COMPARISON OF FATIGUE PERFORMANCE OF BELOW-KNEE PROSTHETIC SOCKETS FABRICATED VIA NOVEL, DIRECT AND LAMINATION TECHNIQUES

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Abstract - Various techniques have been proposed to manufacture prosthetic sockets, which are essential in improving the quality of life among amputees and individuals with special needs. However, the fabrication of prosthetics using the available approaches is uneconomical due to the type of materials utilized during the production, as well as the direct methods that use expensive materials to produce prosthetic parts. Considering this, it is crucial to enhance the direct methods by exploiting cost-effective materials to produce prosthetic parts with desirable behaviors. Therefore, this study aimed to compare the fatigue performance of below-knee (BK) prosthetic sockets manufactured using three different techniques: laminate, direct, and novel. The three sockets specimens were first manufactured. Specimen A was made via the direct method using 4 layers of carbon fiber as the reinforcement and AX140401 as the matrix. Specimen B was also fabricated via the lamination method using 4 layers of carbon fiber as the reinforcement and lamination resin + hardener acrylic as the matrix. Finally, specimen C was made via the direct novel method using 4 layers of carbon as the reinforcement, and the matrix was composed of 20% polyurethane resin (part A: resin, part B: hardener) + 80% acrylic. Subsequently, the pressure distribution at the contact point between the socket and the residual limb was analyzed using the F-SOCKET device. Furthermore, the numerical analysis included the distribution of the stress and the highest internal pressure, the number of cycles ascertained through the utilization of the SOLIDWORKS software. Based on the results, the S-N curves for each specimen show that all three specimens behaved similarly. Using the F-socket, the pressure during the patient's walking cycle reached its highest point at 190 kPa. In addition, applying ground reaction force from the bottom of the direct, lamination, and novel BK prosthetic sockets demonstrated the pressure distribution of the part that reacts to the loading condition. The SOLIDWORKS program revealed from the pressure distribution of the three sockets measured a maximum internal pressure of 191 kPa, 193 kPa, and 191 kPa sequentially, which was close to the pressure within the F-socket. Besides, the number of cycles for the direct, lamination, and novel BK prosthetic sockets was 1,332,345, 1,202,345, and 1,203,567 cycles. In summary, all three specimens fabricated via the direct, lamination, and novel methods achieved similar fatigue performance of BK prosthetic sockets. So, the novel BK prosthetic socket wad designed in which fabricated using a new matrix material was considered acceptable, similar to specimens A and B.

Keywords: Prosthetic, Socket, Below Knee, Direct, MSS, Fatigue, F-socket, Laminate.

1. Introduction

Roughly 30 million individuals have experienced limb amputations worldwide [1]. Limb loss can occur due to various factors, including diseases, road accidents, and military activities. Amputations in war and post-war areas are often carried out due to severe trauma caused by direct warfare or the persistence of active Explosive Remnants of War (EWR), even after the cessation of hostilities [2][3][4][5]. In view of this, a prosthesis is a synthetic medical apparatus employed to replace a missing or absent bodily component. In particular, a lower-limb prosthesis provides the essential structural support that the missing or severed portion of the skeletal system would otherwise provide [9]. A transfemoral amputee's lower limb prosthesis comprises four primary components: socket, knee joint, and foot/ankle unit. The socket is often fabricated using plastic polymer laminates, which are reinforced with textiles, such as fiberglass, carbon fiber, and nylon, to improve its structural strength [10][11].

There are numerous techniques available for manufacturing a prosthetic socket, including the conventional and modern approaches. An example of a conventional approach is the fabrication of a polypropylene prosthetic from polypropylene thermoplastic sheet or composite materials (lamina) commonly utilized in rehabilitation centres.

Conversely, the modern method, also widely known as the direct method, entails the direct laminating of the patient's remaining limb. Among the various direct methods include the Modular Socket System (MSS), Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM), Selective Laser Sintering (SLS), and three-dimensional (3D) printing.

Despite the significance of prosthetics in restoring the quality of life of individuals, it remains a costly medical procedure among those who have undergone amputations [6]. The type and quality of the materials utilized in the production of a prosthesis directly impact its overall expense. Therefore, opting for cheap materials can enhance the affordability of such prostheses for a wider population [7]. In addition, rehabilitation facilities for individuals with special needs can promote the advancement and enhancement of prostheses and orthotics to produce desirable materials that meet the criteria of durability and comfort for amputee patients, providing a valuable service to humanity [8]. While the direct methods are considered modern and fast, they utilize expensive materials to produce prosthetic parts. Therefore, there is a need to enhance the direct methods by exploiting cost-effective materials that exhibit the same preferable behavior and sustain a fast-paced manufacturing rate.

To date, numerous research groups have dedicated their scientific efforts to the development of novel materials [12-21]. These materials have demonstrated successful performance in terms of their stiffness and strength relative to weight. Consequently, they have been extensively employed in rehabilitation facilities in Iraq. The use of composite materials has enabled the fabrication of several improved engineering structures, such as sockets made in rehabilitation institutions [22-28]. Comprehending and evaluating the tensile and fatigue properties of these materials could aid in choosing the appropriate design for a patient's prosthesis, considering various parameters, such as age, weight, health, activity level, and psychological conditions [29][30].

In the case of below-the-knee amputation (BK), patients felt discomfort and a lack of steadiness in their movement following the use of prosthetic sockets due to the stress and abnormalities encountered in the socket region. The patient's weight during movement and walking directly causes these anomalies, such as drooping and socket fracture [31-33]. The resultant tension and compression loads created during the gait cycle will result in fatigue in the socket. In light of this, numerous researchers have characterized the fatigue properties of composite materials utilized in the manufacturing of socket structures. In one study, Al-Razaq *et al*. (2016) investigated the effect of high temperature on a socket manufactured by the direct MSS method using two layers of materials comprising carbon fiber and perlon. The results indicate the exceptional thermal and chemical stability as well as the outstanding fatigue capabilities of the carbon fiber. Contrary to perlon, the safety factor of both materials fell by 47.6% and 43%, respectively [34].

In another study, Abbas *et al*. (2018) evaluated the fatigue properties and mechanical attributes of the socket on four different laminated composite materials (perlon, carbon fiber, glass fiber, and Nyglass). The findings indicated a decreasing trend in failure stress and a rising trend in the number of cycles required to reach failure at a constant temperature. Perlon recorded a safety factor of around 1.83, which is considered acceptable and safe [35]. Meanwhile, Takhakh *et al*. (2018) examined the variations in load distribution on the sockets of BK prostheses throughout the walking cycle. Sample no. 2 consisting of a perlon-carbon fiber-perlon layer/arrangement, exhibits the highest decay factor in the constant amplitude test, allowing for the most extended cycles before failure [37].

Furthermore, Al-Waily et al. (2020) used several nanoparticle materials, such as nano-SiO_2 and nano-Al_2O_3 particles, to improve the mechanical properties of composite materials and enhance their resistance to fatigue. The experimental data was validated, and the fatigue life and strength of the composite materials were determined using an Artificial Neural Network (ANN) technique. The computed findings demonstrated that the incorporation of nanoparticles led to enhanced mechanical characteristics, fatigue life, and strength. They also indicated that the use of nano-SiO_2 improved the fatigue limits of the composite materials to a greater extent compared to other reinforcement materials. The addition of nano-SiO_2 reinforcement significantly increases the fatigue strength by 60% compared to the fatigue limit without the Nano additive. [38].

Mankai *et al*. (2021) utilized various fiber materials and performed empirical trials on a range of laminate composites, both with and without diverse nanomaterial enhancements and reinforcements. Based on the analysis of different nanomaterials and their weight fractions, SiO_2 (weight fraction of around 2%) showed the most advantageous performance. The observed occurrence involved a composite sample Consisting of perlon (2 layers), kevlar (2), perlon (1), 2kevlar, 1perlon, carbon (2), perlon(1) , kevlar(2), and perlon (2) . The stress on the socket was reduced by about 40%, while the deformation decreased by about 38% [39]. Besides, Hussien *et al*. (2017) assessed the impacts of ultraviolet (UV) radiation in conjunction with temperature using perlon (group A) and perlon and carbon fibers (group B). According to the results, the carbon fiber-reinforced material displayed the highest fatigue limit and safety factor values (5.0638, 4.6565, 5.0424, and 4.4613). However, the combined effect of temperature and UV radiation decreased the safety factors and rendered the materials of group A unsafe. [40].

Additionally, Jweeg *et al*. (2012) evaluated the impact of temperature on the socket of composite material while walking in hot-climate areas. The fatigue safety factor in the socket was reduced as a result of temperature variations. The study concluded the significant effect of temperature on fatigue strength in Iraq and regions with high temperatures [41]. Apart from that, Abdulameer and Al-Shammari (2018) determined the fatigue resistance of Syme's prosthetic socket. The reinforcement materials consist of several layers of woven carbon fiber cloth with layers of perlon and acrylic resin. The material exhibited exceptional durability against recurring strains. The fatigue analysis indicates that the fatigue safety factor reached a minimum value of 4.637 [42].

2. Experimental Procedures

2.1. Materials

The vacuum molding technique (lamina) and direct method (MSS) were employed to manufacture the specimens for this study. Table (1) lists the materials used in manufacturing the specimens, as applied in a previous study [34]. Note that the AX140401 matrix comprises diphenylmethane diisocyanate, which consists of its isomers and homologs, as well as isoparaffinic hydrocarbons and alkoxylate amine.

Table 1. Methods and materials employed for fabricating the specimens

Group	Materials		Method	Reference
	Reinforcement	Matrix		
A	4 layers of carbon fiber	AX140401	Direct	[34]
B	4 layers of carbon fiber	Lamination resin + hardener acrylic	Lamina	[34]
C	4 layers of carbon	20% polyurethane resin (part A: resin, part B: hardener) + 80% acrylic	Direct/New (Novel)	Present study

2.2. Equipment

The equipment used in this study consists of a gypsum mold made from a mixture of plaster of Paris and water (dimensions of 24 cm x 14 cm x 3 cm). The vacuum-forming system consists of a vacuum pump and various stands, pipes, and tubes. A digital vernier device was also used to measure the dimensions of the samples. In addition, a sensitive weighing device was employed to weigh the materials. The cutting procedure of the specimen was performed using a Rapimill 700 CNC machine.

2.3. Fabrication of Specimens

The specimens were fabricated by applying the mixed plaster on the gypsum mold, followed by an additional Polyvinyl Alcohol (PVA) coating. Beforehand, the mold was moistened with cold water and talcum powder to facilitate the dressing procedure. The PVA film was placed over the object and then pulled taut against the surface to generate a vacuum condition. Subsequently, four layers of carbon fiber, employed as reinforcement materials, were placed on the mold as layers over the PVA coating. Another PVA bag was placed on top, and an air vacuum was executed. The opening of the PVA bag was specifically designed to accommodate the liquid plastic, which is composed of a mixture of resin (consisting of lamination resin and hardener) making up 80% and polyurethane (consisting of part A resin and part B hardener) making up 20%, as shown in Figure 1.

Figure 1: Fabrication of specimens (Direct Method)

2.4. Preparation of Specimens

The specimen was precisely cut using the Rapimill 700 CNC machine. The fabrication of the fatigue specimens complied with the instructions provided by the fatigue apparatus [43-45].

2.5. Mechanical Properties Analysis

2.5.1. Tensile Testing

The tensile qualities of a material can be influenced by several factors, such as specimen preparation, testing speed (at a rate of 5 rpm), and the testing environment. Therefore, tensile testing was performed to determine the strength and behavior of the materials under tension and at standard room temperature. The measured parameters include the yield strength (σy), ultimate tensile strength (σ UTS), and Young's modulus (E). Upon measuring the specimens and placing them between the grips, the gadget began recording the load-extension curve of the specimen.

2.5.2. Fatigue Testing

The primary objective of the fatigue testing examination is to ascertain the maximum stress that a material can withstand over a particular number of cycles before it fails. The fatigue performance of the composite materials was assessed by subjecting several samples to different maximum stress levels. The fatigue testing commenced once the yield stress and Young's modulus were determined via tensile testing. The highest stress of the specimen positioned in the middle of the reciprocating mechanism was selected as the initial reference for calculating the deflection. The velocity of the testing apparatus is contingent upon the composition of the materials under examination and the intended amount of bending. Composite materials use a lower velocity than metals. Hence, the electric motor in this experiment was set at a velocity of 1500 rpm. Consequently, the deviation was measured using the dial gauge. Stress is incrementally applied until either a break appears in the specimen or deflection occurs. These events happen under normal environmental conditions for seven specimens.

2.5.3. F-socket Testing

An F-socket device was used to measure the interface pressure between the residual limb and the socket, which is made up of sensors. (F – Scan/2012). The test was conducted on a 36-year-old person weighing 71 kg with symmetrical lower limb amputation, as depicted in Figure 2. The monitoring interface pressure involves placing the sensors of the F-socket software at various locations on the residual limb, followed by applying the socket. As the patient starts to walk, the program begins to record the movement and generate a graphical representation illustrating the correlation between pressure and time.

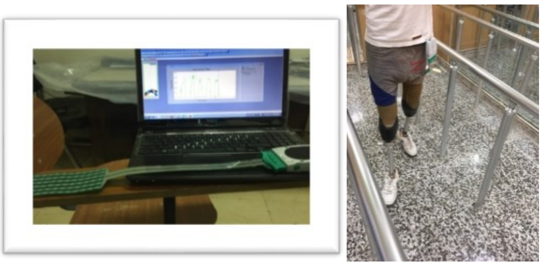


Figure 2: The F-socket device fixed on the patient's limb to monitor the pressure during walking

3. Results and Discussion

The experimental and numerical results, which encompassed various mechanical properties, such as fatigue testing of material, were acquired and analyzed in this section. The numerical results cover the stress distribution and deformation analysis within the prosthetic socket and the life span of the socket.

3.1. Tensile Results

Table (2) lists the estimated mechanical properties of the three specimen groups.

Table 2. Mechanical properties of the three specimen groups

Group	Materials		Method	σult (MPa)	E (MPa)
	Reinforcement	Matrix			
A	4 layers of carbon fiber	AX140401	Direct	150	1792
B	4 layers of carbon fiber	Lamination resin + hardener acrylic	Laminate	100	3023
C	4 layers of carbon	20% polyurethane resin (part A: resin, part B: hardener) + 80% acrylic	Direct/New	191.5	1733

3.2. Fatigue Results

The fatigue-life diagram is commonly employed to analyze fatigue failures in materials.

As depicted in Figure 3, the stress findings for the new materials (group C) were compared with the earlier results from groups A and B.

The fatigue-related failure of the flat specimen occurred when the specimen fractured was exposed to high cycle fatigue stress. The fatigue tester equipment recorded the test findings, providing the number of cycles at which the samples fractured. The S-N curves for each specimen show that the groups of samples behaved similarly.

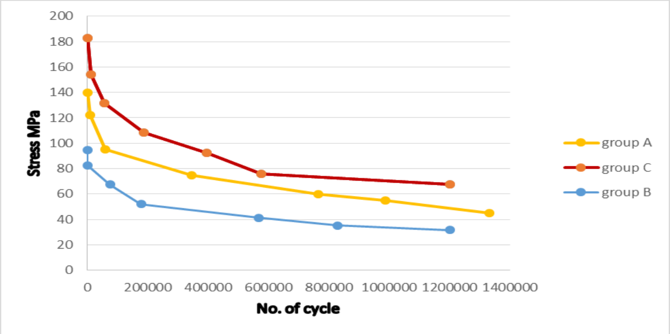


Figure 3: The S-N curves of specimens A, B, and C

3.3. Numerical Analysis of the Pressure Exerted at the Interface between the Socket and the Residual Limb

The interface pressure between the socket and the remaining part of the limb was measured as the subject walked at a certain speed to examine the patient's motion system.

Figure 4 illustrates the exerted pressure in the case study conducted using F-socket software. At the peak of the patient's gait cycle, the pressure reached a maximum of 190 kPa.

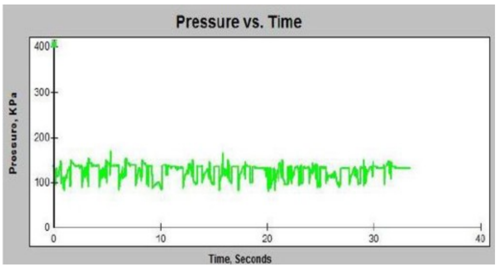


Figure 4: Numerical analysis and results

Using the SOLIDWORKS application, the socket materials, bones, and muscles were computed to analyze them numerically, as depicted in Figure 5.

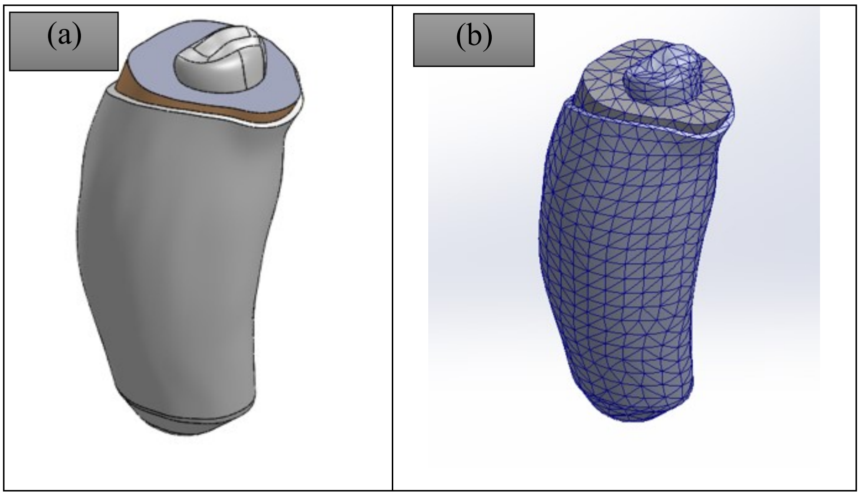
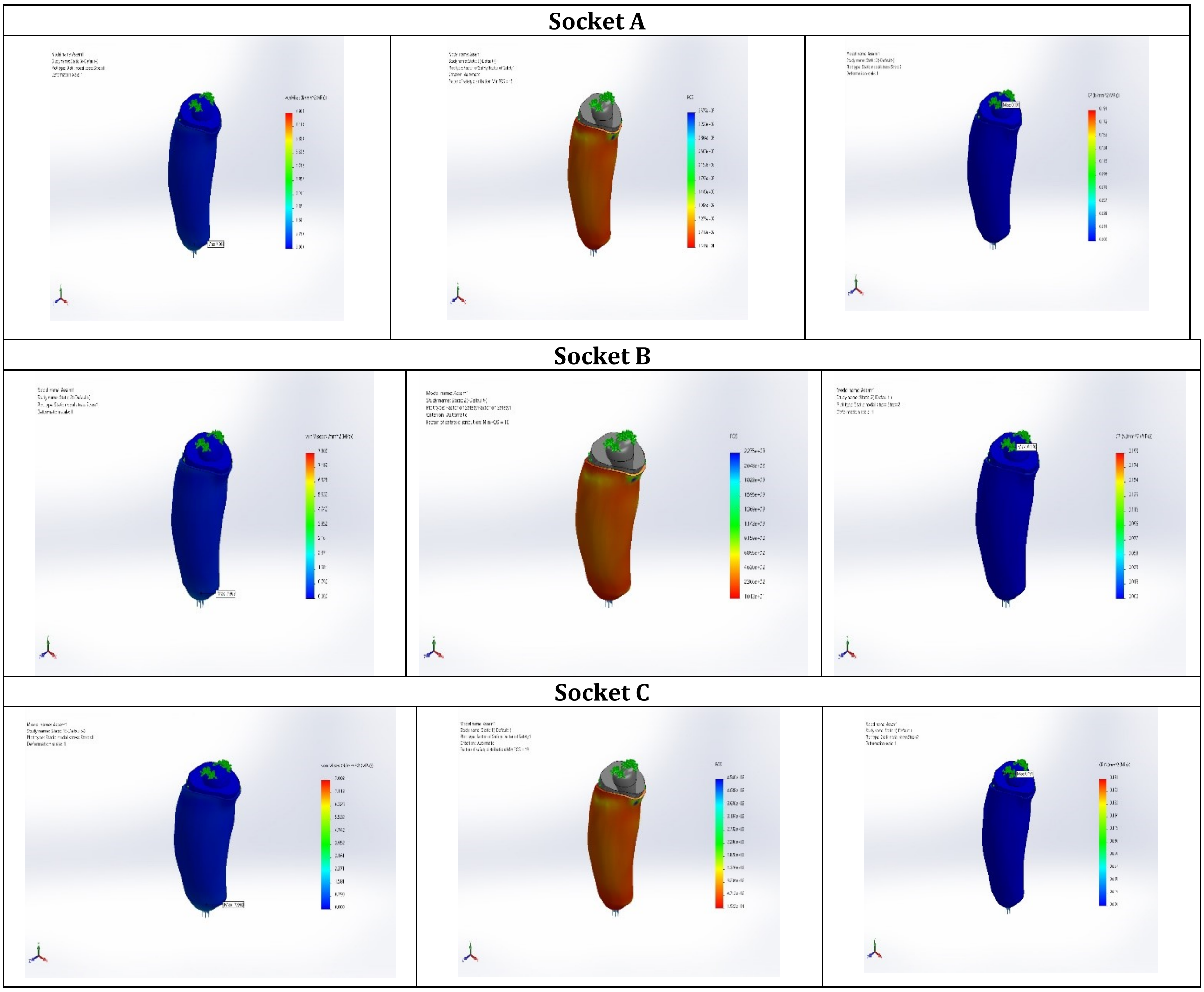


Figure 5: (a) Socket with materials, bones, and muscles using the SOLIDWORKS software, and (b) Pressure distribution for all socket type

The pressure distribution of a component's response to a specific loading condition was analyzed by applying the ground reaction force (weight * 1.2 = mass * 9.8 * 1.2) from the bottom of the direct, lamination, and novel BK prosthetic sockets. The SOLIDWORKS program revealed the maximum internal pressure of 191 kPa, 193 kPa, and 191 kPa sequentially for the three specimens, which are nearly identical to the pressure within the F-socket, as depicted in Figure 6.

Additionally, when a repeated load is applied, the life span of the socket depends on the number of cycles for each of the direct, lamination, and novel BK prosthetic sockets. Based on Figure 7, the life span of specimens A, B, and C was 1,332,345, 1,202,345, and 1,203,567 cycles, respectively.

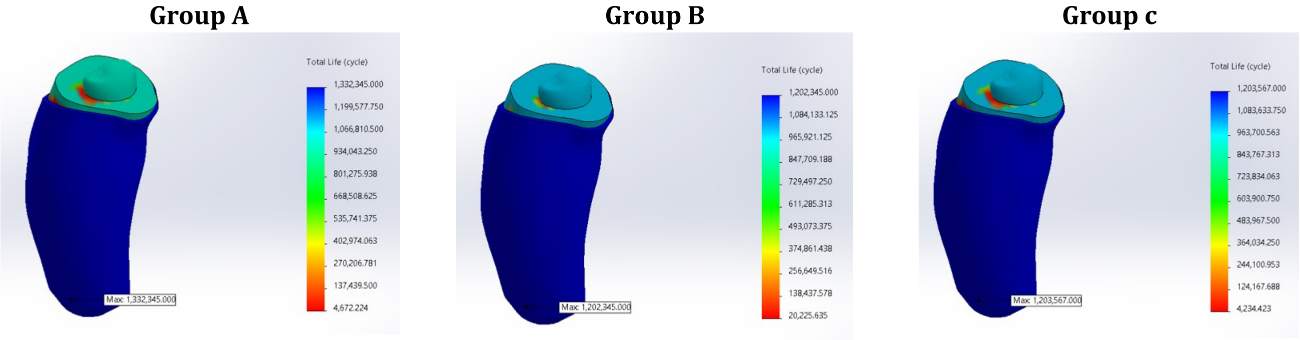


Socket A

Socket B

Socket C

Figure 6: The pressure distribution for all socket type



Group A

Group B

Group c

Figure 7: The number of cycles for all socket type

4. Conclusions

In this work, a novel BK prosthetic socket wad designed in which fabricated using a new matrix material comprising 20% polyurethane resin (part A resin and part B hardener) + 80% acrylic via the direct novel approach (specimen C) which was exhibited similar behavior to those manufactured through the direct (specimen A) and lamination (specimen B) methods. The prosthetic socket's interface pressure displayed a sinusoidal pattern, peaking at 190 kPa during the initial contact of the heel and the final push-off of the toe. In addition, the maximum internal pressure determined by numerical analysis for each direct, lamination, and novel BK prosthetics were 191 kPa, 193 kPa, and 191 kPa sequentially, whose values were closer to the pressure in the F-socket. Moreover, the specimens in group C have a life span of 1,203,567 cycles, which was considered acceptable, similar to specimens A (1,332,345 cycles) and B (1,202,345 cycles).

Another potential advantage of the proposed prosthetic socket is the low manufacturing cost compared to other direct method sockets. It is manufactured from matrix material consisting of 20% polyurethane resin (part A resin and part B hardener) and 80% acrylic that is less expensive than AX140401 from which the direct prosthetic sockets are manufactured. In addition, the matrix materials used in the proposed method cost approximately the same as the matrix materials used in the lamination manufacturing method.

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