ISSN 2712-0562
Original Research

Sustainable Engineering and Innovation
Vol. 6, No. 2, October 2024, pp.213-224
https://doi.org/10.37868/sei.v6i2.id368

A novel approach for improving material stiffness using a direct method in below-knee prosthetic sockets

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Received Mar. 13, 2024
Revised Jul. 02, 2024
Accepted Sep. 14, 2024

Abstract

The conventional techniques for producing a socket are time-consuming disproportionate to the significant population afflicted by limb amputations. Although the new manufacturing direct method, the modular socket system (MSS) method, involves reduced labor time, the technique produces sockets with high stiffness that cause discomfort for those with lower limb amputations during walking. This study investigated the tensile characteristics of numerous materials in below-knee prosthetic sockets. Initially, a vacuum molding approach was used to produce the sockets, which involved various polymers and composite materials to improve the prosthesis socket properties. An F-socket device was also employed to ensure efficient production and optimized pressure distribution at the interface between the socket and the residual limb. A SOLIDWORKS® software was then applied to determine the numerical analysis (stress distribution and the maximum internal pressure). The samples from Group E involved utilizing a novel mixture compared to the direct and traditional methods of various materials. This study presents a novel prosthetic limb socket made from a mixture of four carbon fiber layers, utilizing 20% polyurethane resin and 80% acrylic as the matrix. The resulting material demonstrated acceptable stiffness, extended socket life, and reduced curing time. During the patient's gait cycle, peak pressure of 300 KPa was recorded using the F-socket, while SOLIDWORKS® software indicated an internal pressure of 343 KPa, aligning closely with F-socket measurements. The new direct-fit socket design prioritizes comfort and flexibility using materials with reduced stiffness.

Keywords: Prosthetic, Socket, Below-knee, Direct-Method, Modular socket system, Tensile, F-socket.

1. Introduction

Amputation, or the loss of limbs, refers to the complete removal of a limb from the body, regardless of the level at which it occurs [1]. Also is a significant physical and psychologically challenging event that an individual may undergo. This event not only diminishes physical capabilities but also induces mental demotivation or even depression [2]. Amputation is defined and classified based on the amputated part of the body, which can occur in any region of the body at any given moment. For example, lower extremity amputations can vary from partial removal of a toe to complete removal of the leg and portion of the pelvis. Amputations are a global occurrence that can occur at any time and place, including in developed countries. Nonetheless, a constant demand for assistive technology in this field is necessary [3]. In addition, the availability of conventional therapeutic approaches and advanced rehabilitation technologies is still restricted [4].

Most classifications of lower limb amputations involve below-knee amputations, which encompass the removal of any portion of the lower part of the body (see Figure 1a). Transtibial amputations involve surgical removal of a limb at any level between the knee and ankle. Knee disarticulation refers to surgically removing a limb at the knee joint. Transtibial amputation (sometimes called below-knee amputation) is a less severe form of amputation [5,6]. Most individuals who undergo this procedure retain the ability to perform knee movements, such as turning and swinging. Amputation is primarily performed to preserve a person's life; other factors may necessitate this procedure. Given that technology has developed a solution for amputees by allowing them to "regain" the missing body part through a prosthesis, engineers must develop and carefully choose suitable materials for the prosthesis meticulously. Furthermore, the below-knee sockets connect the residual limb and the prosthetic device. Several material properties of the sockets can influence their performance, including comfort, durability, and the ability to withstand loading conditions experienced during daily activities. Hence, selecting a suitable socket material is essential for optimal patient satisfaction and prosthetic function. Figure 1b depicts the four critical components of the below-knee prosthesis: socket, pylon (shank), adapter, and foot [7,8].

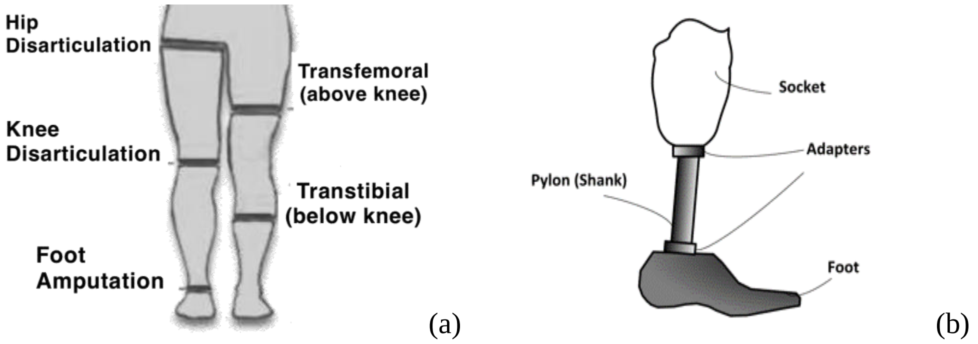

Figure 1. (a) Various levels of lower limb amputations, and (b) Various below-knee prosthetic components

Numerous techniques are available for producing a prosthetic socket. The conventional approach entails using polypropylene and composite materials (lamina). This method is known for its labor-intensive manufacturing process and lengthy duration. In contrast, the direct method, such as the modular socket system (MSS), is considered faster and more modern. Meanwhile, selective laser sintering is a method of additive manufacturing that employs a laser to fuse specific powdered materials. Alternatively, computer-aided design/computer-aided manufacturing (CAD/CAM) includes computer software to design and manufacture sockets. At the same time, 3D printing is a process in which sockets are constructed by depositing material layer by layer [9,10]. Using a socket material with a lower surface roughness decreased friction energy dissipation at the interface between the prosthetic socket and the skin. This, in turn, reduced skin heating and deformation and lowered the risk of skin damage [11].

Several studies have employed various polymers and composite materials to investigate their impact on the mechanical properties of the prosthetics used. Takhakh *et al.* examined different materials' tensile and fatigue properties in below-knee prosthetic sockets. These sockets comprised a combination of eight carbon fiber layers and 11 carbon fiber layers with Perlon. The study measured the Ground's Reaction Force (GRF), the Centre of Pressure (COP), and the pressure distributions for a patient using a mixture of carbon fiber and Perlon materials in an 80:20 ratio [12]. Another study reported the effect of temperature on a composite material socket consisting of 12 layers (4 Perlon + 4 fiberglass + 4 Perlon) with acrylic. The study focused on the effect of walking in hot climate countries and utilized a fatigue test. The impact of temperature on fatigue strength is typically significant in Iraq and other high-temperature states. Nonetheless, no variation in stress values is observed between the lateral and medial regions [13]. Likewise, Al-Shammari and Jweeg proposed using Kevlar instead of carbon fiber to enhance the durability and lifespan of the prosthetic sockets [14, 15]. The study indicated that the suggested socket was composed of Perlon and Kevlar and exhibited 96 percent symmetry to the intact leg. A study by Mechi assessed the impact of incorporating a natural kenaf fiber into below-knee socket prosthesis systems comprised of composite laminated materials with different reinforcement fibers [16]. The study examined how this fiber addition affected stress and deformation. Similarly, Jebur determined the GRF by a patient's foot while using the F-socket test to measure the contact pressure between the below-knee (BK) prosthetic socket and the residual lower limb [17]. The prosthetic socket was fabricated using a composite material consisting of three layers: pyrlon, carbon, and pyrlon. Meanwhile, Challoob discovered that the polypropylene below-knee prosthetic socket experienced a lower strength and hardness over time at high temperatures due to the relaxing effect [18]. The study revealed that this effect led to the socket failure.

Another study necessitated considering the interface pressure for an amputee patient [19]. The prosthetic socket also supported the entire body weight of the amputee during the walking cycle. Thus, the severity of these interface stresses required consideration to determine the extent of damage caused by the socket to the remaining limb tissues. Numerous researchers have explored novel approaches to measuring, developing, and enhancing the BK socket using various polymer and composite materials. A study by Lenz developed a novel method for assessing liner deformation in prosthetic sockets for individuals with below-the-knee amputations [20]. This process was achieved using a reflective marker system and a specialized, transparent socket. The study proposed that this distinctive approach should be examined on a group of amputee individuals during walking to assess displacements and the distribution of liner deformation within the socket. Physicians and researchers could access new information by accurately measuring changes in gel liner deformation.

A study by Sewell utilized an inverse problem technique and artificial intelligence in medicine to predict static and dynamic pressure for prosthetic socket fitting assessment [21]. Alternatively, Pew used CAD topology optimization to develop a custom-designed transtibial prosthesis that resembled a human gait [22]. The study examined the relative motion analysis in transtibial amputees wearing a transverse rotation adapter between the socket and residual limb. Consequently, the study implied that transverse limb loading could indicate residual limb shear stress, and the prosthesis configuration could be customized for each standard motion capture and inverse kinematic analysis. Another study by Golovin concluded that modern prosthetics relied on general-purpose and specialty programming to operate effectively [23]. Several advanced techniques (3D scanning, mathematical modelling, CAD tools, and 3D printing) were utilized for all stages, from design through production. The study facilitated the expedited production of prosthetic limbs, mainly due to a noticeable increase in amputees. Meanwhile, Allen (2022) focused on developing systems and procedures for preparing a prosthetic device's inner surface contour and outside shell socket [24]. The manufacturing process involved utilizing technology such as three-dimensional printing to produce a prosthetic insert socket. This socket was designed to precisely fit the inner surface contour of a pre-made outer shell socket. The prosthetic insert socket was explicitly shaped to align with the contour of the patient's remaining limb surface. A study by Moulic determined that the digitally transformed and 3D-printed sockets with endoskeleton components were critical in rehabilitating future typical transtibial (TT) amputees [25]. This structure could also be utilized to create and improve trans-femoral prosthetic sockets with orthoses and other weight-bearing systems. Similarly, Hamzah discovered a growing interest in the use of CAD/CAM technology for producing transtibial prosthetic sockets (TPS) in developed and developing countries [26]. On the contrary, underdeveloped nations have yet to use this technology's potential fully. The main factors contributing to the limited amount of CAD/CAM system-related studies were insufficient funding, limited accessibility, knowledge gaps, and a shortage of qualified prosthetists. Kamel showed that amputees experienced significant suffering due to lower limb amputation and developed an innovative knee joint prosthesis designed to enable amputees to perform common daily activities such as walking, standing, and going up and down stairs [27].

The user of the active prosthesis experiences reduced physical strain compared to the passive prosthesis yet can still walk normally. Literature has discussed this topic since it is essential to provide prostheses capable of meeting challenging walking needs [28, 29]. Another study by Gubbala demonstrated the satisfactory comfort levels reported by patients who utilized 3D-printed transtibial prostheses [30]. The prosthetics were tailored using a simulation technique to guarantee accurate fitting. This study employed a generic material selection method to determine the material for transtibial prostheses. Various problem-solving analyses were conducted to offer further insights to address this issue, including failure analysis and value engineering. The manufacturing process was also considered for cost-reduction purposes. Finally, environmental considerations related to the process and material were discussed.

The traditional methods of manufacturing a socket require a significant amount of time, which is not commensurate with the large number of people who suffer from limb amputations. Therefore, there is a need to improve the direct method of manufacturing the socket, which is considered one of the most modern and fast methods, particularly the MSS method. However, even though the direct manufacturing method (MSS) is effective in a short period (approximately 10 minutes), there are still some drawbacks, such as the presence of high resistance to creep and low deflection [31]. This means that the high stiffness of the direct manufacturing method (MSS) causes discomfort for lower-limb amputees when walking in warm and humid conditions, leading to pain and skin problems. Additionally, its high cost contributes to these issues. Therefore, there is a need to use different materials to enhance the properties of the prosthesis socket manufactured by direct methods, guarantee the speed of manufacture, and be low-cost.

In this study, a new direct-fit socket for a prosthetic limb was designed and manufactured using new materials with reduced stiffness by investigating the tensile characteristics of numerous materials in below-knee prosthetic sockets. Initially, a vacuum molding approach was used to produce the sockets, involving various polymers and composite materials to improve the prosthesis socket properties. This will ensure that the new socket is more comfortable and has reasonable flexibility. An F-socket device was also employed to ensure efficient production and optimized pressure distribution at the interface between the socket and the residual limb. A SOLIDWORKS® software was then applied to determine the numerical analysis (stress distribution and the maximum internal pressure).

2. Materials and methods

The specimens were manufactured using five distinct material combinations of polymers and composite materials and tabulated as Group A to Group E (Table 1). Two manufacturing methods were employed for testing: the vacuum molding technique (lamina) and the direct method, such as MSS. The equipment utilized in this study comprised a gypsum mold (plaster mixture of Paris and water) with a dimension size of 24 cm × 14 cm × 3 cm, a vacuum forming device consisting of a vacuum pump and various stands, pipes, and tubes, a digital Vernier device for calculating sample dimensions, a sensitive weighing device, and a computerized numerical control (CNC) machine (Rapimill 700) employed for cutting the specimens.

Table 1. Summary of the materials and methods used to produce the specimens.

Group	Materials (reinforcement)	Matrix	Method
A	4 carbon fibre layers	(AX140401)	Direct method
B	4 carbon fibre layers	Lamination resin with acrylic hardener	Lamina
C	9 layers (2 Perlon + 2 Nyglass + 1 carbon + 2 Nyglass +2 Perlon)	Lamination resin with acrylic hardener	Lamina/vacuum molding technique
D	9 layers (2 Perlon + 2 Nyglass + 1 carbon + 2 Nyglass + 2 Perlon)	50% polyurethane resin (part A resin and part B hardener) + 50% acrylic	Lamina
E	4 carbon fibre layers	20% polyurethane resin (part A resin and part B hardener) + 80% acrylic	Direct method

Note that (AX140401) contains diphenylmethane diisocyanate, isomers with homologs, isoparaffinic hydrocarbons, and alkoxylates amine [8]. The specimens were manufactured using traditional and direct methods, incorporating various proportions and thicknesses for matrix and reinforcing materials. These specimens are categorized as follows:

- ***Group A:*** The specimens of group A were manufactured using several steps. Once the positive mold was formed by combining the plaster of Paris and water (24 cm × 14 cm × 3 cm), four carbon fiber layers were added as reinforcement. The matrix materials (AX140401) were injected into the layers using an injection tool. This process was accomplished using a small plastic tubing. Subsequently, an ice cast anatomy was employed for 10 minutes to induce socket clicks on the residual limb. After completing this step, the mold was prepared for the cutting process.
- ***Groups B and C:*** The specimens of group B were manufactured by creating a gypsum mold (24 cm × 14 cm × 3 cm) and then applying a coating of polyvinyl alcohol (PVA) over the plaster. This process was conducted after the mold was dampened with chilled water and talcum powder to facilitate the application process. A vacuum was used beneath the PVA film during contact with the cast. Four carbon fiber layers were then used, followed by applying another PVA bag. Subsequently, an air vacuum was performed. The top of this PVA bag was opened to allow the liquid plastic (lamination resin and hardener) to be poured in. Approximately 600 ml of resin and hardener were used with a volume fraction of 0.99845041. After the drying phase, the mold was prepared for the cutting process. These steps were repeated for the specimens of group C using a different combination of reinforcement layers. The four carbon fiber layers were replaced with two Perlon, two Nyglass, one carbon, two Nyglass, and two Perlon layers (see Figure 2 (a)).
- ***Groups D and E:*** The same stages as the preceding vacuum modeling technique (lamina method) were applied for these groups. Group D utilized matrix materials (50% polyurethane) (part A resin and part B hardener). Meanwhile, group E involved four carbon fiber layers instead of two Perlon, two Nyglass, one carbon, two Nyglass, and two Perlon layers. Additionally, group E utilized matrix materials (20% polyurethane) (part A resin and part B hardener) (see Figure 2 b and c).

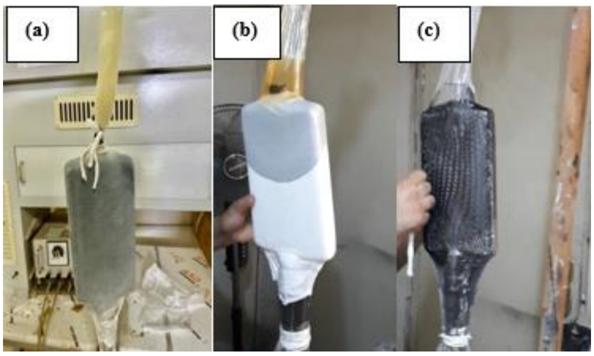

Figure 2. Vacuum process concerning the specimen fabrication for: (a) Group C; (b) Group D; (c) Group E.

Figure 3 illustrates that the specimens are cut using a CNC machine (Rapimill 700). The mold was used to create tensile specimens following the American Society for Testing and Materials (ASTM) D-3039 [29].

Figure 3. The CNC cutting machine (Rapimill 700) and the specimens

Two different tests are performed on the specimens as follows:

Mechanical tensile test: This test was performed under ambient temperature to ascertain the yield strength (σy), ultimate tensile strength (σ UTS), and Young's modulus or modulus of elasticity (E). Various factors could affect the material's tensile properties, including specimen preparation, testing speed (5 rpm), and the testing environment. When the size of the specimens was measured and positioned between the grips, the device began capturing the load-extension graph of the specimen (see Figure 4).

Figure 4. Mechanical testing tensile test

F-socket test: An F-socket device detected the pressure at the interface between the residual limb and the socket. The socket was equipped with sensors (F – Scan / 2012). The experiment was performed on an individual with bilateral lower limb amputation weighing 82 kg (see Figure 5). Initially, the sensors of the F-socket software were attached to various regions of the residual limb to measure interface pressure. Subsequently, the socket underwent placement. The patient then started moving, which caused the program to begin recording the movement and creating a graphical representation (correlation between pressure and time).

Figure 5. F-socket sensor measuring the interface pressure and connecting to a patient

3. Results and discussion

This test involved comparing the mechanical tensile test parameters of various composite material groups, such as Modulus of Elasticity (E) and Ultimate Tensile Strength (σ UTS). Figure 6 (a) portrays that the direct method is time-efficient based on the tensile results. Nevertheless, certain limitations were observed. This constraint included a high stiffness socket, rendering the E value unsatisfactory and high.

The lamina approach demonstrated a lengthy manufacturing process. In contrast, no observations were made regarding the stiffness, implying the stiffness value was deemed satisfactory. The specimens produced using the direct method (group A) acquired a much higher E (3700 MPa) compared to the lamination method (group B) (1100 MPa). Despite using identical reinforcement materials, the stiffness of the specimen manufactured using the direct method was higher than that of the traditional method. The direct method applied socket materials composed of various matrix materials with high E. This outcome was the primary cause of the discomfort experienced by amputees when wearing this particular socket type.

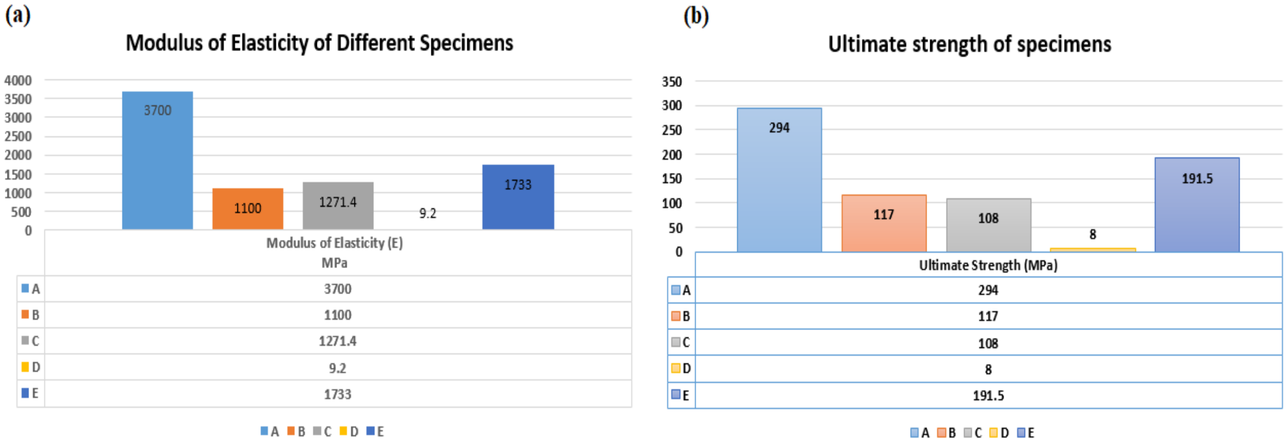

Figure 6. (a) E values and (b) σ UTS values of the specimens

The samples from groups B and C exhibited modest variations in the E values of 1100 MPa and 1271 MPa, respectively. These values were attributed to the composition of identical matrix materials with distinct reinforcing material layers. Therefore, the specimen's stiffness was manufactured using a different reinforcement material, which was deemed satisfactory compared to the direct method. Meanwhile, the E for group D specimen was significantly lower (9.2 MPa) than that for groups A, B, C, and E (3700 MPa, 110 MPa, 1271 MPa, and 1733 MPa, respectively). This observation occurred due to using distinct matrix materials, such as a mixture of polyurethane and acrylic, in equal amounts (50% each). Consequently, the resulting specimens exhibited a notably lower stiffness.

The properties of the new additive material in the specimens in group E were compared with previous traditional and direct methods concerning their properties (stiffness, socket lifespan, and curing time). The direct method incorporated a new matrix material (polyurethane resin) (20%-part A resin and part B hardener) with 80% acrylic. Thus, the properties of this additive were compared to the materials used in traditional (lamina) and direct methods, focusing on cost-effectiveness. The specimens in group E exhibited a moderate E (1733 MPa) compared to the samples in groups A, B, C, and D (3700 MPa, 1100 MPa, 1271 MPa, and 9.2 MPa) due to the addition of a different matrix material (20% polyurethane resin). This process resulted in an acceptable level of stiffness for the specimens.

Figure 6 (b) presents that the maximum strength of the specimens produced using the direct approach (group A, 294 MPa) is significantly higher than that produced using the traditional method (group B, 117 MPa). Despite the unfavorable high stiffness, the socket lifespan would be excellent due to its high strength value. Therefore, the direct approach yielded a favorable outcome. The analysis also revealed that the specimens from groups B and C demonstrated marginal disparities in their maximum strength values (117 MPa and 108 MPa). Although the low stiffness benefited both specimen groups, the low strength value indicated that the socket lifespan would be worse than the direct method (group A, 294 MPa).

The highest specimen strength of group D (8 MPa) was significantly lower than that of groups A, B, C, and E (294 MPa, 117 MPa, 108 MPa, and 191 MPa). This outcome was attributed to the different matrix materials in group D (polyurethane and acrylic in equal proportions), which would cause the socket lifespan to be inferior when compared to the other groups. Furthermore, the highest specimen strength of group E (191.5) MPa was relatively modest compared to the specimens from groups A, B, and C (294 MPa, 117 MPa, and 108 MPa). This result was due to the distinct matrix materials in Group E, which significantly improved the socket lifespan (particularly when compared to groups B and C). Table 2 lists the estimated mechanical properties of the five groups stated above.

Table 2. Summary of the mechanical characteristics derived from the stress-strain curves.

Group	Materials (reinforcement)	Matrix	Method	σ UTS /MPa	E/ MPa	Properties
A	4 carbon fibre layers	(AX140401)	Direct method	294	3700	High stiffness, good socket lifespan, and less time to manufacture the socket (about 10 minutes)
B	4 carbon fibre layers	Lamination resin with hardener acrylic	Lamina/vacuum molding technique	117	1100	Low stiffness, low socket lifespan, and more than 1 hour to manufacture the socket
C	9 layers (2 Perlon + 2 Nyglass + 1 carbon + 2 Nyglass + 2 Perlon)	Lamination resin with hardener acrylic	Lamina/vacuum molding technique	108	1271.4	Low stiffness, low socket lifespan, and more than 1 hour to manufacture the socket
D	9 layers (2 Perlon + 2 Nyglass + 1 carbon + 2 Nyglass + 2 Perlon)	50% polyurethane resin (part A resin and part B hardener) + 50% acrylic	Lamina/ vacuum molding technique	8	9.2	Very low stiffness and less than 1 hour (about 35 minutes) to manufacture the socket
E	4 carbon fibre layers	20% polyurethane resin (part A resin and part B hardener) + 80% acrylic	Direct method	191.5	1733	Moderate stiffness, moderate life socket lifespan, and less than 1 hour (about 35 minutes) to manufacture the socket

The socket and residual limb interface pressures were computed while the subject walked at a self-selected pace. This process was conducted to assess the patient's motion system. Figure 7 depicts the applied pressure results achieved using the F-socket program. Consequently, the pressure reached its maximum value of 300 KPa during the patient's gait cycle.

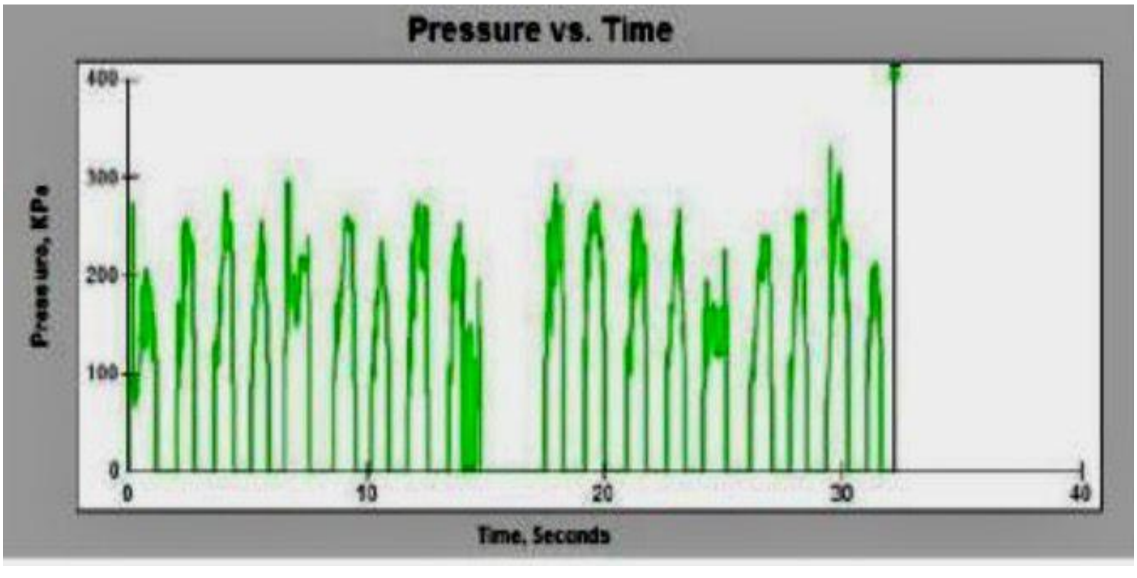

Figure 7. The applied pressure results of the F-socket test

The SOLIDWORKS$^{®}$ software was used to input the socket material, bones, and muscle requirements. This process allowed for a different approach to be used for the numerical analysis (see Figure 8 (a)). Thus, the pressure distribution behavior of a component under a loading condition could be analyzed using numerical analysis. This outcome is conducted by applying a force from the bottom of the socket (GRF) as follows:

$$GRF = Weight \times 1.2 = (Mass \times 9.8) \times 1.2 \text{ (N)} \quad [32]$$

SOLIDWORKS® software was utilized to identify the pressure distribution at the socket. Consequently, the maximum internal pressure reached was 343 kPa, nearly equivalent to the pressure in the F-socket (see Figure 8 (b)).

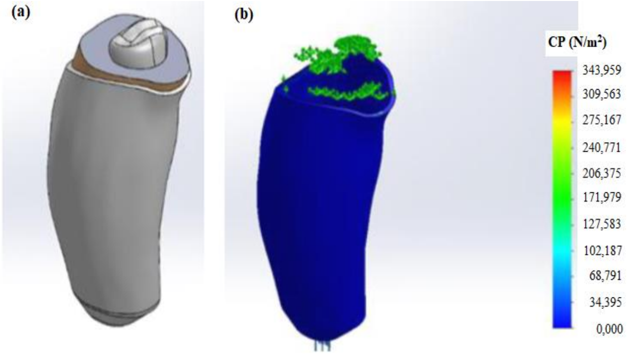

Figure 8. (a) Socket with materials, bones, and muscles using the SOLIDWORKS® software, and (b) Pressure distribution for all socket type

4. Conclusion

This study investigated the tensile characteristics of materials used in below-knee prosthetic sockets, leading to several key findings. Group C specimens, made of a composite of layers including Perlon and carbon, showed a modulus of elasticity (E) of 1271.4 MPa and an ultimate tensile strength (σ UTS) of 108 MPa. While they were safe for skin contact, their low durability indicated a shorter lifespan. Conversely, group E specimens, composed of four carbon fiber layers with a polyurethane-acrylic matrix, achieved an E of 1733 MPa and a σ UTS of 191.5 MPa, offering better stiffness and durability, which could reduce skin wounds on residual limbs. Additionally, the reduced curing time for this material allows for quicker production cycles. Interface pressure measurements within the socket peaked at 300 KPa during critical gait phases, while numerical analysis indicated a maximum internal pressure of 343 KPa, validating the modeling approach used. Overall, the novel material demonstrated promising properties, balancing acceptable stiffness with cost-effectiveness, making it advantageous for prosthetic design and benefiting amputees through improved comfort and durability. Future research should focus on long-term performance assessments to enhance material properties further.

Declaration of competing interest

The authors declare that they have no known financial or non-financial competing interests in any material discussed in this paper.

Funding information

No funding was received from any financial organization to conduct this research.

Author contribution

Inas Zaki Hadi Al-Araji: Conceptualization, Methodology, Writing-review & editing, Formal analysis and investigation, Writing, and editing. Meenaloshini A/P Satgunam, Abreeza Manap, Kadhim k. Resan: Review and supervision.

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