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CLINICAL RESEARCH

Femoral Head Size and Wear of Highly Cross-linked Polyethylene at 5 to 8 Years

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Abstract Wear of highly cross-linked polyethylene is reportedly independent of head size. To confirm that observation we asked in our population whether head size related to wear with one type of electron beam highly cross-linked polyethylene. Of 146 hips implanted, we evaluated complete clinical and radiographic data for 90 patients (102 hips or 70%). The minimum followup was 5 years (mean, 5.7 years; range, 5–8 years). The head size was selected intraoperatively based on the size of the acetabular component and presumed risk of dislocation. Polyethylene wear measurements were performed in one experienced laboratory using the method of Martell et al. There was no hip with pelvic or femoral osteolysis. The median linear wear rate was 0.028 mm/year (mean, 0.04 mm/year), and the median volumetric wear rate was 25.6 mm^3/year (mean, 80.5 mm^3/year). Median total volumetric wear was 41.0 mm^3 (mean, 98.5 mm^3). We found no association between femoral head size and the linear wear rate, but observed an association between larger (36- and 40-mm) head size and volumetric wear rate and total volumetric wear. Although the linear wear rate of polyethylene was not related to femoral head diameter, there was greater volumetric wear (156.6 mm^3/year) with the 36- and 40-mm heads. Pending long-term studies of large head sizes, we advise caution in using larger femoral heads in young or active patients and in those with a low risk of dislocation.

Level of Evidence: Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the University of North Carolina at Chapel Hill, Chapel Hill, NC, USA, and the University of Chicago Medical Center, Chicago, IL, USA.

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Introduction

Osteolysis is related to particulate polyethylene wear debris and is considered an important cause of aseptic loosening and late implant failure of THA. Highly cross-linked polyethylene (XLPE) is an alternative bearing surface that was developed to improve polyethylene wear resistance and decrease osteolysis. XLPE has been studied extensively in vitro and reportedly has decreased wear rates substantially compared with conventional polyethylene in hip simulator studies [2, 18, 31]. Preliminary clinical studies of XLPE in small series of patients undergoing THA have confirmed these promising findings with a 45% to 99% reduction in wear compared with conventional polyethylene in wear at 3 to 5 years [8–11, 13, 15, 34].

There is a wide variety of methods to fabricate XLPE acetabular liners. These include various cross-linking radiation doses (50–100 kGy) and techniques (gamma or electron beam), thermal treatment (melted or annealed) used to remove free radicals, and terminal sterilization method (gas plasma, ethylene oxide, or gamma radiation in nitrogen) [17]. These differences influence the mechanical properties, crystallinity, and preaging and postaging oxidation levels of the various components [6]. Thus, currently available XLPE acetabular liners are not all equivalent, and their performances in vivo may differ [8–11, 18, 27].

Biomechanical studies of electron beam XLPE showed extremely low in vitro volumetric wear even when paired with larger (greater than 32-mm) femoral head sizes [2, 12, 32]. This is in contrast to the behavior of conventional polyethylene, which in one study had increased wear with a 32-mm femoral head compared with 28-mm and 22-mm femoral heads [23]. The concept that XLPE wear rates are independent of head size has led to the suggestion that larger femoral heads may be safely used in THA without increasing the production of particulate polyethylene debris that can lead to osteolysis and aseptic loosening [5]. The theoretical advantages of larger femoral head sizes are decreased component impingement, increased range of hip motion, and decreased risk of dislocation [4, 21]. Two clinical studies evaluating the wear of XLPE with large femoral heads reported low linear wear rates at 3 years [1, 14]. However, these studies are limited by small sample sizes, short followup times, and lack of measurement of volumetric wear.

We therefore asked whether there would be (1) no difference in the linear wear rates among the different femoral head sizes; and (2) no difference in volumetric wear rate with larger femoral head sizes (36 and 40 mm) compared with standard femoral head sizes (26, 28, and 32 mm).

Materials and Methods

We retrospectively reviewed all 130 patients (146 hips) who had primary THAs between December 1, 1999, and April 1, 2003. All patients had a modular titanium fiber metal-coated acetabular component fixed with screws (Trilogy; Zimmer, Warsaw, IN). The acetabular liner was an electron beam irradiated highly cross-linked polyethylene (Longevity; Zimmer). Before a minimum 5-year followup, 13 patients (14 hips) had died, 23 patients (25 hips) were lost or refused to return for followup, and two patients (two hips) had reoperations (one for recurrent dislocation, one for two periprosthetic fracture fixation procedures). This left 92 patients (71%) with 105 hips who had a minimum 5-year (mean, 5.7 years; range, 5–8 years) followup with complete clinical and radiographic evaluations. For three patients (three hips), the pelvic position on the digital radiographs precluded an accurate measurement of wear. Thus, the study group consisted of 90 patients (102 hips); 52 were males (60 hips) and 38 were females (42 hips). The mean age of the patients was 61.1 years (range, 27–87 years). Forty-five patients were younger than 60 years. The mean body mass index (BMI) was 29.0 kg/m^2 (range, 18.9–46.4 kg/m^2). The preoperative diagnosis was osteoarthritis in 65 hips, osteonecrosis in 20 hips, rheumatoid arthritis in five hips, and other in 12 hips.

All procedures were performed through the posterior approach by one surgeon (PFL) who was not involved in the development of the implants. The choice of femoral component fixation was based on several factors, including bone quality, femoral anatomy, and other patient demographic factors. There were 60 uncemented titanium femoral components and 42 cemented chrome-cobalt alloy femoral components implanted. The choice of femoral head size used was based on several anatomic and demographic factors, including the outer diameter size of the acetabular component implanted, the risk of dislocation (including history of alcohol abuse and patient age), as determined in previous studies from the authors' institution [20–22, 33], and liner availability from the manufacturer. The femoral head sizes selected were 26 mm in 14 hips, 28 mm in 33 hips, 32 mm in 35 hips, 36 mm in 15 hips, and 40 mm in five hips. Because there were only five hips with a 40-mm head, these hips were combined with the hips with a 36-mm head as a single group for the wear analysis.

Clinical evaluations were performed at 6 months, 1 year, and yearly thereafter by one clinical research nurse (ESS) using the Harris hip score [17].

Standard anteroposterior and frog-lateral radiographs were performed in one outpatient orthopaedic clinic by technologists who were extensively trained. The radiographs were performed at 6 to 8 weeks postoperatively, at 1 year postoperatively, and, if possible, at yearly or biannual visits. All 90 patients were recalled for the most recent or minimum 5-year followup. The radiographs were evaluated for radiolucent lines, component migration, and osteolysis by one observer (ESS) [7, 28]. The acetabular abduction and anteversion angles were measured by one observer (JMM) as a component of the polyethylene wear analysis. The mean acetabular abduction angle and acetabular anteversion determined by the Martell method were 43° (range, 24°–58°) and 22° (range, 10°–39°), respectively [25–27].

The digital radiographs were evaluated blindly at another medical center for acetabular component position and linear and volumetric wear by one orthopaedic surgeon (JMM) not involved in the care of these patients. Of the 105 sets of radiographs evaluated, 102 sets of hip radiographs were acceptable for wear measurements (inclusion rate of 97%). Two-dimensional wear analysis was performed using the method of Martell et al., a semiautomated, computerized, edge detection method [19, 25–27, 29]. Each reading of linear wear (femoral head penetration) was expressed as a magnitude (millimeters) and a rate (millimeters per year) for each of the femoral head sizes. Total volumetric wear and volumetric wear rates were calculated using custom equations based on the two-dimensional wear magnitude, femoral bearing size, and the direction of wear with respect to the face of the polyethylene liner [25–27]. We did not measure bedding-in because each hip had more than two observations after the 1-year radiograph. To obtain linear and volumetric wear rates at each year postoperatively for each hip (Figs. 1, 2), we calculated the median value of multiple wear measurements among all available radiographs for each hip (Year 2 versus Year 1, Year 3 versus Year 1, Year 3 versus Year 2, etc). Total linear and volumetric wear was obtained using only the first and latest followup radiographs for each hip. 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 a dislocation that was treated nonoperatively, was included in the clinical and wear analyses.

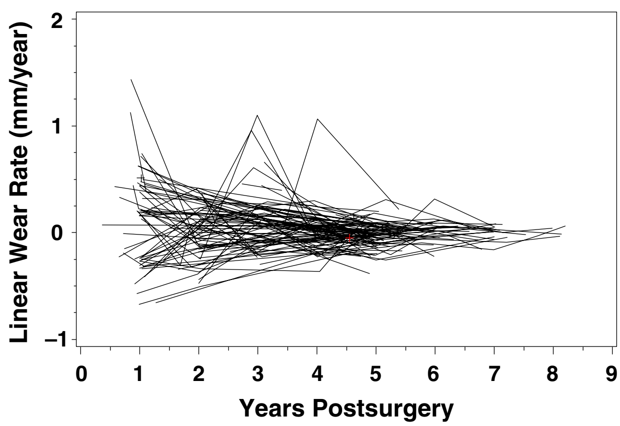

Fig. 1 A spaghetti plot of the estimated linear wear rates with time for the entire cohort (n = 102 hips) is shown. Each line represents one hip. The variation in the estimated linear wear rates decreases with time as more data points became available for inclusion in the analysis.

Fig. 2 A spaghetti plot of the estimated volumetric wear rates with time for the entire cohort (n = 102 hips) is shown. Each line represents one hip. The variation in the estimated volumetric wear rates decreases with time as more data points became available for inclusion in the analysis.

The linear and volumetric wear data were analyzed using a specific multivariate analysis [30]. We adjusted for patient age, gender, BMI, preoperative diagnosis, and method of femoral component fixation. We also adjusted for time since surgery and, for annual wear rates, time between radiographs. This regression analysis explicitly accounted for the repeated-measures nature of the wear data as a result of multiple radiographs of the hips and the multiple comparisons made between all radiographs at each time. The overall number of radiographic measurements included in the analysis was 789, reflecting the number of comparisons made between all the various pairs of radiographs on the 102 hips. However, the degrees of freedom used in the tests comparing wear by head size was based on the total number of hips (n = 102). We deleted five clear outlier wear estimates (less than 1% of the data). However, this did not affect the number of hips in the study, only the number of measurements used per hip. The three-level multivariate analysis used random intercepts for hip and time since surgery and standard errors to account for the statistical correlation introduced by the multiple measurements on the same set of hips with time. The number of radiographic wear measurements per hip ranged from two to 20. When comparing one head size with another, we adjusted for multiple comparisons using the Bonferroni correction. Linear wear tended to be approximately normally distributed, whereas volumetric wear was skewed. The multivariate analysis is appropriate for skewed data with a sample size greater than 65 [24]. All volumetric wear analyses were repeated using a rank transform and a log transform. Only 12 of the 90 patients had bilateral hip data; therefore, we treated all hips as statistically independent. A power analysis of the statistical data also was performed to determine the effect size of the different femoral heads.

Results

We observed no difference ($p \leq 0.598$) between femoral head size and the mean linear wear rate (Table 1) but found a difference between femoral head size and the mean volumetric wear rate ($p \leq 0.0005$) (Table 2) and the mean total volumetric wear ($p \leq 0.0131$) (Table 3). The overall

Table 1. Adjusted mean linear wear rates by femoral head size*

Head size (mm)	Mean linear wear rate (mm/year)
26	0.060 ± 0.042
28	0.032 ± 0.019
32	0.011 ± 0.023
36/40	0.075 ± 0.040
	$p \leq 0.5976$

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

Table 2. Adjusted mean volumetric wear rates by femoral head size*

Head size (mm)	Mean volumetric wear rate (mm^3/year)
26	52.213 ± 13.166
28	53.845 ± 7.150
32	57.642 ± 11.230
36/40	156.57 ± 21.228
	$p \leq 0.0005$

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

Table 3. Adjusted mean total volumetric wear by femoral head size*

Head size (mm)	Mean total volumetric wear (mm^3)
26	88.431 ± 36.341
28	95.519 ± 21.719
32	34.290 ± 23.945
36/40	159.64 ± 33.430
	$p \leq 0.0134$

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

linear rate was close to zero at 5 to 7 years (Fig. 1). Excluding bedding-in, the median linear wear rate was 0.028 mm/year (mean, 0.04 mm/year) (Fig. 3). The overall volumetric wear rate was less than 100 mm^3/year at 5 to 7 years (Fig. 2). The median volumetric wear rate was 25.6 mm^3/year (mean, 80.5 mm^3/year) (Fig. 4). The median total volumetric wear was 41.0 mm^3 (mean, 98.5 mm^3) (Fig. 5). The mean linear wear rates for the larger head sizes (36 and 40 mm) and each of the standard head sizes (26, 28, and 32 mm) were similar (Table 4). We observed a difference between the mean volumetric wear rates of the larger head sizes and each of the standard head sizes (Table 5). There was less ($p \leq 0.0056$) total volumetric wear in the 32-mm head group compared with that in the 36- and 40-mm head group but not between the 26-mm and 28-mm groups compared with that in the 36- and 40-mm head group (Table 6). We found no relationship between

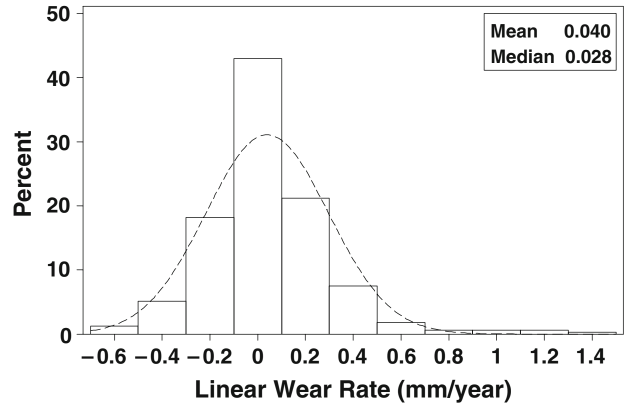

Fig. 3 A histogram of the linear wear rates for the entire cohort (n = 102 hips) shows the approximately normal distribution of this data set. The mean and median linear wear rates for the entire cohort are displayed on the histogram.

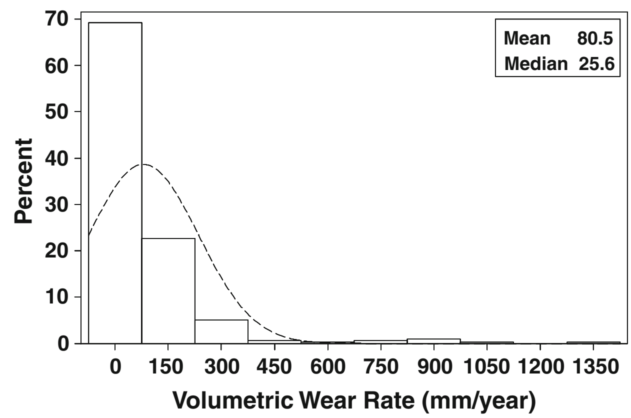

Fig. 4 A histogram of the volumetric wear rates for the entire cohort (n = 102 hips) shows the skewed distribution of this data set. The mean and median volumetric wear rates for the entire cohort are displayed on the histogram.

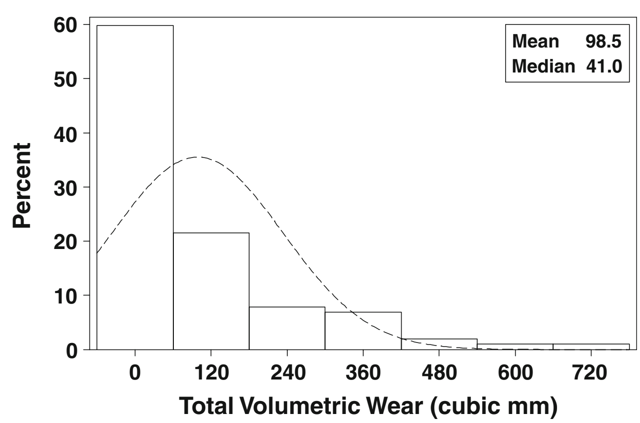

Fig. 5 A histogram of the total volumetric wear for the entire cohort (n = 102 hips) shows the skewed distribution of this data set. The mean and median total volumetric wear for the entire cohort is displayed on the histogram.

Table 4. Differences between adjusted mean linear wear rates for large and conventional head sizes*

Head size (mm)	Mean difference (mm/year)	p Value
26 versus 36/40	−0.016 ± 0.059	0.9999
28 versus 36/40	−0.043 ± 0.046	0.9999
32 versus 36/40	−0.064 ± 0.050	0.6177

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

Table 5. Differences between adjusted mean volumetric wear rates for large and conventional head sizes*

Head size (mm)	Mean difference (mm^3/year)	p Value
26 versus 36/40	−104.40 ± 26.663	0.0005
28 versus 36/40	−102.70 ± 23.946	0.0001
32 versus 36/40	−98.93 ± 24.187	0.0003

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

Table 6. Differences between adjusted mean total volumetric wear for large and conventional head sizes*

Head size (mm)	Mean difference (mm^3)	p Value
26 versus 36/40	−71.21 ± 55.259	0.6024
28 versus 36/40	−64.12 ± 43.415	0.4295
32 versus 36/40	−125.30 ± 39.096	0.0056

* Adjusted for patient age, gender, body mass index, preoperative diagnosis, method of femoral component fixation, and activity component of the hip score.

the mean linear wear rate or mean volumetric wear rate and patient gender, patient age, BMI, preoperative diagnosis, and femoral component fixation. There was no relationship between the total volumetric wear and patient age, BMI, or preoperative diagnosis. We did find associations between the total volumetric wear and male gender ($p \leq 0.0374$) and uncemented femoral component fixation ($p \leq 0.0137$).

There were no hips with osteolysis or component migration at the most recent followup. Eighteen radiolucent lines (all less than 1 mm) were observed in the acetabular components of 14 hips (13 patients). Seven radiolucent lines were in Zone 1, three were in Zone 2, and eight were in Zone 3. There no radiolucent lines in any of the femoral components.

Discussion

Biomechanical and short-term clinical studies suggest substantially reduced wear rates with XLPE compared with conventional polyethylene sterilized in an inert environment [8, 9, 11]. Electron beam XLPE reportedly is associated with extremely low rates of wear that appear independent of femoral head size even when paired with femoral heads as large as 46 mm [1, 3, 12, 32]. There are little clinical data of electron beam XLPE with larger femoral heads with two small studies of hips with followups less than 5 years [3, 14]. The purposes of our study were to determine if there were differences in the linear and volumetric wear rates with the larger femoral head sizes (36 and 40 mm) compared with the standard femoral head sizes (26, 28, and 32 mm).

There are several limitations to this study. First, the study was not randomized and only 20 hips were implanted with a 36- or 40-mm femoral head. However, we found adequate power to detect relevant clinical differences in linear and volumetric wear among the head sizes (Table 7). Second, the low median linear wear rate of 0.028 mm/year in this cohort means wear values representing less than 3 years followup are below the detection limits for the measurement technique. Wear is near zero with this polyethylene implant, which makes the "noise" of the measurement system more apparent. Reporting the negative values allows the reader to interpret the effect of noise on the measurement series. To discard the absolute value of negative measurements would artificially decrease the standard deviation of the measurement system while insidiously raising the mean wear values. Because our statistical methods deal with the range of measurements, we are able to draw conclusions on the effect of head size with these data. Third, we did not routinely have patients complete a validated activity scale. However, there is no reason to believe patients with higher activity level were in the 36- and 40-mm head size group; there were no differences in the age, gender, and BMI in the patients with the larger and standard femoral head sizes. Fourth, 25 hips (17%) of the original cohort were lost to followup, and these could have included patients with high or low wear rates. However, our sample size was greater than 100 hips, and the followup period was 5 to 8 years (mean, 5.7 years). The technique and quality of the radiographs were excellent, because only three hips were excluded as a result of pelvic positioning, which precluded the wear measurements.

The use of large femoral heads (36, 38, or 40 mm) in THA offers several theoretical advantages, including decreased impingement, increased range of hip motion, and decreased risk of dislocation [4, 5]. A reduced risk or elimination of dislocation of hips with larger femoral heads may result from decreased component-component or component-bone impingement and increased translation that is required for hip dislocation [4, 15, 21]. Despite these theoretical advantages, the use of larger femoral heads (greater than 32 mm) in THA has been limited as a result

Table 7. Statistical power to detect relevant clinical differences

Parameter	Linear wear rate of 0.15 mm/year	Volumetric wear rate of 100 mm^3/year	Total volumetric wear of 150 mm^3
Head size (mm)			
26 versus 36/40	89%	96%	87%
28 versus 36/40	98%	99%	97%
32 versus 36/40	98%	99%	97%

Measurement	36 and 40 versus 26		36 and 40 versus 28		36 and 40 versus 32	
	SD/effect size	Power	SD/effect size	Power	SD/effect size	Power
Linear rate	0.115/0.150	> 99%	0.126/0.150	> 99%	0.118/0.150	> 99%
Volumetric rate	27.7/100	> 99%	19.27/100	> 99%	8.1/100	> 99%
Volumetric wear	87.8/150	> 99%	107/150	> 99%	121.63/150	> 99%
Number	27		35		45	

SD = standard deviation.

of concerns regarding increased production of polyethylene wear debris. This is based primarily on the study of Livermore et al., in which wear of 385 cemented total hips with conventional polyethylene liners articulating with 22-, 28-, and 32-mm femoral heads was measured [23]. They reported increased volumetric wear rates, total volumetric wear, and amount of osteolysis for 32-mm heads compared with 22-mm and 28-mm heads.

Biomechanical studies have reported the wear behavior of electron beam XLPE is different from that of conventional polyethylene [2, 16, 31]. One study using a Boston hip simulator showed the linear wear rate of electron beam XLPE was extremely low and independent of femoral head size for standard size femoral heads (22 to 32 mm) [31]. Other hip simulator studies showed this unique phenomenon also was true for larger femoral head sizes up to 46 mm [5, 12, 32]. Muratoglu et al. reported negative wear rates similar for femoral head sizes from 22 to 46 mm [32]. Even when paired with 46-mm heads, electron beam XLPE retained its machining marks to 11 million cycles of simulated gait. Bragdon et al. reported electron beam XLPE third-body wear in a hip simulator also was independent of femoral head size [3].

There are relatively little comparative clinical data evaluating electron beam XLPE wear with larger femoral head sizes. In one prospective study of 30 hips, radiostereometric analysis was used to evaluate the wear rate of electron beam XLPE with standard (28-mm) and large (36-mm) femoral head sizes [1]. The authors reported no difference in the linear wear rates or total linear wear between the standard and large head groups at 3 years followup. However, the steady-state linear wear rates for both groups were below the detection limit of the radiostereometric analysis method. Another prospective study of 45 hips (42 patients) in which electron beam XLPE was paired with large (36-, 38-, or 40-mm) femoral heads showed a linear wear rate that approximated zero (0.06 mm^3/year) at a median followup of 3.3 years [14]. There were no differences in total linear wear among the three femoral head sizes. That study concluded electron beam XLPE with larger femoral heads should be considered for patients with a high risk of dislocation. These two clinical studies were limited by short-term followups and relatively small sample sizes. These two studies did not report volumetric wear rates or total volumetric wear, which may be a more accurate predictor of polyethylene wear debris and osteolysis.

The particular variety of electron beam XLPE in the implants in our study had extremely low linear and volumetric wear rates with excellent clinical and radiographic results at 5 to 8 years followup. These data confirm the biomechanical and shorter-term clinical studies. Although the larger femoral heads (36 and 40 mm) also had extremely low linear wear rates, we observed greater volumetric wear rates compared with the three standard size heads. We also observed a difference in total volumetric wear with the larger femoral heads compared with the standard size femoral heads, but only when compared with the 32-mm femoral head. Our study may modify the concept that the wear of electron beam XLPE is independent of femoral head size. Although the linear wear rate was not related to the femoral head diameter, there was a greater volumetric wear rate with the larger heads. Additional studies are needed to evaluate the long-term effect of larger femoral head sizes with electron beam XLPE and the potential association with osteolysis and late material failure or fracture of the polyethylene. Until these studies are completed, we advise caution using large femoral head sizes in young or active patients with stable hip reconstructions.

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