ACCEPTED MANUSCRIPT

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

Evan R. Deckard BSE,[1] R. Michael Meneghini MD[1,2]

[1] Indiana University School of Medicine, Department of Orthopaedic Surgery, 1120 W. Michigan Street, Room 600, Indianapolis, IN 46202

[2] Indiana University Health Physicians, Orthopedics & Sports Medicine, IU Health Hip & Knee Center, 13100 East 136th Street, Suite 2000, Fishers, IN 46037

Corresponding Author:
R. Michael Meneghini, MD
Indiana University Health Physicians Orthopedics and Sports Medicine
Indiana University School of Medicine, Department of Orthopaedic Surgery
13100 East 136th Street
Suite 2000
Fishers, IN, USA 46037
Phone: 317-688-5980
Email: rmeneghi@iuhealth.org

ACCEPTED MANUSCRIPT

This is the author's manuscript of the article published in final edited form as:
Deckard, E. R., & Meneghini, R. M. (2018). Femoral Head Penetration Rates Of Second Generation Sequentially Annealed Highly Cross-Linked Polyethylene At Minimum Five Years. The Journal of Arthroplasty. https://doi.org/10.1016/j.arth.2018.12.004

ACCEPTED MANUSCRIPT

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

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*≥0.092). No correlations existed between penetration rates and age, BMI, UCLA Activity Level, polyethylene thickness, cup inclination or anteversion (p≥0.10). 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

ACCEPTED MANUSCRIPT

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.

ACCEPTED MANUSCRIPT

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

ACCEPTED MANUSCRIPT

(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 *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.

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

ACCEPTED MANUSCRIPT

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 (X^2) 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

ACCEPTED MANUSCRIPT

distributed variables while Spearman rho (ρ) 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 mm^3/year (mean 76 ± 66, CI 61 – 91) through

ACCEPTED MANUSCRIPT

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

ACCEPTED MANUSCRIPT

heads (median 100 and mean 89 ± 70 mm^3/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 ± 0.083 CI 0.072 – 0.112) compared to the CoCr penetration rate of 0.142 mm/year (mean 0.115 ± 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 ± 68, CI 57 – 90) to CoCr heads (median 104 mm^3/year and mean 92 ± 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

ACCEPTED MANUSCRIPT

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

ACCEPTED MANUSCRIPT

($p \geq 0.40$). 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

ACCEPTED MANUSCRIPT

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 0.104mm/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 0.109mm/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 0.096mm/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

ACCEPTED MANUSCRIPT

mm/year) and significantly lower volumetric head penetration rates (35 mm^3/year v. 100 mm^3/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 ($p \geq 0.09$). Lastly, as a limitation, although UCLA Activity Level was not correlated with head penetration rates in this cohort ($\rho = -0.160$, $p = 0.170$), unknown elevated activity levels could explain the

ACCEPTED MANUSCRIPT

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.

ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT

References

1. Engh, C.A., Jr., et al., *A randomized prospective evaluation of outcomes after total hip arthroplasty using cross-linked marathon and non-cross-linked Enduron polyethylene liners.* J Arthroplasty, 2006. **21**(6 Suppl 2): p. 17-25.
2. Cooper, R.A., et al., *Polyethylene debris-induced osteolysis and loosening in uncemented total hip arthroplasty. A cause of late failure.* J Arthroplasty, 1992. **7**(3): p. 285-90.
3. Ollivere, B., et al., *Current concepts in osteolysis.* J Bone Joint Surg Br, 2012. **94**(1): p. 10-5.
4. Hirakawa, K., et al., *Mechanisms of failure of total hip replacements: lessons learned from retrieval studies.* Clin Orthop Relat Res, 2004(420): p. 10-7.
5. Harris, W.H., *Wear and periprosthetic osteolysis: the problem.* Clin Orthop Relat Res, 2001(393): p. 66-70.
6. Dumbleton, J.H., M.T. Manley, and A.A. Edidin, *A literature review of the association between wear rate and osteolysis in total hip arthroplasty.* J Arthroplasty, 2002. **17**(5): p. 649-61.
7. Wroblewski, B.M. and P.D. Siney, *Charnley low-friction arthroplasty in the young patient.* Clin Orthop Relat Res, 1992(285): p. 45-7.
8. Sochart, D.H., *Relationship of acetabular wear to osteolysis and loosening in total hip arthroplasty.* Clin Orthop Relat Res, 1999(363): p. 135-50.
9. Dowd, J.E., et al., *Characterization of long-term femoral-head-penetration rates. Association with and prediction of osteolysis.* J Bone Joint Surg Am, 2000. **82-a**(8): p. 1102-7.
10. McKellop, H.A., T.M. Wright, and S.B. Goodman, *What Evidence is There for Using Alternative Bearing Materials?*, in *Implant Wear in Total Joint Replacement*. 2001, American Academy of Orthopaedic Surgeons. p. 206-215.
11. Harris, W.H., *"The lysis threshold": an erroneous and perhaps misleading concept?* J Arthroplasty, 2003. **18**(4): p. 506-10.
12. Estok, D.M., et al., *Comparison of Hip Simulator Wear of 2 Different Highly Cross-linked Ultra High Molecular Weight Polyethylene Acetabular Components Using Both 32- and 38-mm Femoral Heads.* J Arthroplasty, 2007. **22**(4): p. 581-589.
13. Muratoglu, O.K., et al., *A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award.* J Arthroplasty, 2001. **16**(2): p. 149-60.
14. Bragdon, C.R., et al., *Third-body wear of highly cross-linked polyethylene in a hip simulator.* J Arthroplasty, 2003. **18**(5): p. 553-561.
15. Bragdon, C.R., et al., *The 2012 John Charnley Award: Clinical multicenter studies of the wear performance of highly crosslinked remelted polyethylene in THA.* Clin Orthop Relat Res, 2013. **471**(2): p. 393-402.
16. Babovic, N. and R.T. Trousdale, *Total Hip Arthroplasty Using Highly Cross-Linked Polyethylene in Patients Younger Than 50 Years With Minimum 10-Year Follow-Up.* J Arthroplasty, 2013. **28**(5): p. 815-817.
17. Glyn-Jones, S., et al., *The John Charnley Award: Highly Crosslinked Polyethylene in Total Hip Arthroplasty Decreases Long-term Wear: A Double-blind Randomized Trial.* Clinical Orthopaedics and Related Research®, 2015. **473**(2): p. 432-438.

18. Glyn-Jones, S., et al., *Does Highly Cross-Linked Polyethylene Wear Less Than Conventional Polyethylene in Total Hip Arthroplasty?: A Double-Blind, Randomized, and Controlled Trial Using Roentgen Stereophotogrammetric Analysis.* The Journal of Arthroplasty, 2008. **23**(3): p. 337-343.
19. Lachiewicz, P.F., J.A. O'Dell, and J.M. Martell, *Large Metal Heads and Highly Cross-Linked Polyethylene Provide Low Wear and Complications at 5-13 Years.* J Arthroplasty, 2018.
20. Lachiewicz, P.F., E.S. Soileau, and J.M. Martell, *Wear and Osteolysis of Highly Crosslinked Polyethylene at 10 to 14 Years: The Effect of Femoral Head Size.* Clin Orthop Relat Res, 2016. **474**(2): p. 365-71.
21. Howie, D.W., O.T. Holubowycz, and S.A. Callary, *The Wear Rate of Highly Cross-Linked Polyethylene in Total Hip Replacement Is Not Increased by Large Articulations: A Randomized Controlled Trial.* JBJS, 2016. **98**(21): p. 1786-1793.
22. Cross, M.B., D. Nam, and D.J. Mayman, *Ideal femoral head size in total hip arthroplasty balances stability and volumetric wear.* HSS J, 2012. **8**(3): p. 270-4.
23. Galvin, A.L., et al., *Wear and creep of highly crosslinked polyethylene against cobalt chrome and ceramic femoral heads.* Proc Inst Mech Eng H, 2010. **224**(10): p. 1175-83.
24. Garvin, K.L., et al., *Wear analysis in THA utilizing oxidized zirconium and crosslinked polyethylene.* Clin Orthop Relat Res, 2009. **467**(1): p. 141-5.
25. Hamadouche, M. and L. Sedel, *Ceramics in orthopaedics.* Vol. 82. 2000. 1095-9.
26. Dorlot, J.M., *Long-term effects of alumina components in total hip prostheses.* Clin Orthop Relat Res, 1992(282): p. 47-52.
27. Teeter, M.G., et al., *Highly crosslinked polyethylene wear rates and acetabular component orientation.* Bone Joint J, 2018. **100-b**(7): p. 891-897.
28. Lee, J.H., et al., *Midterm results of primary total hip arthroplasty using highly cross-linked polyethylene: minimum 7-year follow-up study.* J Arthroplasty, 2011. **26**(7): p. 1014-9.
29. Zietz, C., et al., *The Divergence of Wear Propagation and Stress at Steep Acetabular Cup Positions Using Ceramic Heads and Sequentially Cross-Linked Polyethylene Liners.* J Arthroplasty, 2015. **30**(8): p. 1458-63.
30. Haw, J.G., et al., *Wear Rates of Larger-Diameter Cross-Linked Polyethylene at 5 to 13 Years: Does Liner Thickness or Component Position Matter?* J Arthroplasty, 2017. **32**(4): p. 1381-1386.
31. Wang, A., et al., *Wear, oxidation and mechanical properties of a sequentially irradiated and annealed UHMWPE in total joint replacement.* Journal of Physics D: Applied Physics, 2006. **39**(15): p. 3213.
32. Samujh, C., et al., *Wear Analysis of Second-generation Highly Cross-Linked Polyethylene in Primary Total Hip Arthroplasty.* Orthopedics, 2016. **39**(6): p. e1178-e1182.
33. Callary, S.A., J.R. Field, and D.G. Campbell, *The rate of wear of second-generation highly crosslinked polyethylene liners five years post-operatively does not increase if large femoral heads are used.* The Bone & Joint Journal, 2016. **98-B**(12): p. 1604-1610.
34. Campbell, D.G., J.R. Field, and S.A. Callary, *Second-generation Highly Cross-linked X3™ Polyethylene Wear: A Preliminary Radiostereometric Analysis Study.* Clinical Orthopaedics and Related Research, 2010. **468**(10): p. 2704-2709.

ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT

35. Selvarajah, E., et al., *The rates of wear of X3 highly cross-linked polyethylene at five years when coupled with a 36 mm diameter ceramic femoral head in young patients.* Bone Joint J, 2015. **97-b**(11): p. 1470-4.
36. Selvarajah, E., et al., *Measurement of early wear rates with X3 polyethylene and 36-mm femoral heads in young patients – a prospective study.* Current Orthopaedic Practice, 2013. **24**(6): p. 641-646.
37. D'Antonio, J.A., W.N. Capello, and R. Ramakrishnan, *Second-generation annealed highly cross-linked polyethylene exhibits low wear.* Clin Orthop Relat Res, 2012. **470**(6): p. 1696-704.
38. Kurtz, S.M., et al., *Retrieval analysis of sequentially annealed highly crosslinked polyethylene used in total hip arthroplasty.* Clin Orthop Relat Res, 2015. **473**(3): p. 962-71.
39. Gaudiani, M.A., et al., *Wear Rates With Large Metal and Ceramic Heads on a Second Generation Highly Cross-Linked Polyethylene at Mean 6-Year Follow-Up.* J Arthroplasty, 2018. **33**(2): p. 590-594.
40. Amstutz, H.C., et al., *Treatment of primary osteoarthritis of the hip. A comparison of total joint and surface replacement arthroplasty.* J Bone Joint Surg Am, 1984. **66**(2): p. 228-41.
41. Zahiri, C.A., et al., *Assessing activity in joint replacement patients.* J Arthroplasty, 1998. **13**(8): p. 890-5.
42. Little, N.J., et al., *Acetabular Polyethylene Wear and Acetabular Inclination and Femoral Offset.* Clinical Orthopaedics and Related Research, 2009. **467**(11): p. 2895-2900.
43. Lee, P.C., et al., *Early polyethylene wear and osteolysis in cementless total hip arthroplasty: the influence of femoral head size and polyethylene thickness.* J Arthroplasty, 1999. **14**(8): p. 976-81.
44. Bankston, A.B., et al., *Polyethylene wear in total hip arthroplasty in patient-matched groups. A comparison of stainless steel, cobalt chrome, and titanium-bearing surfaces.* J Arthroplasty, 1993. **8**(3): p. 315-22.
45. Ayers, D.C., et al., *Radiostereometric analysis study of tantalum compared with titanium acetabular cups and highly cross-linked compared with conventional liners in young patients undergoing total hip replacement.* J Bone Joint Surg Am, 2015. **97**(8): p. 627-34.
46. Ayers, D.C., et al., *Two-year radiostereometric analysis evaluation of femoral head penetration in a challenging population of young total hip arthroplasty patients.* J Arthroplasty, 2009. **24**(6 Suppl): p. 9-14.
47. Fukui, K., et al., *Wear comparison between a highly cross-linked polyethylene and conventional polyethylene against a zirconia femoral head: minimum 5-year follow-up.* J Arthroplasty, 2011. **26**(1): p. 45-9.
48. Capello, W.N., et al., *Continued improved wear with an annealed highly cross-linked polyethylene.* Clin Orthop Relat Res, 2011. **469**(3): p. 825-30.
49. Takada, R., et al., *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.* Orthop Traumatol Surg Res, 2016. **102**(6): p. 717-21.
50. Schroder, D.T., et al., *Retrieved highly crosslinked UHMWPE acetabular liners have similar wear damage as conventional UHMWPE.* Clin Orthop Relat Res, 2011. **469**(2): p. 387-94.

ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT

51. Glyn-Jones, S., et al., *The creep and wear of highly cross-linked polyethylene: a three-year randomised, controlled trial using radiostereometric analysis.* J Bone Joint Surg Br, 2008. **90**(5): p. 556-61.
52. Miura, Y., et al., *In-vivo degradation of middle-term highly cross-linked and remelted polyethylene cups: Modification induced by creep, wear and oxidation.* J Mech Behav Biomed Mater, 2015. **51**: p. 13-24.
53. Korduba, L.A., et al., *Effect of acetabular cup abduction angle on wear of ultrahigh-molecular-weight polyethylene in hip simulator testing.* Am J Orthop (Belle Mead NJ), 2014. **43**(10): p. 466-71.
54. Verdonschot, N., et al., *Effects of metal-inlay thickness in polyethylene cups with metal-on-metal bearings.* Clin Orthop Relat Res, 2002(404): p. 353-61.
55. Pijls, B.G., H.M. Van der Linden-Van der Zwaag, and R.G. Nelissen, *Polyethylene thickness is a risk factor for wear necessitating insert exchange.* Int Orthop, 2012. **36**(6): p. 1175-80.
56. Penmetsa, J.R., et al., *Influence of polyethylene creep behavior on wear in total hip arthroplasty.* J Orthop Res, 2006. **24**(3): p. 422-7.
57. Oonishi, H., et al., *The effects of polyethylene cup thickness on wear of total hip prostheses.* J Mater Sci Mater Med, 1998. **9**(8): p. 475-8.
58. Goebel, P., et al., *The influence of head diameter and wall thickness on deformations of metallic acetabular press-fit cups and UHMWPE liners: a finite element analysis.* J Orthop Sci, 2013. **18**(2): p. 264-70.
59. So, K., et al., *Minimum 10-Year Wear Analysis of Highly Cross-Linked Polyethylene in Cementless Total Hip Arthroplasty.* J Arthroplasty, 2015. **30**(12): p. 2224-6.
60. Shen, F.W., Z. Lu, and H.A. McKellop, *Wear versus thickness and other features of 5-Mrad crosslinked UHMWPE acetabular liners.* Clin Orthop Relat Res, 2011. **469**(2): p. 395-404.
61. Nashed, R.S., D.A. Becker, and R.B. Gustilo, *Are cementless acetabular components the cause of excess wear and osteolysis in total hip arthroplasty?* Clin Orthop Relat Res, 1995(317): p. 19-28.
62. Kelly, N.H., et al., *High stress conditions do not increase wear of thin highly crosslinked UHMWPE.* Clin Orthop Relat Res, 2010. **468**(2): p. 418-23.
63. Elfick, A.P., et al., *The effect of socket design, materials and liner thickness on the wear of the porous coated anatomic total hip replacement.* Proc Inst Mech Eng H, 2001. **215**(5): p. 447-57.
64. D'Antonio, J., W.N. Capello, and R. Ramakrishnan, *Once Annealed Highly Cross-Linked Polyethylene Exhibits Low Wear at 9 to 15 Years.* Orthopedics, 2016. **39**(3): p. e565-71.
65. Snir, N., et al., *10-year follow-up wear analysis of first-generation highly crosslinked polyethylene in primary total hip arthroplasty.* J Arthroplasty, 2014. **29**(3): p. 630-3.
66. Feng, J.E., et al., *Up to 18-Year Follow-Up Wear Analysis of a First-Generation Highly Cross-Linked Polyethylene in Primary Total Hip Arthroplasty.* J Arthroplasty, 2018. **33**(10): p. 3325-3328.
67. Sodhi, N., et al., *Linear Wear Rates of a Highly Cross-Linked Polyethylene Hip Liner.* Surg Technol Int, 2018. **33**: p. 265-270.
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*

oxidation of a shelf-aged acetabular component. Bone Joint J, 2017. **99-b**(10): p. 1286-1289.

69. Takahashi, Y., et al., *Mechanisms of plastic deformation in highly cross-linked UHMWPE for total hip components—The molecular physics viewpoint.* Journal of the Mechanical Behavior of Biomedical Materials, 2015. **42**(Supplement C): p. 43-53.
70. Bevill, S.L., et al., *Finite element simulation of early creep and wear in total hip arthroplasty.* J Biomech, 2005. **38**(12): p. 2365-74.
71. Rajadhyaksha, A.D., et al., *Five-year comparative study of highly cross-linked (crossfire) and traditional polyethylene.* J Arthroplasty, 2009. **24**(2): p. 161-7.

ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT

Table 1. Overall patient demographics.

n = 77	**Mean**	**SD**	**95% CI**	**Median**
Age (years)	60.6	13.1	57.6 – 63.6	61.6
BMI (kg/m^2)	30.2	5.7	29.0 – 31.5	29.7
Cup Inclination (°)	54.6	6.4	53.2 – 56.1	55.1
Cup Anteversion (°)	19.4	4.4	18.4 – 20.3	19.3
Poly Thickness (mm)	6.2	0.9	6.0 – 6.4	5.9
Follow-up (months)	63.4	7.3	61.7 – 65.0	61.6
% Female	61%	-	-	-
% Ceramic	87%	-	-	-
% 32mm	31%	-	-	-
% Satisfied	93%	-	-	-
% >5 UCLA Score	59%	-	-	-

SD, standard deviation
kg, kilogram
mm, millimeter
CI, confidence interval

ACCEPTED MANUSCRIPT

Table 2. Demographic breakdown by femoral head size.

	32mm	**36mm**	**Test Statistic**	***p***
N	24	52	-	-
Age (years)	63.3	61.6	W = 934.0	0.915
BMI (kg/m^2)	30.6 SD 5.9	29.8 SD 5.3	T = 0.52	0.604
% Female	100	44	X^2 = 21.6	**≤ 0.001**
Cup Inclination (°)	55.5 SD 6.4	54.0 SD 6.1	T = 1.00	0.322
Cup Anteversion (°)	20.0 SD 4.2	19.0 SD 4.5	T = 0.97	0.339
Poly Thickness (mm)	5.9	5.9	W = 856.0	0.277
% Ceramic	83	88	X^2 = 0.4	0.716
% Satisfied	91	94	X^2 = 0.2	0.647
% >5 UCLA Score	43	65	X^2 = 2.9	0.127

W, Mann-Whitney
T, Two Sample T-Test
X^2, 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.

ACCEPTED MANUSCRIPT

Table 3. Demographic breakdown by femoral head material.

	Ceramic	**CoCr**	**Test Statistic**	***p***
N	67	10	-	-
Age (years)	61.6	63.2	W = 2593.0	0.768
BMI (kg/m^2)	30.3 SD 5.7	30.0 SD 5.8	T = 0.12	0.906
% Female	58	80	X^2 = 1.7	0.300
Cup Inclination (°)	54.9 SD 6.4	53.2 SD 6.1	T = 0.81	0.433
Cup Anteversion (°)	19.3 SD 4.5	19.4 SD 4.0	T = 0.07	0.943
Poly Thickness (mm)	5.9	5.9	W = 2576.0	0.434
% 32mm	30	40	*invalid*[1]	*invalid*[1]
% Satisfied	92	100	X^2 = 0.742	1.000
% >5 UCLA Score	58	63	X^2 = 0.054	1.000

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

[1] The *invalid* chi-square test was due to low cell counts.

ACCEPTED MANUSCRIPT

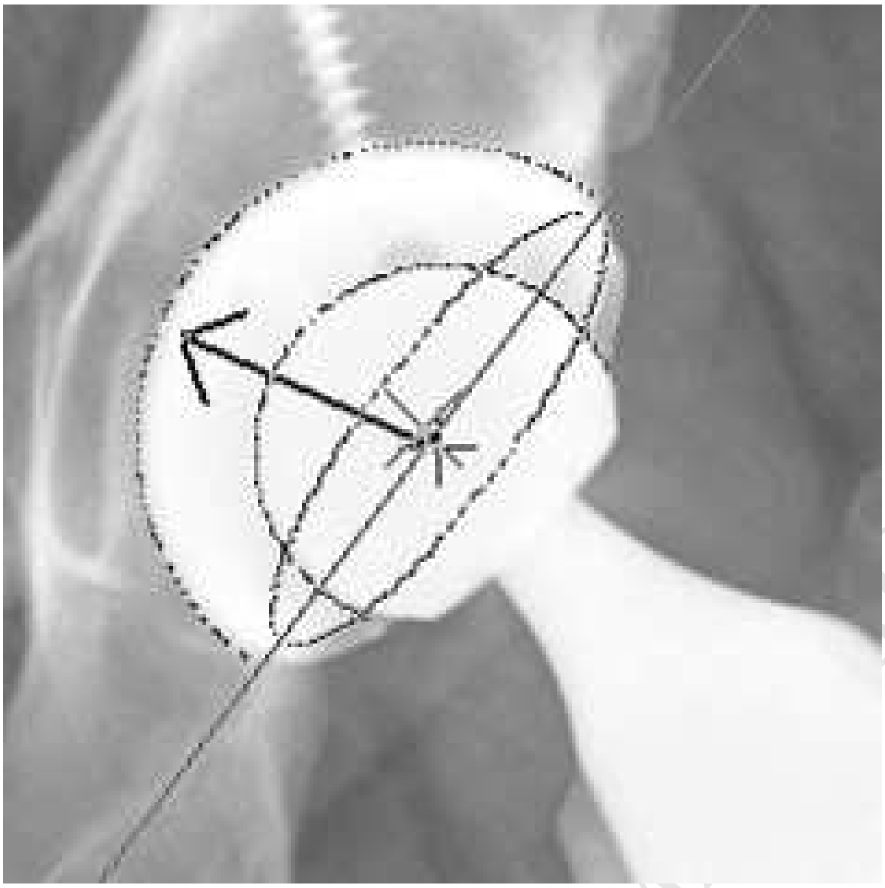
ACCEPTED MANUSCRIPT

Table 4. Demographic breakdown by femoral head size and material.

	32mm Ceramic	**36mm Ceramic**	**32mm CoCr**	**36mm CoCr**	**Test Statistic**	***p***
N	20	46	4	6	-	-
Age (years)	60.9	61.6	64.7	61.3	H = 0.1	0.994
BMI (kg/m^2)	30.8 SD 6.0	29.7 SD 5.3	29.3 SD 6.0	30.5 SD 6.2	F = 0.21	0.889
% Female	100^A	41^B	100^{AB}	67^{AB}	X^2 = 23.1	**≤ 0.001**
Cup Inclination (°)	55.3 SD 6.9	54.4 SD 6.0	56.8 SD 1.9	50.7 SD 6.9	F = 1.04	0.381
Cup Anteversion (°)	19.6 SD 4.3	19.2 SD 4.6	22.2 SD 3.5	17.6 SD 3.3	F = 0.92	0.435
Poly Thickness (mm)	5.9	5.9	5.9	5.9	H = 2.69	0.443
% Satisfied	89	93	100	100	*invalid*[1]	*invalid*[1]
% >5 UCLA Score	50	61	0	100	*invalid*[1]	*invalid*[1]

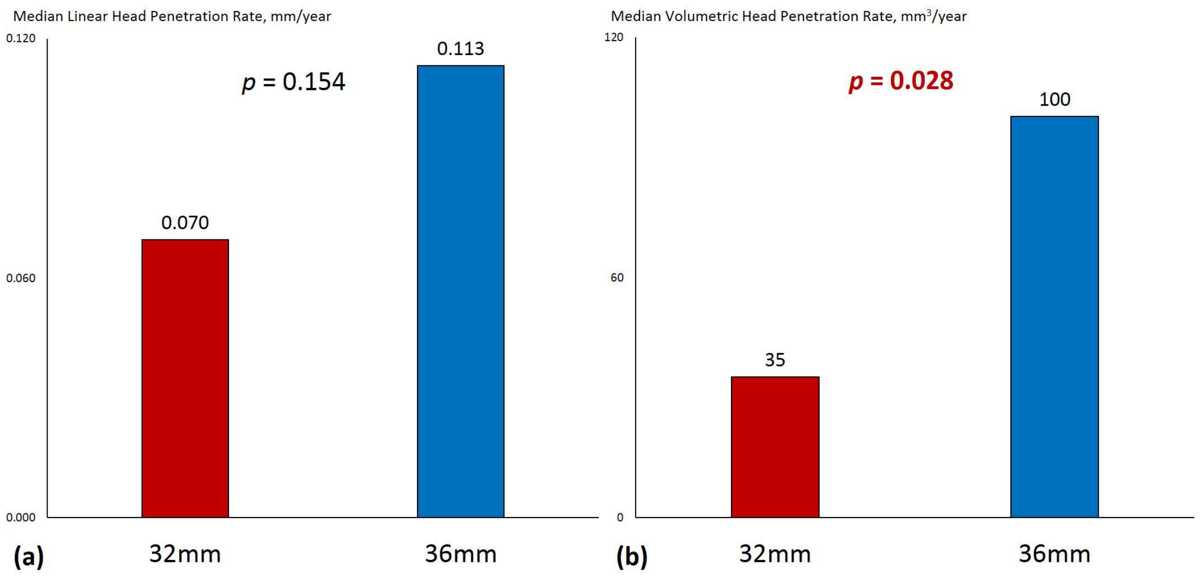
H, Kruskal-Wallis
F, One-way ANOVA
One case utilized a 40mm femoral head and was removed from this analysis.
[1] The *invalid* chi-square test was due to low cell counts.

ACCEPTED MANUSCRIPT



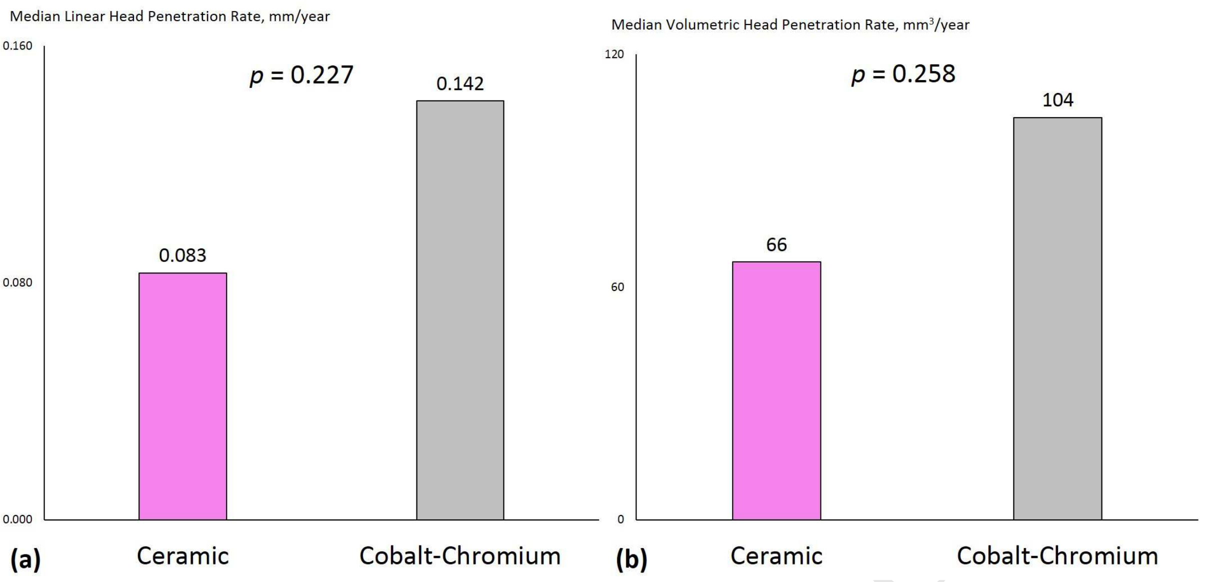
ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT



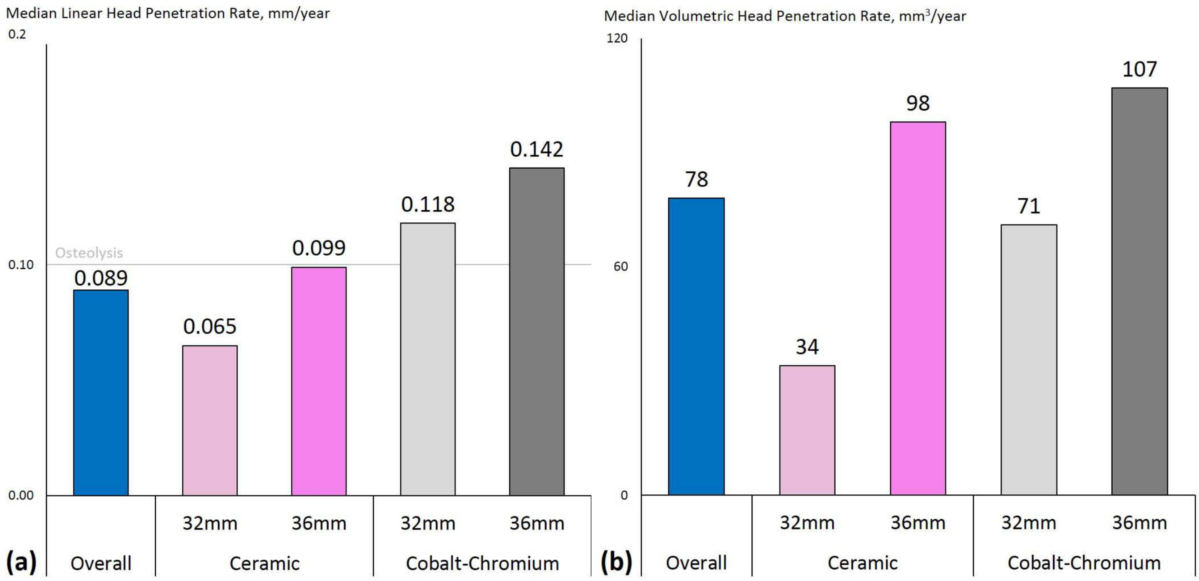
ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT



ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT



ACCEPTED MANUSCRIPT

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.

ACCEPTED MANUSCRIPT

ACCEPTED MANUSCRIPT

Source of Funding

The Indiana University Hip and Knee Center Research Program is supported by the Indiana University Health – Indiana University School of Medicine Strategic Research Initiative.

ACCEPTED MANUSCRIPT