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ORIGINAL ARTICLE

Wear is Reduced in THA Performed with Highly Cross-linked Polyethylene

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Abstract Highly cross-linked polyethylene (HCLPE) has been used extensively to decrease osteolysis and related implant failure in THA. We compared the wear rate of HCLPE and noncross-linked conventional PE (CPE) liners and the rate of radiographic calcar resorption and osteolysis in young patients (35–60 years of age) who underwent THA by one surgeon. Thirty-four patients (41 THAs) who received a hybrid THA using a HCLPE liner were match-paired for age, gender, body mass index, and diagnosis with a group of patients who underwent THA with identical implants but with a CPE liner. The minimum followup was 4 years (average, 5.3; range, 4–8 years). Using the Livermore measurement technique, the averages of total wear of the HCLPE and CPE liners were 0.01 mm (range, −0.23–0.4) and 0.64 mm (range, 0–1.7), respectively. The average annual wear was less for the HCLPE than the noncross-linked PE (0.002 mm, range, −0.05–0.1 versus 0.12 mm, range, 0–0.29, respectively). Four hips in the HCLPE group and 23 in the CPE group had calcar resorption measuring averages of 2.5 mm (range, 2–3) and 7.5 mm (range, 1.8–23.8), respectively. Periprosthetic osteolysis occurred in two and eight hips in the HCLPE and CPE groups, respectively. Longer followup is needed to determine if these findings will result in improved implant survivorship.
Level of Evidence: Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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Introduction

The long-term survivorship of the metal-on-PE THA is limited by the biologic reaction to PE wear [23, 24, 30]. Consequently, attempts have been made to reduce PE wear with the ultimate goal of increasing implant survival [5, 6]. This is particularly important as indications of THA have expanded to younger, more active patients.

In vitro [35, 36, 42] and early (2–4 years average followup) in vivo studies [10, 11, 18, 25, 31, 33, 35] suggest HCLPE has improved wear resistance compared with standard noncross-linked PE. However, studies reporting on the midterm ($\geq$ 5 years average followup) in vivo performance of these PE liners are scant [1, 4, 7, 9, 37]. Such studies are of utmost importance because radiographic osteolysis is a phenomenon rarely seen before 5 years of followup.

We therefore addressed the following two questions: How does the wear rate of HCLPE liners compare with that for noncross-linked CPE liners in young patients at midterm followup? What is the incidence of calcar resorption and radiographic osteolysis in the two groups?

Materials and Methods

Because clinical wear rates can vary depending on patient demographics, diagnosis, and implant characteristics, we performed a matched-pair study. We retrospectively reviewed 64 consecutive primary THAs performed between December 2000 and November 2003 by one orthopaedic surgeon (EAS) in 53 patients who were 60 years or younger (mean age, 50 years; range, 35–60 years) at the time of surgery. All patients received an identical uncemented acetabular cup (Trilogy®; Zimmer, Inc, Warsaw, IN), a HCLPE liner (Longevity®; Zimmer), and a cemented stem (VerSys® Heritage®; Zimmer) with a cobalt-chrome modular head. Of the 53 patients (64 hips), we included 34 (41 hips) with minimum clinical and radiographic followups of 4 years (average, 5.3 years; range, 4–8 years) in the study (study group). Of the remaining 19 patients (23 hips), 17 (21 hips) were contacted by phone; they had successful clinical results but refused radiographic followup. Two patients (two hips) were lost to followup.

We compared the study group with an historical control group [21] selected from 271 consecutive patients who underwent 308 primary THAs between 1997 and 1998 by the same surgeon (EAS) using an identical surgical technique with a Trilogy® cup but with a conventional PE liner gamma-sterilized in nitrogen and a cemented stem (VerSys®) with a cobalt-chrome modular head. This is the only type of stem that the senior author used for all primary THAs during the study period. All patients underwent surgery at the same institution using an identical posterolateral approach with enhanced posterior soft tissue repair [40]. Comparison was made by retrospectively match-pairing patients in the two groups for age (within 5 years), gender, body mass index (within 5 kg/m^2), radiographic followup (within 6 months), and diagnosis of osteoarthritis with one osteonecrosis and one posttraumatic arthritis in each group (Table 1). The match-pairing process was performed manually by one of the authors not involved in the operations (BB). In addition, and to avoid bias, the process was performed using a table containing only the variables included in the matching criteria. All patients had clinically successful results and well-fixed acetabular and femoral components as determined from the evaluation of AP and lateral radiographs at last followup. There was no difference in demographic and perioperative data between the two groups (Table 1).

The Trilogy® cup has a hemispheric titanium alloy acetabular shell with a titanium fiber mesh surface for ingrowth. A modular liner is secured to the shell by a locking ring that engages in a circumferential slot located in the equator of the liner [21]. The HCLPE liners used in the study group were made from compression-molded GUR 1050 ultrahigh-molecular-weight PE bar stock. The square bar stock was irradiated using an electron beam accelerator to an absorbed dose level of 100 kGy. After cross-linking, the bar stock was heated to a temperature (150°C) above the material's melting point until complete melting was achieved and then cooled to room temperature. The liners were sterilized using gas plasma. The CPE liners used in the control group were machined out of compression-molded sheets with resin-type GUR 1050 and were sterilized with gamma irradiation (25–37 kGy) in nitrogen. There were four 10° elevated liners in the study (HCLPE) group. All the liners in the control (CPE) group had a standard, nonelevated geometry.

The VerSys® femoral components used in this study are made of cobalt-chromium alloy double-tapered with proximal and distal centralization. They were implanted with a modern cementing technique, which included vacuum mixing, use a cement restrictor, retrograde canal filling, and pressurization with a cement gun. We preheated the

Table 1. Patient demographics

Variable	HCLPE group	CPE group	p Value
Patient gender (male:female)	20:15	20:15	NA
Hips	41	41	NA
Age (years)	50 ± 7	53 ± 7	0.107
Body mass index (kg/m^2)	28 ± 5.2	30 ± 6.1	0.132
Followup (years)	5.3 ± 0.9	5.3 ± 0.7	0.955
Diagnosis	32 OA, 1 PTOA, 1 AVN	32 OA, 1 PTOA, 1 AVN	≈ 1
22/26/28/32 mm head	0/2/38/1	3/1/37/0	0.99
Cup inclination	43° ± 5.6°	43° ± 4.5°	0.903
Cluster/nonholed shell	5/36 THA	11/30 THA	0.164

Values are expressed as median ± standard deviation; HCLPE = highly cross-linked polyethylene; CPE = conventional (noncross-linked) polyethylene; OA = osteoarthritis; PTOA = posttraumatic osteoarthritis; AVN = avascular necrosis; NA = not applicable.

femoral components and the polymer (Simplex™ P; Stryker Howmedica Osteonics, Allendale, NJ) to 41°C [39].

All patients were personally evaluated clinically and rated according to the Hospital for Special Surgery hip score [45], which evaluates pain, walking, motion and muscle power, and function, and also radiographically. Anteroposterior and lateral radiographs of the pelvis centered on the pubic symphysis were obtained by the same group of radiology technicians with the patient in the supine position. All radiographs were evaluated and measured by one observer (AGDV) who was not involved in the surgeries and was blinded to the type of liner. The total wear rate was determined by comparing the AP radiograph obtained 6 weeks after surgery with the one obtained at last followup using the method described by Livermore et al. [29], which has been used extensively in clinical research and validated [19–21]. In these previous studies, the intraobserver consistency of the wear measurements calculated as the average 95% confidence interval was ± 0.06 mm (range, 0.02–0.13 mm) [20]. Measurements were obtained using a digital caliper (Absolute Digimatic, Mitutoyo, Japan) with a resolution of 0.01 mm. The annual wear was calculated by dividing total wear by the years of followup.

On AP and lateral radiographs obtained at last followup, we determined the incidence, location, and extent of calcar resorption and periprosthetic osteolytic lesions. Calcar resorption was defined as rounding of the calcar with a convex shape and loss of the prosthesis microcollar bone contact and was differentiated from calcar osteolysis, which was defined as a punched-out, expansive area with a concave shape. Calcar resorption was quantified with a digital caliper and corrected for magnification following previously described methodology [20]. Radiographic osteolysis was defined as so-called punched-out areas devoid of trabecular bone, usually with a sclerotic border. Osteolytic lesions were located according to DeLee and Charnley [8] in the acetabulum and Gruen et al. [22] in the femur.

The data were included in a computerized worksheet (Microsoft® Excel® 2003; Microsoft Corp, Redmond, WA). Range, standard deviation, and 95% confidence intervals were calculated for all continuous variables. We compared the demographic and perioperative data using the paired (age, body mass index, followup) and unpaired (anteversion, cup inclination) t test. Statistical normality tests were conducted to examine the distribution of the total and annual wear data; as the wear data showed a nonGaussian distribution, a nonparametric test (Mann-Whitney U test) was used to compare the wear measurements for significant differences at the 95% level. We also compared the difference in the incidence of calcar resorption and periprosthetic osteolysis using Mann-Whitney U test. We performed post hoc power analyses to assess the power of the total and annual wear measurements and incidence of calcar resorption and periprosthetic osteolysis between the groups. The post hoc power analysis yielded 95% power to detect a clinically meaningful difference in the total and annual wear of 0.3 mm and 0.06 mm, respectively, with a probability of 95%. These clinically meaningful differences were calculated as follows. The mean annual wear measurements of eight HCLPE studies [1, 9, 12, 14, 17, 18, 33, 43] (Table 2) were averaged. We presumed a meaningful difference would be the difference between this number and the mean annual wear of our control group generated from our historical cohort [21]. The post hoc power analysis showed a 92% power to differentiate a 3-mm calcar resorption difference and a 41% power for the osteolysis calculation.

Results

Patients with a HCLPE liner had less ($p < 0.0001$) wear than those who had a CPE liner. The average total and annual wear of the HCLPE liners were less ($p = 1.07 \times 10^{-10}$ and $p = 4.06 \times 10^{-10}$, respectively) than the CPE liners (Table 3). All cups were radiographically well fixed, and none had progressive radiolucent lines.

Hips with HCLPE liners had less calcar resorption ($p = 0.0024$) but a similar incidence of periprosthetic osteolysis ($p = 0.09$) compared with those in the control group. In the study group, there were 37 hips without calcar resorption, three hips with calcar resorption measuring an average of 2.5 mm, and one hip with calcar osteolysis measuring 1.2 mm. In the control group, there were 18 hips without calcar resorption, 23 hips with calcar resorption measuring an average of 5.5 mm (range, 1.8–23.8 mm), and seven hips with calcar osteolysis measuring an average of 7.6 mm (range, 3.3–14.3 mm) (Table 3).

Overall, periprosthetic osteolysis was detected in 10 hips, two in the HCLPE group (no acetabular, two femoral) and eight in the CPE group (no acetabular, seven femoral, one ischium) (Table 4). We observed a similar ($p = 0.09$) incidence of periacetabular osteolysis in the two groups. In the study group, there was one hip with osteolysis detected in Gruen Zone 7 and another with osteolysis detected in Gruen Zone 6. Neither affected the stability of the implants. In the control group, osteolysis was detected in eight hips. Seven hips had osteolysis in the calcar (Gruen Zone 7), one of them had an additional lesion in the greater trochanter, and one had ischial osteolysis. The average total wear in the hips that had osteolysis develop was 0.121 mm (range, −0.018–0.26 mm) in the study group and 0.792 mm (range, 0.119–1.705 mm) in the control group. All these patients were asymptomatic.

Table 2. Comparative HCLPE studies

Study	Name of the HCLPE/CPE	Number of THAs (study/control = total)	Followup (years)*	Annual wear HCLPE/CPE (mm/year)†	p Value	Periprosthetic osteolysis	p Value
Glyn-Jones et al. [18] (2008)	Longevity®/CPE (Zimmer, Inc, Warsaw, IN)	26/25 = 51	2 (not given)	0.06 ± 0.06/ 0.10 ± 0.07	0.04	Not studied	
Martell et al. [33] (2003)	Crossfire™/$N_{2/Vac}$™ (Stryker Howmedica Osteonics, Allendale, NJ)	24/22 = 46	2.3 (1.8–3.2)	0.12 ± 0.05/ 0.20 ± 0.1	0.001	Not studied	
Geerdink et al. [17] (2006)	Duration™/CPE (Stryker)	45/54 = 99	4.7 (3.3–5.9)/ 4.7 (3.1–5.5)	0.083 ± 0.056/ 0.12 ± 0.082	0.04	Acetabular 1/4 hips Femoral 1/5 hips	Not given
Digas et al. [9] (2007)	Durasul®/Sulene™ (cemented) (Zimmer)	28/27 = 55	5 (not given)	0.15 (−0.1–0.86)/ 0.36 (−0.27–1.12)	< 0.001	Not studied	
	Longevity®/CPE (hybrid) (Zimmer	19/19 = 38	5 (not given)	0.08 (−0.02–0.24)/ 0.34 (0.09–1.41)	< 0.001	Not studied	
Dorr et al. [12] (2005)	Durasul®/Sulene™ (Zimmer)	23/17 = 40	5 (not given)	0.029 ± 0.02/ 0.065 ± 0.026	< 0.005	Not studied	
Engh et al. [14] (2006)	Marathon™/Enduron™ (DePuy Orthopaedics, Inc, Warsaw, IN)	86/83 = 169	5.5 (4.1–7.0)	0.01 ± 0.07/ 0.20 ± 0.13	< 0.001	24%/57.8% incidence of any osteolysis	< 0.001
Röhrl et al. [43] (2007)	Crossfire™/Exeter™ (Stryker)	9/12 = 21	5/6 (not given)	0.006/0.072	Not given	Not studied	
Bitsch et al. [1] (2008)	Marathon™/Enduron™ (DePuy)	32/24 = 56	5.8 (5–7.7)	0.031 ± 0.047/ 0.104 ± 0.094	0.003	0/8 hips	< 0.001
Current study	Longevity®/CPE (Zimmer)	41/41 = 82	5.3 (4–8)	0.002 ± 0.084/ 0.12 ± 0.071	< 0.001	2/8 hips	0.9

*Values are expressed as average, with range in parentheses; †values are expressed as mean ± standard deviation or as average, with range in parentheses; HCLPE = highly cross-linked polyethylene; CPE = conventional (noncross-linked) polyethylene.

Table 3. Results of the two groups

Variable	HCLPE group	CPE group	p Value
Total wear (mm)*	0.01 ± 0.34 (−0.23–0.4)	0.12 ± 0.073 (0–0.29)	1.07×10^{-10}
Annual wear (mm)*	0.002 ± 0.084 (−2.3–0.4)	0.12 ± 0.071 (0–0.29)	4.06×10^{-10}
Osteolysis	2 patients	8 patients	0.09
Calcar resorption (mm)†	2.5 (3 hips)	5.52 (23 hips)	< 0.0001
Preoperative HSS score†	17.2 (12–32)	16.8 (12–24)	0.675
Last followup HSS score†	38.8 (34–40)	38.6 (33–40)	0.535

*Values are expressed as mean ± standard deviation, with range in parentheses; †values are expressed as average, with number of hips in parentheses, or as average, with range in parentheses; HCLPE = highly cross-linked polyethylene; CPE = conventional (noncross-linked) polyethylene; HSS = Hospital for Special Surgery.

Table 4. Patients with osteolysis

Patient	Age (years)	Gender	BMI (kg/m^2)	UHMWPE type	Followup (years)	Total wear (mm)	Annual wear (mm)	Location of osteolysis
1	57	Male	26.7	HCLPE	5.66	0.2597	0.0519	Gruen Zone 6
2	38	Male	21.9	HCLPE	6.66	−0.0182	−0.0036	Gruen Zone 7
3	52	Male	27.4	CPE	6	1.2536	0.2089	Greater trochanter Gruen Zone 7
4	36	Male	24.3	CPE	5.83	1.7047	0.2924	Gruen Zone 7
5	51	Male	30.4	CPE	5.33	0.3247	0.0609	Gruen Zone 7
6	51	Male	30.4	CPE	5.33	0.4387	0.0823	Gruen Zone 7
7	53	Male	29.4	CPE	4.41	0.7761	0.1760	Gruen Zone 7
8	43	Male	37.2	CPE	5.66	0.1185	0.0209	Gruen Zone 7
9	60	Female	26.6	CPE	6.83	0.9205	0.1348	Gruen Zone 7
10	57	Female	24.8	CPE	6.83	0.8013	0.1173	Ischium

BMI = body mass index; UHMWPE = ultrahigh-molecular-weight polyethylene; HCLPE = highly cross-linked polyethylene; CPE = conventional polyethylene.

Discussion

Highly cross-linked PE has been used extensively to decrease wear and osteolysis and related implant failure in THA, but whether wear and osteolysis actually are reduced have not been confirmed clinically. We therefore determined the wear rates and the incidence of calcar resorption and periprosthetic osteolysis in HCLPE and CPE liners implanted in young patients at short- to medium-term followup.

Our study has the following limitations. First, it was a retrospective, nonrandomized study, which has the potential for selection bias and in which patients did not undergo surgery during the same time period. However, we included all (nonselected) patients with the CPE liner during the stated time and matched them with historical control subjects having noncross-linked liners; all patients had the same surgical technique by the same surgeon and the other implants were identical. Second, we did not assess bedding-in (creep) of the liners, which can confound the wear measurements. However, Estok et al. [15] and Dorr et al. [12] reported the magnitude of femoral head penetration resulting from creep is approximately 0.1 mm and is nearly the same for HCLPE and CPE. Third, measurement error cannot be eliminated, although it should affect both types of PE liners. In cases in which true wear occurs, the scatter maintains a positive value [3]. However, when the true wear is less than the resolution of the measurement device, an equal occurrence of positive and negative values is expected. Fourth, we recognize the wear measurements made on plain radiographs may underestimate the extent of osteolysis [13] and retroacetabular osteolysis is better detected with CT or MRI [13]. Fifth, the wear performance we report is only valid for this specific type of HCLPE (Longevity®) in a Trilogy® cup.

Our wear values compare well with those reported by others, with low wear rates for HCLPE liners after short- and medium-term followups (Table 2) [1, 9, 12, 14, 17, 18, 33, 43]. However, the comparison of studies of wear reduction observed in HCLPE liners should be made with caution. Production and sterilization of HCLPE and CPE liners differ among companies and these processes affect the oxidation and wear properties of the material [27, 36]. In this respect, studies of the in vivo wear of Longevity® HCLPE liners are few [4, 11]. Moreover, we were unable to find studies comparing the in vivo wear of Zimmer HCLPE and CPE liners of identical geometry implanted by the same surgeon with a similar surgical technique and implants at the same institution in young patients and evaluated at midterm followup. A study of bilateral THAs [11] compared the wear rate of 22 patients undergoing bilateral THAs who received a Longevity® liner in one hip and a CPE liner in the opposite hip. Using radiostereometric analysis measurements, the authors reported a similar mean three-dimensional head penetration for both groups at 1-year followup (Longevity®, 0.25 mm; CPE, 0.24 mm). During the second year, the mean three-dimensional head penetration increased ($p = 0.006$) in the Longevity® group to 0.47 mm and in the CPE group to 0.56 mm. That short-term study did not report on the incidence of calcar resorption or osteolysis. Another study that included patients operated on by three surgeons [4] reported on the wear of Longevity® and Durasul® (Zimmer, formerly Centerpulse) liners. Using the digital measurement method of Martell and Berdia [32], they reported an average total penetration rate of 0.01 ± 0.08 mm for these two different types of HCLPE liners after an average followup of 6.9 years. No patients had radiographic loosening or periprosthetic osteolysis. A prospective study [12] compared wear rates between HCLPE (Durasul®) and CPE (Sulene™; Zimmer) liners in 23 THAs followed for an average of 5 years. Using the digital measurement method of Martell and Berdia [32], they reported a 45% reduction in mean annual linear wear rate in the HCLPE liners (0.029 ± 0.02 mm/year).

We measured the extent of calcar resorption as was measured in a previous study using the same prosthetic design [21], in which the extent of the calcar resorption was shown to relate directly to the annual wear rate. Hips that had less than 0.1 mm per year of wear had an average of 1.7 mm calcar resorption; however, hips that had greater than 0.1 mm of wear had an average of 3.91 mm calcar resorption [21]. In this study, the HCLPE group showed less calcar resorption than the CPE group.

Although cross-linking improves wear resistance, it reduces the mechanical properties of ultrahigh-molecular-weight PE, decreasing its toughness, elastic modulus, ultimate tensile strength, yield strength, elongation at breakage, and hardness [2, 38, 41]. As a clinical implication of the reduced wear resistance, four rim cracks were reported [44] in two patients with 10° elevated HCLPE liners revised for recurrent dislocation. Both of these patients were obese (body mass index, 32 and 34 kg/m^2), and the acetabular cup abduction angles were 62° and 69°. After recurrent dislocations, both had revision to larger heads (32-mm and 36-mm heads in 56-mm and 54-mm acetabular shells, respectively). These thinner liners fractured after 2 years. The authors concluded "the reduced toughness of the highly cross-linked polyethylene compared with non-cross-linked polyethylene likely contributed to fatigue failure of the liners [44]." That report emphasizes the importance of accurate component positioning and avoidance of large-diameter heads articulating with thin liners. Another case of liner failure was reported [28] with a different HCLPE (Crossfire™; Stryker Howmedica Osteonics, Allendale, NJ), which is cross-linked by gamma irradiation as opposed to electron beam irradiation. However, the authors attributed this complication to a phase-transformed 28-mm zirconium femoral head rather than to PE failure [28].

Our wear rate of 0.01 mm per year in the HCLPE group is promising, particularly in view of the low rate of calcar resorption and osteolysis observed. However, in vitro and in vivo wear particle analysis showed HCLPE particles are smaller and rounder compared with those generated by CPE [34, 42]. A recent study [34] raised concerns that these morphologic characteristics of the wear particles might affect macrophage response and osteolysis. These concerns are reinforced by the results of studies that show increased in vitro bioactivity with the HCLPE particles [16, 26]. Only longer followup studies will clarify these questions.

Our matched-pair study of 82 hips in young patients at a mean of 5 years (4–8 years) followup revealed lower wear of HCLPE liners in comparison to CPE liners, with fewer patients having calcar resorption and periprosthetic osteolysis. A longer followup is required to ascertain if the reduction in wear will result in longer prosthetic survivorship.

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