Wear Analysis of Second-generation Highly Cross-Linked Polyethylene in Primary Total Hip Arthroplasty

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abstract

A major limiting factor in the longevity of total hip replacement is the wear rate of the hip bearing. As manufacturing technology has improved during the past several decades, much attention has been focused on developing newer generations of polyethylene that have lower rates of wear while minimizing free radical formation and subsequent osteolysis. The turning point for the manufacture of polyethylene was moving from gamma irradiation in air to irradiation in a low oxygen environment, which reduced free radical formation while increasing the wear resistance. New polyethylene manufacturing methods, including multiple cycles of irradiation and annealing, have resulted in greater wear resistance. Wear analysis studies are essential to determine if these new liners actually show a benefit from prior generations of polyethylene and, more importantly, if they are safe to use. This study involved a single center retrospective review of 60 patients with a mean follow-up of 5.5 years who underwent primary total hip arthroplasty with a second-generation highly cross-linked polyethylene manufactured by 3 cycles of sequential irradiation and annealing. Linear and volumetric wear rates were determined from digitized radiographs using contemporary wear analysis software. The mean linear wear rate for the entire group was 0.025 millimeters per year (mm/y). This value represents a linear wear rate 2.7 times less than that of a first-generation highly cross-linked polyethylene and 4.2 times less than that of a conventional polyethylene. At an average of 5 years, compared with a first-generation highly cross-linked polyethylene, a second-generation highly cross-linked polyethylene appears to show significant improvement regarding wear. [*Orthopedics.* 2016; 39(6):e1178-e1182.]

Despite advances in total hip arthroplasty (THA), osteolysis and subsequent loosening secondary to bearing surface wear debris remains a significant cause of failure.[1] Polyethylene, the most common bearing surface used in modern THA, has undergone significant improvements in the past few decades regarding wear properties. Cross-linking of polyethylene molecules via ionizing radiation or through chemical means was developed as a way to increase the wear resistance of polyethylene.[2,3] Performing this process in the presence of heat not only increases the rate of cross-linking, but also reduces the amount of free radicals created by irradiation. A major disadvantage of this method is a reduction in

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material properties, which occurs when polyethylene is heated above its melting point to eliminate as many free radicals as possible. The alternative to remelting is annealing, which heats the polyethylene to just below its melting point.[2] Although annealing is less effective in eliminating free radicals, it can promote cross-linking while retaining desirable mechanical properties.

On the basis of the above premise, several implant manufacturers have developed methods to maximize cross-linking and minimize the amount of free radicals created. An example of a first-generation highly cross-linked polyethylene (HXPE) is Crossfire (Stryker, Mahwah, New Jersey), which is manufactured by a 1-cycle irradiation/annealing process followed by sterilizing with a final dose of gamma irradiation.[4] According to several studies, the wear rate of this first-generation HXPE at an average of 5 years was 0.054 to 0.067 mm/y (±0.022 to 0.033 mm/y).[4-6] At an average of 9 years, the wear rate was 0.037 mm/y (±0.022 mm/y).[5] Compared with the moderately cross-linked polyethylene Duration (Stryker), which has a 5-year wear rate of 0.106 mm/y (±0.037 mm/y), the first-generation HXPE represents a significant improvement.[7]

Recent studies have reported that second-generation HXPE has low wear rates.[8-10] The current study evaluated the midterm performance of a second-generation HXPE, X3 (Stryker), at a minimum of 5 years following primary THA to determine whether wear rates had improved from the initial generation of HXPE. Midterm results of new technology provide information helpful for predicting wear behavior using a second-generation HXPE.

MATERIALS AND METHODS

Institutional review board approval was obtained for this retrospective review of patients who underwent primary THA with the second-generation HXPE X3 between September 2005 and January 2008. Patients were excluded from the study if required radiographs were not available for analysis, or if radiographs were determined to be of poor quality. Patients with ceramic femoral heads were also excluded. Those who underwent revision for any reason within the 5-year follow-up period were also excluded. After exclusions, there were 60 patients available for analysis. The cohort consisted of 51 women and 9 men with an average age of 68.0 years (range, 39.8-85.5 years) and a mean±SD body mass index of 28.8±6.2 kg/m^2 (range, 14.6-47.9 kg/m^2). The mean±SD abduction was 45.9°±9.0° (range, 29.0°-67.4°) and the mean±SD anteversion was 22.8°±7.7° (range, 7.1°-42.3°). The mean±SD acetabular component size was 52.1±4.1 mm (range, 48-64 mm). The primary diagnosis in 52 of the cases was osteoarthritis. There were 4 patients with avascular necrosis, 1 patient with dysplasia, and 3 patients with posttraumatic arthritis or failure of fracture fixation (**Table 1**).

Table 1

Patient Demographics

Demographic	Value
Patients, No.	60
Sex, F/M, No.	51/9
Follow-up period, mean (range), y	5.5 (4.8-6.6)
Age, mean (range), y	68.0 (39.8-85.5)
Body mass index, mean±SD (range), kg/m^2	28.8±6.2 (14.6-47.9)
Abduction, mean±SD (range)	45.9°±9.0° (29.0°-67.4°)
Anteversion, mean±SD (range)	22.8°±7.7° (7.1°-42.3°)
Acetabular component size, mean±SD (range), mm	52.1±4.1 (48-64)
Head size, No.	
32 mm	33
36 mm	27
Diagnosis, No.	
Osteoarthritis	52
Avascular necrosis	4
Dysplasia	1
Posttraumatic arthritis	3

Abbreviations: F, female; M, male.

The surgical technique consisted of a standard posterior approach with a posterior capsular repair.[11] The femoral and acetabular components used in all cases were the Accolade TMZF (Stryker) femoral stem and the Trident Acetabular Shell (Stryker) and all components were uncemented. All patients received either a 32-mm (33 patients) or a 36-mm (27 patients) cobalt-chromium head. The thickness of this second-generation HXPE varies with the size of the implant head and the acetabular cup (**Table 2**).

Standing anteroposterior pelvis radiographs were obtained for each patient in the senior author's (A.L.M.) clinic during follow-up at 6 weeks and 1, 2, and 5 years. These radiographs, with the exclusion of the 6-week radiograph, were digitized using a radiograph digitizer (VIDAR Diagnostic Pro; VIDAR Systems Inc, Herndon, Virginia).

Parameters of polyethylene wear, including penetration distance and rate, were determined using Martell's software (Hip Analysis Suite; University of Chicago, Chicago, Illinois), which relies

Table 2

Second-generation Highly Cross-Linked Polyethylene Thickness[a]

	Cup Size, mm								
Head Size, mm	**44**	**46**	**48, 50**	**52, 54**	**56, 58**	**60, 62**	**64, 66**	**68, 70**	**72, 74**
36	n/a	n/a	3.9	5.9	7.9	9.4	11.2	12.7	14.7
32	3.9	4.9	5.9	7.9	9.9	11.4	13.2	14.7	16.7

Abbreviation: n/a: not applicable.

[a] *Trident Acetabular Shell (Stryker, Mahwah, New Jersey) and X3 Liner (Stryker).*

Table 3

Linear and Volumetric Wear by Head Size

Wear	Rate
All cases	
Linear	0.025 mm/y (±0.029 mm/y)
Total linear	0.107 mm (±0.125 mm)
Volumetric	21.96 mm^3/y (±24.93 mm^3/y)
32-mm head	
Linear	0.032 mm/y (±0.033 mm/y)
Total linear	0.136 mm (±0.142 mm)
Volumetric	25.76 mm^3/y (±26.64 mm^3/y)
36-mm head	
Linear	0.017 mm/y (±0.022 mm/y)
Total linear	0.072 mm (±0.092 mm)
Volumetric	17.31 mm^3/y (±22.28 mm^3/y)

on edge detection.[12] The computer-aided analysis of the digitized radiographs was performed by an independent observer not involved with the surgical procedures or the postoperative clinical evaluations. Total penetration and the subsequent wear rates were measured for each patient from years 1 through 5. Patients with negative values for wear rate and penetration were included in the data pool. The presence of acetabular osteolysis was classified under the system of DeLee and Charnley.[13]

RESULTS

The mean 1- to 5-year linear wear rate was 0.025 mm/y (±0.029 mm/y), the mean total penetration was 0.107 mm (±0.125 mm), and the mean volumetric wear was 21.96 mm^3/y (±24.93 mm^3/y). These 1- to 5-year parameters were also determined for different head sizes. In the 33 patients with 32-mm heads, the mean linear wear rate was 0.032 mm/y (±0.033 mm/y), the mean total penetration was 0.136 mm (±0.142 mm), and the mean volumetric wear was 25.76 mm^3/y (±26.64 mm^3/y). For the 27 patients with 36-mm heads, the mean linear wear rate was 0.017 mm/y (±0.022 mm/y), the mean total penetration was 0.072 mm (±0.092 mm), and the mean volumetric wear was 17.31 mm^3/y (±22.28 mm^3/y) (**Table 3**). No acetabular or femoral osteolysis was seen on radiographs.

DISCUSSION

The failure of early metal-on-metal and other bearing surfaces led to the dominance of polyethylene in THA. Despite its long and successful track record, polyethylene wear is the major limiting factor in the longevity of hip replacement. The discovery of gamma irradiation as a means to increase the wear resistance via cross-linking was a major evolutionary step in the development of polyethylene.[14] Up until the early 1990s, the irradiation occurred in air, which led to free radical generation and polyethylene oxidation. Concerns about osteolysis and loosening prompted researchers to improve polyethylene manufacture and processing. The most significant improvement was changing the sterilization method to gamma irradiation in low oxygen environments to minimize free radical production while retaining the benefits of cross-linking.[15]

The addition of thermal processing led to the development of first-generation HXPE. A previous study examining wear characteristics of a first-generation HXPE liner, Crossfire, found mean linear wear rates at 5 and 9 years of 0.067 mm/y and 0.037 mm/y, respectively.[5] Kurtz et al[15] reviewed several studies using first-generation liners from various implant companies and found that the weighted mean wear rate was 0.042 mm/y. In that same report, studies using conventional polyethylene liners were reviewed and the weighted mean wear rate was found to be 0.137 mm/y. The wear rate of moderately cross-linked polyethylene falls between those of conventional polyethylene and HXPE. Geerdink et al[7] determined that the 5-year wear rate of a moderately cross-linked polyethylene, Duration, was 0.106 mm/y, compared with 0.152 mm/y for historical polyethylene.

Despite the lower wear rates reported for first-generation HXPE, the potential remains for postprocessing oxidation because the single-step irradiation/annealing process leaves behind residual free radicals. Second-generation HXPE has been developed using methods to further decrease the amount of free radicals present. One such method involves separate sequential gamma irradiation and annealing steps, which is the basis for X3. The principle behind sequential steps is that smaller doses of radiation in summation can achieve the same levels of cross-linking without generating the amount of free radicals created by a single large dose. The cumulative dose of radiation in the manufacture of X3 is 90 kGy, split into 3 smaller doses of 30 kGy. Each cycle consists of a separate 8-hour annealing step with sterilization at the end via gas plasma.[16] By comparison, the first-generation HXPE Crossfire has a single radiation dose of 75 kGy, followed by a single annealing process, followed by an additional dose of 30 kGy for sterilization.[6,16]

In the current series of 60 patients, the mean 1- to 5-year linear wear rate was 0.025 mm/y (±0.029 mm/y) with a mean total penetration of 0.107 mm (±0.125 mm). This wear rate is approximately 2.7 times less than that of the first-generation HXPE Crossfire described by Reynolds et al.[5] Compared with the moderately cross-linked polyethylene Duration and conventional polyethylene as described by Geerdink et al,[7] this wear rate is 4.2 and 6.1 times lower, respectively (**Figure**).

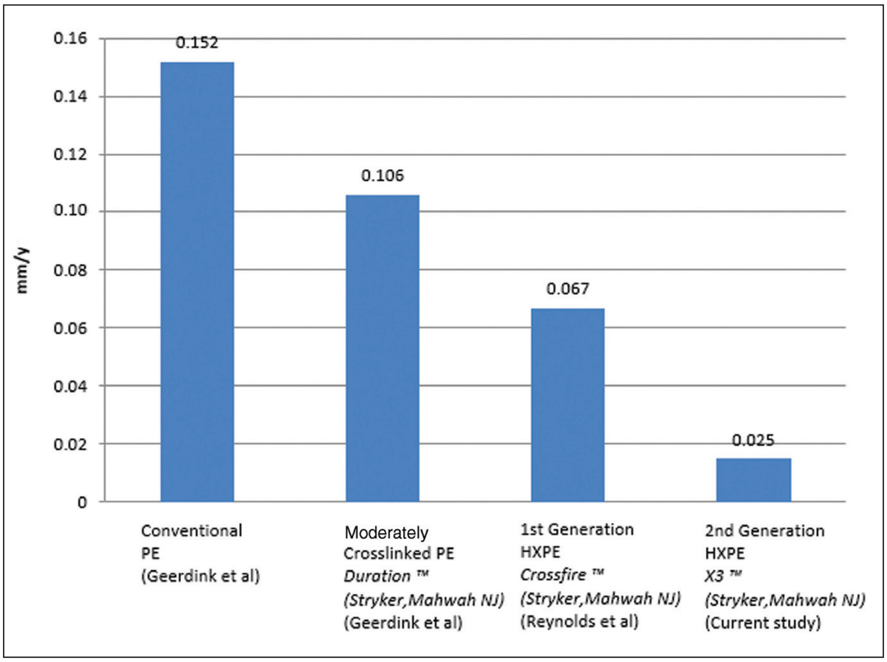

Figure: Mean 5-year wear rates. Abbreviations: HXPE, highly cross-linked polyethylene; PE, polyethylene.

Multiple studies have examined the link between polyethylene wear and acetabular cup orientation.[17,18] Lachiewicz et al[19] showed that the linear wear rate for the first-generation HXPE Longevity (Zimmer, Warsaw, Indiana) at a 5- to 8-year follow-up interval was independent of head size. A significant finding in that study was that larger heads (36 and 40 mm) resulted in greater volumetric wear than smaller heads (32 mm). There was no correlation between head size and linear wear rates. Lachiewicz et al[19] concluded that caution must be exercised with the routine use of large-diameter femoral heads with these liners. The current series had a contradictory finding regarding head size and wear rates, with 36-mm heads actually showing lower linear and volumetric wear, but this study was not powered to address this issue. Given these conflicting results, additional studies with larger numbers of patients must be conducted to determine the relationship between head size and linear/volumetric wear using a second-generation HXPE.

This study had several limitations. Because it was a retrospective chart review, selection bias is a concern. Negative values for wear rates, which is a known shortcoming of the Martell's software Hip Analysis Suite,[20] were excluded. Negative wear results from the inability of the software to precisely determine penetration when the wear rates are very low. Additional factors include the inconsistency of clinical radiographs and their quality when they are digitized.[21] As others have concluded, the removal of negative values may result in a falsely elevated wear rate. Several authors have used negative values in their analyses.[8,22-24] The current authors chose to analyze their data by turning negative values into zero to account for the inherent imprecision of the software to quantify low wear rates. Their findings are also limited by the small cohort and midterm follow-up. The predominance of female patients combined with the patient population being older (mean age, 68 years) could affect the ability to extrapolate these findings to the general population. A long-term analysis with a larger, more diverse cohort would better characterize the safety and efficacy of this liner and help determine the effect of larger heads, which are more commonly used currently.

CONCLUSION

Despite the shortcomings of this study, the results have shown that, in the midterm, second-generation HXPE liners perform better than first-generation liners, which have low wear rates. Additional studies are necessary to better understand the effect of head size on wear rates using newer second-generation HXPE. Longer follow-up is essential to determine whether the benefits of second-generation HXPE can be realized.

REFERENCES

1. Harris WH. The problem is osteolysis. *Clin Orthop Relat Res.* 1995; 311:46-53.
2. Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. *J Arthroplasty.* 2001; 16(2):149-160.

3. Bracco P, Oral E. Vitamin E-stabilized UHMWPE for total joint implants: a review. *Clin Orthop Relat Res.* 2011; 469(8):2286-2293.
4. D'Antonio JA, Manley MT, Capello WN, et al. Five-year experience with Crossfire highly cross-linked polyethylene. *Clin Orthop Relat Res.* 2005; 441:143-150.
5. Reynolds SE, Malkani AL, Ramakrishnan R, Yakkanti MR. Wear analysis of first-generation highly cross-linked polyethylene in primary total hip arthroplasty: an average 9-year follow-up. *J Arthroplasty.* 2012; 27(6):1064-1068.
6. Rajadhyaksha AD, Brotea C, Cheung Y, Kuhn C, Ramakrishnan R, Zelicof SB. Five-year comparative study of highly cross-linked (Crossfire) and traditional polyethylene. *J Arthroplasty.* 2009; 24(2):161-167.
7. Geerdink CH, Grimm B, Vencken W, Heyligers IC, Tonino AJ. Cross-linked compared with historical polyethylene in THA: an 8-year clinical study. *Clin Orthop Relat Res.* 2009; 467(4):979-984.
8. D'Antonio JA, Capello WN, Ramakrishnan R. Second-generation annealed highly cross-linked polyethylene exhibits low wear. *Clin Orthop Relat Res.* 2012; 470(6):1696-1704.
9. Sayeed SA, Mont MA, Costa CR, et al. Early outcomes of sequentially cross-linked thin polyethylene liners with large diameter femoral heads in total hip arthroplasty. *Bull NYU Hosp Jt Dis.* 2011; 69(suppl 1):S90-S94.
10. Campbell DG, Field JR, Callary SA. Second-generation highly cross-linked X3 polyethylene wear: a preliminary radiostereometric analysis study. *Clin Orthop Relat Res.* 2010; 468(10):2704-2709.
11. Osmani O, Malkani A. Posterior capsular repair following total hip arthroplasty: a modified technique. *Orthopedics.* 2004; 27(6):553-555.
12. Martell JM, Berdia S. Determination of polyethylene wear in total hip replacements with use of digital radiographs. *J Bone Joint Surg Am.* 1997; 79(11):1635-1641.
13. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res.* 1976; 121:20-32.
14. Grobbelaar CJ, du Plessis TA, Marais F. The radiation improvement of polyethylene prostheses: a preliminary study. *J Bone Joint Surg Br.* 1978; 60(3):370-374.
15. Kurtz SM, Gawel HA, Patel JD. History and systematic review of wear and osteolysis outcomes for first-generation highly crosslinked polyethylene. *Clin Orthop Relat Res.* 2011; 469(8):2262-2277.
16. Dumbleton JH, D'Antonio JA, Manley MT, Capello WN, Wang A. The basis for a second-generation highly cross-linked UHMWPE. *Clin Orthop Relat Res.* 2006; 453:265-271.
17. Kennedy JG, Rogers WB, Soffe KE, Sullivan RJ, Griffen DG, Sheehan LJ. Effect of acetabular component orientation on recurrent dislocation, pelvic osteolysis, polyethylene wear, and component migration. *J Arthroplasty.* 1998; 13(5):530-534.
18. Patil S, Bergula A, Chen PC, Colwell CW Jr, D'Lima DD. Polyethylene wear and acetabular component orientation. *J Bone Joint Surg Am.* 2003; 85(suppl 4):56-63.
19. Lachiewicz PF, Heckman DS, Soileau ES, Mangla J, Martell JM. Femoral head size and wear of highly cross-linked polyethylene at 5 to 8 years. *Clin Orthop Relat Res.* 2009; 467(12):3290-3296.
20. Wan Z, Boutary M, Dorr LD. Precision and limitation of measuring two-dimensional wear on clinical radiographs. *Clin Orthop Relat Res.* 2006; 449:267-274.
21. Hui AJ, McCalden RW, Martell JM, MacDonald SJ, Bourne RB, Rorabeck CH. Validation of two and three-dimensional radiographic techniques for measuring polyethylene wear after total hip arthroplasty. *J Bone Joint Surg Am.* 2003; 85(3):505-511.
22. McCalden RW, MacDonald SJ, Rorabeck CH, Bourne RB, Chess DG, Charron KD. Wear rate of highly cross-linked polyethylene in total hip arthroplasty: a randomized controlled trial. *J Bone Joint Surg Am.* 2009; 91(4):773-782.
23. Dowd JE, Sychterz CJ, Young AM, Engh CA. Characterization of long-term femoral-head-penetration rates: association with and prediction of osteolysis. *J Bone Joint Surg Am.* 2000; 82(8):1102-1107.
24. Bragdon CR, Kwon YM, Geller JA. Minimum 6-year followup of highly cross-linked polyethylene in THA. *Clin Orthop Relat Res.* 2007; 465:122-127.