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Up to 18-Year Follow-Up Wear Analysis of a First-Generation Highly Cross-Linked Polyethylene in Primary Total Hip Arthroplasty

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ABSTRACT

Background: The advent of highly cross-linked polyethylene (HCLPE) has significantly improved total hip arthroplasty survivorship. HCLPE has been shown to improve wear properties in midterm outcomes when compared to traditional polyethylene liners; however, there is a paucity of studies evaluating long-term outcomes. In addition, there is concern that wear rates may accelerate as the implant ages. Thus, the aims of this study are to report on the longest-to-date follow-up of a specific first-generation HCLPE liner and to determine whether there is a change in the annual wear rate over time.

Methods: Forty hips in 38 patients which were previously reported on in a midterm study were included in this long-term follow-up study. Patients in this cohort all received total hip arthroplasty between March 1999 and August 2004 using the Crossfire HCLPE liner. Annual wear rates (mm/y) were calculated for this cohort. Patients were contacted and asked about complications or revision procedures they may have had since the index procedure.

Results: Clinical follow-up averaged 12.9 years with a range of 7-18 years. The average follow-up duration was 12.5 years with a range of 10-17 years. Linear wear was found to be 0.056 ± 0.036 mm/ y. Osteolysis was not observed in any of the patients with greater than 10-year radiographic follow-up. Furthermore, only 1 patient required revision surgery following a mechanical fall.

Conclusion: Our study demonstrates the long-term wear rates associated with HCLPE liners continue to match rates published in midterm studies. Previously, we have reported that this cohort had an average annual wear rate of 0.05 mm/y over 10 years. This most recent report demonstrates a similar wear rate with up to 18-year follow-up.

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Total hip arthroplasty (THA) has widely been touted as one of the most successful orthopedic procedures available today. A large part of this success stems from the long-term survivorship of the implant components including the polyethylene liners which act as a bearing surface for the hip joint [1]. Over time, however, this component can wear, potentially leading to periprosthetic osteolysis and limiting the life span of the prosthetic implant [2,3]. This was particularly problematic in traditional and first-generation liners as it had the potential to cause symptomatic failures, which often necessitated revision as well. Technological advancements in the manufacturing of polyethylene liners have led to the development of highly cross-linked polyethylene (HCLPE) liners, which have been proposed to reduce the incidence of particle wear, osteolysis, and most importantly, the rate of revision THA [4–7].

Unlike conventional polyethylene (CPE) liners, first-generation HCLPE liners, such as the Crossfire (Stryker, Mahwah, NJ) liner, are subjected to gamma irradiation in air to increase the number of

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interchain covalent bonds and polymer cross-links through the creation of free radicals [8-11]. Postirradiation thermal treatment via annealing (heating below the melting point) preserves the underlying crystalline structure by reducing the number of free radicals [12]. However, due to the irradiation technique (open air), the treatment fails to eliminate residual free radicals trapped within the crystalline polymer structure [10,13,14]. Several investigators have demonstrated that free radical levels in the Crossfire liner can be severalfold higher than later designs, largely due to gamma sterilization in nitrogen [15–18]. These increased residual free radicals are concerning as they can promote reactions with oxygen leading to component embrittlement, de-crosslinking, and ultimately failure [19,20]. Although previous studies have shown favorable short-term and midterm outcomes of HCLPE liners when compared to CPE in their ability to resist wear and osteolysis [6,7,11,14,21-23], long-term in vivo follow-up is necessary to ensure that oxidative stress and residual free radicals formed over time do not lead to liner failure. However, there is growing concern regarding the incidence of osteolysis in patients receiving HCLPE. Previous studies have demonstrated that despite lower wear rates of HCLPE compared to CPE liners, the smaller particle sizes of HCLPE elicit a more dramatic biological response and potentially predispose patients to a higher risk of osteolysis [24,25].

Previously, we reported on the wear rates of the Crossfire polyethylene liner at a mean follow-up of 10 years [26]. This previous study demonstrated acceptably low total and annual linear wear rates of 1.26 and 0.122 mm/y, respectively [26]. Here, we report on the latest follow-up (up to 18-year follow-up liner wear rates) of the same population of patients who underwent THA with the Crossfire HCLPE liner. The aim of our study is to evaluate linear penetration rates of patients who have had THA using HCLPE acetabular liners and to report the longest-to-date follow-up of a first-generation HCLPE liner and its long-term annual linear wear rate. Secondary goals included assessing for the presence of acetabular osteolysis, and long-term implant survival. We hypothesize that THA using the HCLPE liners will continue to demonstrate predictable and reliable wear rates, with no increased risk of osteolysis or implant failure.

Materials and Methods

This is a single-center, retrospective study of 40 THAs in 38 patients who had received the Crossfire HCLPE acetabular liner between the period of March 1999 and August 2004 by a single surgeon. All surgeries were performed by a single surgeon through an anterolateral approach. During this period, a variety of implant systems were used and selected based on patient-specific factors. Only patients who had received the Crossfire HCLPE acetabular liner were included in this study. Patients receiving any other type of liner were excluded. Baseline demographics and surgical factors were obtained and reviewed from our institution's electronic health record system, Epic (Verona, WI). Baseline demographics (age, gender, preoperative/postoperative body mass index, and race), follow-up duration (radiographic and clinical), and surgical data (primary vs revision surgery, surgical laterality, acetabular cup size, and head size) were recorded. Patients who did not present to our clinic for a radiograph within the past 2 years were called for follow-up.

To assess polyethylene liner wear, digital anteroposterior (AP) pelvis radiographs were imported into Rontgen Monogrammetric Analysis v1.70 (ROMAN Software; Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry, UK), an accurate computerassisted method for assessing linear wear rates, with a reported intraobserver and interobserver reliability of 0.97 and 0.87, respectively [27]. Those with less than 2 radiographs were excluded from further radiographic analysis. Radiographic measurements were performed in accordance with the methods described by Heyligers et al [28]. Radiographs were calibrated using the femoral head, and the pelvis was horizontally aligned using the teardrop line. Then, 3-point circles with central markers were used to outline the perimeter of the femoral head and acetabular shell. Head-liner deviation from concentricity was used as a surrogate marker for HCLPE liner wear. This was assessed by measuring the direct distance between the center of the femoral head and the center of the acetabular cup. Measurements for acetabular inclination angle were also recorded and referenced to the teardrop line. The incidence of acetabular osteolysis was also recorded and defined by the presence of linear or focal lucencies >1 cm AP radiographs and localized by the Charnley zone classification system [29,30]. Subjects with suspected osteolysis were compared to their oldest postoperative radiograph to assess for progression. These measurements were recorded and analyzed with descriptive statistics using Microsoft Excel version 1710 (Microsoft Corporation, Redmond, WA).

Results

In total, 40 hips in 38 patients were included in this study (Table 1). Four hips received the Crossfire liner while undergoing revision surgery, while all others were primary surgeries. Additionally, 2 hips received 22-mm heads, 36 hips received 28-mm heads, and 2 hips received 32-mm heads.

Clinical follow-up averaged 12.9 years with a range of 7-18 years (Table 2). Only 1 patient underwent revision THA for aseptic loosening. Two hips sustained periprosthetic fractures requiring open reduction internal fixation of the femoral shaft, but did not require any revision of the THA. No hips demonstrated signs of clinically significant femoral or acetabular osteolysis requiring further intervention.

For 26 hips with greater than 10-year follow-up, the average follow-up duration was 12.5 years with a range of 10-17 years (Table 3). Linear wear was found to be 0.056 ± 0.036 mm/y. No acetabular or femoral osteolysis was observed radiographically. Additionally, mean cup anteversion (11.48° ± 6.03°) and inclination

Table	e 1
Base	line Demographics and Clinical Follow-Up

Demographics	$38 \; \text{Subjects} \; (\text{N} = 40 \; \text{Hips})$		
Age (surgery)	60.7 ± 11.8		
Gender			
Female	20 (52.6%)		
Male	18 (47.4%)		
Laterality			
Left	20 (52.6%)		
Right	18 (47.4%)		
Preoperative BMI	25.8 ± 4.5		
Race			
White	35 (92.5%)		
African American or Black	1 (2.5%)		
Hispanic	1 (2.5%)		
Other	1 (2.5%)		
Primary vs revision			
Primary	36 (90%)		
Revision	4 (10%)		
Head size			
22 mm	2 (5.0%)		
28 mm	36 (90%)		
32 mm	2 (5.0%)		
Liner			
Crossfire HCLPE	40 (100%)		

BMI, body mass index; HCLPE, highly cross-linked polyethylene.

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