ORIGINAL ARTICLE

Patient-Specific Design of Passive Prosthetic Leg for Transtibial Amputee: Analysis Between Two Different Designs

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ABSTRACT

Introduction: Amputee patients are usually utilized prosthetic leg for daily activities such as walking, climbing, and running. However, the current prosthetic leg that available from the market often associated with poor comfortability due to its conventional way of socket manufacturing. Therefore, this research aims to build custom-made passive transtibial prosthetic legs and to evaluate the aspects of biomechanical analysis. **Methods:** The residual leg of a subject was scanned using the Sense three-dimensional scanner. By referring to scanned residual leg model, two design of prosthetic legs which are the low-cost solid ankle cushion heel (SACH) foot (D1), and the high-cost flex foot (D2), were developed by using computer aided software (CAD), SolidWorks and Meshmixer. Each of the components were then meshed with triangle edge length of 5 mm in 3-Matic software. Marc.Mentat software was used to simulate the midstance phase of a gait cycle where an axial load of 350 N was applied. **Results:** The overall maximum stress of the D1 (190.2 MPa) was higher than D2 (38.47 MPa). In addition, socket and pylon in D1 showed tendency to yield because the maximum stress is higher than yield stress of respective materials. In displacement analysis, D2 showed higher overall displacement than D1 because the flex foot has higher flexibility. **Conclusion:** From overall result, prosthetic leg of D2 is better in biomechanical strength as compared with the D1 because it can withstand the loading from subject's weight without showing any sign of yield.

Keywords: Passive prosthetic leg, Transtibial amputee, finite element

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INTRODUCTION

Lower limb amputation is defined by the International Classification of Functioning, Disability and Health (ICF) as a physical disability causing impairment of limbs and limiting activity and participation (1). It should be noted that loss of limbs could be associated with congenital abnormality, trauma, injury, disease or surgery (2). According to the World Health Organization (WHO), lower limb amputation is 84 percent of the total amputation recorded and upper limb amputation is the remaining 16 percent (3). It is usual to categorize lower limb amputation as transfemoral or transtibial amputation. Transtibial amputation is the dissection, through the tibia and fibula shaft, of the lower leg in the transverse plane. The International Standard Organization describes the prosthesis leg as an externally applied medical device consisting of a component or assembled component to replace the lost or inadequate portion of the upper or lower limb, partly or entirely (4). In general, a combination of three common components includes the socket, pylon and foot is normally known as the transtibial prosthesis leg.

The cost of the prosthetic leg is the main problem often that experienced by amputee patients. In Malaysia, the price range for prosthetic legs is between RM 5000 to RM 10000 (5). However, this is not the final price where extra expenses are excluded from it. The expenses are including services, training fees and health insurance. Other than that, the design element may have an effect on pricing as well (5). As complex systems and advanced components were used, the active prosthetic leg would apparently cost more than the passive prosthetic leg. In designing the prosthetic limb, the material used could determine the overall functionality of the prosthetic limb and total costs. Pylon made from titanium, for instance, is more expensive and durable than stainless steel. Therefore, the raw material of the prosthetic leg components used is also taken into consideration for the prosthetic leg total cost estimate. Materials used for the construction of prostheses can usually be classified into several groups, such as carbon fibers, metals, polymers and other materials (5, 6). In addition, the cost of the type of parts in the customized prosthetic leg varies. The flex-foot, for example, is high cost than the solid ankle cushion heel foot (6). The target customer, in terms of activity level is different, despite the cost. Thus, the price can vary slightly, since the prescription of prosthetics for each person varies depending on their functional level and limb state.

Despite spending a lot of money on prosthetic legs, many amputees were still not pleased, and even some of them rejected these prosthetic legs due to the poor design. In fact, the most reported problems with regard to the prosthetic leg design were socket-related problems such as low biomechanical functionality, impaired or reduced control and poor comfort (5,6,7). The sockets serve as an interface between the residue and the prosthesis apparatus (7). Skin lesions were experienced by 63-82% lower extremity amputees and approximately 25-57% abandoned prosthetic leg rate, according to Meulenbelt et al. (8). The biomechanical issues that have arisen due to amputation can be overcome by constructing a patient-specific socket. There were other comfortability factors, however, such as the parts of the prosthesis, the suspension mechanism and the orientation of the prothesis (9). The attempt to mimic the natural movement of the ankle-foot is made by inserting active parts, but it is still under development because the established prototype was large and heavy. Moreover, without a shock-absorbing system, the conventional pylon is rigid in structure that can induce user imbalance (10). Schmalz et al. (9) have shown that some of the kinematic data is affected by the orientation of the prosthetic leg.

The aim of the project is to compare the performance of lower cost prosthetic leg to higher cost prosthetic leg with different structure and built material in aspect of strength and deformation by analyzing the von Mises stress and displacement. SolidWorks and Autodesk Meshmixer were utilized to build two prosthetic leg designs. In order to evaluate the von Mises stress and displacement, Marc. Mentat software was used to simulate the final design. Simulation results were analyzed to identify the different between two different type of foot. The solid ankle cushion heel (SACH) foot and flex foot were chosen and the performance of both designs were compared. This study is expected to provide data of strength analysis to scientist, engineers and researchers to improve the design of passive prosthetic leg in the nearest future.

MATERIALS AND METHODS

Three-dimensional scanning of volunteer's residual Leg

A 50-year-old amputee is the recruited volunteer where he experienced motorcycle accident caused the amputation of his right leg. His weight is seventy kilograms during the interview session. The volunteer was given with a consent form before the scanning process to obtain permission in actively participating the entire development of prosthetic leg procedures. The right volunteer's residual leg was scanned using the Sense three-dimensional (3D) scanner (Sense 3D, 3D Devices, Inc., USA) as shown in Figure 1(a) and 1(b). Later, a computer-aided design (CAD) or a digital model of the residual limb could be reconstructed by using optical scanning system (11). To prevent loss tracking, the scanner was moved with stable and consistent movement around the residual leg of the volunteer (12). In the final form, the scanned leg was modified to remove unnecessary sections as shown in Figure 1(c). The overall process of 3D scanning until completed 3D modified model is shown in Figure 1.

(a) (b) (c)

Figure 1: a) Scanning process of patient's leg. A total of 360° rotation have been made for the scanning; b) Pre-processed scanned residual leg; and c) modified residual leg.

Three-Dimensional Design of Prosthetic Leg

Components of prosthetic leg such as socket, pylon, adapter and foot were made in short period with less technical work needed using CAD software (13), SolidWorks (Dassault Systиmes, France) and Autodesk Meshmixer (Autodesk, Inc., USA). Those components were separately built since each of the parts has their respective materials. By using Autodesk Meshmixer with a scanned leg as a reference, the socket was built. The imported stereolithography (STL) file of the scanned residual leg was used for patient-specific socket design. The socket was built on the base of the scanned residual leg size and shape from the imported stereolithography (STL) file. The socket base was constructed and then joined with the socket developed in SolidWorks. For other components (pylon, adapter and the foot), it was designed using SolidWorks. The pylon was built to be a hollow, 5 mm thick tube, the adapters built were composed of three distinct designs and functions. For the socket and pylon connection, a connector was built. To link the foot and the pylon, two other adapters were made. The pylon and all the adapters were combined as one solid body in order to minimize the body number and the sophistication of the simulation. In this study, there are two type of foot that was chosen: 1) SACH foot and 2) flex foot. The final 3D model of prosthetic leg for both designs were shown in Figure 2(a).

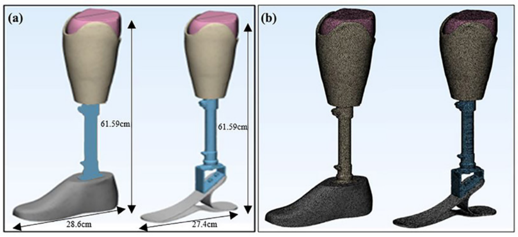

Figure 2: a) First design (left) and second design (right) of transtibial prosthetic leg; and b) Meshed models of transtibial prosthetic leg.

Meshing

Once the designing step were completed, all components in stereolithography (STL) format were imported files into 3-Matic (Materialise N.V., Belgium) for next pre-processing. Before meshing the parts, they were properly aligned in 3-Matic software. Each of the components were then meshed with triangle edge length of 5 mm (14) as shown in Figure 2(b). For all components with edge length of 5 mm, the models were solidified using tetrahedral element (15).

Finite element analysis

For the purposes of the finite element analysis (FEA), the model was assumed as linearly elastic, isotropic, and homogeneous (15). The Young's modulus and Poisson's ratio of each part were assigned with referring to the values as stated in Table I. By referring to ISO 10328, a compressive test force was applied at top load application point, the flat top surface of residual leg. The magnitude of force applied was 350 N which is correspond to half of the subject's weight as one leg was used and pointed downward in direction (27). The phase of gait is assumed to be during midstance. Thus, the anterior part of the sole and the posterior of the sole were fixed at all degrees of freedom (16). The contact between all parts in contact was set to bonded. Figure 3 shows the boundary condition of the finite element analysis in this study.

Table I: List of parts and material properties

Design	Parts	Material	E (MPa)	*v*	Refer-ence
I	Leg	Skin	20	0.48	11
	Socket	Polypropylene (PP)	1235	0.33	12
	Pylon	Stainless steel	200000	0.3	12
	Foot	Polyurethane (PU)	1600	0.4	13
II	Leg	Skin	20	0.48	11
	Socket	PP	1235	0.33	12
	Pylon	Stainless steel	200000	0.3	12
	Foot	Carbon Fibre	58500	0.3	14

To make sure the model is reliable to be used for finite element (FE) analysis, therefore the passive prosthetic leg model (first design in Figure 2) was validated with previous published paper by Omasta et. al (14). In our study, a vertical force of mid-stance condition as used by (14) was applied to the FE model. From it, the peak von Mises stress (190.2 MPa) was observed at the connector component as shown Figure 4a. This stress was similar to that of reported by (14) where they found a peak stress of 192.2MPa during mid-stance phase.

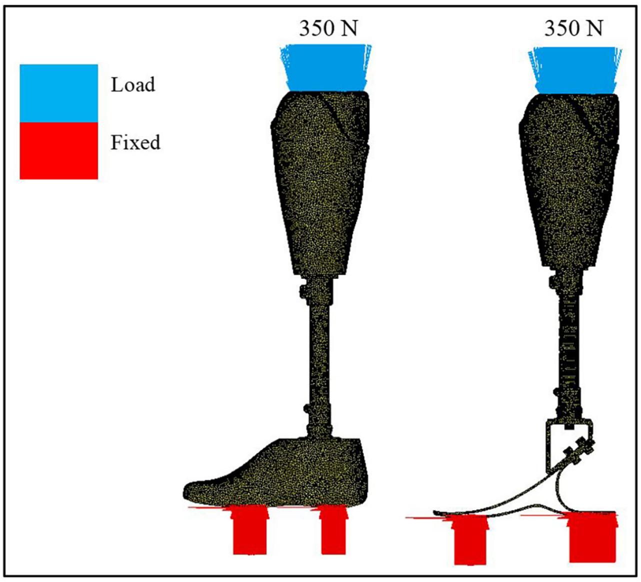

Figure 3: Boundary condition of finite element analysis.

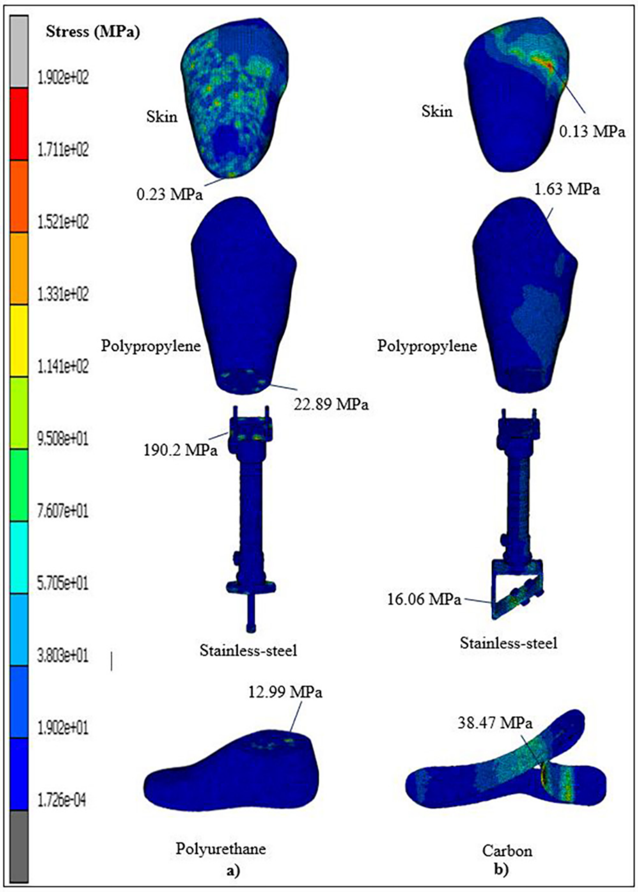

Figure 4: Von Mises stress distribution for residual skin (first row), socket (second row), pylon (third row) and foot (forth row) for: (a) first design (left) and (b) second design (right)

RESULTS

Effect of axial loading to Von Mises stress distribution

The contour plot displaying the stress distribution of each parts is shown in Figure 4 whereas the peak magnitudes of stress for each part are tabulated in Table II. The results were analyzed part by part and compared between two different designs. The residual skin in the first design experience higher peak stress (0.23MPa) as compared with the second design (0.13MPa). Apart from that, the peak stress of socket in the first design (22.89 MPa) is approximately 14 times greater than socket in the second design (1.63 MPa). Generally, the first design experienced stress that concentrated at the base of the socket in which contact with pylon component. Whereas the peak stress of socket in the second design is located at the lateral proximal of the socket. Apart from that, the peak stress of overall design is located at the stainless-steel pylon in the first design (190 MPa). This magnitude is approximately 11.84 times greater (approximately 168.8% difference) than peak stress of pylon in the second design (16.06 MPa) despite having same mechanical properties. For the foot component, medial region in the second design (38.47 MPa) has 3 times greater (99.0% difference) than the peak stress in the first design (12.99 MPa). Thus, the second design can be categorised as a flexible structure as not too much rigid compared with the first design. Based on the findings, we assumed that the high stress is due to the structure of the foot that allow more flexible movement, rather than the foot body in the first design. Even though, the second design demonstrated high stress (38.47 MPa) at the foot, nevertheless, the value is still under the yield strength of that material (Table II) and can be considered safe to be used by the users.

The maximum stress and the yield strength of materials of each part for both designs are listed in Table II From the table, the possibility of each components to be failed or broken could be recognized by comparing the maximum stress and the yield strength. In the first design, the maximum stress of the socket and the pylon exceeding the magnitude of yield strength of their respective materials. However, the foot maximum stress still under the magnitude of the yield strength of the material. In the second design, maximum stress experienced by socket, pylon and foot are lower than yield strength of respective material.

Table II: List of parts, materials, maximum stress and the yield strength (note: PP is polypropylene, SS is stainless steel, PU is polyurethane and CF is carbon fiber) (15)

Design	Parts	Material	Max. stress (MPa)	Yield strength (MPa)	Percentage different
I	Leg	Skin	0.23	-	55.56
	Socket	PP	22.89	20.7	173.41
	Pylon	SS	190.2	170	168.86
	Foot	PU	12.99	40	99.03
II	Leg	Skin	0.13	-	55.56
	Socket	PP	1.63	20.7	173.41
	Pylon	SS	16.06	170	168.86
	Foot	CF	38.47	550	99.03

Effect of axial loading to the displacement

Figure 5 shows a contour plot of displacement to compare between the first and the second design of passive prosthetic leg. In general, the kinetics movement start with proximal region of the model where high displacement occurred for the second design. The proximal part for both designs seemed to experience the highest displacement whereas the distal part experiences the lowest displacement. The maximum overall displacement for the second design (6.14 mm) is 20 times greater (197.4% difference) than the first design (0.04 mm). Again, the displacement for the second design is higher due to its foot structure that allow flexible movement. Nevertheless, the structure did not fail as the stress not exceeding the yield strength (Table II). However, the bending for both design of prosthetic leg was not very noticeable with bare eyes. The overall model of second design tend to bend backwards.

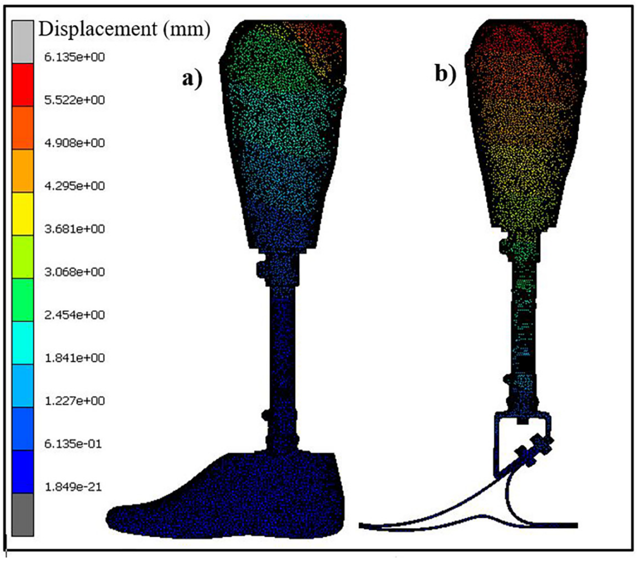

Figure 5: Displacement contour plot for: (a) second (left) and (b) first (right) design.

DISCUSSION

Socket and residual leg interface are one of the crucial aspects that could determine the comfortability and performance of prosthetic leg user. The socket that is too tight may cause discomfort and pain to residual leg while socket that is too loose can hinder the movement of wearer (14, 17, 18). The contour plot of residual leg (Figure 4) displayed the stress distribution throughout the region. In the first design, the residual leg seems to experience maximum stress at the distal part of the skin. To be noted, high stress the distal end of tibia and fibula can cause pain because the site is pressure intolerant (18). Meanwhile, the maximum stress experience by residual skin in the second design is located at posterior compartment which is the pressure tolerant area (18). In this case, the socket has lower possibility to damage the leg (18). For other component, the socket in the first design experience maximum stress located at the base. The maximum stress exceeding the yield strength of material (Table 2); therefore, the base is possible to fail or fracture. This may be due to the socket have weak connection with the pylon and could possible to detach from the connection. Meanwhile, the socket in the second design can sustain the pressure from the applied force because the magnitude of stress below the yield strength of materials (Table 2). Next, small portion at the adapter part of the pylon in the first design experience high stress as compared to the second design. Consequently, it has high possibility to yield and affect the connection with the socket. In contrast, the pylon in the second design possesses low tendency to yield as the maximum stress does not exceed the yield strength of material (Table 2). For the foot region, both designs have low possibility to be yield due to the maximum stresses are below than the yield strength of that material. The deformation of both feet is very low thus can act as stabilizer to the wearer (19).

From previous finite element analysis conducted by Ali et al., (15) they analyzed prosthetic leg socket of different materials including polypropylene with 1100 MPa Young's modulus and 0.37 Poisson's ratio. Their subject weight is 70kg (15). The fixed support was applied at distal of the socket where the loading during midstance was 707 N (15). The maximum stress (7.45 MPa) was noticed accumulated at the distal part of the socket (15). As compared to our study, the maximum stress (22.89 MPa) accumulated at the base socket. Even though there is a big different, it should be noted that the model from previous study was only a socket. Our model in this study was in a full scale of prosthetic leg where it shows a completed set. Nevertheless, both stresses from previous study by Ali et al. and this recent study has low magnitude as compared with yield strength of that material (Table 2).

In a study conducted by Omasta et al., (14) they performed FEA to analyse the deformation of carbon composite dynamic response foot and aluminium alloy pylon. The Young's modulus and Poisson's ratio of carbon composite are 58500 MPa and 0.3 respectively whereas 70000 MPa and 0.33 respectively for aluminium alloy (14). From the boundary condition, the proximal part of the pylon was fixed in displacement and normal load of 700 N was applied from the base of the foot (14). From their results, it can be seen clearly the maximum stress (231 MPa) accumulated at the toe part of foot (14). The result was comparable to our second design where the peak stress located at lateral side of the foot (14). The anterior side of the pylon experienced peak stress (100.1 MPa) on the outer surface. As compared to our study, the peak stress experienced at anterior distal part of the pylon (38.47 MPa) (14).

Balaramakrishnan et al. (20) conducted a finite element study and experimental work to analyze the deformation of SACH foot. The model of the foot used by them consisted of polyurethane foot shell and polypropylene keel where the SACH foot was attached to an extended pylon. From the boundary conditions, 800 N of load was applied axially on the top of pylon and sole of the foot was fixed. From the results, it shows the stress distribution throughout the foot, however, the peak stress of during midstance was not discussed briefly (20). Nevertheless, the study found that the SACH foot is acceptable to be used for the prosthetic leg development for normal activities. In contrast, our findings shows that the SACH foot could possibly experiencing mechanical failure due to the von Mises stress is exceeding the yield strength of that materials as shown in Table 2. A nearest future experimental study is needed to verify and validate the current form of finite element analysis.

In other study involving SACH foot, Casallas et al. (21) constructed a whole three-dimensional prosthetic leg including socket, pylon and foot. The model was simulated via FEA in order to determine the deformation and displacement of the model. The load was corresponded to half of subject's weight which is 400 N and the sole of the foot was fixed in displacement (21). The material assigned for the socket was carbon fiber (21). From the findings, the von Mises stress of the socket was incomparable to our study due to the fact that the Young's modulus of carbon fiber is about 50 times greater than polypropylene (21). To be noticed, the results from them showed the peak stress was located at the base of the socket in which similar to our study (21). Besides, the steel pylon experienced maximum stress of 140391 Pa which is 1354 times smaller than maximum stress (190.2 MPa) of our pylon and showed no possibility of yield (21). Other than that, the peak stress of foot concentrated at lateral side of the foot. As compared to our foot model, the maximum stress located at the connection side to pylon.

From the displacement result, the severity of the deformation of parts could be analyzed. As far as authors concerns, the higher the displacement of model from the original position, the higher the deformation of the model. In the first design, the overall displacement is very low. This indicates that during midstance phase the wearer may has acceptable stability compared to the second design. For the former design, the displacement is low and acceptable as the foot is made from flexible carbon fiber material that compressed when load is applied. Nevertheless, from biomechanical point of view, some displacement is still required throughout the model to provide the pylon flexibility, which permits for natural lower body movement (22). However, too high displacement can cause imbalance towards the user because excessive bending of prosthetic leg can affect the height of prosthetic leg compared to other unamputated leg.

In this study, there were some limitations that affected the precision and consistency of the result compared to real life condition. These limitations unavoidable when dealing with 3D model and finite element analysis. However, the previous studies showed that the use of finite element method could give promising results and accepted by many experts in engineering (14, 15, 20, 22, 23). One of the limitations from our study is the model of the residual leg, where it was only consisting of skin and other hard or soft tissue were excluded. Thus, the loading distribution was not similar to natural leg loading. Besides, the model of the SACH foot was simplified where the keel was absent in which it should be attached at the wooden keel. Nevertheless, this simplicity is not only happened in this recent study, but it was applied by many other researchers with acceptable results (14, 15, 20, 22, 23). Another limitation is the gait condition where we simulated the stance phase only. In the future studies, it should include other phases of gait such as heel strike and toe off since the load magnitude is different for each phase.

CONCLUSION

In conclusion, SACH foot (first design) and flex foot (second design) exhibited different performance due to material and structure of the design. Overall prosthetic leg with SACH foot experience higher overall stress as compared with flex foot design. The prosthetic leg with SACH foot provides low performance as it shows potential to yield at connection part between pylon and socket thus can give harm towards user. The findings from this study are expected to give crucial data of strength and deformation analysis for researchers, scientists and engineers to improve the design of passive prosthetic leg so they can develop a better comfort and enhance the durability of prosthetic leg in the future. Other than that, it is expected that the recent findings from this study could support justification from clinician on their choices of prosthetic leg for patients.

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