



Original research

Sequentially Irradiated and Annealed Highly Cross-Linked Polyethylene: Linear Vector and Volumetric Wear in Total Hip Arthroplasty at 10 Years

Ethan A. Remily, DO^a, Scott J. Douglas, MD^a, Oliver C. Sax, DO, MS^a, Sahir S. Pervaiz, MD, MS^a, Nequesha S. Mohamed, MD^a, Wayne A. Wilkie, DO, MHSA^a, Langan S. Smith, BS^b, James Nace, DO^a, Arthur L. Malkani, MD^b, Charles E. Jaggard, MS^c, Frank R. Kolisek, MD^c, Ronald E. Delanois, MD^{a,*}

^a Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore, Baltimore, MD, USA

^b Department of Orthopaedic Surgery, University of Louisville Adult Reconstruction Program, Louisville, KY, USA

^c OrthoIndy, Indianapolis, IN, USA

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ABSTRACT

Background: There is a paucity of data on the long-term performance of highly cross-linked polyethylene (HXLPE). Therefore, this study evaluated 10-year 1) functional, 2) radiographic, and 3) surgical outcomes in patients who underwent total hip arthroplasty with sequentially irradiated and annealed HXLPE.

Methods: A retrospective, multicenter study was conducted on patients who underwent primary total hip arthroplasty and received HXLPE polymer (n = 151). Two-dimensional radiographic linear and volumetric wear analyses were quantified using the Martell Hip Analysis software, while functional outcomes were assessed by analyzing postoperative Short-Form-12 (SF-12) Physical and Mental Health Surveys and Harris Hip Scores. Radiographic outcomes included yearly linear (mm/y) and volumetric (mm³/y) wear rates. Surgical outcomes included additional operations and survivorship.

Results: SF-12 scores were within 1 standard deviation (SD) of the normal population (SF-12 Physical: 47.0; SF-12 Mental: 52.0), while the Harris Hip Scores of 89.5 was borderline between “good” and “excellent.” Total and annual linear wear rates were 0.164 mm (SD: 0.199 mm) and 0.015 mm/y (SD: 0.018 mm/y), respectively. The mean total volumetric wear rate was 141.4 mm³ (SD: 165.0) and 12.6 mm³/y (SD: 14.9 mm³/y) when broken down into a yearly rate. Eleven patients required revisions, resulting in an all-cause polyethylene survivorship of 92.7%, with a polyethylene wear survivorship of 100.0%.

Conclusions: Our results demonstrate clinically undetectable linear and volumetric wear rates after 10 years in those who received the unique sequentially irradiated and annealed HXLPE. Furthermore, high rates of survivorship coupled with low all-cause revision rates illustrate the polymers' capability to potentially increase implant longevity.

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Introduction

As the expanding indications for total hip arthroplasty (THA) encompass an increasing number of younger individuals, pressure to improve the longevity of implants continues to mount [1]. The

major factor limiting the longevity of THA implants has traditionally been polyethylene (PE) wear, which can be dependent on several factors, namely implant placement, PE type and thickness, patient gait, and activity level [2–4]. Conventional ultra-high-molecular-weight polyethylene is typically sterilized with 3 mrad of radiation but not otherwise intentionally crosslinked. These materials produce small particle debris as a byproduct of continued wear [5]. This debris elicits an osteolytic response in periprosthetic bone, eventually causing aseptic loosening of the implants and necessitating a revision procedure [5]. To alleviate the risk of this

* Corresponding author. 2401 West Belvedere Avenue, Baltimore, MD 21215, USA. Tel.: 410-601-8500.

E-mail addresses: rdelanoi@lifebridgehealth.org, delanois@me.com

potentially catastrophic complication, highly cross-linked PE (HXLPE) materials were developed in the late 1990s with the goal of reducing wear rates [6].

The initial generations of HXLPE are produced through a singular process of high-dose irradiation followed by thermal treatment and sterilization in an oxygen-depleted environment [5,7]. The thermal treatment (“remelting” or “annealing”) in this method is purposed to quench free radicals produced from irradiation and has been identified as a key factor in the longevity of PE in vivo [5,8]. Remelting involves heating the PE past its crystalline melting point, resulting in nearly nonexistent free radical loads [9]. However, this approach compromises the mechanical integrity of HXLPE, which can result in cracking and fracturing [10]. Conversely, annealing involves heating the PE to just below its melting point, which retains its mechanical properties, although at the expense of a larger free radical load [6,11–13]. Consequently, higher rates of oxidation have been observed in the form of white-banding and fatigue-related damage at the PE subsurface [7,14–16]. To further decrease wear rates and address the potential issues observed with initial generation HXLPEs, a newer generation HXLPE was developed in 2005 [6]. This polymer differs by undergoing 3 phases of sequential low-dose irradiation and annealing to further reduce free radical production [6,12,13]. In theory, this method is an improvement upon its predecessors by decreasing wear rates while simultaneously mitigating the risk for white-banding and rim damage, thereby allowing the use of thinner PE liners [6,8,12,17]. Despite its theoretical advantages, there is scant literature on the long-term performance of this newer HXLPE.

The encouraging wear rates and outcomes of HXLPE in short- and mid-term studies have led to its widespread use in THA. Yet, a limited number of studies investigating the long-term characteristics and performance of the sequentially irradiated and annealed HXLPE have been performed. Therefore, the purpose of this study was to assess long-term wear rates and survivorship in THA patients receiving this polymer. Specifically, we assessed long-term 1) functional outcomes, 2) radiographic outcomes, and 3) surgical outcomes in primary THA patients receiving the newer generation HXLPE.

Material and methods

Patient selection

A retrospective review was performed at 3 institutions for patients who underwent THA and received the sequentially irradiated and annealed HXLPE insert. These procedures were conducted between July 18, 2005, and April 12, 2010. Inclusion criteria included THA patients receiving HXLPE, appropriate follow-up (10 years), imaging (10-year radiographs), and osteoarthritis as a primary indication for surgery. Patients were excluded from radiographic wear analysis if they lacked any of the inclusion criteria; however, patients with the absence of radiographs were included for demographic and functional score outcomes. After review, 151 patients were included in the study with 101 available for complete radiographic review. Each site’s respective institutional review boards provided approval for this investigation.

Patient demographics

The mean time to follow-up was 11.1 years (range: 10.0 – 14.4 years) (Table 1). Caucasians (76.8%) and females (65.6%) comprised the largest portions of the cohort. The mean age and Body Mass Index were 62 years and 30.0 kg/m², respectively. The most common side of operation was the right (53.0%). The most common femoral head size used was a 36 (53.6%), followed by 32 (39.7%),

Table 1

Demographics for primary total hip arthroplasty patients implanted with a highly cross-linked polyethylene insert.

Demographics (n = 151)	
Time to follow-up (y) ^a	11.1 (10.0–14.4)
Sex ^b	
Female	99 (65.6)
Male	52 (34.4)
Race ^b	
Caucasian	116 (76.8)
African American	34 (22.5)
Asian	1 (0.7)
Age (y) ^c	62 (10.0)
Body Mass Index (kg/m ²) ^c	30.0 (6.3)
American Society of Anesthesiologists (ASA) Score ^c	2.4 (0.6)
Laterality ^b	
Right	80 (53.0)
Left	71 (47.0)
Femoral head size ^b	
28	5 (3.3)
32	60 (39.7)
36	81 (53.6)
40	5 (3.3)
Femoral head type ^b	
Ceramic	56 (37.1)
Metal	95 (62.9)
Cup inclination (degrees) ^c	43.5 (8.6)
Anteversión (degrees) ^c	18.3 (9.4)

^a The values are given as the mean with value range in parentheses.

^b The values are given as the number and percentage in parentheses.

^c The values are given as the mean and standard deviation in parentheses.

while the most common type of head was metal (62.9%). The mean cup inclination was 43.5° (standard deviation [SD]: 8.6°), while the average anteversion was 18.3° (SD: 9.4°).

Implants

All patients received a hemispherical, porous, press fit, metal-backed acetabular shell (Trident Acetabular System; Stryker Orthopedics, Mahwah, NJ) with a HXLPE liner insert (X3; Stryker Orthopedics, Mahwah, NJ) and a cemented or uncemented femoral stem (Accolade; Stryker Orthopedics, Mahwah, NJ). In addition, ceramic (BIOLOX Delta; CeramTec, Plochingen, Germany) or chromium-cobalt (CrCo) metal heads (LFIT V40 Femoral Heads; Stryker Orthopedics, Mahwah, NJ) were used in all patients.

Polyethylene preparation

The newer generation HXLPE being analyzed was manufactured from compression-molded GUR 1020 PE stock material, then prepared by undergoing 3 sequential cycles of irradiation and annealing [18]. Each cycle subjected the polymer to 3 mrad of gamma irradiation, which was then followed by an 8-hour annealing phase at 130°C [19]. After the completion of the aforementioned cycles, the polymer was then terminally sterilized with gas plasma.

Variables analyses

Functional outcomes were assessed by recording postoperative Short-Form-12 (SF-12) Physical and Mental component scores and Harris Hip Scores. Radiographic outcomes included total and yearly linear (millimeters [mm]) and volumetric (mm³) wear rates. Surgical outcomes included medical complications, additional operations, and survivorship. Survivorship endpoints included revision

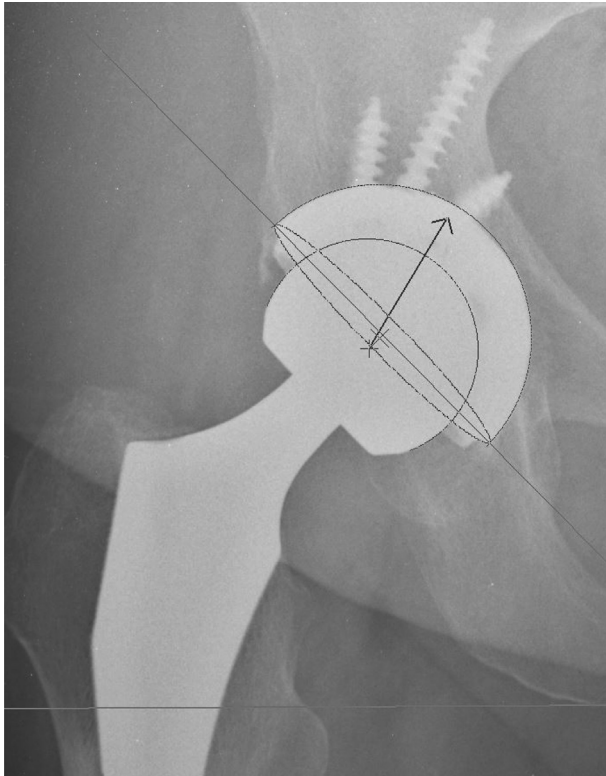


Figure 1. An illustration of the Martell Hip Analysis Suite software.

of PE for wear and revision of PE for any reason. Revision cases were excluded from radiographic and functional analyses as they lacked the implants being analyzed.

Polyethylene wear analysis

PE wear was assessed using the Martell Hip Analysis Suite (University of Chicago, Chicago, IL) software (Fig. 1). This program uses a semi-automated, edge-detection method to calculate two-dimensional wear, and analysis was performed by 2 authors (E.A.R, S.J.D.) trained to use the Martell software. Linear and volumetric wear was calculated by measuring postoperative (within 1 year of index procedure) and 10-year anteroposterior pelvis radiographs in sequence (first-to-last method). This process was then repeated, and findings were averaged. For analyses presenting negative wear rates, the number was converted to zero in a method similar to that of Deckard and Meneghini [20] to avoid false reductions in rates. The rate (mm per year) was determined by taking the overall magnitude and dividing the number by the patient's length of follow-up. This particular program was chosen as it is highly accurate with a median margin of error being less than 0.01 mm [21,22]. Furthermore, this method of analysis has been

validated in a number of studies analyzing in vivo wear in THA [20,23–26].

Statistics

Descriptive statistics were used for all categorical and continuous variables. Survivorship was determined via Kaplan-Meier analysis with endpoints being revision of PE for wear and revision of PE for any reason. All analyses were conducted using the Statistical Packages for the Social Sciences (SPSS; IBM Corporation, Armonk, NY) version 26. A *P* value of 0.05 was set as the threshold for statistical significance.

Results

Functional outcomes

At 10 years, mean SF-12 scores in the analyzed cohort fell within 1 SD of the mean United States population scores (SF-12 Physical: 47.0 [SD: 7.8]; SF-12 Mental: 52.0 [SD: 5.1]) [27] (Table 2). Moreover, the retrieved Harris Hip Score of 89.5 (SD: 10.5) is considered borderline between “good” and “excellent” [28].

Radiographic outcomes

The total linear and volumetric wear after 10 years was 0.164 mm (SD: 0.199 mm) and 141.4 mm³ (SD: 165.0 mm³), respectively (Table 3). When broken down into a yearly rate, linear wear rates were 0.015 mm/y (SD: 0.018 mm/y), and volumetric wear rates were 12.6 mm³/y (SD: 14.9 mm³/y).

Surgical outcomes

Eleven (7.3%) patients required revisions of their primary implants (Table 4). Five necessarily needed revision because of mechanically assisted crevice corrosion, 2 for mechanical loosening, and 1 each for infection, periprosthetic fracture, continued pain, and instability. Of note, 4 out of the 5 mechanically assisted crevice corrosion revision cases possessed recalled LFIT V40 heads. The mean time to revision was 8.6 years (SD: 4.2 years). All-cause survivorship of PE was 92.7%, while survivorship pertaining to revision of PE for wear was 100% (Fig. 2).

Discussion

As the indications for THA continue to expand and allow younger individuals to undergo this procedure, the importance of optimizing implant longevity to avoid the morbidity of revision surgeries cannot be understated. As a result, manufacturers developed a sequentially irradiated and annealed HXLPE to address this concern. Several studies have quantified the short- and mid-term outcomes of this specific polymer; however, only a select few have investigated its long-term outcomes. Therefore, the present study evaluated functional, radiographic, and surgical

Table 2

Functional outcomes for primary total hip arthroplasty implants with a highly cross-linked polyethylene insert.

Functional outcomes ^a (n = 151)	
SF-12 Physical	47.0 (7.8)
SF-12 Mental	52.0 (5.1)
Harris Hip Score	89.5 (10.5)

SF-12, Short-Form Health Survey.

^a The values are given as the mean and standard deviation in parentheses.

Table 3

Radiographic outcomes for primary total hip arthroplasties using a highly cross-linked polyethylene insert.

Radiographic analyses ^a (n = 101)	
Total linear wear (mm)	0.164 (0.199)
Linear wear by year (mm/y)	0.015 (0.018)
Total volumetric wear (mm ³)	141.4 (165.0)
Volumetric wear by year (mm ³ /y)	12.6 (14.9)

^a The values are given as the mean and standard deviation in parentheses.

Table 4

Additional surgeries and survivorship for total hip arthroplasties implanted with a highly cross-linked polyethylene insert.

Additional operations (n = 101)	
Number of THAs requiring revisions ^a	11 (7.3)
Indication for revision ^a	
MACC ^b	5 (3.3)
Mechanical loosening	2 (1.3)
Infection	1 (0.7)
Periprosthetic fracture	1 (0.7)
Pain	1 (0.7)
Instability	1 (0.7)
Time to revision (y) ^c	8.6 (4.2)
Implant survivorship (n = 101)	
Survivorship of polyethylene for wear	100.0%
Survivorship of polyethylene for any reason	92.7%

MACC, mechanically assisted crevice corrosion; THA, total hip arthroplasty.

^a The values are given as the number and percentage in parentheses out of the entire cohort.

^b Four out of the five MACC revision cases possessed recalled LFIT V40 heads.

^c The values are given as the mean and standard deviation in parentheses of revision patients.

outcomes in patients providing 10-year follow-up, finding the polymer to confer excellent functional scores, extremely low linear and volumetric wear rates, and high rates of survivorship. The method in which this newer HXLPE polymer is manufactured appears to successfully improve the long-term viability of THA implants and may delay or prevent the need for subsequent revision.

The study is not without limitations. First, the investigation was performed retrospectively, and we were unable to eliminate selection bias. However, this study aimed to report descriptive results on the performance of the newer HXLPE and less on patient demographics. Second, a proportion of the analyzed patients did not possess the required initial postoperative films. As such, we were unable to include them for radiographic analysis. However, they

were included in demographic, functional, and surgical measures and aided in conveying the polymer's durability. Finally, unless visually analyzing the polymer during surgery, there is no ideal way to quantify in vivo PE wear ex vivo. However, the Martell software chosen to measure wear has been repeatedly demonstrated to be highly accurate [21,22]. Furthermore, we performed multiple measurements with 2 individuals to achieve the most reliable results. Despite these limitations, including the difficulty in identifying patients with appropriate clinical follow-up, we were able to perform a long-term analysis of HXLPE wear rates in THA.

After analysis, our cohort demonstrated yearly linear and volumetric wear rates at 0.015 mm/y and 12.6 mm³/y, respectively. These rates align similarly with other studies examining this newer HXLPE. In an investigation by Gaudiani *et al.* [29], the authors examined 6-year wear rates in matched patients receiving either metal or ceramic heads with the sequentially irradiated and annealed HXLPE. Annual mean wear rates were found to be similar to the present study, with linear wear rates being 0.012 mm/y and 0.018 mm/y for ceramic and metal heads, respectively. Moreover, mean volumetric wear rates for ceramic heads were 11.9 mm³/y, while rates were slightly higher in metal heads at 17.3 mm³/y. In another study performed by Samujh *et al.* [13], the authors performed a retrospective analysis similar to the present study and found mid-term linear and volumetric wear rates to be 0.025 mm/y and 21.95 mm³/y, respectively. While these wear rates are higher, taking them in conjunction with our wear rates may highlight the fact that the latest generation of HXLPE reaches a “steady state wear rate” after the initial bedding-in period of typically 1 year. As such, studies providing longer term follow-up for this polymer may exhibit wear rates lower than what has been reported in mid-term studies.

The sequentially irradiated and annealed HXLPE was developed to reduce wear rates and mitigate the risk for complications such as aseptic loosening and in vivo oxidation. In comparison to initial generations of HXLPE, the method in which this polymer is

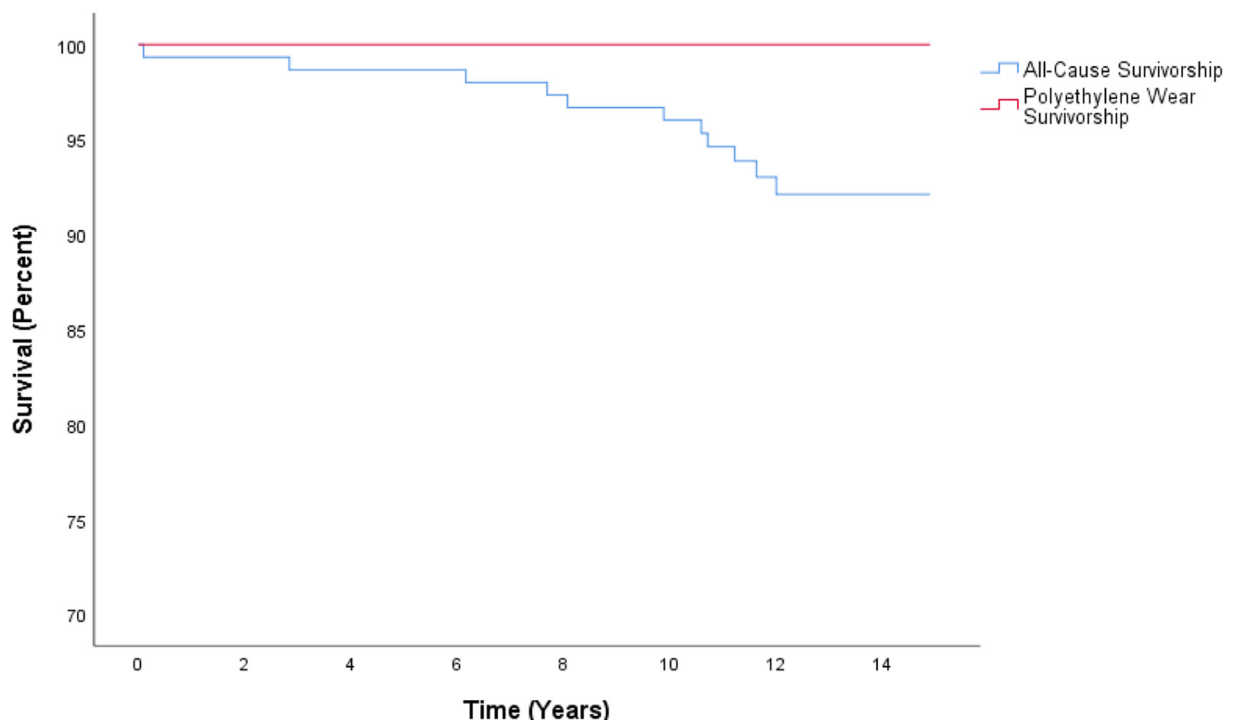


Figure 2. Kaplan-Meier survivorship plot of total hip arthroplasties receiving highly cross-linked polyethylene.

manufactured appears to have improved wear rates and survivorship. In a retrospective study performed by Takada *et al.* [30], the authors compared wear rates between a single-sequence remelted HXLPE (Longevity; Zimmer Inc., Warsaw, IN) and a single-sequence annealed HXLPE (Crossfire; Stryker Orthopedics, Mahwah, NJ). Both cohorts demonstrated similar linear wear rates, with the remelted and annealed groups having mean rates of 0.032 (SD: 0.020) and 0.031 (SD: 0.022) mm/y, respectively. In comparison to our linear wear rates (0.015 mm/y), the newer generation of HXLPE reduced wear by nearly half the rate of the initial-generation polymers. Whether or not these reduced wear rates translate into improved survivorship remains inconclusive, as the literature examining the matter in initial generations of HXLPE has demonstrated satisfactory rates. For example, in a long-term (mean: 12.9 years) retrospective analysis of a single-sequence annealed HXLPE (Crossfire), Feng *et al.* [31] noted a linear wear rate of 0.056 (SD: 0.036) mm/y, which was substantially higher than our reported rate. Although this rate was higher, survivorship was nearly identical at 97.5% when the endpoint was revision due to aseptic loosening. Predicated off the existing literature of HXLPE, manufacturers may have achieved the optimal wear rates as aseptic loosening seems to have decreased; however, longer term follow-up is necessary to characterize the entire lifespan of these implants.

Conclusions

The current demand for superior implant longevity has led to the increased use of HXLPE in total joint arthroplasties. The present study's results demonstrate clinically undetectable linear and volumetric wear rates in patients undergoing THA who received a sequentially irradiated and annealed HXLPE after 10 years. Furthermore, survivorship of these implants fared exceedingly well. Despite the positive early to mid-term and long-term outcomes, longer term studies evaluating 20-year outcomes are necessary to assess how HXLPE performs over time. Larger studies assessing the head size variability and related complications may also be warranted.

Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: A.L.M. reports relevant financial activities outside the submitted work from the *Journal of Arthroplasty* and Stryker. F.R.K. reports relevant financial activities outside the submitted work from Ortho Tech Review, Orthopaedic Knowledge Online Journal, Orthopedics, and Stryker. J.N. reports relevant financial activities outside the submitted work from the *Journal of Arthroplasty*, *Journal of the American Osteopathic Medicine Association*, *Orthopedic Knowledge Online*, *Journal of Knee Surgery*, and Stryker. R.E.D. reports relevant financial activities outside the submitted work from Baltimore City Medical Society, Orthofix Inc., Stryker, United Orthopedics, Flexion Therapeutics, and TissueGene. E.A.R., S.J.D., O.C.S., S.S.P., W.A.W., N.S.M., L.S.S., and C.E.J. have no relevant disclosures.

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