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10-Year Follow-Up Wear Analysis of First-Generation Highly Crosslinked Polyethylene in Primary Total Hip Arthroplasty

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ABSTRACT

Our goal was to report a 10-year follow up of linear penetration rates for HCLPE, and to determine whether a difference exists between penetrations measured on pelvis or hip anterior–posterior radiographs. We reviewed 48 total hip arthroplasties where a first-generation HCLPE liner was used. Femoral head penetration was measured on both AP pelvis and hip radiographs. Total wear and wear rate at 10 years were 1.26 mm and 0.122 mm/y, respectively. The rate decreased significantly after the first 2–3 years, plateauing at a wear rate of 0.05 mm/y for the last 5 years. The AP hip total wear and wear rate were 1.38 mm and 0.133 mm/y respectively, while rates were 1.13 mm and 0.109 mm/y respectively for the pelvis radiographs ($P < .05$). We found a significant difference in measurements of linear penetration when comparing AP pelvis vs. hip radiographs with lower rates recorded using an AP pelvis.

Wear-induced periprosthetic osteolysis was a long-term problem associated with total hip arthroplasty with traditional polyethylene liners [1,2], causing aseptic loosening and hip instability resulting in revision surgery [3,4]. The particles released by wear incite an inflammatory cascade that may culminate in bone degradation [5–7]. Highly cross-linked polyethylene (HCLPE) implants were developed in an effort to reduce wear and osteolysis, thereby increasing survivorship. Traditional polyethylene has been shown to wear down at a faster rate than first generation HCLPE implants in hip simulator studies and clinical follow-up reports [8–10]. With these improvements in wear rate, instability and infection have begun to play a larger role in total hip arthroplasty revision surgery.

Cross-linking is accomplished by exposing the polyethylene liner to gamma radiation, inducing covalent bond formation and free radical formation. Thermal stabilization is required to reduce the quantity of free radicals, and can involve either melting or annealing. With annealing, crystallinity is preserved. Free radical levels are decreased but remain detectable and are concerning for long-term oxidation and degradation [11]. Each HCLPE product has a slightly different manufacturing process, and should be evaluated individually [8,9,12].

Various methods for radiographic assessment of linear penetration have been proposed and evaluated [13–16]. The majority are computerized measurements of the distance between the femoral head and proximal acetabular cup edges. However, the existing literature does not clarify whether an AP pelvis or hip is more accurate for radiographic assessment of wear.

In vitro studies as well as several clinical studies with up to 9 years of follow-up have shown decreased wear and excellent clinical results with HCLPE liners. The purpose of this study was to evaluate the total wear and wear rate of an annealed HCLPE acetabular liner with a mean follow-up of greater than 10 years, a time at which oxidation and ageing may potentially have deleterious effects. A secondary goal of this study was to compare the use of the Roman software between AP radiographs of the hip and AP radiographs of the pelvis and determine if there is a statistically significant difference between the two views.

Materials and Methods

This study received approval from our Institutional Review Board. It was a single-center retrospective cohort study of 48 primary total hip arthroplasties in 45 patients all performed by the senior author (FJJ) using the Crossfire acetabular liner (Stryker, Mahwah, New Jersey) combined with a 28 mm cobalt–chrome femoral head (L-fit, Stryker). All primary cementless THAs included in this study were performed between September 2000 and March 2004 through the anterolateral approach to the hip. Over the same time period, other total hip arthroplasties were performed, by the senior author, using various implants. Implant selection during this period was based both on surgical case complexity and implant characteristics as well as the

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natural adaptation of a new implant technology and the establishment of indications for its utilization. Every patient that had undergone a THA with the configuration of interest and had adequate follow-up and radiographic images was included in the study. In this cohort of 48 primary total hip arthroplasties, five total hip arthroplasties in 4 patients were lost to follow-up or excluded based on inadequate baseline radiographs. Of the 41 patients included in the study, 20 were men and 21 were women. The mean age was 59.6 years (range, 34–75). Patients had a mean BMI of 25.8 (range, 19.6-41.5). Cohort characteristics are shown in Table 1.

The polyethylene liner in the current study is produced from Ram-extruded GUR 1050 resin. It is then cross-linked by gamma radiation at 7.5 Mrad, followed by annealing for thermal stabilization. Annealing avoids the reduction of crystallinity that occurs with melting and maintains the mechanical properties. Next, the rod is doweled off at its outer layers. Once the production is complete and the liner is packaged in an inert environment (N2), it is sterilized with a final 3.0 Mrad dose of gamma radiation [17]. The sum total dose of gamma radiation is 10.5 Mrad.

Patients were evaluated preoperatively, immediately postoperatively, and annually thereafter. Assessment included standard history, physical exam, radiographs and Harris Hip Scores. All patients had both AP views of the hip and pelvis obtained at the aforementioned time points. Radiographs taken at mid-term and last follow-up were assessed for femoral penetration using the Roman software V1.70 (Robert Jones & Agnes Hunt Orthopaedic Hospital, Oswestry, United Kingdom). This software was used to measure the primary endpoints: total penetration (mm) and wear rate (mm/year).

Radiographical images were obtained in the same radiology department using a standardized protocol. Pelvic images were taken where both legs were internally rotated 15°–20°, and the heels were placed 20–25 cm apart. The beam was centered midway between the mid point of both ASIS and the pubis symphysis with a surface-to-image distance of 100 cm. Hip images were obtained immediately following the pelvic view with the patient in the same position and the beam centered 2.5–5 cm distal to the mid point of the femoral neck.

Acetabular inclination and anteversion were measured as well. The latter was analyzed using the length of the major and minor diameters of the ellipse formed by the face of the cup. An inverse-sine formula [$\theta = \sin^{-1}$ (minor diameter/major diameter)] was applied to calculate the acetabular anteversion angle. Acetabular osteolysis was classified based on zones described by Delee and Charnley [18], while femoral osteolysis was described using the Gruen zones classification [19].

Paired t-tests, linear regressions and analyses of variance were conducted using SPSS software (SPSS, Chicago, IL). A P value cutoff of less than 0.05 was determined to be statistically significant.

Results

The mean follow-up for our cohort was 10.5 years (range, 8.5–14), with final radiographs for assessment obtained at this time point. Our results for total wear and wear rate were 1.26 mm and 0.122 mm/y, respectively. These results included the bedding-in period. The wear rate decreased significantly after the first 2–3 years (typical bedding-in period), plateauing at an annual mean wear rate of 0.05 mm/y (SD, 0.04) for the last 5 years.

Subdividing total wear and wear rate into AP hip and AP pelvis radiographic assessments produced statistically significantly different values (Fig. 1). The AP hip total wear and wear rate for the 10-year interval were higher at 1.38 mm and 0.133 mm/y respectively, while the total wear and wear rate were 1.13 mm and 0.109 mm/y respectively for the AP pelvis radiographs ($P < .05$).

Minimal evidence of osteolysis was encountered in 2 of 43 hips (4.6%). One hip had lucency in Gruen zone 1 and the other in zone 7. No evidence of osteolysis was found around the acetabulum in any of the cases. There was no clinically relevant osteolysis with loosening of the implants. Harris Hip Scores improved from a mean of 58 (SD, 14.7) preoperatively to a mean of 95 (SD, 4.0) at the latest follow-up visit.

Table 1
Sample Characteristics.

Mean age at Surgery (y)	59.6
Male:Female	20:21
Right:Left	20:23
Mean BMI (SD)	25.8 (SD, 4.5)
Mean follow-up (y)	10.5 (range, 8.5–14)
Femoral head size (mm)	28
Cup inclination (deg)	46.5 (SD, 4.1)

Patient demographics and implant characteristics.

Discussion

First generation highly cross-linked polyethylene liners were introduced in the 1990's to cut down on wear and osteolysis [2]. Cross-linking reduces the wear rate but generates free radicals that must be stabilized with either melting or annealing. Melting more thoroughly eliminates free radicals but also reduces the crystallinity, which may affect mechanical properties. The proposed advantage of annealing is that it lowers wear rate while maintaining the mechanical properties [11]. The concern is that it leaves residual free radicals contributing to late oxidation and degradation that may lead to an increased wear rate over time. While many studies have demonstrated the oxidative resistance of highly cross-linked polyethylene [9,15,20,21], long-term clinical studies are needed to ensure that oxidative stress and free radicals do not accelerate wear resulting in osteolysis, loosening, and eventually the necessity for revision total hip arthroplasty.

Roman software was utilized for measuring and evaluating linear penetration due to its open access availability, accuracy, and ease of use. In a recent study by Geerdink et al [16], Roman software was shown to be the most precise of four methods evaluated, including Martell Hip Analysis suite 7.14, Rogan HyperOrtho, and Rogan View Pro-X. Roman software also performed the best in terms of inter-observer and intra-observer reliability with an intra-class correlation coefficient of 0.87 compared with Martell (0.39). Although it took the most time to measure one image (2.63 min/image), it outperformed its competitors in all other clinical ease of use and handling measures [16].

Our results using Roman software on AP hip and AP pelvis radiographs show a total wear and wear rate of 1.38 mm and 0.133 mm/year, and 1.13 mm and 0.109 mm/y, respectively. The difference between the two radiographic views was statistically significant ($P < .05$). Most studies to date, irrespective of measurement instrument, have utilized AP pelvis radiographs for quantifying femoral penetration [12,14,22–25]. Total wear and wear rate may be underestimated with AP pelvis views, in which the x-ray beam is centered over the pelvis. In AP hip radiographs the beam is centered over the hip, which may be more orthogonal to the vector of penetration (Fig. 2). Based on these results, we advocate using a constant method (pelvis or hip) for the measurement of wear, this will help guarantee reproducible results of linear penetration wear measurements.

The high linear penetration rate for the 10-year interval includes the bedding-in period, characterized by an increased wear rate [26]. Results were subdivided into the first and second five-year time periods. The first five years had significantly higher total wear and wear rate measurements compared to the last. Studies have