Original Article

Polyethylene and highly cross-linked polyethylene for cemented total hip arthroplasty: A comparison of over ten-year clinical and radiographic results

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ABSTRACT

Introduction: We investigated the long-term tribological outcomes of conventional polyethylene (CPE) and highly cross-linked polyethylene (HXLPE).

Methods: Ninety-four consecutive primary cemented THAs were performed using either HXLPE or CPE at our hospital. CPE sockets were used in 26 hips, and HXLPE sockets were implanted in 68 hips.

Results: A 10-year follow-up was completed for 69 cases. Linear wear rates of 0.138 ± 0.074 mm/year for CPE and 0.011 ± 0.020 mm/year for HXLPE were calculated. Osteolysis was identified in 10 cases (CPE group, 7; HXLPE group, 3).

Conclusion: HXLPE had significantly less wear than CPE, and polyethylene wear was associated with osteolysis.

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1. Introduction

Although total hip arthroplasty (THA) is a popular surgical treatment for degenerative hip joint disease, several issues still need to be resolved, with periprosthetic osteolysis and subsequent loosening of the prosthesis being an important problem affecting long-term outcomes. Loosening can possibly be induced by an immunologic response, and may be related, in part, with increase wear of the acetabular polyethylene, which is frequently associated with periprosthetic osteolysis. To solve this problem, highly cross-linked polyethylene (HXLPE) has been developed, with clinical and tribological results of using HXLPE in cementless THA having been reported. Recently, long-term wear performance of HXLPE in cementless THA has also been reported. However, the long-term wear performance of HXLPE in cemented THA remains to be evaluated.

In a previous study, we reported on the clinical outcomes of HXLPE and compared its wear performance to conventional polyethylene (CPE) over a minimum 3-year follow-up after cemented THA.¹ Our aim in our present study was to evaluate the long-term clinical results and wear performance of HXLPE after

a minimum 10-year follow-up in patients with cemented THA to determine its clinical relevance.

2. Materials and methods

2.1. Patients and materials

All patients provided informed consent and the study protocol was approved by the institutional review board of our hospital. Between 1999 and 2001, we implanted a 22.225-mm head in 94 consecutive cases of primary cemented THA in our hospital. Four implant combinations were used, as summarized in Table 1, and patients were classified into groups based on the combination used, as follows. The 26 hips in group A received CPE sockets with a zirconia femoral head and Charnley-type stems (BC socket, PHS head, and KC stem, Kyocera Medical Corp., Kyoto, Japan). HXLPE sockets (Aeonian, Kyocera Medical Corp.) were implanted in all other cases. The 25 hips in group B received PHS zirconia femoral heads and KC stems, with the 23 hips in group C receiving zirconia femoral heads and distal cylindrical stems (HHZ head, K-MAX stem, Kobelco, Kobe steel Ltd, Kobe, Japan), and the 20 hips in group D, stainless steel femoral heads (Elite head, DePuy Inc., Warsaw, Ind.) and C-stems (DePuy Inc.). The surface finish of all femoral head components was similar (R_a , $<0.02 \mu\text{m}$, R_y , $<0.2 \mu\text{m}$). The conventional BC sockets were fabricated with GUR415, with stearic acid applied by ram extrusion, and sterilized

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Table 1
Implants for each group.

	Acetabular socket/ material	Inner head/ material	Femoral stem	N
Group A	BC/CPE	PHS/zirconia	KC	26
Group B	Aeonian/HXLPE	PHS/zirconia	KC	25
Group C	Aeonian/HXLPE	HHZ/zirconia	K-max	23
Group D	Aeonian/HXLPE	Elite/stainless-steel	C-stem	20

CPE = conventional polyethylene; HXLPE = highly cross-linked polyethylene.

Table 2
Preoperative clinical details and evaluation scores for each group.

	Group A	Group B	Group C	Group D
Age (year)	60	61.5	62.6	60.8
mean (range)	(43–81)	(48–71)	(45–76)	(47–74)
Weight (kg)	50.2	50.6	51	54.7
mean (range)	(40.6– 62.0)	(38.5– 76.0)	(35.6– 70.0)	(38.0– 82.0)
JOA hip score	54	43.4	56.8	49.5
mean (range)	(29–84)	(20–76)	(39–85)	(20–86)
UCLA activity score	3.58	3.60	3.76	3.65
mean (range)	(3–6)	(3–5)	(3–5)	(2–5)
Follow up period (months)	14.20	13.80	14.00	13.90
mean (range)	(12.5– 15.0)	(10.0– 15.0)	(12.6– 15.0)	(11.1–15.0)

JOA = the Japanese Orthopaedic Association, UCLA = the University of California at Los Angeles. No significant between-group differences were identified.

by ethylene oxide gas. The CLPE Aeonian sockets were fabricated with GUR1050 without the use of stearic acid, by compression molding, and highly cross-linked using gamma irradiation at a dose of 35 kGy, heat annealed at 110 °C, and sterilized with 25 kGy of gamma irradiation in nitrogen.

2.2. Surgical procedures

All surgeries were performed by three experienced surgeons using a direct lateral approach with an anterior-trochanteric osteotomy (Dall's approach). The acetabular sockets and femoral stems were fixed with vacuum-mixed bone cement (Endurance, DePuy Inc., Warsaw, Ind.). Using a cement gun, we inserted bone cement into the femoral stems, the so-called third-generation technique.²

2.3. Radiographic evaluations

Anterior-posterior radiographs were obtained for each patient annually. We considered the first post-operative year as a 'settling-in' period for the THA and, therefore, measured polyethylene wear at one year post-operatively and every two years thereafter, up to the last follow-up visit. Polyethylene wear was measured by determining the penetration of the center of the head relative to the center of the acetabular socket, using the computer-aided technique described by Sychterz et al.³ and modified by Tanaka et al.⁴ To determine the rate of wear, radiographic measurements

Fig. 1. Follow-up flowchart of patients in our study group. For patients who require THA revision, radiographs were evaluated radiographs up to the time of revision surgery. THA = total hip arthroplasty.

Table 3

Linear wear rate and volumetric wear rate of each group.

	Linear wear rate(mm/year $\pm$ SD)	Volumetric wear rate(mm[3]/year $\pm$ SD)	N
CPE (Group A)	0.138 $\pm$ 0.074	59.54 $\pm$ 28.20	17
Group B	0.010 $\pm$ 0.015	11.15 $\pm$ 3.233	22
Group C	0.012 $\pm$ 0.020	11.21 $\pm$ 7.848	16
Group D	0.007 $\pm$ 0.011	8.871 $\pm$ 4.538	14

SD = standard deviation; CPE = conventional polyethylene; HXLPE = highly cross-linked polyethylene.

were compared to those obtained at 1-year post-operatively. To standardize the location of measurement from year-to-year, 10 reference points were defined on the head of the femoral component and the cement-polyethylene interface of the acetabular socket, and the location was determined by best-fit alignment using an image analysis software (Image-Pro Plus version 4.0, Media Cybernetics Inc., Silver Spring, Md). The amount and direction of penetration of the head into the acetabular polyethylene was measured, after correction for magnification and pelvic tilt.⁵ Volumetric wear was calculated using the equation described by Hashimoto et al.⁶ Radiographic measurements were repeated three times at 1-week intervals to determine the reliability of measurement using the intraclass correlation coefficient (ICC). A least-squares linear regression was performed based on the magnitude of the wear vector versus time, measured in situ, was used to calculate the slope of the best-fit line on the two-dimensional graph. The calculated slope represented the steady-state linear wear rate.

Radiographic loosening of the acetabular component was assessed according to the criteria of Hodgkinson et al.⁷ and confirmed as type 3 (complete demarcation) or type 4 (socket migration). The criteria of Harris et al. were also used to assess the radiologic evidence of loosening of the femoral component.⁸ Component migration or a continuous radiolucent line surrounding the entire cement mantle was defined as loosening.

2.4. Clinical evaluation

For clinical evaluation, a detailed physical examination was conducted preoperatively, at one-year postoperatively, and

annually thereafter, up to the last follow-up visit. The Japanese Orthopaedic Association hip score (JOA hip score)⁹ and the University of California at Los Angeles activity score (UCLA activity score)¹⁰ were recorded as functional scores (Table 2).

2.5. Statistical analyses

For statistical analyses, we used JMP[®] Pro 12.2.0 software (64 bit, SAS institute Inc., Cary, NC). The differences between the groups were evaluated using an analysis of variance (ANOVA), followed by Fisher's post hoc test. Single regression analysis or ANOVA was also performed to investigate the correlation between the rate of linear wear and age, sex, body weight, body mass index (BMI), height, pre-operative JOA scores, final JOA scores, pre-operative UCLA scores, final UCLA scores, and osteolysis. Kaplan Meyer survival analyses were also performed, using radiographic implant loosening and revision for aseptic loosening as end-points. The survivorship curves for the CPE group and HXLPE groups were compared using the log-rank test. Statistical significance was set at $P < 0.05$.

3. Results

The mean follow-up period was 14 years (range, 10–15 years). Wear measurements were performed for 69 cases which were followed-up for over 10 years. Among these 69 cases, 7 patients (nine hips) died and 12 patients (14 hips) were lost to follow-up (Fig. 1). The linear rate of wear for the 4 groups were as follows (Table 3): group A, 0.150 ± 0.070 mm/year; group B, 0.010 ± 0.015 mm/year; group C, 0.012 ± 0.020 mm/year; and

Fig. 2. Typical radiograph of the left hip obtained immediately postoperatively and of the right hip, 10-years post-surgery, for each group. (a) group A; (b) group B; (c) group C, and (d) group D. Penetration of the femoral head was apparent in group A.

Table 4

Clinical evaluation of each group at the final follow-up.

	JOA hip score	UCLA activity score
CPE (Group A)	87.30 ± 3.42	5.71 ± 0.32
Group B	81.64 ± 2.63	5.00 ± 0.26
Group C	81.73 ± 3.19	4.73 ± 0.31*
Group D	80.07 ± 3.42	4.69 ± 0.34*

Values are expressed as a mean ± the standard deviation. "*" means statistically significant difference compared to the CPE group. There were significant differences between group A and groups C and D ($P=0.032$, 0.030). JOA=Japan Orthopaedic Society; UCLA=University of California at Los Angeles; CPE=conventional polyethylene; HXLPE=highly cross-linked polyethylene.

group D, 0.007 ± 0.027 mm/year. Significant differences in linear and volumetric wear rates were identified between group A and all other groups ($P < 0.0001$), with no differences between groups B–D. The ICC of wear measurement was 0.9334. No cases of infection were identified, and there 4 cases of THA revision, including 2 cases of socket revision in group A due to aseptic loosening at 7 and 14 years post-operatively. The linear wear rates for these 2 cases were 0.749 and 0.153 mm/year, respectively. Two stems in group B and C were revised due to aseptic loosening at 9 and 10 years post-operatively, with linear wear rates of 0.041 and 0.007 mm/year, respectively.

With regard to our 10-year outcome analysis, one case in group A and one in group C underwent THA revision and were excluded. Osteolysis was identified in 10 cases (group A, 7 cases; group B, 1 case; group C, 1 case; and group D, 1 case), with a significantly higher occurrence of osteolysis for the CPE group (group A) than HXLPE group (groups B–D; $P=0.012$).

Typical radiographic images are shown in Figs. 2(a–d). Apparent penetration of the femoral head in the acetabular socket was

identified on the 10-year post-operative images for group A. There was no evidence of penetration of the femoral head into the acetabular socket for groups B, C, or D.

A significant difference in linear wear rates were identified between cases *with* and *without* osteolysis (osteolysis+, 0.157 ± 0.083 mm/year versus osteolysis–, 0.030 ± 0.053 , $P=0.0019$). No correlation was identified between linear wear rates and age, sex, BMI, body weight, height, pre-operative JOA scores, final JOA scores, pre-operative UCLA scores, or final UCLA scores.

The clinical evaluations at the final follow-up are shown in Table 4. There were no significant differences in JOA hip scores among each group, but the JOA hip scores in the CPE group were better than those in the HXLPE groups. Regarding the UCLA activity scores, there were significant differences between group A and groups C and D ($P=0.032$, 0.030).

The 10-year Kaplan-Meier survivorship analysis, using radiographic socket loosening as the end point (Fig. 3a), was 96.0% for the CPE group and 100% for the HXLPE groups ($P=0.023$). The 10-year survival rate using socket revision for aseptic loosening as the end point of analysis (Fig. 3b), was 95.0% for the CPE group and 100% for the HXLPE group ($P=0.027$). On the other hand, the 10-year survival rate, using radiographic stem loosening and stem revision as the end points of analysis, were 100% for the CPE group and 96.4% and 96.1%, respectively, for the HXLPE group, with no between-group difference (Fig. 3a–b).

4. Discussion

In this study, we prospectively investigated the long-term tribological outcomes of CPE and HXLPE in cemented THAs, and

Fig. 3. Kaplan-Meier survivorship analysis. The solid lines indicate survival rates, with the 95% confidence interval shown with the dashed lines. (a) Radiographic loosening was the end-point of analysis; and (b) Revision for aseptic loosening was the end-point of analysis. The rate of radiographic loosening ($P=0.023$) and revision due to aseptic loosening ($P=0.027$) were significantly lower for the highly cross-linked polyethylene than conventional polyethylene group. No differences in radiographic stem loosening ($P=0.384$) and revision ($P=0.394$) were identified between the conventional and highly cross-linked polyethylene groups.

assessed the clinical relevance of HXLPE in cemented THAs. We also investigated whether different type of femoral head components influenced clinical and tribological outcomes of HXLPE. For cemented THAs, using a 22.225 femoral head, HXLPE sockets were associated with less polyethylene linear wear and a lower incidence of osteolysis than CPE. The material properties of the femoral heads did not affect the linear wear rate of HXLPE sockets.

HXLPE sockets were fabricated to reduce wear, and many studies have compared the mid-to-long term wear rates between HXLPE and CPE sockets. In their systematic review, Kurtz et al.¹¹ reported a linear wear rate for HXLPE between 0.002 mm/year and 0.120 mm/year (mean 0.042 mm/year) compared to 0.020 mm/year and 0.267 mm/year (mean 0.137 mm/year) for the CPE liners.¹¹ Our results were consistent with this review; with an annual wear rate of 0.011 mm/year for the HXLPE liner and 0.138 mm/year for the CPE liner. In our previous study, we reported a 3-year wear rate for the HXLPE liner of 0.065 mm/year,¹ which was quite different from the 10-year rate reported in our current study. It is important to note that the 1-year settling-in period was not considered in our previous study.

Few studies have evaluated the mid-to-long term wear rate for cemented THAs. Johansson et al.¹² conducted a randomized study and reported a very low wear rate for HXLPE, compared to CPE, although the 10-year rate of aseptic loosening was comparable for HXLPE and CPE liners. There were no cases of aseptic loosening or osteolysis of HXLPE sockets in our study group. By comparison, 2 revisions for aseptic socket loosening were required for CPE cases, possibly due to aggressive polyethylene wear, with osteolysis around the socket or proximal femur identified in another 5 cases with CPE liners during the follow-up period. On the other hand, revision was required in two cases with HXLPE liners due to aseptic loosening of the stem, and in one case due to osteolysis around the proximal femur. No evidence of aggressive socket wear was identified in the 2 cases of THA revision in the HXLPE group. Serial radiographs indicated that fracture of the cement can possibly be caused by femoral osteolysis and stem loosening.

Osteolysis was identified in 7 of 17 (41.2%) hips with CPE liners, and in 3 of 52 (5.8%) hips with HXLPE liners. Previous studies have also reported a higher incidence of osteolysis CPE liners than HXLPE liners.¹³ Our results also identified a greater linear and volumetric wear rate in cases with osteolysis than without. We do note that the one case in group A which required socket revision, due to massive osteolysis at 7-years post-operatively, was excluded from analysis, which increased the linear wear rate of hips with osteolysis. Our findings were consistent with other studies that have compared the linear wear rate in patients *with* and *without* osteolysis.¹³ The overall results of our study indicate that the amount of wear debris play an important role in osteolysis, with evidence that polyethylene wear negatively influenced radiographic socket survival.

In our study group, the JOA and UCLA hip scores in the CPE group were higher than for the HXLPE groups. This result may have been biased by the 5 patients (7 hips) who had cerebral hemorrhage or cerebral infarction with residual paralysis: group A, 0; group B, 2; group C, 3; and group D, 2. The clinical scores for these patients decreased the mean scores for the HXLPE groups.

It is unclear whether the material property of the femoral head affects the wear rate of HXLPE sockets. Zirconia is influenced by phase transformation, with a decrease in material property *in vivo*. In this study, we used two types of zirconia femoral heads and one type of stainless steel femoral head, and compared the effect of these different material properties on the wear of acetabular socket liner. The wear rate on HXLPE was comparable for the zirconia and stainless steel femoral heads, with both materials being associated with a low rate of wear.

Our study has several limitations. First, 12 patients (14 hips) were lost to follow-up for unknown reasons, with a total follow-up rate or 85.1%. The lower than expected rate of follow-up may have biased identified between-group differences, from actual conditions. However, the linear wear rate we identified was not significantly different from previously reported rates. Secondly, we assessed osteolysis on plain radiographs, which might have underestimated its extent. Computed tomography provides a more specific assessment of osteolysis. Lastly, we used only a 22.225-mm femoral head, which is the smallest femoral head component available. The size of the femoral head may affect the amount of wear debris, with some studies reporting an increase in volumetric wear rate with larger femoral head components.¹⁴ However, based on the analysis of 6 national and regional registries, Allepuz et al.¹⁵ did not identify significant differences in the rate of revision for different femoral head sizes. Therefore, the effect of femoral head size on HXLPE wear and clinical results still appears to be controversial. However, our results indicate that a larger size of femoral head with thinner HXLPE sockets can be effectively used to minimize the risk of implant dislocation.

Conflict of interest

The authors have none to declare.

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