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Holistic approaches to pre-clinical TKR analysis: computationally-enriched experimental testing

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SYNOPSIS

The drive for better TKR designs necessitates better understanding of TKR mechanics through pre-clinical analysis methods. Currently, corroboration between *in-silico* and *in-vitro* testing methods is limited, and the opportunity for collaboration is underexploited. Here we demonstrate how *in-silico* and *in-vitro* testing methods can be complementary and mutually supportive. The case study is a corroboration of the AMTI knee simulator (displacement & force control) including control-plant modelling, *in-silico* wear prediction and probabilistics. We demonstrate that more rigorous *corroboration* between numerical & experimental techniques can benefit both approaches, and ultimately provide much richer data for pre-clinical analysis; *however*, to be effective this requires close and open *collaboration* between different research specialists. Only by working together to share information and ideas more effectively can the next major advances in our understanding of TKR be achieved.

1. INTRODUCTION

Considerable work goes into pre-clinical analysis of TKR designs, to refine them as much as possible before time-consuming costly clinical trials. Historically, individual research groups specialised either in computational or experimental approaches. These have provided valuable insights into TKR performance, but are limited in scope. Whilst many *in-silico* studies are based on experimental data (e.g. [1, 2]), the degree of interaction is often limited. The need exists to establish better collaborative links between theoretical, experimental, and computational modelling methods. This demonstrates not only that test results are repeatable and consistent, but also that the underlying physics of the test conditions are correctly and fully understood.

2. METHODS

This paper focuses on an exploratory review of the AMTI knee wear simulator, operating under both displacement & force control, based on closer corroboration between experimental & computational methods. Rigid-body models were created using MSC.ADAMS [3-5]. These models were modified to reflect the configuration of the AMTI simulator assembly (including the full tibial platen and associated bearings). Further, a full control-plant model was implemented in MATLAB/Simulink, and finally the model was fully parameterised to facilitate probabilistic modelling. Tests were corroborated for different gait profiles with fixed-bearing PCL-retaining implants.

For *displacement-driven* models kinematic-feedback data from individual tests was used directly, so a control plant was not required. *In-silico* force & torque predictions were compared to experimental load-cell feedback. For *force-driven* tests a model of both the plant mechanics *and* control system was used, to more fully model the system. Simple 'isolation profiles' were used to explore dynamic effects (inertia, friction & damping) on each of the different axes individually. This was followed by corroboration of force-driven gait tests.

Wear was predicted *in-silico* using a number of standard algorithms, including Archard wear [6], A/A+B 'cross-shear' wear [7] and crossing-intensity wear [8]. Wear models were considered with and without contact-pressure terms. The results were also decomposed to explore individual wear influences (sliding distance, cross-shear maps & contact pressures), to reveal which factors seemed to correlate best with experimental data.

Studies were not merely deterministic: probabilistic methods were also used to model experimental variability (similar to [9]), *and* further to corroborate this with statistical data from multiple wear tests. This is believed to be the first time probabilistic results for TKR have been corroborated against experimental data.

3. RESULTS AND DISCUSSION

The displacement-driven tests corroborated well, closely matching force-feedback *once test-specific variables were tuned* (e.g. AP-dwell position, bearing friction). The results reveal the sensitivity of the model to these variables (e.g. deviations of only 1mm in AP-dwell alter the AP axis force-feedback by as much as ±100%). These tests also show the importance of accurately modelling friction not just at the implant articulation, but also the other bearings in the mechanical rig. *If* experimental conditions are correctly accounted for, the *in-silico* results lie well within experimental variation ranges [figure 1].

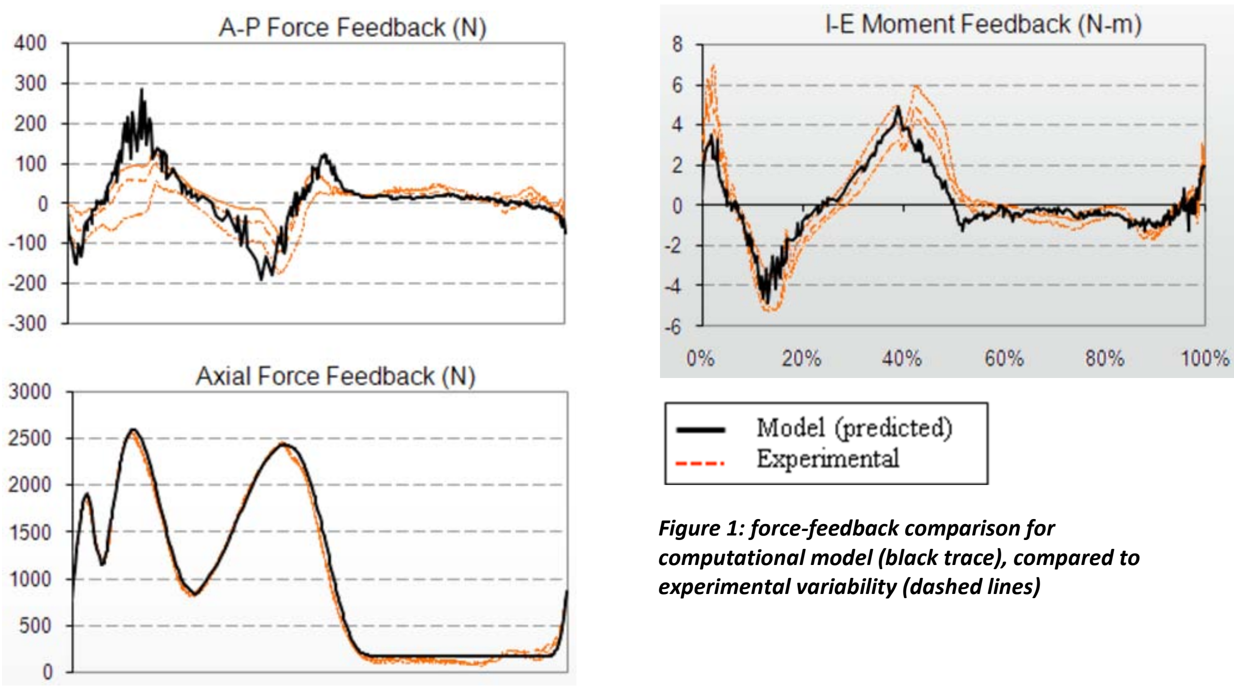
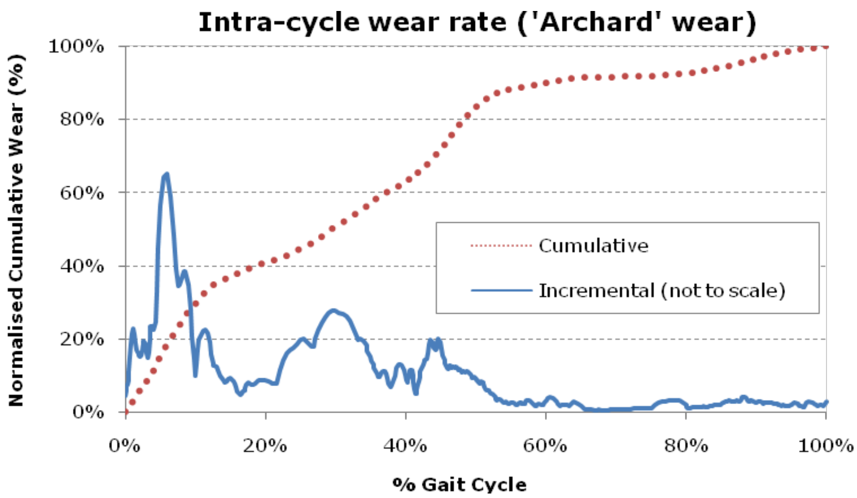


Figure 1: force-feedback comparison for computational model (black trace), compared to experimental variability (dashed lines)

Force-controlled simulation proved more challenging; a simple ‘quasi-static’ mechanical model could *not* adequately describe the system – the dynamics are highly influential. The influence of friction (of the implant and other bearings) and damping in the system is considerable, and must be accounted for. The role of inertia is relatively limited. Because the mechanical system sits within a control loop the demanded and achieved waveforms will not perfectly match. Further, due to inertial and damping elements between the actuator application point and the load cells, it is *not* adequate to use force-feedback. Rather, the demanded inputs should be used with a control system (the achieved feedback can be used to corroborate this control system). Corroboration of the ‘isolation tests' has been successful in predicting output kinematics and load-cell feedback. However discrepancies remain for the full gait test; these are believed to be related to further uncharacterised system dynamics and the influence of pliancy in the fixed axes [10], on the tibial as well as the femoral side.

Wear results demonstrate that (whilst not quantitatively precise) current *in-silico* algorithms provide a useful qualitative 'ranking' tool for TKR wear. *In-silico* methods can provide a richer diagnostic data set than *in-vitro* tests alone (e.g. surface maps and probability distribution functions for cross-shear, sliding distance & contact pressure [figure 2]). This is valuable for designers, clinicians & theoreticians trying to better understand the causal influences of wear.



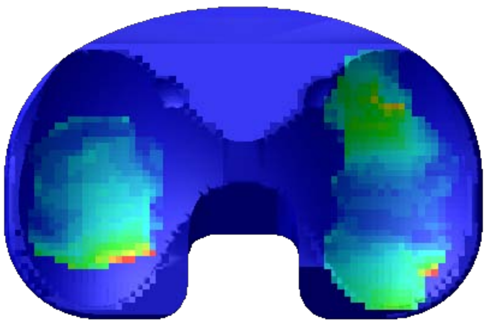


Figure 2: examples of in-silico visualisations: cross-shear maps (above) & intra-cycle wear rate plots (left)

In addition to this, *corroborated* probabilistic studies provide additional insight into wear characteristics. By comparing the distributions for experimental and predicted wear, it is possible to compare the performance of different theoretical wear algorithms against *in-vitro* data [figure 3]. Note that it is very clear from this probabilistic vantage-point that current wear algorithms are not ideal. They are able to match the 'mean' deterministic value for wear rate (with appropriate tuning of the wear constant). However, they are *not* accurately capturing the 'spread' of wear rates based on variations in the experimental set-up. This clearly shows further work is needed to better understand the mechanics of wear, and also the factors influencing test variability.

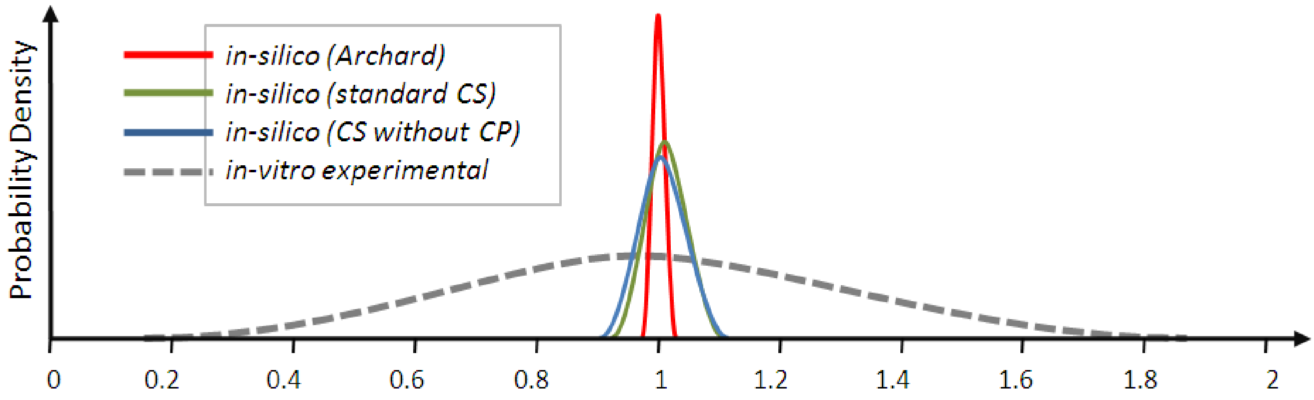


Figure 3: using probabilistics to compare wear rate PDFs; all existing models drastically under-predict the full range of experimental variability.

Conventionally, numerical models are ‘validated’ using experimental results, and the AMTI simulator has been a popular target for this (e.g. [10, 11]). The present work advances this practice by rigorously corroborating the system dynamics, controller behaviour & experimental variability- not just the most basic mechanics. It is apparent that these test rigs are more complex than older models have assumed, and artefacts of the rig construction and dynamics are influencing results. In the past, a ‘first-approximation’ was adequate to lay the foundation for theories of knee mechanics and wear, but we now require a more detailed appreciation of these tests if we are to further our theories of wear. Specifically, researchers testing with the AMTI simulator are advised to pay particular attention to the AP-dwell position, and the degree of friction from the roller bearing assembly. An advantage here of computational modelling is that it can be used *post-hoc* to further investigate anomalous *in-vitro* test outcomes or sensitivity to experimental uncertainty.

Considering the wear algorithms, we know that these empirical models are imperfect [4]; however they represent the state-of-the-art, and to advance further, more accurate corroboration is required. Accounting for discrepancies between *in-silico* and *in-vitro* tests (especially using probabilistic methods) can provide valuable insights into the underlying factors involved in wear.

In conclusion, closer collaboration on these tests has lead to a better-understanding of the existing experimental data, along with more accurate and powerful computational models. As a result, advances have been made in our fundamental understanding of wear simulator mechanics. Researchers in all fields of TKR testing are strongly encouraged to engage in closer collaboration across disciplines, to more provide a better, richer and more rigorous toolset for pre-clinical analysis.

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