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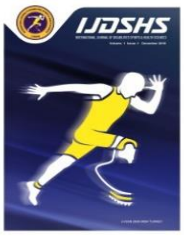

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REVİEW ARTICLE

Design and Manufacturing Ankle Foot Prosthetics for Patients with Transtibial Amputation

Wahyu Dwi LESTARI[1,4*], Ndaru ADYONO[1], Ahmad Khairul FAIZIN[1], Aridhotul HAQIYAH[2,4], Wyke KUSMASARI[3,4], Kadek Heri SANJAYA[4] and Asep NUGROHO[4]

[1]Universitas Pembangunan Nasional Veteran Jawa Timur, Faculty of Engineering, Department of Mechanical Engineering, Surabaya / Indonesia
[2]Universitas Islam 45, Physical Education Health and Recreation Department, Bekasi / Indonesia
[3]Universitas Serang Raya, Industrial Engineering Department / Indonesia
[4]Research Centre for Smart Mechatronics, Research Organisation for Electronics and Informatics, National Research and Innovation Agency (BRIN), Bandung / Indonesia
*Corresponding author: wahyu.dwi.tm@upnjatim.ac.id

Abstract
Rapid Prototyping (RP) is a technology used to incrementally shape products or add material using 3D printing equipment. 3D printing is extensively utilized throughout several industries, particularly in the medical sector. This study aims to make a valuable contribution to the field by specifically focusing on the manufacturing of foot prosthetics for patients who have undergone below-knee amputations. The design step on Solidwork software is initiated, followed by the realization of the chosendesign utilizing a 3D printing machine, which utilizes PLA as the preferred material. The main focus of this study is to optimize the manufacturing process in order to determine the parameters that result in the most effective production of foot prosthesis, while minimizing the time required for machining. Optimization analysis revealed that the most effective parameters for producing PLA foot prosthesis using a 3D printing machine are a layer height of 0.1 mm, infill density of 100%, print speed of 100 mm/s, and nozzle temperature of 210°C. These adjusted parameters are essential benchmarks for the production sector of foot prostheses.

Keywords
Ankle-Foot Prosthesis, 3D Printing, PLA, Rapid Prototyping

INTRODUCTION

A prosthetic foot is a replacement device for a lost leg that is designed to restore its original function (Hoque et al., 2023). A prosthesis that is between the knee joint and the ankle joint is called a transtibial prosthesis (DeWees, 2019). The prosthesis consists of several components, namely the socket, shank, and ankle foot (Lestari & Adyono, 2022). Foot prostheses are divided into three types based on their design and mechanism, including (a) conventional or passive foot prosthetic, which do not use active components and provide essential functions (Amirreza et al., 2023; Schlafly & Reed, 2020), (b) powered or active foot prosthetic, which is equipped with a motor that provides external power (Proebsting et al., 2020; Cherelle et al., 2017; Fylstra et al.,2020; Zelik & Honert, 2018; Kieran et al., 2023), and (c) bionic foot, which are equipped with sensors that function as detectors of muscle signals in amputees so that they can imitate the function of a natural foot (Rui et al., 2023; Dianlei et al., 2021). Furthermore, the passive foot is summarized into a Solid Ankle Cushion Heel (SACH) Prosthesis (Yu et al., 2014) and an Energy Store and Return

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(ESR) Prosthesis (Emily et al., 2022). The SACH foot has the characteristics of being light, simple, and cheap, offering minimal functionality. In contrast, the ESR has a mechanism to store and release strain energy during the running cycle. A total of 57.7 million people worldwide in 2017 lived with traumatic limb amputation. The most common amputation is below-the-knee amputation at 71% estimated to continue to increase by 47% from 1995 to 2020 (Childers & Takahashi, 2018). Therefore, creating comfortable, safe, simple, and affordable transtibial prostheses is crucial. The comfort and safety of the prosthesis are determined by the design results, where the price level is based on the material selection and manufacturing process. The manufacturing process is a significant factor in determining the price of a prosthesis because its shape is quite complex, so it takes time to make it.

Rapid prototyping (RP) is a process to accelerate product development by creating prototypes directly from three dimensional CAD designs (Umesh et al., 2023). Rapid prototyping reduces product development time by allowing prior corrections to the product being created (prototype). Some of the Rapid Prototyping methods currently being developed are Fused Deposition Modeling (FDM), Laminated Object Manufacturing (LOM), Stereolithography (SLA), Selective Laser Sintering (SLS), and Solid Ground Curing (SGC). In order to reduce the length of time required to process a complex product, a 3D printer machine has been introduced. 3D printerare called Additive Manufacturing (AM) for creating three- dimensional objects where layers of material are formed under computer control to create an object (Childers & Takahashi, 2018).

In 3D printing processing, files in STL format are imported into the “slicer” software appropriate to the 3D printing machine used. Next, based on this file, the parameters are set for the printing process. Applications of 3D printing in medical devices include printing implants (PEKK skull implants, orthopedic implants, spine, teeth), hearing aids, and prostheses.

There are many prosthetic leg designs available on the market, offering a variety of materials and functions. However, design standards have yet to be established, so there are still many researchers who are improving the quality of foot products. The purpose of this design is to be able to use it for normal walking.

The aim of this research is to develop a passive ankle-foot that is cheap but has good structural and mechanical performance and is light. The manufacturing process plays an important role in getting an ankle foot product that meets these criteria. In this research, the manufacturing process chosen to make ankle foot products is by using a 3D printing machine with FDM technology made from PLA. Several researchers have previously made transtibial prosthetics from PLA since 2015. Applying additive manufacturing will shorten production time on complex geometries with high product quality (high precision and accuracy), which would be difficult to achieve using conventional methods. Additive manufacturing is very suitable for making orthosis prosthesis products because it is cost-effective and has a fast process.

MATERIALS AND METHODS

The process of making a foot prosthesis requires several stages of activity, which can be seen in the flow diagram in Figure 1 below.

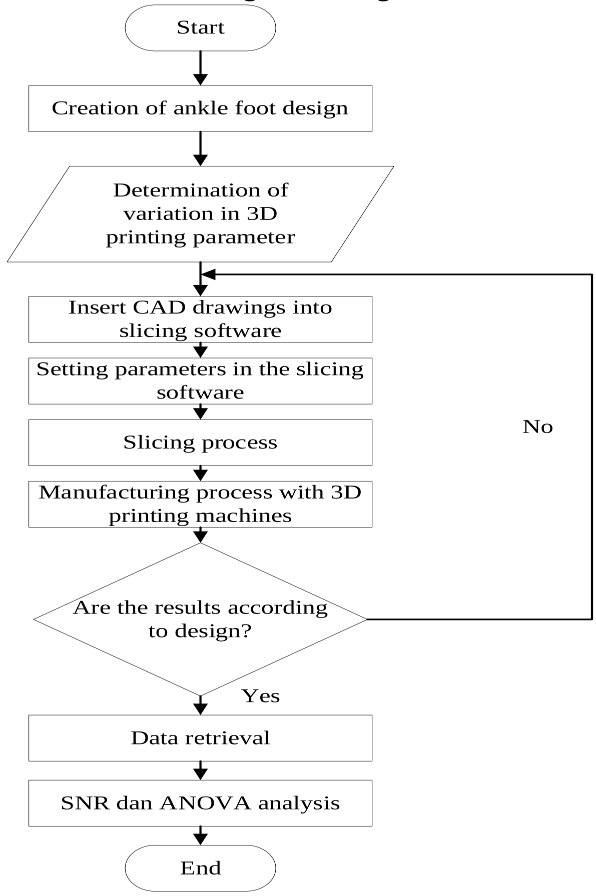

Figure 1. Research Flow Diagram

Making a foot prosthesis design begins with scanning the original foot to obtain its original size and shape. The scanning results are then measured to continue with the process of designing the ankle-foot design concept. After obtaining the design concept, proceed with creating the design using the Solidwork software. The results of the ankle-foot design are shown in Figure 2.

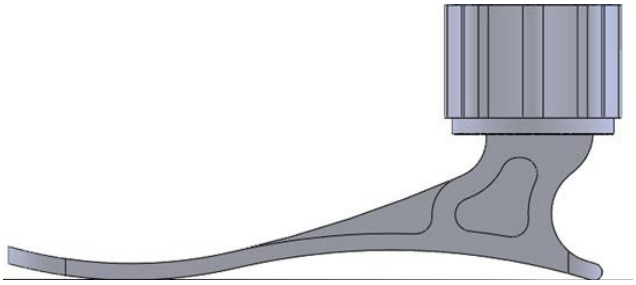

Figure 2. Ankle foot prosthesis design

After obtaining a picture of the ankle-foot design, proceed with the manufacturing process. The manufacturing process in this research uses a 3D printing machine with the Taguchi optimization method. The Taguchi method is a methodology for improving product quality and can reduce costs and resources to a minimum. This optimization method is carried out to obtain optimal parameters in producing ankle foot prosthetics. There are four 3D printing parameters determined with three levels for each factor (Table 1). The 3D printing machine used is Flashforge, which has a nozzle diameter of 0.4 mm. The material used is PLA with a Young's modulus of 3.54 GPa and a Poissons ratio of 0.33.

Table 1. Factors and levels used in the experiment

Factor	Level			
	Level 1	Level 2	Level 3	Symbol
Layer height (mm)	0.1	0.15	0.2	A
Infill Density (%)	80	90	100	B
Print Speed (mm/s)	70	80	100	C
Nozzle Temperature (C^0)	190	200	210	D

Statistical Analysis

The results of calculating the machining time needed to make an ankle-foot prosthesis product made from PLA (Polylactic Acid) using a 3D printing machine can be seen in Table 2. This data was then processed using Minitab 19 software to obtain S/N ratio (Figure 3) and ANOVA data. The S/N ratio is formulated to choose the smaller, the better because the smaller the time required to process the ankle-foot product, the better it is. After determining the S/N ratio value, the optimum level value for the 3D printing parameters regarding the response was obtained by separating each parameter based on the S/N ratio at different levels (Table 3)

RESULTS

Table 2. Design matrix of orthogonal array $L_{27}\,3^4$ for the experimental runs

No	Layer Height	Infill Density	Print Speed	Nozzle Temperature	Machining Time
1	0.10	80	70	190	1227
2	0.10	80	70	190	1292
3	0.10	80	70	190	1285
4	0.10	90	80	200	792
5	0.10	90	80	200	798
6	0.10	90	80	200	794
7	0.10	100	90	210	421
8	0.10	100	90	210	431
9	0.10	100	90	210	430
10	0.15	80	80	210	1806
11	0.15	80	80	210	1805
12	0.15	80	80	210	1811
13	0.15	90	90	190	763
14	0.15	90	90	190	771
15	0.15	90	90	190	763
16	0.15	100	70	200	706
17	0.15	100	70	200	700
18	0.15	100	70	200	707
19	0.20	80	90	200	1327
20	0.20	80	90	200	1315
21	0.20	80	90	200	1322
22	0.20	90	70	210	1278
23	0.20	90	70	210	1305
24	0.20	90	70	210	1286
25	0.20	100	80	190	1072
26	0.20	100	80	190	1076
27	0.20	100	80	190	1073

Table 3. Optimum machining time parameters

Level	Layer Height	Infill Density	Print Speed	Nozzle Temperature
1	-57.68	-63.29	-60.50	-60.22
2	-59.97	-59.35	-61.29	-59.18
3	-61.78	-56.80	-57.64	-60.04
Delta	4.11	6.49	3.66	1.04
Rank	2	1	3	4

Figure 3. Main effect plots of S/N ratios

Furthermore, analysis variance (ANOVA), a calculation technique that allows quantitative estimation of the contribution of each factor to all response measurements, is used to interpret experimental data. The confidence level is 95% or 5% significance. The P value is the error value obtained from the statistical calculation results. If the P-value is less than or equal to the alpha value, then the parameter has a significant effect; if it is greater than alpha, then the parameter does not have a considerable impact. The analysis of variance (ANOVA) results in this study are shown in Table 4. Based on the table, all parameters have a significant influence on machining time because the P-value is less than 0.05. Furthermore, the mathematical model in this research can be concluded to be reliable because the R^2 value is close to 1, namely 99.98% (Table 5). The results of the manufacturing process based on the optimal parameter combination are shown in Figure 4.

Figure 4. Results of manufacturing a foot prosthesis using a 3D printing machine

Table 4. ANOVA for machining time

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Layer height	2	707213	353606	8964.67	0.000
Infill Density	2	2595081	1297541	32895.40	0.000
Print Speed	2	698499	349249	8854.21	0.000
Nozzle Temperature	2	248965	124483	3155.90	0.000
Error	18	710	39		
Total	26	4250468			

Table 5. The coefficient R^2

S	R-sq	R-sq (adj)	R-sq (pred)
6.28048	99.98%	99.98%	99.96%

DISCUSSION

The study examined the complex procedure of creating and producing ankle-foot prosthesis specifically designed for patients who have undergone transtibial amputation. The inquiry methodically examined several aspects, and the findings revealed important factors that have a substantial impact on the production of these prosthetic devices.

Table 3 and Figure 3 concisely display the optimal parameters that are crucial for the fabrication process. The settings consist of a layer height set to 0.1 mm, infill density set to 100%, print speed set to 100 mm/s, and nozzle temperature set to 210°C. These optimized levels act as important reference points, guaranteeing the effectiveness and accuracy of the manufacturing process.

Out of these characteristics, infill density was found to be the most influential element on the machining time needed for the ankle-foot prosthesis. The complex interaction between layer height, print speed, and nozzle temperature also played a key role in the whole production process.

The hierarchical structure of influential elements offers crucial insights for the design and production of prosthetics. Recognizing that the density of infill has the greatest influence on machining time enables strategic modifications in the manufacturing process. Further process optimization involves fine-tuning nozzle temperature, print speed, and layer height to provide a careful balance between efficiency and precision.

Moreover, the methodical use of ANOVA clarified each parameter's statistical importance. The P-values, all below the 0.05 level, validate the significant influence of each parameter on machining time. The results of the study are strengthened by this thorough statistical analysis, which supports the validity of the mathematical model.

The study is important because it not only reveals the best criteria for making ankle-foot prosthetics, but also offers a systematic technique that may be used in the wider field of prosthetic design. These observations lay the foundation for progress in custom-made prosthesis for patients, ultimately improving the well-being of persons who have undergone transtibial amputations. This research establishes a basis for future advancements in the development and production of prosthetic devices, paving the way for improved and personalized solutions for amputees, and contributing to a more promising future.

Conclusion

The main goal of this research is to make quality foot prosthesis products at low prices. The foot prosthesis produced is aimed at users of transtibial prostheses. A manufacturing optimization process is also carried out to achieve this goal, apart from creating a design that is adapted to its original function. Optimization aims to improve product quality from better machining. Based on the research results, the 3D printing process parameters that influence the response time variables for machining sole products with PLA material are layer height, infill density, print speed, and nozzle temperature. The optimal combination of process parameters to produce foot prosthesis products with minimum processing time is layer height at level 1 (0.1 mm), infill density at level 3 (100%), print speed at level 3 (100 mm/s), and nozzle temperature at level 3 (210^0C).

Author Contributions

The study design was conducted by WDL, data collecting was conducted by NA, statistical analysis was performed by AKF, and data interpretation was performed by KHS, AH, and WK. WDL was responsible for preparing the text, while AN conducted the literature search. The published version of the manuscript has been reviewed and approved by all authors.

Conflict of Interest

The authors declare no conflict of interest.

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