CUSTOMIZATION DESIGNS AND BIOMECHANICAL ANALYSIS OF TRANSTIBIAL PROSTHETIC LEG

AHMED J. M. MUBARAK

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Faculty of Engineering
Universiti Teknologi Malaysia

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DEDICATION

This thesis is wholeheartedly dedicated to my parents, who have always loved me, who gracefully provided me their moral, spiritual and emotional support.

It cannot be expressed in words but all my sincere appreciation and respect to my family and colleagues for their prayers and assistance.

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ABSTRACT

A prosthesis 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. Therefore, the main purpose of this study is to biomechanically evaluate and optimize the prosthetic's socket to produce a better construct for the improvement of performance. In this project, the methods started with a definition of the construction of the finite element model which is divided into four parts: amputee leg, sockets model. Modelling of the pylon, three-dimensional foot model. 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, gait conditions. To do that, first and foremost, a three-dimensional prosthetics was designed. The sockets were developed 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 (1.146 MPa), as compared to the conventional socket VMS (3.22347 MPa), and the displacement (0.19 mm) while open-sided socket von Mises stress (1.182 MPa), displacement (0.22 mm). Lastly, the von Mises stress and displacement analysis is applied on the prosthetic in three different gait conditions and the result of the socket was the VMS on the condition of toe-off (6.14 MPa) and the displacement during the toe-off phase, the results indicated that the model had a maximum displacement of (10.67 mm). In contrast, the lowest value was during the stance phase the von Mises stress (1.13 MPa), and the displacement was (0.21 mm). During heel strike VMS (5.52 MPa) and displacement (0.96 mm).

ABSTRAK

Prostesis adalah mekanisme teknikal yang dirancang sebagai pengganti fungsi anggota badan atau bahagian badan yang hilang. Peranti ini telah digunakan dengan berkesan sebagai alat penting untuk amputees. Oleh itu, tujuan utama kajian ini adalah untuk menilai dan mengoptimumkan soket prostetik secara biomekanik untuk menghasilkan konstruk yang lebih baik untuk peningkatan prestasi. Dalam projek ini, Kaedah dimulakan dengan definisi pembinaan model elemen dan ia terbahagi kepada empat bahagian: kaki amputee, model soket. Pemodelan tiang, model kaki tiga dimensi. Fokus adalah pada reka bentuk soket kemudian beralih ke kajian biomekanik menggunakan kaedah elemen hingga yang melibatkan beberapa analisis mengenai kesan reka bentuk soket serta sifat materialnya, keadaan berjalan. Untuk melakukan itu, pertama dan terpenting, prostetik tiga dimensi dirancang. Soket dikembangkan dengan anggaran ketebalan seragam 5 mm. Hasil kajian elemen hingga menunjukkan bahawa konfigurasi soket berlubang mempunyai kestabilan yang lebih baik dari segi anjakan (0.19 mm) dan tegangan von Mises (1.146 MPa), berbanding dengan soket konvensional VMS (3.22347 MPa), dan anjakan (0.19 mm) semasa soket terbuka von Mises tegangan (1.182 MPa), anjakan (0.22 mm). akhir sekali analisis tekanan dan anjakan von Mises diterapkan pada prostetik dalam tiga keadaan berjalan yang berbeza dan hasil dari soket adalah VMS pada keadaan toe-off (6.14 MPa) dan anjakan semasa fasa toe-off, hasilnya menunjukkan bahawa model tersebut mempunyai perpindahan maksimum (10,67 mm). Sebaliknya, nilai terendah adalah pada fasa pendirian tekanan von Mises (1,13 MPa), dan perpindahannya adalah (0,21 mm). Semasa pemukul tumit VMS (5,52 MPa) dan perpindahan (0,96 mm).

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CHAPTER 1

INTRODUCTION

1.1 Background of the Problem

A prosthesis is a technical mechanism that is designed as a substitution of the function or appearance of a missing limb or body part (Arvela *et al.*, 2010). In other words, a prosthesis is a replacement for a missing part of the body. Protheses are essential tools for amputees, which help them executing daily motoric performances such as walking, running, climbing and grabbing. The function of a prosthesis is optimal when a person can perform these tasks prior to the amputation. The manufacturing of prosthetics has been developed due to demands from either war victims or people born with handicaps (Ramachandran *et al.*, 2010). 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 the reason for the total amputations (Berke *et al.*, 2010). The high rate of traffic victims due to accidents is another reason for the worldwide increase in lower limb amputations (Laszczak *et al.*, 2015; Pirouzi *et al.*, 2014).

Every body part that is missing has its own type of prosthesis. This 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 (any amputation transecting 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' (Facoetti *et al.*, 2010). Trans-tibial is amputations transecting the tibia bone or a congenital anomaly resulting in a tibial deficiency. In the field, these prostheses are referred to as 'BK' or below the knee prosthesis.

An ideal prosthesis adheres to different qualities and standards. It should be comfortable, easily removable, with high durability, light in weight, cosmetically pleasing, maintainable and, perhaps most importantly, well functioning. All these standards are the cause of high manufacturing costs and therefore a high price. This makes the affordability difficult for those in need of it (Bierbaum *et al.*, 2002). Personalized parts of the aesthetic leg, such as the socket, are custom made, while all the other parts, such as the foot, are manufactured in the factory. These parts are sent to the prosthetist and there assembled according to the patient's need. The prosthetic legs are completely custom made, this is due to the high costs. Approximately twenty percent of all the costs of a prosthetic leg is dependable on the socket excluding the workmanship of the prosthetic leg. Therefore, if these costs could be reduced, it will be financially beneficial for the patient (Highsmith *et al.*, 2009). One could argue that due to cosmetically attractive prototypes the production costs will still be high, however, when less raw materials are used in the production of the protheses, the prices will go down naturally (Jensen and Raab, 2007; McFarland *et al.*, 2010).

Socket comfort directly affects the function and extent of prostheses (Klute *et al.*, 2009). In addition, the residual limb skin is very sensitive, so serious skin conditions may appear if the patient is not careful. The prosthetic socket will trap limb perspiration, thus creating a risk of pathologic conditions for the limb skin. Furthermore, the skin can be affected due to weight stress. Even though the skin strength varies between people, there is always sensitivity in one way or another which leads to the experience of compression under a certain amount of force (Al-Fakih *et al.*, 2016).

1.2 Statement of the Problem

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 (Laing *et al.*, 2011). Skin disturbance can take place out of sweat appearing in the skin aggravated by the absence of airflow (Mak *et al.*, 2001). These issues can be triggered within the established residual limbs with no track records of skin issues owing to alterations in the liner 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, this in turn can exert impact on skin friction, temperture and likely to bring about blistering (Dickinson *et al.*, 2017). Unsuitable socket ventilation and low moisture permeability of socket walls bring about elevated residual-limb skin temperature as well as perspiration accumulation within the socket. These effects could passively impact life quality, prosthesis suspension, prosthesis use, and activity level. Additionally, they bring about the inconvenience, skin disturbance, skin maceration, friction blister, infection, annoying odor, and a suitable ambiance for a bacterial infestation to hair follicles of the residual limb (Hachisuka *et al.*, 2001; Köhler *et al.*, 1989). The outcomes of a 2001 survey showed that thermal inconvenience with the prosthetic socket could case life quality to decline for people with amputation. Another study reported that around 60 to 70 individuals with amputation experienced elevated perspiration within their prosthetic socket as a major issue (Dudek *et al.*, 2005).

Compared to developed countries, developing countries are in search of new technologies. Available technology in developing countries is, in general, costly, thus it is out of reach and cannot be accessed in an easy way (Herdiman *et al.*, 2015). The main issue that often affects a prosthetic leg is the price. The practical transtibial prosthesis would cost a person between $5,000 and $7,000 which would only allow the wearer to stand and walk on level ground (Valladares, 2016). The prosthetic leg prices range from RM 5000 to RM 10000 in Malaysia (Arifin *et al.*, 2017). When developing countries attempt to emulate and adopt technologies like that in developed countries, they encounter a serious issue in terms of cost, spreading technology in the market, and ultimately it would be inappropriate and with limited benefits. Due to the burdensome cost of prosthetic limbs, only affluent people are able to afford it. Affluent people, who are able to access necessary technology, must be also amputees, and therefore the size of this market is expected to be very small; this means the product is limited (Van Nostrand). It has been stated that fundamental elements, which are taken into consideration in developing countries in the case of singling out socket materials are function, durability, stability, cost, accessibility, sustainability, climatic condition, and easiness of conservation (Mtalo, 2000). A great number of people of Third World countries are in dire need of an affordable leg prostheses; however, it is out of their reach due to its costly modern components (Hahl and Taya, 2000).

1.3 Objectives of the Study

The objectives of this document are:

I. To establish a 3D model of customized socket prosthetic leg.

II. To biomechanically analyse the customized 3D model of socket prosthetic leg.

III. To evaluate the strength and stability of different type of design, materials, and gait conditions for socket prosthetic leg.

1.4 Research Questions

I. What is the best design for trans-tibial prosthetic leg to overcome a problem of high price?

II. Which type of material is used for having a low-cost prosthetic leg?

III. What the effect of prosthetic design on mechanical behavior?

1.5 Scope of the Study

This study focused on the customization of the transtibial prosthetic socket design with low-cost for one amputee patient. The 3D scanner used to take the accurate amputee leg geometry. This process used two main softwares, 3-Matic and Marc to design and test all designs, materials properties. The design of 3 different sockets was established on 3matic then the analysis of mechanical analysis was on Marc software. The researcher looked for a new design of a prosthetic leg that imitates the human system, with a functional solution that allows the users to used prostheses in all economic statuses.

1.6 Significance of the Study

The overall objective of this project was to use the best designing method, and more suitable materials to be used in the manufacture of prostheses so that low-income wearers can afford to buy them. It was difficult for wearers to afford these prosthetic legs. Because of this, a solution should be found for more affordable and less costly parts and components to allow more wearers to experience ambulation with less expensive and high-quality prosthetic legs. There was little knowledge of the medical effects of losing an arm(s) or leg(s) in military attacks. For instance, during repeated Israeli military incursions, many Palestinians in Gaza had suffered the loss of one or more limbs. This severe physical damaged causes serious health problems not only to the amputee but also to their families and to society. Nevertheless, prosthetic legs become extremely important to amputees' people in Gaza to help them in executing daily activities like normal people; this was a great encouragement for the researcher.

The second objective of this study was to know the best designs to increase reliability and increase the life span of the prosthesis during the examination of several materials used in the design of the socket. The best of them were selected based on the results of the mechanical properties analysis of several designs and also the design ventilation was taken into account to reduce the common sweating rate to help rehabilitate amputee patients by specifically addressing one of the largest problems facing the residual limb's increased sweating due to high temperatures around the residual limb. This high temperature and excessive sweating can cause numerous skin problems, diminishing patient's quality of life. Advances in the prosthetic liner and socket technology to help cool the air around the residual limb will support the amputee group. The goal was to measure the thermal barrier posed by materials currently used in prosthetic liners and sockets. The majority of the amputee population would benefit from all efforts to help with residual limb cooling. Socket changes offer a possible solution to the residual limb heating problem.

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