Dislocation remains a major mode of failure in contemporary total hip arthroplasties (THAs) [1–3]. As such, many surgeons have transitioned to utilizing larger femoral heads and comparatively smaller acetabular components to reduce the risk of dislocation [4]. Larger femoral heads paired with first-generation polyethylenes (PEs) have been shown to generate increased wear particles from greater volumetric wear, which contribute to osteolysis and aseptic loosening [5]. Over the past two decades, there has been near universal adoption of highly cross-linked polyethylene (HXPLE) given its improved wear characteristics and ability to mitigate wear-induced osteolysis [1,2,6].

While convincing data show that HXPLE minimizes wear-induced complications, concerns remain in regards to mechanical failures when larger femoral heads are paired with smaller acetabular components, and thus thinner PE liners [7–9]. Currently, there are limited data on the mechanical failures, long-term outcomes, and wear rates in THAs utilizing a combination of large-
diameter femoral heads and small-diameter acetabular components with HXLPE liners.

Therefore, the goals of this study are to evaluate primary THAs with 36-mm femoral heads and acetabular components ≤52 mm with HXLPE liners in regards to the incidence of liner fracture or dissociation, the cumulative incidences of dislocation, any revision, and any reoperation, and the long-term HXLPE liner wear rates and osteolysis incidence.

Patients and Methods

After obtaining Institutional Review Board approval, all patients undergoing primary THAs between January 1, 2000 and April 1, 2017 were identified using our institutional total joint registry (TJR). This TJR prospectively captures demographic information, patient and implant survival, complications, patient-reported outcomes, and radiographs at 1, 2, 5, and every 5 years thereafter [10]. Dislocation was defined as an event requiring closed or open reduction. Revision was defined as a surgical intervention involving replacement of at least one component. Reoperation included any surgical intervention without alteration of the implants.

We identified 882 THAs (796 patients) utilizing 36 mm femoral heads and acetabular components with diameters ≤52 mm and HXLPE acetabular liners during the study interval. The mean age at the time of surgery was 66 years (range 20–96) and 88% were female (Table 1). Mean body mass index (BMI) was 30 kg/m² (range 16–56). Mean follow-up was 4 years (range 2–12).

Indications for THA included primary degenerative joint disease in 86% (n = 761), avascular necrosis in 6% (n = 50), post-traumatic arthritis in 4% (n = 37), acute femoral neck fracture in 2% (n = 20), rheumatoid arthritis in 1% (n = 8), and developmental dysplasia of the hip in 1% (n = 6). Clinical outcomes were assessed using the Harris Hip Score (HHS) [11]. Complications were captured in the TJR and confirmed through review of the electronic medical record.

Highly Cross-Linked Polyethylene Wear and Osteolysis Analysis

We identified 18 THAs in 17 patients with follow-up greater than 10 years (range 10–12). The mean age at the time of primary THA was 64 years (range 39–81), and mean BMI was 28 kg/m² (Table 1). Seventy-eight percent of patients (n = 14) were female.

Surgical Techniques and Implants

All primary THAs were performed by high-volume surgeons at a single academic medical center. The surgical approach was posterior in 459 (52%), anterolateral in 311 (35%), direct anterior in 110 (12%), and transtrochanteric in 2 (1%).

Uncemented acetabular components were used in all cases with outer diameters of 48 mm (1%, n = 3), 50 mm (15%, n = 132), or 52 mm (84%, n = 747). Acetabular components included DePuy Synthes Pinnacle in 435 (49%; Warsaw, IN), Zimmer-Biomet Trilogy in 208 (34%; Warsaw, IN), Zimmer-Biomet G7 in 102 (12%), Stryker Tritanium in 65 (7%; Mahwah, NJ), Stryker Trident in 25 (3%), Zimmer-Biomet Trabecular Metal Modular in 22 (2%), and other in 25 (3%).

As previously mentioned, HXPLE liners were used in all cases. A neutral liner was used in 731 hips (83%) and an elevated rim or face-changing liner was used in 151 hips (17%). The HXPLE liners utilized included DePuy Synthes Marathon neutral in 278 (31%) and 10° elevated in 134 (15%), DePuy Synthes Altrx neutral in 23 (3%), Zimmer-Biomet Trilogy Longevity standard in 235 (27%), Zimmer-Biomet G7 neutral in 93 (11%) and high wall in 9 (1%), Stryker Trident X3 neutral in 91 (10%) and 10° in 1 (0.1%), and other (n = 18, 2%). Liner thickness varies by manufacturer, acetabular component, and along the arc of curvature of the liner. Liners are generally thickest at the central dome and become progressively thinner toward the rim. Published manufacturer data generally does not include liner thickness at the rim. The minimum published PE liner thickness for components in this study ranged from 3.9 mm (at the

<table>
<thead>
<tr>
<th>Table 1 Patient Characteristics for Entire Cohort and Subanalysis of Patients With Minimum 10-y Follow-up.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Entire Cohort (n = 882)</strong></td>
</tr>
<tr>
<td><strong>Age at surgery (y)</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Side</strong></td>
</tr>
<tr>
<td>Left</td>
</tr>
<tr>
<td>Right</td>
</tr>
<tr>
<td><strong>Surgical approach</strong></td>
</tr>
<tr>
<td>Posterior</td>
</tr>
<tr>
<td>Anterolateral</td>
</tr>
<tr>
<td>Anterior</td>
</tr>
<tr>
<td>Transtrochanteric</td>
</tr>
<tr>
<td><strong>Femoral head size (mm)</strong></td>
</tr>
<tr>
<td>36</td>
</tr>
<tr>
<td><strong>Femoral head material</strong></td>
</tr>
<tr>
<td>Cobalt-chromium</td>
</tr>
<tr>
<td>Delta ceramic</td>
</tr>
<tr>
<td><strong>Acetabular component size (mm)</strong></td>
</tr>
<tr>
<td>52</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>48</td>
</tr>
<tr>
<td><strong>Acetabular component liner type</strong></td>
</tr>
<tr>
<td>Neutral</td>
</tr>
<tr>
<td>Elevated</td>
</tr>
</tbody>
</table>
45° mid-arc for 48-mm Stryker Trident acetabular component with X3 liner) to 6.2 mm (at the 45° mid-arc for 52-mm DePuy Synthes Pinnacle acetabular component with Marathon liner).

All femoral heads had a diameter of 36 mm. The material of the femoral head was cobalt-chromium in 529 hips (60%) and fourth-generation BIOLOX delta ceramic (CeramTec, Laerens, SC) in 353 hips (40%) (Table 1).

In the 18 hips that were analyzed radiographically for PE wear and osteolysis at minimum 10-year clinical follow-up, acetabular components were 52 mm in 13 (72%) and 50 mm in 5 (28%). Acetabular components included Zimmer-Biomet Trabecular Metal Modular in 10 (56%), DePuy Synthes Pinnacle in 6 (33%), and Stryker Trident in 2 (11%). A neutral liner was used in 16 hips (89%) and an elevated liner was used in 2 hips (11%). Acetabular liners included Zimmer-Biomet Trilogy Longevity neutral in 10 (56%), DePuy Synthes Pinnacle Marathon neutral in 3 (16%) and 10° elevated in 2 (11%), and Stryker Trident X3 neutral in 3 (16%). The material of the femoral head was cobalt-chromium in 17 hips (94%) and fourth-generation BIOLOX delta ceramic in 1 hip (6%).

For assessment of long-term PE wear and osteolysis, anteroposterior views of the pelvis at the initial postoperative visit and most recent follow-up were analyzed for femoral head penetration using freely available software, ROMAN [12], and a validated radiographic technique (Fig. 1) [13,14]. Linear wear rate was calculated by dividing femoral head penetration (mm) by the interval in years between the selected radiographs. Negative femoral head penetration occurs when the most recent value is less than the initial value, paradoxically indicating that the liner has increased in thickness over time. This is a recognized occurrence with femoral head penetration analysis and controlled using a variety of non-standardized methods. Volumetric wear was calculated using a model based on a cylindrical wear pattern perpendicular to the face of acetabular component: \( V = \pi \times r^2 \times w \), where \( \pi \) is 3.1416, \( r \) is the radius of the femoral head size in mm, and \( w \) is the linear wear rate [14].

All radiographs were analyzed and measured independently by 2 authors (CEB, BRB). Radiographs were scrutinized at final follow-up for evidence of periacetabular and femoral osteolysis, radiolucent lines, and loose components as previously described [15–19]. Any periacetabular osteolysis was recorded by zone and estimated size [20]. Postoperative periprosthetic femur fractures were assessed according to the Vancouver classification system [21].

Statistical Analysis

Descriptive statistics were reported as means with standard deviations (SD) or confidence intervals (CI) for continuous variables and as frequencies for categorical variables. Continuous variables were compared between groups using unpaired t-tests; paired t-tests were used to compare preoperative and postoperative HHS. Categorical variables were evaluated using the chi-squared test or Fisher’s exact test. Intraclass correlation (ICC) analysis was performed to determine inter-rater and intra-rater reliability of radiographic wear measurements between independent evaluators. ICC analysis demonstrated satisfactory intra-rater reliability (ICC = 0.87) and inter-rater reliability (ICC = 0.95).

The cumulative incidences of dislocation, any revision, and any reoperation were calculated using a competing risk analysis with death as the competitor [22]. Cox proportional hazard analysis was performed to evaluate risk factors predictive of dislocation, any revision, and any reoperation, including age, gender, BMI, surgical approach, acetabular component size, degree of acetabular liner constraint, and femoral head material. Results were reported as hazard ratios (HR). Hazard ratios based on surgical approach were calculated using the anterolateral approach as a reference. All statistical tests were 2-sided with significance set at alpha = 0.05. All analyses were performed using R, version 3.4.2 (R Core Team; R Foundation for Statistical Computing, Vienna, Austria) and JMP, version 14.1.0 (SAS Institute Inc, Cary, NC; 1989-2019).

Results

Linear Fracture, Liner Dissociation, and Clinical Outcomes

There were no instances of liner fracture or dissociation identified at any time point. Mean preoperative HHS improved from 53 (range 18–98) preoperatively to 84 (range 22–100) at most recent postoperative follow-up (P < .001).

Cumulative Incidences of Dislocation, Any Revision, and Any Reoperation With Death as a Competing Risk

The cumulative incidence of dislocation with death as a competing risk was 1.4% at 1 year (95% CI = 0.6-2.1), 1.7% at 5 years (95% CI = 0.8-2.6), and 3.2% at 10 years (95% CI = 0.1-6.2) (Fig. 2). There were 15 dislocations during the study interval: 12 occurred in 459 posterior approach hips, 2 in 311 anterolateral approach hips, and 1 in 110 direct anterior approach hips. Directionality of dislocation was posterior in 9 patients (posterior approach in 8 of 9), anterior in 3 patients (anterolateral approach in 1 of 3 and direct anterior approach in 1 of 3), and unknown in 3 patients who underwent closed reduction at an outside hospital. Seven patients experienced recurrent hip dislocations with at least one additional dislocation event and underwent revision THA. Using the anterolateral approach as a reference, Cox proportional hazard analysis demonstrated an increased risk of dislocation in THAs performed through a posterior approach (HR 4.1, 95% CI = 1.1-26.2, P = .03). There were no significant differences in incidence of dislocation based on age at surgery, gender, BMI, femoral head material, or acetabular component liner type.

The cumulative incidence of any revision with death accounted for as a competing risk was 1.4% at 1 year (95% CI = 0.6-2.1), 2.6% at 5 years (95% CI = 1.4-3.9), and 5.6% at 10 years (95% CI = 1.6-9.5) (Fig. 3). There were 23 revision THAs performed during the study interval. Indications for revision THA included recurrent dislocation
with component retention and conversion to a constrained liner \( (n = 5) \), acetabular revision and conversion to constrained liner \( (n = 1) \), femoral head and PE liner exchange with increased neck length \( (n = 1) \), conversion to an elevated rim PE liner \( (n = 1) \); periprosthetic joint infection with femoral head and PE liner exchange \( (n = 4) \); periprosthetic joint infection with 2-stage exchange \( (n = 3) \); psoas tendon impingement with psoas release and acetabular component revision \( (n = 2) \); periprosthetic femur

![Cumulative Incidence of Dislocation](image1)

**Fig. 2.** Cumulative incidence of dislocation with death as a competing risk.

![Cumulative Incidence of Revision](image2)

**Fig. 3.** Cumulative incidence of any revision with death as a competing risk.
fracture with femoral component revision (n = 3, all Vancouver B2); femoral head exchange for recurrent debilitating trochanteric bursitis attributed to leg length discrepancy and increased offset (n = 1); and unknown in patients managed at an outside hospital (n = 2). Cox proportional hazard analysis demonstrated no significant differences in revision rate based on age at surgery, gender, BMI, surgical approach, femoral head material, or acetabular component liner type.

The cumulative incidence of any reoperation with death accounted for as a competing risk was 2.5% at 1 year (95% CI = 1.5-3.5), 4.4% at 5 years (95% CI = 2.8-5.9), and 9.3% at 10 years (95% CI = 4.6-13.6) (Fig. 4). Seventeen patients underwent a reoperation other than revision: superficial irrigation and debridement for delayed wound healing or a draining wound (n = 8), open reduction internal fixation of periprosthetic/interprosthetic femur fracture (n = 3), abductor repair/reconstruction (n = 2), open reduction internal fixation with bone grafting of previous subtrochanteric osteotomy nonunion (n = 2), hardware removal for painful cerclage cables/wires (n = 1), and open reduction internal fixation for impending pathologic femur fracture (n = 1). Cox proportional hazard analysis demonstrated no significant differences in incidence of reoperation based on age at surgery, gender, surgical approach, BMI, femoral head material, or acetabular component liner type.

Polyethylene Wear Rates and Osteolysis

For THA with minimum 10 years of follow-up, mean femoral head penetration was 0.38 mm (95% CI = 0.76-0.68) (Table 2). Mean linear wear rate was 0.042 mm/y (95% CI = 0.0039-0.082) at final follow-up. Six hips had negative femoral head penetration values averaging –0.21 mm. With negative wear values set equal to zero, mean femoral head penetration was 0.45 mm (95% CI = 0.19-0.71) and mean linear wear rate was 0.05 mm/y (95% CI = 0.014-0.086). When negative wear values were excluded, mean femoral head penetration was 0.68 mm (95% CI = 0.35-1.0) and mean linear wear rate was 0.075 mm/y (95% CI = 0.025-0.12). The mean volumetric wear rate was 44 mm³/y (95% CI = 4-84) when negative wear rates were considered, 50.2 mm³/y (95% CI = 13.1-87.4) when negative wear rates were set equal to zero, and 76.2 mm³/y (95% CI = 25.1-127.1) when negative wear rates were excluded.

At final radiographic follow-up, no THAs demonstrated evidence of osteolysis (Fig. 5). Two hips had evidence of mild zone 1 acetabular stress shielding. Comprehensive review of all available radiographs and pelvic computed tomography studies for these 2 patients (obtained for indications unrelated to evaluation of the operative hip) from the time of THA demonstrated no progression of stress shielding from 5 and 7 years postoperatively, respectively, to final follow-up.

Discussion

Contemporary primary THAs commonly maximize femoral head diameter to prevent dislocation. However, implementation of large-diameter femoral heads has been shown to increase volumetric wear and case reports raise concern for liner fracture or dissociation [7-9,23]. The long-term performance of pairing large-diameter femoral heads and small acetabular components with HXPLE liners is unknown. In this large series of 882 primary THAs with 36-mm femoral heads and acetabular components ≤52 mm with HXLIPE, we found no instances of PE liner fractures or dissociations.

Liner fracture or dissociation is a relatively rare occurrence, but is theoretically increased in implant combinations utilizing the thinnest acetabular liners [7-9]. The novel finding of this study was that even with thin HXLIPE liners due to large femoral heads, we found no cases of HXLIPE liner mechanical failures. This is essential data as surgeons are increasingly utilizing larger femoral heads (ie, 28 mm) with small acetabular components.
36 mm and greater) to mitigate dislocation, with universal adoption of HXLPE to mitigate PE wear and wear-induced osteolysis. Some studies examining all size pairings with a single acetabular component that comprised a significant proportion of the THAs in this series have raised concern over liner dissociation specific to that implant [24–26]. However, this was not replicated in our study. Despite previously published case reports [7–9,24–26], our data do not indicate large femoral head and small acetabular component pairings are at increased risk for this failure mechanism.

The second aim of this study was to investigate the incidences of dislocation, any revision, and any reoperation with this unique implant pairing. Large femoral heads and small acetabular components are intentionally used to optimize stability and decrease the risk of dislocation. The incidence of dislocation remained low in this series at 3.2% at 10 years. The incidence of revision THA in this cohort was also low at 5.6% at 10 years. Despite the use of larger femoral heads to increase stability, dislocation remained the most common indication for revision THA, followed by infection, which is consistent with contemporary THA modes of failure [27].

The third aim was to specifically investigate long-term PE wear rates and osteolysis in this population. Prior investigations evaluating the association of femoral head size and HXPE with over 10 years of follow-up have shown linear wear rates ranging from 0.005 to 0.024 mm/y, with no correlation between femoral head size and linear wear rates, but a correlation between larger femoral heads and greater volumetric wear [23,28]. However, these investigations provided limited or no data on the associated acetabular component sizes used. The wear rate demonstrated in the current series ranged from 0.042 to 0.075 mm/y depending on calculation method. These are higher than previously reported linear wear rates, but below the “osteolysis threshold” of 0.1 mm/y of linear wear established for conventional PE [14,29–32]. Similarly, the volumetric wear rate in this series (44–76 mm³ depending on the calculation method) is higher than previously published volumetric wear rates with HXLPE [14]. PE wear rate is multifactorial and is affected by the analysis method employed. The ROMAN software used for calculating femoral head penetration was previously shown to be the most precise and user-friendly compared to other methods [13,33]. All studies regarding wear rates must manage the interpretation of negative wear rates which result from inherent challenges of obtaining clinical radiographs in a standard fashion across a decade of time. As such, we have included all 3 analyses for completeness.

Osteolysis is related to particle generation from PE liner wear. In the subset of patient with long-term radiographic follow-up, there were no cases of osteolysis, but two examples of stress shielding around the acetabular component. Despite having higher linear and volumetric wear rates, these values appear to not be clinically significant based on the absence of osteolysis on radiographic review in this subgroup and lack of increased rates of implant failure or aseptic revisions in the general cohort. It has been hypothesized that linear wear less than 0.05 mm/y may prevent osteolysis entirely, which is consistent with the findings in this study [32]. However, radiographs have been previously demonstrated to be less sensitive than computed tomography scans for detecting osteolysis [34].

Finally, the study raises the question of “how thin is too thin?” for HXLPE liners. Currently, there are no accepted standards, and this study does not answer that specific question.

This study has limitations. Notably, patients with 10-year radiographic follow-up are a select group of “best cases” which limit their generalizability. However, our results represent the best evidence to date and suggest that the combination of large-diameter femoral heads and small-diameter acetabular components is a safe and durable option. In addition, the study was primarily comprised of two implant systems and a small number of surgeons, which could limit the generalizability of the results. The findings of this study are most representative of 52-mm acetabular components paired with 36-mm heads, since 50 mm and 48 mm acetabular components comprised a minority of the cohort. Given the trend of using larger-diameter femoral heads with smaller acetabular components, future studies with greater numbers of 50 mm and 48 mm acetabular components with 36 mm heads as well as implants from other manufacturers will add to the generalizability of these results.

In a large cohort of THAs pairing large femoral heads with small acetabular components utilizing HXLPE, there was no evidence of liner fractures or dissociations. Cumulative incidences of dislocation, any revision, and any reoperation were low at mid-term. No osteolysis was appreciated in the cohort of patients with minimum 10-year radiographic follow-up.

References


Menon AR, Cwynne-Jones D. Polyethylene liner dissociation with the Pinnacle acetabular component: should we be concerned? Arthroplasty Today 2020;6:5.


Bebergall AK, Greene ME, Rubash H, Malchau H, Troelsen A, Rolfsom O. Thirteen-year evaluation of highly crosslinked polyethylene articulating with either 28-mm or 36-mm femoral heads using radiostereometric analysis and computerized tomography. J Arthroplasty 2016;31(9 Suppl):269.


