Design and Development of Custom Knee Replacement Implant for Osteoarthritis Patients to Support Bone Fracture.

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ABSTRACT

Due to the rising number of osteoarthritis patients at Hospital Tengku Fauziah, there is a need to improve knee transplant designs. Current issues include excessive design choices, allergic reactions to materials, and limited implant lifespan (up to 20 years). This study aimed to develop a new knee transplant design compatible with various patient conditions and using hypoallergenic materials. The design process involved interviews, benchmarking, and tools like the house of quality and morphological charts. A final concept was developed, modeled in 3D, and analyzed using finite element analysis (FEA), which confirmed strong structural integrity with a high Factor of Safety (FOS) of 155.

Keywords: Osteoarthitis, knee transplant, design improvement, structural integrity

1. INTRODUCTION)

Osteoarthritis (OA) is a progressive condition that weakens the knee joint, leading to pain, stiffness, and reduced mobility. Total knee replacement (TKR) remains the standard treatment for severe OA; however, conventional off-the-shelf implants often fail to address the unique anatomical variations and deformities found in OA patients. This mismatch may result in suboptimal outcomes, including malalignment, instability, and restricted mobility.

A major challenge in current practice is the reliance on generic implant designs that may not adequately fit individual patient anatomy. Surgeons often face difficulties in selecting the most suitable implant during surgery, which may compromise alignment, prolong the procedure, and increase the risk of complications. Custom knee replacement implants, designed using imaging technologies such as CT and MRI, can be tailored to match a patient's anatomy more precisely, thereby improving surgical efficiency, functional outcomes, and overall patient satisfaction.

In addition, the choice of implant material remains a critical issue. While cobalt chromium is widely used for its strength and durability, it carries risks such as metal toxicity, wear debris, allergic reactions, and stress shielding, which may necessitate revision surgery. Alternative materials, including titanium and ceramics, offer enhanced biocompatibility and long-term performance. Addressing both design and material challenges through collaborative efforts between surgeons, engineers, and materials scientists is essential to advancing custom implants and ensuring better outcomes for OA patients

1.1 Custom Knee Replacement

Osteoarthritis (OA) is widely recognized not as simple "wear and tear," but as a condition involving abnormal remodeling of joint tissues, influenced by inflammatory mediators and risk factors such as age, sex, obesity, genetic predisposition, and prior joint injury (Hirschmann & Becker, 2015). For severe OA, total knee replacement (TKR) is a standard intervention aimed at restoring mobility and function (Cherian et al., 2016). However, the success of TKR depends significantly on implant design and performance. Conventional off-the-shelf implants, developed for general populations, often fail to accommodate patient-specific anatomical variations, leading to malalignment, instability, and limited range of motion (Fitzpatrick & Rullkoetter, 2014.

In response, research has increasingly focused on custom knee implants tailored to individual anatomy. Modern imaging techniques such as computed tomography (CT) and magnetic resonance imaging (MRI) enable three-dimensional modeling of knee joints, which can guide implant design for improved fit and alignment (Bellemans et al., 2002). Additive manufacturing technologies, particularly 3D printing, have further enhanced the ability to produce complex, patient-specific implants efficiently and cost-effectively (Teo et al., 2020). Clinical studies have reported improved outcomes for patients with custom implants, including reduced pain, better functional scores, and higher satisfaction rates compared to standard implants (Hirschmann & Becker, 2015). Nonetheless, further long-term studies are needed to evaluate durability, cost-effectiveness, and broader clinical applicability.

Material selection also plays a critical role in implant success. While cobalt chromium alloys are commonly used due to strength and durability, they present risks such as wear debris, metal toxicity, and allergic responses (Cherian et al., 2016). Alternatives such as titanium and ceramics have demonstrated improved biocompatibility and reduced risks of stress shielding, offering promising directions for safer and longer-lasting implants (Teo et al., 2020). Multidisciplinary collaboration between surgeons, biomedical engineers, and material scientists is therefore essential to advance implant design and improve patient outcomes in knee arthroplasty.

Custom knee replacement implants tailored to individual anatomy can provide better joint function, alignment, and adaptability. Moreover, the widespread use of cobalt chromium in implants poses risks such as wear, metal toxicity, and implant failure, emphasizing the need for alternative biocompatible materials like titanium or ceramics. The aim of this study is to develop and evaluate an improved custom knee replacement implant design by identifying limitations of current implants, enhancing the design, and validating its performance through finite element analysis (FEA).

2. MATERIAL AND METHODS

The methodology of this project involved data collection through questionnaires to identify user needs and target requirements, followed by concept generation using morphological charts and evaluation through concept screening and scoring to select the best design. The chosen concept was developed into a 3D CAD model using CATIA V5 and analyzed with finite element analysis (FEA) in ANSYS to assess structural integrity under physiological loading. Finally, prototypes were fabricated using additive manufacturing to provide tangible representations for testing, evaluation, and refinement of the custom knee replacement design indentation.

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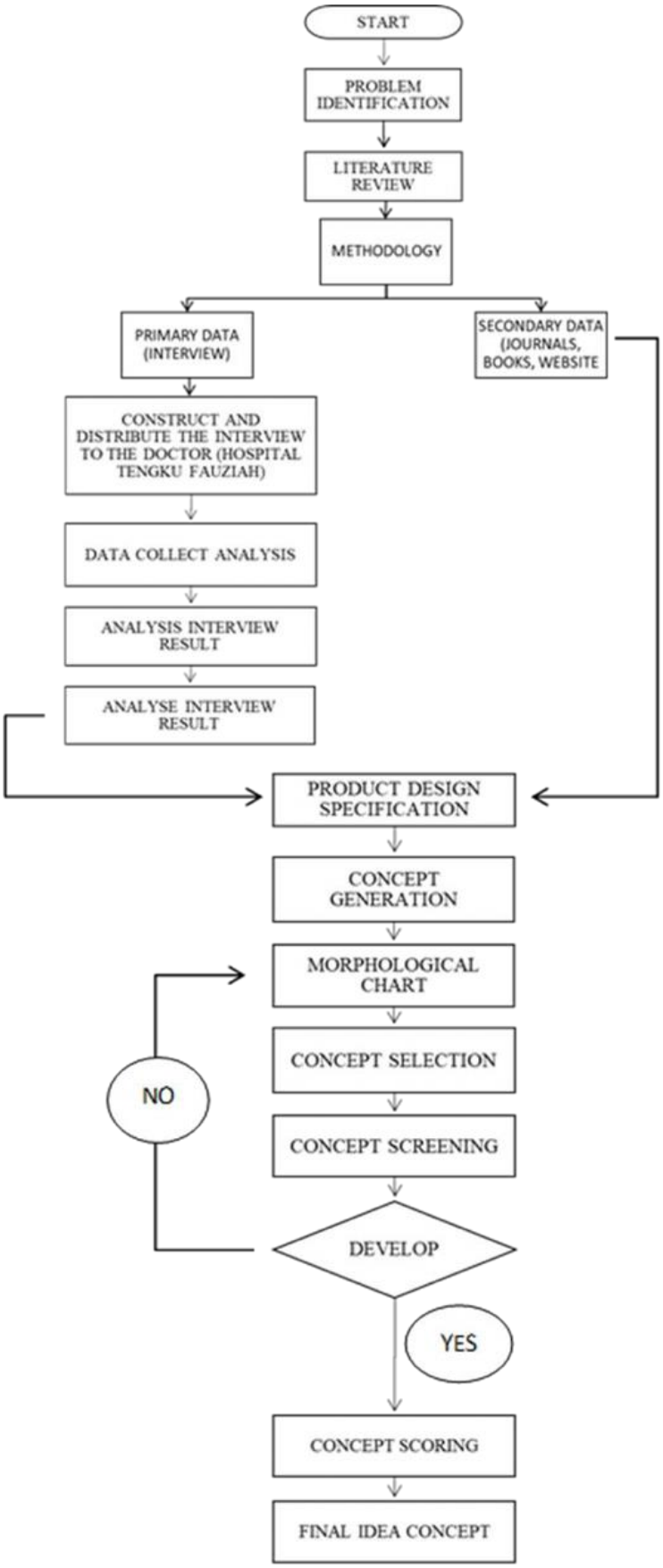

Figure 2.1 Study framework

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2.1 Interpretation Data Collection

Primary data were collected through online surveys and questionnaires targeting osteoarthritis patients and orthopedic specialists. The survey aimed to identify key issues with existing implants, including pain, discomfort, instability, and poor fit. Additional inputs were gathered from published medical literature and clinical studies to establish design requirements.

The collected raw data were filtered and categorized into functional and non-functional needs. Responses were interpreted into clear need statements, which formed the foundation for implant design specification.

The user needs were organized into a hierarchical structure:

Table 1 The Hierarchical Need

Hierarchical Needs	Need Statement
Primary	Comfort, anatomical fit, biocompatibility, and mechanical stability
Secondary	Ease of surgical placement, reduced wear, and long-term durability
Tertiary	Aesthetic design and cost-effectiveness.

A weightage scale (1–5) was used to prioritize the needs, with 5 = critically desired and 1 = least desired. This ensured that primary requirements were emphasized during the design process.

Concepts were generated using morphological charts and sketches. Concept screening and scoring methods were applied to select the best candidate design for further development. The final concept was modeled in CATIA V5. 3D modeling included designing, modifying, and analyzing implant geometry, shape, and features. The final concept was modeled in CATIA V5. 3D modeling included designing, modifying, and analyzing implant geometry, shape, and features. A physical prototype was fabricated using 3D printing and rapid prototyping techniques. The prototype was used to evaluate fit, functionality, and manufacturability before final product development.

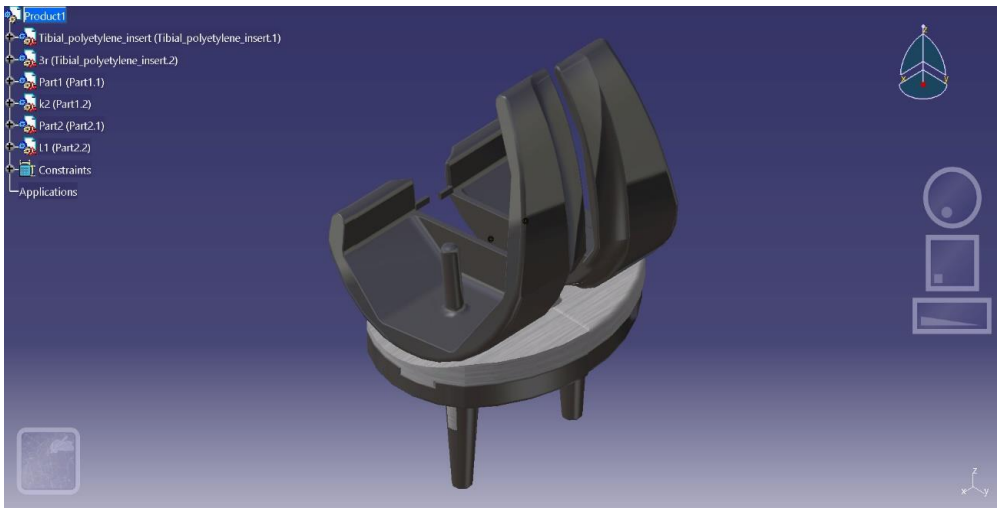
- 

Figure 2.1 . 3D Modelling

The 3D rendering of the knee implant was created using Keyshot 11. This process provided a realistic visualization to evaluate aesthetics, surface finish, and overall implant design.

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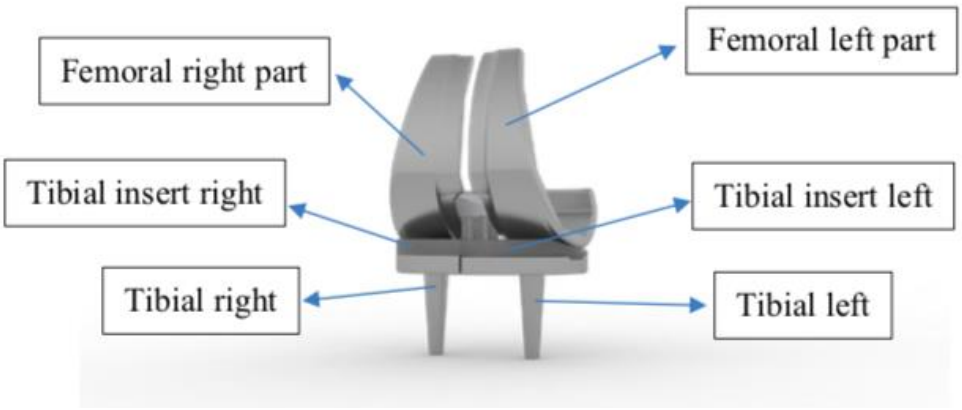

Figure 2.2 3D rendering using Keyshot 11

2.2 3D CAD Modelling

The selected design was developed into a 3D CAD model using CATIA V5. The model was then subjected to finite element analysis (FEA) using ANSYS to assess its structural integrity under simulated physiological loading. This ensured that the implant design met mechanical performance requirements before physical fabrication.

Structural analysis is performed to identify potential failures in the new design. The design's structural integrity is scrutinized to ascertain its safety. Table 2 and present the pertinent properties associated with the design, and it is important to note that temperature effects are excluded from the testing. Each material in use possesses distinct values for Young's modulus, Poisson ratio, and Yield strength.

Table 2 Properties analysis of Polyethalene material

No	Material properties	Values
1	Young Modulus	1.1GPa
2	Poisson's Ratio	0.42
3	Yield Strength	25MPa

A static load of 1500 N was applied to the femoral surface to simulate joint forces equivalent to approximately twice the body weight of a 70 kg individual, while the tibial baseplate was constrained with fixed support. These boundary conditions were defined to replicate physiological loading and provide realistic insights into the implant's mechanical response under functional stresses.

To achieve this, the pressure acting on the knee joint is estimated using the equation:

$$P = \frac{F}{A} \tag{1}$$

where F is the applied force and A is the contact area. This pressure is used as a boundary condition in the FEA to replicate realistic physiological loading on the implant. Incorporating these pressure-based loading conditions ensures that the custom implant design is evaluated under physiologically relevant scenarios, thereby supporting the validation of its structural performance and addressing the limitations of current implant designs. Additionally, the Factor of Safety (FOS) is determined using

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$$.FOS = \frac{\sigma_y}{\sigma_{max}} \quad (2)$$

where σ_y is the material yield strength and σ_{max} is the maximum von Mises stress obtained from FEA. These calculations ensure that the proposed implant design is evaluated not only for its stress distribution and deformation but also for its safety and reliability under expected loading conditions.

The Factor of Safety (FOS) plays a crucial role in validating the reliability of the custom knee replacement implant. An FOS of 1 indicates that the structure or component will fail precisely at the design load, leaving no margin for additional stress. If the FOS is less than 1, the design is deemed non-viable as it cannot sustain the applied load. Conversely, an FOS greater than 1 demonstrates that the implant can endure loads beyond the design condition, ensuring operational safety. Yield strength represents the maximum stress a material can withstand without undergoing permanent deformation, while von Mises stress is a criterion used to predict yielding under complex loading. Thus, the failure condition is defined as:

$$\sigma_{max} > \sigma_{y=} \ Failed \quad (3)$$
$$\sigma_{max} < \sigma_{y=} \ Safe \quad (4)$$

In the setup phase, boundary conditions were defined to replicate real-world loading and constraints, ensuring realistic representation of the implant's working environment. This step is critical in achieving accurate and reliable analysis results. The solution phase followed, where ANSYS Workbench applied numerical algorithms to evaluate the implant's response using the meshed geometry and specified input parameters. Subsequently, the results phase was carried out to analyze stress distribution, deformation, and overall structural performance of the implant. This systematic workflow—comprising material definition, geometry modeling, meshing, boundary condition assignment, solution, and result interpretation—ensures a comprehensive static analysis of the custom knee replacement implant.

3. RESULTS AND DISCUSSION

The finite element (FE) analysis provided important insights into the mechanical behavior of the proposed custom knee replacement implant. The von Mises stress distribution (Figure 4.13) revealed that the peak stresses ranged between 2.514×10^{-7} Pa 59.998 MPa. These values are within acceptable limits compared to the yield strength of common implant materials such as titanium alloys (~800–900 MPa) and cobalt-chromium alloys (~450–1000MPa), suggesting that the implant can withstand physiological loads without undergoing permanent deformation.

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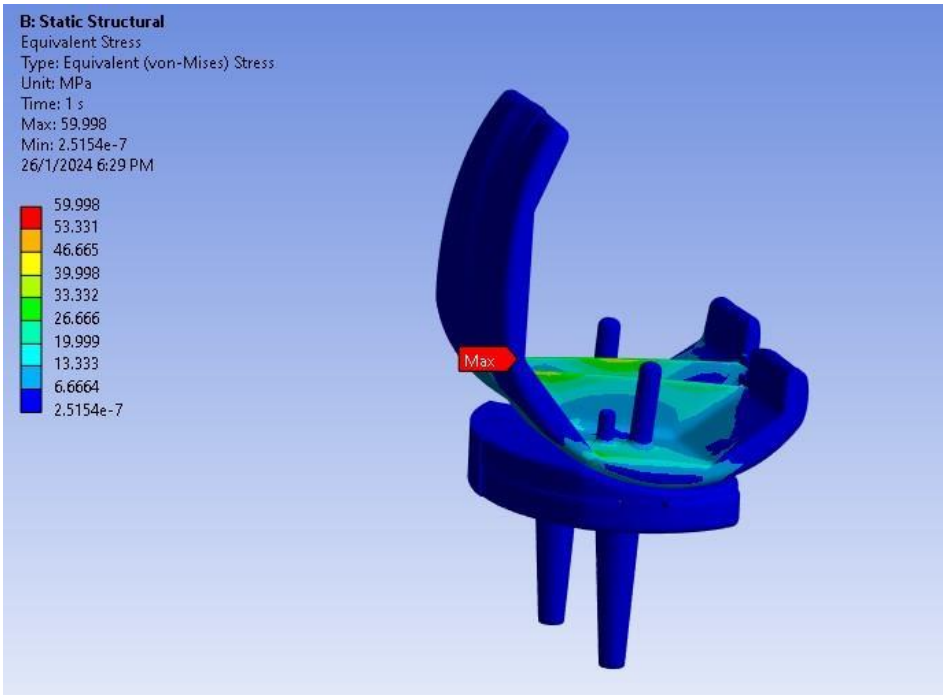

Figure 3.1 Equivalent von Misses

3.1 Structural Analysis

The stress concentration observed in the medial compartment of the tibial component is consistent with clinical findings, as the medial side of the knee typically bears a higher proportion of the load during locomotion. This highlights the importance of customizing implant geometry to accommodate patient-specific load distributions, as conventional off-the-shelf implants may not sufficiently address asymmetrical loading, potentially leading to premature wear or implant failure.

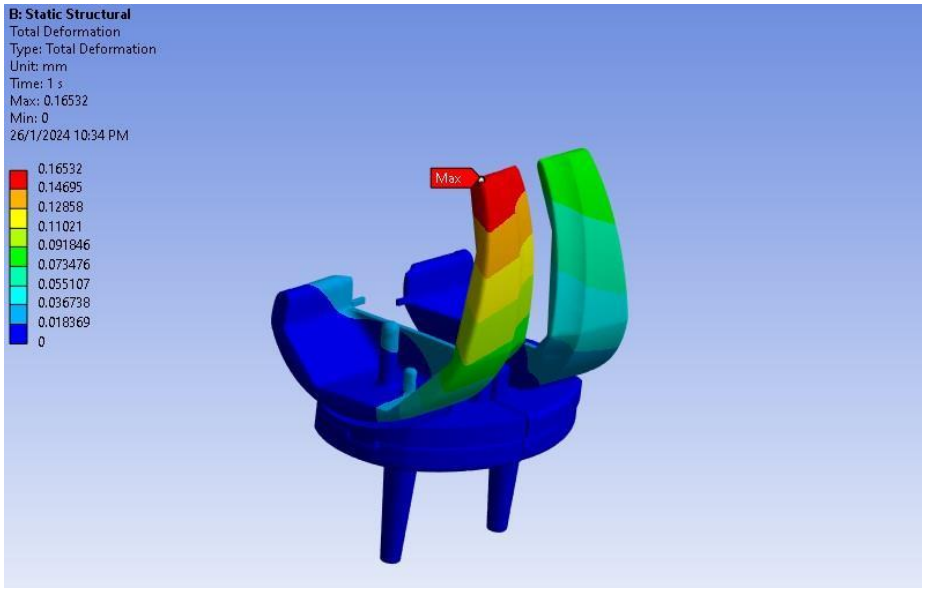

Figure 3.2 Total deformation

The calculated Factor of Safety (FOS) of 155 further reinforces the structural stability of the proposed design. An FOS significantly greater than 1 demonstrates that the implant can safely

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sustain applied loads far beyond normal physiological conditions, thereby minimizing the risk of implant fracture or early failure. However, while a high FOS indicates reliability, excessively high values may also suggest overdesign, potentially leading to increased material usage, stiffness mismatch, and stress shielding effects in surrounding bone tissue. Therefore, careful balance between safety and biomechanical compatibility must be maintained.

The validation of the model involved the development of a three-dimensional representation of the knee joint, incorporating a patient-specific implant, which was then exposed to diverse loading conditions. The finite element analysis (FEA) outcomes demonstrated superior implant fit, leg alignment, contact area, contact pressure, and stress. distribution for the patient-specific implant. As a result, the third objective has been successfully attained. Figure 3.3 shows the final prototype of the knee implant after finishing the fabrication step

3.2 Final Product Knee Implant

A fabrication prototype for a knee implant serves as a preliminary model to evaluate the design, functionality, and performance prior to final production. Developed through methods such as additive manufacturing, 3D printing, or rapid prototyping, the prototype allows assessment of fit, motion, wear, stress, and overall implant behavior under varying loading and environmental conditions. This process not only aids in detecting and correcting design flaws but also ensures performance validation through finite element analysis (FEA), physical prototype testing, and safety evaluations.

Figure 3.3 Final prototype

4. CONCLUSION

In conclusion, the objectives of this study have been successfully achieved. A personalized knee replacement implant was designed to accommodate diverse patient knee conditions, thereby eliminating the need for multiple alternative design trials. Careful attention was given to material selection to minimize risks of allergic reactions, ensuring patient safety and comfort. The application of ANSYS finite element analysis played a pivotal role in validating the implant's performance, particularly in terms of structural integrity, stress distribution, and durability.

Furthermore, the integration of simulation-driven design ensured the development of a robust and long-lasting implant capable of restoring patient mobility and supporting normal daily activities. This holistic approach by combining customization, biocompatible material selection, and rigorous computational analysis demonstrates the effectiveness of the proposed design and

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highlights its potential to improve clinical outcomes for patients with osteoarthritis and bone-related complications.

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