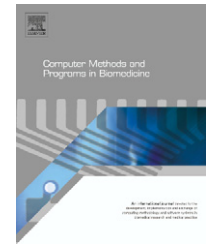




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Finite element-based probabilistic analysis tool for orthopaedic applications

Sarah K. Easley^a, Saikat Pal^a, Paul R. Tomaszewski^b, Anthony J. Petrella^b,
Paul J. Rullkoetter^a, Peter J. Laz^{a,*}

^a University of Denver, Computational Biomechanics Lab, 2390 S. York, Denver, CO 80208, United States

^b DePuy, a Johnson & Johnson Company, 700 Orthopaedic Dr., Warsaw, IN 46581, United States

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ABSTRACT

Orthopaedic implants, as well as other physical systems, contain inherent variability in geometry, material properties, component alignment, and loading conditions. While complex, deterministic finite element (FE) models do not account for the potential impact of variability on performance, probabilistic studies have typically predicted behavior from simplified FE models to achieve practical solution times. The objective of this research was to develop an efficient and versatile probabilistic FE tool to quantify the effect of uncertainty in the design variables on the performance of orthopaedic components under relevant conditions. Key aspects of the computational tool developed include parametric and automated FE model creation for changes in dimensional variables, efficient solution using the advanced mean-value (AMV) reliability method, and identification of the most significant design variables. Two orthopaedic applications are presented to demonstrate the ability of the computational tool to efficiently and accurately represent component performance.

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1. Introduction

Inherent scatter exists in many variables in engineering design, for example, component geometry, loading conditions, and material strength and fatigue properties. The combined effects of variability in individual parameters can dramatically affect component performance. Probabilistic modeling provides an approach to quantitatively determine the impact of multiple variables on specific performance metrics. Each variable is typically represented as a distribution, and a distribution of performance is predicted. By understanding the distribution of performance, evaluations of quality (e.g. design for six sigma) and risk assessment can be performed. Sensitivity factors are also determined as a result of probabilistic analysis and provide quantitative evaluation of the

contribution of each design variable to the overall variation in performance.

Probabilistic modeling has been widely used in the automotive and aeronautical industries [1–3] and has recently been applied to orthopaedic applications. The most common applications are in structural reliability where distributions of stress are compared to distributions of material strength. Recently, studies have taken a probabilistic approach to assessing the structural integrity of orthopaedic implants. Browne et al. [4] applied reliability theory to aid in fracture mechanics-based life prediction procedures for a tibial tray component represented as a cantilever beam subjected to constant amplitude loading. Dar et al. [5] demonstrated how Taguchi and probabilistic methods could complement each other to account for uncertainties when predicting stresses

* Corresponding author at: Computational Biomechanics Lab, University of Denver, 2390 S. York St., Denver, CO 80208, United States.
Tel.: +1 303 871 3614; fax: +1 303 871 4450.

E-mail address: plaz@du.edu (P.J. Laz).

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with finite element analysis (FEA) in a study of a fixation plate represented as a cantilever beam. Ng and Teo [6] studied the influence of material moduli uncertainty in cervical spine components on biomechanical responses and disc annulus stress using a 3D FE model and Monte Carlo simulation methods.

The femoral stem component of a total hip replacement has been the subject of several probabilistic structural integrity studies [7–10]. Nicoletta et al. [7] developed a 3D model of an implanted cemented hip stem as the subject of a probabilistic study where variability in material properties and loading was considered in order to predict a probability of failure due to three separate cement failure modes. Bah and Browne [9] used an idealized cylindrical FE model to represent an implanted cemented hip stem in order to assess the most likely mode of failure and to identify which parameters had the largest contribution, where geometry, material properties and loading were considered random variables.

Studies to date have typically used a simplified finite element model, such as a cantilever beam or idealized cylindrical geometry, or a two-dimensional representation. Variability was commonly applied to material properties and loading conditions, while geometric uncertainty was only considered for idealized geometry. Typical results reported from these studies include a distribution of predicted stress, predicted probability of failure and/or sensitivity factors. The common objective of the previous studies was to demonstrate the applicability of probabilistic methods to orthopaedic components, and clinical or experimental verification was not reported.

In addition to structural integrity studies, probabilistic methods have also been used in orthopaedic applications to represent inherently random features such as numerical crack densities in bone [11] and porosity in bone cement [12]. This approach can account for the scatter seen experimentally in damage accumulation and fatigue life at a constant stress level.

The primary objective of this research was to develop a generalized computational tool to facilitate probabilistic analysis of orthopaedic components. The computational tool improves on previous probabilistic studies by including dimensional variability in a complex geometry and incorporating more realistic modeling conditions while maintaining computational efficiency. The secondary objective was to demonstrate the tool for two applications, one investigating the effect of geometry and material property variability on implant performance, the other the effect of component placement and experimental setup variability on the kinematics of a total knee replacement.

Traditionally, probabilistic analyses present several challenges, including potentially significant computational time due to the many trials required. This work utilizes an efficient reliability method coupled with calibrated rigid body analyses to deliver an efficient and accurate solution. Geometric perturbations are also typically difficult with FE-based analyses due to the impact of a dimensional change on the mesh. As a result, deterministic or simplified geometries are generally used. This work presents a fully automated computational tool to update parametrically defined 3D models by modifying geometries and meshes through custom programming with

commercially available interfaces. Together, these techniques enable an efficient, versatile probabilistic analysis tool.

2. Methods

2.1. General probabilistic approach

A wide array of probabilistic methods exists, with methods differing in the efficiency and accuracy of their solution. A brief description of probabilistic methods is included here; more detailed descriptions can be found in Refs. [13–15].

In probabilistic analyses, variables are represented as distributions, where common types are normal, lognormal and Weibull. The probability density function (PDF) is essentially a continuous histogram; the area under the curve for some interval gives the probability that the performance metric will lie in that interval. The cumulative distribution function (CDF) is the integral of the PDF and specifies the probability of the response occurring at or below a specified value. The CDF always ranges in value from 0 to 1, representing a 0% probability at the lower bound and a 100% probability at the upper bound.

Probabilistic methods predict a distribution of the performance metric, from which the likelihood of a specific level of performance can be determined. In structural reliability applications, the performance function, g , is typically defined as

$$g(x) = R(x) - S(x)$$

where R is the strength or resistance and S is the applied stress. The probability of failure (p_f) is the likelihood that the stress exceeds the strength or that the performance function $g < 0$. The reliability or probability of survival, p_s , is the converse; $p_s = 1 - p_f$.

2.2. Probabilistic methods

The most commonly applied probabilistic model is the Monte Carlo method which involves randomly generating values for each variable according to its distribution and then predicting the distribution of performance through repeated trials. The Monte Carlo method will always converge to the correct solution, but is computationally expensive as the accuracy of the solution method is dependent on the number of trials.

The most probable point (MPP) methods are considerably more efficient than the Monte Carlo simulation; this is especially significant when performing repeated FE analyses. The MPP methods are based on mapping of the original random variables into independent standard normal variables and determining the most probable point using optimization [15]. Reliability can be computed based on the location of the MPP by a variety of methods including first or second order reliability methods (FORM or SORM) or a higher-order method such as advanced mean-value with iterations (AMV+) method [17]. While the MPP methods are approximate, they have been shown to be quite accurate in comparisons with Monte Carlo simulation results, while requiring a small fraction of the number of computations.

The mean-value (MV) method constructs a mean-based response function and computes the MPP for the specified

probability levels. As a first-order method, it provides a good approximation of the solution near the mean, but can deviate significantly toward the tails for non-linear problems. The MV method requires $n + 1$ trials, where n is the number of random variables. The advanced mean-value (AMV) method utilizes higher-order terms to achieve a better representation of the response and requires $n + 1 + m$ trials, where m is the number of specified probability levels. The advanced mean-value with iterations (AMV+) method involves the implementation of AMV but also includes iterations on the MPP to ensure that convergence to a specified level is reached. AMV+ has been shown to be very accurate even for non-linear problems, though the number of trials varies with the problem [16].

2.3. Sensitivity factors

Design sensitivity factors are another valuable result of probabilistic analyses, as they indicate the effect of each individual parameter on the reliability function. There are relative and absolute sensitivities, each with unique advantages. Relative sensitivities are commonly referred to as probabilistic sensitivity factors, α , and give the change in safety index, β , with respect to the standard normal variate, u . The probabilistic sensitivity factor is defined as

$$\alpha_i = \frac{\partial \beta}{\partial u_i} = \frac{\partial p}{\partial u_i} \frac{\partial \beta}{\partial p}$$

for each variable with p equal to a specific probability level. The sensitivity factor α is useful for relative ranking of random variables. A positive sensitivity indicates a direct relationship between the value of the variable and the response, while a negative sensitivity indicates an inverse relationship. The safety index, β , is represented in standard normal variate space, where, for example, probabilities of 0.01 to 0.99 are represented by standard normal variates of -3 to $+3$. The standard normal variate is a function of the mean, standard deviation and distribution type, so the α sensitivity factor is not always ideal for the design process.

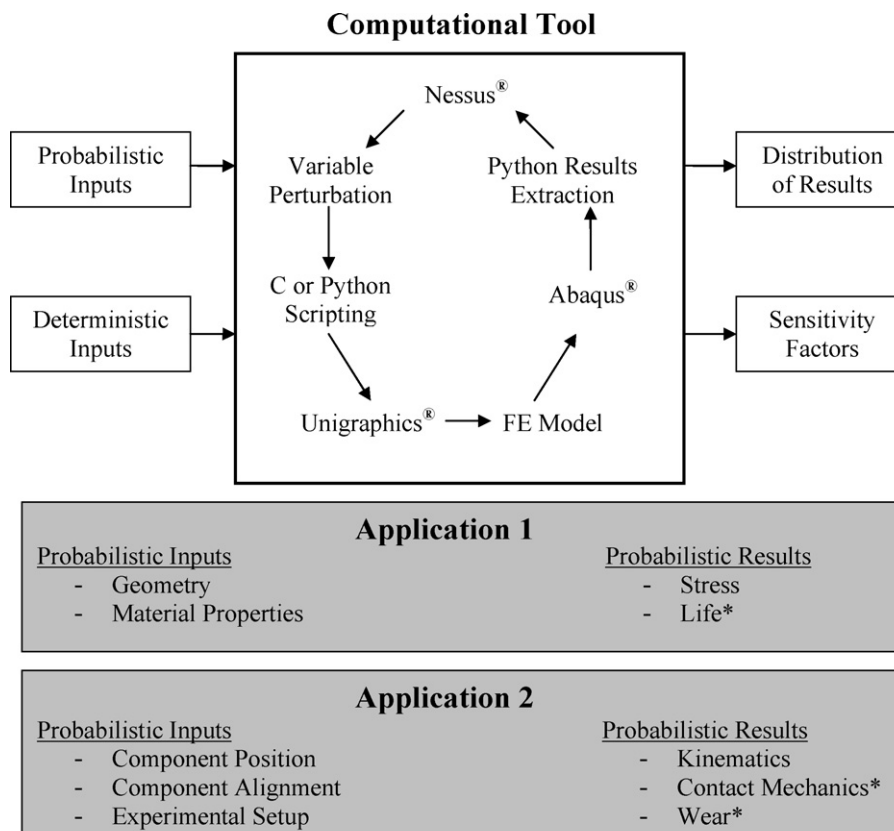
Instead, absolute sensitivities, S_μ and S_σ , may be evaluated. These give the change in probability with respect to the mean and standard deviation, respectively, and are determined by

$$S_\mu = \frac{\partial p}{\partial \mu_i} \frac{\sigma_i}{p}, \quad S_\sigma = \frac{\partial p}{\partial \sigma_i} \frac{\sigma_i}{p}$$

where the sensitivities are non-dimensional, allowing comparisons to be made between all of the variables. These sensitivities indicate how much the mean and standard deviation of each random variable contribute to the variability in the response.

2.4. Computational tool for probabilistic FE modeling

The computational tool developed in this research combines commercially available software with custom scripting to develop a flexible and robust model. The computational



* Not presented in this study

Fig. 1 – Flowchart of automated FE-based probabilistic model, integrating Nessus, Unigraphics, and Abaqus.

tool combines a probabilistic software package (Nessus¹) with CAD/CAE software (Unigraphics NX²) and a finite element solver (Abaqus³/Standard and Explicit) (Fig. 1). Nessus was used to define the variables, implement the probabilistic model and perturb the variables for each trial. The geometry was defined parametrically within Unigraphics NX (UG), and custom C scripting used UG Open API functions to update the geometric parameters, regenerate and remesh the model. The scripting developed was generic and applicable to any parametrically defined part or finite element model. Abaqus/Standard or Explicit was used as the finite element solver, as specified by the FE model, and a custom Python script extracted the results. The results for each trial were returned to Nessus, which then specified the perturbed variables for the next trial. This automated process was continued until the analysis was complete when convergence or the specified number of trials was reached.

3. Application 1: effect of variability in geometry and material properties on fatigue performance of a hip stem

The objective of the first application was to provide quantitative measures of component reliability or probability of failure which accounts for uncertainties inherent to manufacturing tolerances and material properties.

3.1. Deterministic model

A deterministic FE model was developed and validated as the basis for the probabilistic model. A set of geometric parameters was used to describe the pertinent characteristics of a three-dimensional femoral stem: stem diameter (d), stem length (L), radius of curvature of the stem (R), neck length (N), attachment point of the neck (x , y), and neck angle (θ) (Fig. 2). Loading and boundary conditions were developed to represent a standard experimental fatigue test, such as ASTM F-1440 [17], ISO 7206 [18], or Semlitsch and Panic [19]. The experimental test consisted of a concentrated force on the femoral head, while the distal third of the stem was fixed. Under these conditions, the component experiences a more severe loading condition than *in vivo*; the loading is representative of a loosened stem which is not supported proximally by surrounding bone. The maximum stress occurred at the lateral aspect of the stem, where most fatigue cracks are known to initiate [20,21].

3.2. Probabilistic model

Ten parameters were selected for variable inputs to the probabilistic model: the seven geometric parameters cited above and three material properties (Table 1). The geometric variables were described by normal distributions, while the material property variables were described by lognormal distributions, as this best represents observed behavior [13].

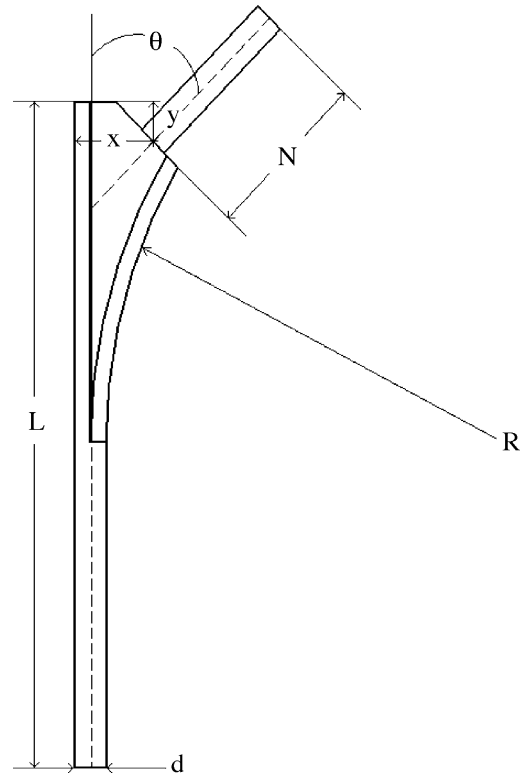


Fig. 2 – Parametric design of hip stem.

Mean values for the hip stem dimensions were based on representative values, and the standard deviations were estimated based on historical metrology data. The values for Young's modulus and Poisson's ratio were selected for cast Co–Cr–Mo [22,23]. Representative mean and standard deviations were used for the fatigue limit of cast Co–Cr–Mo, where fatigue limit is defined as the stress corresponding to a fatigue life of 10 million cycles. For this analysis, a deterministic load of 507 N was applied.

The deterministic model of the hip stem geometry served as the foundation for the probabilistic study. A series of scripts generated new geometry within UG based on the perturbed variables. The mesh (~31,400 tetrahedral elements), loading and boundary conditions were then updated for the new geometry before an Abaqus/Standard input file was written.

A 1000-trial Monte Carlo simulation and the MPP (MV, AMV, AMV+) reliability methods were employed for the probabilistic analyses; the former served as verification for the latter, efficient methods. The structural integrity performance function was defined as

$$g(\mathbf{X}) = S_f - \sigma(\mathbf{X})$$

where S_f is the fatigue limit of the material, σ the stress predicted by the FE analysis, and \mathbf{X} is the vector of random variables. Additionally, a performance function based on component life could be implemented using a stress-life material relation.

¹ Southwest Research Institute, San Antonio, TX.

² UGS, Plano, TX.

³ Abaqus, Inc., Providence, RI.

Table 1 – Hip stem probabilistic study parameters (application 1)

Parameter	Description	Distribution	Mean	S.D.
d (mm)	Stem diameter	Normal	9.0	0.08
L (mm)	Stem length	Normal	180.0	1.50
R (mm)	Radius of curvature	Normal	144.0	0.25
N (mm)	Neck length	Normal	39.0	0.25
x (mm)	Horizontal distance to neck	Normal	22.5	0.25
y (mm)	Vertical distance to neck	Normal	10.7	0.25
θ (°)	Neck angle	Normal	45	1
E (GPa)	Young's modulus	Lognormal	210.0	38.0
ν	Poisson's ratio	Lognormal	0.280	0.005
S_f (MPa)	Fatigue strength	Lognormal	356	23

3.3. Application results and discussion

The model predicted the distribution of peak stress in the hip stem from the Monte Carlo analysis with a mean of 367 MPa and a range from 340 to 399 MPa between the 1% and 99% bounds. The probability of survival or reliability is based on the performance function and represents the likelihood of the component surviving 10 million cycles. For the applied load and the fatigue strength distribution (Table 1), the probability of survival was 31.90% for the Monte Carlo analysis based on 1000 trials (Fig. 3). Since the sampling error for the Monte Carlo analysis (1000 trials) was calculated as 4.33% [24], the actual probability of survival could range between 28.95% and 34.85%.

The MV first-order approximation predicted a probability of survival of 39.87% and required 10 FE analyses. While the non-linearity of the model results in a notable inaccuracy of the MV method, the results of the AMV and AMV+ compared well with the Monte Carlo results (Fig. 3). The probabilistic model using the AMV method predicted a probability of survival of 34.19% in 12 trials. The AMV+ analysis predicted a probability of survival of 33.77%, respectively, and required 212 trials for convergence.

The difference in predicted probability of survival between the AMV method and the 1000 trial analysis was within the absolute error of the Monte Carlo analysis. The good compar-

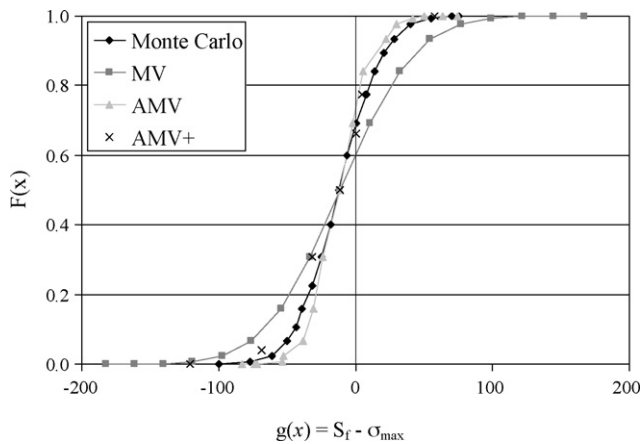


Fig. 3 – Cumulative distribution functions of performance function from MV, AMV, AMV+, and Monte Carlo probabilistic analyses of a hip stem.

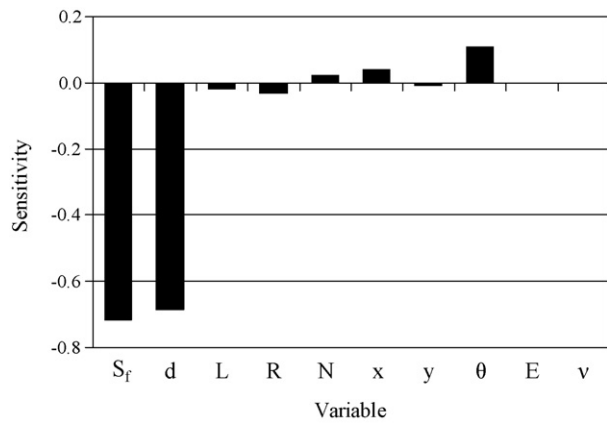


Fig. 4 – Sensitivity factors (α) for the probabilistic analysis of a hip stem.

isons between the AMV and Monte Carlo results are especially notable when considering the small number of trials required to achieve the AMV results. The computation time to run a single trial was approximately 60s on a 3GHz PC, requiring ~17 h for 1000 trials.

In experimental testing at a fixed load level, fatigue lives have been shown to vary by as much as 1.5 orders of magnitude in a Ti-6Al-4V stem under ISO 7206 test conditions [25] and by more than an order of magnitude in a Co-Cr-Mo stem under four-point bend conditions [26]. The probabilistic model attempted to reproduce the observed fatigue life variability and predicted probability of survival representing the likelihood of the component surviving 10 million cycles. The variability in geometry and material properties predicted a range of peak stresses that may account for some of the variability observed in component life. Fatigue data from the literature showed that a 10% reduction in stress range near the endurance limit produced an 80x increase in median life, resulting in a significant number of the specimens surviving 5 million cycles [25].

Probabilistic sensitivity factors, α , showed that uncertainty in the fatigue strength and the stem diameter contributed most to the variability in the predicted stress, and the neck angle variable contributed to a lesser extent (Fig. 4). The uncertainty in the material properties (Young's modulus, Poisson's ratio) did not contribute significantly. The absolute sensitivity factors S_{μ} and S_{σ} showed that the mean value of the fatigue

input file to update the variables with the values generated by Nessus for each trial. The performance metrics evaluated were relative tibiofemoral kinematics, AP translation and IE rotation, through which sliding distance has the potential to impact wear. The performance metrics were evaluated at 80 locations throughout the gait cycle.

Both Monte Carlo and AMV methods were used to predict the bounded response of each performance metric. The Monte Carlo simulation was performed for 1000 trials. The implementation of the AMV method was complicated by the applied gait loading conditions. In order to determine the performance metrics, AMV analyses were performed at percentile levels (1%, 50% and 99%) for each discrete location in the gait cycle. A total of 253 evaluations (~24 h on a 3 GHz PC) were conducted for each performance metric evaluated at 3 probability levels with 12 variables and 80 points throughout the gait cycle.

4.3. Application results and discussion

The results of the probabilistic analysis described the range of kinematics that could be observed in the simulator with the specified level of variability. The AMV and Monte Carlo results showed excellent agreement and differed by less than the error for the 1000-trial Monte Carlo analysis; the AMV results are presented. Envelopes representing the 1% and 99% bounds are predicted for tibiofemoral AP translation and IE rotation (Fig. 6). The maximum ranges were 3.44 mm for AP

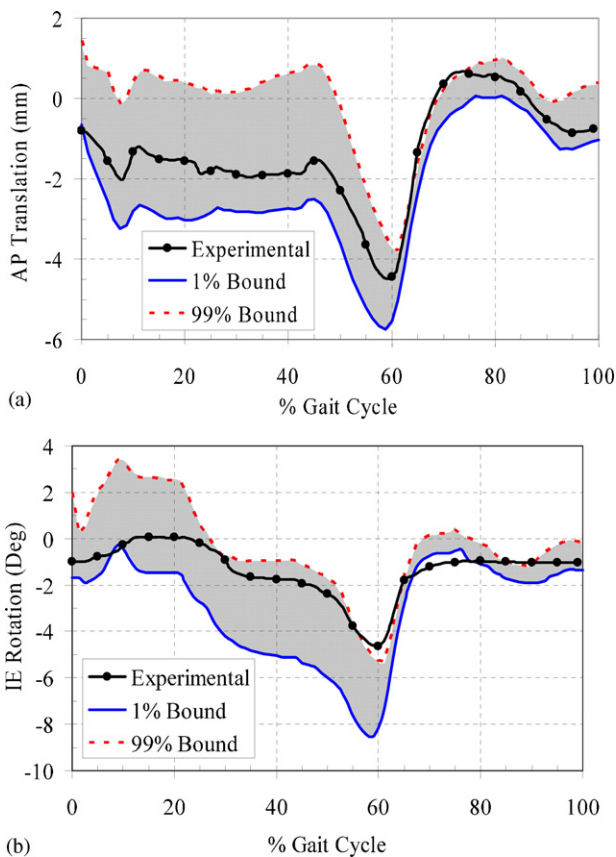


Fig. 6 – Model-predicted envelope (1-99%) for experimental (a) AP translation and (b) IE rotation over the gait cycle.

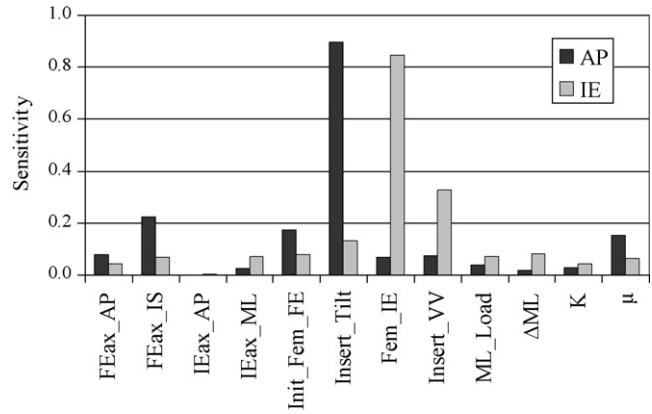


Fig. 7 – Probabilistic sensitivity factors (α) for AP translation and IE rotation. Results are normalized averages for the entire gait cycle.

translation and 4.30° for IE rotation. The predicted envelope captured nearly all of the experimental data for both AP translation and IE rotation (Fig. 6) with the exception of a portion of the swing phase between 60% and 100% gait. The results show good tracking; however, differences in magnitude are likely caused by the presence of friction and damping in the experimental simulator that are not included in the model. While presented for kinematics, the modeling approach can be applied similarly for other performance metrics, including contact pressure and wear.

The probabilistic sensitivity factors, α , were averaged over the entire gait cycle and normalized (Fig. 7). Uncertainty in the tilt of the tibial insert was shown to contribute most to the variability in AP translation. The inferior–superior (IS) position of the femoral FE axis, the initial femoral flexion–extension (FE) rotation, and the coefficient of friction were also significant. The AP and ML position of the tibial IE axis, the ML position of the spring fixation, the spring constant and the ML load split were determined not to have a significant contribution to the scatter in AP translation for the standard deviation level investigated. The femoral IE rotational alignment was found to be the most significant variable with respect to the variability in IE rotation. The varus–valgus (VV) position of the insert was also important, while position of the femoral FE and tibial IE rotational axes, ML position of the spring fixation, the spring constant, and initial femoral FE rotation contributed negligibly to the scatter in IE rotation.

5. Discussion

In both applications, small variability in the parameters led to substantial variability in the performance metrics. In the first application, variability in dimensions and material properties under fatigue test conditions produced a stress range (1-99%) from 340 to 399 MPa in the hip stem resulting in a probability of the component surviving 10 million cycles of 33.77%. In the second application, the probabilistic model predicted kinematic ranges (1-99%) of 3.44 mm for AP translation and 4.30° for IE rotation based on small variability levels in component alignment and experimental setup. It is important to note, that

the predicted variability in performance, as well as the sensitivity parameters, are dependent on the standard deviation levels of the input parameters.

The broad capabilities of the computational tool were demonstrated for structural reliability and kinematic performance applications. An understanding of the variability in performance allows component design to be assessed and provides a platform to evaluate the reliability of orthopaedic implants. While parameter sensitivity studies of joint mechanics (e.g. [32–35]), including design of experiments, have been performed previously, this research represents a novel application of probabilistic modeling to quantify the effects of component alignment variability. The primary advantage of probabilistic analysis over single degree-of-freedom sensitivity studies is that the effects of variable interaction on performance are incorporated.

The sensitivity factors provided insight into the significant and insignificant parameters. In experimental testing and manufacturing, knowledge of the sensitivities can lead to time and cost savings by controlling variables to greater or lesser precision. The effect of changes to a manufacturing process, material property, and/or experimental procedure can be quantitatively assessed using this approach. More broadly, sensitivity factors can provide surgeons with insight into the critical component placement variables to ensure consistent long-term performance.

The computational tool addressed some of the historical challenges of probabilistic modeling. Probabilistic modeling has typically been performed on simplified models in order to be computationally viable. In this work, dimensional variability, complex and realistic FE models and efficient probabilistic methods were realized. Scripting developed with UG's Open API programming interface demonstrated perturbation of dimensional parameters within a 3D parametric geometry and automated meshing and finite element solution. Greater FE model realism was incorporated in application 2 where TKR components were run under simulator gait loading conditions. Viable computation times were realized both through the use of efficient probabilistic methods (AMV) and efficient finite element methods (explicit rigid body analysis [30]) without sacrificing accuracy or complexity. The AMV technique proved to be significantly more efficient ($4\times$ to $83\times$) while achieving similar results to the 1000-trial Monte Carlo method. The demonstration of two distinct applications illustrates the versatility of the computational tool to perform evaluations of any orthopaedic or structural component.

6. Conclusions

A computational tool for performing probabilistic FE modeling has been developed that links commercially available software with custom scripting to perform efficient and accurate analyses of complex problems. The capabilities were demonstrated for two applications including an assessment of the structural reliability of a hip stem component and an evaluation of the impact of component alignment and experimental setup on knee wear simulator kinematics. The model helps to address traditional challenges in probabilistic modeling including dimensional perturbation of FE geometry, complex

and realistic loading conditions, and computational efficiency (AMV method). The computational tool is robust and versatile, allowing the assessment of performance of a wide range of orthopaedic and structural components.

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