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Understanding the differences in wear testing method standards for total knee replacement

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ABSTRACT

Preclinical evaluation of the wear of total knee replacements (TKR) is usually undertaken using International Standards Organization (ISO) test methods. Two international standards for the preclinical wear simulation of TKRs have been developed; using either force or displacement control. In addition, based on previously published measured kinematics of healthy subjects, a gait cycle (displacement control) was also developed at the University of Leeds, which pre-dates the ISO displacement control standard. Furthermore, different test methods have adopted different approaches to defining the centres of rotation and polarity (direction of application) of motions. However, the effects of using these different control regimes and input conditions on the kinematics, contact mechanics, and wear of any one TKR have not been fully investigated previously.

The current study investigated the kinematics, contact mechanics, and wear performance of a TKR when running under ISO force and displacement control test methods as well as the Leeds gait cycle inputs using experimental and computational simulation methods, with the aim of understanding the mechanical and tribological outcomes predicted by the different test method standard conditions. Three ISO wear testing standards were investigated using a mid-size Sigma curved TKR (DePuy, UK), with moderately cross-linked UHMWPE curved inserts; ISO-14243-3-2004, ISO-14243-3-2014 and ISO-14243-1-2009. In addition, the Leeds displacement control gait cycle was also investigated.

According to the computational simulation predictions, reversing the anterior-posterior (AP) displacement and tibial rotation polarities in the displacement control ISO-2014 standard compared to the ISO-2004 standard resulted in high stress, of more than 65 MPa, at the posterior edge of the inserts with more than 10% increase in wear rate for this TKR design. Although Leeds gait input kinematics produced femoral rollback, it did not result in high stress edge loading on the posterior lip of the insert. This was attributed to different test input kinematics and different centres of rotation of the femoral component adopted in the displacement control standard ISO-2014 and Leeds gait test methods. The predicted AP displacement and tibial rotation from the force control ISO-2009 had different polarities and magnitudes to the corresponding displacement control profiles. In addition, the predicted wear rate, from the computational model, under the force control ISO-2009 standard was more than double that predicted under displacement control ISO standards due to the increased AP displacement and tibial rotation motions predicted under the force control standard.

These major differences, in the mechanics and wear, between different test methods imply that each standard must therefore be used with its own predicate control results from a device with proven clinical history and results across different standards should never be compared, as the choice of test method standard may well be dependent on the design solution for the knee. Clinically, the kinematics in the population are extremely variable, which results in highly variable wear rates. While a standard method is necessary, on its own it is not adequate and needs to be supported by tests under a portfolio of representative conditions with different kinematic conditions, different soft tissue constraints, as well as with different alignments, so that the variability and range of wear rates expected clinically might be determined. This study enables further progress towards the definition of such a portfolio of representative conditions, by deepening the understanding of the relationships between currently used input conditions and the resulting mechanical and wear outputs.

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1. Introduction

Total knee replacement (TKR) is currently facing a new challenge, due to the increasing number of younger and more active patients requiring TKR (National Joint Registry, 2020). The number of TKR primaries recorded in patients under 60 years in England, Wales and Northern Ireland increased by more than 22% between 2013 and 2019 (National Joint Registry, 2014, National Joint Registry, 2020). In addition, the revision rate amongst this patients' group (under 60 years) was more than 10 times that amongst patients over 75 years (National Joint Registry, 2020).

Preclinical evaluation and understanding the long-term wear performance of TKR is therefore important, particularly in these groups. Experimental full-joint simulation has extensively been used for the preclinical evaluation of TKR (Fisher et al., 2010; Jennings et al., 2007; Galvin et al., 2009; Asano et al., 2007). The advancements in experimental simulators, with improved performance and capabilities, enabled such simulations to be undertaken under more complex and clinically relevant conditions including the influence of activity, materials, and surgical alignment (Abdelgaied et al., 2017; Johnston et al., 2018; Johnston et al., 2019).

International Standards Organization (ISO) wear testing method standards specify the relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the preclinical wear testing of total knee joint prostheses (ISO-14243-1, 2009, ISO-14243-3, 2014). Based on an average patient, two different international standards have been developed, such that the anterior-posterior (AP) displacement of the tibial component and tibial rotation can be driven in either force (ISO-14243-1, 2009) or displacement control (ISO-14243-3, 2004, ISO-14243-3, 2014). In the displacement control standard, the AP displacement and tibial rotation that occur during the gait cycle are predefined. In the force control standard, the inputs are AP force and tibial rotation torque profiles, allowing the TKR to move according to the applied forces, with TKR design, alignment of the TKR, and the applied constraints simulating the cruciate ligaments action (Abdelgaied et al., 2018, ISO-14243-1, 2009). Displacement and force control standards should be utilised to answer different research questions. If the aim of the research is to study a specific factor, such as material for example, while eliminating other factors, such as friction and design parameters, using a displacement control method would be more appropriate. In studies where the kinematics are not known or where it is important to consider the effects of other factors such as friction and design, using a force control method may be the better choice (Abdelgaied et al., 2018; Johnston et al., 2018; Johnston et al., 2019). Furthermore, different test methods have adopted different approaches to the femoral centre of rotation, in particular in the sagittal plane, i.e. the flexion-extension axis, and the axis of rotation of the femoral component relative to the machine frame. (ISO-14243-3, 2004, ISO-14243-1, 2009, ISO-14243-3, 2014). In addition, there have been differences in polarity definitions, i.e. direction of application of motions/forces, (referred to as 'sign convention' within the ISO standards). Such differences in centres of rotation and polarity of motions will affect the effective motions at the articulating surfaces, the contact mechanics, kinematics, and hence wear of TKR. In addition, based on measured kinematics of healthy subjects (Lafortune et al., 1992), and pre dating the first ISO knee wear test methods being developed, a displacement controlled gait profile was developed at the University of Leeds and extensively used to systematically study many factors independently (Barnett et al., 2001; Jennings et al., 2007; Galvin et al., 2009; Fisher et al., 2010; Abdelgaied et al., 2011; Abdelgaied et al., 2014; Abdelgaied et al., 2018).

Using a simplified mathematical model to describe the mechanics of the knee joint, Morrison calculated the forces transmitted to the knee joint from gait measurements of healthy male and female volunteers, assuming the normal knee joint to function according to the mechanical principals (Morrison, 1970; Paul, 1970). It is understood that the calculated knee forces during gait by Morrison and Paul (Morrison, 1970; Paul, 1970, 1976; Paul and McGrouther, 1975) formed the basis for the force controlled ISO-14243-1, 2002 and ISO-14243-1, 2009 standard test protocols for TKR, with the main difference between the two standards being the anterior-posterior motion and tibial rotation restraint systems (ISO-14243-1, 2002, ISO-14243-1, 2009). These gait force profiles were inputs to early experimental force control knee simulation studies of TKR (Walker et al., 1997; Sathasivam and Walker, 1997; Johnson et al., 2000; Sutton et al., 2010). It is understood that the measured output AP displacement and tibial rotation from these experimental studies, using the force inputs and a fixed bearing TKR, formed the basis for the displacement controlled ISO-14243-3, 2004 and ISO-14243-3, 2014 standard test protocols for TKR (ISO-14243-3, 2004, ISO-14243-3, 2014).

Both force and displacement control ISO standard wear testing methods adopt a centre of the rotation of the femoral component representing an average centre of the femoral distal and posterior radii. The axial force and flexion-extension angle (of the femoral component) is also the same for ISO force and ISO displacement control methods, with the axial force profile varying between 268 N and 2600 N and the flexion-extension profile varying between 0° and 60°. The AP profiles vary between 110 N and −265 N and between 0 mm and 5.2 mm (ISO-14243-3, 2014) for the force and displacement protocols respectively. The tibial rotation profiles vary between −1.0 Nm and 6.0 Nm and between −1.9° and 5.7° for the force and displacement protocols respectively (ISO-14243-1, 2009, ISO-14243-3, 2014). The only difference between the displacement control ISO-14243-3, 2004 and ISO-14243-3, 2014 is reversal of AP displacement and tibial rotation polarities between the two standards, as shown in Table 1 (ISO-14243-3, 2004, ISO-14243-3, 2014). The reversed polarities in the new ISO-14243-3, 2014 are thought to produce more clinically relevant test conditions, such as femoral rollback, which could not be achieved using ISO-14243-3, 2004 standard (Brockett et al., 2016).

The University of Leeds displacement control test method, which pre-dates the ISO displacement control standard, used axial force and flexion-extension profiles similar to those of the ISO test methods. The AP displacement and tibial rotation angle profiles were however, different from those of the ISO test protocols and were based on the data of Lafortune et al. who analysed healthy patients without replacement prostheses (Lafortune et al., 1992). This resulted in AP displacement and tibial rotation profiles varying between −3.5 mm and 10 mm and between −5.0° and 5.0° respectively (Barnett et al., 2001; McEwen et al., 2005; Fisher et al., 2010) (Table 1). In addition, the Leeds displacement control test method adopted a distal centre of rotation of the femoral component to replicate femoral rollback (Brockett et al., 2016).

The effects of using these different control regimes and input conditions on the kinematics, contact mechanics, and wear of any one TKR have not been fully investigated. The aim of this study was therefore to investigate the kinematics, contact mechanics and wear of the same TKR design when the ISO force and displacement control standards, and Leeds displacement control methods were followed, using a

Table 1
Different test methods for total knee replacements.

	ISO-14243-1, 2009	ISO-14243-3, 2004	ISO-14243-3, 2014	Leeds
Femoral centre of rotation	ISO (an average centre of the femoral distal and posterior radii)			Distal
Control	Force	Displacement		
AP range	268 N–2600 N	−5.2 mm–0 mm	0 mm–5.2 mm	−3.5 mm–10 mm
Tibial rotation range	−1.0 Nm to 6.0 Nm	−1.9°–5.7°	−5.7°–1.9°	−5.0°–5.0°

combination of experimental and computational simulation methods. This would provide understanding of the differences in mechanical and tribological outcomes predicted by the different test methods. In addition, the computationally predicted output kinematics using the ISO force control standard inputs (including the recommended ISO soft tissue constraints) were compared to the measured output kinematics from the experimental simulator to investigate the possibility of using the force control standard to generate displacement control inputs. In this approach, computational models could be used to predict displacements from the TKR responses to the force control standard inputs and soft tissue constraints. The resulting kinematics could then be used as displacement control inputs if required.

2. Materials/methods

A combined experimental and computational approach was used to investigate the effects of using different control regimes and input conditions on the kinematics, contact mechanics, and wear of the same TKR design. A computational model, that has previously been validated for the same TKR design as that used in this study (Abdelgaied et al., 2018), was used to investigate the kinematics, contact mechanics and wear under all conditions investigated. Experimental simulation was used to investigate the contact mechanics (contact area) under all conditions investigated, and to determine wear using the Leeds gait displacement control input conditions. In addition, experimental wear rates obtained under ISO-14243-1, 2009 force control standard, using the same TKR and same simulator (Johnston et al., 2018; Johnston et al., 2019), were used to further validate the study.

Mid-size (size 3) Sigma fixed bearing cruciate retaining total knee replacements (DePuy Synthes, UK) comprising Co–Cr–Mo alloy femoral components, and polished Co–Cr–Mo tibial trays, were used throughout with curved polyethylene tibial inserts. The inserts were moderately cross-linked UHMWPE (XLK™) (GUR 1020, 5 Mrad gamma irradiation). In the experimental simulation studies, six sets of bearings were mounted anatomically in each of the six simulator stations. For all test methods, the central axis of each implant was offset from the aligned axes of applied load from the centre of the joint by 7% of its width in the medial direction, in accordance with the ISO recommendation (ISO-14243-1, 2009, ISO-14243-3, 2014). The centre of rotation of the femoral components was taken as either an average centre of the femoral distal and posterior radii, for ISO test methods, or as the distal radius of the implant, as indicated by the device design, for Leeds gait.

Experimental simulation was run using a six station electromechanically driven knee simulator (Simulation Solutions, UK). The simulator had six fully independent stations in two banks; three stations per bank (Fig. 1). Each station had six degrees of freedom with five controlled axes of motion – axial force to the femoral component, femoral flexion extension, tibial internal-external rotation, tibial anterior-posterior displacement, and tibial adduction-abduction rotation (Abdelgaied et al., 2017).

Two different test control methods were investigated; displacement control (ISO-14243-3-2004, ISO-14243-3-2014, and Leeds gait) and force control (ISO-14243-1-2009) test methods. Axial force and flexion-extension angle were common for all test methods (Fig. 2a). AP translation (Fig. 2b) and tibial rotation (Fig. 2c) motions were displacement controlled in ISO-14243-3-2004 and ISO-14243-3-2014, with the only difference being a reversal of AP displacement and tibial rotation polarities between the two standards. The test setup and soft tissue constraints were used in accordance with ISO recommendations (ISO-14243-1, 2009, ISO-14243-3, 2014, ISO-14243-3, 2004). In addition, the Leeds gait displacement controlled method, which includes axial force and flexion-extension as defined by the ISO standards, with AP displacement and tibial rotation motions based on the work by Lafortune et al. (Lafortune et al., 1992) was also investigated (Fig. 2). Six samples were studied for each condition.

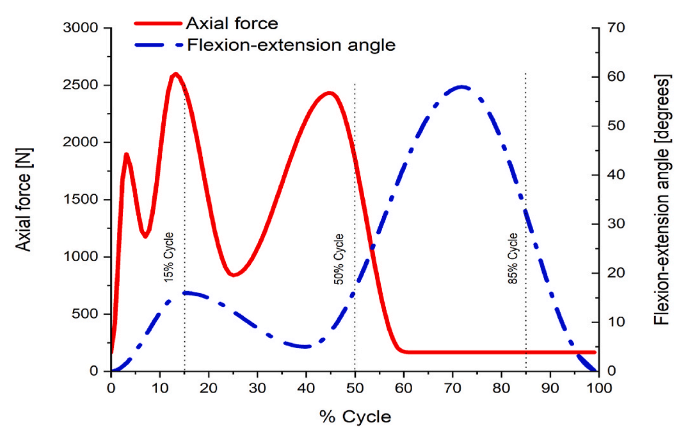

Fig. 2.a. Axial force and flexion-extension angle input profiles for all test methods.

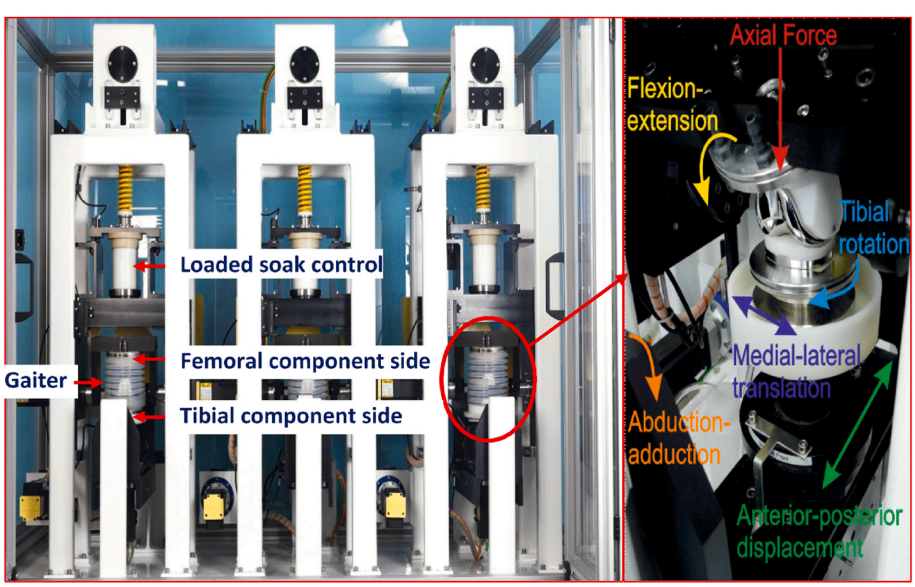

Fig. 1. Six station electromechanically driven knee simulator (Simulation Solutions, UK), and the six degrees of freedom for each station.

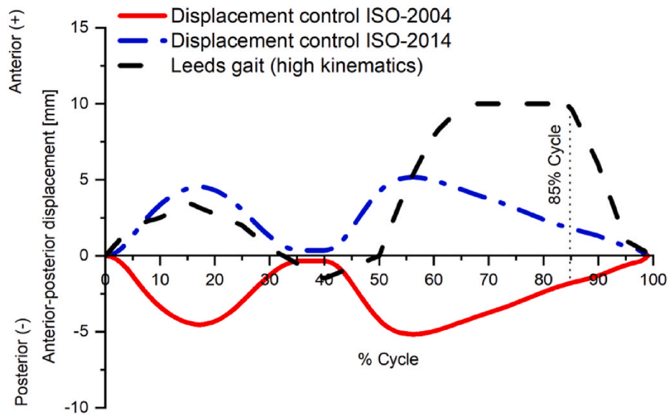

Fig. 2.b. Anterior-posterior displacement input profiles for different displacement controlled test methods (ISO-14243-3, 2014, McEwen et al., 2005; Barnett et al., 2001, ISO-14243-3, 2004).

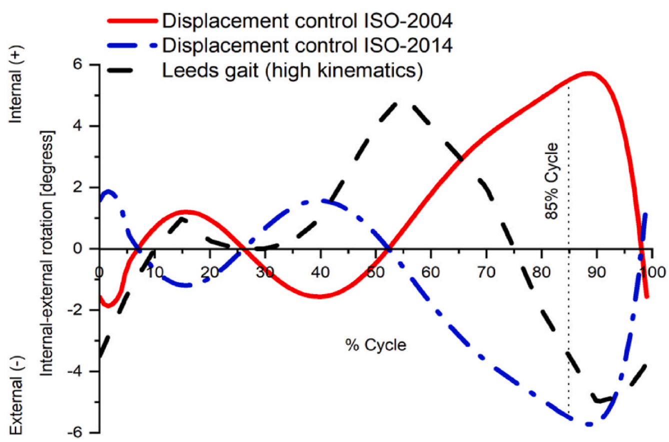

Fig. 2.c. Tibial rotation input profiles for different displacement controlled test methods (ISO-14243-3, 2014, McEwen et al., 2005; Barnett et al., 2001, ISO-14243-3, 2004).

For ISO-14243-1-2009 force control test method, AP translation and tibial rotation motions were force controlled (Fig. 3). The test setup and soft tissue constraints were used in accordance with ISO recommendations (ISO-14243-1, 2009, ISO-14243-3, 2014, ISO-14243-3, 2004).

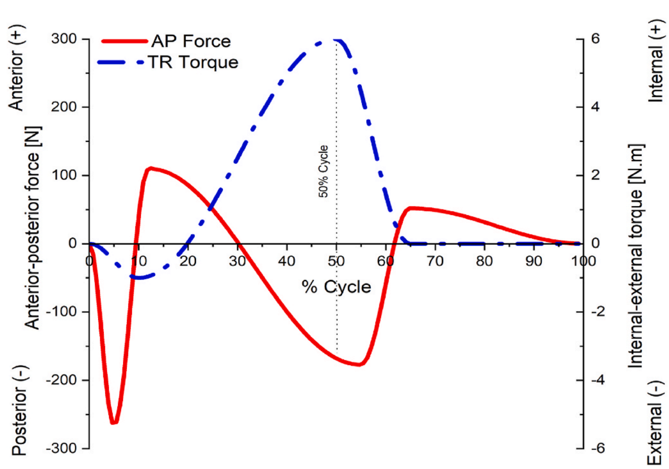

Fig. 3. Anterior-posterior force and internal-external tibial rotation torque input profiles for the ISO force controlled test method (ISO-14243-1, 2009, ISO-14243-3, 2014).

The total contact scar area on each tibial bearing insert was determined experimentally for every input condition. This experimental contact mechanics simulation was run for 1000 cycles, for each condition. An ink and Vaseline mixture was spread between the articulating surfaces (Fig. 3), and the removal of the ink mixture reflected the total contact area. Photographs were taken from above each tibial insert with a digital camera. Calibrated images were used to determine the total contact scar areas using Image Pro software (Image Pro, v6.3, USA. The studies were carried out on all six stations of the knee simulator using six independent samples. 100 consecutive cycles (during the 1000 cycles test) of kinetics and kinematics from a six axis load cell (on the tibial side) and anterior-posterior and tibial rotation position sensors were recorded for each station. The average total contact scar area, and output kinematics for the 100 cycles across all the stations was calculated and presented with 95% confidence intervals (CI).

The experimental wear simulation was run for 3 million cycles of Leeds gait. The simulator was run at a frequency of 1 Hz. The lubricant used was new-born calf serum, diluted to 25%, supplemented with 0.03% (v/v) sodium azide to retard bacterial growth, and was changed every 0.33 million cycles. Prior to testing, all inserts were soaked in deionised water for a minimum period of four weeks. This allowed an equilibrated fluid absorption level to be achieved prior to the commencement of the wear study, reducing variability due to fluid weight gain. Wear was determined gravimetrically at one million cycle measurement intervals throughout the study. A Mettler XP205 (Mettler-Toledo, USA) digital microbalance, which had a readability of 0.01 mg, was used for weighing the bearing inserts. The volumetric wear was calculated from the weight loss measurements, using a density of 0.93 mg/mm^3 for the polyethylene material, and using unloaded soak controls to compensate for moisture uptake. The cumulative volumetric wear was calculated for each station and the mean wear rate was then calculated for all 6 stations (mean ± 95% Confidence Intervals).

A validated computational simulation model was used to predict contact area, contact stress, sliding distances, and wear, utilising elastic contact mechanics and a modification of Archard's law where the wear volume is defined as a function of contact area, sliding distance, cross-shear and non-dimensional contact stress (Abdelgaied et al., 2018). The model was used to run different test methods investigated and, for the ISO force control method, was used to predict AP displacement and tibial rotation angle. Each condition was simulated for 3 million cycles, each cycle was split into 127 steps (the same number of steps as the experimental simulator inputs), and the insert geometry was updated at 0.5 million cycles to account for the surface changes due to surface wear (Abdelgaied et al., 2018). The computational model simulated the ProSim knee simulator and followed the appropriate recommendations for each of the test methods investigated.

The tibial and the femoral components were meshed using quadratic tetrahedral elements (C3D10M). An isotropic coefficient of friction of $\mu = 0.04$ was assumed in a penalty contact formulation to describe the contact between the tibial and femoral contact surfaces. Polyethylene was defined as an elastic material using equivalent Poisson's ratio and elastic modulus of the XLK inserts. The input equivalent Poisson's ratio and elastic modulus of the XLK inserts (GUR 1020, 5 Mrad gamma irradiation), were 0.32 and 553 MPa respectively (Abdelgaied et al., 2018). These parameters were determined from mechanical tests under compressive conditions and accounted for the plastic deformation of polyethylene (Abdelgaied et al., 2018). The contact area, contact stress, and sliding distance predictions from the computational simulation were recorded for each step during the simulation. Where needed, the predictions at 15% (high axial force), 50% (high AP force and tibial rotation torque), and 85% (high AP displacement, tibial rotation angle, and flexion-extension angle) through the gait cycle, as shown in Fig. 2, were presented. Root-mean square error was calculated as a metric to quantify the difference in computationally predicted and experimentally measured kinematics.

The data associated with this article are openly available through the

University of Leeds data repository (Abdelgaied and Jennings, 2022).

3. Results

3.1. Part one: displacement control test methods

Experimental total contact scar examples of the Sigma TKR with XLK inserts, under different displacement control test methods, are shown in Fig. 4a. The contact area using the more recent displacement control ISO-14243-3-2014 inputs was located more posteriorly compared to that using displacement control ISO-14243-3-2004. The total contact scars using the displacement control Leeds gait were larger and shifted posteriorly compared to that of the displacement control ISO-14243-3-2014 and ISO-14243-3-2004 profiles. The average total contact scar areas using the displacement control ISO-14243-3-2004, ISO-14243-3-2014, and Leeds gait profiles were 958 ± 39, 876 ± 55, and 1087 ± 63 [mm^2] respectively (mean ± 95% CI, n = 6). The contact stresses, taken as an indication of contact scar areas, determined computationally at 15%, 50%, and 85% through the gait cycle, are shown in Fig. 4b. In addition, the total contact areas determined computationally at different points through the gait cycle, for different test methods, are shown in Fig. 4c. The computationally predicted total contact area from ISO 2014 was generally lower than that predicted from ISO 2004 and Leeds gait test methods. In addition, the anterior-posterior displacement and tibial rotation angle of the lowest point of the medial condyle are shown in Fig. 4d and Fig. 4e respectively.

The computationally predicted maximum contact stress at each step of the gait cycle is shown in Fig. 5. For displacement control, reversing the AP displacement and tibial rotation directions in the displacement control ISO-2014, compared to ISO-2004, resulted in high contact stresses of more than 65 MPa, at the posterior edge of the inserts.

The computationally predicted wear rates were 1.8, 1.4, and 5.6 [mm^3/million cycles] for ISO-14243-3-2004, ISO-14243-3-2014, and Leeds gait respectively. The experimental wear rate for the Leeds gait condition was 5.02 ± 2.1 mm^3/million cycles (mean ± 95% CI, n = 6). The computationally predicted wear rate [mm^3/million cycles], at different percentages through the gait cycle, for different displacement control test methods is shown in Fig. 6.

3.2. Part two: force control test method

The computationally predicted AP displacement and tibial rotation angle using the force control ISO-2009 inputs are shown in Fig. 7 and Fig. 8 respectively alongside those obtained from the experimental simulation. The predicted AP displacement and tibial rotation angle ranged between −5.3 and 1.5 [mm] and between −1.4 and 9.5 [degrees] respectively. The predicted AP displacements were in generally good agreement with the measured average experimental values (root-mean square error ~ 0.9). The root-mean square error between the predicted tibial rotation angles and the measured average experimental values was approximately 0.5. There was however a large variation in the measured experimental tibial rotation values and the predicted tibial rotation angles were mostly within the 95% CI of the experimental measurements. In addition, the anterior-posterior displacement and tibial rotation angle of the lowest point of the medial condyle are shown in Fig. 9.

The experimental total contact scar areas of the Sigma TKR with XLK inserts using the force control ISO-14243-1-2009 are shown in Fig. 10 a. The contact area scars using the force control ISO-14243-1-2009 were located more towards the centre of the inserts. The average total contact area using the force control ISO-14243-1-2009 was 1031 ± 67 [mm^2] (mean ± 95% CI, n = 6). The contact stresses, indicative of contact scars, determined computationally at 15%, 50%, and 85% through the gait cycle, are shown in Fig. 10 b. In addition, the total contact areas determined computationally at different points through the gait cycle are shown in Fig. 10 c. The computationally predicted total contact areas from ISO-14243-1-2009 and Leeds gait were generally similar.

The computationally predicted maximum contact stress at each step of the gait cycle is shown in Fig. 11. The predicted maximum contact stress though the gait cycle was approximately 35 MPa.

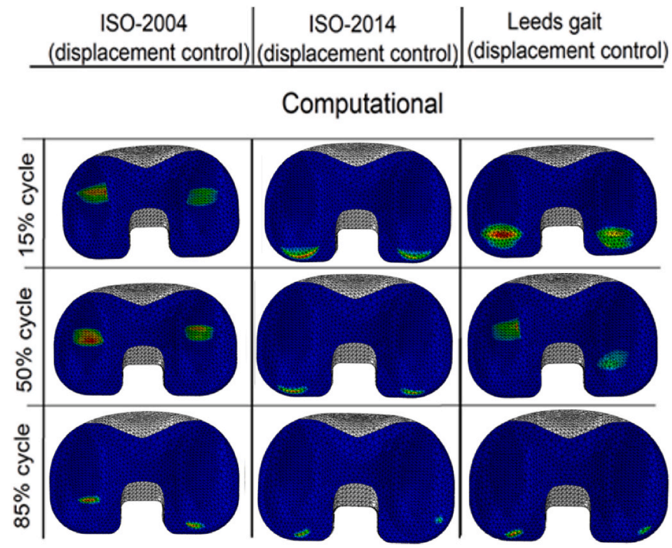

Fig. 4.b. Computational contact scars at 15%, 50%, and 85% through the gait cycle using different displacement control test methods (more points throughout the cycle are openly available through the University of Leeds data repository (Abdelgaied and Jennings, 2022)).

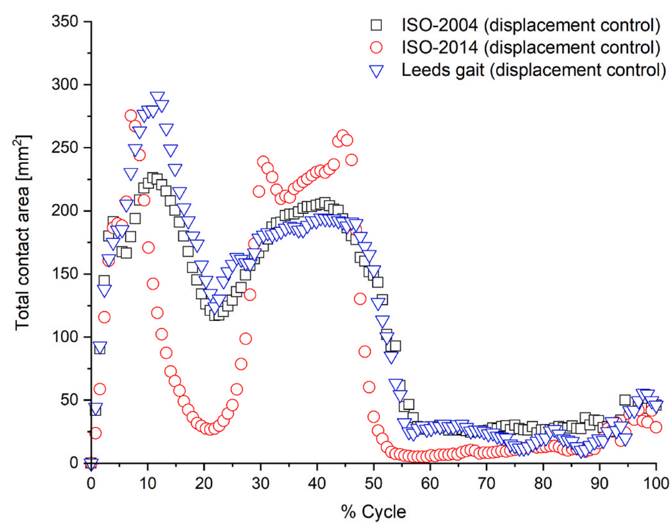

Fig. 4.c. Computational total contact areas at different points through the gait cycle using different displacement control test methods.

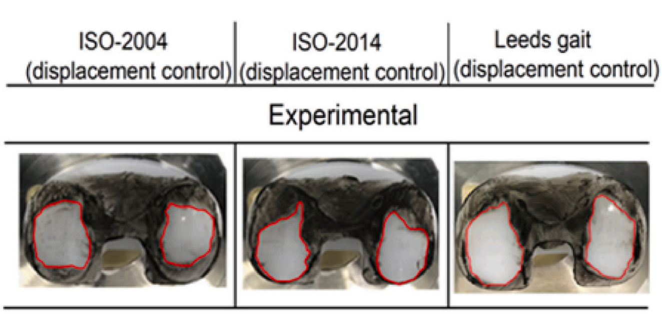

Fig. 4.a. Experimental total contact scar areas using different displacement control test methods.

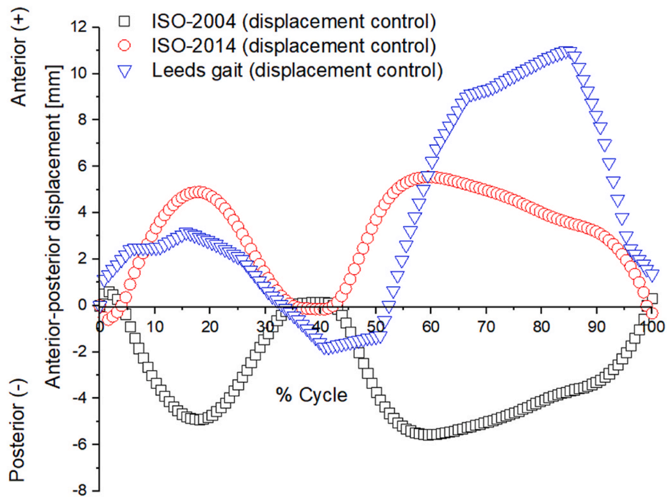

Fig. 4.d. Computationally predicted anterior-posterior displacement [mm] of the lowest point of the medial condyle using different displacement control test methods.

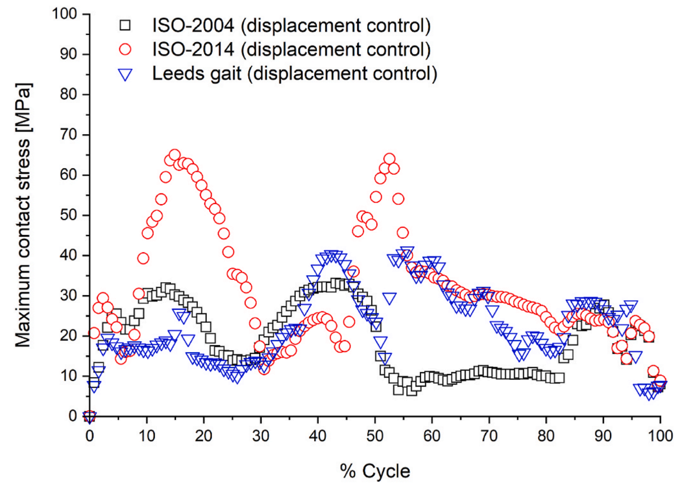

Fig. 5. Computationally predicted maximum contact stress [MPa], at different percentages through the gait cycle, for different displacement control test methods.

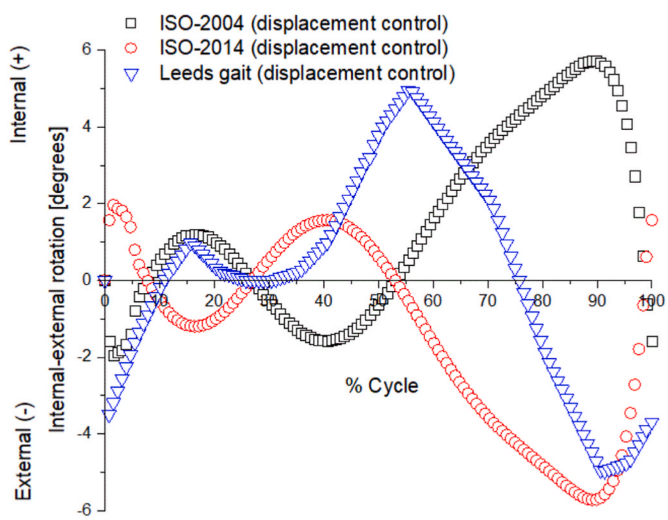

Fig. 4.e. Computationally predicted tibial rotation angle [degrees] of the lowest point of the medial condyle using different displacement control test methods.

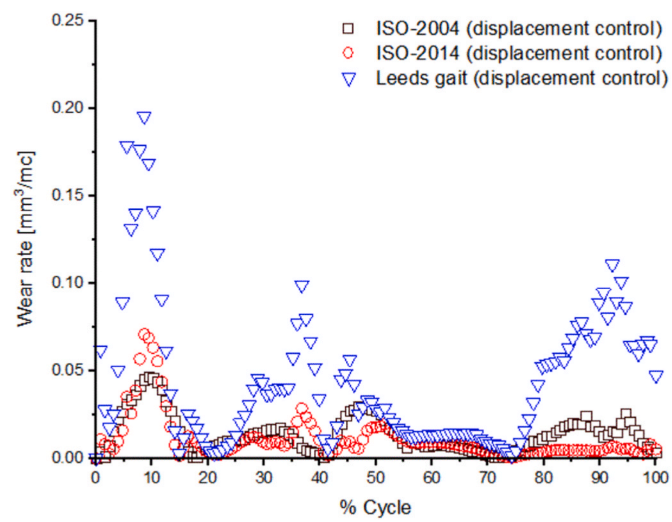

Fig. 6. Computationally predicted wear rate [mm^3/million cycles], at different percentages through the gait cycle, for different displacement control test methods.

The computationally predicted wear rate for the force control ISO-14243-1-2009 was 5.4 [mm^3/million cycles]. The computationally predicted wear rate [mm^3/million cycles], at different percentages through the gait cycle is shown in Fig. 12.

4. Discussion

Different versions of standards and test methods to determine the wear of total knee replacements have adopted different approaches to control regimes, input profiles, centres of rotation, and polarity of motions. Each of these parameters affects the effective motions at the articulating surfaces of TKR and therefore, results in different contact mechanics, kinematics, and wear in TKR. The effects of using these different control regimes and input conditions on the contact mechanics, kinematics, and wear of any one TKR have not been fully investigated. The current study is the first study to investigate the kinematics, contact mechanics and wear performance of a TKR (a size 3 Sigma fixed bearing cruciate retaining total knee replacement, DePuy Synthes, UK) when running under ISO force and displacement control standards test

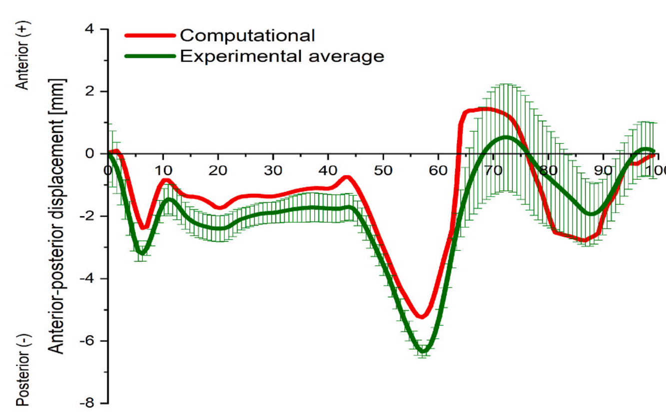

Fig. 7. Computationally predicted AP displacements [mm] compared to experimental AP displacements [mm] (mean ± 95% CI, n = 100 cycles) using the force control ISO-2009 input kinematics.

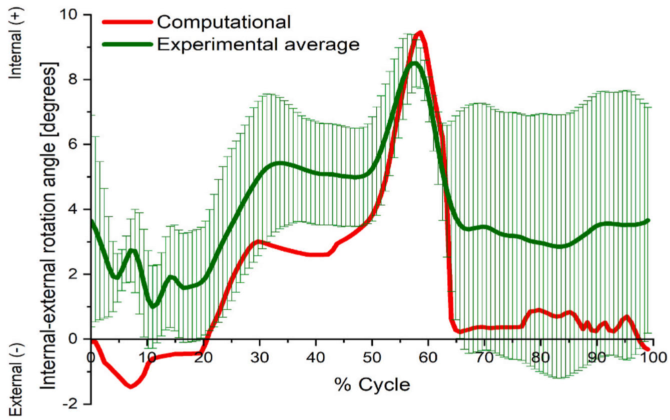

Fig. 8. Computationally predicted tibial rotation angle [degrees] compared to experimental tibial rotation angle [degrees] (mean ± 95% CI, n = 100 cycles) using the force control ISO-2009 input kinematics.

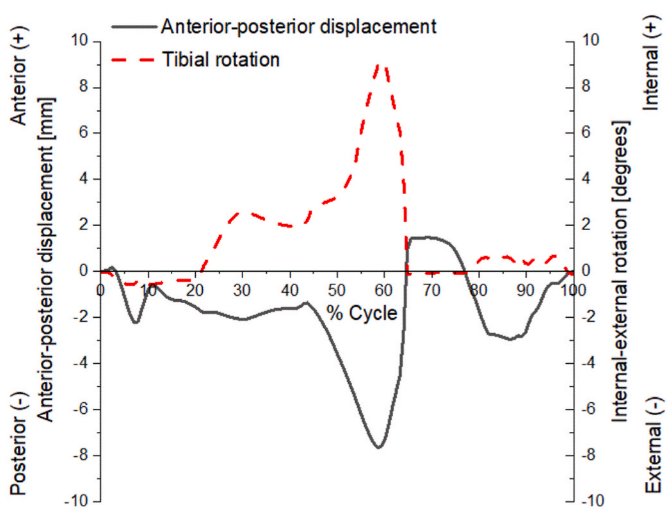

Fig. 9. Computationally predicted anterior-posterior displacement [mm] and tibial rotation angle [degrees] of the lowest point of the medial condylar using ISO-14243-1-2009 force control test method.

conditions (ISO-14243-3-2004 displacement control, ISO-14243-3-2014 displacement control, and ISO-14243-1-2009 force control) as well as Leeds gait inputs (based on the work by (Lafortune et al., 1992)), using experimental and computational simulation methods. The study is a significant step towards understanding the mechanical and tribological outcomes predicted by the different standard conditions in order to choose a suitable test method for the preclinical evaluation of TKRs and to make a better-informed choice of test conditions for different design solutions. This will also help to understand differences in results from different test centres.

4.1. Part one: displacement control test methods

Reversing AP displacement and tibial rotation angle profiles in the displacement control standard ISO-2014, compared to the ISO-2004 standard, resulted in the contact shifting more posteriorly, as shown from both experimental and computational results in Fig. 4. With ISO 2014 inputs, the AP motion of the tibial insert is predominantly in the anterior direction (relative to the neutral position at the start of the cycle), producing femoral rollback similar to Leeds gait and clinical data, with two mean peaks of ~5 mm at ~15% and 55% of the cycle. However, reversing AP displacement and tibial rotation angle profiles in

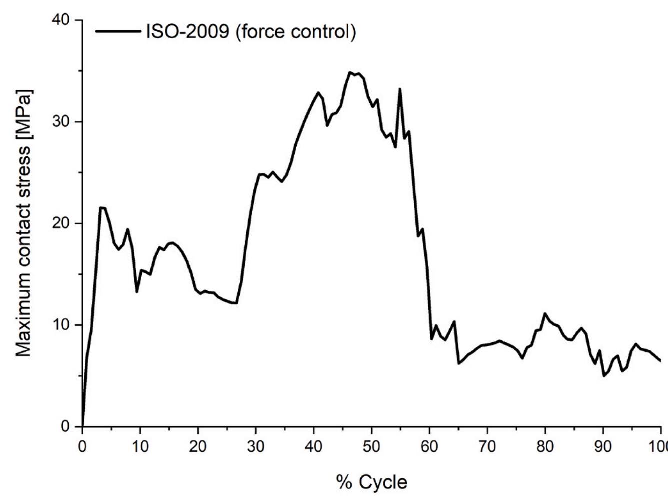

Fig. 11. Computationally predicted maximum contact stress [MPa], at different percentages through the gait cycle, for ISO-14243-1-2009 force control test method.

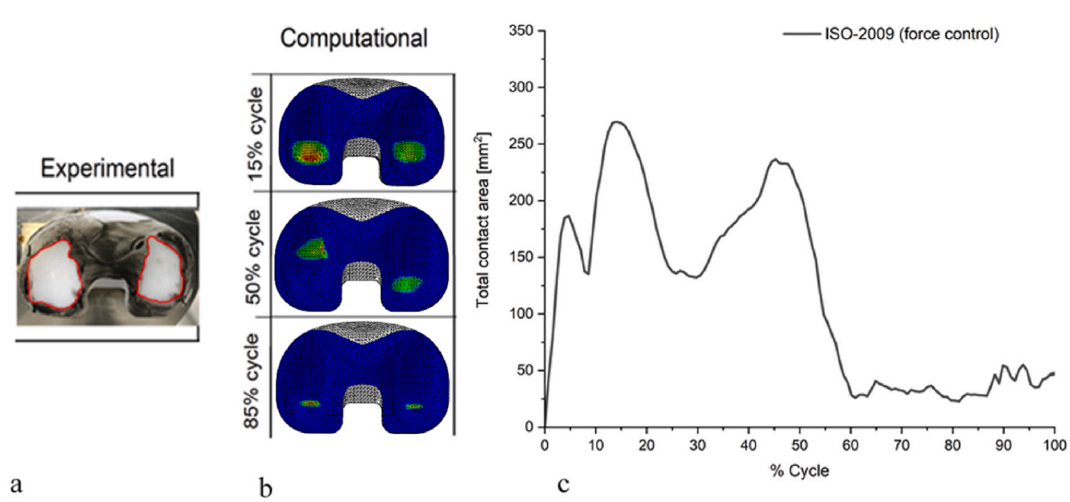

Fig. 10. (a) Experimental total contact scars, (b) computational contact scars at 15%, 50%, and 85% through the gait cycle, (c) computational total contact areas at different points through the gait cycle using ISO-14243-1-2009 force control test method.

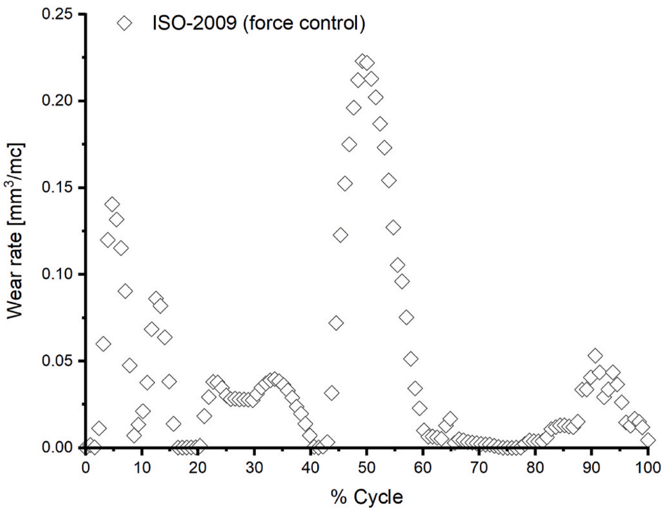

Fig. 12. Computationally predicted wear rate [mm^3/million cycles], at different percentages through the gait cycle, for ISO-14243-1-2009 force control test method.

the displacement control standard ISO-2014, compared to the ISO-2004 standard, resulted in reduced contact areas with high stress edge loading on the posterior lip of the insert, for this TKR design and size, as shown in Figs. 4 and 5. The combined effect of decreased contact area and increased contact stress seemed to dominate the wear prediction from the computational model and resulted in a slight reduction in the computationally predicted volumetric wear rate using ISO-2014, compared to ISO-2004, of approximately 10%. It is recognised that the predicted volumetric wear rate also depends on many factors, such as sliding distance and cross-shear, however, ISO-2014 and ISO-2004 had the same AP displacement and tibial rotation profiles, but with different polarities, and therefore similar sliding distances and cross-shear ratios at the articulating surfaces.

Although Leeds gait kinematics produced femoral rollback, similar to the displacement control standard ISO-2014 and clinical data, it did not result in high stress edge loading on the posterior lip of the insert, as shown in Figs. 4 and 5. This can be attributed to both the different input kinematics, and different femoral centre of rotation adopted in the Leeds gait test methods compared to the displacement control standard ISO-2014. The distal centre of rotation of the femoral component and input kinematics adopted in Leeds gait test methods, which aligns more closely to the stance phase centre of rotation when loading is high, maintained a more centred contact between femoral and the tibial components, with no edge loading on the posterior lip of the insert, and resulted in a maximum contact stress of approximately 40 MPa, compared to a maximum contact stress of more than 65 MPa under the displacement control standard ISO-2014. In addition, the predicted wear rate under the Leeds kinematic profiles was more than double that predicted under the displacement control ISO-2004 and ISO-2014 standards due to the increased AP and tibial rotation motion in the Leeds kinematics. Note that the Leeds gait test method predates the displacement control ISO standard (Barnett et al., 2001).

4.2. Part two: force control test methods

Force control test methods are relevant to fixed pivot bearing designs or highly constrained bearings, where soft tissues are sacrificed or not present functionally. It can also be used with other bearings provided that artificial ligament constraints are used. When artificial ligament constraints are used with force control test methods, these artificial soft tissue constraints control the motion kinematics, contact mechanics, and therefore wear in non-highly constrained bearings. So, defining soft tissue constraints defines the resultant kinematics, similar to defining input kinematics in displacement control test methods.

The experimental and computational AP displacement of the tibial insert using ISO 2009 force control standard was mainly in the posterior direction (was only in the anterior direction between ~63% and 76% of the cycle). The tibial rotation angle of the tibial insert using ISO 2009 force control inputs, was ~2° in the internal direction at the start of the cycle, ranging between ~2° in internal direction and 2° in the external direction for the first half of the cycle before reaching its peak of ~6° in the external direction at ~85% of the cycle. However, the experimental and computational tibial rotation of the tibial insert using the ISO 2009 force control inputs was mainly in the internal direction (relative to the neutral position of the insert to the femur at the start of the cycle). However, there was some variation between the stations of the simulator under ISO-2009 force profiles, particularly during the swing phase, when the low-tension (soft tissue) control springs were applied. The high variation meant that comparison to the computational predictions was less clear. This variation was partly attributed to station related factors, such as friction between bearings, weight of the station, and the zero position at the start of the test (Johnston et al., 2018). This is a limitation of any force control method.

5. General discussion

The predicted total AP and tibial rotation displacement ranges from ISO-2009 were ~25% and ~45% higher than the corresponding displacement inputs in ISO-2014, respectively. This increase in motions could explain the increase in wear rate under ISO-2009 compared to that under ISO-2014. In addition, the differences between the resultant kinematics from the force control ISO-2009 and the input kinematics to the displacement control ISO-2014 may also explain the differences in the contact mechanics between the two test methods, shown in Figs. 4, 5, 10 and 11. The predicted total AP displacement from ISO-2009, of 6.8 mm (from −5.3 mm to 1.5 mm) was almost a half of the Leeds kinematics displacement inputs (from −3.5 mm to 10 mm). However, the tibial rotation ranges were similar at 10.9° and 10° from ISO-2009 and Leeds kinematics respectively. Although the average wear rates from the force control ISO-2009, of 4.71 ± 1.29 mm^3/million cycles (Johnston et al., 2018), and Leeds gait, of 5.02 ± 2.1 [mm^3/million cycles], were similar (<7% difference from both experimental and computational results), it should be noticed that the force control ISO-2009 produced different kinematics compared to the Leeds kinematic conditions. The predicted wear rates under the Leeds kinematic and the force control ISO-2009 profiles were more than double that predicted under the displacement control ISO-2004 and ISO-2014 standards due to the increased AP and tibial rotation motion profiles in the Leeds kinematics and predicted from the ISO-2009 force control standard compared to the displacement control ISO-2004 and ISO-2014 AP and tibial rotation motion profiles (Figs. 4 and 6–9 and 12).

Force control test methods are in effect just another different set of standard conditions, where artificial soft tissue effectively defines actual kinematics simulated, unless the design controls the displacement as in a medial pivot knee design. However, the differences in kinematics, contact mechanics, and wear behaviour between the ISO force and ISO displacement test methods, from both experimental and computational results, imply that the two test methods are completely different and therefore results from the two methods should be interpreted with caution. It should be noted that a standard is a test method standard, not a performance standard, and results from different standards cannot be compared. Therefore, results from force control standard test methods should not be compared to results from any of the displacement control standard test methods. In addition, results from any one standard method need to be compared to a predicated device using an identical standard test method.

Through dynamic videofluoroscopy measurements of 6 patients with a DePuy unilateral PFC Sigma Curved cruciate retaining (CR) fixed-bearing TKA, Schutz et al. (2019) measured the tibio-femoral kinematics throughout complete cycles of walking, stair descent, sit-to-stand and stand-to-sit. Their study showed that the measured kinematics were task dependant and subject specific. In comparison with this study, the predicted kinematics under ISO force control ISO-14243-1-2009 from our study showed similar trend and polarity for the output anterior-posterior displacement profiles, and the ISO-14243-3-2014 displacement control profiles better reflected the trend and polarity of tibial rotation. However, the kinematics from neither ISO-14243-1-2009 force control nor ISO displacement control ISO-14243-3-2014 test methods fully reflected the magnitude and polarity of the posterior anterior displacement and tibial rotation profiles from the in vivo fluoroscopic measurements made on this similar implant used in this study (Schutz et al. 2019). However, these in vivo fluoroscopic measurements were taken from a relatively small number of TKR recipients; it is recognised TKRs operate under a wide set of conditions in the patient population and a portfolio of standard preclinical conditions are needed to simulate the range of performances seen in the patient population. While preclinical simulation should always be undertaken in comparison to a device with proven clinical history, these results indicate the choice of simulated test conditions, even for similar TKR designs with similar material properties, result in different kinematics, contact mechanics, and wear of the bearing materials and may well influence the outcome of such comparisons. However, it should be emphasised that different test methods are required and should be utilised to answer different research questions. Although ISO 2009 force control test method allows the joint to move according to the applied forces, joint design, alignment of the joint, and the soft tissue constraints and account for the effects of other factors, such as friction and deformation of the articulating surfaces, on the performance of TKR, displacement control kinematics eliminate these effects and allow studies to answer specific questions. However, the differences between different test methods should be fully understood. In order to develop displacement control inputs specific to a certain TKR design or size, computational models could be used to predict displacements from the TKR responses to the force control profiles. These computationally predicted kinematics could then be used as displacement control inputs where required.

6. Limitations

There are some limitations to the current study. Firstly, the experimental wear study was conducted for Leeds gait (high) kinematics test method only. This was mainly due the high cost and time required to run the experimental simulations. However, the computational model, used to predict the wear rates where no experimental data was available, has previously been validated under three different kinematic conditions (Abdelgaied et al., 2018). In addition, the predicted wear rate under the force control ISO-2009 of 5.4 mm^3/million cycles was within the 95% confidence limits of the reported experimental wear rate for the same TKR, of 4.71 ± 1.29 mm^3/million cycles (Johnston et al., 2018), which gives confidence in the model. Secondly, although the variation in the input tibial torque was within the ISO recommended tolerances for all stations (ISO-14243-1-2009), there was some variation between the stations of the simulator under ISO-2009 force profiles, particularly during the swing phase, when the low-tension control springs were applied. The high variation meant that comparison to the computational predictions was less clear. This variation was partly attributed to station related factors, such as friction between bearings, weight of the station, and the zero position at the start of the test (Johnston et al., 2018). This is a limitation of any force control method. Finally, the results of the study are limited to the tested TKR design. Different TKR designs could show different kinematic, contact mechanics, and wear behaviours under different test protocols.

7. Conclusion

This study showed differences in the kinematics, contact mechanics, and wear between ISO 2009 force, ISO displacement (ISO, 2004 & ISO, 2014), and Leeds kinematics test methods and between ISO displacement standards with different AP displacement and tibial rotation polarities (ISO, 2004 & ISO, 2014) for a single prosthesis design. Different standards are in fact different test methods, not performance standards. No single standard can be considered correct or better than another standard. Each standard must be used with its own predicate control results from a device with clinical history and results across different standards should never be compared. Clinically, the kinematics in the population are extremely variable, which results in highly variable wear rates. While a standard method is necessary, on its own it is not adequate and needs to be supported by tests under a portfolio of representative conditions with different kinematic conditions, different soft tissue constraints, as well as with different alignments, so that the variability and range of wear rates expected clinically might be determined. This study enables further progress towards the definition of such a portfolio of representative conditions, by deepening the understanding of the relationships between currently used input conditions and the resulting mechanical and wear outputs.

CRediT authorship contribution statement

A. Abdelgaied: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **J. Fisher:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **L.M. Jennings:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

There are no conflicts to declare.

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