Risk-based analysis of femoral stem considering uncertainty in its design parameters

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RISK-BASED ANALYSIS OF FEMORAL STEM CONSIDERING UNCERTAINTY IN ITS DESIGN PARAMETERS

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ABSTRACT
The number of young people getting total hip arthroplasty surgery is on the rise and studies have shown that the average number of perfect health years after such surgery is being reduced to about 9 years; this is because of complications which can lead to the failure of such implants. Consequently, such failures cause the implant not to last as long as required. The uncertainty in design parameters, loading, and even the manufacturing process of femoral stems, makes it important to consider uncertainty quantification and probabilistic modeling approaches instead of the traditional deterministic approach when designing femoral stems. This paper proposes a probabilistic analysis method which considers uncertainties in the design parameters of femoral implants to determine its effect on the implant stiffness. Accordingly, this method can be used to improve the design reliability of femoral stems. A simplified finite element model of a femoral stem was considered and analyzed both deterministically and probabilistically using Monte Carlo simulation. The results showed that uncertainties in design parameters can significantly affect the resulting stiffness of the stem. This paper proposes an approach that can be considered a potential solution for improving, in general, the reliability of hip implants and the predicted stiffness values for the femoral stems so as to better mitigate the stress shielding phenomenon.
Keywords: femoral stem, stiffness reduction, probability, finite element analysis, Monte Carlo simulation

INTRODUCTION

1.1 Background
The aging of the population and the obesity epidemic in the USA have been pointed out among the main causes of the high incidence of arthritic hip joint diseases, driving the demand for orthopedic surgery [1,2]. Total hip arthroplasty (THA) is the most performed surgical procedure in such cases and, despite the satisfactory short-term and long-term outcomes, several technical issues related to the implant design may lead to early revision surgeries. Furthermore, the desire of perfect quality of life by patients with a high-activity profile and the need for increased longevity of such implants has been pushing the development of the next generation of total hip replacement implants which are more biological compatible and mechanical resistant [3]. Currently, different types of commercial implants are available which attempts to mimic the bone natural functionality. However, most of them do not fulfill completely some required properties related to biological and chemical compatibility, osseointegration, wear and fatigue resistance [4]. One of the major issues is related to the stiffness mismatch between the femoral stem and the bone structure, which leads to stress shielding in the femur, and consequently to bone resorption and aseptic loosening of the implant [5]. In order to overcome these issues, considerable effort has been addressed over the past decade at the design of more biomechanical compatible orthopedic implants through the application of porous materials [6]. It is well known that porous structures can reduce the stiffness of metallic femoral stems, as well as facilitate bone cell ingrowth in order to improve the implant fixation [5,7,8]. Recently, several design approaches for complex porous stems have been proposed based on topology optimization design techniques, finite elements (FE) modeling and advanced additive manufacturing (AM) technologies [5,8–10].

However, existing studies have pointed out that manufacturing errors in porous structures are introduced by AM processes that result in significant uncertainties in the mechanical response of the porous implant, which cannot be handled by conventional deterministic design approaches [11]. On the other hand, only recently probabilistic design approaches have been applied to

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evaluate the effect of randomness in the design parameters on the structural integrity of orthopedic implants. Dopico-González et al. [12] conducted a probabilistic investigation of an uncemented hip replacement using Monte Carlo and Latin hypercube simulations in an FE model of a femoral stem. Easley et al. [13] developed a probabilistic FE tool to quantify the effect of uncertainty in the design variables on the performance of orthopedic components. Bah et al. [14] presented a statistical investigation into the effects of implant positioning on the initial stability of an uncemented femoral stem. Kharmanda et al. [15] used shape optimization to produce hollow stems and applied probabilistic analysis to study the boundary conditions change in a two-dimensional FE femoral stem model. Nicolella et al. [16] investigated the effect of three-dimensional prosthesis shape optimization on the probabilistic response and probability of failure of a cemented femoral stem. Other relevant probabilistic methods and analysis techniques commonly used in orthopedic biomechanics applications were reviewed in Laz and Browne [17]. Most of the above-mentioned probabilistic design approaches do not consider a proper uncertainty quantification of the design parameters of the femoral stems. Furthermore, the variability of the mechanical properties and its impact on the stem stiffness still needs clarification.

1.2 Motivations and Specific Aims

The motivations of this work are:

- Fully solid implants have stiffness/strength values significantly greater than surrounding tissue leading to failures due to phenomenon like stress shielding [5]. Thus, there is a need to design biomimetic porous orthopedic implants considering geometry which reduces stiffness and allows for bone tissue ingrowth.
- There is a higher chance of introducing manufacturing error when structures are fabricated by the additive manufacturing processes. Therefore, it is necessary to account for the uncertainties in FE modeling and design processes [11].

Based on the motivations listed above, the following research question was developed: Can uncertainties be accounted for in hip stems designed for stiffness reduction?

The following specific aims were developed to answer the research question (1) design a 3-D solid model of the femoral stem with uncertainty in design parameters and loading conditions, and (2) develop an uncertainty quantification framework to accurately predict the effects of variability on the stiffness of a femoral stem.

METHODOLOGY

1.3 Femoral Stem Finite Element Model

A 3-D model of the stem was designed using Autodesk Inventor 2017 software package. This design is fully dense and can be made porous for the sake of analysis by defining a portion of the stem with mechanical properties which represents the porous material. This approach for material characterization is the same adopted in Jetté et al. [5]. The FE model of the femoral stem was developed using the ANSYS Workbench 19.1 software (ANSYS, Canonsburg, PA, USA) to calculate the elastic response of the stem for several constant loads applied in the top of the stem. The material used for the stem was Ti-6Al-4V alloy in which Young's modulus of the fully dense and porous part of the stem was 114 and 8.4 GPa, respectively, and the Poisson ratio of the material was 0.3. Meshes were generated using quadratic tetrahedral elements with 14305 elements and 26969 nodes. No friction or relative movement at any interface was assumed so both portions of the stem have fully bonded contact.

A constant load was applied as a downward vertical force in the top of the femoral stem while the bottom of the stem was constrained to no movement in any direction. The loads were varied linearly from 0 to 800N with steps of 80N and the maximum displacement in the femoral stem was mapped in each step. Fig. 1 shows the FE model with the mesh used, the porous region and the point of load application.

Table. 1. Statistics of input parameters used in ANSYS

Random Variable	Distribution Type	Mean	Standard Deviation
Young's modulus [GPa]	Lognormal	114	5.7
Young's modulus of porous part [GPa]	Lognormal	8.4	0.42
Force [N]	Gaussian (truncated normal)	800	11.56

2.2 Probabilistic Model

Hip stems are considerable stiffer than surrounding bones this high stiffness, results in complications and eventual failures of such implants. Current femoral stems are designed such as to reduce its stiffness to get stems with stiffness values which are close enough to that for bone. Consequently, this makes percent stiffness reduction between fully dense and porous stem an important output parameter of interest. Stiffness is calculated from the slope of a Force-Displacement graph with the displacement gotten as an output from ANSYS.

ANSYS DesignXplorer and MATLAB was used to perform the probabilistic analysis. For the input random variables, distributions were assumed to characterize their uncertainties, in which the distribution type, mean and standard deviation considered are listed in Table 1. In these simulations, the maximum vertical directional displacement is the defined output parameter. During the probabilistic analysis, ANSYS executes multiple analysis loops to compute the random output parameters as a function of the set of random input variables [15]. The samples of the input random variables were generated randomly using the Latin hypercube sampling method and their uncertainties were propagated to the maximum displacement in the femoral stem. The uncertainties of the maximum displacements (obtained from the probabilistic FE analysis) and the loads were then propagated to the stem stiffness through a

Monte Carlo simulation algorithm developed in MATLAB. The corresponding percentage stiffness reduction was then obtained from the difference between the distributions of the stiffness of the fully dense stem and porous stem. The output parameter or failure criterion considered in this study was the percent stiffness reduction between the fully dense and porous stem. It should be noted that although the output, in this study, is not a failure as such, it can be used as a reference for the 'limit state'.

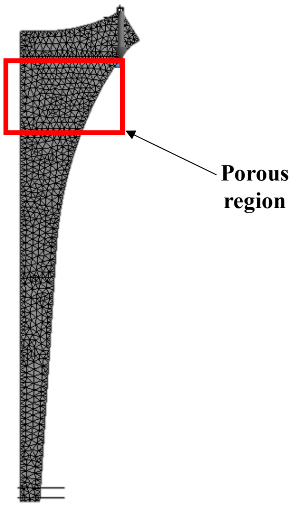

FIGURE 1: FINITE ELEMENT MODEL OF FEMORAL STEM SHOWING THE MESH, APPLIED LOAD, AND POROUS REGION

The processes involved in the design and manufacturing of femoral stems have some degree of uncertainties thus the traditional deterministic methods are not sufficient for stem designs. Based on these, a novel probabilistic framework to determine stiffness for a femoral stem is developed and is depicted in Fig. 2. A brief explanation of the process is given below.
The probabilistic risk-based modeling for the femoral stem can be done using ANSYS and MATLAB. In ANSYS the input parameters (material properties, loading etc.) and the output parameter (displacement) is defined. For comparison purposes only, a deterministic analysis can be conducted in ANSYS using the mean values for the inputs listed in Table 1. The uncertainties of design parameters and the loads are provided as inputs through an interfacing code (ANSYS with MATLAB). MATLAB can be used to define the mean and standard deviation of each input variable and using uncertainty quantification techniques (e.g., maximum entropy principle, kernel density function), the resulting input probability density functions (PDFs) can be generated which is then passed to ANSYS as input parameters. ANSYS probabilistic FE model calculates the PDFs of the maximum displacements which is used as one of the inputs in the MATLAB Monte Carlo simulation algorithm to calculate the final output (stiffness). A risk-based analysis can be carried out based on the definition of a limit state function from a design minimum stiffness reduction criterion and a target reliability. After implementing the Monte Carlo simulation, the results which comprise of PDFs, cumulative distribution functions (CDFs), the reliability and sensitivity of the output to all input variables can be recorded. The results can be used to verify if the femoral stem reliability matches the target reliability. If there is no match, the design parameters are modified, and the process is repeated until the desired reliability is achieved. This entire process is shown in steps in the flowchart with numbers which indicate the order of occurrence of each step. As a first validity study, a simplistic stem is modeled and analyzed.

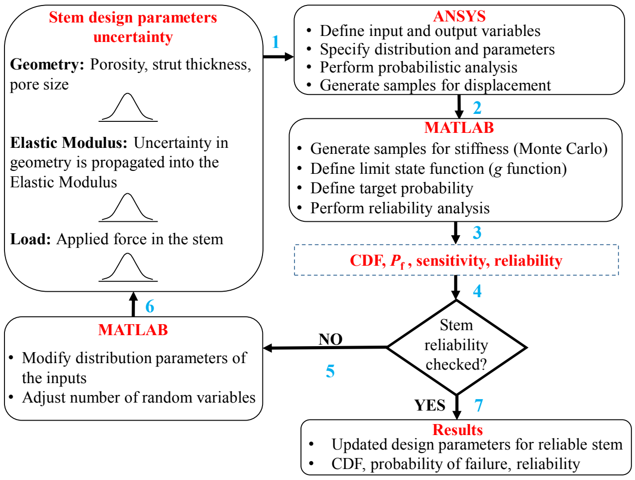

FIGURE 2: FRAMEWORK FOR THE DESIGN OF A FEMORAL STEM TO REDUCE STIFFNESS CONSIDERING THE QUANTIFICATION OF UNCERTAINTIES OF THE DESIGN PARAMETERS

RESULTS

3.1 Deterministic Analysis

The displacement vector of one point of the stem is monitored for the applied force on the stem head and the results are shown in the diagram presented in Fig. 3. This analysis was used to determine the stiffness of the stem. The results for the fully dense are compared to that of the porous stem and the amount of stiffness reduction between the two was calculated.

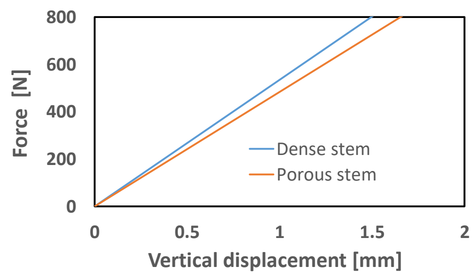

FIGURE 3: FORCE-DISPLACEMENT DIAGRAMS OF FULLY DENSE AND POROUS FEMORAL STEM

The stiffness of the fully dense and porous stem was evaluated by calculating the slope of the force-displacement diagram to be 534.7 N/mm and 484 N/mm respectively. The stiffness reduction obtained from the porous stem in comparison to the fully dense stem is 9.5%. This is the current traditional deterministic analysis method used to determine the stiffness and stiffness reduction of femoral stems. The results of the deterministic analysis are shown in Table 2.

Table. 2. Deterministic results for fully dense and porous stem design

Stem	Stiffness
Dense	534.7 N/mm
Porous	484 N/mm
Stiffness reduction	9.5%

3.2 Probabilistic Analysis

The output parameter from ANSYS was the displacement in the femoral stem and the obtained distributions of the displacements for the fully dense and porous stem are shown in Fig. 4. Both PDFs have a similar shape with the only difference being the range of displacement values. The range of the displacement probability distribution was found to be 1.2–1.9 mm and 1.4–2.1 mm for the fully dense and porous stem, respectively.

Monte Carlo simulation with 1000 samples was carried out in MATLAB to find the stem stiffness. Fig. 5, presents the convergence plot of the mean stem stiffness for the fully dense and the porous stem. It can be observed that, for both stems, the mean of the stiffness gradually stabilizes with the increasing number of samples. For the 1000 samples used for the simulations, one can see that the curve starts to stabilize at around 510 N/mm after approximately 800 samples for the dense stem and 462 N/mm for the porous stem and is very stable after 900 samples.

Fig. 6 shows the PDF of both stiffnesses of the dense and porous stems, and also the resulting amount of stem stiffness reduction. It can be observed that the range of the stiffness was 460–580 N/mm and 420–520 N/mm for the fully dense and porous stem, respectively. The extent to which considering uncertainties affected the stiffness, can be seen in the CDF plot of the stiffness reduction depicted in Fig. 7. Considering the result obtained from the deterministic analysis (9.5%) as the baseline, Fig. 7 shows that, the probability of obtaining a stiffness reduction for the stem above 9.5% (reliability) is around 37%.

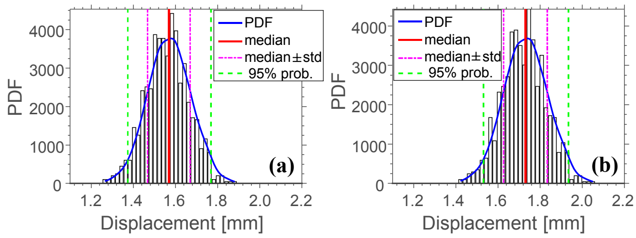

FIGURE 4: (a) PROBABILITY DENSITY FUNCTION OF DISPLACEMENT FOR DENSE STEM (b) PROBABILITY DENSITY FUNCTION OF DISPLACEMENT FOR THE POROUS STEM

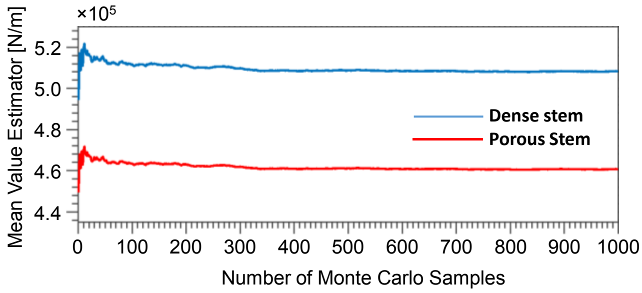

FIGURE 5: MONTE CARLO CONVERGENCE OF THE MEAN VALUE OF THE STIFFNESS FOR THE FULLY DENSE AND POROUS STEMS

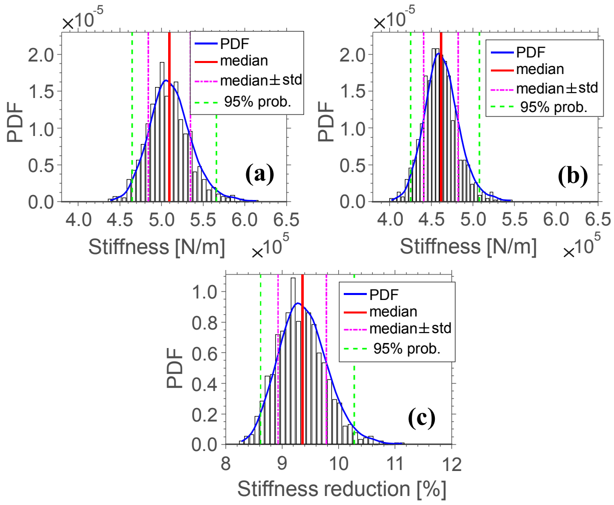

FIGURE 6: PDFS FOR: (a) STIFFNESS OF FULLY DENSE STEM (b) STIFFNESS OF THE POROUS STEM, AND (c) STIFFNESS REDUCTION

4. DISCUSSION

A risk-based analysis was performed to determine the effect of uncertainties on the predicted stiffness reduction of a porous femoral stem compared to the equivalent fully dense. The analysis allows the uncertainty associated with the stem FE model parameters to be considered in the numerical analysis when assessing the elastic response on the loaded stem.

Compared to the proposed probabilistic method, one can notice that the traditional deterministic analysis does not account for uncertainties in the design parameters. Rather, deterministic studies typically utilize a factor of safety approach which can often lead to overdesign or, in some rare cases, infeasible designs. Uncertainties in numerical model inputs result in uncertainties in the numerically computed model output, thus system response is predicted with an associated probability [18].

The probabilistic risk-based analysis was made easy to implement in this study by making several simplifications; most notably were, a simple representative 3-D solid model of the femoral stem and assumed distributions for the design input parameters. The input random variables chosen, have been considered in prior studies and shown to have a role in influencing the risk of failure of implants [5,19], and other studies have shown that the output, femoral stem stiffness plays an important role in bone remodeling and stress shielding [20,21]. This study also showed that the variability of material properties and load (FE input parameters) had a noticeable effect on the stem stiffness. So, it is not enough to use a single value for each of these parameters.

The CDF function can be used to determine the probability that a critical value of the response parameter is reached or exceeded. For example, the value of the CDF for 9.5% stiffness reduction in Fig.7 is the probability that the values of percentage stiffness reduction will be below 9.5%. Reducing stiffness of femoral stem is a major challenge and many different studies have provided unique designs to accomplish this task [5,8,22,23]. Some of these previous design works reported achieving stiffness reduction between 20% and 90%. Prior studies are different from the current one, because they all used deterministic approaches.

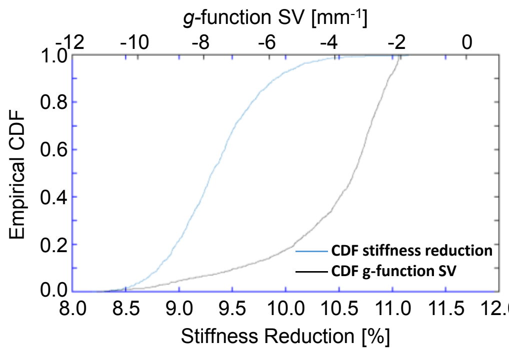

FIGURE 7: EMPIRICAL CDF OF THE PERCENTAGE OF STIFFNESS REDUCTION AND G-FUNCTION OF SV

The deterministic percent stiffness reduction in this study was 9.5%; using this as our limit value, an acceptable design should have a stiffness reduction greater than that. The greater the stiffness reduction the better when dealing with femoral stems due to the stress shielding phenomenon [5,22,24]. The CDF plot in Fig. 7 indicates the probability of obtaining a stiffness less than 9.5% is approximately 63% which is considerably high for most of the design applications. Such high probability of failure implies this is not a good design and thus can be improved, for example, by performing sensitivity analysis to determine what parameters have the greatest effect on the probability of failure or modifying the design input parameters (see proposed framework Fig. 2). While these numbers are hypothetical due to the various assumptions and simplifications adopted here, the results show that probabilistic methods can provide robust design approaches, in which by setting a desirable stiffness reduction for the porous stem, one can determine the risk to achieve it when considering uncertainties in design. If the risk is high, the design parameters can be modified to achieve the acceptable risk.

It is not sufficient to reduce the stiffness of hip implant designs; they should be capable to allow for sufficient bone ingrowth which enables the implant to achieve good fixation. The surface-to-volume-ratio (SV) is the property in porous structures which determine the potential of the structure for bone cell growth. The SV value in porous implants should be equal to or greater than that of bone in order to favor bone cell formation [25]. SV depends on the porous volume fraction (porosity) which implies SV is also a function of pore size and strut thickness [26]. Since pore size and strut thickness are design parameters which are affected by manufacturing errors, the porosity is considered as a random variable to account for these uncertainties. A resulting PDF is gotten for the surface-to-volume-ratio. The risk-based design concept g-function of SV is defined as $g(\phi) = SV(\phi) - R$, where ϕ is porosity and R is the SV value for bone. By defining a target probability of failure (P_f), it is possible to determine if our design will be reliable in terms of permitting sufficient bone growth. For this study, it appears that the porous structure is not reliable because the probability of having an SV value greater than or equal to that of bone is zero as seen in fig.7. Thus, design parameter distributions can be changed to monitor improvements in reliability in relation to bone growth to meet target P_f. The main contribution of such analysis is that it can provide information about the probability of failure, which can never be obtained from similar deterministic approaches.

CONCLUSIONS

This study presented a probabilistic risk-based approach to assess the stiffness and surface-to-volume-ratio of a femoral stem model, which is part of a total hip implant. The objective was to consider uncertainties in the stem input parameters and see how this affects the stiffness in a femoral stem (porous and its fully dense equivalent) and the porous stem SV. Based on the results of the probabilistic analysis the probabilistic framework for assessing femoral stem stiffness can be considered as generally validated. This study does, however, have many limitations, the most significant being the fact that our numerical simulations were not being applied to a realistic design of a stem but rather a simplified model just to validate the probabilistic design framework. Further studies are therefore needed to assess the stress shielding reduction capacity and bone in-growth potential of femoral stem designs by using a more realistic model of the stem, while considering all uncertainties in design parameters like porosity, pore size, strut thickness of the porous lattice and propagating that to its Young's modulus. The results of this study showed that probabilistic design approaches have the capability to deliver more robust design alternatives in a single analysis which covers both the mechanical (stiffness) and the biological (SV) aspect. This represents an improvement over prior deterministic design analysis.

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