Modeling and Manufacturing of a Flexible Socket for Above-Knee Amputation Prosthesis

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ABSTRACT

There is a high incidence of Above-Knee (AK) amputations in Iraq due to factors, such as war, birth defects, explosives, and accidents. The development of advanced prosthetic solutions is critical in improving the comfort and life quality of the amputees. Traditional prosthetic sockets for AK amputations often cause discomfort, limit mobility, and increase the risk of secondary health issues, such as scoliosis. Creating a socket that balances both support and flexibility for the amputee, addressing these concerns while also ensuring comfort and ease of use is a major challenge. The objective of this project is to design a prosthetic socket combining stiff and flexible materials to optimize comfort, support, and functionality for AK amputees. The goal is to develop a socket that alleviates back discomfort, reduces the risk of scoliosis, and improves suspension while being easier to wear and more aesthetically pleasing. This project employs a composite material approach, using a combination of silicon, carbon, perlon, and laminate to create the socket. The socket is designed in two parts: the first part utilizes rigid materials to support the weight of the amputee, while the second part incorporates flexible materials to allow for muscle movement during gait. Tensile tests were conducted to determine the mechanical properties of silicon with perlon, and the performance of the flexible socket was evaluated in terms of pressure distribution and comfort. The tensile testing of silicon with perlon yielded a Young's modulus of 0.0165 GPa, a yield strength of 0.283 MPa, and an ultimate tensile strength of 1.386 MPa. Additionally, the maximum F-socket pressure measured in the anterior region was 490 kPa.

Keywords-carbon fiber; hardener; silicone rubber; tensile test; flexible socket; F-socket; force plate; solid work

I. INTRODUCTION

AK amputation is a transfemoral amputation. Compared to lower level amputation, the former has a significant impact on a patient's life [1, 2]. There are three degrees of thigh amputation: long AK, which is equivalent to two thirds of the normal thigh length, mid AK, which is equivalent to half of the natural thigh length, and short AK, which is equivalent to one third of the natural thigh length [3]. For the AK amputation, there are three levels of stumps. The first is the long stump, which is the most energy-efficient, has adequate ischial weight bearing, and adductor muscle balance, medium stump is a shorter stump that uses more work to raise the prosthesis, reduces the adductors' range of motion, and increases the flexion joint [4], and the short stump that has weak anterior and medial muscles, poor prosthetic balance, increased flexion and abduction joint, stronger suspension, and higher energy consumption for walking and lifting [5]. There are several components to the prosthesis [6]. Depending on their structure, residual limb, and muscle activity, prosthetic sockets come in three different varieties, namely flexible transfemoral sockets, ischial containment sockets, and quadrilateral sockets. In transfemoral sockets, the socket's quadrilateral form is visible. The anatomy of the amputee and the muscle and socket biomechanics cause the four walls to point in various directions [7].

Many important studies on prosthetic materials and sockets have been conducted. Authors in [8] investigated the stiffness of five prosthetic sockets made of different materials. Authors in [9] evaluated the tensile and impact properties of the materials used to make prosthetic check sockets and copolymer sockets. Authors in [10] used a number of conventional laminated materials to create a range of laminated below-knee prosthetic sockets, so that the best laminated socket may be selected. In [11], a revolutionary modular socket system that used four layers of carbon fiber in order to build the BK prosthetic socket was proposed and compared to perlon.

Furthermore, research has looked at the creation of prosthetic sockets using natural or recycled materials, such as plant fiber composites made of renewable plant oil resin and sustainable reinforcing fibers, like flax, jute, and pineapple fiber [12-14]. The creation of prosthetic sockets with regulated weight has been made easier by additive manufacturing [15, 16]. Authors in [17-18] focused on the shank part of the prosthesis for those who had below-knee amputations. Authors in [19] worked on several lower limb prosthetics-related components to provide the patients with support and functionality [19]. Improvements and progress in the field of orthotics are still ongoing, as many researchers have conducted various studies that include aspects of movement, walking evaluation, control, and additive manufacturing, all of which contribute to the continuous development in the lower amputation prosthetic and orthotic field [20-22].

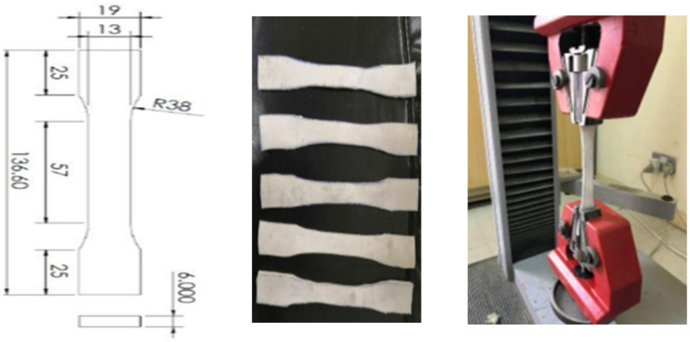
In this work, silicone rubber lamination samples and composite material samples (liquid silicone rubber plus eight layers of perlon) and carbon fiber samples were put through tensile testing according to ASTM standards.

II. EXPERIMENTAL WORK

The materials utilized to make the flexible socket for this study include polyvinyl alcohol (PVA) and silicone rubber (part B-Catalyst), carbon fiber, liquid silicone rubber, and C-orthocryl lamination resin to be utilized with carbon fiber hardening powder, which is specialized and formulated for use with C-Orthocryl lamination resin and carbon fiber to create durable, lightweight, and high-strength composite materials. This hardener has high reactivity, temperature stability, toughness enhancement, compatibility, and low viscosity.

A. Tensile Test

All samples of silicone rubber, composite material (silicone plus 8 perlon layers), and four layers of carbon fiber were tested using the universal testing tool (testometric) at a speed of 2 mm/min. The samples that underwent a tensile test are shown in Figure 1. The tensile test criteria were in accordance with ASTM D638 [8].



a- The dimensional of specimen **b- The Specimens** **C- Tensile test**

Fig. 1. Tensile testing of samples.

B. Manufacturing Procedure

The prosthetist's description will restrict the kind of prosthesis, after assessing the patient, taking measurements, and determining the patient's capacity for recovery. The following stages will be used to describe the AK manufacturing process:

The positive mold is mounted at the laminating stand in accordance with the dimensions of the patients who had AK amputation. The vacuum forming system is connected through the pressure tubes, the inner (PVA) bag is pulled into the positive mold, and the pressure valves are opened to the appropriate value, as seen in Figure 2.

Fig. 2. The mold of AK prosthetics and the inner PVA being pulled.

The mold is filled with six layers of carbon fiber, with the outer layer (PVA) positioned over the value area, and tied off with cotton string. The C-orthocryl lamination resin is mixed with carbon fiber and hardener, resulting in a matrix that is homogeneously distributed over the lamination area, and then placed inside a PVA bag, as depicted in Figure 3.

Fig. 3. Lamination used for manufacturing the AK prosthesis.

To create a carbon fiber socket, a constant vacuum should be maintained until the material is cold and dry. The socket is cut by a vibrational cutter and grinding machine in the desired design, minimizing the contact with the stump and solid carbon areas for support and weight bearing. Then, a hole is created in the socket to release weight and allow liquid silicone rubber to enter. The inner perlon is smoothed by grinding, as illustrated in Figure 4.

Fig. 4. Steps of cutting and smoothing the socket for manufacturing the required design of AK prosthesis.

The vacuum tube is covered with four layers of perlon. The previously constructed solid carbon socket is applied, four layers of perlon are drawn, and secured to the tube. The PVA is tied under tension to the vacuum pipe beneath the lower suction hole after closing the socket adapter's cavity and pulling the outer PVA bag over the finished lay-up. The PVA is checked after turning on the vacuum. One and a half liters of liquid silicone rubber resin are combined with hardener (part B-Catalyst) in an electrical combination in 100:2 ratio. After pouring the contents into the PVA, the bag opening is tied off, as portrayed in Figure 5. The socket is cut to the desired shape and proximal brim with a margin of about 2 cm with an electric cast cutter (vibrational cutter) and then the dummy is taken out of the socket adapter. The socket is removed from the mold, a hole is drilled next to the adaptor, and the form is completed, as demonstrated in Figure 6.

Fig. 5. Mixing of liquid silicon rubber with hardener and PVA addition.

Fig. 6. Final form of the flexible socket.

C. Case Study

Measurements were taken for a patient who is approximately 42 years old, has a height of 168 cm, weighs 95 kg, and suffered from left side below-knee amputation and right side AK amputation due to an accident. The parts that need to be put together are the socket, valve, clamp adapter, rotation adapter, knee joint, foot adapter, and foot. The test of interface pressure was applied on the patient with ethical approval from Al-Nahrain University's College of Engineering (02/2020).

Fig. 7. Patient with the F-socket.

III. NUMERICAL ANALYSIS

The Finite Element Method (FEM) is a powerful numerical method used in engineering and science due to its ability to analyze complex geometrical boundaries and non-linear material properties. This work uses FEM with the ANSYS Workbench 17.2 software to illustrate the fatigue performance of a structure element, determining the maximum stress, total deformation, fatigue life, and safety factor. This model was drawn with the use of SOLIDWORKS 2020 and in accordance with the fabricated 3D original prototype. Most of the above details were taken into account when drawing this model, as evidenced in Figure 8.

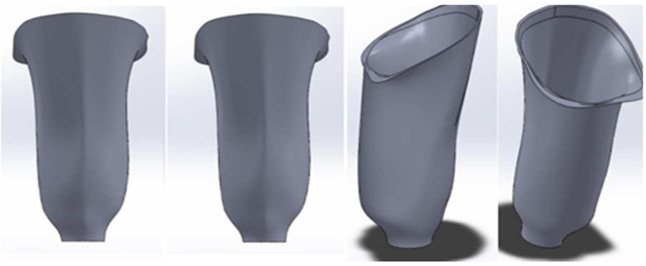


Fig. 8. AK model used in this work.

The meshing process was conducted with 10-node tetrahedral elements (nodes = 6427 and elements = 3169), specifically the SOLID187 element type (automatic meshing) and applied boundary conditions with fixed supports were applied at the end of the socket (adapter socket). Pressure was applied at the anterior side of the socket, as exhibited in Figure 9.

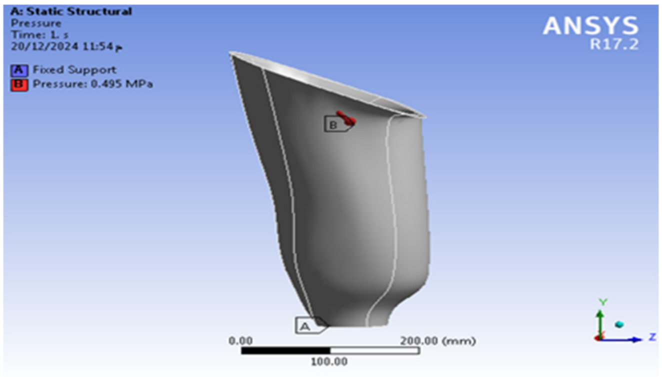


Fig. 9. Model subjected to pressure load.

IV. RESULTS AND DISCUSSION

A. *Tensile Test*

Table I displays the tensile test results for the materials utilized in the flexible prosthetic socket. To determine the stress-strain curve, tests were conducted using six layers of carbon fiber (Group A) and eight layers of silicone rubber resin (Group B) and perlon (Group C). The stress-strain curves for carbon fiber and perlon with silicone rubber are displayed in Figure 10. The tensile test results were used to simulate the socket in ANSYS.

TABLE I. LAYERS, THICKNESS, AND MECHANICAL PROPERTIES OF PROSTHETIC SOCKET MATERIALS

No.	**Total layers**	**Thickness (mm)**	**σ_y MPa**	**σ_{ult} MPa**	**E GPa**
Group A	6	3.8	94.66	141	3.26
Group B	8	3	12.643	54.673	1.1466
Group C	Silicone resin	6.2	0.355	1.59	0.0151

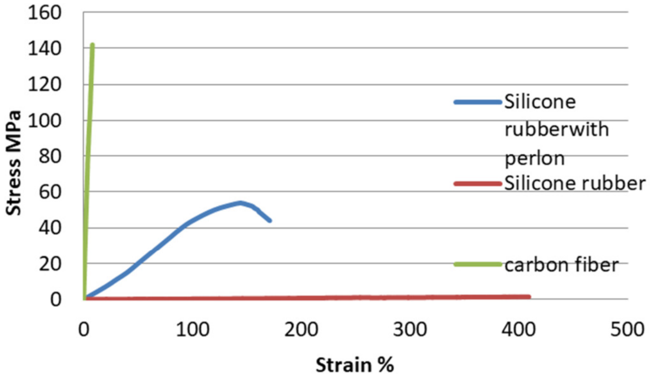


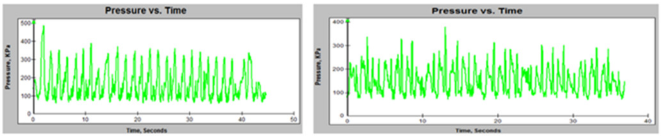
Fig. 10. Stress-strain curve for flexible and solid materials.

B. *F-Socket Results*

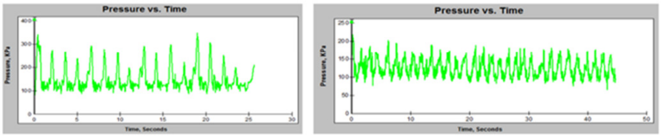
As the patient walked, the interface pressures between the socket and stump (residual limb) were computed. Figure 11 displays the patient's pressure results. Table II demonstrates the distribution of pressure at the socket's four sides. The anterior portion of the socket had a higher-pressure value (305 kPa), which is a satisfactory outcome since the quadriceps muscle, the biggest muscle in the anterior portion, can easily and painlessly withstand such pressure.

TABLE II. INTERFACE PRESSURE

Regions	Anterior	Lateral	Posterior	Medial
Interface Pressure (kPa)	495	355	375	220



Anterior Region Lateral Region



Posterior Region Medial Region

Fig. 11. Interface pressure vs time for the four sides of the socket.

C. *Numerical Results*

Using software Workbench 17.2, the model for the AK prosthetic socket was examined in order to determine the overall deformation and stress (Von-Mises) of the socket when pressure was applied to its four walls based on the anterior, lateral, posterior, and medial F-socket findings. The outcome indicates that the lateral side has a total deformation of 0.188

mm. The safety factor, equivalent stress, and total deformation are displayed in Figures 12-14. The safety factor is 3.677, which is considered acceptable.

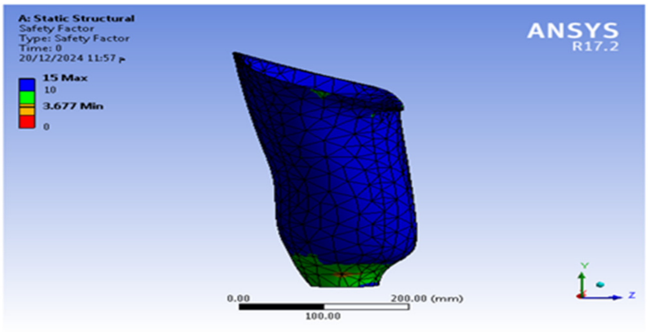


Fig. 12. Safety factor.

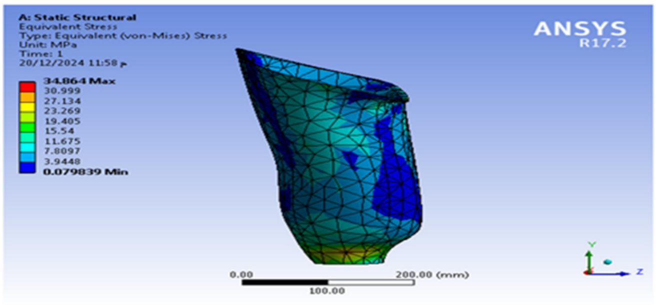


Fig. 13. Equivalent stress.

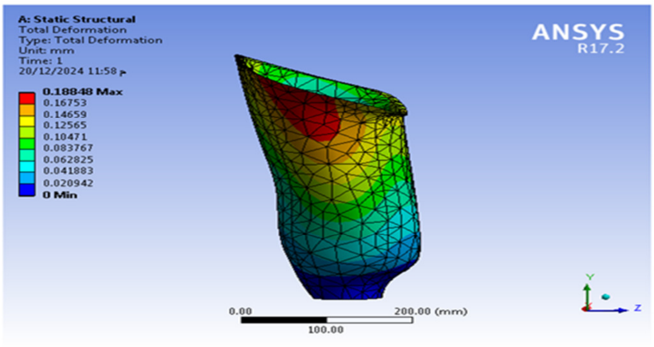


Fig. 14. Total deformation.

V. CONCLUSION

This study developed a prosthetic socket for Above-Knee (AK) amputees that improves comfort, mobility, and reduces the risk of scoliosis by combining rigid and flexible materials. The proposed socket has the following characteristics:

- It is simple to wear and lightweight. In contrast to solid sockets, it permits more muscle mobility. Additionally, it gives the illusion of a typical person under garments.
- Regardless of the kind of sitting surface, it offers seating adaptability. The height of the amputated side, which has a solid socket in comparison to the correct side, causes discomfort in the muscles and the onset of spinal deformation (scoliosis) in the majority of AK amputees when they sit with the prosthesis on.
- The σ_y and σ_{ult} properties of silicone rubber with five layers of perlon increased by approximately 97.2% and 97.145%, respectively, while the module of elasticity remained constant. This indicates that the socket is good and flexible when the patients sit, extend their muscles, and increase the bearing stress on the prosthesis.
- The maximum applied F-socket pressure is 495 kPa in the anterior area.
- The outcome indicates that the lateral side has a total deformation of 0.188 mm. The safety factor is 3.677, which is acceptable in design.

Further improvements in the modeling and manufacturing of flexible sockets for AK amputations could involve integrating advanced materials that enhance comfort, durability, and adaptability to dynamic loads. Additionally, leveraging 3D printing technologies and smart sensors could enable personalized, real-time adjustments to improve fit and functionality for each individual amputee.

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