The wear of fixed and mobile bearing unicompartmental knee replacements

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Abstract: Unicompartmental knee replacements (UKR) are an option for surgical intervention for the treatment of single-compartment osteoarthritis. The aim of this study was to compare the wear of a low-conformity fixed-bearing UKR with a conforming mobile bearing UKR under two kinematic conditions, to investigate the effect of implant design and kinematics on wear performance in a physiological knee wear simulator. Under both sets of kinematic conditions, the relatively low-conforming fixed UKR showed lower wear, compared with the more conforming anterior–posterior sliding mobile bearing. However, it should be noted that differences in materials between the two designs also contribute to the relative wear performance of the bearings. The combined wear of the medial and lateral bearings of the fixed-bearing UKR as a 'total knee' were significantly reduced compared with a fixed-bearing total knee replacement studied under the same kinematic conditions.

Keywords: knee replacement, wear, arthroplasty, *in vitro*, unicompartmental

1 INTRODUCTION

Unicompartmental knee replacement (UKR) is an option for surgical intervention for the treatment of osteoarthritis when only one compartment of the natural knee is affected. Although the overall rate of implantation in the UK for UKRs has remained relatively consistent over the last five years, there has been an increase in its application to younger patients [**1**]. This arthroplasty is often employed as an alternative to total knee replacement (TKR) or high tibial osteotomy [**2**]. Early UKRs were developed from the 1970s, with mixed clinical performance; issues with subsidence, loosening and high wear were related to implant design, materials, and patient selection [**3**, **4**]. Recent clinical literature is much more promising, with excellent long-term survivorship for both fixed and mobile bearing UKRs. Survivorship levels have been reported up to 98 per cent at 10 years [**5**] and 84 per cent at 22 years [**6**, **7**]. These studies tend to report clinical data from centres of excellence relating to the UKR, which may demonstrate more favourable outcomes. National joint registries have noted reduced survivorship (for example 9.1 per cent revision rate at 5 years [**1**] and 91 per cent survivorship at 7 years (New Zealand [**8**])). It has been suggested that the reduced clinical performance, with respect to TKR, in the general registries may be attributable to surgeon inexperience with several new designs introduced over the last decade with small volumes of implantation. However, it was noted that the percentage of serious complications related to UKR was much less compared with TKR [**9**]. Fixed-bearing knees appear to have shown more consistency in long-term performance [**10**].

There are several advantages of the UKR compared with a TKR as it is considered to be a more conservative intervention. As only one compartment is replaced, the overall geometry of the knee remains similar to the natural knee. There is significantly less bone resection involved with a UKR, and the soft tissues and ligaments are retained, hence the balance of the knee after implantation is closer to the natural knee [**11**]. The effect of this retention is two-fold; first, through a minimally invasive surgical approach the patient often has a shorter rehabilitation period, earlier weight-bearing, and reduced post-operative pain

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[**1**, **12**, **13**]. Second, retention of most natural structures permits better proprioception, range of motion, and more natural knee kinematics [**10**, **14**, **15**]. In addition, there is less blood loss associated with UKR surgery compared with a TKR, and potential for revision to a TKR at a later stage, if required, is greater [**16**].

Initially, UKR was indicated for older patients with low physical demands [**17**]. However, clinical studies have shown good results for young, unicompartmental patients [**18**, **19**], and the potential for the device to maintain natural knee kinematics makes it a desirable choice for a younger patient who may wish to maintain a more active lifestyle.

Historically, one of the main causes of failure for both TKR and UKR has been the oxidation and fatigue failure of ultra-high molecular weight polyethylene (UHMWPE), with delamination of inserts observed both clinically and *in vitro* [**20**, **21**]. Changes to design in UKR to reduce contact stresses aimed at preventing delamination resulted in more conforming bearings, such as the Oxford UKR [**5**]. Improvements in sterilization procedures, enhanced material properties, and superior manufacturing processes have significantly improved the performance of UKR and TKR. As the incidence of such catastrophic failures reduced, wear debris generation and osteolysis became the prominent factors in affecting the long-term clinical performance of a knee joint replacement [**22**, **23**]. Improvements in the material properties and enhanced stability have made it possible to consider bearing designs with reduced conformity and higher contact stress [**24**]. Additionally recent studies have shown reductions in conformity and surface contact area can reduce surface wear [**24**, **25**].

Previous experimental studies have suggested that there are differences between the wear performance of medial and lateral unicompartmental bearings, significant in some studies, when configured such that they can be tested in parallel [**26–28**]. The differences in wear performance may be attributed to the offset in loading, and different sliding patterns on each condyle. It should be noted that the studies compared different bearing designs under different input kinematic conditions, and this may influence the significance of the outcome. There are no reported studies comparing the *in vitro* wear performance of fixed and mobile bearing UKRs. It is hypothesized that low-conforming fixed-bearing UKRs can produce lower wear than conforming mobile bearings.

The purpose of this study was to investigate the influence of bearing design and kinematics on the *in vitro* wear performance of medial and lateral unicompartmental knees by comparing the wear of a conforming mobile bearing UKR with a less-conforming fixed-bearing UKR in a physiological knee wear simulator.

2 MATERIALS

The wear of two UKRs was investigated using commercially available bearings: the Oxford mobile bearing UKR (Biomet, UK) and the Sigma High Performance Partial Knee fixed-bearing UKR (Sigma HP PK, DePuy International, UK). The Oxford mobile bearing UKR is well established clinically, with approximately 70–80 per cent of all UKR in the UK joint registry being Oxford bearings. The Sigma HP PK is a more recently introduced design and has only appeared in the registry in the last two years [**1**]. The two bearings were size-matched right knees (size large for the Oxford bearing, and size 3 for the Sigma HP PK). The Sigma HP PK had a low-conformity moderately cross-linked XLK3 polyethylene insert (4MRad irradiated and remelted GUR 1020 polyethylene) which clipped into a polished cobalt-chrome tibial tray. The Oxford mobile inserts had a flat inferior surface and a spherical, conforming superior surface, and were manufactured from ArCom polyethylene (3.3MRad irradiated Argon packaged, compression moulded 1900H polyethylene [**29**]). The Oxford bearings were guided to slide anteriorly-posteriorly along polished cobalt-chrome tibial trays. The femoral bearings of both UKR systems were polished cobalt-chrome material. Three sets of medial and lateral bearings were studied for each design.

3 METHODS

Two different designs of UKRs were studied using the Leeds ProSim six station force/displacement controlled knee simulator ([**28**], Simulator Solutions, UK). Each station had six degrees of freedom with four controlled axes of motion – axial load, femoral flexion, tibial internal/external (I/E) 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 14243-1 [**30**] for all testing (Fig. 1). The I/E tibial rotation was displacement controlled and set at $\pm 5^\circ$ based on the natural kinematics of the knee as described by Lafortune *et al.* [**17**]. Anterior–posterior translation was displacement controlled for both bearings, as unicompartmental bearings rely on soft tissue restraint *in vivo*. Two displacement test condi-

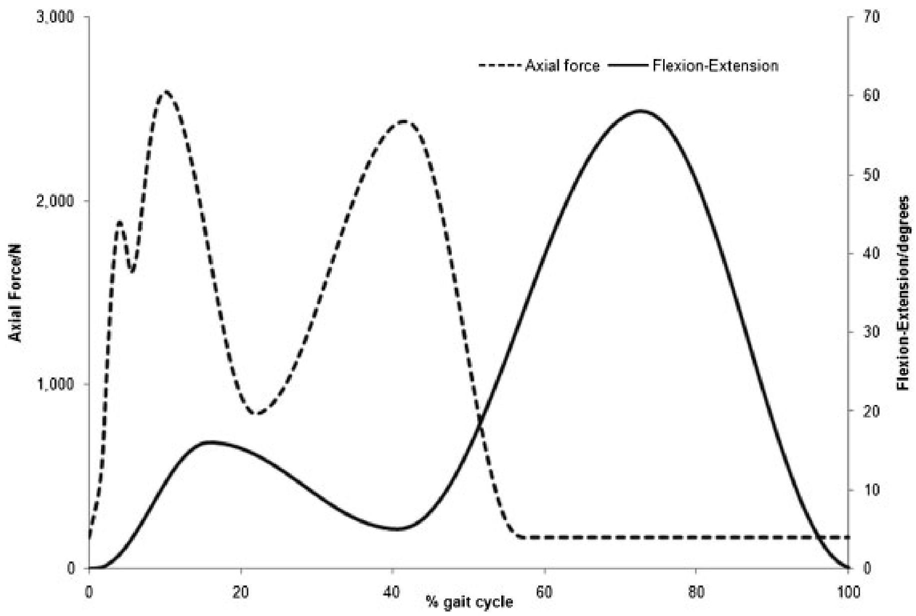

Fig. 1 Knee simulator input profiles for axial load and flexion–extension (F–E) [**27**]

tions were used during this study; intermediate kinematics with an anterior–posterior displacement of 0–5 mm, and high kinematics with an AP displacement of 0–10 mm ([**31**, **32**]; Fig. 2). Abduction/adduction was allowed but not controlled. Three sets of medial and lateral bearings were tested for each design, mounted anatomically in each station, and tested in a 'total knee' configuration. The central axis of the two implant 'total knees' was offset from the aligned axes of applied load and tibial rotation from the centre of the joint by 7 per cent of its width, in accordance with ISO 14243-1, to replicate a right knee. In order to eliminate station specific differences the UKRs were moved around the stations every million cycles [**33**].

The bearings were tested for five million cycles (Mc) under intermediate kinematics, followed by three million cycles under high kinematic conditions. The simulator was run at a frequency of 1 Hz. The lubricant used was newborn calf serum, diluted

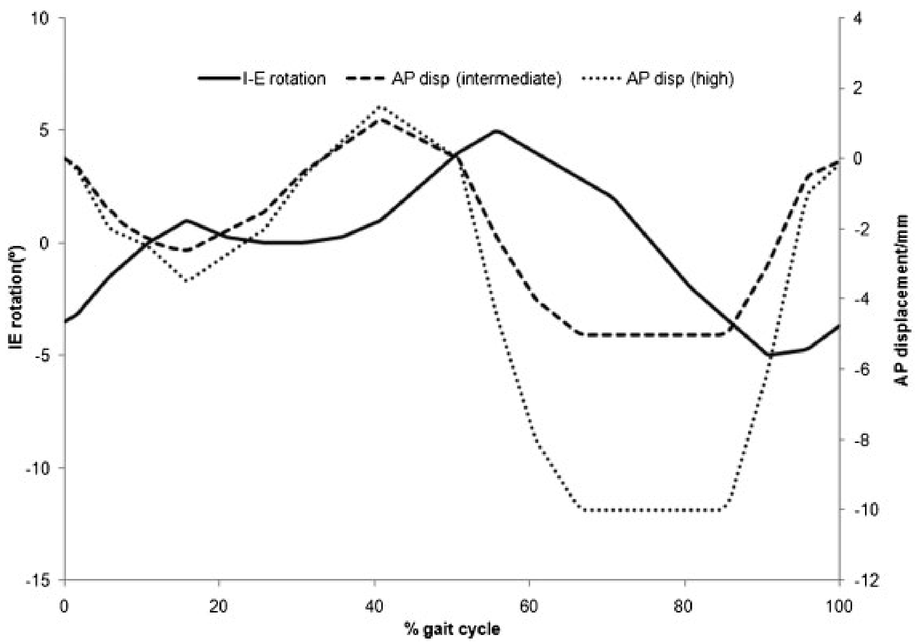

Fig. 2 Knee simulator input profiles for anterior-posterior displacement and internal–external rotation [**27**]

to 25 per cent, supplemented with 0.03 per cent (v/v) sodium azide to retard bacterial growth, and was changed every 330 000 cycles. Prior to test, the test and soak control UHMWPE inserts were soaked in deionized water for a period of four weeks. This allows 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 [**31**, **32**]. 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 micro-balance was used for weighing the bearing inserts, which had a resolution of 0.01 mg. The volumetric wear was calculated from the weight loss measurements, using a density of 0.934 mg/mm^3 for the XLK material and 0.933 mg/mm^3 for the ArCom material [**29**], using unloaded soak controls to compensate for moisture uptake. The wear rate was defined as the slope of the regression line of cumulative volumetric wear versus the number of cycles.

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 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 articulating area. Statistical analysis of the wear data was performed using one-way ANOVA, and significance taken at $p < 0.05$; however, it was noted that, owing to the small sample size, the power of the analysis, and thus the potential to determine significance, would be limited.

4 RESULTS

Wear was assessed gravimetrically at several stages throughout the study (Fig. 3), and the mean wear rates ($n = 3$) for each design and condyle were calculated (Fig. 4). A higher wear rate was observed in the medial bearings compared with the lateral for both designs, and under both kinematic conditions, but this was not statistically significant ($p > 0.05$). Under intermediate kinematics, the wear rates for the Sigma HP PK bearings were low, at 1.13 ± 0.62 mm^3/Mc and 1.99 ± 0.80 mm^3/Mc for the lateral and medial bearings respectively. The mean wear rate for the lateral Oxford bearings (3.45 ± 1.81 mm^3/Mc) was significantly higher than the wear rate of the Sigma HP PK lateral bearings ($p < 0.05$). The medial wear rate was also higher (5.72 ± 5.98 mm^3/Mc), but this was not

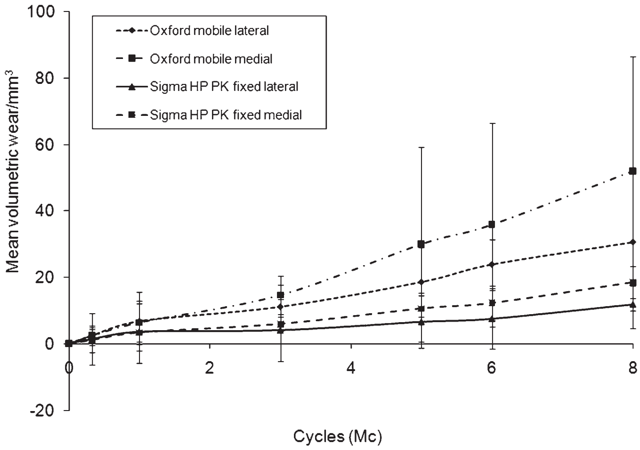

Fig. 3 Mean cumulative wear for UKR bearings ($n = 3$) $\pm$ 95 per cent confidence limits

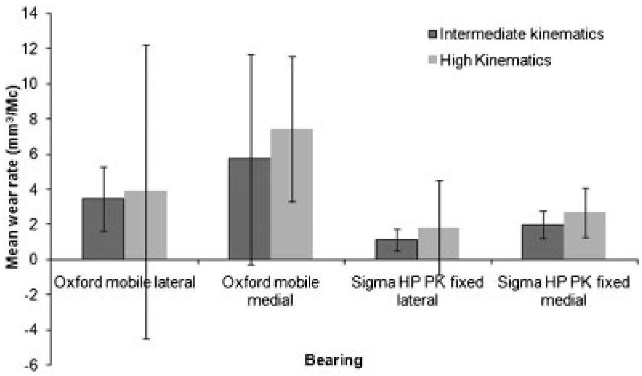

Fig. 4 Mean wear rates for UKR bearings ($n = 3$) $\pm$ 95 per cent confidence limits

statistically significant. It should be noted that during the first stage of the study, between three and five million cycles of intermediate kinematics, evidence of edge loading was noted on one of the medial Oxford bearings (Fig. 5), resulting in elevated wear. This mode of wear was only noted on one bearing, and caused the large confidence intervals shown in Fig. 3. An increase in wear rate for both bearing designs was observed during high kinematics, but this was not statistically significant ($p > 0.05$). Comparing the designs under high kinematics, the wear rates for the Oxford medial bearings (7.44 ± 4.16 mm^3/Mc) were significantly higher than the Sigma HP PK medial bearings (2.70 ± 1.4 mm^3/Mc; $p < 0.05$). The wear of the lateral Oxford bearings (3.89 ± 8.34 mm^3/Mc) was also higher than the Sigma HP PK bearings (1.81 ± 2.70 mm^3/Mc), but this was not statistically significant. It should be noted that, owing to the small sample size ($n = 3$), the power of the statistical analysis is limited and therefore the potential to show significance is reduced.

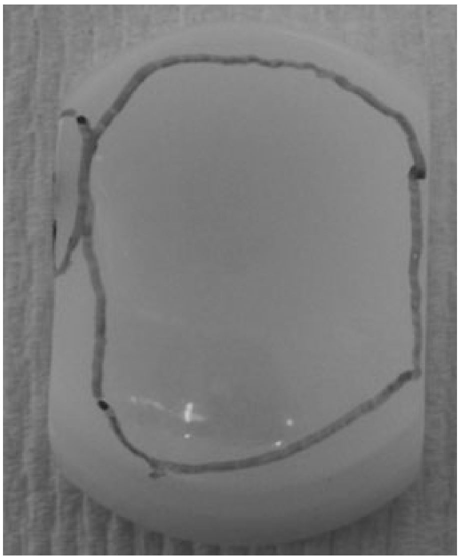

Fig. 5 Evidence of edge loading noted on one of the medial Oxford bearings

As there was no statistically significant difference between the medial and lateral bearings for either design, the data for all six inserts were combined and a mean wear rate calculated to assess the overall wear rates of the two bearing designs ($n = 6$). Again, the wear rates under high kinematics were higher than those under intermediate kinematics, but this was not statistically significant for either design (Fig. 6, $p > 0.05$). The mean wear rate of the Sigma HP PK under intermediate kinematics was $1.56 \pm 0.57\,mm^3$/Mc, increasing to $2.26 \pm 0.96\,mm^3$/Mc under high kinematics. Both were significantly lower than the Oxford mobile bearings when compared under the same kinematic conditions ($p < 0.05$). The mean wear rate of the Oxford bearings under intermediate kinematics was $4.58 \pm 2.12\,mm^3$/Mc, increasing to $5.66 \pm 3.21\,mm^3$/Mc under high kinematics.

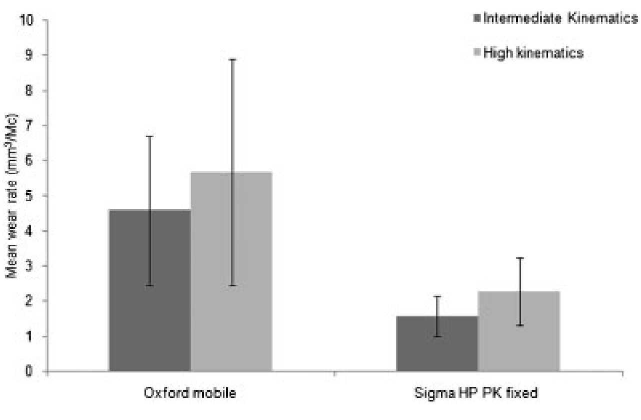

Fig. 6 Mean wear rates for all bearings ($n = 6$) $\pm$ 95 per cent confidence limits

The wear of each medial and lateral bearing set, as tested, was combined to give a 'total knee' wear rate for each design ($n = 3$). The mean wear rate for the Oxford bearing ($9.16 \pm 7.80\,mm^3$/Mc) was significantly higher than the Sigma HP PK knee ($3.12 \pm 0.78\,mm^3$/Mc) under intermediate kinematics ($p < 0.05$), but there was no significant difference between the wear rates under high kinematics, although the wear rate for the Oxford bearing ($11.33 \pm 11.09\,mm^3$/Mc) was higher than the Sigma HP PK bearing ($4.51 \pm 4.00\,mm^3$/Mc; Fig. 7).

The mean wear scar areas on the superior surfaces of the bearing inserts (expressed as a percentage of the total bearing surface) were compared at the completion of the wear study (Fig. 8). The wear scar areas of the Sigma HP PK bearings (20.8 ± 3.1 per cent) were significantly smaller than the areas on the surface of the Oxford bearings (60.7 ± 6.6 per cent).

5 DISCUSSION

This study investigated the *in vitro* wear performance of medial and lateral variations of fixed and mobile bearing UKRs. The increased wear rate of the medial bearings, with respect to the lateral bearings, was not statistically significant. The higher wear rates observed in the medial bearings were less notable than a previous wear study [**25**]. The increased wear rates may be attributed, in part, to the slightly increased sliding distance and load experienced by the medial bearing compared with the lateral bearing, during testing. Laurent *et al.* also proposed that, owing to slight differences in wear tracks for the condyles, the levels of cross-shear on the two bearing surfaces would differ, and this may contribute to the increase in wear for the medial bearing. The observed increase in wear for the medial UKR is consistent with

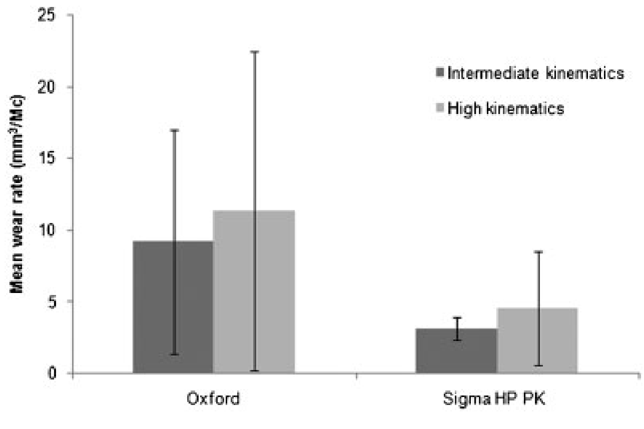

Fig. 7 Mean wear rates of 'TKR' arrangement ($n = 3$) $\pm$ 95 per cent confidence limits

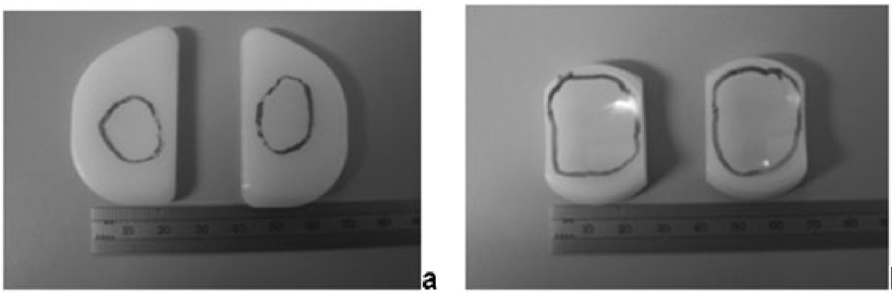

Fig. 8 Example wear scars for (a) Sigma HP PK fixed inserts, and (b) Oxford mobile inserts

retrieval analysis which has demonstrated higher wear associated with the medial condyles of TKRs compared with lateral [**20**].

The wear rates for the mobile bearing UKRs was significantly higher in the lateral bearings under intermediate kinematics and the medial bearings under high kinematics, than the low-conforming fixed-bearing UKR. Although the wear rates of the Oxford bearings appeared higher than the Sigma HP PK in the medial bearings under intermediate kinematics, and the lateral bearings under high kinematics, neither were statistically significant, which may be attributed to the high variability in wear rates of the mobile bearings ($n = 3$ for each sample group). An incident of edge loading, and elevated wear was noted on one of the Oxford inserts between three and five million cycles. It is not clear how this occurred, as consistency in setup from station-to-station was ensured during each measurement interval and serum change. However, clinical cases of bearing dislocation have been noted [**5**, **34**], and it may be that, under the simulation load, the bearing did not fully dislocate, but remained between the femoral and tibial components under edge loading conditions for a period of time, resulting in elevated wear. It is noted that, owing to the lack of axial constraint in the mobile bearing construct, this type of contact and wear may be possible in a clinical setting/*in vivo*.

As there was no significant difference between the medial and lateral bearings within a design, the data sets were combined to give overall wear rates for the Sigma HP PK and Oxford bearings ($n = 6$). There was a significant difference between the mean wear rates of the two designs under both intermediate and high kinematics. The Oxford bearing is a mobile bearing UKR, but does not have the features of a mobile bearing rotating platform TKR. A rotating platform mobile bearing TKR decouples the motion of the knee joint to give a unidirectional motion between the femoral bearing and insert on the superior surface, and a unidirectional rotational motion between the tibial tray and insert on the inferior surface, thus reducing surface wear [**32**]. However, in the spherical Oxford unicompartmental bearing, the tibial tray has a guide rail along which the polyethylene insert runs parallel. This would prevent substantial rotation occurring between the inferior surface of the insert and the tibial tray, hence the benefits of the mobile bearing rotating platform TKR would not apply to this design. There is potential for multidirectional motion, and hence increased cross-shear to occur on both surfaces. Hence this mobile bearing does not benefit from reduced wear associated with reduced cross shear [**24**, **32**, **35**]

There was a significant difference in wear scar areas, when expressed as a percentage of total articulating area. The higher area measured on the Oxford bearings confirmed the greater conformity of these spherical bearings compared with the Sigma HP PK bearings. The small wear scars of the Sigma HP PK bearings were similar to those observed in a recent study examining the wear in low-conforming bearings [**25**]. This study illustrated the potential for a low conformity fixed TKR bearing to have low wear rates owing to a smaller contact area. The low wear measured for the low conformity Sigma HP PK bearing supports the findings of this recent study, with a low wearing fixed bearing for UKR. Historically, designs of UKR with high contact stresses have been associated with early polyethylene failure through fatigue and delamination [**8**, **36**, **37**]. However, early polyethylene failure was related to poor material quality and oxidative degradation [**38**] and the development of new stabilized and enhanced polyethylene materials has had a significant impact on material performance.

The difference in mean wear rates shown in this study may also be affected by the materials used for each design. The Sigma HP PK uses a 4MRad irradiated cross-linked GUR 1020 polyethylene, whereas the Oxford bearing is manufactured from a 2.5–

4MRad cross-linked argon packaged compression moulded 1900H polyethylene [**39**]. As there are no studies at present directly comparing the wear performance of these two bearing materials, it is difficult to comment upon the relative effect of the material on the wear rates observed within this study. However, several studies have demonstrated a significant reduction with increased cross-linkage for polyethylene tibial inserts [**40–42**]. Both bearings had cobalt-chrome femoral and tibial components, and therefore it may be expected that the contribution of the relative composition of the bearing on the overall wear may be less compared with the effect of bearing design or insert material.

It is interesting to note that the mean wear rate of the medial and lateral bearings combined as a total knee for the Sigma HP PK are significantly lower than a comparable fixed-bearing TKR under the same kinematic conditions [**32**]. Indeed, the combined 'total knee' wear rates are similar in value to the low-conformity flat test inserts reported in the recent study by Galvin *et al.* [**25**]. However, this does not correspond with the joint registry data [**1**, **8**, **9**], which indicate the survivorship of UKR in general to be less than TKR. It should be noted that reasons for revision may differ between the devices, with progression of arthritis in the non-operated compartments and bearing dislocation being indications for revision in UKR patients [**43**] in addition to the more conventional failure mechanisms such as aseptic loosening and implant wear. Furthermore, studies have indicated there is an increased risk of revision where less than 10 UKR procedures are conducted per year, and hence the limited numbers performed each year compared with TKR are reflected in the survivorship figures [**9**, **43**].

6 CONCLUSIONS

This study has investigated the *in vitro* wear of medial and lateral designs of two different designs of UKR; the spherical Biomet Oxford mobile bearing UKR and the fixed-bearing DePuy Sigma High Performance Partial Knee. Anatomical mounting of the bearings, including an offset, allowed the medial and lateral bearings to be tested in parallel in a 'total knee' configuration. This study has shown that under *in vitro* wear conditions the relatively low conformity fixed unicompartmental knee, Sigma HP PK replacement shows reduced wear, in both medial and lateral bearings, compared with a more conforming anterior-posterior sliding mobile bearing Oxford UKR. Furthermore, the combined 'total knee' wear rate of the fixed-bearing UKR was significantly lower than a fixed TKR under identical kinematic conditions.

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