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Numerical Analysis and Manufacturing of an Adjustable Below Knee Prosthesis for Children

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ABSTRACT

This research study focused on design, produce, and test an adjustable below-knee prosthetic limb for an 8-year-old with below knee amputation that can be modified to accommodate the child's growth, and to achieve the purpose of the below knee prosthetic limb design in terms of its alterability, also control the length of the shank, with low costs. An adjustable and transtibial prosthetic limb was designed, manufactured, and tested as part of this project. Three steps were taken during the process of designing, creating, and testing the prosthetic limb. The adjustable socket and shank were designed in stages, starting with theoretical and numerical design using 3D CAD software. With an abduction in the upper lateral bone of lower leg, the maximum pressure in the socket was 394 KPa for lateral part, and this is fairly acceptable due to the prominent deformation of the leg bone. According to the numerical findings for the shank, the equivalent stress was 63.303 MPa, and the lowest acceptable stress was 0.040332 MPa. The total deformation of the shank 0.014206 MPa max and zero min. The safety factor for the shank was 5.7122 min, therefore the shank was safe. The readings in this instance for the safety factor and fatigue life were acceptable. The design paves the method for the development of new ways to manufacture lightweight and adjustable limbs. These results are acceptable, the proposed design is aimed at children, and it carries weights exceeding 63 Kg. Socket gives 2 cm for expansion in both sides and allow extra space when the size of the bones in the suspension area grow.

1. INTRODUCTION

Limb amputation significantly alters the quality of life, mobility and ability to perform daily activities [1]. Lower extremity amputations are the most common and 97% of amputations due to vascular disorders occur in the lower extremity. Transtibial or below-knee amputations are the most common amputations. As the term implies, amputations are performed proximal to the ankle joint and distal to the knee joint. A transtibial amputation is usually considered a short amputation if it is performed on the proximal third of the tibia, but there are no formal criteria for this. Transtibial amputations are preferred to more proximal amputations, such as trans-femoral amputations, as the knee joint is preserved. In addition, the presence of the knee joint for transtibial amputations allows for a much more practical, simple and affordable prosthesis. A typical below-knee prosthesis typically consists of four main components:

(1) Socket, which transmits forces between the prosthesis and the residual limb (also called residual limb);

(2) Suspension system, which supports the prosthetic leg during the swing phase of the gait cycle and when no weight is applied to the prosthetic leg;

(3) Pylon, an intermediate body that transfers forces between the socket and the prosthetic leg;

(4) The prosthetic foot is attached to the distal end of the prosthetic leg and is made from a variety of materials as shown in Figure 1 and has a variety of designs, ranging from a simple block of wood to a highly technical carbon fiber splint prosthetic foot. After the foot, the socket is the most important part of a typical artificial tibial prosthesis. Ground reaction forces from the prosthetic foot are transmitted through the socket to the other toe and from there to the rest of the body. The entire weight of the user is transferred to the residual weight during the stance phase of the gait cycle. The soft tissue of the residual is often used to distribute interface stresses to protect the prosthesis.

Various socket options are available for transtibial amputations. Since the 1960s, sockets with a patellar tendon-bearing design have been the most widely used [2]. All-surface supported sockets, first used in the 1980s, are an alternative. As a result of the current situation and the development of the prosthetic limb industry, the challenges of accommodating transtibial amputations have been considered in terms of prosthesis design and material selection. The idea was to develop a prosthetic limb for below-knee amputations. The design considered weight and durability, especially the design of the handle and whether it could be resized to account for the child's growth without the need to replace it after a short period of time.

Figure 1. Below knee prosthesis [3]

Previous research has focused on materials and adjustable socket technology for adult use, especially for above-knee amputations. The aim of this study is to design and manufacture a resizable, lightweight and low-cost adjustable below-knee prosthesis for children. The design can also solve the problem of stump length, especially since long stumps cannot be used comfortably.

Shasmin et al. [4] found that pylons are commercially available in stainless steel or titanium and are used to connect the socket to the ankle joint. Nowadays, there are an equal number of options available on the market for trans-tibial amputations. In this study, commercially available pylons (shafts) were replaced with bamboo. Gigantocloa Ligulata and Bambusa Heterostachya were selected based on FRIM mechanical tests of different bamboo species in the setup used for mechanical testing of the prosthesis and meeting ISO 10328 standards. These bamboos have high tensile properties of 341-530 MPa, making them suitable for steel tower specifications. However, natural bamboo cannot last more than three years due to deformation.

Gholizadeh et al. [5] presented that a bicone motion system was used to compare the piston effect of Seal In® X5 and Dermo Liner; both Iceross Seal In® X5 and Iceross Dermo Liner were used and six trans-tibial amputees were used. Three static vertical loading conditions were used to measure the vertical misalignment (piston) between the liner and socket (30, 60 and 90 N). The results showed a 71% reduction in piston in the socket when Sealin X5 was applied compared to Iceross Dermo liner. A significant difference between the two linings was observed under various static conditions (0.05 pb).

According to the study of Cornell [6], this work is a patent involving the design of an adjustable socket for femoral prostheses that includes a rigid partial stent, an inflexible stent, and an additional adjustment device. The socket can be used for various types of amputations in addition to trans-tibial and trans-femoral amputations. The invention has a number of advantages over conventional sockets. The invention provides comfortable weight bearing and stability for controlling the prosthesis in space. The invention's hole size control was unprecedented due to the use of adjustable elastic supports and garments.

The aim of this work conducted by Quezada [7] is to redesign an adjustable socket for trans-tibial amputation. The first phase of this work was the creation of several prototypes to improve the adjustment mechanism of existing prosthetic sockets. The adjustment system was redesigned to improve ease of use and provide a more robust bond between the socket and the remaining prosthetic components. The second stage was the creation of a new socket wall design with supports attached to a flexible inner socket. The flexible socket was likely to provide a more comfortable feel due to reduced load on pressure-sensitive areas, and weight analysis also showed reductions for the redesign.

Mitton et al. [8] described the problem of prosthetic socket prescription in left femoral transposition amputations secondary to chronic patellofemoral instability complicated by complex regional pain syndrome [9]. An adjustable modular socket was tested. The socket could be fitted in a 60-minute physiotherapy session without problems of fit, distal end strangulation or skin irritation. The patient continued with an intensive rehabilitation program focusing on gait retraining and strengthening of the hip and trunk muscles. The patient wore the prosthesis for eight hours a day and was able to walk indoors and outdoors without assistance. In this case, the design of the adjustable modular socket accommodated daily fluctuations in residual limb volume with good results.

Dillingham et al. [10] focused on evaluating the utility of a standardized immediate fit prosthetic system (IFIT). The luminal material design for trans-tibial amputation consisted of a soft insert and silicone dermal suspension system. For participants with this hole, results were satisfactory and tip fit was good. Participant outcomes differed slightly in terms of self-satisfaction, and overall, the intra-socket peak pressure was significantly lower with the IFIT prosthesis.

The aim of this study of Abbas and Abdulrahman [11] was to develop, fabricate and test an adjustable above-knee prosthesis for children with femoral transposition amputation that can be modified as the child grows at least two years (1-2 years). Using 3D scanning technology, an adjustable socket and pylon were theoretically and numerically designed. The design was then modified using SolidWorks to add adjustable straps; ABAQUS/CAE and ANSYS software were used to analyze the model and determine equivalent (von Mises) stresses, safety factors and deformation distributions. Composite materials (adjustable model) were used for the socket lamination. The proposed adjustable socket and pylon model increased the service life by 300% and 260%, respectively, compared to the choice of aluminum material for the adjustable pylon model.

In this study conducted by Ibarra Aguila et al. [12], a socket interface pressure (SIFP) system was implemented. A comparative study of the SIFP and F-Socket systems showed that the performance of both systems in measuring interface pressure is comparable, as both systems show similar patterns of pressure change when loading artificial relics simulating walking protocols. sensors, but they cannot adapt to the irregular geometry of the relic as effectively as the SIFP system.

The aim of this study conducted by Owen and DesJardins [13] was to evaluate the strength at failure and failure mechanics of carbon fiber definitive laminated artificial tibial sockets, thermoplastic artificial tibial control sockets and 3D printed artificial tibial sockets. Three clinically accessible materials (carbon fiber, PETG thermoplastic and 3D printed polylactic acid) were used to produce uniformly shaped sockets. There were four different socket failure mechanisms. The strongest sockets were carbon fiber sockets, but 3D printed sockets were as strong as conventional thermoplastic sockets; the ISO 10328 test standard was sufficient to perform these analyses, but there were a variety of socket-specific measurements and loading conditions that would strengthen the comparison between socket types.

Jweeg et al. [14] found that four optimal lamination methods and appropriate nanomaterial percentages were used for the numerical analysis of below-knee prostheses. The numerical analysis using the finite element method was used to predict the von Mises stresses and deformation behavior along with the mechanical properties of the appropriate composite materials. Comparison of different nanomaterial types and weight ratios shows that sio2 with a weight ratio of about 2% is the best nanomaterial for the 2 Perlon+2 Kevlar+1 Perlon+2 Perlon+2 Carbon+1 Perlon+2 Perlon+2 Kevlar+2 Perlon specimen and the socket stresses are about 40% The socket below the knee was analyzed using SolidWorks. Comparison of different nanomaterial types and weight ratios shows that socket stresses are reduced by about 40% and deformations by about 38%. The best nanomaterial was sio2 with a weight ratio of about 2%.

Comparing the previous study with this study, the previous study focused on a series of attempts to design and manufacture multifunctional sockets and grips for both above and below knee amputations. In this study, additional non-traditional research was conducted to achieve a number of goals, including obtaining resizable prostheses at low cost and extending use as much as possible before replacement.

2. METHODS

2.1 Below knee proposed design

A new design for the socket and shank is proposed. The design was created using CAD software as shown in Figure 2.

Figure 2. Proposed design of the prosthetic limb

2.2 Proposed socket design

Initially, the shape of the socket was designed to be a traditional below knee socket by lofted many circles as shown in Figure 3.

Then, three holes were made in the front and sides (medial and lateral, respectively). Each hole had a width of 10 mm and length of 55 mm. The upper back was cut to allow extra space when the size of the bones in the suspension area changed shown in Figures 4(a) and (b).

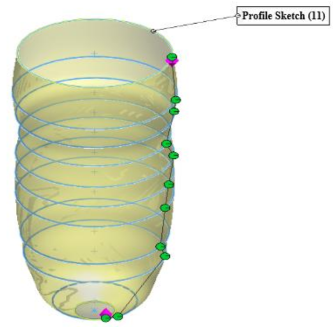
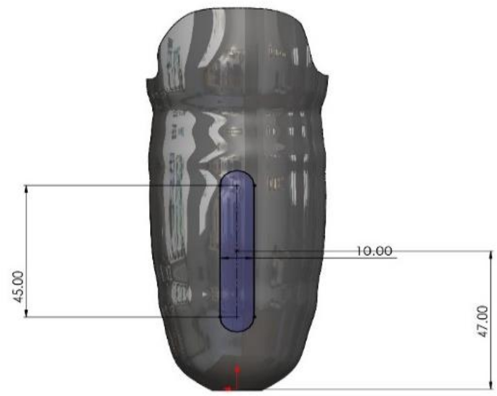
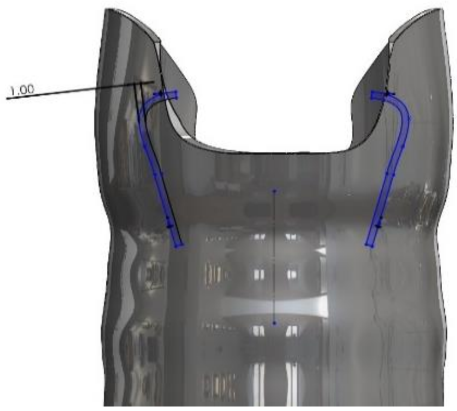


Figure 3. Steps of socket design



(a)



(b)

Figure 4. Proposed design for below knee socket

2.3 Proposed shank design

This design is located between the adapter and foot. It is composed of three pieces, as described in Figure 5.

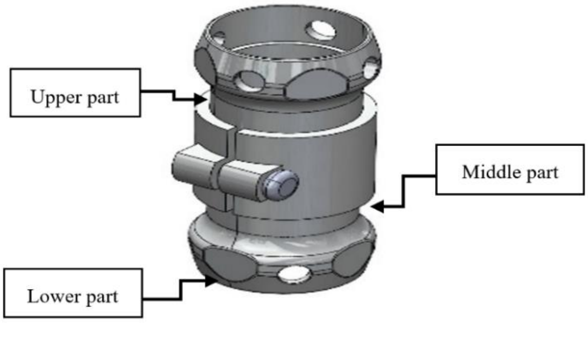


Figure 5. Proposed shank

The measurements of the shank will be shown in Table 1.

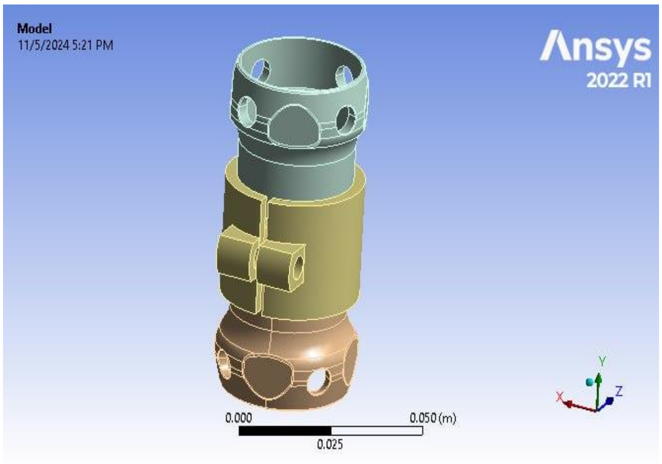
Table 1. Measurements of shank

Part	Length mm	Internal Diameter mm	External Diameter mm
Upper & Lower	35	30	31.86
Middle	30	32.06	38

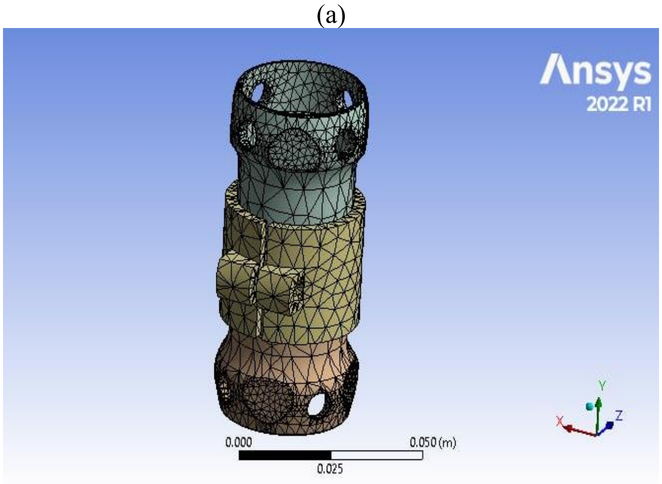
3. NUMERICAL ANALYSIS

Today, the finite element method (FEM) is used in a wide range of engineering and scientific disciplines. It benefits from rapid advances in digital computers, which allow for large memory capacity and high computational speeds. Due to its ability to handle complex geometric boundaries and nonlinear material properties, the method is considered one of the most powerful numerical methods. In this study, FEM and ANSYS Workbench 2022 R1 were used to obtain the maximum stress, total deformation and factor of safety [15, 16]. Figures 6(a) and (b) show the analysis process.

Creating the geometry as a model, applying boundary condition loads, finding the solution and analyzing the results are the three steps of a typical analysis process used by ANSYS. As shown in Figure 7, fixed supports were applied to the upper surface of the model and loads were applied to the lower surface.



(a)



(b)

Figure 6. Process of shank analysis

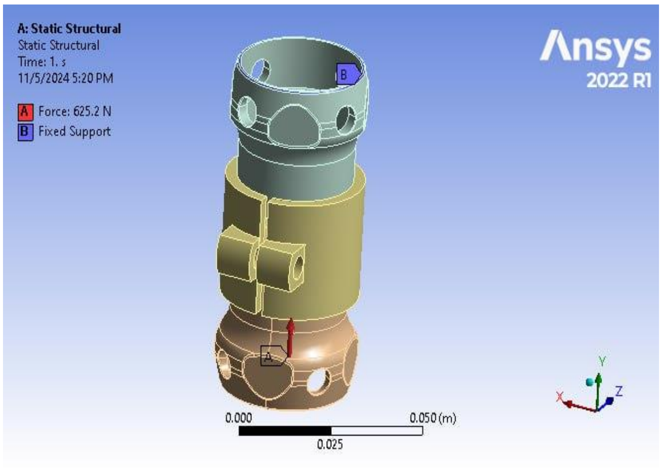


Figure 7. Fixed support and force

The other settings to complete analysis shown in Table 2.

Table 2. Data for analysis shank

Material	Aluminum 6061-T6
Physics Type	Structural
Analysis Type	Static Structural
Analysis Type	3D
Nodes	32824
Elements	16435
Mean Stress Theory	Goodman
Type Force	Fixed Support
Define	Components

4. EXPERIMENTAL WORK

Composite materials have been used as below knee socket materials, as described in Table 3.

Table 3. Below knee socket materials

No. of Samples	Thickness [mm]	Type of Materials	Arrangement of Layers
Sample 1	3	PMMA + Perlon Layers	10 Perlon layers
Sample 2	3	PMMA + Perlon Layers	10 Perlon layers
Sample 3	3	PMMA + Perlon Layers	10 Perlon layers

Figure 8. Patient with below knee amputation

4.1 Case study

Measurements were collected for male patient who were about 8 years old, with a weight of 26 kg and a length of 120, and who suffered from left side below-knee amputation due to an accident, as shown in Figure 8.

The first step for experimental work, is taking measurements. The length of the stump was taken as 16 cm and recorded in the chart. Circumferences of the calf were 23.5 cm at the upper and stump end at 17.5 cm, and the middle of the stump was 19 cm. For handing casting, four layers of nylon were added above the patella and twisted distally to the end of the stump. The elastic plaster of Paris was wetted and started wrapping with one turn above the knee, continued downwards wrapping diagonally. After the suspension regions were marked, the mold was left to dry for a certain period of time, as shown in Figure 9.

Figure 9. Mold taking

To prepare for rectification, the mold was left to dry completely, as shown in Figure 10. For cast rectification, the plaster with water was mixed until the water was saturated. Negative filled the vacuum tube inside. The negative result was cut and removed. Special contours, sensitive areas, and plumb lines are marked. The measurements were checked, and the cast was smoothed.

Figure 10. Mold with plaster

Figure 11. Steps of soft insert fabrications

Eva was used as a below knee soft socket with a thickness of 3 mm, length of 25 cm, proximal width of 30, and distal width of 19 has been take from the mold. The piece has been inserted inside the furniture 5-10 minutes with 200℃-250℃. Piece was wrapped onto the mold. The cap was made using the same procedure to cover the distal end of the soft socket, as shown in Figure 11.

PVA was wrapped onto the mold then the 10 layers of perlon, finally the second layer of PVA. Adapter was aligned and fixed to the mold after the sixth layer of perlon, then two layers of black perlon was added for the purpose of clarifying and fixing the color as shown in Figure 12. Last addition of 300 g acrylic resin with hardener & color mixed for 3 minutes then the mixture has been added to the mold. Vacuum turned on during the casting. After 30 minutes socket was ready to modification procedures.

Figure 12. Lamination of socket

Three holes were made in the socket to minimize the weight. The length increased by 2 cm at the distal end. The posterior section of the suspension was cut to provide a wide circumference when the size of the bone changed. In the suspension section, the small metal plates connected between them function as straps, as shown in Figure 13.

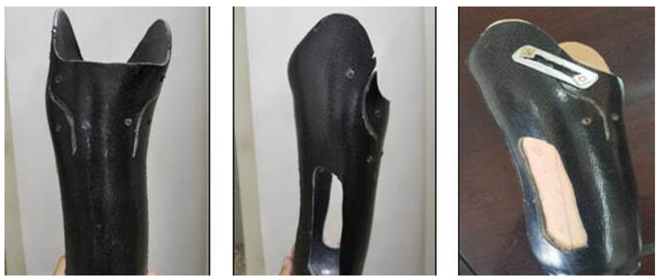


Figure 13. Modification of proposed design

The step of Manufacturing proposed shank done by using CNC machine with aluminum material 6061-T6 as shown in Figure 14.

Figure 14. Proposed shank

4.2 Assembly of proposed artificial limb

At the final experiment artificial limb assembled. The parts for assembling the limb are:

- Socket
- Adapter socket
- Double adapter
- Adapter foot
- Foot

The parts connected together, then it was worn by patient as shown in Figure 15.

Figure 15. Artificial limb assembly

5. MECHANICAL PROPERTIES ANALYSIS AND TESTS

Experimental test. The samples were tested using a Testometric machine (Al-Nahrain University/Mechanical Engineering). Tensile tests were performed using a Hi-Tech device as shown in Figure 16.

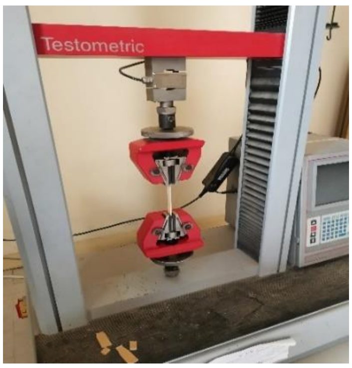


Figure 16. Testometric device

5.1 Tensile test for composite materials (resin + perlon)

Fibbers are used in orthopedic technology as stockinet [17]. Layers as reinforcing materials in PMMA resins. Table 4 lists the types of lamentation. All tensile test samples were tested using a universal testing instrument (Testometric).

Table 4. Lamination materials for the proposed socket design

Material	σult [MPa]	Elongation Percentage	Elastic Modulus [GPa]	Poisson's Ratio
Perlon	78	1-30	2.6-3	0.39
Resin	48.3-72.4	2-5.5	2.24-3.24	0.35

Three samples have been used for each socket and shank material. The crosshead speed for the composite material was 5 mm/min.

The tensile test parameters were limited in accordance with the ASTM specifications; the tensile specimen's shape and dimensions for the standard (D638) were specified for the composite material used in socket production, as depicted in Figure 17.

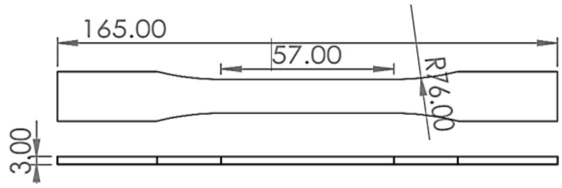


Figure 17. The general shape and dimensions of tensile specimens D638 for 3 samples of socket material [18]

5.2 Tensile test for aluminum material

For the shank, Table 5 shows the details of the materials used in manufacturing the samples.

Table 5. Proposed shank materials

No. of Samples	Thickness [mm]	Type of Materials
Sample 1	3	Aluminium 6061-T6
Sample 2	3	Aluminium 6061-T6
Sample 3	3	Aluminium 6061-T6

Figure 18 illustrates the geometry and dimensions of the tensile specimen for standard (E8) [19] for aluminum material used in shank manufacturing according to the specifications provided by the American Society for Testing and Materials (ASTM).

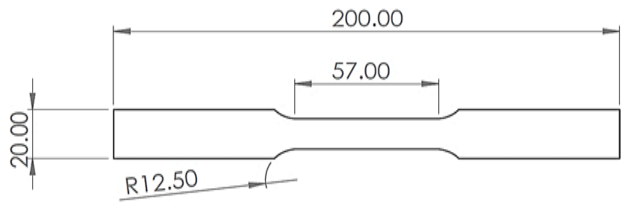


Figure 18. The general shape and dimensions of tensile specimens E8 for 3 samples of shank

The test was stopped when the sample broke, as shown in Figure 19.

Figure 19. The samples after testing

5.3 Interface pressure

The interface pressure between the residual limb and socket during F-Socket test was measured by the prosthetic and orthotic department/Al-Nahrain University using an F-socket system consisting of sensors. The procedure for measuring the interface pressure begins by placing the socket on the residual limb and applying F-socket software sensors at the anterior of the residual limb. The patient then moved, and the software began to record the movement and draw a pressure-time curve. The procedure was repeated for the posterior, lateral, and medial sides of the residual limb, as shown in Figure 20.

Figure 20. Sensor inside the socket

6. RESULTS AND DISCUSSION

6.1 Experimental test results

The proposed design yielded good results as initial attempts to implement the design of a transtibial tip in this way, as it is known that it is difficult to manipulate the socket. Despite the challenges that faced the design in the beginning, it bodes well for results that can be said to open new horizons in the development of transtibial sockets.

Tensile test results in Tables 6 and 7 present the test results for the mechanical qualities of the socket and shank materials (tensile test).

Table 6. Mechanical properties of composite material for socket (PMMA + perlon)

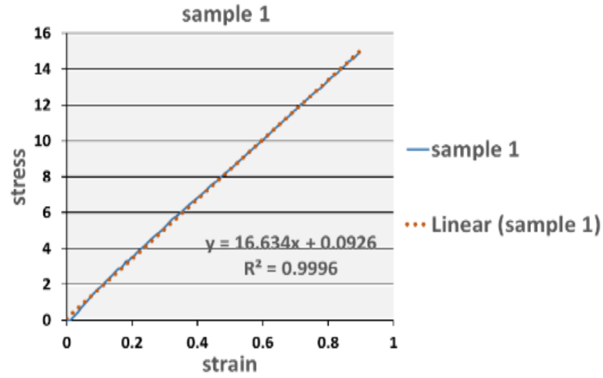
No. of Sample	Thickness [mm]	σy [MPa]	σult [MPa]	E [MPa]
Sample 1	3	32.631	32.631	1634.602
Sample 2	3	9.367	23.715	1044.292
Sample 3	3	5.444	24.182	996.490

Table 7. Mechanical properties of shank material (Aluminium 6061-T6)

No. of Sample	Thickness [mm]	σy [MPa]	σult [MPa]	E [MPa]
Sample 1	3	79.520	96.613	6642.485
Sample 2	3	69.893	94.293	8537.214
Sample 3	3	77.413	94.240	5775.950

According to the values of testing material, having an ultimate stress that is significantly higher than the yield stress allows for a safety margin in the design and application of the material. Ultimate stress equal to yield stress in first sample, while other sample achieved the principle of strength, when the ultimate stress is higher than yield stress [17].

Figures 21(a)-(c) depict the stress-strain curve for the material used in stress-strain curve for socket material and Figures 22(a)-(c) for shank.



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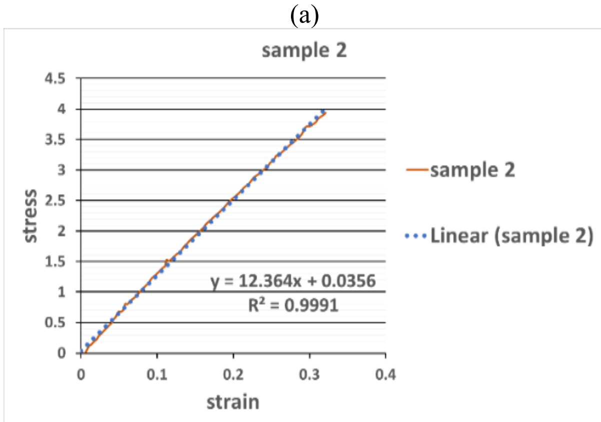

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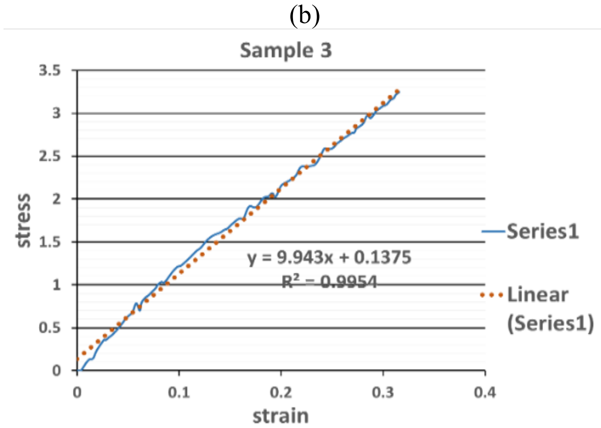
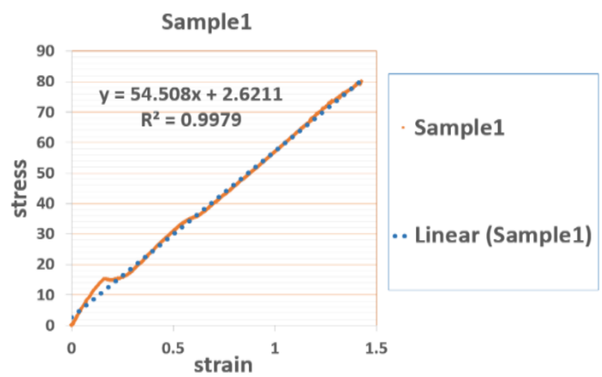


(c)

Figure 21. Proposed socket samples



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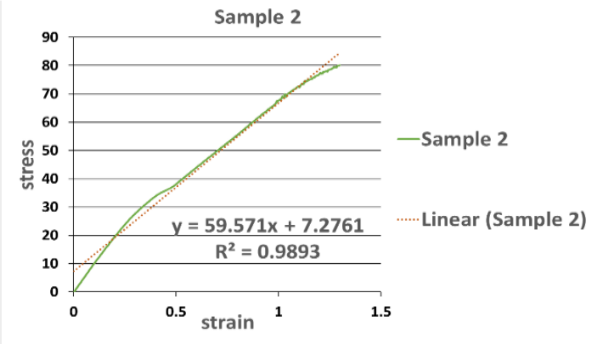

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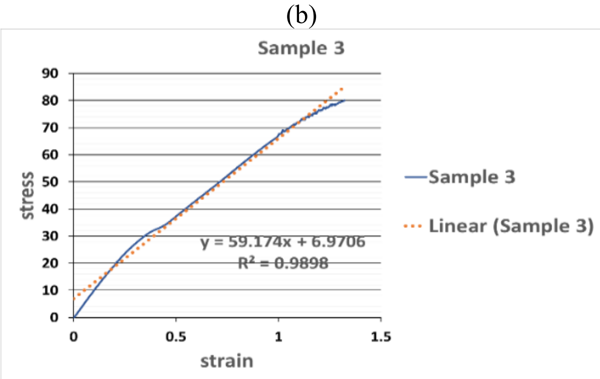


(c)

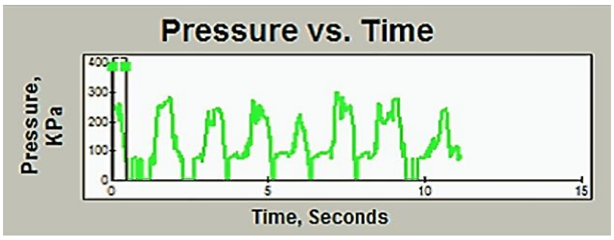
Figure 22. Proposed shank material samples

F-Socket test indicated that the highest value of pressure was in the lateral region of the socket and are recorded in Table 8.

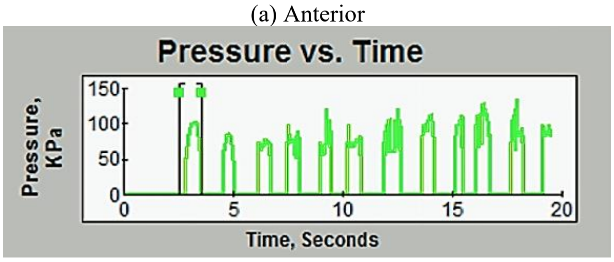
Table 8. Readings and results for IP

Socket Parts	Anterior	Lateral	Posterior	Medial
IP(KPa)	139	394	101	105

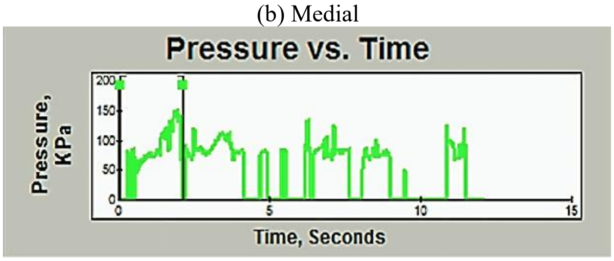
Comparing with another research [15], the results was acceptable. The interface pressure (IP) distribution at the four sides shown in Figures 23(a)-(d) socket.



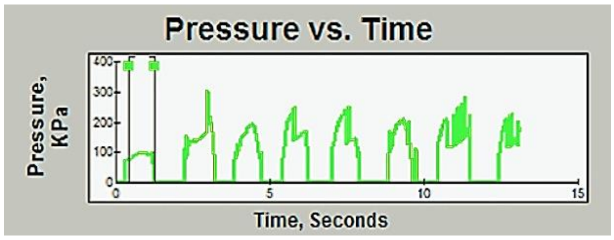
(a) Anterior



(b) Medial



(c) Lateral



(d) Posterior

Figure 23. Pressure vs. time

6.2 Numerical analysis results

The results of the shank models are presented in Figures 24-28. As shown below, static stress analysis was performed in the gait cycle, and the boundary conditions were given with a load and fixed position. The equivalent stress, shear stress, and total are listed.

Conversions have been obtained and all values are safe and acceptable range. According to the results shown in Figure 24. The equivalent stress 63,303 MPa was maximum. Minimum value equivalent stress 0.040332 MPa. Total deformation of the shaft the maximum total deformation 0.014206 MPa and minimum deformation of the shaft were zero as shown in Figure 25 according to the von Mises hypothesis.

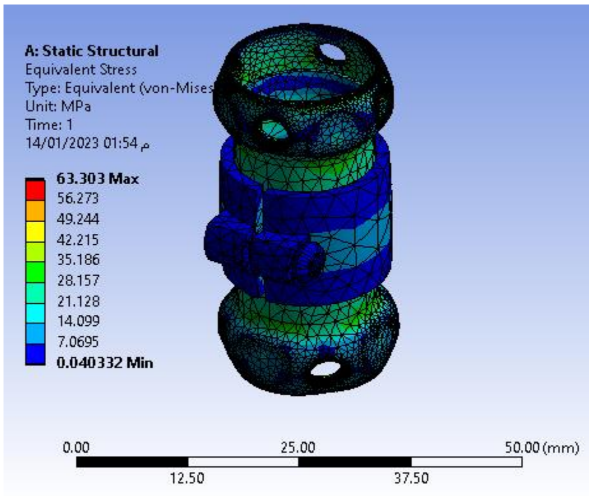


Figure 24. Equivalent stress

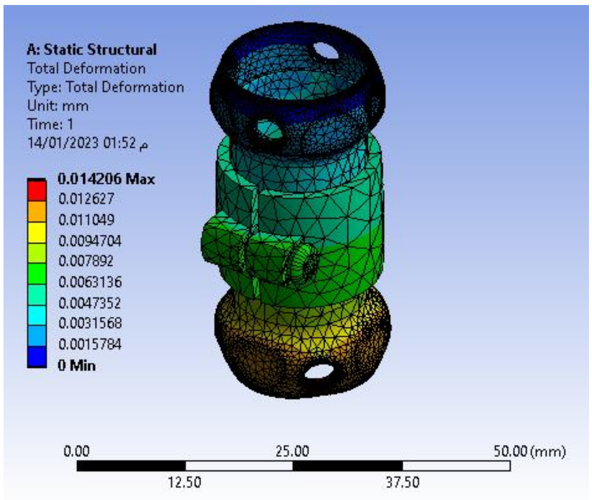


Figure 25. Total deformations

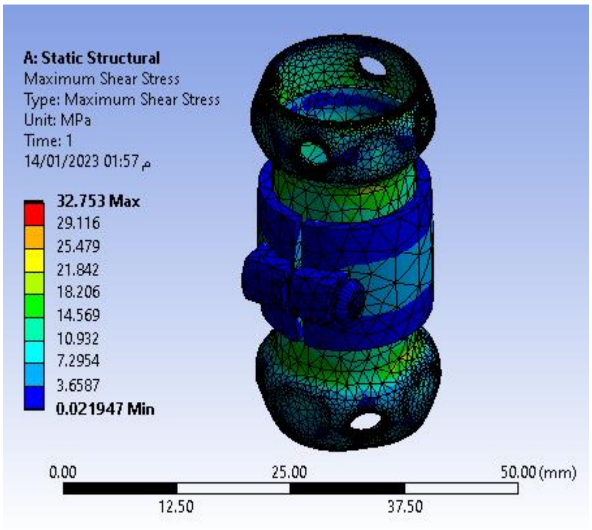


Figure 26. Maximum shear stress

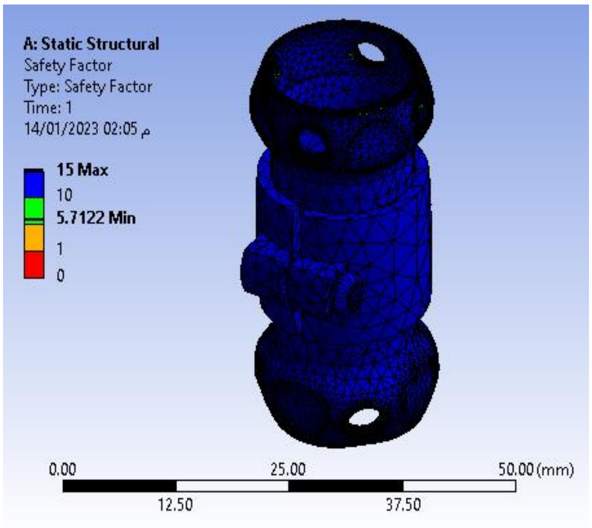


Figure 27. Safety factor

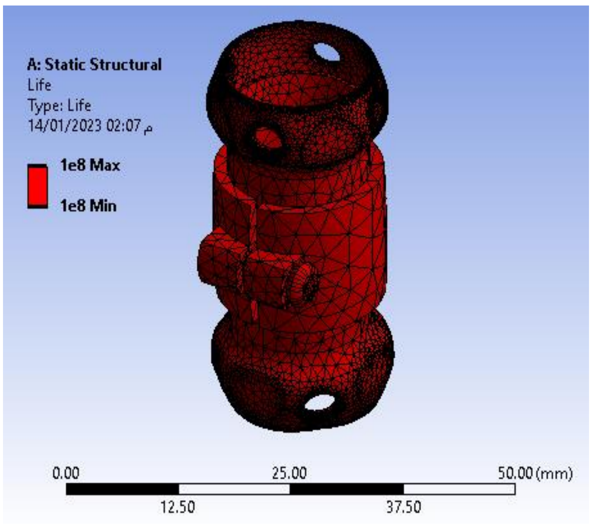


Figure 28. Fatigue life

Yield stresses σe [0.014206 Mpa ($\sigma e < \sigma y$, safe), ($\sigma e = \sigma y$, critical) and ($\sigma e > \sigma y$, fracture $\sigma e < \sigma y$, safe), ($\sigma e = \sigma y$, critical) and ($\sigma e >$, respectively), where (σe) is the equivalent stress and (σy) is the yield stress. According to the safety factor, a material is safe if the safety factor is greater than or equal to 1. It is safe if it is approximately above 1.25 [20, 21].

This design is a prototype. It is the first of its kind to study the possibility of manufacturing a variable-sized prosthetic in terms of socket and shank for children with below-knee amputation, therefor it needs more analysis and testing in the future to develop and make it more effective.

7. CONCLUSIONS

This research has been concerned with the design of a modified prosthetic limb that takes into account the size of the stump and the variables that accompany it when growing and changing the weight of the patient, as well as the design of the shank in a way that allows it to change the length according to the amputation length, which is different from the rest of the designs. The socket and shank design in this research showed the ability to achieve the adjustable principle. The proposed socket design provides a wide range of circumferences of approximately 2 cm for each side; in this case, it provides comfort for the patient. The holes make sockets lightweight by 346 g to each prosthetic limb. This weight is attributable to the fact that when perlon is mixed with acrylic resin, becomes heavy, especially with increase the number of layers of perlon for manufacturing the socket. The maximum pressure of the F-socket for patients with below knee amputation is (394Kpa) in the lateral region because the patient had an abduction in the leg, and the fibula head press on the socket lateral wall was higher than in other regions.

The design needs more tests with more than one patient to get more specific results. The experimental results of a socket could have been better if the perlon had been reinforced by other materials such as carbon fiber, have good mechanical properties giving lighter weight and more strength.

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NOMENCLATURE

F	force
A	area

Greek symbols

σ_{ult}	ultimate stress
σ_y	yield stress
E	young’s modulus
MM	millimetre
KPa	kilopascal
MPa	megapascal
KG	kilogram
CM	centimetre

Subscripts

CAD	computer aided design
SACH	solid ankle cushion heel
CNC	computer numerical control
EVA	ethylene-vinyl acetate
ASTM	American society for testing and materials
PVA	polyvinyl alcohol
3D	3 dimensional
ISO	International Organization for Standardization