THE EFFECT OF LIGAMENT VARIABILITY ON TKR PERFORMANCE – A PROBABILISTIC STUDY

Introduction: The continuing drive to improve the performance of total knee replacement (TKR) has led to the development of many experimental and computational simulations to predict implant performance. Historically, these have been deterministic models, or else parametric studies focusing on a minimal number of variables. Improvements in computational capabilities now enable more extensive probabilistic studies, modeling a wide range of factors in conjunction. This makes it possible to identify complex inter-relationships between factors, which otherwise might not have been detected. This study develops the approach of Laz et al [1], extending the scope to include factors within a simplified ligament restraint model. Results from such probabilistic studies can be used to predict performance envelopes, and sensitivity results can identify factors that contribute most to variability in kinematics & pressures, and hence failure mechanisms.

Methods: Two fixed-bearing cruciate retaining TKR designs were modeled for this study: a semi-constrained and unconstrained design. The implant was driven through a gait cycle using force & displacement waveforms adapted from the Stanmore knee simulator [2]. However, whereas the Stanmore simulator uses a transverse-plane spring restraint system, for the present study this was replaced with a representative ligament model, featuring three nonlinear spring forces configured to represent the remaining posterior cruciate ligament (PCL) and the two collateral ligaments as single unified bundles. The model was developed as a rigid-body simulation, greatly reducing computation time, as has been demonstrated in comparative studies [3,4]. Variability in both implant positioning and ligament properties was considered. The positional variables were adapted from [1] and included: rotational axis positions (4 factors), component malorientations (4 factors), friction coefficients, and medial-lateral (ML) axial force location. In each case, the previous levels of standard deviation were adopted: 0.5mm for axis malpositioning, 1° for implant malorientation, 2.5% for ML load balance, and 0.01 for friction coefficient. Alongside these, ligament property parameters were also included. These were the linear region stiffness, pre-strain, and toe-in & toe-out strain, with standard deviations of 20%, 0.10, and 0.01 respectively, giving a total of 19 factors for the study. Given the sporadic data available, independent normally-distributed variables were assumed for this pilot model. Analyses were performed to produce 1%-99% performance envelopes for anterior-posterior (AP) translation, internal-external (IE) rotation & maximum contact pressure. A sensitivity analysis was also performed to compare the ligament variables to the existing positional variables. Results were produced for different fast probability integration (FPI) techniques, and compared against a 1000-trial Monte Carlo analysis for both implant designs. All analyses were performed using Adams (MSC Software).

Results: The results show considerable variability in the kinematics and contact pressures, e.g. contact pressure variations of up to ±2MPa compared to the deterministic analysis alone (fig. 1). Furthermore, the variability in kinematics was more significant for the unconstrained implant than the semi-constrained design, e.g. the envelope is around 40% larger for the unconstrained design in swing phase (fig. 2). Sensitivity results (fig. 3) reveal that, for the levels of variability selected, the effect of varying the ligament model properties is significant, although small variations in the orientation of the components were still found to have more influence than relatively large variations in the ligament stiffness. Predictably the PCL and MCL factors were more significant than the LCL factors, and toe-in & stiffness are the more significant influences, given the input variability levels investigated. The cycle-averaged sensitivity factors were very similar for the semi-constrained and unconstrained devices; however this masks local variations within the gait cycle, where differences were more apparent.

Discussion: The levels of variability observed are similar to previous studies, and demonstrate the value of applying probabilistic techniques. The differences between the semi-constrained and unconstrained inserts conform to expectations, with the larger variability in the unconstrained device corresponding to larger kinematics and contact pressures. The sensitivity results must be interpreted in light of the input variability levels; also, in the present study, the influence of ligament length and position of the insertion sites relative to the prosthetic components have not been considered. Future modeling should take this into account and explore alternatives to study higher levels of variability in soft tissue or mal-positioning of components. However, the probabilistic approach provides a valuable tool for quantifying variability effects and should continue to be applied to inform future implant design.


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