Wear of a sequentially annealed polyethylene acetabular liner

RSA measurements in 19 hips

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Background and purpose — We previously reported on a randomized controlled trial (RCT) that examined the effect of adding tobramycin to bone cement after femoral stem migration. The present study examined femoral head penetration into both conventional and highly crosslinked polyethylene acetabular liners in the same group of RCT patients, with a minimum of 5 years of postoperative follow-up.

Patients and methods — Linear penetration of the femoral head into an X3 (Stryker) crosslinked polyethylene (XLPE) liner was measured in 18 patients (19 hips) using radiostereometric analysis (RSA). Femoral head penetration was also measured in 6 patients (6 hips) with a conventional polyethylene liner (CPE), which served as a control group.

Results — The median proximal femoral head penetration in the XLPE group after 5.5 years was 0.025 mm with a steady-state penetration rate of 0.001 mm/year between year 1 and year 5. The CPE liner showed a median proximal head penetration of 0.274 mm after 7.2 years, at a rate of 0.037 mm/year.

Interpretation — The Trident X3 sequentially annealed XLPE liner shows excellent in vivo wear resistance compared to non-crosslinked CPE liners at medium-term implantation. The rate of linear head penetration in the XLPE liners after > 5 years of follow-up was 0.001 mm/year, which is in close agreement with the results of previous studies.

It is well established that crosslinked polyethylene (XLPE) as a bearing surface in total hip replacements undergoes substantially less wear than conventional polyethylene bearings (Bragdon et al. 2007a, Calvert et al. 2009). Concerns regarding reduced mechanical properties of XLPE, such as susceptibility to oxidation (Currier et al. 2007), fracture (Furmanski et al. 2009, 2011), and delamination (Bradford et al. 2004) ushered in a second generation of crosslinked polyethylene liners (Digas et al. 2007, Glyn-Jones et al. 2008a).

Stryker Orthopaedics (Mahwah, NJ) developed a sequential stepwise process involving moderate doses of gamma irradiation followed by annealing (heating to just below melting point) of the polyethylene in order to create their X3 crosslinked polyethylene material (Dumbleton et al. 2006). This iterative process forms the crosslinked polyethylene structure necessary for wear resistance while removing the majority of free radicals, which are damaging to the molecular structure. The X3 liners have shown promising mechanical strength and wear resistance in vitro (Dumbleton et al. 2006), with limited reports of in vivo follow-up to 5 years (Callary et al. 2013, D'Antonio et al. 2012). The purpose of the present research was to confirm the low in vivo wear of the X3 crosslinked acetabular liner at the 5-year mark.

Patients and methods

In this study, we examined patients who were enrolled in a randomized controlled trial (RCT) beginning in 2003, which examined femoral stem migration between standard and antibiotic-laden bone cements (Bohm et al. 2012). Ethical approval for extending this RCT to include analysis of femoral head penetration was obtained from the University of Manitoba Biomedical Research Ethics Board (B2003:108).

Surgeries were performed between 2003 and 2007 on patients over the age of 65 who required total hip replacement. An Exeter femoral stem with a modular stainless-steel femoral head of varying sizes (28 mm, 32 mm, and 36 mm) was used in all patients. A Trident (Stryker Orthopaedics) conventional polyethylene (CPE) acetabular liner was implanted into patients who were enrolled in the primary RCT between 2003 and April of 2005. The study institution then switched to use of the X3 (Stryker Orthopaedics) crosslinked polyethylene (XLPE) liner based on evidence of improved in vitro wear resistance (Wang et al. 2003) and because the bearing material

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was not the focus of the original RCT. Patients enrolled after April 2005 received the XLPE liner.

Of the original 30 patients (32 hips) recruited for the primary RCT, 25 patients (27 hips) were followed beyond 5 years; 2 patients moved away, 2 patients were lost to follow-up, and 1 patient was in poor health. Of the 27 hips, 8 were implanted with a CPE liner and 19 were implanted with an XLPE liner. In the CPE group, 6 were 28-mm diameter and 2 were 32-mm diameter. The latter were removed from the analysis of CPE head penetration, as previous studies have shown that femoral head size statistically significantly affects linear head penetration (Kesteris et al. 1996, Tarasevicius et al. 2008). In the XLPE group, 2 were 28-mm diameter, 16 were 32-mm diameter, and 1 was 36-mm diameter. Despite the different femoral head sizes, data were combined in the XLPE group, as some studies have shown that femoral head size does not statistically significantly affect linear head penetration into crosslinked polyethylene (Muratoglu et al. 2001, Bragdon et al. 2007b, Lachiewicz et al. 2009).

The CPE group consisted of 6 women with a median age of 70 (63–73) years at the time of surgery, and a median follow-up of 7.2 (5.8–8) years. The XLPE group consisted of 8 men and 10 women (1 bilateral) with a median age of 68 (63–85) years and a median follow-up time of 5.5 (4.9–6.0) years.

Radiostereometric examinations were performed at 6 weeks, at 6 months, and at 1, 2, 3, and > 5 years postoperatively. The 5-year RSA examinations were performed using a digital radiography system consisting of 2 ceiling-mounted X-ray sources (RAD-92; Varian Medical Systems, Palo Alto, CA) and corresponding digital detectors (Canon CXDI-55C; Canon USA, Lake Success, NY). The uniplanar calibration cage and overall RSA setup remained the same throughout the study. Radiographic analysis was performed with the UmRSA software suite version 6.0 (RSA Biomedical, Umeå, Sweden). Femoral head penetration was analyzed using automated edge-detection algorithms and was measured as the change in proximity between the center of the femoral head and the exterior of the acetabular cup—quantified as both proximal migration and a Pythagorean sum of 3-D motion, commonly termed maximum total point motion (MTPM). The rate of femoral head penetration (clinical wear rate) was calculated as the group median slope of linear regression lines computed for each individual patient (McCalden et al. 2009) between the 1-year and the 5-year follow-up periods. The 6-week and 6-month follow-up data were not analyzed for this study, as bedding-in (creep) of the polyethylene usually occurs within the first 6–12 months of use (Glyn-Jones et al. 2008b) and cannot be differentiated from wear during the same time using this technique.

We report WOMAC outcome scores obtained for each patient at each follow-up as part of the primary RCT. The WOMAC scores recorded at the 2-year follow-up and the 5-year follow-up are reported for comparison of clinical outcomes between polyethylene groups and follow-up periods.

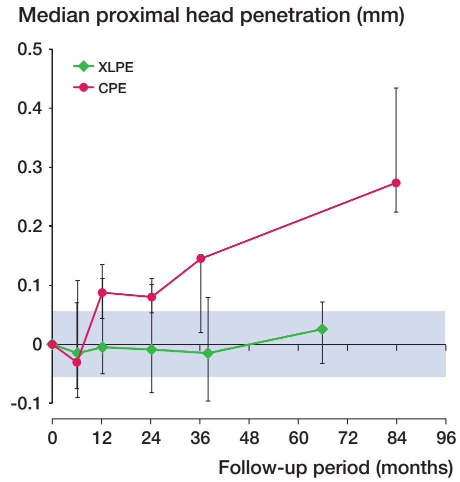

Figure 1. Median femoral head penetration in the proximal direction with 95% CI (vertical error bars). The shaded region indicates the precision limit of the RSA system based on double examinations.

Statistics

Due to the small sample sizes, non-parametric statistics are presented: medians and 95% confidence intervals (CI) based on ordered rank. 17 double examinations were performed in order to ascertain the clinical precision of the digital X-ray system. Precision was calculated as the width of the CI of double-examination error, a non-parametric version of the method recommended by Derbyshire et al. (2009). Polyethylene groups were compared using Mann-Whitney U-tests, while Wilcoxon signed rank tests were used for comparison within groups. Significance for all statistical tests was set at $p < 0.05$.

Results

None of the patients who were enrolled in the primary RCT underwent a revision of their hip replacement at the latest follow-up. WOMAC scores were similar between polyethylene groups at the 2-year and 5-year follow-up periods ($p = 0.9$ and $p = 0.5$, respectively). A decline in WOMAC scores was noted between the 2-year follow-up and the 5-year follow-up in both groups, but statistical significance was not reached (CPE group: $p = 0.06$; XLPE group: $p = 0.08$).

Based on double examinations, the precision of the clinical RSA measurements was 0.06 mm (proximal migration) and 0.20 mm (MTPM). The median femoral head penetration at a median follow-up time of 5.5 years for the XLPE patients was 0.025 mm (proximal migration) and 0.197 mm (MTPM) (Figures 1 and 2). The median rate of femoral head penetration between year 1 and year 5 for the XLPE group was 0.001 mm/year proximally (95% CI: –0.002 to 0.002), and –0.010 mm/year for MTPM (95% CI: –0.003 to 0.001). CPE patients

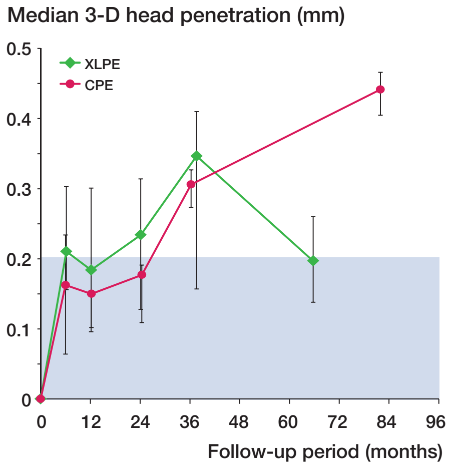

Figure 2. Median and total linear femoral head penetration in all directions (MTPM) with 95% CI (vertical error bars). The shaded region indicates the precision limit of the RSA system based on double examinations.

experienced a median femoral head penetration of 0.274 mm (proximal migration) and 0.442 mm (MTPM) at a median time of 7.2 years after surgery (Figures 1 and 2). The median rate of head penetration in this PE group was 0.037 mm/year (95% CI: 0.001–0.005) proximally and 0.046 mm/year (CI: 0.003–0.006) for MTPM.

Discussion

We found 0.025 mm of proximal penetration into XLPE over a median period of 5.4 years, which is substantially less than the values found by other studies examining crosslinked polyethylene bearings after 5 or more years in vivo: 0.15 mm (Digas et al. 2007) and 0.08 mm (Rohrl et al. 2007).

The rate of femoral head penetration of the X3 polyethylene bearing in the coronal plane between the 1-year and the 5-year follow-up has previously been reported to be 0.014 mm/year in vitro (Dumbleton et al. 2006) and 0.015 mm/year in vivo (D'Antonio et al. 2012) with < 0.001 mm/yr in the proximal direction (Callary et al. 2013). These reported rates of linear head penetration are within the range of 0.001 mm/year measured in the present study. Furthermore, the rate of total linear head penetration (MTPM) between year 1 and year 5 was –0.010 mm/year, which is almost identical to the mean rate of –0.007 mm/year reported by Callary et al. (2013).

Little to no bedding-in of the polyethylene bearing (due to creep) in the proximal direction was measured within the first postoperative year (Figure 2). This lack of detectable bedding-in is partially explained by the use of a reference RSA examination done 6 weeks postoperatively. As most creep has been shown to occur within the first 2–3 months of implantation (Glyn-Jones et al. 2008), it is possible that our delayed reference examination missed much of the creep process.

This study was limited, as the polyethylene groups were not randomized, therefore possibly introducing selection bias. Stem subsidence, not linear head penetration, was the subject of the primary RCT, which is why the patients in the present study were not randomized and why the control (CPE) group consisted of only 6 subjects. The patients enrolled in this study had a median age of 69 years at the time of surgery, which may have resulted in a reduced clinical wear rate compared to a younger and perhaps more active patient cohort. A bilateral XLPE patient was included in the analysis of linear head penetration, which may have introduced inter-patient bias into the results (Bryant et al. 2006). Accordingly, this patient's data were provisionally removed, resulting in miniscule changes to the median rate of femoral head penetration (a decrease in proximal penetration of 0.006 mm/year and a decrease in MTPM penetration of 0.007 mm/year).

Different femoral head sizes in the PE groups may also have contributed some amount of error to our results. However, a number of studies have shown that femoral head size does not affect head penetration, specifically with highly crosslinked polyethylene bearings (Bragdon et al. 2007, Lachiewicz et al. 2009, Muratoglu et al. 2001). The opposite is true for non-crosslinked polyethylene, where smaller head sizes show reduced linear wear (Kesteris et al. 1996, Tarasevicius et al. 2008). Accordingly, the 2 patients in the CPE group with 32-mm heads were not included in the calculation of wear.

We believe that the decline in patient-reported outcomes seen in both polyethylene groups between the 2-year and the 5-year follow-up periods was the result of declining health of the patients as they aged and was not a result of poorly-performing total hip replacements. Also, the sample size of this study was too small for us to make statistically meaningful conclusions regarding patient function as it relates to choice of polyethylene.

In summary, the X3 sequentially irradiated and annealed crosslinked polyethylene acetabular liner used in this study showed excellent in vivo wear properties, as the rate of linear head penetration after 5.5 years was 0.001 mm/year in the proximal direction.

TG: radiographic examinations, measurements, analysis of data, and preparation of manuscript. MP: radiographic examinations and preparation of manuscript. TT: interpretation, final review of manuscript, and contribution of surgical cases. EB: lead investigator, lead surgeon, preparation of manuscript.

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