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Large Metal Heads and Highly Cross-Linked Polyethylene Provide Low Wear and Complications at 5-13 Years

Paul F. Lachiewicz, MD [a, *], Jane A. O'Dell, BSN [a], John M. Martell, MD [b]

[a] Chapel Hill Orthopedics Surgery & Sports Medicine, Chapel Hill, NC
[b] Department of Orthopaedic Surgery and Rehabilitation Medicine, University of Chicago Medical Center, Chicago, IL

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ABSTRACT

Background: Highly cross-linked polyethylene (XLPE) is reported to have low rates of linear and volumetric wear at 10-14 years. In a prior study, larger (36 and 40 mm) femoral heads were associated with more volumetric wear, but there were only 12 hips with these heads.
Methods: We evaluated 107 hips (93 patients, with a mean age of 76 years) with one design of uncemented acetabular component, a 36 (90 hips) or 40 mm (17 hips) metal femoral head, and one electron beam 100 kGy irradiated and remelted XLPE at a mean follow-up of 8 years (range 5-13 years). Selection of these femoral heads was based on several factors, including the perceived risk of dislocation, the outer diameter size of the acetabular component, and liner availability. Measurements of linear and volumetric wear were performed in one experienced laboratory by the Martell method and analyzed using the first-to-last method. Standard radiographs, with additional Judet views, were used to detect periprosthetic osteolysis. Clinical records were used to determine the complications of dislocation, liner fracture, and painful trunnion corrosion.
Results: For the entire cohort, the median linear wear rate was 0.041 mm/y (95% confidence interval, 0.031-0.057) and the median volumetric wear rate was 34.6 mm^3/y (95% confidence interval, 31.4-53.5). With the numbers available, there was no difference in linear or volumetric wear between the 36 and 40 mm head sizes. Small, asymptomatic osteolytic lesions were noted in 3 hips (2%). There were 3 patients (3%) with dislocation (2 early and 1 late), but these have not had a revision. There were no revisions for loosening, no liner fracture, and no patient with symptomatic trunnion corrosion.
Conclusion: This acetabular component and XLPE with large metal heads had low rates of linear and volumetric wear. Large metal femoral heads did not lead to liner fracture, loosening, or symptomatic trunnion corrosion in this patient population. However, we recommend longer clinical follow-up studies and caution in the routine use of larger metal femoral heads in other, younger patient populations.

Metal-on-highly cross-linked polyethylene (XLPE) seems to be the optimal bearing surface for modern uncemented total hip arthroplasty (THA) [1–3]. Historically, 22, 26, 28, or 32 mm metal femoral heads were the usual options for primary THA, but innovations in materials have fostered the introduction of thinner polyethylene liners articulating with 36, 38, 40 mm, and even larger metal or ceramic femoral heads [2]. Biomechanical studies of XLPE acetabular liners have shown low in vitro linear wear even when paired with larger (>32 mm) femoral head sizes [4,5]. One randomized study reported significantly less dislocation with a 36-mm head compared with a 28-mm head in primary THA at short-term follow-up [6]. Our first study using one titanium fiber-metal acetabular component and one XLPE showed low linear wear and no osteolysis in 105 hips at 5-8 years (mean 6 years) follow-up, but there was significantly more volumetric wear in hips with 36 and 40 mm femoral heads [7]. The 10-14 years (mean 11 years) follow-up of 84 hips of that initial cohort confirmed the finding of more volumetric wear with larger heads [8]. However, both these

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* Reprint requests: Paul F. Lachiewicz, MD, Orthopedics, Chapel Hill Orthopedics Surgery & Sports Medicine, PO Box 2393, Chapel Hill, NC 27514.

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studies were limited by the presence of only 12 hips with larger heads [7,8]. Symptomatic trunnion corrosion with metal-on-polyethylene uncemented THA has been reported with increasing frequency, and there may be an association with larger metal femoral heads [9–11]. There are also concerns of fracture with thin XLPE liners when used with larger femoral heads, and that increased frictional torque of larger heads may increase component loosening [12,13]. To our knowledge, there are only 2 cohort studies of XLPE with larger metal femoral heads, and they are limited by short follow-up times and multiple confounding variables [14,15].

The purposes of this study were to determine: (1) What are the linear and volumetric wear rates of 36 and 40 mm metal femoral heads with XLPE at 5-13 years? (2) What proportion of hips developed osteolysis? (3) What proportion of hips developed dislocation, liner fracture, loosening, or symptomatic trunnion corrosion?

Materials and Methods

We obtained approval from an institutional review board (Copernicus, Research Triangle Park, NC) for this retrospective study of 190 patients (209 hips) who had a primary THA with a 36- or 40-mm metal femoral head by one surgeon between December 2001 (when these components were available) and June 2010. This represents 45% of all primary THAs performed, and the selection criteria are noted below. The remaining 55% of the primary THA patients had a 28- or 32-mm metal femoral head. This study was a continuation of the previous study and included the 12 hips previously described [8]. All patients had a modular titanium fiber-metal uncemented acetabular component fixed with screws (Trilogy Multi-Hole; Zimmer, Warsaw, IN). The acetabular liner was an electron beam 100 kGy irradiated remelted highly XLPE (Longevity; Zimmer). Before a minimum 5-year follow-up time, 47 patients (48 hips) had died and 36 patients (38 hips) were lost or refused follow-up. Fifteen patients (15 hips) with 5-year follow-up were excluded because of inadequate historic radiographs or radiographs inadequate for wear measurements. One patient (1 hip, with a 36-mm head) with less than 5-year follow-up was excluded, because wear measurements could not be performed, because of head and liner revision (to a tripolar) for 2 posterior dislocations at 4 years. This left 93 patients with 107 hips who had complete clinical and radiographic examination at a minimum 5-year follow-up (mean 8 years; range 5-13 years). There were 33 hips with minimum 10-year follow-up. Of these 93 patients, 36 were men (41 hips) and 57 were women (66 hips). The mean patient age was 76 years (range 56-92 years). The mean body mass index was 29 kg/m^2 (range 20-43 kg/m^2). The preoperative diagnosis was osteoarthritis in 78 hips, osteonecrosis in 6 hips, rheumatoid arthritis in 8 hips, femoral neck fracture in 5 hips, and other diagnoses (traumatic arthritis, pediatric hip disease, or others) in 10 hips.

The approach and methods for the THA procedures by one surgeon have been previously reported in detail [16–18]. The choice of femoral component fixation was based on several factors, including diaphyseal bone quality, femoral anatomy, and other patient demographic factors. There were 32 uncemented titanium femoral components and 75 cemented chrome-cobalt alloy femoral components implanted. The femoral head was cobalt-chrome alloy in all hips. The choice of femoral head size was based on several factors, including the outer diameter size of the acetabular component implanted (36 liner can only be used with 50 mm or larger; 40 liner can only be used with 58 mm or larger), an increased risk of dislocation (history of alcohol abuse, fracture diagnosis, and patient age) as previously determined in studies from the senior author [16,17,19,20], and liner availability from the manufacturer. We consider hips in patients aged 75 years or greater at higher risk for dislocation and there were 68 hips in this category [17]. Other risk factors for dislocation were femoral neck fracture in 5 hips, an associated neurological disorder in 7 hips, poor tissue quality because of steroid use in 11 hips, and other factors (alcohol use, history of contralateral hip dislocation, hip dysplasia, or others) in 16 hips. We do not have information about lumbar spine deformity or prior surgery in these patients. The femoral head sizes used were 36 mm in 90 hips and 40 mm in 17 hips. The 14 patients with bilateral hips had the same head size in both hips. The minimum polyethylene thickness was 6.8 mm with the 36-mm head (50-, 52-, and 54-mm shell) and 6.8 mm with the 40-mm head (58-mm shell), with 1 mm increase in thickness with each successive size of shell.

Clinical evaluations were performed at 6 months, 1 year, and yearly or biennially thereafter by one experienced clinical research nurse using the modified Harris Hip Score [21]. We specifically inquired about hip pain during the most recent visit.

Standard supine anteroposterior (AP) pelvis and frog-lateral radiographs were performed in one outpatient orthopedic clinic by trained technologists. The radiographs were performed at 6-8 weeks postoperatively (baseline radiograph), at 1 year postoperatively, and, if possible, at yearly or biannual visits. All 93 patients (107 hips) were recalled for the most recent or minimum 5-year follow-up, and if there was 10-years follow-up (33 hips), following our routine office research protocol, 2 additional 45° Judet views were performed to detect osteolytic lesions of the pelvis. However, there were no preoperative or 6-8 weeks postoperative Judet views. The radiographs were evaluated for radiolucent lines and component migration by one observer [22,23]. The acetabular component abduction angle, anteversion angle, and polyethylene wear were measured by one observer on the AP pelvis radiograph using a previously described Martell method [24–26]. The follow-up radiographs were digitized and evaluated blindly at another medical center for acetabular component position, and linear and volumetric wear by one experienced researcher who was not involved in the care of these patients. Osteolysis on the AP pelvis or Judet views radiographs was defined as a localized area of bone loss, at least 1 cm, with a well-defined sclerotic border, a communication between the joint space and the lesion, and the absence of acetabular cysts on the preoperative or early postoperative AP pelvis radiograph [27].

Two-dimensional wear analysis was performed using the method of Martell et al, as previously reported [14,24–26]. Volumetric wear rate was calculated using custom equations with numerical integration based on the 2-dimensional wear magnitude, femoral head size, and the direction of wear with respect to the face of the polyethylene liner [24–26]. Bedding-in (from the 6-week to 1-year postoperative radiograph) was not included in the wear measurements. The best method for analyzing polyethylene wear measurements is not certain or agreed on [8,14]. For the present study, linear and volumetric wear rates were obtained using the first and last follow-up radiographs for each hip (first-to-last method) [8,14].

Acetabular component radiographic anteversion was calculated based on the ratio of the major and minor axes of the ellipse formed by the rim of the cup (sin a = minor axis/major axis). One patient, with an anterior dislocation that was treated nonoperatively, was included in the clinical and wear analyses. The mean acetabular abduction angle was 41° (range 22°-64°). The mean acetabular anteversion angle was 23° (range 10°-27°). The acetabular abduction and anteversion angles between the 36 and 40 mm head groups were not significantly different.

For the statistical analysis, continuous variables were tested for normality using the Anderson-Darling normality test. Acetabular