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in-silico Predictions of TKR Robustness to Wear Variability: A Probabilistic Cross-Design Comparison

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INTRODUCTION:

Wear of TKR is a key concern for designers, but is highly variable in clinical retrievals. Conventional *in-vitro* knee wear simulators are limited to relatively small numbers of tests and cannot fully address this uncertainty; *in-silico* models can use large numbers of trials with low associated time & cost. Using probabilistic methods we can explore whether input variability (e.g. component mal-positioning) can account for the high degree of wear variability observed.

Because we are able to simulate many trials, we can also explore the predictions of different wear algorithms, and also run studies concurrently for different TKR designs, allowing us to compare implant designs and observe whether some are more robust to wear variability than others.

METHODS:

Existing TKR designs were incorporated from CAD geometry or reverse-engineering, including 6 fixed CR and 2 RP designs. For each one, an *in-silico* simulation of an *in-vitro* wear test was used [1] (based upon the Instron/Stanmore configuration [2, 3] running ISO-gait [4]). For each design, a probabilistic analysis was used including six component mal-positioning angles with higher levels of variability up to +/-6°, and M/L load split up to +/-37.5%.

Wear was evaluated using standard algorithms extracted from the literature, with the conventional Archard model [5] alongside models featuring cross-shear [6], or excluding contact pressure terms [7]. Distributions were fitted to the results to form a probability density function (PDF) of wear rate for each design with each of the different wear algorithms. These PDFs could then be compared to evaluate the different TKR designs and wear algorithms.

RESULTS:

The choice of wear algorithm has a major influence on the degree of variability observed (see fig 1 as an example). Algorithms excluding cross-shear (e.g. Archard) grossly under-predict wear variability. Algorithms ignoring contact-pressure predict a moderate probability of wear levels below the 'neutral' (unperturbed) wear rate.

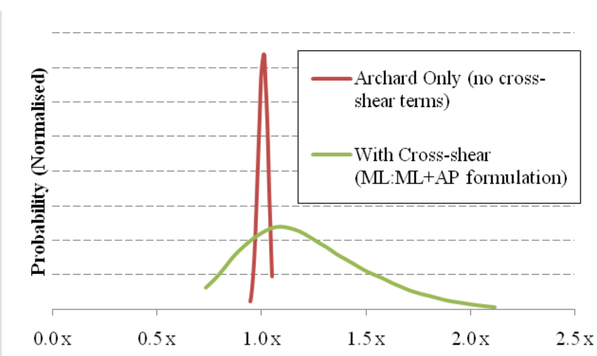

Figure 1: Comparison of wear algorithms for one specific implant design. Models must include cross-shear to predict wear variability. The distribution becomes asymmetric, with a significant upper 'tail' representing high-wear outcomes.

The comparison between designs (fig 2) reveals that there are clearly design-specific differences. The 'neutral' wear rate for designs varies, as has been reported in many *in-vitro* studies. However, this probabilistic study reveals that the spread of wear rates due to variability is also different. Some designs appear more resilient to mal-positioning and do not exhibit such a high spread of wear rates. Note that wear rates of 3 or more times the neutral level have a significant (>5%) probability of occurrence for many of the designs studied.

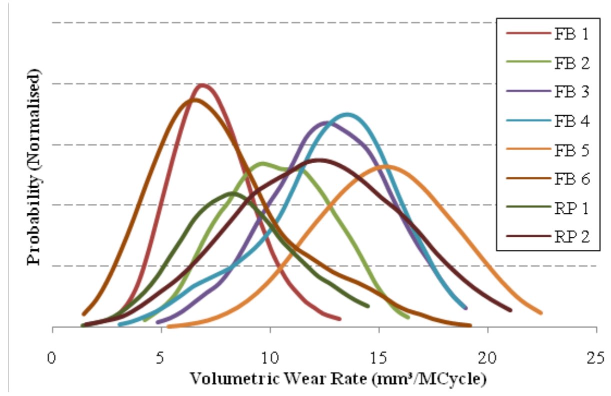

Figure 2: Comparison of different TKR designs; the amount of variability varies by design. Note that certain designs (e.g. FB1) exhibit much less wear-rate variability under the same set of conditions than others (e.g. FB5).

DISCUSSION:

We again reinforce the observation that wear models without cross-shear do not predict the variations reported by *in-vitro* wear tests; cross-shear must be included to capture this degree of variability.

Probabilistic studies provide another avenue by which wear algorithms may be selectively tested; because a PDF of wear results is generated, this provides a more complete data set to corroborate against than an individual wear rate value. In future this may prove valuable in identifying the most accurate wear models.

The design-comparison reveals two very important observations; firstly, wear rates can be much higher (greater than three times) the 'neutral' wear rates seen in correctly-aligned *in-vitro* simulators. This implies that those *in-vitro* results may also under-predict clinical *in-vivo* wear with mal-positioning; further work would be needed to explore this.

Secondly, wear distributions appear to be design-dependent. This implies that the TKR designer does have some ability to 'design-in' a degree of robustness to reduce the 'spread' of wear rates.

There are important limitations to this study; the models used represent *in-vitro*, not *in-vivo*, conditions (future models should use musculoskeletal models with muscle-force variability), and the wear algorithms remain only empirical, as UHMWPE wear mechanisms are still not fully quantitatively understood. However the key conclusions that variability results in much higher wear rates, and that this is a design-specific effect, are important enough to warrant further attention.

ACKNOWLEDGEMENTS:

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