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High Stress Conditions Do Not Increase Wear of Thin Highly Crosslinked UHMWPE

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Abstract Introduction of highly crosslinked polyethylene has increased interest in large femoral heads, because thin acetabular liners can be used while maintaining low wear rates and larger heads decrease the incidence of instability. However, crosslinking and subsequent thermal treatments can cause decreased mechanical properties that might obviate the reduced wear under extreme conditions. To examine whether increased contact pressures would adversely affect wear in thin liners, we tested thin and thick highly crosslinked liners (3.8 mm thickness/44-mm head and 7.9 mm thickness/36-mm head, respectively) to 5 million cycles on a hip simulator under near impingement conditions. Conventional polyethylene liners (7.9 mm thickness/36-mm head) served as controls. Large femoral heads with highly crosslinked polyethylene liners as thin as 3.8 mm in thickness do not wear at a higher rate than a thicker liner of the same material, even when subjected to large contact pressures such as occur under near-impingement conditions. Crosslinked polyethylene may allow for liners that are thinner than has been traditionally accepted. This conclusion, however, is based solely on wear test results with idealized cup position, no intentional edge loading, no head subluxation, and no artificial aging. Continued monitoring will be necessary to elucidate the clinical efficacy of these devices.

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Introduction

The use of large femoral heads in THA can increase range of motion and decrease the incidence of dislocation [1, 2] but requires the use of thin ultrahigh-molecular-weight polyethylene (UHMWPE) liners to retain acetabular bone. A major disadvantage of large-diameter femoral heads is the resulting increased sliding distance and sliding velocity, which can lead to increased wear compared with smaller heads [16]. The introduction of highly crosslinked polyethylenes, with their improved wear properties, has allowed for the marketing of thin acetabular liners in conjunction with large femoral heads.

When used in conventional head sizes, crosslinked polyethylene has led to marked reductions of 40% to 95% in wear as measured clinically from serial radiographs and radiostereometric measurements [4, 5, 7, 10, 23]. Laboratory experiments using a hip simulator demonstrated reduced wear could be expected with larger heads (up to 46 mm in diameter) and 3-mm thick highly crosslinked polyethylene liners when tested under normal gait conditions and orientation [17].

A potential disadvantage of highly crosslinked polyethylenes is the decrease in mechanical properties that accompanies some of the crosslinking/thermal processing, including lower yield strength, ultimate tensile strength, and elongation to break and decreased resistance to fracture and fatigue [9, 22]. This is particularly worrisome at the extremes of hip motion under impingement or near-impingement conditions. Finite element studies have demonstrated stresses above the yield strength of

UHMWPE under subluxation and impingement conditions [3, 14]. Impingement is a common occurrence in patients undergoing THA. In a recent retrieval study of conventional polyethylene acetabular components, impingement was found in 96 (56%) of the 170 implants analyzed [24]. Furthermore, two recent retrieval studies of highly cross-linked acetabular liners reported fracture of the rims, reinforcing this concern [11, 25]. Large femoral heads increase impingement-free range of motion by 28% [3], making it less likely that impingement will occur. However, this increased range of motion allows patients to achieve motions that still result in near-impingement conditions, thus exposing the polyethylene near the rim opposite the impingement to increased contact stresses and, therefore, potentially increased propensity for wear.

We therefore asked whether weight loss and wear damage of acetabular liners under large stress, near-impingement conditions would demonstrate a dependence on: (1) material (conventional versus crosslinked); and (2) thickness in highly crosslinked liners (liner thickness associated with a 36 mm head versus that associated with a 44 mm head).

Materials and Methods

We tested three groups of UHMWPE acetabular liners. Two groups were made of X3® material (GUR1020 resin; Stryker Orthopaedics, Mahwah, NJ), which is highly crosslinked by three sequential exposures to gamma irradiation at 3 Mrads followed by annealing below the melt temperature [6]. One highly crosslinked group had an inner diameter of 36 mm and a thickness of 7.9 mm. The other highly crosslinked group had an inner diameter of 44 mm and a thickness of 3.8 mm. The third group of liners was made from conventional UHMWPE (Stryker Orthopaedics) machined from GUR 1050 bar stock with an inner diameter of 36 mm and a thickness of 7.9 mm, equal to that of the thicker highly crosslinked group. The conventional polyethylene components were packaged in nitrogen and sterilized using 30 kGy of gamma irradiation. We measured specimen thicknesses at 34° from the pole, near the location of maximum loading that was applied in the wear test. There were four test specimens per group as well as three soak controls for both of the highly crosslinked groups and two soak controls for the conventional group.

The polyethylene liners were articulated against commercially produced cobalt chromium alloy femoral heads of either 36 mm or 44 mm diameter (LFIT™ Anatomic C-Taper; Stryker Orthopaedics). A stainless steel sleeve was manufactured to interface between the trunion taper on the hip simulator and the taper of the femoral heads. This sleeve did not extend beyond the head sufficiently to impinge with the liner. We seated the liners in hydroxyapatite-coated 54-mm titanium alloy cluster hole acetabular shells (Trident® PSL® HA cluster; Stryker Orthopaedics). The polyethylene locking bead was removed from the acetabular liners to assist in removal and reassembly for the periodic weight measurements performed during the test.

We oriented the liners in the test stations of the hip simulator so that the superior pole of the femoral head would sweep near the edge of the liner at maximum load during each wear cycle, creating a near-impingement condition of the femoral neck on the opposite side of the liner. This required 33° inclined blocks to be added to the 23° blocks on each test station (Fig. 1A–B). Anatomically, this orientation corresponded to 101° of flexion with acetabular anteversion of 20° and acetabular inclination of 45°. We confirmed that this orientation increased the contact stresses by performing finite element analyses of a simplified model of the highly crosslinked liner that did not include the rim, locking geometry, or other geometric details. The half symmetric model consisted of a variable thickness liner supported by a 4 mm thick conforming titanium shell with inner diameter 48 mm and liner-shell friction coefficient of 0.40. The head was modeled by a rigid surface with friction coefficient of 0.025 between it and the conforming liner. Two head diameters were modeled: 36 mm and 44 mm. The offset between the head centers and the shell center was 2 mm. A 2000 N radial load was applied at 23 or 56 degrees with respect to the polar axis of the shell.

Liners were soaked before wear testing in a deionized water bath for a minimum of 28 days to allow for fluid absorption. We ran the liners for 5 million cycles on a 12-station Shore-Western hip simulator (Monrovia, CA) using a Paul-type hip-load profile with a maximum load of 2000 N applied at a frequency of 1 Hz. All components were tested in 50% bovine calf serum with the addition of EDTA to inhibit protein precipitation. The 12 test stations were disassembled, and the liners were cleaned, weighed, photographed, and viewed with a light stereomicroscope (magnification ×10 to ×32) every half million cycles. Light stereomicroscopy was used to determine the presence and extent of wear damage and to identify the presence of rim cracks. Each station was specimen-specific; liners were not randomized during testing. The soak controls in each group underwent the same dynamic loading regime as the test liners but applied in uniaxial compression without any wear motion.

We determined wear rates for each liner from linear regression of the loss in liner weight (adjusted using the weight gains from the loaded soak control liners) versus the number of cycles over which the loss was measured. We determined differences in wear rate among the three test

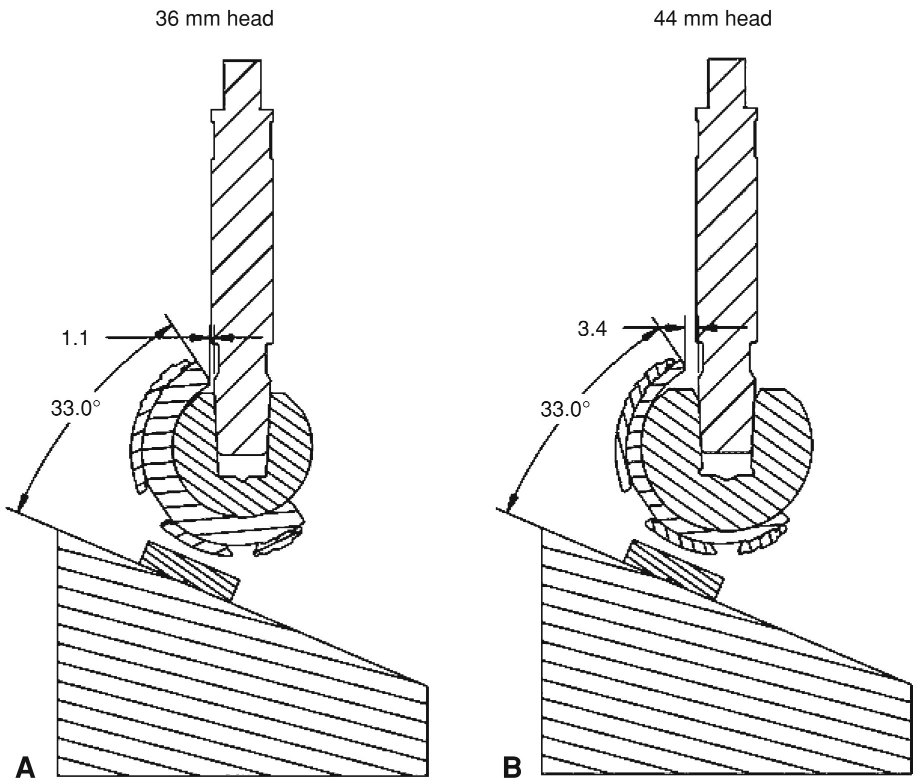

Fig. 1A–B The acetabular liners were tested under high stress conditions created by positioning the rim of the liner at 33° to the axis of the femoral neck (56° from the horizontal plane of the test station). During each cycle of wear testing, the maximum load of the applied gait cycle coincided to the point in the cycle that the components were in this position. The clearance between the femoral neck and the liner rim for this position was (**A**) 1.1 mm for the 36-mm femoral heads and (**B**) 3.4 mm for the 44-mm heads.

groups using one-way analysis of variance followed by a post hoc analysis with a Tukey test (SigmaStat 3.1, San Jose, CA).

Results

The preliminary finite element analysis demonstrated that contact stresses always increased with increased load angle. The stress increase was 70 percent for the thin liner and 58 percent for the thick liner. The average weight loss of the conventional liners was higher ($p < 0.001$) than that of both crosslinked groups: 20 times higher than the thick crosslinked group and 37 times higher than the thin crosslinked group (Fig. 2). Burnishing and scratching were the main damage modes observed on the bearing surfaces of the conventional liners under light stereomicroscopy. Greater wear damage was seen on the articular surfaces of the conventional liners than either of the crosslinked groups. The original machining marks on the articular surface of the conventional liners had been removed by burnishing of the original machining marks. This

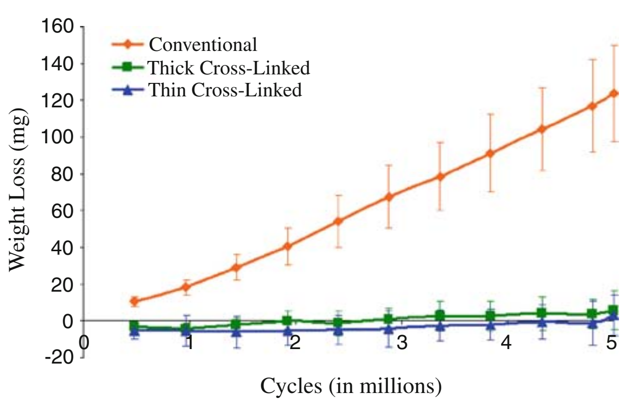

Fig. 2 Weight loss in the acetabular liners was plotted against the number of cycles for the wear test.

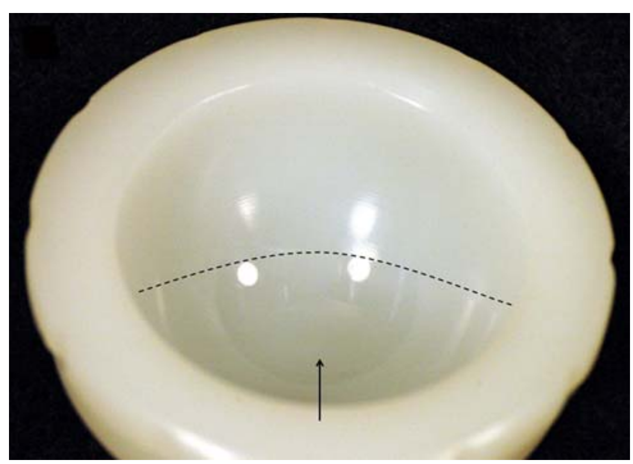

Fig. 3 Photograph of articular surface wear at 5 million cycles in a conventional liner. Note the asymmetric burnishing (indicated by the dashed line).

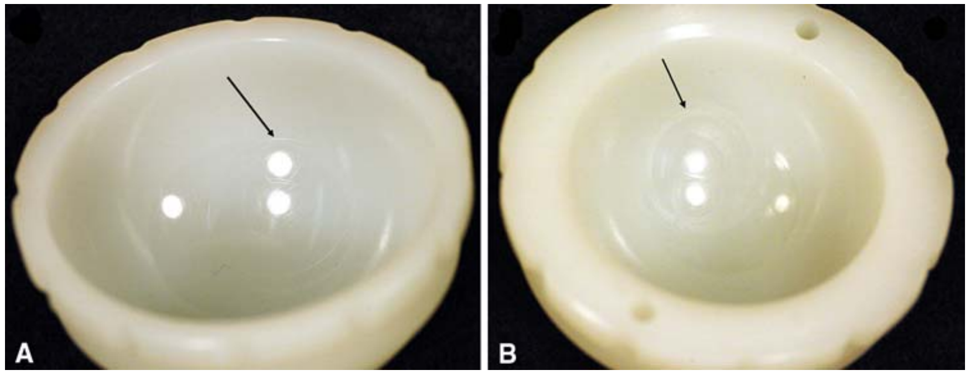

Fig. 4A–B Photographs of the articular surface wear at 5 million cycles in (**A**) a thin crosslinked liner and (**B**) a thick crosslinked liner. Note the circular scratching patterns in the crosslinked liners.

burnishing of conventional liners had an asymmetric pattern with an area that was virtually undamaged on the nonarticulating aspect of the liner (Fig. 3). Further damage was observed on the backsides of liners where evidence of creep of the polyethylene into the screw holes of the metallic shells was noted. Although the test was designed to be a near-impingement condition, we observed impingement in two of the four conventional liners. Liners that underwent impingement had higher weight loss than the nonimpinging liners.

The wear rate of the thin crosslinked material was similar to ($p = 1.00$) that for the thick crosslinked material. The main damage modes on the crosslinked liners were also burnishing and scratching in the area opposite the site of impingement. However, a high frequency of fine, circular scratching was seen on the crosslinked liners, whereas burnishing was more prevalent on the conventional liners (Fig. 4A–B). Both groups of crosslinked liners also had evidence of asymmetric wear and backside screw hole creep. Unintentional impingement was seen in three of the four thick crosslinked liners but was not seen in any of the thin crosslinked liners (Table 1). No cracks were observed in any of the liners.

Table 1. Head size, polyethylene thickness, material, incidence of impingement, and weight loss of test components

	Head size (mm)	Polyethylene thickness (mm)	Material	Impingement?	Weight loss (mg)
1	36	7.9	Conventional	No	85.7
2				Yes	144.1
3				Yes	138.3
4				No	126.8
5	36	7.9	Highly crosslinked	Yes	5.2
6				Yes	7.9
7				No	−7.3
8				Yes	18.3
9	44	3.8	Highly crosslinked	No	12.7
10				No	11.5
11				No	−0.5
12				No	−10.5

Discussion

Although highly crosslinked UHMWPE has shown improved wear in clinical and laboratory testing, there is concern regarding wear resistance and fatigue properties under adverse loading conditions. Using a hip simulator model that created large contact pressures, we therefore asked whether a conventional material would display increased wear when compared with crosslinked material with the same geometry. Furthermore, we tested whether reduced thickness in a highly crosslinked polyethylene acetabular liner would result in increased wear and damage under these high stresses when compared with a thicker liner made from the same material.

Our study has limitations. First, we removed the polyethylene locking beads so liners could be removed for weighing during the test without creating mechanical damage at the locking mechanism that could have created unintentional errors in the wear measurements. This eliminated the ability to assess the mechanical performance of the locking mechanism itself and eliminated the locking mechanism as a potential site of crack initiation, but it represents a worst-case scenario for liner wear, because the liner was not securely fastened to the metallic shell. Locking mechanism failures have been related to fracture of highly crosslinked liners. Tower et al. reported rim failures in four highly crosslinked liners (Longevity; Zimmer, Inc, Warsaw, IN) that had rim-locking mechanisms with minimum thicknesses of less than 4 mm [25]. All four liners had sustained cracking or rim failure along a groove in the polyethylene that engaged the locking ring of the metallic shell. The locking mechanism for the components used in our study (Trident; Stryker Orthopaedics) differs from those reported in the literature in that it uses a positive polyethylene bead that engages a groove in the metallic shell. Second, the high stress conditions were applied on every wear cycle. Patients undergoing THA approach impingement or indeed impinge during daily activities [11, 24, 25], but not with every cycle of activity. So our test represents a worst-case scenario. Furthermore, while in vivo impingement loads have not been measured, high stress conditions in the rim of the thin and thick liners occurred with Paul-type hip-load profile as used in our study. Several of the liners in our study underwent impingement, most likely as a result of the tight clearances, especially in the thick liners, and the inability to control motion in the hip simulator to retain these tolerances. Although this was not intended, our analyses were not concerned with the site where the neck of the implant swept close to the rim. Rather, we were concerned with the region opposite this site, where contact pressures were markedly increased. Third, we conducted the test to 5 million cycles. While typical for hip simulator studies, the risk of mechanical damage and fracture would be expected to rise with longer test intervals. Liner thickness was varied by changing the head diameter; the results therefore intertwine the effect of thickness with the increased sliding distance, and corresponding wear rate that can occur with larger heads. Another limitation is that we did not artificially age the liners in this study or look at oxidation. A retrieval study of cross-linked, annealed liners showed an increase in the oxidation index in the unworn regions of the liners [15]. However, the sequentially annealed cross-linked material used in this study has been shown to have low free radical content and to perform the same after accelerated aging as virgin UHMWPE [6]. Finally, we relied solely on wear as our performance measure. Excessive plastic deformation of very thin polyethylene components could be a cause of failure, although it might not be expected in acetabular liners given their shape and the constraint provided by the shell.

A simulator study looking at the same conventional material in neutral alignment reported a wear rate of 17.2 mg/million cycles [20]. Another study created impingement in a hip simulator model and reported a wear rate of 40 mg/million cycles in conventional liners [12]. At an average wear rate of 25 mg/million cycles, the conventional liners in this study fall between these two extremes, consistent with the increase in contact pressures created by our wear simulator conditions. When comparing the wear rate of the conventional material in this study with that of the crosslinked material, crosslinking decreased wear rate by 93%. This is similar to another study that reported a 97% decrease in wear between X3 and conventional material when tested in 50° abduction [6].

Several hip simulator studies conducted under normal conditions reported negative or "undetectable" wear rates in crosslinked liners [8, 17–19]. We also observed liners that displayed negative wear, but nonetheless our average wear rates were positive for both crosslinked groups, indicating wear was occurring. Similarly, clinical studies of wear in acetabular components reported positive, albeit low, wear rates [4, 5, 7, 10, 23], suggesting patients are engaging in activities beyond those simulated with conventional hip wear testing conditions. Based on the higher stresses that occur with thinner liners [21], we expected wear and damage would be greater with the thinner liner. Our data, however, did not support this hypothesis. In fact, the thin crosslinked liners displayed the lowest average weight loss. Despite the high stresses in the contact region, no cracks were found in any of the liners. This may be partly the result of the short duration of the test. Larger number of wear cycles might lead to cracking, so longer tests may be justified. We are therefore planning to continue to test these liners to see if crack initiation occurs.

Our results can be explained by considering how material properties and geometry affect the stresses associated with wear and mechanical damage. The crosslinked material in our study does not display the decreased mechanical properties of other crosslinked polyethylenes, at least in terms of the reported yield and ultimate strengths and ductility [6]. Therefore, it should be more resistant to surface damage and cracking than other crosslinked polyethylenes with inferior properties tested under similar conditions [12].

Backside damage was observed in the form of creep (screw hole extrusion) in all three groups. This was likely the result of the high stress test conditions, for which the maximum load during the wear cycle was oriented directly in line with one of the screw holes. We noted similar screw hole creep in a previous study of retrieved conventional liners [13]. The amount of screw hole extrusion (creep) tended to be higher in components that showed evidence of impingement while implanted, suggesting the same high stress conditions as in our simulator study.

In summary, our data show large femoral heads with highly crosslinked polyethylene liners as thin as 3.8 mm in thickness do not wear at a higher rate than a thicker liner of the same material, even when subjected to large contact pressures such as occur under near-impingement conditions. The ideal liner thickness remains unknown, but crosslinked polyethylene may allow for liners that are thinner than has been traditionally accepted. This conclusion, however, is based solely on the results of a wear simulator test with idealized cup position, no intentional edge loading, and no head subluxation. We recognize that clinically this issue is quite complex, and is dependent upon multiple factors such as implant positioning, implant design (i.e. locking mechanism and material properties of the polyethylene), and patient factors. Further retrieval analyses and continued in vivo monitoring will be necessary to elucidate the clinical efficacy of these devices.

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