BIOMECHANICAL, MECHANICAL AND CLINICAL ANALYSIS ON THE IMPROVEMENT OF PROSTHETIC LINER USING POLYURETHANE, FOCUSING ON ANTERIOR-DISTAL PART OF THE RESIDUAL LIMB

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DISSERTATION SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF ENGINEERING SCIENCE

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Field of Study: Biomedical Engineering

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ABSTRACT

Most transtibial prosthesis users experience pain sensation at the distal side of the residual limb due to bony prominences and nerve endings. Many initiatives have been taken to resolve this problem, including using softer material such as silicone or gel liner and designing a distal off-load prosthetic socket. This study aims to conduct a survey among the users on the effect of the prosthetic liner on their daily living activities, to design a new prosthetic liner using polyurethane at the anterior-distal part of the residual limb to replace Pelite as a prosthetic liner and to compare the biomechanical gait analysis of the new modified liner using polyurethane with common Pelite as liner. A total of four left unilateral transtibial amputees were recruited and two transtibial prosthesis with different liners were fabricated for each subject. One was the Patellar Tendon Bearing socket with Pelite liner transtibial prosthesis and the other was the Patellar Tendon Bearing socket with modified liner using polyurethane foam transtibial prosthesis. The modified liner using polyurethane foam consists of ethylene-vinyl acetate–polyurethane–ethylene-vinyl acetate sandwich placed at the anterior-distal part of the residual limb. The function of the ethylene-vinyl acetate–polyurethane–ethylene-vinyl acetate sandwich is to improve the walking gait and compensate for pain sensation experienced by the user when wearing Pelite liner. Biomechanical analysis is done using the Vicon Motion Analysis System on the prosthesis user when using three types of liners which are Pelite (new) liner, modified liner using polyurethane foam that were fabricated for this study and the Pelite (original) liner from the subject. During the loading response phase, the Pelite (original) liner exerted a slightly higher force than Pelite (new) and modified liner. Meanwhile, at 30 % and 50 % of the gait cycle, the Pelite (original) liner exerted low force compared to the Pelite (new) liner and modified liner for Ground Reaction Force at the amputated side. However, for Ground Reaction Force (Non-Amputated), no difference was shown between all prosthetic liners. The biomechanical analysis shows that the modified liner using polyurethane foam improves the walking gait cycle of the prosthesis user.

Keywords: gait analysis, polyurethane, rehabilitation, transtibial liner

ABSTRAK

Kebanyakan pengguna kaki palsu bawah lutut sering mengalami sensasi kesakitan pada hujung baki anggota disebabkan oleh penonjolan bertulang dan hujung saraf. Banyak inisiatif telah dilakukan untuk menyelesaikan masalah ini, termasuklah menggunakan bahan lembut seperti pelapik silikon atau pelapik gel dan juga mereka bentuk soket prostetik tiada beban di hujung. Antara pendekatan lain ialah menggabungkan busa poliuretana dalam pembuatan pelapik prostetik. Kajian ini bertujuan untuk menjalankan tinjauan ke atas pengguna terhadap kesan pelapik prostetik dalam menjalani aktiviti harian, mereka bentuk pelapik prostetik baharu menggunakan poliuretana pada bahagian distal anterior baki anggota sebagai pengganti Pelite dan membandingkan analisis gait biomekanik di antara pelapik poliuretana terubah suai dan pelapik Pelite biasa. Seramai 4 orang amputee bawah lutut sebelah kiri telah direkrut sebagai subjek. Dua kaki palsu bawah lutut galas tendon patelar dengan dua pelapik yang berbeza telah dibuat untuk subjek, iaitu pelapik Pelite (baharu) dan pelapik poliuretana terubah suai. Pelapik poliuretana terubah suai terdiri daripada sandwic etilena vinil asetat–poliuretana–etilena vinil asetat yang diletakkan pada bahagian hujung baki anggota. Fungsi sandwic etilena vinil asetat–poliuretana–etilena vinil asetat adalah untuk memperbaiki langkah gait dan mengimbangi sensasi kesakitan yang dialami oleh subjek semasa memakai pelapik Pelite. Analisis biomekanik telah dilakukan menggunakan sistem analisis gerakan Vicon terhadap subjek ketika menggunakan kedua-dua kaki palsu baharu dan kaki palsu asal dengan pelapik Pelite (original) miliknya. Semasa fasa memuatkan tindak balas, pelapik Pelite (original) miliknya menghasilkan daya yang agak tinggi berbanding pelapik Pelite (baharu) dan pelapik terubah suai. Pada 30% dan 50% kitaran gait, pelapik Pelite (original) miliknya menghasilkan daya yang kurang berbanding pelapik Pelite (baharu) dan pelapik terubah suai untuk daya tindak balas tanah di bahagian sebelah badan yang diamputasi. Analisis biomekanik *menunjukkan bahawa pelapik terubah suai menggunakan busa poliuretana memperbaiki kitaran gait dan langkah gait pengguna kaki palsu.*

Kata Kunci: analisa gait, pelapik bawah lutut, poliuretana, rehabilitasi

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As the opportunity presents itself, I am also thankful that I have very supportive parents, Mohamed Nizam Bin Zakariah and Huzaipah Binti Istamar, as well as cheerful siblings, who always encourage me to move forward and to preserve during the process of completing this project. Last but not least, thank you to all my closest friends who always inspire me with their support and motivational words upon my hardships throughout the journey.

Finally, I have put my best and sincere efforts into this project, and I surely hope this will be helpful as future references for researchers and/or professionals who shall study or work on this field of interest.

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LIST OF SYMBOLS AND ABBREVIATIONS

ASTM	:	American Society for Testing and Materials
COF	:	Coefficient of Friction
CPO	:	Certified Prosthetist and Orthotist
EVA	:	Ethylene-vinyl acetate
ISPO	:	International Society of Prosthetics and Orthotics
PEQ	:	Prosthetic Evaluation Questionnaire
POP	:	Plaster of Paris
PTB	:	Patellar Tendon Bearing
PTB-SC	:	Patellar Tendon Bearing Supracondylar
PTB-SC-SP	:	Patellar Tendon Bearing Supracondylar Suprapatellar
PU	:	Polyurethane
TSB	:	Total Surface Bearing

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

This chapter describes briefly the basic knowledge needed in this study. The information on the lower limb amputation, type of sockets, type of liners, the materials used for the prosthesis liner, the prosthesis type of alignments and Vicon Motion Analysis System are very essential in understanding the study. This chapter will also describe the problem statement that drove this study. The objectives of study, the scope of work and thesis organization are described at the end of this chapter.

1.1 Amputation of lower limb

Limb loss or also known as limb amputation is becoming more common day by day. Amputation is performed on any part of the body, but lower limb amputations are the most common (Anderson, 2007; Kirkup, 2007; Miller, 2017). A person may be amputated because of vascular disease, trauma, and growth of a tumour or infection from previous injuries or diseases. Under other conditions, a person can also have congenital limb loss or limb deficiency which occurs at birth (Smith, 2004; Biddiss & Andrysek, 2016). As a matter of fact, limb amputation is the last option for the surgeon to take in order to save the remaining limbs from any further damage.

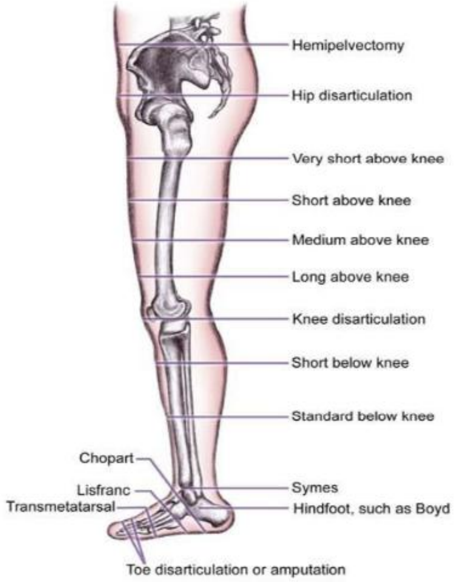

Figure 1.1 Level of amputation of lower limb

(Adapted from: Lower-Extremity Amputation. Retrieved from https://emedicine.medscape.com/article/1232102-overview)

One of the most popular major limb amputations in Malaysia is transtibial amputation. A total of 43.5 % of lower limb amputation is transtibial amputation. Followed by partial foot amputation (36.3 %) and transfemoral amputation (16.2 %). Besides that, the major cause of amputation is dysvascularity (53.2 %) (Yusof, 2015). Figure 1.1 above shows the level of amputation at the lower limbs.

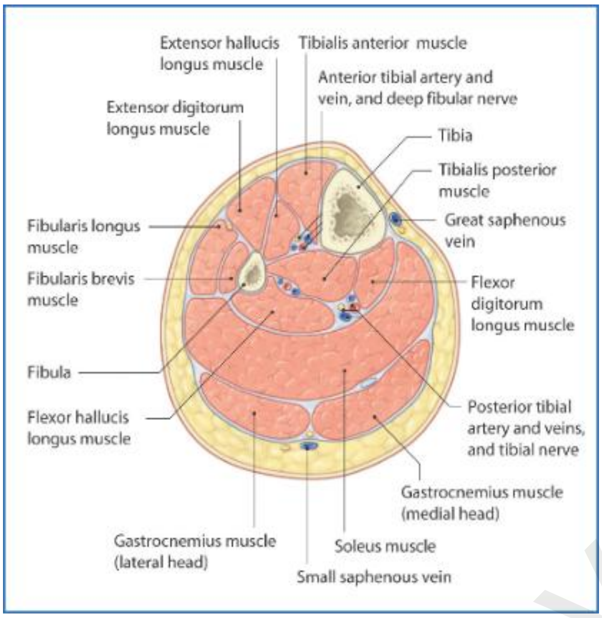

Figure 1.2 Cross section of below knee

(Adapted from: Gastrocnemius Muscle Cross Sectional. Retrieved from https://anatomy-learn.com/item/313607/gastrocnemius-muscle-cross-sectional-anatomy-cross-sectional-anatomy-gastrocnemius-muscle-cross-sectional-anatomy-cross-sectional-anatomy-leg-image-collections-learn-human.html)

A good amputation should remove the wounded section and make sure it can heal well afterwards. Next, the surgeon should keep as much of the joints and the functioning parts of the leg as possible. Furthermore, the stump should be in good shape so that it will be easy to fit into the prosthesis.

Transtibial amputation is conducted on a person when their below knee part of the leg have problem such as necrotic tissue or tumor present. The amputation is done by cutting the skin, flesh and both tibia and fibula bones. The the residual limb is closed with the excess skin flap. Figure 1.2 above shows the anatomy of below knee cross section.

After amputation, a person cannot ambulate as a normal person without assistive device or prosthesis. A prosthetic device is defined as any device that replaces the missing body part.

1.2 Transtibial Prosthesis

Transtibial prosthesis is a device that replace the missing limb below the knee. It is meant for a person that had undergone a below knee or transtibial amputation. Transtibial prosthesis consist of multiple different component that are assembled together. The components of transtibial prosthesis are prosthetic liner, prosthetic socket, socket adapter, pylon, foot adapter and prosthetic foot. In some cases, the pin and lock system component also included.

The first component is prosthetic liner, it is usually made up from a soft and flexible material such as Pelite, gel and silicone. The prosthetic liner acts as an interface between the residual limb and the prosthetic socket, so it has to be soft and flexible so that it can give comfort to the user. Different materials are meant for different condition. Some user might not suitable wearing a Pelite prosthetic liner, and some user might not suitable wearing silicone liner. As an example, if the user is allergic with silicone, they cannot use silicone prosthetic liner.

The next component is prosthetic socket, it is made from hard material like thermoplastic and resin. There are two main method of fabricating the prosthetic socket globally. The first one is draping, the material used in this process is thermoplastic, such as polypropylene and polyethylene thermoplastic. The process is done by heating the thermoplastic in the oven until it melt and drape it over the positive model of the residual limb. The other process is called lamination, and resin is used. Resin is liquid in it nature state, so in this process, hardener is added to solidify the resin. The process started by putting polyvinyl acetate bag onto the positive model of the residual limb, then the reinforcement such as fabric and fibre glass is put on. After that, another polyvinyl acetate bag is put on top of it. Next the resin that had been mixed with hardener is poured in between the two polyvinyl acetate bag and is let hardened. The major difference of thermoplastic and resin socket is the resin socket is lighter and stronger than the thermoplastic socket.

After the prosthetic liner and socket, the other components are socket adapter and pylon. Usually they are made from aluminum, stainless steel and titanium. Pylon acts as the shank of the leg, connecting the prosthetic socket and prosthetic foot.

There are various types of prosthetic foot that is used in prosthetic field. The examples are soft ankle cushioned heel (SACH) foot, single axis foot, multi-axis foot and energy storage foot. There are also prosthetic foot that have specific use like for running, riding bicycle and swimming. The type of the prosthetic foot is determined by the physician or the prosthetist before prescribing to the user.

1.2.1 Prosthetic Socket

Prosthetic socket is a medium that acts as an interface between the prosthesis and the residual limb and it is the most important part. The design of the socket must be perfectly catered to the needs of the user to achieve satisfactory load transmission, efficient ambulatory control and stability. There are two different essential ideologies for designing a transtibial socket. The first is to consistently distribute the weight of the body over the residual limb and the other is to distribute most of the weight over precise weight bearing regions at the residual limb (Ali, 2015).

There are two major socket designs regularly used in fabricating transtibial prosthesis, which are patellar-tendon-bearing (PTB) socket and total surface bearing (TSB) socket. PTB sockets have subdesigns such as the patellar-tendon-bearing-supracondylar (PTB-SC) sockets and the patellar-tendon-bearing-supracondylar-suprapatellar (PTB-SC-SP) sockets. The prescription of the socket type is decided based on the user's needs and pathology (McMonagle, 2007).

1.2.1.1 Patellar Tendon Bearing (PTB) Socket

The patellar-tendon-bearing (PTB) socket, as the name suggests, the load bearing will be concentrated on the patellar tendon. Meanwhile, the rest of the residual limb will have less load bearing on it. The indication of PTB sockets is for patients with medium to long stumps with no knee contracture. Furthermore, this particular design as shown in Figure 1.3 is suitable for users that experience pain on the residual limb.

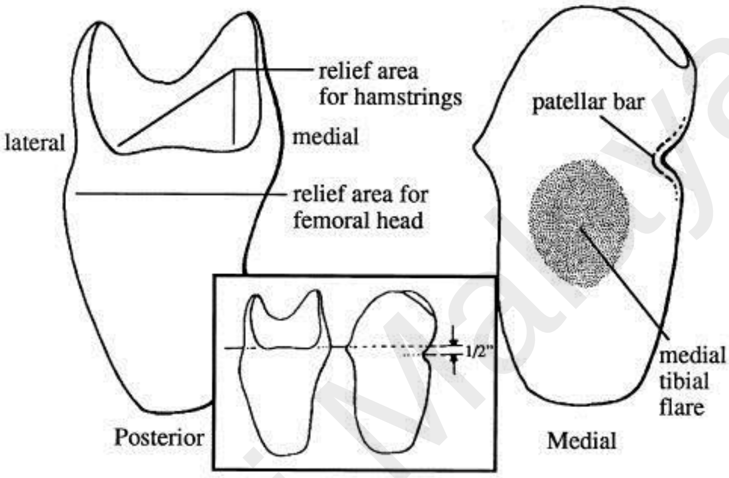

Figure 1.3 Patellar Tendon Bearing (PTB) socket

(Adapted from: The Patellar-Tendon-Bearing Socket. Retrieved from http://www.oandplibrary.org/alp/chap18-02.asp)

In addition, there are also subdesigns for PTB sockets which are patellar-tendon-bearing-supracondylar (PTB-SC) sockets and patellar-tendon-bearing-supracondylar-suprapatellar (PTB-SC-SP) sockets.

1.2.1.2 Patellar Tendon Bearing Supracondylar (PTB-SC) Socket

The trim line of PTB-SC sockets rises above supracondylar which acts as an anatomical suspension for the user as shown in Figure 1.4 below. The indications for this socket are long to short stump length, peripheral vascular disease, and mild mediolateral knee ligament laxity (McMonagle, 2007).

Figure 1.4 Patellar Tendon Bearing - Supracondylar (PTB-SC) socket

(Adapted from: Patellar-Tendon-Bearing-Supracondylar Socket. Retrieved from https://www.waoandp.com/patients/socket-finder/transtibial)

1.2.1.3 Patellar Tendon Bearing Supracondylar Suprapatellar (PTB-SC-SP) Socket

The trim line of PTB-SC-SP sockets rises above supracondylar and encapsulate the patellar which also acts as an anatomical suspension for the user as shown in Figure 1.5 below. Next, this socket design is usually prescribed for patients with medium to very short stump length. Furthermore, other indications also include moderate mediolateral knee ligament laxity, mild anteroposterior knee ligament laxity and peripheral vascular disease. The disadvantage of this design is that the user has limitations when flexing the knee (McMonagle, 2007).

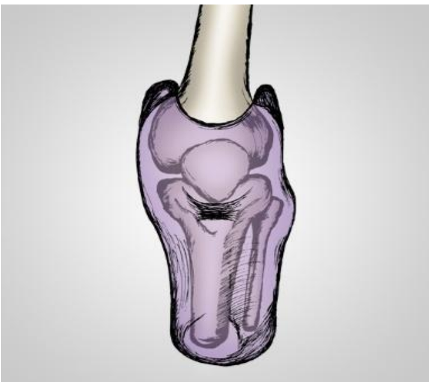

Figure 1.5 Patellar Tendon Bearing - Supracondylar - Suprapatellar (PTB-SC-SP) socket

(Adapted from: Patellar-Tendon-Bearing-Supracondylar-Suprapatellar Socket. Retrieved from https://www.waoandp.com/patients/socket-finder/transtibial)

1.2.1.4 Total Surface Bearing (TSB) Socket

The total surface bearing socket (TSB) is suitable for users that have no pain at the residual limb. This is because TSB sockets distribute the weight evenly on the residual limb. The contour of the socket takes the shape of the residual limb exactly as shown in Figure 1.6, so there will be no concentrated pressure on the patellar as the PTB socket.

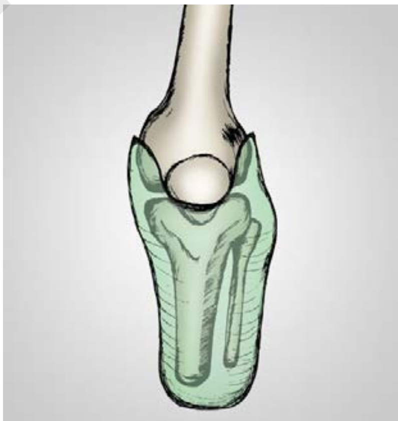

Figure 1.6 Total Surface Bearing (TSB) socket

(Adapted from: Total Surface Bearing Socket. Retrieved from https://www.waoandp.com/patients/socket-finder/transtibial)

1.2.2 Prosthetic liner

Protecting the remaining soft tissues at the residual limb of lower limb amputees is a tough challenge. Residual limb soft tissues are not designed to bear weight, unlike the foot plantar tissues (Dudek, 2005). Repetitive load on the soft tissues of the residual limb by the prosthetic socket can cause ulceration and other skin conditions (Sankaran, 2019). Liners act as interface between the residual limb and the prosthetic socket. The purpose of liners is to provide cushioning to the residual limb (Andrysek & Eshragi, 2017).

1.2.2.1 Pelite liner

Pelite foam is a top choice material to use as prosthetic liner around the world. Pelite foam is a closed cell polyethylene foam and manufactured in various hardness and thickness. Pelite foam is a high temperature thermoplastic and can be easily formed over positive models after heating. Figure 1.7 below shows the Pelite liner.

Pelite liners are often prescribed for patients with peripheral disease, sharp bony prominences on the stump and thin sensitive skin. The advantages of Pelite liner are such as weight bearing due to its softness and allowing volume fluctuation of the stump.

Figure 1.7 Pelite liner

1.2.2.2 Silicone liner

Recently, silicone liners are becoming more common in prescribing prosthesis to users. The properties of silicone liners like soft, sticky and closely follow the contours of the residual limb make it suitable for users that have skin problems. All the properties stated can prevent abrasion of the skin due to minimal friction between the skin and the liner. Figure 1.8 shows the silicone liners that are used in prosthetics field.

Figure 1.8 Silicone liner

(Adapted from: Silicone liners. Retrieved from https://opedge.com/Articles/ViewArticle/NEWS_2014-12-01_19)

1.3 Transtibial prosthesis alignment

The prosthesis alignment can be described as the orientation of the prosthesis components such as prosthetic foot, pylon and socket. Proper alignment of prosthesis alignment plays an important role in satisfaction and comfort of the user. The prosthesis alignment can be classified into three categories which are bench alignment, static alignment and dynamic alignment (Luengas, 2017).

1.3.1 Bench alignment

Before fitting the prosthesis on the patient, bench alignment must be done. Bench alignment means assembling the components, which are socket, pylon and foot, to each other following proper relationship on the workbench. Before the components are attached with one another, the socket must undergo socket alignment. The socket is adjusted with 5-degree flexion and 5-degree adduction. The alignments at the frontal and sagittal plane were checked using a plumb line. The plumb line was made sure to be passing through the centre of patellar and 1/3 of the foot length from the back of the heel when checking the alignment at the sagittal plane. Furthermore, when checking the frontal plane alignment, the plumb line should be parallel to the mid of the patella and the centre of the heel (Wu, 2010).

1.3.2 Static alignment

The user is required to don the prosthesis and apply equal weight on the anatomical and prosthetic leg by standing in between parallel bars during static alignment. Before donning, the condition of the stump is checked. There should be no cuts, abrasions, or wounds on the stump. If the stump is in good condition, the stump sock is put on, followed by the liner. The liner should be a snug fit and go all the way in easily. If the liner is too loose, some paddings can be added onto the exterior of the liner. The prosthesis is then put on and the fit is checked. There should be no major gaps at the brim, and the patient should have no discomfort (McMonagle, 2007).

The length for both the anatomical and prosthetic leg was measured. To measure the length, the distances between iliac crest to the ground is measured. The length of the prosthetic leg should be the same with the anatomical leg to prevent future gait deviation. Sometimes, clinicians will prescribe 1 cm shorter for the prosthetic leg to give better ground clearance during walking (Chow, 2006).

1.3.3 Dynamic alignment

Dynamic alignment is where the motion of the prosthetic leg in the complete gait cycle is observed by the clinician when the patient is ambulating. The patient will walk in between the side bars as a precaution. The clinician is required to observe the gait deviations that occur, identify the causes of that particular gait deviation and make adjustments to the alignment of the prosthetic leg to minimize the deviations.

1.4 Gait analysis system

Gait analysis is an important factor in deciding the walking pattern and stability in the motion of an individual. A usual gait analysis comprises two parts, the stance phase and the swing phase. The stance phase includes the initial contact or heel strike where the heel touches the ground, then the loading response or with foot flat where the body is prepared prior to accepting the body mass or weight on a single limb before moving forward to the midstance where the weight of the body is completely balanced on a single limb. Terminal stance or heel off is the last part of the stance phase. The swing phase includes the pre-swing, initial swing, mid swing and terminal swing. It is vital that a lower limb amputee has a gait cycle close to a normal person to be able to ambulate without having to compensate at other joints or limbs. The gait cycle phase is shown more clearly in Figure 1.9.

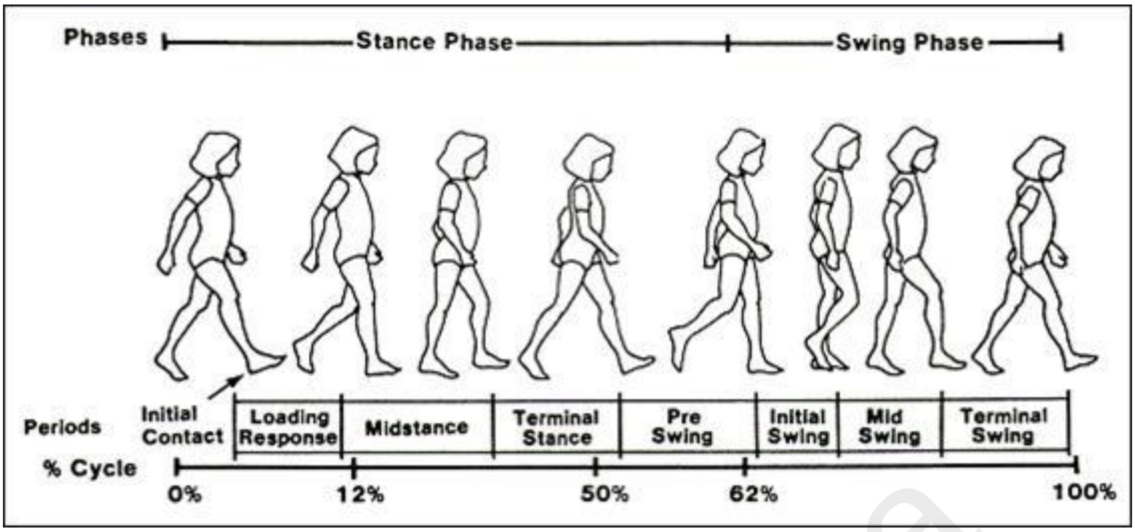

Figure 1.9 Gait cycle phase

(Adapted from: Describing Normal Gait. Retrieved from https://minerva.leeds.ac.uk/bbcswebdav/pid-4444457-dt-content-rid-496311_4/institution/MEDHLTH/MED/common-MBChB-resources/Elearning%20in%20Gait%20analysis%20v3/page_09.htm)

1.4.1 Vicon Motion Analysis System

Vicon Motion Analysis System is a software that can analyse the biomechanics of human. The system needs to be installed in a closed room or laboratory because a camera that is sensitive to reflective objects is used.

To perform the experiment, the subject needs to be put on with reflective markers at the landmarks on the body (Figure 1.10). Experiment with full body marker placement or half body (upper or lower) marker placement can be done on the subject. After the markers are put on the subject, the movement of the subject can be captured by the system using 5 cameras.

After the experiment has been done, the joint angle, moment and ground reaction force will be analysed from the data captured by Vicon Motion Analysis System for comparison of which prosthesis improves the user biomechanically.

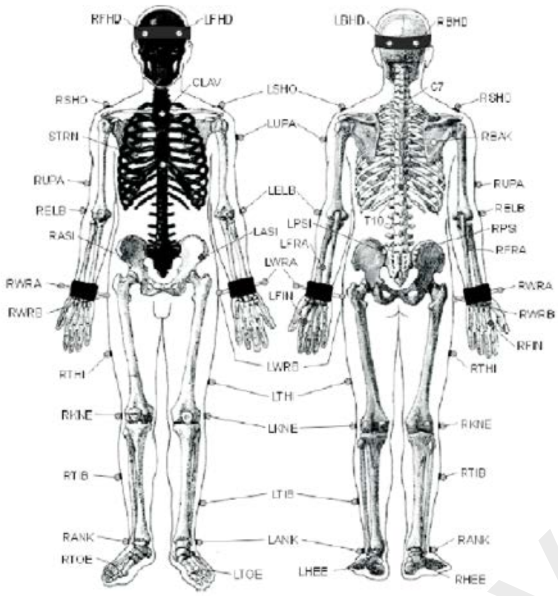

Figure 1.10 Markers placement

(Adapted from: Cain C. T. Clark, C. M. B., Mark Holton. (2016). A Kinematics Analysis of Fundamental Movement Skills. *Sport Science Review*, 261-275.)

1.5 Problem statement

Most transtibial prosthesis users experience pain sensation at the distal part or the end of the residual limb. This is because there is a bony prominence (tibia bone) at the distal part or the end of the residual limb (Bosse, 2019). Some prosthesis users develop skin wounds at the distal part of the residual limb (Lenz et al, 2018).

The liner material properties play a major role to ensure the user is comfortable when using the prosthesis. Currently Pelite foam is widely used for a low cost prosthetic liner. But for some users, they found the Pelite liner did not provide comfort needed for them. It is because of the nature of the Pelite liner is semi rigid. A group of 50 transtibial prosthesis users were asked to answer a questionnaire regarding the effect of using the prosthetic liner on their daily living activities.

There are various types of materials used in fabricating prosthetic liners. Different materials have different properties and serve different purposes. Four materials were tested with mechanical testing to find out which is the most suitable in fabricating prosthetic liners.

In addition, this study tries to incorporate the use of polyurethane foam in the design of prosthesis liners. Polyurethane foam is cheaper than the existing material such as silicon and gel. The modification is done at the anterior-distal part of the liner to accommodate the pain sensation experienced by the user.

1.6 Objectives

The objectives of this study are:

I. To conduct a survey among the users on the effect of the prosthetic liner on their daily living activities.

II. To design a new prosthetic liner using polyurethane foam at the anterior-distal part of residual limb as a replacement for Pelite as a prosthetic liner

III. To compare the biomechanical gait analysis of the new modified liner using polyurethane foam with the common Pelite as liner

1.7 Scope of work

This research concentrates on designing a new prosthetic liner using polyurethane foam at the anterior-distal part of residual limb as a replacement for Pelite as a prosthetic liner. Mechanical testing is applied on common materials for prosthetic liners to find which material is the best to use as prosthetic liners.

In addition, further studies on finding the effects of modified liners using polyurethane foam on biomechanics of transtibial amputee is carried out. The variable in this study focuses on comparing the biomechanical gait analysis of transtibial amputee using a new modified liner that uses polyurethane foam with the common Pelite as liner.

1.8 Thesis organization

This thesis consists of 5 chapters. In the first chapter, the introduction and the basic knowledge about transtibial prosthesis are given. This includes the components of the prosthesis such as types of prosthetic socket and types of prosthetic liners. Also, foundation knowledge of biomechanical gait analysis is discussed. Chapter 2 focuses on the background studies by past published articles related to the study. This includes anatomy of the knee, the material testing for prosthetic liner materials, prosthetic liner material, effect of material on subject, and effect of type of liner on biomechanics of subjects. In addition, chapter 3 explains the methodologies and procedures of the research. The manufacturing of transtibial prostheses was explained in detail in this chapter. Also, the procedure in handling Vicon Motion Analysis System is explained clearly. Furthermore, chapter 4 discusses the results obtained from mechanical testing and biomechanical gait analysis. Finally, chapter 5 includes the conclusion of the study, the limitations encountered in this study and future improvements that can be applied in this study. The Figure 1.11 below shows the flowchart of the study.

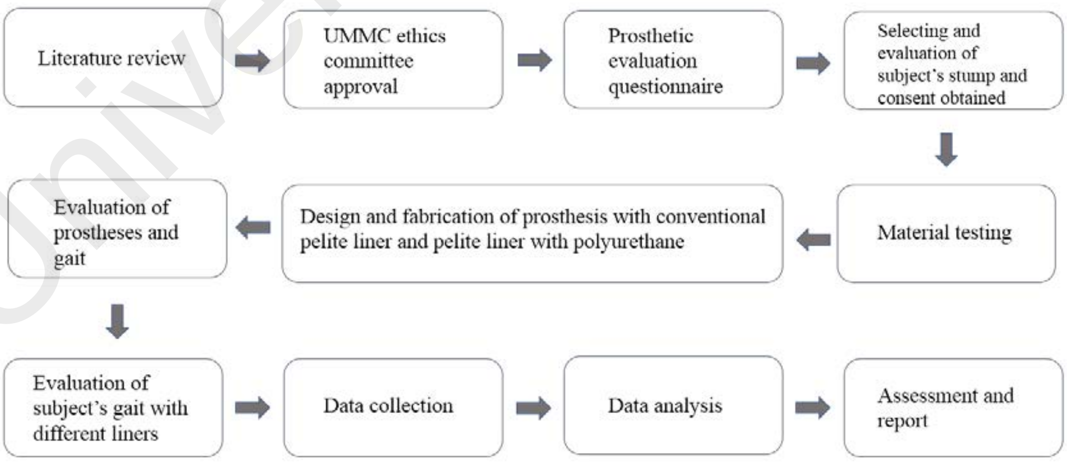

Figure 1.11 Project flowchart

CHAPTER 2: LITERATURE REVIEW

Several related studies were reviewed to investigate the effect of type of liner on the biomechanical activity. The chapter is divided into four main categories that include: (i) materials in prosthetics and orthotics field, (ii) prosthetic liner material, (iii) effect of material on subject, (iv) effect of type of liner on biomechanics of subjects.

2.1 Materials in prosthetics and orthotics field

2.1.1 Pelite liner

Prosthetic liner can be made from many material, separately or combined. Polyethylene-Light (Pelite™) is a foam liner that is the most frequently used in prosthetics, but it does not cater to all amputees' limb and skin conditions (Lutfi, 2020). It is because some transtibial amputee have some conditions at the residual limb such as very prominent bone ending cannot use Pelite liner since it will make the amputee experienced discomfort. Clinicians have been using Pelite foam in the production of transtibial prosthesis liners since 1950 (Weg, 2005; Coleman, 2004 & Ali, 2013).

Pelite is a low-cost option for prosthetic liners but offer good quality and lifespan. Pelite liners are suitable for users with weak skin sites and protect them from breakdowns (Sanders, 2004). Pelite have deformation properties that could allow a better adaptation to the stump sensitivity and are best for bony or scarred residual limbs (Fernandes, 2018).

Relatively, the time consumed for donning a transtibial prosthesis with Pelite liner is quicker than liners with the pin and lock system. The study by Coleman et al. (2004) and Highsmith et al. 2016) concluded that the majority of transtibial prosthesis users preferred Pelite liners over Alpha liners with the pin and lock mechanisms because of wearing time and improved ambulatory activity.

Patellar Tendon Bearing (PTB) socket design is suitable for Pelite liners rather than Total Surface Bearing (TSB) socket. This is because PTB sockets will concentrate most of the weight of the prosthesis user at the patellar area. On the other hand, TSB sockets will distribute the weight of the user evenly in the socket. The TSB socket is usually prescribed for liners with pin and lock suspension. The suspension that is commonly used for Pelite liners is Supracondylar. The design will suspense the prosthesis at the superior part of the condyle (Eshragi, 2014).

Furthermore, a study was conducted to compare a conventional suspension with a polyurethane foam concept that concerns amputees' satisfaction. They incorporate polyurethane foam in the liner production and found that the polyurethane foam concept increases the satisfaction of the subjects (Åström, 2004).

Based on the study by Caldwell et al. (2017), prosthetic liners increase the internal temperature of the prosthesis, thus, causing sweating and moisture build-up. Socket wear, hot climate, and users' daily living activities increase residual limb temperature by 1 to 2 °C in residual limb skin temperature and potentially causing discomfort. Increased humidity leads to dermatitis and infections. It also disrupts suspension forces, and skin with slight moisture is more susceptible to blisters than wet or dry skin (Caldwell et al., 2017).

Thermal conductivity characterizes the ability of each liner to transfer heat away from the residual limb. Overheating and excessive sweating are two of the most commonly reported issues affecting active prosthesis users, and many users would prefer liners that do not strongly insulate their residual limb. Conversely, another study reported that 15 % of lower-limb prosthesis users experienced issues with their residual limb being too cold. A liner with high thermal conductivity will move more heat away from a warm limb to the cooler external environment. A liner with low thermal conductivity will help to retain heat (i.e., insulate the residual limb) and may be suitable for lower activity users or those who use their prosthesis in a colder environment (Cagle, 2018).

Generally, more than 53 % of prosthetic users feel discomfort due to excessive heat or sweating, and an increment of 1–2 °C is sufficient to cause this kind of problem (Klute, 2005). Because amputees have less surface area to allow heat dissipation, the excessive perspiration negatively affects the residual limb/socket interfaces. For this reason, relative humidity is another important parameter that should be monitored at the residuum interface. Instability, skin maceration and bacterial invasion may occur especially in patients affected by vascular diseases (Klute, 2007). These patients represent the vast majority of the amputees and they have compromised thermoregulatory responses (e.g., reduced capacity to vasoconstrict in response to cold environments and vasodilate in response to warm environments). In addition, when the skin is moist, the frictional load on the residuum will be higher, facilitating irritations and blisters, making it impossible for the amputee to wear the prosthesis.

In comparison to temperature results, relative humidity was characterised by a continuously increasing trend not only during the rest period and the physical activity, but also during the rest period after exercise (~3 %). This suggests that the amputee needs to stop periodically to doff the prosthesis and remove the sweat. In addition, when donning the prosthesis, the new personalised liner showed lower values of relative humidity compared to the patient’s usual Pelite system. However, there was an increase of 7 and 9 % for the Pelite and the new liner respectively after 50 min of resting. The exercise (30-min treadmill walking) increased the relative humidity by 2–3% for both liner systems, showing similar results to a previous preliminary study that measured an increase of 4 % relative humidity in the socket after 15 min of walking activity (Cutti, 2014). However, only one sensor was used, and the absolute values at resting were not reported (Paterno, 2020).

2.1.2 Silicone liner

The silicone liner socket has been used in the transtibial prosthesis since the 1980s. Silicone liners are sleeves of silicone material that are rolled onto the stump and the prosthesis is fixed onto it. The producers of the liners propagate many advantages in their use, i.e., better suspension of the prosthesis, protection of the stump skin and improved cosmetic appearance (Baars, 2005).

First, the suspension of the silicone liner socket is claimed to be superior to the other socket types because of the close adhesion of the liner to the stump. The liner is also said to offer skin protection and diminish friction between the socket and the stump surface. Delicate skin would therefore be a good indication for liner use. The general comfort in wearing the prosthesis is also claimed to be improved. Lastly, it is stated that the cosmesis is better and easily accepted by the amputee (Kapp 1999; Lake and Supan 1997). The material properties of the silicone liner, i.e., adherence to the skin, are reported to be partly responsible for these improvements in combination with the way the stump is fitted in the socket (Fillauer et al. 1989; Kristinsson 1993). The silicone material is pliable and sticky and closely follows the whole contour of the stump surface and a vacuum is created between the liner and skin. These properties also influence the soft tissue which is compacted, formed and controlled by the liner socket. The latter makes it possible to use the total surface bearing principle of the stump surface during loading of the prosthesis (Kristinsson, 1993).

Another material that is widely used as transtibial prosthesis liner is silicone. Silicone liners are suitable for users with excessive soft tissue at the residual limb. This is because silicone liners would not give additional deformation on top of the tissue and prevent the residual limb from sliding outwards of the socket (Sanders, 2004 & Fernandes, 2018).

Figure 2.1 Pin and lock silicone liner

There are two common suspension systems used for silicone liners, which are the pin and lock mechanism and vacuum. However, silicone is more suited for the pin and lock mechanism because of its nature that can retain thickness and volume (Fernandes, 2018).

Meanwhile, in other studies, they only use gel liners in the experiment. But the liners were in different uniform thicknesses. They found that the thicker the material, the more comfortable the liner (Boutwell, 2012).

In one study, they conducted an experiment to investigate whether washing the residual limb and silicone liner reduces the associated skin problems in transtibial amputees who wear total surface bearing (TSB) socket. They found out that by cleaning the residual limb and liner, it helps to reduce skin problems (Hachisuka, 2001).

Poor suspension increases slippage of the residual limb inside the socket during ambulation. Effective suspension systems and prosthetic components can improve the gait of a person with amputation and decrease their energy expenditure. Prosthetic limbs should have an intimate fit with the residual limb in order to replace the lost body part with a device that offers high levels of comfort and satisfaction. Individuals with amputation believe that both the suspension method and the fitting of a prosthetic device have significant effects on their overall satisfaction with the prosthesis. Evidence shows that silicone liners are preferred by many people with lower-limb amputation because they offer enhanced suspension and fit within the socket as well as improved function. Previous research on silicone liners found that patient comfort and satisfaction are particularly higher in contrast with other suspension systems, such as belt for PTB sockets. Silicone liners are believed to be more effective in controlling the pistoning within the prosthetic sockets than Pelite liners (Gholizadeh, 2012).

2.1.3 Fabrication of transtibial prosthesis

There are many techniques to fabricate a transtibial prosthesis based on the types of the socket. There are two major types of transtibial prosthesis sockets that are mainly used globally: total surface bearing (TSB) socket and patellar tendon bearing (PTB) socket (Eshragi, 2014).

In this study, the PTB socket was chosen as the socket type as it is suitable with the usage of Pelite as the prosthetic liner. When fabricating the PTB socket, the focus during the modification process is to make the patellar groove on the model. The patellar groove will bear the weight of the users when they are using the prosthesis. About 60 % of the user's body weight will be concentrated at the patellar groove instead of other areas on the residual limb. The user should not feel high pressure in the other areas on the residual limb (Gholizadeh, 2012).

After the modification process, the model was draped with Pelite foam to make the prosthetic liner. Then, the polypropylene plastic was draped on the Pelite liner to become the prosthetic socket. The socket and liner were then cut from the model. Finally, all components of the prosthesis were assembled together, and static alignment was applied (Ali, 2015).

2.2 Area at the end of residual limb

After a person gets amputated, there will be bony prominences at the end of the residual limb (Portnoy, 2008). The bony prominences at the end of the residual limb can cause some problems such as discomfort and pain to the user (West, 2010). The prosthetic liner acts as soft interface between the hard socket made from plastic with the residual limb (Klute, 2010). For transtibial amputees, the most prominent bone at the residual limb is the tibia bone (Portnoy, 2010). Since the residual limb is not engineered to bear weight as the sole of the foot, the user will feel discomfort and pain because of the bony prominences. Based on previous study by Laferrier et al. (2010), paddings were added to the area that experienced pain and discomfort.

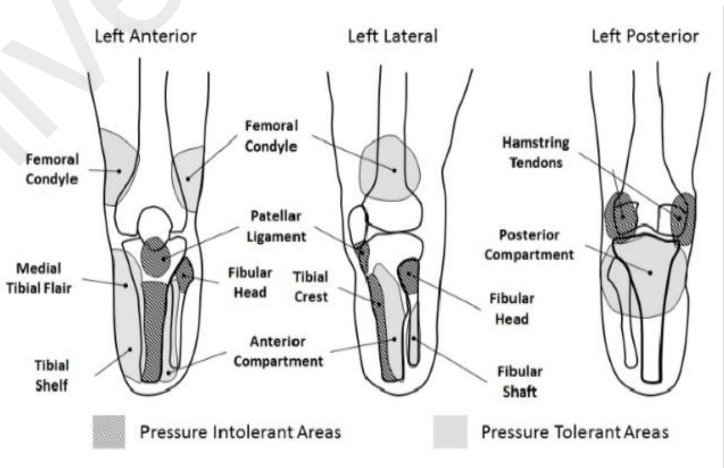

Figure 2.2 Anatomy of transtibial amputation

Based on the study by Lee et al. (2005), the area that is most prone to experience pain or discomfort is at the distal end of the residual limb. There are various solutions created for this issue, such as the use of suitable materials as prosthetic liners. Sometimes, the user not only experiences physical pain, but may also experience phantom limb pain. Phantom limb pain is the pain sensation at the limb that is no longer there or amputated (Petersen, 2019). By donning and using the prosthesis, the phantom limb pain experienced will be reduced (Hill, 1999).

Variations in the shape and volume of an individual's residual limb are common amongst individuals with amputations (Tantua, 2014). Some of the causes of such variations are the fluid volume changes in the residual limb, weight variations of the user, muscle activity of the limb, muscle atrophy and oedema in immature residual limbs—defined as less than a year post-amputation. Even in mature residual limbs, both diurnal and long-term fluctuations in the volume of the limb may occur. The amount of volume variations in mature residual limbs varies considerably amongst individuals depending on their activity level, socket fit, dietary habits, etc. (Sanders, 2009). Although volume changes occur in both upper and lower extremities, due to the weight bearing nature of lower residual limbs, such volume fluctuations are more considerable in individuals with lower extremity amputations, which accounted for more than 65 % of all amputations in the United States in 2005 (Ziegler-Graham, 2008).

Variations in the size of the limb can negatively impact the quality of the prosthetic socket fit, leading to the user's discomfort and causing skin health problems, such as oedema, dermatitis, and ulceration, which are common problems in individuals with amputations of the lower limb (Ahmadizadeh, 2019).

A commonly prescribed volume management method to mitigate variations in the volume of the residual limb is to add or remove prosthetic sock plies worn on the limb. Although prosthetic socks and other volume management methods are available and commonly used to compensate for volume fluctuations in the residual limb, management of sock plies remains an issue amongst users, especially those with cognitive issues and/or limited sensation in their residual limbs (Ahmadizadeh, 2020).

2.3 Material testing

An experiment was conducted to study the friction between the human skin and three interface materials that are commonly used as prosthesis liners: block copolymer, silicone gel and silicone elastomer. In this experiment, the material was tested on the palm of the hand of able-bodied subjects. All materials that have been tested show a high coefficient of friction (COF) that verify their ability to prevent residual limbs from slipping and pistoning while using the prosthesis. Silicone elastomer had maximum COF, followed by block copolymer and silicone gel (Cavaco, 2016).

In addition, a research has studied the biomechanical reaction of the stump sliding with particular attention to the liner stiffness effects of the transtibial prosthesis. They concluded that stump sliding behaviour is a vital factor in the socket evaluation. The peak interface stresses are moderately sensitive to the liner stiffness (Lin, 2004).

A research was conducted to characterize prosthetic liners across six clinically relevant material properties. The properties are compressive elasticity, shear elasticity, tensile elasticity, coefficient of friction, volumetric elasticity, and thermal conductivity. This research focused on 18 commercially available elastomeric liners made from thermoplastic elastomer, silicone and urethane (Cagle, 2017).

Furthermore, another research was conducted to assess the thermodynamic properties of currently available components. The material of liners used are closed cell foam, gel, polymer gel and silicone. From the research, it shows that liners made from silicone have higher thermal conductivity and liners made from closed cell foam have the least thermal conductivity. The higher the thermal conductivity of a material, the lesser the temperature elevation in the socket. Thus, silicone-based liners are the best to make sure users are comfortable temperature wise (Klute, 2007). In addition, a study was done to characterise the prosthetic liner materials. They chose polyurethane liner, silicone and thermoplastic elastomer (TPE) liners. Various tests such as compressive, shear, tensile, volumetric elasticities, coefficients of friction (COF), and thermal conductivities were tested on all the materials. They concluded that polyurethane liners are softer and less sticky than 16 years ago, and TPE liners have higher tensile stiffness than previously. Compressive stiffness may be used to characterise the ability of the liner to flow (Cagle, 2018).

Material	Manufacturer	Product	Liner Code	Section Thickness, mm	Compress Elasticity, kPa	Shear Elasticity, kPa	Tensile Elasticity, kPa	Volumetric Elasticity, kPa	Poisson Ratio, mm/mm	Coefficient of Friction, N/N	Thermal Conductivity, W/m·K
Polyurethane	Otto Bock	6Y512(NF)	1	2.79 (proximal) 4.45 (distal)	290 (proximal) 296 (distal)	59.3 (proximal) N/A* (distal)	157 (proximal) N/A* (distal)	92,600	0.4995	0.51	0.164
	Otto Bock	6Y512	2	3.59 (proximal) 5.15 (distal)	347 (proximal) 336 (distal)	65.2 (proximal) N/A* (distal)	N/A†	128,000	0.4996	0.44	0.145
	Otto Bock	6Y520(NF)	3	4.56	252	59.3	124	173,000	0.4998	0.67	0.170
	Otto Bock	6Y520	4	5.26	318	62.2	216	191,000	0.4997	0.44	0.143
Silicone	Medi	Relax 3C	5	3.12 (proximal) 5.96 (distal)	458 (proximal) 359 (distal)	104.6 (proximal) 79.6 (distal)	353 (proximal) 268 (distal)	78,300	0.4991	2.65	0.158
	Össur	Iceross Comfort	6	5.88	224	41.5	158	147,000	0.4997	2.82	0.171
	Össur	Iceross Dermo	7	6.19	156	51.2	154	8,360	0.4969	2.18	0.151
	Össur	Iceoross Original	8	2.11 (proximal) 3.81 (distal)	354 (proximal) 375 (distal)	84.3 (proximal) 84.2 (distal)	232 (proximal) 244 (distal)	92,400	0.4993	3.07	0.175
	Össur	Iceoross Sport	9	2.92 (proximal) 3.62 (distal)	263 (proximal) 228 (distal)	56.7 (proximal) 56.8 (distal)	194 (proximal) 173 (distal)	8,785	0.4953	1.95	0.150
	Össur	Iceoross Synergy	10	3.04	370	76.0	241	8,740	0.4929	1.79	0.122
	Otto Bock	6Y75	11	3.15	384	68.5	286	82,500	0.4992	2.23	0.183
	Prosthetic Design	SealMate	12	2.99 (proximal) 6.34 (distal)	186 (proximal) 187 (distal)	56.1 (proximal) 64.4 (distal)	170 (proximal) 199 (distal)	113,500	0.4997	1.95	0.160
	Renew	Shore 10A Silicone	13	5.70	307	81.0	237	208,000	0.4998	2.95	0.181
	WillowWood	Alpha Si-Se	14	4.36	349	53.6	3,450	111,000	0.4995	1.36	0.146
TPE	Alps	EasyLiner	15	4.00	141	15.2	124	94,700	0.4998	0.81	0.124
	Alps	Extreme	16	3.90	111	16.0	1,510	73,000	0.4997	>3.0	0.144
	Alps	General Purpose	17	3.75	96	16.0	225	77,000	0.4998	>3.0	0.126
	Alps	Winter's Gel	18	5.24	96	21.4	1,560	101,000	0.4998	>3.0	0.130
	Freedom Innovations	Inception	19	5.87	144	39.3	1,554	126,000	0.4998	1.52	0.139
	Otto Bock	6Y92	20	4.49 (proximal) 6.57 (distal)	121 (proximal) 116 (distal)	24.9 (proximal) 22.8 (distal)	136 (proximal) 110 (distal)	123,000	0.4998	2.80	0.128
	WillowWood	Alpha Cl-Mx	21	6.84	134	26.2	145	151,000	0.4999	2.78	0.124
	WillowWood	Alpha Cl-Or	22	6.33	157	26.1	294	143,000	0.4998	2.79	0.141
	WillowWood	Alpha Cl-Sp	23	6.39	144	28.0	309	125,000	0.4998	2.75	0.138
	WillowWood	Alpha Hy-Se	24	6.14	196	22.2	2,280	99,500	0.4997	>3.0	0.130

* Liner has an anatomic thickness profile, which made it impossible to collect distal specimens of uniform thickness.
† Fabric backing is present, but was not bonded to the elastomer above midpatellar tendon. Property is best approximated by liner no.12.
N/A, not available.

Table 2.1 Material testing of prosthetic liner materials

2.4 Biomechanics of prosthesis user

In a study by Boutwell et al., they investigated the effects of gel liner thickness on peak socket pressures and gait patterns of users with unilateral transtibial amputations. They found that thicker gel liner thickness increases the comfort of the prosthesis and assist in gait cycle (Boutwell, 2012).

In another research, they investigated whether elevated vacuum suspension could improve the gait of transtibial amputees during slope walking. They recruited a total of 12 subjects with unilateral transtibial amputation and each of them were fitted with the Unity elevated vacuum suspension system (Össur) and Pro-Flex XC foot. 3D motion analysis was performed for 7° incline, 7° decline, and level walking on the subjects. Randomised and blinded walking trials were completed with the vacuum active or inactive system. They concluded that active vacuum improved gait symmetry for incline walking (Gholizadeh, 2012).

In addition, comparison of a conventional suspension with a polyurethane foam concept with regards to the amputees' satisfaction, socket comfort, physical capacity and to analyse the long-term effect is carried out in a study. There were 117 (67 %) subjects that agreed the polyurethane foam concept was much better in physical capacity and 119 (82 %) agreed that socket comfort was much better compared to the conventional suspension. They concluded that the polyurethane foam concept increased comfort considerably and physical activity as well (Astrom, 2004).

In a study, they found that the size of the prosthesis socket affects the step time and width asymmetry, anterior and anterior-distal morning-to-afternoon limb fluid volume change, and self-reported utility. They fabricated two transtibial prostheses: duplicate of current prosthesis and either larger or smaller by 1.8 mm from the current prosthesis for the subjects. The activity of the subjects was monitored for 4 weeks (Sanders, 2017).

In another study, they analysed the thorax, pelvis, hip kinematics and the hip internal moment in the frontal plane during gait for unilateral transtibial amputees. They recruited a total of 25 unilateral transtibial amputees and 25 healthy (non-amputee) individuals as control subjects. They performed gait analysis on the subjects using the Vicon® Motion Analysis System. They concluded that there were significant differences between the prosthetic side and the sound side (Molina-Rueda, 2014).

2.5 Summary of literature review

No	Title	Author	Objectives	Methodology	Discussion	Conclusion
1.	Comparative Study between Dermo, Pelite, and Seal-In X5 Liners: Effect on Patient's Satisfaction and Perceived Problems.	(Ali, 2015)	To compare the effect of satisfaction and perceived problems between Pelite, Dermo with shuttle lock, and Seal-In X5 liners on the transtibial amputees.	All subjects were fabricated with two transtibial prostheses. A total of 17 male and 13 female subjects were recruited. The subjects are asked to answer Prosthetic Evaluation Questionnaire (PEQ) for three different liners.	Dermo liner showed a very significant score (*P* = 0.05) in walking, walking on uneven surfaces, stairs walking, fitting, donning/doffing, sitting, suspension. Overall satisfaction was 34% higher with Dermo liner than Seal-In X5 liner and 28% higher than Pelite liner. For sweating, skin irritation, frustration, and pain subjects reported less	Dermo liner gives high satisfaction to the subjects. There were fewer problems with Dermo liner. To conclude, Dermo liner is a good choice for transtibial users.

					problems with Dermo liner and significant differences (*P* < 0.05) were recorded between the three liners in compared with Seal-In X5 and Pelite liners.	
2.	Friction of prosthetic interfaces used by transtibial amputees.	(Cavaco, 2016)	To study the friction between the human skin and three common interface materials: block copolymer, silicone gel and silicone elastomer.	This study recruited 4 subjects (2 females, 2 males) with no amputation. The parts of the body that were tested in this study were on the palm of the hand and the anterior region of forearm. Three commercial interfaces were	The maximum COF is by silicone elastomer has the maximum COF whereas the silicone gel exerted minimum values.	All materials present a high COF against skin (N1.5). This confirmed the ability to avoid slipping and pistoning of the

				studied, one made of a block copolymer, a silicone gel and a silicone elastomer.		residual limb from the liner. Highest COF is exerted by silicone elastomer.
3.	Effect of prosthetic gel liner thickness on gait biomechanics and pressure distribution within the	(Boutwell, 2012)	To investigate the effects of gel liner thickness on peak socket pressures and gait patterns of persons with unilateral transtibial amputations.	The subjects recruited had unilateral transtibial amputation without serious problems, and at least 6 months experience using a prosthesis. Subjects must be to ambulate at least 10 m over level ground without the use of	Fibular head peak pressures were reduced ($p = 0.04$) with the thicker liner by an average of 26 +/– 21%, while the vertical ground reaction force (GRF) loading peak increased 3 +/– 3% ($p = 0.02$). Most subjects perceived increased	As conclusion, the thicker the material liner, the more comfortable it is.

	transtibial socket.			an assistive device. A thin 3 mm liner and a thick 9 mm liner were used. The subjects were asked to walk at a self-selected walking speed. Pressure sensors were placed over five anatomical locations on the residual limb.	comfort within the prosthetic socket with the thicker liner, which may be associated with the reduced fibular head peak pressures. Thicker liner presumably increased comfort.	
4.	A comparison between the suction	(Brunelli, 2013)	To compare the effect of the hypobaric Iceross Seal-In® liner	10 transtibial amputees were recruited for this study. The Prosthesis Evaluation	The pistoning significantly reduced with hypobaric Iceross Seal-In® X5.	The quality of life in transtibial amputees can be

	suspension system and the hypobaric Iceross Seal-In® X5 in transtibial amputees.		with that of the suction suspension system for quality of life, pistoning, and prosthesis efficiency in unilateral transtibial amputees.	Questionnaire and the Houghton Scale Questionnaire of perceived mobility and quality of life with the prosthesis are answered by all subjects.		improve by replacing the suction suspension system with the hypobaric Iceross Seal-In® X5.
5.	Effects of liner stiffness for trans-tibial prosthesis: a	(Lin, 2004)	To study the biomechanical reaction of the stump sliding with attention	A unilateral transtibial amputee wearing a Kondylen Betrung Munster suspension	The vertical downward displacement of the superior bone surface was 21.3 mm when the total of the reaction	Stump sliding behaviour is a vital factor in the socket

	finite element contact model.		to the liner stiffness effects of the transtibial prosthesis.	socket was recruited in this study.	forces (at the three loaded nodes) reached 600 N for the 0.4 Mpa liner simulation. The simulated peak interface pressures of the 0.4 Mpa liner model under 600 N reaction force were 660, 397, 783 and 88 Kpa on the anterior, lateral, posterior and medial regions of the stump.	evaluation. The peak interface stresses are moderately sensitive to the liner stiffness.
6.	Residual-limb skin temperature in transtibial sockets.	(Peery, 2005)	To characterise the thermal environment at the skin-prosthesis interface.	This study recruited five transtibial amputees with varying prosthetic prescriptions. All subjects	Mean residual-limb skin temperature increase of 0.8 °C (2.5%) after donning and resting. Mean residual-limb	Residual skin temperature increases after

				were asked to wear the prostheses at least 8 hours a day. To calculate skin temperature, we placed sensors (thermistors) at 14 locations on each subject's residual limb where significant skin temperature differences were expected. Subjects then donned their prostheses over the sensors. They recorded temperature measurements for the next 28 min. Subjects began the test	skin temperature increase by 1.7 °C (5.4%) from the donning temperature after walking for 10 minutes. It was demonstrated that the insulation properties of prosthetic socket systems can raise skin temperatures while subjects rested. Walking for even short periods of time can result in a greater increase in skin temperature.	donning and after walking.

				while resting comfortably in the seated position for 15 min. We allotted 3 min to transition the subject onto the treadmill. The subjects then walked at a slow pace (0.27 m/s) for 10 min to complete the test.		
7.	Development of Standardised Material Testing Protocols for Prosthetic Liners.	(Cagle, 2017)	To characterise prosthetic liners across six clinically relevant material properties.	Compressive elasticity, shear elasticity, tensile elasticity, coefficient of friction, volumetric elasticity, and thermal conductivity were selected to characterise liner	This research provides a means to quantitatively characterize and directly compare existing and emerging liner products. All properties were associated	Future research needs to be done to find information

				performances. Focused on elastomeric liners.	with characteristics that contribute to user's prosthesis function, health, or quality of life.	about liner materials.
8.	The thermal conductivity of prosthetic sockets and liners.	(Klute, 2007)	To assess the thermodynamic properties of currently available components	This study measures heat flow from a hot surface, through a material to a cold surface. The hot surface was maintained at 408C using five resistive polyamide heaters.	The Pelite closed cell foam had a thermal conductivity of 0.085 W/m 8K and the Bocklite closed cell foam had a thermal conductivity of 0.091 W/m 8K.	Some prosthetic components can act as a barrier to conductive heat transfer due to low thermal conductivity.

9.	A Pressure and Shear Sensing Liner for Prosthetic Sockets.	(Wheeler, 2016)	To monitor interface pressures that related to the comfort and fit of a lower-limb prosthetic socket.	The subject stand and walk using the prosthesis that have 16 sensors. Normal and shear stresses were recorded from all 16 sensors continuously	No discomfort was reported by the subject.	The system was successfully tested on a transtibial amputee subject over several sit/stand/walk cycles.
10.	Transtibial amputee gait during slope walking with the unity suspension system.	(Gholizadeh, 2018)	To investigate whether elevated vacuum suspension could benefit transtibial amputee	A total of 12 subject with unilateral transtibial amputation were recruited and each of them were fitted with the Unity elevated vacuum suspension system (Össur)	Statistically significant differences ($p < 0.05$) were found between vacuum conditions when walking uphill or downhill for temporal spatial, kinematic,	Active vacuum improved gait symmetry for incline walking

			gait during slope walking.	and Pro-Flex XC foot. 3D motion analysis was performed for 7° incline, 7° decline, and level walking on the subjects. Randomised and blinded walking trials were completed with the vacuum active or inactive.	and kinetic gait parameters. Symmetry index was<10% for step length, step time, and stance time for both vacuum condition during downhill walking, indicating acceptable symmetry.	
11.	Effect on gait and socket comfort in unilateral transtibial amputees after	(Astrom, 2004)	To compare a conventional suspension with a polyurethane concept about the amputees' satisfaction, socket	In this study, 29 unilateral transtibial amputees were recruited. The subjects answered a questionnaire after 2 months use of the polyurethane concept and	The subjects agreed that the polyurethane concept was much better in physical capacity in 117 (67%) and socket comfort was much better in 119 (82%) compared	The polyurethane concept increased comfort considerably and

	exchange to a polyurethane concept		comfort, physical capacity and to analyse the long-term effect.	were interviewed after 3 and 5 years.	with the conventional suspension.	physical activity increased.
12.	Hygiene Problems of Residual Limb and Silicone Liners in Transtibial Amputees Wearing the	(Hachisuka, 2001)	To investigate whether washing the residual limb and silicone liner reduces the associated skin problems in transtibial amputees who wear a	A total of 83 unilateral transtibial amputees (65 males, 18 females) are recruited. The subjects must have used TSB socket with silicone liner for about 5 years.	Perspiration was noted less by women, eruption more by older subjects, and itching and odor more by younger subjects. Washing the silicone liner every day was associated with fewer reports of skin eruption.	Keeping the residual limb and silicone liner clean is important to reduce skin problems, but hygiene

	Total Surface Bearing Socket		total surface bearing (TSB) socket.			problems of the residual limb and silicone liner still remain to be resolved.
13.	Effects of socket size on metrics of socket fit in trans-tibial prosthesis users.	(Sanders, 2017)	To distinguish a good socket from an oversized socket transtibial amputee.	Subject were fabricated with two sockets, duplicate of current socket and modified socket that was either enlarged or reduced by 1.8 mm. The subjects were required to do activities for 4 weeks and been monitored.	High effect size, step time and step width asymmetries, experienced greater values for the smaller socket.	Size of socket affect the step time and width asymmetry, anterior and anterior-distal morning-to-afternoon limb fluid volume

						change, and self-reported utility.
14.	Characterization of Prosthetic Liner Products for People with Transtibial Amputation.	(Cagle, 2018)	To characterise the prosthetic liner materials.	Polyurethane foam, silicone, and thermoplastic elastomer (TPE) liners were chose in this study. The compressive, shear, tensile, volumetric elasticities, coefficients of friction (COF),	Polyurethane foam and silicone liners tended to be stiffer in compression and shear than TPE liners. Polyurethane liners demonstrated low COF than other materials. Meanwhile silicone and TPE liners	Polyurethane liners are softer and less sticky than 16 years ago, and TPE liners have higher tensile stiffness than

				and thermal conductivities were tested on all materials.	exerted higher COF. Thermal conductivities of all materials were comparable.	previously. Compressive stiffness may be used to characterize liner's ability to flow.
15.	Thorax, pelvis and hip pattern in the frontal plane during walking in unilateral transtibial	(Molina-Rueda, 2014)	To find the thorax, pelvis, and hip kinematics and the hip internal moment in the frontal plane during gait for unilateral transtibial amputee.	A total of 25 unilateral transtibial amputee and 25 healthy (non-amputee) individuals as control subjects were recruited. Gait analysis was performed using the Vicon® Motion System.	The joint internal moment at the hip in the frontal plane for prosthetic side was lowered than on the sound side. Thorax and pelvis kinematics were altered during the stance phase	There were significant differences in gait analysis for prosthetic side and sound side.

	amputees: biomechanical analysis.				presumably because there are mechanisms which affect postural control during walking on the prosthetic side.	
16.	Qualitative study of prosthetic suspension systems on transtibial amputees' satisfaction and perceived	(Ali, 2012)	To investigate the effects of 3 dissimilar suspension systems on participants' satisfaction and perceived problems with their prostheses.	A total of 243 participants that using prostheses with polyethylene foam liner, silicone liner with shuttle lock, and seal-in liner were asked to answer a questionnaire survey.	There are significant differences between 3 groups regarding the degree of satisfaction and perceived problems with the prosthesis.	The results of the survey provide a good indication that prosthetic suspension is improved with the seal-in liner as compared

	problems with their prosthetic devices					with the polyethylene foam liner and silicone liner with shuttle lock.
17.	Quantification of prosthetic outcome: Elastomeric gel liner with locking suspension polyethylene foam liner with	(Coleman, 2004)	To study if increased ambulatory activity, wear time, comfort, and satisfaction would be found with the elastomeric suspension system	13 subjects completed the study. The subject is completed three questionnaires specific to prosthesis use and pain: The Prosthesis Evaluation Questionnaire (PEQ), a Brief Pain Inventory (BPI) excerpts,	10 subjects referred the Pelite and three the Alpha. Subjects spent 82% more time Wearing the Pelite and took 83% more steps per day.	No statistically significant differences were found in questionnaire results. Subject feedback for each system was

	neoprene sleeve suspension			and the Socket Comfort Score (SCS).		both positive and negative.
18.	Technique for perforating a prosthetic liner to expel sweat	(Caldwell, 2018)	To describe a simple, inexpensive technique for perforating a silicone prosthetic liner to expel sweat and enhance use of a lower limb prosthesis.	A liner holder consisting of a towel and socks layered over a mandrel to mimic the distal Liner shape was made to stabilise the liner during the perforation process. With the liner placed over the holder such that the exterior surface was exposed, a perforating	Expulsion of sweat through the perforations was demonstrated by pouring water into the liner, folding the proximal, open and of the liner to create a seal, and forcing water droplets to escape the perforated liner after the active wear.	Initial clinical experience with this technique suggested that expulsion of sweat occurred and user feedback indicated

				roller was used to perforate the distal end of the liner. When the liner was inverted, the holes were visible all the way through to the inner surface of the liner.		improved prosthesis use as a result. Current experience using this technique in clinical practice has been limited to silicon liners.
19.	The use of a satisfaction with prosthesis and quality of life in patients with combat related	(Demir, 2019)	To evaluate the prosthesis use, level of satisfaction, reported problems and quality of life in patients with	A total of 30 patients with 35 amputations were included. The survey collected data on basic demographics including age, time since amputation, gender, level of amputation,	The leading reasons for rejecting or dissatisfaction with the lower limb prosthesis were excessive perspiration, itching and pain.	Participants reported high levels of use and satisfaction with prosthesis, in spite of

	lower limb amputation, experience of a tertiary referral amputee clinic in Turkey.		combat related lower limb amputation.	daily prosthetic use frequency, daily total prostatic wearing time, satisfaction with prosthesis, causes of dissatisfaction.		excessive perspiration, itching and pain.
20.	Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect	(Klute, 2011)	To investigate the effect of a vacuum-assisted socket suspension system as compared with pin suspension on lower extremity amputees.	Two prostheses were fabricated for a total of 20 unilateral amputees. The participants were asked to perform a 30-minute walk on a treadmill and answered Prosthesis Evaluation Questionnaire (PEQ).	Activity levels and residual limb pistoning were significantly lower while wearing the vacuum-assisted socket suspension system than the pin suspension.	The VASS resulted in a better fitting socket as measured by pistoning of the residual limb.

	on fit, activity, and limb volume.					
21.	Regional differences in pain threshold and tolerance of the transtibial residual limb: including the effects of age	(Lee, 2005)	To compare pain threshold and pain tolerance of different regions of the residual limbs of amputees by the indentation method and to evaluate the interface pressure distribution and	A total of 8 transtibial amputees for indentation test and 1 for FE analysis.	The patellar tendon and distal of the fibula were the best and the worst load-tolerant regions, respectively.	Regions with a thicker layer of soft tissue did not have a higher load-tolerant ability than thin-skinned regions.

	and interface material		distortion of the skin surface on indentation by finite element (FE) analysis.			
22.	Internal mechanical conditions in the soft tissues of a residual limb of a transtibial amputee	(Portnoy, 2008)	To characterise the mechanical conditions in a muscle flap of a transtibial amputee patient during static load bearing,	The pressure-sensing mats were placed between the prosthetic socket and residual limb to obtain static interface pressure diagram.	There were strain and stress concentrations in the flap under the tibial end.	The approach is adequate for characterising internal strains/stresses in residual limbs, and that its contribution in understanding

						pressure ulcers, and flap necrosis etiologies is significant.

CHAPTER 3: METHODOLOGY

This chapter will explain in detail about the methods and procedures being carried out in this study. First, a survey was conducted on 50 transtibial users. Questions regarding the users' satisfaction and usage of the prosthesis were asked in the survey. Next, material testing procedures are explained in this chapter. The material testing is carried out by using Precision Universal Tester AGS-X (Shimadzu Corporation, Kyoto, Japan). There were four different materials tested in this study and will be discussed further in this chapter. The information of the ethics and the subjects are also presented. Furthermore, the process of manufacturing transtibial prosthesis with Pelite liner and modified liner using polyurethane foam is explained precisely. In addition, at the end of this chapter, the procedure of biomechanical gait analysis using Vicon Motion Analysis System is explained.

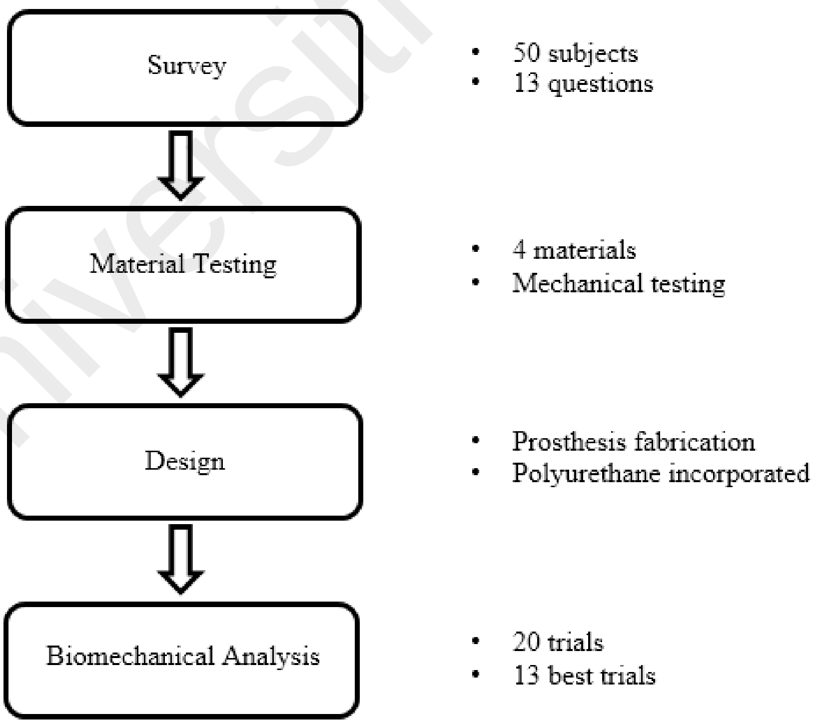

Figure 3.1 Methodology flowchart

3.1 Users' feedback

3.1.1 Subject recruitment

This study included 50 transtibial amputees (29 males, 21 females; mean age 55.4±14.7 years; range 18 to 78 years). The respondents were randomly chosen from University Malaya Medical Centre. The study required the respondents to meet certain criteria to be considered as respondents for the study. The study was conducted under the supervision of the Certified Prosthetics and Orthotics (CPO) of the International Society of Prosthetics and Orthotics (ISPO) Category 2.

The 50 respondents were randomly selected from all ages and genders, regardless of left or right amputation side. The selection was made only after the participants met the following criteria: transtibial amputee and were able to communicate efficiently. The survey was done in the duration of 6 months.

3.1.2 Questionnaire

Data were collected using a set of questionnaires which were filled in by the respondents. The types of information included in the questionnaire was demographic data (age and sex) (Refer Appendix A for the set of questionnaires).

The second part of the questionnaire consisted of information about the respondents' usage of the prosthesis. The first question is on the number of prostheses the respondents had worn after the amputation. The second question asked on the duration in terms of years that the respondents had worn their current prosthesis. Next, was the question on the duration that the respondents wear the prosthesis in a day. Other questions that were asked include the type of liners the respondents currently used and had used previously.

In addition, the respondents were also asked about the pain or discomfort experienced while using the prosthesis. After that, the respondents were asked to choose the area at the residual limb that they experienced pain or discomfort The areas are (A) the patellar tendon bearing, (B) the end of the residual limb, (C) the fibula head, (D) the suprapatellar, and (E) the medial and lateral parts of the residual limb. The areas were chosen after verbal interview with the transtibial prosthesis user.

Then, the respondents were asked of any complains and future recommendations about the prosthesis. Finally, the respondents were required to rate the prosthesis from a scale of 1–5, where 1 is very poor and 5 is very good.

3.2 Mechanical testing

In this study, we performed compression and tensile test on 4 materials that can be used as prosthetic liner (Figure 3.2). The reason why tensile test were conducted is because tensile force occurs when the user take out the prosthethic liner from the socket One of the materials is a combination of polyurethane foam and EVA foam.

Liner foam is made up of two EVA foam as outer sandwich and a polyurethane foam in the middle. They are attached together with glue. All materials were tested three times and the average values from the tests were recorded.

3.2.1 Compression testing

The applicable test procedures for polymers, i.e., plastics and foamed rubbers have been reviewed and published by the American Society for Testing and Materials (ASTM). The following procedure is an amended version of the Compression Deflection Test described in ASTM D1667-70 (Campbell, 1982).

Round shaped specimen with thickness from 6.30 mm to 12.50 mm and with diameters from 13.0 mm to 29.0 mm are recommended by ASTM standards D94521 and D614722.

Limb-socket normal stresses were often reported; therefore, a strain limit that involved reported studies on the value of stress for liner products that are clinically available was required. Pelite foam liners were reported in past studies to have 100 kPa mean pressures with maximum up to 200 kPa.

3.2.2 Tensile testing

The sample was prepared in the shape of a dumbbell (shown in Figure 3.2) as recommended in ASTM standard test number D412-98a-Die C, "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension". For each material, three samples were prepared and tested. Both ends of the samples were held with stainless steel clamps that gave out consistent force. In ASTM D412, specimen geometry of 3.00–12.00 mm for width and of 33.00–59.00 mm for length were used to limit the concentration of stress effects. Therefore, the size of the sample for this test were prepared with 4.0 mm in width and 40 mm in length. The speed rate of the test is 5 mm/min. The test was carried out under the same conditions for all materials.

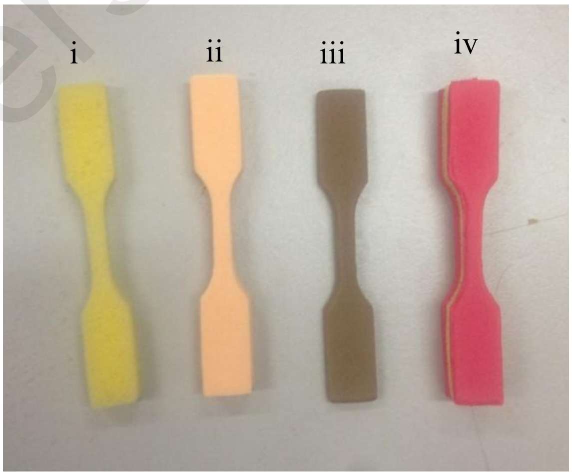

Figure 3.2 Material used for the study; i- Polyurethane Foam (PU foam), ii-Pelite, iii- Ethylene-vinyl acetate (EVA) and iv- Liner Foam (PU+EVA+PU)

3.3 Ethics approval and consent

This research is conducted with the approval of National Medical Research Register Secretariat 37912 and under the guidance of Certified Prosthetist and Orthotist (CPO) of International Society of Prosthetics and Orthotics (ISPO) Category 2.

3.4 Subject recruitment

Four left unilateral transtibial amputees were recruited in this study. The reason for choosing only four subjects is because this is a pilot study that focusing on whether the liner is suitable for user to use. Informed written approval was obtained from the subjects. The inclusion criteria of the subjects are minimum 10 cm residual limb, no serious skin conditions (i.e., no visible wound and ulcers in the residual limb), no drastic volume changes, and the ability to walk without the use of assistive devices. The reason for minimum 10 cm residual limb length is because shorter than that is considered very short, usually a transtibial amputee with short residual limb requires additional suspension. It was also a requirement that the subjects are experienced prosthetic users (more than 6 months). The subjects' condition was assessed by the Certified Prosthetist and Orthotist.

3.5 Prosthesis user information

3.5.1 Subject 1

The prosthesis user is a 25-year-old male and a left unilateral transtibial amputee. The prosthesis user has a height of 162 cm and weight of 55 kg. He was amputated in 2012 due to motor vehicle accident. He works at a call centre and is fully independent. The prosthesis user is able to drive a car and ride a motorcycle.

The residual limb of the prosthesis user is in good condition. There is no red rash on the skin. The residual limb has good sensation and have no phantom pain. The length of the residual limb is classified as a medium stump.

His knee has a full range of motion, there is no contracture. The manual muscle testing score is 5 for the knee. He has a K-level of 4.

3.5.2 Subject 2

Subject 2 is a 37-year-old male and a left unilateral transtibial amputee. The prosthesis user has a height of 170 cm and weight of 95 kg. He was amputated in 2014 due to tibia bone cancer. He works as an engineer and is fully independent. He is able to drive a car independently.

His residual limb is in good condition. There is no red rash on the skin. The residual limb has good sensation and have no phantom pain. The length of the residual limb is classified as a short stump.

Subject 2 has a full range of motion knee joint, there is no contracture. The manual muscle testing score is 4 for the knee. He has a K-level of 4.

3.5.3 Subject 3

The prosthesis user is a 42-year-old female and a left unilateral transtibial amputee. The prosthesis user has a height of 159 cm and weight of 57 kg. She was amputated in 2009 due to motor vehicle accident. She is a housewife and fully independent.

Her residual limb for the prosthesis use is in good condition. There is no red rash on the skin. The residual limb has good sensation and have no phantom pain. The length of the residual limb is classified as a short stump.

Her knee has a full range of motion, there is no contracture. The manual muscle testing score is 4 for the knee. She has a K-level of 4.

3.5.4 Subject 4

Subject 4 is a 30-year-old female and a left unilateral transtibial amputee. The prosthesis user has a height of 165 cm and weight of 63 kg. She was amputated in 2012 due to motor vehicle accident. She is an office clerk and fully independent. The prosthesis user is able to drive a car and ride a motorcycle.

The residual limb of the prosthesis user is in good condition. There is no red rash on the skin. The residual limb has good sensation and have no phantom pain. The length of the residual limb is classified as a medium stump.

Her knee has a full range of motion, there is no contracture. The manual muscle testing score is 5 for the knee. She has a K-level of 4.

3.5.5 Subjects summary

Table 3.1 Subjects' information

Parameters	Age (years)	Height (cm)	Weight (kg)	Residual limb length (cm)
Subject 1	25	162	55	17
Subject 2	37	170	95	10
Subject 3	42	159	57	11
Subject 4	30	165	63	15

Table 3.2 Descriptions for the Medicare functional classification level

K level	Description
K0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility
K1	Has the ability or potential to use a prosthesis for transfer or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2	Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4	Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.

(Adapted from: Orendurff, M. S., Raschke, S. U., Winder, L., Moe, D., Boone, D. A., & Kobayashi, T. (2016). Functional level assessment of individuals with transtibial limb loss: evaluation in the clinical setting versus objective community ambulatory activity. *Journal of Rehabilitation and Assistive Technologies Engineering*, *3*, 2055668316636316.)

3.6 Prosthetic intervention

A total of two transtibial prostheses made up with two different liners which are Pelite liner and modified liner using polyurethane foam were fabricated for each subject. Both prostheses were made with identical types of components. In addition, both prostheses were fabricated by the same prosthetist to avoid any alterations due to manufacturing, alignment and fitting.

First, the subject's residual limb was wrapped with cling wrap. All landmarks and bony prominences were marked with indelible pencil and all measurements were recorded accurately. Plaster of Paris (POP) bandages were soaked in water and wrapped on the subject's residual limb. The POP bandages were massaged to capture the contour of the residual limb. The cast was removed from the residual limb once it dried. All marks were refreshed using an indelible pencil and filled with POP slush. The negative cast was removed, and recommended modifications were done on the positive model. Then, the Pelite liner was fabricated onto the positive model and polypropylene plastic was draped onto it. The procedure was repeated for the liner with modification. The anterior-distal part of the liner was added with the EVA-polyurethane-EVA sandwich as shown in Figure 3.8. The polyurethane and EVA sheets were first cut into the cut-outs. Then, the cut-outs were assembled into a sandwich as in Figure 3.7 and glued together. Finally, the sandwich was placed at the anterodistal part of the positive model as shown in Figure 3.8 before the Pelite draping process. All components were assembled together to make 2 prostheses.

3.6.1 Casting

Casting is the process of taking the impression or the shape of the residual limb. Plaster of Paris bandages are usually used as a medium in this process. Before casting was done, the tools and materials such as measuring tape, calliper, cling wrap, indelible pencil, scissors, knife, cutting tube, a bucket of water, and Plaster of Paris (POP) bandages were prepared. The subject was let to sit comfortably on the casting bench throughout the casting process. The subject's residual limb was wrapped with cling wrap so that the subject is clean after the casting process. The landmarks and bony prominences on the subject's residual limb were drawn using an indelible pencil, as shown Figure 3.3. All required measurements were taken using measuring tape and body callipers and recorded. A cutting tube was placed superior to the patellar to help during cast removal after the casting process.

After the preparation was done, the POP bandage was soaked in a bucket of water. The subject's residual limb was positioned with 15° flexion to give pre-contraction to the quadricep muscle when the subject is donning the prosthesis. Then the subject's residual limb is wrapped with the soaked POP bandages. The POP bandage is massaged onto the limb to capture the shape of the residual limb and make sure the position is correct. Light pressure is applied on the patellar tendon using both thumbs. In addition, pressure is applied using the middle and ring fingers to the popliteal area. The negative cast is left to dry and harden before doffing it from the subject's residual limb. The negative cast is carefully doffed from the residual limb. The holes on the negative cast is covered, if any.

A. Outline of the patella.
B. Middle of the patellar tendon – mark with a horizontal line midway between the distal pole of the patella and the superior border of the tibial tubercle.
C. Outline the head of the fibula.
D. Anterior border of the tibia (tibial crest).
E. Medial border of the tibia.
F. Outline the anterior distal end of the tibia.
G. Outline the distal end of the fibula.
H. The inferior border of the medial flare of the tibial condyle.
I. The inferior border of the lateral flare of the tibial condyle.
J. The femoral epicondyles

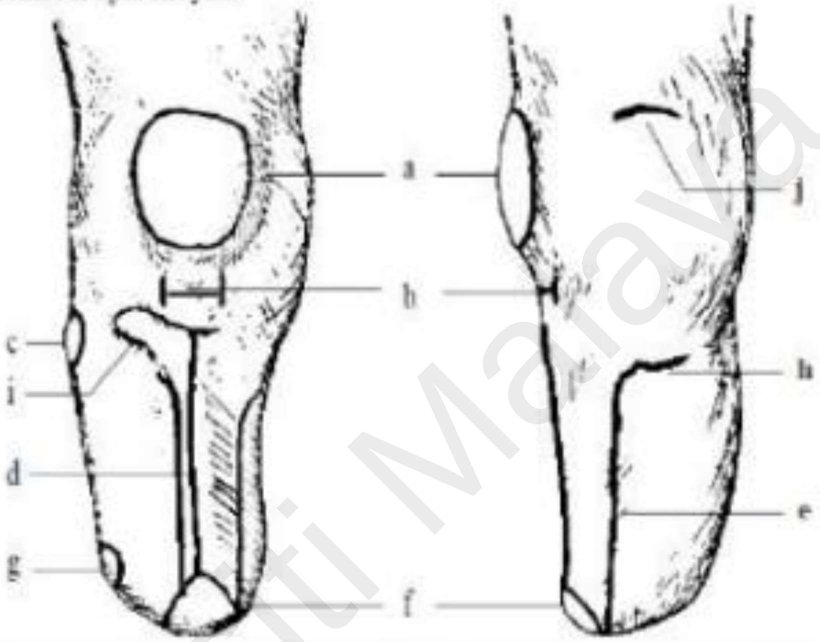

Figure 3.3 Landmarks on residual limb

Figure 3.4 Negative cast on subject's residual limb

3.6.2 Rectification

The next process is rectification, where the positive model is rectified according to the required shape. Before rectification, the landmarks in the negative cast were refreshed using the indelible pencil. The negative cast was reinforced by wrapping it with more layers at the required part. The negative cast was rinsed with soapy water so that it will be easier to remove it from the positive model. There should be no leaks on the negative cast. A mixture of POP powder and water or POP slush was poured into the negative cast. While the slush is still soft, a metal pole with 5° flexion is placed inside. The metal pole must not touch the wall of the negative cast by holding it while the mixture was setting. After the slush was set, the negative cast was removed from the positive model. The landmarks were refreshed using an indelible pencil on the positive model and the measurements were measured.

The rough surface of the positive model was smoothed using half round Surform and the patellar tendon, supracondylar, and popliteal areas are reduced by 0.5 cm. The distal part of the positive model was shaped into a triangular shape to prevent rotation of the prosthetic leg when the subject is ambulating with it. After the rectifications were done, the positive model is measured and compared to the residual limb measurements. Then, the surface of the positive model was smoothed using wire mesh. The measurements of the positive model were measured and recorded.

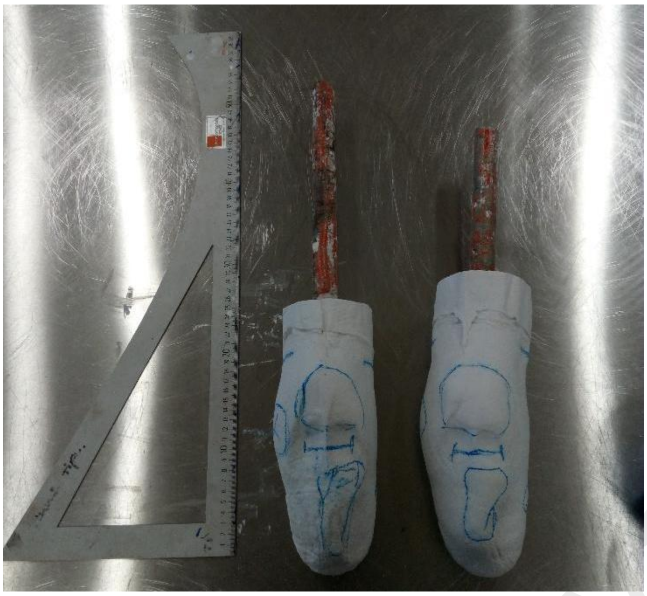

Figure 3.5 Positive models

3.6.3 Moulding

After the positive model is smoothed, it is placed on the draping bench. The Pelite foam is cut as shown in Figure 3.6. Then, the edges of the Pelite foam were ground using a router machine. Contact glue was put on the edges and the Pelite foam was placed in the oven at 80 °C. The Pelite foam is taken out after 2 minutes and the edges were combined together. Next, the Pelite foam was put back into the oven. After 2 minutes, the Pelite foam was taken out and draped over the positive model. A bandage was quickly wrapped over to ensure the Pelite foam follows the shape of the positive model. An end cap is made and glued at the distal end of the model. Excess Pelite foam was ground using a router machine. The polypropylene plastic was placed between the metal frames that have been smeared with Vaseline. Then, put in the oven at a temperature of 180 °C. After the polypropylene sheet is ready (curved down), it was taken out of the oven and talcum powder was put on it. It is then put on the positive model. Then, the vacuum is turned on to suck out any air bubble between the polypropylene and the positive model. It is left to cool for 10 minutes before moving to another place.

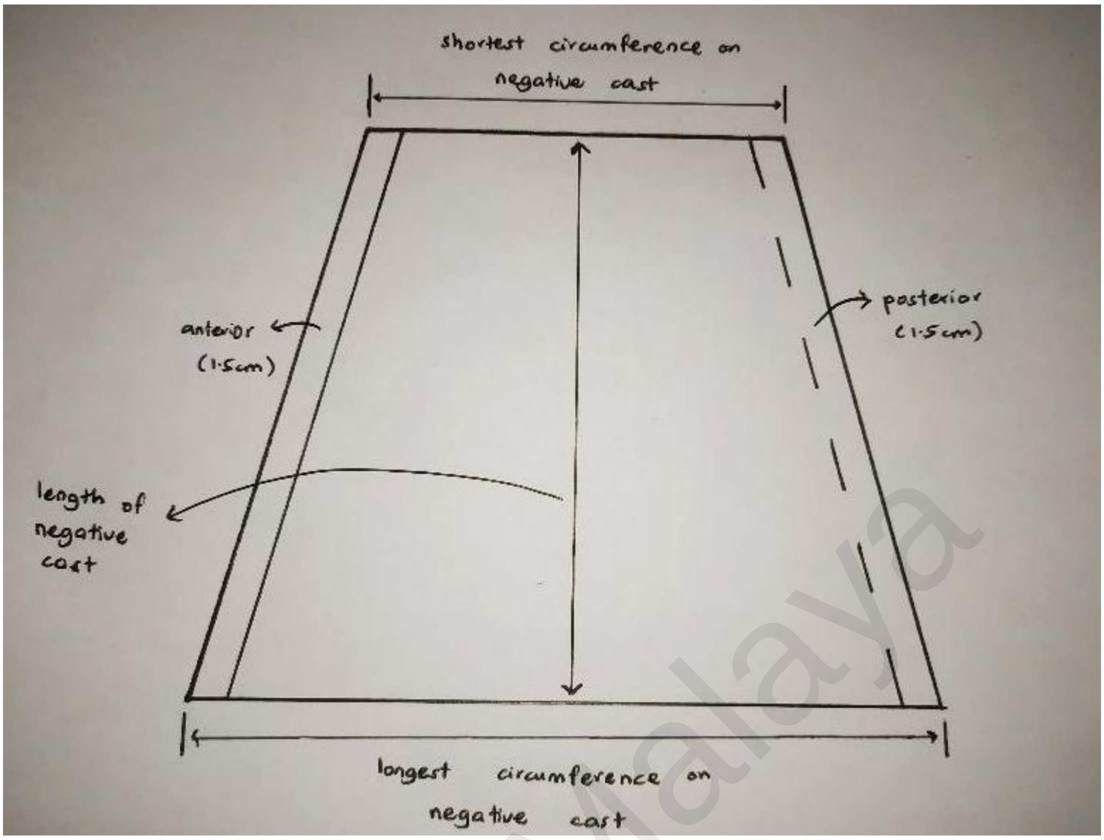

Figure 3.6 Pelite foam dimension

3.6.3.1 Modified liner

For the modified liner, the anterior distal part of the positive model was first measured. Then, two identical EVA sheets were cut based on the measurements of the anterior-distal part of the positive model. Next, one polyurethane foam is cut 1 cm smaller width wise and length wise from the EVA sheets. A sandwich is made with EVA sheets and polyurethane foam (EVA-polyurethane-EVA), then glued together, as shown in Figure 3.7**.** After the sandwich is glued, it is put on the anterior-distal part of the positive model and the edge is nailed to the model, as shown in Figure 3.8. The Pelite foam is cut as shown in Figure 3.5. Then the edges of the Pelite foam was ground using a router machine. Contact glue is put on the edges and the Pelite foam is placed in the oven at 80 °C. The Pelite foam is taken out after 2 minutes and the edges were combined together. Next, the Pelite foam was put back into the oven. After 2 minutes, the Pelite foam was taken out and draped over the positive model. A bandage is quickly wrapped over to make sure the Pelite foam follows the shape of the positive model. Make an end cap and glue it at the distal end of the model. Excess Pelite foam is ground using a router machine. The impression of the sandwich on the Pelite liner was cut. The edge was ground to make it smooth then the Pelite liner with the sandwich was glued. The polypropylene plastic was placed between the metal frames that have been smeared with Vaseline. Then, it is put in the oven at a temperature of 180 °C. After the polypropylene sheet is ready (curved down), it is taken out of the oven and talcum powder put on it. It is then put on the positive model. Then, the vacuum is turned on to suck out any air bubble between the polypropylene and the positive model. It is left to cool for 10 minutes before moving to another place.

Figure 3.7 EVA-polyurethane-EVA sandwich

Figure 3.8 Placement of EVA-polyurethane-EVA sandwich

3.6.4 Finishing

After the moulding process, let the cool down socket before handling it. The trim line was drawn on both the sockets. The sockets were cut using the cast cutter along the trim line. The excess polypropylene was disposed inside the appropriate bin. The trim line for both sockets were smoothed using a router machine so that it will not be rough and dangerous when the subject dons the sockets. Then, the socket was assembled with the rest of the components. A line along the PTB was made, followed by a perpendicular line to it, which is 60 % at the posterior part and 40 % at the anterior part. A 5° angle was measured from the perpendicular line and a line was made. A straight line on the anterior part that has been aligned using plump line was made. The prong is shaped based on the shape of the distal part or the socket. It is then aligned based on the line drawn on the socket. The holes were drilled on the socket when the prong is aligned. The prong and the socket were combined using bolts and nuts. The socket, pylon and prosthetic foot was then assembled. Bench alignment was applied on the prosthesis. The foot, pylon and the line on the anterior part of the socket should be straight. This bench alignment was done with 2 cm heel height.

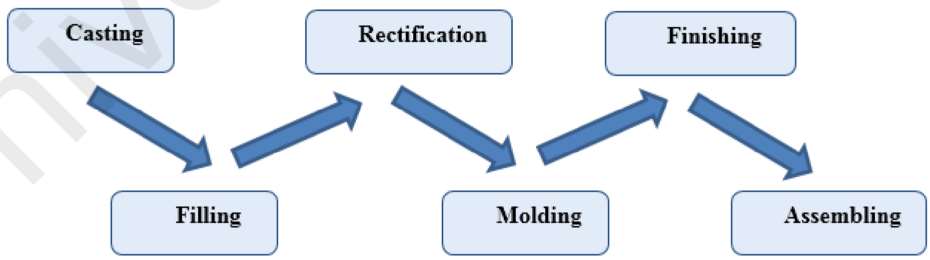

Figure 3.9 Transtibial Prosthesis Production Flow

3.7 Vicon Motion Analysis System procedure (biomechanics experimental setup)

The biomechanical analysis was conducted using the Vicon Motion Analysis System (Vicon, United Kingdom), which has an accuracy level of less than ±0.1 mm. The system works by capturing the motion of the subject doing numerous activities such as walking, running and jumping. The usage of this system provided more reliable and accurate results (Gholizadeh et al., 2012). There were five MX T40-S cameras used to capture the video of the activities. Two force plates were embedded in the middle of the capture volume using the Kistler 9821C force plate technology (USA) with a frequency of 1000 Hz. Force plates recorded ground reaction forces when the subject walked on it. However, for the data on moments and powers, the forces need to be calculated through inverse dynamic analyses. The subject was required to walk 8 meters with both prostheses in the gait analysis laboratory under the supervision of the prosthetist. The system used for biomechanical analysis was Vicon Nexus 1.8.5 Motion Analysis System. First, the system was set up and the required calibrating process was done. For the calibrating process, T stick was waved across the area and captured by the camera. This process is necessary to ensure all markers on the subject are captured during the experiment (Ali, 2015). The details of the subject such as the width of the left and right ankle, and the width of the left and right knee were measured using a body calliper. The length of the residual limb was measured using a measuring tape. All the measured parameters, the height and the weight of the subject were recorded in the system software. The subject was attached with 16 reflectors on his lower limbs both left and right such as the anterior superior iliac spine, posterior superior iliac spine, thigh, calf, head of the tibia, second toe, heel and the lateral malleolus following the Helen Hayes marker set (Staros, 1988). The subject was asked to walk at his preferred constant speed with standardized footwear (sport shoes), which was monitored through the Vicon Motion Analysis System from one point to another with the requirement that both feet step on the force plates separately using three different liners: the Pelite liner, the modified liner and his original liner. The activity was repeated 20 times for each liner with resting period after every 4 times. The sampling rate chosen for the data collection was 100 Hz. The signals from the motion analysis system were filtered by a Butterworth filter with the cut-off frequency of 10 Hz. Figure 3.10 shows the bird-eye's view of the cameras and force plate setupl. The gait analysis data were recorded and analysed using Microsoft Excel. All subjects were fitted with standardized and identical parts of prosthetic components, as an example all of them were fitted with SACH foot during the experiment.

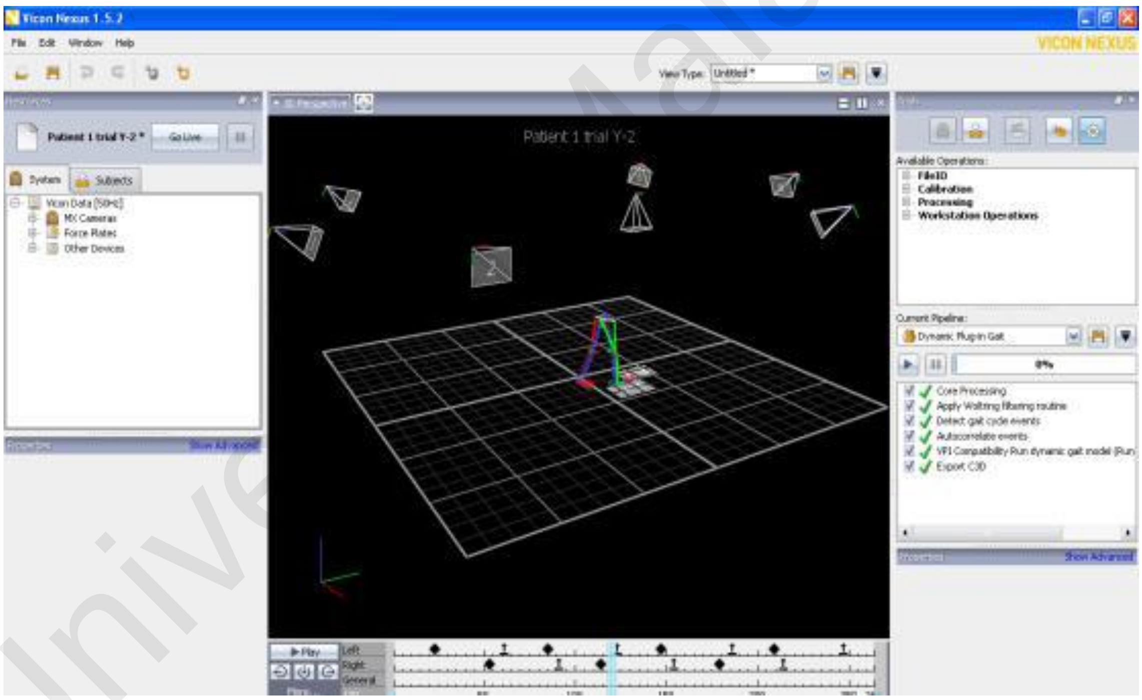

Figure 3.10 Bird-eye's view of the cameras and force plates setup

CHAPTER 4: RESULTS AND DISCUSSION

In this chapter, the results for prosthesis user feedback, material testing, designing liner using polyurethane foam and comparison of biomechanics using Pelite liner and modified liner using polyurethane foam were discussed thoroughly.

4.1 Prosthesis user feedback

The respondents chosen are transtibial prosthesis users with different demographics and characteristics. The majority of the respondents are first time users and 69 % of Pelite liner users and 58 % of silicone liner users. As shown in Table 4.1, two of the silicone liner users have used 5 transtibial prostheses within 20 years, while the others were second and third time users. None of the respondents were forth times users.

Table 4.1 Information about prosthesis usage comparing Pelite liner and silicone liner users in term of number of prosthesis used

Number of prosthesis used	Pelite	Silicone
1	18 (36%)	14 (28%)
2	6 (12%)	7 (14%)
3	2 (4%)	1 (2%)
4	0 (0%)	0 (0%)
5	0 (0%)	2 (4%)

Table 4.2 Information about prosthesis usage comparing Pelite liner and silicone liner users in term of period of using the prosthesis after amputation

Period of using the prosthesis after amputation (year)	Pelite	Silicone
< 1	9 (18%)	5 (10%)
1	6 (12%)	10 (20%)
2	2 (4%)	5 (10%)
3	0 (0%)	1 (2%)
> 3	9 (18%)	3 (6%)

Typically, a transtibial prosthesis user usually wears the prosthesis for a maximum of 3 years prior to changing into a new one. Based on the data obtained in Table 4.2, most of the respondents have used their prostheses for one year. However, only one respondent used the prosthesis for 3 years.

Table 4.3 Information about prosthesis usage comparing Pelite liner and silicone liner users in term of prosthesis wearing duration in a day

Prosthesis wearing duration in a day (hour)	Pelite	Silicone
< 4	1 (2%)	1 (2%)
4 to 6	2 (4%)	2 (4%)
6 to 8	8 (16%)	6 (12%)
> 8	15 (30%)	15 (30%)

Based on Table 4.3, 60 % of respondents used their prostheses more than 8 hours in a day to conduct their daily activities with both Pelite liner and silicone liner users showing 30 % each. Only 2 respondents used their prostheses less than 4 hours. This is more likely because they are first time prosthesis users. Longer periods of prosthesis use can lead to pain and discomfort on the residual limb.

A study by Caldwell et al. found that the temperature of the residual limb increases when the user is wearing the prosthesis causing moisture and sweat build-up inside the liner (Caldwell, 2017). In addition, Demir et al. reported that more than half of the subjects experienced excessive perspiration at the residual limb when using the prosthesis (Demir, 2019). The sweating and moisture build-up inside the liner can cause a major effect on user comfort and satisfaction. Based on previous literatures, Pelite liner users experienced less sweating compared to silicone liner users (Ali, 2014). This condition is similar to one of the silicone liner users in this study that complained about the sweat build-up in the liner and she had to doff the prosthesis regularly to remove the sweat. In

Table 4.4 Pain and discomfort experienced by the respondents

Variables		Pelite	Silicone
Pain	Yes	5 (10%)	3 (6%)
	No	21 (42%)	21 (42%)
Discomfort	Yes	8 (16%)	5 (10%)
	No	18 (36%)	19 (38%)

In this study, we gathered that the Pelite liner users experienced pain more statistically than silicone liner users. Based on the data obtained in Table 4.4, 10 % of Pelite liner users experienced pain while using the prosthesis. On the other hand, only 6% of silicone liner users experienced pain. The pain experienced by the user while using the prosthesis can be at various parts of the stump. In addition, we obtained that Pelite liner users experienced discomfort when using the prosthesis more than silicone liner users. A total of 16 % of Pelite liner users experienced discomfort and only 10 % of silicone liner users experienced discomfort while using the prosthesis.

Table 4.5 Rating of the prosthesis by the respondents

Rate	Pelite	Silicone
1	0 (0%)	0 (0%)
2	0 (0%)	0 (0%)
3	5 (10%)	3 (6%)
4	17 (34%)	12 (24%)
5	4 (8%)	9 (18%)

Furthermore, the respondents were asked to rate how comfortable the prosthesis is from 1 to 5. This study gathered that silicone liner users rated their prosthesis higher than Pelite liner users with 18 % of silicone liner users giving a rating of 5 for their prosthesis compared to only 8 % of Pelite liner users, as shown in Table 4.5.

A prosthesis should serve the function well but at the same time, provide comfort to the user since it will be worn most of the time in a day. Sometimes, comfort could affect the function as well, when the user feels uncomfortable or pain, they will not wear the prosthesis. Prosthetic satisfaction is a multifactorial issue (Ali, 2012 & Gholizadeh, 2018). These aspects mainly include prosthetic alignment, prosthetic components, prosthetist's skills, residual limb condition, level of activity, and socket fit (Ali, 2012).

Two types of liners discussed in this study are the Pelite liner and silicone liner. Pelite foam is a polyethylene closed cell foam that is widely used as a prosthetic liner

(Sanders, 1994). Pelite is usually prescribed to a patient that have water retention due to vascular disease. The residual limb of the user will fluctuate in size throughout the day. By using Pelite liners, the user can add stump socks when the residual limb shrinks. On the other hand, silicone liners are commonly prescribed to patients with bony prominences at the residual limb because of the soft nature of silicone that lessen the shear pressure on the skin (Bertels, 2011).

Pelite liners can last longer than silicone liners (Hawari, 2017). Based on the data obtained, silicone liner users tend to change their liner more frequently in a short period of time. In this study, two of the respondents that use silicone liners had changed their prosthesis within an average of 12 years. This means that one prosthesis was roughly used for 2.4 years, while the average of transtibial prosthesis is 3 years (Verhoeff, 1999). This shows that silicone liners are not as sustainable as Pelite liners. Plus, silicone liners cost more than Pelite liners (Edwards, 2000).

The wearing duration of the prosthesis is up to the transtibial prosthesis user. Most transtibial prosthesis users prefer to wear the prosthesis as maximum as they can since the function of the prosthesis is to replace the missing limb. Based on the study by Morlock et al., the average period of wearing the prosthesis is 12 hours a day (Morlock, 2001), but discomfort and pain can affect the wearing duration. When the user experiences discomfort or pain, they prefer not to wear the prosthesis which can affect their quality of life (Meulenbelt, 2006).

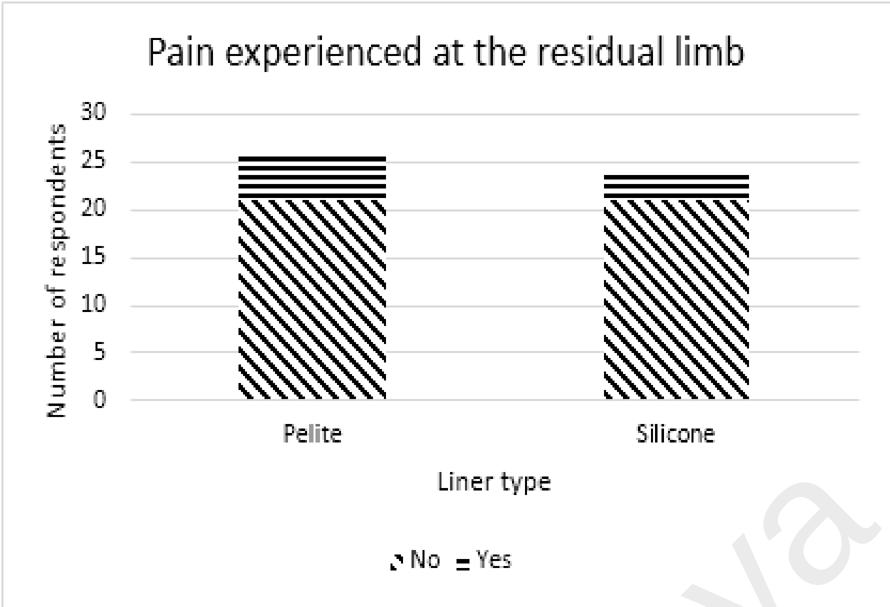

Figure 4.1 Pain experienced at the residual limb

The condition has significant impacts on the prosthesis users. Based on Figure 4.1, more Pelite liner users experienced pain at the residual limb than silicone liner users. The presence of pain at the distal part of the residual limb may prevent them from achieving optimum prosthesis usage. The reason for this is that pain disrupts the gait of the users which could lead to a number of complexities during walking, such as gait deviations (Caldwell, 2017 & Zhang, 1998).

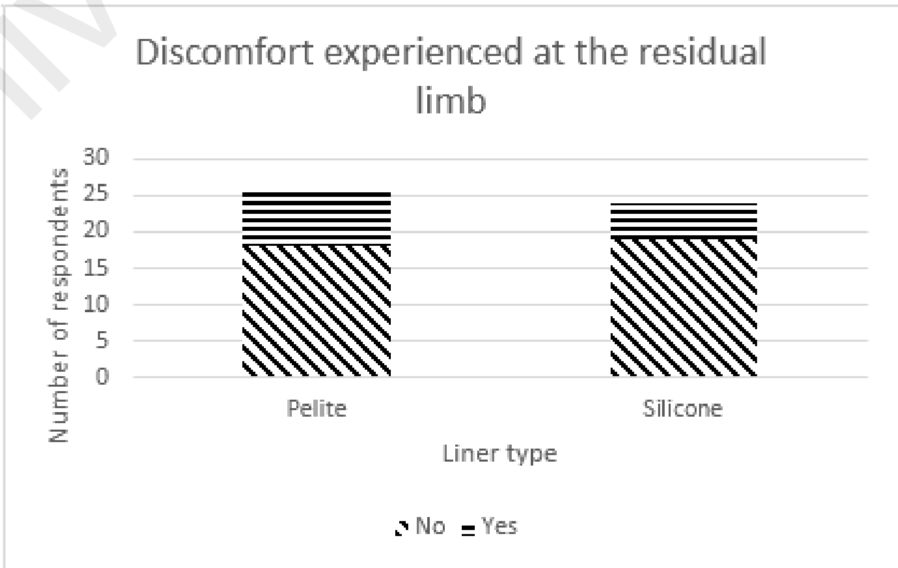

Figure 4.2 Discomfort experienced at the residual limb

Moreover, in this study we found that the majority of transtibial users experienced discomfort and pain at the end of the residual limb (Ali, 2014). The data in Figure 4.1 and Figure 4.2 show that Pelite liner users are more likely to experience pain and discomfort rather than silicone liner users. The pain and discomfort experienced are more likely due to the presence of tibia bone at the end of the residual limb (Dou, 2006 & Lin, 2004). When the user is donning and ambulating using the prosthesis, there will be pressure pushed at the end of the residual limb that can cause discomfort and pain. The prosthetist can reduce the discomfort and pain experienced by the user by prescribing softer material as the prosthetic liner (Coleman, 2004).

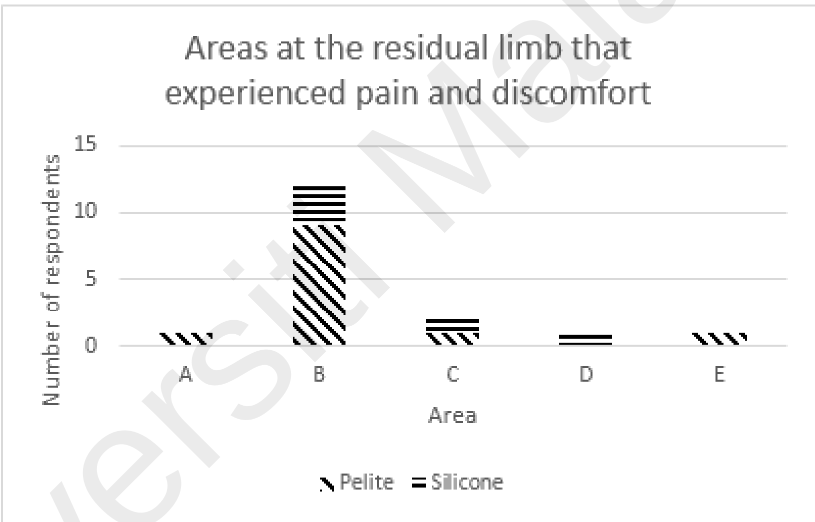

Figure 4.3 Areas at the residual limb that experienced pain and discomfort (A= patellar tendon, B= anterior-distal of residual limb, C= fibula head, D= supracondylar, E= medial and lateral part of the residual limb)

There are various areas in the residual limb that a prosthesis user experiences pain and discomfort. Based on Figure 4.3, the areas are the patellar tendon bearing, the end of the residual limb where the end of the tibia bone is located, the fibula head, the suprapatellar, the medial, and lateral parts of the residual limb. It is not abnormal for a transtibial prosthesis user to experience pain and discomfort in those areas. This is because the residual limb is not designed to bear weight as the sole of the foot. In addition, the end of the residual limb is more likely to experience pain and discomfort due to the presence of the tibia bone end. In fact, one of the respondents had to change his Pelite liner to silicone liner because he had blisters on the distal end of the residual limb. Based on Figure 4.3, most of the respondents from both the Pelite liner and silicone liner users experienced pain and discomfort at the end of the residual limb. But the pain and discomfort experienced by the users can be overcome by prescribing a suitable prosthetic liner (McGrath, 2019).

4.2 Material testing

Material testing is a measurement of the properties and behaviours of such substances as plastics, ceramics, or metals under various conditions. There are five major types of material testing: mechanical testing, electrical conductivity testing, thermal conductivity testing, corrosion resistance testing, and non-destructive testing (Hofer, 2018).

In this study, we focused on the mechanical properties of the materials. Two mechanical tests were carried out on the materials: compression test and tensile test. Table 4.6 below shows the mean thickness of the specimens tested. We tested the materials with their original thicknesses because that is the thickness used when fabricating a liner.

Table 4.6 Material and mean thickness of specimen tested

Material	Mean Thickness (SD)(mm)
Pelite (Polyethylene-Light)	6.22 (0.04)
EVA	3.22 (0.01)
Polyurethane Foam	6.10 (0.00)
Polyurethane and EVA Foam (Liner Foam)	11.87 (0.23)

4.2.1 Compression test

The stress-strain curve for compression test is shown in Figure 4.4. The highest stress exerted by the Pelite foam is 566.63 kPa at a strain rate of 60 %. Meanwhile, the lowest compressive stress achieved by PU Foam is 2.80 kPa. Liner foam shows a slightly lower value than the Pelite foam with 551.83 kPa. In addition, EVA shows intermediate compressibility with value of 377.47 kPa. EVA exerted the highest compressive test at the plateau phase and the lowest was exerted by the Pelite foam. At 10 % compression, the PU foam shows the lowest stress with 2 kPa while the highest is obtained by EVA with 147.47 kPa. The Pelite foam and liner foam achieved 111.06kPa and 122.99kPa of compressibility, respectively.

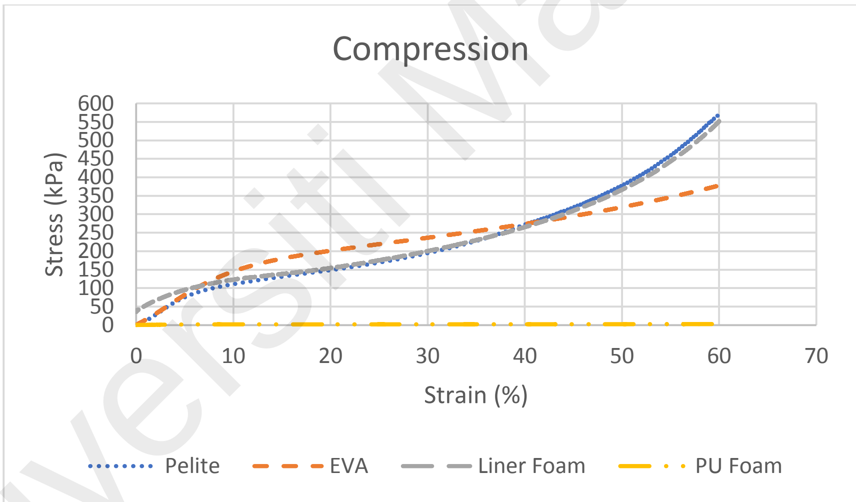

Figure 4.4 Compression test Stress-Strain curve

Compression testing is used to find the compressive force of certain materials and the ability of the material to recover after a specified compressive force. Based on the compression test held in this study, we found that the Pelite foam and liner foam are the strongest materials and have almost the same strength. EVA foam has an intermediate compressive strength compared to other materials while polyurethane foam has the weakest compressive strength. High compressive strength is good in fabrication of a prosthetic liner since it will need to be load bearing when the user is wearing it (Cagle, 2017).

4.2.2 Tensile test

The stress-strain curve for compression test is shown in Figure 4.5. The PU foam exerted the lowest stress among all materials in the compression test. On the other hand, liner foam and EVA achieved intermediate stress with 715.40 kPa and 811.59 kPa, respectively. At strain rate from 10 to 80 %, the stress for all materials increases linearly.

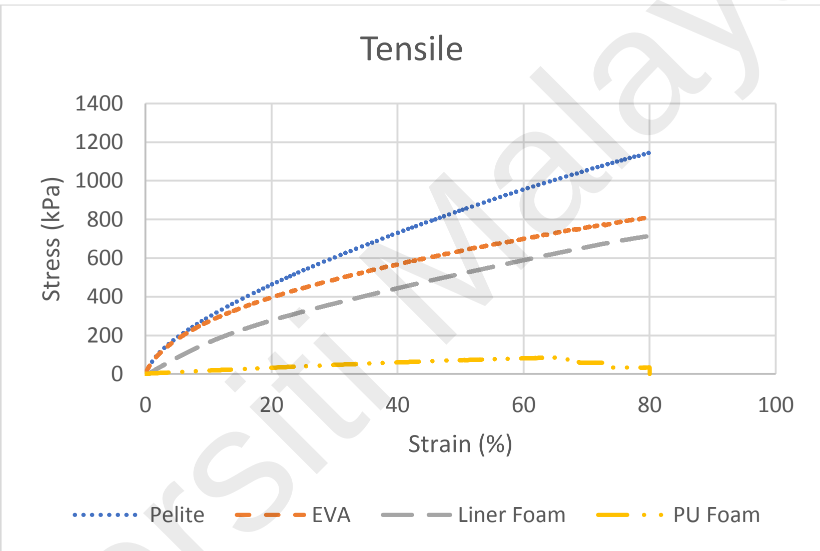

Figure 4.5 Tensile test Stress-Strain curve

Tensile test is carried out to measure the resistance of certain materials to a static or slowly applied force. The specimen of the material is placed in between the clamp of the testing machine and a pulling load is applied. The elongation of the material is measured using a strain gauge or extensometer (Cagle, 2018). Based on the test carried out in this study, we found that the Pelite foam has the strongest tensile strength among all materials, followed by EVA foam, liner foam and polyurethane foam.

4.3 Designing liner using polyurethane foam

Polyurethane foam is a softer material compared to the Pelite foam. In this study, we try to incorporate polyurethane foam in designing a prosthetic liner but paired with EVA foam. Specifically, polyurethane foam will be sandwiched between two EVA foams.

After producing the EVA-polyurethane-EVA sandwich, it was then placed at the anterior-distal part of the positive model, as shown in Figure 4.6. The user often complained that they experienced pressure that led to pain at the anterior-distal part of the residual limb when wearing the Pelite liner. So, in this study we placed the EVA-polyurethane-EVA sandwich at the anterior-distal part of the residual limb to compensate the pain sensation experienced by the user at the residual limb (Eshraghi, 2015). Then Pelite foam was draped onto the positive model with EVA-polyurethane-EVA sandwich. The part of the sandwich on the Pelite liner is cut off and the edge was glued together.

Figure 4.6 Prosthetic liner with polyurethane foam modification

4.4 Comparison of biomechanics when using Pelite liner and modified liner using polyurethane

The prosthetic liner with polyurethane modification was produced as shown in Figure 4.7. Biomechanical gait analysis was performed on each subject to determine whether the Pelite liner and modified liner using polyurethane foam affected the gait of the subject. Vicon Motion Analysis System was used in this study to perform the motion analysis experiment.

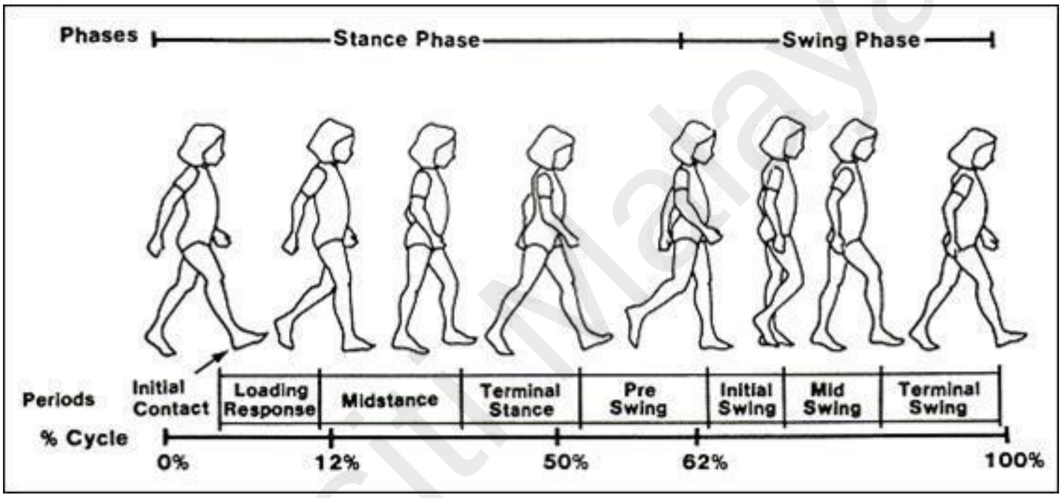

Figure 4.7 Gait cycle

4.4.1 Biomechanical analysis

The results obtained from the gait analysis experiment were analysed from 8 different graphs. The graphs generated were the ground reaction force for both left and right side of the body, right ankle angle, right ankle power, left knee angle, left knee power, right knee angle, and right knee power. For each graph, there were 3 different data plotted, the first one was the gait of the subject using Pelite (new) liner, followed by the gait of subjects using the modified liner and the gait of the subjects using their Pelite (original) liner. Pelite (new) liner is the liner that is fabricated for this study and Pelite (original) is the subject's current liner. The reason why we compare this two is because to check whether there is difference between them.

4.4.1.1 Subject 1

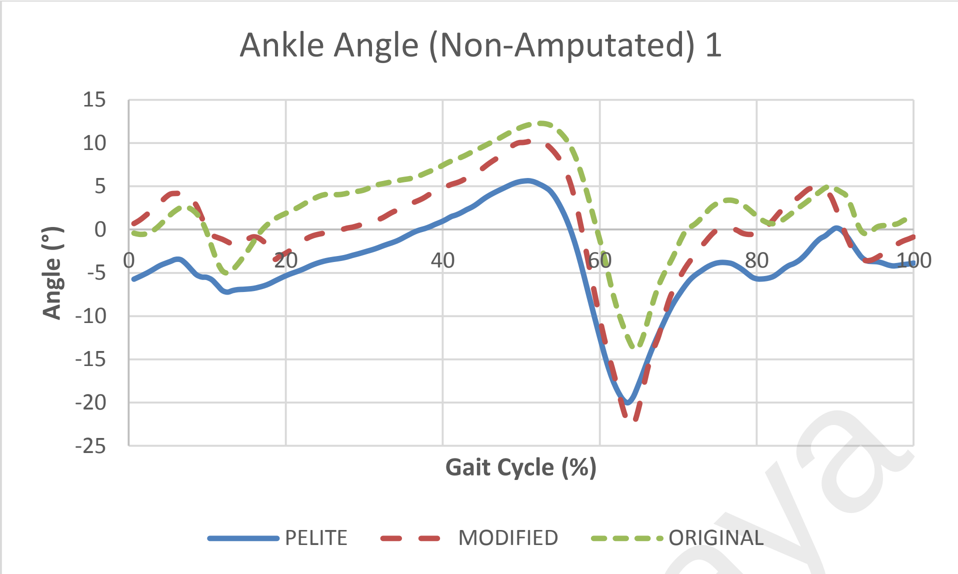

Figure 4.8 Subject 1 non-amputated ankle angle

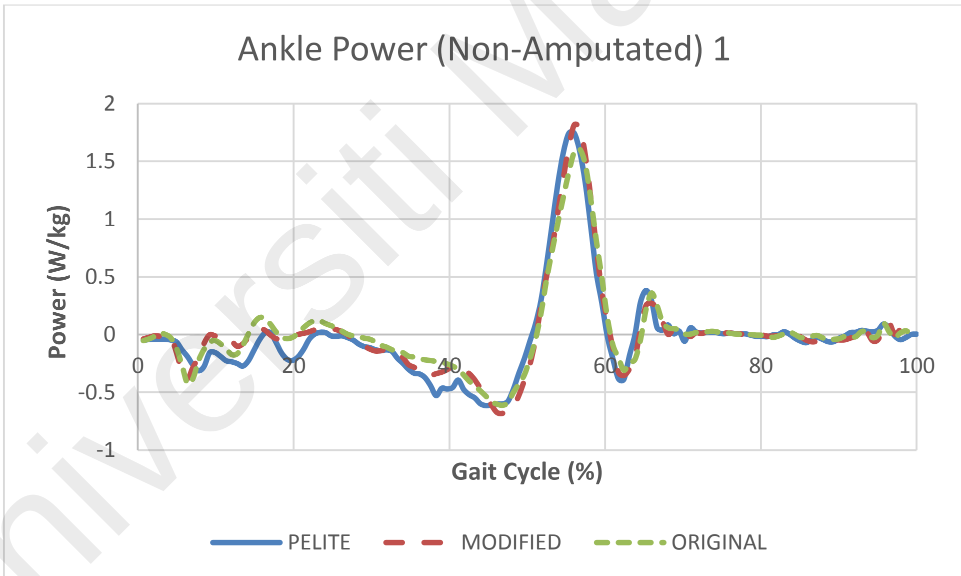

Figure 4.9 Subject 1 non-amputated ankle power

Based on the graph, the non-amputated ankle angle of subject 1 is different between all 3 liners. The Pelite (original) liner shows the highest ankle angle throughout the gait cycle, followed by the modified liner and the Pelite (new) liner. For non-amputated ankle power, there is no difference between all liners.

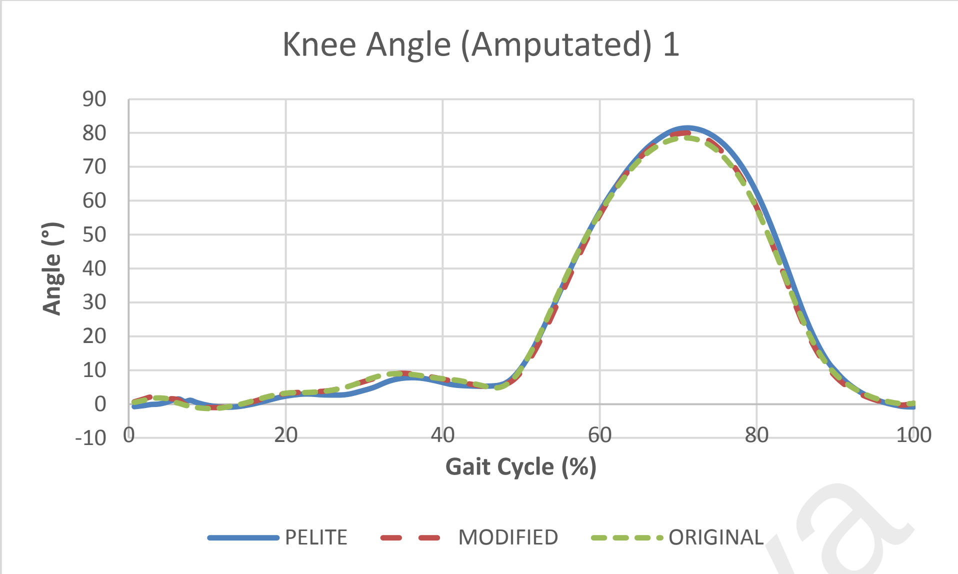

Figure 4.10 Subject 1 amputated knee angle

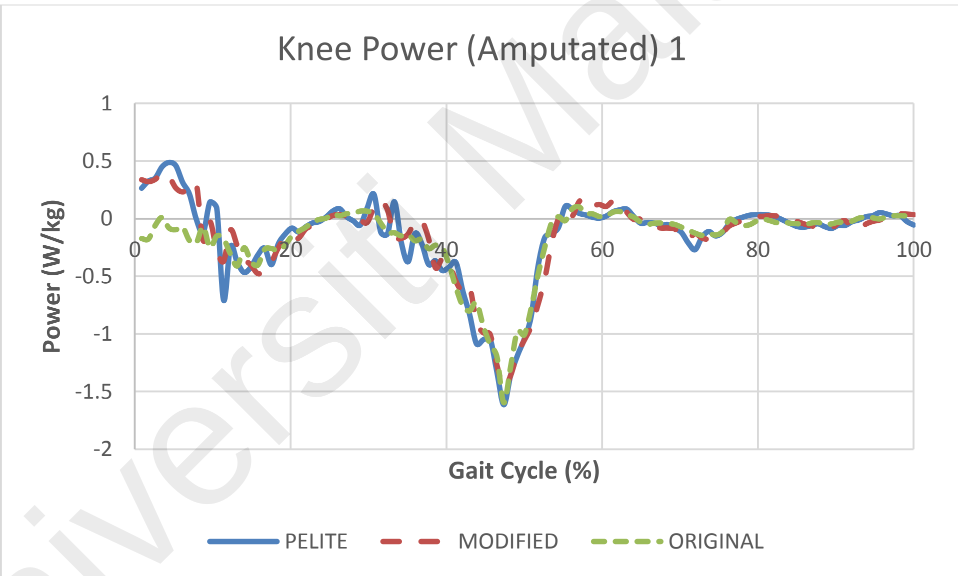

Figure 4.11 Subject 1 amputated knee power

Both knee angle and knee power for amputated side for subject 1 show no difference.

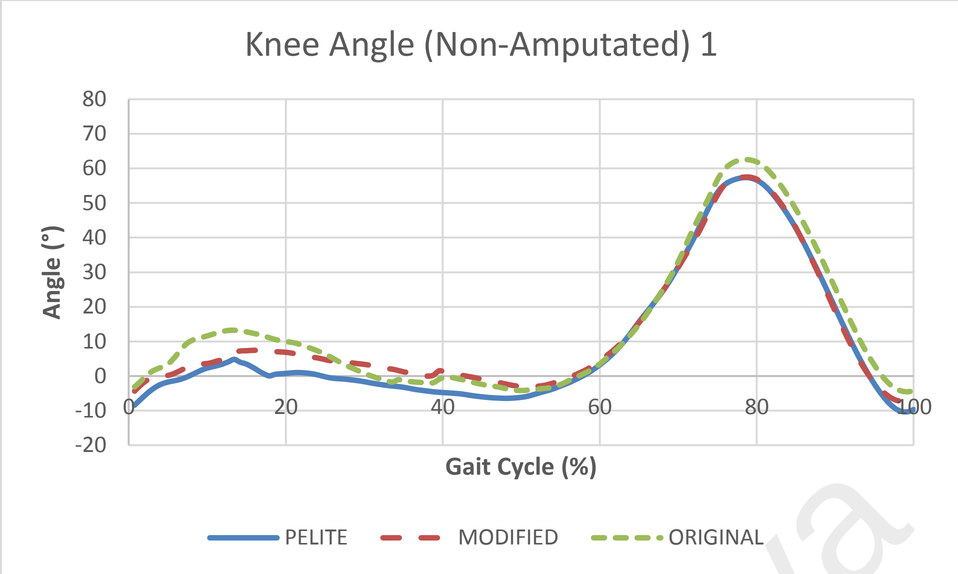

Figure 4.12 Subject 1 non-amputated knee angle

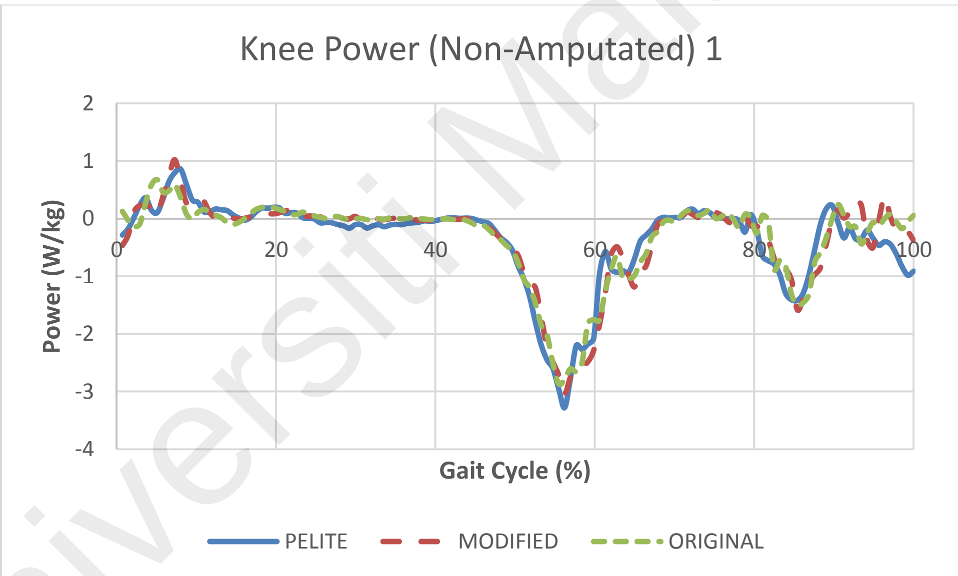

Figure 4.13 Subject 1 non-amputated knee power

For the non-amputated side of subject 1, the Pelite (original) liner shows higher knee angle than Pelite (new) and modified liner. However, there is no difference between all 3 liners.

4.4.1.2 Subject 2

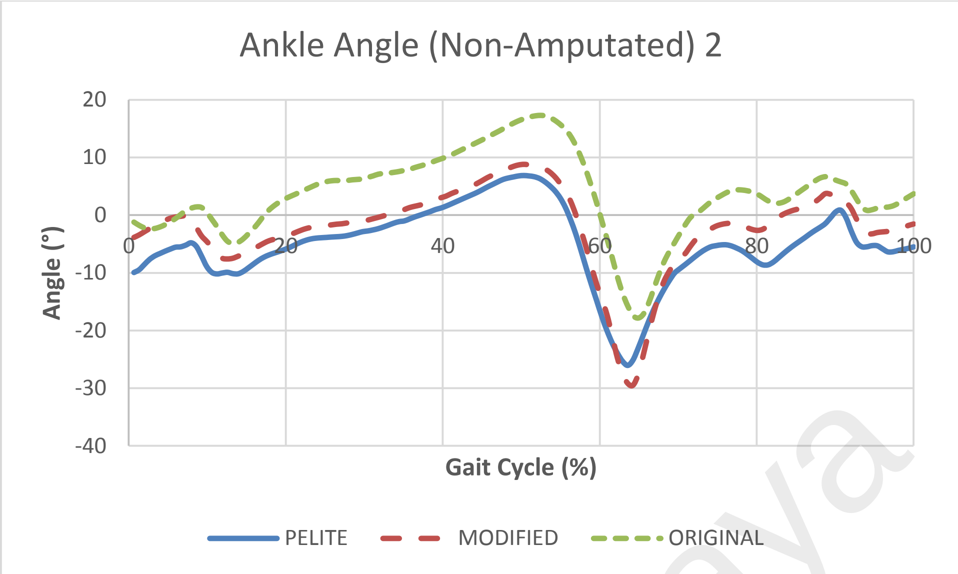

Figure 4.14 Subject 2 non-amputated ankle angle

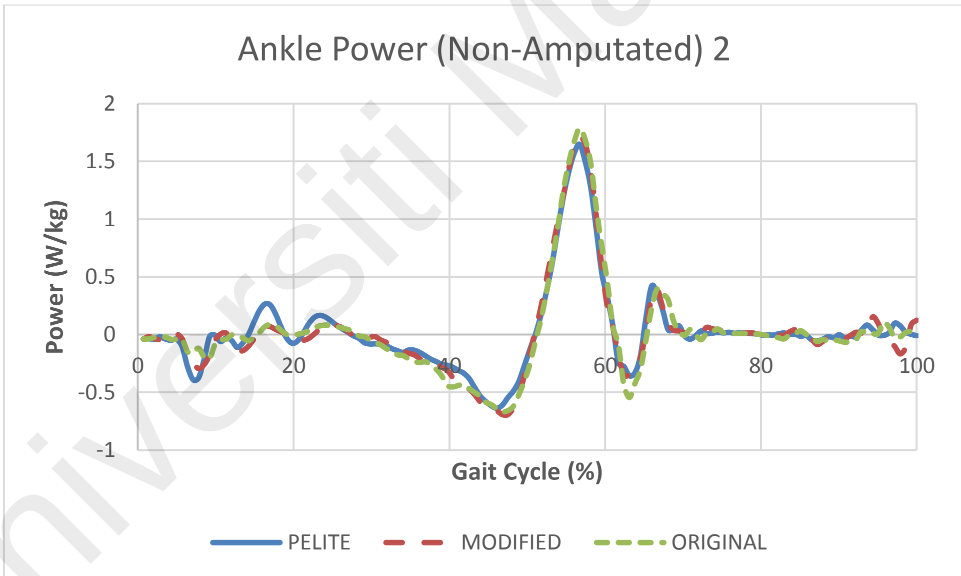

Figure 4.15 Subject 2 non-amputated ankle power

The graph shows that the non-amputated ankle angle of subject 2 is different between all 3 liners. The Pelite (original) liner shows the highest ankle angle throughout the gait cycle, followed by modified liner and Pelite (new) liner. For non-amputated ankle power, there is no difference between all liners.

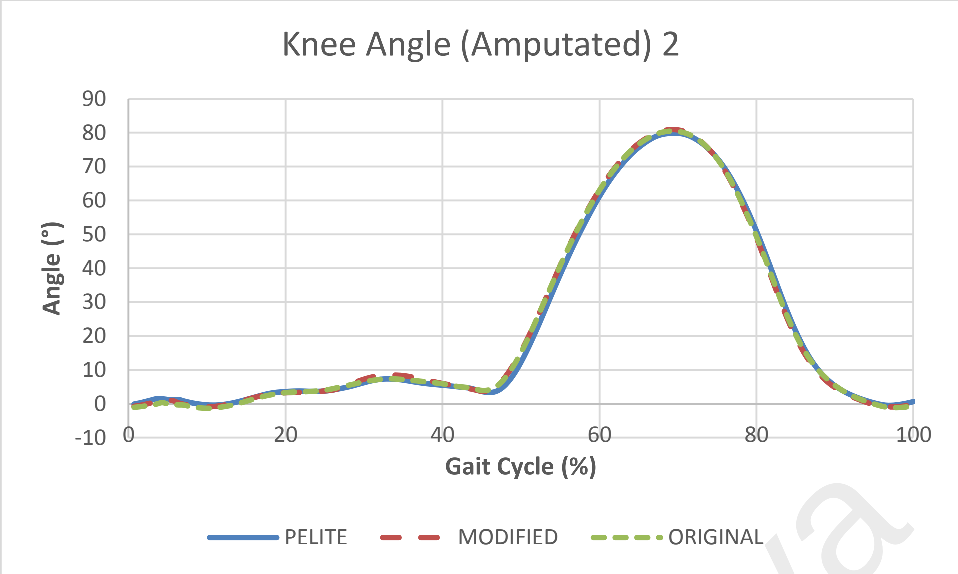

Figure 4.16 Subject 2 amputated knee angle

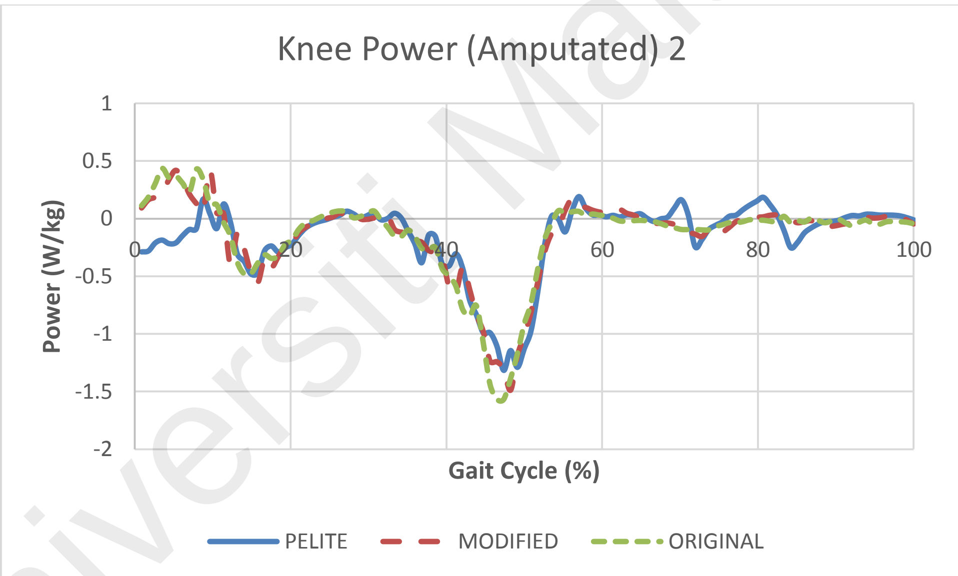

Figure 4.17 Subject 2 amputated knee angle

For the amputated side of subject 2, there is no difference for knee angle. Meanwhile for knee power, the Pelite (new) liner shows some differences at the beginning and at the 70–90 % of the gait cycle.

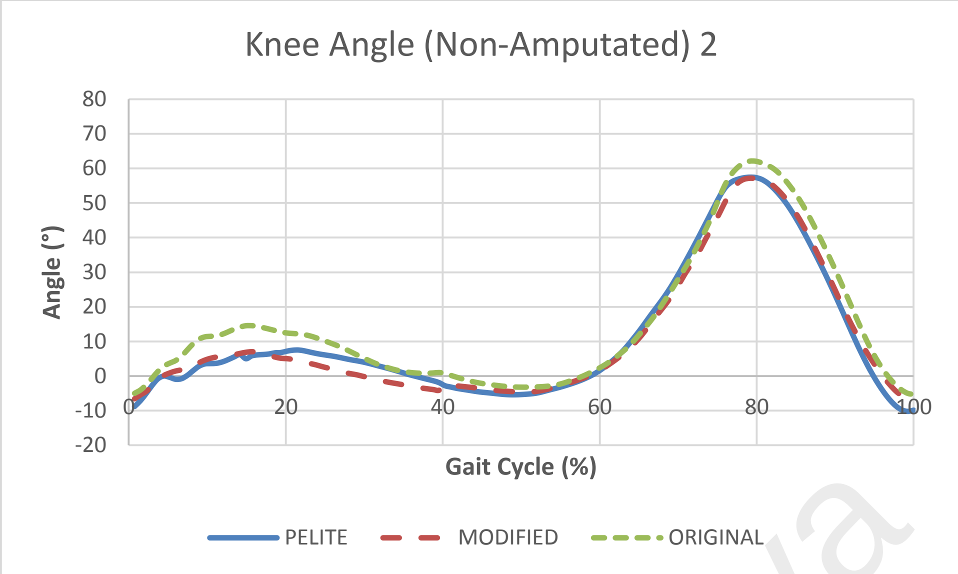

Figure 4.18 Subject 2 non-amputated knee angle

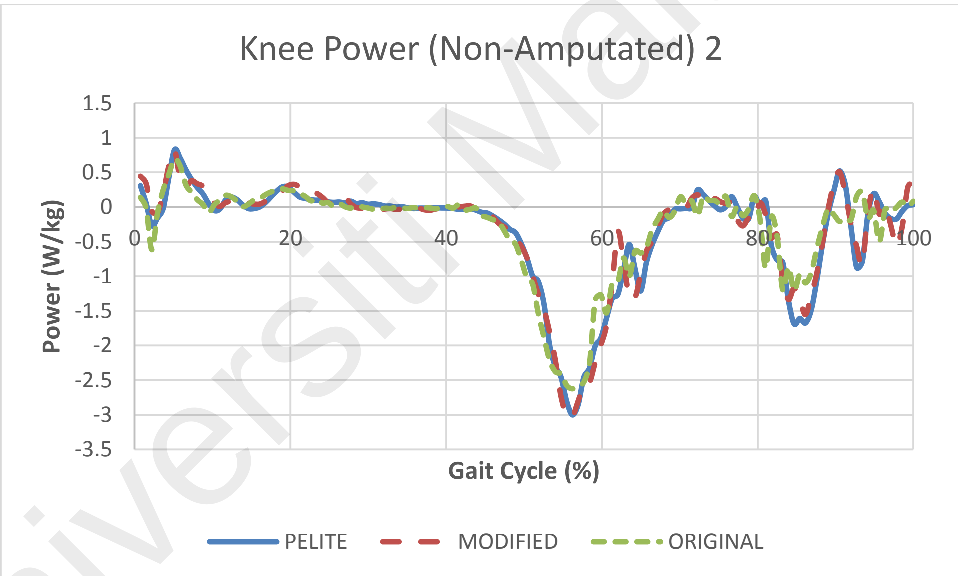

Figure 4.19 Subject 2 non-amputated knee power

For the non-amputated side of subject 2, the Pelite (original) liner shows higher knee angle at the beginning and at the end of the gait cycle compared to the Pelite (new) and modified liners. However, there is no difference between all 3 liners.

4.4.1.3 Subject 3

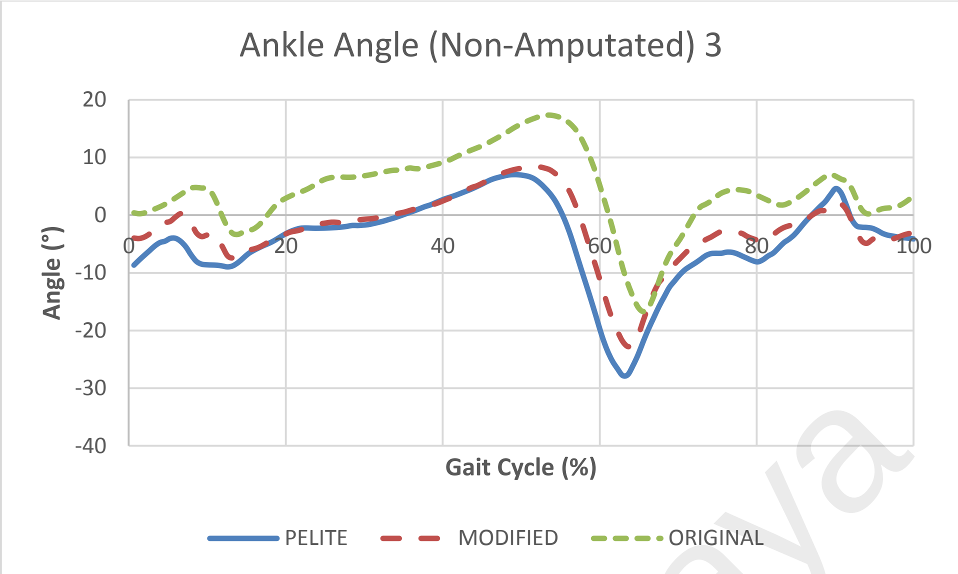

Figure 4.20 Subject 3 non-amputated ankle angle

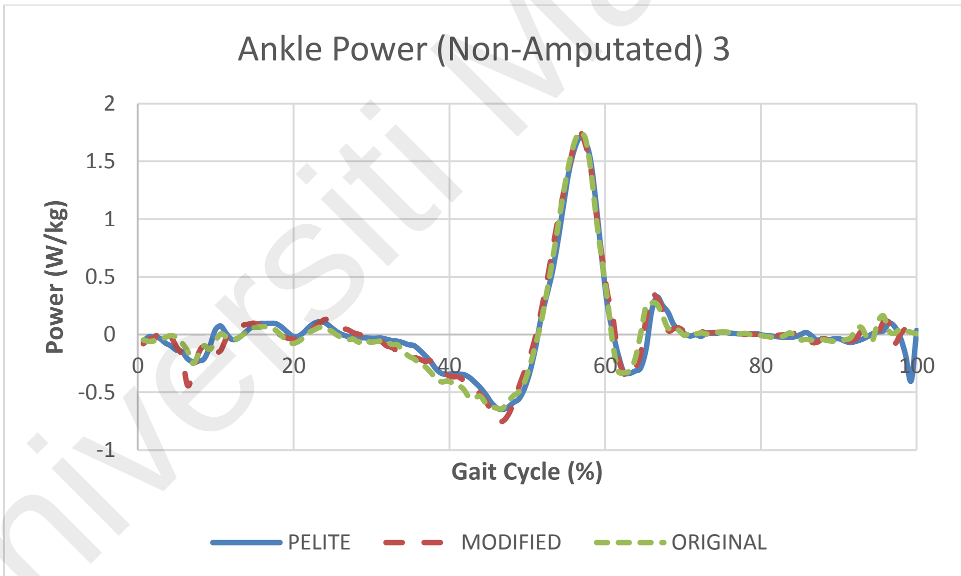

Figure 4.21 Subject 3 non-amputated ankle power

Based on the graph, the non-amputated ankle angle of subject 3 has difference between all 3 liners. The Pelite (original) liner shows the highest ankle angle throughout the gait cycle, followed by the modified liner and the Pelite (new) liner. For non-amputated ankle power, there is no difference between all liners.

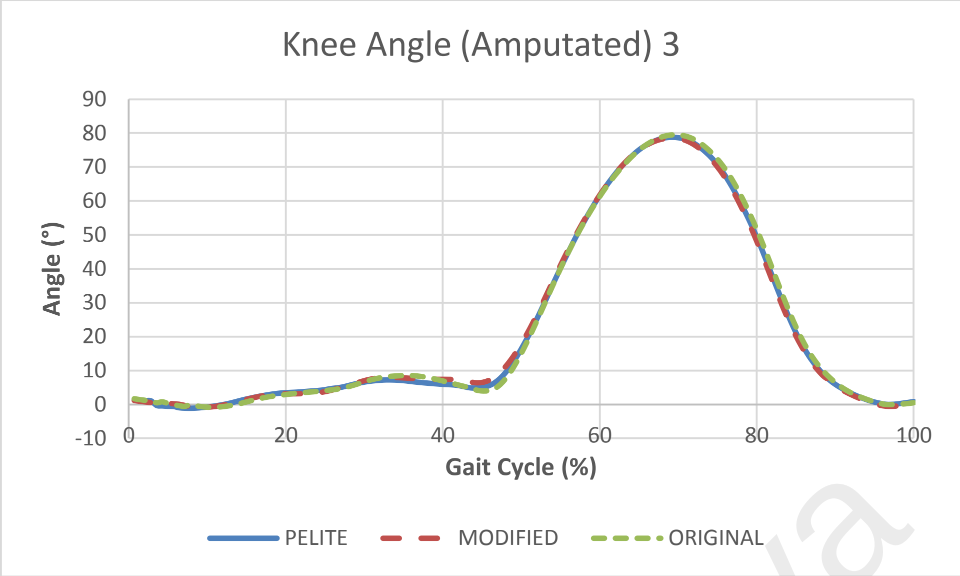

Figure 4.22 Subject 3 amputated knee angle

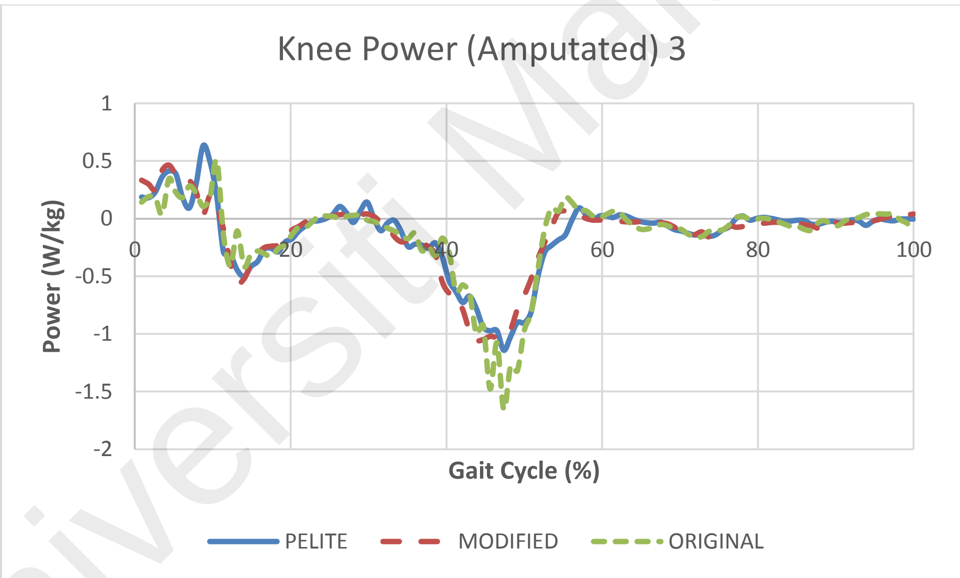

Figure 4.23 Subject 3 amputated knee power

For the amputated side of subject 3, there is no difference for knee angle. Meanwhile for knee power, the original liner shows lower power at the middle of the gait cycle than the other two liners.

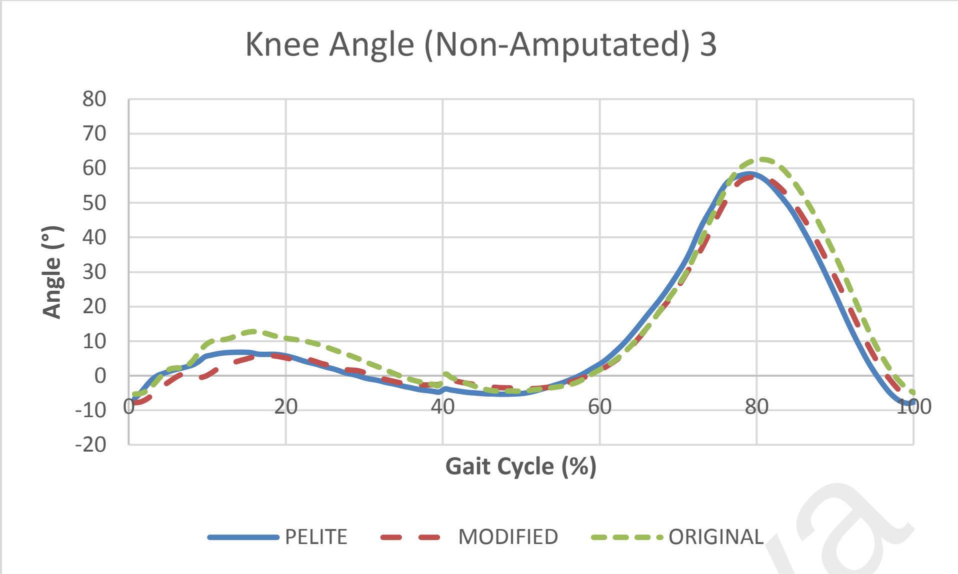

Figure 4.24 Subject 3 non-amputated knee angle

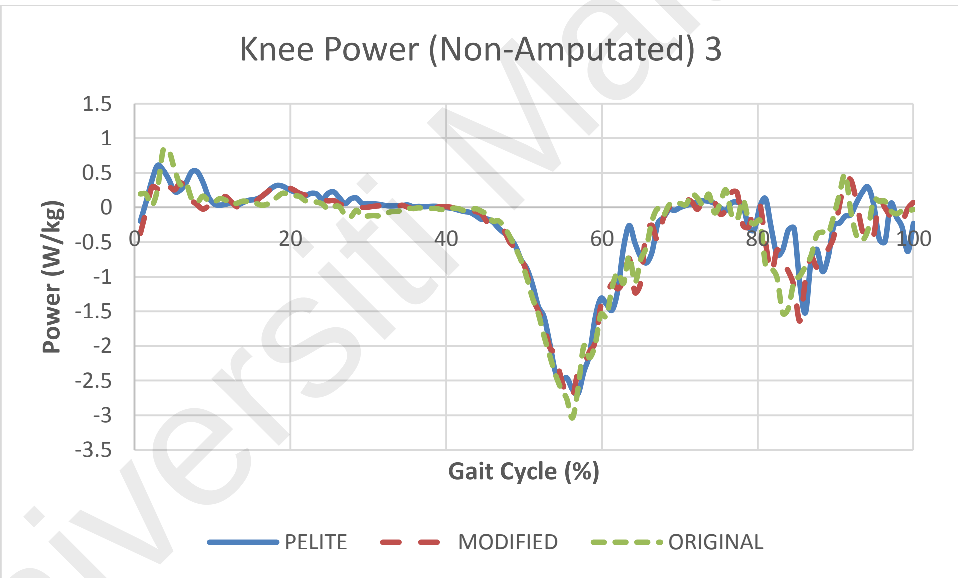

Figure 4.25 Subject 3 non-amputated knee power

For the non-amputated side of subject 3, the Pelite (original) liner shows higher knee angle at the beginning and at the end of the gait cycle than the Pelite (new) and modified liner. However, there is no difference between all 3 liners.

4.4.1.4 Subject 4

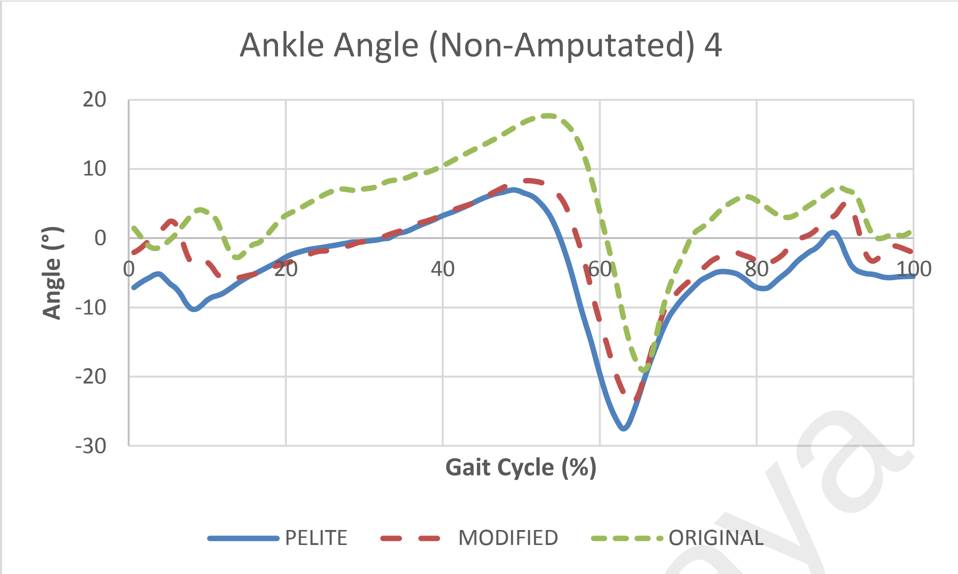

Figure 4.26 Subject 4 non-amputated ankle angle

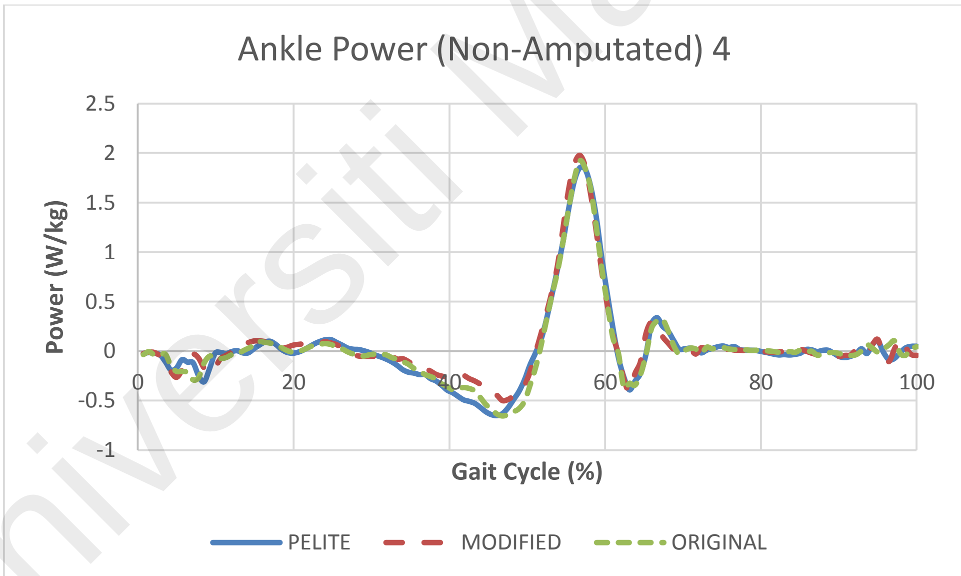

Figure 4.27 Subject 4 non-amputated ankle power

Based on the graph, the non-amputated ankle angle of subject 4 has a difference between all 3 liners. The Pelite (original) liner shows the highest ankle angle throughout the gait cycle, followed by the modified liner and Pelite (new) liner. For non-amputated ankle power, there is no difference in all liners.

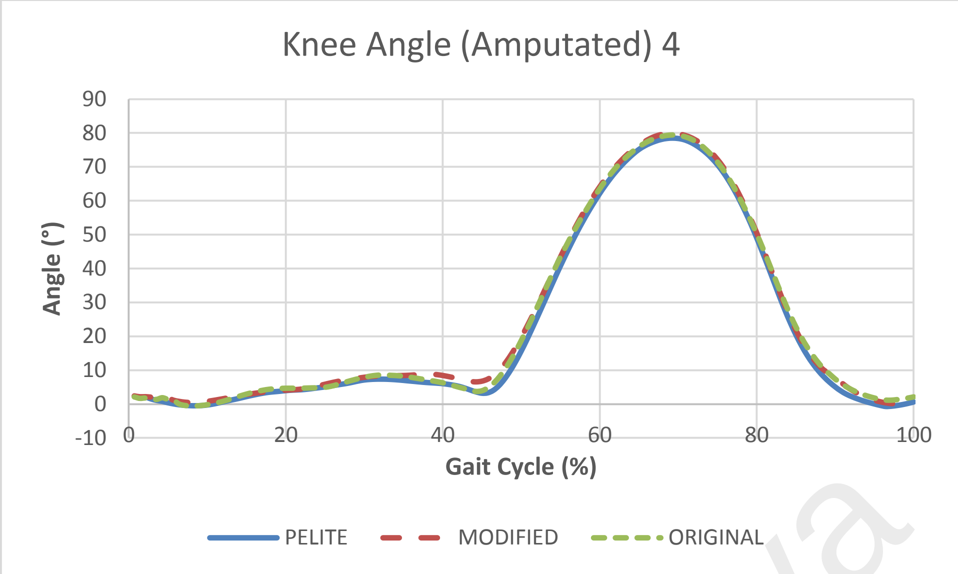

Figure 4.28 Subject 4 amputated knee angle

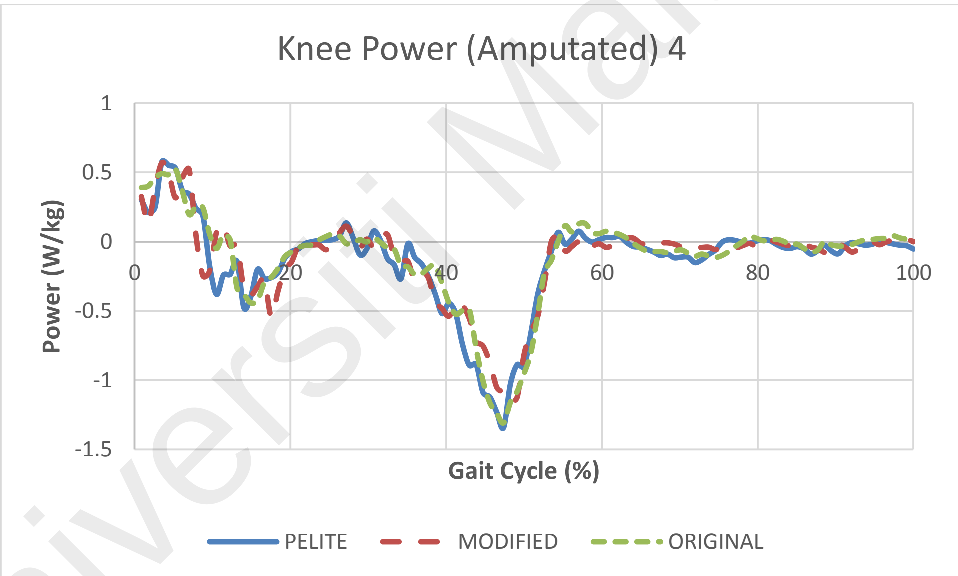

Figure 4.29 Subject 4 amputated knee power

For the amputated side of subject 4, there is no difference for both knee angle and knee power.

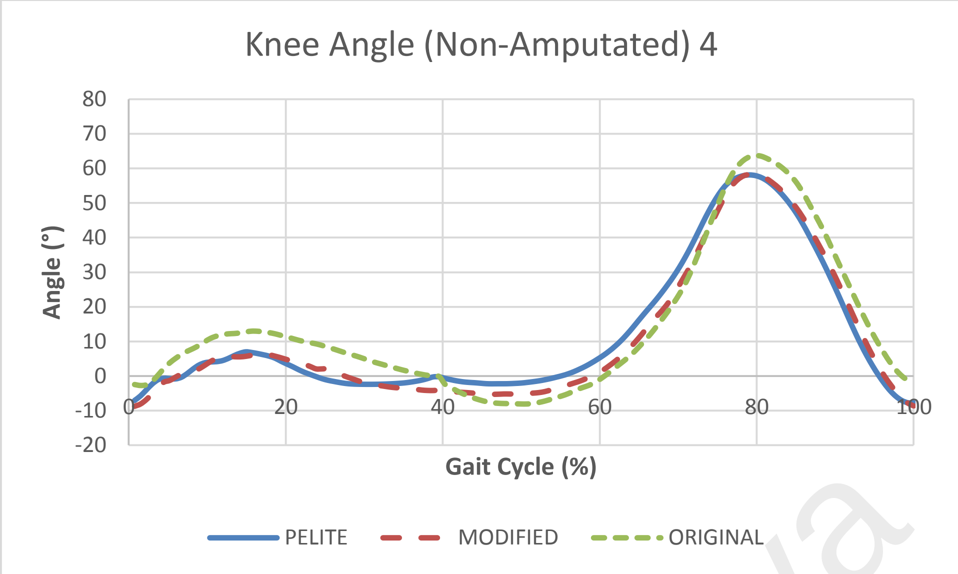

Figure 4.30 Subject 4 non-amputated knee angle

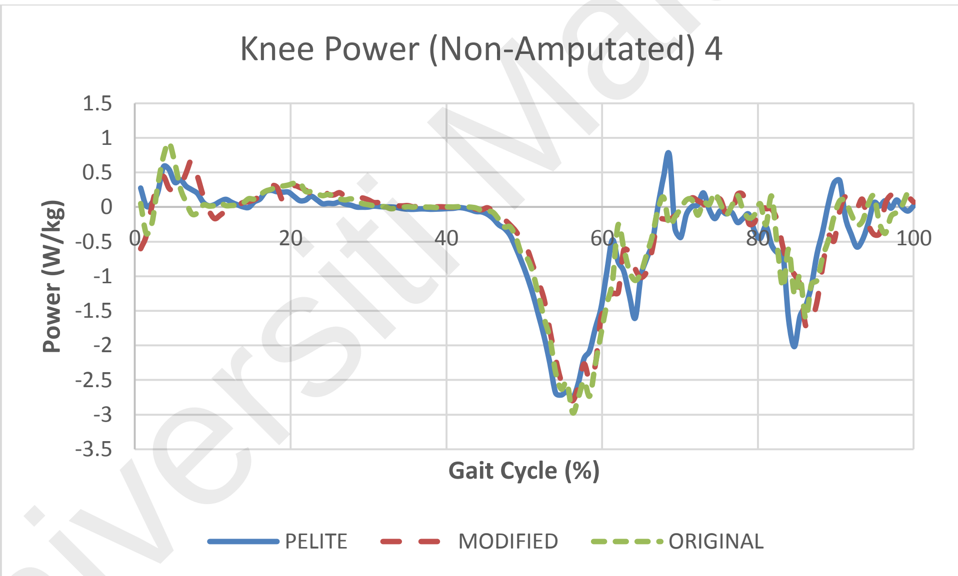

Figure 4.31 Subject 4 non-amputated knee power

For the non-amputated side of subject 4, the Pelite (original) liner shows higher knee angle than the Pelite (new) and modified liner. However, there is no difference between all 3 liners.

4.4.1.5 Overall analysis

Table 4.7 shows the average and standard deviation of parameters in gait analysis. The maximum knee flexion at the stance phase for all three liners in the amputated side were consistent: Pelite (new) (0.2°), modified (0.3°), and Pelite (original) (0.3°). The non-amputated side also showed consistent knee flexion angle at the stance phase for all three liners: Pelite (new) (−4.7°), modified (−4.2°), and Pelite (original) (−5.0°). Next, the maximum knee flexion during the swing phase for the amputated side were consistent for all three liners. For the non-amputated side, the Pelite (original) liner showed higher maximum knee flexion during the swing phase (62.7°) than the Pelite (new) liner (57.8°) and modified liner (57.9°). Significant differences ($p < 0.05$) were identified at the 1st peak of the vertical ground reaction force between all three liners. The subjects produced greater ground reaction force at the first peak for both the amputated and non-amputated sides for modified liner compared to the other two liners. Meanwhile, at the 2nd peak of vertical ground reaction force, the subjects produced lesser ground reaction force for modified liner compared to the other two liners.

Table 4.7 Average and standard deviation (in bracket) of parameters in gait analysis (n= 4 subjects)

Parameters	Pelite (new)		Modified		Pelite (original)	
	Amputated side	Non-amputated side	Amputated side	Non-amputated side	Amputated side	Non-amputated side
Knee position at initial contact (°)	6.8 (1.5)	6.2 (2.3)	7.8 (1.1)	5.8 (2.6)	0.2 (2.1)	13.2 (1.3)
Maximum knee flexion at stance (°)	0.2 (0.4)	-4.7 (2.0)	0.3 (1.7)	-4.2 (2.2)	0.3 (0.3)	-5.0 (3.0)
Maximum knee flexion during swing (°)	79.1 (2.3)	57.8 (1.2)	79.4 (1.6)	57.9 (1.6)	80.1 (1.3)	62.7 (1.6)
Vertical GRF, 1st peak (N)	101.8 (0.3)	110.7 (0.5)	98.3 (0.2)	107.7 (0.5)	105.4 (0.2)	111.6 (0.2)
Vertical GRF, 2nd peak (N)	104.3 (0.2)	97.0 (0.1)	105.2 (0.2)	97.5 (0.3)	99.3 (0.2)	97.5 (0.2)

Polyurethane foam is a softer material compared to the Pelite foam. This study incorporated polyurethane foam in the manufacturing of prosthetic liner. The polyurethane foam was incorporated between two EVA foam to build a sandwich of EVA-polyurethane-EVA as shown in Figure 3.7. The sandwich was then placed at the anterior-distal part of the positive model, as shown in Figure 3.8. The user often complained of pressure that causes pain at the anterior-distal part of the residual limb when wearing the Pelite liner. So, the EVA-polyurethane-EVA sandwich was placed at the anterior-distal part of the residual limb to compensate for the pain sensation experienced by the user at the residual limb (Eshragi et al. 2015). Previously, silicone was used as the soft material to compensate for the pain sensation at the residual limb (Eshragi et al. 2015). Then, the Pelite foam was draped onto the positive model with EVA-polyurethane-EVA sandwich. The part of the sandwich on the Pelite liner was cut off and the edge was glued together.

Biomechanical gait analysis was performed on the subjects to determine the effect of different prosthetic liners on the gait of the subject. The Vicon Motion Analysis System was used to perform the motion analysis experiment. Three different prosthetic liners were used: (i) Pelite (new) liner (ii) modified liner using polyurethane foam and (iii) Pelite (original) liner used by the subjects. There were 13 experimental trials performed for each type of liner. Then, the average was calculated from all of the trials after the data was analysed.

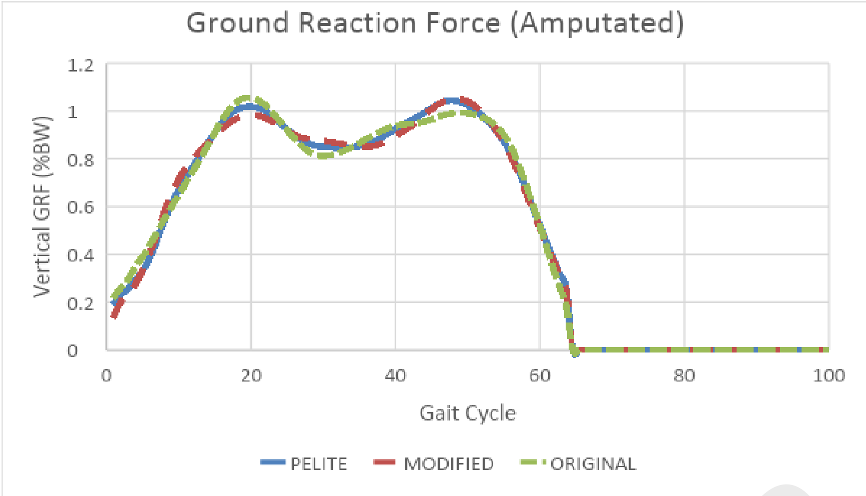

Figure 4.32 Ground reaction force (Amputated) (n= 4 subjects)

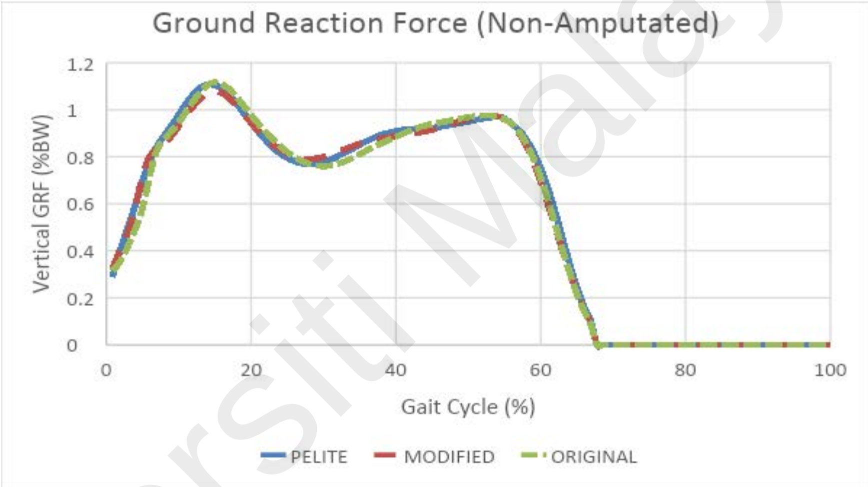

Figure 4.33 Ground reaction force (Non-Amputated) (n= 4 subjects)

The ground reaction force is the equal and opposite force that acts on the body when the body exerts some force while resting or hitting the ground (Porter, 2013). By analysing the ground reaction force, the force exerted by the body during the gait cycle can be studied. In this study, it showed that the subjects walked better using the modified liner, followed by the Pelite (new) liner. The subjects showed the least performance walking in their Pelite (original) liners. Based on the Ground Reaction Force (Amputated) graph in Figure 4.9, no difference was found between all three types of liners during the gait cycle. At 20 % of the gait cycle, which was the loading response phase, the Pelite (original) liner exerted slightly higher force than the Pelite (new) and modified liners.

Meanwhile, at 30 % and 50 %, the Pelite (original) liner exerted a lower force than the Pelite (new) liner and modified liners. This showed that the subjects had inconsistent Ground Reaction Force while wearing the Pelite (original) liner. Based on the Ground Reaction Force (Non-Amputated) graph in Figure 4.10, no difference ($p > 0.05$) was observed between all prosthetic liners. This is because the prosthetic users were left transtibial prosthesis users. Thus, the force exerted by the left side of the body should be almost the same.

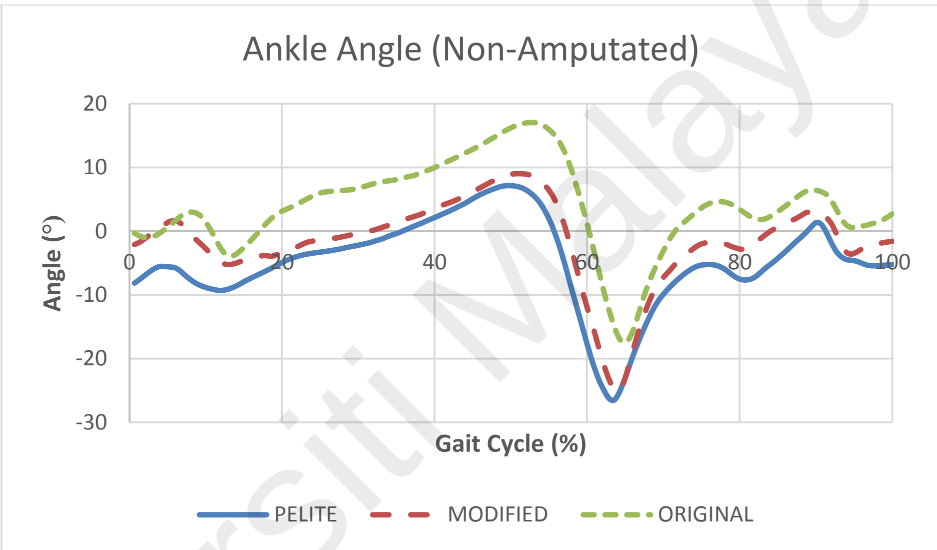

Figure 4.34 Ankle angle (Non-Amputated) (n= 4 subjects)

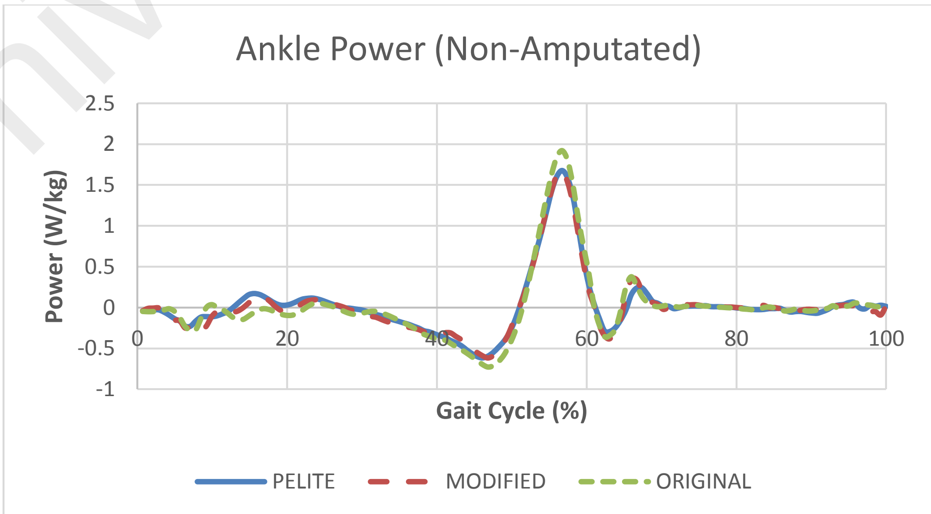

Figure 4.35 Ankle power (Non-Amputated) (n= 4 subjects)

The subjects used more ankle power (Non-Amputated) when using the Pelite (original) liner because they have the highest angle throughout the phases, followed by the modified liner and the Pelite (new) liner. The greater angle values caused high power output from the subjects (Plitz et al. 1993). The result showed that the Pelite (original) liner exerted slightly higher ankle power than the Pelite (new) and modified liner, as shown in Figure 4.12. There are many potential reasons for this output, including the alignment of the prosthesis, mechanical characteristics of the feet, or others. A study by Esposito et al. (2017) stated various external reasons might affect the output of the gait analysis experiment. Even though the graph was based on the sound limb of the users, the prosthesis side might affect the gait of the sound side as the sound side need to compensate for the prosthesis side. This study did not analyse the left ankle because at the prosthesis side, the ankle angle was not reliable since the usage of SACH foot caused the ankles to be stiff. Only the prosthetic foot was flexible.

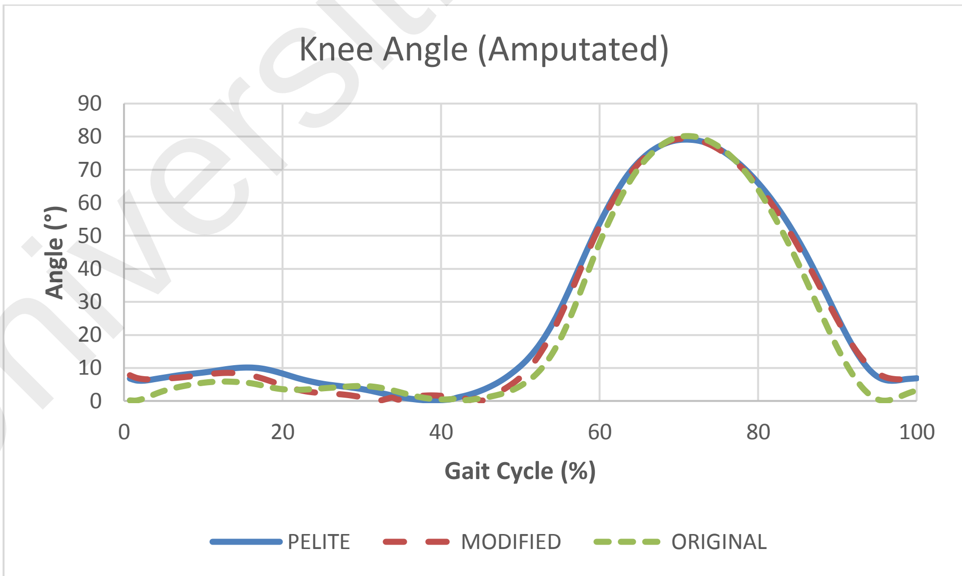

Figure 4.36 Knee angle (Amputated) (n= 4 subjects)

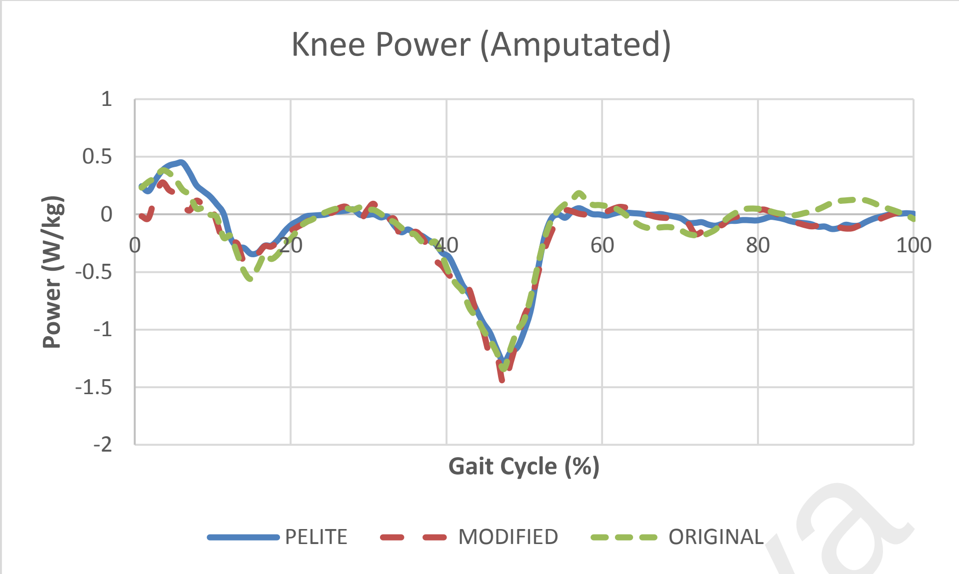

Figure 4.37 Knee power (Amputated) (n= 4 subjects)

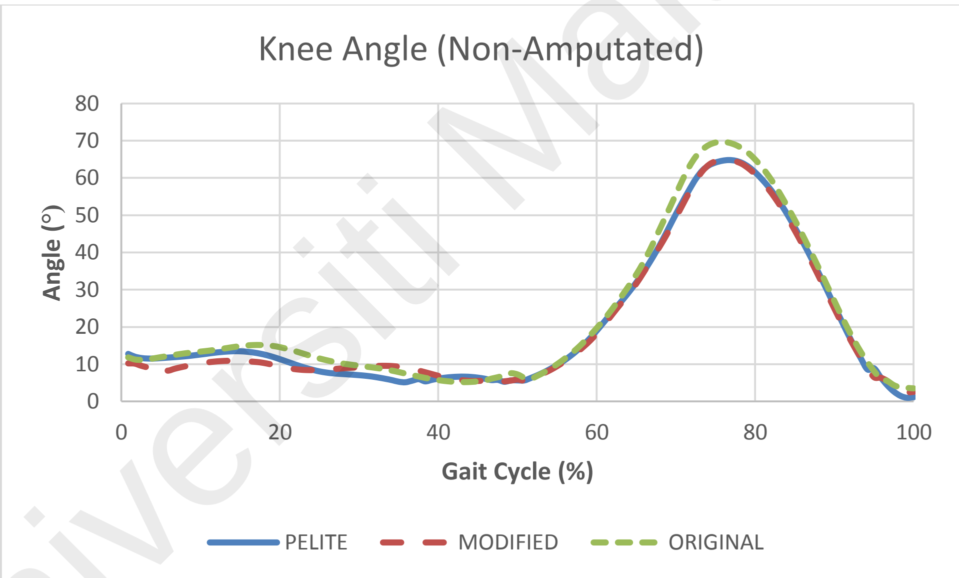

Figure 4.38 Knee angle (Non-Amputated) (n= 4 subjects)

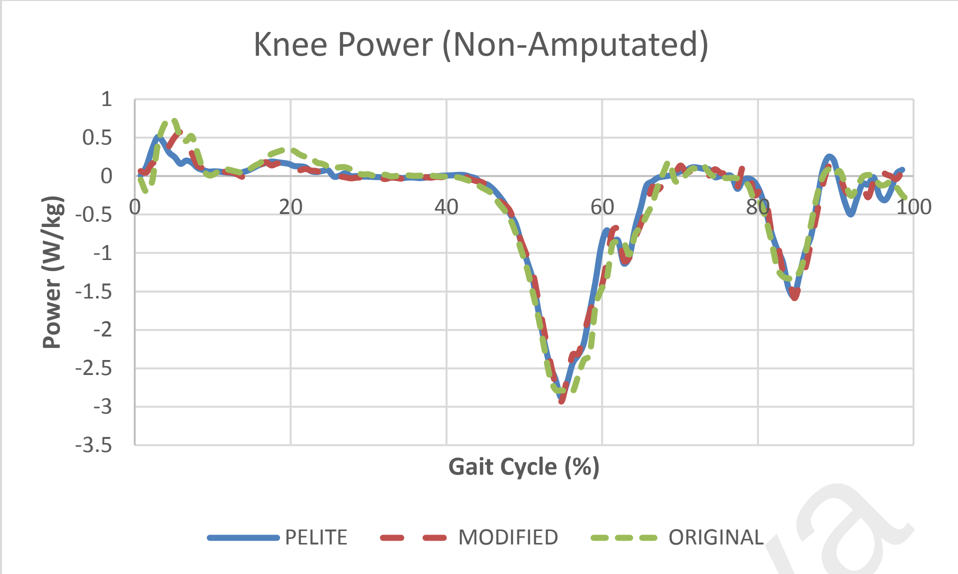

Figure 4.39 Knee power (Non-Amputated) (n= 4 subjects)

There was a major difference between the Knee Angle (Amputated) graph and Knee Angle (Non-Amputated). This study showed that the Knee Angle (Amputated) has a greater angle value than the Knee Angle (Non-Amputated) for all three liners, which resulted in the weight of the prosthesis. The prosthesis was considered foreign to the body, so the subject needed to compensate for the weight of the prosthesis. Grimmer et al. (2017) found that prosthesis users needed to compensate for the weight of the prosthetic limb when ambulating, thus, affecting their gait. In the same scenario as the Knee Power, Knee Power (Amputated) was higher than Knee Power (Non-Amputated) throughout the gait phase. This result supported the earlier statement that the users needed to compensate for the weight of the prosthesis when walking.

CHAPTER 5: CONCLUSION

This chapter include the conclusion and the overall findings of this study. There are few recommendations suggested in this chapter to improve the study.

5.1 Conclusion

The first objective which is to conduct a survey among transtibial prosthesis users on the effectof the prosthetic liner on their daily living activities was achieved. 50 respondents responded to the questionnaires.

The second objective which is designing a new prosthetic liner using polyurethane foam at the anterior-distal part of residual limb to replace the Pelite as a prosthetic liner of this study was achieved. A liner that has been modified with polyurethane foam is manufactured.

Furthermore, we found from the material testing that the Pelite and liner foams have high compressive strength. For tensile test, we found that the Pelite foam have the greatest tensile strength among other materials.

The third objective which is to compare the biomechanical gait analysis of the new modified liner using polyurethane foam with Pelite as liner is achieved. We compared three different liners which are the modified liner, Pelite (new), and Pelite (original). We found that the usage of polyurethane foam at the anterior-distal part of the liner improves the walking gait of the users.

5.2 Study limitations

There are some limitations in this study. First, in this study we only recruited four subjects due to the pandemic.

Next, in this study we only compared Pelite liner and modified liner by using polyurethane foam on biomechanical gait of transtibial amputees. Furthermore, even though the components in fabricating the prosthesis such as prong, adapters, and prosthetic foot are the same, commercially they do not use the same components we use in this study.

5.3 Future works

There are some recommendations to improve this study. First, the sample size should be increased to minimum 50 subjects to give better comparison on the effect of modified liner by using polyurethane foam on biomechanical gait of transtibial amputees. The data collected will be more accurate and reliable if the sample size is bigger.

In addition, the type of liners compared should also be increased. In this study, we only compared between two liners which are the Pelite liner and modified liner using polyurethane foam. If more types of liners were studied, we can find the most suitable liner to prescribe to transtibial amputees.

Finally, experiment regarding the interface pressure between the residual limb and the prosthetic liner can improve this study.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

The research presented in this study has led to publications of the following:

Journal

1. Mohamed Nizam, M. A., Abd Razak, N. A., & Abu Osman, N. A. (2021). Biomechanical Analysis of an Improvement of Prosthetic Liner using Polyurethane Focusing at the Anterior-Distal Part of Residual Limb. *Sains Malaysiana Journal.* (Accepted)

Award

1. Mohamed Nizam, M. A., Abd Razak, N. A., & Abu Osman, N. A. (2020). Sustainability in Prosthetic's Materials Usage for Improvement of Amputee Quality of Life. Poster presented at University for Society International Conference (U4SIC) 2020. (2nd runner up best poster)

Proceeding

1. Mohamed Nizam, M. A., Abd Razak, N. A., & Abu Osman, N. A. (2020). Sustainability in Prosthetic's Materials Usage for Improvement of Amputee Quality of Life. Poster presented at University for Society International Conference (U4SIC) 2020.
2. Mohamed Nizam, M. A., Abd Razak, N. A., & Abu Osman, N. A. (2021). Qualitative Study of Prosthetic Liner Materials on Transtibial Amputees' Satisfaction in term of Positional Pain and Discomfort.