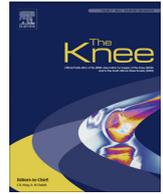


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The Knee

journal homepage:



The wear and kinematics of two medially stabilised total knee replacement systems

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ARTICLE INFO

Article history:

Received 20 July 2023

Revised 16 November 2023

Accepted 18 January 2024

Keywords:

Total knee replacement

Medially stabilised

Experimental simulation

UHMWPE

Wear

Biomechanics

ABSTRACT

Background: Medially stabilised total knee replacement systems aim to provide a more natural feeling knee replacement by providing increased stability through flexion. The aim of this study was to compare the kinematics and wear of two different medially stabilised total knee replacement systems in an experimental simulation study. The Medial Rotation Knee™ system (MRK) is an early medially stabilised knee (>20 years clinical success); the SAIPH® knee system being a more modern and refined, bone conserving evolution of the original design with a larger size range.

Methods: Three SAIPH and three MRK total knee replacements (MatOrtho Ltd, UK) were investigated. The study was performed on a knee simulator with load controlled input kinematic conditions (ISO 14243–1). 6 million cycles of simulation were carried out with the wear of the UHMWPE tibial components assessed gravimetrically. The resulting anterior-posterior translation and tibial rotation position was measured throughout the study.

Results: The mean UHMWPE wear rate was 0.57 ± 0.71 and 1.24 ± 2.0 mm³/million cycles for SAIPH and MRK total knee replacement systems respectively with no significant difference in wear ($p = 0.24$). Analysis of simulator output kinematics showed a larger range of anterior-posterior motion for SAIPH total knee replacements compared to MRK. The magnitude of tibial rotation was low for both knee replacement systems.

Conclusion: The small magnitude of anterior-posterior displacement and tibial rotation motion demonstrates the inherent stability of this knee system design offered by the constrained medial compartment. This study shows the potential for medially stabilised knee systems as a low polyethylene surface wear solution.

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1. Introduction

Total knee replacement is one of the most common and successful surgical procedures carried out with a > 95% survivorship at 10 years [1]. In excess of 100,000 total knee replacement surgeries were carried out annually in the UK between 2015 and 2019 [1], with predicted trends showing the number of implantations set to continue to rise [2,3]. Despite the high survivorship, approximately 20% of patients report dissatisfaction with their procedure [4,5]. There are several contributory factors to poor outcomes including, pain, stiffness, swelling, an abnormal feeling knee and difficulties in carrying out activities

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of daily living particularly those involving high flexion [6]. Several approaches have been investigated to improve patient satisfaction including; better management of patient expectations [6], enhanced prehabilitation and rehabilitation [7], improvements in component positioning [8], changes in implant materials [9], and changes to the total knee replacement design and geometry to facilitate better replication of physiological knee kinematics.

The majority of total knee replacement designs fall broadly into one of two categories. In cruciate retaining designs, anterior-posterior stability is provided by a combination of retention of the patients posterior cruciate ligament coupled with a generally part-conforming curved tibial insert; whilst in posterior stabilised designs, the interaction between a cam on the femoral component and a post on the tibial insert is intended to recreate femoral roll-back and provide joint stability [10,11]. The geometrical design of the condyles for both cruciate retaining and posterior stabilised total knee replacements, particularly those with symmetric condyles (which make up the majority of those implanted), do not reflect the geometry or kinematics of the anatomical tibiofemoral knee joint. This leaves many patients reporting a feeling of instability and abnormal kinematics typically the result of paradoxical motion and ligament laxity associated with posterior stabilised and cruciate retaining designs respectively [12]. For a total knee replacement to function like the anatomical tibiofemoral joint, a balance between joint stability and range of motion must be made. In medially stabilised designs of total knee replacements, the rationale for the geometry of the articulating surfaces is to more closely replicate the function of the ligaments in providing joint stability. These designs of knee replacements are asymmetric with a highly conforming medially stabilised compartment that minimises anterior-posterior translation in the medial condyle through flexion; the lower conformity of the lateral compartment allows anterior-posterior translation, more closely reflecting the physiological kinematics of the anatomical tibiofemoral joint [13,14]. Despite potential advantages in terms of more physiological kinematics and improved patient satisfaction [11], only ~ 2.5% of the total knee replacements listed in the National Joint Registry are described as medially stabilised. For medially stabilised knee replacements with > 15 years post implantation data, a lower than average, <3% revision rate has been shown [1].

To ensure long-term survivorship of the knee replacement, as well as understanding its biomechanical function, it is important to understand wear performance. The accelerated nature of experimental wear simulation means that the equivalent of several years of daily use can be replicated in a few months. Despite extensive research into wear simulation of total knee replacements, very few studies have investigated the wear of UHMWPE in medially stabilised knee replacements. In a study by Schmidt et al, low UHMPWE wear was measured for a medially stabilised knee (Evolution[®] Medial-Pivot knee system, Wright Medical Technology, USA at the time of the study, now MicroPort Orthopaedics Inc, USA) [15], comparable or lower than that of cruciate retaining knee replacements. However, in this investigation, the knee replacements were studied under displacement controlled conditions, meaning that the knee replacements were displaced directly to pre-defined anterior-posterior and tibial rotational positions, and not in response to loading and torques in these directions. For total knee replacements in which their geometrical design could significantly influence their motion, it would be important to understand the resulting motions to input forces and torques and to understand how these motions affect wear. Low wear rates have also been observed in retrieved medially stabilised knee replacements [16,17].

The aim of this study was to investigate and compare the wear and kinematics of two designs of medially stabilised total knee replacement systems from MatOrtho Ltd. (Leatherhead, Surrey, UK) using load controlled experimental wear simulation. The medially stabilised total knee replacements were the Medial Rotation Knee[™] (MRK) system, which is an early medially stabilised implant with > 20 years clinical success; and the SAIPH[®] Knee System, an evolution of the original MRK design (Figure 1). The main differences between the two knee systems include the following: The SAIPH knee system can treat a



Figure 1. Images of a Medial Rotation Knee[™] (MRK) system, left, and SAIPH[®] knee system, right [provided by MatOrtho Ltd, Leatherhead, Surrey, UK].

wider demographic than MRK through its increased size range (8 vs. 6 femoral sizes, 6 vs 5 tibial sizes). SAIPH knee implants adopt an anatomical form and grow proportionally in size compared to the MRK which employs a fixed bearing form across the size range. Improved bone conservation is achieved in the SAIPH knee system through optimised bony resections and an integrated 7° tibial slope whilst the MRK has a zero degree tibial slope. The patellofemoral joint is lateralised in both systems, however the SAIPH system offers both cemented and cementless saddle and dome shaped patellae implants while the MRK system employs a saddle shaped cementless design.

2. Materials and methods

2.1. Materials

The total knee replacements investigated were four left size F5 Medial Rotation Knee (MRK) femoral components paired with size T5 tibial trays and size 3, 8 mm tibial inserts; and four left size 8 SAIPH knee system femoral components paired with Size F tibial trays and size F, 10 mm tibial inserts (MatOrtho Ltd, Leatherhead, Surrey, UK). The largest size in each range were chosen as the worst case scenario for surface wear due to the larger contact area between the femoral and tibial components, which has previously been shown to correlate with higher surface wear [18,19]. Three sets of knee replacements were studied under full loading and motion conditions, with the fourth set undergoing axial force loading only so that the tibial inserts could be used to compensate for uptake of moisture by the polyethylene in the gravimetric analysis of wear (loaded soak control). Prior to the start of the study, the UHMWPE tibial components (GUR1020, conventional, irradiation sterilised between 25 kGy and 35 kGy) were aged to ASTM F2003 [20], and were then soaked in deionised water (minimum 2 weeks) to maximise their moisture uptake prior to the start of the study.

2.2. Methods

The femoral components were cemented to custom fixtures with the centre of rotation of the medial compartment aligned with the flexion axis of the simulator; the tibial components were cemented with respect to the femoral components.

The study was carried out in a 6 station ProSim electromechanical knee simulator (Simulation Solutions Ltd, Stockport, UK) run under load controlled input conditions as per the international standard for wear of total knee-joint prostheses (ISO 14243–1) and calibrated prior to use [21,22] (Figures 2–4). The axial force and flexion/extension were delivered through the femoral component and the anterior-posterior force and tibial rotation torque through the tibia. Both the medial–lateral

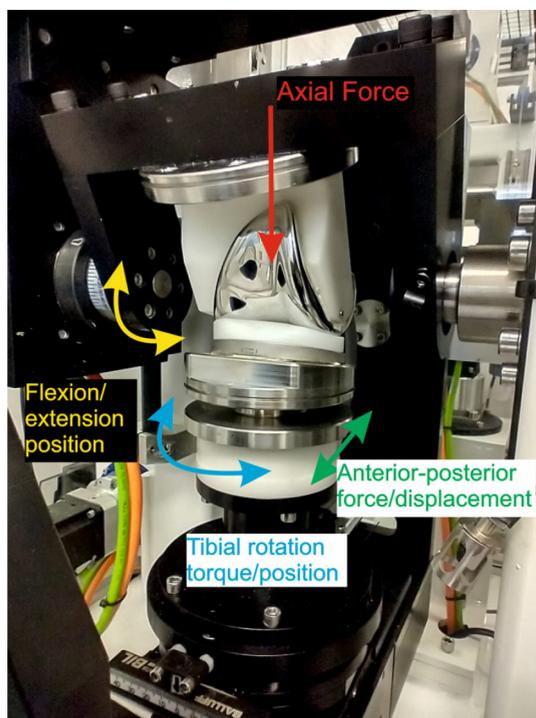


Figure 2. A SAIPH knee system total knee replacement in a ProSim electromechanical knee simulator, the controlled axes of motion are shown.

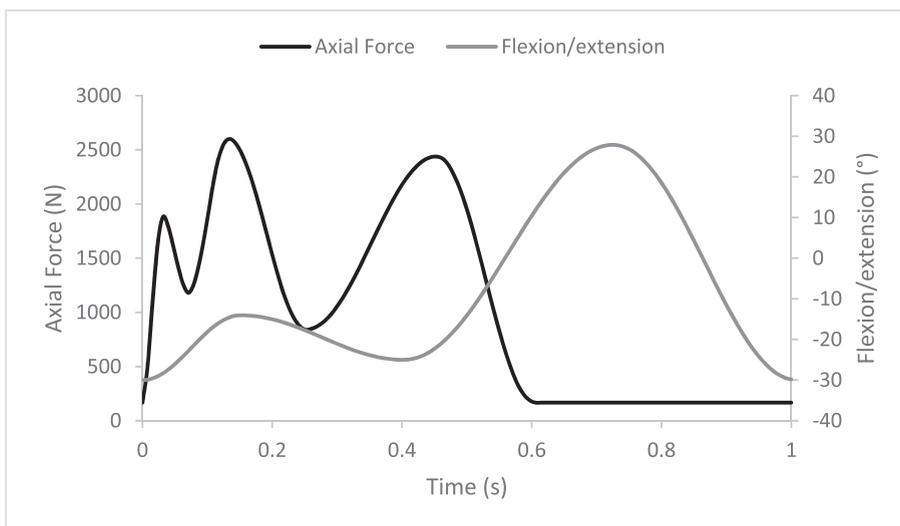


Figure 3. Input axial force and flexion/extension position.

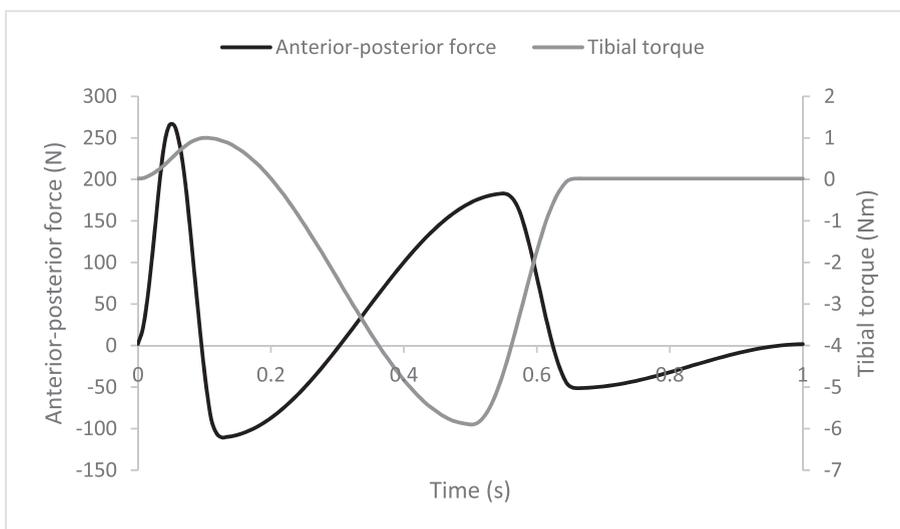


Figure 4. Input anterior-posterior force and tibial rotation torque.

offset and the axis of tibial rotation were fixed at 0.07 x implant width and the abduction/adduction axis was unconstrained. Load controlled conditions were chosen for the anterior-posterior and tibial rotational axes which allowed the geometry of the different medially stabilised designs to dictate their motion. The output anterior-posterior displacement and tibial rotation position of the tibial component with respect to the femoral component were measured for each knee replacement over the duration of the study (Figure 5). The anterior-posterior displacement was measured using a calibrated magneto inductive sensor (Balluff GmbH, Neuhausen, Switzerland) attached to the anterior-posterior axis (repeatability ± 0.1 mm), and the tibial rotation was measured through encoders in the tibial rotation motor (ABB Ltd, Zurich, Switzerland) (repeatability $\pm 0.1^\circ$). It is important to note that the anterior-posterior displacement and tibial rotation were measures of the position of the tibial slide (simulator station itself), i.e. not a direct measure of kinematics at the level of the knee replacement system. To determine the anterior-posterior displacement and tibial rotation position over the duration of a gait cycle, one cycle of output anterior-posterior displacement and tibial rotation position data was collected every 100,000 cycles for each implant at a sample rate of 128 points per cycle. For each total knee replacement, the anterior-posterior displacement and tibial rotation position was therefore determined from the average of 60 cycles taken over the duration of the study.

The lubricant used was new born calf serum diluted to 20 g/l in accordance with ISO 14243-1 [21] with 0.03% sodium azide solution (v/v) added to retard bacterial growth. During simulation, the lubricant was maintained at 37 ± 2 °C by the incorporation of a heater system into the simulator [23,24]. 6 million cycles of wear simulation was carried out with

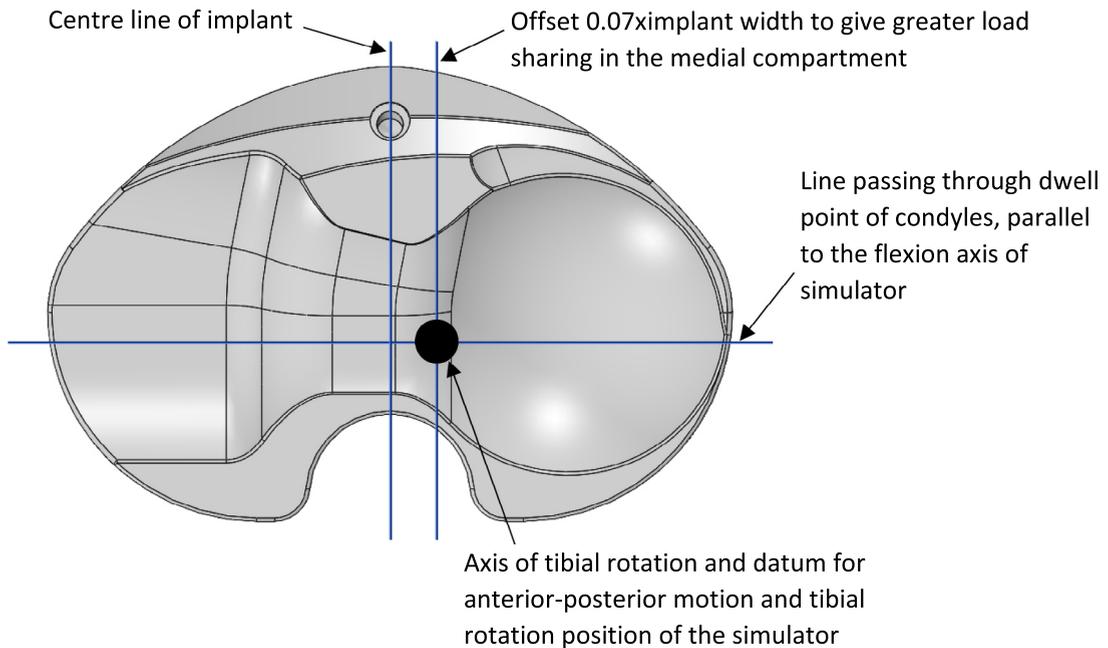


Figure 5. Schematic showing the approximate position of the axis of tibial rotation and the datum from which the anterior-posterior translation and tibial rotation position were taken on an MRK tibial component.

gravimetric measurements taken at a minimum of every million cycles. Gravimetric analysis was carried out using an XP205 digital microbalance (Mettler Toledo, Leicester, UK) with a readability of 0.1 mg, the loaded soak controls (one for each design) were also maintained at 37 ± 2 °C and used to compensate for the uptake of moisture by the polyethylene. The loss in mass of the UHMWPE tibial components was converted to a wear volume using a density of 0.934 g/cm^3 for GUR 1020 UHMWPE and the wear rate defined as slope of the regression line of cumulative wear volume versus number of cycles. Surface topographical measurements of the femoral and tibial articulating surfaces were taken using a contacting Form Talysurf (Taylor Hobson, Leicester, UK) with a $2 \mu\text{m}$ conical tip stylus prior to and post-test. Measurements were taken in a perpendicular direction to the flexion axis. Form removal, filtering and cut-offs appropriate to the materials and ISO 21920–3 [25] were applied to the measurements. The surface roughness parameters of interest were the arithmetic mean surface roughness, Ra; maximum profile height, Rp; and maximum valley depth, Rv.

The percentage area of wear scars on the tibial components was assessed first by drawing an outline of the polished wear scar on the tibial insert using a fine non-permanent marker pen before photographing the component using a digital camera (Panasonic Lumix GF6, Osaka, Japan) and calculating the area of the wear scar as a percentage of the area of the tibial insert using ImageJ [26].

The mean \pm 95% confidence limits were calculated for the wear rate, Ra, Rp and Rv, and mean \pm standard deviation for the anterior-posterior displacement and tibial rotation position. Statistical analysis was carried out using ANOVA to compare the MRK system to the SAIPH knee system with significance taken at $p < 0.05$.

The data associated with this paper are openly available through the University of Leeds Data Repository [27].

3. Results

The mean wear volume of the MRK and SAIPH UHMWPE tibial inserts with 95% confidence limits over the duration of the study is shown in Figure 6. The mean wear rate (\pm 95% confidence limits) of the UHMWPE tibial components over the duration of the 6 million cycle study was $1.24 \pm 1.98 \text{ mm}^3/\text{million cycles}$ for the MRK system and $0.57 \pm 0.71 \text{ mm}^3/\text{million cycles}$ for the SAIPH knee system. There was no significant difference in wear rate between the two different designs of knee replacements ($p = 0.24$).

The anterior-posterior motion of the simulator over a gait cycle for each tibial component with respect to the femoral component is shown in Figure 7. For both designs, at heel strike (~ 0.07 s) there was a posterior shift in the motion and a broad peak in an anterior direction during swing phase (~ 0.7 s). The motion of the two knee replacement designs was different with the SAIPH knee system implants offset in a more anterior (negative) direction than the MRK implants, the range of motion of the SAIPH knee system was also larger than for MRK.

The output tibial rotation motion of the simulator is shown in Figure 8. For the SAIPH knee system, during the first half of the gait cycle, there was approximately 1.5 to 3° internal rotation. Two of the MRK knee replacements moved to a maximum external rotation of 1 and 1.5° , whereas there was very little tibial rotation for the third MRK knee replacement.

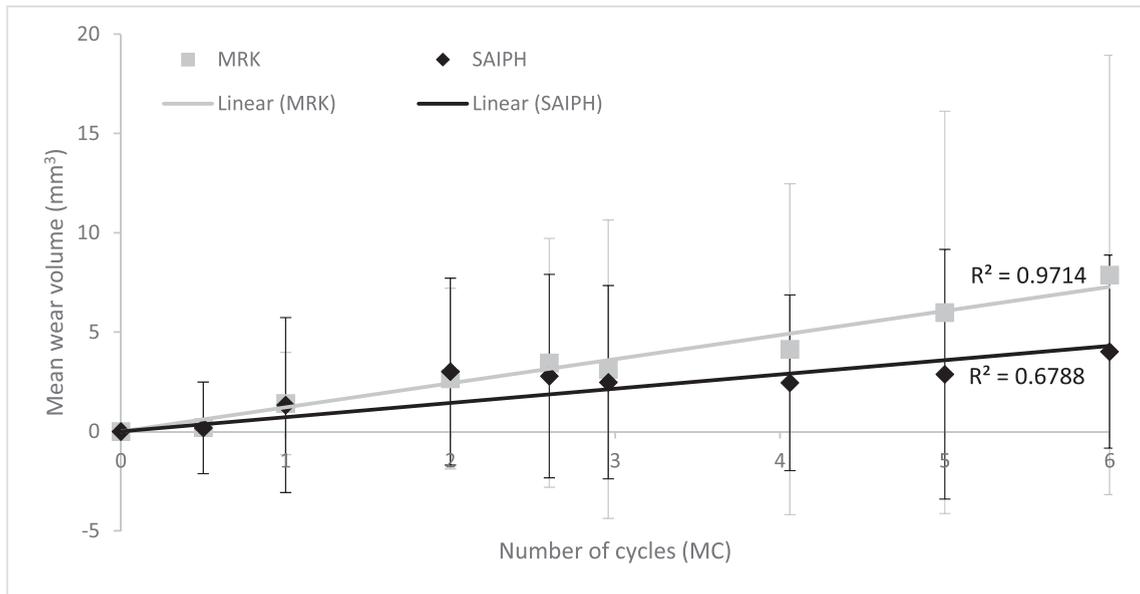


Figure 6. Mean wear volume of the MRK and SAIPH UHMWPE tibial components (mm³) ± 95% confidence limits over the duration of the study with linear trendlines showing the progression of wear (n = 3).

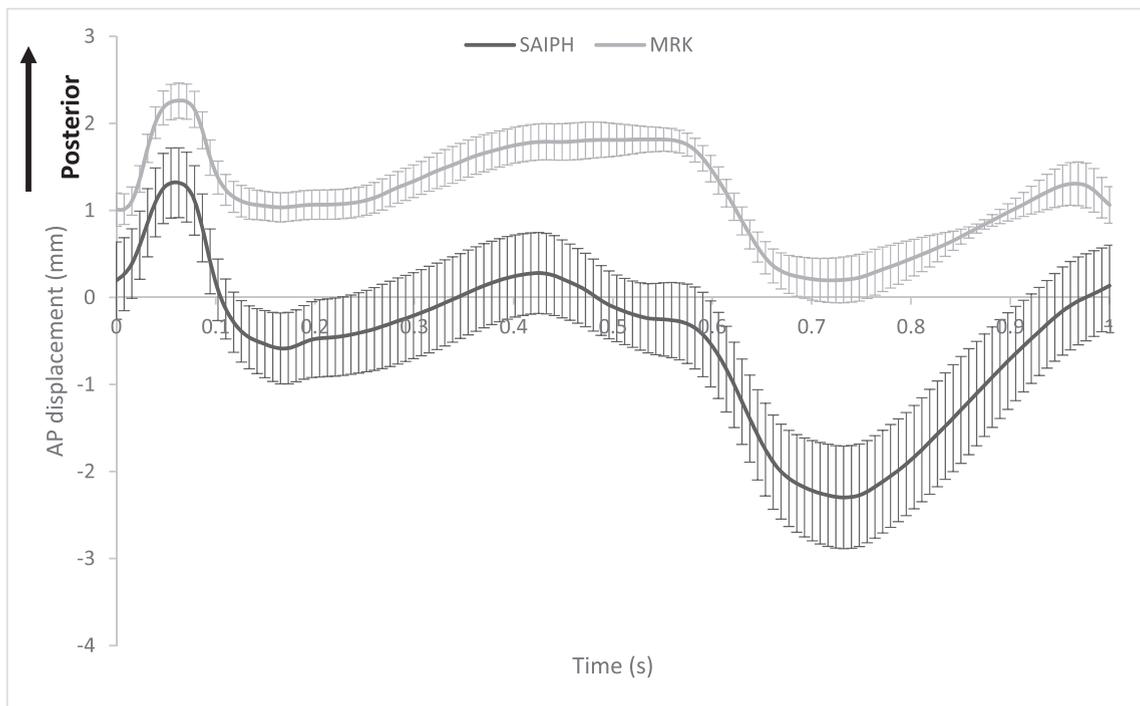


Figure 7. Anterior-posterior displacement (mm) ± standard deviation of the tibial components for the MRK and SAIPH knee systems over the duration of the gait cycle with 95% confidence limits.

Prior to the start of the study, there was no significant difference in the mean surface roughness of the femoral components between the SAIPH knee system and MRK systems ($p > 0.05$) for any of the surface roughness parameters of interest however, the superior surface of the SAIPH knee system tibial components had higher initial overall surface roughness (R_a) and maximum profile height (R_p) values compared to the MRK tibial components ($p < 0.05$). At the conclusion of the study, for all the knee replacements subjected to loading and motion, a polished region was evident in the contact region on all the

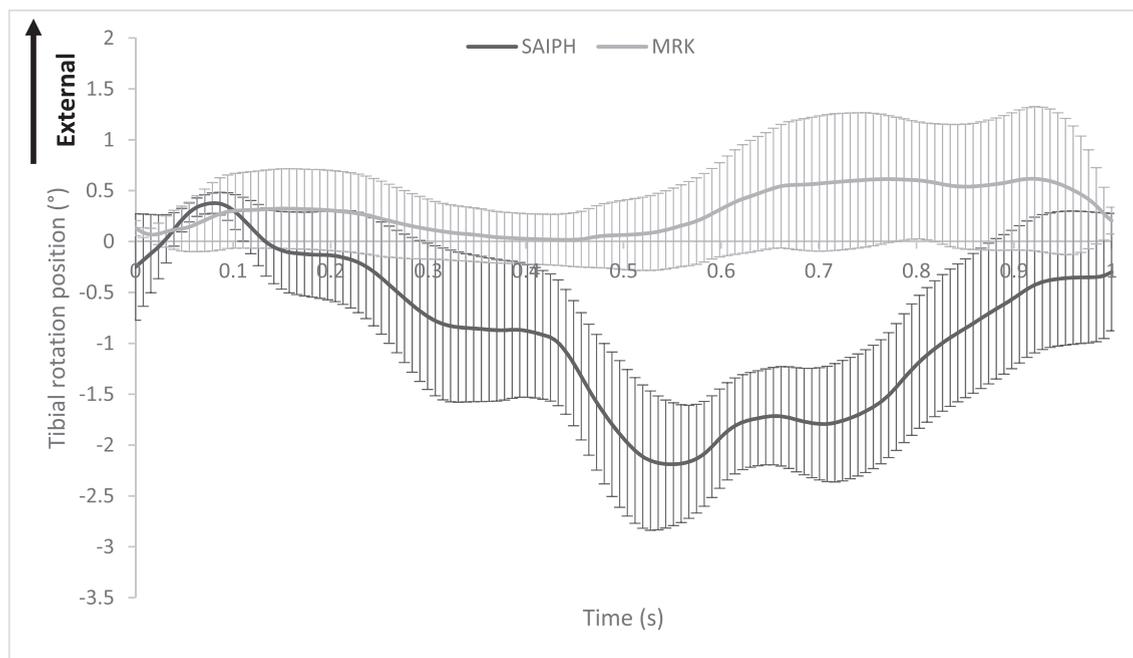


Figure 8. Tibial rotation position (°) ± standard deviation of the tibial components for the MRK and SAIPH knee systems over the duration of the gait cycle with 95% confidence limits.

UHMWPE tibial inserts with linear scratching on the femoral components running in an anterior-posterior direction. This resulted in an increase in the mean surface roughness of the femoral components compared to pre-test values and a decrease in the mean surface roughness of the tibial components compared to pre-test. There was no significant difference ($p > 0.05$) in the mean surface roughness of the SAIPH knee system or MRK femoral components, only the maximum valley depth (Rv) of the MRK tibial inserts was significantly lower ($p < 0.05$) than the superior surface of the SAIPH knee system tibial inserts (Table 1).

There were no visible changes to the superior surface of the tibial tray or the inferior surface of the tibial insert. On one MRK tibial component, there was some evidence of polyethylene damage aside from the polishing/burnishing typical during this type of study (Fig. 9). Pitting and some surface cracking around the medial compartment of the UHMWPE tibia was seen.

Representative images of the wear scars on the UHMWPE tibial inserts are shown in Figure 10, the mean percentage area of the component covered by the wear scar was $30.4 \pm 0.8\%$ and $36.1 \pm 9.9\%$ for the SAIPH knee system and MRK system knee replacements respectively.

4. Discussion

The aim of this study was to investigate and compare the wear and kinematics of two medially stabilised total knee replacement systems using experimental whole joint simulation. The single radius of curvature in the femoral component and asymmetric polyethylene tibial insert with a highly conforming medial compartment and a lower conforming lateral compartment with curvature in the anterior-posterior direction only aims to replicate the physiological kinematics of the

Table 1

Pre- and post-test surface roughness parameters (mean ± 95% confidence limits) of SAIPH knee system and MRK system femoral and tibial component articulating surfaces. Measurements were taken in a medial–lateral direction, * denotes $p < 0.05$.

Parameter	SAIPH knee system				MRK knee system			
	Femoral components		Superior surface of tibial components		Femoral components		Superior surface of tibial components	
	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-
Ra (µm)	0.022 ± 0.023	0.029 ± 0.017	1.699 ± 0.163	0.452 ± 0.417	0.020 ± 0.002	0.034 ± 0.017	1.282 ± 0.478*	0.216 ± 0.237
Rp (µm)	0.088 ± 0.055	0.099 ± 0.045	4.155 ± 0.361	1.005 ± 0.891	0.090 ± 0.015	0.113 ± 0.022	3.186 ± 1.090*	0.544 ± 0.408
Rv (µm)	0.071 ± 0.047	0.168 ± 0.113	3.802 ± 0.206	1.699 ± 0.163	0.074 ± 0.007	0.171 ± 0.103	2.789 ± 1.871	1.282 ± 0.478*

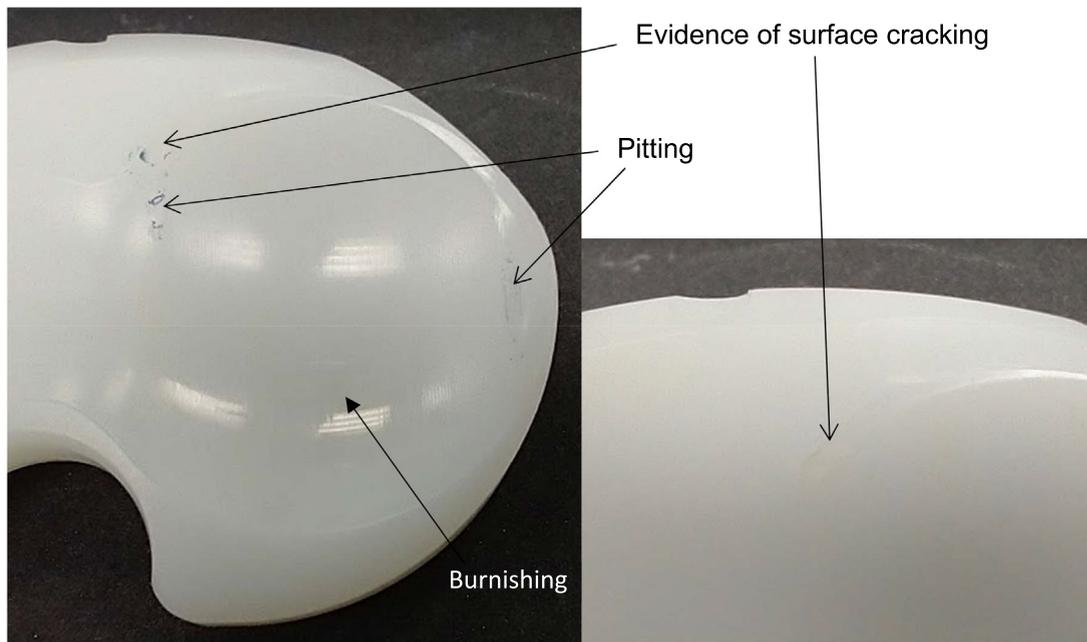


Figure 9. Images of pitting and surface cracking on one of the MRK system UHMWPE tibial inserts.

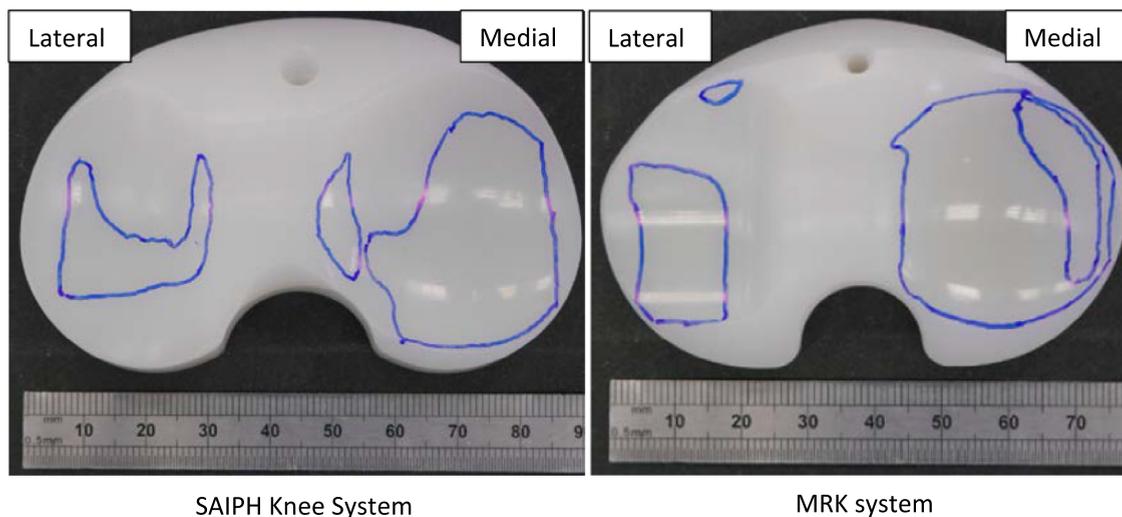


Figure 10. Typical wear scars of the UHMWPE tibial inserts following 6 million cycles wear simulation under ISO 14243-1.

knee. The total replacement knee systems of interest were both from MatOrtho Ltd with the Medial Rotation Knee system being a forerunner of the SAIPH knee system, a contemporary design.

In both medially stabilised knee replacement systems investigated, the magnitude of anterior-posterior and tibial rotation motion of the tibial axis of the simulator (as defined in Figure 5) was relatively small, likely as a result of the high conformity of the medial compartment constraining the anterior-posterior motion. In the anatomical tibiofemoral knee joint, through flexion, there is a small magnitude of anterior-posterior translation in the medial compartment and greater motion in the lateral compartment [28] resulting in the contact patch on the lateral tibial plateau moving posteriorly through flexion. Particularly for the SAIPH knee system, the shape of the tibial rotation position output and the anterior shift of the tibia in swing phase are consistent with kinematic analysis of the human knee during walking [29] with a similar magnitude of anterior-posterior translation of the tibia [30]. The small magnitudes of translation in the medial compartments have previously been reported in cadaveric and *in vivo* fluoroscopic investigations of medially stabilised implants [31,32]. The low levels of translation in the medial compartment were observed for both knee replacement designs (Figure 11) showing

the tendency of the knee system to rotate about the highly conforming medial compartment. The larger magnitude of rotation for the SAIPH knee system resulted in greater translation in the lateral condyle (Figure 11), consistent with previous investigations of the anatomical tibiofemoral knee joint [33].

The mean anterior-posterior displacement range of the simulator was approximately 3 mm and 1.5 mm for the SAIPH knee system and the MRK system respectively. Studies of low, moderate and highly conforming cruciate retaining total knee replacements and posterior stabilised knees in the same or similar *in vitro* simulation system have all shown higher ranges of anterior-posterior translation (up to 8 mm), with only a mobile bearing knee with high conformity in the sagittal plane resulting in a similar magnitude of anterior-posterior translation to the SAIPH knee system implants [22,34,35]. Similar findings were seen for the tibial rotation position of the simulator, the mean range of which was approximately 0.5° and 2.5° for MRK and SAIPH knee system replacements respectively [34]. For example, in a study by Desjardins et al, a low conforming cruciate retaining knee design was shown to have a magnitude of tibial rotation > 18 times that of the MRK system and > 7 times that of the SAIPH knee system [35]. For each medially stabilised knee system investigated, the motion of the implants followed similar trends however, there was some variability in kinematic output between samples, likely as a result of slight variations in knee replacement set up and small differences between each station of the simulator.

A potential drawback of having high conformity in the medial compartment is the possibility of malalignment of the femoral and tibial components that could result in edge loading on the rim of the socket leading to high contact stresses being generated in the UHMWPE tibial insert and the increased risk of fatigue failure of the polyethylene [36]. Surface cracking was visible around the edge of the medial compartment of one MRK tibial insert. The cracking may have been as a result of poor alignment between the tibial and femoral components which may have been accentuated by the rigidity of the simulation system where there is no motion along the medial–lateral axis. When implanted *in vivo*, the system is self-aligning and more forgiving so it should compensate for small malalignments, hence this potential edge loading scenario may not occur. No cracking was observed in the SAIPH knee system tibial inserts which had a more softened profile to the UHMWPE tibial insert leading to less contact between the femur and the rim of the medial socket of the tibial component than for the MRK system (Figure 10). The lower conformity between the femoral and tibial components in the SAIPH knee system likely makes the implant less sensitive to simulator malalignment than the MRK system. The wear scar area was smaller in the lateral compartments of both knee replacement systems compared to the medial compartments highlighting the reduced conformity.

The UHMWPE wear rate of both knee replacement systems was low (<2 mm³/million cycles) and there was no significant difference between the two designs. These findings are consistent with previously reported wear simulation of a medially stabilised knee replacement system carried out under displacement control [15]. Measuring low rates of wear (<5 mm³/million cycles) by gravimetric methods is difficult and brings about potential random errors in the system [37]. To date, reliable geometric techniques for measuring polyethylene wear in the knee are not widely available. A typical wear rate for a moderately conforming cruciate retaining total knee replacement with highly cross-linked polyethylene investigated under similar conditions in similar simulators is approximately 5 mm³/million cycles [34]. Previous experimental wear simulation has shown higher conformity implants with a higher contact area to result in higher wear [36,38], this trend was not observed in the current study. To achieve lower magnitudes of wear in conventional polyethylene, the relative motion of the femoral and tibial components must be reduced [34,39,40]. It is likely that the small magnitude of rotation of the tibial component resulted in a lower cross-shear ratio condition [41] and that this had a greater influence on wear than the high contact area on the polyethylene. In this experimental simulation system, the anterior-posterior translation and tibial rotation position of the MRK knee system was lower than SAIPH knee system although not sufficiently lower to influence wear.

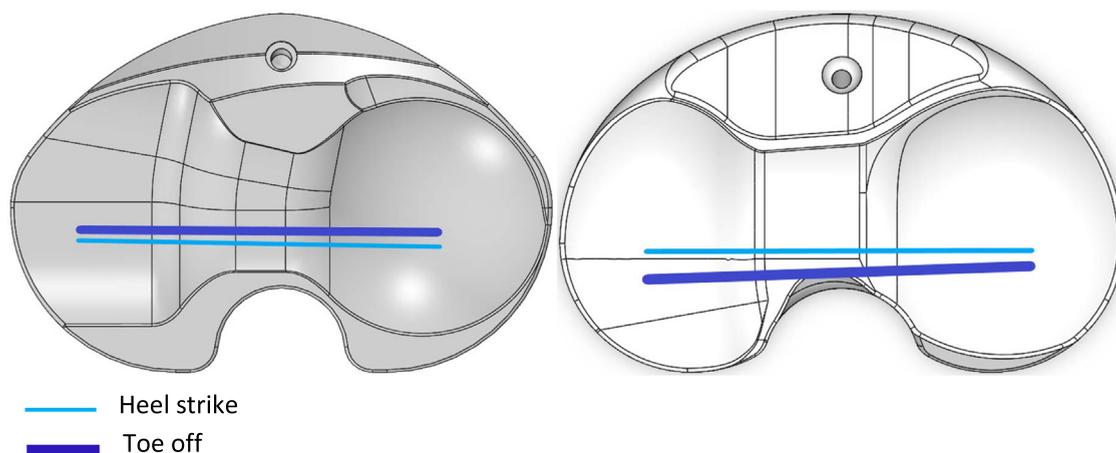


Figure 11. The contact between the femoral component and the tibial component derived from the simulator output positions of the tibial component. The contact position of the femoral components on the tibial components at heel strike are shown by a thin light blue line; the thicker darker blue line represents the contact points between the femoral and tibial components during toe off. Left: MRK system, right: SAIPH knee system.

Accelerated ageing of the UHMWPE tibial inserts was carried out prior to the start of the study. Ageing likely had little influence on the wear of this conventional, non-cross-linked polyethylene. Although there is a shift towards the use of moderately or highly cross-linked polyethylene in UHMWPE tibial components [42], concern remains about the potential for fatigue failure of highly cross-linked polyethylene. Findings from this study suggest that depending on the design of the knee replacement systems, conventional polyethylene which typically also has a lower functional biological activity [43] may result in low wear for some knee replacement designs such as medially stabilised knee systems.

There are several limitations associated with this study, primarily, the low sample size. The simulator used has 6 stations, carrying out investigations of the two knee replacement systems in parallel is best practice so the study was restricted to 3 knee replacements per design. Also, the kinematic outputs are an indirect measure, describing the motion of the simulator (tibial slide) rather than the motion directly occurring at the knee joint system level. The simulator was set up as per the ISO standard with the tibial axis offset from the centreline of the implant 0.07 x implant width however, the design intent of the medially stabilised knee system is for the knee to rotate about the medial condyle so the rotation axis of the simulator and the intended rotation axis of the implant were not coincident. The anterior-posterior translation and tibial rotation position outputs from the simulator therefore likely do not fully represent the motion of the knee system *in vivo* where very small magnitudes of translation occur in the medial compartment and larger displacements in the lateral compartment. However, investigating the wear of medially stabilised knee systems in accordance with the ISO standard is best practice and allows a direct comparison of the wear rate of this knee system with other designs. In addition, a single kinematic, tissue tension and alignment condition was investigated, which does not fully represent the patient population or activities of daily living and does therefore not fully explore potential failure modes of these knee replacement systems.

5. Conclusion

In this study, the wear and kinematics of two medially stabilised knee replacements was investigated. The wear rate of both knee replacement systems was low ($<2 \text{ mm}^3/\text{million cycles}$) and there was no significant difference between the two designs. The magnitude of both the anterior-posterior and tibial rotation motion was low for both knee replacement systems demonstrating the inherent stability of this design of knee replacement through flexion.

Funding and role of funding source

This work was primarily supported by MatOrtho Ltd. who provided funding and components for the study and were involved in the study design, writing the manuscript and in the decision to submit the article for publication. Partial funding was received through the EPSRC Medical Technologies Innovation and Knowledge Centre Phase 2 Regenerative Devices (EP/N00941X/1) who had no involvement in the study design or article preparation or submission.

CRediT authorship contribution statement

Raelene M. Cowie: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Visualization, Writing – original draft. **Charles J. Cullum:** Conceptualization, Writing – review & editing. **Simon N. Collins:** Conceptualization, Writing – review & editing. **Louise M. Jennings:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Methodology, Project administration, Resources, Supervision, Validation, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: CJC and SNC are paid employees of MatOrtho Ltd. MatOrtho Ltd. provided research support and implants for this study.

Acknowledgements

Thanks to Mr Phil Wood and his team for their technical expertise.

Data Access Statement

The data associated with this paper are openly available from the University of Leeds Data Repository. <https://doi.org/10.5518/1436>

Ethics statement

No ethical approval required for this study.

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