Once Annealed Highly Cross-Linked Polyethylene Exhibits Low Wear at 9 to 15 Years

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abstract

A once annealed highly cross-linked polyethylene (HXLPE) was introduced in 1998. Concerns regarding its long-term performance and oxidative resistance exist because of the presence of retained free radicals. The authors studied 48 patients with 50 hip implants having an average age of 62 years. They were followed for 9 to 15 years. The purpose of this study was to determine linear wear rate and the incidence of osteolysis and/or mechanical failure. At an average follow-up of 12.2 years, the annual linear wear rate was 0.018 mm (SD, 0.024 mm). No mechanical failures or osteolysis have been found to date. The clinical performance of this HXLPE continues to meet expectations despite the presence of free radicals. [Orthopedics. 2016; 39(3):e565-e571.]

Highly cross-linked polyethylene (HXLPE) was introduced in 1998 to reduce wear and osteolysis experienced with conventional polyethylene. Cross-linking is accomplished by first irradiating the material with gamma or electron beam irradiation (5 to 10 mrad) and then thermal processing the material either above (re-melting) or just below (annealing) the melting point. Although the former quenches residual free radicals at the expense of an initial reduction in physical properties, the latter maintains the physical integrity of conventional polyethylene while leaving free radicals within the processed material. Since their introduction, annealed and re-melted materials have shown similar and dramatically reduced polyethylene wear rates and osteolysis when compared with conventional materials. However, concerns remain regarding the mechanical properties and long-term wear characteristics of these first-generation materials. There have been isolated reports of fracture of re-melted HXLPE but not of the annealed material. Several studies comparing once annealed with re-melted HXLPE using accelerated artificial aging found oxidation, decreased ultimate strength, and higher wear with the former. Contrary to these artificial aging predictions, the clinical performance of once annealed HXLPE out to 10-year follow-up has continued to show low wear without osteolysis or mechanical failure.

Even with these positive reports to date, concerns about the long-term performance of once annealed material continue because of the presence of free radicals. The fundamental question and concern is whether the presence of any amount of free radicals in an HXLPE will eventually result in component failure through locking mechanism disruption or accelerated wear and subsequent osteolysis.

The objectives of this study were to (1) determine the wear rate of once annealed HXLPE out to 15 years; (2) report on an analysis of plain radiographs for evidence of wear debris–related osteolysis; and (3)
report any mechanical failures, including locking mechanism issues.

**Materials and Methods**

A group of 64 nonconsecutive patients underwent 66 primary total hip arthroplasties performed by one of the authors (J.D.) between January 1999 and May 2000 and were prospectively followed. Patients were included if they provided written informed consent, were younger than 75 years, and had non-inflammatory pathology. During this same time, primary total hip arthroplasties with other bearing surfaces were performed for 97 patients (104 hips); however, these are not part of this study. Of the 64 patients, 5 (7.8%) died, 6 (9.3%) were lost to follow-up, 4 (6%) had clinical data from mailings but no radiographs after 5 years, and 1 (1.5%) underwent revision for recurrent dislocations. Clinical data included Harris Hip Scores and the rate of adverse events. Clinical data were collected at 6 to 7 weeks, 1 year, and 2 years postoperatively, cup inclination, and anteversion. All radiographic analyses were performed by one of the authors (R.R.). The 1-year radiographs were used to estimate initial bedding-in rates. Wear from 1 year to last evaluation then served as the basis for the yearly linear and volumetric wear rates. Mean volumetric wear rate (V) was calculated using the geometric formula

\[ V = P_i \cdot R \cdot R \cdot W \]

where \( P_i \) (the ratio of the circumference of a circle to the diameter) is 3.1416, \( R \) is the radius of the femoral head in millimeters, and \( W \) is the mean 2-dimensional wear rate. The formula is based on a cylindrical wear pattern perpendicular to the face of the cup.

Hips were evaluated radiographically for osteolysis in acetabular component zones as described by DeLee and Charnley\(^\text{18}\) and in all femoral Gruen zones\(^\text{19}\) on anteroposterior and mediolateral radiographs by 2 of the authors (J.D., W.N.C.). Implant stability was evaluated according to criteria described by Engh et al.\(^\text{20}\) The distribution of wear data was examined with the goodness of fit test. The wear data are presented as mean and SD. SAS statistical software version 9.1 (SAS Institute Inc, Cary, North Carolina) was used for data analysis.

**Results**

The wear rate at recent follow-up, excluding negative values, was found to be gamma distributed [goodness of fit test, \( P=.158, \) scale (sigma)=0.012, and shape (alpha)=2.01]. The mean linear wear rate
was calculated as 0.018 mm/y (SD, 0.024 mm/y) at an average of 12.2 years. No patient had a wear rate greater than 0.085 mm/y, and this rate occurred in a patient who was 45 years old and weighed 265 lb (body mass index, 35 kg/m²) at the time of surgery. The wear data were sorted and plotted as a bar chart (Figure 1). Volumetric wear was calculated to be 11.1 mm³/y.

The 1 revision (1.5%) in the study was for recurrent dislocations. There were no fractures of the bearing surface, and no revisions are impending. The mean Harris Hip Score at last follow-up was 94.4.

All acetabular and femoral implants are well fixed. The mean cup inclination was 50.2° (SD, 5.1°) and the mean anteverision was 18.6° (SD, 8.3°). One patient was thought to have an early osteolytic lesion in Gruen zone 7 at 5 years. However, recent radiographs (at 15 years) showed no change or slight regression and it is no longer considered an osteolytic lesion (Figure 2). No other patient had evidence of osteolysis on either the acetabular or the femoral side.

**DISCUSSION**

The purpose of this study was to report on the linear wear, incidence of osteolysis, and mechanical failure of a once annealed HXLPE out to 15-year follow-up.

This study had several limitations. First, there were patients who were lost to follow-up, meaning that there was the potential to miss outliers with high wear or implant failure. Second, there was no intraobserver and interobserver validation of radiographic wear measurements, but the authors believe the data are acceptable based on the Martell software. Repeatability of the measurements (on the basis of 5 measurements per patient) using Martell’s technique was reported by Hui et al., using use of an intraclass correlation coefficient. Third, this was a nonconsecutive single-surgeon series that potentially could have biased the selection of patients. Fourth, the authors had no control cohort and were relying on historic reports. Fifth, an independent reviewer did not perform the review of the radiographs for osteolysis and implant fixation.

At an average follow-up of 12.2 years (maximum, 15 years), the annual linear wear rate was 0.018 mm (SD, 0.024 mm) and the annual volumetric wear rate was 11.1 mm³. These results compare favorably with those of reports of annealed and re-melted HXLPEs with 5 to 10 years of follow-up (Table 2). The 5 studies in which re-melted HXLPE was implanted report a range of positive wear from 0.005 to 0.040 mm/y. One of the studies reported negative wear (-0.012 mm/y). The 6 studies, including the current one, with annealed highly cross-linked material had wear rates ranging from 0.001 to 0.037 mm/y. A multicenter study with the same once annealed HXLPE found 0.036 mm/y wear at 5 years and 0.031 mm/y wear at 9 years, representing a 72% and a 78% reduction, respectively, compared with N2 vacuum conventional polyethylene (Stryker Orthopaedics) (irradiated at 3 mrads). Not a single case had wear above 0.08 mm/y. A 9-year study of the clinical experience with the same once annealed material (Crossfire) reported a wear rate of 0.037 mm/y at 9 years, and a recent study with 10-year follow-up of patients with an average age of 54 years reported a linear wear rate of 0.015 mm/y. The annual volumetric wear from 1 to 15 years (mean, 12.2 years) of 11.1 mm³ is comparable to the 14 mm³ from 1 to 10 years reported for a re-melted HXLPE. Osteolysis is reported to be a rare occurrence with annual volumetric wear below 80 mm³.

Wear debris–related osteolysis has not been found on routine radiographs out to 15-year follow-up. In addition, no osteolysis has been reported by the other 5 studies (range, 5-10 years) using annealed HXLPE. Two studies using re-melted HXLPEs have reported osteolysis rates of 5% and 10.6%. No mechanical failures, either through fracture or disruption of the locking mechanism of annealed HXLPE, have been reported to date, in agreement with the current authors’ experience. Although fractures have occurred with the re-melted materials, the reports have been isolated and related to the use of a thin polyethylene insert. Since its introduction, the concern regarding annealed HXLPE has...
been about the presence of free radicals and their long-term effect on clinical performance.

Preclinical bench or in vitro testing is a necessary part of total hip replacement bearing development. The ability of this tool to accurately predict clinical performance is variable and ultimately depends on the in vivo outcome. Several studies comparing once annealed with re-melted HXLPE subjected to accelerated artificial aging have found oxidation, decreased ultimate strength, and higher wear with the former. There is no debate that polyethylene, irradiated and once annealed, has free radicals. However, it shows excellent wear resistance, comparable with that of re-melted material, and superior strength. These artificial aging techniques do not always predict in vivo experience; they more closely parallel changes seen with components that are shelf aged. When materials were shelf aged for 4.3 to 9 years, the materials cross-linked and annealed showed significantly more oxidative damage than those cross-linked and re-melted. In an in vitro wear study of polyethylene subjected to 100 mrad of radiation in air and then aged for 30 years, samples triple packaged in air were compared with those shelf aged without packaging. The polyethylene cups aged in an air-containing package for 30 years had significantly lower wear in a wear simulator than samples shelf aged without packaging after 5 million cycles. This experiment is consistent with results from artificial aging techniques. The packaged material, although containing some oxygen at packaging, was shielded from further contact with oxygen. In contrast, the unpackaged was essentially bathed in oxygen for the duration of the aging process (similar to artificial aging) and showed a marked degradation and significantly increased wear compared with oxygen-deprived materials.

Of particular interest is a clinical study from early attempts (1970-1980s) at cross-linking with irradiation in air. Doses of 100 mrad in air (10 times the currently used doses) were used and followed for 25 years. This study showed no indication of increasing wear rates with time. In fact, just the opposite occurred, with no outliers having wear rates greater than 0.1 mm/y.
Retrievals of first-generation annealed components have shown evidence of in vivo oxidation, but the extent of oxidation is not uniform throughout the material. The rims of the annealed acetabular components routinely show oxidation, while the areas involving the locking mechanisms and bearing surfaces show minimal evidence, well below the critical level, of oxidative damage. Equally unexpected were changes in the first-generation re-melted components, which showed increasing evidence of oxidation (although still minimal) with increasing time in situ.

Until 1998, polyethylene cross-linking was an unintended consequence of gamma sterilization. The first attempt at enhanced cross-linking was Duration (Stryker Orthopaedics), which was irradiated at 3 mrad and annealed. With 14-year follow-up, its wear properties were an improvement over the predicate material but fell short of the dramatic improvement seen with the highly cross-linked materials introduced in 1998. Following the development of Crossfire, a sequentially annealed and irradiated HXLPE product named X3 (Stryker Orthopaedics) was manufactured to significantly reduce the presence of free radicals. At 7-year follow-up, using a 32-mm head, it has a reported linear wear rate of 0.018 mm/y and no osteolysis. The current authors have no clinical experience using 32-mm heads with Crossfire liners.

Thus far, one can conclude that laboratory testing and clinical experience agree regarding markedly improved wear resistance of HXLPE. No such agreement exists when accelerated aging techniques are compared with clinical data. Retrieval of HXLPE components yields some insight as to why this disconnect exists. The locking mechanism and bearing surface

### Table 2

<table>
<thead>
<tr>
<th>Cross-Linking Process</th>
<th>Study</th>
<th>Femoral Head Size, mm</th>
<th>Follow-up, y</th>
<th>No. of Hips</th>
<th>Osteolysis</th>
<th>Wear Measurement Method</th>
<th>Mean Wear Rate, mm/y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marathon—irradiated (5 mrad) and re-melted (150°C)</td>
<td>Engh et al</td>
<td>28</td>
<td>10</td>
<td>116</td>
<td>0%</td>
<td>Martell</td>
<td>0.040</td>
</tr>
<tr>
<td>Longevity—irradiated (10 mrad) and re-melted</td>
<td>Lee et al</td>
<td>32</td>
<td>7</td>
<td>113</td>
<td>10.6%</td>
<td>PolyWare</td>
<td>0.031</td>
</tr>
<tr>
<td>Thomas et al</td>
<td>28</td>
<td>8.6</td>
<td>22</td>
<td>5%</td>
<td>Model-based RSA</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td>Bragdon et al</td>
<td>28</td>
<td>7-10</td>
<td>768 from 3 studies</td>
<td>0%</td>
<td>Martell</td>
<td>+0.010 (32 mm); -0.012 (28 mm)</td>
<td></td>
</tr>
<tr>
<td>Glyn-Jones</td>
<td>28</td>
<td>10</td>
<td>39</td>
<td>RSA</td>
<td>0.003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>X3—sequentially irradiated and annealed (3 × 3 mrad)</td>
<td>D’Antonio et al</td>
<td>32</td>
<td>5-7</td>
<td>118</td>
<td>0%</td>
<td>Martell</td>
<td>0.015</td>
</tr>
<tr>
<td>Callary et al</td>
<td>32</td>
<td>5</td>
<td>18</td>
<td>Not assessed</td>
<td>Model-based RSA</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Crossfire—irradiated and annealed (10.5 mrad)</td>
<td>Reynolds et al</td>
<td>28</td>
<td>9</td>
<td>46</td>
<td>0%</td>
<td>Martell</td>
<td>&lt;0.037</td>
</tr>
<tr>
<td>Capello et al</td>
<td>28</td>
<td>9</td>
<td>42</td>
<td>0%</td>
<td>Martell</td>
<td>0.031</td>
<td></td>
</tr>
<tr>
<td>Ranawat et al</td>
<td>28</td>
<td>10</td>
<td>40</td>
<td>0%</td>
<td>Roman</td>
<td>0.015</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>28</td>
<td>15</td>
<td>50</td>
<td>0%</td>
<td>Martell</td>
<td>0.018</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviation:** RSA, radiostereometric analysis.

*DePuy, New Brunswick, New Jersey.
Zimmer, Warsaw, Indiana.
Stryker Orthopaedics, Kalamazoo, Michigan.
All were cobalt chrome.
*Draftware Developers, Inc, Conway, South Carolina.
appear to be protected from in vivo oxidation either by shielding from oxygen-containing fluids and/or contact with the femoral head or by mechanisms yet to be described.

At this juncture, with solid clinical data now out to 10 to 15 years, both remelted and annealed materials show excellent clinical performance. Reduced mechanical properties in the former have not proved to be a major clinical problem and residual free radicals in the latter have not resulted in increased wear or mechanical issues.

Longer follow-up of well-designed studies is crucial to establishing whether free radical content in polyethylene components causes significant clinical problems. Once annealed HXLPE continues to have low wear without occurrence of osteolysis or mechanical failure out to 15-year follow-up.

REFERENCES


