The creep and wear of highly cross-linked polyethylene

A THREE-YEAR RANDOMISED, CONTROLLED TRIAL USING RADIOSTEREOMETRIC ANALYSIS

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The creep and wear behaviour of highly cross-linked polyethylene and standard polyethylene liners were examined in a prospective, double-blind randomised, controlled trial using radiostereometric analysis.

We randomised 54 patients to receive hip replacements with either highly cross-linked polyethylene or standard liners and determined the three-dimensional penetration of the liners over three years.

After three years the mean total penetration was 0.35 mm (SD 0.14) for the highly cross-linked polyethylene group and 0.45 mm (SD 0.19) for the standard group. The difference was statistically significant (p = 0.0184). From the pattern of penetration it was possible to discriminate creep from wear. Most (95%) of the creep occurred within six months of implantation and nearly all within the first year. There was no difference in the mean degree of creep between the two types of polyethylene (highly cross-linked polyethylene 0.26 mm, SD 0.17; standard 0.27 mm, SD 0.2; p = 0.83). There was, however, a significant difference (p = 0.012) in the mean wear rate (highly cross-linked polyethylene 0.03 mm/yr, SD 0.06; standard 0.07 mm/yr, SD 0.05). Creep and wear occurred in significantly different directions (p = 0.01); creep was predominantly proximal whereas wear was anterior, proximal and medial.

We conclude that penetration in the first six months is creep-dominated, but after one year virtually all penetration is due to wear. Highly cross-linked polyethylene has a 60% lower rate of wear than standard polyethylene and therefore will probably perform better in the long term.

Wear of the acetabular component with the production of polyethylene wear debris is thought to be one of the principal causes of aseptic loosening after total hip replacement. In an attempt to improve survival of the implant and to reduce the amount of wear debris generated by the bearing surface, the material properties of ultra-high molecular weight polyethylene (UHMWPE) have been manipulated by irradiation. Over the past ten years, several manufacturers have produced highly cross-linked polyethylenes.

In vitro studies have shown that highly cross-linked polyethylene has a greatly increased resistance to wear despite there being no long-term clinical evidence to support the widespread use of this modern development. Retrieval studies of first-generation highly cross-linked polyethylene acetabular components showed low rates of wear. However, early forms of highly cross-linked polyethylene cannot be compared with contemporary varieties since they used a base material which has now been discontinued. Retrieval studies have reported wear and fatigue cracking in some types of highly cross-linked polyethylene liner.

The assessment of new types of highly cross-linked polyethylene in vivo is therefore required. Several authors have studied this over a period of two years and have described a biphasic pattern of penetration. The first phase is rapid and creep-dominated but thereafter a much slower phase of penetration begins which is dominated by wear.

A considerable problem with the evaluation of polyethylene wear in vivo is the determination of when creep-dominated penetration slows and when wear-dominated penetration begins. It is important to establish the point at which this transition occurs since the degree of wear can only be determined accurately once the dominance of creep has decreased considerably.

In vitro studies have suggested that significant creep continues for approximately two...
million loading cycles, although variations in the activity of patients means that this target may be reached at any point between three months and two years after surgery. In vivo studies do not clarify matters since they also suggest that there is great variability in the point at which this transition occurs. Consequently, it has been recommended that the penetration of polyethylene should be measured in vivo for at least three years if the rate of wear is to be measured accurately. Studies which do not do this risk overestimating the wear rate.

Several varieties of highly cross-linked polyethylene have recently been developed for use in hip replacement, none of which has long-term in vivo data to support its usage. Longevity (Zimmer, Warsaw, Indiana) is one such polyethylene which is widely used in Europe and the United States. It is an oxidation-stabilised, electron-beam irradiated, highly cross-linked polyethylene produced from GUR 1050 resin. The manufacturer’s hip-simulator studies suggest that it wears at one-tenth of the rate of its standard UHMWPE and less than its metal-on-metal bearings. We have previously reported the difference in penetration between Longevity (Zimmer) and standard UHMWPE at two years. Our results indicated that Longevity had a wear rate which was approximately 40% lower than that of UHMWPE. A limitation of this study was the difficulty in estimating wear since it was not easy to distinguish wear from creep at two years.

Our aim in this study was to compare the wear rate of Longevity highly cross-linked polyethylene with that of standard UHMWPE after three years on the basis that it should be possible to establish the steady-state wear rate and subsequently determine the amount of penetration attributable to creep. The hypothesis was that Longevity polyethylene would wear at a significantly lower rate than standard UHMWPE in vivo after an initial period of rapid penetration, but that the wear would be in a similar direction for both types of polyethylene.

Patients and Methods

We recruited 54 patients with primary osteoarthritis of the hip from the routine waiting list. Ethical approval was granted and patients with significant comorbidities were excluded from the study. In each patient a cemented CPT (Zimmer) femoral component with a 28 mm head and an uncemented Trilogy acetabular component (Zimmer) were implanted. At the time of surgery, the patients were randomised to receive either a Longevity highly cross-linked polyethylene liner (n = 27), or a standard UHMWPE liner (n = 27). This was done using randomisation software: the patients were stratified for gender and age. Both liners were identical in appearance and patients, surgeons and investigators were blinded to the type of polyethylene. Two surgeons (PMS, DWM) from the same centre operated on both groups over a period of two years. Each operation was performed through a modified Hardinge approach with the patient in the lateral position. The femoral components were implanted with CMW3G cement (DePuy, Leeds, United Kingdom), using a third-generation cementing technique. The wound was drained in each case. Patients underwent routine post-operative rehabilitation. Details of both study groups are given in Table I. The abduction angle of the acetabular component was determined from post-operative radiographs in each case.

**RSA measurement.** The RSA system which was used has been described previously and has an accuracy in vivo of 0.2 mm. It uses ‘off-the-shelf’ implants and does not therefore require special implants with attached markers.

 RSA radiographs were taken with the patient bearing weight equally on each leg. Measurements were made post-operatively and then after 3, 6, 12, 24 and 36 months. Analysis began by determining the vector between the centre of the femoral head and the centre of the metal shell. By subtracting the vector at the beginning of a time interval from that at the end, a further vector, representing the penetration during that period was determined. The length of this vector represented the total amount of penetration. The components of the vector in the anteroposterior (sagittal plane), mediolateral (coronal plane) and proximal-distal directions represented the amount of penetration in each of these directions.

There was a marked difference in the pattern of penetration before and after one year. After one year, the relationship between penetration and time was linear. The rate of penetration after one year was determined by fitting a regression line to the data points at one, two and three years for each patient. The gradient of this line was taken to be the wear rate in mm/year. Wear begins soon after implantation, therefore by using this wear rate at each time point we were able to calculate the amount of wear which

Table I. Clinical details of the patients in the highly cross-linked polyethylene (HXLPE) and ultra-high molecular weight polyethylene (UHMWPE) groups

<table>
<thead>
<tr>
<th></th>
<th>Mean age in yrs (range)</th>
<th>Gender (M:F)</th>
<th>Mean weight in kg (range)</th>
<th>Median (min) shell outer diameter (mm)</th>
<th>Median stem size</th>
<th>Median stem offset</th>
<th>Mean (range) abduction angle of the acetabular component (˚)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HXLPE</td>
<td>68 (52 to 76)</td>
<td>13:13</td>
<td>79 (49 to 117)</td>
<td>56</td>
<td>2</td>
<td>Standard</td>
<td>43.3 (34 to 55)</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>67 (51 to 76)</td>
<td>13:12</td>
<td>82 (75 to 108)</td>
<td>56</td>
<td>2</td>
<td>Standard</td>
<td>45.1 (33 to 58)</td>
</tr>
</tbody>
</table>
had occurred. Creep was determined by subtracting the calculated wear from the total penetration at each time point.

The direction of wear and creep was also calculated in three dimensions. After one year the direction of wear was the same as that of penetration. The direction of creep was determined by subtracting the wear vector from the penetration vector. In order to express the direction of wear in clinical terms, the wear and creep vectors were projected onto the coronal and sagittal planes. The direction was defined as the angle subtended in each plane between the direction of creep and wear and the vertical axis.

**Statistical analysis.** Before starting the study, a sample size calculation was performed using Altman’s nomogram. Based on the work of Oonishi et al. a rate of penetration of 0.02 mm over two years for the UHMWPE liner was chosen. We expected a wear rate of 0.1 mm or less over two years for the highly cross-linked polyethylene. A SD of 0.1 mm was chosen based on our previous RSA studies. The power calculation indicated that a total of 20 patients was needed for each group (\( \alpha = 0.05, \beta = 0.9, 2n = 40 \)). The study was constructed as a superiority study.

The data were examined for distribution using the Shapiro-Wilk test. The \( t \)-test was then used for statistical analysis. All statistical analyses were performed using SPSS version 12.0 (SPSS Inc., Chicago, Illinois). A \( p \)-value \( \leq 0.05 \) was taken as significant.

**Results**

We excluded three patients, one because she had moved away and two because they had poor radiographs. This left 26 patients in the highly cross-linked polyethylene group and 25 in the UHMWPE group. There were no revision operations during the period of study. There were no differences in the clinical details or abduction angle of the acetabular component between the two groups (\( p = 0.31 \)).

The penetration data were found to be normally distributed in each group (highly cross-linked polyethylene \( p = 0.39 \); UHMWPE \( p = 0.45 \)). After three years the mean total penetration was 0.35 mm (SD 0.14) for the highly cross-linked polyethylene group and 0.45 mm (SD 0.19) for the UHMWPE group (Fig. 1). There was a significant difference in total penetration between the two groups at three years (\( p = 0.0184 \)). The penetration during the first year was greater than that in subsequent years (Fig. 1). After the first year the relationship between penetration and time was virtually linear. To confirm this, correlation coefficients were calculated and found to be very high (\( R^2 = 0.90 \) for highly cross-linked polyethylene and \( R^2 = 0.99 \) for UHMWPE). The gradient of the regression lines fitted to the penetration data from one year onwards gave a mean wear rate of 0.03 mm/yr (SD 0.06) for highly cross-linked polyethylene and 0.07 mm/yr (SD 0.05) for UHMWPE. The difference in wear rate was significant (\( p = 0.012 \)) between the two types of polyethylene; highly cross-linked polyethylene had a 57% lower wear rate than UHMWPE.

The amount of creep was similar between the groups (\( p = 0.83 \)), as was the pattern of creep (Fig. 2). Creep mainly occurred in the first year, with an exponential pattern. The mean total creep at one year was 0.26 mm (SD 0.17) for highly cross-linked polyethylene and 0.27 mm (SD 0.2) for UHMWPE. With highly cross-linked polyethylene, 83% of the creep occurred within the first three months and 93% within the first six months. With UHMWPE, 74% of the creep occurred within the first three months and 96% within the first six months.

Creep occurred predominantly in a proximal direction in both groups, whereas wear occurred in an anterior, proximal and medial direction (Fig. 3). The direction of creep differed significantly from the direction of wear in both groups (highly cross-linked polyethylene, coronal
plane $p = 0.01$, sagittal plane $p = 0.03$; UHMWPE, coronal plane $p = 0.01$, sagittal plane $p = 0.04$). There was no significant difference in the direction of creep or wear between the groups (Fig. 3). The coronal plane creep was proximal and slightly medial for highly cross-linked polyethylene and proximal and lateral for UHMWPE (Fig. 3). This difference was not significant. There was no significant difference in the direction of creep ($p = 0.35$).

**Discussion**

Our study supports our hypothesis that highly cross-linked polyethylene wears at a significantly lower rate than UHMWPE. It also shows that there are two distinct patterns of penetration of the polyethylene, namely, liner creep and wear (Fig. 1).

After one year there was a linear relationship between time and penetration with very high correlation coefficients for both types of polyethylene. We can therefore be certain that the penetration after one year is predominantly due to wear, since this occurs at a constant rate, as opposed to creep which occurs at a decreasing rate. The wear rate is therefore the same as the penetration rate after one year. Since the wear rate was constant we could not only predict what the wear would be in the long term, but also calculate what the wear was during the first year. By subtracting the wear during the first year from the penetration during the first year we could calculate the creep.

With conventional polyethylene the mean wear rate was 0.07 mm/yr, which was similar to estimates made by other authors. We have now shown that, in the clinical situation, the rate of wear of highly cross-linked polyethylene is approximately 60% less than that of conventional polyethylene. Although this is substantially worse than the manufacturer’s prediction of 90% less, based on hip-simulator data, it still represents a major clinical advance. The use of highly cross-linked polyethylene should therefore decrease both the mechanical complications of wear such as catastrophic failure and impingement, and the biological consequences such as osteolysis and loosening.

The direction of wear in our study was in the superior, medial and anterior directions for both materials. This agrees with the results of some retrieval studies but not others, which showed that wear was predominantly superior, and lateral. The direction of wear was probably depen-
dent on both movement and loading, in contrast to creep which was dependent on loading alone.29

Creep occurred early after implantation and accounted for a mean penetration of 0.26 mm. It was similar for both highly cross-linked polyethylene and UHMWPE. Approximately 80% of creep occurred in the first three months and 95% by six months. Assuming that creep continued to decrease in this exponential manner, an assumption which was supported by our data, then 99% would have occurred by nine months and virtually all by one year. The direction of creep in our study was predominantly in the superior direction and was not significantly different for the two materials (p = 0.35). The direction of creep was thought to be in the same direction as the joint reaction force,29 but seemed to vary significantly between individuals.30 The rapid early penetration measured in our study, which we have described as ‘creep’ may not only be due to creep within the polyethylene, but also to movement between the polyethylene and the liner, creep of polyethylene into drill holes within the acetabular component, or bedding-in wear, where surface asperities, left by manufacturing, are worn away.31,32

Our measurements of creep reflected the findings of other studies. Estok et al11 showed that in vitro most of the early penetration in both highly cross-linked polyethylene and UHMWPE was due to creep and occurred for up to two million loading cycles, measuring around 0.2 mm in both materials. Other workers have shown differences in creep resulting from cross-linking.29 The creep measured during the first year of our study was of a similar magnitude to that reported in vivo by Ooishi et al8 and Ooishi and Kadoya.9 However, most of the penetration occurred during the first six months of our study, much earlier than that reported in some studies,8,9 but similar to that reported by others.18,33

In all polyethylene wear studies in vivo, the main difficulty with interpretation of the data is the determination of the point at which creep-dominated penetration becomes wear-dominated penetration. Our data, however, clearly showed that after six months approximately 95% of the creep had occurred and by one year this has risen to 99%. In future, it should be acceptable to perform a preliminary analysis of polyethylene wear by measuring penetration between one and two years, although penetration measured between one and three years gives a much more accurate estimate of wear. Penetration measured from six months to one year or two years overestimates wear. It is for this reason that our previous analysis at two years overestimated the wear rate of highly cross-linked polyethylene.

There has been a rapid expansion in the use of highly cross-linked polyethylene in North America and Europe over the past five years and it is used in 65% of hip replacements in some countries.10 Although the results of in vitro studies are promising,3,34 past experience has shown that hip-simulator findings can differ greatly from those of clinical studies.35 Our study confirmed this since the rate of wear in vivo was approximately five times greater than that measured in vitro in a hip simulator by the manufacturer.21 Clinical studies are therefore essential. These should probably have been completed before highly cross-linked polyethylene became so widely used. Other in vivo studies of highly cross-linked polyethylene based on digitised plain radiographs have suggested significantly reduced wear,36,37 but these are less precise than comparable RSA studies and cannot accurately determine the direction of wear.20,28 Our study has shown that cross-linking reduces in vivo wear substantially and provides valuable evidence to support its use.

Some authors37,39,40 have raised concerns about the effects of cross-linking on the mechanical properties of highly cross-linked polyethylene which has decreased toughness and elastic modulus when compared with standard UHMWPE and is more likely to fracture. There is also some in vitro evidence that highly cross-linked polyethylene produces more biologically active wear particles than conventional UHMWPE.41,42 Long-term surveillance therefore remains essential.

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References


