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A preclinical method for evaluating the kinematics of knee prostheses

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ABSTRACT

The primary intent of anatomical knee implants is to replicate the motions of a normal knee joint. In developing such designs, a preclinical evaluation of kinematic behavior is needed. This study introduces an in vitro testing method for recording movements of the knee joint. A novel testing jig was developed and incorporated into a knee simulator setup alongside a motion capture system to directly track the medial and lateral movements of a knee prosthesis. The test system developed in this study required a number of factors to be validated; (i) gait inputs to the knee simulator (result: 0.37–1.575% error), (ii) validity of global coordinate system in the motion capture system, (iii) the position of flexion facet centers (FFCs) detected by the motion capture system (result: a maximum error of 0.08 mm in AP direction and 0.3 mm in SI direction), (iv) local coordinate system in the motion capture system (result: 1.09% error for the measurement of flexion angle), (v) that FFC results were in good agreement with inputs. In conclusion, the system developed in this study for recording FFC is a direct and reliable in vitro test method for analyzing the kinematics of a knee prosthesis.

1. Introduction

During knee flexion the medial femoral condyle remains at an almost constant position relative to the tibia, whereas the lateral femoral condyle rolls back along the tibial surface [1,2]. This phenomenon demonstrates the different kinematics between the medial and lateral femoral condyle. Therefore, analyzing the femur as a whole does not provide sufficient kinematic data, regional data for the medial and lateral femoral condyle is also needed.

Total knee arthroplasty (TKA) has been found to reduce femoral rotation during flexion and produce an unexpected ('paradoxical') anterior translation of the femur along the tibia [3,4]. These motions may influence the maximum flexion angle achievable, the efficiency of the quadriceps, patellar tracking, and joint stability, as well as creating an abnormal sensation in the knee joint [5].

There have been many attempts to reproduce normal kinematic behavior with knee implants by using anatomical designs [6–8]. In developing such design concepts, a preclinical evaluation of kinematic behavior is required. Several different in-vitro approaches have been developed, including the Oxford-style knee rigs and robots [9,10], finite element models [6,7], and knee simulators [11,12]. The medial and lateral femoral flexion facet centers (FFCs), defined by the centers of the posterior circular surfaces of the femoral condyles, are commonly used to as defined points on the knee for recording knee kinematics [13–15]. Knee rigs and robotic simulators have the advantage of being able to use cadaveric joints implanted with knee replacements, and so can closely replicate the normal anatomical conditions experienced by patient's after undergoing TKA. However, the medial and lateral FFC are difficult to pinpoint with the soft tissues in place [10]. The second option for recording knee kinematics is to use computational models, such as finite element models, to reconstruct the knee joint to a level that is very much at the discretion of the researcher. These models then need to be validated against a reliable source, and so cannot completely replace the need for in vitro testing. The third option is to use knee simulators. But knee simulators can only record movements of the whole femur, they cannot provide regional data on medial and lateral translation and rotation.

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Motion capture systems are often used to study joint kinematics by recording the motion of positioning markers attached to specific points on the skin [16,17]. However, as the FFC is not on the skin surface but rather at the center of the femoral condyles, motion capture systems have a limited ability to directly record anterior–posterior (AP) displacements of the medial and lateral FFCs. Amiri et al. demonstrated a method of combining a knee simulator with a motion capture system to record knee kinematics [18]. Amiri used the lateral epicondyle of the femur as a reference point for calculating movement of the lateral condyle. Movements of the medial and lateral condyles were not detected directly by the motion capture system, but instead were calculated manually using a defined equation. The complicated equation was based on medial ball-and-socket knee implants, but could not be generalized to any kind of knee implant design.

The ability to predict and replicate in vivo kinetic and kinematic conditions makes in vitro kinematic analysis possible. ISO 14243 and ASTM F3141 standards provide source data represented as waveforms that can be input into models for simulating various joint motions, including walking, stair ascent, stair descent, sit-to-stand to sit, pivot turn and crossover turn [19–23]. The waveforms, based on in vivo studies [19,21], represent motions, or represent forces and moments resulting from body dynamics, gravitation and active musculature acting across the knee [20]. For robotic simulations with cadaveric bone typically only deep flexion motions can be performed, but with a knee simulator a greater variety of movements could be evaluated based on the above studies.

The purpose of this study is to develop a direct and reliable method of recording joint motion in vitro by using a novel testing jig on a knee simulator and using little-known functions of motion capture systems. This system will be used to directly track the medial and lateral movements of a knee prosthesis using the location of FFCs given directly by the motion capture system without manual calculation. The system will have the capability to be used with any design of knee implant currently on the market which aims to reproduce normal human kinematics; different knee designs may require custom jigs to be developed, but the tracking methods presented in this study remain the same. This study will use walking as an example, but the method could be further extended to a wider variety of motions.

2. Material and methods

2.1. Materials

A right-sided posterior-stabilized primary PFC knee prosthesis (SIGMA® Total Knee System, Depuy Synthes, Salt Lake, Utah, USA) was used in this study (Fig. 1). Using a 3D scan (TopoCAM, GFMesstechnik GmbH, Berlin, Germany), a 3D model was constructed by reverse engineering the PFC knee prosthesis in UG software (Siemens PLM Community, Cincinnati, Ohio, USA), which was then used to create the jigs for the practical tests in this study.

2.2. Experimental setup

Eight markers from an NDI motion capture system (Optotrak certus, NDI) were attached to the novel jigs (four on femoral component, four on tibial component) so that knee motions could be accurately recorded from the knee simulator (Fig. 2). The maximum accuracy of the NDI motion capture system at an optimal measuring distance of 2.25 m was 0.15 mm at a resolution of 0.01 mm. Prior to beginning this study, the NDI motion capture system was calibrated by the National Measurement Institute with an error of less than 0.02 mm. For testing, the motion capture system was placed at a distance of 1.5 m to 7 m from the markers. If the distance was less than 1.5 m or greater than 7 m, the markers may not be accurately detected by the NDI system. During test setup, the distance of the NDI motion capture system was adjusted slowly until the eight markers were visible during the whole gait cycle. An electromechanically-controlled knee simulator, Prosim (Simulation Solutions, Shrewsbury, Massachusetts, USA), was used to perform the gait movements according to ISO 14243-3 and human gait data [13,14,18,22,24]. The frequency was set at 1 Hz and the gait movements were performed in air without a secondary medium. The loading points for the tibia and femur were offset medially by 0.07 times the width of the tibial insert [22].

Figure 1. PFC knee prosthesis.

2.3. Measurement of FFC

The flexion facet centers (FFCs) were determined according to the method detailed in ISO 14243-3 [22], as follows (Fig. 3a). The FFC was defined by considering the condyle of the femoral component to be in contact with an imaginary plane perpendicular to the tibial axis, with the femoral center being the point of intersection of lines normal of an imaginary plane running through the contact point when the knee is placed under 30° and 60° of flexion. Previous studies defined the FFCs as lying at the centers of the posterior circular surfaces of the femoral condyles [13,14]. As demonstrated in Figure 3a, when identified using the method described in ISO 14243-3, the FFCs also lie precisely on the centers of posterior circular surfaces of the femoral condyles. Therefore, two definitions are consistent. The flexion axis was defined by a line connecting the medial and lateral FFC.

While the method presented above defines the FFC, during the test the NDI motion system cannot determine the exact position of the FFCs as they are not located on the surface of the femoral condyles. Therefore, a novel jig was developed for this study which included the locations of the lateral and medial FFC (Fig. 3b), which were determined according to the ISO 14243-3 method detailed above [22]. The jig was fixed to the knee simulator and four markers were then secured to the jig on the femoral side (F1, F2, F3 and F4 marker points in Fig. 3b); the positioning of the markers was not critical, only that they could not be placed in the same plane. The lateral and medial FFCs were located at the base of the holes on the jigs as shown in Figure 3b and d, which were then detected using a special probe that works with the NDI motion capture system (Fig. 3c). The NDI system could detect the location of the P1–P4 and F1–F4 markers from the infrared LEDs on the markers, but could not directly detect the location of the probe tip. However, due to fixed and known distance of the P1–P4

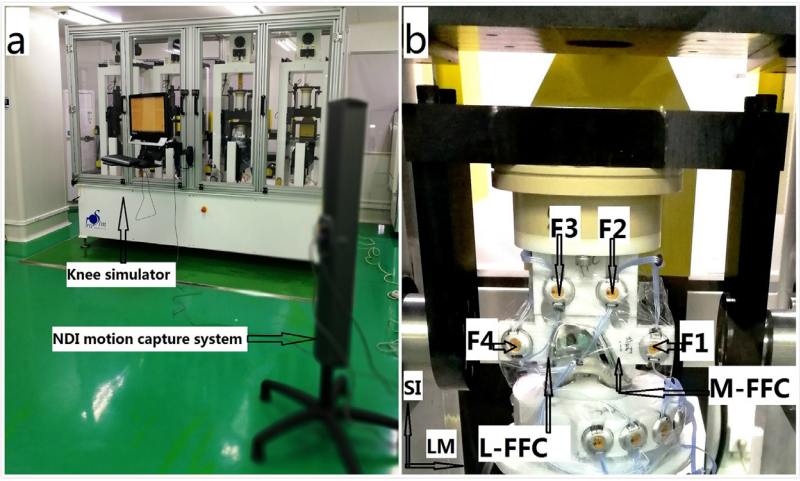

Figure 2. (a) Knee simulator (Prosim) and the NDI motion capture system used for simulating and recording knee movements and (b) eight marker points from the NDI motion capture system were attached to the implant (four on femur, four on tibia); LM: lateral to medial direction. SI: inferior to superior direction. The anterior-posterior direction lies perpendicular to LM and SI directions (perpendicular to the image).

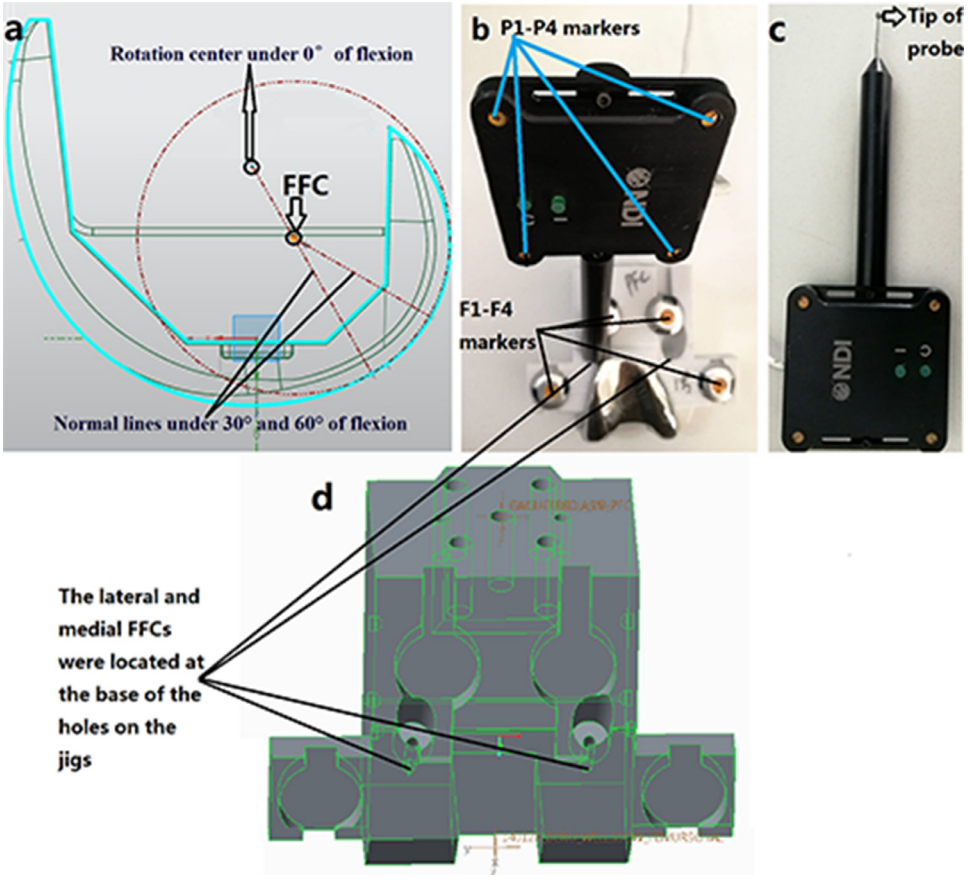

Figure 3. (a) Determination of the location of flexion facet centers (FFCs); (b) the novel jig for detecting the location of FFCs; (c) probe of the NDI motion capture system and (d) 3D model of the novel jig.

markers on the probe, the NDI system could calculate the exact position of the probe tip, which corresponded to the position of the FFC. The NDI system was then able to calculate the relative position between the probe tip (position of FFC) and the F1–F4 markers on the femoral jig in Figure 2b. Using this method, two virtual markers representing the medial FFC and lateral FFC were generated. During gait, the NDI system simultaneously recorded the translations of the FFC and F1–F4 markers.

2.4. Procedure

Two coordinate systems were built for the test setup. A global coordinate system was created first, and then a local coordinate system relative to the tibial component (to record the relative movement between femur and tibia) was created in the NDI motion capture system based on the eight motion capture markers and the NDI probe.

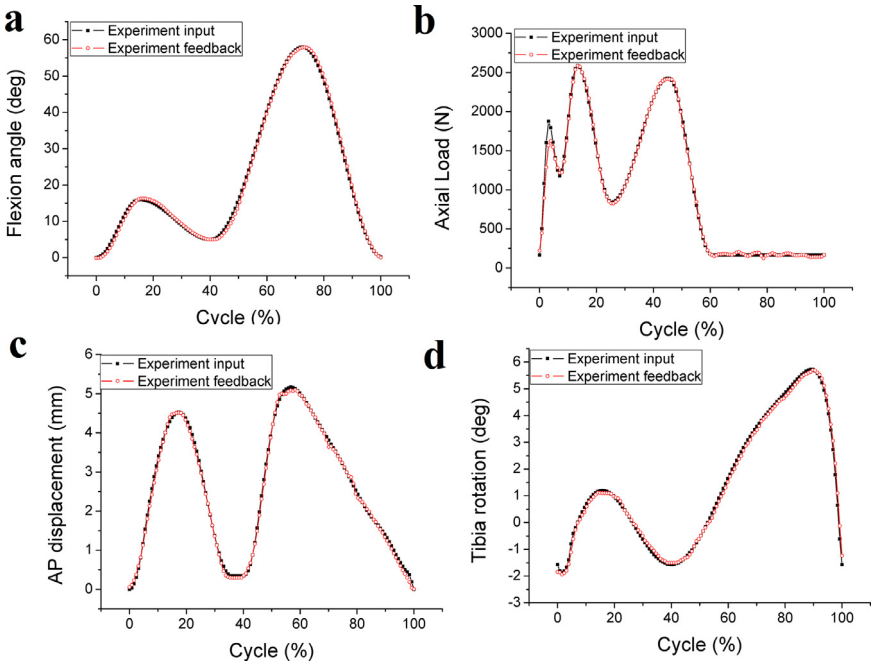

Figure 4. Comparison between experimental feedback and input curves: (a) flexion angles; (b) axial loads; (c) anterior–posterior displacement and (d) tibial rotation.

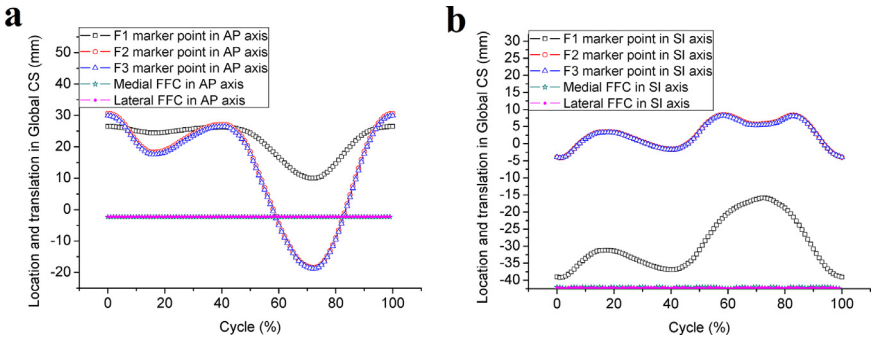

Figure 5. Location and translation of key points in the global coordinate system (CS); (a) AP axis and (b) SI axis.

After building the local coordinate system, the NDI probe was removed from the setup prior to commencing gait simulations.

To track the FFC, AP translations of the lateral and medial FFC relative to the tibial component were collected directly during the gait movements using the NDI motion capture system (Fig. 2a).

3. Results

3.1. Validation

The gait inputs to the knee simulator were validated using feedback curves. The feedback curves for flexion angle, tibial rotation, AP displacement, and axial force fulfilled the ISO 14243-3 requirements of a tolerance of ± 5% of the maximum value, with calculated results ranging from 0.37% to 1.10%, and ± 3% of the full cycle time for phasing of gait, with calculated results ranging from 0.787% to 1.575% [22] (Fig. 4).

The global coordinate system (CS) was validated using the results recorded for the locations and translations of the medial FFC, lateral FFC, and F1/F2/F3 marker points in the anterior–posterior (AP) and superior–inferior (SI) axes (Fig. 5). The initial location of the implant (0% of the gait cycle) in the superior–inferior and anterior–posterior direction was determined by the position of the F1, F2 and F3 markers, medial FFC and lateral FFC (Fig. 2b), which was in agreement with the results of the global coordinate system (Fig. 5). Markers F2 and F3, which were farther from the femoral flexion axis, showed greater translation than the F1 marker.

In the present study, a line connecting the medial FFC and lateral FFC was used to define the femoral flexion axis, which maintained a constant position in the global coordinate system during the gait cycle. As shown in Figure 5, there was little motion for both medial FFC and lateral FFC in the AP axis (Fig. 5a) and SI axis (Fig. 5b). The maximum differences between the measured and averaged values for both medial FFC and lateral FFC across the entire gait cycle were calculated as 0.08 mm in the AP direction and 0.3 mm in the SI direction.

The local CS relative to the tibial component was also validated. Flexion of the femoral component around the medio-lateral (ML) axis (Fig. 6) in the local coordinate system showed a 1.09% difference with the input curve for flexion angle in the global coordinate system (Fig. 4a), with a maximum flexion angle of 58.61° and 57.98°, respectively. The local coordinate system was fixed on the tibial component, which meant that the translation and rotation of the tibial component in the local coordinate system was always zero during the gait cycle, which was reflected by the three overlapping static lines in Figure 6.

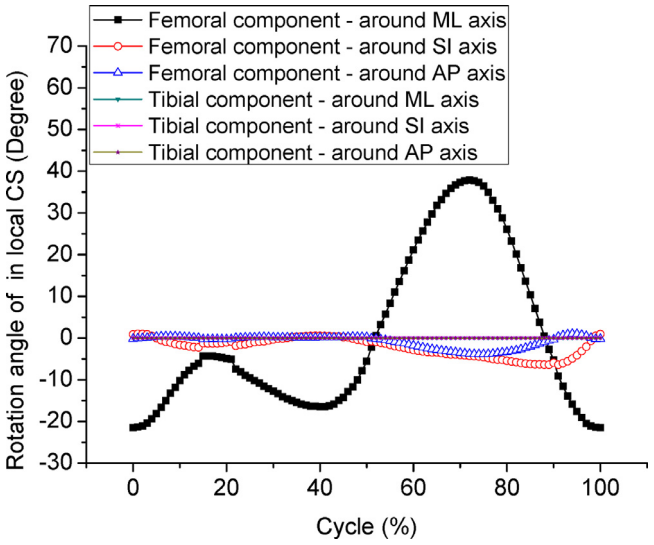

Figure 6. Rotational angles of the femoral and tibial components around the ML, SI and AP axes in the local coordinate system (CS).

3.2. FFC results

Translation of the medial and lateral FFC for a typical cycle is plotted in Figure 7. Theoretically, a displacement controlled machine as shown in Figure 4 should not generate any difference between the medial and lateral FFC in AP translation when the forced rotation is 0° and the results should match the forced AP translation input (Points 2, 3 and 5 in Fig. 7). On the other hand, a minimal forced AP translation with a forced rotation should result in a visible difference in AP translation between the medial and lateral FFC (Points 1, 4 and 6 in Fig. 7). These anticipated results are clearly present in Figure 7, demonstrating the reliability of the in vitro test method.

The maximum anterior and posterior translations are listed in Table 1. The medial FFC exhibited less translation than the lateral FFC, but the difference was small (0.6 mm versus 0.8 mm in the anterior direction, and 5.0 mm versus 5.8 mm in the posterior direction).

Table 1
Maximum AP translations from FFC measurement.

	Anterior	Posterior
Medial side	0.6	5.0
Lateral side	0.8	5.8

4. Discussion

The most important contribution of the present study was the development of a reliable and direct in vitro testing method for tracking medial and lateral AP translations of a knee prosthesis. A novel testing jig was developed and incorporated into a knee simulator set up alongside an NDI motion capture system to track the medial and lateral FFC directly without the need to manually process the data.

With progressive developments in knee implants that aim to mimic normal knee kinematics, such as anatomical polyethylene inserts or medial pivot inserts, there is an increasing need to assess joint kinematics during the design phase [6–8,25,26]. Markers placed on the knee joint surface in this study were tracked directly by a motion capture system which recorded translations of the medial and lateral FFC.

The test system developed in this study required a number of factors to be validated to ensure reliability; (i) gait inputs to the knee simulator, (ii) global coordinate system in the NDI motion capture system, (iii) the position of FFCs detected by NDI motion capture system, (iv) local coordinate system in the NDI motion capture system, and (v) FFC results.

There was little anterior movement of both the medial and lateral FFC (0.6 mm and 0.8 mm, respectively), which was near to zero and was reasonable. The gait movements in this study were displacement controlled according ISO 14243-3, which specifies movements for the femur relative to the tibia as a whole (zero anterior movement), not specifically for the medial or lateral side. Because of the tibial rotation during knee flexion, little anterior movement would be expected both on the medial and lateral side.

The patterns of translation for the medial and lateral FFC were different to those present in a normal knee. In a normal knee, the medial compartment has a more conforming contact than the lateral compartment [27]. In addition, the lateral meniscus is more mobile than the medial meniscus [27,28], with the result that the

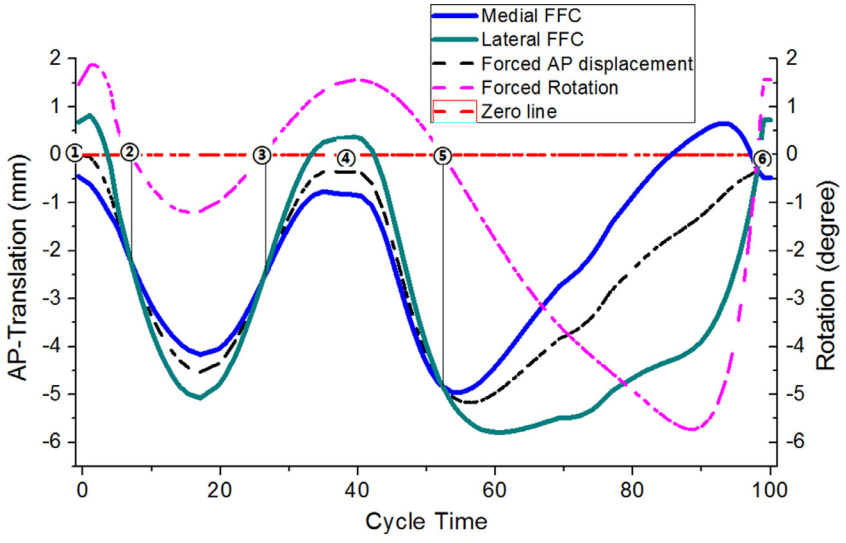

Figure 7. AP translation of medial FFC and lateral FFC in the local coordinate system during the gait cycle.

medial femoral condyle remains at an almost constant position relative to the tibia, whereas the lateral femoral condyle rolls back along the tibial surface. This is supported by extensive studies on a variety of movements in healthy adult knees [13,14,29,30], where it has been reported that the tibiofemoral contact points have greater AP movements in the lateral compartment than in the medial compartment. However, in contrast, some studies [31] demonstrated that knee kinematics are uniquely dependent on the specific activity and suggest that the AP motion of the knee is predominantly in the lateral compartment during normal walking. In any way, the present study provides a reliable preclinical in-vitro testing method to study joint kinematics of knee prostheses during different daily activities. The results of the present study show that both the medial FFC and lateral FFC had large AP translations, which could be expected given that the knee prosthesis used had a symmetrical design for the tibial insert. The small difference in translation between the medial and lateral FFC may be because the loading points for the tibia and femur were offset medially by 0.07 times the width of the tibial insert, in accordance with ISO 14243-3.

There are some limitations to this study that should be noted;

(i) A 3D model was constructed in this study by reverse engineering a commercial knee, which was used to create the novel jig in Figure 3d. This may produce minor differences between the model and the original knee, but the articular surfaces were meticulously constructed to maintain a maximum difference of 0.1 mm. If the original design files could be accessed, this discrepancy might be less. A jig was designed and manufactured to place the FFC axis coincident with the flexion axis of the knee simulator, which was validated in this study.

(ii) Only a walking motion was simulated in this study, but similar setups for the knee simulator and NDI motion system can be done for other motions. Therefore, the in vitro testing method could also be extended to other movements, such as stair ascent, stair descent, sit-to-stand to sit, pivot turn, crossover turn and so on.

(iii) This in vitro method could not account for individual physiological differences. However, the ISO standards used in this study represented the average forces and displacements from body dynamics, gravitational forces and active musculature acting across the knee [19,22].

(iv) A wet or liquid medium cannot be used with this method as the marker points for the NDI motion system on the knee simulator would not be clearly visible because of the outer container. In other studies a layer of petroleum jelly was applied to reduce friction in order to visualize the motion patterns of the knee [11]. This study analyzed translations of the medial FFC and lateral FFC in the AP direction based on the displacement control method, so the use of dry conditions or wet conditions might not influence the results greatly.

(v) This study used a highly-constrained primary implant with a displacement controlled loading method. The prevalence of this implant in clinical use and the authors' interests with this specific type of implant are the primary reasons why it was chosen for this study. The loading point of the femoral component was close to the middle of the femur (offset medially by 0.07 times the width of the tibial insert), which was known prior to the test, but the anterior-posterior translation of the medial FFC and lateral FFC was not known prior to the test as this depends on the design of the knee implant. For example, if the AP displacement of the center of the femur was zero but there was a forced rotation, the AP displacement of the medial and lateral FFC would not zero. For a normal knee, during knee flexion the medial femoral condyle remains at an almost constant position relative to the tibia, whereas the lateral femoral condyle rolls back along the tibial surface [1,2]. It is meaningful to evaluate the movements of the medial and lateral condyles after total knee arthroplasty in comparison to a normal knee. On this point, although displacement control was used in this study, it was valuable to evaluate the kinematics of the knee implant used.

5. Conclusion

The present study developed a reliable and direct in vitro testing method for tracking medial and lateral AP translations of a knee prosthesis. The FFC was directly measured using a novel jig incorporated into a knee simulator alongside a motion capture system.

The in vitro testing method was fully validated in the following aspects; (i) there was minimal error with the gait inputs to the knee simulator, with the error rate ranging from 0.37% to 1.575%, (ii) the global coordinate system in the NDI motion capture system was validated, (iii) the position of FFCs detected by the NDI motion capture system had a maximum error of 0.08 mm in the AP direction and 0.3 mm in the SI direction, (iv) the local coordinate system in the NDI motion capture system only showed a 1.09% error for the measurement of flexion angle, (v) the FFC results were in good agreement with the forced AP translation and forced rotation inputs.

Future work could consider extending this method to a wider variety of daily movements, such as walking, stair ascent, stair descent, sit-to-stand to sit, pivot turn, crossover turn and so on.

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Conflict of interest

We confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

Ethical approval

Not required.

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