Assessment of Temporary Spacer Design for Knee Arthroplasty Through Finite Element Analysis

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Abstract: *The rising demand for total knee arthroplasty coincides with a considerable growth in revision total knee arthroplasty surgeries, frequently necessitating the use of temporary spacers consisting of moulded bone cement. Three-dimensional (3D) printing has become a viable alternative for the production of precise, personalised moulds for anatomical spacers, thereby ensuring a superior fit, stability, and reduced failure risks. This project aims to develop and evaluate 3D-printed temporary knee spacers for knee arthroplasty, emphasising improved biomechanical accuracy and performance. Three designs of temporary knee spacers were constructed in SolidWorks and evaluated by finite element analysis (FEA) to assess parameters such as displacement, stress, strain, displacement, and factor of safety. The three designs were KSDA, KSDB, and KSDC. The biomechanical characteristics of KSDC were superior to those of KSDA and KSDB, as evidenced by the lowest maximal stress (6.315×10^{7} Pa), strain (4.632×10^{-4}), and displacement (1.797×10^{-1} mm). Additionally, KSDC's maximal factor of safety (FOS) of 13.10 demonstrated structural integrity under duress conditions, surpassing both KSDA (9.072) and KSDB (1.025). Given its superior biomechanical qualities, KSDC was selected as the best suited design.*

Keywords: 3D Design, FEA, Knee Spacer, SolidWorks

1. INTRODUCTION

Finite Element Analysis (FEA) is a computational method that is employed to approximate the behaviour of intricate structures under a variety of loading conditions [1]. It divides the geometry into smaller, discrete elements, solving the governing equations for each to predict stress, strain, and displacement [1]. The fundamental equation in FEA stress and strain is derived from,

$$\sigma = \frac{F}{A}$$

$$\varepsilon = \frac{\Delta L}{L} \qquad \text{(K. Wang \& Pierscionek, 2019).}$$

Stress and strain characterise the behaviour of a material irrespective of its shape. Stress is defined as force per unit area and is measured in Pascals (Pa) or Newtons per square meter (N/m²) [2]. Strain is defined as the extension per unit length and is dimensionless [2]. A material subjected to complicated loading circumstances experiences stress and strain in normal orientations. An implant composed of a homogeneous material with a uniform cross-sectional area, A, and a length, L, would experience a change in length, ΔL, when subjected to a uniaxial load, F [2]. The conventional stress, σ, and the conventional strain, ε [2].

2. METHODOLOGY

2.1 FEA Parameters

In the context of knee spacers, FEA simulates the mechanical performance under physiological loads, which are typically derived from gait analysis and patient-specific conditions [3]. The simulation examines the material and design's reaction to these stresses, assuring that the spacer can sustain in vivo circumstances without excessive deformation or failure [4]. A load of 1500N is advised for assessing knee spacers in FEA as it approximately simulates the typical peak force applied to the knee joint during routine activities such as walking and stair climbing [5]. In contrast to lesser loads, such as 600N or 1000N, it provides a more accurate assessment of stress distribution, contact pressure, and deformation without being too elevated [5]. Elevated loads, such as 3000N or 5000N, can simulate extreme conditions but may not accurately represent typical knee performance and could result in overstated failure predictions in the study [5].

Four crucial parameters, such as Von-mises stress, strain , displacement, and factor of safety are to be assessed by the simulation. The material's ability to yield under a specified load is determined by Von Mises stress, which is derived from the distortion energy theory [6]. The potential failure regions of the material are indicated by strain, which is the relative deformation of the material as a result of applied forces [7]. The optimal distribution of mechanical stresses in the surrounding bones under the effect of the various biomechanical loads applied to the Femur-RTKA-Tibia system determines greatly the initial stability of the prosthetic components and their long-term osseointegration [8]. The purpose of displacement analysis is to assess the extent of shape modifications that result in misalignment and cause wear due to excessive loads on the tibial plateau during the patient's normal ambulation over time [8].The factor of safety (FoS) is the ratio of the material's yield strength to the maximal induced stress, which guarantees that the design is within safe limits [9]. In addition, The reliability and strength of each design are assessed using the factor of safety, which shows how strong the spacers are in comparison to the anticipated loads [10]. After the simulations for each of the design were finished, the outcomes were methodically examined and contrasted. The best option is the one with the lowest maximum stress, the least amount of deformation, and the highest safety factor [11]. The chosen design variant satisfies the strict criteria for both structural integrity and functional efficacy in knee arthroplasty, it is thus seen to be the most appropriate for clinical use.

The FEA results yielded detailed contour graphs for stress, strain, displacement, and factor of safety (FOS). The Von-Mises stress for Ti-6Al-4V was determined to be 10.006 MPa when subjected to a 1500 N load, and the total deformation at the same load was 0.038 mm [5]. The stress value of 10.006 MPa is significantly lower than the material's yield strength of 880 MPa, which guarantees safety under the applied load [5]. The material's structural reliability and rigidity are underscored by the minimal displacement of 0.038 mm [5]. The results revealed that whilst stress and strain levels were lowered in areas far from the main load zones, the load-bearing surface in direct contact with the femur showed the largest stress concentrations. Enhanced clinical performance with a minimum factor of safety of 4.6 was shown by porous Ti-6Al-4V structures for tibial-knee implants [12]. The factor of safety is invariably more than 1, ranging from a minimum of 1.2 to a maximum of 20 [13]. Low safety factors are often allocated in scenarios where material characteristics are thoroughly understood, operating circumstances are highly foreseeable, loads and associated stresses and strains are completely acknowledged, and environmental conditions are well predicted [13]. Mechanical reactions were graphically shown using contour plots, as blue signalling minimal values (little mechanical impact) and red stressing key locations (high stress or strain) [8].

2.2 Titanium Alloy (TI-6AL-4V) as FEA Materials

The titanium alloy (Ti-6Al-4V) surpasses other materials for FEA knee spacers owing to its exceptional mechanical qualities, biocompatibility, and corrosion resistance [5]. It exhibits a reduced von Mises stress (33.35 MPa at 5000N) relative to other materials such as Co-Cr-Mo (38.65 MPa) and ZrO_2 (40.50 MPa), hence diminishing the likelihood of implant failure under substantial loads [5]. This alloy is characterised by its superior mechanical properties, including high strength, fatigue resistance, and durability [14,15]. The knee spacers were constructed from PMMA (polymethyl methacrylate) in real life due to their biocompatibility and favourable characteristics for moulded temporary knee spacers. In finite element analysis (FEA), if complete mechanical property data for PMMA is unavailable, Ti-6Al-4V can serve as an initial reference or be used for model validation. Ti-6Al-4V was selected for simulations due to its well-documented mechanical behaviour, which enables a conservative and reliable assessment performance of the spacers [16]. Fig. 1 shown contour plot of Ti-6Al-4V and stress distribution using various loads and materials.

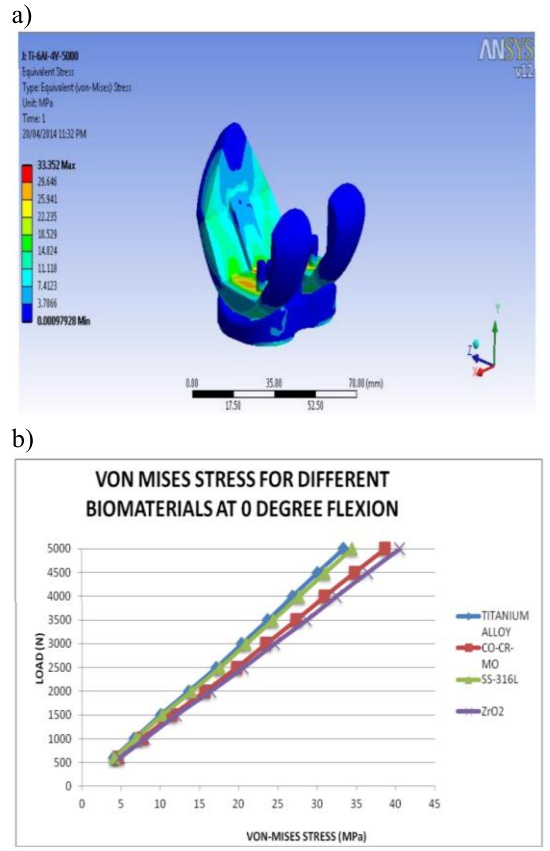


Fig. 1. FEA contour plot and stress distribution. (a) Von-mises stress distribution at 5000 N using Ti-6Al-4V, and (b) graphical illustration of Von Mises stress among prosthetic biomaterials [5].

In order to accurately evaluate the structural integrity of the knee spacer under load, the FEA simulations were conducted using Ti-6Al-4V, a titanium alloy that is frequently employed in biomedical implants. Ti-6Al-4V is a widely used material for knee implant components, particularly in the femoral and tibial component of prostheses [5]. The overall safety and performance limits can be estimated using the results of the Ti-6Al-4V simulations. These insights can be subsequently adjusted for PMMA, which possesses distinct mechanical properties, particularly in terms of tensile strength and rigidity. Table 1 shows the Ti-6Al-4V material properties.

Simulating the minimal friction and attrition anticipated in clinical use, the contact conditions between the knee spacer and the knee bone were modelled as precisely conforming, with a friction coefficient of 0.05 (Ti-6Al-4V against Ti-6Al-4V) [17,18]. These settings made it possible to accurately and reliably reproduce the spacer's mechanical performance. The study uses a FEA mesh with around 0.006 m element size, 7,000 elements, and 10,000 nodes. This resolution was selected to balance accuracy and efficiency in order to ensure that the more intricate features of stress and strain distributions could be captured without taxing computational resources. Coarser elements were used in locations where the load was less crucial, while the mesh was adequately refined in areas with significant stress concentration, such as the load-bearing surface in contact with the femur.

Table 1. FEA material property of the Ti-6Al-4V knee implants [5].

Components Material	Density (kg/m^3)	Yield Strength (Pa)	Young Modulus (Pa)	Poisson's Ratio ($\boldsymbol{\mu}$)	Ultimate Strength (Pa)
Ti-6Al-4V	4430	8.80×10^{8}	1.15×10^{11}	0.342	9.50×10^{8}

2.3 Design and Evaluation of Temporary Spacer

The process of designing the 3D model of the temporary precision mould involves two distinct phases. The phases include the pre-design process, which involves creating a 3D model of the femoral and tibial spacers, as well as building a 3D mould using the SolidWorks research programme. Subsequently, a finite element analysis was conducted on the three designs in order to choose the optimal design, which was subsequently be used to create a mould.

2.4 3D Design of Knee Spacers Using SolidWorks Software

Three distinct knee spacer designs were created to assess their efficacy under static physiological loading conditions. The initial design was characterised by a straightforward geometry and was used as a benchmark for mechanical behaviour comparison. This design was uncomplicated, emphasising fundamental structural requirements without the need for further refinements. The second design, which was inspired by the study carried out by Azam [19], used a more complex structure that featured curvatures that were precisely calibrated in order to maximise the mechanical capabilities of the product. These improvements were made with the intention of more efficiently distributing the loads that were applied, which would result in a reduction in von Mises stress and deformation in contrast to the basic design before it was simplified [19]. It was hypothesised that the more sophisticated geometry would enhance load-bearing performance by optimising the overall structural response and reducing stress concentrations.
The third design was inspired by the research conducted by Shuib [20] and incorporated additional improvements in structural details, thickness, and complexity. The objective of this design was to achieve superior mechanical stability under strain by incorporating a larger profile and increased intricacy [20]. In comparison to the initial two designs, the modified geometry reduced total deformation, stresses, and pressure by addressing critical sites of stress and deformation [20]. The third design outperformed the other two because of its increased level of detail, which allowed it to lessen the likelihood of failure and distribute the load more evenly. The importance of precise geometry and intentional design adjustments in maximising the performance of knee spacers is shown by this incremental improvement.

2.4.1 Femoral Component Design

The femoral spacer component is constructed from the Base Plate, which functions as the design's foundation. This base was subsequently providing support for supplementary structural features, thereby guaranteeing stability when positioned between the femoral and tibial components.
The design is enhanced by the inclusion of Two Raised Curved Arms to facilitate articulation. Two symmetrical arc-shaped features are drawn on the upper face of the base in a new design. The Two Circular Pins are subsequently incorporated to guarantee that the tibial component is properly aligned. This pin is critical for securing the femoral spacer as it provides for a controlled range of motion while preventing undesired movement. While preserving strength, this perforation enhances material efficiency without losing mechanical integrity, hence lowering the weight of the spacer.
A recent study reveals that Design A, Design B, and Design C may be differentiated from one another based on their thickness, intricacy, and curvature. As a consequence of its moderate thickness and streamlined profile, Design A is ideal for applications that are more frequent and incur a minor level of mechanical stress. Design B enhances anatomical fit and articulation by combining a relatively slimmer profile and more curvature, and it may potentially impair the overall load-bearing capabilities of the construction. Design C, the most complex form, features a streamlined shape and better curvature to optimise biomechanical efficiency and contact areas. This variant is the most complicated to create. These modifications are done to improve mechanical durability, range of motion, and stability, since they are personalised for each patient.

2.5 Tibial Component Design

The tibial spacer component is constructed with a conical base to give structural support and stability. The Top Plane is selected as the draughting surface to begin the design process. A vertical centerline is constructed to assure symmetry, succeeded by a triangle symbolising the cone's cross-section. The lower brace, which functions as the intermediate section of the tibial spacer, is intended to offer supplementary support and interface with the femoral component. While, the cushion, which is the upper section of the tibial spacer, is intended to reduce peak tensions at the bone-implant interface and distribute burdens uniformly.
A full examination is undertaken to validate dimensional accuracy and guarantee that all aspects are precisely specified in order to finalise the design. Material properties are allotted to various sections in accordance with their functional requirements. For instance, the brace and base are constructed from matte titanium to ensure durability and strength, while the cushion is coated with rubber or a similar compliant material to improve impact absorption. This material combination optimises the tibial spacer's function by achieving a

precise balance between mechanical stability and cushioning benefits. To assure that the finished component fulfils the biomechanical requirements for a successful knee arthroplasty, it is held aside for extra assembly, simulation, or production testing.

2.6 FEA Using SolidWorks

This part mainly discussed the finite element analysis (FEA) of the tibial and femoral spacer component, which is responsible for the stabilisation and distribution of load in knee arthroplasty. The structural integrity and efficacy of the spacer are guaranteed by conducting FEA experiments on its mechanical behaviour under physiological loading conditions. The design is optimised in this study by modelling tension, strain, and displacement to identify vulnerable points and refine geometric aspects, such as the base, lower brace, and cushion. Material, parameter, particularly load-bearing surfaces and contact situations are also investigated to enhance functionality and durability. The development of more reliable and effective orthopaedic implants is facilitated by a computational evaluation of the biomechanical efficacy of the knee spacers. Fig. 2 shows the FEA flowchart using SolidWorks.

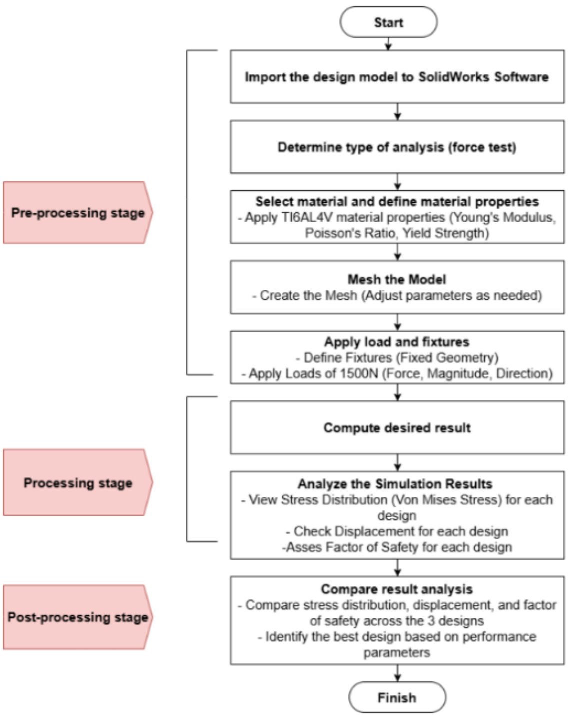


Fig. 2. FEA workflows.

2.7 Boundary Conditions

The mechanical behavior of the knee spacers under physiological loading conditions was assessed through the use of SolidWorks Simulation for finite element analysis (FEA). As shown in Fig. 3, the upper surface in direct contact with the femoral component was subjected to a static force of 1500 N, which simulated moderate activity loading that are indicative of the normal distribution of body weight during movement [5]. The fixed support was applied to the surface area that meets the tibial bone in order to simulate realistic boundary conditions [5]. SolidWorks was chosen for its exact meshing capabilities, user-friendliness, and ability to precisely mimic material behavior. The models excluded base and lower braces of tibial component, which solely serve as connections to the tibial bone and do not undergo substantial contact or stress transmission. The tibial component lower brace and base were excluded from the FEA in order to streamline the computational model and prioritise the critical load-bearing components. The inclusion of these components could result in an unnecessary level of complexity without significantly altering the primary stress distribution of the primary construction [21]. Moreover, compared to other important structural components, the tibial lower brace and base may undergo little deformation or stress due to it is bonded with tibial cushions, therefore their contribution to general mechanical behaviour is minor [8,21]. Eliminating them helps the analysis to keep accuracy in evaluating the key load pathways and failure risks while increasing computing efficiency.

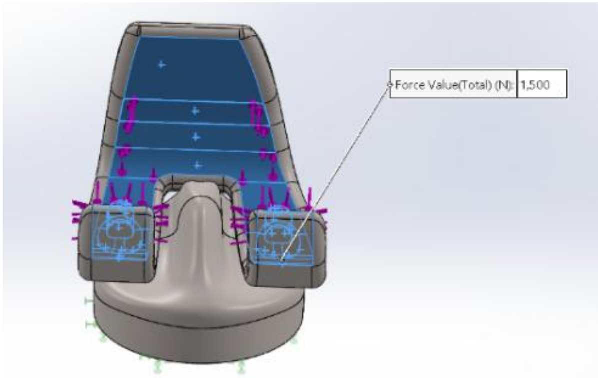


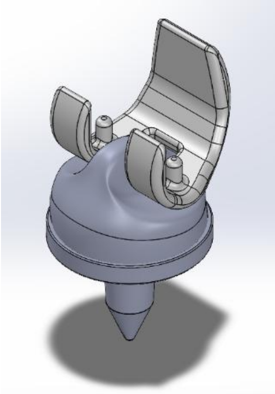
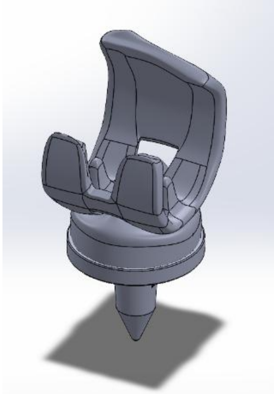
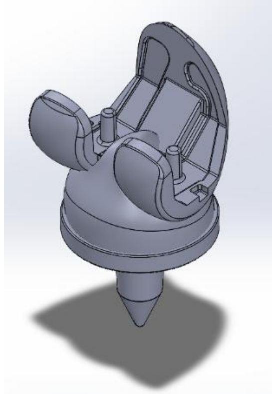
Fig. 3 Boundary Conditions- fixed support and direction of load.

3. RESULT AND DISCUSSION

3.1 Variations of Knee Spacers Design

The results of the study show that three different types of temporary knee spacers were successfully conceived and developed utilising SolidWorks software. The anatomical and functional criteria for temporary spacers used in knee arthroplasty were carefully considered while designing these variants, guaranteeing their viability for clinical application. Each design demonstrates a thorough effort, keeping to the parameters specified during the design process while also using findings from prior research that offered the core notion for exploring alternatives. The study aims to improve the adaptability and performance of temporary knee spacers by incorporating previous findings and addressing a wide range of clinical circumstances. Table 2 shows the design of 3 variations of knee spacers.

Table 2. Design of 3 variations of knee Spacers

View	Knee Spacer Design A	Knee Spacer Design B	Knee Spacer Design C
Isometric			

SolidWorks methodically developed the design variants of the knee spacers (KSDA, KSDB, and KSDC) to assure their anatomical compatibility and mechanical efficacy under physiological stress situations. The initial design, KSDA was successfully designed, provides simplicity of manufacture and vital structural integrity, with a fundamental form that serves as a platform for comparison. However, because of its extremely basic structure, stress concentrations are more obvious, particularly at the contact surfaces. Building upon previous research, the second design, KSDB was successfully designed and has advanced curvature enhancements that appropriately allocate contact stress, hence augmenting its load-bearing capacity [19]. This refinement reduces von Mises stress and deformation, hence improving its biomechanical stability compared to KSDA.
The third design, KSDC was successfully designed, has enhanced thickness and intricate structural elements, as recommended [22], therefore mitigating stress concentration effects. This variant exhibit improved mechanical stability because to the increased complexity, which enhances force distribution and resistance to deformation under specified loads [22]. The increased surface complexity of KSDC facilitates improved load distribution, hence reducing peak stress at critical locations where implant failure commonly occurs in clinical environments. The qualitative assessment of these three designs underscores the necessity for iterative enhancements in knee spacer development, where each subsequent modification is based on previous outcomes to enhance overall structural integrity and clinical relevance. The findings support existing research emphasising the necessity of optimum geometry in orthopaedic implants to enhance mechanical reliability and ensure long-term functional success in total knee arthroplasty [22].

3.2 FEA Result

Maximum stress, deformity, and safety factors are some of the important factors considered while analysing the outcomes of a SolidWorks FEA for knee spacers. This investigation utilised finite element analysis (FEA) to analyse the material under investigation. Table 3 shows the FEA results from SolidWorks FEA using load force test.

Table 3. FEA results.

Mechanical Properties	Range		
	KSDA	KSDB	KSDC
Stress (Pa)	0.891×10^{3} – 9.120×10^{7}	41.230×10^{3} – 80.690×10^{7}	0.406×10^{3} – 6.315×10^{7}
Strain	0.699×10^{-8} – 5.937×10^{-4}	17.710×10^{-8} – 49.310×10^{-4}	6.212×10^{-8} – 4.632×10^{-4}
Displacement (mm)	1.000×10^{-30} – 18.200×10^{-1}	1.000×10^{-30} – 1.806×10^{-1}	1.000×10^{-30} – 1.797×10^{-1}
Factor of Safety	9.072×10^{0} – 2.824×10^{4}	1.025×10^{0} – 2.007×10^{4}	13.100×10^{0} – 20.400×10^{4}

The FEA results demonstrate that Design KSDC has the most advantageous biomechanical performance, with the lowest maximum stress (6.315×10^{7} Pa) and strain (4.632×10^{-4}) relative to KSDA and KSDB in the findings. The findings align with those of [22], which indicated that improved knee spacer shapes can mitigate the likelihood of material fatigue and failure by reducing stress concentrations. The analysis is further focused on the most mechanically relevant regions by excluding non-load-bearing structures, such as the lower brace and base. This method was recommended by [23], who discovered that the stress distribution in these peripheral areas does not significantly affect the overall integrity of the implant.
Additionally, displacement analysis demonstrated that Design KSDC exhibited the least deformation

(1.797×10^{-1} mm), which further fortified its structural stability. Instability and misalignment have been linked to excessive displacement in orthopaedic implants, which may result in implant failure over time [24]. The decision to omit marginally affected areas aligns with earlier computational modelling methods, where researchers meticulously refined meshing in essential load-bearing regions while streamlining less critical structures to enhance computational efficiency and precision [25].

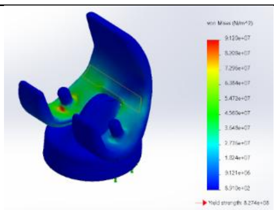
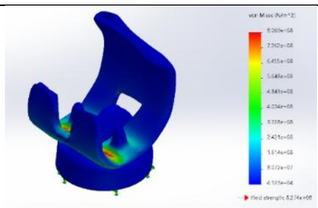
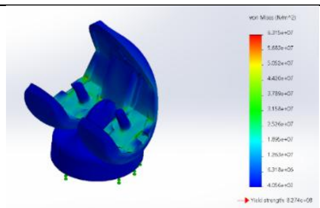
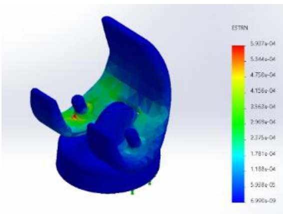
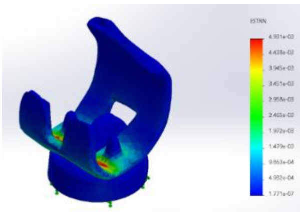
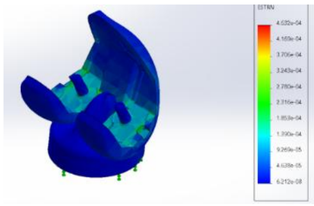
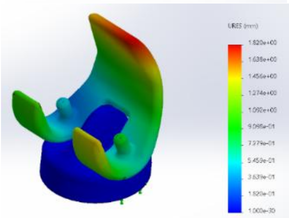
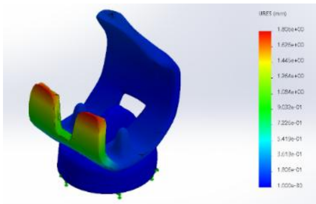
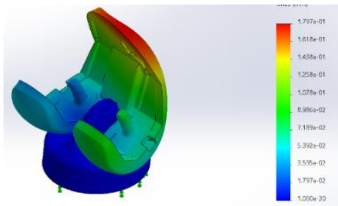
The dependability of the knee spacer during excessive loading circumstances is assessed by the factor of safety (FOS), which is a crucial element included in this research. According to the findings of the finite element analysis (FEA), Design KSDC has the greatest factor of safety (FOS) at 13.10. This place is ahead of KSDA, which has a factor of safety of 9.072, and KSDB, which has a factor of safety of 1.025. The fact that KSDC is able to withstand larger stress without experiencing mechanical failure is demonstrated by this. The necessity of establishing a high Factor of Safety (FOS) in orthopaedic implants has been underlined in previous studies by [13]. This ensures that the implants are able to withstand extended cyclical loading without compromising their functionality.

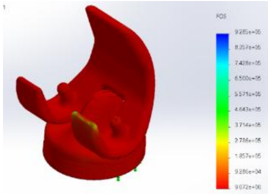
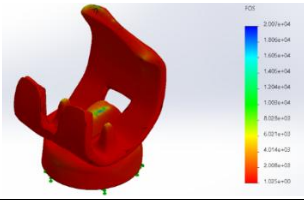
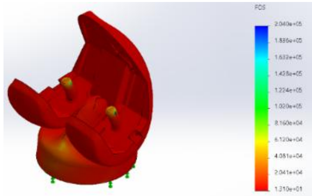
These findings are supported by the graphical analysis of stress and strain distributions, which demonstrates that KSDC is able to efficiently disperse mechanical loads while simultaneously reducing localised stress concentrations. This is demonstrated by contour plots as shown in Table 4. Conversely, KSDA and KSDB demonstrate regions of excessive deformation that may result in premature failure. These patterns are consistent with the research of [5,26], who emphasised that the most effective knee spacer designs should prioritise even stress distribution to improve the long-term stability of implants. This is accomplished by the selective exclusion of low-impact regions in this study.

The contour plot of the knee spacer's FEA displays distinct colour distributions that correspond to the factor of safety, displacement, strain, and stress as shown in Table 4. The middle region of the stress-strain diagram is green, indicating moderate stress concentration as a result of direct compressive loading between the femoral and tibial components. This distribution of forces is more even. This pattern is consistent with prior research, which has shown that tension accumulates in load-bearing regions and dissipates towards the periphery [26]. The colour of the displacement contour plot transitions from blue to red, with the highest displacement occurring at the free end of the femoral component. This confirms that unrestricted regions experience the greatest deformation. In the interim, the factor of safety (FoS) plot is predominantly red, implying that the majority of the structure has a FoS within the range of 1–2, which suggests that the operation is near the material's strength limits.

As a conclusion, the finite element analysis substantiates the assertion that Design KSDC is the knee spacer that has the highest level of mechanical efficiency. This is because it demonstrates a higher factor of safety and lower values for stress, strain, and displacement. The omission of the lower brace and base was verified by previous study, which showed that these locations have a small influence on the total stress-strain response of knee spacers. Through a focus on the most important load-bearing components, this work ensures an accurate and computationally efficient evaluation of knee spacer performance. This, in turn, makes it easier for future experimental validation and clinical application to take place.

Table 4. FEA Contour Plot Result.

Mechanical Properties	KSDA	KSDB	KSDC
Stress			
Strain			
Displacement			

Factor of Safety			

4. CONCLUSION

The optimal combination of biomechanical performance and structural compatibility was the aim of this study by the development of three varieties of temporary knee spacers and the selection of the most acceptable design based on FEA results in SolidWorks. The KDSC design was identified as the most effective, exhibiting superior load-bearing capacity and stress distribution, hence demonstrating its suitability for revision total knee arthroplasty. The result for the aims of the development of the most appropriate knee spacer mould with SolidWorks and produced by FDM. The 3D-printed moulds exhibited excellent dimensional precision and functionality, facilitating the production of temporary knee spacers with consistent structural integrity. However, opportunities for future advancements in mould manufacturing techniques are underscored by challenges such as the difficulty in extracting the femoral component from the mould, as well as issues such as bubbles and fractures.

The conclusion for the last aim of this study is that measurements of surface roughness demonstrated that reduced layer heights, especially 0.1 mm, yielded enhanced surface finishes and diminished roughness values, which are essential for ensuring proper articulation and minimising wear in clinical applications. The results underscore the importance of selecting an ideal layer height to improve the overall effectiveness and durability of temporary knee spacers. This study established the viability of employing 3D-printed moulds for temporary knee spacers in revision total knee arthroplasty. The utilisation of SolidWorks models and additive manufacturing optimises the creation of knee spacers and moulds. The integration of FEA research with surface roughness assessment shown that 3D printing yields biomechanically reliable and therapeutically appropriate temporary knee spacers with rapid manufacturing capabilities.

4.1 Limitations and Future Recommendations

This chapter describes the limits discovered in this investigation, including constraints relating to the experimental set-up, software capabilities, manufacturing issues, and measurement approaches. These limitations emphasise areas that might be improved in future study to enhance the accuracy, reliability, and application of the findings. The key issues are the reliance on predicted surface roughness measurements, manufacturing imperfections, SolidWorks FEA constraints, and measurement challenges. Furthermore, the study did not analyse alterations in infill patterns, extrusion temperatures, or material compositions, nor did it involve post-processing processes that might potentially impact the spacer's final qualities.

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