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Design of a High-Performance Bone Substitute using Finite Element Analysis and Topology Optimization

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Abstract: The development of bone substitutes that meet biomechanical requirements remains a significant challenge in biomedical engineering. This study integrates finite element analysis (FEA) and topology optimization to design high-performance bone substitutes optimized for load-bearing applications. Bone geometries were obtained through advanced scanning technologies, and FEA simulations were carried out using Ansys software to refine the designs. Iterative optimization enhanced the load-bearing capacity and biocompatibility while ensuring a lightweight structure. Material selection and microstructural adjustments were made to achieve optimal mechanical and biological performance. The combination of FEA and topology optimization in this research offers advancements in the design of bone substitutes, showing promising results under physiological loads and indicating strong potential for clinical applications.

Keywords: Bone substitutes; Finite element analysis; Topology optimization; Biomechanics

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1. Introduction

The creation of effective bone substitutes is a primary challenge in biomechanical engineering, especially for human tubular bones that play crucial roles in weight support and movement. Successfully replicating and enhancing these bones' structural and functional properties can significantly advance orthopedic treatments.

A thorough understanding of the anatomy and interactions of specific bones is essential for prosthesis design. Finite element analysis (FEA) plays a vital role in assessing the mechanical properties of bone structures under physiological loads. When combined with response surface methodology (RSM), FEA facilitates the optimization of design iterations, making the development of ideal bone substitutes more feasible.

Initial three-dimensional (3D) models are generated using ScanIP X-ray scanning, which ensures accurate biomechanical simulations. Ansys software is employed for its strong FEA capabilities, enabling the modeling of complex geometries and precise meshing, which are crucial for designing optimal bone substitutes.

Material selection and biocompatibility are critical to the success of bone replacements. This research identifies materials that meet the rigorous demands of bone substitute design, integrating these selections with anatomical insights and advanced simulation tools.

This study aims to explore the mechanical behavior of a proposed tubular bone substitute and suggest design optimizations (**Figure 1**). It seeks to bridge the gap between theoretical simulations and practical orthopedic applications, ultimately aiming to improve patient outcomes.

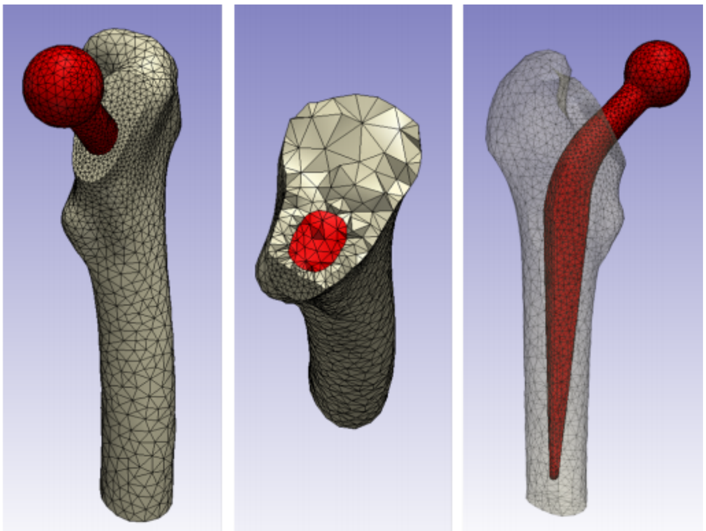


Figure 1. Multipart mesh: mesh with vertex line (left), clipping the mesh (middle), and showing the interior with opacity (right) [1]

2. Literature review

Topology optimization is a computational technique aimed at optimizing material distribution within a defined design space to meet specific performance goals, such as reducing weight while maintaining structural strength. This method finds extensive application in fields like mechanical and biomedical engineering [2].

The procedure generally involves establishing the design domain, setting objectives and constraints, and iteratively modifying the material layout to boost performance. A key challenge in topology optimization is the issue of mesh dependence, where finer meshes result in overly complex designs with unnecessary void formations [3]. To mitigate this, techniques like density filtering and relaxation methods are used to smooth the density distribution and ensure stable convergence to the final design. In modern practices, topology optimization is frequently coupled with FEA to assess the mechanical performance of designs under realistic load conditions, leading to structures that are not only optimized but also feasible for manufacturing.

Topological derivatives play a significant role in the optimization process by guiding the introduction of new voids, thereby increasing the flexibility in shape modifications. However, these methods are computationally demanding and must be implemented with care to avoid issues such as the checkerboard problem, which can occur due to improper element configurations.

This study will utilize the density-based approach for topology optimization, where material distribution is represented by a density variable that can continuously vary within the range [0, 1]. The solid isotropic material with penalization (SIMP) scheme will be applied to address the optimization problem, with a detailed discussion of the method provided later in the text.

3. Basic knowledge and theoretical framework

This paper delves into the use of topology optimization in the design of bone substitutes within the field of biomechanical engineering. Unlike traditional methods that rely heavily on empirical knowledge and lack standardized protocols, this study emphasizes optimizing material distribution through advanced topology optimization techniques to create bone substitutes capable of withstanding physiological loads while enhancing biocompatibility.

Utilizing finite element methods, this research aims to develop scientifically grounded and efficient structures. Specifically, the study employs continuum structural optimization, which focuses on optimizing material distribution within a design space rather than assembling discrete elements. This approach addresses challenges such as managing continuous design variables and achieving optimal material layouts under force constraints, ultimately advancing bone substitute design in biomedical engineering.

3.1. Methodological approach

Selecting an appropriate methodology in topology optimization is crucial for designing structures that fulfill specific performance criteria. The variable density method is a prominent technique recognized for its balance between computational precision and design flexibility.

This method is highly effective in optimizing material distribution by accounting for the interplay between material properties and external loads. The following sections will explore its theoretical foundation and practical implementation.

Emphasizing the variable density method aligns with the objective of achieving mechanically optimal and resource-efficient designs, thereby contributing to advancements in engineering and material science.

3.1.1. Optimizations in continuum structures

Topology optimization in continuum structures can be approached in two primary ways. One method involves combinatorial optimization of 0–1 discrete variables, where 0 and 1 represent the absence and presence of material, respectively. This approach is particularly effective for smaller-scale problems, offering robust global optimization capabilities while overcoming the issue of “singular optimal solutions” [4].

3.1.2. Variable density method

The variable density method is a cornerstone in topology optimization, particularly for structural design. It treats the design domain as a continuum with variable material density, thus avoiding the complexities associated with shape optimization and remeshing.

By defining the structural domain through a continuous density distribution, this method allows smooth transitions between solid and void states without predefined boundaries. The approach utilizes material distribution and homogenization techniques to create optimized topologies that meet specific performance criteria, such as minimizing compliance or maximizing stiffness (**Figure 2**).

The homogenization method, as described by Bendsoe and Kikuchi [2], forms the theoretical basis for this approach, facilitating the design of advanced bone substitutes capable of withstanding complex physiological loads.

In this study, the variable density method is employed to design bone substitutes with optimal mechanical properties. By modulating material density across the design domain, the method addresses the

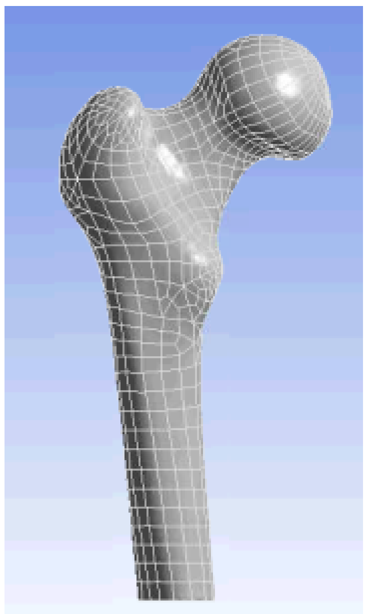


Figure 2. Adapted finite element mesh

mechanical needs of bone structures, including support, strength, and osseointegration.

3.1.3. Theoretical analysis of variable density method

In topology optimization, the variable density method, particularly the interpolation approach proposed by Stolpe and Svanberg [5], is critical for optimizing material distribution to enhance structural stiffness. This method introduces a material interpolation function parameterized by q, designed to promote distinct "black and white" designs, thereby minimizing intermediate material densities.

Compliance, a measure of structural flexibility, is minimized by maximizing stiffness under specified loads. Mathematically, compliance $c(x)$ is defined as $c(x) = f^T u$, where u represents the nodal displacement due to an external load f. Stolpe and Svanberg's interpolation for the elasticity modulus $E(x)$ is expressed as:

$$E(x) = E_0 + \frac{x}{1 + q(1-x)} \Delta E$$

Here, E_0 denotes the elasticity modulus of the void material, ΔE is the difference in modulus between solid and void materials, and q governs the transition from void to solid material. Higher q values lead to sharper transitions, encouraging "zero-one" solutions, which are ideal in structural optimization.

3.1.4. SIMP interpolation and numerical instabilities

The SIMP method is widely adopted in topology optimization for its simplicity and effectiveness. It adjusts material stiffness through a power-law interpolation between void and solid phases, expressed as:

$$E(x) = x^p E_s$$

where E_s is the Young's modulus of the solid material, x represents material density ranging from 0 (void) to 1 (solid), and p is the penalization factor, typically greater than 1. This penalization helps drive the solution towards a 0–1 design, which is crucial for manufacturability (**Figure 3**).

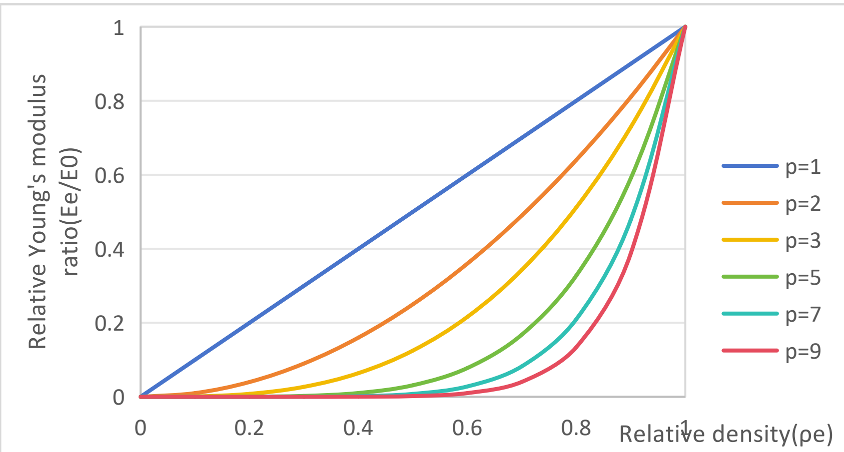


Figure 3. Comparison of the SIMP model and an alternative model when $E_1 = 1$ and $E_0 = 0.1$. Dashed lines represent $E_p(x_j)$ for $p = 2, 3, 10$; solid lines represent $E_q(x_j)$ for $q = 0, 1.5, 4, 9$.

However, SIMP can be prone to numerical instabilities, such as mesh dependency and checkerboard patterns, where alternating high- and low-density elements lead to non-physical solutions. These issues stem from numerical discretization and can be mitigated through regularization techniques like filtering design variables:

$$\tilde{x}_i = \frac{\sum_{j \in N_i} w_{ij} x_j}{\sum_{j \in N_i} w_{ij}}$$

where x_i is the filtered density at element i, x_j are the elemental densities, w_{ij} are filter weights, and N_i represents the neighborhood of element i.

Addressing these instabilities is vital for ensuring reliable and practical topology optimization outcomes in engineering applications.

3.2. Multi-component structures

Recent progress in topology optimization, especially concerning periodic multi-component structures, presents significant opportunities for the efficient design of complex engineering systems. This study applies the variable density method to optimize such structures, leveraging foundational principles to enhance material layout within set constraints.

Topology optimization plays a pivotal role in engineering design, particularly in enhancing the performance of structural components. The SIMP method is a widely adopted approach in topology optimization, facilitating smooth transitions between material and void states by using a penalization scheme that promotes binary outcomes.

$$E(\rho) = \rho^p E_s$$

In this equation, $E(\boldsymbol{\rho})$ represents the interpolated Young's modulus, $\boldsymbol{\rho}$ denotes the material density, and p is the penalization factor, typically set above 1. This strategy ensures that intermediate densities are minimized, resulting in manufacturable designs (**Figure 4**).

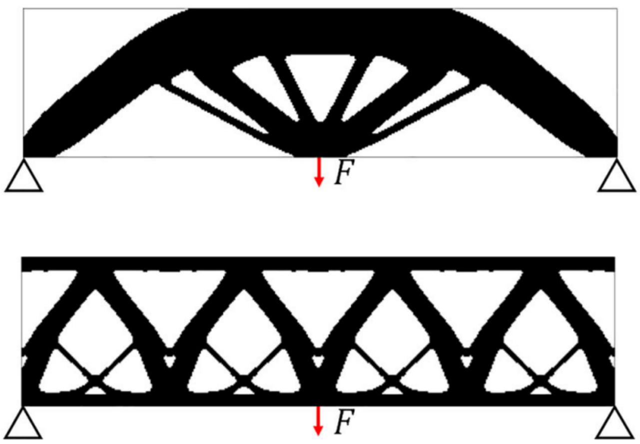


Figure 4. Topology optimization of a simply supported bridge structure for a single component [6]

Sensitivity analysis is crucial in topology optimization, as it assesses how variations in design variables influence the objective function, generally compliance. Compliance, which measures the work done by external forces on displacements, is mathematically defined as:

$$C = \frac{1}{2} F^T U$$

where F is the force vector and U is the displacement vector. Sensitivity analysis drives optimization algorithms, facilitating the strategic addition or removal of material to boost structural stiffness.

Nonetheless, topology optimization encounters numerical issues such as checkerboard patterns and mesh dependency, typically addressed through filtering techniques. These filters smooth sensitivity fields and modify design variables, leading to robust and manufacturable designs. A common filtering approach involves a weighted average of densities:

$$\tilde{\rho}(x) = \frac{\int_{\Omega}\rho(y)H(x-y)dy}{\int_{\Omega}H(x-y)dy}$$

This method ensures that designs remain mesh-independent and are more likely to be manufacturable in practice.

When optimizing periodic multi-component structures, the emphasis is on arranging repeating units to optimize the entire system, a technique particularly beneficial in industrial contexts where mass production and assembly efficiency are vital. The optimization process averages sensitivities across the periodic structure to ensure consistent performance:

$$\alpha_{avg} = \frac{\sum w_i \alpha_i}{\sum w_i}$$

This guarantees that the final design is optimized both for individual components and for the system as a whole.

In scenarios where multiple performance objectives, such as stiffness and natural frequency, are optimized simultaneously, a multi-criteria sensitivity measure \(\alpha_{\text{mc}} \) is employed to balance conflicting objectives:

$$\alpha_{mc} = w \frac{\alpha_c}{|\alpha_c|_{max} \frac{\alpha_f}{|\alpha_f|_{max}}}$$

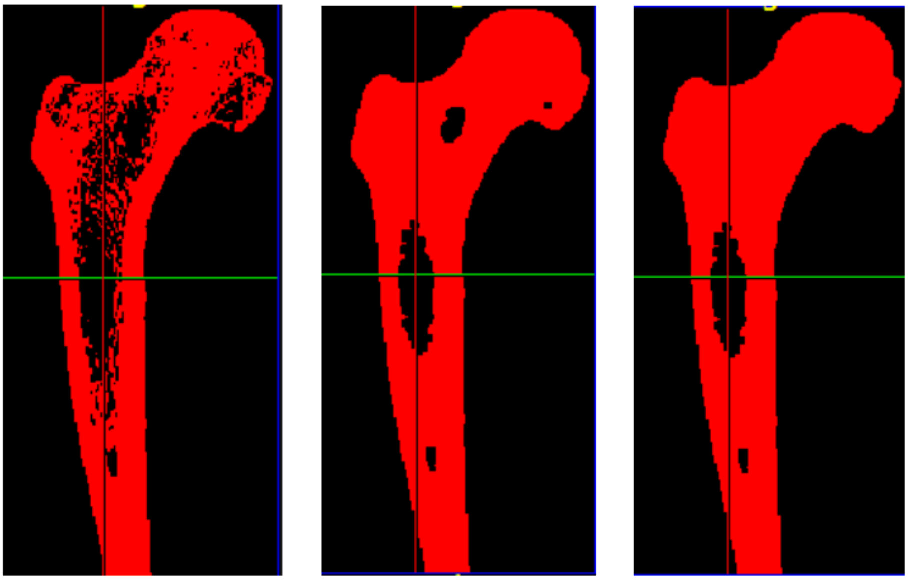
In this context, α_c and α_f represent sensitivities related to compliance and natural frequency, respectively, with w serving as a weighting factor. This approach enables the design to meet multiple criteria, which is essential for applications that require both structural integrity and optimal dynamic performance.

4. Experimental design

The experimental design of this study involves a multi-stage process utilizing advanced software tools to create and optimize a 3D model of a mechanical component. Initially, computed tomography (CT) scan data is processed using ScanIP to reconstruct precise 3D models, which are subsequently optimized and analyzed in Ansys. Finally, SolidWorks is employed to refine the model for manufacturability, ensuring that the design adheres to all required specifications.

4.1. ScanIP

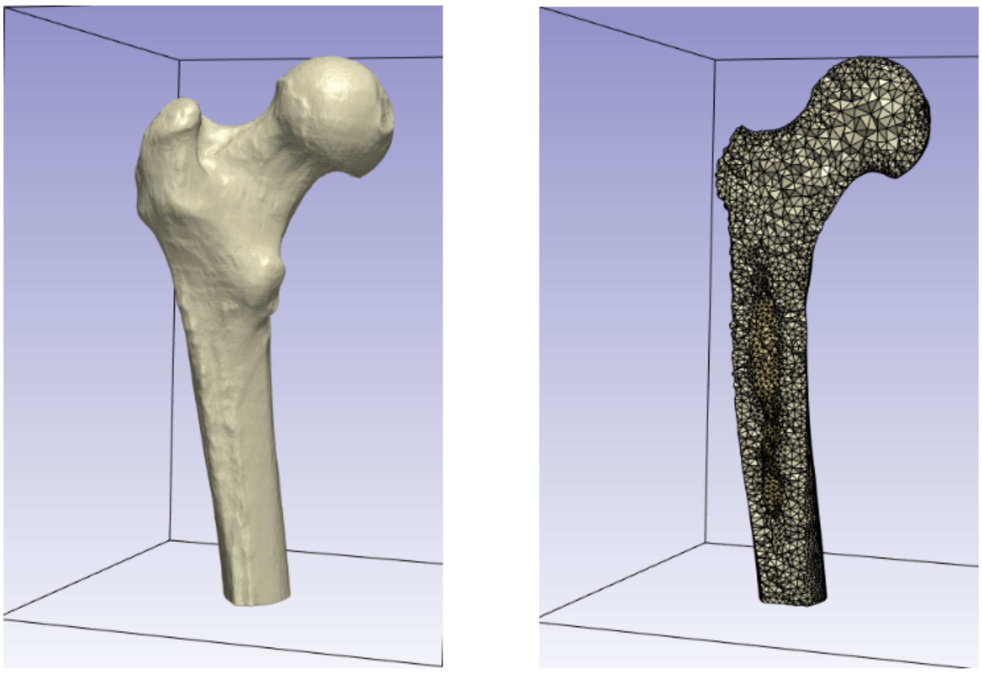
ScanIP is employed to generate detailed models of human leg bones from CT scan data. The software's segmentation and 3D reconstruction capabilities are crucial for isolating bone structures and converting two-dimensional (2D) slices into comprehensive 3D models. These models are integral to medical research, surgical planning, and biomechanical simulations. Integrating ScanIP with Ansys facilitates thorough mechanical analysis, improving the understanding of bone strength and the design of orthopedic implants (**Figure 5**).



((a)) Initial mask ((b)) X, Y, and Z radii set to 2 ((c)) X, Y, and Z radii set to 10

Figure 5. Comparison of morphological close operation with different radii settings on the XZ plane

CT scans provide high-resolution bone images, typically stored in DICOM format. These images are imported into ScanIP, where preprocessing steps such as noise reduction and contrast enhancement are applied to improve image clarity. The data is then cropped and resampled to focus on the region of interest, enhancing the quality for subsequent 3D reconstruction (**Figure 6**).



((a)) 3D model in ScanIP ((b)) Enable part

Figure 6. 3D view

Using ScanIP, the 2D CT images are reconstructed into a 3D model, capturing both internal and external bone structures. This model is essential for FEA in Ansys, providing the anatomical accuracy required for detailed biomechanical evaluations.

4.2. Ansys Workbench

The 3D model generated in ScanIP is imported into Ansys Workbench for stress-strain analysis and topology optimization. The Static Structural module assesses the femur's response to physiological loads, while the Structural Optimization module refines material distribution to enhance strength and reduce weight.

4.2.1. Material setting

The model in this study is developed within the framework of generalized plasticity theory. The total strain is decomposed additively into a purely linear elastic component, ε^{el}, and a transformation component, ε^{tr}[7]:

$$\varepsilon = \varepsilon^{tr} + \varepsilon^{el}$$

The relationship between stress and linear elastic strain is defined as:

$$\delta = E(\zeta_M)(\varepsilon^{el} - \varepsilon^{tr})$$

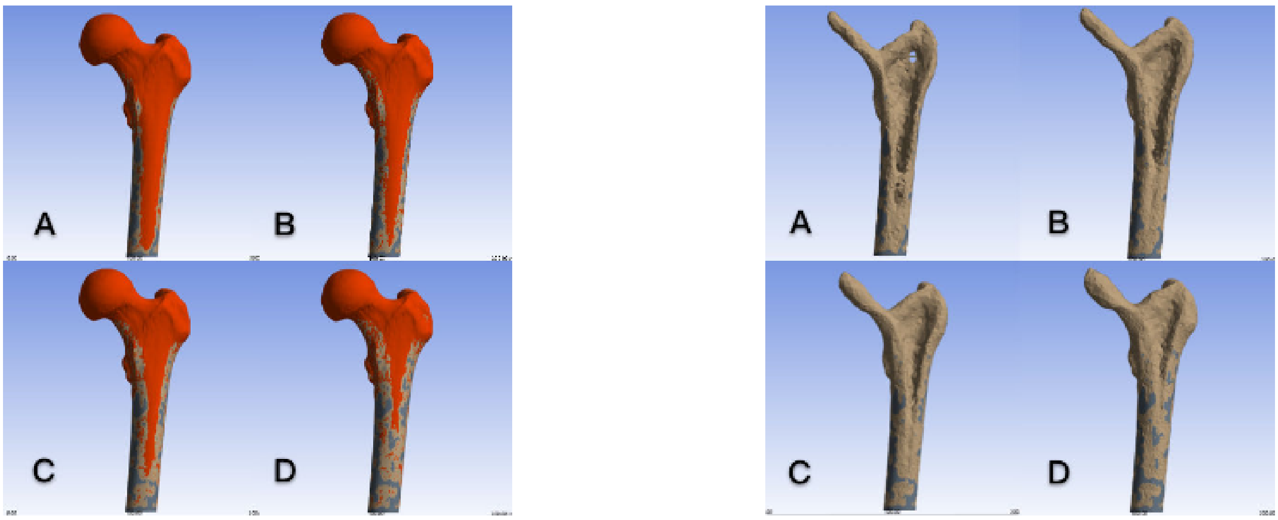
where $E(xi_M)$ represents the modulus, dependent on the Martensite volume fraction:

$$\zeta_M = \begin{cases} 0, fullyAustenite \\ 1, fullyMartensite \end{cases}$$

Previously, standard material models were used to simulate Nitinol's behavior, but these models were inadequate for accurately capturing its unique unloading characteristics. While effective under simple loading conditions, these models fail to replicate Nitinol's behavior during unloading. The hyperelastic model mimics the loading behavior during unloading, whereas the isotropic hardening law inaccurately assumes unloading at the original modulus until double the yield point.

4.2.2. Topology optimization results

During optimization, various material removal percentages were analyzed, significantly reducing material usage while maintaining structural integrity. The final design achieves a balance between weight reduction and mechanical performance, crucial for practical biomechanical applications (**Figure 7**).



((a)) Material Retained ((b)) Material Removed

Figure 7. Topology optimization results with varying levels of material removal

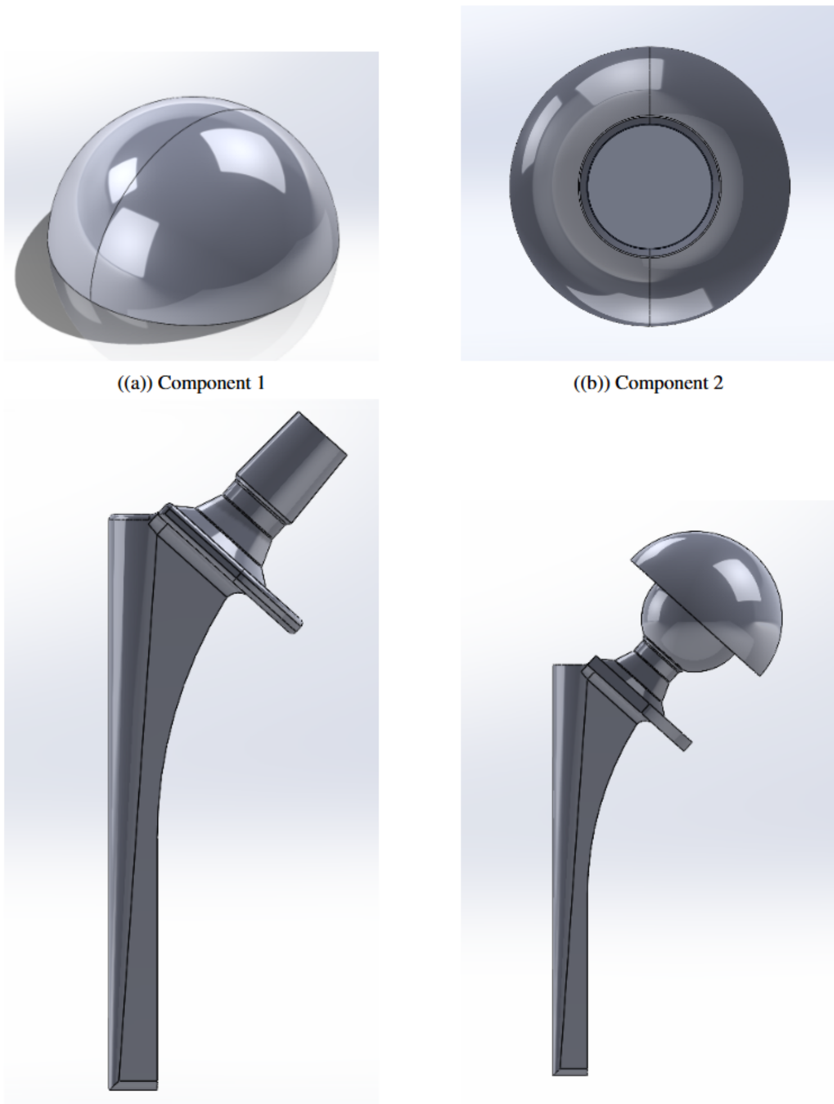
4.2.3. Deformation and volume change

To assess the structural integrity of the optimized model, the maximum deformation criterion was applied. The model retaining 30% of the material was chosen because its weight is comparable to that of a natural human bone. After optimization, the maximum deformation increased from 0.049 mm to 0.070 mm, remaining within acceptable limits, confirming the success of the simulation.

The mesh structure was also examined to evaluate volume changes, with the volume significantly decreasing from 199,805 mm^3 to 88,795 mm^3, demonstrating the optimization's effectiveness in reducing material usage while preserving structural integrity.

4.3. SolidWorks

The optimized model is further refined in SolidWorks to ensure compliance with manufacturing constraints. Detailed components are designed and assembled into the final product, illustrating the feasibility of the optimized design (**Figure 8**).



((a)) Component 1 ((b)) Component 2 ((c)) Component 3 ((d)) Final Product

Figure 8. SolidWorks modeling of the femur showing individual components and the final assembled product

5. Conclusion and outlook

This study used topology optimization and FEA to design an optimized femur replacement, leveraging the variable density method and the SIMP approach to balance material efficiency and structural integrity. The optimized model improved stress distribution, reduced material use, and maintained structural reliability despite a slight increase in deformation.

Future research should focus on evaluating biocompatibility, clinical performance, and transitioning the design to a manufacturable product, including patient-specific customization. Exploring advanced optimization algorithms and alternative materials could further enhance the performance of bone substitutes.

Disclosure statement

The author declares no conflict of interest.

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