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Comparison of wear in a total knee replacement under different kinematic conditions

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A six station ProSim (Manchester, UK) knee simulator was used to assess the wear of six PFC (DePuy) fixed bearing total knee replacements under two different kinematic conditions defined as low and high kinematic inputs. The high kinematics displacement and rotation inputs were based on the kinematics of the natural knee with ISO standards used for the axial load and flexion. Low kinematics were defined as approximately half the magnitude. The six specimens were run for three million cycles under low kinematics and three million cycles under high kinematics. The mean wear rate found during the low kinematics phase was $7.7 \pm 2\,\text{mm}^3$ per million cycles. This then increased significantly to an average wear rate of $41 \pm 14\,\text{mm}^3$ during the high kinematics input phase. The wear areas were characterized by a predominant damage mode of burnishing with some abrasive wear occurring during the high kinematics phase. This study supports the findings that introduction of cross-shearing of the polyethylene by introducing both rotational and anterior/posterior displacement increases the wear rate. This has implications for younger patients with higher levels of activity that need knee replacements.

Introduction

One factor controlling the long-term success of total knee replacements (TKR) is wear of the polyethylene bearing surface and the resulting osteolytic potential of the wear particles. The mechanisms of wear at the articulating surface are dependent on several variables including the motion and loading of the contacting surfaces. Physiologically based wear testing of prosthetic knee components is important to provide appropriate models for pre-clinical studies of new and existing materials and knee designs. Initial studies using both force and displacement controled knee wear simulators have produced very low wear rates [1, 2], however, the kinematic inputs used were simplified. Commensurate with these studies Burgess *et al*. [3] measured wear rates of less than $3\,\text{mg}/10^6$ cycles when using an anterior/posterior translation of 12 mm [3], similar to that found in the natural knee [4], but no rotation was applied to the bearing. Johnson *et al*. [5] showed that the wear rate was sensitive to the kinematic inputs, with an increased wear rate being measured once both displacement and rotation were present [5]. The aim of this study was to assess the influence of increased kinematics, both rotation and displacement, on the wear measured in total knee replacements of one design.

Materials and methods

A six station ProSim (Manchester, UK) knee wear simulator was used to assess the wear of six cruciate retaining PFC (DePuy) TKRs. Each individual knee simulator station had six degrees of freedom with axial load, femoral flexion, tibial interior/exterior rotation and tibial anterior/posterior displacement, all being user controllable. Abduction/adduction of the joint was allowed but not controled and a medial/lateral offset was predefined in accordance with ISO/CD 14243-1. The simulator allows both the I/E rotation and A/P displacement axes to be controled using either force or displacement input. In this study the components were

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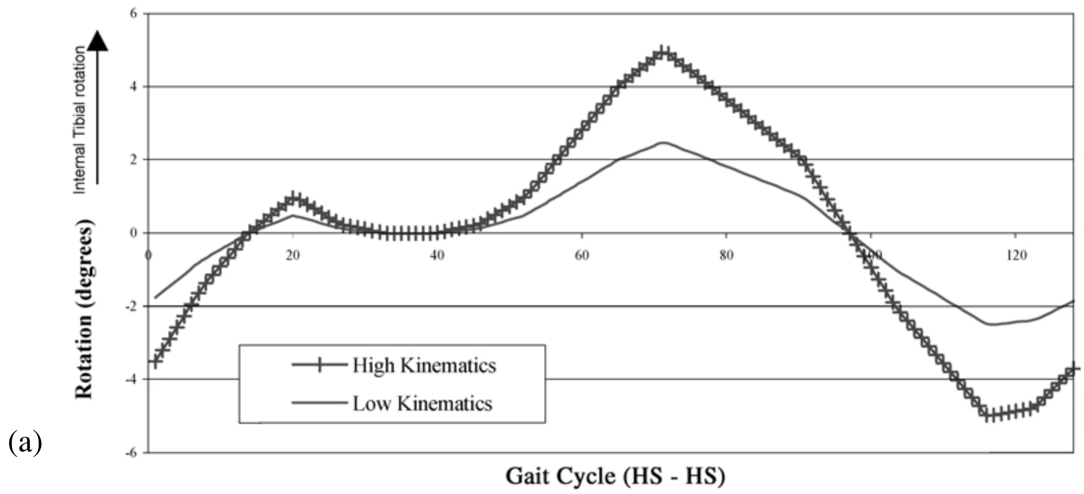


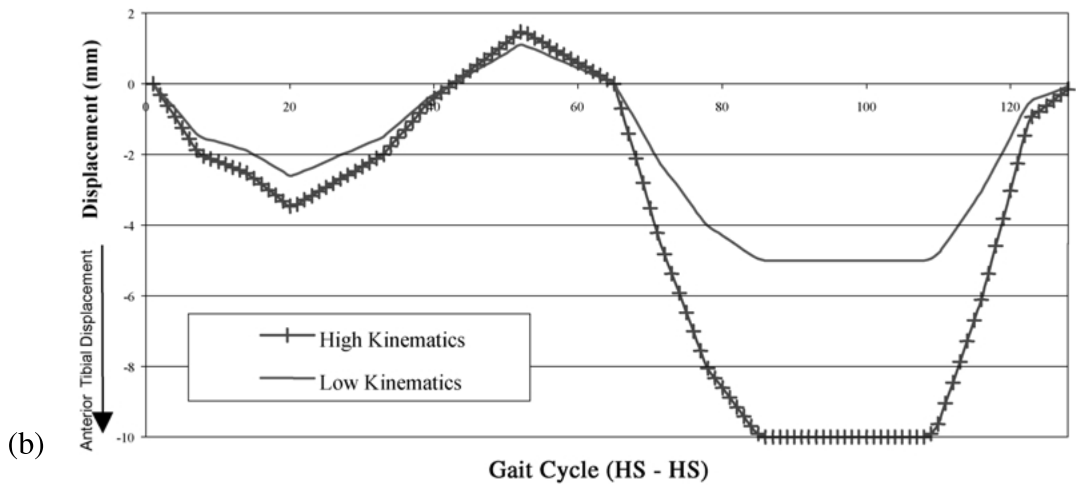


Figure 1 (a) Rotation input for high and low kinematic conditions (heel strike to heel strike); (b) Displacement input for high and low kinematic conditions (heel strike to heel strike).

cruciate retaining and therefore both axes were run under displacement control.

The TKR components were mounted anatomically and were all size three with inserts of thickness 10 mm. The ultra high molecular weight polyethylene (UHMWPE) inserts had been sterilized using gamma irradiation in air and the components had been shelf aged for between 29 and 33 months prior to testing. Prior to testing the UHMWPE inserts were placed in de-ionized water for three weeks, after which they were cleaned, left in a controled environment for 48 h and then weighed. This procedure allowed the samples to establish an equilibrated fluid absorption level prior to the test in order to reduce variability due to fluid weight gain during the first part of the test. As occurs *in vivo* the UHMWPE inserts were held in the trays using a snap fit and both components were cemented into their respective fixtures with any exposed cement being covered with silicone. To assess the impact of kinematics on the wear of the PFC, an initial three million cycles were run under low kinematic input conditions and a further three million under high kinematic input conditions. Low kinematic inputs were defined as a maximum internal/external rotation of $\pm 2.5°$ and a maximum anterior displacement of 5 mm. High kinematic conditions were based on the motions experienced by the natural knee [4], with a maximum internal/external rotation of $\pm 5°$ and a maximum anterior displacement of 10 mm. The input profiles for displacement and rotation are shown in Fig. 1. The ISO standards (ISO/CD 14243-1) for flexion and axial load were applied for both sets of kinematic conditions.

In order to reduce the effect of inter-station variability the TKRs were rotated around the stations after every million cycles. The test lubricant was 25% bovine serum by volume and was changed every 330 000 cycles. The kinematics of all the stations were monitored every 100 000 cycles throughout the duration of the test. After each million cycles the wear was measured gravimetrically and the volumetric wear was then calculated using a density of 0.934 mg/mm^3. At the same intervals, the edge of the wear scar area was manually outlined and a digital image of the insert obtained. Image-Pro Plus (Media Cybernetics) was then used to quantify the damaged wear area from the digital image. The percentage wear area was obtained for each component by dividing the damaged area by the intended articulating surface (excluded the central region of the insert).

Results

The average wear rate during the first three million cycles, run under low kinematic conditions, was 7.7 ± 2 mm^3 per million cycles. This then increased

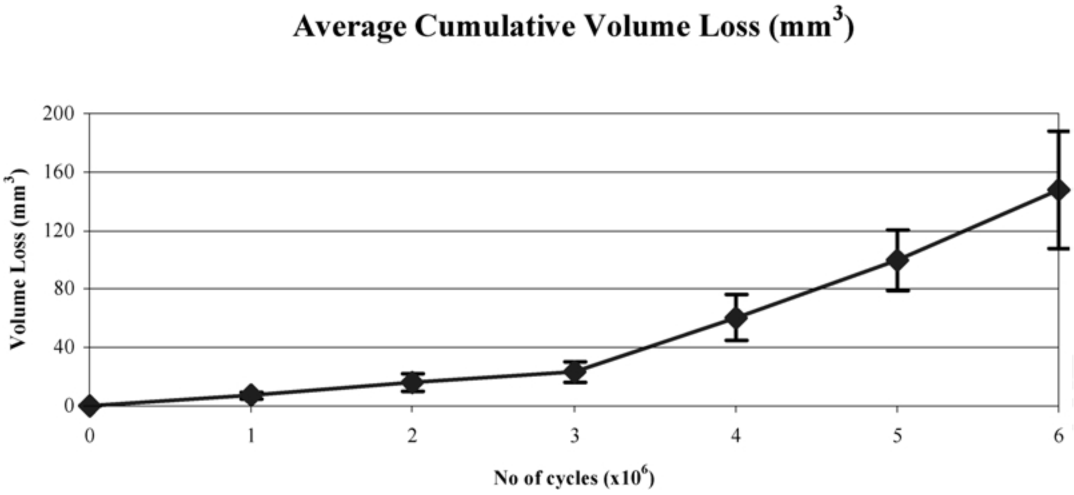


Figure 2 The average cumulative volume loss $\pm$ 95% confidence limits.

significantly to an average wear rate of $41 \pm 14\,mm^3$ during the high kinematics input phase. The average cumulative volume loss across all six stations, over six million cycles, is shown in Fig. 2.

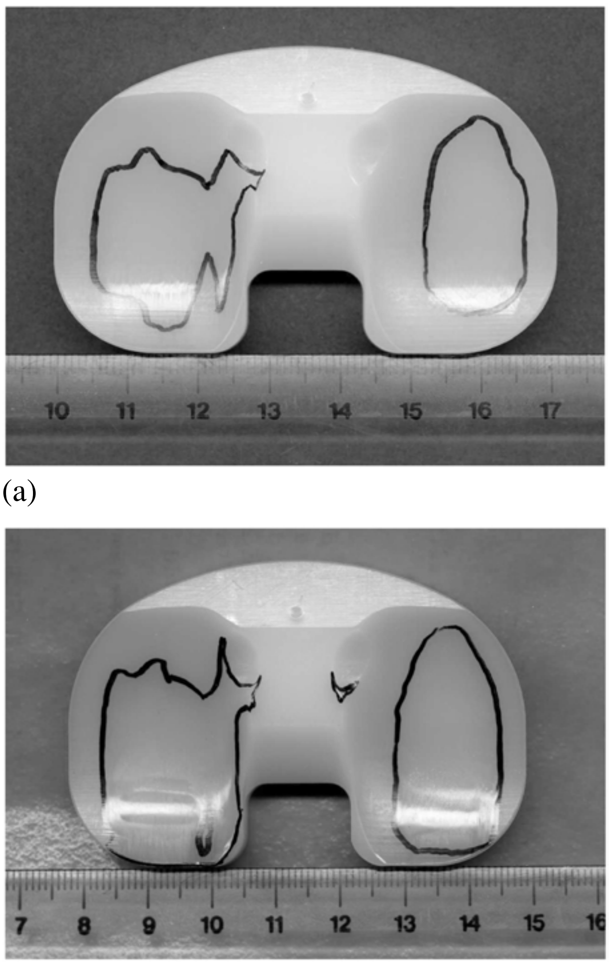
The average wear area determined after one million cycles was 23.7 $\pm$ 3%. This then increased to 30.4% after two million cycles. There was no increase in measured wear area between two and three million cycles. After the kinematic input conditions were increased, the measured wear area increased linearly from 42 $\pm$ 5% after four million cycles to 57 $\pm$ 6% at the end of the test. The positioning of the wear scars was similar on all inserts after the first million, with a central wear area on both condyles. After the second million it was found that the wear scars had encroached upon the central area of the tibial insert. The wear areas then moved posteriorly on both condyles with the increase in AP displacement during the high kinematics input phase. The wear scar areas seen after the low kinematics input phase were compared to those seen after the high kinematics input phase (Fig. 3). The predominant damage mode during the first three million cycles was burnishing, however, when the kinematics were increased some abrasive wear was noted on the articulating surface.

After the three million cycles during low kinematics, no fretting wear was seen on the tibial trays, however after increasing the kinematics, fretting wear was noticed on the trays, and also some abrasive wear was noticed on the polyethylene backside. The fretting wear seen on the top surfaces of the tray was characterized by a decrease in surface roughness of mean value 0.1 μm throughout the high kinematics phase. No delamination was seen on any of the tibial inserts. Heavy scratching in the anterior/posterior direction was observed on the femoral counterface after four million cycles when the kinematic input conditions were increased.

Discussion

The wear rates found during the low kinematics phase of this study were commensurate with those reported by Young *et al*. [1] for the PFC Sigma knee, using kinematic inputs of similar magnitude and the same UHMWPE sterilization method. The wear rates observed during the high kinematics phase were higher than previously reported for either load or displacement controled simulators [2].

Sterilization of UHMWPE using gamma irradiation in air is no longer the method of choice as it has been shown [6] that irradiation in air and subsequent storage will



(a)

(b)

Figure 3 (a) Wear scar area after three million cycles; (b) Wear scar area after six million cycles.

result in an increase in wear rate of the polyethylene. In this particular study, gamma irradiated in air components were chosen to allow for comparison with explanted PFC TKRs. Oxidation of the tibial components during storage may therefore have contributed to the increased wear rates found.

Johnson *et al*. [5] reported that removal of either displacement or rotational movement at the bearing surface resulted in a decrease in wear rate by an order of magnitude [5]. Removal of either input results in a lack of cross shearing action at the surface of the polyethylene. Commensurate with this and shown by this study, increasing the level of cross shearing, by increasing the magnitude of both the displacement and the rotation inputs, significantly increased the wear rate.

All inserts exhibited similar wear scar patterns and the wear areas calculated were within the range found on retrieved inserts of 13%–62% [7]. The damage modes seen on the inserts after simulator testing to six million cycles were also consistent with the predominant mode of burnishing and a secondary damage mode of abrasion found on PFC explants [7]. The change in position, and increase in size, of wear area after two million cycles was probably due to initial bedding in of the insert during the first million cycles, such that during the second million cycles the relatively flat curvature on the femoral components came into contact with the edge of the insert, inducing an edge loading effect.

The flecking and pitting seen on the top surfaces of the trays was taken as evidence of backside wear and is consistent with studies conducted on explanted fixed bearing TKR designs [8] that have reported flecks and lines on the metal trays. As the observed backside wear occurred only under the conditions of high kinematics, it may have been primarily due to an interaction between the simulator kinematics and the prosthesis design.

Whilst the wear rate was low for low kinematic input conditions, wear rates approaching those found in the hip were found with high kinematic input conditions. In the hip, the higher levels of wear have been associated with long-term osteolysis and loosening. While results for current designs of knee prostheses, such as the PFC, are generally excellent for the first 10 years, they have traditionally been implanted in a low demand population. As the demand and activity levels of patients receiving implants rises, and TKR life expectancy increases beyond 10 years, problems associated with osteolysis may become more prevalent.

Conclusion

Based on physiological kinematic inputs, the wear rate increased significantly with an increase in internal/external rotation and anterior/posterior displacement. The wear rates found during the high kinematics input phase approached those found in the hip which have been associated with osteolysis. This study indicates that wear induced osteolysis may become a significant long-term problem in the knee, in patients with high kinematic demands.

Acknowledgments

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