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Polyethylene bearing wear is comparable for cemented and cementless Oxford unicompartmental knee replacements: Ten-year results of a randomized controlled trial

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Abstract

Purpose: There is concern that using cementless components may increase polyethylene wear of the Oxford unicompartmental knee replacement (OUKR). Therefore, this study aimed to measure bearing wear at 10 years in patients from a randomized trial comparing Phase 3 cemented and cementless OUKRs and to investigate factors that may affect wear. It was hypothesized that there would be no difference in wear rate between cemented and cementless OUKRs.

Methods: Bearing thickness was determined using radiostereometric analysis at postoperative, 3-month, 6-month, 1-year, 2-year, 5-year and 10-year timepoints. As creep occurs early, wear rate was calculated using linear regression between 6 months and 10 years for 39 knees (20 cemented, 19 cementless). Associations between wear and implant, surgical and patient factors were analysed.

Results: The linear wear rate of the Phase 3 OUKR was 0.06 mm/year with no significant difference ($p = 0.18$) between cemented (0.054 mm/year) and cementless (0.063 mm/year) implants. Age, Oxford Knee Score, component size and bearing thickness had no correlation with wear. A body mass index ≥ 30 was associated with a significantly lower wear rate ($p = 0.007$) as was having ≥80% femoral component contact area on the bearing ($p = 0.003$). Bearings positioned ≥1.5 mm from the tibial wall had a significantly higher wear rate ($p = 0.002$).

Conclusions: At 10 years, the Phase 3 OUKR linear wear rate is low and not associated with the fixation method. To minimize the risk of wear-related bearing fracture in the very long-term surgeons should consider using 4 mm bearings in very young active patients and ensure that components are appropriately positioned, which is facilitated by the current instrumentation.

Level of Evidence: Level III, retrospective comparative study.

Abbreviations: ACL, anterior cruciate ligament; BMI, body mass index; IM, intra-medullary; OKS, Oxford Knee Score; OUKR, Oxford unicompartmental knee replacement; RSA, radiostereometric analysis.

KEYWORDS
knee arthroplasty, knee replacement, polyethylene wear, radiostereometric analysis, unicompartmental, unicondylar

INTRODUCTION

The Oxford unicompartmental knee replacement (OUKR) was designed to minimize wear using a mobile bearing that is fully congruent throughout the range of motion. Surgeons aim to use thin bearings (either 3.5 mm–Size 3 or 4.5 mm–Size 4) with the OUKR to make a conservative tibial resection. Despite the use of thin bearings wear is a rare cause of failure for the OUKR [1]. Excessive linear wear can result in bearing fracture in the long-term, however this complication can easily be treated by inserting a new bearing [2–4]. The main disadvantage of a mobile bearing is dislocation, but this is also rare (~1%) [5]. In a study of 1000 cemented Phase 3 OUKRs, with maximum follow-up of 23 years, there were four bearing fractures (0.4%) occurring at a mean time of 16 years and 10 dislocations (1%) occurring at a mean of 6 years.

In an analysis of retrieved OUKR bearings evidence of impingement was associated with a marked increase in wear, when combining wear on both superior and inferior bearing surfaces [6]. It is believed that the increased wear on the articular surfaces was caused by detached bone fragments acting as third bodies. There is also a concern that fragments of the porous coating (plasma sprayed titanium covered with hydroxyapatite) of cementless OUKRs may dislodge into the joint space and cause third body wear [7]. Cementless total hip replacements, which have fully congruent articulations like that of the OUKR, have been found to have increased wear with hydroxyapatite particles found embedded in the polyethylene [8, 9].

Radiostereometric analysis (RSA) is an accurate method to measure polyethylene wear in vivo following the OUKR [10–12]. RSA studies found the mean linear wear of Phase 1 OUKR bearing to be 0.07 mm/year [12], whereas Phase 2 bearing wear was found to be significantly lower at 0.02 mm/year [12, 13]. This difference was likely due to impingement which was not obvious during the operation for Phase 1, whereas with Phase 2 it was obvious and it was appreciated that impingement had to be avoided. To assess fixation of the Cementless Phase 3 OUKR a randomized trial using RSA was undertaken to compare the migration of cemented and cementless OUKRs [14, 15]. A short-term analysis of wear at 5 years found that for both cemented and cementless components the wear rate was 0.07 mm/year [10], which was higher than Phase 2. Changes to polyethylene manufacturing were a possible cause, but further RSA analyses showed that this was not the case [16]. The increased wear of Phase 3 relative to Phase 2 is associated with the use of a minimally invasive approach which results in patients having higher activity levels, but may also increase the risk of surgical errors leading to bearing overhang or impingement that may increase wear [10, 16].

In this study, the linear penetration of Phase 3 OUKR bearings in the randomized study of cemented and cementless implants was studied at 10 years. The aim was first to compare the long-term linear wear rate between the two fixation methods and, second, to investigate implant, surgical and patient factors that may be associated with increased linear wear rate in the long-term. It was hypothesized that there would be no difference in wear rate between cemented and cementless.

METHODS

Ethical approval

This study was approved by the Oxfordshire Research Ethics Committee B (CO2.101).

Study design

The cohort of patients analysed in this study were recruited from a randomized controlled trial (ClinicalTrials.gov identifier: NCT05935878) with the primary aim of comparing migration of cemented and cementless implants for the Phase 3 OUKR using RSA [14, 15]. A consecutive series of patients awaiting an OUKR were invited to participate in the study, of which 47 were included (24 cemented and 23 cementless, Figure 1). All patients included in the study had full-thickness cartilage loss in the medial compartment, an intact anterior cruciate ligament (ACL) and no significant cartilage damage on the weight-bearing portion of the lateral compartment. No patients had bone loss and grooving to the lateral patellofemoral joint. Exclusion criteria were age greater than 80 years, American Society of Anaesthesiologists score >3 and previous open surgery or ACL reconstruction on the same knee. Patients who provided informed consent for participation in the trial were operated on at the Nuffield Orthopaedic Centre between November 2008 and March 2010. Block randomization with closed

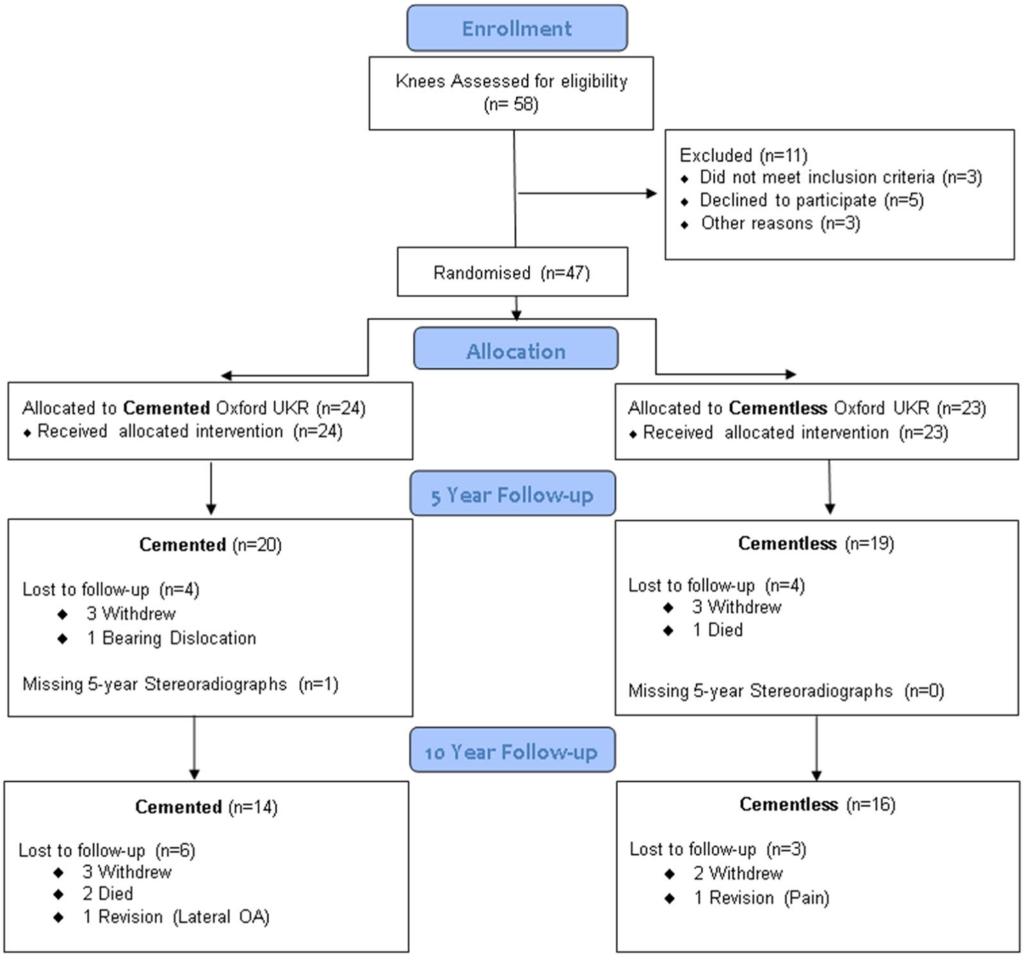

FIGURE 1 Consort diagram for the randomized controlled trial which had the primary aim of comparing migration of cemented and cementless Oxford unicompartmental knee replacements (OUKRs). Patients awaiting an OUKR for isolated medial compartment osteoarthritis were allocated to received either a cemented or cementless OUKR via block randomization and followed up with radiostereometric analysis at postoperative, 3-month, 6-month, 1-year, 2-year, 5-year and 10-year timepoints.

envelopes was used to allocate patients to cemented or cementless implants once they had undergone arthrotomy and their suitability for an OUKR was confirmed. Evaluation of all three compartments of the knee and ACL was recorded for each patient. All cases were performed using a minimally invasive approach, using Phase 3 Instrumentation. Following preparation of the tibia and femur, tantalum marker balls (0.8 mm diameter) were inserted in predetermined positions using a pre-loaded ball injector (RS-M 08, Tilly Medical Products) [17]. Seven markers were inserted in the femur and six in the tibia.

RSA

Patients were followed up at postoperative, 3-month, 6-month, 1-year, 2-year, 5-year and 10-year timepoints with weight bearing stereoradiographs. The stereoradiographs were taken with the patient standing in a calibration frame with full knee extension. The stereoradiographs were analysed using model-based RSA software (version 4.11, Medis Specials; Figure 2) with computer-aided design models supplied by the manufacturer (Biomet). This analysis determined the position of the OUKR femoral and tibial components in 3-dimensional space. The RSA system used was accurate to 0.1 mm for the OUKR [18].The closest linear distance between the femoral and tibial components was calculated using a custom MATLAB programme (The Math Works Inc., Figure 2). This distance was taken as the bearing thickness for each knee at each timepoint. Linear penetration at each timepoint was calculated by subtracting the bearing thickness from the initial thickness measured from postoperative stereoradiographs (Table 1). Polyethylene penetration in the early postoperative period is a combination of creep and wear [10, 19, 20]. When the penetration rate becomes constant, it is assumed that penetration is due to wear only, which for the Phase 3 OUKR was found to be after

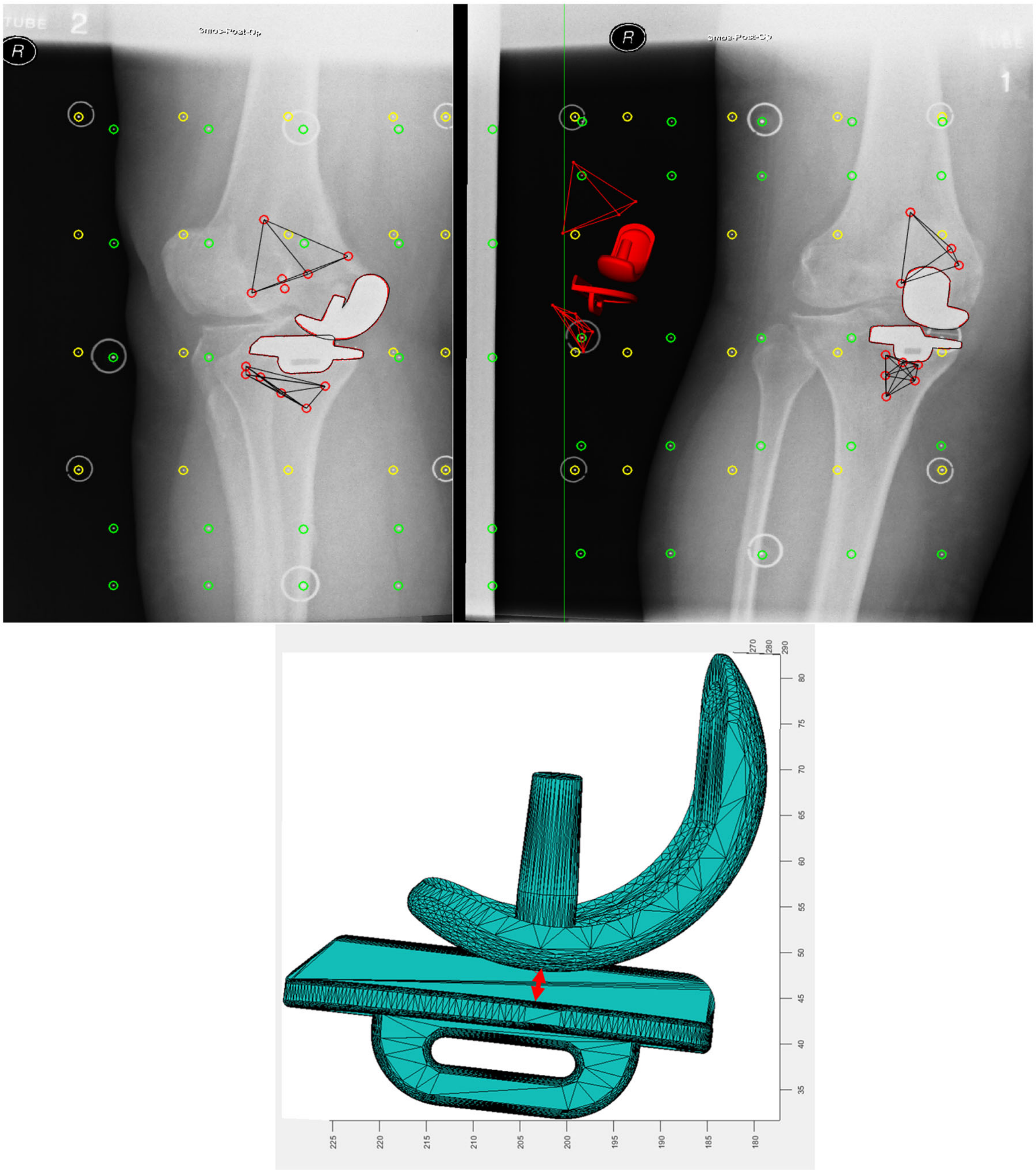

FIGURE 2 Top: An example of the model-based radiostereometric analysis software. Fiducial markers are outlined in yellow, control markers in green and tantalum marker balls in red. The femoral and tibial components are outlined in red. Bottom: Component models exported to a custom MATLAB programme. Red arrows indicate the closest linear distance between the femoral and tibial component which is taken as the bearing thickness.

TABLE 1 Mean bearing penetration at each follow-up timepoint, calculated using the initial bearing thickness as reference.

Months	3	6	12	24	60	120
Number of knees	37	38	38	39	38	30
Mean penetration (mm)	0.10	0.12	0.12	0.22	0.39	0.66
SD	0.13	0.11	0.12	0.13	0.16	0.31
95% Confidence interval	0.04	0.04	0.04	0.04	0.05	0.11

6 months [10]. Therefore, the wear rate in this study was calculated using linear regression of bearing thickness between 6 months and 10 years [10]. Knees were included in the analysis if they had data to at least 5 years and bearing thickness measurements for a minimum of four timepoints between 6 months and 10 years, resulting in 39 knees (20 cemented, 19 cementless) being included in the analysis. Bearing overhang of the tibial component and bearing to femoral

component contact area were calculated using the methods described by Ghosh et al. [10]. Both medial bearing overhang, the linear distance between the medial edge of the bearing and medial edge of the tibial component, and area overhang, the area of the bearing overhanging the tibial component, were calculated. Femoral contact area was defined as the percentage of the superior surface of the bearing that is in contact with the femoral component. Distance between the bearing and vertical wall of the tibial component was also calculated, based on the assumption that the bearing was articulating congruently with the surfaces of the femoral and tibial component. A negative distance between the bearing and tibial wall indicated that the bearing was impinging on the wall and was therefore no longer fully congruent. All calculations were made with the assumption that the bearing was parallel to the wall.

Statistical analysis

Differences in wear rate between fixation method (cemented or cementless), overhanging versus non-overhanging bearings, body mass index (BMI) greater or <30, femoral contact percentage greater or <80% and bearing distance greater or <1.5 mm from the tibial wall were analysed. Unpaired *T* tests (Shapiro–Wilk $p > 0.05$) were used for parametric data and the Mann–Whitney *U* tests for nonparametric data (Shapiro–Wilk $p < 0.05$). Pearson correlation was used to test the association of age, BMI, 10-year Oxford Knee Score (OKS), distance of the bearing from the tibial wall, bearing overhang of the tibial component and femoral contact percentage. The magnitude of Pearson's correlation coefficient (*r*) was used to categorize associations as negligible (<0.1), weak (0.1–0.39), moderate (0.40–0.69), strong (0.70–0.89) or very strong (0.90–1.00) [21]. The associations of component size (femoral and tibial) and bearing size with bearing wear were analysed using one way analysis of variance. A change in wear rate of 0.025 mm/year (0.5 mm at 20 years) was considered clinically significant [16]. A $p < 0.05$ was considered statistically significant. When the study was designed the power calculation suggested that $2n = 32$ was required sample size to compare cemented and cementless implants [15].

RESULTS

The rate of penetration for the 39 Phase 3 OUKRs in this study was constant after 6 months and the mean linear wear rate was calculated to be 0.06 mm/year (SD = 0.03) (Figure 3a). The mean bearing penetration attributable to creep, determined from where the wear regression line crossed the *Y* axis, was 0.08 mm (SD = 0.02). Most (97%) of this creep occurred in the first 3 months.

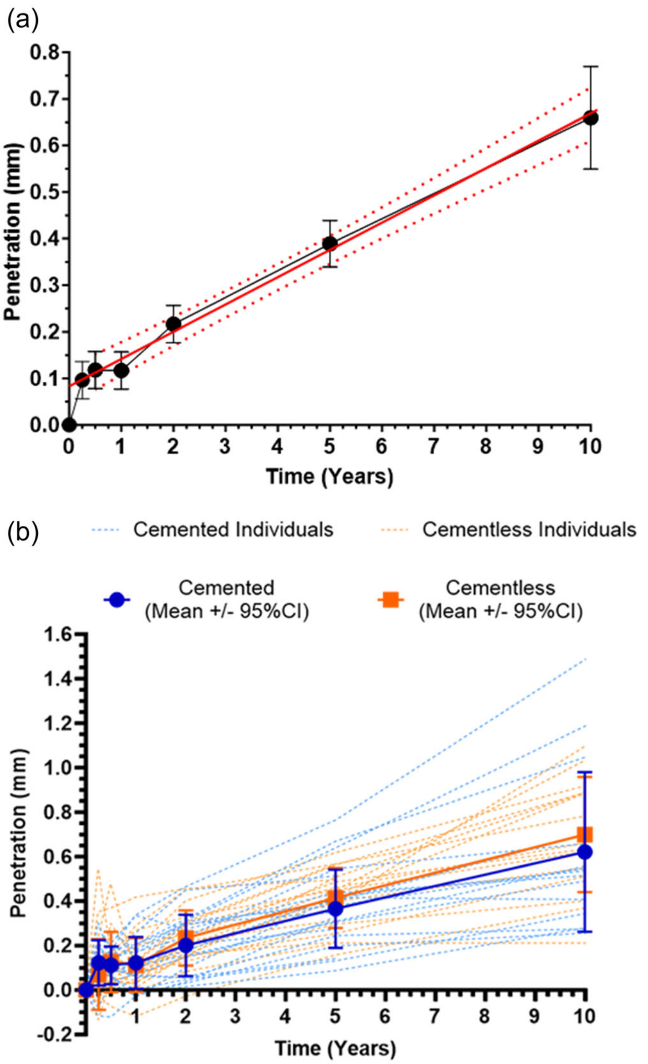

FIGURE 3 (a) Overall penetration of the Phase 3 Oxford unicompartmental knee replacement bearing (mean ± 95% confidence intervals, black). Linear wear rate is calculated by linear regression of penetration between 6 months and 10 years (red line, 95% confidence intervals as red dashed lines). Creep calculated from where the regression line intersects the vertical axis (0.084 mm). (b) Mean penetration (±95% confidence intervals) of bearings from cemented (dark blue) and cementless (dark orange) knees. Penetration of individual bearings is shown for cemented (light blue) and cementless (light orange).

Implant factors

There was no significant difference ($p = 0.18$) in linear wear rate between cemented (0.054 mm, SD = 0.032) and cementless (0.063, SD = 0.025) implants (Figure 3b). The size of the implanted tibial ($p = 0.93$) or femoral ($p = 0.76$) components did not have a

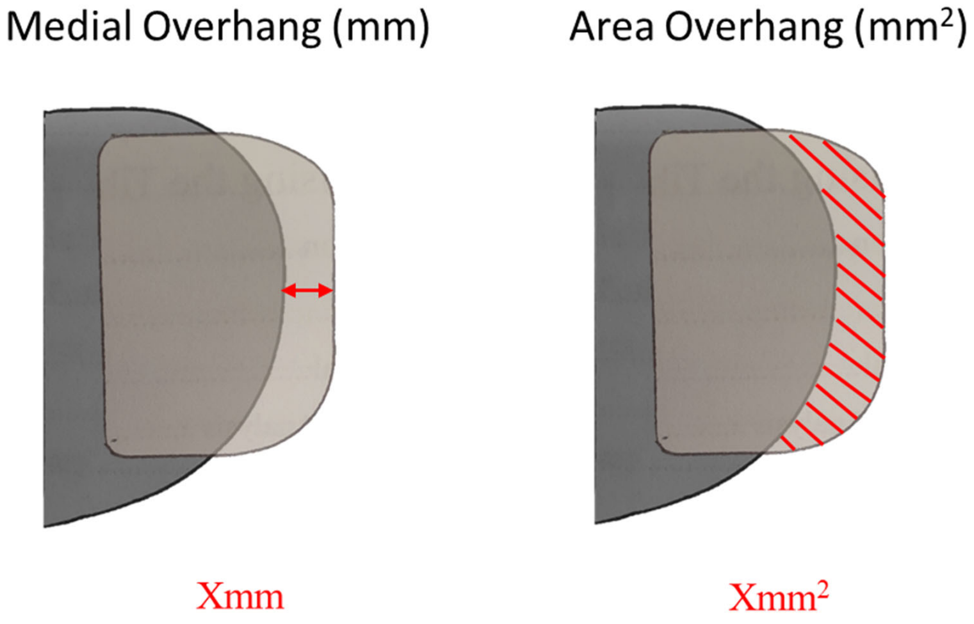

FIGURE 4 An example of a bearing overhanging a tibial component. The medial overhang (mm) is measured as the distance between the medial edge of the bearing and medial edge of the tibial component (shown on the left, indicated by red arrows). The area overhang (mm^2) is the area of the bearing overhanging the component (shown on the right, indicated by red shading).

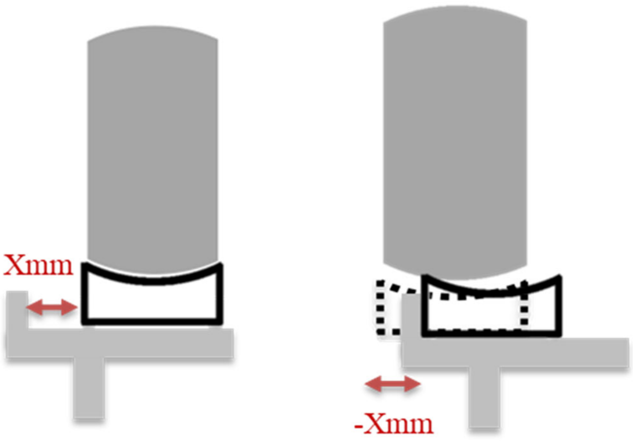

FIGURE 5 Left: An illustration of a bearing positioned *X* mm from the vertical wall of the tibial component. Right: When there is marked impingement of the bearing on the lateral wall of the tibial component, the bearing becomes incongruent. In this study, if the distance between the centre of the bearing and the wall was less than half the bearing width, it was deemed to impinge. The measurement of where the lateral edge of the bearing is relative to the tibial component wall would then be negative, shown as −*X* mm, for where the bearing would be positioned if the wall did not exist (dashed outline).

significant association with linear wear rate, nor did the thickness of the mobile bearing used ($p = 0.35$).

Surgical factors

Bearings had area and medial overhang (Figure 4) of the tibial component in 27 and 25 knees, respectively. There was no significant difference in the wear rate between overhanging and non-overhanging bearings for either area (p = 0.18) or medial overhang ($p = 0.06$) (Table 3). One bearing was found to have slight impingement (0.1 mm) on the medial wall of the tibial component but did not have significantly greater linear wear (0.04 mm/year).

The mean distance between bearings and the vertical wall of the tibial component was 3.9 mm (range −0.1 mm to 8.1 mm) The bearing to tibial wall distance was weakly correlated ($r = 0.338$, $p = 0.04$) with linear wear rate (Figure 5). This translated to wear increasing by 0.025 mm/year for every 6.25 mm further away from the wall the bearing is placed (Figure 6a). Bearings that were positioned less than 1.5 mm away from the vertical wall of the tibial component had almost 40% less linear (0.04 mm/year) wear than those positioned >1.5 mm from the wall (0.06 mm/year), a significant decrease ($p = 0.002$) (Table 3). The mean percentage of the upper surface of the bearing in contact with the femoral component (Figure 7) was 85% (range 68% to 94%) The femoral contact percentage had a weak negative correlation ($r = -0.329$, $p = 0.04$) with linear wear, with a 25% increase in contact area decreasing wear by 0.025 mm/year (Figure 6b).

Patient factors

There was no significant correlation between the patient's age at the time of operation ($p = 0.12$) or 10-year OKS ($p = 0.12$) and linear wear rate. The mean patient BMI

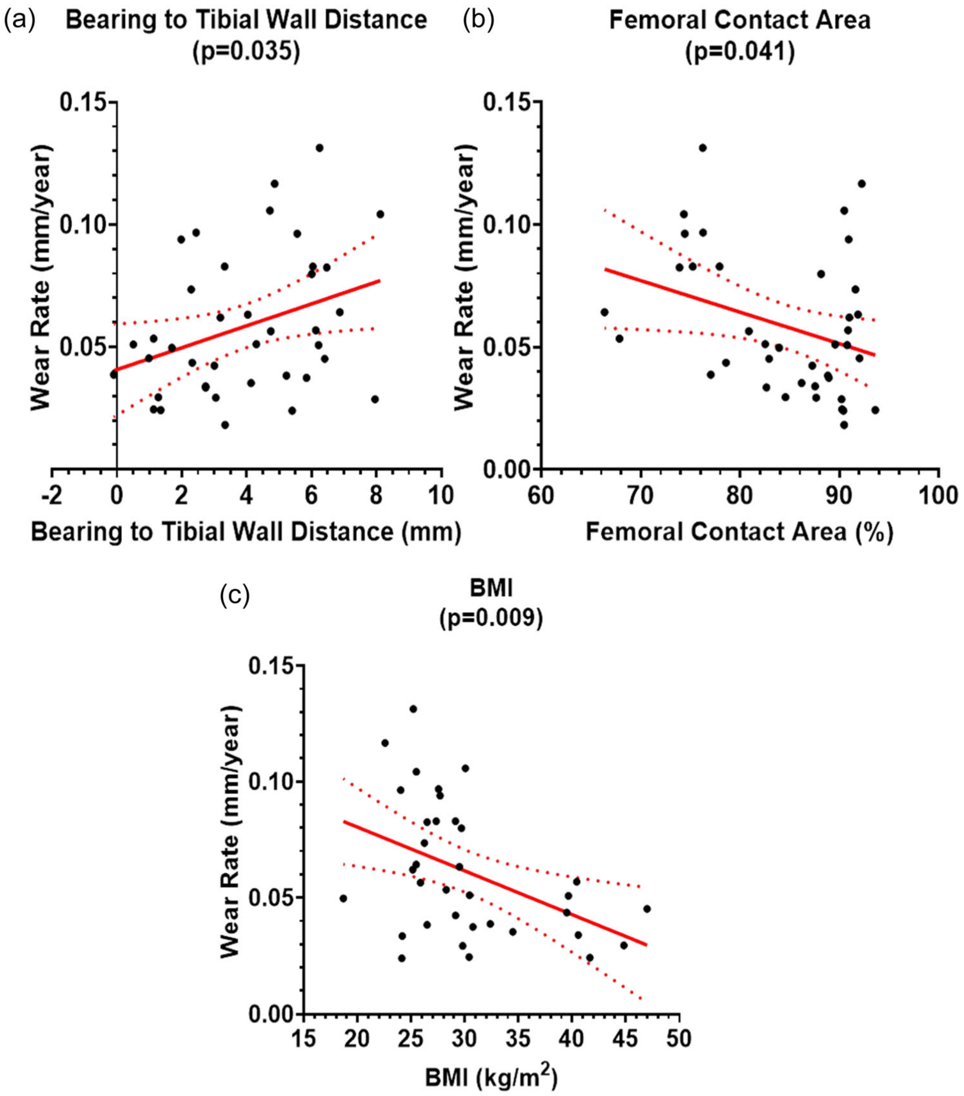

FIGURE 6 Surgical and patient factors that have a significant correlation with linear wear rate. Linear regression ± 95% confidence intervals shown in red. *p* values for Pearson correlation are shown. (a) Distance of the bearing from the vertical wall of the tibial component. (b) Femoral component contact area. (c) Body mass index (BMI).

was 30.1 (range 18.7 to 47.0). BMI had a moderate negative correlation ($r = -0.431$) with wear rate, with a 12.5-point increase in BMI decreasing wear by 0.025 mm/year. Patients with a BMI > 30 (0.04 mm/year) had significantly less ($p = 0.004$) wear than those with a BMI < 30 (0.07 mm/year) (Figure 6c).

DISCUSSION

The most important finding of this study is that there is no significant difference in the long-term bearing wear rate of cemented and cementless OUKR. Overall, the mean linear wear rate was 0.06 mm/year. There was substantial variability (SD 0.03) in the wear rate, so it is possible that a small percentage of the thinnest bearings might fracture due to wear in the very long-term. However, the rate would be similar with cemented or cementless fixation. The study also identified various surgical factors that influenced the wear rate, such as the position of the bearing and the orientation of the femoral component. If these are addressed wear could be minimized bearing fractures prevented.

The finding that there is no significant difference in the long-term polyethylene wear between cemented and cementless OUKR is important as fragments of the hydroxyapatite coated porous surface could potentially be released into the joint and increase the wear rate by acting as third bodies. As well as contributing to fracture, a higher wear rate might contribute to osteolysis and aseptic loosening [22]. National Joint Registry studies have shown that at 10 years the revision rate for the cementless OUKR is about 25% less than for the cemented [5]. This difference was primarily because

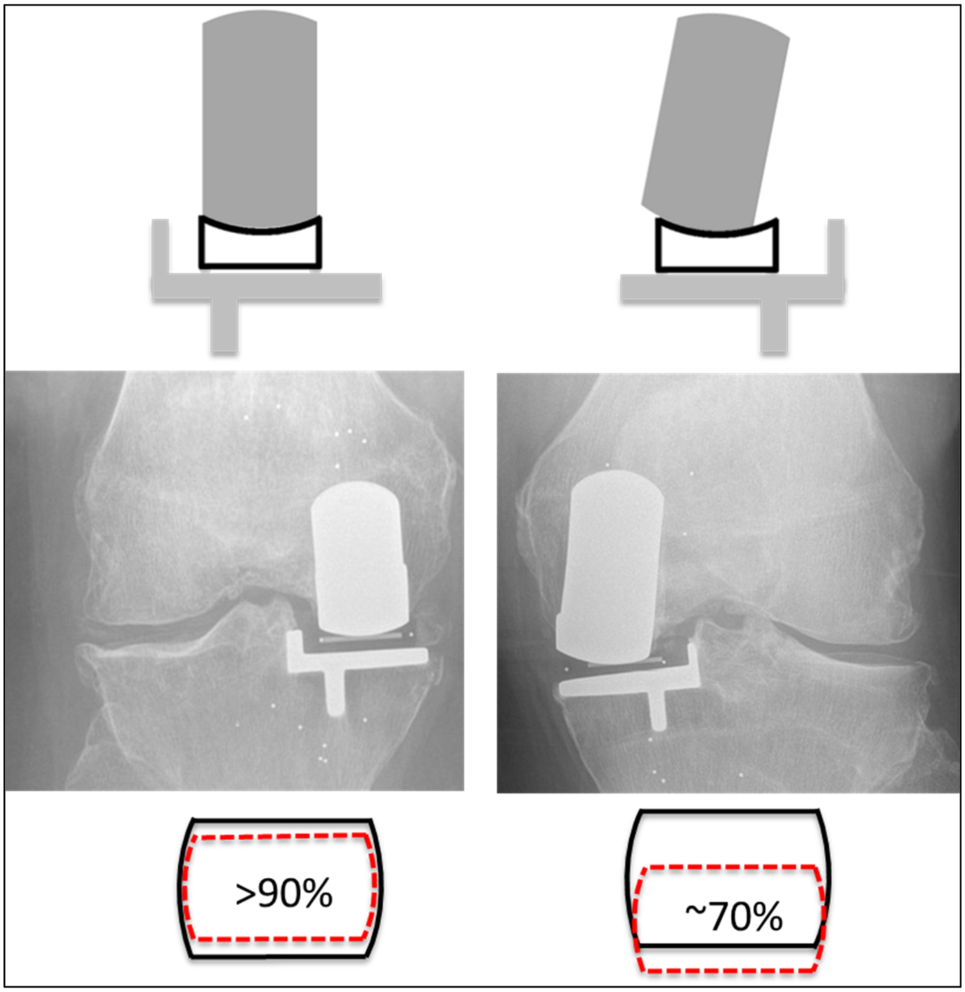

FIGURE 7 Left: Shows a diagram and radiograph of a femoral component aligned neutrally, perpendicular the tibial component tray, which tended to have greater than 90% femoral component contact percentage. The schematic shows a superior view of the mobile bearing, with the femoral contact area outlined in red. Right: A diagram and radiograph showing a femoral component with varus alignment. Femoral components aligned with significant varus/valgus tended to have approximately 70% femoral component contact percentage.

the revision rate for aseptic loosening of cementless components was less than half that for cemented components [5]. As wear is not related to fixation method, in the very long-term the revision rate of cementless is likely to be less than cemented.

The combined linear wear rate on upper and lower surfaces of the bearing is, on average, 0.06 mm/year and is constant, at least out to 10 years, and is independent of bearing thickness (Table 3). This results in wear of about 0.6 mm at 10 years and 1.2 mm at 20 years. Approximately 0.08 mm of creep occurs in the early post-operative period, with almost all creep occurring before 3 months. This wear rate is consistent with previously published short term linear wear rates for the Phase 3 OUKR [7, 10]. It is substantially lower than linear rates published for fixed-bearing knee replacements of 0.15 and 0.49 mm/year from two retrieval studies [23, 24]. It is however larger than the wear of the Phase 2 OUKR (0.02 mm/year) [11, 12]. It is unclear why the Phase 3 wear rate is higher than Phase 2. It has been suggested that, compared to the open approach used for the Phase 2, the minimally invasive approach used for Phase 3 results in higher levels of function which may account for the higher wear rate [10]. However, in the current study the wear rate was not related to the OKS. Another possible explanation is that minimally invasive surgery may result in more surgical errors, particularly with implant positioning, impingement, or cementing, that would account for higher wear rates [25]. Minor changes to the shape of the bearing and tibial component were made between Phase 2 and 3, which may have unintentionally contributed to increased wear. The resin used and manufacturing process for bearings also changed between Phase 2 and Phase 3, however, a previous study found that these changes had no effect on wear rate [16]. To compensate for the higher wear seen with the Phase 3 OUKR, manufacturing bearings from highly cross-linked polyethylene could be considered as it has been shown to decrease wear for total knee replacements [26].

The surgical factor most strongly related to wear was the distance between the bearing and the wall of the tibial component. Bearings positioned less than 1.5 mm from the wall had a wear rate of 0.04 mm/year, which is almost 40% less than those 1.5 mm or more from the wall. The analysis suggested that for every 2 mm further away from the wall the bearing is placed, wear increased by approximately 0.01 mm/year (Table 2). Bearings close to the wall track straight and parallel to the wall. Bearings further away from the wall may rotate as they move resulting in increased wear due to cross-shear [27]. Furthermore, bearings further from the wall will overhang the tibial plateau more, particularly if they rotate. This will increase contact stress and thus wear. There was a trend ($p = 0.06$) towards increased wear with increased bearing overhang, even though the overhang was calculated based on the assumption the bearing did not rotate. Therefore, it is recommended that the femoral component be positioned so that the bearing is <2 mm away from the wall. A further advantage of having the bearing close to the wall is it will decrease the risk of the bearing spinning and dislocating [28]. It is important that the bearing is not jammed against the wall [29]. There was 1 bearing impinging against the wall in this study, but the impingement was only 0.1 mm, which would not be enough to cause problems.

Femoral component contact percentage with the bearing had a significant negative correlation with wear rate, with a 25% increase decreasing wear by 0.025 mm/year (Table 2). Femoral component contact percentage is maximized when the femoral component is neutrally aligned relative to the tibial component, whereas valgus or varus implantation decreases the contact percentage (Figure 7).

Patient BMI was found to be negatively correlated with wear rate, with a 12.5-point increase in BMI resulting in a 0.025 mm/year decrease in linear wear rate (Table 2). This phenomenon may be explained by the fact that patients with a lower BMI are possibly more physically active and therefore may have high wear rates [30].

Excessive linear wear may result in bearing fracture, which although a rare complication, has been increasingly reported for Phase 3 OUKRs compared with Phase 2 [2–4, 31]. This may be a result of an increased wear rate but is also likely a consequence of the operation being done in younger patients with increasing life expectancy, with most reported bearing fractures occurring in the second or third postoperative decade. Thinner bearings, particularly those worn to <2 mm thick, are at higher risk of fracture [4, 16, 31]. In this Study 2 bearings (5%), both Size 3, were projected to be <2 mm thick by 20 years. Although initial bearing thickness is not related to the linear wear rate, OUKRs with bearings of Size 5 or larger are known to have significantly decreased implant survival [32, 33]. Therefore, it is recommended that Size 4 bearings are used in young, active patients, unless they are very small, to minimize their risk of bearing fracture in the long-term without impairing implant survival. In very small patients the tibial resection should be as small as possible to minimize the risk of tibial plateau fracture or damage to the medial collateral ligament, so in these patients it may be sensible to aim for a Size 3 bearing.

The microplasty instrumentation, which was introduced after the OUKRs in this study were implanted and is now routinely used, was designed to make the operation simpler and more reproducible. Several studies have shown that microplasty improves component positioning [34–37] and decreases the rate of bearing dislocation [38].

TABLE 2 Correlation of linear wear rate with implant and patient factors.

Factor	Mean (SD)	Gradient vs. wear/year (mm)	Association–Pearson's correlation, *r* (95% CI)	*p*
Age at operation (years)	65.9 (8.15)	0.001	0.253 (−0.07 to 0.53)	0.121
BMI (kg/m^2)	30.1 (6.69)	−0.002	−0.434 (−0.67 to −0.11)	**0.009****
10-Year OKS (0 = worst, 48 = best)	39.8 (8.86)	0.001	0.260 (−0.07 to 0.54)	0.120
Medial overhang–ALL (mm)	0.486 (2.25)	0.004	0.305 (−0.01 to 0.57)	0.059
Medial overhang–Overhanging bearings only (mm)	1.84 (1.46)	0.004	0.170 (−0.24 to 0.53)	0.416
Area overhang–ALL (mm^2)	31.0 (39.2)	0.0002	0.262 (−0.06 to 0.53)	0.107
Area overhang–Overhanging bearings only (mm^2)	44.7 (40.0)	0.0001	0.158 (−0.24 to 0.51)	0.433
Femoral contact area (%)	84.5 (7.34)	−0.001	−0.329 (−0.58 to −0.01)	**0.041***
Distance of bearing to tibial wall (mm)	3.94 (2.17)	0.004	0.338 (0.03 to 0.591)	**0.035***

Note: Significant values are shown in bold.

Abbreviations: BMI, body mass index; CI, confidence interval; OKS, Oxford Knee Score.

*Level of statistical significance: $p < 0.05$

**Level of statistical significance: $p < 0.01$.

TABLE 3 Comparisons of linear wear between categories of implant and patient factors.

Factor	Group	Mean wear rate mm/year (SD)	*p* (Unpaired *T* test, Mann–Whitney *U* test, or ANOVA)
Overall wear	All knees (*n* = 39)	0.058 (0.029)	Not applicable
Fixation method	Cemented (*n* = 20)	0.054 (0.032)	0.175
	Cementless (*n* = 19)	0.063 (0.025)	
Medial overhang	Overhangers (*n* = 25)	0.064 (0.031)	0.176
	Non-overhangers (*n* = 14)	0.049 (0.023)	
Area overhang	Area overhang (*n* = 27)	0.064 (0.031)	0.055
	No area overhang (*n* = 12)	0.047 (0.020)	
Distance of bearing from the tibial wall	<1.5 mm (*n* = 7)	0.038 (0.012)	**0.002****
	≥1.5 mm (*n* = 32)	0.063 (0.030)	
Femoral component contact area	<80% Contact area (*n* = 11)	0.080 (0.028)	**0.003****
	≥80% Contact area (*n* = 28)	0.050 (0.025)	
Tibial component size	A (*n* = 5)	0.063 (0.026)	0.933
	B (*n* = 8)	0.054 (0.024)	
	C (*n* = 14)	0.055 (0.035)	
	D (*n* = 2)	0.073 (0.033)	
	E (*n* = 7)	0.058 (0.026)	
	F (*n* = 3)	0.069 (0.038)	
Femoral component size	Small (*n* = 16)	0.057 (0.029)	0.762
	Medium (*n* = 12)	0.056 (0.022)	
	Large (*n* = 11)	0.064 (0.036)	
Bearing thickness (size)	Size 3 (*n* = 7)	0.052 (0.021)	0.352
	Size 4 (*n* = 22)	0.058 (0.028)	
	Size 5 (*n* = 8)	0.070 (0.035)	
	Size 6 (*n* = 2)	0.032 (0.019)	
BMI	BMI < 30 kg/m^2 (*n* = 23)	0.070 (0.029)	**0.007****
	BMI ≥ 30 kg/m^2 (*n* = 13)	0.044 (0.021)	

Note: Significant values are shown in bold.

Abbreviations: ANOVA, analysis of variance; BMI, body mass index.

*Level of statistical significance: $p < 0.05$

**Level of statistical significance: $p < 0.01$.

It includes instrumentation to accurately determine the height of the tibial cut, which facilitates selecting a Size 4 bearing in young active patients. It also has instrumentation to prevent impingement of bone on the bearing both anteriorly and posteriorly which is a potent cause of wear. The femoral drill guide is linked to an intra-medullary (IM) rod, which ensures that the femoral component is neutrally orientated. The instrumentation is also designed to position the femoral component so the bearing is about 1 mm from the wall. The IM rod should be inserted about 1 cm in front of the notch and medial to the medial border to the notch. If it is inserted too far laterally it can cause the patella and thus the tibia to sublux laterally, which results in the femoral component being positioned too far laterally [29, 39]. This can cause the bearing to jam against the wall, which can cause early valgus tibial subsidence [40]. To avoid this, some surgeons position the femoral component central on the condyle which may result in the bearing being far from the wall. It is important that the position of the bearing is checked before the keel slot is formed and if it is jammed against the wall the tibial component should be moved laterally. With the correct use of the microplasty instruments, the bearing wear and the risk of bearing fracture should decrease.

This study was limited by the inability to analyse the stereoradiographs of all patients at 10 years, either due to loss to follow-up or stereoradiographs that were unable to be analysed. The loss of nine knees (six cemented, three cementless) between 5 and 10 years reduced the accuracy of the wear rate calculation for these knees. However, as wear rate is linear beyond 6 months, this is unlikely to have an appreciable effect on the results. The sample size of 39 is another limitation. The study was originally designed to measure migration. However, a retrospective power calculation based on wear (SD 0.029 mm/year) indicated that there was adequate power (80%) in the current study to detect a clinically important difference of 0.025 mm/year (0.5 mm at 20 years). The difference in wear between cemented and cementless (0.007 mm/year, $p = 0.175$) is therefore neither clinically or statistically important, whereas the differences related to the distance between bearing and wall (0.025 mm/year, $p = 0.002$) and femoral component orientation (0.03 mm/year, $p = 0.003$) are both clinically and statistically important. Furthermore, the variables determined to have significant associations with wear rate using linear regression also demonstrated statistically significant differences when placed into binary categories. Two assumptions were made when calculating bearing overhang and distance from the vertical tibial wall. It was assumed that the bearing was parallel to the wall and that bearing position in extension, where standing radiographs are taken, is similar throughout the knee's range of motion. If there is appreciable space between the bearing and tibial wall the bearing is likely to rotate so the analysis probably underestimates overhang. Had it been possible to measure bearing rotation and include this in the calculation, there might have been a significant relationship between overhang and wear. The bearing is typically closest to wall in mid flexion and moves ~1 mm medially in extension and full flexion [41]. Therefore, distance between the wall and bearing in this study is likely an indicator of the maximum distance.

CONCLUSION

At 10 years, there is no significant difference in the wear rate between the cemented and cementless Phase 3 OUKR, so the failure rate due to wear should be similar for both devices. Although the mean linear wear rate is low (0.06 mm/year) there is considerable variability (SD = 0.03) in this so there is a small risk of bearings fracturing in the long-term. The wear rate can be minimized by careful surgery aiming for the bearing to be <2 mm from the tibial wall, neutral alignment of the femoral component, avoiding bearing impingent and using Size 4 bearings in very young active patients. The current instrumentation should help surgeons achieve this.

AUTHOR CONTRIBUTIONS

Lachlan W. Arthur collected data, analysed the results and wrote the manuscript. Priyanka Ghosh, Hasan R. Mohammad and Stefano Campi assisted with data analysis and reviewed the final manuscript. Benjamin J. L. Kendrick was involved in the conception of the study and reviewed the final manuscript. David W. Murray was involved in conception of the study, data analysis, writing of the manuscript and supervised Lachlan W. Arthur. Stephen J. Mellon was involved in conception of the study, data analysis, writing of the manuscript and supervised Lachlan W. Arthur.

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CONFLICT OF INTEREST STATEMENT

The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other nonprofit organization with which one or more of the authors are associated.

ETHICS STATEMENT

The study was approved by the Oxfordshire Research Ethics Committee B (C02.101).

CLINICAL TRIAL REGISTRATION

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