DESIGN AND LOAD-CONTROL EXPERIMENTAL TESTING OF A CUSTOMIZED SURFACE-GUIDED TOTAL KNEE REPLACEMENT

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INTRODUCTION

The development and use of total knee replacements (TKRs) aims to relieve the pain and restore the normal knee functionality. However, previous studies on the performance of the artificial knee joints after implantation reported significant alteration in the movement patterns of the joint, which lead into limitations in the range of motion and performing activities of daily living [1,2].

As a normal knee bends, an unequal posterior translation of the femoral condyles along with internal rotation of the tibial insert occurs. The guidance and control of such movement is provided by the complicated surface geometry features, and the cruciate ligament forces [3-6]. Total knee replacement results into simplified and changed articulating surfaces, as well as insufficient control from the remaining ligaments. Abnormal kinematics are reported after TKR, like anterior sliding of the femoral component during flexion, less internal rotation of the tibial insert, or an altered center for the abduction or adduction [2,7-10].

The goal of this study was to introduce and evaluate a customized surface-guided knee implant aiming to achieve close to a normal pattern of motion. The virtual simulation, along with the experimental testing by using a load-controlled knee wear simulator verified the capability of the design features in achieving the predefined design target pattern of motion.

METHOD

The surface-guided design is featured by particularly shaped asymmetric tibiofemoral articulating surfaces that provide the guidance and stability of the motion with no need for any intercondylar post and cam guiding part [11].

For the TKR of this study (Figure 1), the major geometric design features were the following:

- incrementally changing radii of two tangent inner and outer guiding arcs on the lateral articulating surface
- constant distance between the medial and lateral contact points
- partial medial ball and socket configuration, which provides a medial pivot center, and
- a predefined path of the contact points on the tibial plateau

The design target for the path of the contact points was defined based on the data for unloaded knee motion in the literature [11,12], which was consistent with the reported data in the previous studies for normal knee joints [13,14]. The geometric design parameters of the TKR of this study were set based on the measurements performed on reconstructed 3D models of a knee joint from MRI scans [11].
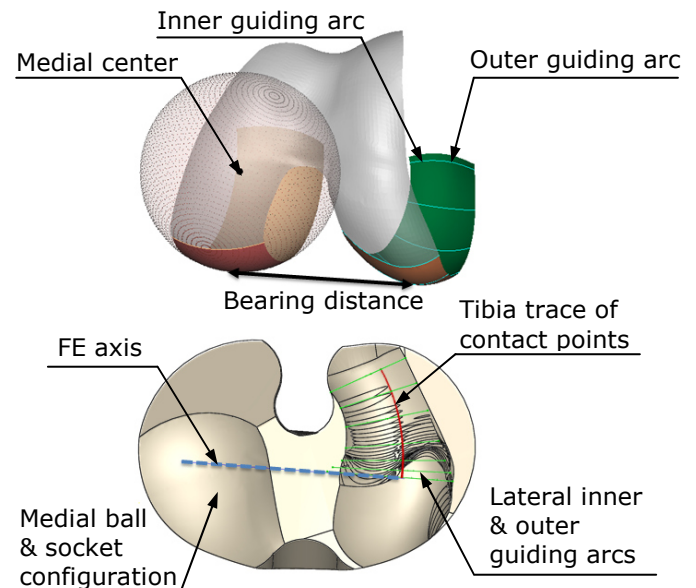

Figure 1: Geometric features of a customized surface-guided knee implant

A cycle of squatting with heels up (reaching up to 123° of flexion) was virtually simulated in MSC.ADAMS. This model consisted of the CoCr femoral component of the customized surface guided TKR in contact with the corresponding ultra-high molecular weight polyethylene (UHMWPE) tibial insert. The "impact" contact function in MSC.ADAMS with a coefficient of friction of 0.04 between the tibiofemoral articulating surfaces was applied. Such a friction coefficient is in agreement with the reported magnitude of the friction between CoCr and PE in the literature [15]. The axial proximal-distal load and flexion-extension angle reported by Smith et al. [16] was used as the inputs for the simulation. Consistent with ISO 14243-1 [17], the input axial compressive load was applied to the center of the tibial insert plus 7% of the width of the tibia towards the medial side. The input flexion-extension angle was implemented to the axis of the flexion of the femur. Similar to the knee wear simulators, the influence of the ligaments was modeled by a linear spring (K=9.4 N/mm) in the anterior-posterior (AP) direction, and a torsional spring (K=0.13 N.mm/deg) in the internal-external (IE) direction [19].

The kinematic behavior of the 3D printed TKR prototypes was evaluated experimentally using the AMTI ADL knee wear simulators (Advanced Mechanical Technology Inc., Watertown, MA) under the load-controlled condition (Figure 2). Such a test set-up can evaluate the effectiveness of the particular design of the customized implant in providing close to normal kinematics.

The femoral component was printed from CoCr, and the tibial insert was manufactured from high-density polyethylene. The input waveforms for the load and pattern of the flexion angle were the same as those used for the virtual simulation. In this test, the axial force was applied to the tibia with a medial offset of 40-60% distribution on the lateral and medial sides. The friction at the articulating surface was controlled by applying a layer of petroleum jelly to the articulating surfaces of the components. Therefore, the test condition was a more severe situation than the tests by the synovial-like fluid. However, it made it possible to check the pattern of motion during the test visually. Using the non-translucent

synovial-like fluid would have required to place the TKR in a bag.

The test was run at 0.33 Hz for 100 cycles, and the angle of IE rotation of the tibial insert and the AP translation of the femoral component was measured and compared to the data predicted by the virtual simulation.
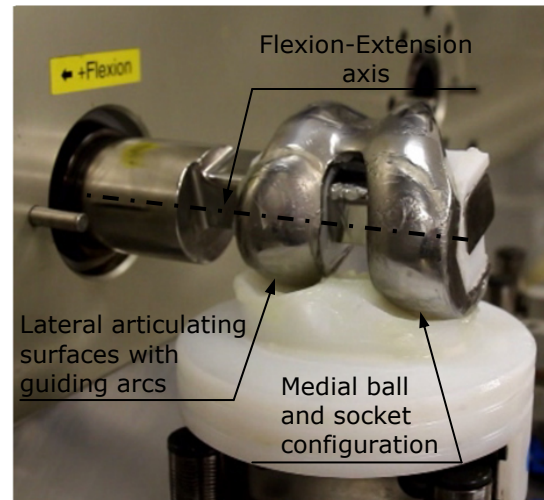

Figure 2: The customized surface-guided TKR components assembled on the AMTI ADL knee wear simulator

RESULTS

Results of the virtual simulation under the squatting load condition show that the pattern of rotation of the tibial insert of the customized surface-guided TKR was following the desired target motion (Figure 3). As the knee bent from 0 to 123° of flexion, the lateral femoral condyle moved 15.5 mm posteriorly, while the medial condyle moved less than 1mm in the AP direction (Figure 4). As a result, 16.7 degrees of internal rotation of the tibial insert was predicted by the virtual simulation. A normalized root mean square error of 3.04% was observed between the results for the tibial IE rotation angle and the design target for the squat activity.

The results of the experimental testing show that as the knee bent during squatting, the tibial insert rotated 19.9° internally (Figure 3). At the same time, the lateral femoral condyle translated 24.2 mm posteriorly and the medial condyle also experienced 6 mm of posterior translation (Figure 4). The mean absolute error

of the measured tibial IE rotation from the experiment in comparison to the design target was 1.2 degrees. There was a 7.3% normalized root mean square error between the design target for the tibial IE rotation and the amount of rotation of the customized surface-guided tibial insert in practice.

DISCUSSION

This study utilized virtual simulation along with load-controlled experimental testing by a knee wear simulator to measure the kinematic behavior of a customized surface-guided TKR. Both, the experiment and the virtual simulation outcomes, confirm that the custom designed surface-guided TKR provides close to the target pattern of motion during a higher flexion activity than walking, such as squatting. Also, the experimental testing successfully validated the virtual simulation showing less than 8% normalized root mean square error between the results of the virtual simulations and tests for the internal-external rotation of the tibial insert.

The achieved IE range of motion from the load-controlled experiment (19.9° for a flexion up to 123°) is in agreement with the reported range of rotation of the tibia for healthy knee joints in the literature [13, 14]. Johal et al. [13] reported a mean IE angle of 20° for flexion from -5° to 120° under a weight-bearing condition. Also, from results of the study by Leszko et al. [14], about 21° of tibial internal rotation could be estimated for a flexion angle of 123 degrees.

A critical feature of the designed TKR is the pivoting around a medial center, which is achieved during a high load and flexion condition such as squatting. There are two articulating circular sections in a healthy knee joint anatomy [3]. A major assumption in the design of the current surface-guided TKR is the zero AP displacement of the center of the medial condyle. Therefore, the medial condyle geometry was designed as a partial ball and socket configuration.

The virtual simulation successfully predicted the AP translations and pivoting rotation around the medial center. However, the peak rotation of the tibia was overestimated by maximally 3 degrees. It is likely due to the simplifications that were considered for the contact modeling.
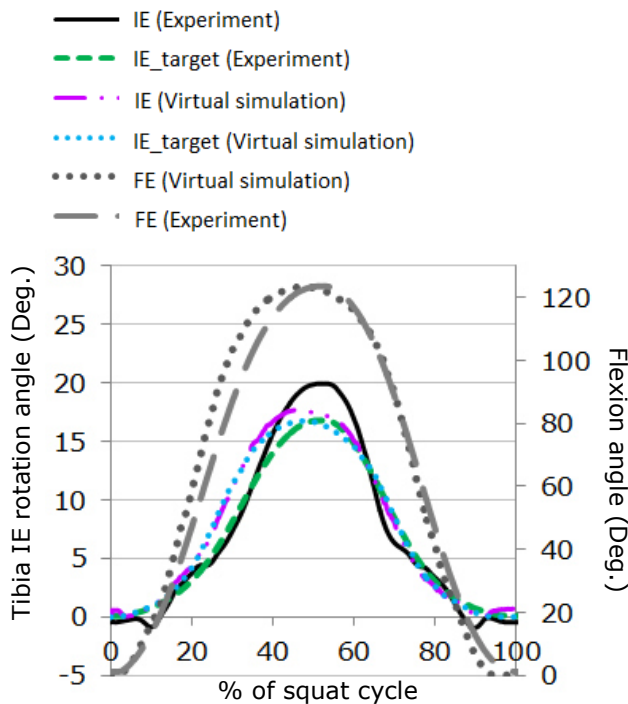

Figure 3: Tibial insert IE rotation angle during a cycle of squatting
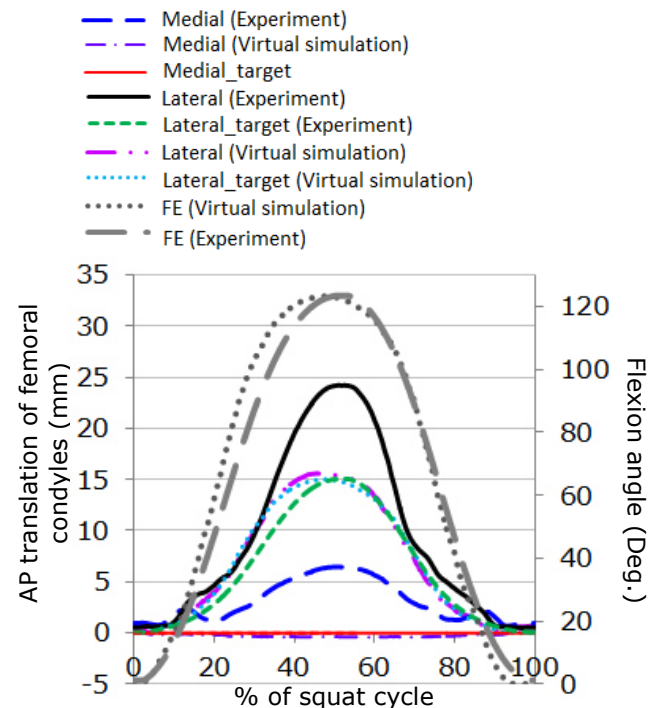

Figure 4: AP translation of the femoral condyles during a cycle of squatting

One of the reasons for the deviation of the experimental testing outcomes from the design target is the limited control on the friction at the articulating surfaces. It is because the friction was controlled by using petroleum jelly, and the thickness of the lubricant film between the articulating surfaces changed during extension and flexion. In addition, the hysteresis in the knee wear simulator and the simplifications considered in the application of the soft tissue forces affect the results. This study considered squatting as a critical condition to be studied. Several of the activities of daily living result in a similar range of motion as analyzed in this study. However, a higher range of flexion of the knee joint is required for activities of daily living such as gardening and sitting cross-legged [18]. Therefore, the influence of different load conditions, either due to surgical and implantation variables or the load conditions for other activities, still needs to be investigated.

This study showed that an implant designed based on medial and lateral guiding features, can provide a close to target kinematic behavior for high flexion activities such as squatting. The findings of this study can be used to improve the design features of the surface-guided total knee replacement (TKR) aiming to restore normal kinematics.

ACKNOWLEDGEMENTS

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