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Original Article

The Relationship Between Polyethylene Wear and Periprosthetic Osteolysis in Total Hip Arthroplasty at 12 Years in a Randomized Controlled Trial Cohort

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ABSTRACT

Background: Polyethylene acetabular components are common in hip arthroplasty. Highly cross-linked polyethylene (HXLPE) has lower wear than ultra-high molecular weight polyethylene (UHMWPE). Evidence suggests that wear particles induce inflammation causing periprosthetic osteolysis contributing to implant loosening with wear rates of 0.05 mm/y were considered safe. We aimed to compare incidence and volume of periacetabular osteolysis between HXLPE and UHMWPE using computed tomography.
Methods: Initially, 54 hips in 53 patients were randomized to HXLPE or UHMWPE acetabular liner. At 10 years, 39 hips in 38 patients remained for the radiostereometric analysis' demonstrating significantly lower wear in the HXLPE group. At 12 years, 14 hips in 13 patients were lost to follow-up leaving 25 hips for computed tomography assessment. Images were reconstructed to detect osteolysis and where identified, areas were segmented and volumized.
Results: Osteolysis was observed in 8 patients, 7 from the UHMWPE group and only 1 from the HXLPE group (Fisher exact, $P = .042$). There was no correlation between the amount of polyethylene wear and osteolysis volume; however, the radiostereometric analysis-measured wear rate in patients with osteolysis from both groups was significantly higher than overall average wear rate.
Conclusion: This data demonstrates lower incidence of periacetabular osteolysis in the HXLPE group of a small cohort. Although numbers are too low to estimate causation, in the context of lower wear in the HXLPE group, this finding supports the hypothesis that HXLPE may not elevate osteolysis risk, and hence does not suggest that HXLPE wear particles are more biologically active than those generated by earlier generations of polyethylene.

Osteolysis caused by polyethylene wear debris is accepted as the major cause of aseptic loosening and implant failure in total hip arthroplasty (THA) [1,2]. Revision surgery as a treatment for this failure constitutes a significant cause of morbidity and mortality [3]. Historically, osteolysis has been identified using plain radiograph-based measures, notably the Charnley [4], Devane [5], and Pedersen [6] methods. The sensitivity of these measures is intrinsically limited because of the 2-dimensional nature of the images, and therefore depends significantly on lesion location with overall sensitivity having been shown to be only 41.5% [7]. More recently, efforts have been made to investigate the use of cross-sectional imaging techniques including computed tomography (CT) and magnetic resonance imaging (MRI), with CT giving greater sensitivity for the detection of osteolysis when compared with radiography [8,9]. Walde et al [10] investigated radiography, CT, and MRI for the identification of osteolytic lesions, and their results supported the poor sensitivity of radiography as well as showing CT to be marginally superior to MRI because of the greater

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interpretative challenges associated with beam hardening due to metal artefact in MRI techniques.

Polyethylene has been used continuously in THA since its inception and has proved a reliable material. Historically, femoral bearings are either metal or ceramic, both of which are considerably harder than polyethylene. Over the lifespan of implants, this causes acetabular component wear, increasing the likelihood of failure [11]. One mechanism for this failure results from the generation of wear particles that induce an inflammatory reaction mediated by proinflammatory cytokines and upregulation of macrophages [12]. This inflammatory reaction has been causally linked with periprosthetic osteolysis seen in aseptic implant loosening [13].

To minimize wear and failure, the material properties of polyethylene have been modified [14,15]. The most recent advance has been the development of highly cross-linked polyethylene (HXLPE), which has been shown to have significantly superior *ex vivo* and *in vivo* wear, when compared with UHMWPE [16,17]. Prospective studies have demonstrated a significant reduction in both linear wear and volumetric wear at 10-year postimplantation, when compared with conventional UHMWPE.

The process of osteolysis is thought to result from the biological reaction generated by wear debris, although it has also been shown to occur in the absence of identifiable wear debris [18]. This problem has been well studied in ultra-high molecular weight polyethylene (UHWMPE), where the concentration of polyethylene particles in tissue surrounding implants has been correlated directly with wear volume [19]. It therefore follows that implants demonstrating less wear should generate less wear debris, and hence fewer instances of osteolysis. However, this may not be the case for every type of polyethylene, as *in vitro* studies have demonstrated that HXLPE particles may be more bioreactive. Hence, lower volumes may be required to generate an inflammatory response [8,20].

Aseptic loosening caused by osteolysis has been well reported using plain radiograph methods in earlier generations of polyethylene [21]. A systematic review of wear and osteolysis outcomes in HXLPE revealed an 87% lower risk of osteolysis [22].

In 2001, we recruited patients to a double-blind randomized control trial, with the aim of measuring the long-term wear of HXLPE vs UHMWPE. This trial has reported that the radiostereometric analysis (RSA) measured linear wear and volumetric polyethylene wear at 2 [23], 3 [24], 7 [25], and 10 years [16], and demonstrated that HXLPE has an order of magnitude lower wear than UHMWPE. This cohort provides a unique opportunity to study the long-term association between osteolysis and volumetric wear. Therefore, the aim of this study was to investigate and compare the incidence and volume of periacetabular osteolysis between UHMWPE and HXLPE using CT to identify any lesions of volumes that may be too small for identification using plain radiography.

Materials and Methods

In the original cohort, 54 hips in 53 patients, with a diagnosis of osteoarthritis, were recruited from the waiting list for arthroplasty. Informed consent was gained from all patients that met the inclusion criteria. All patients received THA using cemented, collarless, tapered, and polished femoral stems (Zimmer CPT) with 28 mm cobalt-chromium head and cementless Trilogy (Zimmer) acetabular shell. Patients were allocated either conventional UHMWPE Trilogy liner or longevity HXLPE acetabular liner at random (n = 27 for each group) using computerized randomization software, with stratification for age and sex. The longevity HXLPE is manufactured from 1050 GUR resin using 10 MRad electron beam irradiation, remelting heat stabilization, and gas plasma sterilization. All components used were manufactured by Zimmer (Warsaw, IN). Baseline cohort demographics are shown in Table 1.

Table 1
Cohort Demographics at Baseline.

Variable	HXLPE (n = 27)	UHMWPE (n = 27)
Age (y), mean (range)	68 (52-76)	67 (51-76)
Weight (kg), mean (range)	79 (49-117)	82 (75-108)
Sex (male:female)	11:9	9:10

HXLPE, highly cross-linked polyethylene; UHMWPE, ultra-high molecular weight polyethylene.

Ethical approval was granted (REC Reference: C01.067) to amend the trial to investigate patients from this cohort using CT to identify periprosthetic osteolysis. Fifty-three patients were initially recruited (54 hips) and 38 patients remained (39 hips) at the 10-year assessment. From this cohort, 13 patients (14 hips) were lost to follow-up (2 deceased, 3 too unwell to attend, 4 withdrew from the study, and we lost contact with 5). Figure 1 shows the CONSORT flow chart.

Patients were recalled at a minimum of 12 years postsurgery for CT scan of the hip. Details of the cohort at 12 years are shown in Table 2. All scans were performed using the same machine; a GE LightSpeed VCT 64 Slice. All scans used the following image acquisition settings: rotation time 0.7 seconds, slice thickness 0.625 mm, fixed kv 120, pitch 0.969:1, noise index 28, auto ma between 120-600, and large field of view. Image sequence reformats were performed at 3 mm depth using the bony window in the 3 anatomical planes (axial, coronal, and sagittal). Images were acquired in the Digital Imaging and Communications in Medicine (DICOM) format.

All images were analyzed using 3-dimensional multiplanar reconstruction views in OsiriX 64-bit software to identify areas of osteolysis. Osteolysis was defined as areas of lucency seen within the bone, where no evidence of trabeculae could be seen, and there was evidence of cortication around the lucent area (Fig. 2). Once areas of osteolysis had been identified, we performed segmentation and volumization of the regions of interest using the ITK-SNAP (www.itksnap.org) software [26] (Fig. 3).

Our RSA system has been shown to be accurate to less than 0.1 mm and has been used to assess this cohort at 3, 6, and 12 months and 2, 3, 5, 7, and 10 years postsurgery. This data has been reported and has generated mean total and annualized linear penetration and volumetric wear rate for each group at 10 years postsurgery [16].

The RSA analysis of this cohort has previously demonstrated a lower volumetric wear in the HXLPE group. The findings from volumization of areas of osteolysis seen on CT images were then plotted against the prior RSA-derived wear data to determine whether there was a relationship between polyethylene wear and volume of osteolysis.

Statistical Analysis

The data were analyzed for distribution. Pearson chi-squared test was used to compare incidence of osteolysis between groups with Fisher exact test adjustment because of the low number of observations. A P value of <.05 was considered significant. Linear

Table 2
Cohort Demographics at 12-y Follow-Up.

Variable	HXLPE (n = 11)	UHMWPE (n = 14)
Age (y), mean (range)	74 (60-83)	75 (60-87)
Sex (male:female)	5:6	8:6

HXLPE, highly cross-linked polyethylene; UHMWPE, ultra-high molecular weight polyethylene.