INTRODUCTION:

Osteolytic aseptic loosening caused by wear debris of ultra-high molecular weight polyethylene (PE) is considered as the most common failure mode in total hip arthroplasty (THA). Reduction of the wear debris from UHMWPE is essential to prevent osteolysis resulting in aseptic loosening, and along with different bearing alternatives, improvement of the PE material has been pursued. As one of such attempts, clinical application of highly pure alumina ceramics in THA started in the 1970s. In addition, various highly cross-linked polyethylene (CLPE) cups with the irradiation of 50 to 105 kGy, have been widely used since 1998. In this study, in vivo wear and oxidation degradation of CLPE cups against ceramic femoral head were evaluated by the retrieval analysis.

METHODS:

The PE (Kyocera Corp., Kyoto, Japan, currently Japan Medical Materials Corp., Osaka, Japan) acetabular cups were machined from the compression-molded PE (GUR1050 resin) bar stock and then ethylene oxide gas sterilized. The CLPE (Aeonion from the same manufacturer) acetabular cups were manufactured using the following process: The compression-molded UHMWPE (GUR1050 resin) bar stock was gamma-ray irradiated with 35 kGy in air and annealed at 110°C in N2 for 12 hours. The cups were then machined from this bar stock and then gamma-ray sterilized with a dose of 25 to 40 kGy in N2. Thus, the total dose of gamma-ray irradiation was 60 to 75 kGy.

The analyzed subjects of PE cup (n = 7) were retrieved for the following reasons: 4 for infection and 3 for cup loosening. All PE cups had been used against alumina ceramic femoral heads. The CLPE subjects (n = 8) were retrieved for infection, 4 for infection, 3 for repeated dislocation and 1 for pelvic fracture. The CLPE cups had been used against either alumina (n = 6) or zirconia (n = 2) ceramic femoral heads. The mean clinical-use period of the each cohort were 21.2 years (16.0–23.4 years) for PE and 2.8 years (0.3–6.7 years) for CLPE.

The linear wear of the retrieved cups was measured using a three-dimensional coordinate measurement machine (BHN-305; Mitutoyo Corp., Kawasaki, Japan). The worn surface of retrieved cups was observed by scanning electron microscope (SEM) (S-3400N; Hitachi Ltd., Tokyo, Japan) at the acceleration voltage of 15 kV. Oxidative degradation of the retrieved cups was expressed as an oxidation index which was calculated from microscopic Fourier transformed infrared spectroscopy analysis, according to ASTM F2102. Surface and interior oxidation indices were determined within 0.1 mm of the articulation surface and 3.0 mm in depth from the surface.

RESULTS:

The linear wear of retrieved PE and CLPE cups was: 3.10 and 0.09 mm, respectively; the wear rate was 0.15 and 0.06 mm/year (Table 1). The linear wear of retrieved PE and CLPE cups was similar to the results reported by the previous radiographic study [1] (Fig. 1). These indicate that retrieved CLPE cups achieved >60% reduction in their wear rate compared with the retrieved PE.

![Figure 1. Linear wear of retrieved PE and CLPE cups.](image1)

![Figure 2. Oxidation index of retrieved PE and CLPE cups.](image2)

<table>
<thead>
<tr>
<th>Liner</th>
<th>Femoral head</th>
<th>n</th>
<th>Head size (mm)</th>
<th>Clinical use (yrs)</th>
<th>Linear wear (mm)</th>
<th>Wear rate (mm/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE</td>
<td>Total</td>
<td>7</td>
<td>0/0/7</td>
<td></td>
<td>21.2</td>
<td>3.10</td>
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<tr>
<td></td>
<td>Alumina</td>
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<td>0/0/7</td>
<td></td>
<td>2.8</td>
<td>0.09</td>
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<tr>
<td>CLPE</td>
<td>Total</td>
<td>8</td>
<td>1/1/6</td>
<td></td>
<td>2.8</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>Alumina</td>
<td>6</td>
<td>0/0/6</td>
<td></td>
<td>3.2</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Zirconia</td>
<td>2</td>
<td>1/1/0</td>
<td></td>
<td>1.8</td>
<td>0.06</td>
</tr>
</tbody>
</table>

In the superficial SEM image of all retrieved CLPE cups, any material failure due to wear, delamination or cracks were not observed (data not shown).

Oxidation indices of retrieved PE cups were: 0.36 (0.20–0.45) in worn surface, 0.14 (0.10–0.21) in unworn surface, and 0.17 (0.00–0.44) in worn interior, respectively (Fig. 2). The oxidation index in worn surface of retrieved PE cups was significantly higher (p < 0.01) compared with that in other area. In contrast, oxidation indices of retrieved CLPE cups were: 0.17 (0.00–0.39) in worn surface, 0.15 (0.00–0.30) in unworn surface, and 0.11 (0.00–0.25) in worn interior, respectively; there was no significant difference (p > 0.05) in the oxidation indices between each area in the CLPE cups. The oxidation indices of the retrieved CLPE cups were lower (p < 0.01) than that of PE cups (including the previous [2] and this study). However, a limitation of this study is that we cannot know how much difference of the oxidation indices is significantly effective in actual clinical situation, because we had only a few numbers of retrieved cups with different clinical-use periods.

DISCUSSION:

The retrieved CLPE acetabular cups in this study showed low and stable wear rates. The results showed a notable reduction in wear of the CLPE cups compared to that of PE cups. And also, the oxidation indices of the retrieved CLPE cups were the same level as that of PE cups, probably. These findings from this retrieval study suggested that there is neither progressive wear in the clinical use for 0.3–6.7 years, nor material failures due to delamination or cracks. In the previous hip joint simulator study, a roughened-metallic femoral head increased the wear damage to the acetabular cup, even in a CLPE (although the wear rate was dramatically lower than for PE against a well-polished metallic head). In this study, the lower wear rate and the smooth surface of the CLPE acetabular cup indicate the possibility of reduced wear debris from those cups articulated against the ceramic femoral head. We expect that the CLPE acetabular cup against the ceramic femoral head has favorable wear properties in long-term clinical use.

REFERENCES: