Journal of the Mechanical Behavior of Biomedical Materials 100 (2019) 103386

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

The effect of surgical alignment and soft tissue conditions on the kinematics and wear of a fixed bearing total knee replacement

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ARTICLE INFO

Keywords:
Total knee replacement
Wear
Surgical alignment
Kinematics
Simulation
Contact mechanics

ABSTRACT

As life expectancy and activity levels of patients increase so does the demand on total knee replacements (TKRs). Abnormal mechanics and wear of TKRs can lead to implant loosening and revision. Component alignment after surgery varies due to the presurgical alignment, the accuracy of the surgical instrumentation and due to patient factors, such as the soft tissue balance.

This study experimentally investigated the effect of variation in component alignment and the soft tissue conditions on the kinematics and wear of a fixed bearing TKR. DePuy Sigma fixed bearing TKRs with moderately cross-linked UHMWPE were used. Different alignment conditions were simulated in the coronal, sagittal and transverse planes in an ISO force-controlled simulation system. Three different soft tissue conditions were simulated using virtual springs to represent a stiff knee, a preserved PCL and a resected PCL.

Four different alignment conditions were studied; ideal alignment, 4° tibial and femoral varus joint line, 14° rotational mismatch and 10° posterior tibial slope. The varus joint line alignment resulted in similar kinematics and lower wear rate compared to ideal alignment. The rotational mismatch alignment resulted in significantly higher tibial rotation and abduction-adduction as well as a significantly higher wear rate than ideal alignment. The posterior tibial slope alignment resulted in significantly higher wear than the ideal alignment and dislocated under the lower tension soft tissue conditions.

Component alignment and the soft tissue conditions had a significant effect on the kinematics and wear of the TKR investigated in this study. The surgical alignment of the TKR is an important factor in the clinical outcome of the joint as factors such as increased tibial rotation can lead to anterior knee pain and instability and increased wear can lead to aseptic loosening and early failure resulting in revision.

1. Introduction

In 2018 over 1,000,000 primary total knee replacements (TKRs) were carried out in England, Wales and the Isle of Man (NJR, 2018). Aseptic loosening due to wear, instability and component malalignment are some of the main causes of failure in TKRs (Sharkey et al., 2002; Galvin et al., 2006; NJR, 2006). As life expectancy and activity levels increase, early failure of TKRs could become more of an issue; demand is projected to increase in the USA by more than 600% by 2030 (Bayliss et al., 2017; Kurtz et al., 2007). The risk of revision also increases as the age at primary implantation decreases, with the lifetime risk of revision at 35% for patients aged 50–54 years (Bayliss et al., 2017). Experimental simulation has been used with different methods and conditions to predict the kinematics and wear performance of total joint replacements. In addition to patient and surgical factors the wear of a TKR has been shown to depend on several factors including insert material (bearing), component design, surface geometry, set up, contact area, stress and knee kinematics (Abdelgaied et al., 2014; Johnston et al., 2018; McEwen et al., 2005; Healy et al., 2001; Brockett et al., 2016). Therefore, understanding the factors that lead to abnormal mechanics and increased wear are vital in developing long lasting TKRs.

Currently the standard conditions for knee simulation are a walking cycle with an ideally aligned knee, with standardised gait and force profiles and does not replicate the range of motions found in vivo. Experimental simulation may generate the average wear rates found in vivo. However, it does not show the range of outcomes found in retrievals (Grecu et al., 2016; Harman et al., 2001). This may be due to factors that are not currently replicated in standard knee simulation.

Abbreviations: AA, Abduction-adduction; AP, Anterior-posterior; AF, Axial force; CI, Confidence interval; CR, Cruciate retaining; FE, Flexion extension; MC, Million cycles; TKR, Total knee replacement; TR, Tibial rotation

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https://doi.org/10.1016/j.jmbbm.2019.103386
Received 12 March 2019; Received in revised form 18 July 2019; Accepted 2 August 2019
Available online 03 August 2019

Different patient factors have been shown to affect the wear rate of TKRs; patient weight (Berend et al., 2008), the extent and type activities they perform (Healy et al., 2001), soft tissues and muscles (Moreland, 1988; Johnston et al., 2018), the surgical alignment of the TKR (Moreland, 1988; Srivastava et al., 2012; Ezzet et al., 2004), and interactions between these factors, such as soft tissue and muscle mechanics producing different kinematics for specific activities. Some patient factors are outside the control of the operating surgeon. The aim of a TKR is to provide a stable knee which will function optimally and last long. Stability of the replaced knee is in part dependent upon muscle strength, ligament integrity and TKR design.

Simulating a wider range of patient conditions may replicate the wider range of outcomes that occur in vivo and increase our understanding of the factors that lead to early or mid-term failure, or higher rates of failure in younger patients.

There are two different approaches to experimental knee simulation; displacement control and force control. Displacement control directly defines the anterior-posterior (AP) displacement and tibial rotation (TR) that will occur during the gait cycle. Conversely, force control uses the AP force and TR torque profiles as inputs, allowing the joint to move in response to the applied forces, design and alignment of the joint and the applied simulated soft tissue constraints. Both methods of simulation have their place, the choice between them depends on the research question. Force control results in more variation in the motions occurring between the stations on the simulator, as small differences such as component position or friction will affect the kinematics. In a study where the aim is to test predefined kinematics, for example to test an action such as walking upstairs, displacement control would be the better option. Conversely under force control the motion of the knee can change in response to the applied loads, soft tissue constraints, insert design, changes in the material deformation and wear scar. For tests where the kinematics are not known, for example under different soft tissue conditions, force control would be used. However, it must be recognised that in defining specific soft tissue constraints as an input in the force control situation, the kinematic output is being indirectly controlled. There are ISO standard TKR test conditions for both force and displacement control simulation (Standard, 2009, 2014). These define test conditions such as the input profiles and methodology.

Under force control simulation springs are used to replicate the effect of all the soft tissues within the natural knee, including the ACL and PCL. As the tension of the tissues within the knee vary between patients the spring gap and stiffness are difficult to choose. Ligament balance during surgery is a subjective process so can lead to unbalanced knees (Griffin et al., 2000; Babazadeh et al., 2009). Ligament balancing has been found to be an important factor in wear, range of motion, and pain (Babazadeh et al., 2009). The ligament balance affects the mechanics of the knee, how it moves and the resulting variation in performance and wear in individual patients.

Component alignment has been shown to vary between patients in the coronal, sagittal and transverse planes (Harvie et al., 2012; Longstaff et al., 2009; Chauhan et al., 2004b; Haaker et al., 2005; Anderson et al., 2005; Bolognesi and Hofmann, 2005). Previous studies have investigated component alignment after surgery. Mechanical alignment is the most common method and aims to maintain the mechanical axis of the leg in the coronal plane. During surgery surgeons aim to get the mechanical axis of the leg within 3° of neutral. Some studies have found that TKRs with a mechanical axis within this envelope have better results (Srivastava et al., 2012; Ezzet et al., 2012).

Previous studies into the effect of alignment on the function of TKRs have found that varus alignment may result in increased wear rates and increased medial loading (Srivastava et al., 2012; Ezzet et al., 2012; Werner et al., 2005). While a computational study found that wear rates are more sensitive to rotational alignment and sagittal alignment than alignment in the coronal plane (Mell et al., 2009b). However, alignment alone may not result in early failure and may instead be due to a combination of factors (Berend et al., 2004). No previous studies have investigated the combined effect of alignment and soft tissue conditions.

Component alignment can affect the function and mechanics of the TKR. Abnormal kinematics of the TKR can result in instability, knee pain and patellar maltracking (Scuderi and Insall, 1992; Ranawat, 1986; Barrack et al., 2001; Brick and Scott, 1988; Emami et al., 2007; Mizuno et al., 2001; Norman Scott, 2018). A previous study found that strong ligaments within the knee could help to counteract the effects of varus or valgus alignment (Werner et al., 2005). The aim of this study was to experimentally investigate the effects of component alignment and soft tissue conditions on the output kinematics and wear of a fixed bearing TKR.

2. Materials and methods

All the investigations were carried out using DePuy Sigma fixed bearing, cruciate retaining, right knee, size 3 TKR components (DePuy Synthes, UK). The Sigma TKR was the most common TKR in England, Wales and the Isle of Man in 2018 (NJR, 2018). The tibial inserts were moderately cross linked ultra-high molecular weight polyethylene (UHMWPE) (5MRad irradiated and re-melted GUR1020).

This experimental study was carried out using a new generation electromechanical six station ProSim knee simulator. The simulator has five fully independently controlled axes and can be run in either force control or displacement control. The electro-mechanical simulators provide better kinematic control (outputs following the demand inputs more closely) than the first-generation pneumatic simulators (Abdelgaied et al., 2017). The lubricant used was 25% bovine serum with 0.04% sodium azide solution. The AP and TR displacements were defined in terms of the tibial insert; anterior displacement was anterior displacement of the tibial component. The axial force (AF) was applied on the femoral component and the flexion-extension (FE) was defined in terms of the femoral component.

For this study force control was used as this allowed the kinematics in each study to be determined as an output of the study, enabling the effect of the soft tissue constraints and component alignment on the kinematics to be investigated. Virtual springs were used within the simulator to represent the effects of soft tissues within the knee. The use of virtual springs allowed any response profile to be used for the springs. The desired spring profile for the AP and TR springs was uploaded into the simulator. This defined the force to be applied for a given displacement. During the cycle the displacement in the previous step was used to determine the spring force that should be applied in the next step. The applied force constrained the motion, replicating the effect of the soft tissues in the knee. The virtual springs within the simulator were validated experimentally by applying either an AP force or a TR torque and measuring the resulting displacements.

The ISO (Standard, 2009) force input profiles were used, with the AF varying between 268 N and 2600 N, the FE between 0° and 60°, the AP force between −111 N and 265 N and the TR torque from -1Nm to 5.9Nm (Fig. 1). The centre of rotation of the femoral component was set in accordance with the ISO standard (Standard, 2009) including the medial-lateral offset. One set of components was used for all the kinematic studies, this was to remove any effect due to differences in the components such as the fixture weight or position.

A literature review was conducted to identify relevant studies which had provided guidance on the surgical technique used to achieve desired component alignment and the corresponding values of the component position were reported. In all these studies intramedullary guide for femoral preparation and extramedullary guide for tibial preparation was used which is the routine clinical practice. The studies included did not include revision surgery or patients with large preoperative varus/valgus, did not use cadavers and measured the angles of the components with the same methods.

For coronal alignment the studies included were those where the angles were measured using a weight bearing, long leg radiograph. The

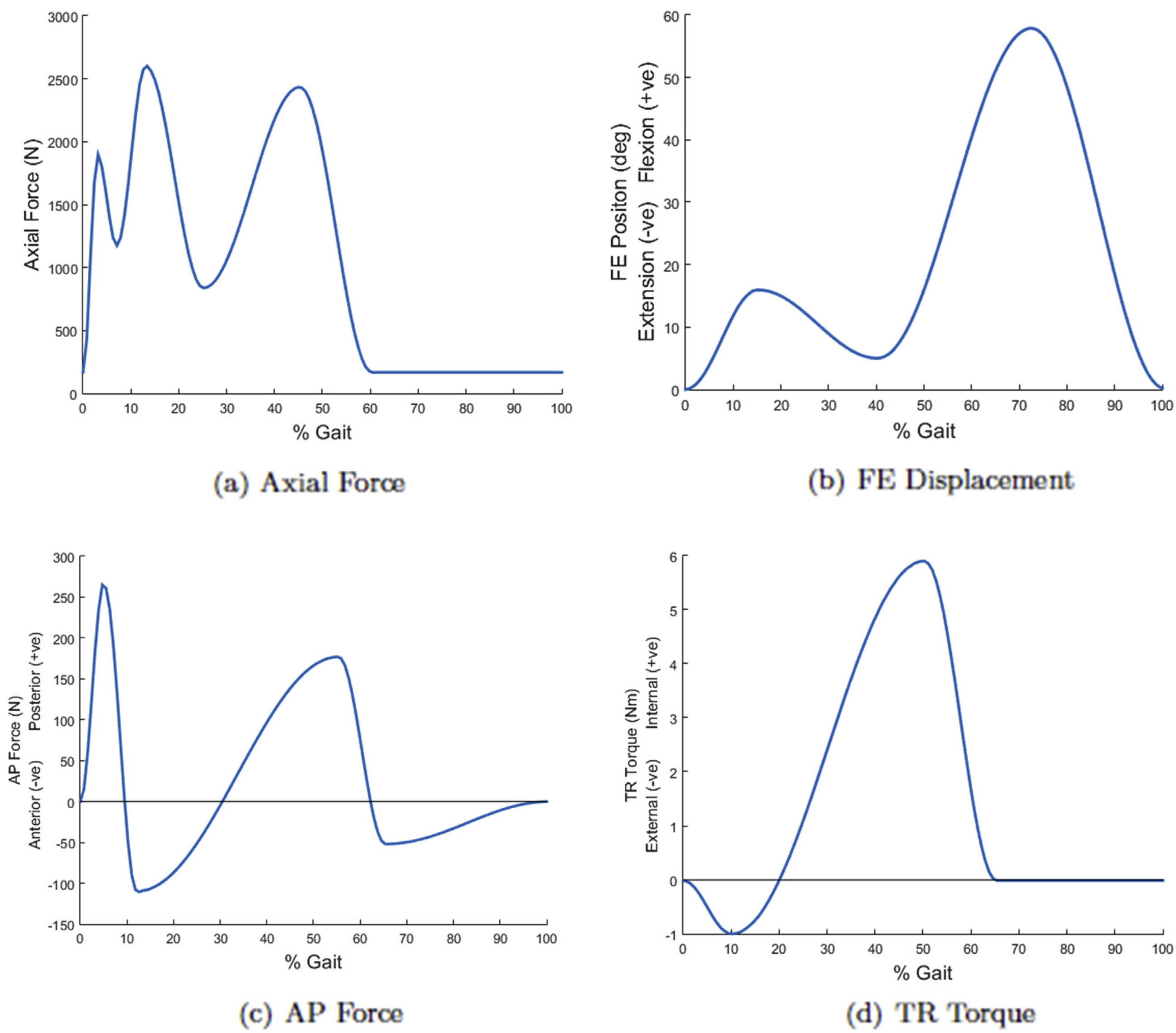

Fig. 1. The input AF, FE displacement, AP force and TR torque profiles (Standard, 2009).

Table 1
Results from studies on the amount of variation in TKR position in the coronal plane. A negative value represents a varus alignment and a positive value valgus alignment.

Study	Number of Subjects	Tibial (°)	Femoral (°)
Haaker et al. (Haaker et al., 2005)	100	−6 to +2	−4 to +10
Anderson et al. (Anderson et al., 2005)	51	−4 to +4	−5 to +5
Bolognesi and Hofmann (Bolognesi and Hofmann, 2005)	50	Not Reported	−5 to +4
Mizu-uchi et al. (Mizu-uchi et al., 2008)	39	−3.7 to +5.1	−6 to +1.8
Chang and Yang (Chang and Yang, 2006)	29	−3 to +8	−1 to +6
Chin et al. (Chin et al., 2005)	30	−3 to +5	−6 to +3
Zumstein et al. (Zumstein et al., 2006)	29	−2 to +4	−5 to +8
Daubresse et al. (Daubresse et al., 2005)	50	−3 to +3	−4 to +3

angle of the tibial component was defined as the angle between the base of the tibial tray and the anatomical axis of the tibia. The angle of the femur was defined as the angle between the mechanical axis of the leg and the tangent to the femoral condyles. There were eight studies that fit these criteria and the range in tibial, femoral and tibiofemoral component alignments are shown in Table 1. A value of 4° was chosen to represent the common range of tibial and femoral alignment found in vivo. A varus joint line angle was also chosen as previous studies had found that varus alignment resulted in worse outcomes than valgus alignment (Suh et al., 2017; Vandekerckhove et al., 2017).

The studies included for the rotational alignment of knee components were those measured using CT scans and using the Perth or Berger CT protocol as these used the same methods (Berger et al., 1993; Chauhan et al., 2004a). The studies that met these criteria and the maximum tibiofemoral rotational mismatch found in each study are shown in Table 2. A value of 14° rotational mismatch was chosen for this study to represent the ranges found in each of the five studies. The femoral component was rotated 7° internally and the tibial component

Table 2
Results from studies on the maximum rotational mismatch of TKR components.

Study	Number of Subjects	Tibiofemoral Mismatch (°)
Longstaff et al. (Longstaff et al., 2009)	159	13
Chauhan et al. (Chauhan et al., 2004b)	36	11
Harvie et al. (Harvie et al., 2012)	22	13.6
Bell et al. (Bell et al., 2014)	56	18.6
Nicoll and Rowley (Nicoll and Rowley, 2010)	26	22.1

Table 3
Results from studies on the variation in TKR position in the sagittal plane. A negative value represents an anterior tibial slope.

Study	Number of Subjects	Tibial Slope (°)
Longstaff et al. (Longstaff et al., 2009)	159	−1 to +13
Chauhan et al. (Chauhan et al., 2004b)	36	+1 to +10
Harvie et al. (Harvie et al., 2012)	22	+1 to +10
Huang et al. (Huang et al., 2014)	27	−1 to +10

7° externally.

For the sagittal alignment the studies included were those where CT scans were used to calculate the alignment angle according to the Perth CT protocol. The four studies that met these criteria are shown in Table 3, in 3 of the 4 studies the maximum posterior tibial slope was 10°, therefore this alignment was chosen.

A total of four alignment conditions were defined to represent the range found in vivo and investigate the effect on kinematics and wear (Table 4).

These were ideal alignment, 4° femoral and tibial varus to represent a varus joint line, 14° rotational mismatch and 10° posterior tibial slope, these values were chosen to represent the range found in vivo. In the rotational mismatch alignment condition the tibial insert was rotated 7° externally and the femoral component rotated 7° internally.

Each alignment condition was studied with the ISO standard (Standard, 2009) input profiles. Three different soft tissue conditions were defined to represent a patient with a stiff knee, a preserved PCL and a resected PCL (Table 5). The ISO standard spring profiles for a CR and CS TKR were used to represent a preserved PCL and a resected PCL respectively (Standard, 2009). For both soft tissue conditions the AP spring profiles had a gap of ± 2.5 mm around the zero position while the TR spring profiles had a gap of ± 6°. The resected PCL soft tissue condition had lower tension AP and TR springs compared to the preserved PCL soft tissue condition.

The stiff knee soft tissue condition was based on clinical data. A previous study (Warren et al., 1994) found the average posterior displacement under a 100 N posterior load was 1.84 ± 1.05 mm. Taking the lower value one standard deviation from the mean to represent a patient with a stiffer than average knee, and assuming there was no laxity within the knee, this gave an AP spring tension of 127 N/mm. A previous study into the rotation of the knee under 10Nm internal torque found that the average rotation was 19.3 ± 4.6° (Kanamori et al., 2002). Taking the lower value one standard deviation from the mean and assuming there was no laxity within the knee as before, this gave a mean TR spring tension of 0.7Nm/°.

Table 5
The AP and TR spring tensions and spring gaps for the three soft tissue conditions studied.

Condition	AP		TR	
	Gap (mm)	Tension (N/mm)	Gap (°)	Tension (Nm/°)
Preserved PCL (ISO CR)	± 2.5	44 posteriorly 9.3 anteriorly	± 6	0.36
Resected PCL (ISO CS)	± 2.5	9.3	± 6	0.13
Stiff Knee	0	127	0	0.7

The output kinematics under each alignment condition were used for comparison as they have previously been shown to affect the wear rate of the TKR (McEwen et al., 2005). Each experimental condition was carried out on all six stations of the simulator with 100 consecutive cycles being recorded on each station. The output kinematics for these cycles were then averaged across all the stations and the data is presented with 95% confidence interval (CI).

In order to compare the output kinematics from each alignment condition minimum and maximum values at defined points throughout the gait cycle were assessed to characterize the profiles (Fig. 2). For the AP displacement points A through to D were defined as the maximum from 0 to 20% gait, the minimum from 20 to 50% gait, the maximum from 50 to 70% gait and the minimum from 70 to 90% gait respectively. For the TR position points E through to H were defined as the maximum from 20 to 40% gait, the minimum from 40 to 50% gait, the maximum from 50 to 65% gait and the minimum from 65 to 80% gait. For the AA displacement profile points I to J were defined as; the maximum value from 0 to 15% gait, the minimum value from 5 to 20% gait and the maximum from 50 to 90% gait. This is a similar method to that used previously to compare kinematics (Barnett et al., 2002). The range of motion over the cycle was defined as the difference between the maximum and minimum displacements.

To investigate the effect of the component alignment and soft tissue conditions on the wear rates, studies were run for 2 million cycles (MC) under each alignment condition and the stiff knee and resected ACL & PCL soft tissue conditions.

Each test had a frequency of 1 Hz. The lubricant was the same as used for the kinematic investigation and was changed every 330,000 cycles. The UHMWPE tibial components were weighed pre-test and after each million cycles. The change in mass was used to determine the wear volume using a density value of 0.9346 kg/mm^3 (Barnett and Fisher, 2001). A Mettler XP205 (Mettler Toledo, USA) balance was

Table 4
The femoral and tibial component positions in the coronal, sagittal and transverse planes to ideal alignment under each alignment condition studied.

Condition	Femoral Component			Tibial Component		
	Coronal	Sagittal	Transverse	Coronal	Sagittal	Transverse
Ideal	0°	0°	0°	0°	0°	0°
Varus	4° varus	0°	0°	4° varus	0°	0°
Rotated	0°	0°	7° internal	0°	0°	7° external
Tibial Slope	0°	0°	0°	0°	10° posterior	0°

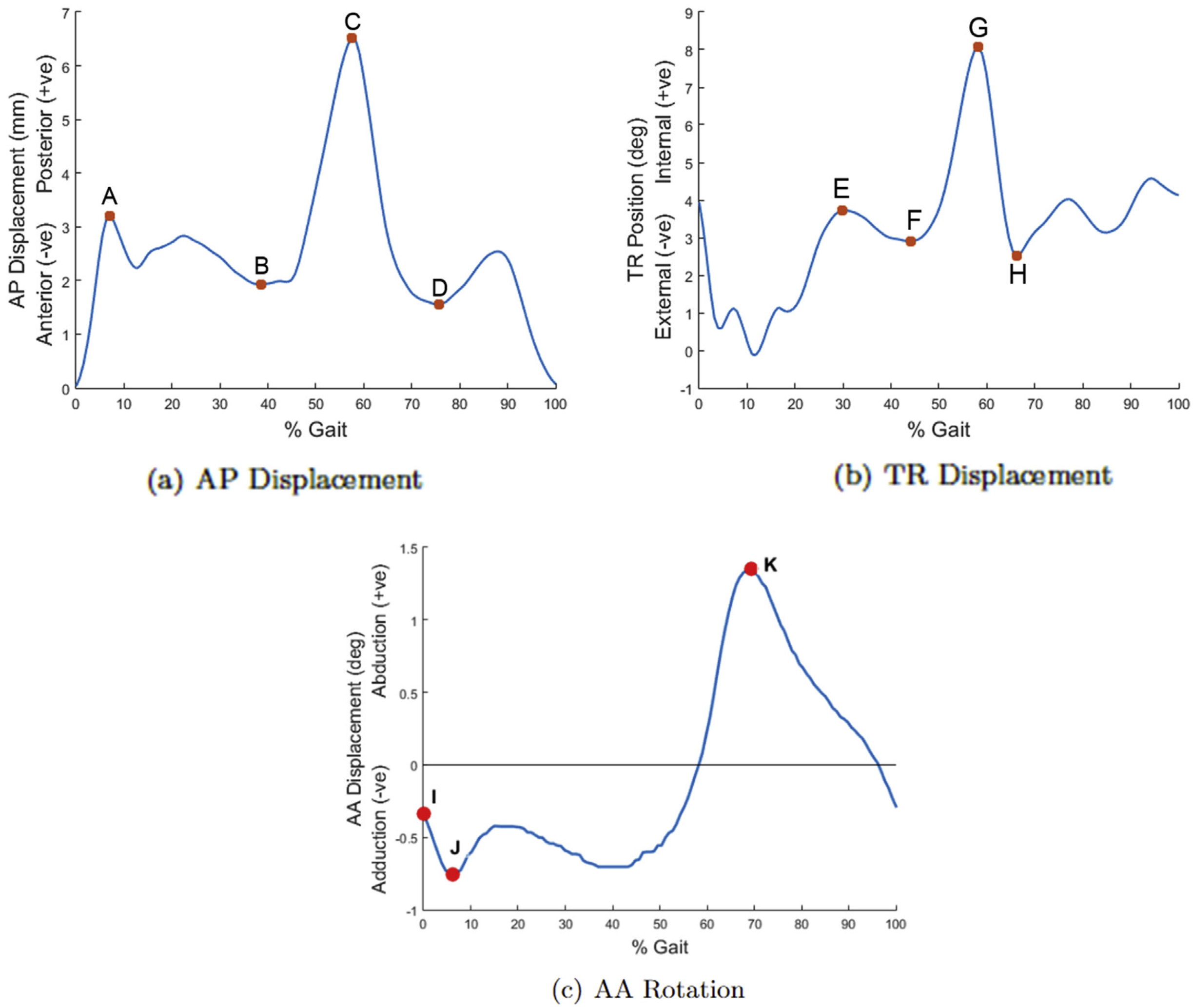

Fig. 2. Maximum and minimum points on AP (a), TR (b) and AA (c) displacement profiles used for statistical comparison between alignment conditions.

used, which has a resolution of 10 µg. Two unloaded control tibial components were soaked in lubricant for the duration of the studies and were used as a reference to compensate for moisture uptake.

The kinematic and wear results were then compared for all alignment and soft tissue conditions using a one-way ANOVA with significance taken at $p < 0.05$ using IBM SSPS Statistics 22. A Welch's test with significance taken at $p < 0.05$ was carried out to determine whether the variances between groups were homoscedastic. If this was determined to be true a post hoc Tukey's test was used to confirm where the differences between the groups occurred, with significance taken at $p < 0.05$, as this assumes equal variance. However, if the variances were determined to be too different a post hoc Games-Howell test was carried out, with significance taken at $p < 0.05$, to determine the differences between the groups.

The data associated with this paper is openly available through the University of Leeds Data Repository (Johnston and Jennings, 2019).

3. Results

3.1. Kinematics

For each alignment and soft tissue condition investigated the average AP, TR and AA displacement values were reported along with the 95% CI across the 6 stations of the simulator. The displacement values at four points in the cycle were used to compare the output kinematics under each alignment condition along with the range of motion during the gait cycle (Fig. 2).

3.1.1. Anterior- posterior displacement

The mean AP displacement for each alignment condition was determined for each of the three soft tissue conditions; stiff knee, preserved PCL and resected PCL (Fig. 3).

All the alignment and soft tissue conditions resulted in a similar AP displacement profile with the peak displacement occurring at 60% gait. The lower tension preserved PCL and resected PCL springs, with gaps around the zero position, resulted in higher peak AP displacements compared to the stiff knee springs. There was a smaller difference in the peak AP displacements between the preserved PCL and resected PCL springs than with the stiff knee springs for all the alignment conditions.

The tibial slope alignment condition was too unstable to run under the preserved PCL and resected PCL springs. Under the stiff knee soft tissue condition it resulted in significantly more anterior displacement than the ideal, varus and rotated alignment conditions at points A-C ($p < 0.01$). Under all the soft tissue conditions there was a significant difference in the AP displacement at points A and B between the alignment conditions (Table 6).

Under all the soft tissue conditions the varus and rotated alignment conditions resulted in a similar AP displacement profile as the ideal alignment condition.

For all the alignment conditions the lowest range of motion occurred under the stiff knee soft tissue condition with similar values under the preserved PCL and resected PCL soft tissue conditions. There

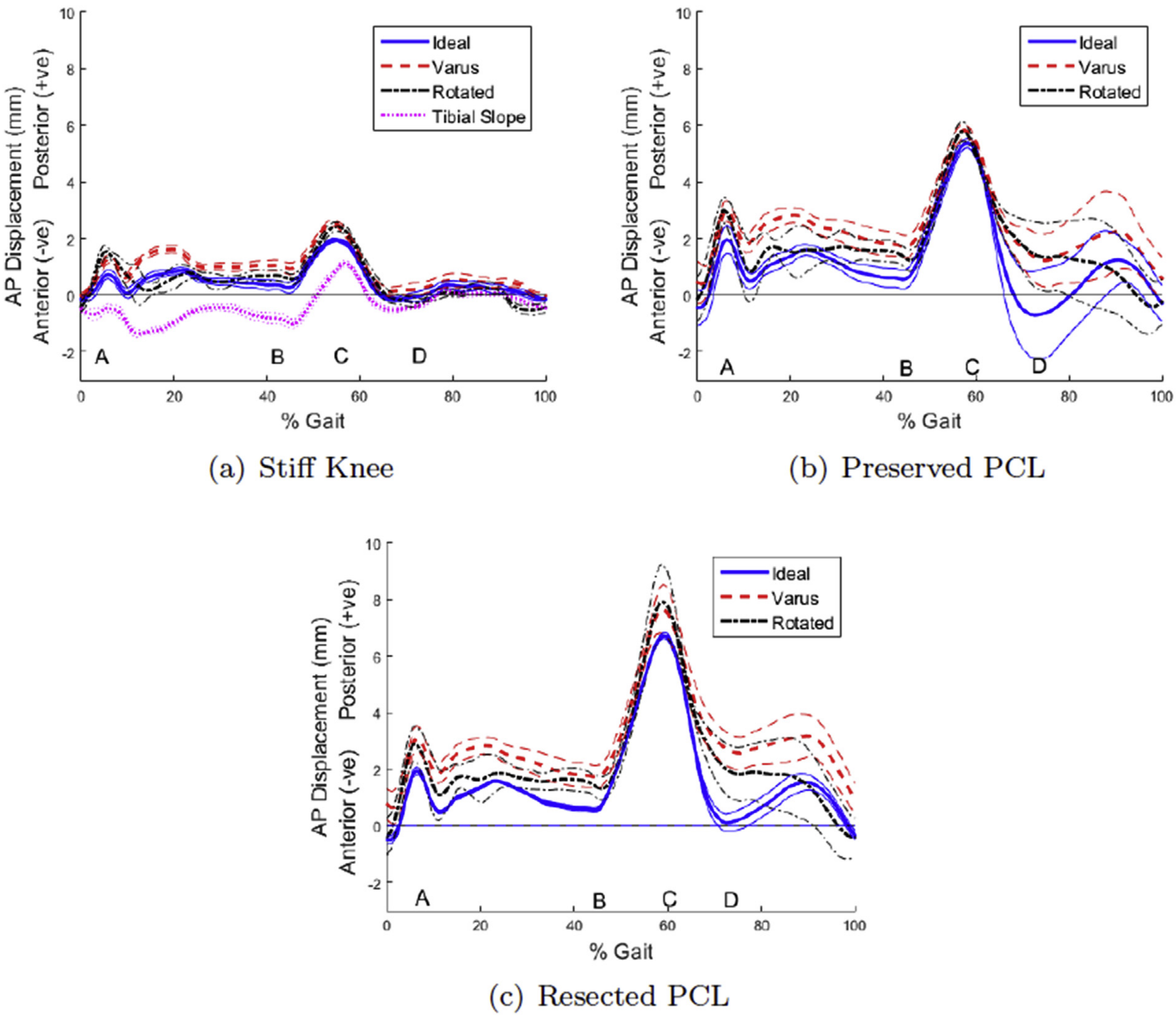

Fig. 3. The mean output AP displacement with the 95% CI for each alignment condition under the stiff knee, preserved PCL and resected PCL soft tissue conditions.

Table 6
Statistical significance of the different AP displacements between the alignment conditions for each soft tissue condition after the one-way ANOVA. Significant values are shown in bold.

Soft Tissue Condition	A	B	C	D
Stiff Knee	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**
Preserved PCL	**< 0.01**	**< 0.01**	**0.02**	0.06
Resected PCL	**< 0.01**	**< 0.01**	0.12	**< 0.01**

was more variation between stations in the range of motion under the lower tension soft tissue conditions than under the stiff knee soft tissue condition.

3.1.2. *Tibial rotation*

The ideal, varus and tibial slope alignment conditions resulted in similar TR rotation output profiles; an increase after 20% gait followed by a plateau and peak displacement at 60% gait (Fig. 4). The varus and tibial slope alignment conditions resulted in similar peak displacements as the ideal alignment condition for all the soft tissue conditions.

The rotated alignment condition resulted in a different output profile under all the soft tissue conditions compared to the other alignment conditions. The initial plateau was present under the stiff knee springs but occurred earlier in the cycle, while under the lower tension springs it was not present at all. For the preserved PCL and resected PCL springs there was a gradual increase in TR rotation for the first half of the cycle. After this point it resulted in a similar profile shape to the other alignment conditions (Fig. 4 (b) and (c)). The peak TR rotation under the rotated alignment condition was significantly higher than the other alignment conditions for all the soft tissue conditions ($p < 0.01$) and occurred earlier in the cycle.

The mean and 95% CI for the range of TR motion was determined for each alignment and soft tissue condition. Under the stiff knee springs the rotated alignment condition resulted in significantly higher range of motion compared to the other alignment conditions ($p < 0.01$). Under all soft tissue conditions there was a significant difference between the TR displacement of the alignment conditions at points E-H (Table 7). However, under the other two soft tissue conditions the range of TR rotation was similar across all the alignment conditions.

3.1.3. *Abduction-adduction rotation*

The ideal, varus and tibial slope alignment conditions resulted in similar AA rotation profiles, with the peak displacement occurring at around 60% gait (Fig. 5). The ideal alignment condition resulted in significantly higher peak AA rotation than the varus alignment condition under the stiff knee springs but the difference between these conditions was still low ($p < 0.01$) (Fig. 5 (a)).

The rotated alignment condition resulted in a different AA profile; there was a peak at the start of the gait cycle followed by a decrease

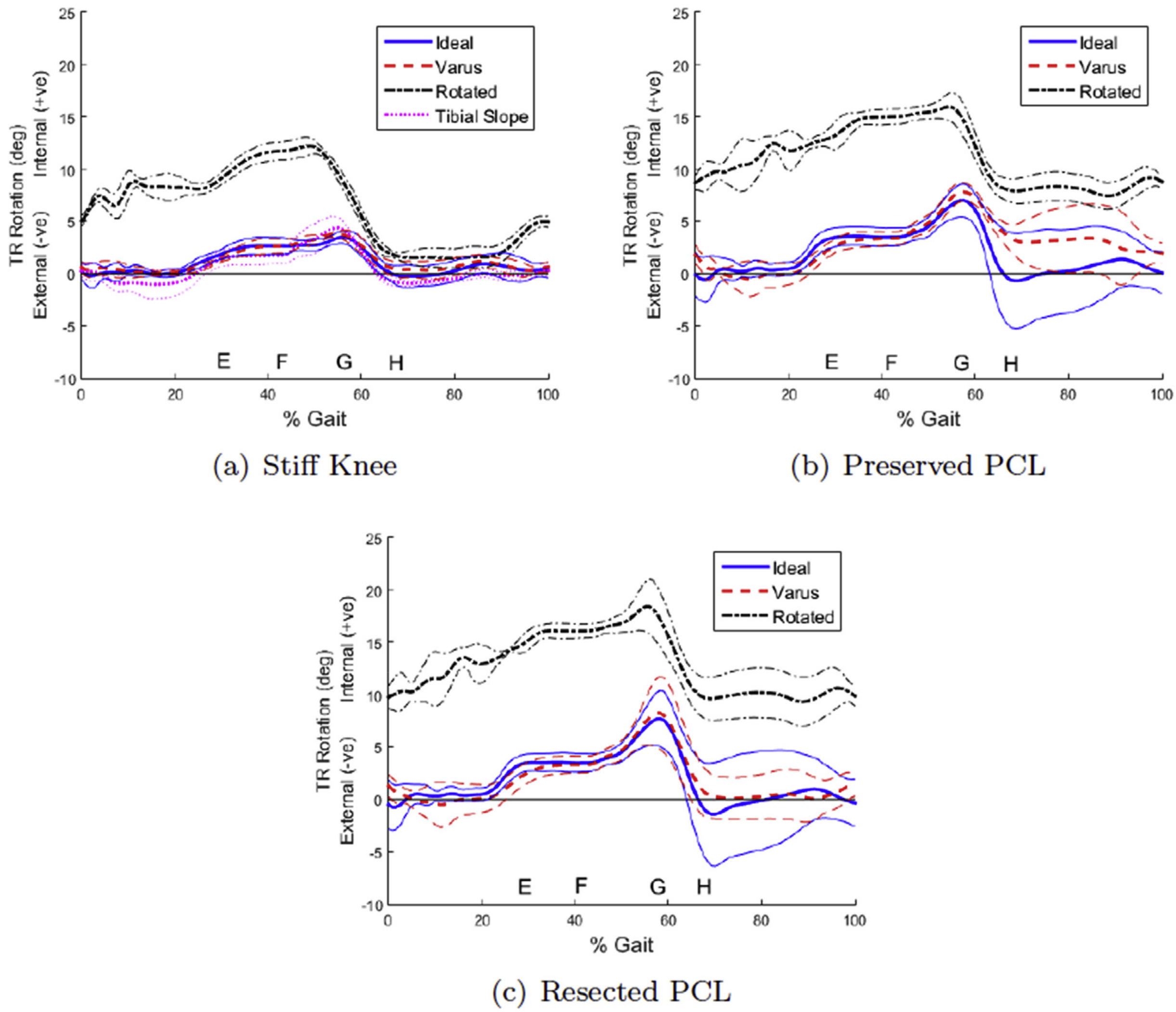

Fig. 4. The mean output TR rotation with the 95% CI for each alignment condition under the stiff knee, preserved PCL and resected PCL soft tissue conditions.

Table 7
Statistical significance of the different TR rotations between the alignment conditions for each soft tissue condition after the one-way ANOVA. Significant values are shown in bold.

Soft Tissue Condition	E	F	G	H
Stiff Knee	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**
Preserved PCL	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**
Resected PCL	**< 0.01**	**< 0.01**	**< 0.01**	**< 0.01**

then plateau from 10 to 50% gait then a large peak in adduction at around 70% gait. Both the shape and amplitude of the AA profile was different for the rotated alignment condition. For all soft tissue conditions there was a significant difference in the AA rotation at points I–K between the alignment conditions (Table 8).

Under all the soft tissue conditions the rotated alignment condition resulted in a significantly higher AA range of motion ($p < 0.01$).

3.2. Wear

The wear rates for the ideal, varus, rotational mismatch and tibial slope alignments under the stiff knee soft tissue condition were $1.58 \pm 1.20\,mm^3/MC$, $-0.10 \pm 1.00\,mm^3/MC$, $10.05 \pm 4.37\,mm^3/MC$ and $9.24 \pm 2.80\,mm^3/MC$ respectively (Fig. 6). The wear rates for the rotated and tibial slope alignments were significantly higher than the other alignment conditions ($p < 0.01$). The varus alignment also resulted in a significantly lower wear rate than all the other alignment conditions ($p < 0.042$).

The mean wear rates with 95% CI for the ideal, varus and rotational mismatch alignments under the resected PCL soft tissue condition were $3.06 \pm 1.57\,mm^3/MC$, $1.79 \pm 1.64\,mm^3/MC$ and $7.33 \pm 3.05\,mm^3/MC$ respectively. Under the resected PCL springs the rotated alignment still resulted in a significantly higher wear rate than the ideal and varus alignments ($p < 0.034$).

For the ideal and rotated alignments there was no significant difference in wear under the resected PCL soft tissue condition compared to the stiff knee soft tissue condition. However, the varus alignment resulted in significantly higher wear under the resected PCL soft tissue condition compared to the stiff knee soft tissue condition, but as the wear was less than $2\,mm^3/MC$ there are limits on the sensitivity of the wear measurements ($p = 0.03$).

4. Discussion

This study experimentally investigated the effect of component alignment and soft tissue conditions on the kinematics and wear of a fixed bearing TKR. The alignment conditions studied were ideal alignment, 4° varus joint line, 14° rotational mismatch and 10° posterior tibial slope. The soft tissue conditions were chosen to represent a stiff knee, a preserved PCL and a resected PCL.

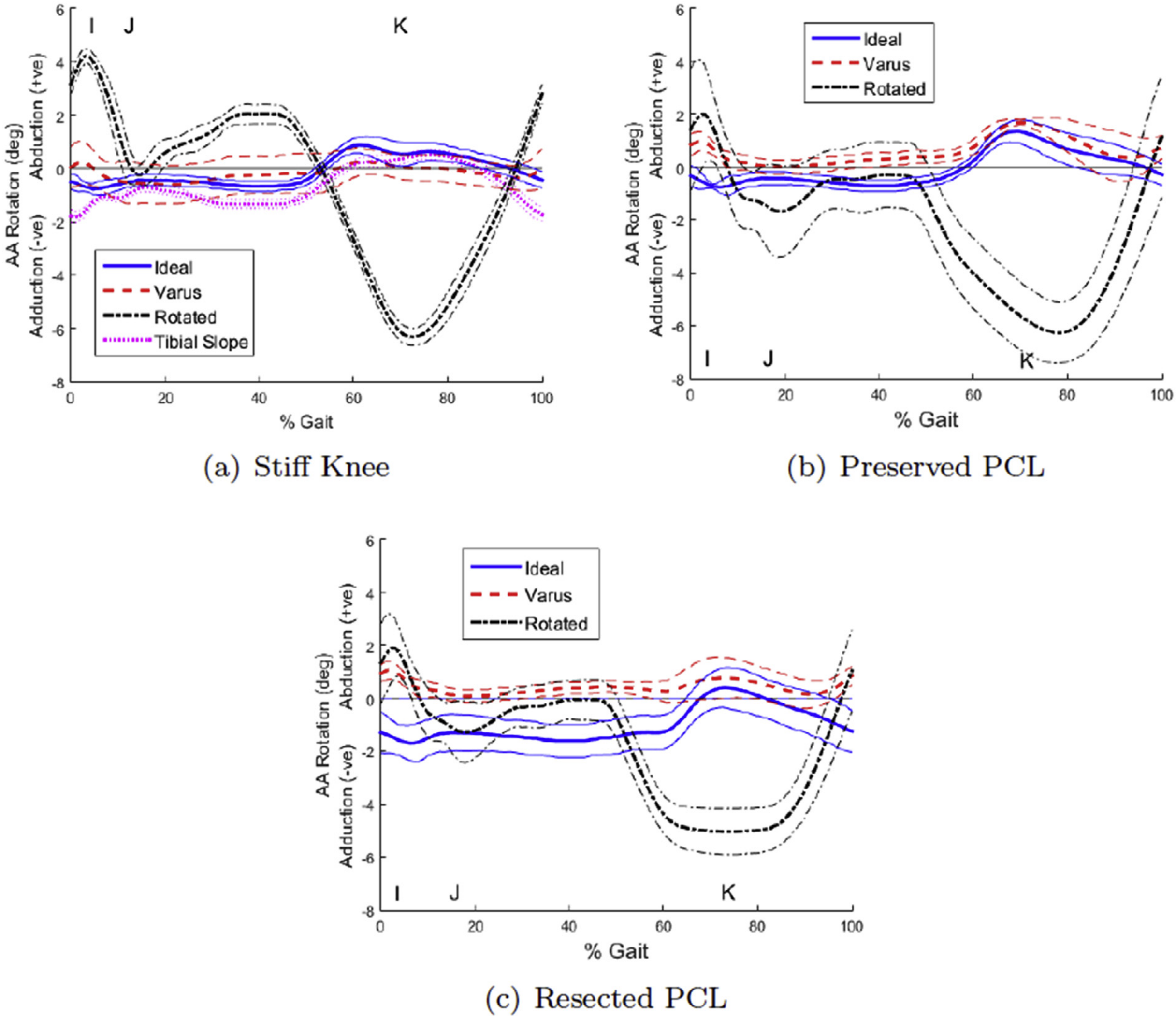

Fig. 5. The mean output AA rotation with the 95% CI for each alignment condition under the stiff knee, the preserved PCL and he resected PCL soft tissue conditions.

Table 8
Statistical significance of the different AA rotations between the alignment conditions for each soft tissue condition after the one-way ANOVA. Significant values are shown in bold.

Soft Tissue Condition	I	J	K
Stiff Knee	< **0.01**	**0.03**	< **0.01**
Preserved PCL	< **0.01**	**0.02**	< **0.01**
Resected PCL	< **0.01**	< **0.01**	< **0.01**

The varus joint line alignment resulted in the most similar output kinematics to those under ideal alignment. Under the varus alignment condition the different soft tissue conditions had a similar effect on the kinematics as under ideal alignment; the lower tension soft tissue conditions resulted in increased displacements, with all the displacement profiles centred around zero.

The wear rate of the varus alignment condition under both soft tissue conditions was found to be lower than the ideal alignment condition. However other experimental (Ezzet et al., 2012) and retrieval (Srivastava et al., 2012) studies have found that an angle of 3° varus resulted in double the wear rate. The retrieval study used laser mapping of the tibial inserts to determine the wear. Differences in the wear rate found in this study to previous studies may be due to the use of explants or may be due to differences in the UHMWPE; for example, the level of cross-linking. This may also be due differences in the simulation of the

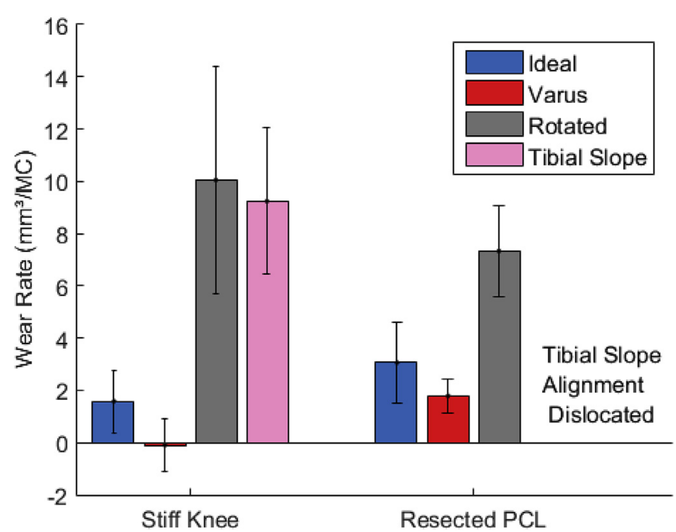

Fig. 6. Mean wear rates with 95% CI over 2 MC for the ideal, 4° varus, 14° rotational mismatch and 10° tibial slope alignment conditions for two soft tissue conditions.

varus leg alignment compared to the varus joint line alignment in this study. As one was a retrievals study patient factors such as BMI or different activity levels could have resulted in higher wear rates (Srivastava et al., 2012).

A varus joint line alignment of 4° or less may therefore not be an issue due to the similar kinematics and lower wear rates found in this study. However clinically a varus leg alignment would result in a more medial joint force (Noyes et al., 1992), which was not represented in the experimental set up. The difference in loading may result in different results clinically, therefore the results in this study for a varus joint line will not represent the conditions under a varus leg alignment.

The rotated components resulted in more internal rotation than all the other components; this may be due to the mismatch between the components resulting in a rotational force as the AF was applied. Internal rotation of the tibia increases the Q angle in the knee, this makes the quadriceps muscle less efficient and results in a lateral pull on the patella which may cause knee pain, instability and patella maltracking (Scuderi and Insall, 1992; Ranawat, 1986; Barrack et al., 2001; Brick and Scott, 1988; Emami et al., 2007; Mizuno et al., 2001; Norman Scott, 2018). A previous study found that the mean Q angle was significantly higher for patients with knee pain than those without (Emami et al., 2007). The TR rotation with the rotated alignment did not centre around 0°, unlike all the other alignment conditions but was shifted.

The rotated components also resulted in higher AA rotation compared to the other alignment conditions. An increased adduction moment within the knee may contribute to the development of knee pain; the adduction moment has been correlated with a compressive force on the medial compartment (Luepongsak et al., 2004). The peak adduction moment during gait has also been related to surgical outcome and pain relief in patients with knee OA (Hurwitz et al., 2002). An increase in the adduction moment caused by the rotational mismatch of the components will affect the force distribution across the TKR, this may result in instability or pain.

The rotational mismatch alignment condition resulted in significantly higher wear rates than the ideal and varus alignment conditions under both the soft tissue conditions studied. Unlike the ideal and varus alignment conditions the rotated alignment condition resulted in a lower wear rate under the resected PCL soft tissue condition than under the stiff knee soft tissue condition. This may be due to the lower tension soft tissue condition allowing the TR rotation to increase and reduce the rotational mismatch between the components.

A previous experimental study using the same TKR design and input profiles under force control conditions found similar kinematics as in this study under varus alignment and rotation of the tibial insert (Haider et al., 2006). In the previous study a varus alignment simulated by applying the axial force 5 mm medially compared to the standard set up was found to result in similar kinematics as under ideal alignment conditions, with all the displacement profiles centred around zero. External rotation of the tibial insert of 10° resulted in a shift in the TR rotation profile by around 5° externally. These results were similar to those found with the varus joint line and rotational mismatch conditions in this study.

In order to reduce the potential for knee pain and instability the rotational mismatch of the femoral and tibial components should be minimised to reduce the TR and AA rotation during gait, especially for patients with lower tension soft tissue conditions.

The posterior tibial slope alignment condition resulted in more anterior AP motion and a more posterior tibiofemoral contact point. This is similar to a previous computational study into the effect of a posterior tibial slope (Kang et al., 2017).

Previous studies have found that a posterior tibial slope may be beneficial for a CR TKR; there tends to be more anterior motion of the femur on the tibia in CR knees (Norman Scott, 2018) compared to rollback of the femur which occurs in natural knees ("paradoxical slide"). One study found that there was 80% of the femoral translation of the natural knee with a TKR at 120° flexion (Most et al., 2003). As the posterior tibial slope resulted in anterior motion of the tibia relative to the femur in this study, a posterior tibial slope may help to counteract the paradoxical motion found in CR knees. This matches that found by previous studies (Shelburne et al., 2011) and a positive correlation has been found between femoral-rollback and higher clinical and functional scores (Fantozzi et al., 2006). Another study found that for every mm of additional posterior femoral translation there was a resulting increase of 1.4° more flexion (Banks et al., 2003).

However, in this study the posterior tibial slope alignment condition was unstable and dislocated under the lower tension preserved PCL and resected PCL soft tissue conditions. The tibial slope alignment condition also resulted in significantly higher wear than the ideal alignment condition. This suggests that although the posterior tibial slope resulted in increased anterior displacement, which may be beneficial, this may result in instability especially in patients with low tension soft tissues.

A previous computational study using a finite element model investigated the effect of component alignment on wear rates (Mell et al., 2009a, 2009b). Rotational alignment and posterior tibial slope alignment conditions were found to result in higher wear rates, while other alignment conditions including TR axis resulted in a lower increase in wear (Mell et al., 2009b). Internal rotation of the tibial insert was also found to result in loading on the edge of the tibial insert as found in this study (Mell et al., 2009a).

Previous clinical studies have determined that poor alignment can result in knee pain, lower knee scores or early failure (Feng et al., 1994; Choong et al., 2009; Bell et al., 2014; Slevin et al., 2017). Some studies found that a TKR with a mechanical axis > 3° resulted in lower knee scores or that internal rotation resulted in knee pain (Choong et al., 2009; Bell et al., 2014). However, alignment of the TKR may not result in failure of the TKR, often failure occurs due to a combination of factors such as alignment and BMI (Berend et al., 2004). One study investigating varus and valgus alignment using cadaveric specimens determined that the changes in the load distribution of the TKR were proportional to the angle of the component alignment (Werner et al., 2005). They also determined that the cadaveric specimens with tight ligaments resulted in more balanced loading. This study suggested that alignment on its own may not result in imbalanced loading, but that it is the combination of alignment and the soft tissue conditions within the knee that are important.

Both the rotated and tibial slope alignment conditions resulted in significantly higher wear than the ideal or varus joint line alignments. The increased wear may be partly due to the kinematics and contact positions. The rotated components resulted in significantly higher AP, TR and AA displacements than ideal alignment. The increased range of motion may therefore have resulted in increased wear rates. The tibial slope alignment resulted in similar AA motion to ideal alignment, significantly higher TR rotation (though significantly lower than the rotated components) and significantly more anterior AP displacement than the ideal alignment. The increased TR rotation may have resulted in higher wear. For both the rotated and tibial slope alignment conditions the contact was also at the posterior edge of the tibial insert, with the wear scar extending over the lip of the tibial insert in some cases.

Overall the varus joint line alignment resulted in similar kinematics and lower wear than the ideal alignment condition. The rotated and tibial slope alignments resulted in significantly higher wear rates and may result in instability and knee pain in vivo.

One limitation of this study is that it only investigated the mechanical impact of the alignment and soft tissue conditions on the TKR. The effect of the overall leg alignment was also not investigated due to the restrictions on the loading direction on the simulator, therefore there may be differences in vivo to the results found in this study. The effect of the component alignment and soft tissue conditions on the patient satisfaction was not investigated and can only be suggested based on other research. Therefore, the clinical guidance from this study should be interpreted with care. A different TKR design may also respond differently to the one in this study. The effect of the alignment and soft tissue conditions can not be generalised to all TKRs, especially those of fundamentally different designs such as posterior stabilising TKRs. In 2018 the Sigma TKR was the most common TKR in England, Wales and the Isle of Man (NJR, 2018), however in future the newer Attune TKR by DePuy Synthes may be more common.

Another limitation is in the definition of the soft tissue conditions. Previous studies have investigated the laxity and ligament tensions of the knee in TKR patients (Warren et al., 1994) or cadaveric specimens (Musahl et al., 2007; Kanamori et al., 2002; Fukubayashi et al., 1982). Due to the variation in ligament stiffness and laxity between patients there is a range of results. The AP displacement under a given load also depends on the flexion position of the knee (Fukubayashi et al., 1982). As with the AP tension there is variation in the rotational stiffness of the knee. Therefore, the chosen definitions in this study may not represent the range of conditions found in vivo.

Currently component alignment aims to be within ± 3° of the mechanical axis of the leg in the coronal plane, however this envelope may vary between TKR designs and has not been validated. This envelope may also vary under different soft tissue conditions within the knee. There is no corresponding envelope for acceptable error in the sagittal or transverse planes. In order to understand the effect of component alignment and the acceptable variation in vivo further investigation should be carried out. Further work will investigate a wider range of component alignment conditions using a combined computational and experimental simulation approach.

5. Conclusions

The component alignment and soft tissue conditions had a significant effect on the kinematics and wear of the fixed bearing TKR investigated in this study. In order to simulate the range of outcomes that occur in vivo a range of component alignment and soft tissue conditions should be pre-clinically investigated.

Acknowledgements

This research work was supported by EPSRC, University of Leeds Alumni Fund and EPSRC Centre of Innovative Manufacturing of Medical Devices (grant number: EP/K029592/1). JF is an NIHR Senior Investigator and supported as director of the EPSRC Centre of Innovative Manufacturing in Medical Devices. This research work was also supported by DePuy Synthes, UK, who supplied the components studied. Thank you to the laboratory technicians in IMBE for their help with the experimental testing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jmbbm.2019.103386.

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