Penerbit Akademia Baru

Malaysian Journal on Composites Science and Manufacturing

Journal homepage:
https://www.akademiabaru.com/submit/index.php/mjcsm/
ISSN: 2716-6945

Design and Development of Printable Prosthetic Foot using Acrylonitrile Butadiene Styrene (ABS) for Below Knee Amputation (BKA)

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ARTICLE INFO

Article history:
Received 1 March 2023
Received in revised form 21 March 2023
Accepted 28 March 2023
Available online 30 March 2023

Keywords:
3D printing, prosthetic foot, Acrylonitrile Butadiene Styrene (ABS)

ABSTRACT

Prosthesis is an artificial replacement for a person's missing limb to help regain mobility and the ability to manage daily activities. The type of prosthetic covered in this project is for people with below-knee amputation (BKA). Muscle fatigue is a major issue for amputees who lose a lower limb after prolonged use of artificial limbs. Available designs of prosthetics for BKA are also expensive. This study aims to design and develop an affordable and comfortable prosthetic foot with an energy-story ability for persons with BKA using an additive manufacturing process to help reduce fatigue. Three conceptual designs based were developed for this purpose. Based on the design selection matrix, the best design was chosen and developed in SolidWorks 2013 environment. Stress and strain analyses were simulated to verify the design's ability to withstand the weight of a sample patient with BKA. A sample of patient details, including weight, amputation side and sole (of the foot) length, were obtained and implemented in the prosthetic foot design. Due to its strength and durability, the design was printed on the Veglar V-821 additive manufacturing machine using Acrylonitrile Butadiene Styrene (ABS) material. A pilot test with a male patient with BKA was conducted under the supervision of a prosthetist under two conditions: standing and walking. The prosthetic prototype did not break during the test, and the patient felt comfortable using it. This finding shows that additive manufacturing can produce an affordable and comfortable prototype of a prosthetic foot using ABS. Hence, more BKA patients can benefit from inexpensive prostheses and finally help them achieve a better quality of life.

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https://doi.org/10.37934/mjcsm.10.1.1123

1. Introduction

Thousands of people throughout the world require limb amputations every year for a variety of medical conditions. Loss of a limb means the loss of all or a part of an arm or a leg [1]. The loss of a limb can be due to accidents, falls, infection or disease trauma [2]. Statistics by Amputee Coalition, a limb loss organization in America, has stated that health factor such as diabetes has been the main contributors to limb loss worldwide [3]. This situation worsens when many people do not care enough about their health by adopting bad eating habits [4] and unhealthy lifestyles.

The prevalence of amputation nowadays due to traumatic causes and diseases makes prosthetics more critical to society [5]—Moreover, protection schemes and insurance cover when one loses limbs [6]. However, not many people can afford it. Not only that, this is not a one-time cost. It will need to be replaced throughout a person's lifetime due to wear and tear. Thus, the price is an essential limiting factor for those who cannot afford it.

This study aims to design and develop an affordable and comfortable prosthetic foot with the energy-story ability for persons with below-knee amputation (BKA). An energy-storing prosthetic foot is a device that attempts to store energy. It is designed to permit below-knee amputees to participate in a wide range of activities [7]. In this study, a prototype is designed for disabled people who lost a limb to regain their normal life activities. Today, improvements ensure the prosthetic foot works efficiently and comforts the user. In the olden days, most soldiers face a high risk of losing their limbs during war. At that point, there is a severe danger of loss or injury to the foot. Prosthetics were not widely discovered in research, equipment, and material then. Instead, they used natural sources like wood and steel to make prosthetics feet [8]. Figure 1 depicts the evolution of the prosthetic foot.

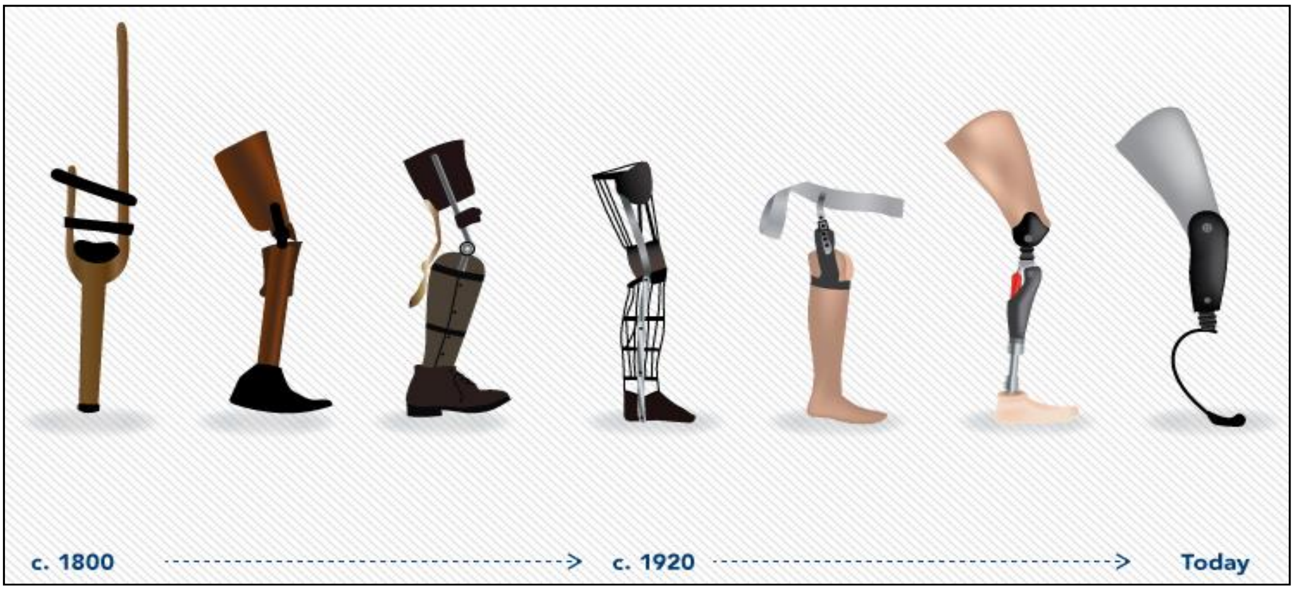

Fig. 1. The evolution of prosthetics foot [9]

The price of prosthetic feet nowadays is costly, but the functions still do not make the patient feel comfortable [9]. Gimpsey and Bradford (2011) mentioned that a few issues arise after the patient uses the prosthetics for a certain period. Muscle fatigue, tiredness, and non-user-friendly prosthetics affect the patient's well-being [10]. This discomfort also can affect a patient's mood and make them passive. Thus, the main objective of this research is to design and develop an affordable and comfortable prosthetic foot with an energy-story ability for persons with BKA using an additive manufacturing process to help reduce muscle fatigue.

2. Literature Review
2.1 Flex-Foot

Flex-foot is a prosthetic leg technology developed by a German company, Otto Bock [11]. The Flex-foot technology focuses on amputees' comfort by offering efficient gait. The Flex-foot was designed with multi-axis foot movement, allowing rocking foot motion from heel to toe and improving the amputee's walking movement. The Flex-foot technology was manufactured with unique capabilities to store the energy during stance and release it during the toe-off [12]. The mechanism of the design is similar to a spring-like mechanism leading to fatigue alleviation during walking. This activity lessens the need to push the body forward, effectively utilizing the collateral foot, and evens walking length [13]. The full-length toe lever coordinates the length of the sound foot, giving enhanced support to the prosthetic appendage amid late position. It guarantees that users invest energy in the prosthetic foot and common appendage, enhancing strolling progression and decreasing the effect on the sound appendage. In addition, this technology was versatile and allowed amputees to customize the prosthetic leg according to their needs [14]. Figure 2 shows an example of the Flex-foot design.

Fig. 2. An example of Flex-foot design [13]

2.2 Energy-storing Prosthetic Foot

The prosthetic foot with energy-storing is a type of prosthetic foot. Commonly, the prosthetic foot of this type was designed similarly to natural foot biomechanics concepts which store the mechanical energy during stance and releases the energy during push-off [15]. This concept uses spring-like material for the prosthetic foot, which can reduce metabolic energy during walking, thus enhancing walking economically. Moreover, it significantly affects gait stability to minimize muscle fatigue [16]. There are several examples of energy-storing prosthetic feet other than Flex-foot: the Echelon foot by Blatchford [17], the Elan foot by Endolite [18], and the Rheo knee by Össur [19].

As the Flex-foot is customized and made from a lightweight material such as carbon fiber composites, the Echelon foot is designed with a waterproof hydraulic ankle that allows the amputee to self-align without needing external force. Meanwhile, the design of the Elan foot includes using a microprocessor to control the foot to improve the amputee's stability during walking. The Rheo knee also uses a microprocessor in its design to enhance stability during walking. However, it's focused on the knee compared to Elan's foot which focuses on the foot.

3. Methodology
3.1 Initial Design and Geometry Model

Three sketches of prosthetic foot models were designed as depicted in Figures 3, 4 and 5. The sketches were made by setting the existing Flex-Foot model as a benchmark. There were two crucial points in designing the models: the heel and keel part. The keel part was essential to provide stability during midstance in the walking cycle. For each of the three designs, the curvature of the prosthetics base and the thickness "B" of the upper part of the S-shape were identified as critical points during the design stage.

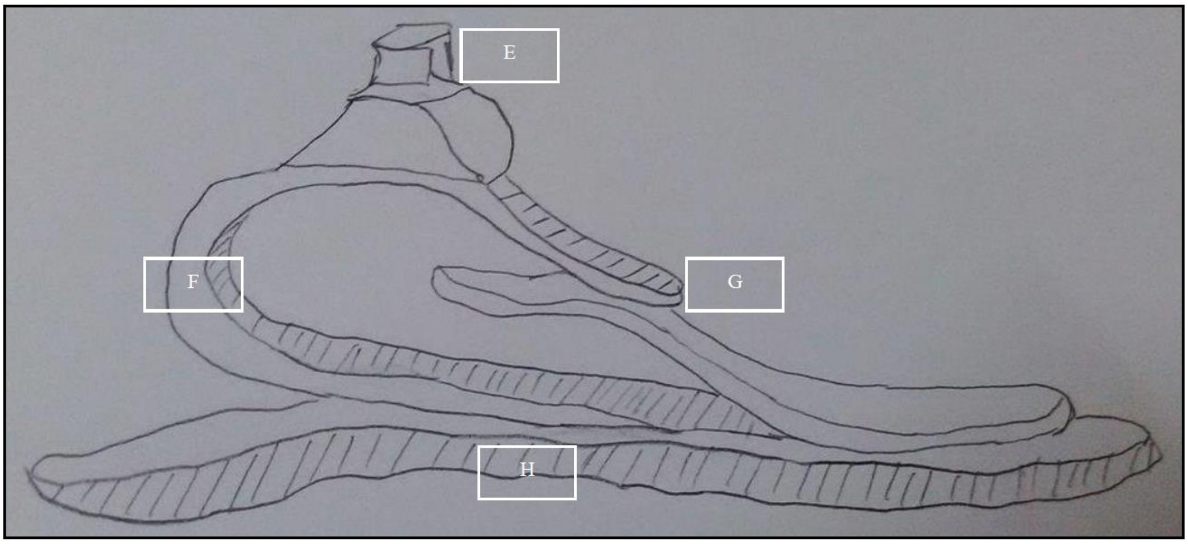

Fig. 3. Design A of the prosthetic foot

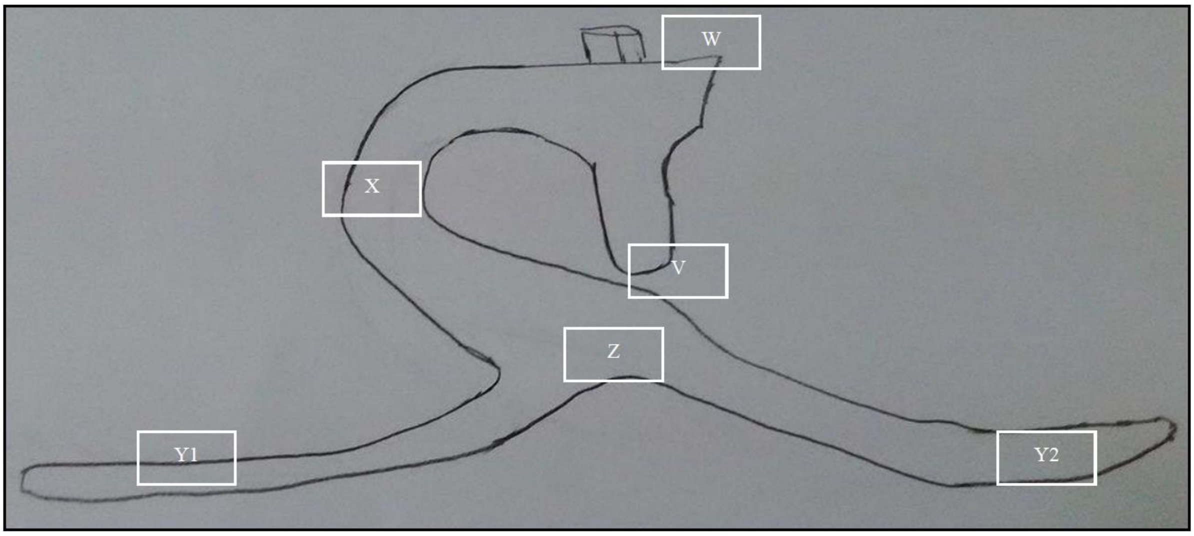

Fig. 4. Design B of the prosthetic foot

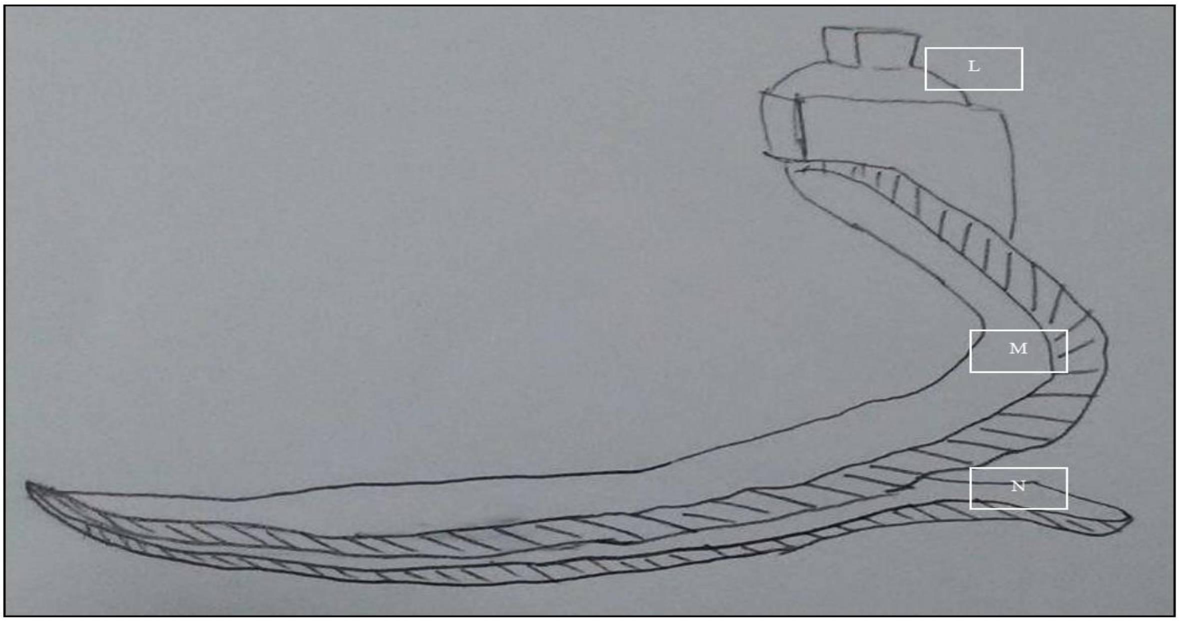

Fig. 5. Design C of the prosthetic foot

Table 1 tabulates the screening matrix for Design A, Design B and Design C. There were four critical points in Design A: Point E, Point F, Point G, and Point H. Point E and Point G indicated the design's uniqueness by acting like a socket. Point G was divided into two parts which were overlapping. The overlap part will bounce and absorb the mechanical loading during walking. Meanwhile, Point H stored the energy during stance, and Point H was a base which provided stability for the design model.

On the other hand, Design B had six critical points named Point V, Point W, Point X, Point Y1, Point Y2, and Point Z. There was a gap between Point V and Point Z, with Point W acting as a socket. Point X had a curve shape and was located at the upper part of the model. Point Y1 and Point Y2 formed the base of Design B, with point Z in their middle. Design B was a solid design without the mating part.

Design C only had three points named Point L, Point M and Point N, where Point M is the curvature of the upper part, and Point N is the base of the design. All designs were inspired by the basic design of the Flex-Foot. The design selection matrix shown in Table 1 was used to screen and select the best design. There are a few criteria and weightage that were considered for this selection. The ergonomic criterion has the highest weightage, which is 40%. This ergonomic criterion refers to the stress relief ability because these criteria help reduce stress on the final product and are followed by durability at 35%. It became the second important criterion to ensure the final product can sustain the patient's body weight. These two criteria are domain criteria to get the best design.

Four criteria were selected as essential to be considered in choosing the best prosthetic foot design. The criteria are ergonomics, complexity, ease of maintenance and durability. The scoring is based on the screening method, and Design A was selected as the most suitable design. Design A was chosen because it is similar to a current prosthetic in the market. In addition, it has a C-curve with the flexibility to bounce back due to the impact absorption during walking. This characteristic will help patients with BKA heel off and strike better during the gait cycle. Nevertheless, even though prosthetic design with C-curve has better performance, they can also be costly, making them unfeasible for many amputees.

Table 1
Design selection matrix for Design A, Design B and Design C

Selection Criteria		Design A		Design B		Design C	
Criteria	Weightage	Scoring	Percentage	Scoring	Percentage	Scoring	Percentage
Ergonomic (Stress Relief)	40%	4	32%	1	8%	3	24%
Complexity	15%	4	12%	2	6%	2	6%
Easy to maintenance	10%	2	4%	1	2%	3	6%
Durability	35%	3	21%	1	7%	2	14%
TOTAL	**100%**	**13**	**69%**	**5**	**23%**	**8**	**50%**

3.2 Materials and Prototype Testing

Nylon and carbon fiber-based composites are the most common materials for prosthetic foot manufacturers. The reason was the prosthetics foot must be robust to support the patient's weight [20]. Nylon usually was used during conventional feet and the early prosthetic foot era [21]. However, the material was heavy, leading to muscle fatigue [19]. Nowadays, prosthetic foot material is replaced with carbon fiber composite materials. However, to meet the recent developments of additive manufacturing methods that enable individual prosthetics to be printed economically, the materials were changed to Acrylonitrile Butadiene Styrene (ABS), cheaper than carbon fiber composites.

Therefore, it was decided that FDM filament ABS would be used for the prototyping, and its mechanical properties were analyzed in the SolidWorks 2013 environment. The prototype was manufactured using a Veglar machine (V-821), an additive manufacturing printing apparatus suitable for products built using ABS filament. The nozzle can be adjusted automatically by selecting the type of filament used. This machine can print objects up to 270 mm width x 200 mm depth x 247.35 mm height and print the drawing if the file is in STL file format.

3.3 Patient Sample Information for Design Purpose

The design and development in the SolidWorks 2013 environment were conducted based on the information on a sample of the patient's background obtained from a professional prosthetist working at a rehabilitation centre in Melaka. This data was important because it served as a guideline in the design process. The specific details of the patient with BKA are tabulated in Table 2.

Table 2
Details on the patient with BKA

Information	Details
Side of Amputation	Left BKA
Length of Sole	28.0 cm
Weight	90kg
Gender	Male
Age	34 years old

The patient with BKA weighed 90 kg. Thus, the prototype design must withstand a minimum of 883 Newton, equivalent to the patient's weight. Hence, a total load of 1,000 N was selected for the load simulation, slightly higher than his actual weight.

4. Results and Discussion
4.1 Design Development using SolidWorks 2013

Detailed design was developed in SolidWorks 2013. The design needs to be comfortable and, at the same time, have an energy-storing feature. This is related to the ability of the developed prosthetic to be shock-absorbing while walking and conducting daily activities. Figure 6 shows the final stage of design, where the simulated design was safe to withstand 1,000 Newton of load.

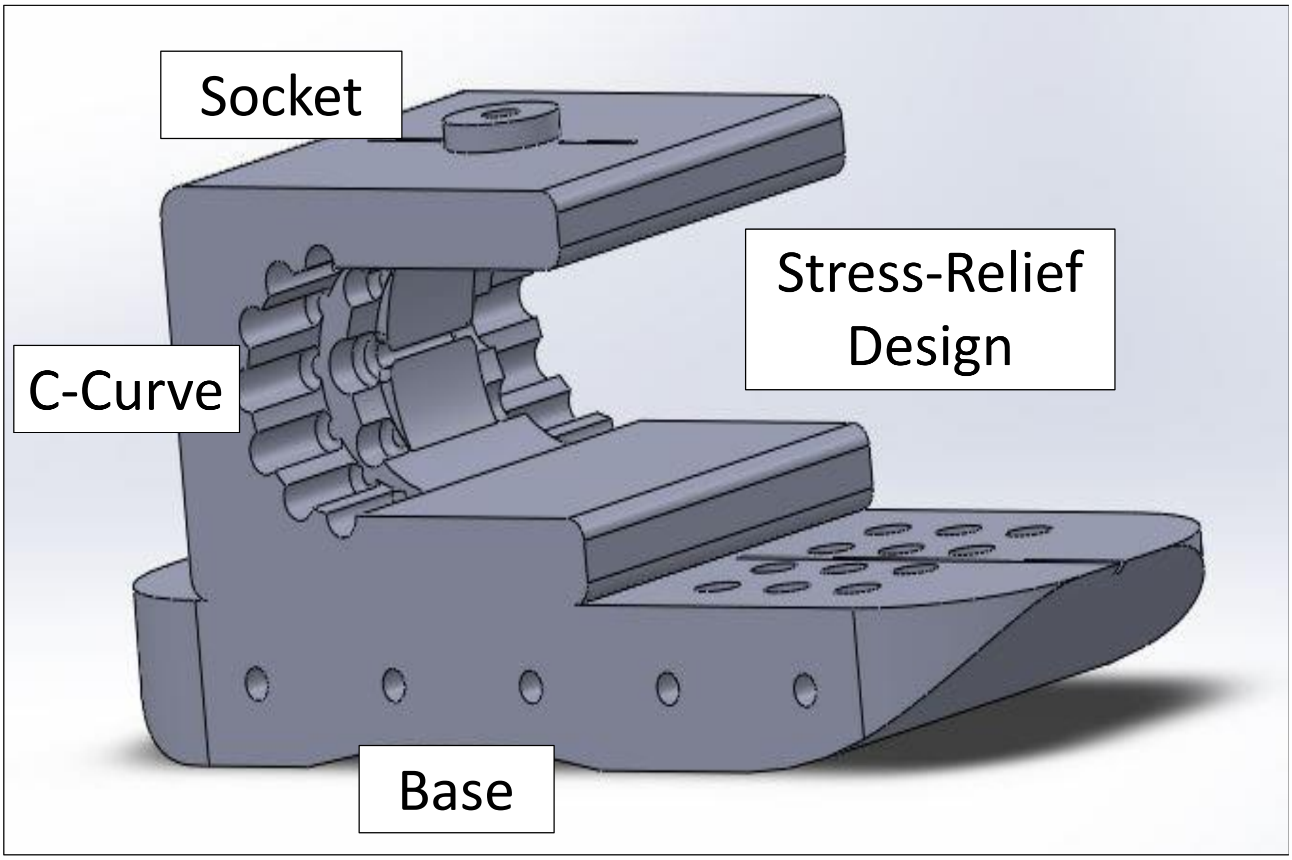

Fig. 6. Finalized design of the prosthetic foot based on the sketch of Design A

4.2 Stress and Strain Analysis using SolidWorks 2013

Stress and strain analyses are used to calculate the effects of steady loading conditions on a structure. The stress and strain analyses were simulated to verify the design's ability to withstand the weight of the BKA patient based on the information in Table 3. It is essential for the estimation of the mechanical strength of the structure. It also depends on the parameters of the 3D printing, such as printing orientation and layer thickness [22]. Therefore, we can find out the failure part of the project before the product is fabricated. This method can help reduce initial costs and save time, especially for products still undergoing research and development.

Acrylonitrile Butadiene Styrene (ABS) material is used for this analysis, and 1,000 Newton force is applied to the prosthetic prototype design. Table 3 shows the material properties of ABS. The static analysis results present the deformation, Von Mises stress, and equivalent strain information. The colour spectrum differentiates the stress in each element. Next, the analysis is started with the process of meshing elements. In this process, fine mesh produces a more accurate solution.

Table 3 Material properties of ABS

Material Name	(Acrylonitrile Butadiene Styrene) ABS
Mass	0.00100658 kg
Volume	9.86845e-007 m^3
Density	1020 kg/m^3
Weight	0.00986451 N
Tensile strength	3e+007 N/m^2
Elastic modulus	2e+009 N/m^2
Poisson's ratio	0.394
Mass density	1020 kg/m^3
Shear modulus	3.189e+008 N/m^2

The maximum deformation occurs at the edge of the "C-curve" because of the high contact area between load force and prosthetic prototype surface design. Figure 7 shows the displacement analysis with the maximum value of the deformation of 3.31643 mm.

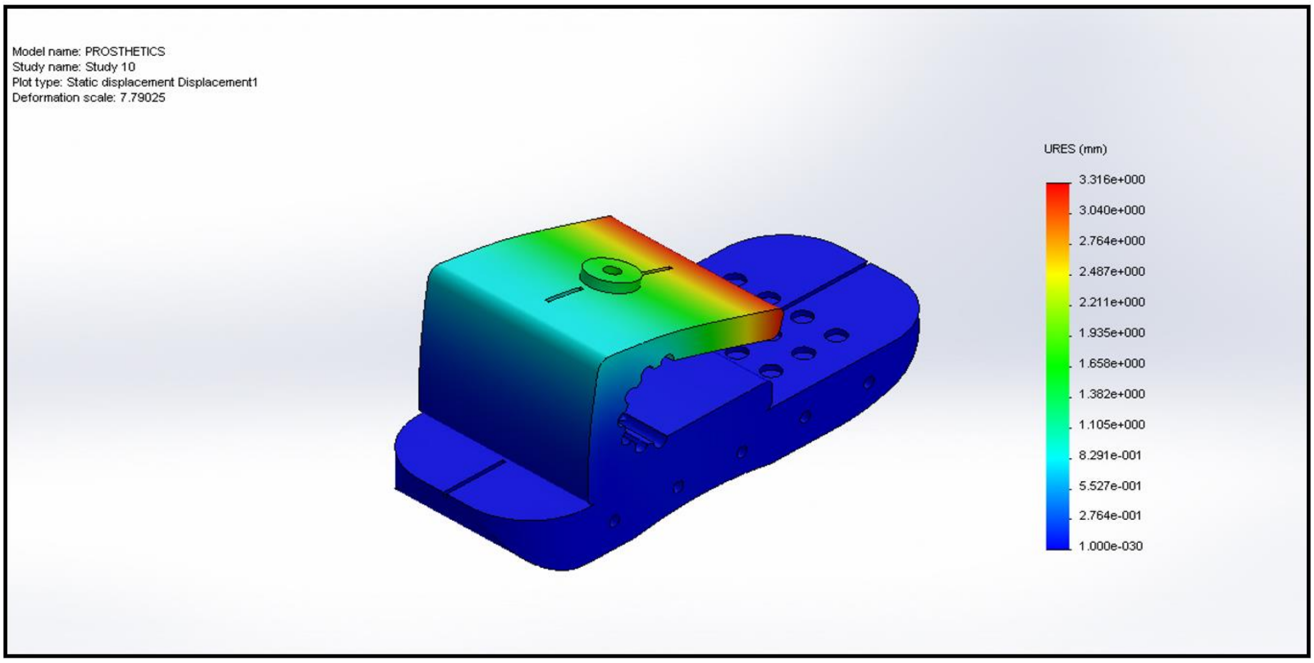

Fig. 7. Displacement analysis of the prosthetic design

The von Mises unit is a material that is said to start yielding when its von Mises stress reaches a critical value known as yield strength. The von Mises stress is used to predict materials yielding under any loading condition from the results of simple uniaxial tensile tests. Figure 8 shows the stress analysis with the safe condition. From this analysis, the von Mises stress value is 44.4 MPa, while the yield strength of ABS material is 44.8 MPa.

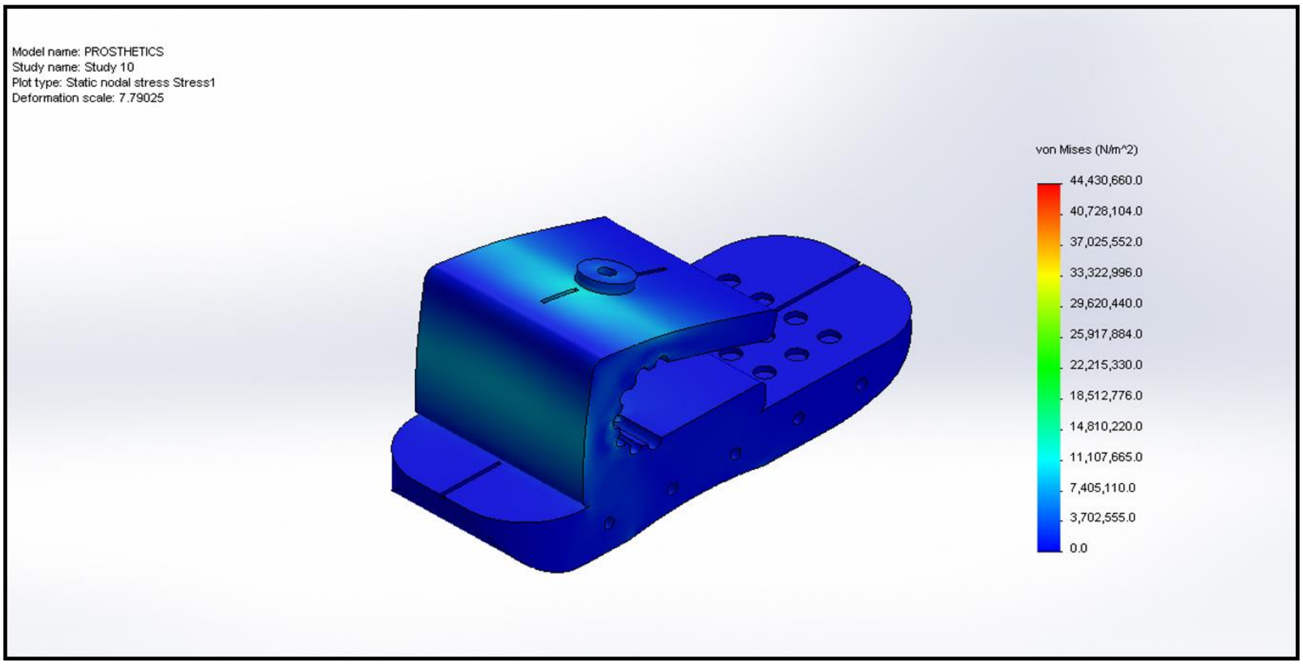

Fig. 8. Stress analysis of the prosthetic design

The maximum strain in the contact area is 0.0166344 mm/mm at the C-curve of the prosthetic prototype design, as shown in Figure 9.

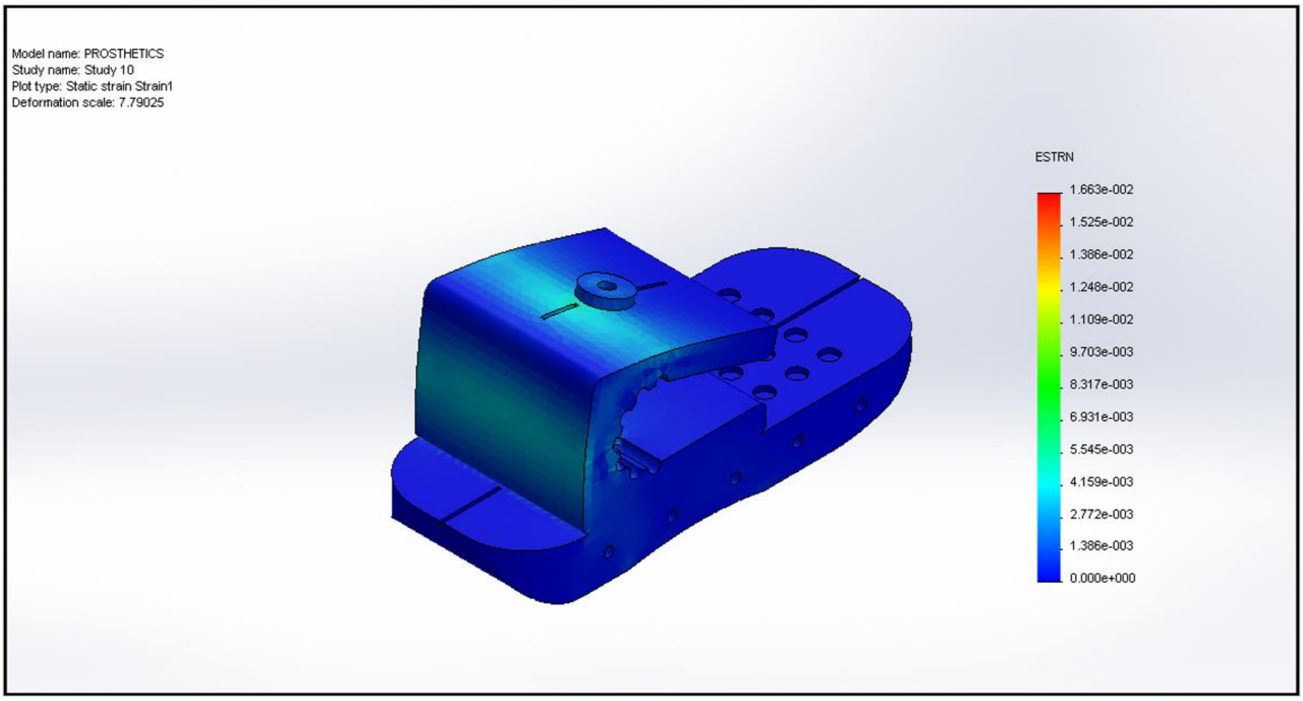

Fig. 9. Strain analysis for the prosthetic design

4.3 Prototype Printing using Additive Manufacturing Process

The design was printed using Acrylonitrile Butadiene Styrene (ABS) material on the Veglar V-821 additive manufacturing printing machine. ABS was chosen due to its strength and durability. Sapphire software was used to set up the design to be printed. The maximum printed areas are 270 mm width x 200mm depth x 247.35 mm height. Due to this maximum printed area, the designs were split into two to avoid insufficient space. The ABS filaments used for printing weighed 2 kg, costing RM 200. Figure 10 depicts the prototype printed using ABS on the Veglar V-821 additive manufacturing machine.

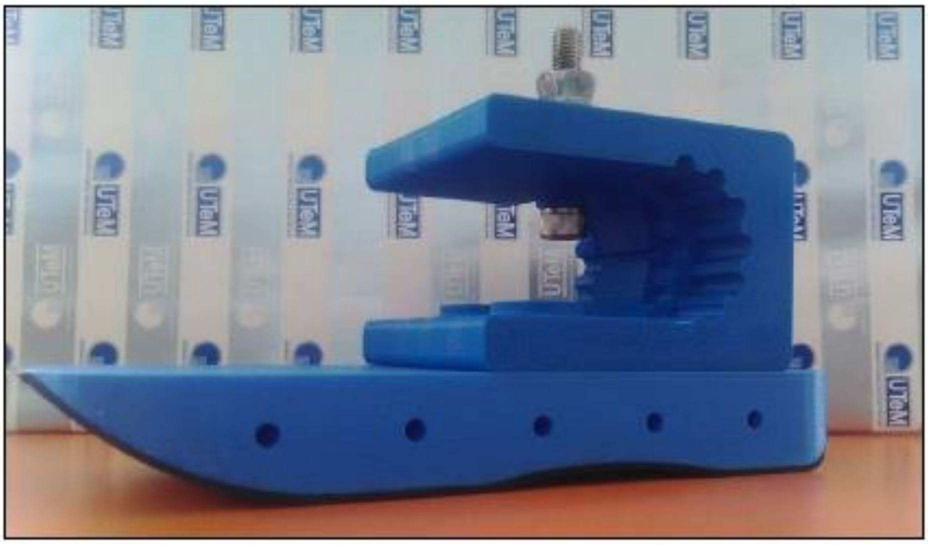

Fig. 10. The actual finished prototype printed using ABS on the Veglar V-821 additive manufacturing machine

4.4 Evaluation Survey with Professional Prosthetist

An expert in prosthetic limbs in the medical field is called a prosthetist. A survey was conducted to get a formal opinion from a prosthetist who has worked for two years at a rehabilitation centre. Throughout his career, more than 50 disabled patients have received care under his supervision. In this survey, the prosthetist was asked about his opinion. He needs to comment on the overall design of the prototype based on the actual prototype. Finally, he was also asked to rate his opinion on questions related to energy story ability, suitability for BKA patients and the prototype's potential in terms of design for commercialization.

The prosthetist had classified the prototype to be successful regarding the design requirement of a basic prosthetic. However, he suggested improving the design to ensure long-term usage. The critical criterion that needs to be considered is the gait cycle of the human ankle, which is divided into heel strike, mid stance, and heel off. Even though the patient with BKA cannot have the exact gait cycle as a normal-walking human, getting the most similar characteristic is important because it can protect the stump muscle from fatigue and injury.

In addition, he had expressed concern that the current market prosthetic Design still needs improvement because certain foot systems still have not gotten the gait cycle. The foot that is able to meet certain gait cycles is expensive. The price range of the current prosthetic in the market can be more than RM10,000, and the widely used material to produce the prosthetic is carbon fiber and stainless steel, which are expensive. He also agreed that, based on the design, the prototype could store energy. Also, additive manufacturing is a suitable process for producing prosthetic feet.

The prosthetist had found that the prosthetic prototype met the basic requirement of a prosthetic foot. He also agreed that this prosthetic design had the potential to be commercialized in the future.

4.5 Pilot Test on Usability with BKA Patient

A pilot test on the prototype's usability was conducted with a patient under the prosthetist's supervision. This test involved two real-life conditions: standing and walking. The respondent was the same male patient whose information was used in the development stage of the prosthetic foot. He was 34 years old, weighed 90 kg, and had been using a foot prosthetic for about two years. He was an amputee on the left side with a length of the sole of 28.0 cm.

After the test, the respondent was asked to answer a short survey. Based on the survey results, the respondent claimed that he felt uncomfortable with his current prosthetic foot. In addition, he frequently felt muscle fatigue after using it for long hours. This condition is despite the current prosthetic has a strong and stable characteristic as it is made of carbon fiber composites.

The test showed that the prosthetic prototype could withstand the patient's weight and did not break during the standing and walking activity. In addition, the patient felt comfortable using it. Even though the prototype's prosthetic was made of ABS material, it was sturdy enough to withstand a load of up to 90 kg.

Other than that, the respondent agreed that the prototype had fulfilled the basic requirements for walking and standing. Therefore, it is proven that the prototype prosthetic performed similarly to the current prosthetic he used daily. Nevertheless, a longer duration of testing is needed for the patient to properly evaluate the comfortability and fatigue level when comparing the current prosthetic and the new prototype.

5. Conclusions

This study aims to create an energy-storage prosthetic foot that is comfortable and inexpensive for people with below-the-knee amputations (BKA). First, a prototype was designed and developed. Then, the experiment was conducted to ensure it could withstand a load of up to 1,000 Newton. The prototype must fulfil the essential prosthetic foot requirements for energy-storing below-knee amputation (BKA) prosthetics. The prototype prosthetic for BKA was designed and analyzed using SolidWorks 2013 software to identify the fracture point. The prototype was then developed using an additive manufacturing process.

This project aimed to design and develop a light and flexible prosthetic foot for BKA at an economical price using an additive manufacturing process to help reduce muscle fatigue. The prototype prosthetic did not break because research and analysis were made before the prototype underwent 3D printing. The high energy-storing ability is needed to avoid sudden breakage and give shock absorbing ability while walking or doing daily activities, hence can help reduce muscle fatigue.

This finding shows that additive manufacturing technology can produce a prototype of a prosthetic foot using ABS material. In addition, the outcome from the pilot test showed that the design could withstand the weight of a patient weighing 90 kg and has energy-storing attributes that make the patient feel comfortable while walking and standing.

This study has developed a prosthetic foot prototype for BKA using additive manufacturing technology. However, some improvements can still be considered for future works:

a) Enhance the gait cycle pattern of the human ankle to be adapted to the prosthetic foot. This condition can help to give more comfort to the patient with BKA during heel off and heel strike while walking.

b) Materials like Thermoplastic-Polyurethane (TPU) or Acrylonitrile-Butadiene-Styrene (ABS) mixed with Nylon can be considered for future works. It is because that kind of material has flexible characteristics and durability. However, just in terms of cost, the material is quite expensive.

Via this consideration of improvement, a better prosthetic foot can be developed and benefit other BKA patients. Disability is no longer a barrier for disabled people who have lost a limb, and findings from this study can help these people achieve a better quality of life.

Acknowledgment

The authors are grateful to the Ministry of Higher Education Malaysia and Universiti Teknikal Malaysia Melaka (UTeM) for the funding and support for this study through the Malaysia Research University Network (MRUN): MRUN-RAKAN RU-2019-003/3 grant (MRUN/2023/FTMK/MR0002).

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