Short-term Wear Evaluation of Thin Acetabular Liners on 36-mm Femoral Heads

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Abstract

Background Dislocation remains the leading cause of revision THA. One approach to decreasing prosthetic dislocation risk has been the use of larger femoral head component sizes. The upper limit of head size in metal-on-polyethylene hip arthroplasty has historically been limited because of concerns about increased wear on thin polyethylene components. It is not known to what degree this concern should apply to more wear-resistant polyethylene components.

Questions/purposes We therefore determined (1) in vitro wear rates of polyethylene liners of varying thicknesses, (2) whether there were differences in the microscopic wear characteristics as a function of polyethylene thickness, and (3) whether thin polyethylene components resulted in early catastrophic failures.

Methods We used a hip wear simulator to compare the wear performance of 12 highly crosslinked polyethylene

acetabular inserts. The internal diameter of all components was 36 mm, and there were three samples tested of each thickness (1.9, 3.9, 5.9, or 7.9 mm). Testing was conducted for 2.4 million cycles. Gravimetric mass loss was converted to volumetric loss, which was subsequently converted to theoretical linear penetration rates.

Results Wear rates decreased with increasing polyethylene thickness. Mean $\pm$ SD wear rates for the 1.9-, 3.9-, 5.9-, and 7.9-mm groups were 5.0 ± 0.5 , 3.2 ± 0.3 , 2.5 ± 1.1 , and 2.2 ± 1.3 mm³/million cycles, respectively ($p < 0.016$). Calculated penetration rates were 0.015, 0.012, 0.011, and 0.010 mm/million cycles, respectively ($p < 0.016$). There were no catastrophic failures in any group.

Conclusions Thinner polyethylene components demonstrated higher wear rates, although even the highest wear rate observed in the thinnest polyethylene specimen was lower than that commonly reported for noncrosslinked

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polyethylene components. While encouraging, these findings should be validated *in vivo* before clinical recommendations can be made.

Introduction

Dislocation remains a leading cause of revision THA in the United States, in one report accounting for 22.4% of 51,345 revision THAs performed between 2005 and 2006, followed by mechanical loosening (19%) and infection (15%) [6]. This will continue to be a concern, as the percentage of revision procedures is expected to increase from 10% to 20% of all THAs by the year 2030 [15]. Numerous factors have been associated with dislocation risk, including femoral head size [7, 13, 14, 22], femoral stem design [1, 32], acetabular component orientation [2, 4, 17], surgical approach [4, 18, 22], soft tissue laxity [27], and other patient-specific factors [4, 12, 22]. Large-head metal-on-metal was one technology that allowed for increased head sizes to reduce dislocation rates. Unfortunately, these implants have fallen out of favor in both the popular [19–21] and scientific communities because of risks of adverse soft tissue reactions [29]. The upper limit of head size in metal-on-polyethylene hip arthroplasty has historically been limited due to concerns regarding polyethylene thickness. In a landmark paper by Bartel et al. [3], the authors concluded that the thickness of the polyethylene component should be maximized to reduce stresses and recommended a minimal thickness of 8 mm. The analysis and focus at that time were on stresses, and the polyethylene used was gamma-in-air sterilized, which allowed increased oxidation and subsequent osteolysis [3].

Early attempts to use thin polyethylene liners resulted in catastrophic failures linked to either a faulty locking mechanism or polyethylene wear-through [5, 31]. These reported results further validated the early conclusion of Bartel et al. [3] that thicker polyethylene liners were needed to minimize stresses and prevent failure. However, modern acetabular component designs have evolved to address the issue of high stresses around locking mechanisms. Furthermore, the polyethylene materials in total joint arthroplasty today have improved wear characteristics when compared to early UHMWPE implants that were plagued by osteolysis. One such manufacturing process implemented to decrease wear rates and the incidence of osteolysis was irradiation crosslinking. It has been shown that wear rates decrease exponentially with increasing doses of radiation, and wear rates have reportedly decreased by 58% to 74% over UHMWPE in various *in vitro* studies [9, 11, 16, 23, 25, 26, 30]. However, as the radiation dose increases, the material becomes increasingly brittle and at risk for fracture. One solution to prevent this occurrence was to implement sequential irradiation and

annealing in smaller doses, which have been shown to have a cumulative effect on wear rates and result in a lower incidence of osteolysis, while having less effect on some material mechanical properties. Due to these improvements in design and manufacturing (including sequential irradiation and annealing, irradiation and melting, or vitamin E stabilization [10]), it may be possible to allow for the introduction of thinner components; however, it is difficult to extrapolate the findings of earlier research performed on UHMWPE to these newer polyethylene acetabular liners.

No convincing studies have determined the minimal allowable thickness for modern polyethylene components. We evaluated the wear characteristics of thin acetabular polyethylene liners from a single manufacturer that underwent sequential irradiation and annealing using a hip simulator model. To assess this, we asked the following questions: (1) What were the *in vitro* wear rates of sequentially irradiated and annealed highly crosslinked polyethylene liners of nominal thicknesses varying from 1.9 to 7.9 mm? (2) Was there a difference in the wear characteristics when visually (microscopically) assessed? And (3) was there any evidence of early catastrophic failure (eg, wear-through, rim fracture, or cup fracture) when the thin polyethylene components were tested in the wear simulator?

Materials and Methods

This study was conducted in the hip simulator as an *in vitro* wear analysis using components varying in size from 1.9 to 7.9 mm. We evaluated four sets of sequentially crosslinked (X3[®]; Stryker Orthopaedics, Mahwah, NJ, USA) Trident[®] design acetabular inserts ($n = 12$) with internal diameters of 36 mm and wall thicknesses of 1.9, 3.9, 5.9, and 7.9 mm. Sequentially crosslinked liners were machined from compression-molded GUR1020 UHMWPE that had been γ -irradiated to 30 kGy followed by annealing three times (total dose = 90 kGy). All inserts were mated against 36-mm-diameter cobalt-chromium femoral heads. Samples underwent hip simulator testing to approximate daily wear while *in vivo*, and wear rates were evaluated. On completion of the testing, samples were evaluated under light microscopy to determine whether there was a difference in the types of wear based on polyethylene thickness. All samples were continuously monitored for any signs of catastrophic failure, at which point the testing on that sample would be terminated and the specimen analyzed for causes of failure. This *in vitro* study was exempt from institutional review board approval.

A hip simulator (Materials Testing Systems, Eden Prairie, MN, USA) was used for testing (Fig. 1), with the cups positioned anatomically (superior) and oriented at 50°

Fig. 1 A hip simulator undergoing testing of various thickness polyethylene components is shown.

of abduction. Testing ran at 1 Hz with cyclic Paul curve physiologic loading applied axially, at a maximum of 2450 N for 2.4 million cycles [24]. Component assemblies were lubricated using Alpha® Calf Fraction serum (Hyclone Labs, Logan, UT, USA) diluted to 50% with a pH-balanced 20-mM solution of deionized water and EDTA (protein level $\approx$ 20 g/L). The serum solution was replaced at minimum every 0.5 million cycles.

Inserts were removed to assess for gravimetric wear at a minimum of every 0.5 million cycles. Dynamically loaded soak control specimens were used to correct for fluid absorption with weight loss data converted to volumetric data (by material density). All samples were weighed until two weights were within 0.05 mg of each other, and the average of these two weights was used in calculations of gravimetric wear, which was defined as change in weight per number of cycles. Linear regression was used to determine wear rates. To better characterize the actual functional impact of this wear on the bearing surface, the volumetric wear rates were subsequently converted to theoretical linear penetration rates, which can be useful when comparing to other studies and clinical wear scenarios. Wear rates were then evaluated to determine whether they varied as a function of polyethylene thickness. Regression statistics were calculated to assess fit of the model.

All specimens were visually inspected after completion of the study for any signs of wear scars, polishing, scratching patterns, pitting, cratering, burnishing, cracking, or particle embedding. This was performed to verify that the wear characteristics were similar among the varying thicknesses of polyethylene components, that the wear process was similar, and that the wear rates could be directly compared among groups.

The following were all considered potential types of catastrophic failure: wear-through, rim fracture, and cup

Fig. 2 A graph shows wear rates of the various thickness polyethylene components. The wear rate in the 1.9-mm group was higher than those in all other groups ($p = 0.016$). Bars = mean; error bars = SD; mc = million cycles.

fracture. All specimens were continuously monitored throughout the test to assess for rim or cup fracture. If any insert was found to have signs of catastrophic failure, it was immediately removed from the testing simulator and assessed for the cause of failure. Furthermore, specimens were evaluated for wear-through at the time of weighing, which was conducted at a minimum every 0.5 million cycles.

Statistical analysis was performed using JMP-8® statistical software (SAS Institute Inc, Cary, NC, USA). A mean value was used from a minimum of three weights for each sample at every weight interval. A mean was then calculated for each group based on nominal polyethylene thickness. The difference in mean weights was then used to calculate a volumetric wear rate based on polyethylene thickness and was further used to calculate the linear wear rate as described above. Regression analyses were assessed using R^2 values for model fit; an R^2 value of 1 was considered a perfect fit model, while an R^2 value of 0 indicated no correlation. ANOVA at the 95% CI was used to compare wear rates among groups. Post hoc analyses were performed using Student's *t*-test to evaluate the significance of differences among groups. We considered *p* values of less than 0.05 significant.

Results

The mean wear rate decreased with increasing polyethylene thickness (Fig. 2). The wear rate in the 1.9-mm group was higher than those in all other groups ($p = 0.016$). The remaining groups, 3.9 to 7.9 mm, were not different from each other ($p = 0.42$). Calculated penetration rates were 0.015, 0.012, 0.011, and 0.010 mm/million cycles, respectively ($p < 0.016$) (Table 1). Linear regression of all wear rates as a function of thickness revealed a linear coefficient of correlation of $R^2 = 0.63$; when the 1.9-mm

Table 1. Volume loss, wear rate, and linear penetration for polyethylene liners of varying thicknesses

Thickness (mm)	Volume loss (mm ³)*	Wear rate (mm ³ /mc)*	Penetration (μm/mc)
1.9	11.2 ± 1.3	5.0 ± 0.5	0.015
3.9	5.4 ± 0.3	3.3 ± 0.3	0.012
5.9	4.3 ± 2.7	2.5 ± 1.1	0.011
7.9	2.5 ± 3.4	2.2 ± 1.3	0.010

* Values are expressed as mean ± SD; mc = million cycles.

Fig. 3 Visual inspection demonstrates typical wear characteristics of the polyethylene components. Note the presence of wear scars, scratching, and polishing. There was no difference in the visual appearance of these wear patterns among the various component thicknesses.

group was removed, there was a linear coefficient of correlation of $R^2 = 0.23$.

Visual examination of the worn inserts revealed similar wear scars and features on the articular surfaces of all thickness liners, notably including polishing and some scratching (Fig. 3). There was no evidence of embedded particles or other third-body wear that could have influenced the wear rates. Furthermore, there was no appreciable difference in observed wear characteristics at any period to indicate that there was any difference in wear patterns at early rather than late cycles.

There were no catastrophic failures; specifically, there was no cracking or fracture of the material noted in any component from any of the testing groups.

Discussion

Dislocation remains one of the most frequent complications after THA and is a leading indication for revision THA, with dislocations accounting for 22% of all revision procedures, followed by mechanical loosening (19%) and infection (15%) [6]. Although some of the risk factors

cannot be modified (eg, patient-specific factors), others can be altered to minimize risk. One such factor that can be modified is femoral head component size. Historically, femoral head size has been limited due to a minimum polyethylene thickness of 8 mm; with the advent of newer polyethylene technology and improved acetabular shell-polyethylene liner interfaces, we believed that this recommendation should be revisited to determine whether thinner polyethylene liners might be safe and effective while allowing for larger femoral heads. To evaluate this, we performed an in vitro hip simulator study with polyethylene liners of varying thickness to assess wear rates, whether the wear rates were dependent on polyethylene liner thickness, and the incidence of catastrophic failures.

There were several limitations to this study. This is an in vitro study conducted to approximate the effects of in vivo wear on polyethylene components in THA. Although the wear rates reported in this study cannot be directly compared to in vivo wear rates, we believe that our data are relevant when compared to the published literature of in vitro wear analyses. Additionally, although the in vivo wear analysis was conducted only to 2.4 million cycles, this is a sufficient duration to reach steady-state wear. However, longer duration may provide additional information for long-term wear, and future studies could continue these experiments to component failure. Furthermore, it should be noted that the original study on which polyethylene thickness has been limited was a purely theoretical mathematical model, whereby stresses were calculated by finite element analysis; consequently, the present study provides data that are more relevant to the practical implementation of component design, as it more closely approximates an in vivo setting. A limitation of the portion of the study devoted to catastrophic failure was that oxidation was not accounted for. As components are exposed to air during storage and continue to oxidize after implantation, this may affect the likelihood of catastrophic failure. Future studies should address oxidation separately. Additionally, oxidation may be related to contact stresses, consequently leading to increased oxidation in vivo. Future studies, such as wear retrieval and explantation studies of components in vivo, may provide insight into this, as well as clinical wear rates. An interesting finding of this study was the variability of wear rates based on component thickness. It is uncertain what the root cause of this phenomenon is; future studies or finite element simulations could be utilized to elucidate this root cause. Another limitation may be sample size. A risk of small sample size is the ability to predict events that may have a small probability of occurrence, such as catastrophic failures. Future studies could address this by conducting the study with variable loading conditions, longer duration of testing cycles, or impact testing the components until failure, to

better characterize the specific loading conditions under which the components fail. Additionally, variable inclination and abduction angles could be modeled to evaluate less-than-ideal loading conditions. Despite this, the study was conducted at a cyclic rate and load parameters that approximate typical in vivo stresses generated in the prosthesis; as such, we believe the conclusions drawn from this study are widely applicable to the typical patient who undergoes a THA. Furthermore, a prospective series of 53 patients who had been implanted with 3.8-mm polyethylene liners made of the same polyethylene we tested has demonstrated no catastrophic failures at short-term 2-year followup [28].

Various studies have demonstrated a reduction of 58% to 74% in wear rates between UHMWPE and highly crosslinked polyethylene (Table 2) [9, 11, 16, 23, 25, 26, 30]. Larger reductions in wear could be expected if the comparison were to 36-mm-diameter conventional polyethylene. Additionally, when the wear rates observed in this study were converted to linear penetration values (taking into account the effect of bearing size and clearance), the values were comparable to clinically reported yearly linear penetration values for sequentially cross-linked polyethylene [8].

Our visual observations of the wear scars for all testing groups suggested that the mode of wear was similar for each group. The absence of fracture lines or cracking of the material throughout the duration of testing implied that the structural integrity of the material may be able to withstand physiologic loading conditions, even for the commercially unavailable 1.9-mm-thick samples, albeit at a higher wear rate than the thicker inserts. Additionally, the fact that the observed wear characteristics (eg, scarring, pitting, etc) were fairly consistent throughout the testing period would suggest that the bedding-in period was most likely minimal and may not have significantly affected the wear rate calculated in this study.

In addition to increased wear rates, catastrophic failures are one of the major concerns with decreasing acetabular liner thickness, due to several reports in the literature that

have demonstrated this effect [5, 31]. Although these failures have been reported in both UHMWPE and highly crosslinked polyethylene, the increased brittleness of highly crosslinked polyethylene puts these liners at greater risk. In a study by Berry et al. [5], 10 cases of catastrophic acetabular liner failure were described. These consisted of wear-through ($n = 2$), fracture ($n = 3$), or a combination of those two failure modes ($n = 5$). All failures occurred in patients who had acetabular liners implanted with thicknesses of less than 5 mm. In another study by Tower et al. [31], catastrophic failures of four acetabular liners were described. These failures, however, were noted to be due to a faulty design, whereby the rim of the acetabular liner had a polyethylene thickness of less than 4 mm, which it was determined led to increased stresses in this region and ultimately catastrophic failure. Our study, in contrast, would suggest that acetabular liners of 3.9-mm thickness do not wear differently from thicker liners and may be able to withstand physiologic loading conditions without catastrophic failure. However, the 1.9-mm liner did have a higher wear rate; consequently, this higher wear rate, in combination with smaller nominal thickness, may ultimately lead to a condition whereby wear-through and catastrophic failure are risks when subjected to physiologic loading, and we do not recommend the use of liners of this thickness.

Thinner polyethylene components demonstrated higher wear rates in this short-term simulator study, although even the highest wear rate observed in the thinnest polyethylene specimen was lower than that commonly reported for noncrosslinked polyethylene components. Clinically, this may have implications on liner thickness and femoral head sizes in the future. However, although encouraging, these findings should be validated in vivo before specific clinical recommendations can be made.

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Table 2. Summary of literature reporting wear rates of highly crosslinked polyethylene

Study	Year	Wear rate (mm/year)
Reynolds et al. [26]	2012	0.037
Ranawat et al. [25]	2012	0.038
D'Antonio et al. [11]	2012	0.015
Lee et al. [16]	2011	0.031
Thomas et al. [30]	2011	0.005
Capello et al. [9]	2011	0.031
Mutimer et al. [23]	2010	0.05

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