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Design, fabrication, and performance testing of an energy storage and return (ESAR) foot prosthesis made of prepreg carbon composite

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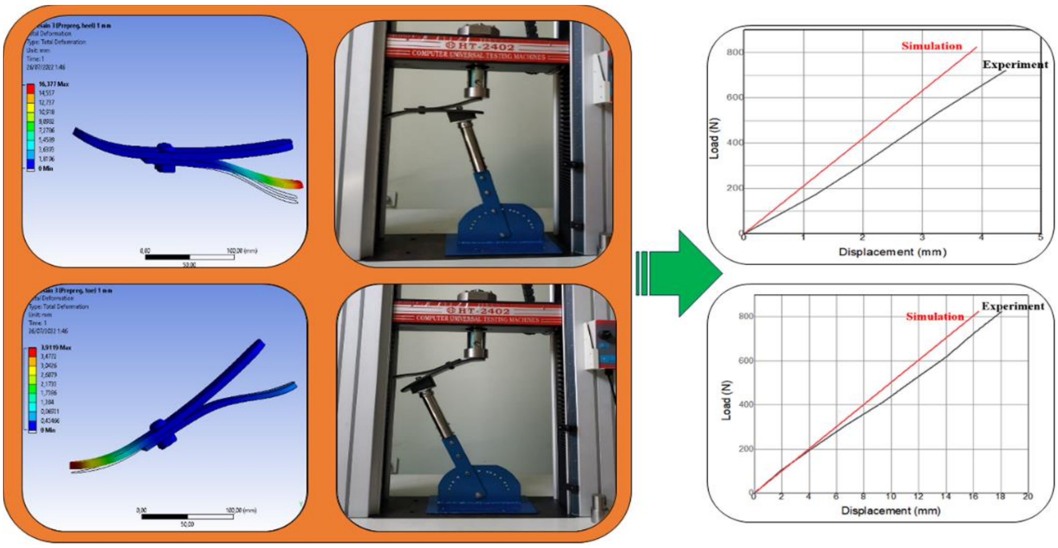

Highlights:

- Three prosthesis designs were based on commercial products and analyzed using finite element method (FEM) simulations to evaluate deformation under specific loading conditions.
- Design 3 emerged as the most effective, with the lowest deformation and mass, albeit with lower aesthetic appeal.
- The prototype was fabricated using an out-of-autoclave method with carbon prepreg material.
- Mechanical testing showed that the prototype exhibited acceptable deformation under compressive loads, meeting comfort standards for amputees during walking cycles.
- The experimental deflections were higher than simulated results due to observed delamination defects, which affected load-bearing capacity.
- The findings provide valuable data for future prosthetic development, highlighting that carbon composites can improve functionality and comfort.

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Abstract

The high demand for prosthetics in Indonesia is not followed by the ability and quality of local production to fulfill the community's needs. There is a lack of comprehensive data regarding the specific challenges encountered by local prosthetic manufacturers in Indonesia, particularly in terms of technological limitations. This study aims to understand the effect of design parameters on the performance of the energy storage and return (ESAR) foot prosthesis prototype in normal walking activities for amputees. Three different designs were created according to commercial products, and a convergence test was conducted to ensure accurate results. Finite element method (FEM) analysis was used to determine the amount of deformation that occurred in each design made when applied with 824 N axial force. The ESAR foot prosthesis prototype made from carbon prepreg was fabricated using an out-of-autoclave method, and the mechanical testing was performed with a compressive test. The results indicated that the optimal design for the ESAR foot prosthesis determined by the decision matrix scoring criteria was Design 3. The final scores for Designs 1, 2, and 3 were 54, 53, and 77, respectively. Design 3 is the easiest to manufacture, has the slightest complexity, and the lightest mass, and undergoes the least deformation during simulation, although it is the least attractive. The study found a significant difference in displacement between the deflections obtained from simulation and experiment. This occurred because the prototype was found to have delamination, which decreased the load-bearing ability of the prototype during compressive testing. Compressive testing on the prototype yielded a deflection of 22.695 mm in heel strike and 18.065 mm in toe-off positions, while FEM analysis showed 16.377 mm and 3.912 mm. Therefore, strict quality control is essential, especially when using materials such as carbon prepreg, which are prone to delamination if not properly processed.

Keywords: Prosthetic; ESAR; FEM; Carbon prepreg; Out-of autoclave; Deflection

1. Introduction

Human and cultural development is a comprehensive process spanning the human life cycle, from the prenatal phase to the elderly. However, some society members face limitations in performing social functions due to disabilities, affecting their daily activities and societal roles. Currently, Indonesia has approximately 22.97 million people with disabilities, or about 8.5% of its total population, with the highest prevalence among the elderly [1]. Disability encompasses physical, mental, intellectual, or sensory conditions that hinder participation in daily life [2]. Disabilities can be congenital or acquired through illness, injury, or medical conditions [2]–[4]. One common type is limb loss, such as lower-limb amputations, which often require prosthetic feet or devices [5], [6].

The demand for prosthetic feet is influenced by factors such as population growth, an increase in accidents and vascular diseases, and advancements in medical technology [5]–[8]. Prosthetic feet are crucial for individuals with physical disabilities to perform activities like walking, running, and cycling [9]. However, local production in Indonesia has not yet met the demand, leading to a significant increase in imports. From 2020 to 2022, the import value of prosthetic feet with HS codes 90213900 and 90219000 rose from $4,385,837.00 to $6,384,450.00 [10]. Imported products generally offer superior quality, advanced technology, and higher usability than locally produced alternatives, which still face challenges such as long production times and high costs [11] [12].

The most common type of prosthetic foot currently available is the Solid Ankle Cushioned Heel (SACH) foot, which primarily absorbs impact but does not replicate the kinematics and kinetics of natural gait [13]. This limitation results in higher metabolic energy expenditure for users. The Energy Storage and Return (ESAR) foot offers an innovative solution by minimizing energy expenditure and improving gait efficiency. ESAR designs use advanced materials and mechanisms to store and release energy during walking, enhancing mobility for amputees [14]–[16].

A patient who has lost a limb requires a prosthesis to assist with daily activities and ideally mimic the function of the natural organ it replaces. Therefore, a prosthesis should be comfortable to wear, easy to put on and remove, lightweight, durable, mechanically efficient, and easy to maintain [17]–[20]. Fiber-reinforced composites are widely used in prosthetic applications due to their elasticity, high density, and shock resistance [21]. A composite material is made up of multiple constituent materials having considerably distinct mechanical, chemical, and physical properties [22], [23]. The characteristics of a prosthetic foot depend on factors such as the type of fibers used, the number of reinforcing layers, and the matrix resin. Common reinforcing fibers in prosthetics include carbon fiber, glass fiber, and Kevlar fiber. When combined with epoxy matrix resins, carbon and glass fibers offer a balance of durability, lightness, and energy return which is essential for amputee mobility. Using carbon fiber in an epoxy resin matrix further enhances prosthetic performance by increasing activity levels and efficiency [21], [24]–[30].

Houdijk et. al. [15] conducted a study to investigate whether the enhanced push-off capability of energy storing and return (ESAR) foot designs improves forward propulsion speed, increases intact step length, and enhances step length symmetry while maintaining stability during walking in individuals with transtibial amputations. Fifteen participants with transtibial amputations walked at a fixed speed (1.2 m/s) on a level surface using both an ESAR foot and a solid ankle cushion heel (SACH) foot. Push-off work generated by the prosthetic foot, center of mass velocity, step length, step length symmetry, and backward margin of stability were assessed and compared between the two-foot types. The study found that push-off activity was significantly higher with the ESAR foot than with the SACH foot. Correspondingly, the center of mass velocity at toe-off was higher when using the ESAR foot. Additionally, the ESAR foot improved intact step length and step length symmetry without compromising the backward margin of stability. In comparison to the SACH foot, the ESAR foot demonstrated superior performance by enhancing step length symmetry and maintaining stability at a consistent walking speed. These findings highlight the benefits of ESAR foot designs in promoting efficient and stable gait patterns for individuals with transtibial amputations.

Saleel, et. al. [31] tested two models of the Flex-Foot Cheetah made from carbon fiber and glass fiber materials with a polyethylene (PE) polymer matrix and compared them to a perfect prosthetic foot designed for running at the level of professional athletes. The maximum principal elastic strain, maximum stress, strain energy, and total blade deformation were calculated for both prosthetic feet through numerical analysis. A deflection-load test was conducted on the prosthetic feet to estimate the level of bending. The test results closely matched the numerical analysis, with the curve of the carbon fiber foot sample being lower than that of the glass fiber foot sample, indicating the superior strength of carbon fiber.

Muhsin, et. al. [32] developed a new athletic prosthetic foot and designed a foot impact tester. The prosthetic foot was manufactured using carbon fibers, glass fibers, and epoxy, which provided excellent mechanical performance. For the same drop height, the impact response of samples made with glass fibers and carbon fibers exhibited the same peak load at different drop angles. Moreover, it was evident that the response of the sample made with carbon fibers was smoother compared to that of the sample made with glass fibers. In addition, Hamza et al. [33] evaluated the mechanical properties of two athletic prosthetic foot samples made of fiberglass reinforced with epoxy. The samples were fabricated using the hand lay-up method, and the mechanical properties of the composite material were analyzed. The study employed both analytical methods using ANSYS and experimental tests to examine how the prosthetic foot design influences its mechanical properties.

By reviewing the existing literature, this study aims to investigate how design parameters affect the performance of the ESAR foot prosthesis prototype during normal walking activities for amputees. It is anticipated that this research will contribute to the development of more efficient and comfortable foot prostheses. The findings are expected to provide valuable insights for prosthetic design experts, manufacturers, and rehabilitation practitioners, helping to enhance the quality and functionality of foot prostheses. This improvement can enable amputees to achieve better mobility and an improved quality of life. Furthermore, the study's results could serve as a foundation for advancing prosthetic technology as a whole, delivering significant benefits to individuals in need of prosthetic foots.

2. Materials and Methods

In this study, the design, simulation, fabrication, and performance testing of an ESAR foot prosthesis made from carbon prepreg were carried out. The design of the foot prosthesis was optimized through several proposed design variations, with finite element method (FEM) analysis conducted to evaluate its quality in meeting the required product criteria. A decision matrix was employed to select the best design for prototype fabrication. The next stage involved fabrication, where the ESAR foot prosthesis prototype was manufactured using the out-of-autoclave method in accordance with the Extended Manufacturer Recommended Curing Cycle (EMRCC). Upon completing the manufacturing process, the prototype underwent mechanical testing based on a normal walking cycle.

2.1. Design

The ESAR foot prosthesis was designed using Catia V5 software. The designs obtained in this study are shown in **Figure 1**. Design 1, Design 2, and Design 3 were derived through reverse engineering of commercial products, specifically the VERI-FLEX, FLEX-FOOT ASSURE, and LP VARI-FLEX series, produced by Ossur hf., Reykjavík, Iceland [34]. The geometries of these designs were adjusted accordingly.

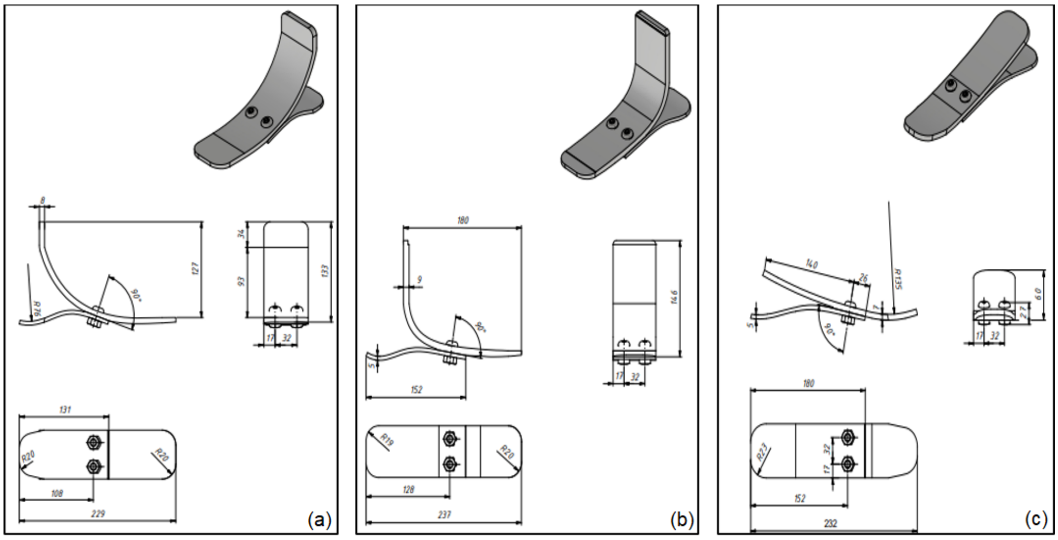

Figure 1. ESAR foot prosthesis design in (a) Design 1, (b) Design 2, and (c) Design 3

2.2. Simulation

The simulation process is carried out using the static structural method on the design that has been made. The simulation process uses Ansys Workbench 18.1 software with the engineering data used is Epoxy Carbon Woven (230 GPa) Prepreg [35]. Modelling is continued by dividing the model into smaller parts for analysis (meshing). This study will conduct a convergence test to test the mesh quality used, including the mesh size and number selection. Convergence testing was conducted to ensure the accuracy and reliability of the deformation findings produced in the simulation process [30], [35]–[37]. In this convergence test, the meshing process is expected to give convergent results. The smaller the size and the more elements used; the more valid results will be obtained. However, this will affect the simulation process, which requires more time. The Finite Element Method (FEM) analysis on the three designs that have been made is carried out in the heel strike and toe-off foot positions according to the ISO 10328 standard (**Figure 2**) [38]. Boundary conditions in this simulation were 1.2 times the average body weight of an Indonesian (70 kg) or 824 N [35]. This loading represents the load of normal walking activities. This loading was done because the ESAR foot prosthesis design developed in this research is intended for normal walking activities.

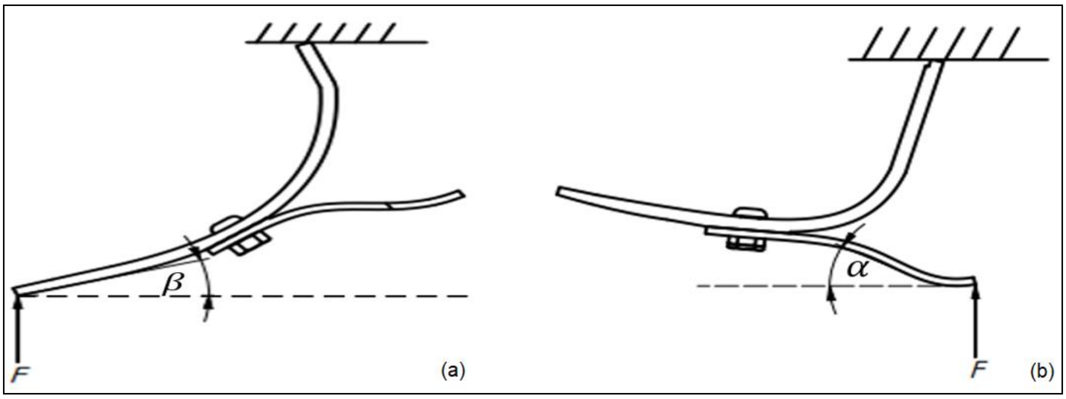

Figure 2. Testing scheme of (a) toe off and (b) heel strike on ESAR foot prosthesis. α is the angle of heel strike (15°) and β is the angle of toe off (20°)

2.3. Decision matrix

To determine the best design from several design alternatives that have been made, an assessment is made based on the decision matrix. The purpose of the decision matrix is to make choices from several design alternatives with several criteria to get the selected concept following several design criteria [39]. The assessment criteria in the decision matrix used in this research include attractive design, ease of production, the mass of the product produced, ease of application, and displacement that occurs in the ESAR foot prosthesis design during the simulation process. In this research, each criterion uses a score of 1 to 5. The design with the highest total weight score is the selected design that will be fabricated to produce an ESAR foot prosthesis prototype.

2.4. Specimen Fabrication

After obtaining the best design, the next step is making the mould using Dural Alumulinum Series 5052. The carbon prepreg material used in this research is prepreg carbon fiber woven twill 3x3 200 gsm RGC200FR-43 obtained from Qingdao Regal New Material Co., LTD, Qingdao City, China. Specifications of prepreg carbon fiber woven twill 3x3 200 gsm RGC200FR-43 are shown in **Table 1**.

The ESAR foot prosthesis mould was coated with PVA evenly and allowed to stand for 30 minutes. After the PVA layer on the mould is dry, the cut carbon fiber prepreg is attached to the mould and then pressed using a roller. This stage is repeated several times until the predetermined number of layers are connected to the mould. The surface of the carbon fiber prepreg that has been arranged on the mould is coated with a breath bleed cloth. Then the mould is wrapped with bagging film, which has been attached to the connector and glued using sealant tape. The next stage is installing an infusion tube connected to a vacuum pump with a connector on the mould. The vacuuming process is carried out for 30 minutes. After 30 minutes, separate the infusion tube from the valve so the mould is separated from the vacuum pump.

Next, the curing process was carried out using the Out of Autoclave (OoA) method in line with the Extended Manufactured's Recommended Curing Cycle (EMRCC). This curing profile is a recommendation from the carbon fiber prepreg provider based on the WP-R5600W3K technical data sheet. The curing cycle starts from room temperature (TA) 20 - 30°C, then a ramp rate of 1°C/min to 70°C with a dwell time of 4 hours. The next ramp rate is 2°C/min for 13 minutes to a temperature of 96°C. At this stage, the dwell time used is 53 minutes. In the next step, the ramp rate is 1°C/min for 24 minutes to a temperature of 120°C and the dwell time is set for 1 hour. The last stage in the curing process is cooling, done by annealing to room temperature.

Table 1. Specifications of carbon fiber prepreg RGC200FR-43 [40]

Items	Carbon Fiber Prepreg
Materials	Epoxy resin + carbon fiber
Curing temperature	70°C
Post curing temperature	120°C
Time curing	120 – 180 min
Storage life at -5°C	6 Month
Storage life at -18°C	12 Month
Resin content	20% - 45%
Width (mm)	1000
Thickness (mm)	0.25
Fabric density (gsm)	200

2.5. Testing and Characterization

After curing, the mould was removed from the oven, and the finishing process was carried out on the obtained foot prosthesis prototype. In this study, the ESAR foot prosthesis obtained was subjected to a compressive test using HT-2402 Computer Servo Control Material Testing Machines from Hung Ta Instrument Co., Ltd., Sammutprakarn, Thailand. This test was based on ISO 10328 by applying several angles and pedestals to the below-knee prosthesis test. Loading was performed at the heel strike and toe-off positions with a loading magnitude of 824 N (**Figure 3**). In the heel strike position, the foot only rested on the back and caused the sole and the plane of the foot to form an angle of 15°. In the toe-off position, the sole and the plane of the footing form an angle of 20° with the fulcrum at the toe. In the next stage, macro-structural observations were made using an SD-30 Olympus Binocular Microscope (Olympus Corporation, Tokyo, Japan). This test was conducted to determine any manufacturing defects found in the ESAR foot prosthesis prototype.

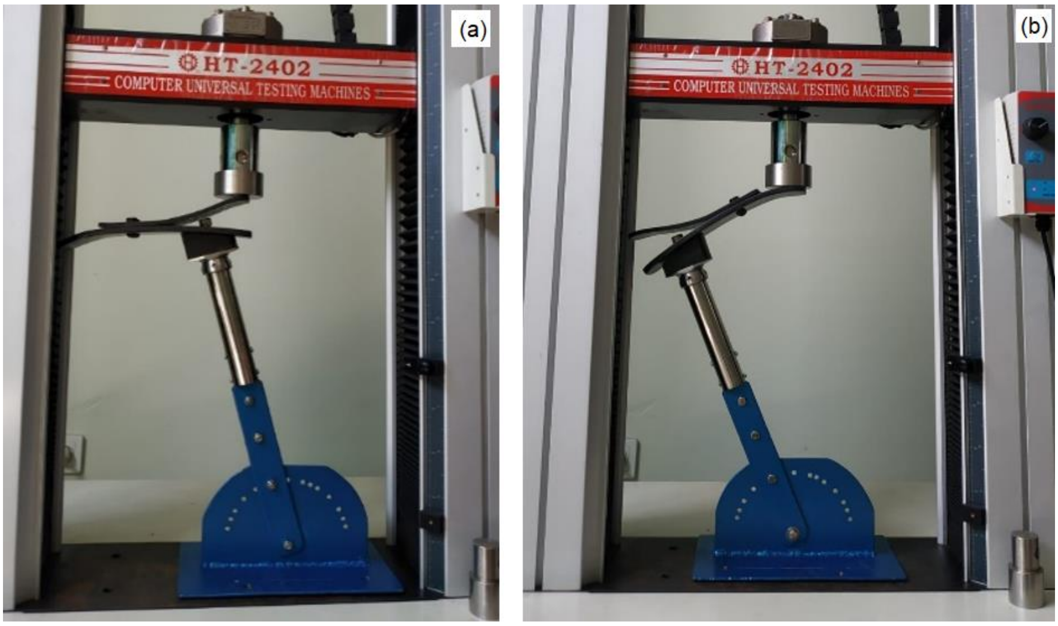

Figure 3. Compressive testing of the prototype ESAR foot prosthesis (a) heel strike and (b) toe-off positions

3. Results and Discussion

3.1. Finite Element Method Simulation

A convergence test was conducted to assess the mesh quality by evaluating whether the selected mesh size produced valid deformation results [41]. In general, smaller element sizes or an increased number of elements lead to more accurate and reliable outcomes. However, this improvement comes at the cost of longer simulation times. This balance between mesh density and computational efficiency is crucial for achieving both accurate and practical simulation outcomes. The meshing results obtained in Designs 1, 2, and 3 are shown in **Figure 4**. Design 1, Design 2, and Design 3 in this study were obtained from reverse engineering results on commercial products with the VERI-FLEX, FLEX-FOOT ASSURE, and LP VARI-FLEX series produced by Ossur hf., Reykjavík, Iceland with adjusted geometry, respectively [34].

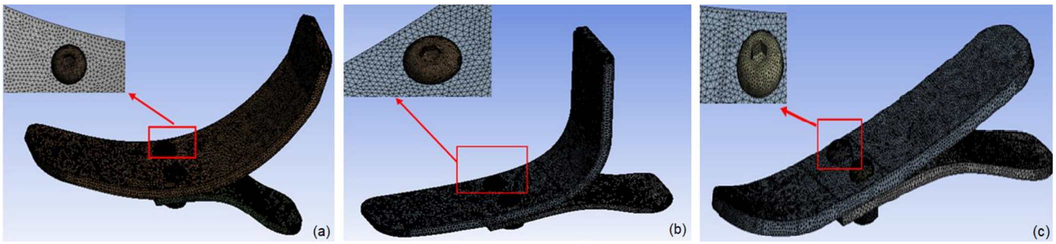

Figure 4. Meshing results in (a) Design 1, (b) Design 2, and (c) Design 3

Then, **Figure 5** shows the convergence test results in Design 1, 2, and 3. The results show that valid deformations in Designs 1, 2, and 3 are obtained with a free number of elements. Valid deformations in Designs 1, 2, and 3 were found when using element size 1 mm and the number of elements 275241, 283587, and 285743, respectively.

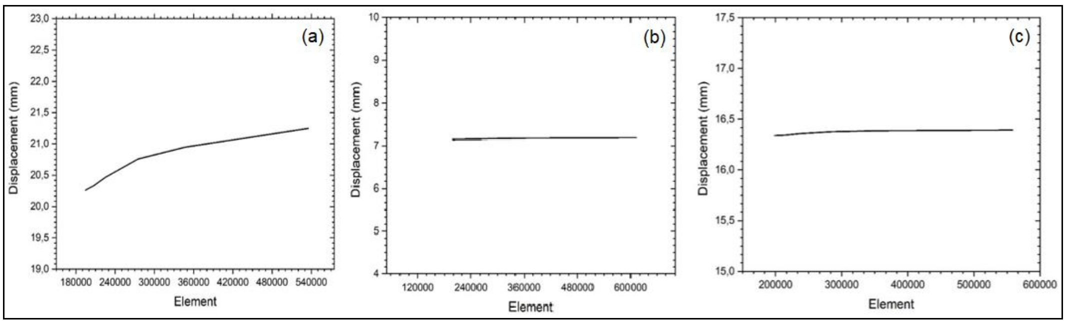

Figure 5. Relationship between the number of elements and displacement in (a) Design 1, (b) Design 2, and (c) Design 3

The results of FEM analysis on Design 1, 2, and 3 are shown in **Figure 6**. The results of FEM analysis on Design 1 show the total deformation that occurs in the heel strike and toe off positions of 20.759 mm and 84.011 mm, respectively. The total deformation that occurs in Design 2 when the heel strike and toe off positions are 7,161 mm, and 43,344 mm, respectively. While the total deformation that occurs in Design 3 when the heel strike and toe off positions are 16,377 mm, and 3,912 mm, respectively. The slightest total deformation at the heel strike position was 7,161 mm, found in Design 2. At the same time, the most significant total deformation at the heel strike position was found in Design 1, with a total deformation of 20,759 mm. Design 3 produces the slightest total deformation at the toe off position, which is 3,912 mm. However, sufficient displacement remains at the heel strike position, which can later be utilized for energy storage during the walking process.

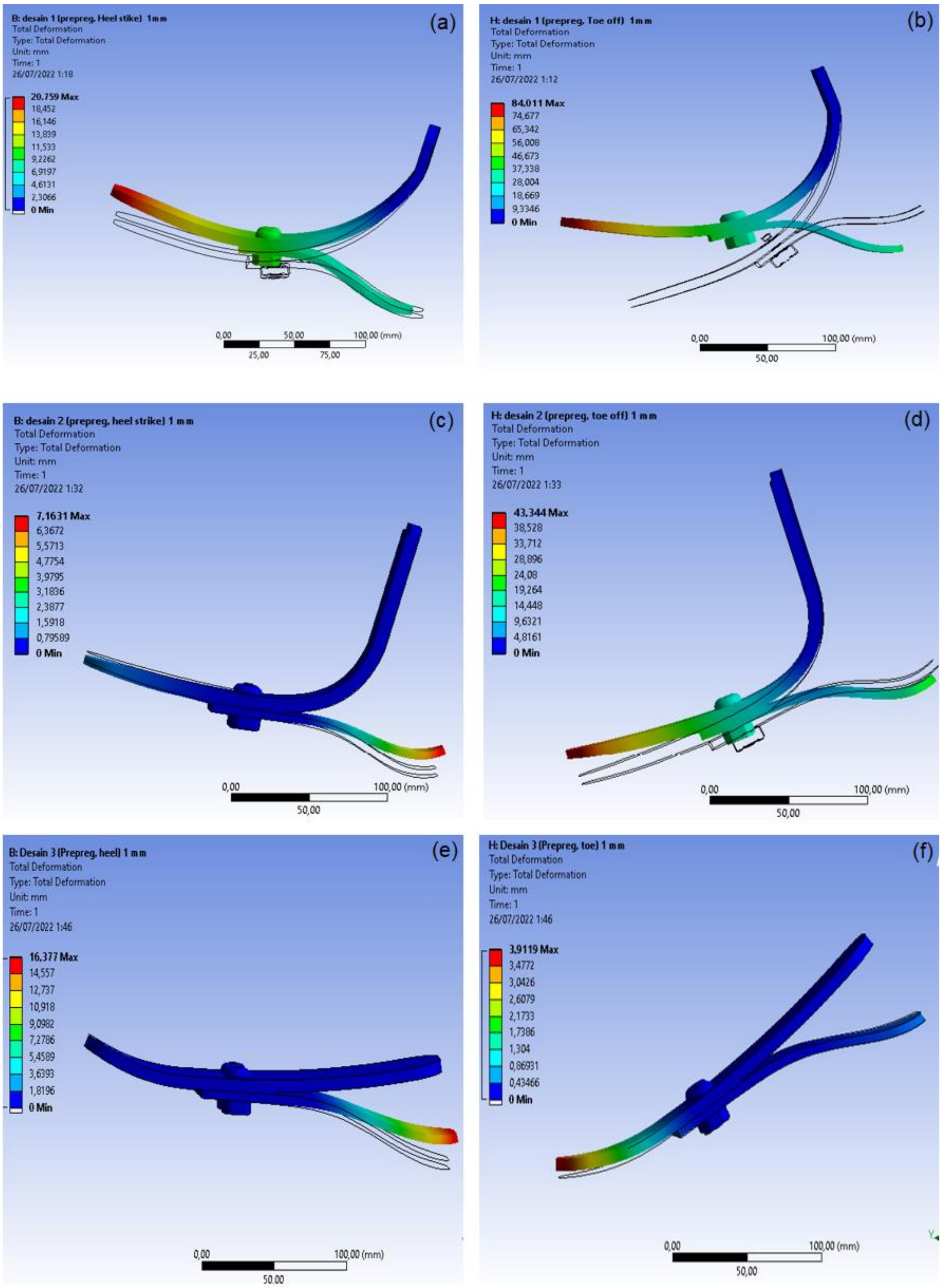

Figure 6. Total deformation of (a) Design 1 at heel strike positions, (b) Design 1 at toe off positions, (c) Design 2 at heel strike positions, (d) Design 2 at toe off positions, (e) Design 3 at heel strike positions, and (f) Design 3 at toe off positions

Then, Table 2 indicates the most significant total deformation at the toe off position was found in Design 1, with a total deformation of 84.01 mm. The results of this study show that the ESAR foot prosthesis in Design 1 produces the most significant total deformation at the heel strike and toe off positions. Furthermore, the results of the FEM analysis show that Design 3 has the lowest mass compared to Design 2 and 3. The mass (g) generated in Design 1, 2, and 3 are 310.70, 354.46, and 300.32, respectively.

Table 2. Finite element method simulation result

Variation	Displacement heel strike (mm)	Displacement toe-off (mm)	Mass (g)
Design 1	20.76	84.01	310.70
Design 2	7.16	43.34	354.46
Design 3	16.38	3.91	300.32

3.2. Decision Matrix Result

The assessment criteria in the decision matrix used in this research include attractive design, ease of production, the mass of the product produced, ease of application, and displacement that occurs in the ESAR foot prosthesis design during the simulation process (Table 3). The first assessment criterion is an attractive design seen from the user's point of view. Interview results with foot prosthesis users positiond that Design 1 is the most attractive. While Design 3 is the least attractive. In the second assessment criteria, it is seen which design is the easiest to produce. Design 3 has the highest score because it does not require too large a mold during production. In addition, Design 3 has the lowest level of complexity compared to Design 2 and 3.

In the third assessment criteria, the design assessment is based on the results of the FEM analysis that produces the lightest mass. In addition, Design 3 had the highest score in the fourth assessment criteria. This was due to the interview with the prosthetic orthotist, who indicated that Design 3 is a low-profile option that allows it to be used for various amputation levels. Design 3 would allow it to be used for the Knee Disarticulation amputation level (amputation of the right ankle joint). If using Design 1 or 2, which are high profile, it is less likely to be used for various lever amputations. The last assessment criterion is displacement. The design with the slightest displacement results during simulation will get the highest score in this assessment criteria. Design 3 experienced the slightest deformation in this study compared to the other two designs. The best design obtained in this study based on the decision matrix is Design 3, with a total score of 77.

Table 3. ESAR foot prosthesis decision matrix

Assessments criteria	Weight	Design 1		Design 2		Design 3	
		Score	Weight score	Score	Weight score	Score	Weight score
Interesting design	2	5	10	4	8	3	6
Simplicity of production	4	3	12	3	12	5	20
Weight of the product	3	4	12	3	9	5	15
Possibility of application	4	3	12	3	12	5	20
Deformation	4	2	8	3	12	4	16
Total score		54		53		77	

3.3. Compressive Testing

The ESAR foot prosthesis prototype based on Design 3 is shown in Figure 7. In this study, the compressive test was conducted by the ISO 10328 standard. The hind foot is set to form a 15° angle that reflects the heel strike foot position. The forefoot is set to begin a 20° pitch that reflects the toe off foot position. The compressive test results on the ESAR foot prosthesis prototype are shown in Figure 8. The results of this study show that when the ESAR foot prosthesis prototype is loaded by 824 N, the heel strike foot position will produce a deformation of 18.065 mm. When the foot position is toe off, the applied loading will produce a deformation of 4.401 mm. Based on the KS P 8403 standard, a foot prosthesis is considered comfortable if the elastic deformation is between 20 to 40 mm at the forefoot and 6 mm to 22 mm at the heel under a vertical force of 400 N [42]. Meanwhile, according to the American Orthotic and Prosthetic Association (AOPA), a foot prosthesis provides a dynamic response if the deflection or deformation at the heel strike position is >= 5 mm [29], [43]. Then, A comparison of the force-displacement curves obtained from simulation and experiment is shown in Figure 9. This study's results show a considerable difference in displacement when loading in the heel strike and toe off positions. In the experimental results, the deflection in the heel strike and toe off positions is 18.065mm, and 4.401 mm, respectively.

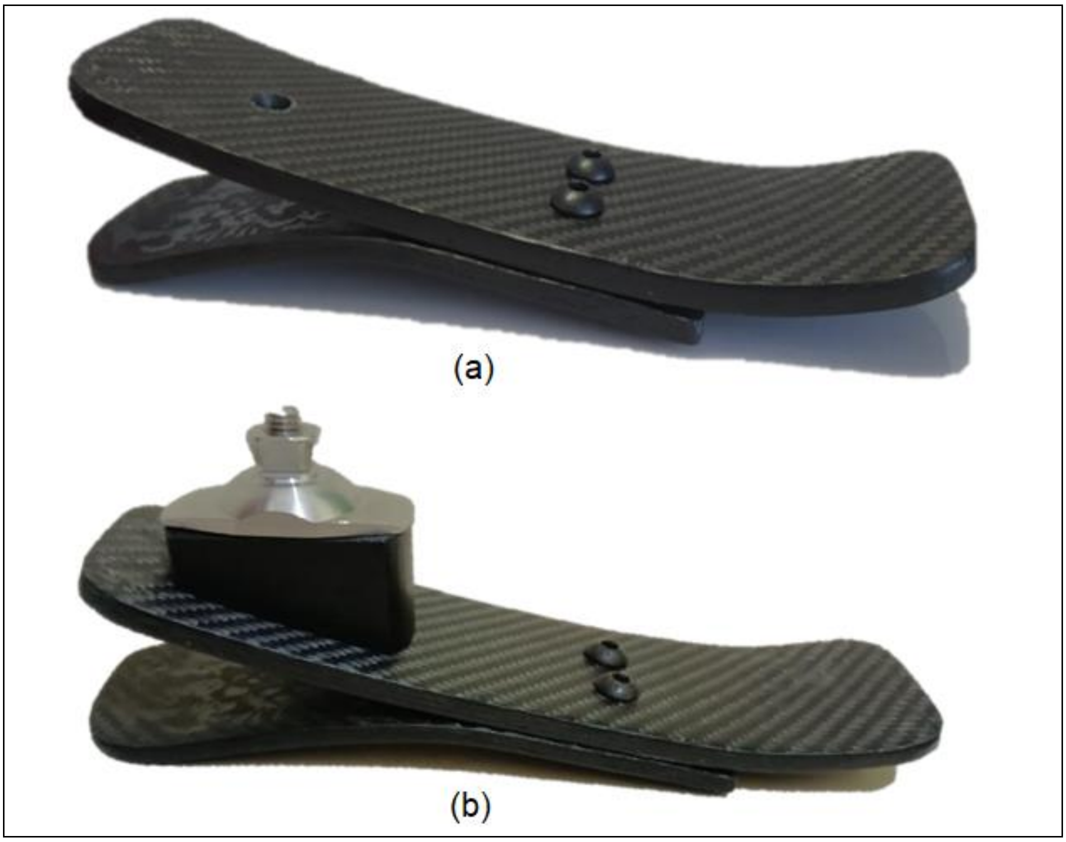

Figure 7. Prototype ESAR foot prosthesis based on Design 3 (a) without adaptor and (b) with adaptor

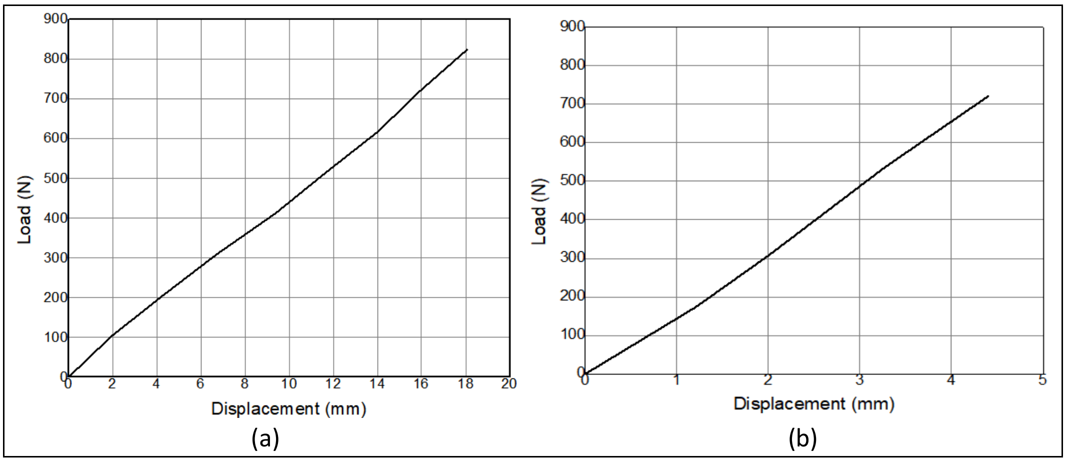

Figure 8. Force-displacement curves under loading at the (a) heel strike, and (b) toe off positions

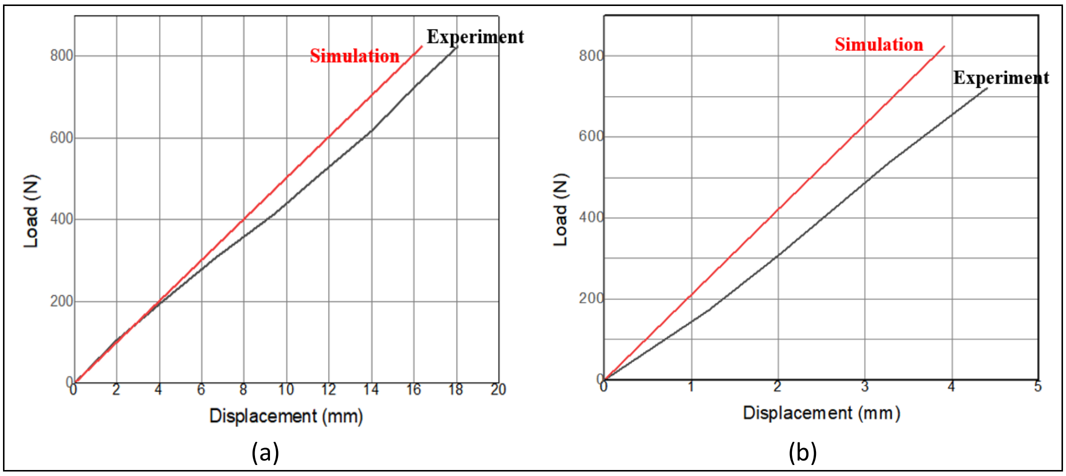

Figure 9. Comparison of simulated and experimental force-displacement curves under loading at the (a) heel strike, and (b) toe off positions

While the results of FEM analysis the amount of deflection that occurs in the heel strike and toe off positions are 16.377 mm, and 3.912 mm, respectively. The difference in deflection obtained from simulations and experiments on prosthetic foot was also found in research obtained by Pham et al. [30] and Song et al. [42]. Their results showed a difference in deflection obtained from simulation and experiment. The considerable difference between simulation and experiment in this study can be caused by several factors, including consistency in material and geometry, experimental loading conditions, and curing treatment during composite fabrication [30], [42].

In addition, the prototype produced in this study was found to have delamination defects (Figure 10). Delamination in composite materials is the separation of the matrix and reinforcement layers that occurs within the material. The leading causes of delamination in prepreg carbon composites include improper handling, insufficient drying, non-uniform fiber layer thickness, surface contamination, improper curing temperatures and times, a mistake during composite fabrication, excessive mechanical loads, and environmental influences [44]–[48]. In general, delamination can significantly decrease composites' mechanical properties and durability as it can reduce load-bearing capacity and strength [44], [49]. In addition, delamination can act as a stress concentrator, leading to accelerated fatigue crack growth, decreased stiffness, and decreased structural integrity of the composite [44]–[52].

Figure 10. Delamination of the prototype ESAR foot prosthesis

4. Conclusion

This study aimed to understand the effect of design parameters on the performance of the Energy Storage and Return (ESAR) foot prosthesis prototype during normal walking activities for amputees. Three designs, inspired by commercial products, were analyzed through finite element method (FEM) simulations. A convergence test was conducted to ensure accurate results. FEM analysis assessed the deformation under an applied force of 824 N. Significant differences in deformation were observed across the designs during heel strike and toe off positions. At the heel strike position, the total deformations for Designs 1, 2, and 3 were 20.76 mm, 7.16 mm, and 16.38 mm, respectively. At the toe off position, the deformations were 84.01 mm, 43.34 mm, and 3.91 mm, respectively. Design 1 exhibited the highest total deformation in both positions. Additionally, the FEM analysis indicated that Design 3 had the lowest mass (300.32 g) compared to Designs 1 (310.70 g) and 2 (354.46 g). The ESAR foot prosthesis prototype was fabricated using carbon prepreg and an out-of-autoclave method, followed by mechanical testing with a compressive load. The decision matrix scoring criteria identified Design 3 as the best overall due to its light weight, ease of production, and minimal deformation in simulations. However, it was noted to be the least visually appealing. Compressive testing revealed that under an 824 N load, the heel strike position produced a deformation of 18.065 mm, while the toe off position resulted in 4.401 mm of deformation. For a prosthesis to be deemed comfortable, elastic deformation should range between 20–40 mm at the forefoot and 6–22 mm at the heel under a vertical force of 400 N. The study found significant discrepancies between simulated and experimental results, attributed to prototype delamination, which compromised load-bearing capacity during testing. In conclusion, this study provides valuable insights for prosthetic design professionals, manufacturers, and rehabilitation specialists. By addressing issues like delamination and optimizing design parameters, future foot prostheses can enhance mobility and improve the quality of life for amputees.

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Authors' Declaration

Authors' contributions and responsibilities - The authors made substantial contributions to the conception and design of the study. The authors took responsibility for data analysis, interpretation, and discussion of results. The authors read and approved the final manuscript.

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Availability of data and materials - All data is available from the authors.

Competing interests - The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Additional information – No additional information from the authors.

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