

In vitro comparison of frictional torque and torsional resistance of aged conventional gamma-in-nitrogen sterilized polyethylene versus aged highly crosslinked polyethylene articulating against head sizes larger than 32 mm

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Submitted 05-02-18. Accepted 06-01-28

Background The advent of highly crosslinked polyethylene has allowed the re-evaluation of the use of femoral heads larger than 32 mm for metal-on-polyethylene total hip arthroplasties. However, the effect of larger heads on the frictional torque of highly crosslinked polyethylene is unknown.

Methods We performed an in vitro examination of the effect of larger chrome cobalt femoral heads (40 mm diameter) on the frictional torque and torsional resistance of hip articulations on aged liners of polyethylene that were sterilized by gamma rays while in nitrogen, and aged highly crosslinked polyethylene. The frictional torque at the femoral head articulation was usually higher for the highly crosslinked polyethylene than for the conventional polyethylene. The aged conventional liners oxidized considerably, which led to gross failure of the polyethylene at the anti-rotation portion of the rim. The aged crosslinked polyethylene showed no such failures despite the higher frictional torque.

Interpretation Our findings suggest that in terms of torsional resistance to fatigue when studied as a device, rather than as an isolated material, under these conditions, aged highly crosslinked polyethylene is preferable to aged conventional polyethylene.

A substantial reduction in wear has been found from increased crosslinking of ultra-high molecular weight polyethylenes (UHMWP) used in acetabular components for total hip replacement surgery (Edidin et al. 1999, Grobbelaar et al. 1999, McKellop et al. 1999, Wroblewski et al. 1999, Muratoglu et al. 2001a, Oonishi et al. 2001, Digas et al. 2004). For some highly crosslinked polyethylenes, in vitro tests have demonstrated that these low wear rates apply to femoral head sizes from 22 to 48 mm diameter (Muratoglu et al. 2001a, b). The potential advantages of larger heads are substantial (Burroughs et al. 2002, 2005). Melting of the UHMWP after irradiation, however, in addition to the increased dose of radiation, affect the mechanical properties of these materials (Pruitt and Bailey 1998, Baker et al. 1999, 2003, Muratoglu et al. 2001a). Two special features of large heads may increase the risk of related to the deterioration in mechanical properties. The frictional torque may be greater and there may be failure of the anti-torsional mechanism of liner.

Kurtz et al. (2003) have shown that the oxidation that occurs in vivo in “gamma in air” UHMWP reduces the mechanical properties. Wang et al. (2004) showed the adverse effect of this oxidation on the fatigue behavior of suboptimally designed

acetabular components. These two studies establish (1) that the properties of conventional UHMWP deteriorate *in vivo* because of *in vivo* oxidation, and (2) that these reduced properties can lead to premature fatigue failure in certain designs.

We postulated that (1) the frictional torque of more highly crosslinked polyethylenes may be higher than that of the conventional material, (2) that this effect of frictional torque would be greater with increasingly larger head sizes, and (3) that deleterious effects of oxidation on the torsional resistance of conventional polyethylene that has been gamma sterilized would exceed the effect of the reduction in fatigue properties of the highly crosslinked, melted polyethylene.

We compared the frictional torque and torsional stability of 40-mm cobalt chrome femoral heads with those of aged conventional liners sterilized in nitrogen and stored in nitrogen, and with those of aged highly crosslinked melted UHMWP. These studies provided a means of assessing the fatigue behavior of the liner as a device, in contrast to testing the fatigue behavior of each material in an isolated materials test.

Material and methods

For the frictional torque testing, clearance between the femoral head and the aged 40-mm acetabular liners was determined using a coordinate measuring machine (CMM) (Global A2; Brown & Sharpe, North Kingstown, RI). The test components were allowed to reach thermal equilibrium at room temperature and to undergo viscoplastic relaxation for 2 days before the measurements were taken. The surfaces of the femoral head and the articular surface of each acetabular liner were digitized with positional data from radial CMM scan lines. The coordinates were measured at 1-mm intervals along each scan line. A total of 20 radial lines were measured for the femoral head, and 24 were measured for each acetabular liner. The radius of curvature for a component was derived from a composition of all scan lines for that component by the CMM software (PC-DMIS; Brown & Sharpe). The clearance was assumed to be uniform over the entire interface between head and liner, and was calculated by simply subtract-

ing the radius of the femoral head from the radius of the articular surface.

The frictional torque that was generated by articulating the femoral heads within Trilogy (Zimmer, Inc., Warsaw, IN) acetabular shells containing aged conventional or aged highly crosslinked acetabular liners identical to those used in the wear and rotational stability studies was measured using a Mini-Bionix MTS 858 machine (Mini-Bionix, Eden Prairie, MN). Each acetabular liner was held and tested in its respective shell. For each head size from 22 mm to 40 mm, liners made of conventional ($n = 5$) and highly crosslinked ($n = 5$) polyethylene were tested. All liners had been artificially aged for 5 weeks at 80°C in a convection oven. The femoral head was loaded directly into each acetabular liner and simultaneously rotated $\pm 15^\circ$ in a sinusoidal fashion at 1 Hz. The load was increased incrementally from 0 to 3000 N in 500-N increments and held at each 500-N increment for 30 sec. The peak-to-peak torque was then recorded for each rotation cycle and averaged for 20 cycles at each load (after eliminating the first and last 5 cycles at each loading increment). Testing was conducted with 22-mm, 28-mm, 32-mm, 36-mm, and 40-mm head sizes. These average peak-to-peak torques were then averaged for each of the five liners for each head size and load. Testing was conducted at 37°C in 100% bovine serum. A two-tailed Student *t*-test was performed between the conventional and highly crosslinked polyethylene liners for head size and load. After the frictional torque testing, the liners were studied for clearance at the articulation between the femoral head and acetabular liner using CMM measurements.

For the hip simulator tests, acetabular liners of the Trilogy design (Zimmer), manufactured from either conventional or highly crosslinked UHMWPE, were examined in their corresponding 58-mm acetabular shells. The conventional UHMWPE liners were gamma sterilized in nitrogen to between 25 and 37 kGy, and stored in nitrogen until aged. The highly crosslinked liners were made from UHMWPE that was electron beam irradiated to 100 kGy at 40°C and subsequently melted (Longevity; Zimmer). The highly crosslinked liners were gas plasma sterilized. All liners were artificially aged in a convection oven for 35 days at 80°C in air. Both the conventional liners

and the highly crosslinked, melted liners were tested against 40-mm implant-grade chrome cobalt femoral heads ($n = 4$ for each type).

Wear testing was conducted under simulated gait on a 12-station Boston Hip Simulator (AMTI, Watertown, MA) for 12 million cycles for the aged conventional material (see below) and 20 million cycles for the aged highly crosslinked material. All components were tested in 100% bovine serum at 37°C containing 20 mmol EDTA and 0.3% w/w sodium azide. The bovine serum was replaced every 0.5 million cycles. The acetabular liners were inspected visually every million cycles and were removed from their acetabular shell and weighed every 3 million cycles. Separate load soak components, which were subject to load only, were used to account for fluid absorption in the gravimetric analysis. The gravimetric wear rate was calculated with least-squares regression of the weight loss. The testing period occurring after the first 3 million cycles was considered to be the “steady-state” wear rate after the bedding-in and fluid absorption period was over.

At every million-cycle interval, the components were also analyzed using a coordinate measuring machine (CMM) to determine the extent of dimensional changes in the articular surfaces. With the exception of those intervals at which gravimetric analysis was performed, CMM analysis was done without removing the liners from their shells, in order to minimize the errors introduced by removal and replacement of the liner. The eccentricity of the liner orifice near the locking mechanisms was quantified as the ratio of the major and minor axes of the best-fit ellipse.

Following hip simulator testing, the oxidation levels in both the aged conventional and aged highly crosslinked liners were measured using infrared microscopy. To permit quantification of oxidation levels using infrared spectroscopy throughout the polyethylene liners, cross sections (200 μm) were cut perpendicular to the face of each liner from one 40-mm aged conventional motion liner, one 40-mm aged highly crosslinked motion liner, and one 40-mm aged conventional load soak liner. Photographic records of these cross sections were made to evaluate any white banding.

Table 1. Average clearance between the head and liner

Head diameter	Clearance, mm (SD)	
	Conventional	Highly crosslinked
22 mm	0.080 (0.026)	0.198 (0.011)
28 mm	0.194 (0.023)	0.224 (0.009)
32 mm	0.148 (0.026)	0.253 (0.011)
36 mm	0.234 (0.020)	0.202 (0.018)
40 mm	0.135 (0.017)	0.093 (0.053)

Results

The 40-mm femoral head used in the frictional torque studies measured 39.964 mm. The measured inner diameters (ID) of the conventional liners after aging averaged 39.938 (39.921–39.959) mm and the measured IDs of the highly crosslinked liners averaged 40.060 (40.098–39.986) mm. The average clearance of the aged conventional liners was 0.013 (0.007–0.021) mm, and for the aged highly crosslinked liners it was 0.048 (0.071–0.027) mm.

Figure 1 shows the average frictional torque measured for each axial load and each femoral head size for the aged conventional and aged highly crosslinked liners. As would be expected, the frictional torque increased with increasing load. For both the conventional and highly crosslinked polyethylene, frictional torque increased with increasing head size for each axial load. With the 6 different axial loads used and 5 different femoral head sizes, 30 comparisons were made between the conventional and highly crosslinked polyethylene. In 17 of these 30 comparisons, the highly crosslinked polyethylene exhibited a significantly higher frictional torque than that of the conventional polyethylene. The remaining 13 cases showed no statistical difference in frictional torque. In no case was the frictional torque for the highly crosslinked polyethylene significantly lower than for the conventional polyethylene.

The clearance between the liners and the femoral head for both the conventional and highly crosslinked liners used in the frictional torque tests are shown in Table 1. These numbers represent the average of 5 liners of each diameter. There was no correlation between the amount of clearance and the amount of frictional torque experienced during testing.

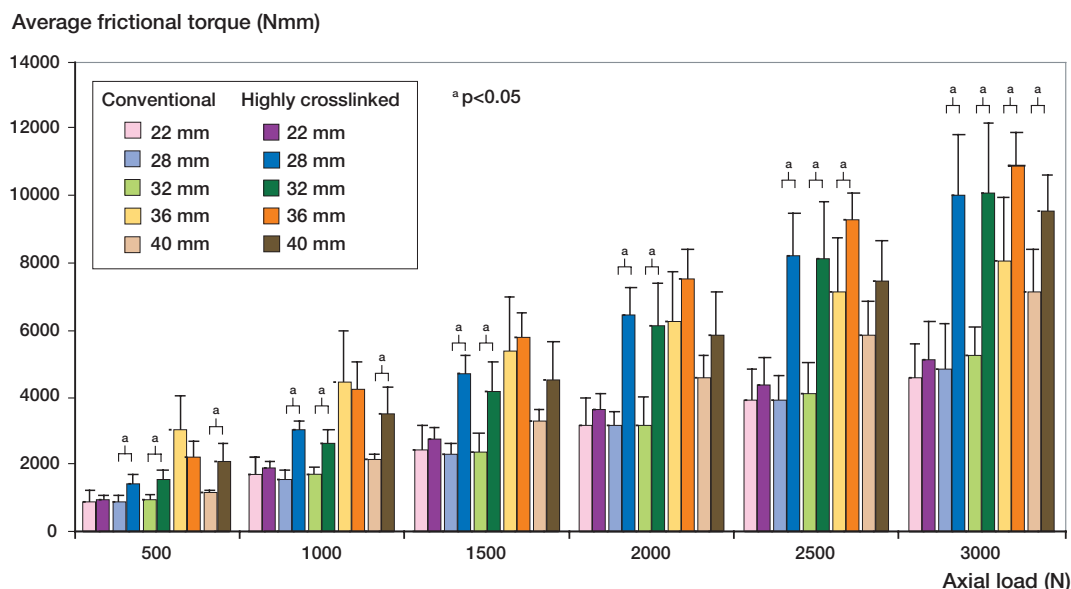


Figure 1. Average ($n=5$) frictional torque for a range of axial loads and femoral sizes for aged conventional and aged highly crosslinked polyethylene acetabular liners.

The average weight gain for the load soak components was similar for both the conventional and highly crosslinked liners, but the highly crosslinked liners gained slightly more weight than the conventional liners at each measurement. By 12 million cycles, the load soak components for the

40-mm highly crosslinked and 40-mm conventional liners gained a total of 16.7 mg and 17.1 mg, respectively.

Figure 2 shows the overall average corrected weight loss as a function of gait cycles for each of the combinations of materials and head diameters tested. Wear rates were determined by linear regression (Table 2). Wear of the aged conventional material was substantially higher than that of the aged highly crosslinked material at all intervals, and a pronounced increase in wear of the aged conventional liners occurred after 3 million cycles compared to the rate prior to the 3 million cycle measurement. No such change in wear rate occurred with the highly crosslinked material after the fluid absorption and bedding-in period. The wear rates of the aged highly crosslinked melted UHMWPE with large femoral heads were significantly lower than those measured with aged conventional polyethylene both before and after 3 million cycles ($p < 0.001$). After the 3 million cycle period, wear of the highly crosslinked polyethylene was nearly two orders of magnitude less.

The CMM analysis showed no gross deformation of any of the articular surfaces of the highly crosslinked liner. The openings of the highly crosslinked liners remained circular, with the ratio of

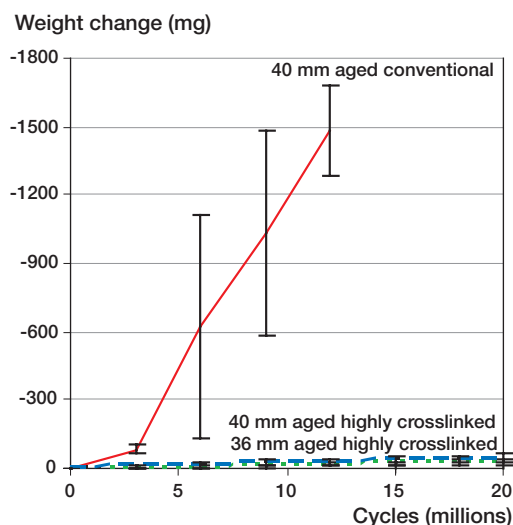


Figure 2. Average corrected weight change as a function of number of simulated gait cycles for each liner/head diameter combination.

Table 2. Wear rates corrected for fluid absorption with load soak data

Component type (size 40 mm)	Gravimetric wear rate in mg/MC ^a (SD)		P-value ^b
	0–3 MC	> 3 MC	
Conventional	28.6 (14.3)	153.7 (20.9)	< 0.007
Highly crosslinked	2.6 (2.9)	1.6 (0.6)	0.6

^a MC: million cycles.
^b P-value determined from two-tailed Student t-test.

maximum/minimum ellipse radii remaining below 1.002. The opening of the conventional polyethylene liners showed a steady increase in the ratio of maximum/minimum ellipse radii up to an average of 1.01, indicating a small increase in eccentricity.

It is interesting that at 7 million cycles, the anti-rotation studs on the rim of the shells in each of the aged conventional liners had begun to penetrate progressively into the abutting polyethylene rim (Figures 3a and 3b). Figure 3a shows a representative example of the early penetration of the anti-rotation studs on the rim of the metal shell, into the polyethylene of an aged conventional 40-mm ID liner after 7 million cycles of simulated gait. At this time, the rotational stability of the liner was only minimally compromised. These liners progressively lost rotational stability during subsequent testing. Figure 3b shows the extensive fatigue damage of the rim of the conventional liner by 12 million-cycles, caused by fatigue failure of the polyethylene when it impacted against the stud. This led to complete failure of the rotational stability of 3 of the 4 conventional liners. Due to the extent of damage on the conventional liners and the loss of rotational stability, they were removed from the study at 12 million cycles. Examination of the backside surfaces of conventional liners after removal from the shell at 12 million cycles did not reveal unusual or extensive loss of material. The backside surface of these conventional liners that lost anti-rotational integrity did not appear any different from those of the highly crosslinked specimen, which had retained anti-rotational stability. No such degradation of the anti-rotation mechanism or other evidence of device fatigue failure was present in any of the aged highly crosslinked liners (Figure 3c), even after 20 million cycles.

Figure 4 shows the oxidation index measured across the entire thickness of both a representa-

tive aged conventional liner after 12 million cycles and a representative aged highly crosslinked liner

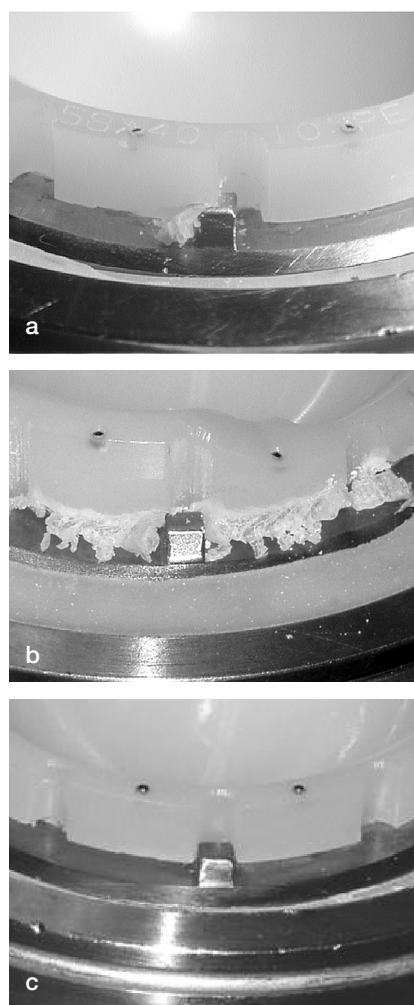


Figure 3. Photographs of anti-rotation portion of the locking mechanism of a) 40-mm aged conventional after 7 million cycles, b) 40-mm aged conventional after 12 million cycles and, c) 40-mm aged highly-crosslinked liner after 20 million cycles of simulated gait.

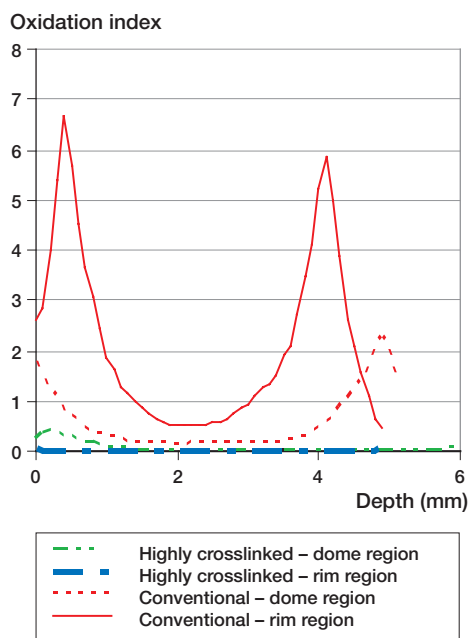


Figure 4. Oxidation index as a function of depth into both an aged conventional and aged highly crosslinked acetabular liner tested on the hip simulator (12 million cycles for the conventional and 20 million cycles for the highly cross-linked). Oxidation profiles were measured both at the rim and dome of each liner.

after 20 million cycles. Oxidation profiles were measured at the rim of the liner as well as near the dome. The peak oxidation indices measured at a depth of 1 mm or less within the aged conventional liner at 12 million cycles were substantially higher than those measured in the aged highly crosslinked liner after 20 million cycles. The aged conventional liner had a peak oxidation index of 6.7 at 0.4 mm from inner diameter at the rim and a peak oxidation index of 5.8 at 0.9 mm from the outer diameter at the rim. The aged highly crosslinked liner had a peak oxidation index of 0.38 at 0.2 mm from inner diameter at the dome and a peak oxidation index of 0.1 at the surface at the outer diameter of the rim.

Figure 5 shows representative photographs of thin cross sections taken from two aged conventional liners (one load soak (Figure 5a) and one motion component (Figure 5b)) and one aged highly crosslinked liner. Figures 5 shows that unlike the aged highly crosslinked liners (Figure 5c)—which showed no white banding (Figure 5c)—the aged conventional liners became heavily oxidized and embrittled, showing the typical sub-surface white

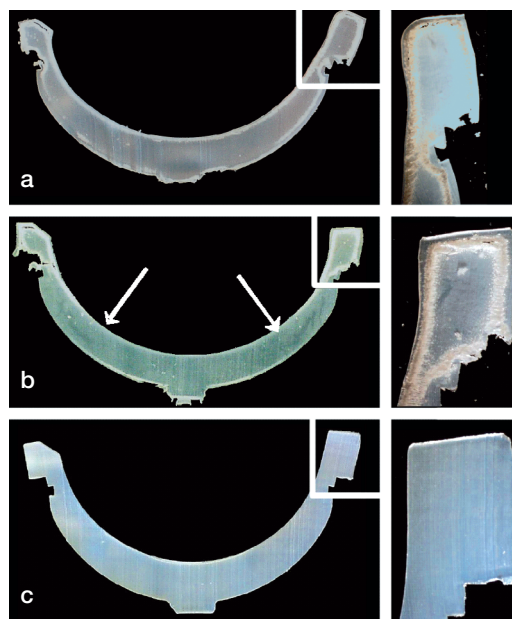


Figure 5. Photographs of thin cross-sections taken from an a) aged conventional load soak liner, b) aged conventional motion liner and, c) aged highly crosslinked liner tested on the hip simulator.

banding (Figures 5a and 5b). The thin section of the aged conventional load soak component (Figure 5a) shows an embrittled subsurface region around the entire circumference of the section including the articular surface. In contrast, the thin section of the aged conventional motion component which had been subjected to 12 million cycles of motion (Figure 5b) showed a similar subsurface embrittled region in general, but with one important exception. The embrittled region at the articular surface was missing because the articulation of the femoral head had worn away both the surface polyethylene and the embrittled polyethylene of the subsurface (the area between the white arrows in Figure 5b).

Note also that in the inserts on the right in Figure 5, there is extreme subsurface oxidation of the aged conventional UHMWP in both the load soak specimen (Figure 5a) and the motion specimen (Figure 5b) in the region of the locking mechanism. Note also the distortion of the contours of the polyethylene in the area of the locking mechanism. No such oxidation or distortion occurred in the aged highly crosslinked material (Figure 5c).

Discussion

The concerns expressed about the reduced fatigue properties of highly crosslinked, subsequently melted polyethylene (Baker et al. 1999, 2000, 2003, Greenwald et al. 2001, Bradford-Collins et al. 2002) have arisen largely from bench tests of the isolated material when tested without taking oxidation into account. The oxidation of conventional polyethylene sterilized by gamma irradiation occurs *in vivo*; it progressively increases with time (Kurtz et al. 2003, Muratoglu et al. 2003, Bhat-tacharyya et al. 2004) and reduces the mechanical properties (Collier et al. 2003, Kurtz et al. 2003). Consequently, comparative tests of the material properties of fresh gamma sterilized conventional polyethylene against fresh highly XLP that has been melted may be misleading, because the highly crosslinked, melted material does not oxidize *in vivo* whereas the conventional UHMWP does.

There is another important issue: the ultimate function of a device in terms of fatigue is not solely dependent on the properties of the material from which the device has been made. It is also strongly influenced by the design of the device. For example, the failure of the ACS acetabular component in fatigue was directly related to its poor design (Bono et al. 1994, Wang et al. 2004). Thus, it is appropriate to assess the fatigue behavior of highly cross-linked, melted UHMWP under two specific conditions which are not represented in isolated studies of fatigue crack propagation which are done using fresh highly crosslinked material versus fresh conventional, gamma-irradiated UHMWP. These two conditions are (1) testing of the device itself, and (2) testing after accelerated oxidation. The studies reported here are the first such tests to consider these factors in metal on polyethylene articulation using femoral head sizes greater than 32 mm.

In hip simulator studies also comparing aged conventional, gamma-in-nitrogen sterilized polyethylene with aged highly crosslinked, melted UHMWP but using head sizes from 22–32 mm, Crowninshield et al. (2002) noted two important parallel observations, namely that the aged gamma-in-nitrogen sterilized conventional polyethylene showed extensive oxidation while the aged highly crosslinked melted material did not, and the wear rate of the conventional material accelerated with

time—apparently as the wear process first exposed and then progressively wore through the embrittled zone.

As expected, and consistent with prior studies, the aged highly crosslinked liners had superior wear resistance to that of the aged conventional liners. However, it had not been fully anticipated that there would be a pronounced increase in wear of the aged conventional liners after 3 million cycles. The sharp inflection in wear rate at that point did not correspond to loss of rotational stability of the aged conventional liners, which first began after 7 million cycles. Also, there was no additional increase in wear rate for the aged conventional liners after 7 million cycles as the rotational instability progressively increased, indicating further that the inflection in wear rate of the aged conventional material after 3 million cycles was not directly related to loss of rotational stability. These observations, coupled with the white banding data shown in Figures 5a and 5b, suggest that the primary mechanism of the increase in UHMWPE wear after 3 million cycles occurred at the articulation rather than at the backside of the liner, even after failure of the anti-rotation portion of the locking mechanism, and was caused by accelerated wear occurring as the wear penetrated through the white banding area. However, no *in vivo* evidence exists that such acceleration in wear is associated with white banding over time (Charnley et al. 1975, Orishimo et al. 2003).

Other adverse effects of the extensive embrittlement of the aged conventional liners are clearly shown in the high oxidation indices and in the distortion of the contour of the locking mechanism. All these observations support the conclusion that the extensive oxidative degradation of the aged conventional polyethylene at the rim was the cause of the fatigue failure of the anti-rotation mechanism in the aged conventional liners, despite having been irradiated in nitrogen and stored in nitrogen.

Of the 30 comparisons made of frictional torque between conventional and highly crosslinked polyethylene, 17 showed a significantly higher torque for the highly crosslinked polyethylene. None of the comparisons showed a significantly lower frictional torque for the highly crosslinked polyethylene. These data suggest that highly crosslinked polyethylene possesses some characteristic that

increases the friction between the femoral head and liner upon articulation. Despite the generally higher frictional torque measured with the highly crosslinked liners, none of the aged highly cross-linked liners experienced rotational fatigue failure, as was seen with the aged conventional liners subjected to the same simulated gait conditions.

The frictional torque values measured in this study for the corresponding head size and load were slightly higher than those reported by Anderson et al. (1972). Further work will be necessary to determine the reasons for these differences. However, our aim was to do a parametric analysis of the frictional torque, comparing aged melted highly cross-linked UHMWP with aged conventional UHMWP that had been gamma sterilized in nitrogen.

In this hip simulator study, aged highly cross-linked melted UHMWPE was shown to have important advantages over aged conventional polyethylene which had been gamma sterilized in nitrogen and stored in nitrogen until artificially aged, in addition to its substantially improved wear resistance, even against larger femoral heads. These advantages were (1) substantially higher fatigue resistance as demonstrated by maintenance of the integrity of the anti-rotation locking mechanism, (2) maintenance of the integrity of the locking mechanisms, and (3) the absence of oxidation.

Contributions of authors

WHH, OKM and BRB conceived and designed the overall study. BRB, CRB, KKW, SC and AJL designed the specific fixturing necessary to the study and the quantifications of the torque measurements. They also made the observations and measurements necessary to complete the data. OKM, BRB, CRB and WHH analyzed the data, interpreted it and created the manuscript.

Supported by Zimmer Inc. (Warsaw, IN) and the William H. Harris, MD Foundation.

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