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OPTIMAL DESIGN OF A HIP JOINT IMPLANT WITH HALLOW STEM USING FINITE ELEMENT METHOD

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ABSTRACT

Complication of artificial joint replacement is often attributed to the distribution of mechanical stresses over the bone-cement, and cement-implant interfaces. This study represents the analysis and optimization of a hollow-stem hip prosthesis to reduce the micro-motion and maintain uniformity of stress distribution over the interface regions. A three-dimensional finite element model of the proximal femur was constructed in ANSYS, including the cortical bone, the cancellous bone, the bone cement and the femoral component of hip joint implant. Three design parameters were considered for the implant stem, including the length of the stem and the length and radius of the distal cylindrical cavity. The optimization criterion was defined as a linear combination of the standard deviations of the equivalent Von-Misesstresses and the total displacements at the cement-implant interface nodes. The Response Surface Method and sensitivity analysis indicated that the length of the stem has a major impact on the optimization criterion and the length and the radius of the cavity stand as the minor factors. The optimal design was obtained to have a 10.5 cm length stem with a cylindrical cavity of 23.4 mm length and 1.3 mm radius. The assumed optimization criterion reduced substantially from 3.1 in the initial design to 2.52 in the optimal deign.

INTRODUCTION

Hip arthoplasty is considered the most popular and successful operation in the orthopedic surgery with over 800000 operations performed worldwide per year [1]. However, the success of hip arthroplasty is disturbed by the long term complications due to the implant loosening. This is often associated with the mechanical stresses within the bone-implant, bone-cement, and cement-implant interfaces [2], which are determined by several factors, e.g., the load magnitude and orientation, the geometry, surface conditions and mechanical characteristics of the implant, the geometry and mechanical properties of the cement mantle, the position of stem in femur, etc [3].

The effect of stress distribution on the bone remodeling and subsequent implant loosening of total hip replacement patients has been studied in detail by several researchers [3-5]. It has been shown that the dissimilarity of the bone and implant stiffnesses, due to different elastic moduli, should be a major concern for implant designers. This can cause unnatural levels of stress within the adjacent bone, leading to bone resorption. It can also produce high concentrated stresses in the bone cement, contributing to its mechanical failure; the bone cement has the lowest mechanical strength in the bone-cement-implant system and is most potential for crack initiation. So, with the loss of full contact and stress concentration within the bone-cement and cement-implant joints, the implant loosening would not be unexpected.

A successful design of hip prosthesis should provoke minimal changes to the natural stress (or strain) distribution within the femur and simultaneously provide a stable fixation to the host bone. Although there are limitations in choosing the implant and cement materials, due to the biocompatibility and mechanical strength requirements, one can alter the geometry of the implant to reduce its structural stiffness and obtain a more uniform stress distribution within the adjacent bone. This has been targeted in the literature by shape optimization of the stem based on minimization of some measures of stress or strain components [1,3,6-12]. However, for a regular stem the design parameters are limited to the stem's length and curvature and can result in little success. A new design of hip joint prosthesis has become commercial recently which includes a distally hollow stem [5]. While this innovation is thought to significantly reduce the structural stiffness of the implant, its effect on the mechanical strength and stress concentration at the distal end of the cement-implant interface makes major concerns. In the present study a three-dimensional finite element model was employed to analyze the stress distribution in a hip joint prosthesis with a cylindrical hollow stem. A numerical shape optimization approach was also used to investigate the optimal dimensions for such a stem, based on the uniformity of Von-Misesstress es and reduced micro-motions in the implant-cement interface.

NOMENCLATURE

σ_{von} *Von-Mises stress*
F_1 *Objective function based on the standard deviation of the Von-Mises stresses at the interface nodes*
F_2 *Objective function based on the standard deviation of the resultant displacements at the interface nodes*
n *Number of interface nodes of the bone-cement-implant system*
u_{sum} *Resultant displacement*
DoE *Design of Experiment*
RSM *Response Surface Method*

METHOD

Finite Element Modeling

The geometry of the model was obtained from the CT-Scan images of the femur of a 45-year-old, 80 kilogram man. Cross sections of the mid shaft were taken from the 200 mm proximal femur with a distance of 5 mm between successive slices. A standard medullar, non porous total hip prosthesis (Exeter, Wright Medical Technology Co., Italy) with an oval cross section, bent shape and distally tapered stem was considered. Solid models of the femur and prosthesis were constructed using the geometrical data in ANSYS finite element software. The femoral head was removed with a 60 degree cutting angle and the prosthesis model was implanted inside the femoral model. To create a cemented type hip prosthesis, a thin layer (with a thickness of 3 mm distally, 5 mm proximally) [1] at the interface of the femur and stem was removed and replaced with PMMA cement. The solid model and a schematic diagram of the prosthesis are illustrated in Fig. 1.

To include the variation of material properties within the femoral bone, the cortical and cancellous parts were distinguished. The cancellous bone was assumed between the external surface of the Polymethylmethacrylate (PMMA) cement and internal surface of the cortical bone, from proximal end to 1cm lower than trochanter minor. This was then divided further by 8 horizontal sections in order to assign different material properties. Finally, the femoral intermedullary canal was removed in the mid section of the distal femur (below the stem) considering its very low stiffness.

The solid model was meshed to create a finite element model with 3D, 10 node; tetragonal brick element (solid 187). This provided a finite element model including 13747 elements and 29415 nodes with 3 degrees of freedom (all displacement) for each node. Four different material regions were introduced for implant, PMMA, and cancellous and cortical bone. The implant material was assumed to be cobalt-chromium with an elastic modulus of 200000 MPa. The PMMA cement was assumed isotropic with a 2000 MPa elastic modulus, considering the variation of its properties among different manufacturers [1].

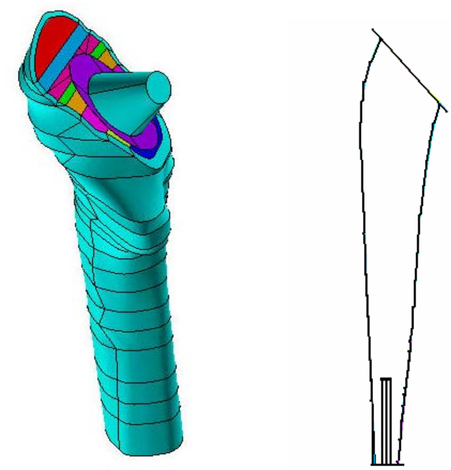

Fig.1- *The solid model of the bone, cement and prosthesis (left) and a schematic diagram of the distally hollow stem (right).*

The bone tissue was considered isotropic with variable mechanical properties in different regions. For cortical bone an elastic modulus of 20000 MPa was considered. For cancellous bone a range of 2000 to 10000 MPa elastic modulus was assumed in different transverse sections, with a 1000 MPa increment in successive sections from distal to proximal. Table 1 summarizes the mechanical properties of the different materials in the model.

Table 1- *Mechanical properties of the materials within the model*

Material	Elastic modulus (MPa)	Poisson's ratio
Implant (Cobalt Chromium)	200000	0.3
PMMA Cement	2000	0.3
Cortical Bone	20000	0.3
Cancellous Bone	2000-10000	0.3

As the boundary conditions, the nodes at the distal end of the cortical bone were fixed for all the three degrees of freedom. Also it was assumed that no gap and slippage could occur between the prosthesis stem, cement and bone. The force on the prosthesis head was taken to represent the load that the hip joint experiences at the terminal stance of normal walking cycle [1]; the 3-D components of this force have been described by Kotzar et al. [2] and are shown in Table 2. This force was distributed over the prosthesis head in the nearby of an action point, to avoid stress concentration. The action point was set along the mechanical axis of the femur, the line passing through the center of the coxo-femoral joint.

Table 2- *The force components at the head of the hip joint*

Component	Magnitude (N)
Antero posterior force	166
Medio-lateral force	233
Axial force	800

Optimization

Three design parameters were considered for the hollow stem of the hip joint prosthesis including the length of stem, and the length and radius of its cylindrical cavity. For each parameter, an upper a lower bound were assumed considering the dimensions of the ordinary prosthesis [13]. Table 3 shows the range of variation for each design parameter.

Table 3- *Range of variation for design parameters*

Stem length	Cavity length	Cavity diameter
8-15 Cm	20-50 mm	2-5 mm

A double component criterion was chosen as the objective function for design optimization procedure of the prosthesis, based on the interface separation and loosening mechanism of the stem. The first component represented the stress uniformity at the bone-implant and implant-prosthesis interfaces; this was to avoid unnatural levels of stress within the contact regions which could cause bone resorption and/or mechanical failure of bone cement, both contributing to the implant failure due to the stem loosening. The second component represented the reduced relative motion of the bone, cement and prosthesis at their contact region; this was to avoid slippage in the interfaces which is considered a major cause of aseptic loosening due to the fixation loss and failure of the cemented femoral components in THR [3].

The stress uniformity and reduced relative motion concepts were formulated mathematically using the standard deviations of the Von-Mises stresses and resultant displacements, respectively, at the interface nodes of the bone-cement-implant system. The combined objective function to be minimized was defined as the linear summation of these functions following normalization:

$$F_1 = \sqrt{\frac{\sum_1^n \sigma_{von}{}^2}{n-1}} \quad , \quad F_2 = \sqrt{\frac{\sum_1^n u_{sum}{}^2}{n-1}}$$

$$\text{Objective Function} = F_{1N} + F_{2N}$$

where σ_{von} and u_{sum} are respectively the equivalent Von-Mises stress and the resultant displacement at the interface nodes, n is the number of nodes, and F1N and F2N are the normalized F1 and F2, respectively.

A combination of Response Surface Method (RSM) and Design of Experiment (DoE) method with finite element analysis was employed to conduct the optimization procedure. RSM is a model-dependent approach for system identification, sensitivity analysis and experiment pre/post-processing which explains the relationship between inputs and an output, in the form of a response surface. We used this method to determine the sensitivity of the objective function to the design parameters and found the proper variation step for each parameter when conducting the experiments (analyzing the models). DoE, on the other hand, is a process for careful planning of a study which allows for maximum interpretation of resulting data with minimal experimentations; the process includes discussion on parameters that may affect the system, proper design of experiments and statistical analysis of the results. We used this method to determine the required combinations of the design parameters in order to form and analyze the candidate models in search for the optimal design.

Each finite element model was then constructed and analyzed to obtain the Von-Misesstress and total displacement distributions and calculate the objective function. Finally the optimal design was determined as the design with the minimum objective function magnitude among the optimization candidates. The optimization procedure is illustrated in the schematic diagram of Fig. 2.

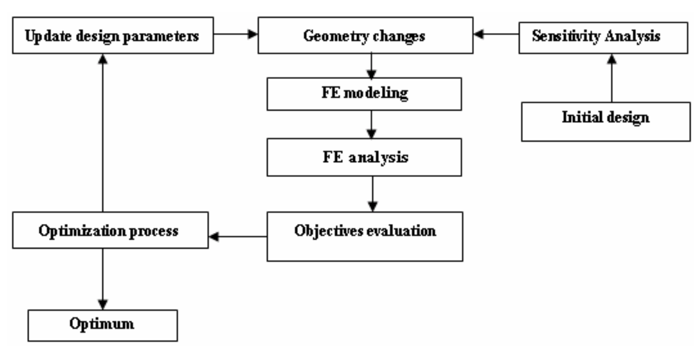

Fig.2- *Schematic diagram of the optimization procedure based on the combination of the RSM+DoE method with finite element analysis.*

RESULTS

The initial design of the implant was considered the design with the lower bunds of the design parameters including 8 cm stem length, 20 mm cavity length and 1 mm cavity radius. The results of the finite element analysis for the initial design are shown in Fig. 3 and Fig. 4 in terms of the Von-Misesstress counters on the surfaces of the stem and the cortical bone. The stress distribution within both objects included high stresses in the distal parts, with maximums of 25.5 MPa and 15.4 MPa, and low stresses in the proximal parts, with minimums of 357 KPa and 3 KPa, in the implant and cortical bone, respectively. The general pattern of stress distribution was similar to that of the Timoshinkov beam which is not unexpected considering the model's general configuration including distal fixation and proximal force application; the resulting bending moments become larger when going distally causing higher Von-Mises stresses. The general distribution patterns of stress and displacement within the cancellous bone and cement were quite similar to those of the cortical bone and implant, however, with different magnitudes; it was concluded that a design with uniform Von-Misesstress and reduced displacement distribution on the stem's surface (the cement-implant interface) provides also a uniform distribution in the bone-cement interface.

In the next step, considering the 3 design parameters, 23 models were constructed and analyzed, according to the RSM method. By performing sensitivity analysis, it was found that the stem length is the major factor affecting the objective function (the Von-Mises stress and total displacement distribution in the implant-cement interface) and the radius and length of distal cavity play the minor roles. The sensitivity analysis also provided the proper variation steps for each of the design parameters. Then resulting 15 finite element models, with different combinations of the design parameters, were constructed and analyzed, based on the DoE approach, in order to find the optimal design.

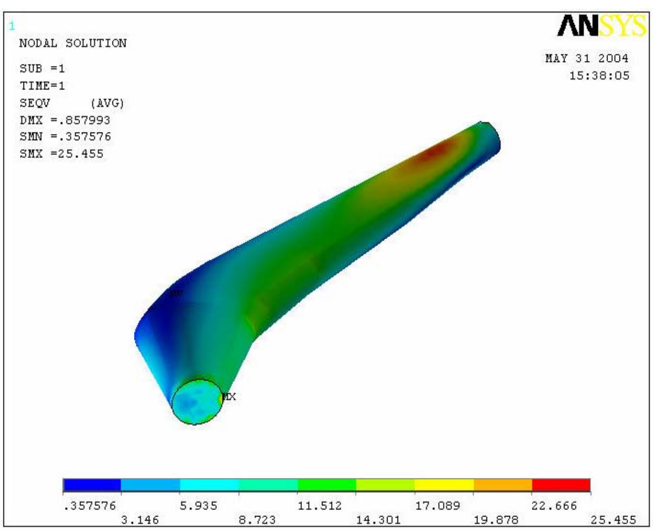

Fig. 3- *Von-Mises stress distribution over the Stem's surface*

The objective function results for the 15 experiments (finite element analyses) are shown in Fig. 5-a. The experiment number 6, with a 10.5 cm stem length, a 23.4 mm cavity length and a 1.3 mm cavity radius, provided the minimum objective function with a magnitude of 2.52, in comparison with 3.1 obtained for the initial design. The maximum/minimum ratios of Von-Mises stress at the cement-implant (Fig. 5-b) and bone-cement (Fig. 5-c) interface nodes were also calculated; again the experiment number 6 had the lowest ratio and the best stress uniformity among the 15 experiments.

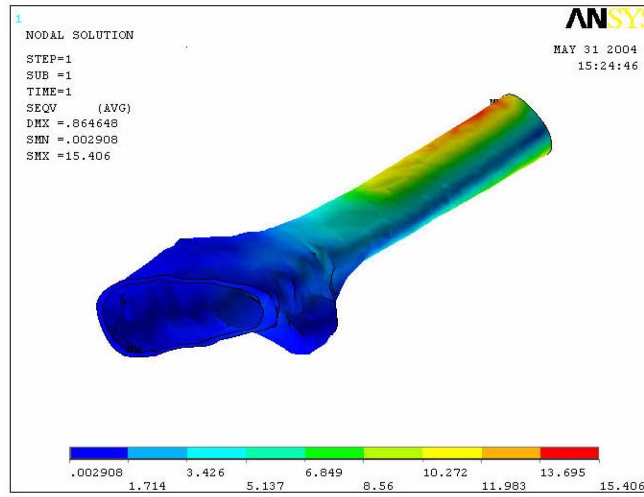

Fig. 4- *Von-Mises stress distribution over the Bone's surface*

DISCUSSION

The finite element method allows for parametric and quantitative analysis of very complex mechanobiological phenomena and has proved to be an invaluable tool for implant designers. It has been widely used in order to evaluate the influence of the implant design parameters, e.g., the size, the shape, the implanting position, the elastic modulus, the coating and ingrowth conditions, etc., as well as the bone variables, e.g., the geometry, the density, the anisotropy, etc. Finite element method has been also used to investigate the failure mechanisms of the bone-cement-implant system, e.g. the debonding mechanism, the crack initiation mechanism, etc.

In the present study, the finite element method was employed to determine the optimal design of a hollow hip joint prosthesis. One of the most critical tasks in design optimization of orthopedic implants is the choice of the objective function. For the stem of hip joint prosthesis, loss of fixation to the host bone is a major concern since it ends up loosening and failure of the THR. Several objective functions can be proposed considering different mechanisms of interface separation and fixation loss; a successful choice needs to include all major mechanisms. The objective function, considered in the present study, includes both the stress uniformity and reduced motion in the bone-cement and cement-implant interface nodes. The stress uniformity within the interfaces was evaluated using the standard deviation of the equivalent Von-Misesstress es. The Von-Mises stress has been proved to be an appropriate representation for the state of stress in a structure with complicated geometrical and loading conditions in which a combination of torsional, shear and bending stresses are developed. Furthermore the Von-Mises stress is a common criterion to predict the yield and mechanical failure of a material based on the distortion energy theory. So, two main causes of implant loosening can be well evaluated using Von-Misesstress distribution: (1) the cancellous bone resorption due to the low levels of stress, and (2) the mechanical failure of the cement bulk due to the concentrated high stresses.

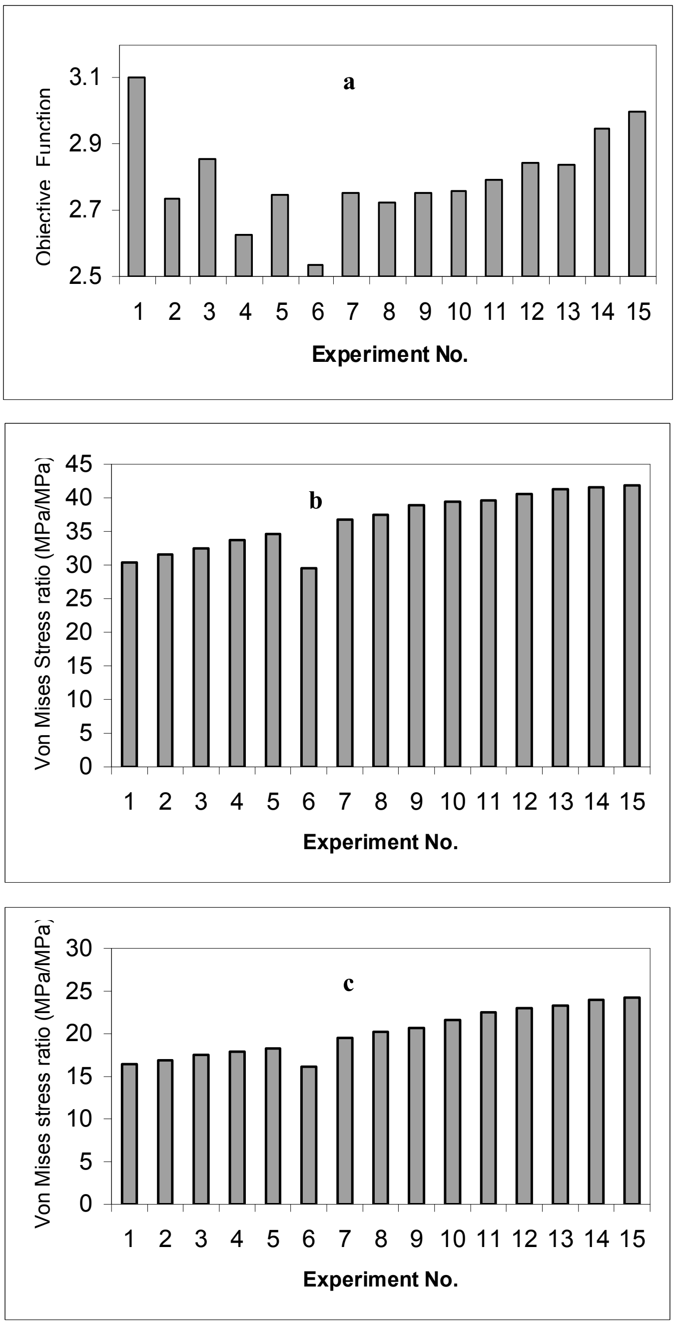

Fig. 5- *Objective function (a) and Max/Min Von-Mises stress ratio of bone-cement (b), and cement-implant (c) interfaces in different experiments.*

The second component of the objective function, considered in the present study, was the relative motion of the bone and prosthesis at their contact region as a major cause of aseptic loosening of THA. A reduced relative motion was described mathematically by the standard deviation of resultant displacements at the cement-implant interface nodes [3]. Of course, tangential (shear) relative displacements in the bone-cement and cement-implant interfaces play the most critical role in the implant loosening and might form a more effective objective function. However, considering the tapering stem and the compressive loading conditions at the prosthesis head, the tangential displacement is the major component of the resultant displacement; calculation of different displacement components showed that 90 percent of the resultant nodal displacement is contributed by the tangential component leaving a trivial effect for normal and radial components. So, the use of resultant nodal displacements is an appropriate alternative for tangential nodal displacements; it not only manifests the tangential component, but also allows for other displacement components to be taken into account.

The optimization procedure was performed in our study by integrating the Response surface Method (RSM) and Design of Experiment (DoE) with finite element method. RSM was used as a theory which indicated the minimum number of experiments necessary to develop an empirical model for our optimization function (as a physical phenomenon) and a methodology for setting up the FE models (experiments). Typically, the RSM is modeled using a second-order quadratic; we used steepest descent method by moving alongside a path which had maximum negative slope. DoE technique, on the other hand, was used to obtain the regression data intelligently for different combinations of the design parameters. The overall outcome of this study indicates the effectiveness of these optimization techniques, as a complementary to the finite element method, for design of orthopedic prostheses.

The results of the present study suggests that a distally hollow stem has advantages over the regular designs; it can remarkably reduce the structural stiffness of the implant to improve the bone's remodeling conditions and avoid concentrated high stresses in the cement bulk, it can also reduce the relative displacements in the bone-cement and cement-implant interfaces. In order to demonstrate the effectiveness of our method in providing the optimal design of a distally hollow stem, the resulting optimal dimensions have been compared with those of the initial design and a commercially available system [13] in Table 4. Our results for optimal dimensions are quite close to the dimensions of the existing stem which has been designed based on experimental trials.

Nevertheless it has to be admitted that the results of this kind of studies can mostly be considered as design guidelines, rather than definite facts. Fist of all, the accuracy of a model is based on the mathematical form chosen to represent the physical phenomenon under study and the numerical strategies employed to solve it. All these decisions involve uncertainties and assumptions, which may dramatically affect the accuracy of the model in predicting the behavior of the phenomenon. This is obviously true for our model too; we considered a simplified geometry, a single loading condition and a linear variation of cancellous bone properties from distal to proximal. We also excluded several factors e.g., the muscular loads, the anisotropic mechanical properties of bone, the different failure and fracture modes of bone and cement, etc. A major simplification of our model was the assumption of perfectly bonded interfaces at the bone-implant and cement- implant contact regions and the simple load transfer mechanisms between prosthesis and bone; this can cause considerable differences in comparison with the real behavior of the system. The bone-cement and cement-implant interfaces are extremely complex regions with surface irregularities and voids filled with fluids due to the lack of contact between the objects. Also the bonding conditions vary in real human joints due to the multiple functions and activities in real life; the joint loads are usually dynamic and even can appear as sharp impacts.

Table 4- *Comparison between design parameters of initial, optimized and existing model*

Model type	Stem length (m)	Cavity length (mm)	Cavity radius mm)
Initial design	8	20	1
Optimized design	10.5	23.4	1.3
Existing model	10	25	1.2

The considerable differences of biological systems among individual subjects magnify the degree of uncertainties of our results. For instance the angle between the mechanical axis and the femoral stem varies from person to person, depending on height, posture and overall skeletal structure; these differences could imply maximum stress concentrations at different locations in the femur. Moreover, the time variation of a biological system's behavior with external conditions is a matter of concern. For instance, it has been well demonstrated in the biomechanical literature that the distribution of mechanical properties in the bone changes in time due to remodeling.

Finally, the optimization criterion we applied was quite simple and did not include some major mechanical and biomechanical processes that are responsible for prosthesis failure. Stress shielding and micro-motion are certainly not the only mechanisms that can lead to aseptic loosening. Other factors such as wear debris particles and quality of the bone-implant interface also contribute to the prosthesis loosening; however, they have not been addressed in this study.

So, in the interpretation of the results of the present study its several limitations must be kept in mind. While the benefits of an optimized hollow stem to uniform the stress distribution, avoid stress concentrations and reduce the relative motion seems promising, further work should be undertaken on a more accurate anatomical model with realistic loading and interface conditions to achieve a more accurate detailed design. Also evaluation of modified hollow stem designs, e.g. a taper-locked cemented stem, might be an interesting subject for future studies.

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