Development and Analysis of 3D-Printed Knee Orthosis for Post-Anterior Cruciate Ligament Injuries Rehabilitation

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Abstract: An anterior cruciate ligament (ACL) rupture is one of the most severe injuries an athlete can suffer, resulting in knee joint instability and significant pain. This study aims to develop and analyze 3D-printed knee orthoses for post-ACL injury rehabilitation to overcome conventional orthoses' drawbacks. The project uses 3D scanning, modeling, and printing techniques. It evaluates knee orthoses performance of three different thicknesses and designs through finite element analysis using Marc software, focusing on von Mises stress and displacement. For the compression test, a face load is applied to the knee model's top surface, consisting of half the subject's body weight multiplied by 10 N. For the 3-point bending test, a point load of 134 N is applied to the tibia's posterior part. Results show that a 7 mm thickness is optimal, exhibiting the lowest stress and displacement, providing the best support.

Keywords: ACL Injuries, Knee Orthosis, 3D Scanning, 3D Modelling, FEA

1. INTRODUCTION

The knee experiences a broad range of intense loadings during sports and other physical activities, making knee injuries common and significantly disruptive to the lives of those affected. Among the various knee injuries, a frequent and severe one is the ruptured or tear of the anterior cruciate ligament (ACL). ACL is a strong tissue band within the knee joint that connects the thigh and shin bones. It is a critical stabilizer of the knee which preventing the tibia from moving forward relative to the femur. According to Greenfield [1] reported that, when the ACL is torn, the knee joint becomes highly unstable, and rehabilitation can take up to 18 months, with some individuals never fully regaining their pre-injury level of physical performance due to medical complications. In the United States alone, approximately 200,000 ACL injuries occur annually, with over half of those injured requiring reconstructive surgery to restore stability and muscle strength [1]. Meanwhile in Malaysia, the Sports National Institute (ISN) reports receiving 3 to 4 ACL-related cases per month involving athletes from sports such as hockey, kick volleyball, and netball [2]. This highlights the financial burden that ACL injuries impose on the healthcare system due to the costs associated with surgical and rehabilitative treatments [3].

Complete ligament tears may lead to predictable patterns of physical instability and varying levels of functional instability. These injuries often result in fluid accumulation around the knee joint, altered movement, muscle weakness, and decreased overall functional performance [2]. Individuals with severe knee injuries often require surgery to regain stability. During the surgery, the ruptured ligament is removed and replaced with a tendon autograft or allograft. This graft is typically sourced from the medial hamstrings or positioned between two of the patellar tendons. The ACL injury treatment showed long-term success rates in knee functionality. However, this technique had the potential to fail in a short time due to the lack of neurosensory tissue control, graft tissue degradation, and neuromuscular deficits [4].

After surgery, it is crucial for patients to avoid excessive physical activities to protect the knee. Therefore, knee orthoses are commonly used as part of post-rehabilitation to support and guard knee movement. Knee orthosis use after ACL injury and reconstruction is continuously managed by a qualified practitioner and is designed to improve over time. However, previous study stated that using a knee brace after surgery could lead to several complications such as joint stiffness, degeneration of collagen structures, and muscle atrophy [5]. Given the uncertainty surrounding in this issue, the primary goal of a knee orthosis is to control the range of joint motion, whether to enhance coordination or stability, minimize pain or injury risk, or address muscle weakness, thereby reducing or preventing the severity of knee injuries [6]. The orthosis should assist the individual without compromising the knee joint's performance. Mechanically, the knee orthosis must allow the knee joint to function normally, enabling individuals to participate in their activities without decreasing their performance level.

Furthermore, the knee orthosis also stabilizes the knee, preventing sudden twisting when an individual changes direction. This makes it a reliable choice for secure and high-performance applications. The main function of the orthosis is to prevent excessive tibial dislocation relative to the femur, thereby enhancing knee stability and security during rotation. Complete ligament injuries lead to predictable physical instability patterns and variable levels of functional instability [2]. Nevertheless, a previous study indicated that using three different types of conservative knee braces showed no significant differences in pain reduction or discomfort [7].

In this project, the goal is to create a customized passive three-dimensional knee orthosis that meets the high demand in the medical field by utilizing 3D printing [8]. This type of orthosis is more cost-effective and quicker to produce than conventional orthosis. To achieve this, 3D printing technology will be employed, involving three key steps: 3D scanning, 3D modeling, and 3D printing. Finite element analysis (FEA) was employed to simulate both a 3-point bending test and a compression test. In a prior study, Baharudin et al. [9] utilized FEA to model the midstance phase of a gait cycle for a passive prosthetic leg designed for transtibial amputees. Additionally, Chen et al. [10] applied FEA to investigate how the modulation of internal stress distributions in knee cartilage meniscus structures can be achieved through the control of footwear stiffness properties. Therefore, FEA is eassential to deliver crucial strength analysis data to scientists, engineers, and researchers, in order to facilitate enhancements in the design of knee braces in the near future. The focus is on post-ACL rehabilitation following surgery, with the knee orthosis designed to be statically flexible, allowing individuals to use it while walking daily. A static flexible orthosis enables muscle stretching while restricting the range of joint motion [11].

Three different thicknesses and three different designs will be analyzed to determine the best knee orthosis for fabrication, which will then be compared with conventional knee orthoses. Finite element analysis will be used to evaluate the performance of the printed knee orthosis. Subsequently, the three-dimensional printed product will be assessed for comfort and thermal imaging patterns, alongside conventional orthoses. Finally, this innovation in knee orthosis assisted in reducing pain by shifting the weight from the most damaged portion of the knee, thereby avoiding excessive force on it. In other words, knee orthoses were used to support, guard, and stabilize a knee that needed assistance in order to recover or to prevent damage to the knee joint or ligaments, which could have slowed down the rehabilitation process [12].

2. MATERIALS AND METHODS

A 25-year-old female volunteer was recruited for this research project. During the interview, she weighed 69 kg and had an ACL injury on her left leg. She underwent ACL reconstruction and meniscus repair surgery on April 29, 2021. Following the surgery, she wore an orthosis for five months and was in the recovery phase for 12 months. Table 1 presented the patient's personal details for this study. The volunteer provided informed consent before proceeding with the 3D scanning process.

Table 1. Patient Personal Details

Patients	Descriptions
Age	25
Gender	Female
Weight (Kg)	69kg
Height (Kg)	171cm
Leg Injuries	ACL injury
Position Leg	Left Leg
Surgical Procedure	Reconstruction ACL and repair Meniscus
Surgery Date	29/4/2021
Duration Wearing Orthosis	5 months
Recovery Duration	12 months

The scanning process utilized a Sense three-dimensional (3D) scanner (Sense 3D, 3D Devices, Inc., USA) as shown in Figures (a) and (b). Using an optical scanning system, a computer-aided design (CAD) or digital model of the knee was reconstructed [13]. To acquire a quality image, the scanner was positioned directly above the subject's knee, allowing it to scan nearly 360° around the knee, which required full rotation. The 3D scanner images were prone to become obscured and losing tracking. Therefore, it is essential to maintain a distance of 20-30 cm between the scanner and the knee while slowly scanning the volunteer's knee. After completing the scanning process, the image was saved in stereolithography (STL) file format in MIMICS 3-Matic software (Materialise NV, Leuven, Belgium) for 3D modeling and re-uploaded to the software.

Fig. 1. Left picture depicted researcher was scanning leg of the patient and right figure showed 3D scan image of it.

After the 3D image was uploaded to the 3-Matic software, the knee orthosis is designed based on the acquired image. The 3D knee orthosis was created using the tools in the 3-Matic software. The procedure included processes such as trimming unnecessary parts, smoothing surfaces to remove undesired noise on the surface, generating holes, shaping the knee orthosis, and applying smooth edges as a finishing step. The knee orthosis was designed with three different thicknesses: 3 mm, 5 mm, and 7 mm. The final designs of the knee orthosis are depicted in Figure 2. Table 2 depicted the dimension and parameter of hinges and pins. Based on previous study, shape of hole used in this study is hexagon and the dimension of hole is 8mm each side of hexagon shape. 30% infill was utilized in 3D printing of the knee braces as shown in Table 3.

Table 2. Dimensions of Hinges and Pins [3]

Parts	Elements	Dimension (mm)
Hinges	Thickness	5 (follow desired thickness)
	Length	140
	Width	40
Pins	Inner	19.5 (tolerance ± 0.5)
	Outer (holes diameter)	19.4 (tolerance ± 0.5)

Table 3. Variation of Design Approach for Knee Orthosis

Design	1	2	3
Thickness	3mm	5mm	7mm
Shape of hole	Hexagon	Hexagon	Hexagon
Dimension of hole	8mm each side	8mm each side	8mm each side
Infill	30%	30%	30%

a) b) c)

Fig. 2. 3D Design of knee orthosis with thicknesses, a) 3mm, b) 5mm and c) 7mm respectively.

Once the designs are finalized, meshing was implemented on the knee orthosis. This process entailed by dividing the entire component into discrete elements to ensure uniform distribution of load during mechanical testing. In this study, a mesh size of 3.0 was utilized for the knee orthosis and 5.0 for the knee by employing fixed triangles. Furthermore, a mesh size that was too small on the part resulted in oversensitive modeling and prolonged simulation times. Conversely, a mesh size that was too large led to limited simulation precision. The mesh sizes for the knee and orthosis were detailed in Table 4. Figures 3 illustrated the mesh on both the knee and knee orthosis were presented.

Table 4. Parameters of Meshing [3]

Mesh	Part	Dimension (mm)	Descriptions
Surface Mesh (Fix Triangles	Orthosis	3.0	Adaptive Mesh
	Knee	5.0	Adaptive Mesh
Volume Mesh (Convert to Solid)	Orthosis	3.0	-
	Knee	5.0	-

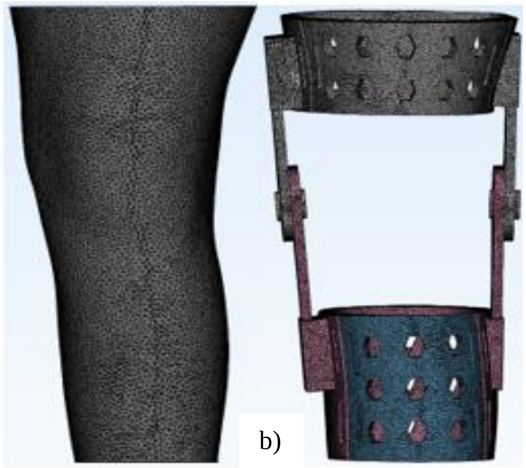

Fig 3 Mesh on Knee (a) and Knee Orthosis (b)

The Finite Element Analysis (FEA) for the 3D model design was conducted using the software (MSC Software, California, US). Boundary conditions were set to delineate the interface between skin and orthosis by determining the model's interactions with its surroundings. The knee's contact mode with the 3D model was configured as 'glued' which permitting friction at the knee. The boundary interface between the knee model and orthosis was defined as stiff to prevent perpendicular movement of the brace towards the knee. While the orthosis remains mobile relative to the knee surface, the interface between them was assumed to be frictionless. The Marc software is utilized to simulated 3-point bending and compression test by applying varied loads to assess the endurance, quality, and longevity of the knee orthosis on different thickness which are 3mm,5mm and 7mm (Fig 4). In this 3-point bending test, a load of 134N was applied to the posterior part of the tibia to simulate the anterior drawer test (ADT). With a 134N anterior tibial load (ATL) applied to the knee joint, the femur was stabilized in all degrees of freedom, while the tibia was restricted to internal-external rotation and medial-lateral translation [14].

This test was conducted to measure the flexural strength of a product. The flexural strength of a 3D-printed model was determined using this test under real-life conditions. In addition, for the compression test, a face load was applied to analyze the performance of the knee orthosis when the subject is standing. This involved applying force to the tibia and femur, as shown in Figure 4 [3]. The study utilized software to simulate pressure on the knee model. The force was calculated by entering the patient's body weight (BD) into a table and multiplying it by ten to convert it into Newtons (N). A compression load equal to half the patient's body weight was applied to the femur and tibia to simulate a standing leg [3]. However, the parameter used in the software was pressure. Thus, during the simulation, a face area was calculated to obtain the pressure value by dividing the force (N) by the face area (mm^2) of the top surface of the leg model where the load was applied. Furthermore, Table 5 show the boundary condition of the finite element analysis in this study. Furthermore, Table 6 depicted the convergence study details of the knee orthosis model for 3-point bending and compression test.

Table 5. Specifications adopted for simulated inverter [9]

Properties	Body	Values
Young's Modulus	PLA	3500MPa
	Skin	20 MPa
Poisson Ratio	PLA	0.38
	Skin	0.48
Stiffness Coefficient	Link (Velcro)	5

Table 6. Convergence study details of the knee orthosis model for 3-point bending and compression test.

Model	Number of nodes	Number of elements
3 mm	261018	1469822
5 mm	288901	1639749
7 mm	334812	1905945

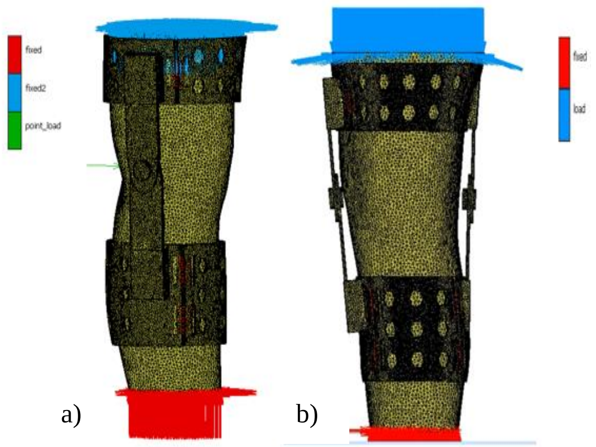

Fig 4 FEA on 3-Point a) Bending Testing Boundary Condition and b) Compression Testing Boundary Condition.

3. RESULTS AND DISCUSSION

3.1 Effect of Compression Test to VMS and Displacement

Table 7 presented the VMS value for orthosis and skin. The highest stress was observed at the lateral side of 3D knee orthosis. The von Mises stress is a measure used to predict if a material will yield or fracture. According to the von Mises yield criterion, if the von Mises stress equals or exceeds the material's yield strength under simple tension, the material will yield. In this study the yield strength was 60 MPa. For the orthosis, the stress was lowest at a thickness of 7mm with 1.8257 MPa. This result was followed by a thickness of 5 mm at 2.4366 MPa with the highest stress occurred at 3mm of thickness with 2.6730 MPa. In contrast, for the skin the lowest VMS was 0.1062 MPa at 3mm. Meanwhile, the highest VMS was 0.1143MPa at 5 mm. In addition, Figures 5 and Figure 6 below showed the contour plots of von Mises stress (VMS) distribution simulation results for various thicknesses at the orthosis and skin.

Table 7. Von Mises Stress of Orthosis and Skin

Thickness	Von Mises Stress (VMS), MPa	
	Orthosis	Skin
3mm	2.6730	0.1062
5mm	2.4366	0.1143
7mm	1.8257	0.1086

Based on the results, maximum VMS for all the thickness does not exceed the yield strength of polylactic acid (PLA) (60 MPa). From previous study, PLA exhibit significant Young's Modulus and Poisson's ration which are 3500MPa and 0.38 respectively compared to other materials. In addition, it's have portrayed significantly lower VMS compared to its tensile strength of 3600 MPa [9]. The VMS results for the orthosis indicated that it has reached its yield strength. Hence it was assumed to have failed. Therefore, if the stress has exceeded the ultimate tensile strength, the orthosis will indeed fail. Besides, previous studies have shown that the higher strength is achieved with thicker layers of material [15]. This compression test manifested the same results as the previous. For instance, orthosis with greater thickness will have improved structural integrity which enabled to support body weight. Hence, the analysis of the data indicates that PLA-based orthoses, when designed with appropriate thickness, can effectively support body weight while remaining within safe stress limits.

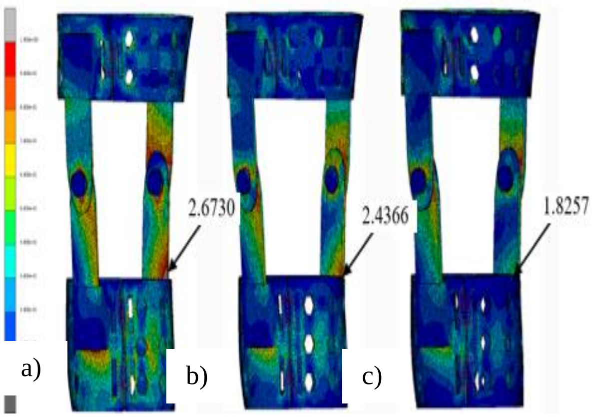

Fig 5. Maximum VMS on Orthosis at different thickness a) 3mm, b) 5mm and c) 7mm respectively.

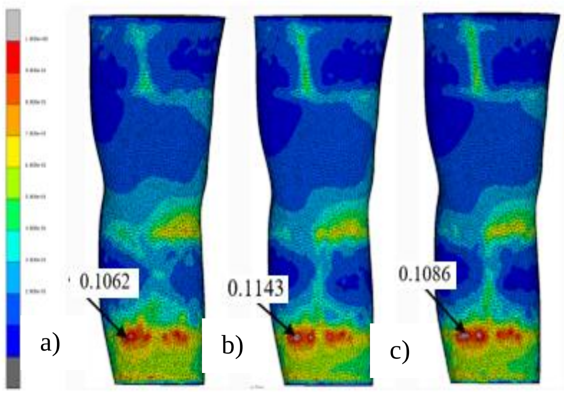

Fig 6. Maximum VMS on the skin at different thickness of knee orthosis a) 3mm, b) 5mm and c) 7mm.

Next, as presented in Table 8, are the displacement measurements for both the orthosis and skin. Furthermore, Figures 7 and 8 displayed the contour plots for displacement on both the skin and the knee orthosis. For the orthosis, the displacement is minimal at a thickness of 7 mm (0.7698 mm), followed by 5 mm (0.7861 mm), and reaches its maximum at 3 mm (0.9466 mm). Similarly, for the skin, the lowest displacement is recorded at 7 mm followed by 5mm with 0.7827 mm and 0.8038 mm respectively. Meanwhile, the highest displacement occurs at 3 mm with 0.9735 mm.

Table 8. Displacement of Orthosis and Skin

Thickness	Displacement (mm)	
	Orthosis	Skin
3mm	0.9466	0.9735
5mm	0.7861	0.8038
7mm	0.7698	0.7827

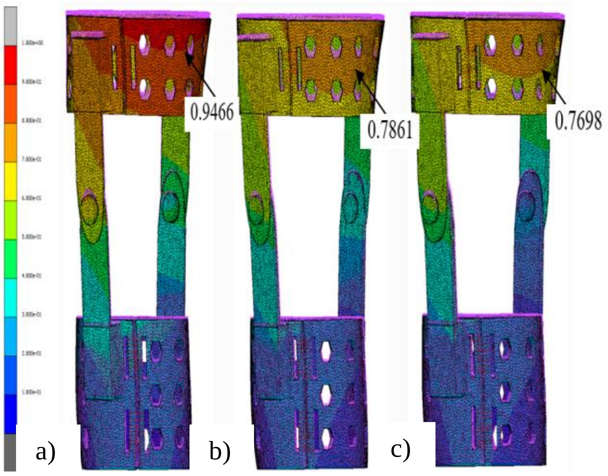

Fig 7. Displacement on Orthosis at different thickness a) 3mm, b) 5mm, c) 7mm respectively.

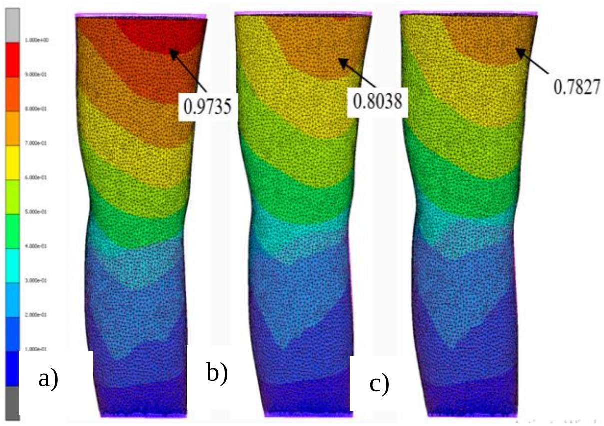

Fig 8. Displacement on Orthosis at different thickness a) 3mm, b) 5mm, c) 7mm respectively.

Previous studies have established that the lowest displacement is indicative of the most stable orthosis thickness. A certain degree of displacement is essential to facilitate micromovement, which is crucial for maintaining stability during the healing process [14]. Consequently, the results of the compression test in this study reveal that a thickness of 7 mm yields the lowest displacement for both the orthosis and the skin. This finding substantiates that a thickness of 7 mm is optimal for ensuring the stability of the knee orthosis during use, as it demonstrates the lowest displacement and stress levels.

3.2 Effect of 3-Point Bending to VMS and Displacement

In this 3-point bending test, stress distribution was observed primarily at the lateral part of the knee orthosis. This is attributed to the design, which includes a large square edge that induces pressure between the square box and the orthosis body. As illustrated in Table 9, the VMS values for the orthosis and skin show that the highest stress occurs at the lateral end of the 3D-designed orthosis body. For the orthosis, the lowest stress is observed at a thickness of 7 mm, with a VMS of 0.6745 MPa. This is followed by a thickness of 5 mm, which shows a VMS of 1.5028 MPa, and the highest stress is recorded at a thickness of 3 mm, with a VMS of 1.8863 MPa. In contrast, for the skin, the lowest stress is found at a thickness of 3 mm, with a VMS of 2.1403 MPa. This is followed by a thickness of 5 mm, with a VMS of 2.2635 MPa, and the highest stress is at a thickness of 7 mm, with a VMS of 2.2637 MPa.

Table 9. Von Mises Stress of Orthosis and Skin

Thickness	Von Mises Stress (VMS), MPa	
	Orthosis	Skin
3mm	1.8863	2.1403
5mm	1.5028	2.2635
7mm	0.6745	2.2637

According to previous studies, a design must surpass competing designs in terms of yield strength to ensure safety in use. Yield strength is the maximum stress that a material can endure before failure in certain areas when subjected to force. To substantiate this finding, Figures 9 and 10 illustrated the maximum von Mises stress (VMS) on the skin and knee orthosis. Prior research has identified the design with the smallest stress value as the safest for patient use. Consequently, based on the results, a thickness of 7 mm, which exhibited the lowest stress distribution, is recommended as the optimal thickness. This finding supports the conclusion that a 7 mm thickness is the safest and most suitable for further use.

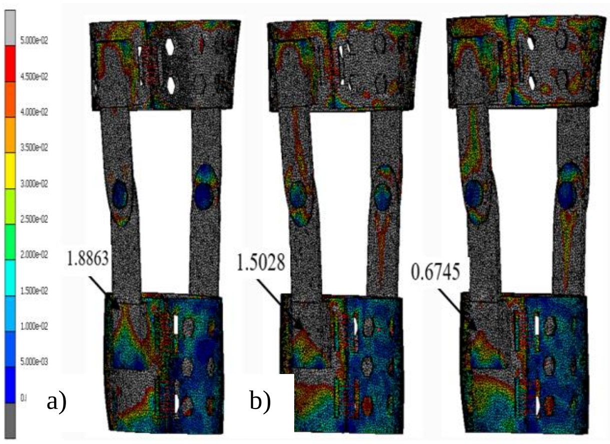

Fig 9. Maximum VMS on Orthosis at different thickness a) 3mm, b) 5mm and c) 7mm respectively

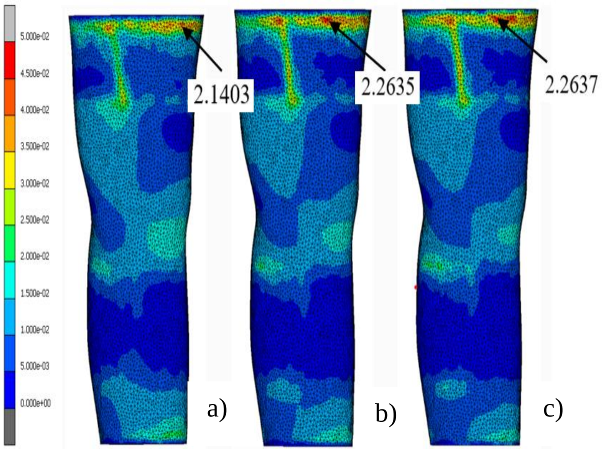

Fig 10. Maximum VMS on Orthosis at different thickness a) 3mm, b) 5mm and c) 7mm respectively

Moreover, Table 10 presented the displacement values for the orthosis and skin. For the orthosis, the lowest displacement was observed at a thickness of 7 mm, with a value of 0.1293 mm, followed by 5 mm with 0.1360 mm, and the highest displacement occurs at 3 mm with 0.2108 mm. For the skin, the lowest displacement was recorded at a thickness of 3 mm, with a value of 1.2358 mm, followed by 7 mm with 1.2370 mm, and the highest displacement was at 5 mm with 1.2422 mm. This report was reinforced by the contour plots in Figures 11 and 12, clearly illustrating that the maximum displacement occurred on the lateral side of both the knee orthosis and the skin. Based on the displacement results, the 7 mm thickness, with a displacement of 0.1293 mm, performs better than the previous work, which only considered a thickness of 5 mm. This suggests that the thickness of the knee orthosis plays a crucial role in ensuring the stability of the design for practical use.

Table 10. Displacement of Orthosis and Skin

Thickness	Displacement (mm)	
	Orthosis	Skin
3mm	0.2108	1.2358
5mm	0.1360	1.2422
7mm	0.1293	1.2370

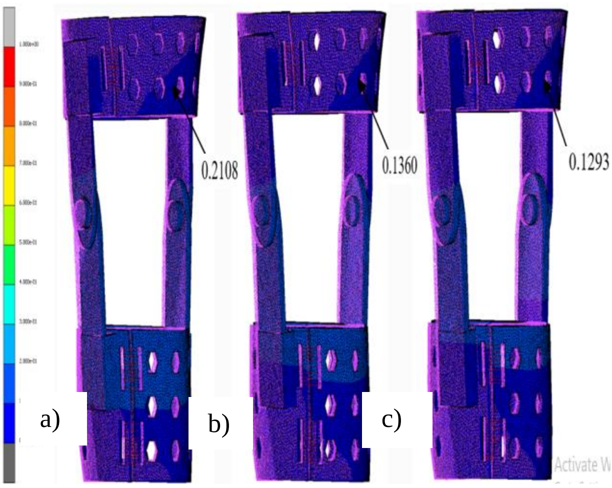

Fig 11. Displacement on Orthosis at different thickness a) 3mm, b) 5mm, c) 7mm respectively.

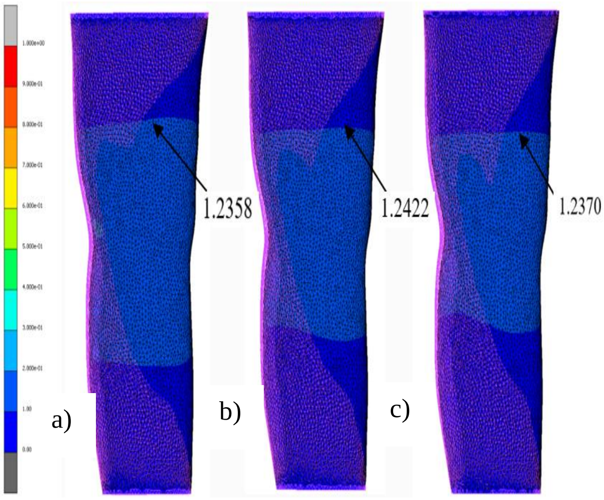

Fig 12 Displacement on Orthosis at different thickness a) 3mm, b) 5mm, c) 7mm respectively.

4. CONCLUSION

In conclusion, the overall results focused on orthosis and VMS to determine the optimal thickness, as the displacement differences between each thickness were minimal. Based on the 3-point bending test results, a thickness of 7 mm exhibited the lowest stress, with a value of 0.6745 MPa, compared to thicknesses of 3 mm and 5 mm. Moreover, previous research indicates that greater orthosis thickness results in lower maximal stress [16]. In addition, this study produces customized knee braces that fit the patient, providing comfort and reducing pain during the healing process. This analysis corroborated that finding which demonstrated that increased thickness enhances structural integrity. Consequently, a thickness of 7 mm is recommended as the best option for knee orthosis design. In this study, no padding was used in the knee orthosis. Hence, applying padding on the interior surface of the knee orthosis will help distribute pressure evenly, provide comfort to the knee and skin, and prevent any irritation or skin scratching. In recent years, more studies have been conducted to analyze the gait pattern of patients wearing knee orthoses, which was not done in this study. Therefore, an analysis of kinematics could provide valuable data to support the knee in real time and enhance its functionality.

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