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Pre-clinical assessment of total knee replacement anterior-posterior constraint

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ABSTRACT

Pre-clinical, bench-top assessment of Total Knee Replacements (TKR) can provide information about the inherent constraint provided by a TKR, which does not depend on the condition of the patient undergoing the arthroplasty. However little guidance is given by the ASTM standard on test configurations such as medial-lateral (M:L) loading distribution, flexion angle or restriction of secondary motions. Using a purpose built rig for a materials testing machine, four TKRs currently in widespread clinical use, including medial-pivot and symmetrical condyle types, were tested for anterior-posterior translational constraint. Compressive joint loads from 710 to 2000 N, and a range of medial-lateral (M:L) load distributions, from 70:30% to 30:70% M:L, were applied at different flexion angles with secondary motions unconstrained. It was found that TKA constraint was significantly less at 60 and 90° flexion than at 0°, whilst increasing the compressive joint load increased the force required to translate the tibia to limits of AP constraint at all flexion angles tested. Additionally when M:L load distribution was shifted medially, a coupled internal rotation was observed with anterior translation and external rotation with posterior translation. This paper includes some recommendations for future development of pre-clinical testing methods.

1. Introduction

According to the UK National Joint Registry (NJR, 2016), 59 different designs of Total Knee Replacement (TKR) were implanted into patients in 2015. Post-operative data may be available for established replacements but there is a lack of information about how a new device is likely to perform clinically (Liow and Murray, 1997). The ASTM standard tests F1223 (ASTM-F1223, 2014) measure the *inherent* constraint of the TKR prosthesis itself, that which is independent of the patient's physiological condition or the surgical implantation process. The ASTM standard describes test guidelines for determining constraint in anterior-posterior (AP) drawer, medial-lateral shear, internal-external and varus-valgus rotations, and in distraction. This information may help the surgeon in choosing the most appropriate TKR for each patient, depending on factors such as the intrinsic stability of the native knee which is affected by the condition of the soft tissues surrounding it (Kakarlapudi and Bickerstaff, 2000). The ASTM-F1223 (2014) standard aims to: "*provide a database of product functionality capabilities ... that is hoped will aid the physician in making a more informed total knee replacement (TKR) selection*". In the European Union, this testing is mandatory for all new TKRs before they are marketed and used clinically if CE marking is required by the manufacturer (European Parliament, 2007).

Haider and Walker (2005) used the test methods outlined in the 2005 version of the standard to assess the constraint of three designs of TKR. Moran et al. (2008) assessed one TKR device experimentally in order to validate a computer simulation of the ASTM test methods. These studies looked at TKR AP constraint, but did not consider the effect on constraint of the medial: lateral (M:L) tibiofemoral loading distribution, which varies depending on subject and activity (Mündermann et al., 2008; Varadarajan et al., 2008; Zhao et al., 2007). The ASTM standard itself does not include guidance on this M:L loading distribution, therefore experiments attempting to replicate this standard would likely assume a 50:50 M:L axial load.

Haider and Walker (2005) explored whether keeping secondary motions restricted during translation tests, as suggested by the ASTM standard, led to anomalous results. They concluded that, other than flexion angle and the degree of freedom (DoF) being measured, all the other motions should be left unrestricted in order to obtain reliable results. Heim et al. (1996, 2001) looked at AP

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constraint of mobile bearing and posterior stabilised TKRs but restricted all the DoF of motion other than the one being measured. That restriction could be expected to lead to unrealistic edge-loading conditions when there is displacement between the components of an asymmetrical TKR, for example. In a symmetrical TKR with equal M:L loading, we would expect minimal coupled rotation with AP drawer. However a shift of the resultant force either medially or laterally would create friction-induced constraint on the more-loaded compartment and more displacement on the less-loaded compartment, which overall manifests as a coupled internal-external rotation.

The objective of this study was to assess how AP displacement outcomes from the ASTM-F1223 standard for measuring AP constraint in TKRs were affected by unrestricting coupled rotations, and varying the M:L loading distribution, axial load and flexion angle. It was expected that altering the load distribution medially would cause a coupled internal rotation and external rotation of the tibia when displaced anteriorly and posteriorly respectively, with the opposite occurring with a more lateral load distribution. When considering different flexion angles, it was hypothesised that most AP constraint would be shown at full extension, with an increase in laxity exhibited with flexion. Furthermore, increasing the compressive joint load was hypothesised to increase the displacing AP force required to reach the translation limits of TKR.

2. Materials and methods

The tests described for this study follow the general standard as set out in ASTM-F1223 (2014). Any changes to this standard have been highlighted in the methods.

2.1. Test rig set-up

A single-axis, screw-driven Instron model 5565 materials testing machine was employed for the constraint tests. A test rig was designed and constructed, which could accommodate the femoral and tibial components of a TKR (Fig. 1). The femoral component was mounted using polymethylmethacrylate (PMMA) bone cement onto an aluminium alloy cross-bar shaped to match the component's internal geometry, similar to the shape of the distal femur as prepared during surgery. The flexion angle could be adjusted by rotating and then fixing the cross-bar into position. A pivoting frame was used so that the femoral component was free to rotate in varus-valgus, about an anterior-posterior axis at the level of the flexion axis, not far from the joint line. The pivot point could be adjusted medially-laterally, in order to vary the load distribution between the medial and lateral compartments of the TKR, across the range 30:70–70:30% M:L. The pivot frame was mounted on linear bearings, which allowed it to translate proximally-distally. A calibrated pneumatic cylinder forced the femoral mounting distally, against the tibial component, thus providing the compressive joint force. Being a pneumatic cylinder, it did not prevent secondary proximal translations occurring when the TKR was tested.

The tibial components were mounted into the end of a freely-rotating shaft, which allowed internal-external rotation. The posterior slopes of the tibial components were set at 0° in this study. This assembly was mounted onto a linear bearing which allowed free medial-lateral translation. The whole tibial assembly was then mounted on another linear bearing, which allowed anterior-posterior translation. This was attached directly to the load cell on the moving cross-head of the Instron, which provided the AP motion and measured both force (N) and translation (mm).

Thus, the Instron machine imposed AP translation of the TKR at a chosen angle of flexion and M:L load distribution, while all other degrees-of-freedom were unrestricted. This varies from ASTM-F1223, which restricts movement other than AP translation and does not suggest M:L variation. ASTM-F2083 (2012) recommends testing implants at 0°, 15°, 90° and maximum flexion; in this study 0°, 30°, 60° and 90° flexion were chosen to fully explore extension to deep flexion at equal increments and a 'true maximal flexion' was not be tested because of the difficulty of relating it to the clinical situation.

2.2. Implants and tests

Four TKRs were tested. AP constraint tests were conducted on two MatOrtho TKRs (MatOrtho, Leatherhead, UK): the Medial Rotation Knee (MRK) which had been in clinical use for over twenty years; and a newer design, the Saiph Knee. Both of these devices were medial-sphere, highly congruent posterior cruciate ligament (PCL)-sacrificing type TKRs, with asymmetrical condylar geometry. AP constraint tests, at a range of compressive loads and ML loading distributions, were also conducted using the conventionally designed, PCL-retaining Stryker Triathlon (Stryker (UK) Ltd, Newbury, UK) and Smith & Nephew Legion (Smith & Nephew, Memphis, TN, USA), which both had symmetrical condylar geometries. The schedule of tests conducted is shown in Table 1.

2.3. Test method

ASTM-F1223 determines the neutral position by either 'applying a compressive force of 100 N and allowing the implant to settle or by measuring the vertical position of the movable component with respect to the stationary and using the low point of the component as the neutral point'. Pilot testing deemed this not to be a repeatable method with which to find a neutral position with differing geometries, therefore a different method at a higher load was proposed. The femoral component was fixed at the desired flexion angle and required M:L load distribution, then AP drawer was imposed by the Instron. To first approximate the neutral AP position, a 350 N axial compressive load was applied and the AP position was adjusted until the femoral components sat in the lowest compressive point on the concave tibial surface. Small AP translations of ±3 mm were applied to the tibia and the neutral AP position was adjusted until the hysteresis loop of the force versus displacement graph was symmetrical above and below the zero load axis (Fig. 2).

Once the AP position was adjusted, a 710 N compressive axial load was then applied and the tibial component was anteriorly translated at a speed of 0.1 mm/s until, as the ASTM stipulates, 'dislocation of the components is imminent... or if a dangerous or unrealistic situation is about to occur'. In this experiment, the anterior limit was defined as the point at which the force-displacement graph started to plateau (Fig. 2); this suitable limit was chosen by the authors to avoid permanent deformation of the edge of the UHMWPE bearing, which would have affected the results of future tests using the bearing. This displacement limit was recorded and the process was then repeated in the posterior direction using the same procedure. The TKR was returned to the neutral position, lubricated with water, reloaded to 710 N and cycled between the translation limits found previously at a speed of 1 mm/s (ASTM-F1223 states not to exceed 10 mm/s). Three "pre-conditioning" cycles were completed and data were collected on the fourth cycle. For both the Triathlon and Legion implants, the axial load was increased to 2000 N and four further cycles were performed at the same AP limits as the 710 N test (this higher load is not included in ASTM-F1223).

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