Customized Designs and Biomechanical Analysis of Transtibial Prosthetic Leg

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Abstract. A prosthetic leg is a technical mechanism that is designed as a substitution of the function of a missing limb or body part. This device has been effectively used as an essential tool for amputees. The traditional way of producing the prosthetic leg is very tedious and time consuming. Apart from that, comfortability issue is another problem if using casting method. Therefore, the main purpose of this study is to customize and biomechanically evaluate an prosthetic's socket to produce a better construct for the improvement of performance. In this paper, the methods started with a definition of the construction of the finite element model which is divided into four parts: amputee leg, sockets model, pylon and socket. Later, modelling of the pylon and three-dimensional foot model was taken into consideration. The focus was on the design of the socket then moving to the biomechanical study using a finite element method which involved several analyses of the effects of socket designs as well as its material properties. The sockets were initially developed from a data of 3D scanning with an estimated uniform thickness of 5 mm. The results of the finite element study showed that the perforated socket configuration had better stability in terms of displacement (0.19 mm) and von Mises stress (1.15 MPa), as compared to the conventional socket (stress of 3.22 MPa), and the displacement of 0.19 mm. Meanwhile, open-sided socket experienced von Mises stress of 1.18 MPa and displacement of 0.22 mm. In conclusion, a customized design is a promising technique that can enhance the performance of user in terms of biomechanical aspect.

1. Introduction
A prosthetic leg is a technical mechanism that is designed as a substitution of the function of a missing limb or body part [1]. The function of a prosthetic leg is optimal when a person can perform daily activities prior to the amputation. The manufacturing of prosthetics has been developed due to demands from either war victims or people born with handicaps [2]. On the other hand, the main cause of acquired limb loss is poor blood circulation in the affected body part, due to arterial disease. Diabetes Mellitus is in more than half of the cases where it become the main reason of the total amputations [3]. The high rate of traffic victims due to accidents is another reason for the worldwide increase in lower limb amputations [4, 5].
Every missing human part has its own type of prosthesis. Specific typology is used for the determination of the extent of amputation and for localization of the missing body part. In the ‘lower extremity prosthetic devices’, i.e. lower limb prostheses, there are two main subcategories: (a) trans-femoral, and (b) trans-tibial. Trans-femoral can be defined as any amputation transsecting the femur bone or a congenital anomaly resulting in a femoral deficiency. In the industry, these prostheses are known as ‘AK’ or ‘above the knee prostheses’, but the common terminology that have been used by clinicians is trans-femoral prostheses [6]. Meanwhile, the trans-tibial is amputations transecting the tibia bone or a congenital anomaly resulting in a tibial deficiency. For some scientists, these prostheses are referred to as ‘BK’ or below the knee prothesis.

Due to its distinction and intricacy of the amputee’s residual limb, the fitting and layout of a socket are recognized to be a very challenging course of action [7]. These issues can be triggered within the established residual limbs with no track records of skin issues owing to alterations in theliner socket prescription, in addition to the environment at the interface. For instance, trapped air can occur when patients follow a specific process in implementing a liner to their residual limbs before donning a socket. In this case, it can exert more impact on skin (resulting high friction), temperature and likely to cause blistering [8]. Available technology in the developing countries is, in general, very costly. Thus it is out of reach and cannot be accessed in an easy way [9]. The main issue that often affects a prosthetic leg is the price. The practical trans-tibial prosthesis would cost a person between $5,000 and $7,000 which would only allow the wearer to stand and walk on level ground [10]. In Malaysia, the prosthetic leg prices range from RM 5000 to RM 10000 [11]. Another issue on the conventional prosthetic leg is the manufacturing process where casting method is applied. The amputee person needs to spend a lot of time to wait for the casting process can be done. Apart from that, it is reported that amputee person experiencing uncomfortable socket due to the casting method [7-10]. Therefore, this study was conducted to apply three-dimensional (3D) scanning process to scan the amputee leg, in order to reduce time taken and uncomfortable issue. Before it can be applied to real environmental condition, a biomechanical analysis was done to check the strength of the construct, where three different designs were developed in this study. The results of von Mises stress and displacement were included in this paper to discuss the potential of the 3D printed socket to be applied in prosthetic leg in the future.

2. Methodology

2.1 3D scanning

There are many processes and procedures involved in creating a three-dimensional leg socket. The first step in obtaining a residual limb’s 3D model was to collect information from each amputee's leg angle. The solution was to capture the structure of the subject’s leg by using the sense 3D scanner supported operating systems: windows* 7&8 (32-bit or 64-bit), the minimum hardware requirements: Intel* or equivalent, RAM 2GB, USB 2.0 connection.

2.2 Model development

Three different designs of the socket were created using 3-Matic software (Materialise, Belgium) where the measurements were taken after scanning the amputee's leg, as depicted in Figure 1. The size of sockets was determined by the geometry of the subject's leg which was taken by using a Sense 3D scanner. In general, the first design was duplicated two times so all sockets had the same dimension, where the width of the designs from the bottom was 6 cm and from the top around was 12 cm. Meanwhile, the length and the thickness of socket’s wall was 0.5 cm and 22 cm, respectively. For the second design, it was according to some studies in which additional feature (cutting body in circle shape was introduced. Each circle is containing a cooling channel with 0.5 cm in diameter. In this project, the size of the hole is 0.5 cm and regarding to number and placement of it done randomly because no specific reference showed that. There were a total of 43 holes and the placement of the holes were 12 on the front, 12 on the left side, 12 on the right side, and 6 on the back of the socket. The third design had 2 big windows on the sides, the size being 11 cm * 13 cm.
2.3 Finite element analysis

The biomechanical analysis involves measuring finite elements (FEA) simulation performed on all the models using Marc Mentat. Several step procedures need to be prepared before performing the FEA simulation which are the boundary condition and contact, material properties.

Firstly, the finite element analysis was performed on the three socket design models, and the best models were chosen. Once the analysis was completed the chosen socket material properties were changed to two types and the best material was chosen. The comparison simulation block diagram used for this design demonstrated a summary of the process as shown in Figure 2.

One of the design factors of the prosthetics leg that must be taken into consideration is the type of material used. Thus, in this project, a FE study of three different material properties—polylactic acid (PLA), acrylonitrile butadiene styrene [12], and polypropylene (PP)—were conducted to compare the von Mises stress, displacement. Three different material properties in the three simulations were assigned individually for the socket. Other properties such as material properties of the prosthetic are leg and skin, pylon, foot. The value of Young’s modulus, Poisson’s ratio and Yield Strength stated in the Table 1.
3. Results and Discussion

3.1 Von mises stress

Figure 3 displays the contour plots of the von Mises stress for Three Different Design of Prosthetic’s Socket Under Axial Load of 350n; (a) Design 1 is to mimic the conventional socket, (b) Design 2 is a perforated socket, (c) Design 3 is an open-sided socket. During the stance phase, the maximum stress value observed at socket 1 with the conventional design (3.22347 MPa) was approximately three times greater than that of the perforated socket (1.14654 MPa), and two and half times greater for the open-sided socket.

Table 1. List of material properties used on the research

| Materials | Young’s Modules (Mpa) | Ratio Poisson’s | Yield Strength (Mpa) |
|-----------|-----------------------|-----------------|----------------------|
| Skin      | 20 [13]               | 0.48 [14]       | -----                |
| PLA       | 3500 [15]             | 0.38 [15]       | 9.655 [16]           |
| STEEL [17]| 200000                | 0.3             | 520                  |
| PU        | 1600 [18]             | 0.4 [18]        | 51[19]               |
| PP [17]   | 1235                  | 0.33            | 25                   |
| ABS       | 2900 [15]             | 0.35 [20]       | 17.781[16]           |
3.2 Displacement

The FE results illustrated maximum displacement at the top of the sockets, as shown in Figure 4.

Displacements were during balanced standing. The open-sided socket had the highest value for displacement (0.22 mm). While the first and second designs were roughly the same (0.19 mm).

Figure 4 also shows the displacements for the three models. From the results, in general, it could be seen that the deformation of the PP model had a greater displacement compared to the ABS & PLA models.
Generally, it can be observed that on the other hand, the results demonstrated that the maximum displacement produced by the PP model (0.262 mm) was higher than the PLA model (0.197 mm), and ABS (0.206 mm). On the other point, the socket was displaced a little bit more at the top rather than the medial side.

**Figure 5.** Von Mises stress and maximum displacement for three different materials and same design; (a) PLA socket, (b) ABS socket (c) PP socket. The first, second and third column is PLA, ABS, and PP, respectively.

Customized sockets are important as it directly affects the function and extent of prostheses, the residual limb skin is very sensitive and can be affected due to weight stress [21]. However, only a few studies have been performed on the use of a perforated socket [4,11]. In this study, the use of three different designs, were investigated for displacement. From the results, in general, it could be seen that the deformation of the PP model had a greater displacement compared to the ABS & PLA models. Generally, it can be observed that on the other hand, the results demonstrated that the maximum displacement produced by the PP model (0.262 mm) was higher than the PLA model (0.197 mm), and ABS (0.206 mm). On the other point, the socket was displaced a little bit more at the top rather than the medial side.

In general, the results showed that the socket with acrylonitrile butadiene styrene [12], in which that material had more stability than PP in terms of the von Mises stress and displacement. For ABS and PLA, both models demonstrated approximately similar values on displacement, thus the difference in material did not affect the majority of results. This study is concerned with finite element study, which showed that the high value at the socket designs for all models which experienced the stress of not more than the yield strength of the ABS, PLA, and PP material the value mentioned in Table 1. This indicated that the designs can be used safely for amputee patients.

With regards to displacement results, Ali, et al. [22] found that the deformation values for the same conditions (Mid-Stance, Heel Strike and Toe Off) were 0.63, 0.55 and 0.72 mm, respectively. In this study, the result of mid-stance (0.206 mm) was quite better than the previous study’s result, while the authors’ results of deformation of heel strike and toe-off conditions were better than the current study (0.966 and 10.67 mm, respectively). Even though, the current findings of stress and displacement are still under the maximum points, which means that the design conditions are within the safe limits.

To be mentioned, there were some limitations to this study, such as the development of the prosthetic’s leg focused only on the socket and excluding others such as leg, pylon, and foot. This is because the limited access of the current computer resources [21-22]. Furthermore, the size of the holes
and the opening on the socket sides were modelled with an estimated value based on reference which was mentioned in method section. This is due to the lack of published reports of measurement details and considering the reservation of manufacturing information for each company for each manufacturing. Apart from that, the three sockets were customized for one amputee patient and are not suitable for another where it is based on amputee leg geometry. Future studies are needed to study different size of leg and socket. Another limitation is that the use of isotropic, homogeneous and linear material properties in this study [22-24]. The skin and prosthetic leg was defined with those properties. Nevertheless, this simplifications are accepted as demonstrated by previous studies [20,22-24].

4. Conclusion
The success of the biomechanical analysis based on the result of the Finite Element Prosthetic Leg Analysis included changes in designs, and material properties. It is hoped that the outcome of this research project, in terms of providing assistance and informative guidance for future research by researchers and engineers, will contribute to the implementation of the best prosthetic technique, thus providing patients with a healthier and more comfortable life.

Acknowledgement
The work has been carried out with the support of research funding from Ministry of Higher Education Malaysia, under Fundamental Research Grant Scheme (FRGS) (Grant no.: 4F135 and FRGS/1/2019/TG05/UTM/02/3), Universiti Teknologi Malaysia (UTM) under Tier 2 (Grant no.: 15J84), Prototype Development Fund from Innovation and Commercialisation Centre (ICC) (Grant no.: 4J490), Matching Grant (Grant no.: 02M69) and Universiti Kuala Lumpur under Collaboration Research Grant Scheme (Grant no.: 4B618).

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