

DESIGN, DEVELOPMENT, AND EVALUATION OF PROSTHESIS FOR CALCANEOTIBIAL AMPUTATION

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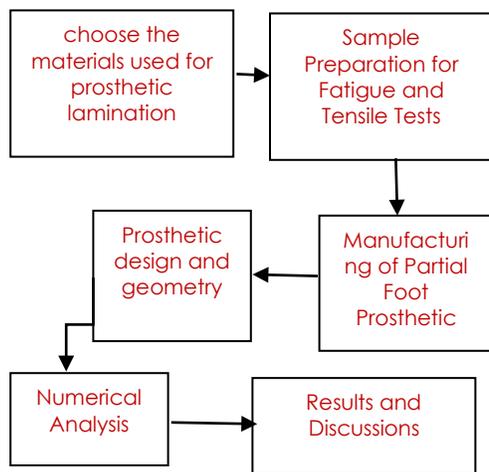
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Graphical abstract



Abstract

The development of durable and safe prosthetic limbs is vital for improving amputees' quality of life. This study aims to enhance the mechanical and fatigue performance of calcaneotibial prostheses using advanced composite materials. Three composite configurations were evaluated and compared to determine their suitability for prosthetic applications. Acrylic resin (Lamination 80:20) served as the matrix material, reinforced with three layering arrangements: (A) four layers of Perlon, (B) four Perlon + four Glass Fiber + four Perlon, and (C) four Perlon + four Carbon Fiber + four Perlon. Mechanical testing was performed to measure yield strength (σ_y), ultimate tensile strength (σ_{ult}), and young's modulus (E). In addition, pressure distribution between the stump and socket was assessed using an F-socket system to evaluate load transfer and user comfort. The findings demonstrated significant improvements with fiber reinforcement. Group C (Carbon Fiber composite) showed a 76% increase in yield strength, an 80% increase in ultimate tensile strength, and a 40% rise in young's modulus compared with Group A (Perlon only). Group B (Glass Fiber composite) exhibited increases of 40%, 71%, and 21%, respectively. Recorded pressures reached 238 kPa in the lateral region and 273 kPa in the posterior region. Safety factor analysis revealed a value of approximately 1.816 for the carbon fiber composite, indicating superior structural integrity. Overall, the 4 Perlon + 4 Carbon Fiber + 4 Perlon configuration provides the best mechanical performance and safety margin for calcaneotibial prosthetic design.

Keywords: Calcaneotibial amputation, pressure stump, composite material, safety factor, FEM

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1.0 INTRODUCTION

A crucial system comprising 28 bones and 33 joints, the foot and ankle are in charge of shock absorption, weight bearing, balance, and ground terrain adaptability. With ankle fractures making up more than 20% of emergency cases, they are frequently the scene of urgent injuries [1]. Treatment is challenging

due to the wide range of causes, which include end-stage osteoarthritis and high intensity trauma. Ankle and foot damage may result in discomfort, loss of function when walking, and difficulty bearing weight [2, 3]. Prosthetic parts, from full limb prosthetics to single bone/joint components, have grown in popularity. The scientific community has thus focused on developing better prosthetic solutions for the feet

and ankles. The most frequent reason for prosthetic device rejection is discomfort from an incorrect fit [4]. Patients must have access to dependable prosthetic devices [5]. Severing the malleoli and the weight-bearing end of the residual leg is part of the ankle disarticulation amputation procedure. The fat pad transfers its stress directly to the distal tibia [6]. Compared to amputations of the upper and midfoot, using dynamic feet at this degree of amputation reduced energy consumption during ambulation [7, 8]. Because a lengthy tibia stump is left behind, this kind of amputation preserves knee function and makes walking easier for patients. To begin, the ankle joint was disarticulated and the malleolar projections were removed [9]. Amputees may have prosthetic limbs to help them walk again after suffering a loss of a limb in a car accident, amputation, or other traumatic event. Amputees may live more easily and appropriately with the support of these therapies, which address their natural demands [10]. Depending on the severity of the amputation, lower extremity prosthesis may replace one or more lower limbs. Individuals with prosthetic feet are better able to modify their stride on their own. An overwhelming number of lower limb amputees are those who have only had part of their foot amputated. The adoption of superior mechanisms and the simulation of true ankle functioning are both impeded by the manufacturing problems, which include limited spacing below the ankle joint [11]. Research by Saif M. Abbas *et al.* [12–14] examined the mechanical and fatigue properties of materials used to make prosthetic sockets, with an emphasis on carbon, glass, or Kevlar, which are thermosetting polymer matrices that include high-performance fibers. M.R. Ismail *et al.* focused on the shank part of prosthesis for below knee amputation patients [15]. Kadhim K. Resan worked on lower limb prosthetics-related elements to provide functionality and support [16, 17]. Ammar and Saif explored using natural or recycled materials like plant fiber composites and sustainable reinforcing fibers like flax, jute, and pineapple fiber [18, 19]. Hamad, Q.A worked on additive manufacturing has made fabrication of prosthetic sockets with regulated weight easier [20]. Yassr. Y. Kahtan studied the numerical analysis of prosthetic socket for lower limb amputation [21, 22]. Numerous researchers have examined the orthotics component utilizing a variety of criteria, such as how to modify the mechanical properties of the materials used in the orthosis portion or how to modify the mechanical representations for its component. Composite materials are therefore the best choice for creating orthosis components. Nonetheless, it was

necessary to look at the properties of composite materials, how they could be modified, and the uses for their components. Subsequently, several researchers investigated how to modify the characteristics of composite materials and how they might be applied in various contexts [23–26]. In this research tensile and fatigue tests were performed on samples of various composite material layers in order to assess the mechanical properties and manufacturing of a prosthetic for calcaneotibial amputation. Additionally, testing was conducted using an F-socket in order to assess the pressures between the inner walls of the socket and the stump. To determine the fatigue safety factor, the prosthesis was analyzed using ANSYS Workbench 17.2.

Higher tensile strength and better fatigue performance are two examples of the increased mechanical qualities this study exhibits in comparison to earlier research. More dependable and long-lasting composite structures are the result of these improvements, which are ascribed to better layer orientation, enhanced manufacturing processes, and optimum material choices.

2.0 EXPERIMENTAL PROCEDURES

This publication details the use of carbon fiber, fiber glass, Perlon stockinet white, lamination resin 80:20, hardening powder, and polyvinyl alcohol PVA for the lamination of prosthetics for calcaneotibial amputation.

2.1 Materials Used for Prosthetic Lamination

Rectangular Jepson mold with dimension 12*18*24 cm³ with vacuum pressure system as shown in Figure 1 was rectified to manufacturing the samples of different layers prosthesis material to evaluate the mechanical properties.



Figure 1 Suction pressure system with Jepson mold

The tensile universal instrument machine (testometric) and fatigue test device was used for flat specimen material as shown in Figures 2 and 3.



Figure 2 Tensile Test Device

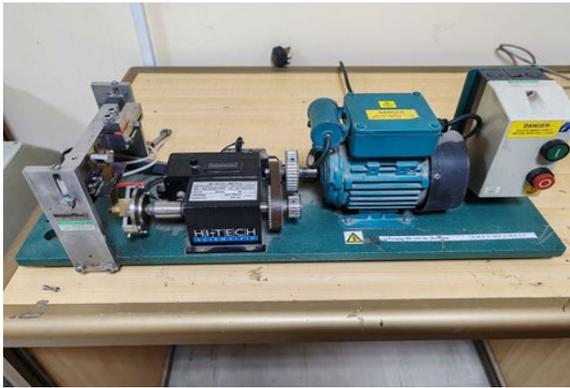


Figure 3 Fatigue Device

2.2 Sample Preparation for Fatigue and Tensile Tests

Position the rectangular mold on the vacuum pressure system stand. As suggested by the overlaying lay-up, use the Perlon, carbon and glass fibers. Mix the hardener with the lamination of 80:20 polyurethane overlay resin. At room temperature, maintain a steady vacuum and pressure of about 20 to 40 KPa until the laminations cool down and then trimmed to fit the sample dimensions.

The samples were made for each group in accordance with ASTM D638 type I for the tensile test [27], and the thickness varied depending on the kind of layup. Figure 4 displays the tensile sample's dimensions. For each lamina, eight specimens were employed in the fatigue test. According to the fatigue device test, these samples' length and breadth were 100 mm and 10 mm, respectively, while their thickness varied according to the kind of layup. The size of these specimens was shown in Figure 5.

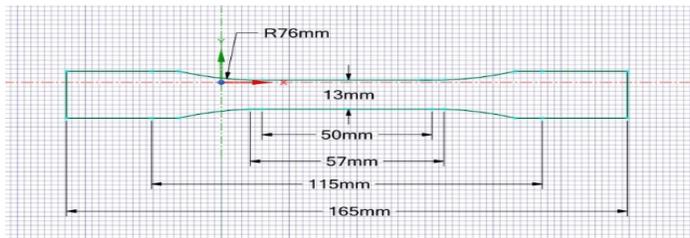


Figure 4 The Dimensions of Tensile Specimen



Figure 5 The Shape of Fatigue Specimen

2.3 Case Study and F -Socket Testing

In the study male participant, who was 53 years old, had a calcaneotibial amputation—a partial amputation of the left foot—done 10 years ago after a car accident. This study was conducted in accordance with the ethical approval granted by Al-Nahrain University's College of Engineering (02/2020). The results are shown in figure 6. Table 1 displays the amputee patient's demographic information together with specifics on their prosthetic limb. The Mat Scan sensor type, which is more appropriate for this sort of dynamic load, was used to conduct Interface Pressure at the P&O department labs at Al-Nahrain University, as shown in Figure 6.

Table 1 The participant's demographic characteristics.

| Patients' characteristics | Component |
|-----------------------------|------------------------------------|
| Age | 53 years |
| Height | 178 CM |
| Weight | 94Kg |
| Duration of amputation | 10 years |
| Type and side of amputation | Left Partial foot (Calcaneotibial) |
| Causes | Car accident |

A pressure-sensing platform called the MatScan system is used to examine the distribution of pressure on the stump when walking or standing. It is made up of a thin mat with many pressure sensors placed in it that record data in real time when the patient stands or walks on it. In order to construct and evaluate prosthetic limbs, it is essential to evaluate gait patterns, balance, and load distribution. The sensor can direct modifications for increased comfort and performance and offers insightful input on how the prosthesis interacts with the user's body.



Figure 6 Patient with MatScan sensor

2.4 Manufacturing of Partial Foot Prosthetic

At the Al Ibtisam Center for Prosthetic and Orthotic, partial foot prostheses for patients who had their feet amputated were measured, manufactured, and aligned. The following is a summary of the production process:

1. Measuring: Stump circumferences, medio-lateral diameter at the malleolus and Calcaneous, amputee's length, normal foot length, and patient shoe heel height.
2. Managing Casting
3. Cast and Rectification
4. The Soft and hard Lamination Socket Fabrication
5. Finishing and Trimming for prosthesis.

3.0 NUMERICAL ANALYSIS

Use of finite element analysis allowed this research to evaluate the prosthesis's safety factor, total deformation, and stresses after calcaneotibial amputation. Figure 7 displays the results of the ANSYS software's measurement and simulation of the prosthetic geometry. Three sets of testing on composite materials were used to create the mechanical properties of the socket, which were then used to define the mechanical characteristics of the model. The mechanical properties of the three groups were utilized to evaluate the strains produced by walking loads and the weight on the prosthesis. The model used to model the prosthesis was a ten-node tetrahedral with 3414 elements and 6743 nodes, of the SOLID187 element type.

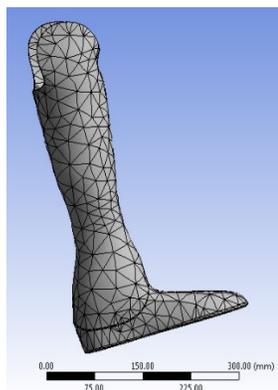


Figure 7 Prosthetic elements

3.1 Prosthetic Geometry

The prosthesis was evaluated using the ANSYS program, which measured and entered the geometry in line with the mechanical properties of the materials used in its construction. We used the mechanical properties of three different material groups to assess the stresses caused by walking loads and body weight in the prosthesis.

3.2 Boundary Conditions

In Figure 8, we can see the prosthesis's applied forces and the fixed support boundary conditions. Understanding the prosthetic foot's touch with the floor in a realistic setting is a crucial boundary necessity. Subjected to test pressures from the patient's foot and the F-socket. By establishing these limits, we can examine the prosthetic foot's performance in a wide variety of settings, which is essential for determining its overall effectiveness.

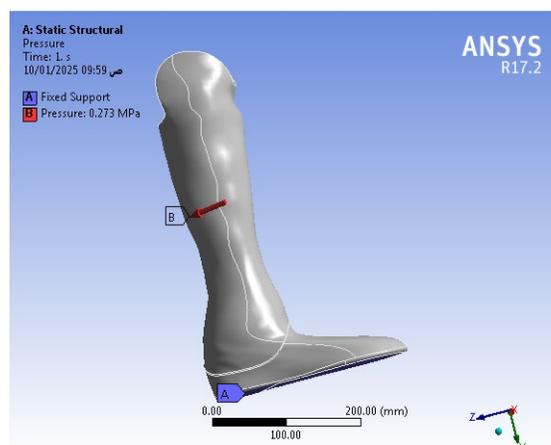


Figure 8 Prosthetic geometry

4.0 RESULTS AND DISCUSSIONS

4.1 Tensile Test Results

As shown in Table 2 and Figure 9, the tensile test measurable properties for each group are described. Pictured in Figure 8 is the stress and strain curve for every single laminate. The findings clearly show that compared to (Group A), (E) has a 21% rise in yield strength, (U) an ultimate tensile strength increase of around 71%, and (G) a constant Perlon increase of 40% when added to (Group B). In contrast to Group A's results, Group C found that adding four layers of carbon fiber with constant Perlon enhanced yield strength by 76%, ultimate tensile strength by around 80%, and E by 40%. Samples improve mechanical qualities; for example, carbon fibers and glass have better mechanical properties than Perlon. The mechanical characteristics of group C are 32% stronger and have an ultimate tensile strength that is over 23% more than those of Sattar MA [28].

Table 2 Mechanical properties of the three groups

| Groups | Total layers | Thickness (mm) | σ_y | σ_{ult} | E |
|---|--------------|----------------|------------|----------------|-------|
| | | | MPa | MPa | GPa |
| Group A (8perlon) | 8 | 3.6 | 42.897 | 43 | 1.138 |
| Group B (4perlon – 4 glass fiber-4perlon) | 12 | 4.5 | 71 | 147 | 1.45 |
| Group C (4perlon – 4 carbon fiber-4perlon) | 12 | 4.2 | 180 | 210 | 1.9 |

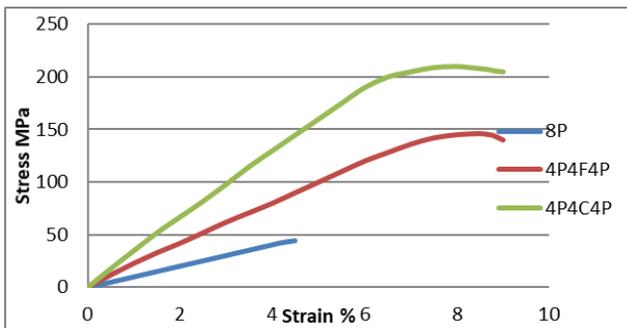


Figure 9 Mechanical properties curve

4.2 The Results of Fatigue Test

If a specimen breaks at different stress levels, it might be because of weariness. According to the data acquired by the fatigue tester, the specimens cracked at a certain number of cycles. All of the laminate samples' S-N curves are shown in Figure 10.

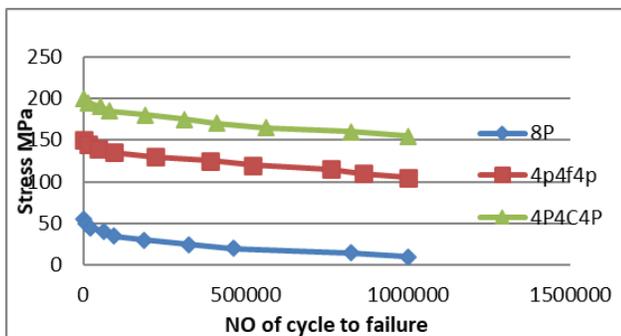


Figure 10 Stress- Number of cycles for three groups

4.3 Interface Pressure Result

The F-Socket sensor might be used to monitor the pressure at the junction of the patient's natural socket and the prosthetic one. The locations of the sensors on the stump were as shown in Figures 11–14: front, side, rear, and center. You can find more details about the socket pressure sensors' locations and the data they collect in Table 3. The pressure in the rear

region is 273 KPa, which is higher than the pressure on the sides, which is 238 KPa. This is due to the fact that as the patient walks, the medial and anterior tibia are relieved of pressure by increased activity in the lateral and posterior muscles.

Table 3 pressure at four sides of socket.

| Socket Direction | Front of socket | left of socket | Back of socket | Right of the socket |
|------------------------|-----------------|----------------|----------------|---------------------|
| Interface Pressure kPa | 150 | 238 | 273 | 168 |

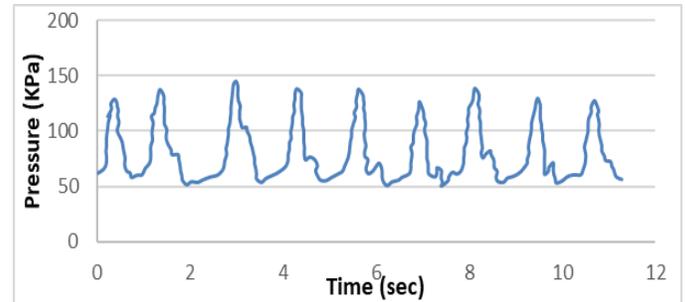


Figure 11 Anterior Socket Region Interface Pressure.

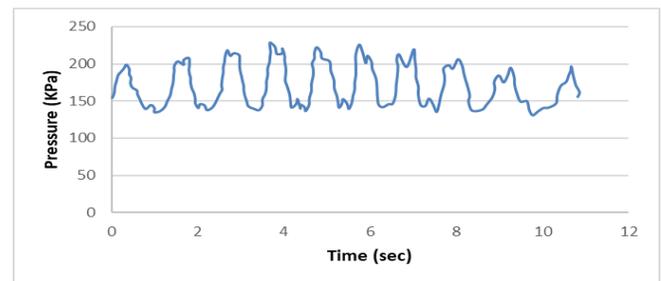


Figure 12 Lateral Socket Region Interface Pressure.

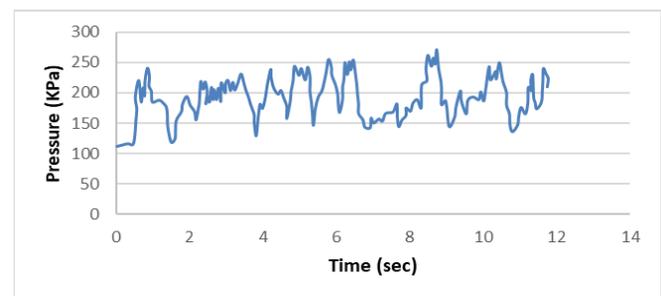


Figure 13 Posterior Socket Region Interface Pressure.

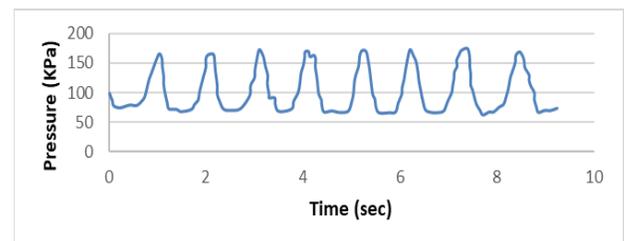


Figure 14 Medial Socket Region Interface Pressure.

4.4 The Results of Fatigue Test

To determine the equivalent stress, total deformation, and Safety factor (S.F.) of fatigue, the patient's Calcaneotibial Prosthesis model was measured and analyzed using finite element software. In Figures 15, 16, and 17, the S.F. for each group of the ankle disarticulation socket model is displayed, along with the various material parameters that affect the Von-Mises stress findings. The Von-Mises stresses for each group are shown in Figures 18, 19, and 20. Figures 21, 22, and 23 show the total deformation of all three kinds of lamination composites. It is safe to use a number of roughly 1.816 for the S.F. of 4Perlon, 4carbon fiber, and 4Perlon layers in design [29]. Table 4 display the summary of ANSYS analysis.

Table 4 Summary of ANSYS analysis

| Group | Von-Mises stress (MPa) | Total deformation (mm) | Safety Factor |
|-------|------------------------|------------------------|---------------|
| A | 130.89 | 0.6625 | 0.658 |
| B | 82.944 | 0.419 | 1.039 |
| C | 47.465 | 0.240 | 1.816 |

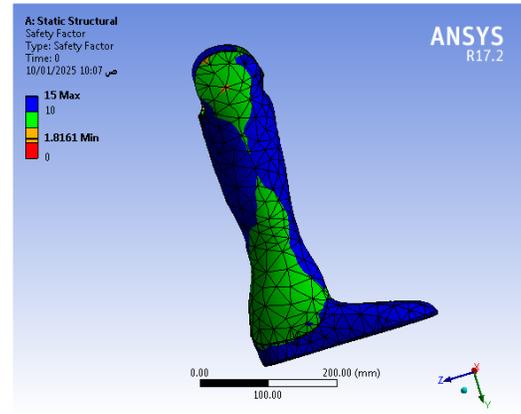


Figure 17 The Safety factor for Group C

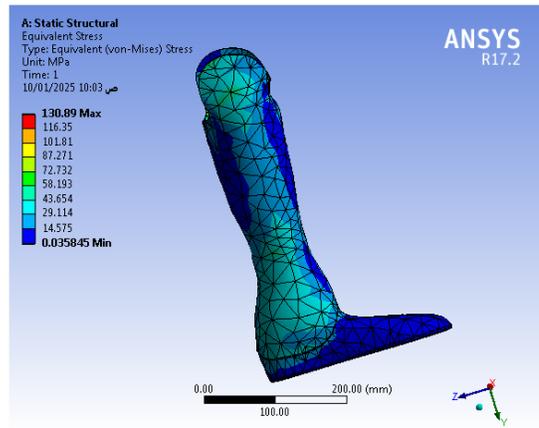


Figure 18 The Von-Mises stress for Group A

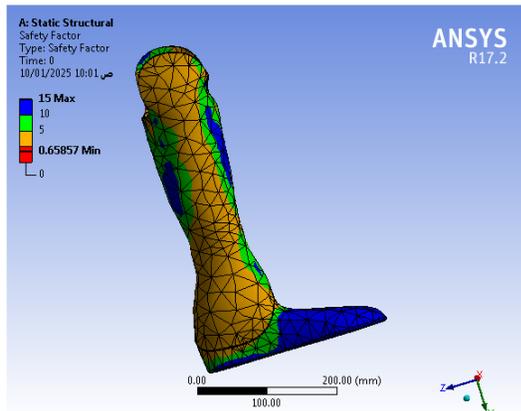


Figure 15 The Safety factor for Group A

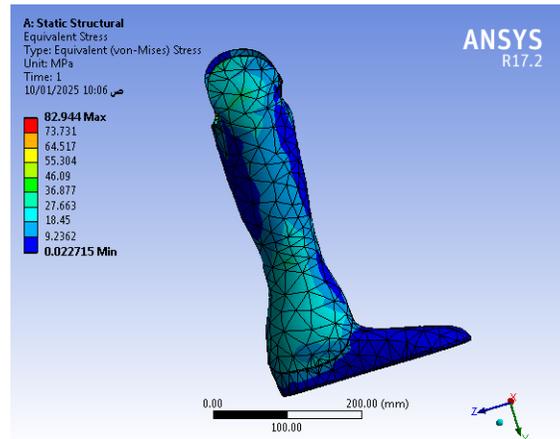


Figure 19 The Von-Mises stress for Group B

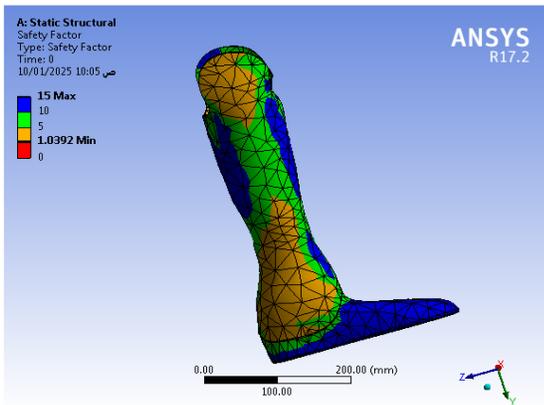


Figure 16 The Safety factor for Group B

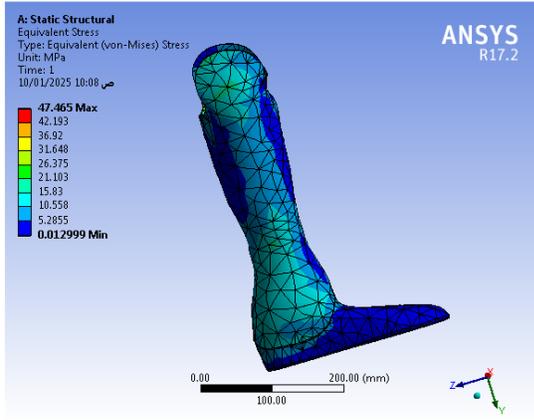


Figure 20 The Von-Mises stress for Group C

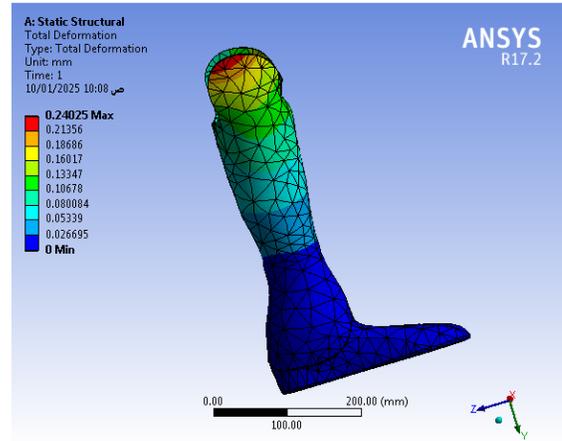


Figure 23 The total deformation for Group C

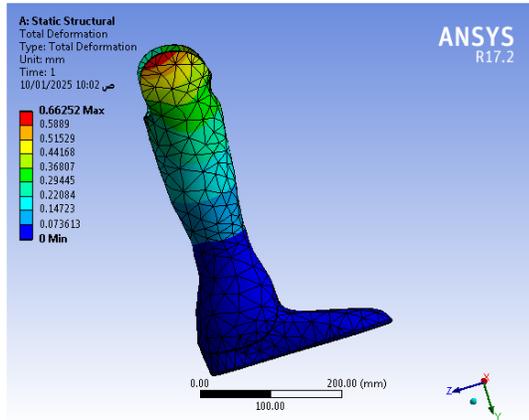


Figure 21 The total deformation for Group A

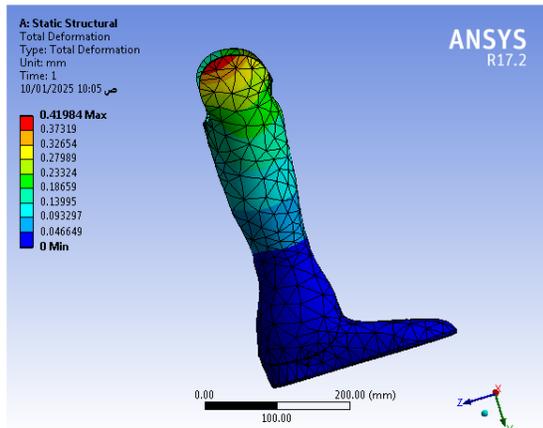


Figure 22 The total deformation for Group B

5.0 CONCLUSIONS

The mechanical parameters (σ_y , σ_{ult} , and E) of group (C) differ considerably from group (A) when four layers of carbon fiber with constant Perlon are added. Yield strength (σ_y) increases by 76%, ultimate tensile strength (σ_{ult}) increases by around 80%, and E increases by 40%. Comparing group (B) to group (A), the results show that adding glass fibers lead to increases yield strength by 40%, ultimate tensile strength by around 71%, and E by 21%.

The kind of composite material and the applied load determine the prosthesis' lifespan. The endurance limit stresses (σ_e) of the (4P4C4P) layer lamination is significantly longer than those of the other laminations. The patient who wears partial foot prosthesis has a longer lifespan.

The patient may lessen the strain on their tibia by increasing the contraction of their lateral and posterior muscles as they move. The reason for this is because the interface pressures are higher in the posterior (273 KPa) and lateral (238 KPa) areas of the socket.

Compared to laminations containing glass fibers, the fatigue stress-free life (S.F.) for (4Perlon + 4carbon fiber + 4perlon) was 1.816, making it a more acceptable and safe material for prosthetics.

In order to further improve mechanical performance, the authors may investigate the usage of sophisticated composite materials in future research, such as nanomaterials or hybrid fiber reinforcements. More resilient and versatile prosthetic limb designs would also result from improving the laminate architecture and carrying out long-term durability tests under actual loading scenarios.

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Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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