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Probabilistic computational modeling of total knee replacement wear

Saikat Pal [a], Hani Haider [b], Peter J. Laz [a], Lucy A. Knight [c], Paul J. Rullkoetter [a,*]

[a] Computational Biomechanics Lab, University of Denver, 2390 S. York Street, Denver, CO 80208, USA
[b] Department of Orthopaedic Surgery and Rehabilitation, University of Nebraska Medical Center, Omaha, NE, USA
[c] Bioengineering Science Research Group, University of Southampton, Southampton, UK

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Abstract

Polyethylene wear remains a clinically relevant issue affecting total knee replacement (TKR) performance, with considerable variability observed in both clinical retrieval and experimental wear studies. Recently, computational wear simulations have been shown to predict similar results to in vitro and retrieval studies. The objectives of this study were to develop a probabilistic wear prediction model capable of incorporating uncertainty in component alignment, constraint and environmental conditions, to compare computational predictions with experimental results from a knee wear simulator, and to identify the most significant parameters affecting predicted wear performance during simulated gait. The current study utilizes a previously verified wear model; the Archard's law-based wear formulation represents a composite measure, incorporating the effects and relative contributions of kinematics and contact pressure. Predicted wear was in reasonable agreement in trend and magnitude with experimental results. After 5 million cycles, the predicted ranges (1–99%) of variability in linear wear penetration and gravimetric wear were 0.13 mm and 25 mg, respectively, for the input variability levels evaluated. Using correlation-based sensitivity factors, the coefficient of friction, insert tilt and femoral flexion–extension alignment, and the wear coefficient were identified as the parameters most affecting predicted wear. Comparisons of stability, accuracy and efficiency for the Monte Carlo and advanced mean value (AMV) probabilistic methods are also described. The probabilistic wear prediction model provides a time and cost efficient framework to evaluate wear performance, including considerations of malalignment and variability, during the design phase of new implants.

Keywords: TKR; Computational wear simulation; Probabilistic; Kinematics; Knee mechanics

1. Introduction

Functionality and survivorship of current total knee replacement (TKR) implants are influenced by joint kinematics, contact mechanics, and wear. Polyethylene wear and wear-related complications (e.g. osteolysis) continue to be a leading cause of revision surgery [1]. Retrieval studies are often used to evaluate wear clinically, with findings exhibiting significant variability both in the wear level on the implant as well as in overall TKR performance [2,3].

Experimental knee wear simulators are often used to evaluate implant designs prior to clinical studies and to provide quantitative insight into the wear process and the effects of kinematic, geometric and material changes. Reported simulator wear results contain a significant amount of variability both in reported experimental wear volume and wear rates. Wear rate standard deviations of up to 14 mm^3/million cycles [4] and up to 2.9 mg/million cycles [5] for aged conventional polyethylene have been reported in the literature. In tibial insert wear testing, Muratoglu et al. [6] reported wear rate standard deviations of up to 0.3, 1.4 and 0.5 mm^3/million cycles for aged highly cross-linked, aged conventional and unaged conventional polyethylene, respectively.

The wear variability observed both in vivo and in simulator testing is likely caused by variability in the implant's kinematics and distribution of contact pressure, both of which are impacted by implant design, alignment, constraint and environmental conditions. Simulator testing has shown that wear is sensitive to kinematic level [4,7,8] and contact mechanics [9] and that a potentially significant level of kinematic variability is

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* Corresponding author at: Computational Biomechanics Lab, University of Denver, 2390 S. York Street, Denver, CO 80208, USA. Tel.: +1 303 871 3512; fax: +1 303 871 4450.
E-mail address: prullkoe@du.edu (P.J. Rullkoetter).

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present [10]. As a precursor to simulator studies, computational wear prediction models may provide a useful tool to efficiently evaluate wear, often as part of the design process where experiments would be time consuming and cost prohibitive. Finite element-based wear predictions are based on a nodal formulation and adaptive remeshing [11,12] and utilize the theory proposed by Archard [13]. While this type of adaptive finite element-based wear prediction has primarily been applied in hip implants [11,12,14,15], recently, computational assessments of TKR components have shown good agreement with both simulator and clinical studies [3,16,17].

Explicit finite element models [18,19] have previously evaluated the kinematics and contact mechanics during gait loading conditions present in the experimental Stanmore–Instron knee wear simulator. Probabilistic finite element analyses have quantified the effects of variability in component alignment, loading, and environmental conditions on the distribution of kinematics and contact pressure [20,21]. However, the impact of the kinematic and pressure variability on potential wear has not been previously evaluated.

Accordingly, the objective of the current study was to develop a probabilistic model to evaluate the effects of variability in component alignment, constraint and environmental conditions on polyethylene wear during simulated gait. The computational framework provides an efficient prediction of wear results, and a viable platform for assessing the effects of parameters that would be difficult to implement experimentally. The probabilistic model predicted the variability in linear wear penetration and gravimetric wear, as well as kinematics and peak contact pressure. Model predictions were verified through comparison with kinematic and wear results from the simulator including comparisons of the efficiency and accuracy of two probabilistic methods. In addition, the sensitivity of the joint mechanics and wear performance was assessed in order to identify the critical input parameters.

2. Methods

2.1. Experimental wear testing

The computational model used as the basis of this study was developed to reproduce the experimental wear test conditions of a Stanmore–Instron knee simulator [10,22] under gait loading conditions. Experimental wear tests were performed at the Orthopaedic Research Laboratories of the University of Nebraska Medical Center on two samples of a semi-constrained, cruciate-retaining TKR (NexGen® Complete Knee Solution Cruciate Retaining, Zimmer, Inc., Warsaw, IN). The experimental wear test conditions were described in detail in [17]; for completeness, a brief description is included here. The tibial inserts, machined from compression molded GUR 1050 ultra-high molecular weight polyethylene (UHMWPE), were sterilized by gamma radiation in nitrogen and artificially aged under pressurized oxygen at 70 °C for 14 days. The tibial component was aligned with a 5 mm medial offset to the axial loading axis to simulate the natural in vivo varus loading in the average TKR [23]. The updated simulator spring restraint included a 2.5 mm gap on each side to represent anatomical laxity, and stiffer springs posteriorly than anteriorly [23]. The force-controlled inputs used were nearly identical to ISO gait loading conditions [24] with the exception of the small change to the axial load profile as described in [17]. Testing was performed at a frequency of 1.1 Hz and carried out to 5 million cycles. During the test, the specimens were lubricated with bovine serum at 37 °C. Weight loss due to wear was determined gravimetrically at regular intervals throughout the test. Surface profilometry was performed on the inserts before and after the test to map the net change in surface geometry using a 3D medical profiling system. Three-dimensional profiles of the specimen surface were obtained by a sensitive stylus with a 0.5 μm depth resolution tracing parallel contours over the surface. Software (ANSUR 3D, University of Minnesota, Minneapolis, MN) was then used to superpose the pre- and post-test profiles. The medial and lateral plateaus of each insert were matched separately to account for any gross bending of the insert and to minimize errors due to creep. Subtraction of the pre- and post-test profiles provided a very good qualitative map of the relative amounts of wear and its distribution, but was deemed not reliable enough for absolute quantitative measurement due to the progression of alignment, creep and recovery errors.

2.2. Finite element model

An explicit finite element model (Fig. 1) was developed in Abaqus/Explicit (Abaqus, Inc., Providence, RI) from CAD models of the TKR. The femoral component was modeled using 17067 3D triangular surface elements (R3D3), while the insert was represented by 9632 eight-noded hexahedral elements (C3D8R). In finite element modeling with contact analyses, eight-noded hexahedral elements are preferred over tetrahedral elements [25] and hexahedral elements with mid-side nodes, which can exhibit irregular reaction forces. Element edge lengths

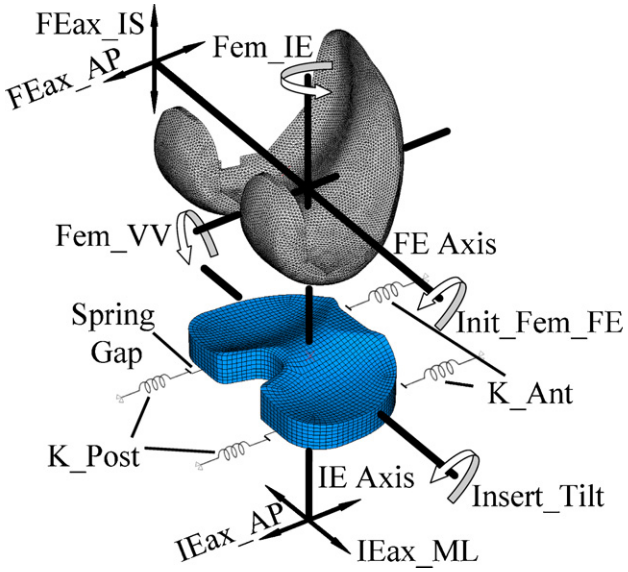

Fig. 1. Finite element model of the components and associated probabilistic parameters (not shown: coefficient of friction and wear coefficient).

were acceptable based on results from a convergence study. The mesh employed in this study had an average edge length of ~1.3 mm, which showed excellent agreement (kinematics and peak contact pressure difference within 5%) compared to a finer mesh with edge length of ~0.9 mm from [19]. For computational efficiency, both the femoral and tibial components were represented as rigid bodies with contact defined using a previously verified nonlinear pressure–overclosure relationship [26].

The loading conditions in the model closely matched the mechanical environment of the simulator. The model reproduced the simulated soft-tissue constraint present in the knee simulator, consisting of a set of four springs that constrain the insert in AP displacement and IE rotation, as well as the spring gap designed to represent anatomical laxity (Fig. 1). Masses and rotary inertia were estimated from measurements of the simulator. The applied force-controlled boundary conditions were from experimental feedback data. In the model, the femoral component was constrained in internal–external (IE), medial–lateral (ML), anterior–posterior (AP), and varus–valgus (VV) degrees of freedom, while flexion–extension (FE) rotation and compressive loading were applied. As in the experiment, the VV rotational axis was offset medially by 5 mm to create a medial–lateral load split. For the tibial insert, the distal surface was fixed in the inferior–superior (IS) direction, tilt was constrained, the VV and ML degrees of freedom were free, and AP force and IE torque were applied.

The numerical wear simulation used Archard's law [13] to estimate surface wear of the polyethylene:

$$H = k_{\mathrm{w}} p S \tag{1}$$

where H is the linear wear depth, k_{w} the empirically determined wear factor, p the contact pressure, and S the sliding distance. The adaptive wear simulation utilized the contact pressure and relative slip (sliding distance) for each node on the surface of the insert from the finite element analysis to compute the wear depth for each increment during the gait cycle [17]. The incremental wear depth was summed over the cycle for individual nodes, and the resulting nodal positions were updated to represent material removed from the surface. Mesh updating was performed every 500,000 cycles, based on a prior convergence study [17]. Computed wear volume was converted to gravimetric wear using a density of 0.93 mg/mm^3 for comparison with the experimental weight loss. Both linear and gravimetric wear were predicted for 5 million gait cycles.

2.3. Probabilistic model

Probabilistic methods allow prediction of the range of kinematics, contact mechanics and wear associated with inherent experimental variability. The probabilistic analysis software Nessus (SwRI, San Antonio, TX) was linked with the finite element-based wear prediction model in a similar manner to Laz et al. [20]. Variability was introduced in 13 experimental variables dealing with component alignment, constraint and environmental conditions (Fig. 1, Table 1). The alignment variables included four translations and four rotations of the femoral component and tibial insert. The rotations and translations defined the position of the femoral component and tibial insert relative to the fixed rotational axes (Fig. 1). The constraint variables included initial spring gap (Sprg_Gap), and the anterior and posterior spring constants (K_Ant, K_Post). The environmental condition variables were the coefficient of friction (μ), and the wear coefficient, k_{w}. All variables were assumed independent and normally distributed. The mean values for the alignment parameters were determined from the neutral experimental position, while mean values for the constraint and environmental conditions were based on the experimental setup. The mean value of k_{w} was 2.64333E−10 mm^3 N^{-1} m^{-1}, an estimate obtained by averaging reported wear factors from TKR and ball-on-flat wear tests [27]. The associated standard deviation was 5.286E−12 mm^3 N^{-1} m^{-1}, within the range of experimentally reported data. Standard deviations for the other input parameters were conservatively estimated at a level that could be achieved with careful experimental practice. Standard deviations were 0.5 mm for the translational alignment parameters, 1° for the rotations, and 0.09 N/mm for the spring constants. The parameters Sprg_Gap and μ were assigned standard deviations of 0.5 mm and 0.01, respectively.

Table 1
Probabilistic analysis variables with mean and standard deviation

Parameter	Description	Mean	S.D.
FEax_AP	AP position of femoral FE axis (mm)	−5.5	0.5
FEax_IS	IS position of femoral FE axis (mm)	28.0	0.5
IEax_AP	AP position of tibial IE axis (mm)	0.0	0.5
IEax_ML	ML position of tibial IE axis (mm)	0.0	0.5
I_Fem_FE	Initial femoral FE rotation (°)	0	1
Ins_Tilt	Tilt (FE rotation) of the tibial insert (°)	0	1
Fem_IE	Initial femoral IE rotation (°)	0	1
Fem_VV	VV position of the femoral (°)	0	1
Sprg_Gap	Insert to springs distance (mm)	3.0	0.5
K_Ant	Anterior spring constant (N/mm)	4.75	0.09
K_Post	Posterior spring constant (N/mm)	22.18	0.09
μ	Coefficient of friction	0.07	0.01
k_{w}	Wear coefficient (mm^3 N^{-1} m^{-1})	2.643E−10	5.286E−12

The Monte Carlo and advanced mean value (AMV) probabilistic methods were both applied in this study. The Monte Carlo method randomly selects parameters according to their distributions and then evaluates the performance measures for multiple trials. The Monte Carlo method is guaranteed to converge to the correct solution, but can be computationally expensive with accuracy dependent on the number of trials. On the other hand, the AMV method combines optimization and reliability theory in order to efficiently approximate the solution. The AMV method uses optimization to determine the combination of parameters that corresponds to performance at a specific probability level. A more detailed description of these methods can be found in [20,28,29]. The AMV method exhibits excellent agreement with Monte Carlo simulation methods, but is less robust for highly nonlinear or nonmonotonic systems.

The model predicted the 1, 50 and 99 percentile results for kinematics (AP and IE), AP and IE range of motion, peak contact pressure, linear wear penetration, and gravimetric wear. The first 12 parameters were varied in all analyses (kinematic and wear), while the last parameter (k_w) was varied only for the wear simulation. The model identified the most important parameters impacting performance by using sensitivity factors, which are a measure of how the variability in each input parameter affected the variability in performance. In this study, sensitivity factors were calculated from the Monte Carlo results as the absolute value of the correlation coefficients between each parameter and the measure [29]. Correlation coefficients near 1 indicate a direct relationship (high sensitivity) between the input parameter and the performance measure, while values near 0 imply no relationship (low sensitivity).

3. Results

Kinematic and contact pressure results are first presented because of their impact on the wear results. Comparisons between predicted and experimental data are to emphasize not only the magnitudes, but also the ranges of predicted variability. The predicted envelopes (1–99%) of AP and IE position captured the experimental data (Fig. 2) through the gait cycle. The envelopes of kinematic variability averaged 5.55 mm with a maximum range of 8.00 mm at 75% gait for AP position and averaged 6.49° with a maximum range of 11.36° at 78% gait for IE rotation (Fig. 2). During the swing phase, less constraint was present due to the small compressive loads and spring gap configuration. As a result, the data presented are based on a Monte Carlo analysis for 1000 trials, because the nonmonotonic behavior of the system caused inconsistent results in the optimization-based AMV method.

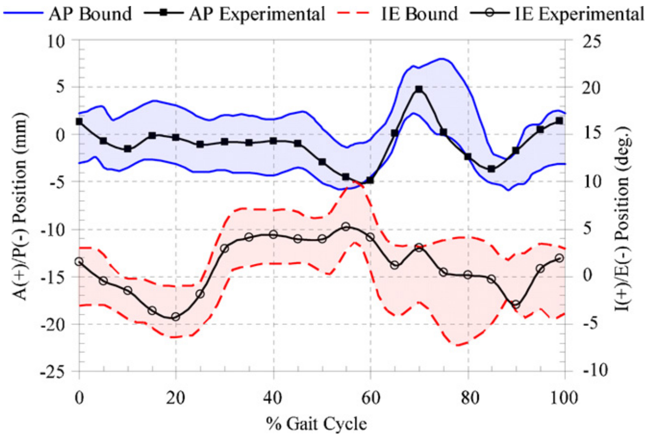

Fig. 2. Experimental AP (left axis) and IE positions (right axis) with model-predicted envelope (1–99%) as a function of gait cycle for the Monte Carlo (1000 trials) method.

Table 2
Average and bounds (1% and 99%) of kinematic range of motion (ROM) and peak contact pressure

Performance metric	Average	Minimum	Maximum
Anterior–posterior (AP) ROM (mm)	9.68	7.59	12.34
Internal–external (IE) ROM (°)	10.11	7.66	13.85
Peak contact pressure (MPa)	25.71	23.94	27.67

The range of motion (ROM), defined as the difference between the minimum and maximum positions during a gait cycle, was treated as a separate performance measure in the analysis. The ROM results are presented in Table 2 with the range between the 1 and 99 percentile results equal to approximately 49% and 61% of the mean for AP and IE position, respectively. Monte Carlo results are again presented for ROM because of the nonmonotonic nature of the measure; multiple combinations of input variables can result in the same predicted ROM. Note that the envelopes for AP and IE position in Fig. 2 are a composite measure representing the 1% and 99% values at each location through the gait cycle, while the ROM values (Table 2) were computed for the profile through an entire gait cycle. The ROM results are a measure of kinematic sliding distance, which potentially correlates to wear. Similar envelopes of performances were also computed for peak contact pressure, although no experimental data were available for comparison. The 1–99 percentile range for peak contact pressure (Table 2) was approximately 7 MPa, representing 27% of the mean value.

The maximum linear wear and gravimetric wear were predicted using the adaptive model described. Because of the computationally intensive nature of the wear model (2.33 h/iteration), results were generated using the Monte Carlo method with 300 trials and the AMV method, which required only 15 trials. The 1 and 99 percentile bounds are shown in Fig. 3 for maximum linear wear penetration and gravimetric wear, where the latter includes experimental data for comparison. After 5 million cycles, the Monte Carlo predicted envelope (1–99%) of linear wear (Fig. 3a) was 0.12 mm, with upper bound linear wear of 0.37 mm. The difference between the AMV and Monte Carlo methods was a maximum of 11.6% at 5 million cycles.

The model-predicted envelope (1–99%) of gravimetric wear measured in weight loss (Fig. 3b) was largely linear and similar in both trend and magnitude to the experimental data. After 5 million cycles, the predicted range of weight loss was 24.8 and 20.4 mg for the Monte Carlo and AMV methods, respectively. The predicted variability range was comparable to the two wear simulator test results, with wear losses of 78 and 97 mg after 5 million cycles. Qualitative comparisons between the simulator wear from the profilometry measurements and the wear patch from the model showed reasonable agreement (Fig. 4). The differences between the Monte Carlo and AMV methods after 5 million cycles for the upper or lower bound had a percent error of ∼4%. The computation time on a 3.0 GHz PC for the AMV

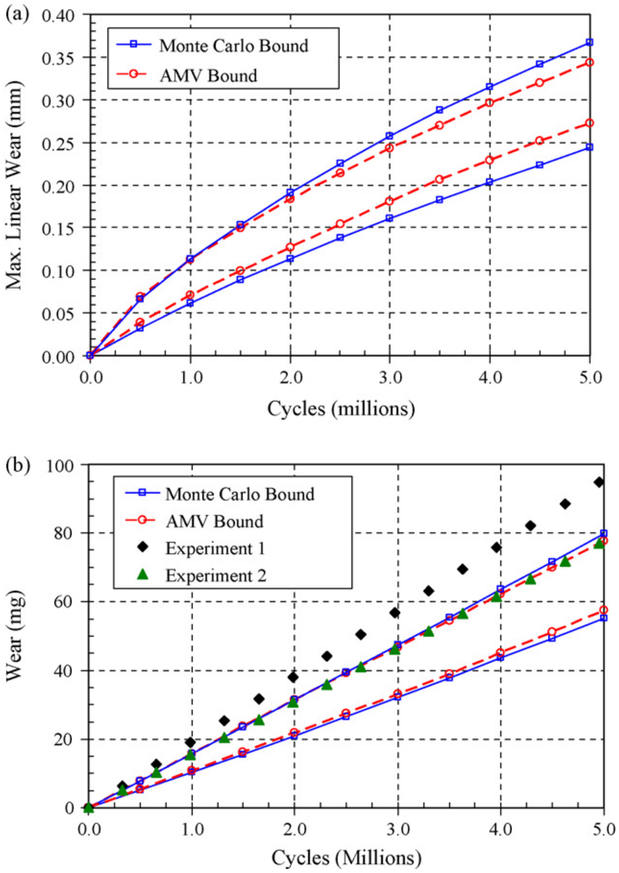

Fig. 3. Model-predicted envelopes (1–99%) of (a) maximum linear wear and (b) gravimetric wear as a function of cycles for the Monte Carlo (300 trials) and AMV methods. Gravimetric wear includes experimental data from two samples of cruciate-retaining TKRs run simultaneously under the same testing conditions.

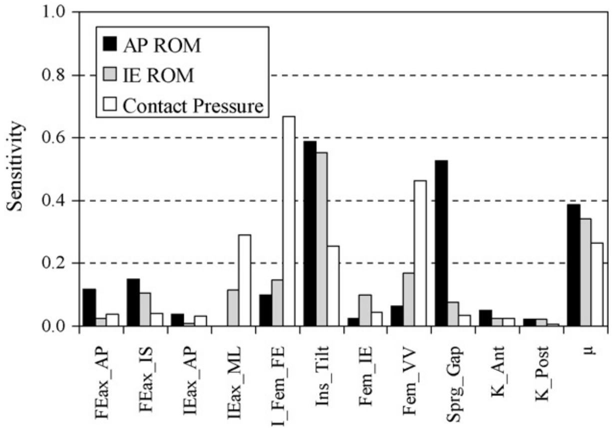

Fig. 5. Correlation coefficient-based sensitivity of AP and IE range of motion (ROM) and peak contact pressure to the model variables.

analysis was 40 h, while the Monte Carlo method with 300 trials required 700 h.

The sensitivity factor results identified the critical parameters impacting the variability in AP and IE ROM and peak contact pressure (Fig. 5) and maximum linear wear penetration and gravimetric wear (Fig. 6). The AP ROM was most affected by insert tilt (0.58), spring gap (0.52) and the coefficient of friction (0.38). Similarly, IE ROM was most affected by insert tilt and friction. It is important to recognize that these sensitivity factors are for ROM and not absolute kinematic position. While parameters like AP position of the rotational (FE or IE) axes or the femoral internal–external position (FEM-IE) will impact the absolute kinematic position, they were shown to not significantly impact the ROM results. Peak contact pressure was most impacted by femoral FE and VV alignment, with lesser contributions from the ML position of the insert rotational axis, the coefficient of friction and insert tilt. By affecting conformity, the alignment variables impact the contact pressure distribution.

The wear sensitivity factors showed good agreement between the AMV and Monte Carlo methods. Variability in gravimetric wear was most affected by the coefficient of friction (0.86), with secondary contributions from wear coefficient (0.32), femoral FE (0.30) and insert tilt (0.25). While friction was again most important, linear wear was impacted more by insert tilt (0.56), followed by femoral FE and VV and the wear coefficient. In addition to the wear coefficient, the sensitivity results for wear are a combination of those parameters important to both ROM and peak contact pressure. Linear wear, representing maximum

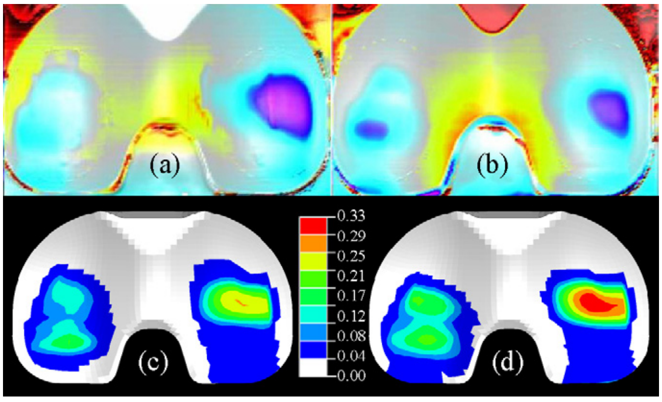

Fig. 4. Experimental surface profilometries (a and b) and simulated linear wear contours for the 1% and 99% bounds (c and d) after 5 million cycles. Predicted wear contour legend in mm.

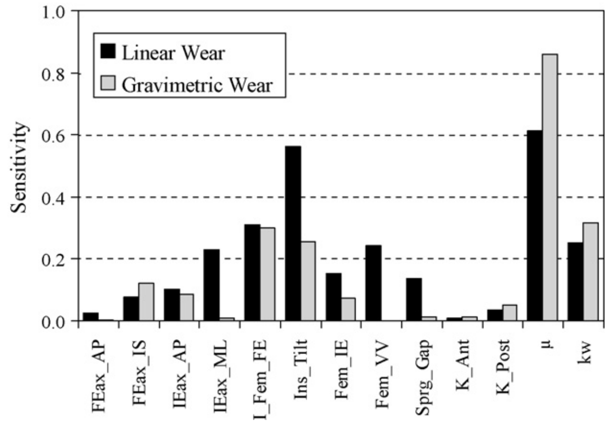

Fig. 6. Correlation coefficient-based sensitivity of total linear and gravimetric wear to the model variables.

linear penetration, was more of a local measure and thereby more affected by component position.

4. Discussion

The probabilistic wear prediction model developed in this study was used to evaluate the effects of component alignment, constraint and environmental uncertainty on predicted wear. Kinematic level [4,8] and contact mechanics [3] have been correlated to wear performance, with the latter shown to differentiate wear performance between implant designs. While Archard's law is a relatively simple representation of the wear process, it does provide a composite measure of the effects of sliding distance and contact pressure and serves as a relative indicator of wear when evaluating TKR designs. The model-predicted linear wear contours and weight loss envelope agreed fairly well in trend and magnitude with simulator data. The predicted weight loss from the deterministic model, based on average values for the input parameters, was smaller than the experimental data, likely due to selecting an average wear coefficient from the literature. The probabilistic, adaptive wear model represents the first attempt to consider the effects of variability in the in vitro conditions on wear. In addition, the identification of the critical alignment parameters affecting wear may influence surgical techniques.

Large variability in wear rate, with standard deviations of up to 14 mm^3/million cycles (∼13 mg/million), has been reported in simulator results [4]. The experimental data for the two samples used for comparison in this study had average wear rates of 19.6 and 15.2 mg/million cycles, which resulted in a difference of 22 mg in accumulated wear after 5 million cycles. In comparison, for the input variability levels assumed, the probabilistic model predicted a 1–99 percentile envelope of 25 mg or 31% of the upper bound. The current study provides insight into the sources of variability and their relative contributions in wear simulator results. The model predictions were also in good agreement with the experimental kinematics. Since the kinematic variability predicted (49% and 61% for AP and IE ROM) was larger than the contact pressure variability (27%), wear variability under these conditions is likely related more to changes in sliding distance due to variable kinematics than changes in pressure distribution.

The correlation coefficient-based sensitivity factors revealed similarities between the important parameters affecting variability in linear and gravimetric wear and those for kinematic ROM and contact pressure. Insert tilt was identified as the most important parameter affecting variability in AP and IE ROM, and linear wear. When considering the updated spring constraint [23], the importance of the coefficient of friction for all of the parameters considered, as well as the spring gap for AP ROM is expected. This result is in contrast to a previous analysis [20] with the restraint springs in continuous contact where the rotational axes were most significant. Frictional dominance is not surprising, however, given the lack of restraint near the neutral tibiofemoral position with the spring gap configuration. It is interesting that while the wear coefficient is very important in a deterministic model when predicting wear, it ranked only second for volumetric wear and fourth for linear wear when evaluating its contribution to the predicted bounds of performance. Also, these findings should be evaluated with consideration of the standard deviation levels of the input parameters which can affect magnitude and relative rank.

While the coefficient of friction, the wear coefficient, and associated variability can only be affected through material improvements, the component alignment parameters can be more easily controlled, especially in light of recent advances in computer-assisted surgery. Component alignment, and specifically, insert tilt and initial femoral FE, impacted both linear and gravimetric wear. Clinical studies have documented considerable variability in these parameters. In a study of 23 TKR, Catani et al. [30] reported ranges in posterior tilt between −2° and 10° and ranges in femoral FE rotational alignment between −6° and 10°. Similarly, Mahaluxmivala [31] reported variability of −8° to 13° in posterior tilt for 673 patients. While these reported ranges include both intentional and inadvertent variability, this study has shown that the variability in these parameters can dramatically influence wear performance in vivo. The predicted variability in mechanics and wear as a result of relatively small experimental deviations underscores the need for careful experimental procedures, as well as the evaluation of the impact of surgical decisions on in vivo performance.

While results with the Monte Carlo method more accurately predicted the kinematic ROMs and contact mechanics, the AMV wear predictions were shown to be within 12% of the Monte Carlo wear predictions, while requiring a small fraction (6%) of the computation time. When selecting a probabilistic analysis method, tradeoffs between accuracy and efficiency must be evaluated. Considering the substantial decrease in the computational time (on the order of several weeks), the AMV method may prove useful when making initial design phase evaluations of wear performance of TKR.

It is important to recognize that several assumptions and simplifications were made in the computational model. In the finite element model, the components were represented as meshed surfaces and assumed to be rigid bodies with contact modeled using a pressure–overclosure relationship. Mesh convergence and rigid body versus fully deformable analyses were performed to verify the integrity of the model predictions. The wear coefficient was empirically derived and assumed to be both temporally and spatially constant. The wear update interval was optimized to ensure convergence. Archard's law is limited to predicting abrasive/adhesive wear and does not account for pitting, delamination and third body wear modes. These latter modes of failure, however, were not observed in the experiments, with the abrasive/adhesive mode being the primary wear on the polyethylene inserts. A material model was utilized which did not include plasticity or creep. The inclusion of creep and plasticity will likely influence wear predictions in the early stages of the simulation, but the extent is currently unclear and was not quantified in this study. The addition of numerical creep models [15,16] to the existing wear model could be performed in the future. Despite the limitations, the current model can provide insight into wear variability and the associated critical parameters.

In closing, this study developed a probabilistic, adaptive wear prediction model for TKR components under simulated gait conditions. The variability in linear and gravimetric wear was predicted for the input variability levels, and the important parameters affecting predicted wear performance were identified. The probabilistic framework developed can be used to evaluate the robustness of implant wear performance to alignment, loading, or constraint variability present in knee arthroplasty patients, and can provide guidance for implant positioning to achieve consistent outcomes.

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