Pitch-based carbon-fibre-reinforced poly (ether–ether–ketone) OPTIMA® assessed as a bearing material in a mobile bearing unicondylar knee joint

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Abstract: The introduction of unicondylar knee prostheses has allowed the preservation of the non-diseased compartment of the knee while replacing the diseased or damaged compartment. In an attempt to reduce the likelihood of aseptic loosening, new material combinations have been investigated within the laboratory. Tribological tests (friction, lubrication, and wear) were performed on metal-on-carbon-fibre-reinforced (CFR) poly (ether–ether–ketone) (PEEK) (pitch-based) mobile unicondylar knee prostheses up to 5×10^6 cycles. Both a loaded soak control and an unloaded soak control (both medial and lateral components) were used to compensate for weight change due to lubricant absorption. For this material combination the loaded soak control gave slightly lower wear for both the medial and the lateral components than did the unloaded soak control. The medial components gave higher steady state wear than the lateral components (1.70 mm^3 per 10^6 cycles compared with 1.02 mm^3 per 10^6 cycles with the loaded soak control). The results show that the CFR PEEK unicondylar knee joints performed well in these wear tests. They gave lower volumetric wear rates than conventional metal-on-ultra-high-molecular-weight polyethylene prostheses have given in the past when tested under similar conditions. The friction tests showed that, at physiological viscosities, these joints operated in the boundary–mixed-lubrication regime. The low wear produced by these joints seems to be a function of the material combination and not of the lubrication regime.

Keywords: tribology, friction, lubrication, wear, carbon-fibre-reinforced poly (ether–ether–ketone), unicondylar knee prosthesis

1 INTRODUCTION

Unicompartmental osteoarthritis of the knee leads to debilitating pain and discomfort that can be treated with arthroplasty of the knee. The introduction of unicondylar knee prostheses has allowed the preservation of the non-diseased compartment of the knee while replacing the damaged compartment [**1**, **2**]. Also, the range of movement after unicondylar knee surgery has been shown to be better than with total knee replacement surgery with a shorter recovery time [**1**]. Unicondylar knee implants have good long-term clinical results with 95 per cent operating well 10 years after implantation [**3**]. There are several different unicompartmental knee replacement designs available on the market, some of which have a plastic tibial component while others have a plastic mobile meniscus. Whatever the design, the most common material used for the plastic component is ultra-high-molecular-weight polyethylene (UHMWPE). However, as is well known, there is concern that the body's biological reaction to UHMWPE wear particles leads to bone resorption and subsequent loosening and failure of the joint [**4**]. Also, delamination of the UHMWPE tibial bearing surface has been found to occur, leading to failure of these conventional joints [**5**].

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The use of an alternative material in place of UHMWPE could lead to a reduction in osteolysis and, therefore, an increase in joint life expectancy. Poly (ether–ether–ketone) (PEEK) is a semicrystalline polymer that has been increasingly employed as a biomaterial for use in trauma applications [**6**]. In hip wear simulator studies, carbon-fibre-reinforced (CFR) PEEK has been shown to produce lower wear than conventional hip prostheses [**7**]. Also, a case report which studied the technical and histological findings of a retrieved CFR PEEK acetabular cup articulating against an alumina femoral head showed very few particles within the periprosthetic tissue [**8**]. This component had been retrieved 28 months after implantation as a result of post-trauma infection. In addition to this, tests have shown that CFR PEEK wear particles have no cytotoxic effects on the cells in culture, suggesting that this material may cause little or no adverse tissue reaction [**9**]. In fact, work performed by Morrison *et al.* [**10**] showed some stimulatory effects from this material on osteoblasts.

Previous work [**11**] suggested that CFR PEEK components produced lower wear than did UHMWPE when articulating against either a metal or a ceramic head in a conforming ball-in-socket contact situation. However, in high-stress non-conforming contact conditions, such as the knee joint, UHMWPE gave lower wear than CFR PEEK, suggesting that CFR PEEK components were not suitable for use in knee prostheses. These tests were performed on a simple ball-on-flat wear-testing device that applied reciprocation motion only, in an attempt to simulate both the loading and the motion conditions encountered by a knee joint. The work performed by Lilley *et al.* [**12**] on a pin-on-disc machine, however, gave different results. They found that ceramic-on-CFR PEEK samples gave lower wear than (Co–Cr–Mo)-on-UHMWPE.

In this study, mobile bearing unicondylar knee joints with CFR PEEK (pitch-based) meniscal components were assessed on a knee joint wear simulator and friction simulator to allow determination of the tribological properties (friction, lubrication, and wear) of this prosthesis. Previous pin-on-plate studies have shown excellent wear performance between CFR PEEK pins and Co–Cr–Mo plates [**13**].

2 MATERIALS AND METHODS

The unicondylar knee that was tested was based on the Oxford® Partial Knee (Biomet UK Ltd, Bridgend, UK) and consisted of a Co–Cr–Mo tibial component and femoral component between which a mobile pitch-based CFR PEEK OPTIMA® meniscal bearing was mounted.

2.1 Simulators

Two machines were used to measure the friction and the wear performance of these knees. The wear tests used the Durham six-station knee wear simulator [**14**] and the friction tests were performed on the Durham friction simulator II [**15**, **16**]. These machines are described below and the tests allowed the assessment of the friction, lubrication, and wear properties of this material combination.

2.1.1 Durham six-station knee wear simulator

The simulator has six stations, five of which were articulating stations and one was used as a dynamically loaded soak control station. In addition to a loaded soak control, an unloaded soak control was used to assess the difference between the fluid absorptions of the loaded and unloaded components. The simulator was hydraulically driven and combined a dynamic axial loading cycle (maximum and minimum loads set at 3000 N and 300 N respectively per station) with active flexion–extension (60–0°), active anterior–posterior translation ($\pm$2.5 mm), and passive internal–external rotation, to produce similar loading and motion profiles to those experienced *in vivo* under normal gait. The simulator was set up to test right knees at a frequency of 1 Hz and the test was run for 5×10^6 cycles (equivalent to approximately 5 years *in vivo*). Although this test assessed the wear of unicondylar knee joints, both a medial and a lateral joint were placed in each station, allowing a similar loading profile to be used as in all previous tests performed on the Durham six-station knee simulator. However, a 5 mm axial load offset was applied to the unicondylar knee joints, leading to a higher load on the medial side than on the lateral side (maximum loads, 1733 N and 1267 N respectively). The unicondylar knee joints all had a Co–Cr–Mo femoral component that articulated against a pitch-based CFR PEEK mobile meniscal bearing placed on a Co–Cr–Mo tibial component. The medial component was a standard tibial piece based on the Oxford unicompartmental knee phase 3 design (with a flat bearing underside and flat tibial component) (Fig. 1(a)) while the lateral component was an Oxford unicompartmental knee phase 3 bicondylar bearing (the underside of this bearing was profiled as was the

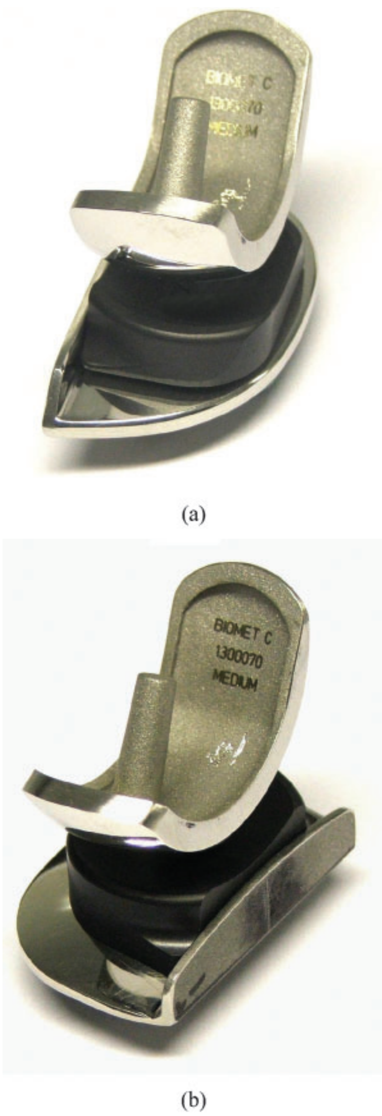


Fig. 1 CFR PEEK mobile bearing unicondylar knee joint: (a) medial (flat bearing); (b) lateral (profiled bearing)

tibial component) (Fig. 1(b)). The meniscal bearings were conditioned at 37 °C in bovine serum (BS) of protein concentration 17 g/l (see section 2.1.3) for 27 days prior to the commencement of the test. The test was run at a lubricant temperature of 37 °C and any evaporation of lubricant from each station was replaced with deionized water (using a platinum wire level sensor) to keep an almost constant level of lubricant.

Throughout the test (approximately every 0.5×10^6 cycles) the wear of the CFR PEEK meniscal bearings was assessed gravimetrically using a Mettler AX205 balance (accurate to 0.01 mg) and the cleaning–drying–weighing protocol (according to ISO 14243-2:2000 [**17**]) is shown in Appendix 2. The mass loss was converted to wear volume using the density of pitch-based CFR PEEK which is quoted by the manufacturers as 1420 kg/m^3.

2.1.2 Durham friction simulator II

Before and after wear testing, friction tests were performed on four meniscal bearings (two medial and two lateral) to determine the lubrication regime under which the joints were operating. For the friction tests performed prior to the wear tests, the components were conditioned for 3 days in the lubricant used (detailed in section 2.1.3) at 37 °C before the testing commenced. The femoral condyle that was used in these tests was the same design as those used in the wear tests, a constant-radius (23.8 mm) Co–Cr–Mo component.

In the friction simulator, a servohydraulic cylinder provided a dynamic loading cycle with maximum and minimum loads set at 1000 N and 100 N respectively. The maximum load was set at 1000 N (as opposed to the standard 2000 N) because only one single unicondylar knee was tested each time. A simple harmonic oscillatory motion of $\pm 32.5^\circ$ was applied to the femoral condyle in the flexion–extension plane. The period of motion was 1.2 s. The simulator consisted of a low-friction carriage into which the meniscal bearing component was positioned and an upper moving frame into which the femoral condyle was fixed. The tibial carriage was supported by externally pressurized bearings which provided a very low friction axis about which the carriage could rotate owing to the frictional torque generated between the bearing surfaces. This rotation was resisted by a Kistler piezoelectric transducer which was calibrated to measure torque. The frictional torque, load, and angular displacement were measured throughout each cycle. The frictional torque was converted to friction factor f using the equation [**18**]

$$f = \frac{T}{rL}$$

where T is the frictional torque between the bearing surfaces, r is the radius of the femoral condyle, and L is the axial load applied. An average friction factor was taken of three runs from the high-load high-velocity stage of the loading cycle.

In order to determine the lubrication regime, several viscosities of lubricant were tested to enable a Stribeck curve to be generated. The Stribeck curve plots the measured friction factor against Sommerfeld number Z according to

$$Z = \frac{\eta u r}{L}$$

where η is the lubricant viscosity and u is the entraining velocity of the bearing surfaces. A decreasing friction factor with increasing Sommerfeld number is indicative of the mixed lubrication regime, a rising friction factor with increasing Sommerfeld number is indicative of full fluid-film lubrication, and boundary lubrication is shown as a flat trend line with no dependence of the friction factor on the Sommerfeld number [**19**].

2.1.3 Lubricants

The lubricant used for the wear test was newborn calf serum (supplied by Harlan Sera-Lab) diluted with deionized water to provide a protein concentration of 17 g/l. To this, 0.2 per cent sodium azide and 20 mM ethylenediaminetetraacetic acid were added in an attempt to retard the growth of bacteria and to prevent calcium phosphate deposition. To provide a protein concentration of 17 g/l, the majority of the test used 30 per cent BS (batch number 5030401). For the last 0.5×10^6 cycles of testing station 3, station 4, and the control station, BS from batch 4030503 was used (this needed to be diluted to 27.5 per cent to give a protein concentration of 17 g/l).

For the friction tests, to produce the Stribeck plots and to determine the lubrication regimes, different viscosities of fluids were tested. A range of viscosities of carboxymethyl cellulose (CMC) solutions ($0.001\,\text{Pa s} < \eta < 0.098\,\text{Pa s}$) was used. In addition to this, different viscosities of BS ($0.001\,\text{Pa s} < \eta < 0.109\,\text{Pa s}$) were used to determine the effects of the introduction of proteins to the lubrication of the CFR PEEK joints (prior to the wear tests, 30 per cent BS was used from batch number 5030401 and post-wear testing 27.5 per cent BS was used from batch number 4030501).

2.2 Surface characterization

At the start of the tests and at intervals throughout the wear test, the surface roughness of the components was measured on the Zygo NewView 100 non-contacting profilometer. The ×10 lens with ×2 zoom was used, giving an area of view of 0.366 mm × 0.272 mm. Ten measurements were taken on each component. These surface roughness measurements were performed on all the bearing surfaces. The meniscal bearings were measured prior to the commencement of the test, at 1×10^6 cycles, at 3×10^6 cycles, and then at the end of the test after 5×10^6 cycles (both the top and the bottom surfaces). The femoral condyles and tibial components were measured before the test, at 1×10^6 cycles and then at the end of the test.

3 RESULTS

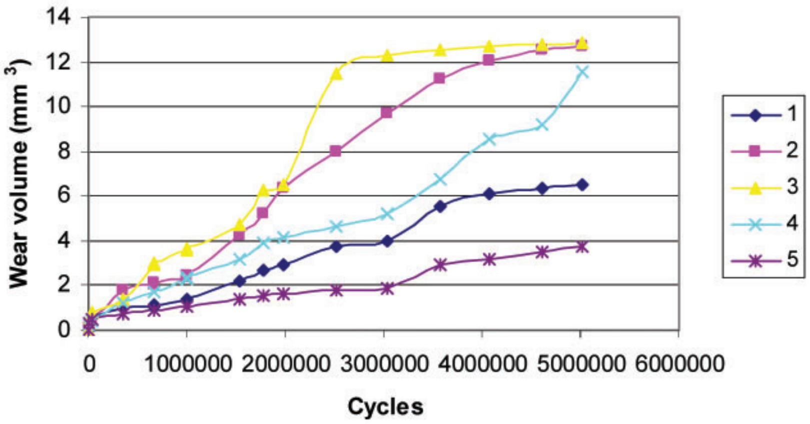
3.1 Wear test

The graphs of wear volume versus number of cycles for the medial and lateral joints using both the loaded soak control and the unloaded soak control are shown in Figs 2 and 3 respectively. Table 1 shows the wear rates (in cubic millimetres per 10^6 cycles) for each station as determined using linear regression analysis. The running-in wear phase (up to 0.35×10^6 cycles) was ignored in this analysis. From the graphs and the wear results given in Table 1 it is clear to see that the loaded soak control gave very similar wear results to the unloaded soak control for this material combination (although both the medial and the lateral bearings gave slightly lower wear when using the loaded soak control to assess the lubricant absorption). The medial joints gave higher wear than the lateral joints using both the loaded and the unloaded soak controls ($1.70\,\text{mm}^3$ per 10^6 cycles in comparison with $1.02\,\text{mm}^3$ per 10^6 cycles with the loaded soak control).

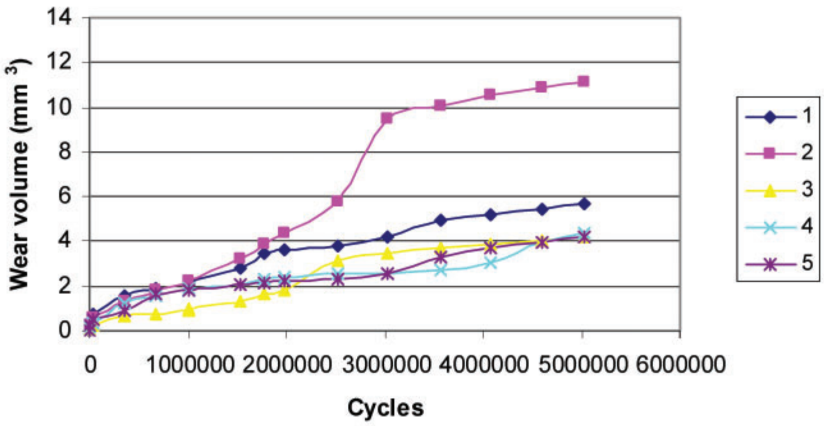
During the wear test (at approximately 2.5×10^6 cycles) the lubricant bath on station 3 leaked. Therefore, the diluted bovine serum decreased and was automatically replaced with deionized water. This led to an increase in wear. When determining the wear rates of the medial and lateral components of station 3 this higher wear period (one measurement) was therefore ignored and, in the subsequent weight measurements, account was taken of this in the calculation of the wear rates. Also, twice during the test (at about 0.5×10^6 cycles and 2×10^6 cycles), station 5 ran partially dry overnight. This, surprisingly, had no obvious effect on the wear produced and, therefore, the results were not amended to take account of this.

3.2 Friction tests

Friction tests were performed on both the medial and the lateral components of joints 1 and 2 both prior to the wear test and at the end of the wear test. These Stribeck plots are shown in Figs 4 and 5 respectively.



(a) medial components



(b) lateral components

Fig. 2 Wear volume (using the loaded soak controls) for (a) the medial and (b) the lateral CFR PEEK tibial components using the knee joint simulator

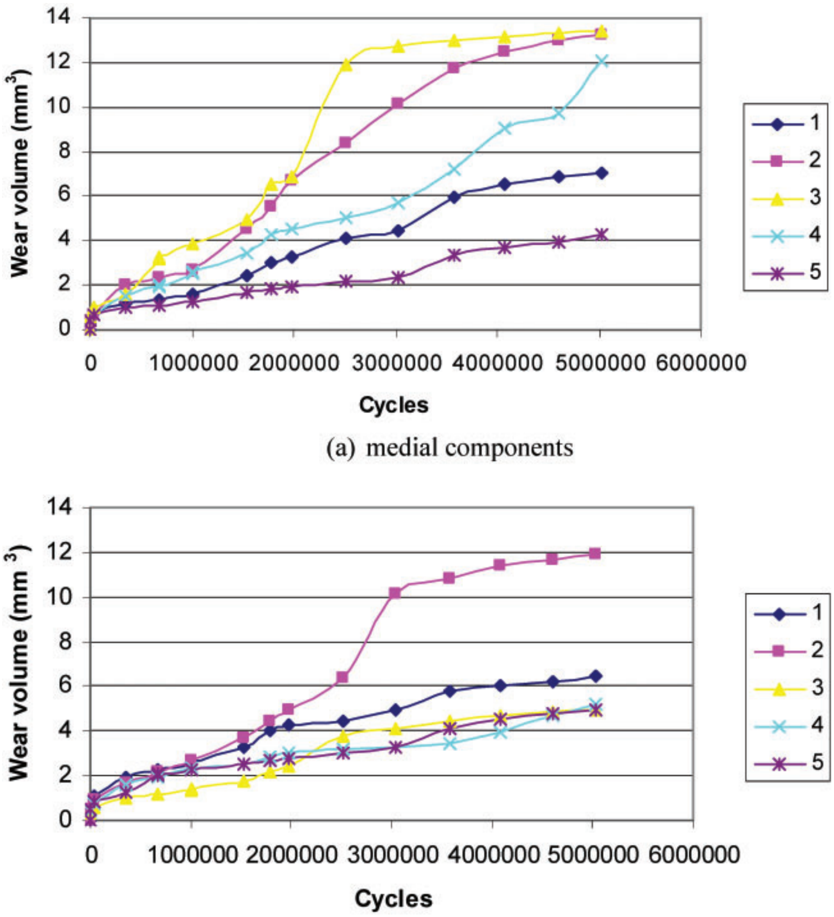
From Fig. 4 it can be seen that, before wear testing, joints 1 and 2 produced similar friction factors. The medial components gave slightly lower friction than the lateral components for the tests performed using CMC fluids as the lubricant and also for those using different viscosities of BS. A slight decrease in friction factor was found when BS was used as the lubricant for the medial and lateral bearings of both joints when compared with CMC fluids. These results indicated that the joints were working within boundary–mixed lubrication.

Figure 5 shows the results from the post-wear friction tests. As with the pre-wear tests, joints 1 and 2 gave similar friction values. The medial components gave similar friction to the lateral components with both lubricants. Unlike the pre-wear tests, the CMC tests gave lower friction than the BS tests. The tests using CMC fluids as the lubricant and also the BS tests showed a downward trend, suggesting that the joints were operating with mixed lubrication.

3.3 Surface characterization

The Zygo measurements were performed on all these joints prior to the commencement of the initial friction tests (and, therefore, also the wear tests). After the friction tests were finished, the components were re-analysed to determine whether there were any changes to the surface topography. This showed unidirectional scratches over the full length of the surface of all joints that were tested (an example is shown in Fig. 6).

Post-wear, both a visual analysis of the upper articulating side of the meniscal bearing surfaces and the surface topography results from the Zygo NewView 100 indicated a polished surface area. From Table 2 and Fig. 7, it can be seen that, as the wear test progressed, the surface roughness of the top face decreased for both the medial and the lateral components up to about 3×10^6 cycles and then remained similar. The roughness measurements for the bottom surfaces are shown in Table 3.



(a) medial components

(b) lateral components

Fig. 3 Wear volume (using the unloaded soak controls) for (a) the medial and (b) the lateral CFR PEEK tibial components using the knee joint simulator

The medial components remained similar throughout the wear tests but the lateral components became smoother and more negatively skewed as the test progressed.

The medial tibial components showed similar surface roughness values both before and after the wear test; however, the surfaces had a few scuff marks visible by eye. The lateral tibial components showed a slight increase in roughness during the test. These results are shown in Table 4.

The surface topography results for the femoral condyles (shown in Table 5) indicate a slight roughening of the surface after the wear test commenced, which could be seen visually by eye as light unidirectional scratches.

4 DISCUSSION

The knee wear simulator was set up with a 5 mm axial load offset on each station which resulted in a

Table 1 Measured volumetric wear for the unicondylar knees

	Wear (loaded soak) (mm^3 per 10^6 cycles)		Wear (unloaded soak) (mm^3 per 10^6 cycles)	
Joint	Medial	Lateral	Medial	Lateral
1	1.35	0.92	1.41	1.03
2	2.73	2.45	2.80	2.56
3	1.76	0.59	1.82	0.70
4	2.01	0.55	2.08	0.65
5	0.66	0.62	0.72	0.73
Average	1.70	1.02	1.77	1.13

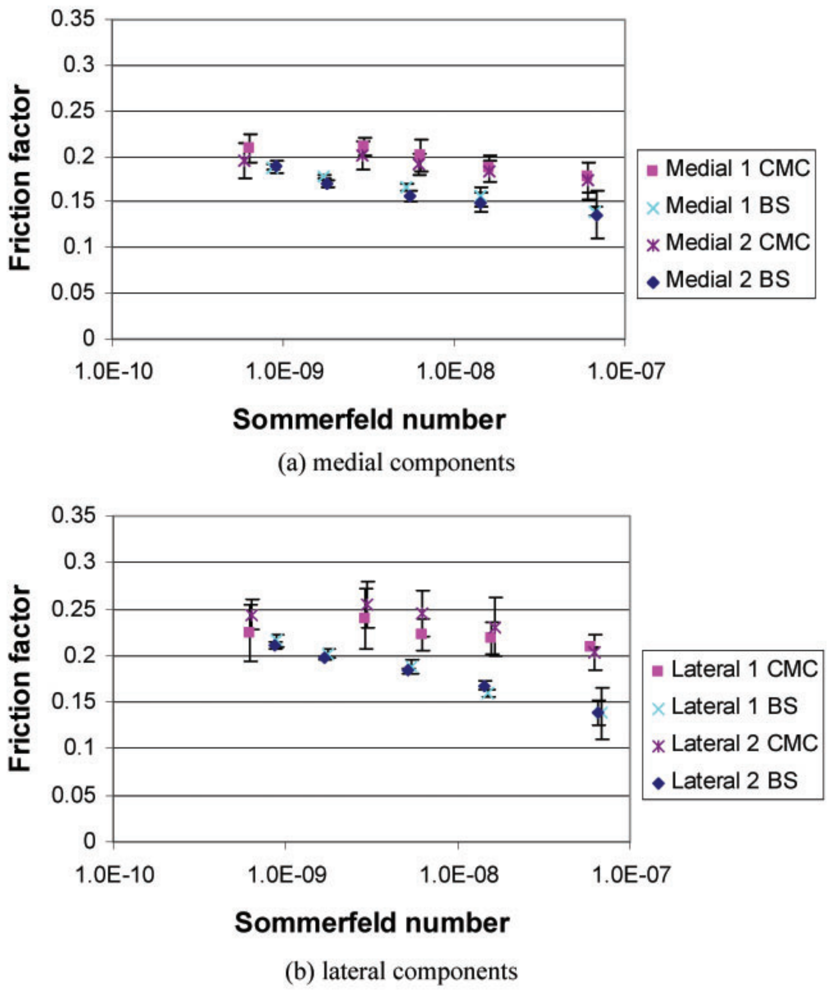


Fig. 4 Stribeck plots for (a) the medial and (b) the lateral unicondylar Co–Cr–Mo-on-CFR PEEK knee joints prior to wear as measured on the friction simulator

higher load on the medial side than on the lateral side. The medial components gave higher wear than the lateral components (1.70 mm^3 per 10^6 cycles in comparison with 1.02 mm^3 per 10^6 cycles with the loaded soak control). This increase in wear on the medial side is likely to be due to the increase in load experienced by the medial bearings. However, in addition to the difference in load applied to the medial and lateral bearings, the meniscal bearings differed in design with the medial bearing having a flat underside while the lateral bearing was profiled, allowing slightly different motion. This, therefore, may also have had an effect on the wear rates produced by these components.

During the last 0.5×10^6 cycles of testing, two different batches of BS were used. There was an increase in the wear produced for the medial component of station 4 during this time. Although this coincided with the change in the batch of BS used for stations 3 and 4, more external rotation of station 4 had also occurred. Figures 2 and 3 show that the change in the batch of BS had no noticeable effect on the wear produced in the final 0.5×10^6 cycles for either component in station 3 or the lateral bearing in station 4. This suggests that the change in BS did not affect the wear performance of the joints and the jump in wear of the medial bearing in station 4 was more likely to be due to the extra rotation that had occurred in this station at this interval.

From Figs 2 and 3 it is clear to see that there is a jump in the wear at 3×10^6 cycles for the lateral component of station 2. As there was no obvious explanation for this, the results have been left unchanged in the calculation of the wear rates given in Table 1. However, if the wear rates for station 2 were calculated from 3×10^6 cycles onwards, this would result in wear rates that match more closely those found for the other joints (1.49 mm^3 and 0.81 mm^3 per 10^6 cycles as opposed to 2.73 and 2.45 mm^3 per

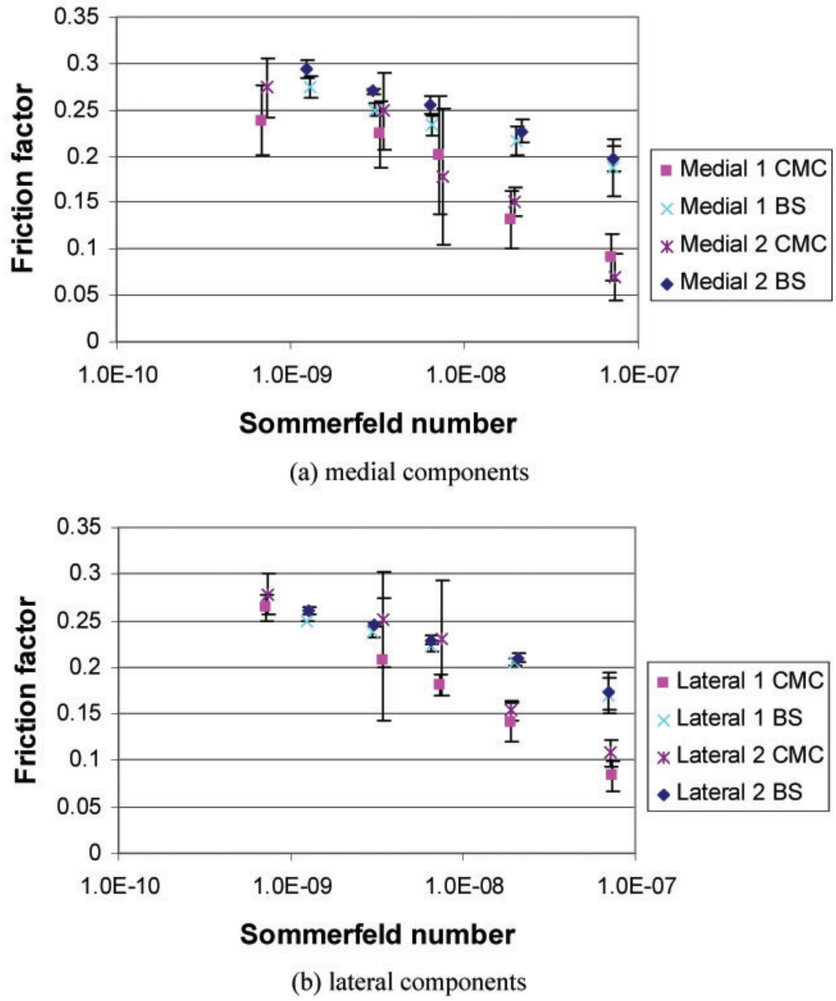


Fig. 5 Stribeck plots for (a) the medial and (b) the lateral unicondylar Co–Cr–Mo-on-CFR PEEK knee joints after 5×10^6 cycles wear as measured on the friction simulator

10^6 cycles for the medial and lateral joints of station 2 using the loaded soak control). Using these values as the wear rates provided by station 2, this gives average wear rates of 1.45 mm^3 and 0.70 mm^3 per 10^6 cycles (using the loaded soak control) for the five stations.

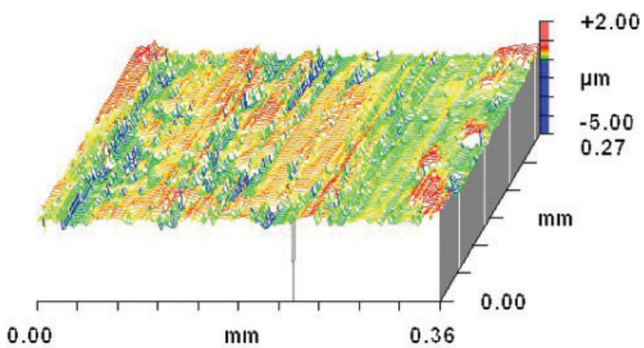


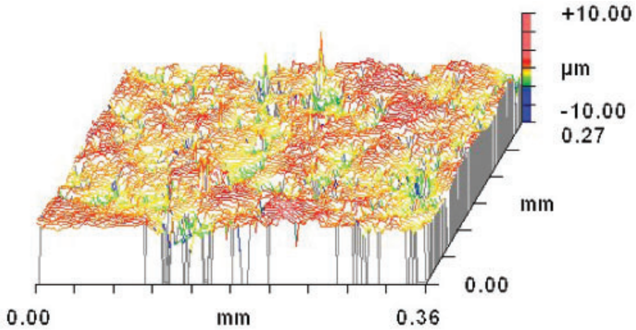
Fig. 6 Surface topographical image of a CFR PEEK meniscal bearing after the initial friction tests (pre-wear)

Other researchers have measured the wear of unicondylar knees. Laurent *et al.* [**20**] studied metal-on-UHMWPE unicondylar components and found the wear to be 6.58 mg and 2.93 mg per 10^6 cycles for the medial and lateral bearings respectively. Using a density of 983 kg/m^3, volumetric wear rates can be calculated to be 6.69 mm^3 and 2.98 mm$^3 \times 10^6$ cycles for the medial and lateral bearings respectively, which is approximately three times the wear rates found in this study. The CFR PEEK joints, therefore, show lower wear than that found for UHMWPE joints.

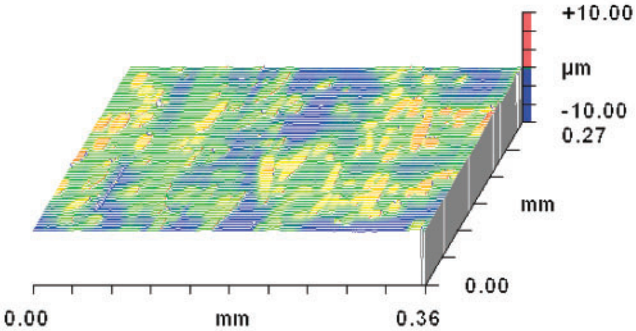
Metal-on-UHMWPE knee joints, tested under similar conditions to this test and on the same simulator, have shown volumetric wear rates of 3.23 mm^3 per 10^6 cycles and 4.06 mm^3 per 10^6 cycles for the entire knee (Kinematic and Kinemax bearings respectively) using an unloaded soak control

Table 2 Average surface topography for the medial and lateral bearings (top surface)

Number of cycles	Medial bearings $S_{r.m.s.}$ (μm)	Medial bearings S_a (μm)	Medial bearings S_{sk}	Lateral bearings $S_{r.m.s.}$ (μm)	Lateral bearings S_a (μm)	Lateral bearings S_{sk}
0	1.664	1.091	−1.750	0.857	0.558	−3.597
1×10^6	0.308	0.159	−7.092	0.144	0.079	−2.509
3×10^6	0.138	0.081	−2.961	0.101	0.066	−2.592
5×10^6	0.158	0.080	−6.484	0.114	0.068	−4.628



(a) pre-wear



(b) post-wear

Fig. 7 Surface topographical images of a CFR PEEK meniscal bearing both (a) pre-wear and (b) post-wear testing

[**14**]. This compares with the average value of 2.90 mm^3 per 10^6 cycles for both the medial and the lateral components combined in this study (under the same test conditions, using the unloaded soak control).

The volumetric wear of retrieved UHMWPE unicondylar knee prostheses was measured by Ashraf *et al.* [**21**]. The prostheses were retrieved after implantation for between 13 months and 156 months (in the majority of cases, revision was necessary because of the progression of osteoarthritis). The mean wear was found to be 17 mm^3/year.

The wear of 16 revised UHMWPE Oxford unicompartmental knee joints was measured by Psychoyios *et al.* [**22**]. They found a mean volumetric wear rate of 6 mm^3/year.

Figures 8 and 9 show the friction results found in this study but these are presented differently from those shown in Figs 4 and 5. In these figures the average friction factors produced with the different lubricants are compared both pre- and post-wear testing for all the samples tested. The CMC fluids tests enabled the lubrication regime acting within the joints to be more accurately assessed. This is because this lubricant has similar rheological properties to synovial fluid (i.e. shear thinning) but contains no proteins that are likely to adsorb to the bearing surfaces and interfere with the friction

Table 3 Average surface topography for the medial and lateral bearings (bottom surface)

Number of cycles	Medial bearings $S_{r.m.s.}$ (μm)	Medial bearings S_a (μm)	Medial bearings S_{sk}	Lateral bearings $S_{r.m.s.}$ (μm)	Lateral bearings S_a (μm)	Lateral bearings S_{sk}
0	0.948	0.679	−1.492	1.311	0.885	−1.584
1×10^6	0.755	0.563	−1.207	0.476	0.264	−6.337
3×10^6	0.577	0.365	−3.715	0.513	0.293	−5.417
5×10^6	0.838	0.596	−1.954	0.733	0.389	−5.446

Table 4 Average surface topography for the tibial components

Number of cycles	Medial component $S_{r.m.s.}$ (μm)	Medial component S_a (μm)	Medial component S_{sk}	Lateral component $S_{r.m.s.}$ (μm)	Lateral component S_a (μm)	Lateral component S_{sk}
0	0.043	0.034	0.083	0.034	0.025	0.232
1×10^6	0.050	0.039	−0.201	0.046	0.035	−0.091
5×10^6	0.052	0.040	−0.318	0.074	0.048	−0.955

Table 5 Average surface topography for the femoral condyles

	Medial component			Lateral component		
Number of cycles	$S_{r.m.s.}$ (μm)	S_a (μm)	S_{sk}	$S_{r.m.s.}$ (μm)	S_a (μm)	S_{sk}
0	0.044	0.033	0.687	0.047	0.035	0.667
1×10^6	0.103	0.081	−0.289	0.080	0.062	−0.496
5×10^6	0.077	0.074	−0.088	0.120	0.096	−0.207

factor values measured. Protein adsorption has been shown either to increase or to decrease the friction, depending on the lubrication regime under which the joint is operating [**23**]; however, it will not affect the mode of lubrication under which these joints are acting.

In Fig. 8, using CMC fluids as the lubricant, these results showed that the joints exhibited boundary–mixed lubrication prior to the wear test. Post-wear the joints showed a definite downward trend, implying mixed lubrication which gives similar friction factors to those measured pre-wear at the lower viscosities but lower friction at the higher viscosities. This may be due to smoothing of the CFR PEEK surfaces during the wear test (see Table 2) which has been observed in previous ceramic-on-CFR PEEK wear tests [**24**]. The friction factors produced by these metal-on-CFR PEEK unicondylar knee joints are considerably higher than those found for conventional metal-on-UHMWPE knees [**15**]. The BS tests

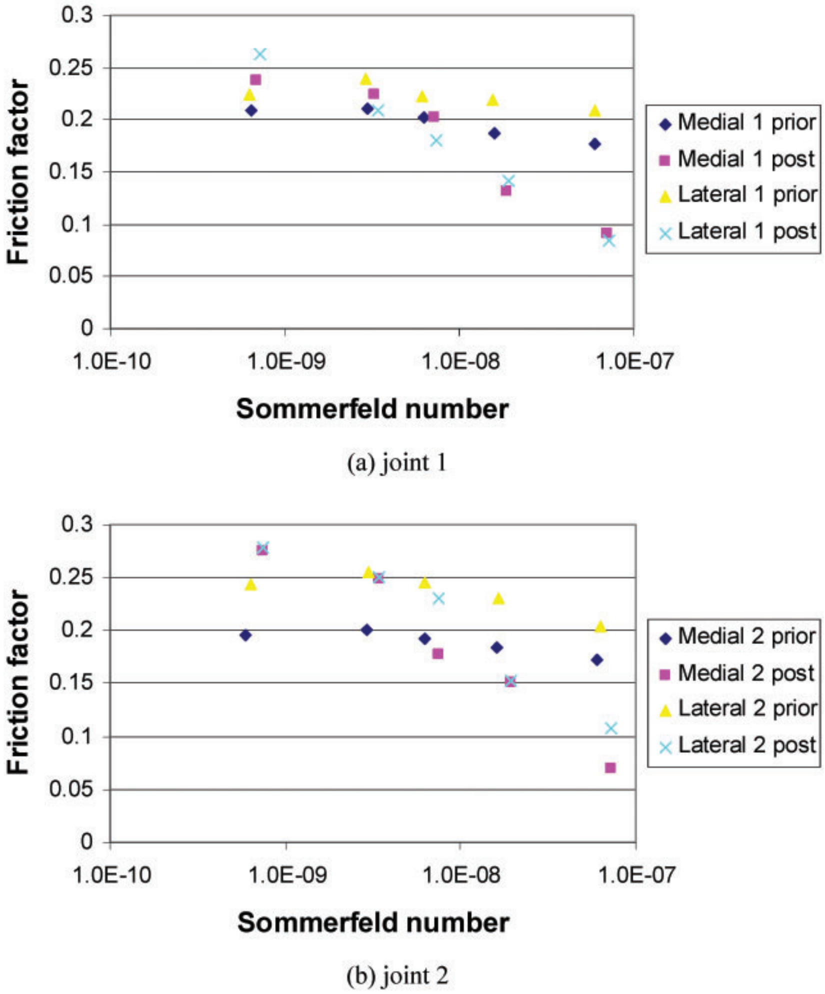
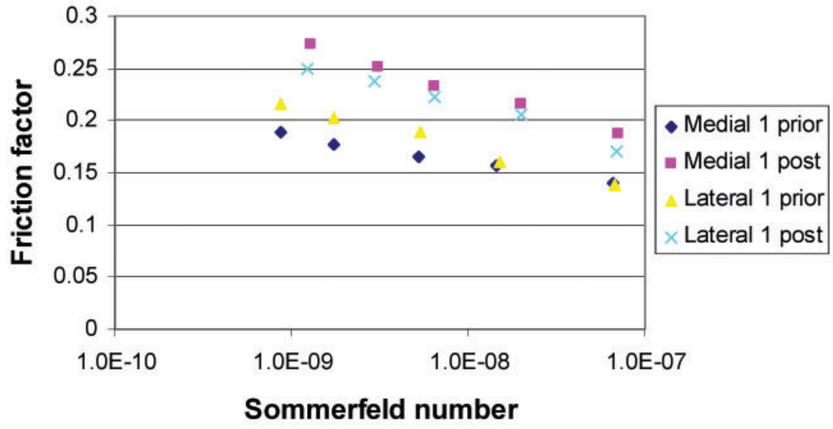
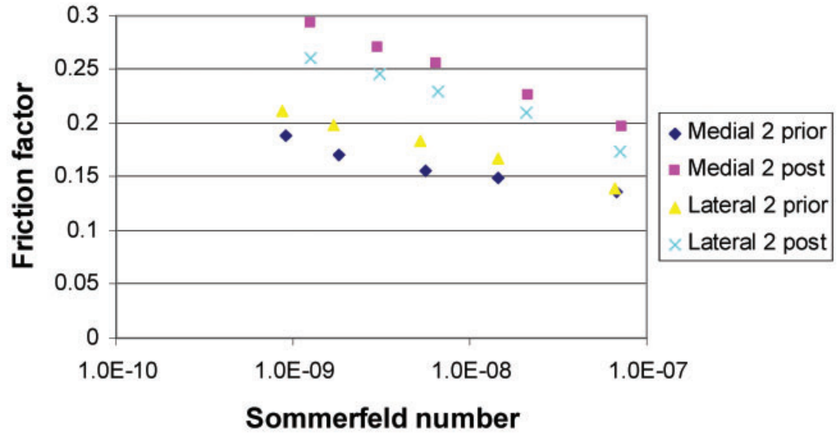


Fig. 8 Pre- and post-wear Stribeck plots for both the medial and the lateral components of (a) joint 1 and (b) joint 2 (Co–Cr–Mo-on-CFR PEEK) using CMC fluids as the lubricant



(a) joint 1



(b) joint 2

Fig. 9 Pre- and post-wear Stribeck plots for both the medial and the lateral components of (a) joint 1 and (b) joint 2 (Co–Cr–Mo-on-CFR PEEK) using BS as the lubricant

(shown in Fig. 9) showed higher-friction post wear for all viscosities.

In boundary–mixed lubrication there is more contact of the bearing surfaces than in mixed lubrication. When BS is used as the lubricant, a protein layer may form on the bearing surfaces, which will lead to a decrease in the friction produced as protein–protein contact will result in lower friction than CFR PEEK–metal contact. Therefore, pre-wear the friction factors produced using BS as the lubricant were lower than when using CMC fluids. As the CFR PEEK surface becomes smoother and more negatively skewed during the wear test, the joints move more towards operating in the mixed mode of lubrication (see Fig. 8). Therefore, when using CMC fluids there is less asperity contact than during the pre-wear tests and more of the surface asperities are separated by the lubricant film. When using BS as the lubricant, a protein layer will form (as it did pre-wear) and some asperities that were not in contact in the post-wear CMC fluids tests could now be in protein–protein contact, which will result in higher friction than the shearing of the CMC lubricant film. Therefore, the BS friction tests on the smoother surfaces post-wear testing will result in higher friction than the post-wear CMC tests will.

5 CONCLUSIONS

The pitch-based CFR PEEK unicondylar knee joints performed well in these wear tests. They gave lower volumetric wear rates than conventional metal-on-UHMWPE prostheses have given in the past when tested under similar conditions. The friction tests showed that, at physiological viscosities, these joints operate in the boundary–mixed lubrication regime.

The wear rates calculated using the loaded soak control were slightly lower than those using the unloaded soak control. As these joints undergo a dynamic loading cycle during testing, in order to simulate the lubricant absorption of these components correctly, a loaded soak control is the preferable option as this is more likely to give more accurate results.

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APPENDIX 1

Notation

f	friction factor
L	applied load
r	radius of the femoral condyle in the anterior–posterior plane
S_a	centre-line average surface roughness
$S_{r.m.s.}$	r.m.s. surface roughness
S_{sk}	skewness value of surface topography
T	frictional torque
u	entraining velocity
Z	Sommerfeld number
η	lubricant viscosity

APPENDIX 2

Cleaning–drying–weighing protocol for Invibio/Biomet knees

This protocol is according to ISO 14243-2:2000 [**17**].

1. Rinse in deionized water.
2. Place in ultrasonic bath in deionized water for 10 min.
3. Rinse in deionised water.
4. Place in ultrasonic bath in weak Neutracon solution for 10 min.
5. Rinse in deionized water.
6. Place in ultrasonic bath in deionized water for 10 min.
7. Rinse in deionized water.
8. Place in ultrasonic bath in deionised water for 3 min.
9. Rinse in deionized water.
10. Dry with a jet of filtered inert gas.
11. Rinse in isopropanol and wipe with a lint-free wipe (all surfaces).
12. Dry with a jet of inert gas.
13. Place in the vacuum oven at room temperature for 30 min.
14. Weigh to achieve three consecutive readings which agree within 0.1 mgf (within 90 min).