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Calf-corset patella tendon weightbearing orthosis modeling and manufacturing

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ABSTRACT

It has proven to be a difficult task to design and provide an ankle-foot orthosis (AFO) that enables the client to walk securely and comfortably without bearing weight through the lower leg and foot skeletal parts. Although it is widely acknowledged that the patella tendon weightbearing (PTB) ankle-loot orthosis only partially unweights the lower tibia, ankle, and foot, it is nevertheless frequently prescribed for this purpose. In this work, two ankle foot orthoses of the AFO PTB type of Calf-corset were manufactured using a vacuum molding technique based on two kinds of materials as composite material reinforcement. The first AFO material was based on 8 layers of Perlon, while the second was based on 8 layers of fiberglass. A tensile and a fatigue test had been used to investigate the mechanical properties of the AFOs' material. The findings revealed that the yield strength (Ϭy) is 42.897 MPa, the tensile strength (Ϭult) for Perlon is 42.993 MPa, and the elongation at break is 1.138 mm, whereas fiber glass has a tensile strength (Ϭult), yield strength (Ϭy), and elongation at break of 224 MPa, 170 MPa, and 2.17 mm, respectively. Additionally, the gait cycle and the collected data on distributed pressure are measured using force plates and F-socket devices. The patellar tendon-bearing model was constructed using the SolidWorks software tool. In addition, for the fiber glass and Perlon PTB orthosis models, the total deformation, safety factor of fatigue, and Von-Mises stress were calculated using the FEM (ANSYS). The safety factor of fatigue values for the material PTBO with 8 layers of fiber glass was 2.2895, and for 8 layers of Perlon, it was 0.083515.

Keywords: tensile, fatigue, perlon, fiber glass, modeling; gait analysis, calf-corset PTB orthosis.

INTRODUCTION

In order to prevent or encourage movement, orthoses are external devices that support, align, and hold bodily components in place. Orthotics can help to improve the function of dynamic body parts while also preventing or correcting deformation. Controlling, correcting, enabling, avoiding, or allowing motions of the extremities or spine are all possible uses for orthoses. Orthotics can also help to relieve muscle stiffness by acting as a substitute for weak or paralyzed muscles. These goals do not have to be mutually exclusive. Many clinical settings necessitate the utilization of these functions in tandem to provide the best possible patient outcome [1]. Due to its high strength-to-weight ratio criterion, PTBO parts are typically made of composite materials [2]. As a result, the compound materials were updated with time through the addition of new components and changing the number of laminated layers using a dynamic plantar pressure system analysis [3]. Saif M. Abbas et al. [4] investigated the effects of unloading in the PTB model on five individuals in good health. The same configuration was employed to investigate a technique for enhancing the impact of the PTB. The leg component of the cast is the main contributor to the 30% reduction in body weight that the traditional partial weight-bearing (PTB) approach achieves, according to the researchers. The unloading effects were 60%, 80%, and 98%

when the depth of the vacuum under the foot inside the PTB cast was 1 cm, 2 cm, and 3 cm, respectively. Saif M. Abbas et al. [5] used fiber glass as a sort of support in compound material when constructing ankle foot orthoses (AFO) with metal valve PTB. They have conducted the tests of fatigue and tensile. The findings show that: Fiberglass has an ultimate tensile strength (σult) of 224 MPa, yield strength (σy) of 170 MPa, and an elongation of 1.9 mm at break. They utilized force plate and F-socket devices to identify the pressure distribution and gait cycle data for 29-year-old patients with a height of 185cm and 83 kg of weight. They expected a 5% heel contact time with no PTBO and a 59% heel contact time when utilizing fiber glass. The stress, fatigue safety factor, and overall deformation of the PTBO model of fiber class were measured using SolidWorks software and the Finite Element Method (ANSYS version 18.2). The ANSYS results show the advantage of the fatigue safety factor (1.1492). Many researchers have investigated the orthotics part using many factors, such as how to adjust the mechanical representations for its component [6–11] or to change the mechanical properties of the orthosis portion's materials [12–18]. As a result, composite materials are the ideal materials for making orthosis parts. However, there was a need to investigate the composite material features and how they may be adjusted, as well as the applications for their materials. Then, numerous researchers looked into ways to change the properties of composite materials and how they may be used in diverse applications. Metals (long-lasting but unattractive and weighty), plastic (thermoplastic, thermoset, etc.), and fiber (carbon fiber, fiber glass, etc.) are items used in orthosis production, and they are normally used in combination. In this study Fiber glass and Perlon were utilized to make two types of patellar tendon-bearing orthotics.

MATERIALS AND TOOLS OF THE MANUFACTURING PROCESS

The practical part is required work for an engineering problem, and the experimental portion has yielded reliable data for mechanical representations of the problem, which can be based on the behavior analysis of its components. Mechanical property evaluations and representations of the PTB orthotics component under various load levels were part of the experimental study. As a result, the manufacturing and testing of composite materials for orthosis components were incorporated into their parts. Following that, the steps for producing and testing materials for orthosis parts were demonstrated.

Materials

The PTBO materials required for this study's lamination are listed below, as shown in Figure 1:

- white Perlon stockinet (8 layers);
- fiber glass (8 layers) and lamination resins 80:20 polyurethane;
- powder of hardening;
- to prepare the test samples, a polyvinylcohol PVA bag is utilized in conjunction with a vacuum system;
- Jepson's materials.

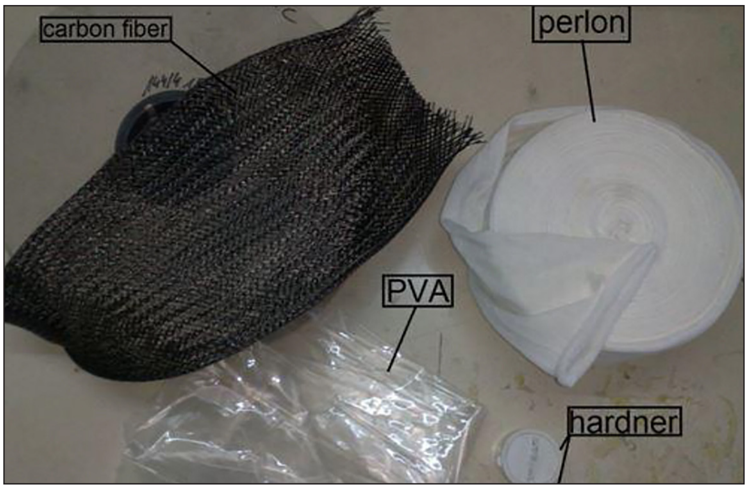


Figure 1. Materials used in PTBO

Sample preparation for tensile and fatigue evaluations

The methodology employed in the preparation of samples for both tensile and fatigue testing is outlined as follows:

1. Place the rectangular mold on the platform of the vacuum pressure system. As the overlying layup indicates, start with the fiber glass stockinet and then move on to the Perlon.
2. Combine the hardener with the 80:20 polyurethane overlay resin.
3. It is necessary to uphold a consistent state of vacuum at the prevailing temperature, while ensuring that the pressure remains within the range of 30-60 kilopascals. Once the laminations have undergone cold-cutting to match the dimensions of the sample.

For the tensile test, ASTM D638 type I laminated three samples was adopted. Figure 2 shows the dimensions of the tensile sample. Furthermore, a total of eight specimens are utilized to assess fatigue representations. The fatigue device test indicates that these samples have a length of 100 mm and a width of 10 mm. The thickness of the laminate varies depending on its nature, as illustrated in Figure 3.

Manufacturing process

The following is a summary of the Calf-corset PTB orthotic manufacturing:

- using the laminating stand to mount the positive mould;
- pulls the outer (PVA) bag while putting the (8 perlon) layers in place;
- combining the Orthocryl lamination resin with the hardener (800–900 mL resin + 2–3% hardener). In the PVA bag on the outside, the resulting matrix mixture is evenly spread;
- while maintaining a consistent vacuum, precisely trim the following layer of material into the desired dimensions of a PTBO and affix Velcro fasteners at the knee area;
- when cutting the orthosis shape, begin by refining the edges and trim lines.

By replicating the aforementioned methods for PTBO manufacture, but utilizing fiber glass material. The PTB orthosis exhibits impeccable alignment and biomechanical congruity. Determine the horizontal alignment of the ankle joint, and subsequently instruct the patient to wear the device and walk in order to evaluate the correction of the deformity. Figure 4 illustrates the Calf-corset PTBO. Then, using the F-socket and gait cycle, assess patellar tendon bearing.

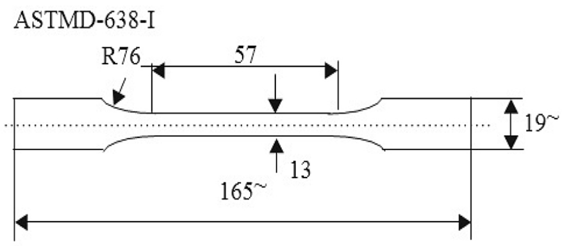


Figure 2. The dimensions of the tensile specimen as specified by ASTM D638 [19], [20]

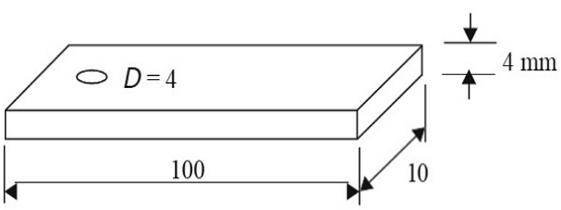


Figure 3. Measurements of fatigue specimens

Figure 4. Calf-corset PTBO

Where, as shown in Figure 5, the Interface pressure test using a sensor type (Mat Scan) for a patient wearing a Calf-corset PTBO orthosis and suffering from left ankle and foot discomfort with an age of 23 years, the height of 154 cm, and weight of 65 kg is adequate for this sort of dynamic load.

IMPLEMENTATION WORK

Can be dividing the Implementation work into two divisions which are:
1. Experimental work.
2. Programing and simulation work.

Experimental work

It's including: Tensile results, Fatigue test results, Gait analysis with PTBO results and Interface pressure results.

Tensile properties results

The anticipated mechanical properties of the laminations utilized are presented in Table 1. The stress-strain curve of perlon, together with the stress-strain curve of one of the fiber glass lamination samples, is illustrated in Figure 6.

When compared to Polypropylene the glass fiber composite and perlon composites' (Ϭult), (Ϭy), and modulus of elasticity were enhanced by more than 81 percent, 75 percent, and 103 percent, respectively.

Fatigue test results

The fatigue test results for lamination samples are presented in Figure 7. When a flat specimen is fractured under periodic loading, it can fail due to fatigue failure. The fatigue tester machine's results were used to determine the number of times the specimens were cracked. Perlon 8 can be classified as a composite material. Under conditions of consistent temperatures, it is observed that as the failure stresses decrease, there is an increase in the number of cycles required to reach failure. Under conditions of thermal stability, failure stresses exhibit a decreasing trend, whereas the necessary number of cycles to induce failure demonstrates an increasing pattern.

Gait analysis with PTBO results /force plate

Figure 8 shows a patient walking with and without PTBO on a force plate device. The biomechanical impacts on the leg when walking and standing generate the ground response force (GRF). This force is distributed under the

Figure 5. Patient with Calf-corset PTBO

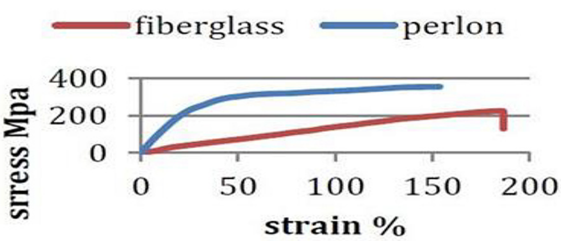


Figure 6. One sample of reinforced composite stress-strain curves for each lamination

Table 1. Mechanical characteristics of composite materials

PTBO material type with the total number of layers	Thickens (mm)	Ϭy (MPa)	Ϭult (MPa)	E (GPa)
8-layer composite perlon	3.2	42.897	42.993	1.138
8-layer composite fiber glass	4.2	170	224	2.17
Polyproylene	4	23	28-41	0.9

sole of the foot as a result of the patient's stride while walking over a fixed plate. The test is divided into two parts: walking before and after the PTBO is worn. Table 2 and Table 3 shows the gait and gait cycle tables for patients who were not wearing the PTBO. Figures 9 and 10 demonstrate the force and pressure distribution created under the sole as a result of the patient's gait for two feet. The patient's right foot had a distinct outcome compared to the left foot. Tables 4, 5, and 6 exhibit the gait table and gait cycle table individually for individuals with PTBO findings. The distribution of force and pressure generated by the patient's gait for both feet are illustrated in Figures 11 and 12. The basic metrics provide a characterization of the gait cycle behavior of patients utilizing metal PTBO based on the average data for one complete gait cycle from heel-to-heel strike (Figure 13 and 14).

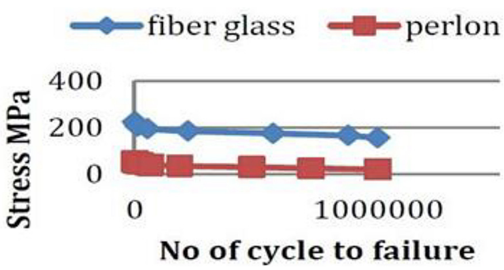


Figure 7. S-N curve for each lamination

Table 2. Patient Gait table without wear PTBO

Gait table	Patient without PTBO
Strike number	9
Cadence (steps/min)	70.8
Duration of Gait (seconds)	4.24
Gait distance (cm)	241.5
Velocity of Gait (cm/sec)	57

Table 4. Patient Gait table wearing PTBO

Gait table	Patient with PTB
Strike number	9
Cadence (steps/min)	56.3
Duration of Gait (seconds)	5.33
Distance of Gait (cm)	171.8
Velocity of Gait (cm/sec)	32.3

Table 3. Patient Gait cycle without PTBO

Table of gait cycles (s)		Patient with PTB	
Parameter	Left	Right	Difference
Time of Gait cycle	1.66	2.75	1.09
Duration of stance	0.83	1.14	0.32
Initial double support time	0.27	0.02	-0.25
Terminal dual assistance duration	0.02	0.27	0.25
Time for total double support	0.30	0.30	0.00
Time of heel contact	0.24	0.83	0.60
Foot flat time	0.03	0.14	0.10
Midstance time	0.09	1.22	1.13

Figure 8. The patient with and without PTBO

Table 5. Gait cycle for the patient with PTBO

Gait cycle table (s)	Patient without PTB		
	Left	Right	Difference
Gait cycle time	1.2	1.31	-0.11
Duration of stance	1.1	0.94	-0.16
Initial double support time	0.15	0.18	0.02
Terminal dual assistance duration	0.18	0.15	-0.02
Total double support time	0.33	0.33	0.00
Time of heel contact	0.67	0.67	0.00
Foot flat time	0.18	0.30	0.12
Midstance time	0.45	0.50	0.04

Table 6. Comparison of step-stride for the case study

Step-stride table	Patient			
	Without PTB		With PTB	
	Left	Right	Left	Right
Step time (sec)	0.73	1.03	0.96	1.22
Step length (cm)	48.6	47.9	41.1	23.6
Step width (m)	19	18.4	21.8	19.6
Velocity step (cm/sec)	67.1	46.5	42.6	19.4
Max. force (N)	33.58	21.51	24.51	26.8
Max. peak pressure (KPA)	151	133	356	204
Foot angle (degree)	7	3	11	-3

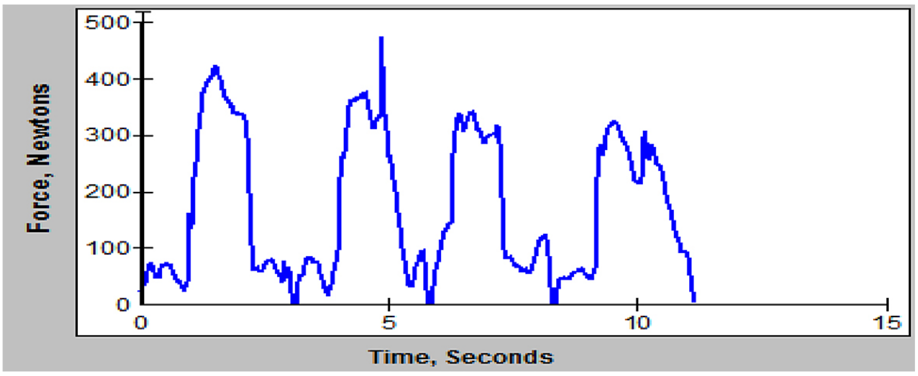


Figure 9. Force vs. time without PTBO

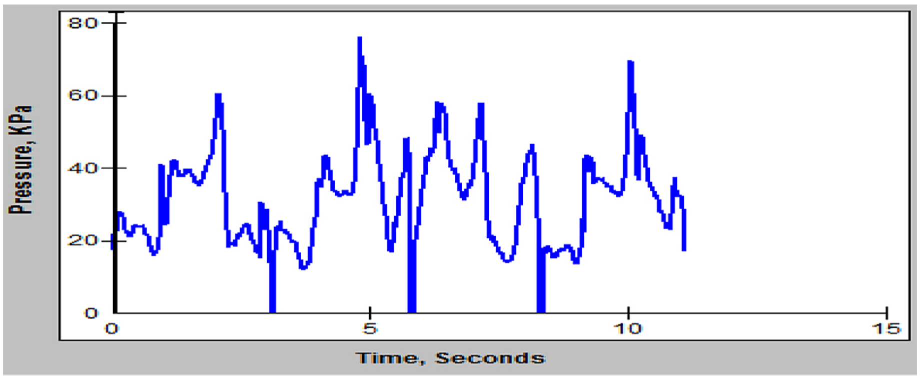


Figure 10. Pressure and time without PTBO perlon

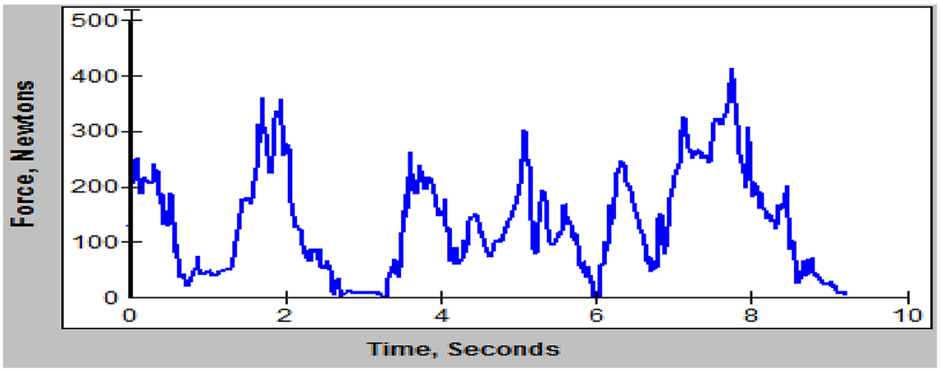


Figure 11. Force and time with PTBO

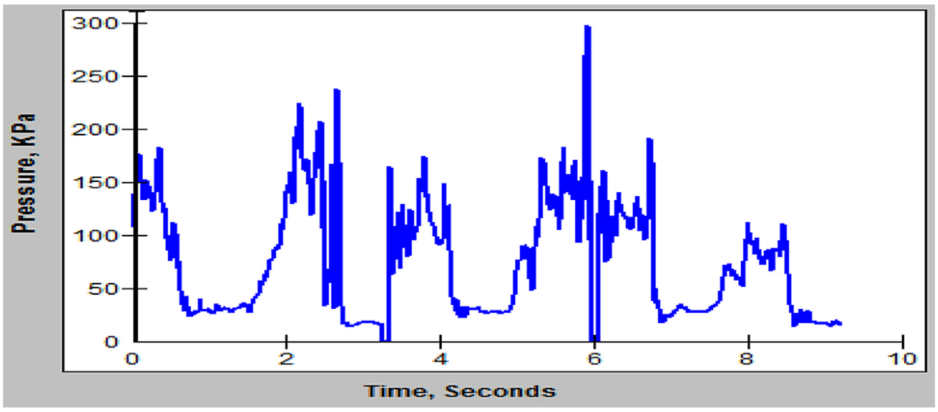


Figure 12. Pressure and time with PTBO

Result of interface pressure

The F-Socket sensor can measure the pressure at the interface between the patient's stump and the socket (Table 7). To measure the applied pressure curve (F-Scan), computer software runs the sensor. The PTB-wearing leg of the patient was alternately weighted with the calf. The maximum pressure measured by the sensor, which was placed on the stump's lateral region, was 332 KPa. Only when the patients and PTB made contact with the calf area during the gait cycle were the pressures taken into account. The information was normalized to a whole gait cycle. The pressure patients experienced during weight acceptance varied, as Figure 15 illustrates.

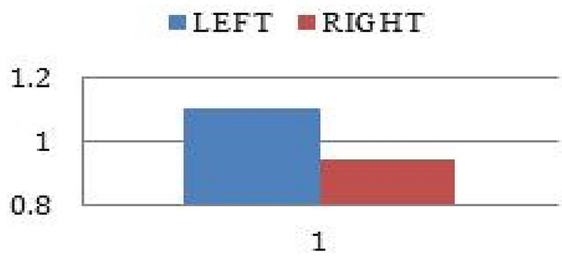


Figure 13. Duration of stance without the use of PTBO

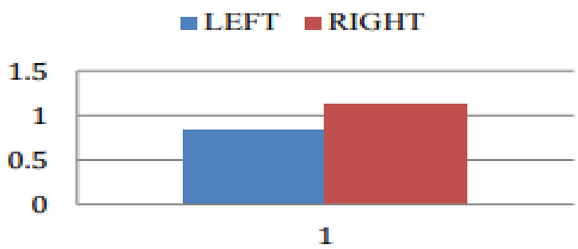
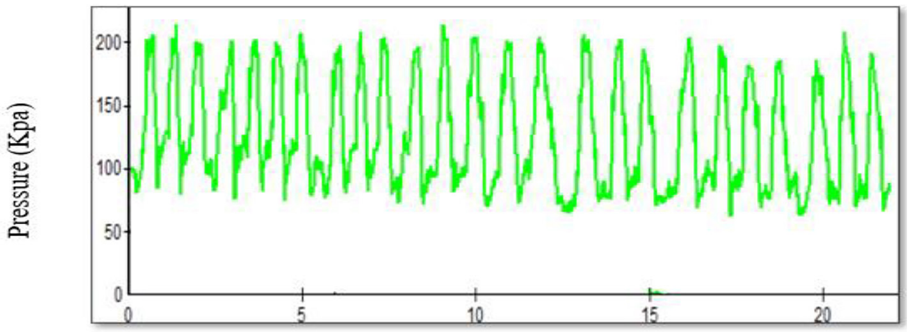


Figure 14. Duration of stance with the use of PTBO

Programing and simulation work

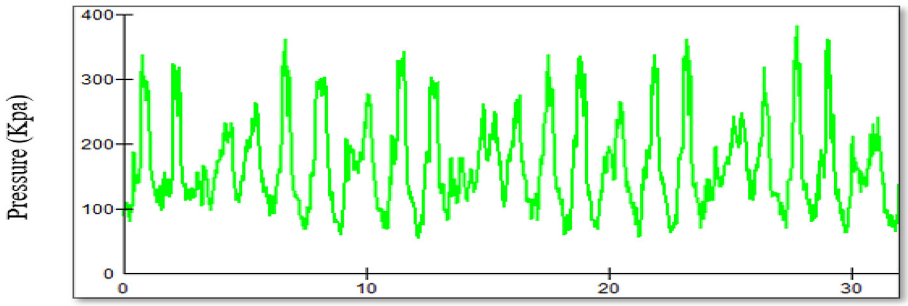
Modeling and empirical analysis results

The PTB orthotic is designed, as seen in Figure 16. To demonstrate the impact of stress performance on a structure element, the numerical tool ANSYS Workbench 18.2 was utilized. FEM software was used to look at the PTBO patient models and figure out the Von-Mises stress, total deformation, and fatigue safety factor.



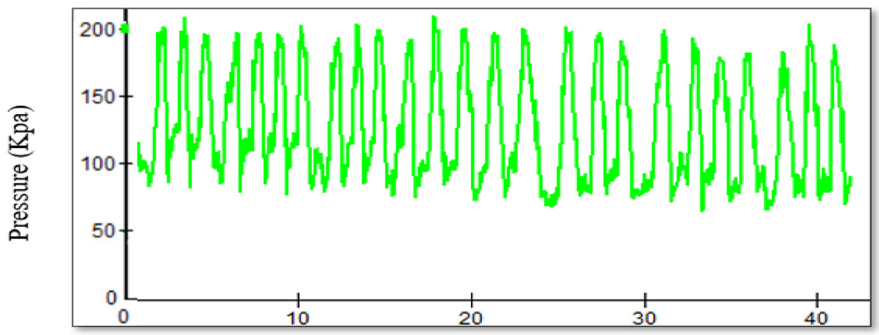
Time (s)

Region (1)



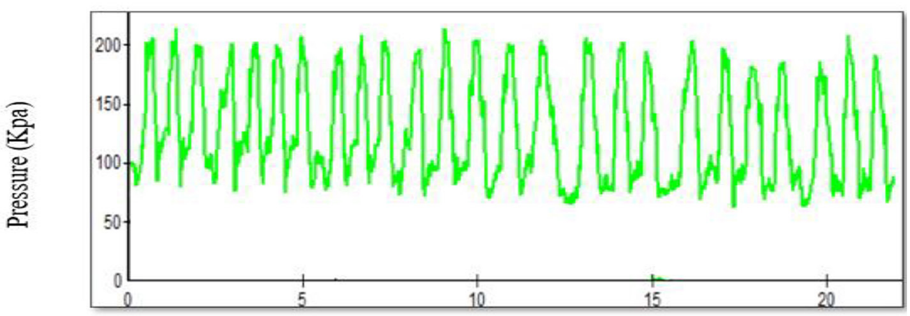
Time (s)

Region (2)



Time (s)

Region (3)



Time (s)

Region (4)

Figure 15. Pressure vs. time percentage at the four regions for patient

Table 7. Values of interface pressure and locations in the socket

Pressure value (kPa)	Location
211	Anterior
332	Lateral
230	Medial
210	Posterior

Equivalent stress (Von-Mises), total deformation and fatigue factor of Safety results

The results illustrate the procedure of measuring and estimating Equivalent stresses, Total deformation, and protection factor.

Equivalent stress (Von-Mises)

Changes in material properties have an impact on the results of Von Mises stress. Figures 17 and 18 show the many types of lamination composites. Perlon and fiber glass had maximum stresses of 119.74 MPa and 4.3677 MPa, respectively.

Total deformation

Figures 19 and 20 depict the utmost distortion observed in each variant of lamination composite consisting of 8 layers of perlon. The overall distortion of 8 layers perlon is 193.33 mm, while the total deformation of 8 layers fiber glass is 5.309 mm, according to the analysis method.

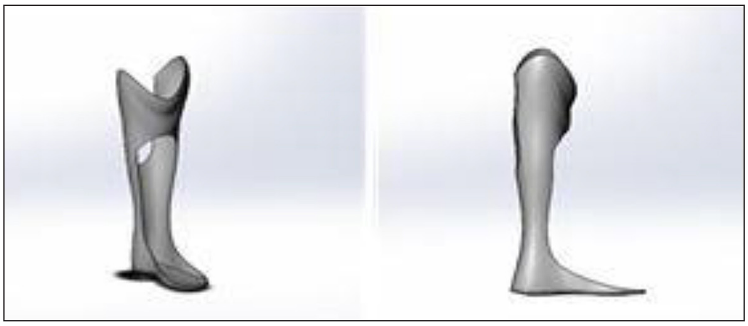


Figure 16. 3-D modeling of Calf-corset PTBO

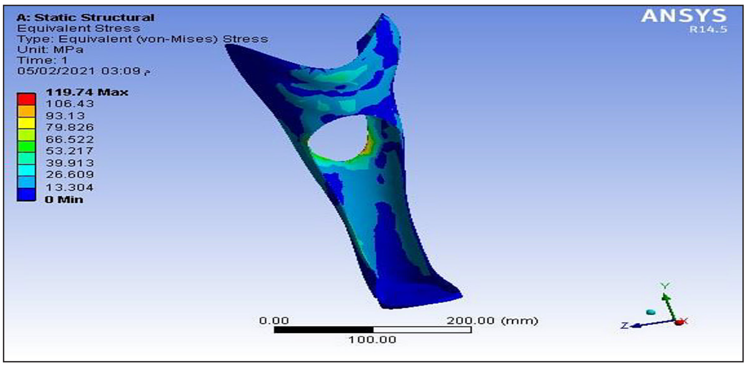


Figure 17. Equivalent stress (Von-Mises) for perlon

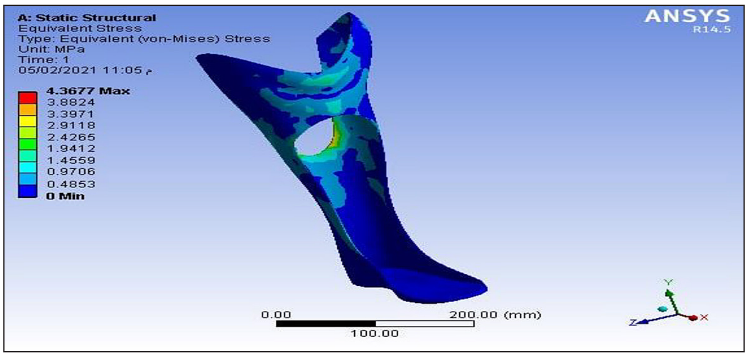


Figure 18. Equivalent stress (Von-Mises) for fiber glass

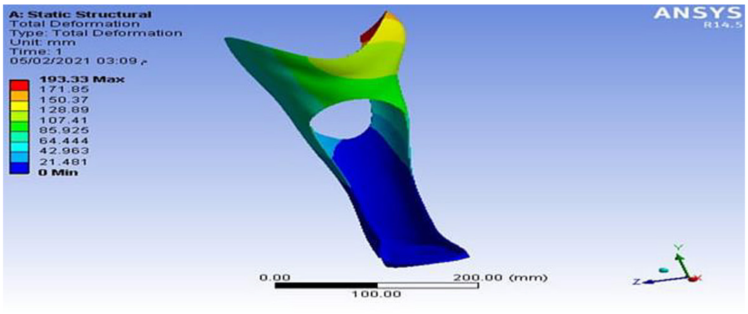


Figure 19. Total deformation perlon

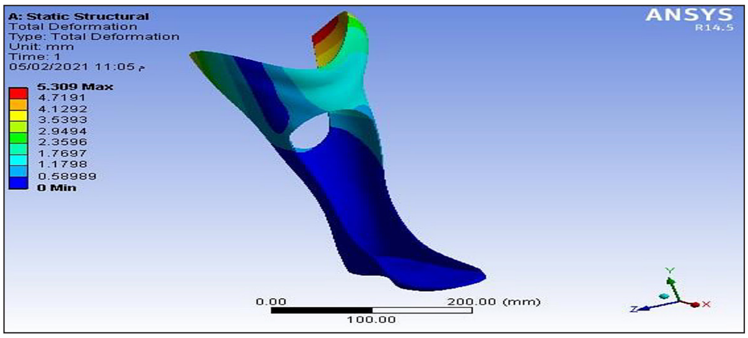


Figure 20. Total deformation fiber glass

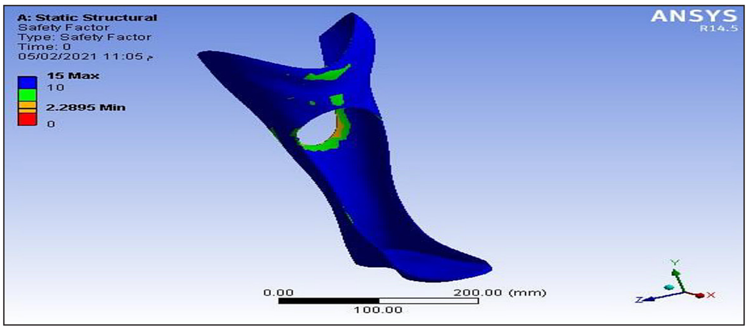


Figure 21. The fatigue safety factor for fiberglass

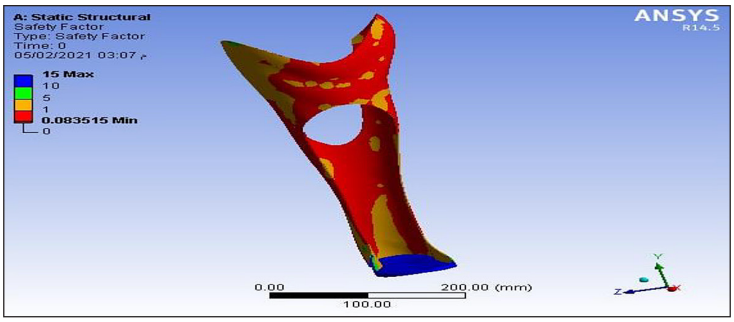


Figure 22. The fatigue Perlon safety factor

Fatigue factor of safety

Figures 21 and 22 illustrate the safety factors of two different AFO models. The safety factor for the AFO model made of Perlon material with 8 layers of fiberglass is approximately 2.2895, which is considered to be safe and sufficient. When compared to the 8 layers of perlon with a 0.083515 safety factor.

CONCLUSIONS

This study provides a useful database for producing appropriate lamination for patients' ankle-foot orthoses. The following are the results of this research:

1. The fatigue safety factor for the material PTBO with 8 layers perlon is 0.08351, while for 8 layers fiber glass, it is 2.2895.
2. Maximum deformation is equal to 193.33 mm for perlon, and for fiber glass is 5.309 mm.
3. The PTBO and the patient have a greater interface pressure in the calf region, with 290 kPa in the lateral region.
4. The mechanical characteristics (ultimate strength, yield strength, and modulus of elasticity) of the KAFO made from 8 layers of glass fiber with orthocryl lamination resin increased by 81%, 75%, and 103%, respectively, when compared to a KAFO made of polypropylene.

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