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Representing the effect of variation in soft tissue constraints in experimental simulation of total knee replacements

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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 early failure. Polyethylene inserts of varying design and conformity have been introduced in the past decade to improve stability and patient's confidence in the replaced knee, particularly in cases where soft tissue support around the knee is sub optimal.

This study experimentally investigated the effect of variation in the soft tissues on the kinematics and wear of a TKR on three different tibial insert designs. DePuy Sigma fixed bearing TKRs with moderately cross-linked UHMWPE and the ISO force control inputs were used. Different soft tissue constraints were simulated using virtual springs in an ISO force controlled simulation system. The spring gaps and stiffness' were varied and their effect on the output kinematics and wear rates assessed. The lower conformity inserts resulted in significantly higher displacements and more variation between the stations on the simulator. They were also more sensitive to changes in the soft tissue constraints than the high conformity insert. The wear rate for the high tension springs was significantly lower than for the lower tension springs tested. Tibial insert geometry and soft tissue constraints significantly affected kinematics and wear in these experimental simulations. Soft tissue constraints and the variability in patients are important considerations in the stratified design of TKRs and approach to patient selection.

1. Introduction

From 2003 to 2015 over 800,000 primary total knee replacements (TKRs) were carried out in England, Wales and the Isle of Man (NJR, 2006). Wear is one 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, wear and 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 wear simulation has been used with different methods and conditions to predict the wear performance of total joint replacements. In addition to patient and surgical factors the wear rates of a TKR has been shown to depend on a number of factors including insert material (bearing), component design, surface geometry, set up, contact area, stress and knee kinematics (Abdelgaied et al., 2014; McEwen et al., 2005; 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, representing an average patient. 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.

Different patient factors have been shown to affect the wear rate of TKRs; patient weight (Berend et al., 2008), the activities they perform, soft tissues and muscles (Moreland, 1988), 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. 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

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Abbreviation: AP, Anterior-posterior; AF, Axial force; CI, Confidence interval; CR, Cruciate retaining; CS, Cruciate substituting; CVD, Curved tibial insert; FE, Flexion extension; MC, Million cycles; PLI, Partially lipped insert; TKR, Total knee replacement

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long. Stability of the replaced knee is in part dependent upon muscle strength, ligament integrity and type of polyethylene insert. A more congruent insert will result in a more stable knee. Increasing ligament laxity will introduce instability.

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 a particular action such as walking up stairs, 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, 2009, 2014) standard TKR test conditions for both force and displacement control simulation. 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. The ISO standard (Standard, 2009) AP and TR springs have a gap around the zero position to replicate the soft tissues within the knee as they are not linearly elastic (Fukubayashi et al., 1982; Kanamori et al., 2002). The size of this spring gap reflects the soft tissue laxity within the knee. The ISO standard for a cruciate retaining (CR) prosthesis has an AP spring with a gap of ± 2.5 mm and a linear restraint stiffness of 9.3 N/mm and 44 N/mm for anterior and posterior motion respectively. The ISO TR spring has a gap of ± 6° and a rotational restraint stiffness of 0.36 Nm/° (Standard, 2009). For a cruciate substituting (CS) prosthesis the same AP and TR spring gaps are applied with a linear restraint stiffness of 9.3 N/mm in both directions and a rotational restraint stiffness of 0.13 Nm/°.

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.

Just as soft tissue tension and laxity influences joint kinematics in the natural knee, similarly soft tissue constraints, spring stiffness and spring gap will influence resultant kinematics in the force control knee simulator. The aim of this study was to experimentally investigate the effects of variation in the soft tissue constraints on the output kinematics and wear of TKR with different tibial insert geometries. A systematic investigation was carried out to address the following research questions about the effect on output kinematics and wear:

Output kinematics:

1. What effect does the tibial insert geometry have on the kinematics?
2. What effect does the laxity of the knee, represented by the simulator AP and TR springs gaps, have on the output kinematics?
3. What effect does the ligament stiffness, represented by the simulator AP and TR spring tensions, have on the output kinematics?

Wear:

4. What effect does the ligament stiffness have on the wear rate of the TKR?

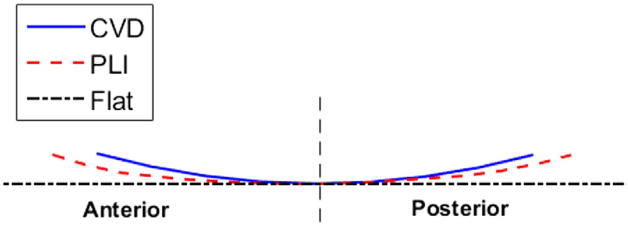

Fig. 1. Three tibial insert designs tested; curved (CVD), lipped (PLI) and flat.

2. Materials and methods

All the investigations were carried out using DePuy Sigma fixed bearing TKR components (DePuy Synthes, UK). The tibial inserts were moderately crosslinked ultra-high molecular weight polyethylene (UHMWPE) (5MRad irradiated and re-melted GUR1020). Three different tibial insert designs were tested; curved (CVD), partially lipped (PLI), and custom flat inserts (Fig. 1). The CVD inserts are used clinically so were used as standard for all tests with the PLI inserts also used for the spring gap and tension tests. All three insert designs were tested under standard ISO (Standard, 2009) test conditions.

This experimental study was carried out using a new generation electro-mechanical 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 are defined in terms of the tibial insert; anterior displacement is anterior displacement of the tibial component. The axial force (AF) is applied on the femoral component and the flexion-extension (FE) is defined in terms of the femoral component.

For this study force control was used as this allowed the kinematics in each test to be determined as an output of the study, enabling the effect of the soft tissue constraints and insert design on the kinematics to be studied. Virtual springs were used within the simulator in order 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 (Fig. 2), 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 − 1 Nm to 5.9 Nm. 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 tests, this was to remove any effect due to differences in the components such as the fixture weight or position.

The output kinematics from each test were used to compare the test