, as in this case, that increased linear wear rates correlated with increased volumetric wear rates.

		AP Cup Rotation angle	Inclination angle	Linear Wear Rate Martell	Volumetric Wear Rate Martell	AP Vector Wear 2D	Volumetric wear 2D
AP Cup Rotation angle	r	1	0.24882	−0.24647	−0.44813	−0.21863	−0.36685
	p-value		0.0954	0.0987	0.0018	0.1444	0.0122
Inclination angle	r		1	0.01289	0.1203	−0.02293	−0.00027
	p-value			0.9323	0.4258	0.8798	0.9986
Linear Wear Rate Martell	r			1	0.71019	0.90548	0.53661
	p-value				<.0001	<.0001	0.0001
Volumetric Wear Rate Martell	r				1	0.55842	0.81703
	p-value					<.0001	<.0001
AP Vector Wear 2D	r					1	0.55842
	p-value						<.0001
Volumetric wear 2D	r						1
	p-value						

Table 4

Total hip arthroplasty failures requiring subsequent revision surgery.

Subject	Time to Revision (months)	Diagnosis	Revision Extent
1	1.5	Recurrent Instability	Complete acetabular revision with upsizing acetabular shell and removing anteversion during intra-operative positioning
2	13.2	Failed osseointegration ("Aseptic Loosening") - Femoral stem	Beaded, full-coat femoral stem + liner exchange
3	34.6	Failed osseointegration ("Aseptic Loosening") - Femoral stem	Beaded, full-coat femoral stem + liner exchange
4	71.3	Failed osseointegration ("Aseptic Loosening") - Acetabulum	Trabecular metal shell with 3 supplemental screws + femoral head/liner exchange
5	113.8	Infection	Explant, articulating antibiotic spacer and cementless component reimplantation