Wear of moderately cross-linked polyethylene in fixed bearing total knee replacements

Claire L Brockett, Louise M Jennings, +Catherine Hardaker, John Fisher

Institute of Medical and Biological Engineering, School of Mechanical Engineering, University of Leeds, Leeds, LS2 9JT, UK

Email: C.L.Brockett@leeds.ac.uk

Tel: +44 113 3437472

Fax: +44 113 242 4611

+DePuy International Ltd, Leeds, UK

Abstract

Cross-linked polyethylene has been introduced into total joint replacement to improve wear resistance. Although the performance of highly cross-linked polyethylene is well documented clinically and experimentally for total hip replacements, the reduction in mechanical properties with increasing irradiation is of concern for application to total knee replacement. The aim of this study was to investigate the wear performance of a moderately cross-linked polyethylene material in a fixed bearing total knee replacement. The study was conducted using two femoral geometries, a conventional cruciate retaining femoral and a high-flexion femoral geometry. The femoral geometry appeared to have no effect on the wear of the knee replacement under standard gait conditions. A significant reduction in wear volume was measured with the moderately cross-linked polyethylene compared with the conventional polyethylene over a six million cycle wear study. This study indicates the use of a moderately cross-linked polyethylene in a fixed bearing total knee replacement may provide a low wearing option for total knee replacement.

Keywords

Total knee replacement, cross-linked polyethylene, wear

1. Introduction

Polyethylene wear in total joint replacement continues to be one of the principal factors influencing the clinical success of an implant. Historical failure in total knee replacement was often due to oxidative degradation of the material resulting in fatigue failure and delamination [1-3]. Improvements in design, material and sterilisation procedure have resulted in more oxidatively stable polyethylene materials, with good clinical results [4-6]. Despite these significant improvements in material performance, and reduction in early failures, concerns remain about the surface wear of the polyethylene material and osteolysis [7-9].

Cross-linked polyethylene material has been introduced to total joint replacement to reduce the volumetric wear. Cross-links within the polyethylene material may be created through several processes; however the most common route is through irradiation. The level of cross-linkage may be controlled by the irradiation dosage, such that a moderately cross-linked polyethylene would be irradiated at approximately 4-6MRad, and a highly cross-linked material may be irradiated at a dosage of approximately 8-10MRad. In the total hip replacement, use of highly cross-linked polyethylene has been demonstrated to significantly reduce wear rates in-vitro [10] [11], and these advantages have also been demonstrated clinically at short- to mid-term follow up ([12, 13]. However, few studies have published wear performance of cross-linked polyethylene for total knee replacement, and there is little clinical data detailing the performance of cross-linked polyethylene in the knee. The wear simulator studies have tended to focus upon highly cross-linked polyethylene; however, there are concerns that the reduction in mechanical properties with increasing irradiation dose makes highly cross-linked polyethylene an unsuitable bearing material for total knee replacement [14, 15]. The translation and rotation experienced in a total knee replacement, make it more susceptible to fracture failure modes, therefore the mechanical properties of the material are very important in terms of preventing fatigue failure. Indeed, clinical incidence of cracking at the edge and rim of highly cross-linked polyethylene cups further raise concerns regarding the suitability as a bearing material for total knee replacement [16] A study investigating the radiation dose effects on the wear and mechanical properties of cross-linked polyethylene demonstrated an approximately linear increase in wear resistance with increasing radiation dose; however, there was a significant reduction in mechanical properties [17].

In younger, more active patients the need to reduce volumetric wear, and hence reduce potential for osteolysis is a significant factor to allow patients to resume a normal, active lifestyle. In addition to increasing the osteolysis-free lifetime of a total knee replacement, younger patients also tend to want greater functionality from their prosthesis, including a large range of motion. Recent total knee replacement designs have included modifications to the polyethylene insert and/or the femoral bearing to allow a more natural and higher range of motion for high flexion activities such as stair climbing and squatting [18, 19]. Clinical outcomes to date present a mixed result, with some studies indicating a significant improvement in range of motion with high flexion knee designs compared with conventional knees [20, 21], whereas some show no significant advantage compared with the conventional knee [22].

The purpose of this study was to compare the wear performance of a moderately cross-linked ultra-high molecular weight polyethylene with a conventional gamma-sterilised in vacuum foil polyethylene in a fixed bearing knee configuration. In addition, the effect of femoral design on the wear performance of the cross-linked material was examined, comparing a conventional cruciate-retaining femoral bearing with a bearing designed for high flexion activities.

2. Materials

The wear of the fixed bearing total knee replacement was investigated using two different femoral geometries and two polyethylene insert materials (Table 1), and compared with historic data from our laboratories [23]. The historic studies were conducted on the same simulator under identical test conditions, and wear measurement assessed using the identical methods. Both femoral geometries are commercially available bearings in current clinical use, the Sigma Cruciate Retaining design (DePuy International, UK) and the Sigma CR150 Cruciate Retaining design (DePuy International, UK), a femoral bearing that has been designed for high-flexion performance. Both femoral bearings were manufactured from the same Co-Cr-Mo alloy. The polyethylene inserts clipped into identical polished cobalt chrome trays. Tests were conducted with GUR1020 UHMWPE inserts which had been sterilised in foil pouches by gamma-irradiation (2.5-4MRad) in a vacuum (GVF^{TM} material), and with a moderately cross-linked GUR1020 UHMWPE (5MRad irradiated and remelted) insert (XLK^{TM} material).

3. Methods

Three studies were conducted using the Leeds ProSim six station force/displacement controlled knee simulator [24], (Simulator Solutions, UK). Each station had six degrees of freedom with four controlled axes of motion – axial load, femoral flexion, tibial internal/external (IE) rotation, and tibial anterior-posterior (AP) displacement. The femoral axis loading (maximum 2600 N) and extension-flexion (0˚ - 58˚) input profiles were taken from ISO 14243-3 [25] for all testing (Figure 1).

The I/E tibial rotation was displacement controlled and set at ± 5˚ based on the natural kinematics of the knee as described by Lafortune et al [26]. Anterior-posterior translation was displacement controlled for all three studies, as these designs have minimal constraints and thus rely on soft tissue in-vivo. Two displacement test conditions were used during each test; intermediate kinematics with an anterior-posterior displacement of 0-5mm, and high kinematics with an AP displacement of 0-10mm [27] Figure 2). Abduction/adduction was allowed but not controlled. Six sets of bearings were tested for each design and material, mounted anatomically in each station. The central axis of each implant was offset from the aligned axes of applied load and tibial rotation from the centre of the joint by 7% of its width, in accordance with ISO 14243-1, to replicate a right knee. In order to eliminate station specific differences the samples were moved around the stations every million cycles [24].

The bearings were tested for three million cycles (Mc) under intermediate kinematics, followed by three million cycles under high kinematic conditions. The simulator was run at a frequency of 1Hz. The lubricant used was newborn calf serum, diluted to 25%, supplemented with 0.03% (v/v) sodium azide to retard bacterial growth, and was changed every 0.33Mc. Prior to testing, all inserts were soaked in deionised water for a period of four weeks. This allowed an equilibrated fluid absorption level to be achieved prior to the commencement of the wear study, reducing variability due to fluid weight gain at the start of the wear study [24]. Wear was determined gravimetrically through measurements of the inserts following the four-week soak period, and at measurement intervals throughout the study. A Mettler AT201 (Mettler-Toledo, USA) digital microbalance, which had a resolution of 0.01mg, was used for weighing the bearing inserts. The volumetric wear was calculated from the weight loss measurements, using a density of 0.934mg/mm^3 for both polyethylene materials, using unloaded soak controls to compensate for moisture uptake. The soak control samples were immersed in 25% bovine serum, as prepared for the test samples, and this serum was also changed every 0.33Mc.

Digital images of the wear scars on the inserts at the completion of the study were obtained by manually tracing the outline of the wear scars on the superior surface of each insert and capturing the image on a Kodak DX6490 digital camera. The wear area was quantified using Image Pro-Plus 3.0 software (Media Cybernetics, Maryland, USA) and was expressed as a percentage of the total area of the insert. Statistical analysis of the wear data was performed using one-way ANOVA, and significance taken at $p<0.05$.

4. Results

The mean wear rates for the Sigma and Sigma CR150 bearings were compared when tested with the XLK material, to examine the effect of femoral geometry under intermediate and high kinematics (Figure 3). There was no significant difference between the two femoral designs under either intermediate or high kinematics (ANOVA, $p>0.05$). A significant increase in wear rate was observed for both designs when the kinematic condition was increased from intermediate to high AP displacement (ANOVA $p<0.05$), as has been reported previously [24, 27].

The effect of insert material was examined by comparing the wear rates for the GVF and XLK materials, tested against the CR150 femoral bearing design under intermediate and high kinematics (Figure 4). There was no significant difference between the wear rates of the two materials under intermediate kinematics (ANOVA, $p>0.05$), with both exhibiting wear rates of approximately 3mm^3/Mc. However, under high kinematics, a significant difference between the wear rates was observed ($p=0.04$). The mean wear rate of the GVF material was 9.22 ± 2.91mm^3/Mc under high kinematics. A mean reduction in wear rate of 35% was observed when the material was changed to XLK polyethylene (5.98 ± 2.07mm^3/Mc).

The mean wear scars for the materials tested against the CR150 femoral bearing were comparable (Figure 5). Expressed as a percentage of the total articulating area, the mean scar areas were 37.5 ± 3.8% and 38.6 ± 2.5% for the XLK and GVF materials respectively, demonstrating that the surface area for wear was comparable for both materials, due to the identical bearing design. The wear scars were also of similar size and shape to a previous Sigma study with curved GVF inserts [23].

A comparison between the wear rates reported in the present study for GVF material and a previous study [23] shows a significant reduction in wear in the current study (Figure 6) under both intermediate and high kinematics. As the present study had shown the femoral bearing design had no effect on wear rate, and the wear scar regions were comparable for both studies, further explanation for these differences was sought. Surface measurements were taken on three samples from the present study and the previous study [23] on unworn regions of the femoral surface to identify any differences between the bearings. Measurements were taken using a contacting profilometer (Talysurf, Taylor Hobson, UK), and six measurements were taken per sample. Each measurement had a trace length of 10mm, and the data was filtered with a Gaussian filter with a 0.25mm cut-off (100:1 bandwidth), and form corrected with a least-squares arc fitting, which accounted for the radius of curvature. The mean surface roughness (Ra) showed a significant difference between the two bearings (Table 2). Whilst both sets of bearings were within the manufacturing tolerance for surface finish, the bearings tested in the present study had improved surface finish.

5. Discussion

This study investigated the effect of femoral geometry and insert material upon the in-vitro wear performance of a fixed bearing total knee replacement. Significant progress in the reduction of wear in fixed bearing knee replacements has already been achieved by improving the sterilisation process for polyethylene [28], and reducing backside wear [1]. This study has examined the effect of introducing a moderately cross-linked polyethylene insert upon wear performance of the fixed bearing knee.

This study, using moderately cross-linked polyethylene (XLK) as the insert material, compared the effect of femoral geometry on the wear performance of the TKR under standard gait conditions. The study compared a Sigma cruciate-retaining femoral geometry with a Sigma CR150 femoral bearing, which has extended femoral condyles to reduce the contact stress at high flexion angles. This study showed there was no significant difference in wear rate through a standard gait cycle; over this range the geometries of the two femoral bearings are identical and therefore it was expected that the wear rates would be comparable. The geometries differ at higher flexion angles, with the CR150 bearing designed for greater conformity and lower contact stresses at higher flexion angles. A high flexion wear simulation should be conducted to determine differences in wear performance over these activities; however this study demonstrates equivalence in the wear performance under standard gait conditions.

The effect of insert material was compared using the CR150 femoral geometry, testing conventional ‘GVF’ polyethylene and moderately cross-linked ‘XLK’ polyethylene. Under intermediate kinematics, with an AP displacement of 0-5mm, there was no difference between the wear performance of the two materials, both having low mean wear rates of approximately 3mm^3/Mc. It seems with improvements in total knee replacement design and material that intermediate kinematics are no longer adequate for comparison of wear performances. Under the high kinematic condition, with an AP displacement of 0-10mm and an increased cross-shear, a significant reduction in wear was achieved by the XLK material compared with the GVF material.

Simple configuration pin-on-plate studies have illustrated a relationship between cross-shear and wear rate [29]. Under uni-directional motion, molecular orientation in the principal direction of motion occurs in conventional polyethylene material, allowing the material to be strong in the direction of motion. Studies have demonstrated that under low or zero cross-shear conditions, there is no significant difference between the volumetric wear of cross-linked or conventional polyethylene [30, 31]. This effect was demonstrated under the intermediate kinematic condition in this wear study, where there was no significant difference in the wear performance of the two materials. Cross-linking in the polyethylene material inhibits the molecular orientation and therefore preferential hardening does not occur and there is no observed benefit in wear performance under low cross-shear conditions. Under high kinematics, the level of cross-shear is increased. As conventional polyethylene undergoes hardening in the principal direction of motion, the resistance to wear in transverse directions – as produced under higher cross-shear conditions is reduced, causing an increase in wear as observed under high kinematics. In the moderately cross-linked XLK polyethylene material, the level of molecular orientation that is achieved is less as the chain mobility is reduced, and therefore this material is more resistant to cross-shear forces. Hence when comparing the XLK and GVF materials under high kinematics, an increased cross-shear condition, the XLK material exhibits a reduction in wear rate compared with the GVF material [29-31].

Few studies document the relative wear performance of a moderately cross-linked polyethylene compared with a 'conventional' polyethylene, with much of the previous work examining highly cross-linked polyethylene in a total knee arrangement [32-34]. Early studies examining polyethylenes irradiated with doses up to 100kGy demonstrated significant reductions in wear rate compared with non-irradiated polyethylene [35, 36]. Accelerated aging studies have also demonstrated a clear reduction in volumetric wear rate when comparing conventional and highly cross-linked polyethylene materials, also demonstrating the resistance of cross-linked polyethylene to oxidation and delamination [37]. However, concerns have been raised regarding the reduction in mechanical properties of polyethylene with increasing cross-linkage. Studies have identified a reduction in fracture toughness for highly cross-linked polyethylene and have recommended the use of a moderately cross-linked polyethylene which still demonstrate a reduction in wear rate compared with non-irradiated material but retain the mechanical properties [17, 38].

A few studies have examined a range of cross-linked polyethylene materials, including moderately cross-linked polyethylene, and demonstrated a reduction in wear. Asano et al showed a 54% reduction in wear with a moderately cross-linked polyethylene irradiated with a dose of 50kGy compared with the non-irradiated material. More recently, Utzschneider et al [39] presented data contrasting six bearing designs, including a range of cross-linked material. Although the study clearly demonstrated a significant reduction in wear rate for each of the cross-linked polyethylene materials, and the moderately cross-linked polyethylenes to have wear rates between the highly cross-linked materials (lowest wear rates) and the conventional polyethylene materials (highest wear rates), the effect of bearing design and type confounds the wear results observed and therefore it is not possible to conclude these differences are a function of the material. The present study compares a conventional GVF polyethylene material with a moderately cross-linked XLK polyethylene in an identical bearing arrangement and under identical test conditions and therefore it is possible to conclude the reduction in wear rate is a function of the cross-linkage of the material. The reduction in wear rate observed in this study (approximately 35%) may not appear as large as previously reported studies [17, 39], however, it should be noted that the conventional polyethylene reported in this study also undergoes irradiation at a level between 2.5MRad- 4MRad and therefore the comparison is not between a moderately cross-linked polyethylene and a non-irradiated material, but a comparison with a material that will have a low level of cross-linkage due to the sterilisation process.

A comparison between the mean wear rates of the conventional polyethylene (GVF) in the present study with a previous study conducted on the same material under identical conditions highlighted a difference between the two studies, with the present study showing significantly reduced wear rates [23]. A comparison of the surface roughness of the femoral bearings showed there was a significant difference in mean surface roughness (Ra), with the present study bearings having a significantly lower surface roughness than the previous study, although both sets of components were very smooth with mean surface roughness values of less than 0.05µm. Several studies have demonstrated that surface roughness has a significant effect on the wear performance of conventional polyethylene [30, 40-42]. Using a power equation derived from pin-on-disc studies for conventional polyethylene [40], the change in surface roughness highlighted between the two femoral sample groups predicts a reduction in wear of approximately 47%, whilst the reduction in wear actually observed in this study was 42%. In addition to changes in surface roughness, there are other factors which may have influenced the wear rate including the sterilisation method for the polyethylene material. The material specification has a radiation dose in the range of 2.5MRad to 4MRad, and it is possible that the material batches for the two studies may have been at the limits of these doses. Studies have demonstrated a clear relationship between radiation dose and volumetric wear, and it is possible the reduction in wear may be related to an increase in irradiation within the limits of the material specification. Although it is not possible to clearly define the cause of the reduction in wear rate in the present study, it is an important result to consider. In addition to identifying the limitations of comparing wear studies from different simulators, materials and designs, it is important to be mindful of manufacturing changes and inter-batch variability when comparing wear study results with historical data.

This study has investigated the in-vitro wear of a fixed bearing total knee replacement with a conventional and moderately cross-linked polyethylene. The hypothesis that moderately cross-linked polyethylene would reduce the wear in a fixed bearing knee compared with conventional polyethylene was supported. A comparison of two femoral designs demonstrated no significant difference in wear rate during a standard kinematic cycle which was expected as the geometries differed only at the posterior condyles of the bearing. The difference in wear of the conventional polyethylene in the current study compared with a historic study highlighted the potential for changes in manufacturing process and inter-batch variability to have a significant effect on the wear performance of a total knee replacement.

Conflict of Interest Statement

C Brockett and J. Fisher are consultants to DePuy International Ltd. J Fisher is a Director and shareholder of Tissue Regenix plc and BITECIC Ltd and a Director of Medilink. C Hardaker is an employee of DePuy International Ltd.

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Table 1: Test configuration

Table 2: Surface roughness measurements of the femoral bearings

Figure 1: Input profiles for axial loading and flexion-extension

Figure 2: Input profiles for anterior-posterior displacement (AP disp) and internal-external rotation (IE rotation)

Figure 3: Mean wear rates comparing the effect of femoral geometry (XLK material, ±95% confidence limits)

Figure 4: Mean wear rates examining the effect of insert material (CR150 femoral geometry, ± 95% confidence limits indicated)

Figure 5: Example wear scar areas for (A) XLK inserts and (B) GVF inserts tested with a CR150 femoral bearing

.Figure 6: Comparison of wear rates for the present study (CR150) with a previous study (Sigma, Galvin et al 2009) tested with GVF UHMWPE inserts (±95% confidence limits)