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Probabilistic Computer-Aided Analysis of Variables Affecting the Performance of Total Knee Replacement

Background: Total Knee Replacement (TKR) is a well-established procedure; increasing numbers of operations are performed, and the age range of patients is also broadening. Although the revision rate is low, many patients still experience pain and reduced function – even a few percent of cases represents thousands of patients per year worldwide. In order to meet the expectation of continuing improvements in prosthetic performance and longevity, a more complete understanding of the underlying knee kinematics and kinetics is required.
Both empirical simulation using mechanical rigs, and computational simulation using numerical methods (such as FEA) can be used to verify the implant behaviour under 'design conditions'; however it is known that many factors cannot be perfectly measured or controlled, and there is an inherent degree of *variability* present.

Approach: Probabilistic modelling techniques will be used to quantify the effect of this variability on implant kinematics & kinetics during normal gait, and the corresponding joint stability under constant-load testing.
The most exhaustive approach to modelling variability for non-analytic systems is to perform many trials using every possible permutation of the variable factors (the 'Monte-Carlo' method); however the number of trials required rises exponentially as the number of factors increases. An alternative is to adapt *reliability theory* (which uses optimisation algorithms to find a 'design point' of most probable failure) to approximate the outcome probabilities with less computational effort.
However the large number of potential variables means a large number of trials will still be required; therefore, fast *rigid-body* models will be used to approximate the contact mechanics of the femorotibial joint.
The expectation is that the small reduction in accuracy for reliability theory methods and a rigid-body model will be outweighed by the much wider range of factors that can consequently be examined in the same computation time.
An 'incremental' approach will be adopted, phasing in sources of variability to gradually extend the model. Early efforts will focus on modelling surgical positioning variability (e.g. component tilt or varus / valgus angle); this will then be extended to other factors; for example soft tissue variability (e.g. ligament stiffness) or potentially, variability in the loading cycle.

Applications: Successful work in this area could provide a valuable tool for implant design, patient selection & surgical practice.

- Understanding how a prosthetic performs across the operating envelope (rather than just under ideal design conditions) would provide early indication of potentially inferior designs, and would also allow designers to identify the design features associated with good tolerance of variability. Using sensitivity analysis to identify the most influential factors would allow attention to be focused on adapting to or managing the variability due to those factors.
- Recognising how much effect inter-patient variability has (for example variation in ligament attachment locations) might provide guidelines for surgical practice, as contra-indications for TKR arthroplasty.
- Understanding how apparent stability is related to gait variability might provide further guidance for intra-operative stability checks.

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Initial Model Configuration

The rigid-body model will be developed using commercial dynamic-body software (MSC.ADAMS, MSC Corporation). Proprietary parasolid CAD 3D model data will be used as the basis for the model geometry, with alternative models for semi-constrained and unconstrained (low conformity) tibial tray designs. The model will be partially force-driven and partially displacement-driven, according to the ambulatory gait loading inputs for the Stanmore Knee Simulator (SKS).

However, the model deviates from the SKS configuration, in that the transverse-plane ligament spring restraint model is removed. Instead, a more anatomically representative three-dimensional ligament model is proposed, incorporating non-linear spring elements to model the (unresected) posterior cruciate ligament (PCL), and the medial and lateral collateral ligaments (MCL, LCL). The individual ligament models for the PCL and MCL will further be divided into separate bundles, to represent the corresponding anatomical structure of the natural ligaments. The transition to a ligament-based model allows the scope of the variability study to be extended – a range of factors can be adjusted for each ligament, including 3-dimensional attachment location at each end (potentially 6 variables), ligament pre-strain, stiffness and 'toe-in' strain (the strain at which the ligament transitions to linear elastic behaviour) – a further 3 variables. For the six ligament bundles, this is a potential 54 additional variables; this is unreasonable for a first study, so again an incremental approach will be adopted, initially considering only stiffness characteristics, then extending this model to include positional variability

The most challenging element within the model is the femero-tibial contact – an accurate mathematical model of the contact mechanics is critical to the validity of all results. However, a compromise must be made in order to achieve acceptable computation time, so a rigid-body model is adopted in place of the true deformable body model. Potentially this introduces only small errors; however for certain physical conditions (e.g. when the femoral component is in contact with the thinner outer ridge of the tibial insert) this assumption may break down. A potential solution is to apply a geometry-specific 'correction factor' corresponding to a map of the tibial surface.

Besides the challenges associated with achieving acceptable accuracy, achieving sufficiently fast computation time also presents challenges. The internal contact solvers provided with MSC.ADAMS are robust, but do not deliver the level of performance required for a large stochastic analysis. Therefore, an alternative 'streamlined' contact model derived from elastic foundation (EF) theory is proposed, using customised FORTRAN code to interface with the commercial software. Essentially, elastic foundation theory proposes that the flexible body (in this case, the polyethylene tibial insert) can be adequately represented as a simple 'bed of springs'; i.e. the surface of the body is divided into a 'mesh', with spring-force elements located at various points, responding directly to the interpenetration distance between the contacting solids. The spring model can then be linear or non-linear to approximate the material characteristics (although linear or 'stiffening' springs with force exponent greater than unity do speed up solver calculations). Unfortunately, computing friction force does complicate this model further, since sliding distance (and hence, time history of the contact locations) is required. Nonetheless, an EF model should provide a significant performance gain against the more involved 3D volumetric calculations of the ADAMS internal contact algorithm.