DEVELOPING AND TESTING AN INTERFACE PRESSURE CONTROL SYSTEM IN 3D PRINTED TRANSTIBIAL PROSTHETIC SOCKET

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2019

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THESIS SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF ENGINEERING

FACULTY OF ENGINEERING
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KUALA LUMPUR

2019

UNIVERSITY OF MALAYA

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ABSTRACT

An interface pressure within prosthetic sockets plays a major role in the fitting and comforting of the user. The continuous change of residual limb size cause poor attachment of the residual limb within prosthetic socket and high interface pressure with skin issues. Thus, the purpose of this study is to control an interface pressure within 3D printed transtibial prosthetic socket. Electronic system was designed to control the interface pressure inside 3D printed socket. The electronic system was attached into the pylon of the prosthetic device in a small box. This system could manage the pressure distribution in the 3D printed socket through the inflation and the deflation of air bladders. The 3D printed socket was built with tiny air bladders which were integrated with the liner. The inflation and deflation of the air bladders inside the 3D printed socket can be controlled using the pre-programmed keypad. The system has three air bladders connected to three separate subsystems (mini pumps and release valve). Universal Testing Machine was used to apply various static loadings into the prosthetic device. The pressure distribution in 3D printed socket was evaluated using F- socket transducers. Pressures reduced and increased in subregions of the artificial stump during the inflation of air bladders. This system minimized the interface pressures within 3D printed socket via inflation of air bladders. Pressures reduction inside the 3D printed socket were recorded at all sides. Posterior and medial sides have been recorded the maximum pressure reduction during inflation of posterior and medial air bladders respectively. The highest pressure reduction was 7.97% which recorded at medial distal and 7.86 % at posterior distal. A notable change in anterior pressure due to not have anterior air bladder. The final product of this project will eliminate the use of expensive silicone liners, relieve the peak pressures on the amputee's residual limb bony areas, and lastly manage the inner size of the socket in order to accommodate the continuous changes of the residual limb, especially for diabetic amputees.

Keywords: interface pressure; electronic system; prosthetic socket; air bladders.

ABSTRAK

Tekanan dalam soket prostetik memainkan peranan utama dalam pemasangan dan memudahkan pengguna. Perubahan berterusan daripada anggota badan yang kudong menyebabkan anggota badan tersebut menghadapi tekanan yang tinggi pada permukaan kulit. Tujuan kajian ini dijalankan adalah untuk mengawal tekanan antara bahagian dalam soket prostesis transtibial. Sistem elektronik direka untuk mengawal tekanan didalam soket tersebut. Sistem elektronik disambungkan ke pylon alat prostetik dalam kotak kecil. Sistem ini boleh menguruskan pengedaran tekanan dalam soket prostesis melalui inflasi dan deflasi pam udara. Sistem bercetak 3D dibina dengan pam kecil yang mempunyai pelapik. Inflasi dan deflasi pundi udara di dalam soket dicetak 3D boleh dikawal dengan menggunakan papan kekunci yang telah diprogramkan. Sistem ini mempunyai tiga pam udara yang disambungkan kepada tiga subsistem berasingan (pam mini dan injap pelepas). Mesin Ujian Universal digunakan untuk menilai pelbagai beban statik ke dalam peranti prostetik. Pengedaran tekanan dalam soket dinilai dengan menggunakan transduser F-soket .Tekanan pada soket dicetak 3D telah diubah mengunakan pam udara dan dicatatkan dari semua bahagian . Tekanan pada posterior dan medial telah direkodkan. Pengurangan tekanan tertinggi adalah 7.97% yang direkodkan pada medial distal dan 7.86% pada distal posterior.Produk akhir projek ini akan mengurangkan penggunaan silikon liner, mengurangkan tekanan pada anggota yang kudung dan akhirnya menguruskan saiz isipadu soket yang sentiasa berubah terutama pesakit diabetes.

Kata kunci: tekanan pada permukaan ; sistem elektronik ; soket prostetik ; pam udara .

ACKNOWLEDGEMENTS

A highest thankfulness for Almighty Allah S.W.T for giving me strength and good health for doing and finishing this study. I would like to acknowledge everyone who played a role in my academic accomplishment. First of all, my parents, who supported me with love and understanding. Without you, I could never have reached this current level of success.

I would like to express my utmost gratitude to my supervisor Dr. Nooranida Binti Arifin who has provided patience advice, continuous motivation, enthusiastic and guidance throughout the research process. It was a great pleasure to me to conduct this study under her supervision.

I would like to extend my highly appreciation and thankfulness for Hadramout Establishment for Human Development, headed by Engineer Abdullah Ahamed Buqshan, for providing me an opportunity to study in high academic institution.

Last but not least, I want to take the opportunity to express my gratitude for everyone who provided me with any technical assistance during my study, especially Dr. Ebrahim Al-Fakih, Engineer Mouaz Al Kouzbary, Bader Al- Mashjary and Omer Shami. Thank you all for your unwavering support.

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LIST OF SYMBOLS AND ABBREVIATIONS

3D	:	Three-dimensional.
MPP	:	Mean peak pressure
kPa	:	Kilopascal
°	:	Degree
kg	:	Kilogram
Hz	:	Hertz
PT	:	Patellar tendon
PTB	:	Patellar tendon bearing
TSB	:	Total surface bearing
AP	:	Anterior proximal
AM	:	Anterior middle
AD	:	Anterior Distal
PP	:	Posterior proximal
PM	:	Posterior middle
PD	:	Posterior distal
LP	:	Lateral proximal
LM	:	Lateral middle
LD	:	Lateral distal
MP	:	Medial proximal
MM	:	Medial middle
MD	:	Medial distal
N	:	Newton
S	:	Second

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CHAPTER 1: INTRODUCTION

1.1 Background

Below knee amputation is mainly caused by trauma, vascular diabetes, tumors and accident (Michael & Bowker, 2004). The number of people who have an amputation due to diabetes diagnostic is greater than those of nondiabetic(Who, 2016). The most common cause for amputation in Malaysia region is diabetes, and approximately 1.2 million people have diabetes (Malaysian Diabetes Association, 2007). According to Who (2016) estimated that 422 million adults have diabetes in 2014, in contrast to 108 million in 1980. Prevalence diabetes could increase the risk of lower extremity amputation due to non-healing for foot diabetes ulcers (Moxey et al., 2011).Moreover, according to the study conducted by the Global Lower Extremity Amputation Group, from 25 to 90% of all below knee amputations are related to diabetes (Boulton et al., 2005).It is anticipated that around 1.7 million of people in Americans with limbs missing. This number is expected to be increased by the year 2050 (Ziegler-Graham et al., 2008).Below knee amputation could be carried out to remove ischemic, infected, necrotic tissue or locally unresectable tumor (Wong, 2005).

Amputation affects negatively on the appearance, physical functions and performance, and the general health in comparing with the normal people (Eiser et al., 2001).Consequently, amputees need an artificial substitute or replacement of a missing body parts . Prostheses are required to restore the normal functions of the missing body parts and carry out the activities (Wolf et al., 2009).

1.2 Below knee prosthetic devices

Prosthesis is an artificial substitute or replacement of the missing body parts, which may be lost through trauma, diseases or congenital conditions. Therefore, the function of prosthetic device is to restore the normal functions of respective missing body parts (Al-Fakih et al., 2016). The prosthetic device for below knee amputation consists from three fundamental components includes a socket, pylon and foot (Figure 1.1). The socket is the core component of a prosthetic limb, and it is the coupling structure between amputee's body and the artificial limb (Al-Fakih et al., 2016; Laing et al., 2011). The socket transmits the mechanical loads from the amputee to the prostatic foot and vice versa (Mai et al., 2012).The fitting and design of the socket is the main issue and challenging in prosthesis in order to have different shape and size of the stump (Laing et al., 2011).The shank of prosthesis(pylon) acts as replacing for the length of the lost body limb and also incorporates a knee joint if the amputation is above the knee (Quezada, 2017).

Figure 1.1: Below knee prosthetic device components (Nurhanisah et al., 2018).

The residual limb of below knee amputation has tibia and fibula bones, as illustrated in Figure1.2. It is known as transtibial amputation. Thereby, the most challenge to make transtibial prosthesis is the socket, which must be in perfect fitting around the stump and the bones. The socket offers coupling between the stump and prosthesis. It should be fabricated in well-fitting to avoid making a wound and discomfort for user. In the socket fabrication, prosthetists customize the socket structure by giving a relief into bone areas and pressure into muscle areas that leads to perfect fitting of socket and comfort (Radcliffe, 1961). Poor fitting in prosthetic sockets acts as a significant point and most issue that can face amputees and prosthetists. The goodness and the relief of a prosthetic socket provide a clue to highlight the activities of the patient and assist to minimize the sweat and perspiration inside the socket (Martinez-Villalpando & Herr, 2009).

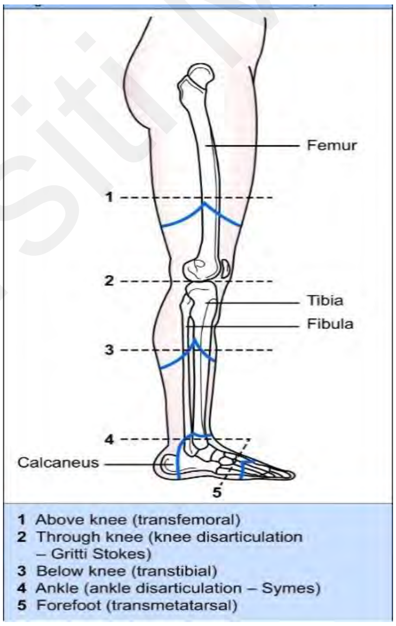

Figure 1.2: Bones level of lower limb amputation

(Harker, 2006).

The prosthetic socket is a cup-like structure that fits around residual limb. It has ability to transfer the mechanical loading from the amputee to the prosthesis. This object plays an important role for the fitness and the comfort of the users. The dimensions and the shape of a prosthetic socket are unique because each amputees' residual limb has a specific size and structure. The fitting of the socket is depending on the quality of socket fabrication (Rogers et al., 2007). The transfer of the mechanical force between the residual limb and prosthetic socket is an indacene for the function of the socket as well as the amputee's satisfaction. Thus, pressure interface between the residual limb and the socket should be fully understood. The pressure distribution inside prosthetic sockets plays a major role in the fitting and comforting the user (Laing et al., 2011).

1.3 Transtibial socket

The most significant item in the prosthesis devices is the socket which directly connected to the stump. The absolute most basic part of any prosthesis is the quality of the interface between the limb (stump) and the artificial prosthesis. The socket of prosthesis device can determine the amputee's comfort and ability to control the artificial limb (Jia et al., 2004).

1.4 Socket fabrication

Trans-tibial sockets are often made by hand casting and modification that are carried out by a prosthetist. Therefore, creating a prosthetic socket needs long time and intensive process(Mehmood et al., 2019). There are three main phases can be included during making socket fabrication namely, measurement rectification and fabrication. The physical measurements of the amputee's stump are taken by prosthetist to determine the size of the socket and identify the area of bones and pressure. The stump is assessed by determining the skin condition, joint function and muscle strength of the remaining part. Stump length can be measured through normal tap from head of the fibula to distal end of the stump. Then, Plaster of Paris is mixed with water. Subsequently, plaster of Paris is warped along amputation area by casting to make a negative mould of the stump and capture the stump as shown in (Figure 1.3a). It is important to press by the thumbs compress bandage in and around patella for pressure as well as the fingers on the back of the remaining part as known as popliteal area. Then, a positive mould is subsequently created by filling the wrap cast with plaster of Paris by gypsum powder mixing with water (Figure1.3b). After that, rectification or modification process to adjust the volume and the size of the socket and to determine the tolerance area of pressure as in PTB socket such as patellar tendon and supracondylar .Plastic as Polypropylene material is put inside thermoplastic machine in high temperature around 180°to make a positive moulding. The socket as drip process Polypropylene is pulled down tightly over the cast closely to the distal end (Figure 1.3c). Vacuum is applied into the casing to assist drying .Plaster mould from socket is removed and the modified positive mould is destroyed. The fabrication of the plastic socket is generated and tried on to make sure that it fits properly (Figure1.3d).Finally, fitting the socket is carried out to check the size and monitor the shape adjustment (Mehmood et al., 2019).This conventional socket manufacturer has some disadvantages .For instance, time consuming to fabricate the socket, needs professional skills and high cost (Al-Fakih et al., 2016).

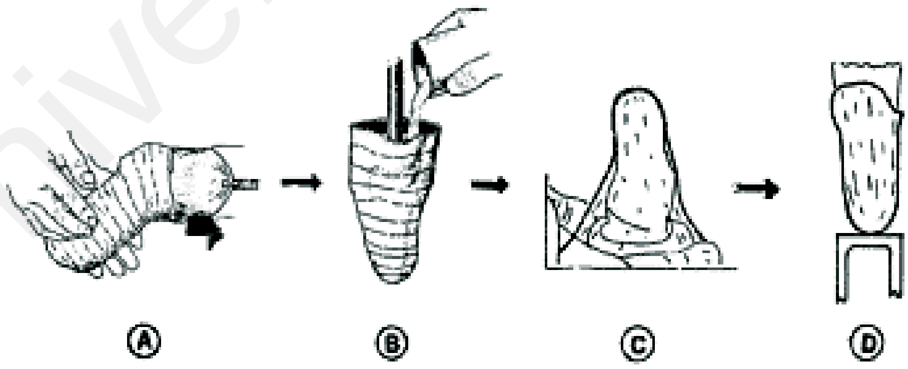

Figure 1.3: Socket fabrication

(Mehmood et al., 2019).

The evolution of transtibial socket design includes two types that are the most used which defended below: -

1.4.1 Patellar tendon bearing (PTB) sockets

The patellar tendon bearing (PTB) sockets is often made of laminated woven materials together with acrylic resins or of molded thermoplastic sheets(Ng et al., 2002). The socket has partial structure offers enclosure of the patella tendon (distal third of the patella) and extends into the medial and lateral aspects of the socket higher up to the level of adductor tubercle of the femur to provide knee stability and share body weight bearing. The posterior aspect is flared out proximally to assist knee during flexion and prevent excessive pressure on the hamstring tendons. The anterior, medial and lateral walls are high and contain patella and femoral condyles. The medial lateral dimension proximal to the femoral condyles is decreased due to offer suspension. The anterior wall proximal to patella is surrounded to provide suspension. The liner of PTB socket is a cushioning substance that has 5-mm thickness of polyethylene materials such as Pelite to decrease the shear force and fraction between the stump and socket (Al-Fakih et al., 2016; Coleman et al., 2004).PTB socket type is commonly used with a different of suspension way to provide well-fitting between the remaining part and PTB socket with inserting Pelite liner or not (Sewell et al., 2000). The PTB design is characterized by distribution loads along the pressure positions of the remaining part like the patellar tendon (PT), the medial flare of the tibia, anterior muscular compartment, and popliteal area, whereas the pressure is low on the anterior tibia crest, fibula head and anterior distal tibia. PTB socket has some limitation and challenges like it needs a good skill to cast and modify (Baars & Geertzen, 2005).Therefore, the prosthetist may spend long time to fabricate and make the socket. Also, it is difficult to fit the bone of remaining part on the socket. Thus, PTB socket is not appropriate for patients who have sharp bone amputation (Osman et al., 2010).

1.4.2 Total surface bearing (TSB) sockets

This socket type has silicone liners. The shape of TSB is different from PBT socket which it not serrated at the PT and posterior popliteal regions(Fergason & Smith, 1999). Furthermore, the most significant thing is regularly pressure distribution along all the remaining part, thus the pressure is equal in all area without pressure peak happens. Also, in TSB sockets, stump is soft tissues and expose to tolerable compressive pressure with the bony areas are stabilized in the stump. Therefore, injury or damage into is less in TSB socket in order to excessive loads occurs when silicone liners are applied. Silcom liner is worn directly next to the skin. The function of silicone liners is to make a good interface and fitting between the stump and the socket as well as reduce the shear force fraction due to the liner of silicone substance are flexible and matching the characteristic of the skin surface (Baars & Geertzen, 2005; Edwards, 2000). Improving the suspension and increase range of flexion are the most privileges of silicon liner. Vacuum at the socket is generated attaching the single pin into the end of silicone liner or through circumferential seals. This vacuum produces suspension methods in TSB socket. TSB sockets have more privilege than PTB sockets. For instance, good suspension in order to have perfect attachment of the silicone liner to the remining part, stump production, better cosmetic look, and enhanced function(Baars & Geertzen, 2005).

1.5 Three-dimensional printing socket (3D Printed Socket)

In the last decades, a new method has been developed to make prosthetic socket and overcome the limitations and drawbacks of the conventional methods fabrication (Herr et al., 2002; Saeed Zahedi, 2004).Computer-aided design (CAD) and computer-aided manufacturing (CAM) are employed to develop modern sockets. This tool has capability to decrease the requirement for physical prototypes and reduce manufacturing costs and times. Socket manufacturing quality was improved by using CAD and CAM technology (Saeed Zahedi, 2004). Thus, 3D printing technique reduces sockets' production time, and enhances the design accuracy (Herr et al., 2002). Moreover, by utilizing the new method both bone and muscle structures were considered during the design process (Sengeh & Herr, 2013).The process of A 3D printed socket is started by getting the image of the stump. One of three techniques can be used to obtain the image of the stump, computerized tomography (CT) scan, Magnetic Resonance Imaging (MRI) technique or scan by 3D laser digitalize of the limb. Then, data is generated through software program to create a 3D model of residual limb. (Aaron et al., 2006). 3D laser scan technology can be used for the external part of the residual limb and MRI or CT scan can be applied to provide the structure of internal bones and skin constituting of the limb(Colombo et al., 2006). The pressure interface in three-dimensional printed variable-impedance prosthetic socket was evaluated for a transtibial amputee at the Biomechatronics Group, Massachusetts Institute of Technology (MIT). The pressure interface was recorded using Tekscan F-Socket pressure sensors during the stance phase of gait cycle. As a result, 3D printed socket reduced the contact pressure at fibula head region and tibia region during single-leg standing in contrast with conventional socket fabrication (Sengeh & Herr, 2013).

1.6 Pressure profile for transtibial prosthesis

The pressure interface between the residual limb of below knee amputation and the socket determines the comfort of the user. Thereby, the prosthetist must know the principle of anatomy and the biomechanical of the below knee limb amputation to develop a precise prosthetic socket (Osman et al., 2010).

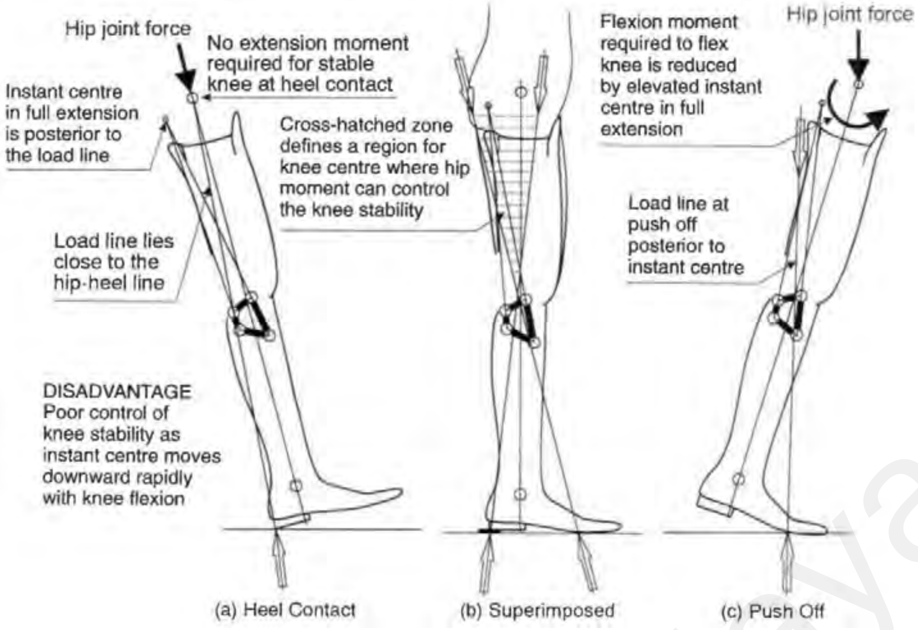

Figure 1.4: Pressure profile for below knee amputation (Radcliffe, 1994).

This Figure1.4 is showed that the force load during one gait cycle for below knee prosthesis .In the heel strike, the knee tendency to flex, but is controlled by active knee extension. Therefore, the high force and pressure is located in the anterior proximal of the stump (patella tendon) and distal of posterior. Then, in midstance back should be kept in high to increase lever arm. The force is reduced in the patella tendon and increase in the anterior distal as well as in the posterior proximal. During the toe off, the active knee extension is increased, and therefore the force in the anterior distal is increased and the pressure in the patella tendon is decreased.

Both prosthesis device and residual limb should be attached perfectly by the socket, which must be guaranteed by utilizing secure suspension system. Several suspension systems could be employed with prosthesis to reduce the pistoning movement inside the socket (Gholizadeh et al., 2012b). The excellent selection of prosthetic suspension system and the superior fitting of the residual limb in the prosthetic socket have a positive impact of amputee's activities. This leads to reduce energy consumption during ambulation

(Baars & Geertzen, 2005). Some available suspension systems have various issues and problems such as high-pressure distribution due to the continuous change in residual limb size, volume, donning, and doffing. Therefore, the residual limb should have a full contact inside prosthetic socket to guarantee proper pressure distribution (Eshraghi et al., 2012; Gholizadeh et al., 2012b; Pirouzi et al., 2014). The continuous change in the residual limb size and volume leads generate strains and injuries in the stump and dissatisfaction of patients with their prostheses.

The Pin/lock suspension system has a liner which encloses the socket into the liner through a distal stainless-steel pin connected to a shuttle lock installed in the end of the socket. The liner and the shuttle lock are attached together. Thus, the liner is removed from the pin / lock through pressing a button on the exterior wall of the socket(Eshraghi, 2014).The pin/ lock suspension system can establish a great suction at the distal side of the residual limb. Therefore, chronic skin change is been created in the stump(Beil & Street, 2004). Patient's satisfaction and prosthetic function can be determined by suspension systems. Total surface bearing socket (TSB) with silicone liners are the most used for suspension system in order to have appropriate suspension, fit, and function during ambulation in contrast with patellar tendon bearing (PTB) socket with Pelite liners (Eshraghi et al., 2012; Gholizadeh et al., 2014a).The pin-lock suspension system has some drawbacks and issues like failure in locking the suspension system to the pylon and blisters on a residual limb of the amputee. Furthermore, the pin suspension system becomes less fit and discomfort with time and activities (Klute et al., 2011; Pirouzi et al., 2014). For those reasons, a new suspension system have been developed such as vacuum and magnetic systems(Pirouzi et al., 2014).Therefore, the suspension system should have ideally interface to be able distribute the pressure between the stump and the socket. The pressure distribution inside prosthetic sockets plays a major role in the quality fit and comfort of prosthesis.

1.7 Problem statement

The socket is considered as indicator of the fitness and the comfort of user. The discomfort and poor in fitting of prosthetic socket is the most challenge which face the amputees and the prosthetists (Rogers et al., 2007).Socket designing in transtibial prosthesis could determine the amputee's satisfaction and comfort level (Ali et al., 2012b; Mccurdie et al., 1997). A report for a study survey said that 146 of amputees were not satisfied with the prosthetic socket and suspension systems because they suffer from skin issues and pain (Dillingham et al., 2001).

Pressure distribution inside the prosthetic socket could be influenced by socket quality design and the type of suspension system used. This suspension systems set the amputee' stump inside the socket via a single distal pin/lock, suction, lanyard, or magnetic coupling (Beil & Street, 2004; Eshraghi et al., 2013a). According to the study conducted by Gholizadeh et al. (2016), high pressure was recorded with patellar tendon bearing compering with the total surface bearing socket and Velcro as suspension system. Increase the pressure between the residual limb and prosthetic socket cause weakness in functions like walk or running. Silicon liners (pin/ lock) and vacuum (suction) system are the most commonly used suspension systems for transtibial prostheses. The silicone liner has perfect fitting with the residual limb .However, it has high cost (Baars & Geertzen, 2005; Gholizadeh et al., 2014b). Furthermore, pin/lock suspension systems generate a tension at the distal of the stump causes chronic skin problems and compression proximally during the swing phase of gait. This skin stretch at the pin site makes amputees facing difficulties in using pin/lock suspension system in contrast with suction suspension systems. Therefore, amputees prefer to use suction suspension systems due to have a suitable fit and donning and low pistoning (Gholizadeh et al., 2012a). Also, pin/lock suspension systems may failure in locking the suspension system into the pylon and blisters on the stump of the amputee(Klute et al., 2011).

In the new magnetic suspension system, which developed by Eshraghi et al, (2013), the anterior side of the stump has greatest value of pressure comparing with other sides. This new suspension system only can decrease the pressure over the residual limb during swing phase in order to not had significant difference in pressure with the pin/lock and suction Seal-In suspension systems during the stance phase.

Later, in 2014 a new air pneumatic suspension system (APSS) has been developed at Applied Biomechanics Lab in University of Malaya. This suspension system can manage the change in the size of the stump. The mean peak pressure was decreased compared with the commonly used suspension systems. The highest value of pressure was recorded in the anterior middle (56.43 kPa) (Pirouzi et al., 2014).This system still uses the expensive silicone liner. The air cuff was attached inside the socket as one bladder. Thus, patient cannot inflate the stump sides individually. The air cuff is one piece and it can inflate and deflate together. On the other words, patient cannot give a relief in one side of the stump as well as pressure in another side at the same time. The air cuff may move up and down during the activities due to not stick in special side inside the socket.

Currently available suspension systems have high interface pressure and poor attachment within stump due to have the continuous change of the residual limb size over time. Thereby, the pressure could be concentrated in some area of the residual limb, and cause skin damage, injury, sweat, pain and perspiration. The user be forced to change the socket after a period of time. Therefore, this research focused on the development and evaluation of an interface pressure control system in transtibial 3D printed socket.

1.8 Purpose of the study

The aim of this study is to develop and test an interface pressure control system in transtibial prosthetic socket through an air pneumatic suspension system. The study aim can be accomplished through two objectives which are:

i. To design an interface pressure control system for inflation and deflation air bladders in the inner wall of prosthetic socket.

ii. To evaluate the pressure interface in the prosthetic socket using F-socket transducers during universal testing machine.

1.9 Significance of the study

1.9.1 Academic contribution

This study will offer knowledge and information of a new suspension system for below knee prosthesis. This suspension system has 3D printed socket with pressure interface control. The study will provide a new value of pressure inside 3D printed socket to study the impact of change and control of pressure by the user during daily activities. Also, this new system will offer information for motion analysis of transtibial prosthesis with pressure control.

1.9.2 Practical contribution

The importance of this study is to improve the pressure distribution inside the prosthetic socket. The 3D-printed socket will control and manage the relief of peak pressures and volume changes of the transtibial amputees' residual limbs during daily activities. This will Lead to the comfort and satisfied of users. Furthermore, the final product of this project will eliminate the use of expensive silicone liners, relieve the peak pressures on the amputee's residual limb bony areas, and lastly manage the inner size of the socket in order to accommodate the continuous changes of the residual limb, especially for diabetic amputees.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

This part involves a critical and evaluative review of the past studies and literature in relation to the research topic. It also provides a clear sense of the structure and content for the whole study based on literature and relevant previous work which has already been done in the field. This review purposes to highlight the interface pressure between the stump and prosthetic socket for below knee prosthesis in different socket designing.

2.2 Transtibial amputation

The failure or losing body parts are the most health problem which could occur to a person. The person who have losing a limb known as amputees. Therefore, losing body parts could be replaced by artificial limbs that called prosthesis to improve the function and lifestyle of persons with limb loss. Prosthesis have potential to increase the functional ability of losing limbs as well as enhance the quality of life by restoring patients' function. Losing limbs s are a very common consequence of modern warfare(Delisa et al., 2005).

The happening of lower limb amputations become widespread because many accidents traffic and other vascular diseases. The prosthetics (artificial limbs) are often been used as a rehabilitation tool to return the function and activity of missing body parts and the manifestation. The prosthetic contains of three fundamental elements the socket, shank, and foot. The socket is the interface between the residual limb (stump)and the mechanical support system to provide the coupling between the stump and the other components of the prosthetic device. The shank replaces the length of the lost limb and also incorporate a knee/elbow joint if the amputation is above the knee/elbow. The fitting and design of socket is the main issue and challenging in prosthesis in order to have different shape and size of the remaining limbs (Al-Fakih et al., 2016).

2.3 Prosthetic socket for transtibial amputation

The socket of prosthetic device is a coupling structure around the amputee' body. The socket has capability to transmit the mechanical load from the amputee to the physical prosthesis components. Prosthetist customs fitting prosthetic socket around the stump of amputee. Thereby, the socket is considered as indicator of the fitness and the comfort of the user. The discomfort and poor in fitting of prosthetic socket is the most challenge which face amputees and prosthetists. The sizes and dimensions of a prosthetic socket are different from one amputee into another due to have the unique volume of a residual limb (Rogers et al., 2007). The common way to fabricate prosthetic sockets includes steps and phases that performed by hand as circumferential measurements, plaster wrapping of the stump, plaster casting for positive mold preparation, and a thermoforming process. This way is time consuming and the quality of the socket depends on prosthetist skills (Rogers et al., 2008). Three Dimensions printing is defined as a new technology to manufacture a three structure through layer by layer of material to form volumetric part with computer control aid (Hsu et al., 2008).

The high pressure between the stump and prosthetic socket cause weakness in functions like walk or running. Silicon liners (pin/ lock) and vacuum (suction) system are the most commonly used suspension systems for transtibial prostheses. The silicone liner has perfect fitting into residual limb (Baars & Geertzen, 2005; Gholizadeh et al., 2014b). However, this liner could increase the tension and pressure at the distal of residual limb during the swing phase of gait cycle which leads to pain and skin problems. Vacuum (suction) system can provide appropriate fit within the socket as well as decrease the quantity of pistoning within the socket in contrast with other systems (Beil & Street, 2004; Street, 2006).

2.4 Pressure distribution between different socket design: Patellar tendon bearing (PTB Socket) and total surface bearing (TSB) socket

Socket design and suspension system play a significant role rehabilitation process and the amputee’s satisfaction. Gholizadeh et al. (2016), tested the pressure distribution between the prosthetic socket and unusual shape residual limb (bulbous) for two different prosthetic sockets, Patellar-Tendon Bearing (PTB Socket) and Total Surface Bearing (TSB) Socket during walking. The subject used the transtibial prosthesis (PTB socket) with silicone liner for two years. In this study, TSB prosthesis was designed with the intension to distribute the load evenly on the stump and facilitate prosthetic donning. Velcro tape was used as suspension system to improve the fitting and donning. Two small slots were established on the medial and lateral of socket walls. The pressure distribution in the amputee' stump was recorded using four F-Socket sensors (9811, Tekscan Inc., USA) and compared for PTB socket (old) and TSB socket (new) during walking on level ground. Those sensors were set on the residual limb part along the medial, lateral, anterior, and posterior sides. The results showed that PBT socket had high pressure at the anterior proximal of residual limb especially in the patellar ligament. Therefore, the mean peak pressure in the anterior proximal at old socket (PBT) during walk was (115 ±5.2 kPa) and around 10 times greater than the mean peak pressure employed to the anterior distal residual limb (12 ±3.4kPa).Also, the pressure at the posterior distal was (110 ± 4.5kPa) and it was higher than the posterior proximal (57 ±2.7kPa) with the PBT socket. The authors concluded that in new socket (TSB socket), the pressure was distributed uniformly along the residual limb (anterior, posterior, medial, and lateral) during walking. Also, the high pressure at the anterior proximal (patellar bar) was successfully decreased. Moreover, same researchers examined the pressure interface during ramp and stairs negotiation. The findings showed that pressure was high at the anterior proximal of the stump (patellar ligament) during slope and stairs. It was 132 ± 6.1kPa and 117±4.1 kPa during walk down the slope and stairs, respectively. Amputee feedback preferred using TSB socket (new one) due to have a perfect fit between the liner and socket. Furthermore, amputee noted that the PTB socket with pin/lock suspension system has a stretch at the distal tissue of the residual limb during the swing phase.

2.5 Pressure in two different liners during walking: Dermo and Seal-In X5 liner

Pressure in Dermo and Seal-In X5 liner was evaluated during normal walking using F- socket sensors. The pressure measurement was recorded at anterior, posterior, medial and lateral of the stump. This evaluation for pressure was to determine the user satisfied for using both liners. The highest value of pressure was recorded at the anterior of the stump in Seal-In X5 liner (84.9 kPa). On the other hand, the pressure in anterior for Dermo liner was 60.2 kPa. Therefore, the user fell comfort and satisfied with Seal-In X5 liner due to have low pressure (Ali et al., 2012a).

2.6 Pressure distribution during walking on stairs, slope and non-flat surface for transtibial prosthetic socket

To avoid poor connecting between the stump and prosthetic socket and prevent skin damage during daily activities, appropriate designing and fitting of prosthetic socket to be able to create a perfect force transformation, equilibrium, and efficient control for mobility. Tolerance of peak pressure distribution should be considered during designing the socket (Zhang et al., 1998).The pressure distribution inside the transtibial amputee socket during walking on stairs, slope and non-flat surface was evaluated by Dou et al. (2006).This study had one participant with below knee prosthesis with Patella-Tendon-Bearing (PTB) socket and Silicone liner and solid-ankle-cushion-heel (SACH) foot for more than five years. A portable Pliance pressure distribution measuring system (Germany-Novel Electronics, Munich, Germany) was used in this study. Signals from calibrated force sensing resistor sensor strips measuring normal forces perpendicular to the sensor surface were converted to pressure signals. Five sensor strips were employed to determine the pressure interface. The subject carried out walking on the non-flat road, stairs and slope. The findings showed that the mean peak pressure changes at the popliteal area during walking on the non-flat road, stairs and slope. The maximal pressure was up to 215.8 kPa over the patellar tendon during walking upstairs, and the maximum pressure over the popliteal area is 190.6 kPa while walking down slope. Furthermore, peak pressure increases over the patellar tendon during walking on stairs and non-flat road, and however decrease or change insignificantly at the patellar tendon on slope.

2.7 Pressure interface profile for transtibial prosthesis in different suspension systems

2.7.1 Pressure distribution in HOLO suspension system

Prosthesis suspension systems are significant factor in allocation pressure inside prosthetic socket (Baars & Geertzen, 2005). New suspension system (HOLO system) was developed and studied by Gholizadeh et al. (2014b), and compared with the pressure distribution of pin/lock suspension system. New suspension system (HOLO) was established by removing the pin from silicone liner and replacement by the loop fastener. The Velcro strap (hook) was contacted to the socket wall at medial and lateral area. F-Socket transducers (9811E) was applied to measure the pressure interface and Spray Mount Adhesive was used to stick the sensors into the residual limb prior to donning the silicone liner. Pressure distribution of the new suspension system (HOLO) was evaluated. High pressure was measured at the lateral and medial side during stance phase. However, in the pin liner high pressure was in the distal region of the stump in anterior, posterior, and medial areas during the stance phase of gait. In the swing phase, the pressure was higher at the proximal and distal areas with the pin/lock suspension system. The pressure in the lateral distal of the stump is higher in the pin/ lock liner. They included that HOLO system can distribute the pressure more uniformly compared with the pin/lock system especially during the swing phase of gait.

2.7.2 Pressure distribution in Pin/Lock and suction suspension

The interaction between the skin and physical components of prosthesis is an indicator of quality designing of the transtibial socket and fitting comfort (Zhang & Roberts, 2000). Load force and pressure should be divided uniformly along the socket to decrease high pressure and skin issues (Mak et al., 2001).

Ali et al. (2015) studied the pressure interface for two types of liners. The pressure between Dermo (pin / lock) and Seal-In X5 silicon liner (vacuum or suction system) was compered during ramp negotiation . Four F- socket sensors arrays (9811E type) were used to determine the pressure at anterior, posterior, medial and lateral regions of residual limb. The sensors were attached with liner using adhesive spray to fix them and cover all areas of the stump. Sensors were calibrated and equilibrated before the test. The participants carried out walk activity with ascent and descent ramp area with prosthesis device. The sensors provided pressure interface for each region during the activity. The mean peak pressure (MPP) (kPa) was investigated at anterior, posterior, medial and lateral during ramp ascent and descent. In ascent ramp, MPP (kPa) in Dermo liner was (60.57, 64.50, 60.54 and 53.47) respectively. However, MPP (kPa) in Seal - In X5 liner was (83.48, 83.08, 71.35 and 53.58) respectively. Also, in ramp descent MPP (kPa) in Dermo liner was (66.43, 61.64, 67.07 and 48.16). On the other hand, in Seal - In X5 liner was (85.21, 90.03, 70.18 and 64.36) respectively.

Thereby, Seal - In X5 silicone liner has higher pressure than Dermo liner in coupling between the skin and physical components of prosthesis device. Anterior and posterior sides of residual limb have the greatest values of pressure in both ascent ramp and descent ramp in Seal - In X5 liner. This high pressure can cause problems into the patient and generate impedances during activities.

Pressure in pin/lock suspension system was evaluated via fiber bragg grating by Al-Fakih et al. (2017). Ten gait cycles were employed by the simulating machine. Pressure was measured on anterior- posterior – medial and lateral. Pressure was determined during stance phase. The high Peak pressure values (kPa) of artificial stump anterior was (34.18) at the middle region, posterior proximal (42.25), Lateral distal (53.99) and medial distal (56.06). Thus, the highest-pressure load during stance phase was recorded at the medial distal region. Therefore, the high-pressure interface between residual limb and socket can cause discomfort fitting and injury.

2.7.3 Pressure distribution in vacuum suspension system

Wernke et al. (2017) validated the relationship between elevated vacuum pressure suspension and prosthetic socket fit to determine and monitor prosthetic socket comfort. Thus, this study was based on application of Boyle's Law on prosthetic socket fit. The change in pressure vacuum inside prosthetic socket cause change in displacement of residual limb into the socket. Tension compression machine was employed to manage the magnitude, direction, and frequency of forces onto a residual limb. The residual limb model was made from a rigid plastic and compliant gel covering formed in a conical shape. Therefore, the residual limb model was connected to the tension–compression machine through a pin joint at the proximal connection and a pyramid adaptor at the distal connection. Various of vacuum pressures were applied into the sockets using LimbLogic Communicator. Valve at the distal of socket was used to control position of the limb model. The findings showed that the higher vacuum pressure inside the socket caused reduction in displacement at distal of the socket relative to a limb model. The vacuum pressure–displacement can provide indicator for attachment between the stump and the socket. The drawbacks for this way that the surface area of contact existed between the stump and socket for increasing and decreasing vacuum pressure was not both the reduced and expanded sockets was not determined.

2.7.4 Pressure profile for new magnetic suspension system during walk

Pressure distribution inside the prosthetic socket depends on the way of suspension system. Eshraghi et al. (2013b) investigated the pressure coupling between the stump and the socket for transtibial amputees for new magnetic suspension system and compared with the pin/lock and suction Seal-In suspension systems using four F-socket transducers. This new suspension system contains from cup-shaped metal plate attached with the distal end of the silicone liner and a magnet assembly embedded in the distal end of the hard socket. The middle of metal plate has a screw to attach the plate into the liner. A switch is connected the liner and the socket to manage the magnetic field. The mean peak pressure in the Magnetic Suspension System during one gait cycle was decreased at anterior and posterior compared with pin/lock system. Furthermore, the highest values of pressure were recorded in the Seal-In system. Also, the mean peak pressure at the anterior side was increased in contrast with the posterior, medial and lateral (79.26 vs. 26.01, 38.07, and 27.41 respectively) in magnetic suspension system. Thus, the mean peak pressure at the anterior a was lower with the magnetic system compared to the pin/lock system during one gait cycle (79.26 vs. 89.89 kPa, P=0.034, t=2.581). Furthermore, at the posterior of the stump the pressure was increased during gait cycle with the pin/lock system in contrast with magnetic suspension system (47.22 vs. 26.01 kPa, P=0.000, t=9.254) (Eshraghi et al., 2013b). This new suspension system only can decrease the pressure over the residual limb, particularly during swing phase in order to not had significant difference in pressure with the pin/lock and suction Seal-In suspension systems during the stance phase.

2.7.5 Air pneumatic suspension system

The prosthetic socket, liner, and stump should be in good attachment to secure convenient pressure distribution(Rommers et al., 2000). The size of residual limb can be changed with time through activities or diabetes. This leads to lose the contact and pressure distribution between the socket and stump (Goswami et al., 2003). A new air pneumatic suspension system (APSS) has been developed at Applied Biomechanics Laboratory at University of Malaya by Pirouzi et al. (2014). APSS is to overcome the of residual limb' size and eliminate drawbacks of the pin-lock like failure in locking and suction systems. This system contains from microcontroller includes a semiconductor pressure sensor, an air cuff attached inside the socket, air pumps, and pressure-regulating valves. The user can control the pressure inside the socket by pressing the control key to inflate the air pumps, which pump air into the bladder until the desired pressure value is reached. Silicon liner was used in that system without pins. This system has less pressure than Dermo Liner and Seal-In X5 Liner according to the study conducted by Ali et al. (2015). The mean peak pressure (kPa) at the anterior middle for APSS is 56.43 kPa, but for a Dermo Liner and Seal-In X5 Liner were 62.7 kPa and 86.5 kPa, respectively. This system has some limitations such as creating stress concentrations at points of the stump and also shear stress increases in small sections due to pistoning.

2.8 Methods of measuring interface pressure in transtibial prosthesis

From the literature review, three methods are the most used to measure the pressure distribution inside the prosthetic socket including F- socket transducers, Fiber Bragg Grating and capacitive.

2.8.1 F- Socket transducers

Most of studies above used this technique to evaluate the pressure distribution inside transtibial prosthesis. This transducer is defined as a piezoresistive sensors which based on Force Sensing Resistors (FSRs). This method depends on the change of resistor according to apply force or pressure. Thus, when high force or pressure is applied into the sensor, the resistor of sensor is dropped. The change in the resistor is converted into electrical signal and values. It is constructed of 96 individual sensing points (sensels) arranged in a matrix of 16 rows and six columns (Almassri et al., 2015).

F-Socket (Tekscan,) system is the most use for piezoresistive sensors to measure the interface pressure inside prosthetic socket. This system does not need a modification inside the socket. Tekscan has reported that F- sensors have 5% of nonlinearity and ±4 kPa sensitivity of pressure. Furthermore, the F-socket has better irregular surfaces. The capability to conform to irregular surfaces would be an advantage in residual limb and socket pressure measurements due to have differences residual limb.(Neumann et al., 2005).The F-Socket sensor (9811E type) is a flexible, rectangular printed circuit with thickness (0.18 mm). Thereby, the sensor can easily fit between the socket and the residual limb. The array of F-socket transducer contains from printed circuits with load sensing areas. The smallest sensing part of the sensor has two of thin, flexible mats that holding the pressure-sensitive ink applied in columns and rows between them. The sensel of sensor are formed from column and row. The F-Socket sensor (9811E type) has 96 sensels exhibited in an array of six columns and 16 rows(Buis & Convery, 1997).This technique has a lot of features such as thin construction, small profile, flexibility, frequency response, high resolution, good sensitivity, relatively simple structure, and ease of use.

Consequently, basing on the resources available, as well as findings from the literature review, in this study F-Socket transducers had been used to map the pressure interface between the stump and the socket. This system allows for evaluating accurate interface pressure between the socket and residual limb. The pressure profiles were recorded using

Tekscan software version 6.51. Each sensor array was affixed to the anterior, posterior, medial, and lateral compartments of the stump. Adhesive spray (3M Spray Mount Adhesive, 3M corporate, St. Paul, USA) was employed to fix the sensors in the stump and cover all areas and avoid displacement. The software of Tekscan can display 2D and 3D real-time and recorded data. Also, it can show contact area, average and peak pressures, and Center of pressure and its trajectory.

Figure 2.1: F- socket transducers

(Ali et al., 2013).

2.8.2 Capacitive transducers

Capacitive transducers contain from two parallel metal plates that are separated by the material such as air, which is called as the dielectric material. The value of capacitive changes due to change in the value of the input which is force or pressure. The change in displacement and distance between the two surface is the value of capacitive. The displacement changes according to the change of force or pressure applied. The drawbacks of this method are requiring more sophisticated electronics to offer higher sensitivity and flexibility. Also, it has crosstalk noise when it arranged in a mesh configuration. Thus, it needs high sophisticated electronics and filter to remove the noise (Tiwana et al., 2012).

2.8.3 Fiber Bragg Grating

The applications of fiber optical sensors in biomechanics are based on various technique including intensity, phase, and wavelength modulation. Latter fiber optical sensors associated with the operation of fiber Bragg grating sensors (FBGs) (Roriz et al., 2014).The optical fiber and Fiber Bragg Grating are coupled , and it has a light source. The light source passes through it and reflected from external mechanical forces (Hill & Meltz, 1997). Fiber Bragg grating (FBG) technique was employed by researchers at Center of Applied Biomechanics Lab in University of Malaya (2017) to measure the interface pressure between the stump and prosthetic socket. This way is based on recording of shift wavelength for light source due to reflect the light according to the change in pressure (Al-Fakih et al., 2017).

According to the literature review, only one study by Al-Fakih et al. (2017) used this technique to measure interface pressures between the residual limb and socket. The sensor has thickness sensing pads (3 mm) in contrast with the F-socket sensing mats (0.2 mm). This technique needs to be examined on a larger sample size to further validate the results (Al-Fakih et al., 2017). This method was recorded only for one subject to validate the pressure. Thus, it needs more studies and applications to investigate the pressure interface in transtibial prosthesis. Furthermore, the risk of fiber optical damage is high and a long operation for this sensor may cause a harmful for the optical fiber compounds. The distance between the light source and the external mechanical force should be in short to avoid light scattering. The light may be weak during measure pressure in walk activity.

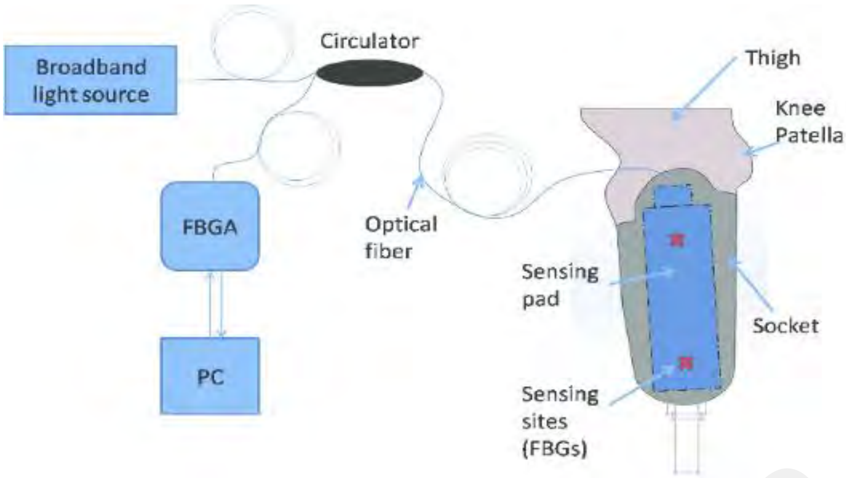

Figure 2.2: Fiber Bragg grating sensor

(Al-Fakih et al., 2015).

The summary of mean peak pressure for all types of suspension systems in the literature review is illustrated in Table 2.1. Pin/lock suspension system has the greatest values of pressure interface among other suspension system. F- socket transducers are the most way used to measure pressure distribution. Few studies show the pressure interface for magnetic and air pneumatic suspension system.

Table 2.1: The Mean peak pressure for different suspension system

NO	Author	Year	Objectives	Mean Peak Pressure(kPa)	Suspension System	Measurement Method
1	Dou et al	2006	To measure pressure during walk, upstairs, slope down and non-flat area for one subject	Walk (PT= 166.2; **P = 182.7**; L= 141.7; M= 76.6) Upstairs (**PT= 215.8**; P=165.5 L=123.9;M= 68.9) Slope down (PT= 165.7; **P=190.6**; L= 129.6; M=71.5) Non-flat (PT=184.1; **P=184.7**; L= 133.5; M= 75.7)	PTB Socket Silicon liner (Pin / Lock)	Capacitive
2	Hossein et al	2016	To test pressure for bulbous residual limb during walk , ramp and stairs	Walk (**PT= 115**; P=110,L=90,M=70) Ramp (PT=132 ; **P= 140**; M=65;L=110) Stairs (**PT= 117** ;P= 90; M= 63;L= 100)	PTB socket Silicone liner (Pin / Lock)	F- Socket

3	Ali et al	2015	To compare the interface pressure between the Dermo and Seal-In X liners during walk on ascent and decent area	Ascent (A=60.57, **P=64.50**, M=60.54 ,L=53.47) Decent(A= 66.43, P=61.64, **M=67.07** ,L= 48.16)	Pin/ lock Dermo liner	F- Socket
				Ascent (**A= 83.48**,P= 83.08,M= 71.35,L=53.58) Decent (A= 85.21, **P=90.03**, M=70.18 L= 64.36)	Silicone Seal – In X5(Suction)	
4	Al-Fakih et al	2017	To measure pressure along artificial residual limb during Walk (stance phase)	A=34.18 P= 42.25 **M=56.06** L=53.99	Pin/ lock	fiber Bragg grating (FBG

5	Eshraghi et al	2013	To evaluate a patented magnetic-based suspension system in-situ with regard to the pistoning during walking	**A= 79.26** P=26.01 M= 38.07 L= 27.41	Magnetic suspension system	F- Socket
6	Pirouzi et al	2014	To test pressure in new air pneumatic suspension system and compare with Ali et al (2012)study during walk	A= 56.43 ; **P= 56.52** M=44.91 L= 50.49	Air Pneumatic Suspension System	F- Socket
7	Ali et al	2012	To measure pressure in the trans-tibial socket with Dermo and Seal-In X5 liner during walking	**A= 60.2**, P=58.1, M=50, L=50	Dermo liner (Pin / Lock)	F- Socket
				A=84.9, P=74.5,M=53.8,L=51.5	Seal - In X5 Suction suspension	F- Socket

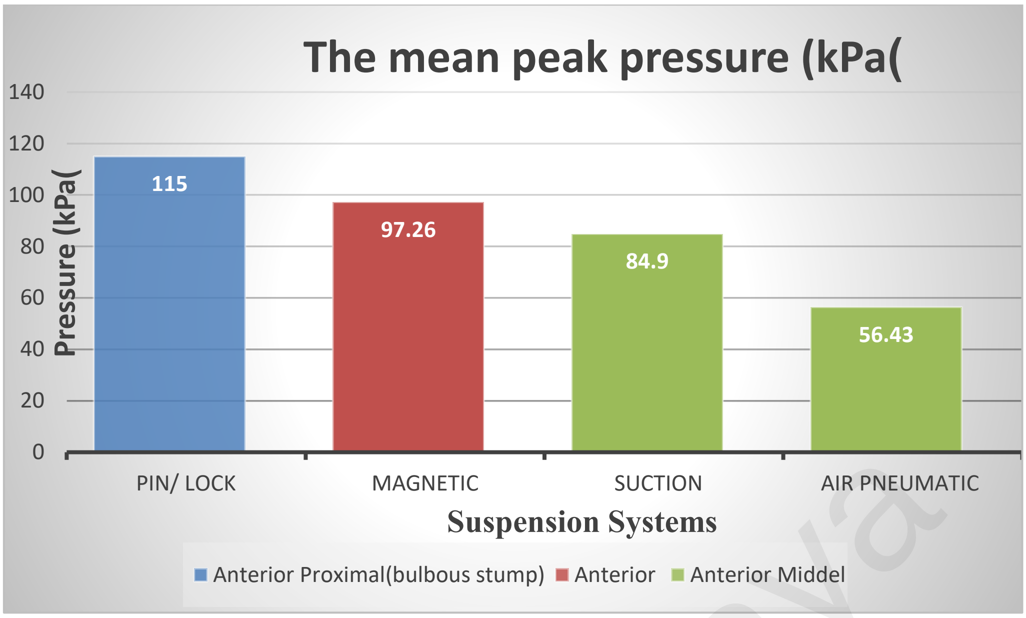

Figure 2.3: The highest values of pressure in walk on ground for suspension systems

The figure 2.3 shows that Pin/ Lock suspension system has the greatest value of pressure distribution at anterior proximal of the stump during walk on flat. However, air pneumatic suspension system has the lowest value of pressure among all suspension systems in the anterior middle. Air pneumatic system is considered as the best suspension for pressure distribution. It has low values of pressure interface. Thus, this system has a great result and perfect fitting.

2.9 Conclusion

The prosthetic suspension system is a critical factor in pressure interface between the residual limb and the physical components of prosthetic device. The high pressure leads to generate skin problems and pain. Furthermore, discomfort and poor attachment of prosthetic device can be occurred during high pressure. Pin/ Lock suspension system has the highest value of pressure compared with other systems especially in the patella tendon side. Air pneumatic system is considered as the best suspension for pressure distribution. It has low values of pressure interface. Thus, this system has a great result and perfect fitting.

CHAPTER 3: METHODOLOGY

This study was to control in interface pressure within 3D printed socket. This system provides a perfect attachment between the stump and the socket through inflation and deflation air bladders. Electronic system was designed to control the desire pressure inside the socket. The electronic system was attached into the pylon of the prosthetic device in a small box. The user can press on the keypad to inflate or deflate the air bladders inside the socket. 3D printed socket was built with tiny air bladders which were embedded in the liner. The inflation and deflation of the air bladders inside the 3D printed socket can be controlled using the pre-programmed keypad. The pressure distribution in the 3D printed socket was evaluated using F- socket transducers through Universal Mechanical Testing. Universal Testing Machine (Instron3369) was used to apply a weight on the prosthetic device. Angle block platforms with slope (20°) was used during the test. F-socket transducers were calibrated and equilibrated through air compressor with 100 kPa pressure. The system reduced the mean peak pressure inside the socket and the user can manage the relief of peak pressures and volume changes of the stump. The pressure control will Lead to the comfort and satisfaction of users.

3.1 3D-printed socket procedures

The acquisition of the amputee's residual limb shape has been done using a 3D laser scanner available in the Centre for Biomedical and Technology Integration (CBMTI) Lab at University of Malaya. The acquired shape was used to design a 3D prosthetic socket that accommodates the pressure and volume management systems. To print the residual limb shape, it is highly recommended that a prototype must be printed first in order to check if the design needs modifications. The next step was to convert the acquisition shape image into 3D model using SolidWorks Software as shown in Figure 3.1.

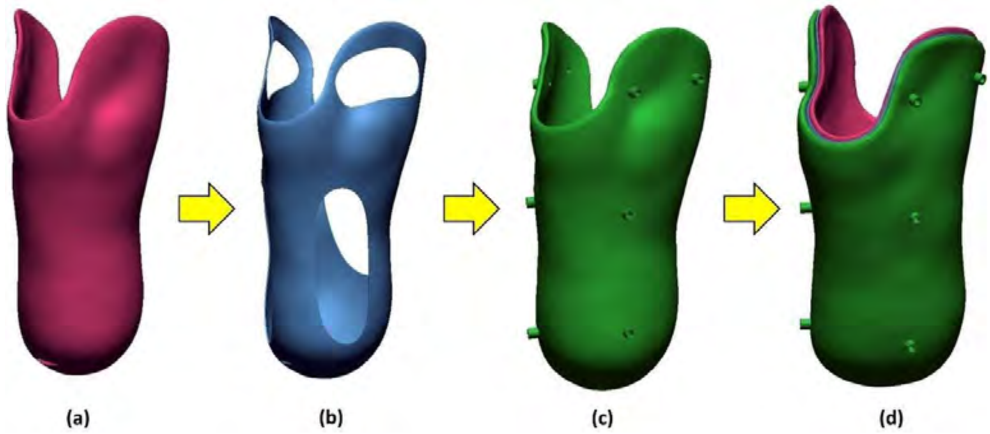

Figure 3.1: The final socket design. (a) the inner layer that represents the silicone liner, (b) the middle layer that accommodates the air bladders (the five empty spaces), (c) the outer solid layer, and (d) is the final socket after all the layers are assembled.

The above design was directly 3-printed using Stratasys Connex 500 printer. The VeroWhite material was used for the outer layer and the TangoBlack was used for the inner layer that contacts with the amputee's residual limb skin. Figure 3.2 shows the final socket after being printed.

Figure 3.2: The final 3D printed socket .The yellowish material is a wax like material used to support the 3D-printed material during the printing process. Once the white material is fully cured, the wax support is removed.

With the aim of developing a pressure control system integrated with the 3D printed socket. This 3D printed socket included several embedded tiny air bladders to form the pneumatic suspension system. (Figure 3.3). The air bladders of the 3D printed socket were connected with the tiny air compressors via small pipes attached to the prosthesis to inflate or deflate the air bladders. These air bladders are used when the residual limb shrinks over time and the socket becomes loose. This added smart volume management system could compensate for the shrinkage by inflating the air bladders so that the printed liner would conform to the geometry of the residual limb which would limit the vertical movements, and thereby reduce the shear stresses within the socket. An additional benefit from this system is that it could be set to apply massaging over the residual limb muscles at the end of a tiring day or while sitting on office chair, which would reduce the pain induced at the interface all day round. The cross-section view of the final socket design with the integrated air bladders is shown in Figure 3.3.

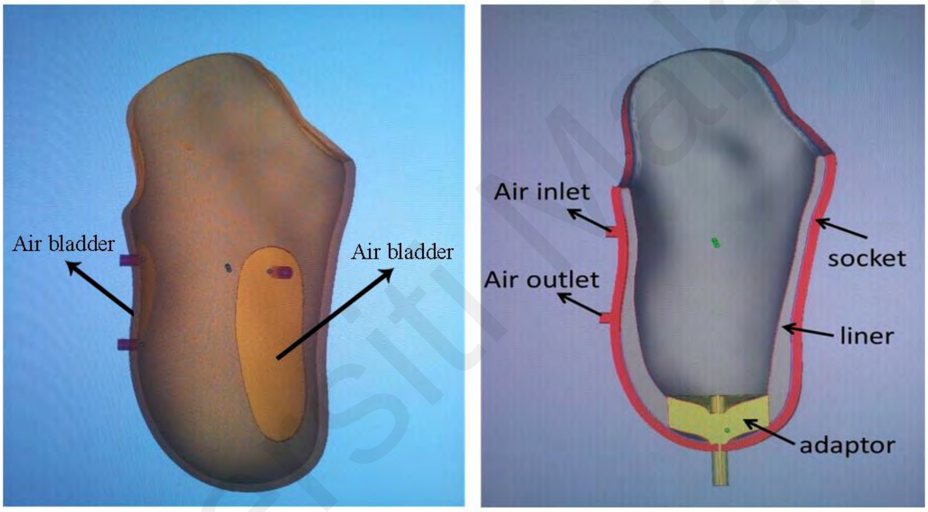

Figure 3.3: The socket final design and its cross-section, within which the air bladders were incorporated.

The 3D printed socket (Figure 3.4) has superior features over the traditionally made sockets, including:

i) It does not require a liner because the liner and socket were 3D-printed simultaneously as one piece.

ii) It is a volume-adjustable socket. Its inner wall contains bladders that inflate and deflate according to the contour of the amputee's residual limb. This benefits those with diabetes whose residual limb volume changes intermittently, and for those whose limb volume changes during the day/nighttime, and also for the other cases when the limb shrinks over time. If the aforementioned problems happen, this volume management system can tackle them and make the socket fit again,

iii) The volume adjusting system also enhances the socket suspension.

Figure 3.4: The 3D printed socket prototype

3.2 Electronic system

The electronic system contains from compressors, valves, keypad, Arduino Board, transistors, resistors, diodes, voltage regulator, battery and connecting wires. The function of this system is to control in inflating and deflating air bladders using the pre-programmed keypad. The compounds of that system were built in the soldering board. The system was fixed in a small box which attached in the pylon of prosthesis device. The user can press on the keypad to inflate or deflate the air bladders inside the socket. 3D printed socket was built with tiny air bladders which were embedded in the liner. The inflation and deflation of the air bladders inside the 3D printed socket can be controlled using the pre-programmed keypad (Figure 3.5).

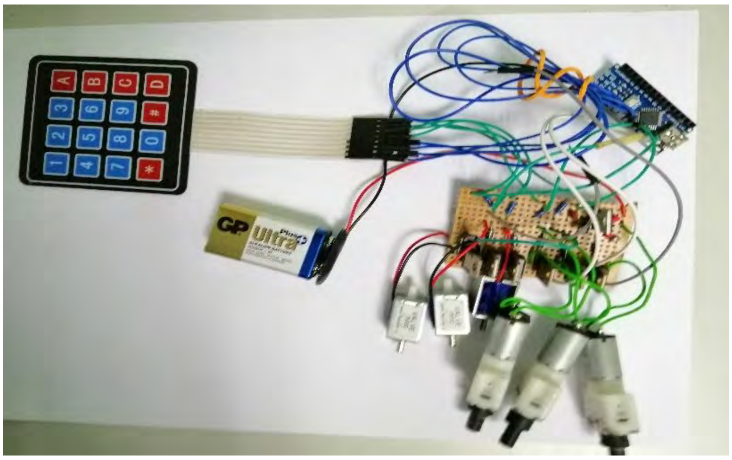

Figure 3.5: Electronic system components

The system has three air bladders connected to three separate subsystems (electronic [compressor + release valve] and air tube circuits) through the control system. The first subsystem is a one bladder located in the posterior aspect of the socket and connected to one compressor and one release valve in order to be inflated/deflated for the aim to compensate for any residual limb volume loss. The two bladders are located medially and laterally to the tibia crest were connected to one compressor and one release valve separately. These two bladders are to be inflated/deflated simultaneously to lift up the artificial stump to reduce the pressures applied onto the crest of the tibia. The tiny air tubes were attached to the air bladders through the holes on the socket wall, and on the other end, they were connected to the compressors and release valves. The Arduino control unit kick-starts the whole system.

3.2.1 Principle work of electronic system

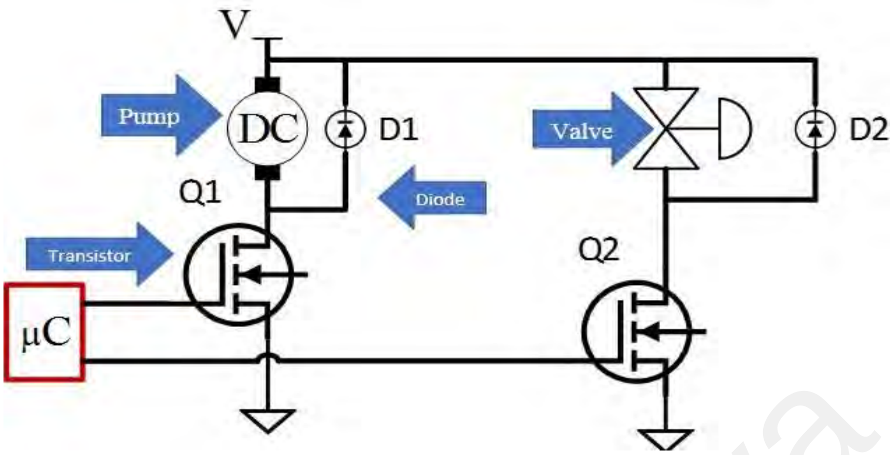

Figure 3.6: Electronic circuit of control system

The electronic system is based on the operation on NPN silicone transistor (TIP47 Type). The transistor is a semiconductor device which used as switch. It has three parts including base, emitter and collector. The base part of transistor is connected into the Arduino Board which is input of transistor and controller. The emitter is connected into the common ground. The collector allows current flow through it into the emitter. The collector is connected into the pumps and valves. Diodes are in parallel with pumps and valves, and it is connected with collector in reverse bias with the main power supply. The main function of diodes is to provide a freewheeling. Thus, it allows current to flow from anode to cathode. The pump or valves can storage a current. Thus, when the circuit is closed, this storage current will pass through transistor and cause damage. Therefore, this diode allows current flows in one direction forward from pumps or valves into anode to pass through diode in order to product the transistor and overcome transistor damage from storage current. When the user presses in the keypad as input, Arduino sends a command into the base of transistor to operate and active the transistor. Thus, the transistor is active and the current flows from collector into emitter. Therapy, pump or valve works.

3.2.2 Main components of the electronic system

3.2.2.1 Arduino board

This board is the heart of the whole system. It houses all the necessary electronics that store the coding program that drives the compressors when the keypad buttons are pressed. All the other electronic components are connected to this board. Figure 6 shows this board and its wirings a new air pneumatic suspension system (APSS) by aid of semiconductor pressure sensor to overcome residual limb volume changes and eliminate problems related to the pin-lock and vacuum locking systems.

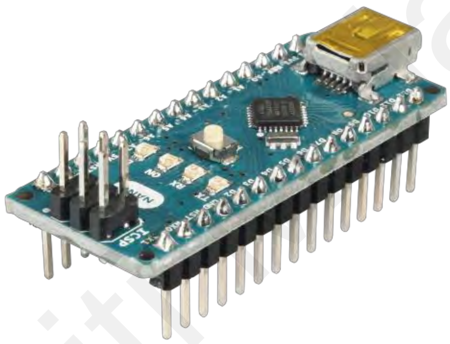

Figure 3.7: Arduino board

3.2.2.2 Keypad

The keypad button works as switches to turn on pumps and Release Valves (RVs).

- Button * turns on the whole system, Button # turns off the whole system

- Button 1 turns on pump 1, Button 2 turns on pump 2, Button 3 turns on pump 3

- Button 4 turns on the Release Valve 1, Button 5 turns on the Release Valve 2, Button 6 turns on the Release Valve 3.

Figure 3.8: Keypad buttons

3.2.2.3 Pumps

The electronic system has three mini air pumps to inflate the air bladders inside 3D printed via small pipe wire. Those pumps are fixed in the small box, and this box is attached into the pylon.

(a) Features of pumps

Outlet Outer Diameter: 3.3 MM (fit 3*5 MM Trachea)

Voltage: 3V, Current: 0.23 A, Weight: 15 g, Maximum pressure (KPa) is 350kpa

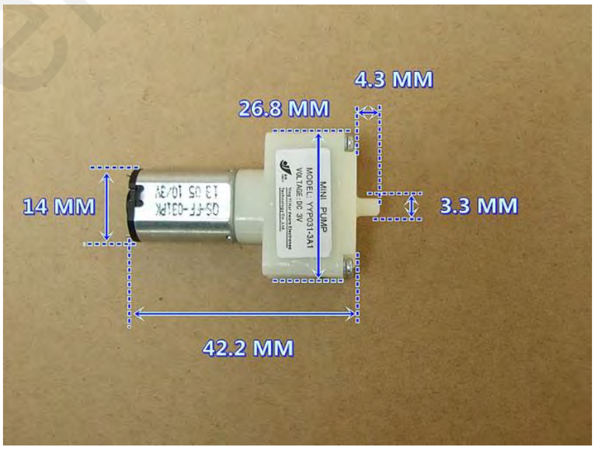

Figure 3.9: Valve dimensions

3.2.2.4 Valves

Valves are miniature solenoid which used to release the air from bladders.

(a) ***Features of valves***

Voltage: DC 3.0V, current: <100mA, Venting speed: <3S (the time required for the air pressure to degas from 300mmHg to 15mmHg in a 500cc container), Pressure range: 0-350mmhg Operating temperature range: 0 ° C ~ 55 ° C.

Figure 3.10: Release valve

3.3 Experiment procedures

3.3.1 F- socket transducers calibration

F- socket transducers were employed to determine the interface pressure. The calibration is an imprtant process to ensure that sensors have acurate results and coorect measurments. Therefore, transducers were tested for equilibration and calibration to eliminate the variation among the load cells. Tekcscan software was instaled to carry out the calibration.The calbration process was carried out in the Motion Analysis Lab at University of Malaya. Compressor has air bladder and indicator to measure the pressure. Pressure 100 kPa was applied to inflate the air bladder.

Figure 3.11: Compreesor with 100 kPa pressure

Each sensor was connected into Tekscan model. The compressor has controlling for vacuum and pressure. The Transducers was inserted into the air bladder and use vacuum control to assist and reduce the pressure. After the sensor was put under air bladder, the control was returned into pressure. Information of the process was filled into the Tekscan software.The function of equilibrium is to make baseline for all transducer cells at zero level. The Tekscan software can show the force. Thus, the area of transducer multiply by pressure applied (100 kPa) should be inserted to display the force applied to the transducer.

Figure 3.12: Tekscan model with pressure control

3.3.2 Pressure recording using the control system

The pressure profiles were recorded using Tekscan software version 6.51. Each sensor array was affixed to the anterior, posterior, medial, and lateral compartments of the artificial stump. Adhesive spray (3M Spray Mount Adhesive) was employed to fix the sensors in the stump and cover all areas and avoid displacement. Four sensors were used to determine the reduction of pressure interface (F- Socket Transducers, 9811E Type). The transducers were located inside the socket at anterior, posterior, lateral and medial sides. Universal Testing Machine (Instron3369) was employed to apply various values of loads into prosthetic device. Pressure interface was measured during static standing with inflating and deflating air bladders inside 3D printed socket.

The pressure was recorded during inflation and deflation of air bladders at all sides of the artificial stump. For acquisition parameter, the framework of data was taken as 600 frames to record pressure during one cycle from deflate into inflate in Tekscan system. Th frequency was 50HZ.Thus, the total period of time for inflation and deflation is 12 second which is counted from total frames (600) divided by frequency 50HZ. The inflation frames were taken after 300 of total frames. The data was taken as static phase without inflation the air bladder and dynamic phase with inflation. This dynamic phase started from frame 300 and timer was used to operate the pump to inflate the air bladder. First, in static without inflation pressure was measured until framework reaches 300. Second, from frame 300 the pump was started inflation until frame 600.

3.3.3 Universal Testing Machine

Universal Testing Machine (Instron3369) was used to apply 500 and 650 N loadings on the prosthetic device in normal static standing (Fig 3.13) to mimic human body weight. This machine compresses the prosthetic device by applying static load. The compression starts from low load until reach the desire value, the load is holding for the setting time.

Universal test machine was used according to ISO 10328 protocols which is international standards for structural testing of lower-limb prostheses.

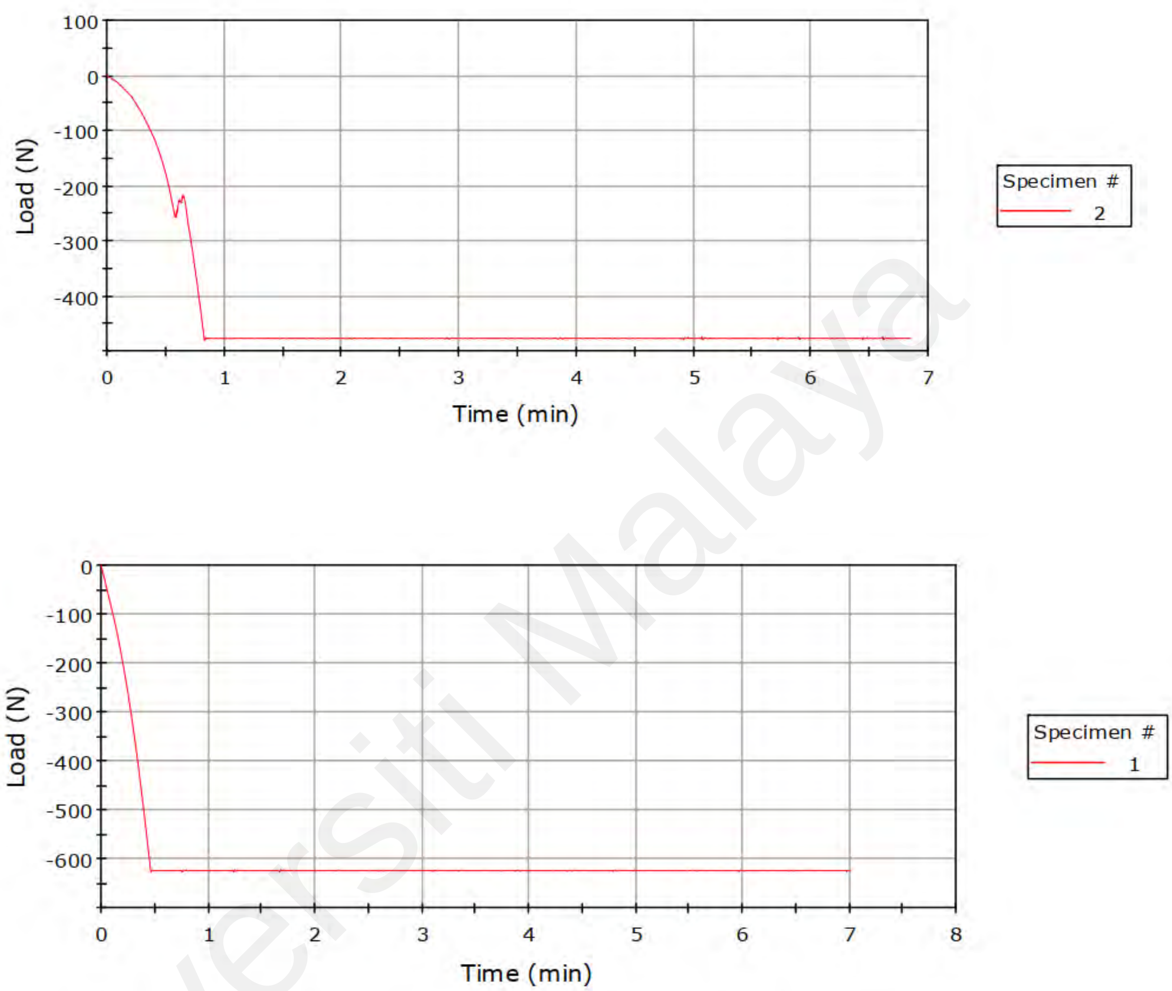

Figure 3.13: Compression load for 500 and 650 N through universal test machine

Block angle platforms (20° slope) was used with heel and forefoot (toes) in static loading during the test to represent an instant during stance phase as illustrate in Fig 3.14. Angle block platforms were made out of wood with 4mm of aluminum thickness. On the top of platforms, teflon sheet is located to minimize the shear forces between the prosthetic foot and the platforms. The platforms were fixed on the base of the Universal testing machine.

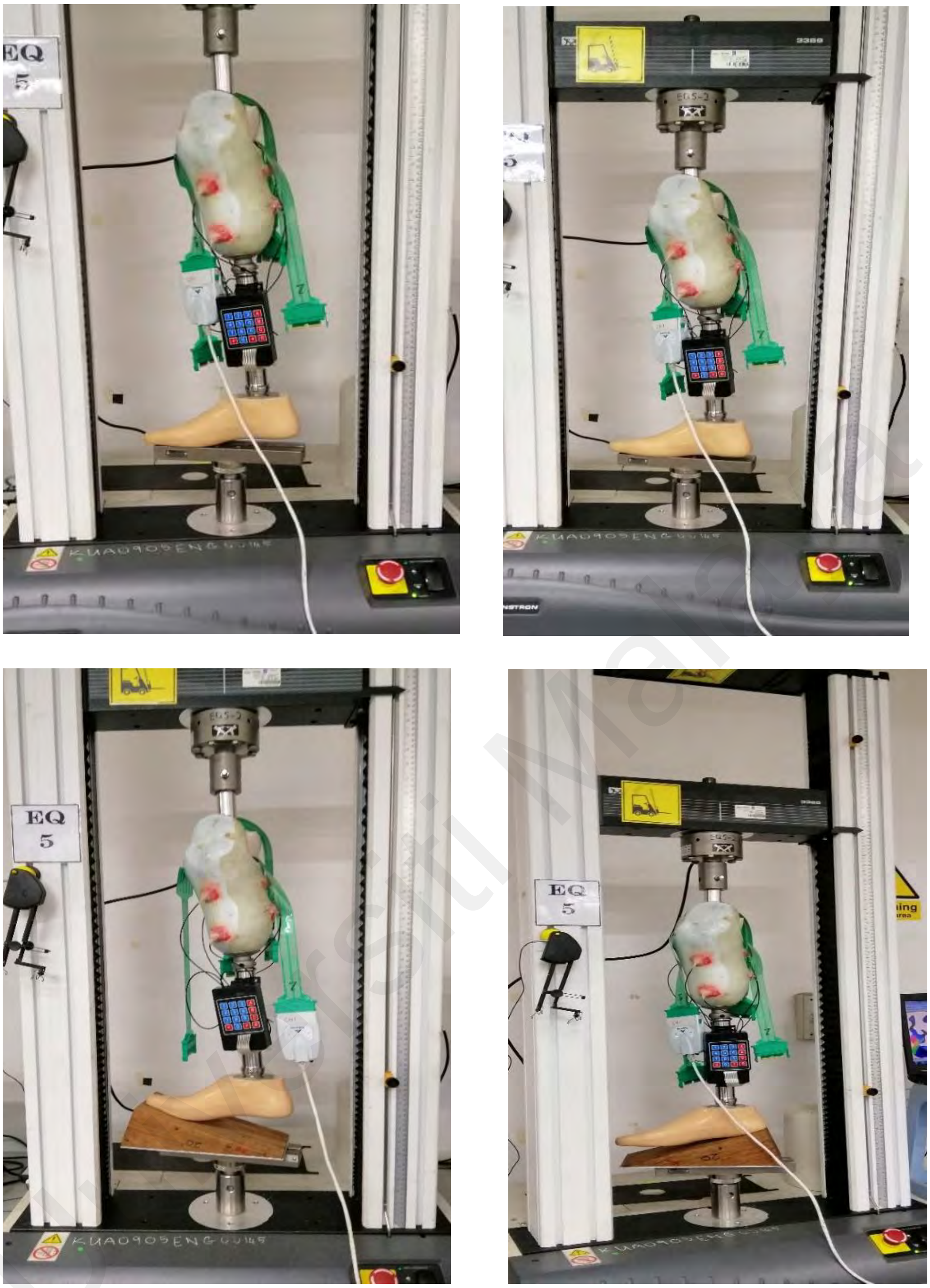

Figure 3.14: Vertical compression load 500 and 650N transferred a bending load during normal standing, forefoot and heel slope to resemble human body weight

The total of trails which carried out to measure the pressure interface were 90 trails. Thus, pressure was recorded three times for each side of the stump during three loads 50 and 65 kg for normal standing and with heel and forefoot 20° slope. The anterior side only had 6 trails in order to inflate medial air bladder and record the pressure, then inflate lateral air bladder and record. Each trail had inflation and deflation of air bladder side. Therefore, each static loading had 45 trails for normal standing, and heel and forefoot 20° slope.

CHAPTER 4: RESULT AND DISCUSSION

4.1 Initial results of verification for the interface pressure control system

To check the functional of electronic system in 3D printed socket, four transducers (F-socket) were used to evaluate the reduction of pressure via using the electronic system to inflate the air bladders within 3D printed socket. Three air bladders are placed on lateral, medial and posterior of 3D printed socket which connected into keypad to inflate or deflate. Artificial stump was inserted within 3D printed socket without applying load.

Table 4.1: The verify of electronic system function with pressure reduction

Keypad button	Function	MPP (kPa)
1	To inflate lateral air bladder	88.56
4	To deflate lateral air bladder	134.22
2	To inflate posterior air bladder	79.61
5	To deflate posterior air bladder	91.41
3	To inflate medial air bladder	45.88
6	To deflate medial air bladder	56.80

Pressures reduction inside the 3D printed socket were recorded at all sides (ranging from 2 to 45 kPa), especially in the lateral (45 kPa) and posterior (12 kPa) sides of the stump. The highest reduction in pressure of 45 kPa was recorded in the lateral side during the inflation of the lateral air bladder. After verification of electronic system functionally, latter, universal test machine was employed into the 3D printed to resemble human body weight.

4.2 Interface pressure mechanical testing with different vertical loadings

Universal test machine was utilized to apply 500 and 650 N as load to resemble human body weight. The pressure interface inside 3D printed socket is discussed based on the analysis results. The result shows the reduction of pressure interface inside 3D printed socket via pressure control system for an air pneumatic suspension system. The inflation and deflation of air bladders have a positive impact in pressure reduction in 3D printed socket. The findings of pressure reduction are illustrated in the Table 4.1. The pressure was recorded at the distal, middle, and proximal sides of the artificial stump at the anterior, posterior, lateral, and medial sides. Pressure interface was measured during static standing with inflating and deflating air bladders inside 3D printed socket.

4.2.1 Pressure color mapping

The pressure color mapping of Tekscan system is changed during the inflation and deflation of air bladders. Some regions of the residual limb have increase or decrease in interface pressure after 300 frames. Thus, the color may change during the inflation. The pressure values range in color from dark blue to red. Thus, dark blue represents low value of pressure, whereas red color forms high interface pressure as shown in Fig 4.1.

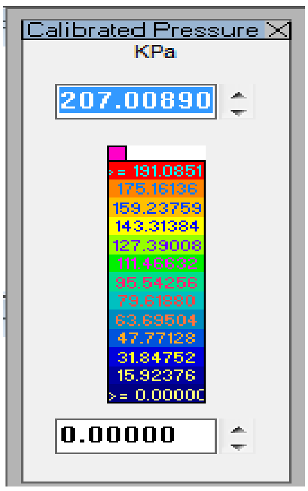

Figure 4.1: Pressure color range

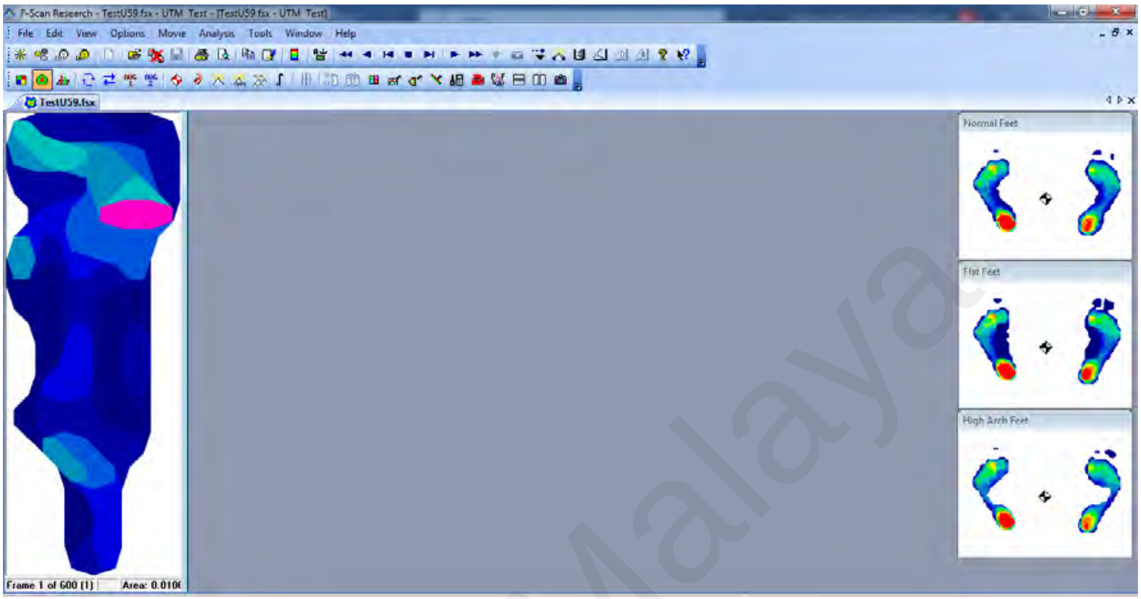

Figure 4.2: Sample of pressure color mapping during deflation

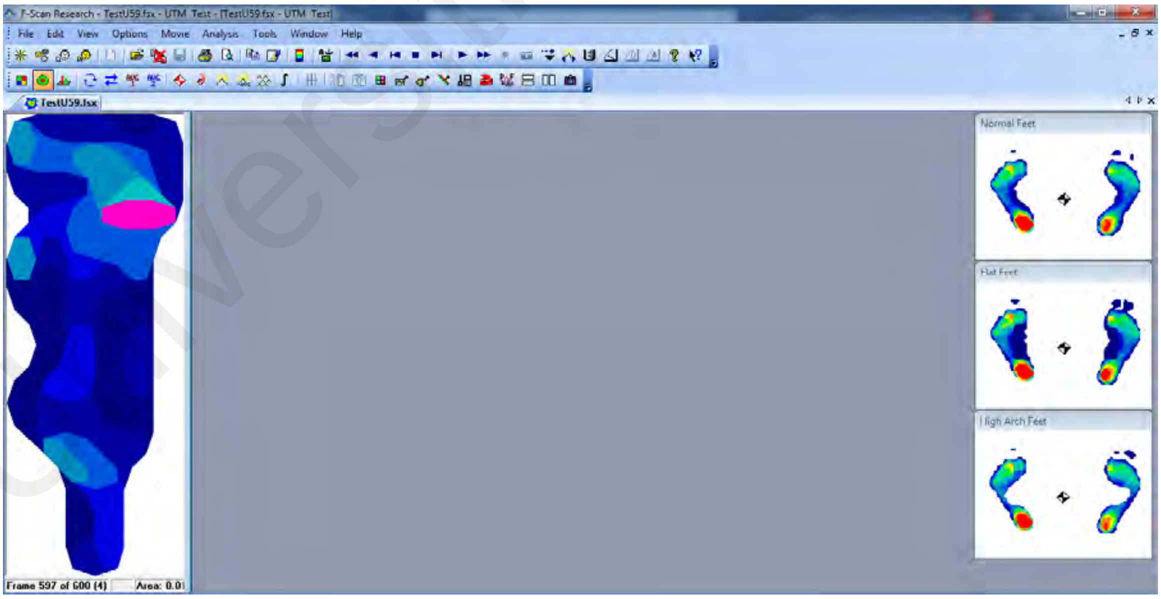

Figure 4.3: Sample of pressure color mapping during inflation

Stump Side	Mean Pressure (kPa) for 50 kg Load						Mean Pressure (kPa) for 65 kg Load					
	Normal Standing		Heel on 20° slope		Toes on 20° slope		Normal Standing		Heel on 20° slope		Toes on 20° slope	
	Deflation	Inflation	Deflation	Inflation	Deflation	Inflation	Deflation	Inflation	Deflation	Inflation	Deflation	Inflation
Anterior Proximal	39.78	39.78	58.02	58.02	33.19	33.19	33.51	33.56	49.43	49.43	45.88	45.88
Anterior Middle	59.48	59.48	66.12	66.12	62.96	62.96	71.69	71.71	79.60	79.60	54.62	55.02
Anterior Distal	55.94	55.94	46.25	46.25	42.39	42.39	70.69	70.71	63.23	63.23	72.27	72.27
Posterior Proximal	28.68	23.47	68.11	60.56	49.11	41.44	55.69	58.32	71.93	71.63	66.20	63.70
Posterior Middle	30.34	38.91	46.60	43.30	36.75	40.52	54.42	48.65	51.94	48.68	46.29	41.81
Posterior Distal	27.52	27.34	52.29	51.90	27.20	30.80	35.14	35.40	55.24	47.38	39.66	38.69
Lateral Proximal	33.22	33.22	33.82	39.84	31.92	31.92	45.01	40.43	56.25	59.76	54.87	55.15
Lateral Middle	25.29	21.86	39.31	41.12	38.75	36.54	35.34	42.63	35.27	30.80	43.64	41.06
Lateral Distal	30.19	38.91	43.93	48.35	32.83	39.58	32.09	40.84	40.59	54.28	40.62	52.06
Medial Proximal	33.09	33.04	44.81	45.01	31.61	31.61	12.90	12.35	51.13	51.13	48.79	48.79
Medial Middle	27.97	26.91	61.90	61.90	36.88	37.19	39.36	34.55	36.91	34.20	41.17	41.39
Medial Distal	47.70	48.51	44.22	44.64	58.91	50.94	22.27	22.70	49.65	49.65	45.48	45.07

Table 4.2: Mean pressure (kPa) during inflation and deflation

Suspension systems are various in pressure interface along the residual limb during daily activities (Eshraghi et al., 2013b).Consequently, the suspension system plays role in satisfied and comfort' user through pressure interface level. (Ali et al., 2012b; Mccurdie et al., 1997). The perfect selection of prosthetic suspension system and the excellent fitting of the residual limb inside the prosthetic socket have a positive impact of amputee's activities. The suspension system should have ideally interface to distribute the pressure between the stump and the socket uniformly (Baars & Geertzen, 2005). The high-pressure interface leads to skin damage and wound. Silicon liners (pin/ lock) and vacuum (suction) system are the most commonly used suspension systems for transtibial prostheses. The silicone liner has perfect fitting with the residual limb .However, it has high cost and high pressure in distal area (Baars & Geertzen, 2005; Gholizadeh et al., 2014b).

Based on the literature review, Pin/Lock suspension system has the highest values of pressure distribution inside the socket during walk at anterior region. However, air pneumatic suspension system has the lowest values of pressure among all suspension systems. Therefore, the most critical factor in all suspension systems is the increasing of pressure interface.

To our knowledge, this is the first study that has employed 3D printed socket with tiny air bladders and portable electronic system to control in pressure interface via inflation and deflation of air bladders. The findings from this study suggest that interface pressure in 3D printed transtibial prosthetic socket reduces by utilizing an interface pressure control system with air pneumatic suspension system. This system reduced the mean peak pressure inside the socket and the user can control the relief of peak pressures and the attachment of the residual limb inside the socket.

The pressure was recorded at the anterior, posterior, lateral, and medial sides of the artificial stump during inflation and deflation of air bladders during static standing. This new suspension system minimizes the pressure interface in the anterior side during static standing in contrast with the study which conducted by Gholizadeh et al. (2016) and Ali et al. (2013) respectively , that found pin/lock and suction suspension system has the greatest values of pressure at anterior side during walk. Thus, this study suggests that air pneumatic suspension system could provide comfort for users and reduces patellar tendon injury due to have low pressure in the anterior side comparing with other suspension system.

The findings of the present study revealed that the anterior middle (Patellar Tendon) and distal region have the greatest value of mean pressure for both load 50 and 65 kg. For both loads, the mean pressure at anterior proximal was lower than anterior middle and distal. This result is similar to the findings of a study conducted by Dumbleton et al. (2009) that observed that the pressure distribution was the lowest at anterior proximal side of the stump. Also, this correspond the study conducted by Ali et al. (2012a) which found that pressure interface was higher at anterior middle and distal than proximal region for both Dermo and Seal-In X5 liner. The current study recommends that the inflation of other air bladders sides could distribute the pressure in subregions of anterior side and minimize the pressure in PT and increase in other area of anterior.

In rormal standing without slope, the highest pressure interface was recorded at anterior middle (Patellar Tendon) during the deflation and inflation of anterior air bladder, which is 59.48 kPa and 71.69 kPa for both 50kg and 65kg load respectively . However, the lowest value of pressure was recorded at lateral middle during inflation of lateral air bladder (21.86 kPa) and medial proximal (12.35kPa) during inflation of medial air bladder for both loads respectively. Moreover, in standing on angle platform (20 slope) of heel strike, the greatest value of pressure interface was noted at posterior proximal during deflation of posterior air bladder (68.11 kPa) and anterior middle (79.60 kPa) during inflation and deflation. Whereas, the minimum mean pressure was found at lateral proximal region during deflation of lateral air bladder (33.82kPa) and lateral middle (30.80 kPa) during inflation of lateral air bladder for both load receptively .Also, in standing on angle platform(20° slope) of toes, the highest mean pressure was recorded at anterior middle (PT) during deflation and inflation (62.96 kPa) and anterior distal (72.27kPa) for both loads respectively , while, the smallest mean pressure was found at posterior distal during deflation of posterior air bladder (27.20 kPa) and (38.69kPa) for both loads respectively.

This system reduced the mean peak pressure inside the socket and the user can control the relief of peak pressures and the attachment of the residual limb inside the socket. For, load 50kg, at normal standing, the pressure reduced at poserior proximal, lateral middle and medial middle during the inflation of air bladders for eachside .However the , pressure increased at posterior middle, medial distaland lateral distal. The hiegest reduction of pressure was 5.21% which was recorded at posterior proximal during the inflation of posterior air bladder.While, in load 65 kg, the pressure reduced at lateral proximal , medial middle and posterior middle during the inflation of lateral, medial and posterior air bladders and increased at posterior proximal and lateral middle and distal. The greatest reduction in pressure was 5.77% that observed at posterior middle during the inflation of posterior air bladder. Therefore, the present study suggests that the inflation of posterior air bladder could minimize pressure distribution for different body weights.

In standing on angle platform (20° slope) of heel strike, the pressure decreced at posterior proximal ,middle and distal as showen in Tabel 4.1. Whearese the pressure increases at lateral subregions and medial proximal. Therefore, the highest reduction of pressure was 7.55% which recorded at posterior proximal during inflation of posterior air bladder. In standing on angle platform (20° slope) of toes, the pressure decreased at posterior proximal, lateral middle and medial distal during the inflation. The highest-pressure reduction was 7.97 % which found at medial distal during inflation of medial air bladders. This study suggests that the inflation of posterior air bladder is more functional during forefoot on 20° slope than normal standing and heel strike for pressure reduction.

Samples of graphs of pressure change for 50kg static loading during inflation and deflation of air bladders during 12s are showed in Fig 4. The deflation period is until 300 frames (6s) and the inflation is taken after 300 frames.

Similar graphs of 65 kg load and are attached in appendix.

Figure 4.4: Sample graph plot of pressure control during inflation and deflation at anterior and posterior sides for 50kg load

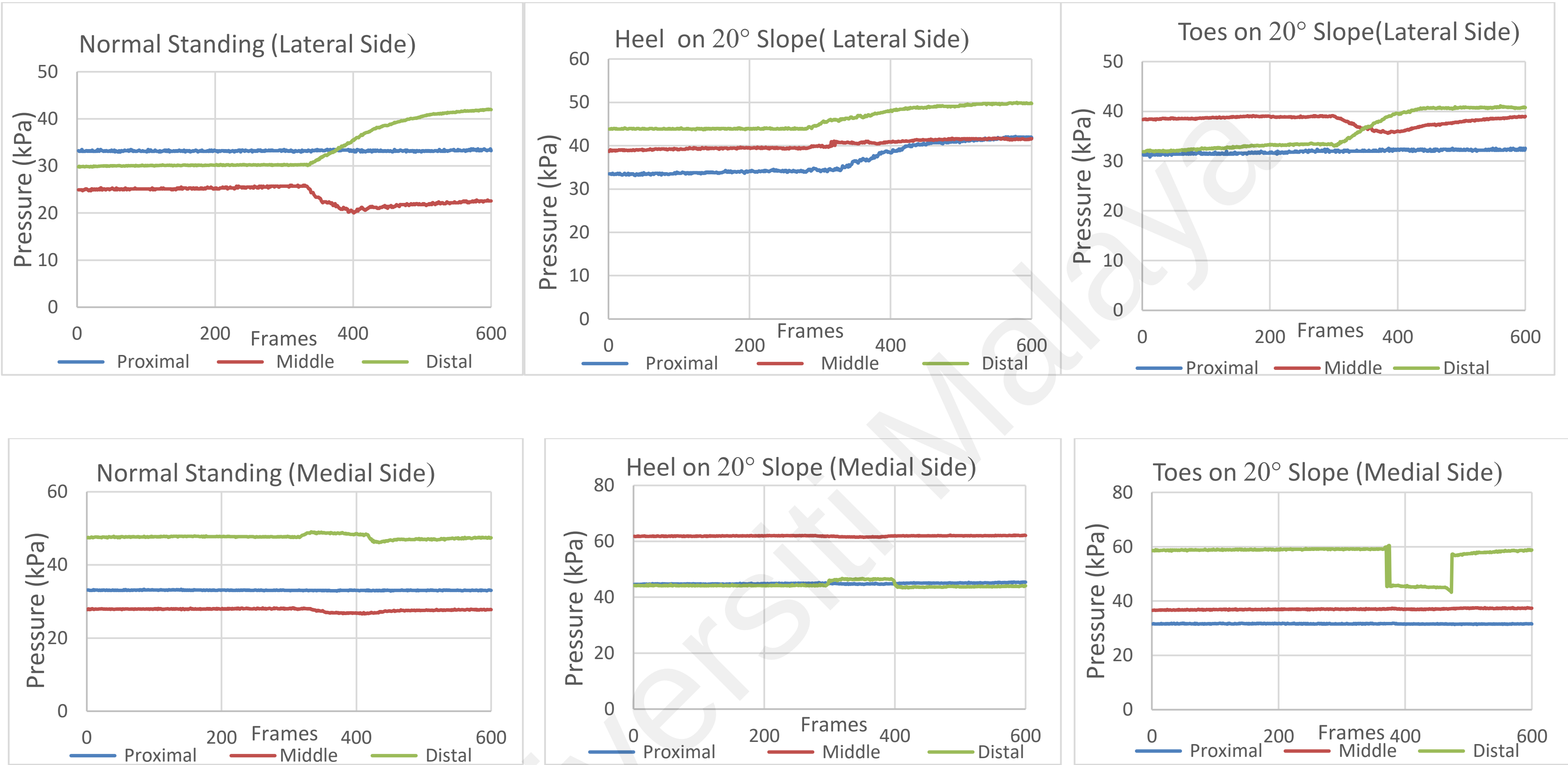

Figure 4.4: Sample graph plot of pressure control during inflation and deflation at lateral and medial sides at 50kg load

In Fig 4.3 during heel strike on 20° slope, the pressure increased at anterior proximal in comparing to normal standing. However, in toes 20° slope the pressure decreased at anterior proximal. Furthermore, the pressure increased at posterior distal during heel strike on 20° slope and increased at posterior proximal during toes on 20° slope in contrast to normal standing. This result is similar to the study conducted by Radcliffe (1961) about pressure profile for below knee prosthesis during gait , which observed that pressure increased at anterior proximal during heel strike and decreased during toe off and increased at posterior proximal during toes on 20° slope. The pressure at anterior side does not change because there is not air bladder at anterior side of 3D printed socket.

Moreover, the pressure reduced at posterior proximal during normal standing, heel standing on 20 ° slope and toes standing on 20° slope in inflation of posterior air bladder, while pressure at posterior middle increased during normal standing and toes standing on 20° slope and decreased during heel standing on 20 ° slope in inflation of posterior air bladder. This result suggest that the user can increase the pressure in muscles and soft tissue areas which will reduces pressure in bony areas.

In Fig 4.4, the pressure in lateral distal is increased during the inflation of lateral air bladder for all normal standing, heel strike and forefoot. The pressure reduction is observed at lateral middle for normal standing and forefoot after 300 frames(inflation). This finding supports that user could reduce the pressure in lateral middle side during gait cycle, which will offer a relief in lateral side of tibial bone and increase the pressure in the soft tissue of lateral distal. However, the pressure does not change at medial proximal and middle during the inflation of medial air bladder for all activities including normal standing, heel on 20° slope and forefoot on 20° slope. This could help user to fix the pressure in one subregion of the stump and change pressure at other subregions of medial side.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The excellent selection of prosthetic suspension system and the superior fitting of the residual limb in the prosthetic socket have a positive impact of comfort and satisfied of users. To our knowledge, this is the first study that has employed 3D printed socket with tiny air bladders and portable electronic system to control in pressure interface via inflation and deflation of air bladders. The interface pressure in 3D printed below knee prosthetic socket reduces by utilizing an interface pressure control system with air pneumatic suspension system. This system minimized the mean peak pressure inside the socket, and the user can control the relief of peak pressures and the attachment of the residual limb inside the socket. User minimize the pressure interface in the bony area and increase in the muscle area. Air pneumatic suspension system has capability to deal with loose or gap inside the prosthetic socket. Thereby, this system could enhance the attachment of amputee' part with prosthesis device and reduce the happening of skin injury. Moreover, user could inflate or deflate the air bladders to make pressure reduction in some regions and increased in others at the same time. 3D printed socket with air bladders eliminates the use of expensive silicone liners, relieve the peak pressures on the amputee's residual limb bony areas, and lastly manage the inner size of the socket in order to accommodate the continuous changes of the residual limb, especially for diabetic amputees.

5.2 Recommendations

This system, as other designs has some limitations which future researchers could enhance and overcome the issues. The inflation of air bladders does not stay for long time due to have a leakage in air from bladders. Also, two air bladders are needed in anterior side to minimize the load from patellar tendon. Moreover, for future study, this system could be enhanced to make it a as smart response for pressure interface to inflate or deflate air bladders as automatically working. In addition, the air bladders should be connected directly into a tiny pipe without external adaptors to overcome air leakage.

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