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Stress Analysis of a Patient-specific Socket Design during Gait Cycle

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Abstract*: Transtibial amputation is one of the common surgical procedure involved removal of lower limbs specifically below the knee. The need of amputation was caused by major accidents or diseases. Prosthetic socket was an important part as it kept the residual limb in place. It should allow amputee to perform daily activities without caused any pains. Most amputees reviewed the socket's design caused pain on their residual limb. This project was purposed to analyse the pressure distribution on the prosthetic socket design. Design of the socket was based on stump's condition which verified from the hospitals. Autodesk Meshmixer software was used to remodel the socket design from 3D Computer Aided Design (CAD) data of real stump. Pressure sensors measured the pressure exerted due to contact between socket and stump. The measured pressure distribution was analysed according to the pressure tolerant and sensitive areas to avoid the uncomfortable pain. The simulation of socket design was simulated using Finite Element Method (FEM) in ANSYS Static Structural. FEM indicated the behaviour of the socket during static and dynamic condition. Then, prosthetic sockets were fabricated in-house manufacturing process based on Fused Deposition Modelling (FDM) technology using 2.85-mm filament of polyamide nylon (PA). Thus, the tensile properties of the nylon socket material were determined according to ASTM D638. The evaluated stress was 11.30 MPa at the mid-stance that proved the material was highly strength to support the load. The structural integrity of the complete prosthesis socket should be investigated according to ISO 10328 for future improvement.

***Keywords* : Fused Deposition Modelling (FDM), ISO 10328, Pressure distribution, Prosthetic socket, 3D CAD data.**

I. INTRODUCTION

Amputee is a person who has lost all or parts of their body which unable for them to perform any activities conveniently. Amputation may occur due to accident or illness. Motorcycle accident and diabetes are two major causes of amputation [1]. In U.S., the number of lower limb amputees are more than 500 000 and increased 60 000 by each year [2]. In Malaysia, the Ministry of Health (MOH) had reported that the diabetic amputee is increasing by years [3]. Most of amputees that lost their leg either above or below the knee are experiencing damage of residual limb or known as stump. Characteristic of amputation can be classified into two categories which are, above-knee amputation namely transfemoral and below-knee is transtibial. From these two categories, higher number of amputees undergoes transtibial amputation due to major causes mentioned earlier [4].

Prosthesis is a device that aims to substitute the loss of a limb with cosmetic and functional desirability for the amputee [5]. As the number of transtibial amputees increasing, orthopaedics needs to design socket which act as a translator connecting residual limb with prosthetic legs that allow amputees to perform daily activities normally and conveniently. However, due to contact of socket and stump, most amputees having uncomfortable experience using the socket which hence causing pain. References [6]-[7] shows that 55% of transtibial amputees experiences pain and skin breakdown on slump area.

In parts of the below-knee (BK) amputation, the socket is the critical part, manufactured manually, and greatly relying on the experience and skills of professional prosthetic [8]. The fitting of the uncomfortable prosthetic socket at interface with residual limb may cause excessive stress, skin irritation and ulcer [9]. Pressure distribution between interface of prosthetic socket and residual limb govern by the design quality of socket as in [10]. Since lower limbs support huge loads, the design of socket needs to be carried out properly to prevent amputees from discomfort and possible tissue trauma [11].

Finite Element Method (FEM) has been use in biomechanics field to obtain stress and deformation in various scenarios. It is an important tool to analyse the load transfer in prosthesis [12]-[14]. FEM also used for parametric analysis such as the study of design, material or alignment parameters effect, whereas the prototype needs not to fabricate in contrary to the experimental analysis [15]-[20].

This study is to propose a good design for the prosthetic socket and analyse the pressure distribution between interface of prosthetic socket and residual limb. To build the prosthetic socket, actual dimension of real stump from hospitals is required. Then, analysis of the socket can be done using the CAD modelling software, which is ANSYS Static Structural. This result will simulate the behaviour of the socket if it is safe and comfortable for amputee to use.

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II. METHODS

Fabrication of the prosthetic socket can be performed in two ways, which are traditional and modern process. However, traditional process is difficult since it requires high skilled worker [16]. Based on Fig. 1, traditional process requires stump mould that is made of plaster which then being filled with resin to form the socket. Preliminary socket will be modified afterwards to meet the load-bearing ability of specific amputee. By this process, sockets produced will have poor fitting and uncomfortable for amputee to use. However, in recent years, new technology improves the manufacturing process as it reduces cost and time consumption to build socket [17]. Technology known as 3D printing is used to fabricate the socket that provides many advantages including shorter time, easy to fabricate and better accuracy for socket. Fig. 1 also shows the step by step in performing fabrication of prosthetic socket using CAD modelling known as modern process.

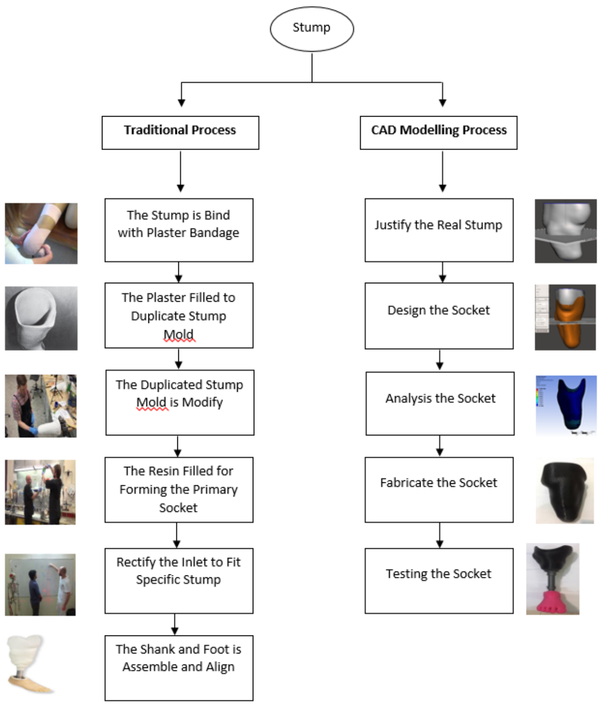


Fig. 1.Methods fabricating prosthetic socket

A. Collecting Data of Actual Stump

Actual stump parameters were taken from one of transtibial amputee that was verified from Shah Alam Hospital. The stump was scanned using 3D scanner and converted into STL file for easier designing using other software.

B. Designing Socket

The socket was designed using CAD modelling software, known as Autodesk Meshmixer which was shown in Fig. 2 below. The design of socket was remodelled from the real stump in order to get more accurate shape and size. In addition, thickness of socket was reduced by 5-mm to 4-mm due to reduction in term of weight, cost and time consumed in 3d printing the socket part.

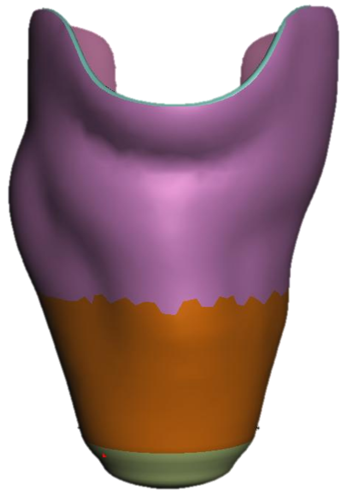


Fig. 2.Socket's design using Autodesk Meshmixer

C. Analysis the Socket

Geometry and Boundary Condition

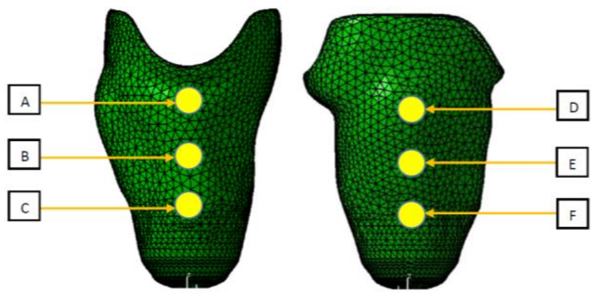
Vertical force of 700N was applied at the top of the socket represents weight of amputee. Fixed support was set at distal end of socket. Properties of materials were assumed to be isotropic and homogeneous. Material's properties were shown in Table I.

Table I: Material's Properties

Properties	Value
Material	Polyamide nylon
Density, ρ (g/cm^3)	1.12
Young's Modulus, E (GPa)	2.3
Poisson's Ratio, ν	0.39
Tensile Strength, σ_{ut} (MPa)	67

Pressure Distribution

Socket were divided into four regions as shown in Fig. 3, which were anterior, lateral, posterior and medial. In each region, it divided into 3 areas known as upper, medial and lower. Pressure from applied force was recorded in these selected areas. The results were tabulated in Table II.



(a) Anterior **(b) Lateral**

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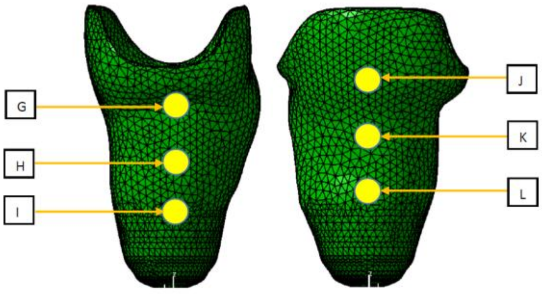


(c) Posterior (d) Medial

Fig. 3.Socket's regions in (a) anterior, (b) lateral,(c) posterior and (d) medial

Table II: Results of applied pressure at selected areas.

Socket Regions	Area	Pressure Values (kPa)
Anterior	A	114.6
	B	121
	C	111.8
Lateral	D	74.2
	E	56.6
	F	51.5
Posterior	G	103
	H	101.5
	I	84
Medial	J	39
	K	52.4
	L	47.1

D. Fabrication

3D printer was used to fabricate the socket as a prototype. The material used was polyamide CoPA, which based on copolymer of Nylon with 2.85-mm of filament size. According to ASTM D638, this material was proven had a high tensile strength, high toughness and lightweight.

III. RESULTS

Results of Von-Mises stress and total deformation which had plotted in Fig. 4 and Fig. 5 respectively were generated by ANSYS Static Structural. Both materials were divided into five phases of gait cycles which were HS – Heel Strike, LR – Loading Response, MS – Mid Stance, TS – Terminal Stance and TO – Toe Off.

Table III: Von-Misses Stress Results on Two Different Materials

Material \ Stress (MPa)	Heel Strike (0-13)%	Loading Response (13-38)%	Mid-Stance (38-63)%	Terminal Stance (63-88)%	Toe Off (88-100)%
Polypropylene	11.42	15.08	11.44	15.08	12.22
Polymide Nylon	11.27	14.62	11.30	14.62	11.84

Table IV: Total Deformation Results on Two Different Materials

Material \ Deformation (mm)	Heel Strike (0-13)%	Loading Response (13-38)%	Mid-Stance (38-63)%	Terminal Stance (63-88)%	Toe Off (88-100)%
Polypropylene	1.1301	1.1303	1.1302	1.1303	1.1302
Polymide Nylon	0.54026	0.54033	0.54027	0.54033	0.54029

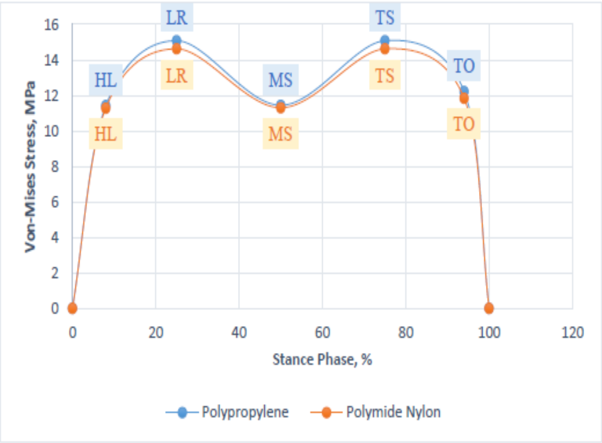


Fig. 4.Von-Mises Stress of Polypropylene and Polymide Nylon during Stance Phase

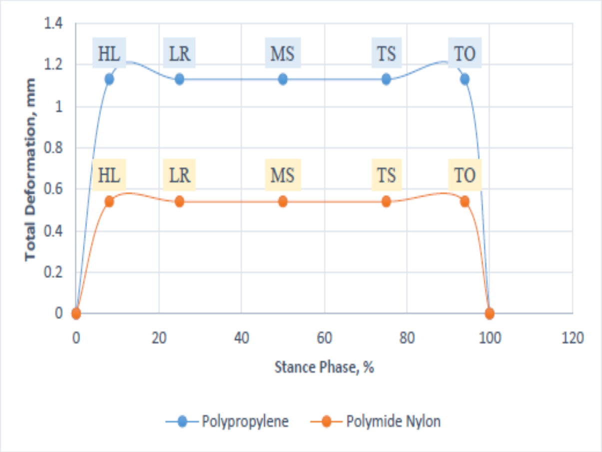
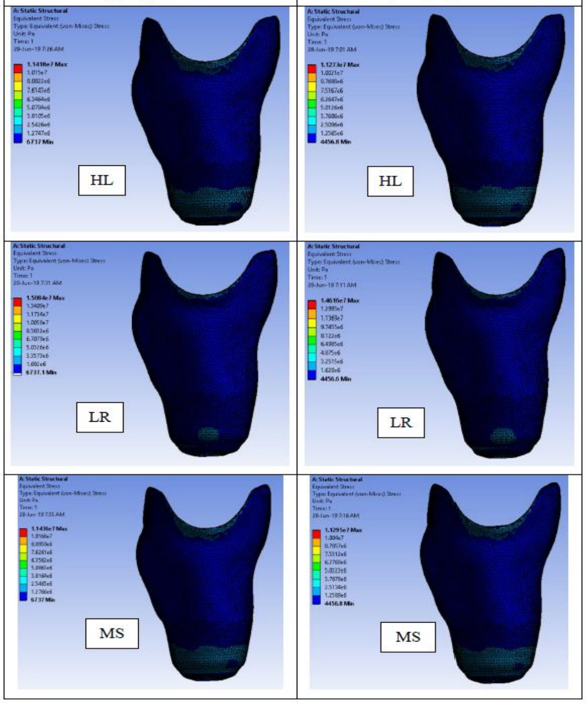


Fig. 5.Total Deformation Polypropylene and Polymide Nylon during Stance Phase

Table V: Comparison of Von-Mises Stress on Two Different Materials and Gait Cycles

Polypropylene, PP	Polymide Nylon, PA



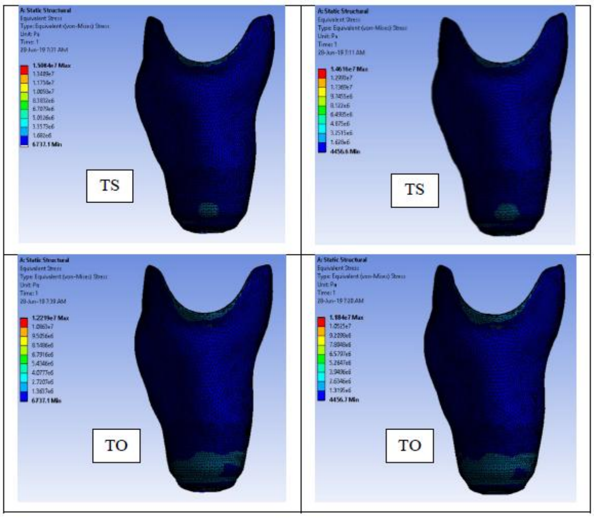
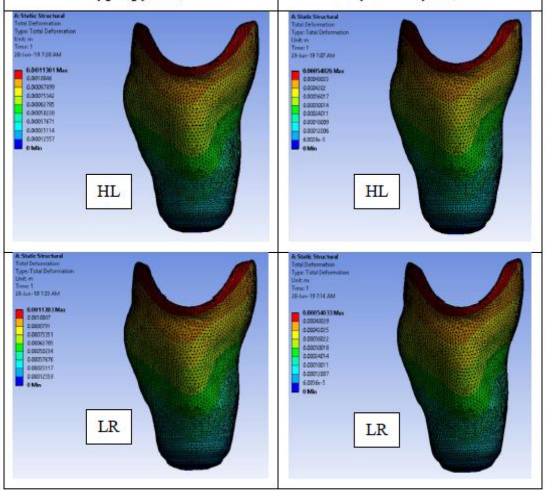
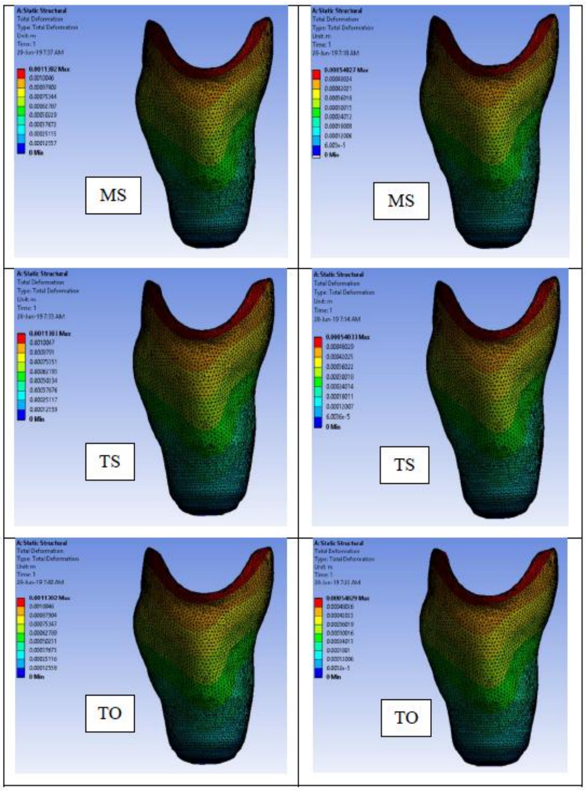


Table VI: Comparison of Total Deformation on Two Different Materials and Gait Cycles

Polypropylene, PP	Polymide Nylon, PA





IV. RESULT AND DISCUSSION

Both Von-Misses stress and total deformation for polypropylene and polyamide nylon were tabulated in Table III and Table IV respectively. Based on Fig. 4, difference could be seen for both Polypropylene and Polyamide nylon graph of Von-Misses stress at different gait cycles. The results shown, indicates Polyamide Nylon was a better material for prosthetic socket compared to polypropylene. It was proven that the Polyamide Nylon had better strength which enabled to withstand high load and pressure. The tabulation of data shows that the loading response and terminal stance were higher in the Von-Mises Stress and total deformation for both materials. For the loading response, the values become high because the high load exerted in order to stable the body and prevent the amputee from felt. For the terminal stance, the amputee needs the high force to push their body forward to continue the cycle. The total deformation gives the information that the high stress can deformed the shape of the prosthetic socket.

In a conclusion, the steps of the design and simulation of the transtibial prosthetic socket had shown above. Through the CAD modelling, the design of socket was able to remodel the shape of the stump smoothly and accurate to the actual dimension. Finite Element Method determined the simulation of the pressure distribution on the socket. All the data of pressure values that applied at the inner socket was justified from the previous study. The fabrication of the socket as a prototype by using the 3D printer was existed and it assigned to the new technology rather than traditional process that involved the quality and cost estimation. In a nutshell, this project was approved by supervisor and success in process of making a good design of prosthetic socket.

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Hokyoo Lee received his Dr. Eng. degree in 2006 from Shibaura Institute of Technology Graduate School of Engineering, Japan and became an assistant professor faculty of life design Toyo University. In 2010, he was a researcher at Hyogo Prefectural the Hyogo Institute of Assistive Technology, Japan. He now works as an associate professor, Faculty of Engineering, Niigata Institute of Technology. His current research interests include mechatronics, robotics, rehabilitation engineering and welfare engineering.