Original article

Comparison of wear rate and osteolysis between annealed and remelted highly cross-linked polyethylene in total hip arthroplasty. A case control study at 7 to 10 years follow-up


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ABSTRACT

Background: Low polyethylene wear rate and low incidence of osteolysis after total hip arthroplasty using annealed and remelted highly cross-linked polyethylene have been reported. However, there is no previous report that directly compared both types of highly cross-linked polyethylene. We therefore performed a retrospective study on a series of highly cross-linked polyethylene, in order to: (1) compare wear rates and the incidence of osteolysis between annealed and remelted highly cross-linked polyethylene at 7–10 years; (2) identify the frequency of complication related to annealed and remelted highly cross-linked polyethylene.

Hypothesis: There is no difference in the linear wear rate and the incidence of osteolysis between the annealed and remelted highly cross-linked polyethylene in total hip arthroplasty.

Patients and methods: Two hundred and sixteen cases of cementless total hip arthroplasties with annealed or remelted highly cross-linked polyethylene, which were performed between January 2003 and December 2006 in one institution, were followed for 7–10 years and received computed tomography scan, in addition to radiography at the latest follow-up. Annealed and remelted highly cross-linked polyethylene was used in 91 cases and 125 cases, respectively. A 26-mm cobalt-chromium head was used in all cases. Penetration rates from 1 year to the last evaluation were used to estimate the yearly linear wear rate. Existence of osteolysis was evaluated by plain radiography and computed tomography.

Results: There were no significant differences in patients’ background between the two groups. The linear wear rate of annealed and remelted group was 0.031 ± 0.022 mm/year and 0.032 ± 0.020 mm/year, respectively (P=0.91). Two cases of small femoral osteolysis were found in the annealed group. Any complication related to highly cross-linked polyethylene was not found in both groups.

Discussion: There was no significant difference in the linear wear rate and the incidence of osteolysis between the annealed and remelted group at postoperative 7 to 10 years. Excellent results of both types of highly cross-linked polyethylene were revealed by this study.

Level of evidence: Level III retrospective case control study.

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1. Introduction

Periprosthetic osteolysis caused by polyethylene wear particles is one of the major complications in total hip arthroplasty (THA). The natural history of osteolysis is asymptomatic and progressive until substantial bone loss causes an eventual loosening of the component [1]. To improve wear resistance and to reduce osteolysis, highly cross-linked polyethylene (HXLPE) with annealing or remelting thermal treatment was introduced in the 1990s instead of conventional polyethylene. Annealing method involved a single thermal treatment below the crystalline melt transition in polyethylene to preserve crystallinity and mechanical properties, but also resulted in a material containing elevated residual free radicals with the potential to oxidize in vivo [2]. Remelting method involved thermal treatment above the melt transition. This resulted in a material with undetectable free radicals but at the expense of reduced crystallinity and lower material properties [3].

According to a systematic review of wear rate and osteolysis outcomes at a minimum of 5 years of follow-up, a mean wear rate of 0.042 mm/year could be expected with annealed or remelted HXLPE compared to 0.137 mm/year using conventional polyethylene [4]. Moreover, the incidence of osteolysis was 87% lower with HXLPE when compared with conventional polyethylene. Thus, low polyethylene wear rate and low incidence of osteolysis of
both types of HXLPE were reported compared to conventional polyethylene. However, there is no previous report that directly compared wear rates and the incidence of osteolysis of annealed HXLPE with those of remelted HXLPE.

The goals of this retrospective case control study were:

- to compare wear rates and the incidence of osteolysis between annealed and remelted HXLPE at 7–10 years;
- to identify the frequency of complication related to annealed and remelted HXLPE.

Computed tomography (CT) scans, considered to be a more accurate and sensitive method for detecting osteolysis compared to plain radiography [5–7], were used to evaluate osteolysis as well as plain radiography in this study. The study hypothesis was that there was no difference in the linear wear rate and the incidence of osteolysis between the annealed and remelted HXLPE in THA.

2. Patients and methods

2.1. Patients

The institutional research ethics committee approved the study protocol. We retrospectively reviewed 367 primary cementless THAs in 306 patients performed with metal on annealed or remelted HXLPE between 2003 and 2006 by two senior orthopaedic surgeons at one institution. In this period, 508 primary cementless THAs had been performed in our hospital (average 127 cases/year). Of the 508 cases, 407 cases had been performed by the two surgeons (80.1%). Of 367 cases that were reviewed, 2 cases underwent revision surgery for reasons unrelated to osteolysis and liner trouble, 14 cases died of unrelated causes, and 44 cases were lost, before postoperative 7 years. The remaining 307 cases were followed for a minimum of 7 years (83.7% in all consecutive cases). At postoperative 7 years or later, we recommended CT-scans in addition to radiography as a part of routine clinical screening for periprosthetic osteolysis regardless of absence of clinical signs and symptoms. Finally, 216 cases of 174 patients were included in this study. Ninety-one cases were missed for a minimum of 7 years who did not receive CT scan screening were excluded from this study (Fig. 1).

2.2. Methods

Primary cementless THAs with metal-on-HXLPE (MOHXLPE) bearings using a posterolateral approach were performed in all cases. Annealed HXLPE (Crossfire, Stryker Orthopaedics, Mahwah, NJ) were used in 91 cases and remelted HXLPE (Longevity, Zimmer Inc., Warsaw, IN) were used in 125 cases. One surgeon performed 41 surgeries in annealed group and 56 in remelted group. The other surgeon performed 50 surgeries in annealed group and 69 in remelted group. There was no specific reason for the types of HXLPE which were chosen. Cementless cups (Ti-6Al-4V alloy) and fit and fill stems with a 26-mm cobalt-chromium head, which was the most common choice of the head material in Japan at that time, were used. In the annealed group, TriAD HA PSL cups were used in combination with Super SecurFit HA stems (Stryker Orthopaedics, Mahwah, NJ). In the remelted group, Trilogy HA/TCP cups were used in combination with VerSys HA/TCP Fibermetal Midcoat stems (51 hips) or VerSys HA/TCP Fibermetal Taper stems (74 hips) (Zimmer Inc., Warsaw, IN). The cups were inserted in a press-fit fashion, and additional screws were used at the surgeon’s discretion. Postoperatively, the patients were allowed full weight bearing as tolerated.

2.3. Methods of assessment

The Japanese Orthopaedic Association (JOA) Hip Score was evaluated preoperatively and at the latest follow-up (a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability) [8]. Additional examination and therapy were performed when they had any hip symptoms. They were followed-up with annual medical examination and screening radiography after the surgery. CT scan was also performed at 3 to 6 months before surgery and at 3 months postoperatively in all cases. Postoperative radiography was routinely performed at 3, 6, and 12 months postoperatively, and annually thereafter. The postoperative radiographs were compared with those taken immediately postoperatively. Femoral and acetabular osteolysis was defined as an area of localized loss of trabecular bone or cortical erosion adjacent to the implants that was not apparent on the immediate postoperative radiographs [9]. The osteolysis was reported on the acetabular side if it was present in any of the three DeLee and Charnley zones [10] and on the femoral side in any of the Gruen zones [11]. The acetabular components were defined as stable, stable with a suboptimal interface, or unstable [12,13]. The femoral prostheses were considered bone-ingrown, fibrous stable, or unstable [14]. Cup size and the number of screws used for cup fixation were recorded. Radiographic cup inclination and anteversion were measured.

All CT scan images were acquired using multidetector CT (Aquilion64, TOSHIBA Medical System Inc., Tokyo). A metal-artifact-minimizing protocol was used [6]. The scanning parameters were as follows: axial plane at 140 kV, 100 to 300 mA, 1.0-mm thickness for slice images. All CT scan images were obtained in supine position. The area from anterior superior iliac spine to the distal end of femoral condyle was evaluated. CT scans were performed before surgery, at postoperative 3 months, and at postoperative 7–10 years in all cases. Osteolysis was defined as the same as in the radiographs, by comparing the CT scan images with those performed at postoperative 3 months. Existence of soft tissue mass related to polyethylene wear [15] in CT images was noted. Existence of abnormal signs in radiographs or CT images suspecting fracture of liner was also noted. Each radiograph and CT scan image was evaluated by two of three independent orthopaedic surgeons including one that did not participate in surgery. Kappa (κ) coefficients, used to quantify the extent of agreement among the surgeons, denoted good to excellent inter-observer reproducibility (κ = 0.67 to 1.00).

Postoperative femoral head penetration was evaluated using a computer-assisted method (PolyWareTM Digital Version 7.24; Draftware Developers, Inc, Vevay, IN, USA) by two observers (RT, MH) independently. Spearman’s correlation analysis showed good intra-observer reliability (r = 0.81, P < 0.01) and inter-observer
Table 1
Demographic details of the patients.

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 216)</th>
<th>Annealed group (n = 91)</th>
<th>Remelted group (n = 125)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (± SD) (range)</td>
<td>61.8 ± 9.9 (31–80)</td>
<td>61.4 ± 10.8 (31–80)</td>
<td>62.0 ± 9.5 (37–80)</td>
<td>0.67&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Male/female</td>
<td>24:192</td>
<td>11:80</td>
<td>13:112</td>
<td>0.70&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>202</td>
<td>83</td>
<td>119</td>
<td></td>
</tr>
<tr>
<td>Osteonecrosis of the femoral head</td>
<td>9</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Mean BMI in kg/m²</td>
<td>23.3</td>
<td>23.3</td>
<td>23.3</td>
<td>0.70&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mean follow-up (years)</td>
<td>8.2</td>
<td>8.2</td>
<td>8.2</td>
<td></td>
</tr>
<tr>
<td>Mean preoperative JOA score (± SD) (range)</td>
<td>47.2 ± 13.9 (10–85)</td>
<td>45.8 ± 13.6 (15–77)</td>
<td>48.9 ± 14.3 (10–85)</td>
<td>0.91&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mean postoperative JOA score (± SD) (range)</td>
<td>91.6 ± 11.7 (62–100)</td>
<td>91.2 ± 12.1 (62–100)</td>
<td>92.1 ± 11.2 (69–100)</td>
<td>0.77&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Unpaired t-test.
<sup>b</sup> Chi-square test.

Fig. 2. Measurement of linear wear of polyethylene liner using PolyWare software (Draftware Developers, Inc. Vevay, IN, USA). The patient was a 59-year-old woman at the time of surgery. In this case, total penetration from postoperative 1 year to the last evaluation (postoperative 9 years) was 0.248 mm. Linear wear rate was calculated as 0.031 mm/year.

reliability (r = 0.74, P < 0.01) [these good or excellent reliability was consistent with those of previous study [16]]. The 1-year antero-posterior plain radiographs were analyzed for head penetration and used to estimate initial bedding-in [17–19]. Penetration rates from 1 year to the last evaluation were then used to estimate the yearly linear wear rate (Fig. 2).

2.4. Statistical analysis

Unpaired t-tests and Chi² test were applied to test the mean difference in age, gender, body mass index, diagnosis, JOA score, cup size, the number of screws, radiographic cup inclination, anteversion, and linear wear rate. The correlation between linear wear rate and cup size was analysed by Spearman’s correlation coefficient test. Differences in the frequencies of presence of osteolysis between annealed and remelted groups were tested for significance by using Fisher’s exact test. The results were considered to be significant if P < 0.05.

A post hoc sample size calculation (G*Power 3; Düsseldorf University, Düsseldorf, Germany) [20] was performed to assure that the subjects available in this study were adequate to assess the significant difference of wear rates between annealed and remelted groups. The post-hoc power analysis using an alpha equal to 0.05 showed that this study had 81.2% power to detect a significant difference of incidence of osteolysis and wear rates between annealed and remelted groups.

3. Results

Two hundred sixteen cases of 174 patients (17 males and 157 females) followed for average of 8.4 years were finally evaluated (58.9% in all consecutive cases). There were no significant differences between the two groups in respect of age, gender, diagnosis, body mass index, or JOA score (Table 1). The linear wear rate of all the cases was as low as 0.032 ± 0.021 mm/year, and the difference between annealed and remelted groups was not statistically significant (P = 0.91) (Table 2). On the plain radiographs in annealed group, no acetabular osteolysis (0%) and 2 asymptomatic cases of femoral osteolysis (2.2%) were found at postoperative 5 and 6 years. All the femoral osteolysis were focal and small (less than 5 mm width), located at the most proximal bone–implant interface (Gruen zones 1 and 7 in one case and in zone 7 in the other case). In the remelted group, no osteolysis was found by radiographs. There was no statistical difference in the incidence of osteolysis between the annealed group (2.2%) and the remelted group (0.0%) (P = 0.18). All cups were stable, and all stems were bone-ingrown in both groups. There was no significant difference of cup size, the number of screws, the radiographic cup inclination and anteversion between annealed and remelted groups (Table 3). There was no significant correlation between linear wear rate and cup size in both annealed (r = −0.04, P = 0.66) and remelted group (r = −0.12, P = 0.92).

No osteolysis was newly found by screening CT scan at the last follow-up. The cases of osteolysis screened by CT scan were exactly the same as those detected by plain radiography. Postoperative soft tissue mass of unknown origin was found in one case of the annealed group (0.11%). The cases with osteolysis or soft tissue mass had not received any treatment because of absence of symptoms and were continued under observation. There was no case of fracture of liner in radiographs or CT images.

Table 2
Linear wear rates of annealed and remelted group.

<table>
<thead>
<tr>
<th></th>
<th>Annealed group (n = 91)</th>
<th>Remelted group (n = 125)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean of linear wear rate (mm/year) (± SD) (range)</td>
<td>0.031 ± 0.002 (0.002–0.097)</td>
<td>0.032 ± 0.020 (0.001–0.10)</td>
<td>0.91&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Unpaired t-test.
Table 3
Cup size, number of screws, and orientation of the acetabular component.

<table>
<thead>
<tr>
<th></th>
<th>Annealed group (n = 91)</th>
<th>Remelted group (n = 125)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cup size (mm)</td>
<td>50.2 ± 2.6 (46–60)</td>
<td>51.0 ± 2.9 (44–58)</td>
<td>0.97*</td>
</tr>
<tr>
<td>(SD) (range)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cup screw</td>
<td>57</td>
<td>83</td>
<td>0.57†</td>
</tr>
<tr>
<td>Not used</td>
<td>34</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Mean Number of</td>
<td>2.21 ± 0.53 (1–3)</td>
<td>2.24 ± 0.69 (1–4)</td>
<td>0.61†</td>
</tr>
<tr>
<td>screws (±SD)</td>
<td>(range)</td>
<td>(range)</td>
<td></td>
</tr>
<tr>
<td>Mean inclination</td>
<td>39.2 ± 4.3 (30–50)</td>
<td>40.4 ± 4.5 (22–50)</td>
<td>0.97†</td>
</tr>
<tr>
<td>(°) (±SD)</td>
<td>(range)</td>
<td>(range)</td>
<td></td>
</tr>
<tr>
<td>Mean anteversion</td>
<td>16.2 ± 6.1 (8–32)</td>
<td>15.7 ± 5.5 (6–31)</td>
<td>0.69†</td>
</tr>
</tbody>
</table>

* Unpaired t-test.
† Chi-square test.

4. Discussion

Low wear rates and low incidence of osteolysis by plain radiographs after THA using HXLPE have already been reported by previous studies [3,5]. Our study, using CT scan as well as plain radiography, confirmed low incidence of osteolysis and a low linear wear rate after THA with both annealed and remelted HXLPE at 7–10 years of follow-up. Moreover, there was no significant difference of linear wear rate and the incidence of osteolysis between annealed and remelted groups in this study. There is no previous single institution study that directly compares linear wear rate and the incidence of osteolysis between both groups. Kurtz et al. [4] reported weighted-average linear wear rate of each type of commercially available HXLPE formulation in a systematic review of 28 studies (0.057 mm/year in Crossfire liners and 0.042 mm/year in Longevity liner.). However, it is considered that these data could not be compared directly because this systematic analysis included a great heterogeneity of study design, patients, surgical technique, femoral head size, and femoral head materials. In fact, values of linear wear rate of both HXLPE varied considerably among respective studies (0.002 to 0.120 mm/year) [4]. In this point of view, our study has a considerable significance.

There are several limitations to our study. First, this is a retrospective study. The choice of type of HXLPE liners (annealed or remelted) was not strictly randomized. However, we did not choose the type of HXLPE by any specific reason, and accordingly the patient background of the 2 groups did not differ significantly. Secondly, our evaluation was performed at 7–10 years postoperatively. Significant difference of wear rate and incidence of osteolysis between two groups may be observed at longer follow-up. Thirdly, our limited follow-up could be a major limitation. Although we actually followed the patients over 7 years with a high follow-up rate (>80%), we excluded many patients who did not receive CT-scan to evaluate osteolysis correctly in this study. Fourthly, we did not evaluate patients’ activity level. Although there was no significant difference between 2 groups in patients’ background (including JOA score), there might be little difference between 2 groups in pre- and postoperative activity level.

Some complications related to HXLPE have been reported [21–24]. For annealed HXLPE, which contains residual free radicals, in vivo oxidation at the rim of the liner has been reported [21], and liner rim delamination has been identified in case studies of chronic instability and impingement [22]. On the other hand, for remelted HXLPE, which contains undetectable free radicals but lower crystallinity, liner rim fracture has been reported in several case studies requiring revision of the bearing [23,24]. In our study, no complication related to liner rim oxidation (in annealed liner) and liner rim fracture (in remelted liner) has been found. The fact of using only 26 mm head might influence these good results. However, it is difficult to evaluate these issues correctly by either plain radiography or CT scan. Complications related to these issues may happen in longer follow-up.

We compared linear wear rates and the incidence of osteolysis after THA with both annealed and remelted HXLPE at 7–10 years of follow-up. We confirmed low incidence of osteolysis using CT-scan and a low linear wear rate of both groups. There was no significant difference of those between both groups. Excellent clinical results of both types of HXLPE were revealed by this study at 7 to 10 years follow-up.

Disclosure of interest

The authors declare that they have no competing interest.

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References


