Wear of ceramic-on-carbon fibre reinforced poly-ether-ether ketone hip replacements

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ABSTRACT

Total hip replacement has been a successful surgical intervention for over fifty years, with the majority of bearings utilising a polyethylene cup. Long-term failure due to osteolysis and loosening has been widely documented and alternative bearings have been sought. A novel carbon-fibre reinforced poly-ether-ether ketone (CFR-PEEK) cup was investigated through experimental friction and wear studies. Friction studies demonstrated the bearings operated in a boundary lubrication condition, with friction factors higher than those for other hip replacement bearings. The wear study was conducted with 36mm diameter bearings tested against Biolox Delta heads for a period of 10 million cycles. The mean volumetric wear rate was 0.3mm^3/Mc, indicating the ceramic-on-CFR-PEEK bearing to be a very low wearing option for total hip replacement.

KEYWORDS

Hip replacement, wear, friction, carbon-fibre reinforced PEEK

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Introduction

Total hip replacements have been a highly successful surgical intervention for over fifty years. Bearings with an ultra-high molecular weight polyethylene (UHWMPE) cup articulating with either a metallic or ceramic head continue to be most widely implanted, with good clinical performance and long-term survivorship over 75% at 20 years follow-up[1]. Failure of polyethylene hip bearings is frequently associated with osteolysis and loosening of the bearings[2,3]. Wear debris is produced from the articulating surfaces of a total hip replacement with every step taken and every activity performed, therefore it may be assumed that, for a particular bearing combination, the wear debris produced is linked to the activity levels of the patient. The occurrence of osteolysis is closely linked to the size of the wear debris particles and the volume of wear debris produced. UHMWPE particles are mainly in the size range of 0.1-1.0µm and are biologically active[4]. Alternative material combinations have been introduced to reduce the wear volume, and thus also reduce the potential for osteolysis. Cross-linked and stabilised polyethylene bearings with increased wear resistance have been utilised[5] in addition to hard-on-hard bearings such as metal-on-metal[6], ceramic-on-ceramic[7], and most recently, ceramic-on-metal[8,9]. Cross-linked polyethylene has been shown experimentally to have lower wear rates than conventional polyethylene[10]; however, the particles generated have been shown to be more biologically reactive than conventional UHMWPE[11], although functional biological activity, which is a function of biological activity and wear volume and thus predicts more closely the potential to cause osteolysis is reduced due to the reduction in wear volume. Short to mid-term clinical studies have demonstrated improved wear performance compared with conventional polyethylene[12], and reduced incidence of osteolysis[13] However, concerns remain regarding long term clinical fatigue performance under adverse conditions such as edge loading[14]. Metal-on-metal bearings also show significantly lower wear rates compared with conventional polyethylene experimentally[6,15], and the potential for osteolysis is reduced[16]. However, there are concerns regarding the systemic effects of elevated Co and Cr metal ions[17-21] in addition to clinical incidence of metal hypersensitivity and allergy responses[22-24]. Ceramic-on-ceramic bearings have also shown very low wear rates experimentally[7,9,15], but the designs are limited by the mechanical properties of the ceramic, preventing thin cups due to risk of fracture. In addition, squeaking has become a clinical issue in recent years, specifically relating to ceramic-on-ceramic bearings, with the cause not yet fully understood[25-28].

Novel bearing materials are being sought to reduce volumetric wear, improve stability and performance and increase longevity, whilst preventing the systemic effects which may occur with some of the current clinically used bearings. Carbon-fibre reinforced poly-ether –ether ketone (CFR-PEEK) has been investigated as an alternative bearing material for a variety of orthopaedic applications since the early 1990s[29], with studies demonstrating a reduction in wear of CFR-PEEK cups tested with zirconia heads compared with a conventional PE cup[30]. More recent tribological studies have also illustrated excellent wear performance in a variety of bearing configurations[31-35].

The aim of this study was to examine the wear and friction of a novel CFR-PEEK cup through a series of in-vitro studies, and to compare the performance of these bearings with more conventional total hip replacement materials from previously reported studies.

Materials and Methods

Materials

Off-the-shelf, clinically available 36mm diameter Biolox Delta ceramic and cobalt chrome heads (supplied by DePuy International Ltd, UK) were paired with custom-made extruded carbon-fibre reinforced PEEK (pitch based) cups (MOTIS^{TM} polymer from Invibio Biomaterial Solutions, UK) for friction and wear testing. All samples were measured for dimension and surface roughness prior to the study using a coordinate measuring machine (accuracy 1µm, resolution ±3µm; Kemco, UK) and two dimensional contacting profilometry (Form Talysurf Series, Taylor-Hobson, Leicester, UK), respectively. Four 36mm diameter cross-linked UHMWPE cups (5MRad cross-linked GUR 1050 UHMWPE, supplied by DePuy International Ltd, UK) were also tested as control samples for the friction study, articulated with Biolox Delta ceramic and cobalt chrome heads, as previously noted. The bearing combination, test configuration and initial measurement results are shown in Table 1. The CFR-PEEK wear samples were soaked in deionised water for a period of 20 weeks prior to the commencement of the wear study, and cleaned and weighed at intervals to assess fluid uptake. At the end of this soak period, a further geometric measurement was completed on each cup to determine whether the fluid uptake had caused any notable changes in geometry.

Friction Test Method

The friction of 36mm CFR-PEEK and cross-linked UHMWPE bearings was investigated using a single station pendulum friction simulator (Simulator Solutions, UK) using methods previously described by Brockett et al [36]. Tests were performed in an inverted position with respect to anatomical, with the cup positioned with the face of the cup horizontal, and perpendicular to the loading axis. Testing was conducted at a frequency of 1Hz, with a flexion extension motion of ± 25^{o} applied to the femoral head. A simple sinusoidal waveform was used through 60% of the cycle to apply a dynamic load with a peak of 2 kN and with a constant load of 100N applied throughout the rest of the cycle as the swing phase load. Testing was conducted in water, 25% bovine calf serum (16 g/L protein concentration) and 100% bovine serum (64g/L protein concentration) to investigate the effect of protein concentration on friction. All tests were conducted on new, unworn samples for a period of 300 cycles, and friction factor calculated as previously reported[36].

Wear Test Method

Five ceramic-on-CFR-PEEK bearings were tested in a ten-station Prosim hip wear simulator (Simulator Solutions, UK). The femoral heads were mounted onto tapered spigots, and the CFR-PEEK cups were supported by a cement mantle. The mounting of both bearings allowed the removal of the components at intervals throughout the study for wear assessment. The cups were mounted at 35^{o} to the horizontal plane and positioned anatomically with respect to the femoral head, This is equivalent to a clinical angle of 45^{o}. The femoral components were mounted vertically beneath the cups, resulting in contact occurring at the pole of the head. The simulator applied a flexion–extension of -15^{o} to +30^{o} to the head, and an internal–external rotation of ± 10^{o} to the cup. The motions were 90^{o} out of phase to generate open elliptical wear paths which produced clinically relevant amounts of cross shear as described previously[37]. Twin peak time-dependent loading was applied vertically to the femoral head. A peak load of 3kN and a swing phase load of 280N (ISO14242-1) were used. One sample was setup to be a loaded soak control, which was loaded as with the wear samples, but did not undergo any motion. Three additional cups were used as unloaded soak controls. The test was conducted for 10 million cycles at a frequency of 1 Hz.

Testing was conducted in 25% (v/v) newborn bovine serum (16 g/L protein concentration), supplemented with 0.03% (w/v) sodium azide solution to retard bacterial growth. The serum was changed every 330 000 cycles and the components cleaned in-situ in the simulator as previously reported [11,15,21]. The samples were removed from the simulator and cleaned at 1, 3, 5, 7 and 10 million cycles. After being removed from the simulator and the fixtures the test specimens were washed in detergent water to remove all visible matter, ultrasonically cleaned in detergent water for 10 min, rinsed in water, soaked in Trigene for 10 minutes to kill bacteria, rinsed with deionized water, ultrasonically cleaned for 10 minutes in 70% isopropanol [21] and then allowed to air dry in a controlled environment for 72 hours before weighing. During the soak control studies, it was found that the CFR-PEEK cups took 72 hours before reaching an equilibrium mass, compared with 48 hours used for UHMWPE studies[11]. The components were weighed using Mettler Toledo AT201 balance (Leicester, UK, accurate to 10 µg). Each component was weighed five times and an average weight determined. Gravimetric measurements were converted to volumetric wear using a density for CFR-PEEK of 1.4g/cm^3. Loaded and unloaded CFR-PEEK cups were used as soak controls, and a correction for moisture uptake was applied to the test samples based on this data. Statistical analysis for the studies was conducted using one-way ANOVA.

Results

Friction Study

A comparative study examining the effect of lubricant and material on the friction of a CFR-PEEK cup was performed. Both the metal-on-CFR-PEEK (MoCFR-PEEK) and ceramic-on-CFR-PEEK (CoCFR-PEEK) bearings showed increasing friction with increasing serum concentration (Figure 1), with the lowest friction measured in water. A significant difference in friction was measured between the water and serum lubricated studies for both the metal and ceramic on CFR PEEK bearings (ANOVA, $p<0.05$). There was no significant difference between the friction of the ceramic or metal bearings under all test conditions (ANOVA, $p>0.05$).

The friction factors of the CFR-PEEK and cross-linked UHMWPE bearings were compared under 25% serum lubricant conditions (Figure 2). The friction for both the CFR-PEEK bearings was significantly higher than the friction for the cross-linked UHMWPE (CoXLP and MoXLP) bearings (ANOVA, $p<0.05$).

Wear Study

Previous literature has indicated that weight gain through fluid uptake may have a significant effect upon the wear measurements of CFR-PEEK bearings[33], and therefore the authors investigated the fluid uptake of the CFR-PEEK cups prior to the start of the wear study. Assessment of the fluid uptake over a period of weeks showed the cups reached equilibrium after approximately 12 weeks of soaking (Figure 3), and on average increased in mass by 0.038 ± 0.001g (approximately 0.2% increase from initial weight). Geometric measurement pre- and post-soak showed no significant changes in cup dimensions, with a mean diameter of 36.100 ± 0.009 mm prior to soak, and 36.099 ± 0.009 mm post soak.

Wear was assessed gravimetrically throughout the study at a number of intervals. It was interesting to note the weight change behaviour of the soak controls throughout the study (Figure 4). The loaded soak control had a mass loss during the first million cycles of the study, and then gained weight throughout the remainder of the study. The unloaded soak control samples maintained weight after the first million cycles of testing, but then gained weight at a similar rate to the loaded soak control for the remaining cycles. A previous study[33] has noted that the wear rates calculated will vary depending on which soak control is used, and therefore the authors have corrected for fluid uptake by a mean value of the loaded and unloaded soak controls throughout this study.

The CFR-PEEK bearings exhibited a step-like wear behaviour throughout the study (Figure 5), with periods with a higher wear rate (approximately 0.4 -1.4 mm^3/Mc), and periods with a lower wear rate (below 0.4 mm^3/Mc), a phenomenon which has been reported previously[33]. The overall wear rate for the 36mm CFR-PEEK cups during the 10Mc study was very low at 0.30 ± 0.07 mm^3/Mc. The wear rate during the first phase of the study (0-5Mc; 0.42 ± 0.05 mm^3/Mc) was higher than the second stage of the study (5-10Mc; 0.22 ± 0.03 mm^3/Mc), although due to the step wise nature of the wear it did not appear that a 'bedding-in' phenomenon occurred as has been observed in other hip replacement bearings. Examination of the cup surfaces showed a polished region, corresponding to the wear area. The mean surface roughness (Ra) decreased by approximately 35% over the study, with a final mean Ra of 0.34µm. There was no significant change in the surface texture of the ceramic femoral heads throughout the wear study.

Discussion

Carbon-fibre reinforced poly-ether-ether-ketone (CFR-PEEK) has been studied as an alternative cup bearing material for total hip replacement. Friction studies were performed to investigate the effect of lubrication and material on the performance of CFR-PEEK. Although friction is no longer reported as a major clinical factor in failure of total joint replacement, measurement of friction provides a useful indication of the lubrication of a bearing[38]. This study highlighted a significant increase in friction factor for both the MoCFR-PEEK and CoCFR-PEEK bearings with increasing protein concentration. A similar trend has been reported previously[33,39], and the same characteristics have been shown with UHMWPE bearings[36,40]. The force required to shear the increased concentration of proteins may result in the increased friction factor. The head material did not affect the friction of the hip, with both ceramic and metal-on-CFR-PEEK exhibiting similar friction factors for all lubricant conditions.

The friction factor measured in this study was higher than that previously reported by Scholes et al [33], however, it should be noted that the previous study used a thickening agent to modify the viscosity of the lubricant, and this may have resulted in lower friction. Furthermore, the recent Flanagan et al study[39] demonstrated a size dependent effect for friction with CFR-PEEK bearings, and thus the increased friction reported in this study correlates well with the reduced head size compared with the Scholes et al study. In addition, it should be noted that both the Flanagan et al[39] and Scholes et al [33] papers have investigated a flexible horse-shoe shaped cup rather than a fully formed cup configuration, and thus the increased flexibility in the other studies may have acted to enhance lubrication and thus reduce the friction.

The relatively high friction factors measured within this study suggest the CFR-PEEK bearings operate within a boundary lubrication regime[41], however Stribeck analysis was not performed within this study, and previous analysis has suggested that CFR-PEEK bearings may operate within a boundary-mixed lubrication regime[33]. The friction factors are significantly higher than those measured under identical conditions for several other total hip bearing combinations[42] of the same diameter. In addition to differing material properties, this study has shown the CFR-PEEK cups to have comparatively high surface roughness. A previous study examining the friction of carbon fibre reinforced materials through simple geometry pin-on-disk studies has shown the friction of CFR-PEEK to be dependent on surface roughness[43], and therefore one may conclude that action to reduce the surface roughness of the CFR-PEEK material may result in reduced friction.

Although friction in conventional total hip replacements is no longer of significant clinical concern, the friction factors measured for the CFR-PEEK bearings are significantly higher than those of conventional bearing couples. There has been documentary evidence that frictional heating may occur within an artificial joint replacement, but the authors demonstrated this varied with the thermal properties of the bearing and several other factors[44]. They also noted that thermally-induced necrosis had not been reported. A more recent study examining percutaneous temperature changes following walking for a range of hip replacement materials demonstrated a ceramic-on-PEEK bearing to have a lower temperature increase than more conventional material combinations such as metal-on-polyethylene[45]. This may indicate that friction is not the only factor in determining the level of heat generated in a joint. Elevated frictional torque has been noted to cause clinical loosening, although studies have also indicated that this is not the primary mechanism for failure [46].

A study of the fluid uptake by the CFR-PEEK cups was conducted prior to the wear study. The mean weight of the cups stabilised after approximately 12 weeks, indicating that an equilibrated fluid absorption level had occurred and no further fluid was absorbed. This period is significantly longer than the period generally allowed for fluid uptake in polyethylene bearings pre-test, which tend to use 2-4 weeks[47]. However, although the time period was longer, the fluid uptake behaviour of the cups showed a similar biphasic trend that has previously been observed in carbon-fibre reinforced polyethylene and conventional polyethylene[48]. This extended period before fluid uptake equilibrium is reached should be noted, as for a low wearing bearing such as CFR-PEEK, this effect could have a significant impact upon the measured wear when assessed gravimetrically. The measured loss in weight of the loaded soak controls during the first million cycles may have been due to fluid that had been absorbed under unloaded soak conditions being squeezed out during the first few cycles of the study.

The wear rates observed in this study were low, with a mean wear rate over the 10 million cycle study of 0.30 ± 0.07mm^3/Mc. Contrasting the overall mean wear rate with a previously reported wear study of 36mm bearings in current clinical use, under comparable conditions[9], showed the CFR-PEEK material to be within the same order of magnitude as metal-on-metal bearings (Figure 6). Comparison of the CFR-PEEK data with experimental studies of UHMWPE and cross-linked UHMWPE showed the CFR-PEEK bearings to have lower wear (Table 2), however it is important to note that the wear assessment technique and experimental method is not consistent therefore it is not possible to draw statistical significance from this comparison.

Two previous studies have investigated the wear of CFR-PEEK in a hip configuration. The wear rates measured within the current study are comparable with the study by Wang et al, which reported a mean wear rate of 0.39mm^{3}/Mc for a study of 28mm bearings articulating with a zirconia ceramic head[30]. The wear rate in this study was lower than that reported by Scholes et al (1.16mm^{3}/Mc over a 25 million cycle study), however the previous study examined a large diameter flexible horse-shoe cup and hence both the bearing geometry and size might have affected the wear rate[33]. The present friction studies indicate that CFR-PEEK bearings operate within a boundary lubrication regime; hence it may be assumed that the reduction in bearing diameter compared to the previous study resulted in reduced sliding distance and thus reduced surface wear.

The wear behaviour of the CFR-PEEK exhibited a 'step-wise' trend which has been observed previously[33]. This may be due to the composition of the material, with the two phases of wear relating to loss of carbon fibre material and loss of PEEK matrix material.

As noted previously, the fluid uptake behaviour of the CFR-PEEK bearing may have a significant effect upon the wear measurements. During this study gravimetric assessment was used for the analysis of wear, but previous studies of cross-linked polyethylene have employed geometric assessment using co-ordinate metrology. The wear rates calculated in this study indicate that assessment with the CMM, with a resolution of ±3µm, may not have been able to determine the wear. A low wearing material which undergoes fluid absorption presents a difficult task for wear assessment, and the full analysis of such materials is limited by current measurement techniques.

Biological studies investigating the response to CFR-PEEK wear particles have demonstrated that CFR-PEEK particles had no cytotoxic effects on cells in the ranges studied when compared with CoCr wear particles[49]. A more recent study investigating the inflammatory response to CFR-PEEK particles compared the effects of UHMWPE particles with two types of CFR-PEEK materials through in-vivo studies of mice and histological assessment, with identical particle dosing[50]. The authors found CFR-PEEK to have comparable biological activity to conventional UHMWPE. When considering this in the context of the present study, it appears that CFR-PEEK is a promising alternative bearing material.

CONCLUSION

This study has demonstrated the ceramic-on-CFR PEEK bearing to be a low wearing option for total hip replacement. Elevated friction of the novel bearings, compared with more conventional materials was noted, and further investigation is required to determine the clinical significance of this factor, with respect to frictional heating and fixation. However, when considering the wear data in the context of current literature examining the biological activity of the wear debris, with no evidence of cytotoxicity compared with CoCr particles, and comparable biological activity to UHMWPE at the same dosage, ceramic-on-CFR PEEK bearings are a promising alternative bearing option for total hip replacement.

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