

Optimised Analysis, Design, and Fabrication of Trans-Tibial Prosthetic Sockets

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Abstract. In this study, two laminated composite materials were used to manufacture residual-limb prosthetic sockets using the vacuum moulding method. Acrylic was used as a matrix material and reinforced with two types of fibres, perlon and carbon. The mechanical properties were calculated using tensile and bending tests, and socket failure characteristics at room temperature were determined by using a fatigue test. F-socket apparatus was used to measure the interface pressure between the residual limb and socket in two subjects with unilateral trans-tibial amputations using patellar tendon bearing prosthetics (PTB). The ANSYS program was used to calculate the deformation, maximum principle stress, and safety factors. The results showed that laminations laid-up from eight layers of perlon plus four layers of carbon gave optimum mechanical properties. Comparing this lamination with other laminations of six layers of perlon plus two layers of carbon, in spite the minimal increase in perlon and carbon layers (from eight layers to twelve layers), the ultimate stress increased by 12.46%. The Young's modulus of a lamination with six layers of perlon and four layers of carbon was 3.66 GPa, higher than other laminations investigated. A high Young's Modulus will result in a total contact socket that produces the best comfort level for patients. The maximum principle stress and total deformation increased with an increase in the length of stump: The maximum principle stress of a long socket increased by 0.3% of medium stress, while the total deformation of the medium socket was lower than that of the long socket.

Keywords: Stump length, Composite material, Trans-tibial, Testing of materials.

1. Introduction

Lower limb prosthetic are devices are used to replace the function or appearance of missing parts as much as possible. Prosthetic components consist of several parts including the socket, pylon, and foot. The socket part of trans-tibial prosthetics is important because the stump (lower limb) does not have the same weight-bearing capabilities as the foot. Thus, the design and fit of a socket are important factors in the successful rehabilitation of the patient [1, 2]. Successful fitting operations for prosthetic sockets may be achieved by understanding the biomechanical structure of such sockets and the appropriate materials, including their weight and thickness, to fulfil the need for desirable load distribution in the soft tissues and bone of the residual limb [3].



Prosthetic sockets can be classified by their respective weight bearing characteristics into three sets: specific area weight bearing or patellar tendon bearing (PTB); total surface weight bearing (TSB); and hydrostatic design (HST) [4]. The residual limb of patellar tendon bearing is loaded proportionally based on gait biomechanics and soft tissue (pressure tolerance limit). One of the important key factors in the design and fabrication of prosthetic sockets is thus the type of material used in construction, which plays a dominant role in increasing the strength and lowering the overall weight of the prosthetic.

Materials, methods of manufacturing sockets, and analysis using the finite element method have been studied by several researchers. M. J. Jweeg, et al. studied the effects of increasing or decreasing composite material (perlon fibre and glass fibre) layers on their physical and mechanical properties by exposing samples of lamination to tensile and flexural tests [5]. I. R. Abd Al-razaq, et al., evaluated the mechanical properties of composite materials used to manufacture prosthetic socket [6]. Maria et al., examined the quality of sockets for lower limb prosthetics and analysed the current state-of-the-art of prosthetic socket performance by assessing static failure loads for check sockets, copolymer sockets, and definitive laminated sockets [7]. E. K. Moo, et al., produced a model based on computed-tomography (CT) graphic data using three-dimensional-image reconstruction software. The pressure data were applied to the inner wall of a PTB socket and PCast socket using finite element analysis software to obtain the pressure profile of both types of socket [8]. C. Mario et al., developed a framework consisting of a systematic manufacturing technique to produce subject-specific sockets made of Duraform PA materials using selective laser sintering. The elements of the framework included obtaining a digital image of the patient's limb and defining the overall socket design using the patellar-tendon bearing approach, before performing a structural analysis using the finite element method [9]. M. J. Jweeg et al. also studied the effects of temperature in hot climates on sockets made of composite materials during the gait cycle [10-16].

In all of these studies, little work has been reported on composite materials layers (arrangement of layers) and pressure applied in the socket region. Furthermore, study of the materials, mechanical properties, and fatigue characteristics of using the vacuum method to fabricate and achieve real subjects tests has been limited. This study thus aims to design and manufacture a socket as well as conducting analysis using the finite element method.

2. Experimental procedure

In this study, composite materials were used in the lamination of trans-tibial prosthetic sockets. These materials contained carbon and perlon fibre as reinforcement, and acrylic as resin, with hardener materials as shown in figure 1. All laminations were performed under a vacuum technique which prevents cavities or defects as follows: a wood negative mould was made to ensure that the surface of final positive mould was smooth and had no defects. The wood mould had dimensions of 30, 15, and 5 cm, as shown in figure 2. The positive mould was prepared by pouring Plaster of Paris into the negative wood mould containing a steel bar, then wetting the polyvinyl alcohol (PVA) bag for ten minutes and covering the positive block before adding the required carbon and perlon fibres and covering the block with a second PVA bag. The acrylic resin was mixed with hardener materials slowly for 1 to 3 minutes before the vacuum device was powered up and the acrylic materials injected into the fibres by means of a small tube. After that, ice cast anatomy was applied for 30 minutes to configure lamination, and the mould became ready for the cutting process. The manufacturing steps were repeated twice for various layers, as shown in table 1.

**Table 1.** Number of layers and arrangement of layers

Name of group	Number of Layers	Lamination lay-up procedures
A	8	2perlon-1carbon-2perlon-1carbon, 2perlon with acrylic resin
B	8	3 perlon-2carbon-3perlon
C	12	2 perlon-1carbon-2perlon-2carbon-2perlon-1carbon-2perlon with acrylic resin

2.1 Tensile test

The tensile test was performed according to ASTM D-638, at room temperature with a speed of 2 mm/min, as shown in figure 3. Three samples for each lamination were subjected to a HI-TECH alternating machine, as shown in figure 4. The dimensions of the specimens for tensile test were 80 mm original length and 13 mm width, while the thickness varied with the type of lamination, as shown in figure 5.

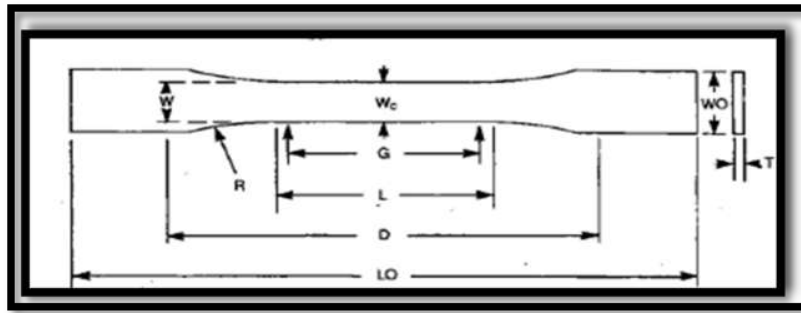


Figure 3. Standard specimens for tensile test.



Figure 4. HI-TECH alternating machine.



Figure 5. Experimental specimens for tensile test.

2.2 Bending test

The bending test was performed according to ASTM D-790, at room temperature with a speed of 5 mm/min. Three samples for each lamination were tested in a Universal Testing Machine as shown in figure 6. The dimensions of the specimens for tensile test were 100 mm original length and 20 mm width, while the thickness varied with the type of lamination, as shown in figure 7. The load was applied midway between the two supports. Under the load, the bottom of the specimen was subjected to tension, and the top of specimen was subjected to compression. The bending stress equalled zero at the neutral axis.

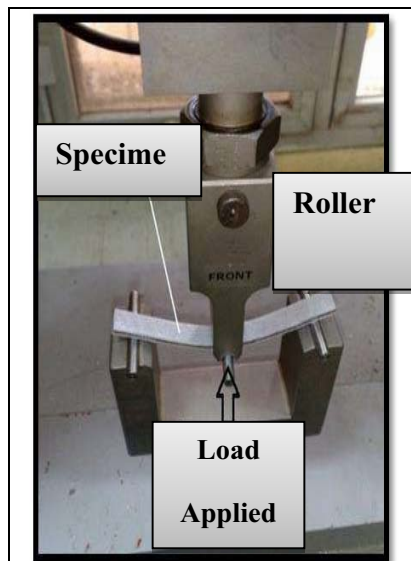


Figure 6. Universal Testing Machine for bending test

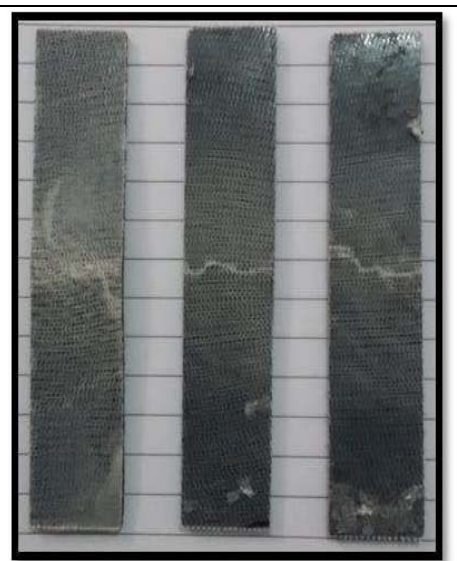


Figure 7. Experimental specimens for bending test

2.3 Fatigue test

The standard fatigue test using Alternating Bending fatigue (HSM 20, 1400 rpm, voltage 230 V, frequency 20 Hz, and power 0.4 Kw) was conducted, as shown in figure 8. The samples were subjected to deflection vertical to the axis at one edge of the samples, while the other edge was fixed. The dimensions of the specimens for fatigue testing were 100 mm length and 10 mm width, as shown in figure 9. The speed of test depended on the material and deflection: the composite material was subjected to a lower speed compared with the metal. Eight samples were tested for fatigue, with a dial gage used to select the deflection. The stress was applied to the specimen until a crack appeared.

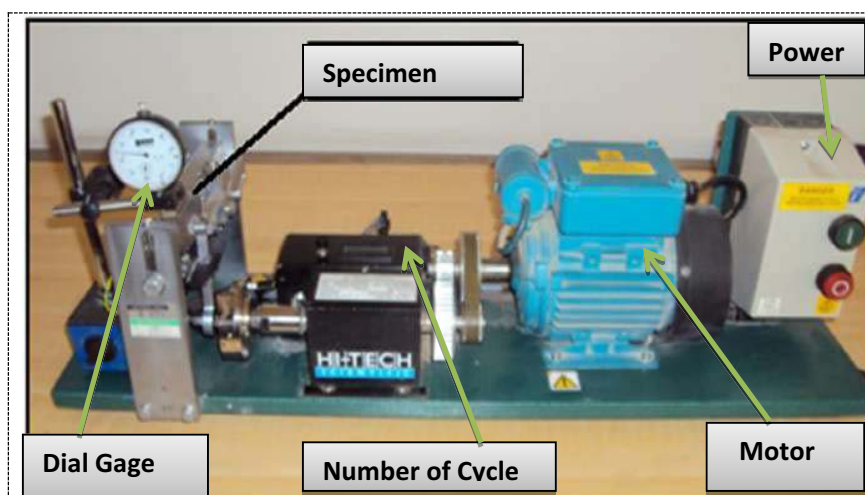


Figure 8. Alternating bending fatigue for fatigue test



Figure 9. Eight specimens for fatigue tests

3. Subjects

Two male subjects with unilateral trans-tibial amputations participated in this study. The lower limbs of the two subjects had strongly contrasting biomechanical features, as shown in table 3. One subject had a longer residual limb than the other subject and much less soft tissue throughout the length.

Table 2. Subject and prosthesis information

Parameters	Subject AM	Subject MS
Sex	Male	Male
Age	54 years	53 years
Weight	86 kg	54 kg
Stump	Left	Left
Height	162 cm	165 cm
Time since amputation	31 years	3 years
Stump length mid-patellar tendon to distal tibia	34 cm	11 cm
Mid patellar tendon circumference	32 cm	33 cm
Mid stump circumference	29 cm	32.5 cm
Near end stump circumference	20 cm	32 cm
Foot size	26 cm	25 cm

4. Socket manufacturing

Two trans-tibial sockets were fabricated with for actual patients. Twelve layers were used in manufacturing the sockets, 8 Perlon and 4 fibre carbon. The adapter was inserted between layers in the form six layers, adapter, six layers. The soft socket was manufactured before the solid socket was made, with the soft socket being fabricated from polypropylene materials with thicknesses of 5 or 6 mm according to the weight of the relevant patient. The procedure for creating the sockets was similar to that for manufacturing test specimens from composite materials, as shown in figures 10 and 11.



Figure 10. Long socket for AM patient



Figure 11. Medium socket for MS patient

5. Interface pressure measurement

The pressure between the lower limb and prosthetic socket was measured using an F-socket device. The F-socket device was connected to a multi-meter to obtain the magnitude of pressure resulting from the responses of sensor throughout each stance phase. The sensors were interfaced with the computer and the recording data, and the pressure was measured in four regions: the anterior, posterior, medial, and lateral region. Each region was divided into three parts longitudinally, one in the middle positions and the others on the terminals. The F-socket software provided maximum and minimum values over time.

6. Finite element method

The general analysis of a trans-tibial prosthetic socket using ANSYS has four distinct steps: building the geometry as a model, applying the boundary conditions and load, obtaining the solution, and reviewing the results. In this study, the model of a trans-tibial prosthetic socket was drawn by using the SolidWorks program. The prosthetic socket models were based on patients' actual geometry and dimensions. The aim of drawing models using SolidWorks was to be able to use the ANSYS Workbench program to mesh the models and apply boundary conditions. Figures 12 and 13 show the meshing process for two patients.

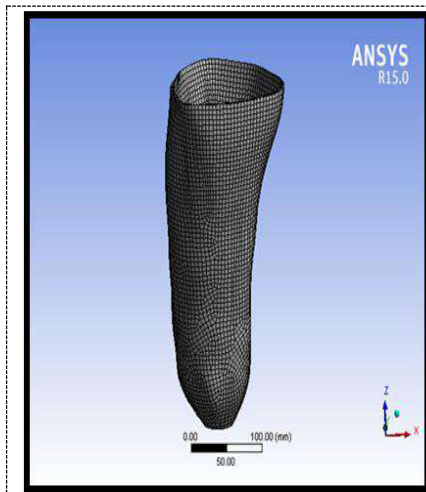


Figure 12. Meshing process for long socket

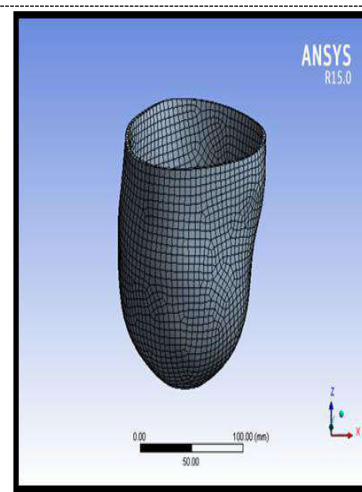


Figure 13. Meshing process for medium socket.

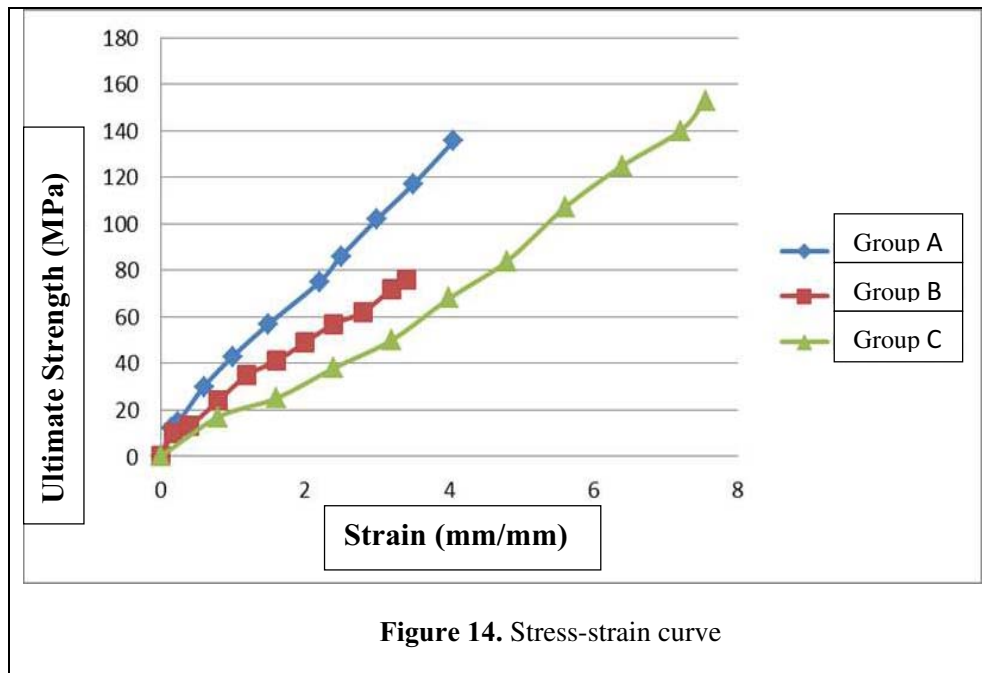
7. Results and discussion

7.1 Tensile test results

Table 3 shows that materials in group C have higher ultimate strengths and higher moduli of elasticity. This is due to the four layers of carbon, which offer excellent mechanical properties. A high Young's Modulus will result in a total contact socket that produces the best comfort level for patients. This should be considered when choosing socket materials. Classical prosthetic sockets are usually made from rigid materials, although some manufacturers prefer a flexible socket (high Young's Modulus) supported by rigid frame, as this provides better comfort during the gait cycle and while sitting. Figure 14 shows typical stress-strain curves obtained for the three groups using carbon fibre and Perlon fibre, respectively; the ultimate tensile stress is seen as the highest point. The ultimate stress and Young's modulus increased with increases in the layers of fibres.

Table 3. Results of tensile tests

Lamination group	Ultimate strength (MPa)	Young's modulus (GPa)
A	135.6	3.414
B	76	3.08
C	152.5	3.65



7.2 Bending test results

The flexural strength of the socket materials is presented in Table 4 for Group A and Group C. The flexural strength of Group C was 242.2 GPa. This result was higher than for the Group A composite materials (124.03 GPa). Flexural strength is required in a socket prosthesis to support body weight and extreme movement.

Table 4 Results of flexural tests

Name of lamination	Flexural strength (MPa)	Modulus of Elasticity (GPa)
Group A	124.03	4.906
Group C	242.95	9.021

7.3 Fatigue test results

The S-N curve can be used to explain the fatigue failure of materials; this refers to the stress over number of cycles for specimens, as shown in figure 15. The highest stress that a specimen can resist for an infinite number of cycles without fracture is called the fatigue limit. Here, the S-N curve fatigue limit is 63 MPa and the number of cycles is 1.14×10^6 . In general, the fatigue limit (strength) of materials is proportional to their tensile strength; hence materials with higher maximum tensile strengths possess higher fatigue limits.

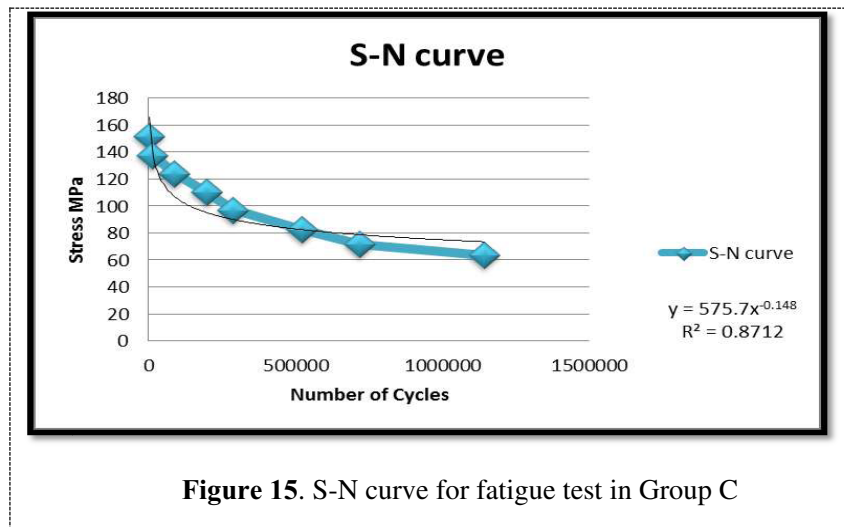


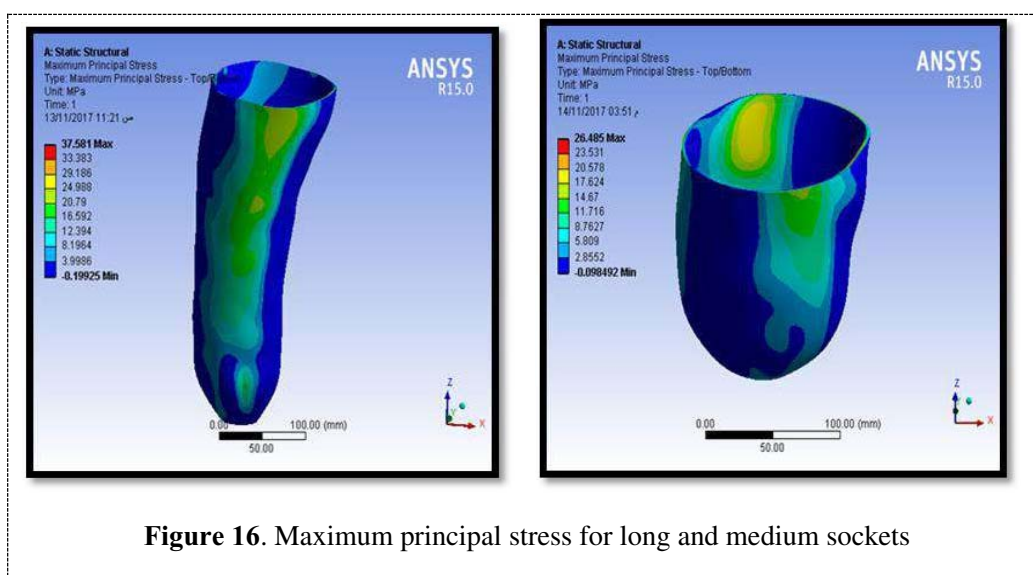
Figure 15. S-N curve for fatigue test in Group C

8. Numerical ansys results

The interface pressure at the prosthetic socket/lower limb region was recorded experimentally using an F-socket device during the gait cycle. The interface pressure results showed that the maximum value was recorded at the socket anterior region at the patella tendon, measuring 200 KPa. Four specific socket regions that experienced pressure exceeding 100 KPa were identified. These four regions were the patellar tendon region, proximal popliteal region, posterior medial flare, and fibula head. The results for maximum principal stress, total deformation, safety factor, and life of applied and modified socket model were obtained using the ANSYS Workbench program.

8.1 Maximum principal stress

The maximum values of maximum principal stress are shown in figure 16. The stress in the long socket was higher than in the short socket, depending on the applied pressure in each case.



8.2 Total deformation results

Deformation is an important factor when designing the prosthetic socket. The results of total deformation are shown in figure 17. The socket displays low deformation because of the high values of modulus of elasticity; this means that the stiffness of these materials is high. In all groups, it was found that the total deformation was proportional to length; thus, the total deformation of the medium socket was lower than that of the long socket.

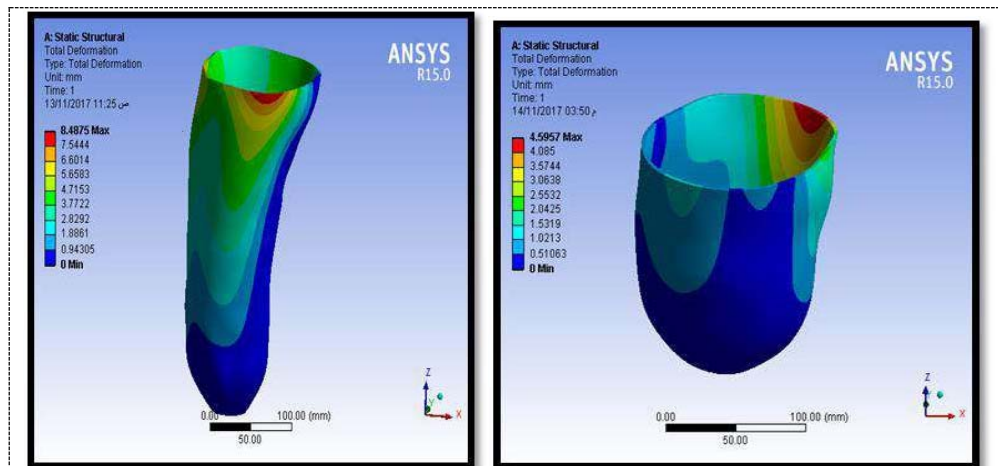


Figure 17. Deformation results for long and medium sockets

8.3 Safety factor results

The maximum equivalent safety factor for a prosthetic socket is equal to 1.8383 for a medium socket and 1.7368 for a long socket, as shown in figure 18. The lamination was safe in this design, and no failure occurred.

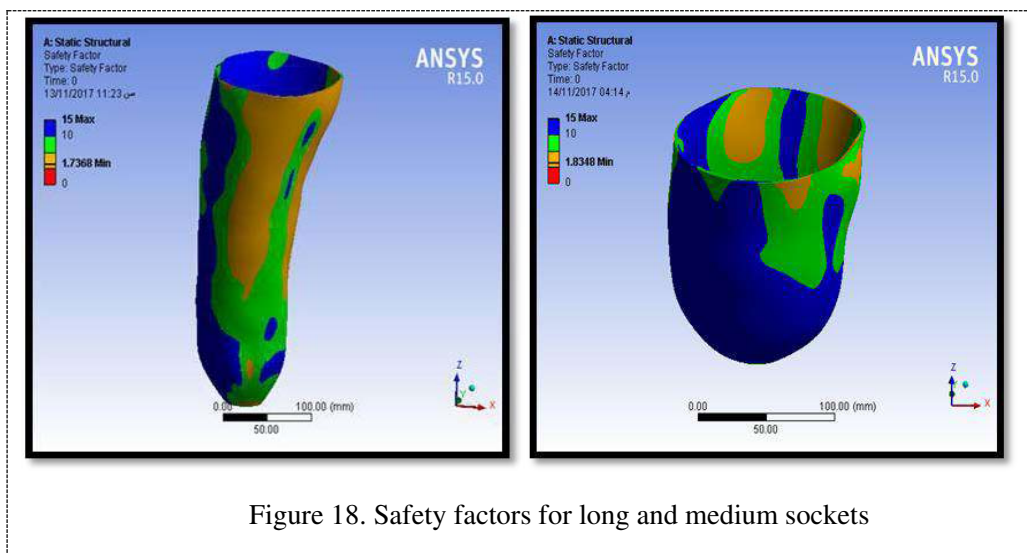


Figure 18. Safety factors for long and medium sockets

9. Conclusions

While the results created in this paper are specific to the socket modelled, the following comments are generally appropriate:

1. Group C (12 layers with acrylic resin) proved to be a suitable material for fabrication of a trans-tibial socket.
2. Group C (12 layers with acrylic resin) offered better mechanical properties than other lamination systems.
3. The upper region of the socket should be reinforced, as maximum deformation occurs in this region.
4. The maximum value of the principal stress was recorded at the patella tendon in the anterior region.

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