DOI: 10.21062/mft.2025.085 http://www.journalmt.com

Innovative Design of a Transtibial Prosthetic Socket through Integration of QFD, Reverse Engineering, and 3D Printing

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This study focuses on addressing the challenges faced by individuals with physical disabilities, particularly lower body impairments, by developing a stump socket using Reverse Engineering (RE), 3D Printing, and QFD. The integration of these three methods is something new in product design development, especially prosthetic products. The research adopted a three-step methodology: 3D scanning the stump, obtaining precise measurements, and fabricating a stump socket using fused deposition modeling (FDM) technology. QFD will produce technical requirements (TR) derived from consumer needs and brainstorming with prosthetists. TR will be the basis for developing the socket design in the 3D Scanning phase. The scanning process utilized Polycam, and the 3D models were refined with Meshmixer. The socket was fabricated using PLA+ material to ensure cost efficiency and customizability. Experimental results demonstrated the accuracy and feasibility of the designed prosthetic socket, with a layer thickness of 0.2 mm and printing temperatures up to 215°C. The study highlights the potential of RE and 3D Printing to address the unique anthropometric variations of Indonesian users, overcome the limitations of conventional crutches, and reduce production costs compared to imported prostheses. This approach demonstrates a scalable and innovative solution to improve accessibility and quality of life for individuals with physical disabilities while contributing to economic inclusivity.

Keywords: Transtibial Prosthetic Socket, Reverse Engineering, 3D Printing, QFD

1 Introduction

Amputation of a limb is a life-changing procedure that significantly alters the patient's physical and mental health [1]. Amputation marks the start of the patient's recovery, they will experience freedom from pain and a gain in function for the first time [2]. Body parts, including arms, fingers, toes, legs (above or below the knee), and other body parts, can typically be amputated [3]. Based on data calculated by the World Health Organization (WHO) in 2023, it is estimated that around 1.3 billion people in the world are classified as people with disabilities. Indonesia itself has 28.05 million disabled people, which is higher in Southeast Asia, according to UNESCAP in 2020. The International Labor Organization (ILO) summarized that one of the global facts is that people with disabilities are more vulnerable to poverty in every country, which is measured by traditional economic indicators such as GDP. An important disability issue is that the number of people who have had amputations due to severe accidents or congenital disorders since birth is growing. Because of their stature, continual growth, and mental development, prosthetic demands can become extremely complex.

One of the reasons for limb disability is transtibial amputation, or amputation of the leg below the knee. Some patients use devices such as prostheses to encourage physical activity after losing a limb. With the right prosthetics, the post-amputation rehabilitation pathway allows people to start over, regain independence and dignity, and return to their previous activities [2]. A prosthetic leg is one kind of assistive device for people who have lost a leg below the knee. Transtibial prosthetic legs (TTP) are used exclusively for disabled below-knee amputees. Since the device replaces leg function, it is expected to improve both the economic circumstances resulting from amputation and the quality of life. TTP consist of three main parts, namely socket, shin tube/pylon/shank, and foot [4] which can be seen in Figure 1. Where the weight of the product ranges from 1.5 kg to 3 kg with a size that adjusts to the user.

A transtibial prosthetic Socket is a spot where individuals with amputated limbs below the knee can place their limb to connect to the prosthetic leg [5]. Users of below-knee prosthetic leg products reported that the socket is the most essential aspect of their comfort and happiness with the prosthesis. This was obtained through a preliminary study conducted using the PEQ (Prosthetic Evaluation Questionnaire) template with several modifications [6]. Twenty responders who have below-knee prosthetic legs reported a number of issues with their prosthetics, including a broken socket cover, a slippery and foul-smelling socket, and a sore and painful stump. Therefore, this paper's primary goal is to make sure that using Their sockets make customers feel pleased and more at ease. Reverse engineering method is employed to address this problem.

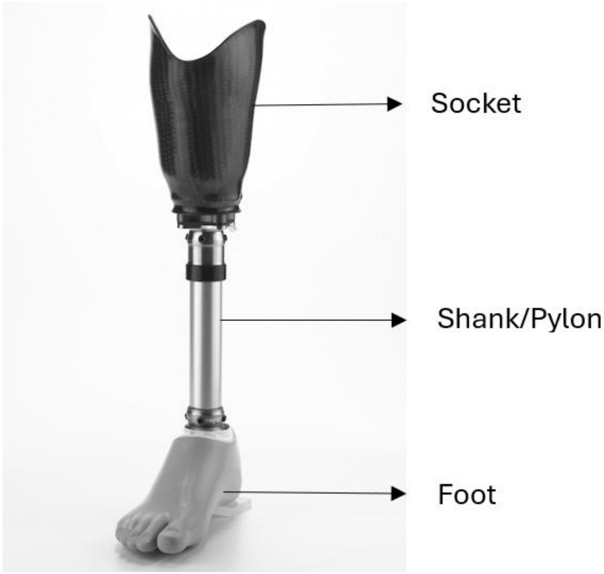


Fig. 1 *Basic Transtibial Prosthetic Foot Specifications*

Reverse engineering involves the analysis of existing products to serve as a reference for creating similar items by enhancing product advantages [7,8]. The reverse engineering method was selected due to its efficiency in product development, allowing for a quicker turnaround [9]. This approach effectively tailors health products to patient needs and enhances the precision of measurements and prosthesis models through data acquisition via scanning [10]. 3D Printing facilitates the production of prosthetic legs featuring intricate designs tailored to the anatomical requirements of the user. This method facilitates the production of prosthetic legs with lightweight yet robust materials, hence ensuring optimal comfort and movement for the user. This technology allows for the customization of prosthetic leg fabrication to meet the specific needs of the user, hence decreasing both production time and costs [11]. 3D Printing can be combined with Reverse Engineering (RE) [12] to get data via the 3D scanning process [13]. Furthermore, the RE function creates Computer Aided Design (CAD) through a 3D scanner that increases the accuracy of the residual stump model [14]. Research indicates that the utilization of 3D printing in the Indonesian health sector, particularly for prosthetic devices, is projected to rise until 2025 [15]. The integration of these two techniques facilitates the accurate fabrication of below-knee prostheses according to customer requirements [16]. Fabian et al. (2023) discussed the combined use of RE and 3D printing methods. The study discussed the rules of prototype activities according to the operating principles of each 3D printing device and the printing materials employed [17]. Figure 2 illustrates the principle of RE and 3D Printing integration.

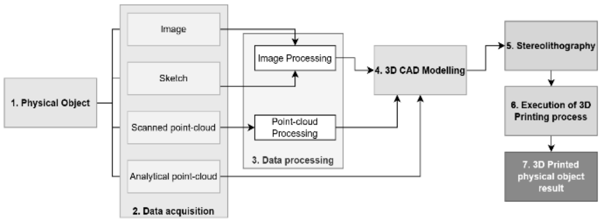


Fig. 2 *Integration of Reverse Engineering and 3D Printing*

However, there are gaps in the image processing stage of the RE and 3D Printing integration steps, where the resulting design is still entirely based on the designer's needs and user desires. There is no consideration for the prosthetic expert in improving the design, resulting in a product that does not meet the user's needs. To address this issue, a proposal is made to combine the QFD method with the image processing step to produce a design that meets standards, as well as aid from prosthetic design professionals. The use of QFD methodologies in the integration of RE and 3D Printing represents a novel aspect of this research, yielding a deeper and comprehensive methodology for product redesign. Later, QFD (Quality Function Deployment) approach will be applied in the initial phases. The QFD method was selected to assess user comfort and needs. Gathering and evaluating consumer needs is a crucial first step [18]. In addition, these needs are transformed into product features and functionalities by also listening to the input of prosthetic design experts [19]. The design concept that meets standards, needs, comfort, and functionality is then created and modeled through the RE and 3D Printing approach. Based on the explanation above, it is clear this study aims to design a transtibial prosthetic socket that fulfills customer needs, by considering insights of prosthesis experts through the integration of RE, 3D Printing, and QFD.

2 Methodology

Rapid advancements in reverse engineering and 3D printing technology present notable challenges for the traditional manufacturing industry. However, it is essential to effectively integrate both technologies and apply them to the new product development process [20]. Integrating 3D Printing or Additive Manufacturing and Reverse Engineering (RE) could possibly redesign and build parts with high complexity and customizable parts. 3D scanners could potentially assist Reverse Engineering (RE) in obtaining high accuracy measurements of the actual object. The flow process of this manufacturing is divided into three steps.

Firstly, the product needed to be scanned. Secondly, the 3D model provides the necessary measurement data. Lastly, the final product was fabricated from a 3D scanner [21].

2.1 Reverse Engineering Technique

Reverse Engineering is a product design methodology that derives a product's design concept from measurements or digitalization, subsequently creating a CAD model to approximate the physical object, which can be further refined to attain an optimal product design. In product design, reverse engineering facilitates the generation of novel design concepts, particularly during the development phase initiated with a physical prototype. It allows for modifications throughout the iterative design process when the altered product lacks CAD data, and it aids in quality control by detecting discrepancies in the design and contrasting them with the original CAD model. In many engineering specialties, reverse engineering (3D Scanning) is a useful technology that makes it possible to transform physical components into digital representations by building virtual models [22]. Helle & Lemu, 2021 asserted in their research that the application of technology, such as 3D scanning, can enhance precision in quality control and measurement of a design product [23]. Haleem et al., 2022 utilized RE and TRIZ in their research to redesign car bodies, successfully reducing development time and costs without incurring significant expenses [24]. Furthermore, Lee & Woo, 1998 employed reverse engineering in contemporary product design to enhance design quality and production precision. The findings from a review of several prior studies regarding reverse engineering techniques indicate that this approach holds considerable potential for application in the development of products. RE demonstrates the ability to deliver product designs with exceptional precision while simultaneously minimizing design time and expenses [25].

The RE engineering processing phase consists of 3. First phase: Data digitization/acquisition. The digitization process can be done with a 3D scanner, which captures the physical characteristics of the object, including shape, size, and, in some cases, color [26]. This study used non-contact laser scanning equipment that is able to capture the geometry of the residual limb efficiently and quickly [20]. Second phase: Segmentation/data point processing (CAD Building), This phase entails the importation of point cloud data, the attenuation of noise within the acquired data, and the reduction of point quantity. A diverse array of commercial software exists for point processing. The output from the point processing stage involves cleaning, merging, and orienting the cloud dataset in many formats to the greatest extent possible. At this juncture, brainstorming and benchmarking techniques in the product development process are included to generate 3D CAD designs aligned with customer requirements. Last phase: CAD Modeling (Prototyping), Advanced surface fitting algorithms are required to generate surfaces that accurately represent the three-dimensional information described in the point cloud dataset [10]. There are three different techniques used for surface reconstruction from triangular mesh files: feature recognition, surface fitting, and NURBS surface patching.

2.2 3D Printing

Additive manufacturing or often called 3D printing is a process of making a 3-dimensional solid object from a digital model [27]. The 3D printing process is done with an additive process, where the object is made by placing/adding material layer by layer. 3D printing technology originated in the late 1970s to early 1980s. 3D printing was first published by Hideo Kodama of the Nagoya Municipal Industrial Research Institute in 1982. The first time a 3D printer could work was the work of Charles W. Hull of 3D Systems Corp. in 1984 [28]. Research conducted by Ryu et al, developed a lightweight active prosthetic hand using 3D printing technology with nylon. The application of 3D Printing can produce comfortable products, light weight without reducing the strength and stiffness factors of the product [29]. The main reasons 3D printing technology is also used today as a suitable technology for prototype production are the following: the ability to produce items that are difficult or impossible to produce with conventional technology; the potential for relatively quick adaptation to complex geometries; and the increasing availability of 3D printing equipment [30]

According to Vaneker et al's 2020 research, the 3D Printing design process is separated into seven parts. Beginning with the creation of a design model using 3D CAD software, the design model in this study was produced from the outcomes of reverse engineering. In addition, the 3D model must be converted into a file format that the 3D Printing machine can understand. The STL file format is widely used and resembles a 3D model with surfaces constructed from triangles. The STL file is transmitted to the machine's software. The software organizes the geometry into layers. Layer geometry data is integrated with machine characteristics like as laser power, layer thickness, and scan pattern to generate manufacturing instructions for the 3D Printing machine. The manufacturing process is then completed using 3D printing equipment. Following the production process, the component is removed from the manufacturing plate/envelope, and any extra material (powder, support structure) is removed, followed by the quality and inspection stages until the product is complete [31].

2.3 Quality Function Deployment

Quality Function Deployment tools help designers keep customer needs in mind when creating design and manufacturing specifications. QFD then translates customer needs into assessment targets based on technical characteristics. HoQ is a QFD matrix that will be used in this study to interpret and analyze customer needs [32]. HoQ will determine the priority technical characteristics of the product based on user needs that will be input to the design concept in the reverse engineering stage.

The stages of constructing a HoQ matrix begin with detecting consumer needs or complaints. In this study, consumer needs were identified through literature reviews, brainstorming sessions with specialists, and the distribution of questionnaires to customers. Then determining the level of importance of customer needs through distributing closed questionnaires [18]. The next step is to analyze the technical requirements. Technical requirements (TR) are critical in determining the final design. TR are defined according to customer needs. Technical requirements are obtained through literature studies and brainstorming with prosthetic design experts. After that, determine the relationship matrix to get the level of importance of TR. Drawing a correlation between TR was critical. The technical requirements of the components were also examined [33]. Use the roof ranking system and the existing symbols to describe the amount of relationship between each TR (e.g., V = strong positive, v = moderate positive, x = moderate negative, X = strong negative, - = no relationship). TR ranking entails determining the level of difficulty and importance, as well as the projected expenses, which can be computed using the formula [34].

$$\text{Difficulty Rating TR-i} = \frac{\text{Weight of TRi}}{\text{Total of weight TR}} \times 100 \tag{1}$$

$$\text{Degree of Importance TR-i} = \frac{\text{Weight of TR-i with Attributes}}{\text{Total of weight TR with Attributes}} \times 100\% \tag{2}$$

$$\text{Cost Estimation TR-i} = \frac{\text{Difficulty Rating TRi}}{\text{Total of Difficulty Rating TR}} \times 100\% \tag{3}$$

2.4 Research Framework

The first step in conducting this research is to identify client wants and complaints. This stage is completed by creating a HoQ matrix. The result of HoQ is in the form of technical requirements, which will be the main focus for constructing a design model in the RE and 3D Printing stages. The use of RE in the construction of a trastibial prosthesis leg socket replicates the structure and shape of the original stump with greater measurement precision than other methods. This is owing to the availability of technology, such as the use of a 3D scanner machine to replicate the shape and dimensions of the object under investigation. 3D Printing is used to 3D print a designed product by gradually adding material. RE produces point cloud data or two-dimensional cross-sectional pictures, which are utilized to reconstruct a computer-aided design (CAD) model. The design findings in 3D CAD format are fed into 3D Printing. The CAD model is transformed into STL file format and uploaded to the 3D Printer system after the appropriate diagnostic procedures are performed on the STL model, resulting in the creation of a physical model of the prototype using 3D Printing techniques. The article was completed in line with the process flow diagram depicted in Figure 3.

3 Result and Discussion

3.1 House of Quality

Customer requirement were determined using an open questionnaire created by the research team based on expert brainstorming meetings and a literature study. Then, a closed questionnaire was created to assess the amount of interest (customer perception) and satisfaction (consumer expectations) with the product. Both questionnaires were distributed to 30 individuals who utilize transtibial prosthetic legs. Table 1 displays the specifics of attributes related to customer requirements.

Tab. 1 *CR and Importance Rating of CR*

No	Customer requirement	Importance rating
1	The product has a mass that is not too heavy	4
2	The cover of the socket part is not easily broken	4
3	The socket part is non-slip and odorless	5
4	The socket design does not cause the stump to sweat and chafe	5

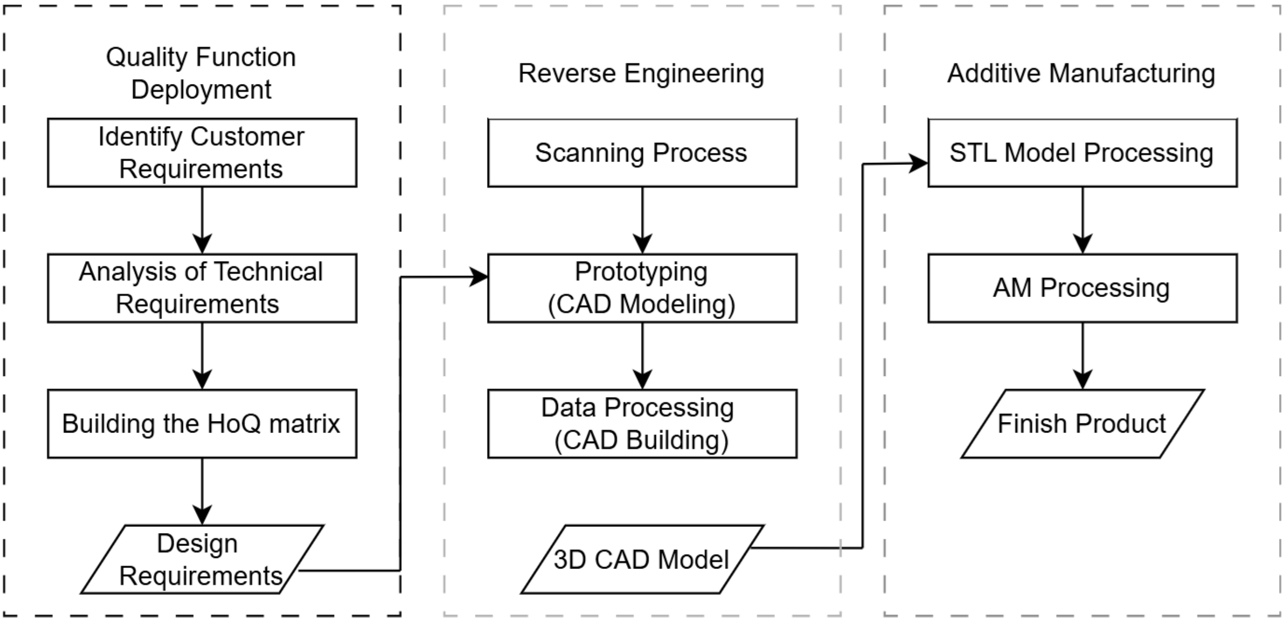


Fig. 3 *Research Flowchart*

The design team will then convert it into technical parameters or technical requirements. Technical requirements are design specifications or manufacturing procedures that influence product qualities. Technical requirements are gathered through professional brainstorming sessions and literature reviews. Fit In, Curvy, Interchangeability, Slight Design, and Flexibility are the technical characteristics necessary to suit customer needs.

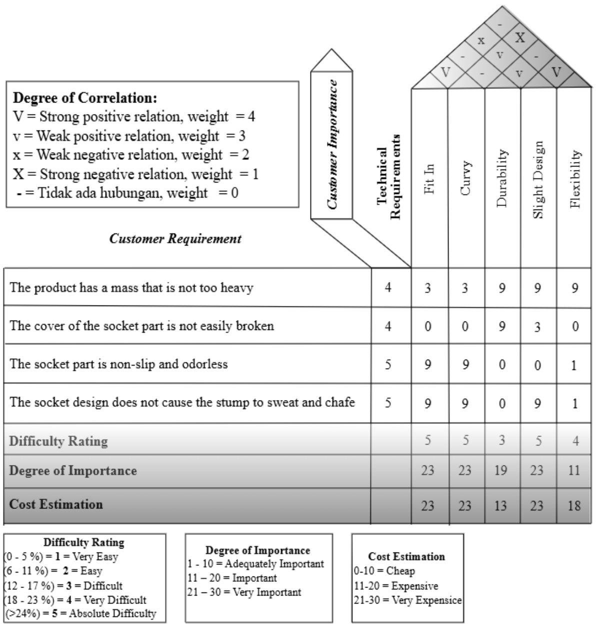


Fig. 4 *House of Quality Design of TFP*

The HoQ matrix is filled by determining the relationship between each TR and the relationship between TR and CR. This relationship is defined by panelists who are experts in this area. The relationship between TRs is determined using the QFD roof ranking method, while the relationship between TR and CR is determined using the QFD body ranking method [18]. Of course, the research team begins by explaining the goal of the study as well as the QFD approach to experts. Everything is created in a HoQ using the QFD process, as shown in Figure 4.

The technical requirements that will be input into the design concept are determined by three criteria: difficulty rating, degree of importance, and cost estimation. The HoQ matrix development yielded priority technical features, namely Fit In, Curvy, and Slight Design, with a difficulty rating of 5, a degree of importance of 23%, and cost estimation of 23%.

3.2 Reverse Engineering

The scanning process is used to find the patient's primary data, such as the size and shape of the stump. In addition to size, the patient's everyday activities, such as driving or other specific activities, are observed. Each patient's stump has a unique shape; therefore, a 3D scanner must be used and processed into a digital format to obtain accurate data. Digital measurements are taken to obtain points, digital sizes, and a three-dimensional image of the stump. PolyCAM was used to perform digital measurements using the LIDAR technology. This program is an application designed to build high-quality 3D models from live photographs or videos that can be accessed by mobile device [35]. Furthermore, LiDAR technology is being used to capture 3D documentation, which includes an integrated photodetector sensor [36]. Figure 5 shows the results of a three-dimensional scan of the stump using PolyCAM. Manual measurements were also taken to validate the dimensions obtained digitally by 3D scanning and to guarantee that the dimensions recorded digitally matched the manual measurements.

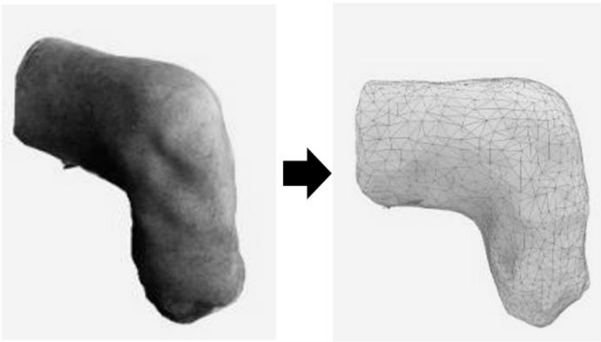


Fig. 5 *3D Scanning Polycam Application*

After obtaining digital data through the scanning process, the next step is to create a CAD model of the transtibial prosthetic socket. Innovation in the redesign of prosthetic socket solutions for transtibial impaired individuals is carried out using concepts derived from technical requirements generated through the QFD approach. The first notion is Fit-in, where the fit that must be had between the socket and the patient's leg stump, where only the knee and the side of the knee can be utilized as support, can be accomplished by taking the shape of the patient's leg stump with a 3D scanner. The second notion is Curvy, in which the shape of the prosthetic limb that respondents are most interested in mimics a real leg stump (the other leg). The Slight Design notion, in addition to materials capable of producing a lightweight prosthetic socket, requires many replacement mechanisms, such as knee and ankle, to enable comfort when walking. The results of the 3D design of the socket and stump can be seen in Figure 6.

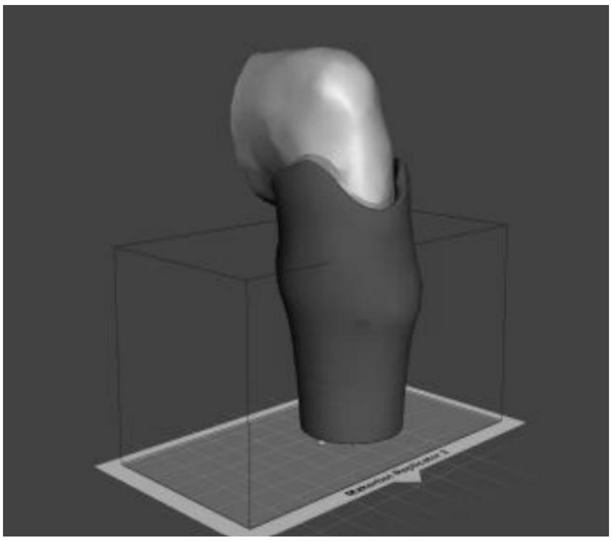


Fig. 6 *Stump and Socket Geometry*

The socket shape is created through a sculpting stage based on the stump shape of the transtibial prosthetic leg users who participated as a sample in this study. The material used in the socket design is PLA+. The material is chosen after consulting with orthotic prosthetic experts in order to provide a strong socket that is resistant to harm. Additionally, a number of beneficial qualities make Polylactic Acid Plus (PLA+) a material of choice for 3D printed prosthetic sockets, especially when using Fused Deposition Modeling (FDM) technology. With the inclusion of chemicals that greatly improve toughness and impact resistance, PLA+ is a modification of regular PLA (polylactic acid). With a low extrusion temperature range and little chance of warping, PLA+ also makes printing simple. Layer-to-layer adhesion is enhanced by PLA+'s additives, which is essential for FDM printing. Compared to traditional lamination techniques, the utilization of PLA+ with FDM technology greatly lowers production costs and processing time. For pediatric prostheses or in settings with limited resources when patients need frequent socket replacement or adjustment, this is very beneficial [37-38]. The temporary socket design in d x h has dimensions of 27 x 18 cm and is shaped like a funnel. Furthermore, a Von-Mises simulation was performed to determine whether a material will yield or fail under a specific load [39]. The results of the Von-Misses simulation of the socket design can be seen in Figure 7.

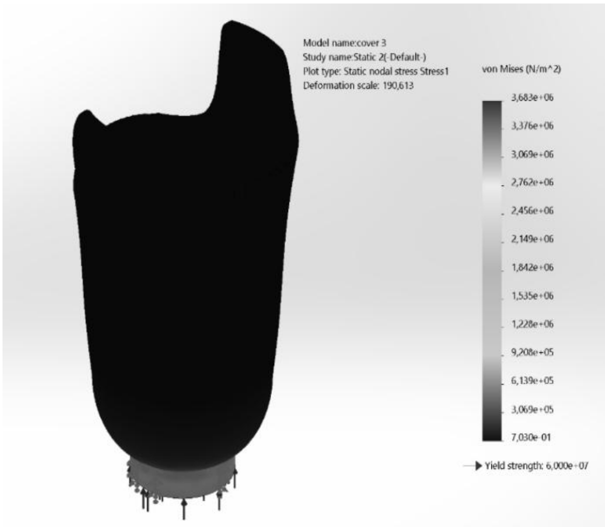


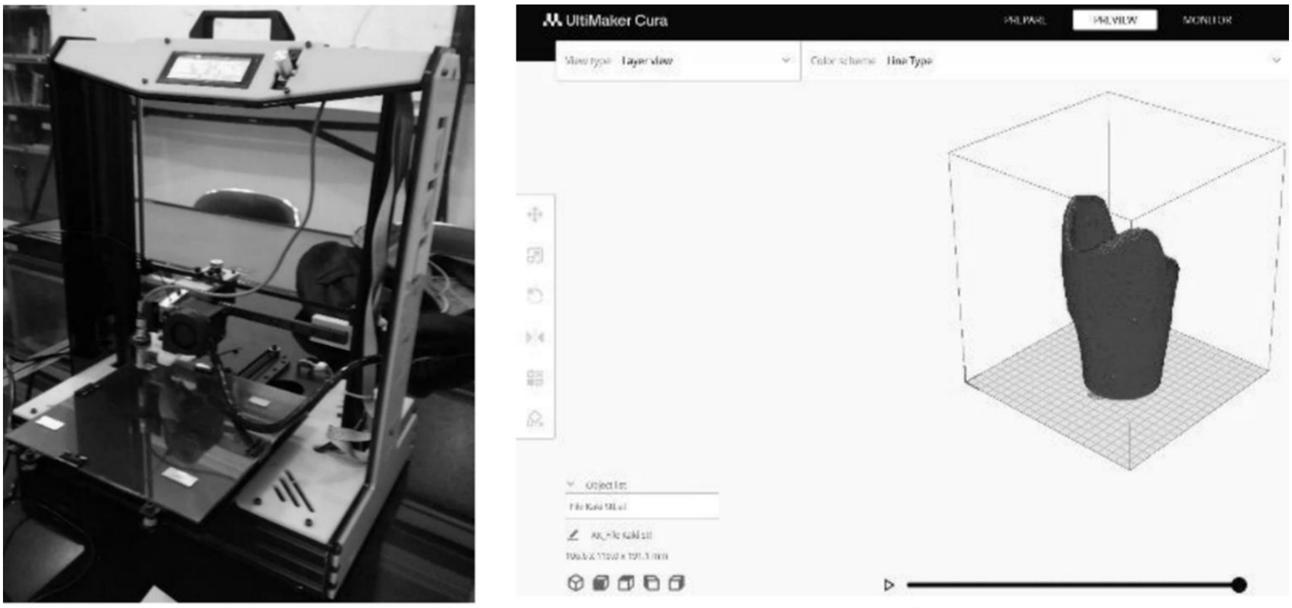
Fig. 7 *Von-Mises Simulation of Socket Design*

It shows that the static pressure on the socket design with Von-Misses simulation spans between 7.030e-01 and 3.683e+06 N/m2. The force exerted on the design is 1000 N, and the direction of the force is shown by the pink magenta arrow, with the green arrow representing geometry. The use of a force value of 1000 N is based on research, assuming that the highest mass that can be accommodated by the design is 100 kg [40]. The socket design process in this study was not subjected to topology optimization simulation because it met the predicted design weight of 382 grams. Topology optimization simulation was used to generate an optimal design by minimizing the design weight according to the researcher's aim [41].

3.3 3D Printing

After determining the ideal design, the following step is to create it with a 3D printer. The "Prusa I4 Sunhokey" 3D printer (Figure 8) uses the Fused Deposition Modeling (FDM) method. Using this type of 3D printer involves two stages: modeling and printer setup. The modeling stage is carried out using 3D printer software, specifically Ultimaker Cura. At this point, the software must be configured according to the printer parameters, beginning with the dimensions of the bed utilized, nozzle size, number of extruders, and others. The next stage is to define the model, which includes the material, printing pattern, wall thickness, density, print speed, and other parameters. Following the model design process, the program will make recommendations for printer setup, including nozzle temperature, bed temperature, and others.

Next, the 3D scanning results are transformed from nrrd (nearly raw master data) to STL format. The Ultimaker CURA application is required to convert the SolidWorks design to an STL (stereolithography) format. Later, the 3D socket results are opened in Meshmixer. When adapting the model for 3D printing (slicing), the socket design is predicted to weigh roughly 376 grams after printing. This socket will be 3D printed using fused filament fabrication printing technology to fit the patient's stump. The 3D printer's specifications for preparing the socket include a 1.75 mm filament extruder and an operating temperature of 220°C. The goal of this printer is to lower the cost of the socket using PLA+ material. The 3D printer's supporting files are STL and G-code files uploaded via SD card. Figure 9 displays the setup preparation for the printing process. The measurements were correctly obtained using the 3D printer.



(a) (b)

Fig. 8 *(a) 3D Printer Prusa I4 Sunhokey; (b) 3D Printing Process Setup Preparation*

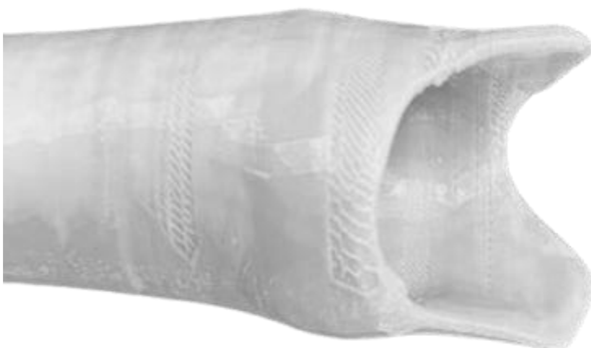


Fig. 9 *50% Scale Socket Printing Results*

The socket is being printed at 50% scale. The layer thickness is roughly 0.2 mm, and the printing process lasts around 5 hours at a maximum temperature of 215°C. The position resolution of the X, Y, and Z axes is about 0.02 mm. Figure 9 shows the printed results for the socket.

4 Discussion & Conclusion

The process of redesigning transtibial prosthetic sockets using QFD, reverse engineering, and 3D Printing begins with recognizing consumer complaints and needs, which are then translated into technical requirements (TR) with the assistance of prosthetic experts. The technical requirements prioritized in design development are fit- in, curvy, and slight design. Furthermore, the reverse engineering procedure begins with scanning the stump on the user's transtibial prosthetic legs to determine the shape and dimensions of the stump, which are then used as the basis for sculpting the design. After getting the shape and dimensions, the design process is carried out by utilizing TR from the QFD results to obtain the ideal design shape based on the patient's needs. The Fit-In, Curvy, and Slight Design concepts are where this product's design innovation stands out from existing products. These three fundamental ideas result in a socket design that closely resembles and fits the user's natural stump in shape. Additionally, the suggested socket material creates a lightweight prosthetic socket that offers a comfortable walking experience with few replacement mechanisms.

The ideal design is utilized as input in the 3D Printing process by converting the SolidWorks model's format or extension into an STL (stereolithography) file. The model is then printed using the proper infill pattern and parameters. 3D printing process took about 5 hours and used PLA+ material at a 50% scale. The application of PLA+ materials can be examined further in subsequent research. There are a number of long-term restrictions on the usage of PLA+ in high-load structural elements, like prosthetic sockets. Even though PLA is stiff, continuous stress can cause it to become brittle over time. In general, PLA is hygroscopic, meaning it absorbs moisture. The material may absorb moisture, including perspiration from the residual limb, which could lead to long-term hydrolytic destruction of the polymer chains and eventually decrease the material's mechanical strength and stiffness. Consequently, the use of protective coatings and composite reinforcement may be incorporated into future design plans. One material that may be taken into consideration is Nylon 101, since it can overcome most of the mechanical and thermal limitations of PLA+. The proposed design for the transtibial prosthetic socket used in this research was 27 x 18 (d x h). Prosthetic socket weighed 381 grams to 376 grams after 3D printing. In the future, more studies can investigate the materials to be used in the 3D printing process, as well as the ease of access to the selected materials. During the process of scanning stumps on patients, the use of more modern technology can also be considered, even within the campus. The integration of RE and 3D Printing can also be considered in conjunction with other methods/techniques for obtaining feedback from consumers, prosthetic experts (doctors), and manufacturers that typically manufacture these goods to make the design more optimal and on target. The study's integrative methodology has great promise for revolutionizing prosthetic socket design and manufacturing, enabling its usage in a wider range of clinical or industrial settings. In broader terms, this integration makes it possible for effective mass customization in healthcare workflows, where prosthetists serve as clinical validators and data interpreters. Decentralized production is made possible via AM. On-site 3D printers and print sockets might be owned by relatively small clinics or prosthetic centers. Through decentralized, digital file-based manufacturing and less material waste, this presents substantial opportunities for increasing production in developing regions, enhancing the quality and accessibility of prosthetic devices.

Acknowledgement

The authors are grateful for the financial support from Talenta Universitas Sumatera Utara grant number: 23088.1/UN5.1.R/PPM/2024. The authors are also grateful to the Faculty of Engineering, Universitas Sumatera Utara for providing Research Development Funding Batch II 2024.

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