FEMORAL HEAD PENETRATION RATES OF SECOND GENERATION SEQUENTIALLY ANNEALED HIGHLY CROSS-LINKED POLYETHYLENE AT MINIMUM FIVE YEARS

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Abstract

Background: Highly cross-linked polyethylene (HXLPE) liners in total hip arthroplasty (THA) have demonstrated decreased wear rates, resilience to cup orientation, and reduced osteolysis compared to conventional polyethylene. Sequential irradiation and annealing below the melting temperature is unique compared to most HXLPE which is irradiated and remelted. This study purpose was to provide minimum five-year femoral head penetration rates of sequentially annealed HXLPE in primary THA.

Methods: A retrospective review of a prospectively collected database identified 198 consecutive, cementless primary THAs utilizing sequentially annealed HXLPE (X3™, Stryker, Mahwah, NJ). Operative technique was standardized. Radiographs were analyzed utilizing the Martell method with minimum five-year and one-year radiographs as baseline to minimize the initial bedding-in period.

Results: Seventy-seven hips with minimum five-year follow-up were analyzed. Mean steady-state linear and volumetric head penetration rates were 0.095 mm/year and 76 mm$^3$/year. Volumetric head penetration was significantly less for 32mm compared to 36mm ($p=0.028$). In addition, less head penetration was observed for ceramic 32mm heads at nearly half the rate compared to CoCr 36mm heads ($p\geq0.092$). No correlations existed between penetration rates and age, BMI, UCLA Activity Level, polyethylene thickness, cup inclination or anteversion ($p\geq0.10$). No radiographic osteolysis was observed.

Conclusion: Surprisingly, linear head penetration rates of sequentially annealed HXLPE were nearly identical to the osteolysis threshold for conventional polyethylene and greater than reports of irradiated and remelted HXLPE. Further, this data corroborates reports that HXLPE is resilient to cup orientation and demographic variables. Longer term follow-up is recommended.

Keywords: total hip arthroplasty, femoral head penetration, bearing wear, highly cross-linked polyethylene
FEMORAL HEAD PENETRATION RATES OF SECOND GENERATION
SEQUENTIALLY ANNEALED HIGHLY CROSS-LINKED POLYETHYLENE
AT MINIMUM FIVE YEARS

Introduction

Historically, long-term success in total hip arthroplasty (THA) has been limited by implant loosening and late failure caused by osteolysis at the bone-implant interface due to third-body wear particles of conventional polyethylene. [1-5] The historical critical threshold for osteolysis in conventional polyethylene is approximately 0.1 mm/year. Some observe this value as the critical threshold and a direct indicator for increased osteolysis, [6-10] while others use it purely for practical purposes [6] and still others reject this threshold due to the evidence of osteolysis being present regardless of the cohort’s wear rates. [7, 8, 11] Over the past two decades, advancements in polyethylene cross-linking and sterilization methods have made possible irradiated and remelted highly cross-linked polyethylene (HXLPE) which has shown improved tribological properties in biomechanical testing [12-14] compared to conventional polyethylene along with encouraging early and mid-term clinical results. [15-18]

Conflicting evidence has been reported for the effect of femoral head size on the amount of wear particles generated for irradiated and remelted HXLPE. [15, 19-22] In theory, the amount of wear particles increase as the femoral head size increases due to a larger sliding distance producing more polyethylene particles per gait cycle. Further confounding the issue is a paucity of definitive data regarding the effect of femoral head material on true wear and femoral head penetration; although some data suggest ceramic heads have better performance in vitro [23] and in vivo [24] compared to cobalt-chromium (CoCr) heads. [25, 26] Further, conflicting data also exist for the effect of implant position on polyethylene wear rates as it may be different for conventional polyethylene and HXLPEs. [27-30]
Recently, a sequential annealing process for HXLPE has been introduced with promising tribological and early clinical results compared to irradiated and remelted HXLPE. [31-39] Few studies to date have reported the effect of femoral head material, femoral head size, and implant position on wear, creep and head penetration rates for this sequentially annealed HXLPE. The purpose of this study was to report minimum five-year femoral head penetration rates of sequentially annealed HXLPE in primary THA and the effect of femoral head size and material.

**Methods**

A retrospective review of a prospectively collected database identified 198 consecutive, cementless primary THAs utilizing sequentially annealed HXLPE (X3™, Stryker Orthopaedics, Mahwah, NJ). Institutional review board (IRB) approval was obtained for this study. All surgeries were performed from October 2010 to October 2013 and utilized a modern posterior approach. All patients received either a ceramic or CoCr femoral head of size 32mm, 36mm or 40mm. In addition, all patients received a porous titanium acetabular cup ranging from 50mm to 62mm. Of the 198 sequentially annealed HXLPE liners, there was only one dislocation six weeks postoperatively, resolved by closed reduction and no recurrence of instability since then. The single dislocation was included in the analysis group as the head penetration rates were comparable to the rest of the cohort.

**Demographic data**

Electronic medical records (EMR) were used to collect all demographic data (age, height, weight, gender, months of follow-up, etc.) along with implant characteristics for each case (femoral head material and size and acetabular component type and size). These implant characteristics were recorded from the EMR for each case via a scanned document of the implant manufacturer labels.
Femoral Head Penetration

Femoral head penetration measured on radiographs was used as a surrogate for characterizing true abrasive wear due to this type of wear requiring a retrieval and physical measurement of the polyethylene liner. Femoral head penetration is a standard measurement technique throughout the orthopaedic literature to characterize wear even though it encompasses both true abrasive wear and creep without a clear differentiation between the two.

Standard anteroposterior (AP) non-weight bearing radiographs were used for linear and volumetric femoral head penetration measurements using the Hip Analysis Suite software (Martell methodology). Non weight-bearing radiographs accurately represent linear head penetration due to the muscular contraction and capsular tension maintaining the femoral head in a completely reduced position within the polyethylene liner. Also, only AP radiographs were used for this study due to the “lateral” radiograph at our institution not being a true lateral view but rather a modified Lowenstein view. Optimal views of the femoral head and acetabular cup were used for head penetration analysis by optimizing radiograph contrast in the digital radiograph database (PACS, Fujifilm Global). If either of the components could not be clearly identified, the radiograph was excluded from analysis. The radiographs were then extracted from the digital radiograph database and imported into ImageJ (imagej.nih.gov) to convert the image file format from .PNG to 8-bit .TIFF format to be readable by the Hip Analysis Suite software as per standardized and software-specific instructions and protocol.

The most recent radiograph (minimum of five-year follow-up) was uploaded into the Hip Analysis Suite software where the distal-most part of the ischial tuberosities were identified. The femoral head size was identified within the system and used to calibrate each radiograph. Next, the acetabular cup position was identified within the system. Next, the baseline radiograph
(the one-year follow-up radiograph) was uploaded and the process described was repeated for
identifying the THA components. Following the identification of the bony landmarks and
radiopaque THA components in both radiographs, the Hip Analysis Suite software calculated the
linear head penetration (in mm) indicated by a vector on the radiograph (Figure 1), the
volumetric head penetration (in mm$^3$), the acetabular cup inclination (in degrees) on the frontal
plane and acetabular cup anteversion (in degrees) on the transverse plane.

For each patient, linear and volumetric femoral head penetration, acetabular cup
inclination and acetabular cup anteversion data were collected between one-year and five-year
radiographs with the one-year radiograph as the baseline. The one-year radiograph was used as
the baseline for all head penetration measurements to eliminate the possible bias of the bedding-
in phenomenon that occurs during the first year and could subsequently elevate head penetration
rates. Once the total linear head penetration (in mm) was calculated by the Hip Analysis Suite
software, the \textit{in situ} implantation time between the two radiographs of interest was divided into
the total linear head penetration to obtain a linear head penetration rate (in mm/year). The same
methodology was applied to calculate the volumetric head penetration rate (in mm$^3$/year).

These data were measured and recorded on three separate measurements by one
independent rater. Discrepancies greater than 2mm between any of the three linear
measurements were resolved. Average head penetration values less than zero were converted to
a ‘0’ value to prevent a false deflation of the head penetration rate by the negative number which
is common practice in polyethylene wear studies reported in the peer-reviewed literature.

\textit{Patient-reported Outcome Measures}

Patient-reported outcomes (PROMs) were evaluated at minimum one-year
postoperatively. Although all inclusions had radiographs at minimum five years, the completion
of PROM questionnaires was not always completed at five-years; therefore, minimum one-year PROMs were analyzed to increase the data response rate. The PROMs utilized were the University of California Los Angeles (UCLA) Activity Level Score and the Likert Satisfaction Scale. The University of California Los Angeles (UCLA) Activity Level Score [40, 41] ask patients to choose their highest level of current activity, ranging from 0 (Wholly Inactive: dependent upon others, cannot leave residence) to 10 (Regularly participate in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor, or backpacking). The Likert Satisfaction questionnaire is a single question asking a patient “What is your current level of satisfaction with your hip replacement surgery?” Answers range from Very Satisfied (1) to Very Dissatisfied (5).

Statistical Analysis

All statistical analyses were performed in Minitab® 18 (State College, PA). Outliers were assessed with a form of Dixon’s outlier test based on the size of the cohort. Data were tested for normality using the Anderson-Darling (AD) normality test. Normally distributed continuous variables of two groups were analyzed with Student’s two-sample t-test (T) while non-normally distributed continuous variables of two groups were compared with the Mann-Whitney (W) test adjusted for ties. Normally distributed continuous variables of three or more groups were compared with a one-way Analysis of Variance (ANOVA, F) while non-normally distributed continuous variables of three or more groups were compared with the Kruskal-Wallis (H) test adjusted for ties. Pearson’s Chi-Square (X²) test was used to test independence among categorical variables, with Fisher’s exact test p values reported for 2 x 2 contingency tables. Pearson (r) correlation coefficient was used to describe the relationship between normally
distributed variables while Spearman rho ($\rho$) correlation coefficient was used for non-normally
distributed variables. A significance level of 0.05 was used for all statistical analyses.

**Results**

Of the 198 sequentially annealed HXLPE liners, there were 31 exclusions: 13 dual
mobility prostheses, five deceased unrelated to the index procedure prior to five-year follow-up,
four early peri-prosthetic infections, three ceramic-on-ceramic THAs, two cases utilizing a direct
anterior approach, two recurrent instability cases, one conversion with distorted anatomy and one
Charcot joint. There were an additional 90 cases missing radiographs: 56 cases were missing a
one-year radiograph and 34 were missing a minimum five-year radiograph. While a substantial
amount of patients were missing radiographs, the inclusion and exclusion patient populations
were similar on demographics of age (median 61.6 v. 59.5, $W = 6843.0$, $p = 0.229$), body mass
index (BMI; median 29.7 v. 30.8, $W = 6320.0$, $p = 0.636$) and gender proportions (48% female v.
61% female, $X^2 = 2.9$, $p = 0.09$).

**Demographics**

Seventy-seven hips (72 patients) with the same sequentially annealed HXLPE obtained
minimum five-year follow-up and were analyzed. Osteoarthritis was the primary or secondary
diagnosis for 94% of the cohort. No radiographic osteolysis was observed in any patient even
though 48% of patients had a linear head penetration rate above the conventional polyethylene
osteolysis threshold (0.10 mm/year). One case was revised for aseptic loosening and fibrous
ingrowth of the acetabular component. Patient demographics were typical for a THA patient
population (Table 1).

The overall median linear and volumetric head penetration rates were 0.089 mm/year
(mean 0.095 ± 0.080, CI 0.077 - 0.113) and 78 mm³/year (mean 76 ± 66, CI 61 – 91) through
minimum five-year follow-up, respectively. Overall, linear and volumetric head penetration rates did not correlate with age, height, weight, BMI ($p \geq 0.10$) or differ by sex ($p \geq 0.16$). Linear and volumetric head penetration rates also did not correlate with acetabular cup inclination, acetabular cup anteversion, nominal polyethylene thickness specified by manufacturer dimensions, or UCLA Activity Level scores ($p \geq 0.17$). Twenty-six percent (20/77) of hips had values that were converted to zero due to negative head penetration. This conversion to a zero value represented the worst case scenario for head penetration as the negative values (when included with analysis) significantly lowered the mean head penetration rates.

**Femoral Head Size**

THAs were compared based on groups defined by the size of the femoral head (Figure 2). There was only one 40mm head so it was excluded from this sub-analysis. The two analysis groups consisted of twenty-four 32mm heads and fifty-two 36mm heads. The two groups did not differ by age, BMI, implant characteristics, acetabular cup position or PROMs (Table 2, $p \geq 0.127$); however, there was a significant difference for the proportion of females to males for the 32mm group as 100% were females compared to only 44% female for the 36mm group (Table 2, $X^2 = 21.6, p \leq 0.001$).

32mm femoral heads showed a lower median linear head penetration rate at 0.070 mm/year (mean 0.075 ± 0.069, CI 0.046 – 0.104) compared to the 36mm head penetration rate of 0.113 mm/year (mean 0.106 ± 0.084, CI 0.083 – 0.129), yet this difference was not statistically different (Figure 2a, $W = 797.0, p = 0.154$). Similarly, volumetric head penetration rates were lower for 32mm heads (median 35 and mean 50 ± 48 mm$^3$/year, CI 29 - 70) compared to 36mm
heads (median 100 and mean $89 \pm 70 \text{ mm}^3/\text{year}$, CI $70 - 109$) but with statistical significance (Figure 2b; $W = 728.0$, $p = 0.028$).

**Femoral Head Material**

THAs were compared based on groups defined by the material of the femoral head (Figure 3). The two analysis groups consisted of 67 ceramic heads and 10 CoCr heads. The two groups did not differ by demographics, implant characteristics, acetabular cup position or PROMs (Table 3, $p \geq 0.300$).

The ceramic femoral heads showed a lower median linear head penetration rate at 0.083 mm/year (mean $0.092 \pm 0.083$ CI $0.072 - 0.112$) compared to the CoCr penetration rate of 0.142 mm/year (mean $0.115 \pm 0.060$ CI $0.072 - 0.158$) although it did not reach statistical significance (Figure 3a; $W = 2533.5$, $p = 0.227$). Similar results were found for volumetric head penetration rates comparing ceramic heads (median 66 mm$^3$/year and mean $73 \pm 68$, CI $57 - 90$) to CoCr heads (median 104 mm$^3$/year and mean $92 \pm 52$, CI $55 - 129$) with no statistical significance (Figure 3b; $W = 2538.5$, $p = 0.258$).

**Femoral Head Size and Material**

Interestingly, a breakdown of THAs by femoral head size and material showed a consistent trend for 32mm ceramic heads to have the lowest linear and volumetric head penetration rates followed by the 36mm CoCr heads with the highest linear and volumetric head penetration rates, (Figure 4). These four groups did not differ by age, BMI, implant characteristics or acetabular cup position (Table 4, $p \geq 0.381$); however, there was a significant difference in the proportion of females to males within the groups as both ceramic 32mm heads and CoCr 32mm heads were all...
female (Table 4, $X^2 = 23.1$, $p \leq 0.001$). The comparisons of UCLA Activity Level and Satisfaction scores were invalid due to low cell counts.

The median linear head penetration rate was 0.065 mm/year (mean 0.070 ± 0.067, CI 0.038 - 0.101) for 32mm ceramic heads, 0.099 mm/year (mean 0.104 ± 0.088, CI 0.078 – 0.130) for 36mm ceramic heads, 0.118 mm/year (mean 0.103 ± 0.083, CI -0.030 – 0.235) for 32mm CoCr heads, and 0.142 mm/year (mean 0.124 ± 0.046, CI 0.076 – 0.171) for 36mm CoCr heads (Figure 4a).

A similar trend was followed for the volumetric head penetration rates: 34 mm$^3$/year (mean 46 ± 47, CI 24 – 67) for 32mm ceramic heads, 71 mm$^3$/year (mean 69 ± 57, CI -21 – 160) for 32mm CoCr heads, 98 mm$^3$/year (mean 87 ± 73, CI 65 – 108) for 36mm ceramic heads, and 107 mm$^3$/year (mean 107 ± 47, CI 57 – 156) for 36mm CoCr heads (Figure 4b). There was no statistical differences between the four groups for linear ($H = 3.67$, $p = 0.299$) or volumetric ($H = 6.44$, $p = 0.092$) head penetration rates; however, the head penetration rates of the larger 36mm CoCr head were always at least twice the rate of the smaller 32mm ceramic head.

Discussion

Highly cross-linked polyethylene has been a dramatic improvement over conventional polyethylene in THA and has ushered in a new era of implant longevity, durability and survivorship through a decrease in wear-related osteolysis during the first in-vivo decade. The steady-state linear head penetration rates of conventional polyethylene range from a mean of 0.05 to 0.20 mm/year with the majority of studies using CoCr heads and 26mm or 28mm sizes. [42-48] Lee et al. compared CoCr heads of 26mm and 32mm and reported higher four-year mean linear head penetration rates (not significant) for the 32mm heads (0.20 mm/year v. 0.15 mm/year). [43] CoCr heads of 28mm have been reported with mid-term head penetration rates
as low as a mean of 0.05 mm/year and median of 0.04 mm/year. [44, 45] However, the majority of studies report conventional polyethylene head penetrations above the historical osteolysis threshold of 0.10 mm/year leading to late failure. [42, 43, 48]

HXLPE has demonstrated an order of magnitude improvement in wear compared to conventional polyethylene. Studies comparing head penetration rates of conventional polyethylene to irradiated and remelted HXLPE (Longevity®, Zimmer Biomet, Warsaw, IN) have shown a substantial reduction in head penetration for this particular HXLPE. Fukui et al. compared irradiated and remelted HXLPE to conventional polyethylene at mid-term follow-up with 26mm zirconia femoral heads and reported head penetration rates of mean 0.068 mm/year for conventional and 0.01 mm/year for HXLPE. [47] However, Takada et al. reported head penetration rates (0.032 mm/year) for irradiated and remelted HXLPE to be lower than conventional polyethylene wear rates with 26mm CoCr heads at 8.2 years follow-up. [49] In contrast, Schroder and colleagues found no differences in wear damage from retrieved conventional polyethylene and retrieved irradiated and remelted HXLPE. [50] Higher wear damage scores from plastic deformation were associated with the HXLPE compared to conventional (0.4 v. 0.3). [50] Further, high levels of plastic deformation occurring in vivo could explain the elevated head penetration rates observed in our series. [23, 50-52]

The annealed HXLPEs also have reported substantial tribological improvements compared to conventional polyethylene in addition to a possible resilience to cup orientation with no effect of polyethylene thickness on the head penetration rates [30] which has been reported to affect head penetration for conventional polyethylene. [43, 53] The series reported here of sequentially annealed HXLPE liners corroborate these resilience findings as no correlations of cup orientation and polyethylene thickness with head penetration were observed.
Further, a controversial topic is the argument for [54-58] or against [30, 59-63] the effect of the polyethylene thickness on the plastic deformation and wear occurring in THA and conclusive evidence is lacking. Polyethylene thickness in this series did not correlate with linear or volumetric head penetration rates for this sequentially annealed HXLPE \( (p \geq 0.40) \). Retrieval analyses would be required to confirm the amount of true abrasive wear, the wear path characterization and the amount of plastic deformation in these bearings.

For the overwhelming majority of studies, once-annealed HXLPE (Crossfire®, Stryker Orthopaedics, Mahwah, NJ) has shown at least equivalent steady-state head penetration rates to irradiated and remelted HXLPE. [49] A study conducted by D’Antonio et al. at 12.2 years follow-up, reported mean linear penetration rates of 0.018 mm/year for this once-annealed HXLPE with CoCr 28mm heads. [64] Similar results were reported by Capello et al. with 8-year follow-up on CoCr 28mm heads for once-annealed HXLPE (0.031 mm/year). [48] Takada et al. compared head penetration rates of irradiated and remelted HXLPE (0.032mm/year) and once-annealed HXLPE (0.031 mm/year) using all 26mm CoCr heads at 8.2 years follow-up and showed equivalent head penetration rates [49] which corroborate previous studies with different femoral head sizes, materials and polyethylene thickness. [48, 64] Still, Snir and colleagues found the wear rate at 10 years for this once-annealed polyethylene bearing against a 28mm CoCr head to be 0.122 mm/year but drop to 0.05 mm/year beyond the bedding-in period of 2-3 years. [65] A follow-up study conducted with this same cohort up to 18 years found the steady-state wear rate to remain at about 0.05 mm/year. [66]

Based on our data, it appears that sequentially annealed HXLPE may not perform as well as irradiated and remelted HXLPE in vivo with respect to linear head penetration. Fukui et al. compared irradiated and remelted HXLPE to conventional polyethylene at mid-term follow-up.
with 26mm zirconia femoral heads and reported head penetration rates of mean 0.068 mm/year for conventional and 0.01 mm/year for HXLPE. [47] Our data reported here show our lowest head penetration rate for 32mm ceramic heads (0.065mm/year) to be nearly identical to the conventional polyethylene (0.068mm/year) and nearly seven times larger than the irradiated and remelted HXLPE rate (0.01mm/year). Further, Takada et al. reported head penetration rates (0.032 mm/year) for irradiated and remelted HXLPE with 26mm CoCr heads at 8.2 years follow-up. [49] This linear rate for irradiated and remelted HXLPE is close to half of the rate observed in this study for 32mm ceramic heads (0.065 mm/year) and significantly lower compared to this study’s linear rates for CoCr heads (32mm and 36mm) - 0.118 and 0.142 mm/year, respectively.

Despite the larger than expected steady-state head penetration in sequentially annealed HXLPE reported in our series (Figure 4a, mean 0.104 mm/year), others have reported similar wear rates. [35, 67] Nearly identical head penetration rates for the same sequentially annealed HXLPE, femoral head size (36mm) and ceramic femoral head material were reported by Selvarajah et al. (mean 0.109 mm/year) with similar radiographic follow-up using the one-year radiograph as baseline to eliminate the bias of bedding-in. [35] Sodhi et al. recently reported two-dimensional linear head penetration of 23 THAs at five-year follow-up via the Martell method. [67] The authors report an overall five-year mean linear wear rate of 0.096 mm/year. [67] These studies corroborate our results presented in this manuscript and further support the need to follow these patients in the longer term.

In our series, ceramic femoral heads showed lower head penetration rates as Rajpura et al., [68] suggesting there may be an advantage to using ceramic femoral heads in primary THA with this particular sequentially annealed bearing surface. 32mm heads (all-comers regardless of femoral head material) showed lower linear head penetration rates (0.070 mm/year v. 0.113 mean linear wear rate of 0.096 mm/year. [67] These studies corroborate our results presented in this manuscript and further support the need to follow these patients in the longer term.
mm/year) and significantly lower volumetric head penetration rates (35 mm³/year v. 100 mm³/year) compared to 36mm heads of either material possibly due to the decreased sliding distance for the smaller femoral head. [22] In addition, all 32mm femoral heads were implanted into females due to the generally smaller female anatomy; however no differences were observed in linear (W = 1807.0, p = 0.79) or volumetric (W = 1700.0, p = 0.16) head penetration rates between females and males.

This study had limitations. First, measurements were recorded from radiographs only. The temporal and mechanical property distribution between plastic deformation and true abrasive wear in HXLPE bearings is unknown and would require long-term retrieval studies to examine the amount of plastic deformation which occurred. The total head penetration is thought to be a combination of the true wear plus the plastic deformation that can occur up to three-years postoperatively for HXLPEs reported in the literature. [51, 52, 66, 69-71] Another limitation to the study is only using AP radiographs to evaluate volumetric head penetration. More accurate volumetric head penetration would have required lateral radiographs in combination with the AP view. One other limitation to this study was acetabular component inclination being slightly elevated compared to the “target” angle of 45 degrees. However, there are data to support that no adverse effect on wear has been observed with acetabular component malposition with HXLPE liners. [30] Another limitation to this study was the exclusion of a large majority of cases due to loss of radiographic follow-up after surgery; however, our cohort is of comparable size to the majority of penetration/wear studies reported in the literature in addition to the exclusions and inclusions having statistically similar demographics (p ≥ 0.09). Lastly, as a limitation, although UCLA Activity Level was not correlated with head penetration rates in this cohort (ρ = -0.160, p = 0.170), unknown elevated activity levels could explain the
elevated penetration rates observed in this study although the patient cohort is older and generally less active.

Our five-year mid-term data reveal surprising qualitative and quantitative information of femoral head penetration behavior in sequentially annealed HXLPE for two femoral head sizes (32mm and 36mm) of ceramic and CoCr femoral head materials. The linear head penetration rates for this sequentially annealed HXLPE were higher than reports for irradiated and remelted HXLPE and were nearly identical to the osteolysis threshold for conventional polyethylene. Longer term follow-up is recommended as femoral head penetration and retrieval studies at ten years and beyond will provide useful information about the plastic deformation, wear-path, and long-term survivorship of this particular sequentially annealed polyethylene acetabular liner.
References


68. Rajpura, A., et al., A 28-year clinical and radiological follow-up of alumina ceramic-on-crosslinked polyethylene total hip arthroplasty: a follow-up report and analysis of the


Table 1. Overall patient demographics.

<table>
<thead>
<tr>
<th></th>
<th>n = 77</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
<th>Median</th>
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<tr>
<td>Age (years)</td>
<td>60.6</td>
<td>13.1</td>
<td>13.1</td>
<td>57.6 – 63.6</td>
<td>61.6</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>30.2</td>
<td>5.7</td>
<td>5.7</td>
<td>29.0 – 31.5</td>
<td>29.7</td>
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<tr>
<td>Cup Inclination (°)</td>
<td>54.6</td>
<td>6.4</td>
<td>6.4</td>
<td>53.2 – 56.1</td>
<td>55.1</td>
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<tr>
<td>Cup Anteversion (°)</td>
<td>19.4</td>
<td>4.4</td>
<td>4.4</td>
<td>18.4 – 20.3</td>
<td>19.3</td>
</tr>
<tr>
<td>Poly Thickness (mm)</td>
<td>6.2</td>
<td>0.9</td>
<td>0.9</td>
<td>6.0 – 6.4</td>
<td>5.9</td>
</tr>
<tr>
<td>Follow-up (months)</td>
<td>63.4</td>
<td>7.3</td>
<td>7.3</td>
<td>61.7 – 65.0</td>
<td>61.6</td>
</tr>
<tr>
<td>% Female</td>
<td>61%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>% Ceramic</td>
<td>87%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>% 32mm</td>
<td>31%</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>% Satisfied</td>
<td>93%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>% &gt;5 UCLA Score</td>
<td>59%</td>
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SD, standard deviation  
kg, kilogram  
mm, millimeter  
CI, confidence interval
Table 2. Demographic breakdown by femoral head size.

<table>
<thead>
<tr>
<th></th>
<th>32mm</th>
<th>36mm</th>
<th>Test Statistic</th>
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<tr>
<td>N</td>
<td>24</td>
<td>52</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Age (years)</td>
<td>63.3</td>
<td>61.6</td>
<td>W = 934.0</td>
<td>0.915</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.6 SD 5.9</td>
<td>29.8 SD 5.3</td>
<td>T = 0.52</td>
<td>0.604</td>
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<tr>
<td>% Female</td>
<td>100</td>
<td>44</td>
<td>X² = 21.6</td>
<td>≤ 0.001</td>
</tr>
<tr>
<td>Cup Inclination (°)</td>
<td>55.5 SD 6.4</td>
<td>54.0 SD 6.1</td>
<td>T = 1.00</td>
<td>0.322</td>
</tr>
<tr>
<td>Cup Anteversion (°)</td>
<td>20.0 SD 4.2</td>
<td>19.0 SD 4.5</td>
<td>T = 0.97</td>
<td>0.339</td>
</tr>
<tr>
<td>Poly Thickness (mm)</td>
<td>5.9</td>
<td>5.9</td>
<td>W = 856.0</td>
<td>0.277</td>
</tr>
<tr>
<td>% Ceramic</td>
<td>83</td>
<td>88</td>
<td>X² = 0.4</td>
<td>0.716</td>
</tr>
<tr>
<td>% Satisfied</td>
<td>91</td>
<td>94</td>
<td>X² = 0.2</td>
<td>0.647</td>
</tr>
<tr>
<td>% &gt;5 UCLA Score</td>
<td>43</td>
<td>65</td>
<td>X² = 2.9</td>
<td>0.127</td>
</tr>
</tbody>
</table>

W, Mann-Whitney
T, Two Sample T-Test
X², Chi-square Test
p, p-value

One case utilized a 40mm femoral head and was removed from this analysis.
The 32mm and 36mm groups consisted of all-comers with ceramic and CoCr femoral head material.
<table>
<thead>
<tr>
<th></th>
<th>Ceramic</th>
<th>CoCr</th>
<th>Test Statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>67</td>
<td>10</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Age (years)</td>
<td>61.6</td>
<td>63.2</td>
<td>W = 2593.0</td>
<td>0.768</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.3 SD 5.7</td>
<td>30.0 SD 5.8</td>
<td>T = 0.12</td>
<td>0.906</td>
</tr>
<tr>
<td>% Female</td>
<td>58</td>
<td>80</td>
<td>X² = 1.7</td>
<td>0.300</td>
</tr>
<tr>
<td>Cup Inclination (°)</td>
<td>54.9 SD 6.4</td>
<td>53.2 SD 6.1</td>
<td>T = 0.81</td>
<td>0.433</td>
</tr>
<tr>
<td>Cup Anteversion (°)</td>
<td>19.3 SD 4.5</td>
<td>19.4 SD 4.0</td>
<td>T = 0.07</td>
<td>0.943</td>
</tr>
<tr>
<td>Poly Thickness (mm)</td>
<td>5.9</td>
<td>5.9</td>
<td>W = 2576.0</td>
<td>0.434</td>
</tr>
<tr>
<td>% 32mm</td>
<td>30</td>
<td>40</td>
<td>invalid²</td>
<td>invalid²</td>
</tr>
<tr>
<td>% Satisfied</td>
<td>92</td>
<td>100</td>
<td>X² = 0.742</td>
<td>1.000</td>
</tr>
<tr>
<td>% &gt;5 UCLA Score</td>
<td>58</td>
<td>63</td>
<td>X² = 0.054</td>
<td>1.000</td>
</tr>
</tbody>
</table>

The ceramic and CoCr groups consisted of all-comers with 32mm, 36mm and 40mm femoral head sizes.

¹The invalid chi-square test was due to low cell counts.
Table 4. Demographic breakdown by femoral head size and material.

<table>
<thead>
<tr>
<th></th>
<th>32mm Ceramic</th>
<th>36mm Ceramic</th>
<th>32mm CoCr</th>
<th>36mm CoCr</th>
<th>Test Statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20</td>
<td>46</td>
<td>4</td>
<td>6</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Age (years)</td>
<td>60.9</td>
<td>61.6</td>
<td>64.7</td>
<td>61.3</td>
<td>H = 0.1</td>
<td>0.994</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.8 SD 6.0</td>
<td>29.7 SD 5.3</td>
<td>29.3 SD 6.0</td>
<td>30.5 SD 6.2</td>
<td>F = 0.21</td>
<td>0.889</td>
</tr>
<tr>
<td>% Female</td>
<td>100&lt;br&gt;</td>
<td>41&lt;br&gt;</td>
<td>100&lt;br&gt;</td>
<td>67&lt;br&gt;</td>
<td>X² = 23.1</td>
<td>≤ 0.001</td>
</tr>
<tr>
<td>Cup Inclination (°)</td>
<td>55.3 SD 6.9</td>
<td>54.4 SD 6.0</td>
<td>56.8 SD 1.9</td>
<td>50.7 SD 6.9</td>
<td>F = 1.04</td>
<td>0.381</td>
</tr>
<tr>
<td>Cup Anteversion (°)</td>
<td>19.6 SD 4.3</td>
<td>19.2 SD 4.6</td>
<td>22.2 SD 3.5</td>
<td>17.6 SD 3.3</td>
<td>F = 0.92</td>
<td>0.435</td>
</tr>
<tr>
<td>Poly Thickness (mm)</td>
<td>5.9</td>
<td>5.9</td>
<td>5.9</td>
<td>5.9</td>
<td>H = 2.69</td>
<td>0.443</td>
</tr>
<tr>
<td>% Satisfied</td>
<td>89</td>
<td>93</td>
<td>100</td>
<td>100</td>
<td>invalid¹</td>
<td>invalid¹</td>
</tr>
<tr>
<td>% &gt;5 UCLA Score</td>
<td>50</td>
<td>61</td>
<td>0</td>
<td>100</td>
<td>invalid¹</td>
<td>invalid¹</td>
</tr>
</tbody>
</table>

H, Kruskal-Wallis
F, One-way ANOVA

One case utilized a 40mm femoral head and was removed from this analysis.
¹The invalid chi-square test was due to low cell counts.
Median Linear Head Penetration Rate, mm/year

- Ceramic: 0.083
- Cobalt-Chromium: 0.142

\[ p = 0.227 \]

Median Volumetric Head Penetration Rate, mm³/year

- Ceramic: 66
- Cobalt-Chromium: 104

\[ p = 0.258 \]
Figure Legend

Figure 1. Hip Analysis Suite output showing the identified femoral head, acetabular cup position and femoral head penetration vector calculated between the one-year baseline and the minimum five-year radiographs.

Figure 2. Median (a) linear and (b) volumetric head penetration rates for 32mm and 36mm femoral heads. The 32mm heads had lower head penetration rates through minimum five year follow-up.

Figure 3. Median (a) linear and (b) volumetric head penetration rates for ceramic and CoCr femoral heads. The ceramic heads had lower head penetration rates through minimum five year follow-up.

Figure 4. Median (a) linear and (b) volumetric head penetration rates by femoral head material and size. 32mm ceramic heads consistently had the lowest head penetration rates followed by the 36mm CoCr heads with the highest head penetration rates.
Source of Funding

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