Low Wear of a Second-generation Highly Crosslinked Polyethylene Liner: A 5-year Radiostereometric Analysis Study

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Abstract

Background A sequentially irradiated and annealed, second-generation highly crosslinked polyethylene (XLPE) liner was introduced clinically in 2005 to reduce in vivo oxidation. This liner design has also been shown to reduce wear in vitro when compared with conventional and first-generation crosslinked liners. To date, there is only one study reporting an in vivo wear rate of this liner at 5 years' followup. However, that study used measurements made from plain radiographs, which have limited sensitivity, particularly when monitoring very low amounts of wear.

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This work was performed at Wakefield Orthopaedic Clinic, Adelaide, South Australia, Australia.

Questions/purposes What is the amount and direction of wear at 5 years using radiostereometric analysis (RSA) in patients who had THAs that included second-generation XLPE? **Methods** We prospectively reviewed 21 patients who underwent primary cementless THA with the same design of XLPE acetabular liner and 32-mm articulation. Tantalum markers were inserted during surgery and all patients had RSA radiographs at 1 week, 6 months, and 1, 2, and 5 years postoperatively. Femoral head penetration within the acetabular component was measured with UmRSA® software. One patient died and two had incomplete radiographs leaving 18 radiographic series for analysis.

Results The mean amounts of proximal, two-dimensional, and three-dimensional head penetration between 1 week and 5 years were 0.018, 0.071, and 0.149 mm, respectively. The mean proximal, two-dimensional, and three-dimensional wear rates calculated between 1 year and 5 years were all less than 0.001 mm/year with no patient recording a wear rate of more than 0.040 mm/year.

Conclusions The head penetration of a second-generation XLPE liner remained low at 5 years and the wear rate calculated after the first year was low in all directions. This low level of wear remains encouraging for the future clinical performance of this material.

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

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Introduction

First-generation highly crosslinked ultrahigh-molecular-weight polyethylene (XLPE) liners used as part of THA have been shown to reduce wear and osteolysis when compared with conventional UHMWPE liners [14]. However, first-generation XLPE may be susceptible to fatigue cracking and annealed XLPE may be susceptible to in vivo oxidation [8]. To improve the efficiency of free radical elimination, a new process of sequential irradiation and annealing was introduced in a second-generation XLPE liner (X3™; Stryker Orthopaedics, Mahwah, NJ, USA). A hip simulator study has shown acetabular liners made from this material have superior wear properties in comparison with both conventional UHMWPE and clinically successful first-generation XLPE [8].

In 2005, we started a prospective study in which we used radiostereometric analysis (RSA) to measure the wear of this second-generation XLPE liner. At 2 years, we found that the mean proximal wear rate was 0.015 mm/year [5]. There is currently only one other published study describing the clinical performance of the second-generation XLPE liner [6]. That study, however, used Martell's Hip Analysis Suite software [15]. Measurements made from plain radiographs have limited precision [11] and may overestimate the wear rate when compared with more sensitive methods such as RSA [3, 10].

We asked the question, what is the amount and direction of wear at 5 years using RSA in patients who had THAs that included a second-generation XLPE?

Patients and Methods

We prospectively enrolled 21 patients who underwent primary THA for osteoarthritis between September 2005 and July 2006. Inclusion was based on the decision of the surgeon (DGC) that a cementless THA was clinically appropriate; during that period, cementless components were used in patients with Type A and B femurs resulting in a bias toward younger and more male patients. The components used for this study cohort (Trident® acetabular component [Stryker Orthopaedics] matched with an X3™ liner) were the routine implant used for cementless THAs in our institution. Inclusion criteria for the study were patients with radiographically verified primary hip osteoarthritis who were between the ages of 45 and 80 years. Exclusion criteria were patients with residence outside the Adelaide metropolitan area, abnormal gross anatomy of the hip, and inflammatory arthritis or severe osteoporosis. All of the patients having cementless THA and meeting these criteria were invited to participate in this study; of these, all 21 did so.

Of the 21 patients, none were lost to followup before the 5-year minimum followup period was completed, one

patient died, and two patients had no RSA radiographic examinations at 1 year. Therefore, 18 patients were included in the study (10 men, eight women). The median age was 63 years (range, 47–73 years); median male body mass index (BMI) was 28 kg/m² (range, 27–31 kg/m²), and median female BMI was 26 kg/m² (range, 22–29 kg/m²). Sixteen were Charnley Grade A and two Charnley Grade B. The median cup size was 54 mm (range, 48–62 mm). The median inclination was 44° (range, 39°–58°). All patients had a cementless femoral stem (Accolade®; Stryker Orthopaedics) with a 32-mm cobalt-chromium femoral head. There were no mechanical failures or reoperations in any of the patients at latest followup.

The XLPE liner was manufactured using a cycle of 3 Mrad of gamma irradiation followed by annealing at 130° C for 8 hours, repeated three times [8].

All patients provided informed consent for the insertion of tantalum markers during surgery and the subsequent RSA radiographs. All patients had RSA examinations at 1 week, 6 months, and 1, 2, and 5 years. The minimum followup was 4.8 years (mean, 5.3 years; range, 4.8–6.2 years). Ethics approval was obtained for this study from the Calvary Wakefield Hospital Research and Ethics Committee.

The detailed methods of the RSA technique and statistics of sample size can be found in an earlier publication [5]. Wear was measured by penetration of the femoral head inside the acetabular component with UmRSA® software (Version 6.0; RSA Biomedical, Umea, Sweden). The ellipse algorithm of the metal-backed shell was used in conjunction with between one and four liner beads to form a reference segment. The maximum condition number and rigid body error accepted for each reference segment was 50 (median, 32; range, 22–48) and 0.35 mm (median, 0.14 mm; range, 0.06–0.33 mm), respectively [17]. Although the authors did not use double examinations in the current study, the precision of RSA measurements in a similar study using the same setup was 0.033 mm, 0.019 mm, and 0.072 mm in the x, y, and z axes, respectively [4].

Bedding-in and creep was assumed to be finished at 1 year. We therefore recorded three separate measurement parameters: femoral head penetration (mm) calculated between 1 week and 5 years; bedding-in (mm) calculated between 1 week and 1 year; and the wear rate (mm/year) between 1 and 5 years calculated as the simple linear regression (slope) of the head penetration values recorded for each individual at 1, 2, and 5 years. Medial, proximal, and anterior measurements were made from translations in the x, y, and z axes of the RSA calibration cage (Cage number 43; RSA Biomedical). To enable comparison to other in vitro and in vivo studies, the two-dimensional (2-D) head penetration was calculated as the vectorial sum of mediolateral (x axis) and proximal-distal (y axis) migrations. The three-dimensional (3-D) head

Table 1. Summary data

Variable	Medial (positive), lateral (negative)	Proximal (positive), distal (negative)	Anterior (positive), posterior (negative)	Two-dimensional	Three-dimensional
Head penetration between 1 week and 5 years (mm)					
Median	0.012	0.013	0.089	0.057	0.130
Mean	0.005	0.018	0.075	0.071	0.149
SD	0.063	0.061	0.123	0.052	0.076
Range	−0.167 to 0.095	−0.108 to 0.128	−0.199 to 0.291	0.014–0.167	0.040–0.321
Bedding-in/creep between 1 week and 1 year (mm)					
Median	0.016	0.010	0.025	0.085	0.161
Mean	0.008	0.007	0.045	0.082	0.187
SD	0.070	0.063	0.182	0.043	0.083
Range	−0.119 to 0.120	−0.094 to 0.119	−0.293 to 0.309	0.017–0.152	0.017–0.317
Wear rate between 1 and 5 years (mm/year)					
Median	−0.002	0.004	0.001	−0.004	−0.005
Mean	−0.002	0.001	0.007	−0.002	−0.007
SD	0.020	0.018	0.038	0.016	0.024
Range	−0.062 to 0.027	−0.033 to 0.033	−0.061 to 0.081	−0.028 to 0.032	−0.061 to 0.040

penetration was calculated as the vectorial sum of mediolateral, proximal-distal, and AP (z axis) migrations.

Results

The mean amounts of medial, proximal, anterior, 2-D, and 3-D head penetration between 1 week and 5 years were 0.005, 0.018, 0.075, 0.071, and 0.149 mm, respectively (Table 1). The majority of this head penetration occurred within the first 12 months and the amount of head penetration was less than 0.2 mm in the proximal and medial directions at 5 years (Fig. 1). The mean medial, proximal, anterior, 2-D, and 3-D wear rates between 1 and 5 years were −0.002, 0.001, 0.007, −0.002, and −0.007 mm/year, respectively (Table 1). No patient in this cohort had a medial, proximal, 2-D, or 3-D wear rate of more than 0.040 mm/year.

Discussion

The dramatic reduction of wear observed with in vitro studies examining crosslinked polyethylene acetabular components [8] is a formidable challenge for in vivo wear measurement. Wear studies using measurements made from plain radiographs have limited sensitivity, particularly when monitoring very low amounts of wear [11]. For example, the amount of wear measured using Martell's Hip Analysis Suite software [15] may overestimate wear in comparison to more sensitive techniques such as RSA [3]. In an optimal experimental setup, the accuracy of RSA to measure femoral head penetration is reported to be 33 μ m,

Fig. 1 Graph showing the femoral head penetration for each individual between 1 week and 5 years in the proximal-distal and mediolateral directions.

22 μ m, and 86 μ m in the x, y, and z axes, respectively [2], which is consistent with the precision measurements reported by Borlin et al [1] for the beaded plus ellipse technique (68 μ m, 98 μ m, and 138 μ m in the x, y, and z axes, respectively). This sensitivity implies the wear of conventional polyethylene can readily be measured and clinically important wear thresholds such as wear greater than 0.05 mm/year should be measurable after 1 to 2 years. However, in vitro testing of this second-generation highly crosslinked polyethylene liner predicted a wear rate as low as 0.014 mm/year and our early report at 2 years found a wear rate of 0.015 mm/year. Hence, it would theoretically take approximately 5 years before there is evidence of measurable wear. Subsequently, we elected to measure the wear of this second-generation highly crosslinked polyethylene liner with RSA at 5 years followup.

We acknowledge the limitations of our study. First, we only provide descriptive data of a small cohort and did not have a control group for comparison. Second, clinical wear studies often include different measurement and wear rate calculation methods, which make comparison between groups difficult. RSA studies may calculate wear differently than other in vivo radiological methods such as Martell's [15] and readers should be aware of the limitations and measurement bias when comparing studies. Differences may even exist when the same software is used as a result of improvements made in later versions [13]. Studies may also report wear parameters (femoral head penetration, bedding-in, wear rate) differently, which we have attempted to present as clearly as possible for future comparative studies. Third, we did not assess the presence of osteolysis in this patient cohort and ultimately osteolysis is the clinically relevant parameter of interest; wear is an imperfect surrogate. Fourth, although RSA is considered the most accurate technique to measure wear in vivo, the amount of femoral head penetration actually occurring in XLPE liners is very low and may actually be less than the sensitivity of RSA at 5 years. The low mean proximal wear rate of 0.001 mm/year (range, -0.062 to 0.027 mm/year) reported in our study is similar to that reported in other RSA studies of first-generation XLPE liners with greater than 5 years' followup (eg, 0.001 [7], 0.002 [16], 0.005 [12], and 0.014 mm/year [4]). As a result of wear being measured as the slope of the penetration measurements made after 1 year for each individual and the penetration being so small, some negative wear rates are reported in all clinical wear studies. To calculate the wear of very low wearing implants, further time is required until the total amount of wear produces a measurable positive wear slope.

In a study of 51 hips using the same second-generation XLPE liner, D'Antonio et al [6] reported the mean 2-D head penetration between 6 weeks and 5 years was 0.072 mm (SD, 0.286 mm), which was similar to our result of 0.071 mm (SD, 0.052) between 1 week and 5 years. However, D'Antonio et al [6] reported a mean 2-D wear rate of 0.015 mm/year, which is higher than our mean 2-D wear rate of -0.002 mm/year (range, -0.028 to 0.032 mm/year). The negative mean wear rate is a result of the small amount of wear being measured over the 4-year period. Unfortunately, no range or SD of the wear rate was included in the previous publication [5] for further comparison. The range is important when reporting the number of individual outliers above certain wear rates. A wear rate of 0.05 mm/year or more has been cited by some to have an association with osteolysis [9]. No patients in our study were found to have a 2-D wear rate of more than 0.04 mm/year. A less sensitive measurement technique may have erroneously reported some patients above this wear rate.

We found that the femoral head penetration within a second-generation XLPE liner remained very low at

5 years, and the wear rate calculated after 1 year is very low in all directions. No patients had a proximal, 2-D, or 3-D wear rate exceeding 0.04 mm/year. However, longer-term and larger studies need to be performed to determine whether this results in decreases in osteolysis. The low observed level of wear remains encouraging for the future clinical performance of this material.

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References

1. Borlin N, Rohrl SM, Bragdon CR. RSA wear measurements with or without markers in total hip arthroplasty. *J Biomech.* 2006;39:1641-1650.
2. Bragdon CR, Malchau H, Yuan X, Perinchief R, Karrholm J, Borlin N, Estok DM, Harris WH. Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model. *J Orthop Res.* 2002;20:688-695.
3. Bragdon CR, Martell JM, Greene ME, Estok DM 2nd, Thanner J, Karrholm J, Harris WH, Malchau H. Comparison of femoral head penetration using RSA and the Martell method. *Clin Orthop Relat Res.* 2006;448:52-57.
4. Callary SA, Campbell DG, Mercer G, Nilsson KG, Field JR. Wear of a 5 Megarad cross-linked polyethylene liner: a 6-year RSA study. *Clin Orthop Relat Res.* 2013;471:2238-2244.
5. Campbell DG, Field JR, Callary SA. Second-generation highly cross-linked X3 polyethylene wear: a preliminary radiostereometric analysis study. *Clin Orthop Relat Res.* 2010;468:2704-2709.
6. D'Antonio JA, Capello WN, Ramakrishnan R. Second-generation annealed highly cross-linked polyethylene exhibits low wear. *Clin Orthop Relat Res.* 2012;470:1696-1704.
7. Digas G, Karrholm J, Thanner J, Herberts P. 5-year experience of highly cross-linked polyethylene in cemented and uncemented sockets: two randomized studies using radiostereometric analysis. *Acta Orthop.* 2007;78:746-754.
8. 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.
9. Dumbleton JH, Manley MT, Edidin AA. A literature review of the association between wear rate and osteolysis in total hip arthroplasty. *J Arthroplasty.* 2002;17:649-661.
10. Ebramzadeh E, Sangiorgio SN, Lattuada F, Kang JS, Chiesa R, McKellop HA, Dorr LD. Accuracy of measurement of polyethylene wear with use of radiographs of total hip replacements. *J Bone Joint Surg Am.* 2003;85:2378-2384.
11. 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;85:505-511.
12. Johanson PE, Digas G, Herberts P, Thanner J, Karrholm J. Highly crosslinked polyethylene does not reduce aseptic loosening in cemented THA 10-year findings of a randomized study. *Clin Orthop Relat Res.* 2012;470:3083-3093.
13. Kraay MJ, Moore RD, Martell JM, Rinnac CM. Reassessment of computerized wear measurement for total hip arthroplasty with correction for projectional image distortion: a brief follow-up report. *J Bone Joint Surg Am.* 2010;92:1858-1867.

14. Kurtz SM, Gawel HA, Patel JD. History and systematic review of wear and osteolysis outcomes for first-generation highly cross-linked polyethylene. *Clin Orthop Relat Res.* 2011;469:2262–2277.
15. Martell JM, Berdia S. Determination of polyethylene wear in total hip replacements with use of digital radiographs. *J Bone Joint Surg Am.* 1997;79:1635–1641.
16. Rohrl SM, Nivbrant B, Nilsson KG. No adverse effects of sub-melt-annealed highly crosslinked polyethylene in cemented cups: an RSA study of 8 patients 10 yaers after surgery. *Acta Orthop.* 2012;83:148–152.
17. Valstar ER, Gill R, Ryd L, Flivik G, Börlin N, Kärrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop.* 2005;76:563–572.