Wear of a 5 Megarad Cross-linked Polyethylene Liner: A 6-year RSA Study

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Abstract

Background One cross-linked polyethylene (XLPE) liner is manufactured using a lower dose of radiation, 5 Mrad, which may result in less cross-linking. The reported in vivo wear rate of this XLPE liner in patients undergoing THA has varied, and has included some patients in each reported cohort who had greater than 0.1 mm/year of wear, which is an historical threshold for osteolysis. Previous studies have measured wear on plain radiographs, an approach that has limited sensitivity.

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Each author certifies that his institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at the Repatriation General Hospital, Adelaide, South Australia, Australia.

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Questions/purposes We therefore measured the amount and direction of wear at 6 years using Radiostereometric analysis (RSA) in patients who had THAs that included a cross-linked polyethylene liner manufactured using 5 Mrad radiation.

Methods We prospectively reviewed wear in 30 patients who underwent primary THAs with the same design of cross-linked acetabular liner and a 28-mm articulation. Tantalum markers were inserted during surgery and all patients had RSA radiographic examinations at 1 week, 6 months, 1, 2, and 6 years postoperatively.

Results The mean proximal, two-dimensional (2-D) and three-dimensional (3-D) wear rates calculated between 1 year and 6 years were 0.014, 0.014, and 0.018 mm/year, respectively. The direction of the head penetration recorded between 1 week and 6 years was in a proximal direction for all patients, proximolateral for 16 of 24 patients, and proximomedial for eight of 24 patients.

Conclusions The proximal, 2-D and 3-D wear of a XLPE liner produced using 5 Mrad of radiation was low but measurable by RSA after 6 years. No patients had proximal 2-D or 3-D wear rates exceeding 0.1 mm/year. Further followup is needed to evaluate the effect of XLPE wear particles on the development of long-term osteolysis.

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Introduction

Conventional UHMWPE used in THA is prone to wear-particle formation [6, 8]. The presence of UHMWPE wear particles elicits an inflammatory reaction that is associated with periprosthetic bone resorption and implant failure [8, 9, 14, 15, 18, 25, 28]. The rate at which wear particles are generated, along with their size and volume are important factors in determining the likely occurrence of osteolysis [18, 23]. Dumbleton et al. in a review of the literature suggested osteolysis is infrequent with a wear rate less than 0.1 mm/year and almost absent at a rate less than 0.05 mm/year [8]. To decrease the wear rates observed with conventional UHMWPE, manufacturers now cross-link polyethylene using different amounts of radiation, then remelt or anneal the material to remove free radicals released during the irradiation process. Bragdon et al. in an *in vitro* hip simulator study of cross-linked polyethylene (XLPE) reported much lower wear than conventional UHMWPE [3].

Radiographic measurements are made to determine the amount of *in vivo* femoral head penetration in the metal-backed acetabular component with time. Penetration in the first postoperative year is assumed to be part of the creep and bedding-in phase. Penetration after 1 year is assumed to be wear of the polyethylene liner. With the small amounts of wear typically seen with XLPE liners, sensitive radiographic techniques are required to measure the *in vivo* wear rates. Radiostereometric analysis (RSA) offers improved accuracy and precision compared with other computer-assisted edge-detection techniques such as Devane's PolyWare (Draftware Inc, Vevay, IN, USA) and Martell's Hip Analysis Suite (University of Chicago, Chicago, IL, USA) [22]. Hui et al. [16] reported the precision for two-dimensional (2-D) wear measurements using PolyWare and the Hip Analysis Suite to be 0.414 mm and 0.242 mm, respectively. Ebrahimzadeh et al. showed that the PolyWare method has a tendency to overestimate the amount of wear by 0.18 mm [10]. Although RSA is an extremely precise method for wear analysis [4, 19], its use has been limited by its expense, its requirement for prospective assessment, and the expertise required for analysis [23].

In 2003 we commenced a prospective cohort study in which we used RSA to measure the wear of one type of cross-linked polyethylene liner (MarathonTM, DePuy Orthopaedics Inc, Warsaw, IN, USA) that had been cross-linked with 5 Mrad (50 kGy) of gamma-radiation and annealed at greater than 150°C to eliminate free radicals. At 2 years we found the wear rate for this material was less than 0.01 mm and below the detectable level with RSA [5]. The precision (95% CI) of the RSA method for this cohort was 0.033, 0.019, and 0.072 mm for medial, proximal, and anterior wear respectively [5]. Recently, the amount of

wear for the same liner has been measured in five prospective studies over five years using the computer-based methods, Polyware Auto [24], Martell's Hip Analysis Suite [1, 11, 12], and AutoCAD[®] (Autodesk[®], San Rafael, CA, USA) [20]. These five studies reported varying mean 2-D wear rates of 0.01 [12], 0.031 [1], 0.04 [11], 0.05 [24], and a 2-D penetration rate of 0.06 mm/year [20]. Given the excellent precision of RSA, and the variability of these findings, we sought to measure the amount and direction of wear of the MarathonTM cross-linked polyethylene liner in a similar cohort at 6 years.

Patients and Methods

We prospectively enrolled 30 consecutive patients who underwent primary THA for osteoarthritis between September 2003 and July 2004. Inclusion was based on the decision of the consulting surgeon that a cementless hip arthroplasty was clinically appropriate. The components used for this study cohort (PinnacleTM acetabular component [DePuy Orthopaedics Inc] matched with a MarathonTM [DePuy Orthopaedics Inc] cross-linked liner) were the routine implant used for cementless hip arthroplasties in our institution. Inclusion criteria for the study patients were radiographically verified primary hip osteoarthritis and between the ages of 55 to 80 years. Exclusion criteria were residing outside the metropolitan area, abnormal gross anatomy of the hip, and inflammatory arthritis or severe osteoporosis. Before the latest followup, one patient died, one withdrew from the study early, and one was unable to attend the 6-year radiographic examination owing to illness but this patient had not undergone revision surgery. Therefore, 27 of the 30 patients were included in the study (nine men and 18 women). The median age of the patients was 72 years (range, 55–80 years), median height was 161 cm (range, 157–190 cm), and median weight was 79 kg (range, 63–105 kg). Ethics approval was obtained for this study from the Repatriation General Hospital Research and Ethics Committee. All patients provided informed consent for insertion of tantalum markers during surgery and the subsequent RSA radiographs.

Two experienced surgeons (DC and GM) performed the surgical procedures using the posterolateral approach. All patients received uncemented femoral stems (CorailTM, DePuy Orthopaedics Inc) with 28-mm Co-Cr femoral heads. The median cup size was 52 mm (range, 48–62 mm). Median inclination was 47° (range, 35°–65°), and the median version was 17° (range, 5°–32°). Six 1.0-mm tantalum markers (RSA BiomedicalTM, Umeå, Sweden) were placed into the outer rim of the polyethylene liner at the time of surgery.

All patients were allowed to bear weight as tolerated after surgery.

RSA examinations were performed at 1 week, 6 months, 1 year, 2 years, and 6 years postoperatively. Examinations were taken with each patient in a supine position. A ceiling-mounted, radiographic tube and a mobile, radiographic tube were used simultaneously to take exposures of the hip above a calibration cage (No. 43, RSA Biomedical™). The radiographic exposures were taken using 100 kV and 4 to 6 mAS. Of the 27 patients who underwent RSA examinations at 6 years, 24 could be evaluated. The reference postoperative radiographs were not taken for two patients, and the radiographs of one patient were not adequate for analysis. Femoral head penetration was calculated using UmRSA® software (v6.0, RSA Biomedical™). An edge-detecting ellipse algorithm in this software was used to outline the outer diameter and the opening of the metal backing of the cup [2]. The ellipse algorithm was used in conjunction with between one and five liner beads visible in consecutive radiographs to form a reference segment. The maximum condition number and rigid body error accepted for each reference segment were 70 and 0.3 mm respectively.

Femoral head penetration into the polyethylene was calculated in three separate ways to enable comparison to other in vitro and in vivo studies. First, proximal head penetration was calculated from translations along the y-axis. Then, the amount of 2-D femoral head penetration was calculated as the vectorial sum of mediolateral (x-axis) and proximodistal (y-axis) translations. Finally, the amount of three-dimensional (3-D) femoral head penetration was calculated as the vectorial sum of mediolateral, proximodistal, and anteroposterior (z-axis) translations. These measurements of femoral head penetration used the

postoperative radiograph at 1 week as baselines, and therefore include bedding in of the femoral head, which occurs during the first 12 months. The penetration recorded after 1 year was assumed to be wear of the polyethylene liner. Therefore, for each individual the proximal, 2-D, and 3-D wear rates were calculated using simple linear regression of the head penetration at 1, 2, and 6 years. Each individual's wear rate then was averaged to calculate the mean proximal, 2-D and 3-D wear rates.

Results

The mean proximal head penetration at 6 years was 0.188 mm (range, 0.003–0.506 mm; SD, 0.121) (Table 1). The majority of proximal head penetration occurred during the first 12 months postoperatively. The mean proximal wear rate calculated between 1 and 6 years was 0.014 mm/year. The mean 2-D femoral head penetration was 0.218 mm (range, 0.032–0.520 mm; SD, 0.127). The mean 2-D wear rate between 1 and 6 years was 0.014 mm/year. The mean 3-D femoral head penetration was 0.320 mm (0.052–0.601 mm; SD 0.140). The mean 3-D wear rate between 1 and 6 years was 0.018 mm/year. The direction of the head penetration recorded between 1 week and 6 years was in a proximal direction for all patients; proximolateral for 16 of 24 patients, and proximomedial for eight of 24 patients (Fig. 1). No patient in this cohort had a proximal, 2-D, or 3-D wear rate exceeding 0.1 mm/year, which is an historical threshold for osteolysis [8], and only three of 24 patients had 3-D wear rates greater than 0.05 mm/year.

Table 1. Summary data

Variable	Medial	Proximal	Anterior	2-D	3-D
Head penetration between 1 week and 6 years (mm)					
Median	−0.040	0.177	−0.098	0.210	0.337
Mean	−0.036	0.188	−0.088	0.218	0.320
SD	0.114	0.121	0.229	0.127	0.140
Range	−0.255–0.270	0.003–0.506	−0.571–0.417	0.032–0.520	0.052–0.601
Bedding-in/creep between 1 week and 1 year (mm)					
Median	0.010	0.111	−0.081	0.151	0.163
Mean	0.026	0.113	−0.096	0.143	0.0230
SD	0.094	0.092	0.210	0.100	0.174
Range	−0.155–0.223	−0.012–0.389	−0.812–0.147	0.010–0.448	0.060–0.928
Wear rate between 1 and 6 years (mm/year)					
Median	−0.009	0.010	0.002	0.009	0.018
Mean	−0.012	0.014	0.004	0.014	0.018
SD	0.022	0.020	0.051	0.020	0.037
Range	−0.058–0.031	−0.019–0.061	−0.089–0.121	−0.025–0.063	−0.109–0.075

2-D = two-dimensional; 3-D = three-dimensional.

Fig. 1 This graph shows the head penetration (mm) recorded between 1 week and 6 years in the proximal and mediolateral directions for each individual.

Discussion

There are numerous different XLPE liners, each produced with various manufacturing methods which may influence their clinical performance. The reported *in vivo* wear rate of a XLPE liner irradiated with 5 Mrad varies from 0.01 to 0.05 mm/year. Some patients in each reported cohort had wear rates greater than 0.1 mm/year which historically is associated with osteolysis. These studies all used measurements made from plain radiographs. RSA is an accurate and precise technique to measure femoral head penetration. Therefore, in 2003 we initiated a study [5] to measure the wear of MarathonTM XLPE liners with RSA. The mean rates calculated between 1 and 2 years in that study [5] suggested that the amount of wear would exceed the precision and be at a detectable level at 6 years.

We acknowledge limitations of the current study. First, we provided only descriptive data for one liner in a small consecutive cohort and did not have a control group receiving conventional UHMWPE or another type of XLPE. A control group in a similar cohort of patients would have allowed further comparisons to previous studies and investigation of other patient factors that may have influenced the reported wear rate. Second, there are various obstacles in comparing clinical wear studies, including different measurement methods and the calculations of wear rates. Other factors may influence the wear rate reported including differing implants, implant positioning, differing patient populations, and uncontrolled activity levels. Unfortunately, it is not possible to adequately analyze these data for influencing factors owing to the small sample size. Third, we did not evaluate the presence of osteolysis. Although we confirmed the low wear rate observed at 2 years, we do not know the long-term effects on osteolysis. Although the wear rate was less

than the osteolysis threshold suggested by Dumbleton et al. [8], Ilgen et al. [17] suggested that the benefit of a decrease in wear rate for XLPE may be offset by an increase in the inflammatory profile of these wear particles compared with those from conventional polyethylene. Leung et al. [21] reported three of 36 patients with MarathonTM liners had osteolytic lesions observed on CT scans at 5 years. Therefore, long-term studies investigating the presence of osteolysis are needed to confirm the clinical benefits of reduced wear with XLPE liners.

Five recent studies [1, 11, 12, 20, 24] measured femoral head penetration of the MarathonTM polyethylene liner, with at least 5 years of followup using computer-based analyses of plain radiographs (Table 2). The 2-D wear rate measured in our study, 0.014 mm/year, was at the lower end of these varying reports and with a smaller range of results. This is likely attributable to the superior accuracy and precision of the RSA method. The 2-D wear rate observed in our study was more than three times less than that reported by Mutimer et al. [24]. Possible explanations for the larger wear rate reported is that the patient cohorts may have been different, and the wear was calculated after 6 months which may have been insufficient to account for all of the creep and bedding-in. Estok et al. [13] reported the majority of creep occurs within the first 2.5 million cycles, which, based on the average walking activity of patients after THA, is likely to be reached at approximately 1 year. This is supported in our RSA study; the majority of head penetration occurred during the first year.

The proximal and 3-D head penetration between 1 week and 6 years (including creep and bedding-in) measured in our study (0.32 mm) was similar to those in other reports [7, 26, 27, 29] of XLPE liners using RSA at greater than 5 years (Table 3). The majority of the head penetration was in the proximolateral direction (Fig. 1), similar to that reported by Thomas et al. [29]. Small differences may exist in the *in vivo* wear rates for different XLPE liners owing to different polyethylene stock and manufacturing methods being used. Our mean 3-D wear rate of 0.018 mm/year for the MarathonTM is higher than 0.005 mm/year for the LongevityTM [29]. The reported 3-D wear rate of the CrossfireTM liner was 0.033 mm/year at 6 years [26], but this decreased to 0.002 mm/year at 10 years followup [27]. This may be attributable to no additional head penetration, however, only nine and then eight patients were included in each report.

The proximal 2-D and 3-D wear of MarathonTM XLPE liners was low but measurable by RSA after 6 years. The majority of the head penetration was in the proximolateral direction. No patients had proximal 2-D or 3-D wear rates exceeding 0.1 mm/year. Additional followup is needed to evaluate the effect of XLPE wear particles on the development of long-term osteolysis.

Table 2. Reports of in vivo wear rates of the Marathon™ polyethylene liner at greater than 5 years followup

Study/year	Analysis method	Femoral head size; material	Mean followup (years) (range)	Number of patients with wear measured/initial cohort	Mean age at surgery (years) (range)	2-D head penetration (mm) mean $\pm$ SD (range)	2-D head penetration rate (mm/year) mean $\pm$ SD (range)	2-D creep/bedding-in (mm) mean $\pm$ SD (range)	2-D wear rate (mm/year) mean $\pm$ SD (range)
Engl et al. 2006 [12]	Martell's Hip Analysis Suite	28 mm; cobalt-chromium	5.5 (4.1–7.0)	86/116	62.5 (26–87)	0.24 $\pm$ 0.42 (–1.18 to 1.02)	NR	0.22 $\pm$ 0.31 (–0.54 to 0.94)	0.01 $\pm$ 0.07 (–0.18 to 0.17)
Engl et al. 2012 [11]	Martell's Hip Analysis Suite	As above	10.6 (9.0–12.5)	79/116	As above	0.60 $\pm$ 0.49 (–0.74 to 2.05)	0.06 $\pm$ 0.05	As above	0.04 $\pm$ 0.06 (–0.09 to 0.19)
Bitsch et al. 2008* [1]	Martell's Hip Analysis Suite	28 mm (n = 27); 32 mm (n = 7); cobalt-chromium (n = 31); ceramic (n = 3)	5.8 (5.0–7.7)	32/34	60 (26–83)	NR	NR	0.139 $\pm$ 0.102 (0.006–0.364)	0.031 $\pm$ 0.047 (0.004–0.196)
Mutimer et al.† 2010 [24]	PolyWare Auto	28 mm; cobalt-chromium	5.5 (4.1–7.0)	55/61	61 (46–75)	NR	NR	0.30	0.05 (95% CI, 0.03–0.07)
Kim et al. 2009‡ [20]	AutoCAD	28 mm; alumina	5.6 (5–7)	100/105	45 (25–49)	NR	0.06 $\pm$ 0.03 (0 to 0.08)	NR	NR
Current study	RSA	28 mm; cobalt-chromium	5.8 (5.3–6.3)	24/30	72 (55–80)	0.218 $\pm$ 0.128 (0.032–0.520)	0.025 $\pm$ 0.020 (–0.009 to 0.072)	0.143 $\pm$ 0.100 (0.010–0.448)	0.014 $\pm$ 0.020 (–0.025 to 0.063)

2-D = two-dimensional; RSA = radiostereometric analysis; NR = not reported; * this study included eight revision hips, all other studies were primaries; † this study assumed creep to finish at 6 months and wear was calculated after 6 months, all other studies assumed creep to finish at 12 months; ‡ this study used 6 weeks as baseline examination; did not separate creep from wear.

Table 3. Reports of in vivo wear rates of the XLPE polyethylene liners using RSA at greater than 5 years followup

Study	XLPE liner	Femoral head size; material	Mean followup (years) (range)	Number of patients with wear measured/initial cohort	Mean age at surgery (years) (range)	Proximal head penetration (mm) mean $\pm$ SD (range)	Proximal wear rate (mm/year) mean $\pm$ SD (range)	3-D head penetration (mm) mean $\pm$ SD (range)	3-D wear rate (mm/year) mean $\pm$ SD (range)
Digas et al. 2007* [7]	Durasul [®] (Zimmer)	28 mm; cobalt-chromium	5	28/30	55 (35–70)	0.15 (–0.10 to 0.86)	0.001 [†]	0.23 (0.02–0.91)	NR
Digas et al. 2007* [7]	Longevity [™] (Zimmer)	28 mm; cobalt-chromium	5	19/32	48 (29–70)	0.08 (–0.02 to 0.24)	NR [‡]	0.20 (0.10–0.60)	NR
Rohrl et al. 2007 [§] [26]	Crossfire [™] (Stryker)	28 mm metal	6	9/10	61 (49–79)	0.08 (0.02–0.13)	0.006	0.23 (0.1–0.35)	0.033
Rohrl et al. [§] 2012 [27]	As above	As above	10	8/10	As above	0.07 (–0.015 to 0.153)	0.002 (–0.003 to 0.006)	0.2 (0.026–0.36)	0.002 (–0.047 to 0.008)
Thomas et al. 2011 [29]	Longevity [™] (Zimmer)	28 mm; cobalt-chromium	7 (7.0–7.8)	22/27	68 (52–76)	NR	NR	0.33 $\pm$ 0.10	0.005 $\pm$ 0.015
Current study	Marathon [™] (Depuy)	28 mm; cobalt-chromium	5.8 (5.3–6.3)	24/30	72 (55–80)	0.188 $\pm$ 0.121 (0.003–0.506)	0.014 $\pm$ 0.020 (–0.089 to 0.121)	0.32 $\pm$ 0.14 (0.052–0.601)	0.018 $\pm$ 0.037 (–0.109 to 0.075)

XLPE = cross-linked polyethylene; RSA = radiostereometric analysis; 3-D = three-dimensional; NR = not reported; * results from supine examinations; [†] wear rate calculated between 2 years and 5 years; [‡] it was stated “no further penetration was detected after 1 year”; [§] creep was assumed to finish at 2 months, therefore wear rate was calculated at greater than 2 months.

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