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RAPID COMMUNICATION

The influence of lubricant temperature on the wear of total knee replacements

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Abstract
Experimental in vitro simulation can be used to predict the wear performance of total knee replacements. The in vitro simulation should aim to replicate the in vivo loading, motion and environment experienced by the joint, predicting wear and potential failure whilst minimising test artefacts. Experimental wear simulation can be sensitive to environmental conditions; the environment temperature is one variable which should be controlled and was the focus of this investigation. In this study, the wear of an all-polymer (PEEK-OPTIMA™ polymer-on-UHMWPE) total knee replacement and a conventional cobalt chrome-on-UHMWPE implant of similar initial surface topography and geometry were investigated under elevated temperature conditions. The wear was compared to a previous study of the same implants under simulator running temperature (i.e. without heating the test environment). Under elevated temperature conditions, the wear rate of the UHMWPE tibial inserts was low against both femoral component materials (mean <2 mm^3/million cycles) and significantly lower ($p < 0.05$) than for investigations at simulator running temperature. Protein precipitation from the lubricant onto the component articulating surfaces is a possible explanation for the lower wear. This study highlights the need to understand the influence of different variables including environmental temperature to minimise the test artefacts during wear simulation which may affect the wear rates.

KEYWORDS
biotribology, PEEK, total knee replacement, UHMWPE, wear

1 | INTRODUCTION

Total knee replacement (TKR) is a highly successful treatment for relief of the pain from osteoarthritis of the knee with >100,000 procedures carried out annually in the UK [1]. Preclinical investigations can help inform device performance prior to implantation and a number of international standards have been developed to replicate the biomechanics and biotribology of total knee replacements in the laboratory [2, 3]. Continuous wear simulation of knee replacements can allow 10 years in vivo use to be replicated in the laboratory in as little as 6 months. There are a number of variables to be controlled within the simulation systems, the temperature of the lubricant being one of them. The international standards for wear simulation of total knee replacements specify the lubricant to be maintained at 37 ± 2°C [2, 3]. Heating, cooling, and/or rest periods have all been adopted to maintain the bulk lubricant temperature within the specified range [4]. Whilst it is difficult to compare intra-articular temperature measurements in the natural knee in vivo to in vitro simulator measurements due to the different volumes of fluid surrounding the joint, studies have shown the temperature in the knee in vivo to likely be lower than that specified in the standards. At rest, temperatures between 31 and 33.7°C have been recorded [5–7], only during prolonged exercise does the temperature reach 37°C [7, 8]. The in vitro and in vivo measurements have been either of the bulk lubricant/synovial fluid temperature or have been taken close to the articulating surfaces. It is likely that at the interface, the

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temperature is higher but taking these measurements whilst the simulator or subject is moving is challenging. In a hip wear simulation study by Liao et al, the temperature was measured via probes embedded 0.5 mm from the surface of different femoral head materials articulating against polyethylene cups. When the bulk lubricant temperature was maintained at ~37°C, for cobalt chrome heads, temperatures up to 50°C were recorded close to the articulating surface; with a ceramic implant higher temperatures were measured, up to 70°C. On the ceramic surfaces, the formation of protein-rich deposits was also apparent. This demonstrates not only the difference between the bulk temperature and the temperature at the articulating surfaces when the simulator is run continuously, but also the magnitude of the temperature rise to be material dependent. The bulk lubricant temperature may therefore influence the biotribology of the bearing couple, in this case, through protein deposition on the articulating surfaces which influenced the wear rates of the hip replacements [4]. Such investigations have not been carried out for knee replacements.

PEEK-OPTIMA™ polymer has been considered as an alternative bearing material to cobalt chrome in the femoral components of total knee arthroplasty. There are several potential advantages of the use of PEEK polymers in this application [9–12]. Studies have shown PEEK materials to have good biocompatibility and relatively inert wear debris, a metal-free implant may be more suitable for patients with metal sensitivity reactions [13]. A PEEK femoral component would have a modulus closer to bone than cobalt chrome, potentially reducing stress shielding. Stress shielding can contribute to bone resorption and subsequent implant loosening [14–16]. Furthermore, the lower weight of a PEEK femoral component would be closer to that of the natural tissue than cobalt chrome and the radiolucency of the PEEK polymer also gives potential for improved imaging of the knee replacement and surrounding tissue in situ [17].

When carrying out pre-clinical wear simulation, especially of novel bearing materials, it is important to understand how different variables influence wear. In this study, the materials of interest were PEEK-OPTIMA™ polymer-on-UHMWPE for use in an all-polymer TKR [14, 15, 18–21] and conventional materials, cobalt chrome-on-UHMWPE. Previous investigations of PEEK-OPTIMA™ polymer-on-UHMWPE in simple geometry wear simulation have shown lubricant temperature to influence wear. Testing at elevated temperature (~35°C) led to artefacts including protein precipitation and deposition onto the articulating surfaces, which reduced the wear factor of the UHMWPE-on-PEEK-OPTIMA™ all-polymer bearing couple compared to investigations carried out at standard rig running (i.e. no lubricant heating) temperature (~27°C) when using a 25% bovine serum lubricant. Similar findings were not seen for UHMWPE-on-cobalt chrome [22], with similar wear factors reported for both temperature conditions when using a 25% bovine serum lubricant. Whilst simple geometry studies can indicate trends, they do not replicate the complex loading and motions in a joint replacement so it is not known whether the findings would be replicated in TKR simulation.

The aim of this study was to better understand the influence of lubricant temperature on the tribology of total knee replacements by investigating the wear of UHMWPE in cobalt chrome-on-UHMWPE and PEEK-OPTIMA™ polymer-on-UHWMPE total knee replacements at elevated temperature and to compare to previously published data of similar total knee replacements carried out under simulator running temperature conditions (i.e. without heating of the test environment or lubricant) [19]. It was hypothesised that bulk lubricant temperature would have no influence on the wear of the cobalt chrome-on-UHMWPE implant but that under elevated temperature conditions, the wear of the all-polymer knee would be lower than when tested at simulator running temperature. This is the first study to investigate the influence of bulk lubricant temperature on the wear of total knee replacements.

2 | MATERIALS AND METHODS

Cruciate retaining, mid-sized, right knee total knee replacements were used throughout. Three cobalt chrome femoral components (Maxx Freedom Knee, Maxx Medical, USA) and three injection moulded PEEK-OPTIMA™ femoral components (Invibio Knees Ltd, UK) of similar initial surface topography and geometry were tested against 6 GUR1020 all-polyethylene tibial components (Maxx Medical, USA) [19]. The tibial components were manufactured from GUR1020 ultra-high-molecular-weight-polyethylene; 2 additional tibial components were used for soak compensation. The PEEK femoral components were sterilised by Gamma irradiation 45 kGy +10% outside dose; cobalt chrome and all-polyethylene components were sterilised in Ethylene Oxide. The initial mean surface roughness (Ra) of the implants was 0.019 and 0.025 μm for cobalt chrome and PEEK respectively and the surface of the PEEK implants was as-moulded so no additional polishing or post-processing of the surfaces was carried out prior to wear simulation. The polyethylene was not cross-linked.

Prior to the start of the study, the UHMWPE was soaked in sterile water for a minimum of 2 weeks to maximise moisture uptake and the knee replacements set up on custom fixtures using Palacos R&G cement (Heraeus Medical GMBH, Germany) with the flexion axis positioned on the distal centre of rotation to facilitate femoral rollback [19]. The tibial and femoral components were paired for the duration of the investigation. Studies were carried out using a 6 station ProSim electropneumatic knee simulator (Simulation Solutions, UK) [23] (Figure 1). The simulator had six degrees of freedom with 4 controlled axes of motion. The axial force and flexion/extension were delivered through the femoral component; the anterior-posterior displacement and tibial rotation were delivered through the tibial component. The input kinematics were consistent with Leeds high kinematic displacement controlled input conditions, Figure 2 [3, 24–26] with a maximum axial force of 2800 N, a flexion/extension range 0–58°, anterior-posterior displacement up to 10 mm and tibial rotation ±5°. The axial force was offset 7% width of the tibial component in

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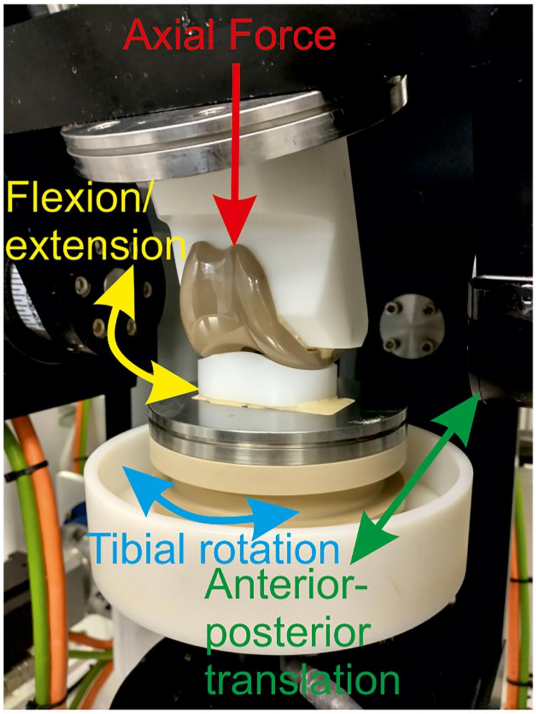

FIGURE 1 The driven axes of motion in the simulator and a PEEK femoral component coupled with an all-polyethylene tibial component.

the medial direction to give greater load sharing in the medial compartment [2, 3] and the abduction/adduction motion was unconstrained. The cycle frequency was 1 Hz.

The lubricant used was 25% bovine serum supplemented with 0.04% (v/v) sodium azide solution to give a final protein concentration of approximately 15 g/L. The lubricant was replaced approximately every 0.3 million cycles (MC). To increase the lubricant temperature, a heater system compromising a series of fan heaters and a closed loop control system was built into the simulator which raised the temperature of the environment above that of the simulator temperature, which in this study is termed 'elevated temperature' [22]. The temperature of the lubricant in the test cells was maintained at 33 ± 2°C for the all-polymer knee. A lower temperature than that specified in the ISO standard [2, 3] was used because in preliminary investigations undertaken at 37 ± 2°C, there was a high risk of bacterial growth in the lubricant, despite the addition of sodium azide. The comparative nature of this study meant that it was important for the lubricant and other test conditions to be consistent to that of the control investigation [19]. It was important to minimise bacterial growth within the lubricant which would likely change the tribology of the system and it was acknowledged that the temperature at the interface would likely be higher than that of the bulk lubricant [4]. The test conditions including the simulator used, grade of

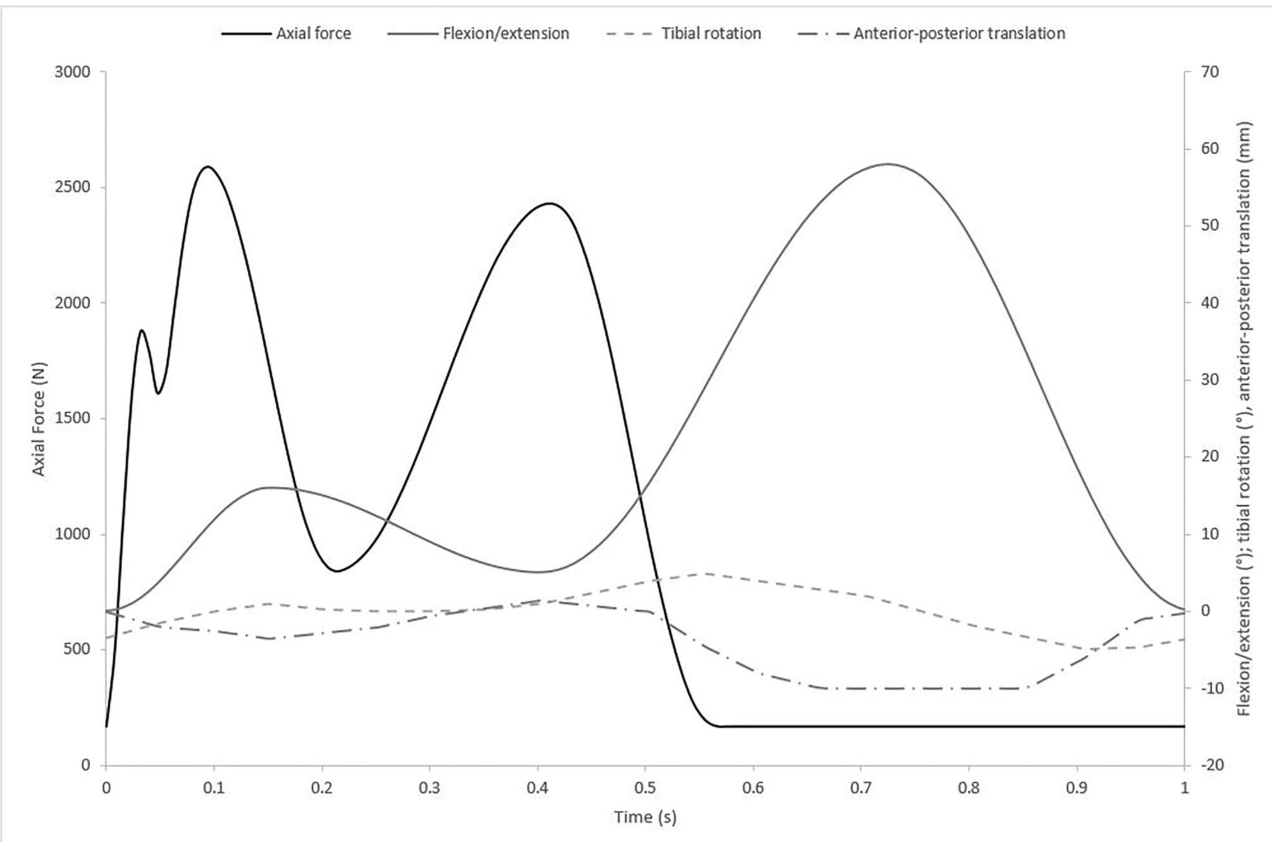

FIGURE 2 Simulator input profiles based on Leeds high displacement controlled kinematic conditions [24].

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polyethylene, lubricant, and component geometry were matched as closely as practicably possible with only the temperature of the environment differing between this study and that of the control investigation [19]. The study was run for 10 MC with gravimetric analysis of the UHMWPE tibial components every 2 MC (minimum). Prior to weighing, components were cleaned ultrasonically in 70% propan-2-ol before drying and being left to stabilise in a temperature (20 ± 1°) and humidity (45 ± 5%) controlled environment. Gravimetric analysis was carried out using an XP205 (Mettler Toledo, USA) digital microbalance with a resolution readability of 0.01 mg and a repeatability of 0.007 mg. Two identical unloaded soak controls were used to compensate for the uptake of moisture by the polyethylene. The wear rate of each implant was calculated using linear regression. The bulk lubricant temperature was monitored continually via thermocouples submerged in the lubricant inside the test cells, once the temperature inside the test cell had stabilised, measurements were recorded daily.

The mean wear rate and bulk lubricant temperature were calculated and expressed with ±95% confidence limits. Statistical analysis was carried out using ANOVA to compare UHMWPE wear rate at elevated temperature to previous wear simulation [19] at simulator running temperature (standard, control condition). Significance was taken at $p < 0.05$.

3 | RESULTS

After 10 MC wear simulation under elevated temperature conditions, the mean wear rate of the UHMWPE tibial components articulating against cobalt chrome femoral components was 0.19 ± 0.70 mm^3/MC, and against PEEK femoral components was 1.77 ± 0.90 mm^3/MC.

Figure 3 shows a comparison between the wear of UHMWPE against cobalt chrome and PEEK femoral components carried out at simulator running temperature [19] and at elevated temperature. Under simulator running temperature conditions, the mean wear rate of the UHMWPE tibial components was 2.23 ± 1.85 mm^3/MC and 4.44 ± 2.35 mm^3/MC articulating against cobalt chrome and PEEK femoral components respectively [19]. At elevated temperature, the wear rate of the UHMWPE tibial components was significantly lower against both material types, $p = 0.011$ and $P = 0.010$ for cobalt chrome and PEEK femoral components respectively.

The bulk lubricant temperature for each condition is shown in Figure 3. The mean bulk lubricant temperature of the cobalt chrome-on-polyethylene study was 31.4 ± 0.2°C and for the all-polymer bearing couple was 33.3 ± 0.5°C under elevated temperature conditions; under simulator running temperature, the

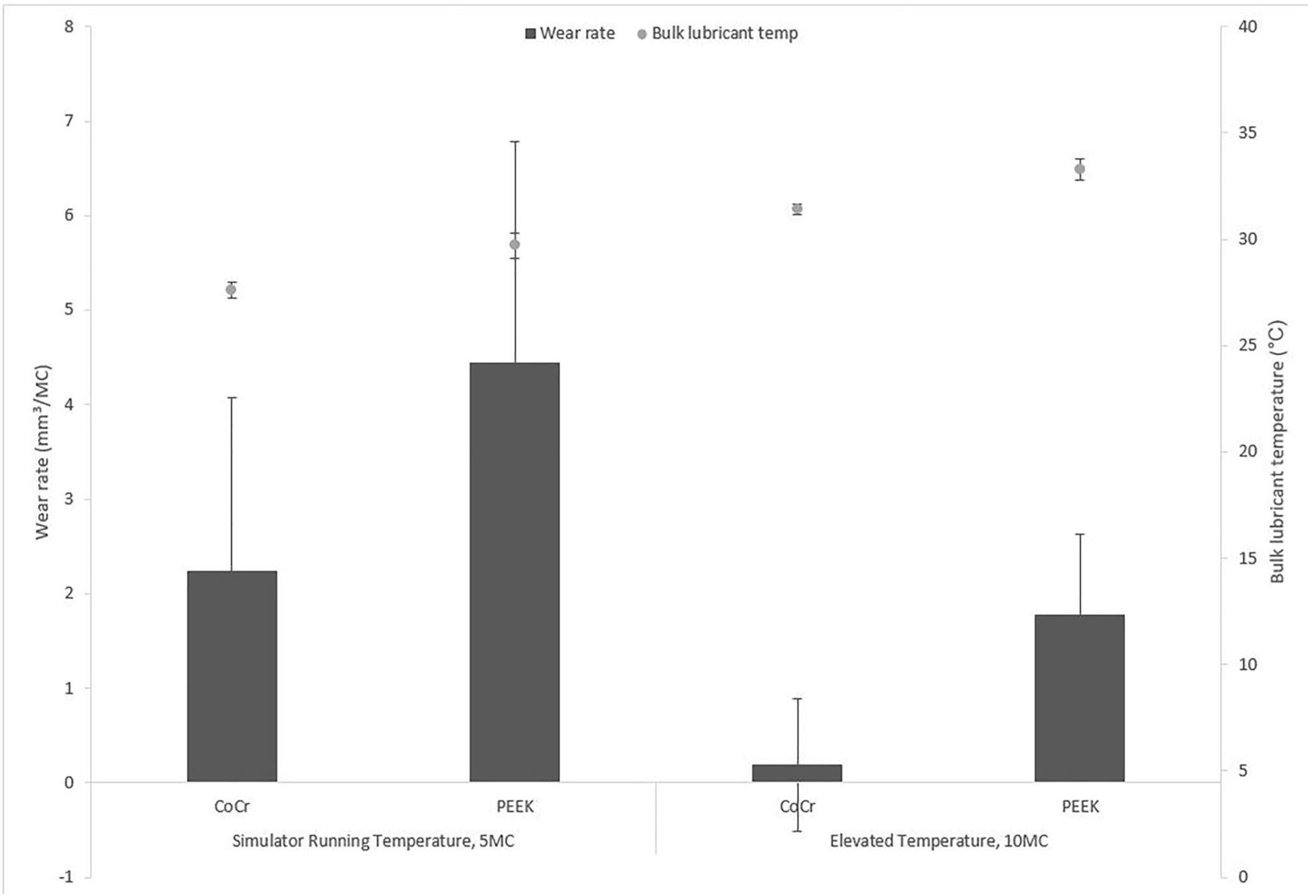

FIGURE 3 Mean wear rate (mm^3/MC) and mean bulk lubricant temperature (°C) ± 95% confidence limits comparison between the current study and previously published data of a similar implant tested under simulator running temperature conditions [19].

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bulk lubricant temperature was lower at 27.6 ± 0.4°C and 29.7 ± 0.6°C for cobalt chrome and PEEK femoral components respectively.

4 | DISCUSSION

The wear rate of the UHMWPE tibial components against both femoral component materials under elevated temperature conditions was low (<2 mm^3/MC). Measuring low rates of wear gravimetrically is difficult, which makes the differentiation between the effect of variables of interest and uncontrolled and random errors in the system complex. This, combined with the small sample size, may have contributed to the high variability in the measured wear rates of the tibial components [27]. The wear rates of the metal-on-polyethylene implant were lower than that of a typical mid-sized, cruciate retaining knee tested at simulator running temperature under Leeds high displacement controlled kinematic conditions where wear rates of 15.9 mm^3/MC have been measured for conventional stabilised UHMWPE and 6.7 mm^3/MC [28] for moderately cross-linked UHMWPE [29]. Similar knee replacements have not been investigated under elevated temperature with these kinematic conditions so no comparison can be made.

The wear rate of the all-polymer knee replacement (1.77 ± 0.90 mm^3/MC) was significantly lower ($p = 0.010$) at the elevated temperature compared to the standard simulator running temperature (4.44 ± 2.35 mm^3/MC). A decrease in wear factor of the UHMWPE-on-PEEK bearing couple under elevated temperature conditions has previously been reported in a simple geometric pin-on-plate configuration [22]. It was hypothesised that the higher friction of the all-polymer bearing couple led to localised heating of the lubricant; heating of the protein rich lubricant resulted in protein coming out of solution and being deposited on the articulating surfaces [4, 30, 31]. The protein precipitation and deposition was thought to artificially protect the surfaces and reduce wear.

The wear rate of the UHMWPE tibial components against cobalt chrome was also significantly lower ($p = 0.010$) at the elevated temperature (0.19 ± 0.70 mm^3/MC) compared to room temperature (2.23 ± 1.85 mm^3/MC), disproving the hypothesis which stated that increasing bulk lubricant temperature would have no influence on wear for metal-on-UHMWPE. This result is in contrast to the pin-on-plate study, where testing under elevated temperature conditions had no influence on the wear performance of an UHMWPE-on-cobalt chrome bearing couple compared to standard rig running temperature conditions when using a 25% bovine serum lubricant [22]. There are a number of reasons why findings from TKR simulation may differ from simple geometry pin-on-plate investigations. The more complex loading and motion of the knee simulator is likely to increase the mechanical agitation of the serum which in turn may enhance protein degradation [32]. With relatively small increases in temperature (20–40°C), large changes in the α-helix and β-structure of bovine serum albumin have been identified [33] and when bovine serum is heated above 60°C, proteins begin to precipitate [32, 34]. Whilst the temperature of the bulk lubricant for both the pin-on-plate and the knee wear simulation studies was below 60°C, the temperature at the articulating surfaces is unknown but likely exceeds that of the bulk temperature [4, 31]. Changes in the rheological behaviour of serum over the duration of a 0.5 MC wear study of total knee replacements carried out under ISO 14243-1 [2] conditions at 37°C have been shown. The increase in lubricant viscosity with test duration is thought to be as a result of protein denaturation and degradation [35]. It is not known whether thermal or mechanical degradation of the lubricant has the greater influence on the change in properties. Lubricant volume has also been shown to influence precipitation rate [30, 36, 37] as well as the frequency of lubricant replenishment. In the knee simulation study, a high volume of lubricant was used in the test cell (>400 mL in the knee simulator compared to 60 mL in the pin-on-plate rig) and the lubricant was replenished more frequently than specified in the standards (every 0.3 MC as opposed to every 0.5 MC) so it is not anticipated that either of these factors had a detrimental effect on wear rate in this study. The process of protein degradation is complex and it is likely that in different simulation systems the rate of thermal and mechanical degradation of protein will differ. Further studies may be required to fully understand the mechanism of protein degradation.

Another study of a PEEK-on-UHMWPE knee replacement tested at elevated temperature under load controlled kinematic conditions showed a similar UHMWPE wear rate compared to a conventional metal-on-polyethylene design and suggested an elevated lubricant temperature for the all-polymer bearing couple compared to metal-on-UHMWPE. Although the likelihood of protein deposition on the articulating surfaces of the implant changing the tribology of the bearing couple was acknowledged, a high lubricant protein concentration was used (38 g/L) and no comparison was made with wear simulation carried out under simulator running temperature conditions. The wear rates measured were higher than those reported in the current study at approximately 6 mm^3/MC [38] but studies carried out under different kinematic and environmental conditions are not equivalent.

When comparing the findings from this study to other research groups, the lubricant concentration and composition should be considered. Ethylenediaminetetraacetic acid (EDTA) and sodium azide are common lubricant additives. Sodium azide was used and is suggested in the international standards to retard bacterial growth; however, an inverse relationship has been shown between increasing sodium azide concentration and wear with minimal effectiveness at reducing bacterial growth [39]. EDTA is a chelating agent, addition of this to the lubricant may reduce the precipitation of calcium phosphate out of the serum [40, 41]. The concentration of EDTA used varies between research groups and this additive is not specified in the ISO standards [3].

Whilst the findings from pin-on-plate studies can help to better understand the interactions between different bearing surfaces, whole joint wear simulation replicating clinically relevant gait profiles are required to fully understand joints

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under functionally relevant conditions. The temperature measured was a combination of the environmental temperature which was consistent for all the stations of the simulator and the temperature increase due to frictional heating once the temperature inside the test cell had reached a steady state. Lubricant temperature rise depends linearly on friction [42], it is likely that the higher friction of the PEEK-on-UHMWPE bearing couple [22] coupled with the lower thermal conductivity of the PEEK compared to cobalt chrome will lead to a higher bulk lubricant temperature compared to cobalt chrome-on-UHMWPE. This difference in bulk lubricant temperature may influence the rate of protein precipitation [4] although in this study, the formation of protein rich layers on the implant surfaces was not visible on either material combination.

Intra articular measurements of knee temperature following exercise have shown higher temperatures in joints with total knee replacements compared to healthy knees. The temperature rise has been shown to be influenced by the implant materials [8] with both the friction between the articulating surfaces and the ability of the materials to dissipate heat affecting the magnitude of the temperature rise. Following 20 min walking, intra articular measurements of metal-on-polyethylene knee replacements have shown a joint temperature increase of between 4 and 7°C depending on the implant design [8] and in the hip, temperature rises up to 10°C have been measured depending on the implant material [43]. The influence of a higher intra articular temperature on wear or fixation of the joint in vivo is unknown.

5 | CONCLUSIONS

For cobalt chrome-on-UHMWPE and PEEK-on-UHMWPE total knee replacements, increasing the temperature of the 25% bovine serum lubricant in a knee simulator led to a significant decrease in wear rate. Care should be taken when carrying out experimental wear simulation to understand how factors, such as protein concentration, lubricant volume, lubricant composition, lubricant temperature and subsequent protein degradation may influence the wear of total knee replacements.

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CONFLICT OF INTEREST STATEMENT

Adam Briscoe is a paid employee of Invibio Ltd. and had a role in the study design and writing the manuscript; Louise M. Jennings has received research funding support from Invibio Ltd.

DATA AVAILABILITY STATEMENT

The data associated with this article is openly available through the Leeds University data repository [44].

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