EVALUATION OF AN AFFORDABLE EVA ROLL-ON (AERO) FABRICABLE LINER IN THE TRANSTIBIAL AMPUTEES

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ABSTRACT

The interface material used between the prosthetic socket and the residuum affects the comfort of the prosthesis wear. The traditional PTB socket with PE-lite has been used for a long time in the developing countries. Many studies suggest improving the prosthetic comfort through the use of roll-on liners. There are many varieties of liner, however, these liners are expensive and difficult to obtain for persons residing in RLE. The aim of this study was to determine the feasibility of the Roll-on liner made from the affordable EVA material (AERO). Five transtibial amputees were invited as the participants in order to evaluate the utility of the AERO liner. The outcomes with respect to pressure distribution, daily step count, questionnaire, and material test were explored. There were no significant difference between daily activities and questionnaires, and the mean pressure uniformity across all five participants showed that the uniformity with the PTB socket with PE-lite was 35.38% (±10.81), PTB socket with AERO liner was 56.77% (±6.73), and TSB socket with AERO liner was 77.53% (±5.44). Thus, the pressure uniformity across the residuum was improved when using the AERO liner, in both PTB and TSB style sockets. Moreover, the AERO liner can be made cheaper than the conventional PE-lite. This low-cost Roll-on liner may contribute to sustainable development in limited resource environments. For future studies, perspiration problems in daily living, and the appropriate socket shape and suspension systems can be considered to enhance the comfort for the transtibial prosthesis wearers in the developing countries.

KEY WORDS: TRANSTIBIAL PROSTHESIS/ AFFORDABLE MATERIAL/
ROLL-ON LINER / PRESSURE DISTRIBUTION

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LIST OF ABBREVIATIONS

QoL	Quality of Life
PE	Polyurethane foam
TSB	Total surface beating
RLE	Resource limited environment
EVA	Ethylene-vinyl acetate
PVD	Peripheral vascular disease
ADL	Activity of daily living
PTB	Patella-tendon bearing
ICEROSS	Icelandic roll-on silicon socket
TPE	Thermoplastic elastomer
AERO	Affordable Ethylene-Vinyl Acetate Roll-on
SOC	Standard of care
SACH	Solid ankle cushion heel
MCFL K	Medicare Functional Classification Level (level ranging from 0 – 4)
FSR	Force sensing resistors
PTF	Polymer thick film
FTIR	Fourier transform infrared spectrophotometer
MPT	Mid patella tendon
OPUS	Orthotics and Prosthetics User's Survey
SCS	Socket comfort score
CaCo3	Calcium carbonate
SiO_2	Silicon dioxide
WHO	World Health Organization
ICRC	International Committee of the Red Cross

CHAPTER I
INTRODUCTION

1.1 Introduction

An amputation refers to the surgical removal of part of the body such as arms or legs. Some of the most common reasons for amputation are trauma, medical illness, and congenital disorders.[1] Fortunately, for these individuals, prostheses are available. The prosthetic device can improve mobility of an amputee patient, restore cosmesis, prevent secondary deformities, and even improve Quality of Life (QoL) for patients.[2] Nowadays, the incidence of disabilities which require a prosthetic device is increasing globally as a result of population growth and an aging society, even in developing countries.[3]

Transtibial amputation is one of the most common amputations and defined as amputation below the knee joint.[1] The distal end of the amputee's residual limb is starkly different from the non-amputated distal plantar foot surface. Soft tissue of the residual limb is not accustomed to bearing vertical and shear forces encountered during bipedal standing and walking.[4] Prosthetic discomfort as a result of skin disturbances often times leads to disturbances in mobility and daily activity of the prosthetic user.[5]

Fortunately, prosthetic socket interface (liner) materials can be placed between the residual limb and prosthetic socket to provide cushioning and better distribution of loads transferred to the limb. Historically, prosthetic liners made from polyurethane foam (PE) have garnered widespread support and use. [6] Foam liners are routinely used in the clinic, but modern liners made from silicone, thermoplastic elastomer, and polyurethane have also been used. Such liners provide cushioning, durability and distribution of forces placed on the residuum through their unique "roll-on" functionality, which works to improve function over PE foam liners. [7]

Polyethylene foam liners might produce large pistoning movement between the residual limb and the prosthetic interface which might produce wounds in the residual limb, particularly when the socket fit is not optimal. However, the roll-on functionality of other liners can mitigate possible pistoning between the residual limb and interface.[8] In addition, and as an added benefit, the ability to maintain residual limb shape and volume offers up the opportunity to utilize total surface bearing (TSB) socket techniques.[9] As a result, it is possible to produce a prosthesis with added comfort which mitigates possible wound issues. Many liners exist on the market in developed countries, however, prosthetists in resource limited environments (RLE) are forced to consider affordability and availability of these liners when designing their prescription. Thus, the patient is often times limited to use of the PE foam liner in places like Thailand. In order for an intervention to add value to a particular patient population it must have clinical utility, which takes into consideration both patient needs and environmental factors at play.[10] As such, any prosthetic technology provided in RLE must consider the proposed technology will have clinical utility.

Therefore, under the supposition that roll-on function liners created with affordable materials will provide improved cushioning, durability and pressure distribution than traditionally offered PE foam liners. Furthermore, it is postulated that use of such roll-on liner will have utility in RLE by reducing both fabrication time and cost.

1.2 Research question

Does the EVA interface material provide added comfort and function over conventional PE foam for a transtibial prosthesis wearer?

1.3 Research hypothesis

We hypothesize that an EVA roll-on liner could provide good shock absorption and comfort better than the PE foam liner.

1.4 Objective

The aim of the study is to identify the clinical utility and comfort in the transtibial prosthesis user while using a novel roll-on EVA liner made from materials sourced in a resource limited environment.

1.5 Scope of the study

This study will focus on low cost EVA roll-on liner clinical utility, pressure distribution and comfort for daily use in transtibial prosthesis wearer. This current study will not consider the quantification of the residuum temperature and volume changes.

1.6 Research method

The study can be considered a pilot study where participants will receive the standard treatment of PE Foam liner and then receive the intervention (roll-on EVA liner) for outcome measurement comparisons.

1.7 Expected benefits

This study will benefit the prothetic field by exploring if, and to what extent, roll-on liner and socket can add clinical utility for prosthetics. As such, prosthetists can expand this research to further develop interventions aimed at addressing quality of life, participation, and inclusion of lower limb prosthesis wearers in Thailand.

1.8 Definition of terms

Transtibial amputation is another term for the stump formed following below knee amputation of a lower limb

Prosthesis is an artificial limb worn following amputation of a body part.

Cosmesis is a cosmetic cover over the mechanical elements of a prosthesis.

Liner is a removable sock like product that fits over the residual limb and acts as a cushion and interface with the socket of the prosthesis.

Pistoning is the movement of the socket relative to the residual limb due to poor fit or lack of suction or friction.

CHAPTER II
LITERATURE REVIEW

2.1 Lower limb amputee

There are approximately 40 million individuals with prosthetic needs in the developing world, yet only about 10% have access to prosthetic care.[3,11] The transtibial amputation is one of the most common amputations, described as a surgical procedure removing the limb below knee joint.[1] Historically, limb amputations occurred as result of conflict, resulting in a major disability. [12] There are a multitude of causes for lower limb amputation, such as traumatic injury, peripheral vascular disease (PVD), diabetes, tumor, as well as congenital limb deformities. Today, the number one cause of amputation is diabetes.[13] Prosthetic devices empower the user to participate in activities of daily living (ADL) and re-engage with society to improve amputee QoL .[14]

2.1.2 Level of amputation

Each surgical amputation level has a distinct name, i.e. transtibial or transfemoral, as the bones and muscles of the lower limb segments are transected. As a result, the shortened length of the remaining residuum will cause a functional impediment requiring use a different type of prosthesis. Lower limb amputee classifications is as follow (Figure 2.1):

(i) Partial Foot Amputations – amputation including any part of the foot. Various types of partial foot amputations exist; mid-tarsal amputations, Chopart and Lisfranc amputation.

(ii) Ankle Disarticulation - Boyds and Symes amputations is an ankle disarticulation with remove of the malleoli.

(iii) Transtibial Amputations – this amputation occurs distal to the knee.

(iv) Knee Disarticulation Amputations – this amputation occurs at the level of knee joint leaving the femur and patella untouched without transecting through bone or muscle.

(v) Transfemoral Amputations – this amputation includes all levels of thigh amputations from below the hip to the knee joint.

(vi) Hip Disarticulation Amputations – this level of amputation is at the hip joint with the entire thigh portion being removed.

In general, the longer the remaining lower limb and the more joints that are preserved, the easier a prosthesis is to use. As a testament to this, is the added energy required to ambulate in a prosthesis as the amputation level gets higher.[15]

Figure 2.1 Lower limb amputee levels

Taken from: Etly et al, 2019. Lower extremity amputations

2.2 Prosthesis for transtibial amputees

The main objective of prosthesis use is to reduce the negative impacts of disabilities, and to restore functionality, amputee autonomy and to support the user's maximum potential. In order to achieve function and a comfortable prosthesis, the socket design must be considered. In fact, the appropriate interface positioned between the amputees limb and the prosthetic device, is a key factor of the socket. A good socket can ensure appropriate load transmission, stability, control, and a well fit socket, all of which contribute to the overall success of a prosthesis user.[16]

Commonly, transtibial prosthesis consists of a socket that residuum will seat into, an interface for cushioning, a pylon that connects the socket and foot, and an ankle foot mechanism.[1] Historically, various materials, components and designs have been developed for the lower limb prosthesis, however, in RLE the use of a conventional prosthesis is common, see Figure 2.2.[6]

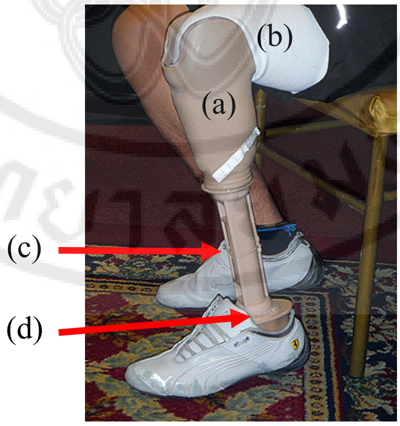


Figure 2.2 Components of ICRC transtibial prosthesis

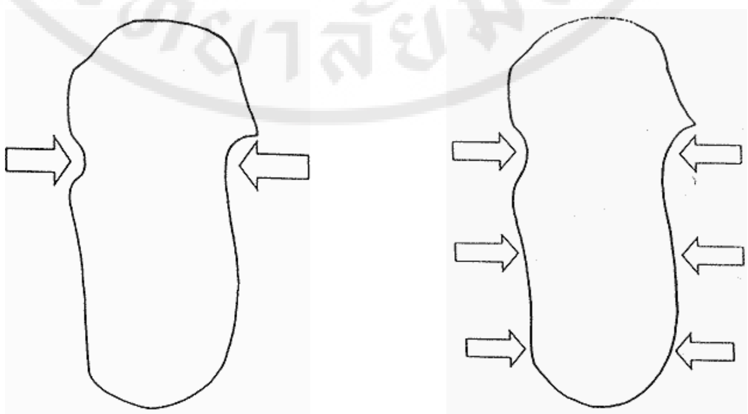
Note: Name of component: (a) Socket (b) Interface (c) Pylon (d) Foot.
Taken from: https://opedge.com/Articles/ViewArticle/2015-06_02

2.2.1 Prosthetic socket

Standard transtibial sockets consist of a metal knee joint and tight corset mechanism in which the residuum weight bearing forces occur at the socket as well as the thigh corset. This style of socket has been commonplace for many years. The patellar tendon bearing (PTB) socket, in which much of the weight bearing occurs ay the patella-tendon, was introduced and made popular in the 1950s.[17] A sleeve or cuff strap is used for suspending this prosthesis and an interface made from polyethylene foam, such as PE lite, is placed between the residuum and socket. This style of prosthesis is used widely in RLE.[6]

In the 1990s, the total surface bearing (TSB) socket was introduced which permitted the entire surface of the limb to be used for weight bearing, also referred to as hydrostatic loading.[18,19] This type of socket recommended use of elastic interfaces fabricated from elastic materials such as, silicone, urethane, and other gels.[7,20]

TSB style sockets are ideal because they have a tendency to decrease fitting times,[21] with better weight acceptance and suspension also a noted advantage of the this type of socket.[22, 23] Compared to traditional foam-based interfaces, elastic interface liners are indicated in order to decrease dependence on assistive walking devices, improve suspension, distribute residual limb socket pressures, decrease pain and increase socket comfort.[24,25] Figure 2.3 illustrates the socket loading forced of the aforementioned socket types.[26]



(a) PTB socket (b) TSB socket

Figure 2.3 Different type of socket

Taken from: Kahle, 1999. Conventional and hydrostatic transtibial interface comparison.

2.3 Interface material

The PTB socket used with PE foam interface (which will be referred to as 'liner' from this point on in the paper) is a closed cell material.[27] The PE foam liner supports cushioning as well as suspension of the prosthesis. This material is harder and cheaper than elastomer liners and is traditionally used with PTB prosthesis. It is the most commonly used material in RLE, however, in the early 1980's Össur Kristinsson developed the Icelandic roll-on silicon socket (ICEROSS) liner.[7] This liner offered good suspension and total surface weight bearing capabilities of the prosthesis.[7,28] In the past, the addition of a cuff-strap or thigh corset were needed to augment prosthesis suspension, the advent of roll-on liners permitted revolutionary methods of suspension. In general, there are three main elastomeric liner materials; thermoplastic elastomer (TPE), silicone, and polyurethane. These aforementioned liners have a "roll-on function". Roll-on functionality refers to the ability to invert the liner and then gradually roll the liner onto the residual limb. This roll-on function provides better cushioning and suspension as well as adaptability to brambly and difficult to fit residual limb surfaces. Gel liners account for approximately 85% of liners used in the United States.[29] There are different types of suspension variants available, such as seal-in, shuttle lock, and suspension sleeves. The benefits of this type liner are well documented as previously mentioned, however, there are reports that roll-on liners can promote dermatological problems as a result of increased sweating.[30] Still, comparisons between PE foam liners and elastomeric liners with respects to user satisfaction, evidences support for elastomer liners with an added benefit of reduction of socket pistoning. As a result of a more intimate connection with the residuum, prevention of wounds is possible.[31] Often times, the residual limb will have volume fluctuations over the course of a single day or across long periods of time. The prosthetist must counter this volume change through use of prosthetic socks or socket replacement. Socks can quickly help to increase whole limb volume by roughly 5 to 10%, via a one-ply or five-ply socket respectively.[32] The main problems for interface material in developing countries are materials availability and costs. [33]

2.3.1 Material property testing

Material property data information is useful to aide in selection of appropriate liner materials for patients. Mechanical property performance of liner materials is dependent upon the unique characterization of each material. The mechanical properties such as shear stiffness, tensile stiffness, compressive stiffness and coefficient of friction is related to the function of liner. Previous scholarship has evaluated the unique properties of elastomeric liner compression, friction, shear, and tensile load, see Figures 2.4-2.7.[34]

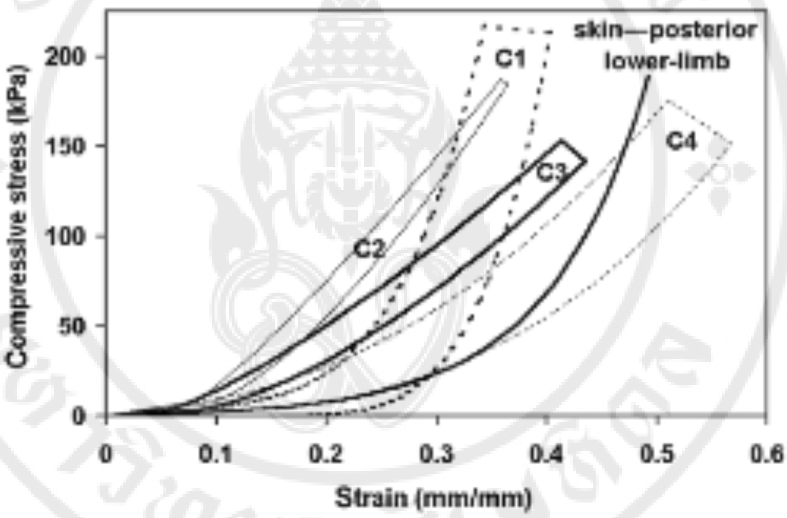


Figure 2.4 Compressive stress testing

Taken from Sanders et al, 2004. Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance

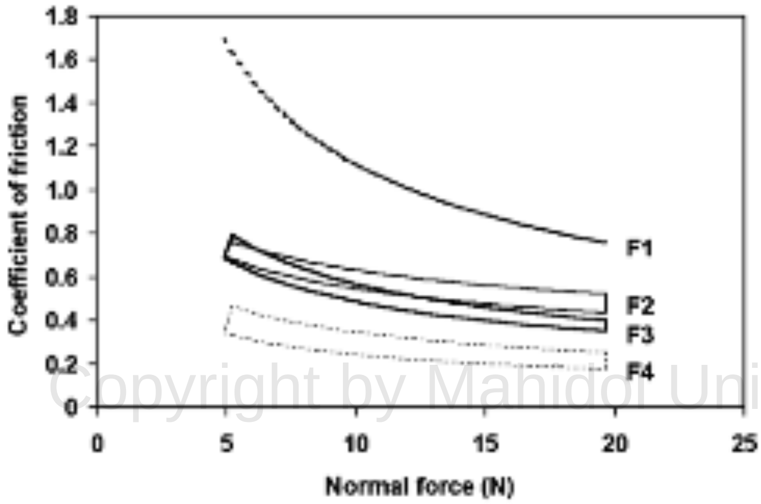


Figure 2.5 Frictional stress testing

Taken from Sanders et al, 2004. Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance

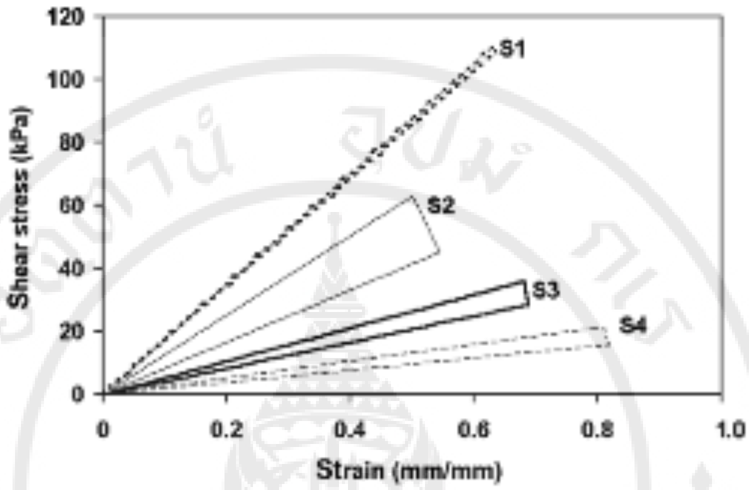


Figure 2.6 Shear stress testing

Taken from Sanders et al, 2004. Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance

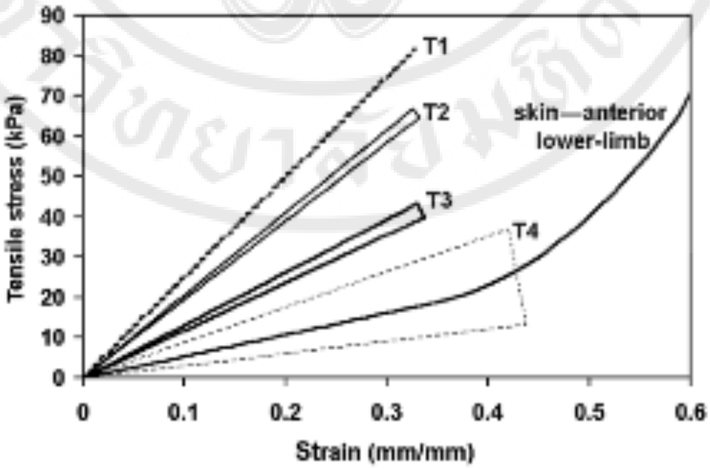


Figure 2.7 Tensile stress testing

Taken from: Sanders et al, 2004. Testing of elastomeric liners used in limb prosthetics: Classification of 15 products by mechanical performance.

The particular material makeup relates to the mechanical properties of the material and plays a pivotal role in the definitive prosthesis. The main factors that a prosthetist considers when choosing a liner are durability, comfort and suspension capabilities (Figure 2.8).[35]

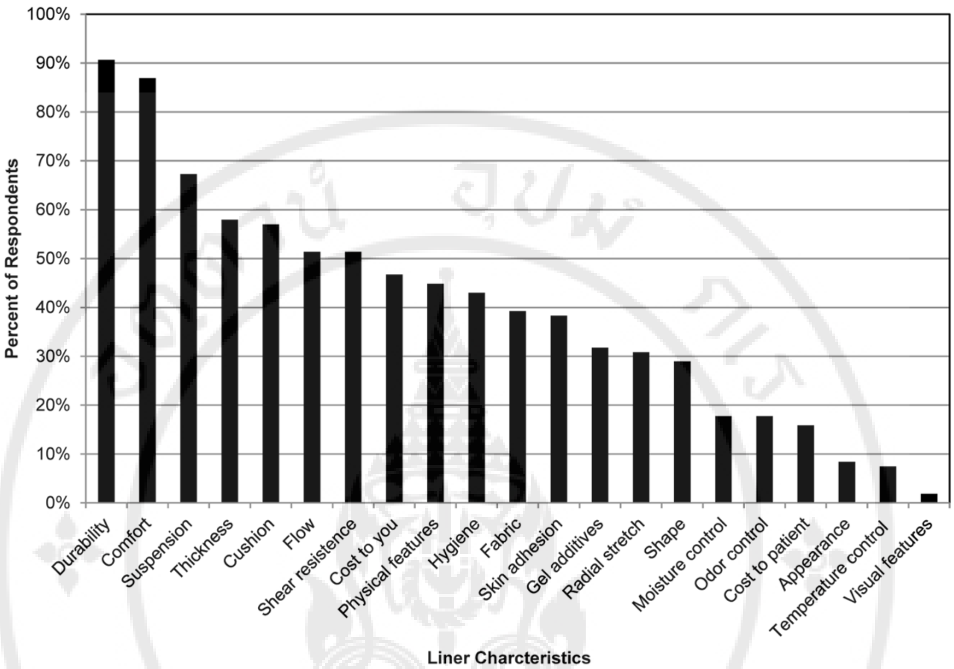


Figure 2.8 Characteristics that affect prosthetists' selection of liner products

Taken from: Hafner et al, 2017. Elastomeric liners for people with transtibial amputation: survey of prosthetists' clinical practices

2.4 Pressure distribution

One unique function of liner material is the ability to better distribute socket pressure, which is the static and dynamic pressure occurring at the residual limb within the socket. Gel liners reduce shear stress between the prosthetic socket and residuum, to create uniform pressure distribution by roll-on functionality. An appropriate liner cushioning works to distribute pressure and improve prosthetic socket comfort as well as physical activity, whereas insufficient shock absorption causes asymmetrical gait, and low back pain joint degeneration.[36,37] Furthermore, repeated high impact forces on the limb are associated with a high incidence of residuum pain.[38] Thus, mitigating pressures in the residuum is a critical task for the prosthetist in order to ensure patient prosthetic comfort, health, and function.

2.4.1 Liner thickness and pressure

Gel liner thickness is related to the rate of shock absorption in the residuum. During ambulation, intensive pressure is applied to the fibular head during walking with the transtibial prosthesis. A thick liner reduces peak socket pressure acting on the fibular head, increases ground reaction force, and can ultimately increase socket comfort (Figure 2.9).[39]

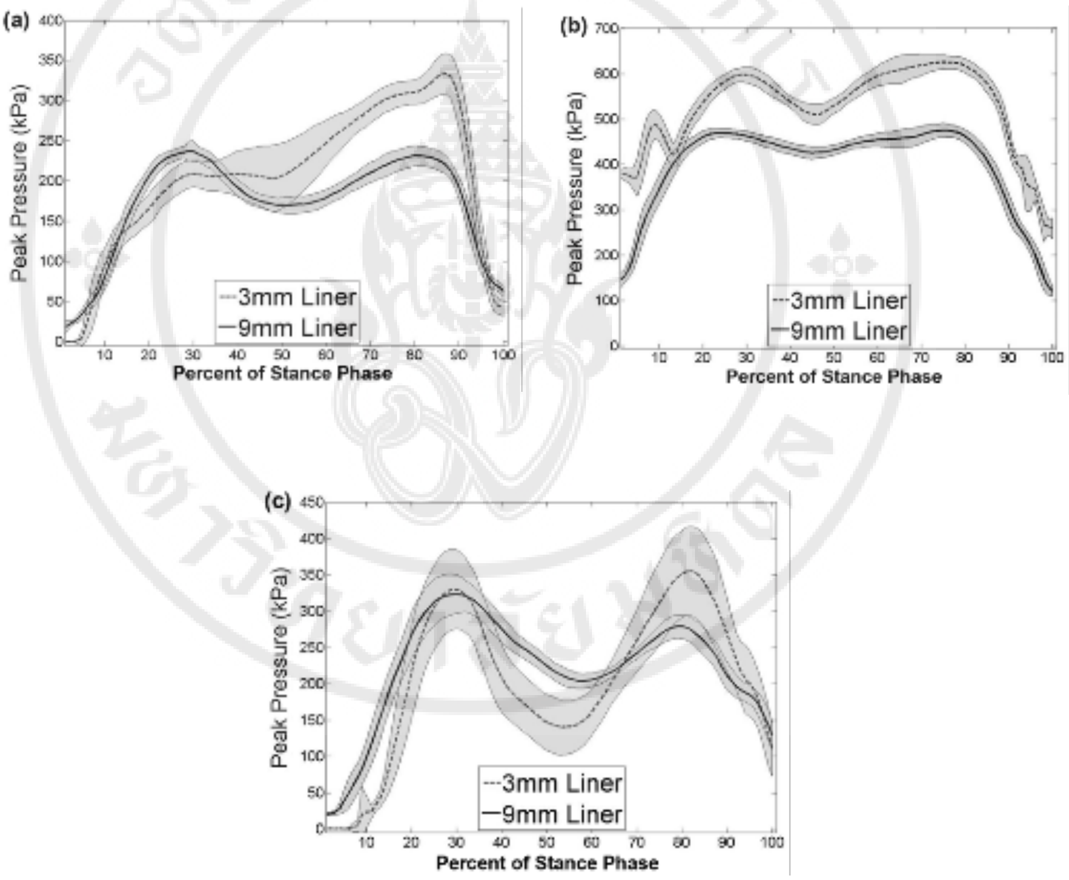


Figure 2.9 Pressure on the residuum using two different thickness gel liners.

Note: **(a)** patellar tendon, **(b)** fibular head, and **(c)** distal anterior tibia pressure sensor locations. Taken from: Boutwell et al, 2012. Effect of prosthetic gel liner thickness on gait biomechanics and pressure distribution within the transtibial socket.

2.4.2 Pressure changes after long-term prosthesis use

The residuum not only undergoes short-term volume changes because of edema but also long-term volume changes as a result of possible muscle atrophy or hypertrophy. During stance phase of walking, peak socket pressure reaches two times that of standing pressure and shear stresses on the residuum also work to increase pressure on the residual limb (Figure 2.10). [40]

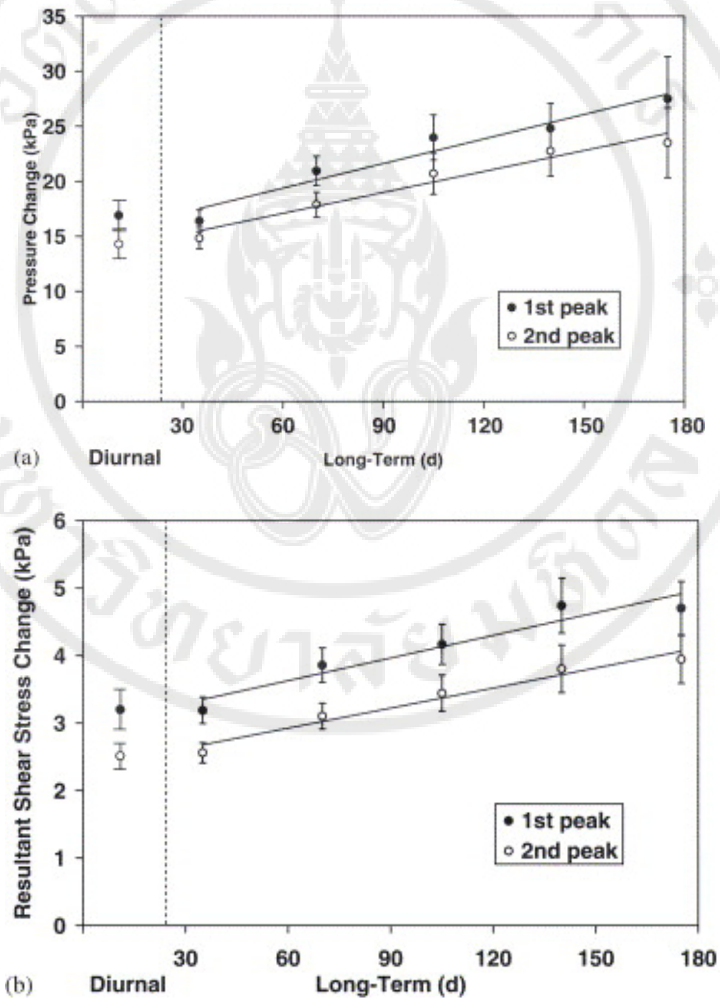


Figure 2.10 Residuum pressure changes during long-term prosthesis use

(a) 1st and 2nd peak in stance phase. (b) Share stress change in long term

Taken from: Sanders et al, 2005. Changes in liner pressures and shear stresses over time on trans-tibial amputee subjects ambulating with prosthetic limbs: comparison of diurnal and six-month differences.

With an inappropriately designed transtibial prostheses socket, problems between the socket and the residual limb occur, leading to increased friction and subsequent surface damage to the soft tissues.[41] Fortunately, metrics from measures of residual limb interface pressure and pressure distribution during ambulation, helps prosthetists better understand prosthesis user comfort.[42]

2.5 Daily activity

The volume of physical activity during daily living has an enormous impact on health. Habitual and moderate intensities of physical activity improve musculature, cardiorespiratory and bone health, and work to reduce the risk of illness.[43] Physical inactivity contributes to global mortality, accounting for approximately 3.2 million deaths annually.[44] Hence, a greater frequency of step counts in a given day is warranted in order to maintain a healthy life and decrease all-cause mortality rate.[45] Prior research suggested a step count of 10,000 steps per day as recommended for healthy adult populations in order to maintain a healthy lifestyle,[46] however more recently, step counts of about 4,400 have evidenced a reduction in mortality.[44] Quantification of daily activity is an important metric in addition to self-reported activity for able-bodied and prosthesis wearers. Self-reported activity measures require the individual to recall previous bouts of activity, which can be challenging and lead to error in measurement.[47] However, using devices such as pedometer has been shown to provide valid and reliable measures of amputee ambulatory activity. [45,48]

Reducing cost of locomotion whilst walking in a prosthesis is often the result of the user reducing walking speed,[49] and perhaps a reduction in daily step counts compared with nonamputee's.[50] Amputee step counts tend to decrease once rehabilitation has ceased, and even so, after rehabilitation, amputee activity is characterized by short-duration types of activities.[51] Thus, to know the daily step count in amputees is wonderful outcome measure in the amputee rehabilitation process.[52]

Prosthesis comfort is cornerstone and most certainly contributes to changes in the amount and type of amputee activity. A prosthetists scope of practice must always be to provide patient comfort so as to encourage an increase in daily activity. The physically active amputee is an amputee whom is in a position to have and maintain a healthy life.

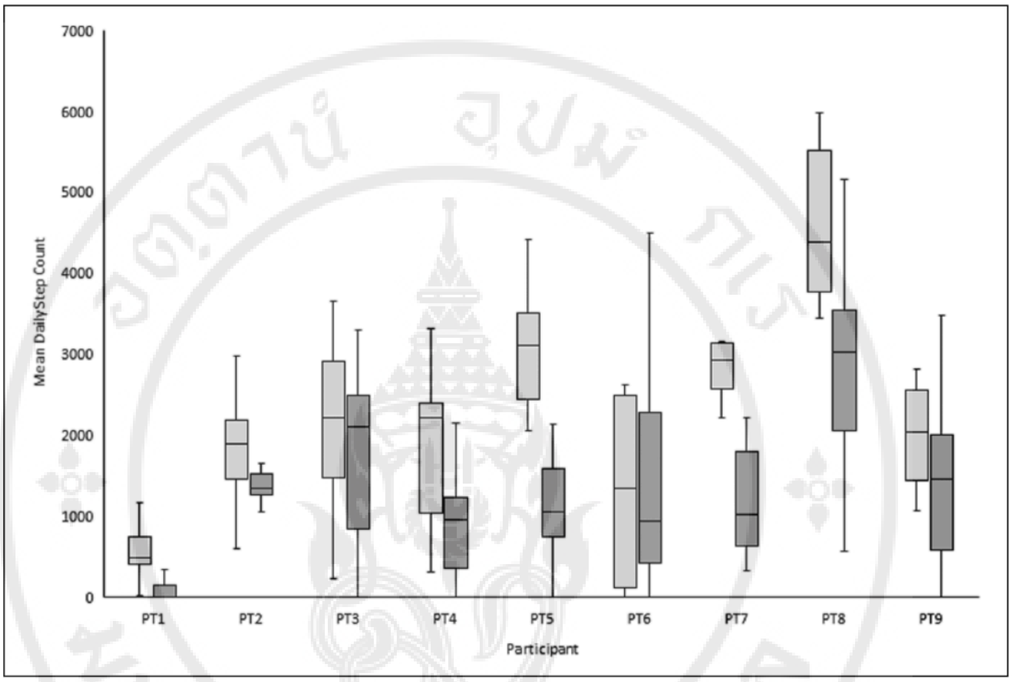


Figure 2.11 Daily step counts of amputees

Note: Daily step count of amputee participants during rehabilitation is indicated by (light gray bars) and post-rehabilitation at home indicated by (dark gray bars). Taken from: Klute et al, 2006. Prosthetic Intervention Effects on Activity of Lower-Extremity Amputees.

CHAPTER III
MATERIALS AND METHODS

3.1 Research design

This study is an interventional pilot study to assess a different type of interface material for transtibial prosthetic wearer. The Affordable Ethylene-Vinyl Acetate Roll-on (AERO) liner was compared to a standard of care (SOC) Polyethylene (PE) liner group.

3.2 Participants

Five transtibial amputees, three males and two females, were invited as participants in this study. The participants had at least one-year prosthetic experience and no current health problems. An IRB was obtained and an informed consent form was obtained from all participants prior to data collection. The participants used an endoskeletal prosthesis with patella-tendon-bearing socket, cuff suspension, four participants used a solid ankle cushion heel (SACH) foot and one participant used single axis foot (1H38), and PE-lite interface material with residuum socks, which is more commonly used in resource limited environments (RLE).

3.2.1 Inclusion criteria

Participants required an activity classification of MCFL K3-K4, over the age of 18 and no older than 70 years of age. The age restrictions were to avoid prosthetic adjustment due to growth of the younger amputee, to avoid risk of diminished physical function, and falls of older amputees. There were no underlying diseases such as cardiovascular disease, respiratory disease, or musculoskeletal disease that affected daily activity. The upper limb functional level of participants required sufficient manual dexterity to roll-on donning by themselves. Residual limb shape was cylindrical or conical in shape and medium length so as to insure that the residuum shape was uniform. The minimum activity classification (Medicare Activity Classification Level) for participation was K3, and all participants underwent the Amputee Mobility Predictor assessment. [53]

3.2.2 Exclusion criteria

Participants requiring use of an assistive device such as cane, walker, and wheelchair, and any major health issues that could directly alter residual limb health or regular disuse of their prosthesis were excluded from participation.

3.2.3 Patient information

The demographics of all five participants is provided in Table 3.1. All participants used their current prosthesis with no major issues.

Table 3.1 Participants profile

Participant	Gender	Age	Height(cm)	Weight(kg)	Cause
A	M	67	175	66	Infection
B	F	62	162	78	Trauma
C	F	66	150	50.5	Trauma
D	M	57	159	60	Trauma
E	M	49	172	80	Trauma

3.2.4 Participants residuum and current prosthesis condition

Participant A was a 67-year-old man, received amputation in 2004 due to infection disease, and K3 activity level. The residuum shape was cylindrical, normal soft tissue, and walked without pain. They wore a traditional PTB style prosthetic socket, cuff suspension, PE-lite interface with a 3-ply sock, and SACH foot.

(a) (b) (c)

Figure 3.1 Participant A. (a) Coronal plane of the residuum. (b) sagittal plane of the residuum. (c) current prosthesis.

Participant B was a 62-year-old woman, and an amputee since 1977 due to an electric shock accident, her activity level was K3. The residuum shape was cylindrical, with good soft tissue and skin condition, and was capable of distal end weight-bearing. A traditional PTB style prosthesis with a PE-lite interface with 2-ply socks and SACH foot were used.

(a) (b) (c)

Figure 3.2 Participant B. (a) Coronal plane of the residuum. (b) sagittal plane of the residuum. (c) current prosthesis.

A 66-year-old woman, an amputee in 1977 due to accident, and K3 activity level. Residuum was slightly short and had a conical shape. They had a traditional PTB style prosthesis with PE-lite interface, 2-ply socks, and SACH foot.

(a) (b) (c)

Figure 3.3 Participant C. (a) Coronal plane of the residuum. (b) sagittal plane of the residuum. (c) current prosthesis.

Participant C was a 57-year-old man, whom received an amputation in 1986 due to bomb, and K3 activity level. Residuum shape was cylindrical and distal end was bony. A traditional PTB style prosthesis with PE-lite interface 2 ply of socks and single-axis foot (Otto Bock 1H38, Dusseldorf, Germany) was used.

(a) (b) (c)

Figure 3.4 Participant D. (a) Coronal plane of the residuum. (b) sagittal plane of the residuum. (c) current prosthesis.

Participant D was a 49-year-old man whom received his amputation in 1996 due to an accident, He had a K3 activity level, cylindrical shaped residuum and could end weight-bear. A traditional PTB style prosthesis was used with a PE-lite interface, 3 ply of sock and SACH foot.

(a) (b) (c)

Figure 3.5 Participant E. (a) Coronal plane of the residuum. (b) sagittal plane of the residuum. (c) current prosthesis.

3.3 Materials and equipment

3.3.1 Costs of local product EVA material

There are a variety of affordable locally produced low density ethylene-vinyl-acetate (EVA) materials in the Bangkok marketplace. The material is sold in various thicknesses (3mm, 4mm, and 5mm). The materials are sold in 1000mm x 2000mm with a price of 200 Thai baht ($6.5) for 3mm, and 250 Thai baht ($8) for 4mm and 5mm versions. This advantage of this material is that it is locally available and sold at a reasonable price point in RLE.

3.3.2 EVA material properties

The tensile and compressive stresses of this EVA material, when compared PE-lite material, is more compressible and stretchable.[54] The EVA material stiffness is more closely related to the Silicone gel interface material, consequently, it enables a Roll-on functionality for this specific local EVA when used made into a prosthetic interface. The material properties data are provided in Table 2.[55]

Table 3.2 Density and Shore A Hardness values for EVA foam prosthesis liners

Material	Density Mean (±SD)	Shore A Hardness Mean (±SD)
Local EVA	92.06 (0.7)	10.96 (0.9)
PE-lite	296.72 (0.0)	42.78 (1.0)

3.3.3 Tools and equipment

3.3.3.1 Vacuum pump

An Otto Bock vacuum pump (Otto Bock, 755E6=220) was used for casting in order to make each participants TSB prosthetic socket. The vacuum pump was set to 500mbar/min, which maintains pressure uniformity during casting. The vacuum machine is comprised of two vacuum circuits, which are to be controlled individually. Each vacuum circuit is provided with one contact pressure gauge and three connections. The connections are secured via input filters and controlled by valves. Exhausted air is withdrawn via a connecting sleeve on the rear of the unit. Exhausted air can be withdrawn with connected rubber hose into evacuation system.

Figure 3.6 Otto Bock vacuum pump

3.3.3.2 L.A.S.A. R posture (Otto Bock, 743L100)

A L.A.S.A.R. Posture was used to optimize the static alignment of all prostheses. This device consists of a force measurement plate with four consolidation force measuring cells, projects laser line optics, a location system with electronics and step motor, a control and display unit as well as a height compensation platform. This device enables the prosthetist to ensure a more biomechanically sound static alignment and to evaluate patient body posture during static fitting of the prosthesis. The body posture in the sagittal plane was visualized by comparing the distances between the ground reaction force and joint centers. The process, enables the static alignment of prosthetic devices to be verified in real-time in order to adjust alignment.

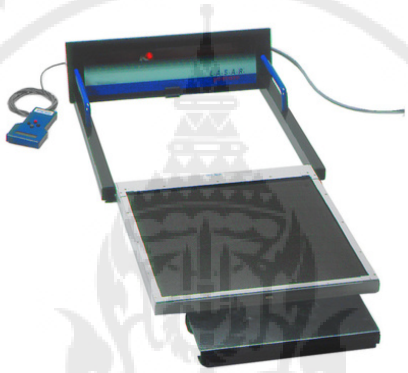


Figure 3.7 Otto Bock L.A.S.A.R posture

3.3.3.3 Omron pedometer

The OMRON HJ-329 pedometer (Omron Healthcare, Shimogyo, Kyoto Japan) was used to collect participant habitual daily step count for 30-days. The pedometer was kept in the participant's prosthetic side pocket and has been previously utilized in prosthesis wearers to accurately measure physical activity. [56]

3.3.3.4 Force Sensing Resistors (FSR)

The pressure measurement selected to monitor and record the interface pressure between the residual limb and prosthetic liner was a FSR sensor. This sensor material is a polymer thick film (PTF) device (Interlink Electronics Inc.) which can be used to accurately determine pressure across various surfaces. This sensor characteristic works off a principle of an electrical resistance value, which will decrease as pressure is applied to an active area of interest. The active area of this sensor was 5mm in diameter with a thickness of 0.30mm.

Figure 3.8 FSR sensor

3.3.3.5 Arduino Uno software and hardware

The data output from the FSR was acquired using an Arduino UNO board, with open source software (Arduino IDE). The Arduino UNO board was capable of acting as a mini-computer like other microcontrollers by taking inputs and controlling the outputs. The microcontroller can thus, receive as well as send information or commands to peripheral devices connected to it.[57] For the pressure distribution test, voltage data from the FSR sensor was transmitted through Arduino microcontrollers board to a computer. The serial code for controlling this software is described in Appendix 1.

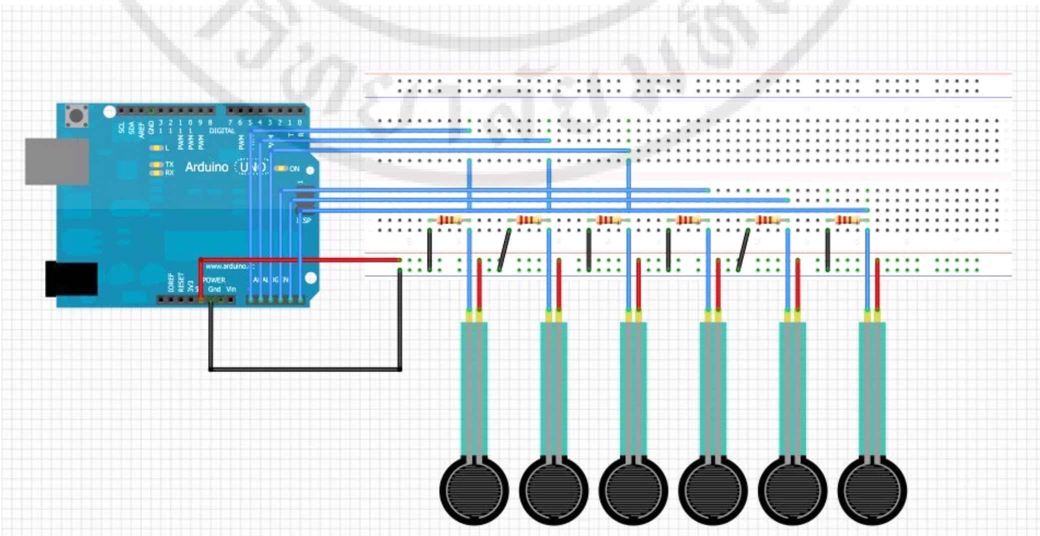


Figure 3.9 Arduino pressure sensor system

3.3.3.6 Treadmill ergometer

For the 2-minute walk test, a single-belt treadmill machine (TS7202I, China) with harness was used. Pressure distribution was measured while the participants used the FSR sensor which was placed across the residuum.

3.3.3.7 Fourier Transform Infrared Spectrophotometer (FTIR)

FTIR spectrometers (Perkin Elmer) are widely used techniques for identifying organic synthesis, polymer science, petrochemical engineering, pharmaceutical industry, and food analysis. Moreover, FTIR can investigate the mechanism of chemical reactions and the detection of unstable substances. In this study, Spectrum One FTIR spectrometer was used to determine the chemical compositions of PE-lite and EVA materials.

Figure 3.10 FTIR machine

3.4 Procedure

This study mainly was divided into three different procedures. Firstly, the AERO liner was provided for evaluation in the patient's current prosthesis for at least one month, they were provided three AERO liners. During this time step count was evaluated using the pedometer, the Orthotic and Prosthetic User's Survey was administered one month after provision. The OPUS was also administered to the patient at the beginning of the study to evaluate patient-reported outcomes of the chosen prosthetic intervention.

Secondly, the investigator fabricated a different type of socket, a Total Surface Bearing (TSB) socket, which is more appropriate for prosthesis wearers using roll-on liners. A pressure distribution test was administered to compare the patients current socket with PE-lite and AERO liner interfaces. Finally, the EVA and PE-lite material's construction was evaluated by FTIR material testing. The participants were invited at least five times for pressure sensor testing.

3.4.1 AERO liner prefabrication

Custom made liners were prefabricated from three residual limb measurements. The EVA material was prepared from a square sheet with a size of 400mm x 350mm. The pattern creation process for AERO liner fabrication can refer to a predetermined table (Table 3.3).

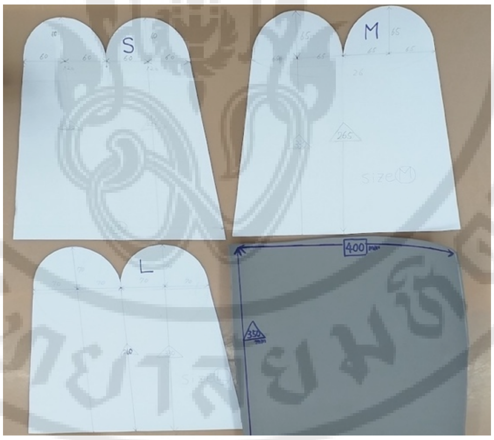


Figure 3.11 Pattern for cutting EVA material

Table 3.3. Size of AERO liner

mm	Size S	Size M	Size L
A	240	260	280
B	330	350	270
C	330	330	330

A: Circumference at the distal 4cm level.

B: Circumference at the apex of femoral condyle.

C: Total height, Supra-patella to apex of distal end of residuum

(a) (b) (c) (d) (e) (f)

Figure 3.12 Process of prefabrication of AERO liner

(a) Grind the edges of the surface to ensure good adhesion between each surface. (b) Glue the edges of the liner which was cut from material using polychloroprene adhesive. (c) Bond the edges together using glue to avoid any splitting. The distal part of the liner was rounded through heating. Make a liner stockinette to cover the surface to provide roll on donning. (d) Apply adhesive to all surface on liner. (e) Stick them with a adhere to provide decrease friction. (f) Don to residuum.

3.4.2 Alternative donning method

Normally, when the patient uses a PE-lite liner, they apply one sock for cushioning and absorption of sweat, and don with stockinette to draw in the PE-lite interface, they then push into prosthetic socket. This method causes poor integration between residuum and PE-lite, thus, pistoning will occur during walking, which easily leads to residuum pain and wounds. On the other hand, use of a roll-on can mitigate issues seen in a push-in liner donning method. After measuring 4cm from the distal end for deciding the AERO liner size, guidance to the participants on how to don this liner was provided. The following description was provided to each participant to make certain they could don independently.


(a)


(b)


(c)


(d)

Figure 3.13 Donning of AERO liner for participant D

(a) Turn inside out of the liner, confirm a rounded part of the bottom end of the liner is exposed and place it against the limb. (b) Check to make sure no air pockets exist between the liner and the end of residuum. (c) With light pressure, roll on the liner over to and above the knee. (d) Push the residual limb into the prosthetic socket. After donning.

After each participant donned the liner, we cut the liner following the edge of a prosthetic socket, otherwise, the liner will hinder knee flexion.

(a) (b)

Figure 3.14 Roll-on donning and Liner cut line
(a)Anterior view. (b) Lateral view

3.4.3 Vacuum pressure casting

An ill-fitting and suspended transtibial prosthesis can lead to pain and scars due to pressure and shear stress at the wrong locations of the residuum during walking. In order to prevent these symptoms, a Total Surface Bearing (TSB) type socket which supports the limb uniformly by applying uniformed pressure across the entirety of the residuum.[24] The TSB socket is expected to have uniform pressure distribution across the entire residuum. In this study, a TSB socket with AERO liner was made, and compared to a PTB traditional style prosthesis. The PTB style is commonly used for transtibial amputee patients in Thailand. When a make TSB socket, following one of the common casting methods using a prosthetic liner.

Initially, a 5mm AERO liner was donned, the circumference at the MPT level, and then every 30mm distal from the MPT level is measured, and residuum length is measured. Then, the participant doffed the 5mm liner and donned a 3mm liner, the same measures are taken again. The difference between these two sets of measurements is roughly 3-4%. In this way, casting with the 3mm liner automatically compresses the limb in a way which reduces the time required for positive model rectification. In addition, the thinner liner is more likely to capture the contours of residuum bony and soft tissue than if using a thicker liner.

The participant was then instructed to contract the muscles of their residuum briefly, and any changes in shape were observed before casting. The casting position of the residuum flexion angle was approximately 10°. Then plaster bandages were applied around the residuum as smoothly as possible in an evenly pressured manner. Next, a stockinette was placed over the plastic bandage which served as a wick for air to flow onto the liner during vacuum casting. A latex casting bag was then pulled over the plaster cast and sealed proximally, vacuum hose was connected and the distal connection of the casting bag was placed on the stockinette. The vacuum pump was then turned on (vacuum: min.500 mbar). The patient was asked to contract and relax the residuum alternately, so that the bone and soft tissue would be reflected in the cast.

Figure 3.15 Vacuum casting

3.4.4 Positive model modification

Reference points for the circumferential and length measurements on the plaster model were determined and marked with indelible ink. Dimensions were recorded on the measurement sheet and compared to data during casting to calculate reduction values. The plaster model was then divided into three sections, Mid patella tendon (MPT) level, MPT to the middle of residuum (area A), and distal from the middle of the residuum (area B), and mark.

Circumference of the positive model was reduced evenly according to the measurements from the 5mm thickness liner. In this study, the MPT level was reduced by 2% to 2.5%. Area A was reduced 3% to 4%, area B reduced 3% to 5% (if the residuum shape is cylindrical 4%, and conical 5%) according Otto Bock modification criteria. [58]

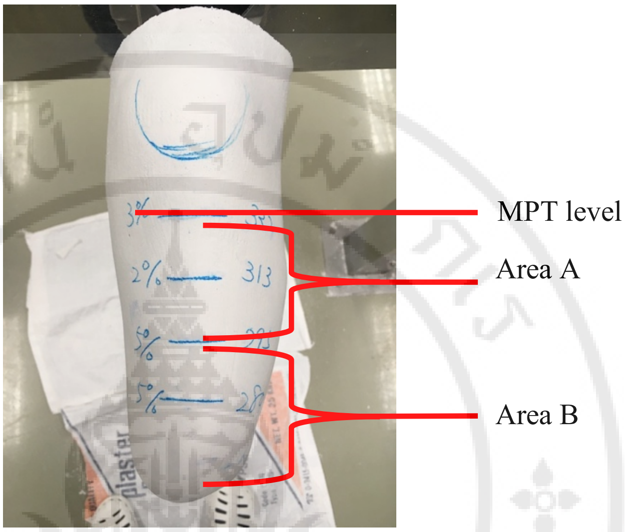


Figure 3.16 Reduction areas of the positive model

3.4.5 Outcome measures

The pedometer was used to evaluate the number of steps the participant took across a period of 30 days. The OPUS questionnaire, and socket comfort score after ambulation was also evaluated. Moreover, the FSR pressure sensor was used to observe changes in pressure applied to the residual limb in each type of prosthesis. Finally, PE-lite and EVA material composition was evaluated in an FTIR material test.

3.4.5.1 30-day activity monitor

Two participants began step count monitoring with their own PE-lite device, in contrast, the other three participants were given an AERO liner on their first visit and then proceeded to the 30-day activity monitoring. All participants began step count upon waking every morning when they donned the prosthesis, and kept the pedometer in their prosthesis side pocket. The pedometer was then removed after from their pocket at the end of the day. Participants were instructed to take a photo of the pedometer which was then to the investigator every day. All participants were measured at least 30 consecutive days. Each participant was swapped interfaces and continued activity monitoring for another 30 days. In total, all participants completed step count monitoring for 2 months.

3.4.5.2 Orthotics and Prosthetics User's Survey (OPUS)

The OPUS is useful when attempting to identify activity, evaluating changes in functional status and quality of life, as well as assessing satisfaction with devices and services. This questionnaire is divides into three main parts with 20 items for lower extremity functional status measure, 23 items for health quality of life index, and 21 items for satisfaction with device and services (11 items for device and 10 items for services). Each raw score can then be converted to a 100 scale using Rasch methods.

3.4.5.3 Socket comfort score

The comfort after one-month of use in either liner was evaluated using the Socket Comfort Score (SCS). There are 11 categories (0-10) which correspond to the participant's socket comfort. Most discomfort is indicated by a score 0 and most comfortable indicated by a score of 10. In addition, participants were asked to provide reasons for their preferred SCS at the time of data collection.

3.4.5.4 Pressure sensor calibration

Before test pressure distribution, the FSR sensor has to calibration performing by loading test. The sensor output voltage was known values of pressure applied to the sensor, the sensor output voltage data recorded for 30 second, the weight was calibrated start from 20g, and increase 20g until 200g to require 10 different weight data. The retrieve data was converted from voltage to millimeters of kilopascals (kPa) by following formula [59]:

$$\frac{\text{force}}{\text{area}}(\text{kPa}) = \left(\frac{\text{weight (g)} \cdot 735.5591}{\text{contact area (cm}^2) \cdot 1000}\right) \cdot 0.133322$$

The relationship between voltage and kPa data for each sensor is shown figure 3.17. Lead a formula from each data extracted by calibration to convert sensor voltage data to a kPa.

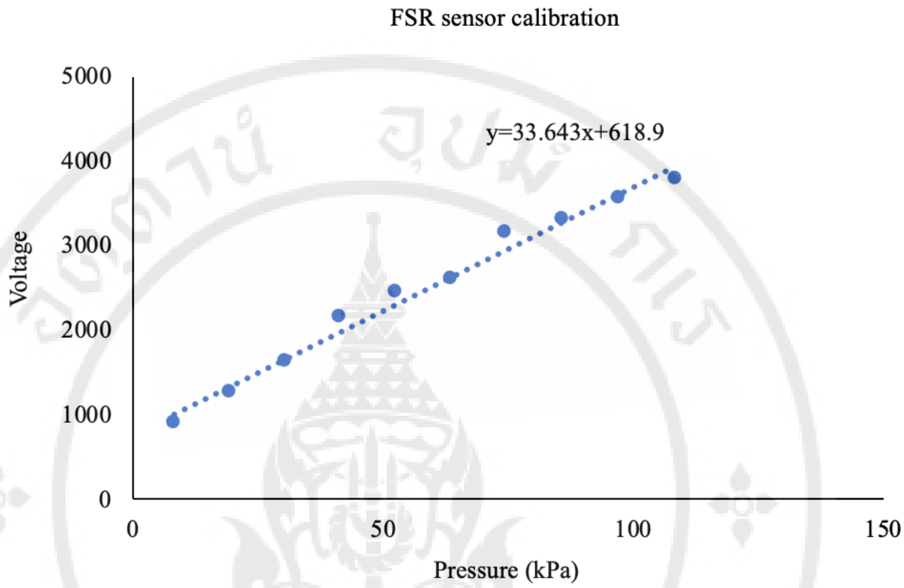


Figure 3.17 Relationship between voltage and pressure (kPa)

3.4.5.5 Pressure distribution evaluation

The participants were provided three different in the participants own PTB prosthetic socket with PE-lite, AERO liner, and TSB socket with AERO liner, and underwent a pressure distribution test. To understand pressure distributed across the residuum during walking, we administered a 2-minute treadmill walk test at each participant's self-selected comfortable walking speed 0.66 m/s (range of 0.38-0.69m/s). Participants performed the test once while wearing either the PE-lite or AERO liner. During the test, pressure sensors were placed on the six points of interest of the residuum and AERO liner and prosthesis were donned. Pressure was evaluated using a novel method we called "pressure uniformity" (P_{unif}). Pressure uniformity is the ratio of each step's maximum pressure peak to the minimum pressure peak (P max/P min) calculated as:

$$\text{Pressure uniformity ratio} = \left(\frac{1}{n} \cdot \sum_{k=1}^{n} \frac{Max\ peak\ (k)}{Min\ peak\ (k)}\right)^{-1} \cdot 100$$

The data was collected across 30 steps cycle of the prosthesis side walking. This method was chosen as it selected a middle section of the trial to avoid potential influence of warm-up and fatigue effects. [60] The figure 3.18 illustrates an example of pressure distribution data for participant A.

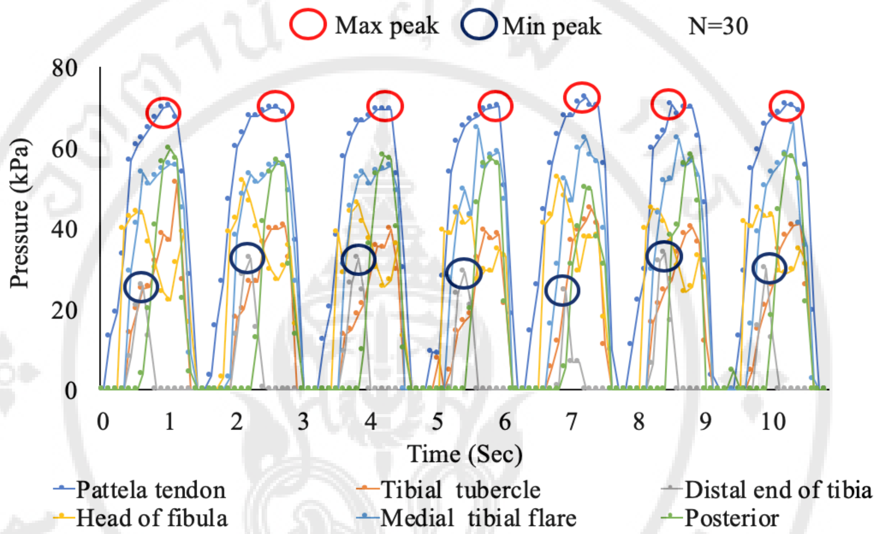


Figure 3.18 Maximum and Minimum peak pressure across 30 steps of walking for participant A

The participants practiced walking to determine a normal self-selected walking speed. Then, 6 sensors were attached to the residuum; patellar tendon, tibial tubercle, anterior distal end of tibia, head of fibula, medial flare, posterior proximal gastrocnemius. The participants were recorded for two-minute during the test, recorded by the Arduino system. The participant then sat in a chair and rested comfortably for 5-minutes with the prosthesis donned while they were asked for their SCS. Three two-minute trials occurred, the interface was swapped, and the test was performed again using the same process.

Figure 3.19 Image illustrating pressure distribution testing

Table 3.4 Participant limb anthropometry, weight and walking speed in (m/s)

Participant	Age	Residuum length(mm)	Weight(kg)	Walking speed (m/s)
A	67	150	66	0.5
B	62	144	78	0.69
C	66	105	50.5	0.38
D	57	147	60	0.66
E	49	165	80	0.69

3.4.5 Material testing

The EVA and PE-lite materials determine the main chemical compositions from a part of sample. structure clarify by Fourier Transform Infrared Spectrophotometer (FTIR) testing.

FTIR used infrared spectrum of emission and absorption of the samples to create a unique molecular fingerprint spectrum. The test was repeated a few times for each sample and the most representative results were used.

3.5 Data analysis

Intervention of PE-lite and AERO liner for each patient have observed change in daily step count for 30-day from each participant. The two different liner data, PE-lite and AERO liner, were calculated using the Wilcoxon t-test.

After collected step count data, OPUS was used to measure the participants satisfaction with the device from 30-day. The data converted to 100% scale from the total 64 questions score. Those calculated PE-lite and AERO liner for each participant using Wilcoxon t-test.

we also intervene socket comfort score to get feedback from participant. Each liner data was calculated by Mann-Whitney U-test to show the significant different.

Pressure distribution data was collected using the FSR sensor placed on the residuum as previously described during 2-minutes of treadmill walking. Thirty steps of data from were extracted from each data set, and the ratio of maximum and minimum pressure data (max/min) of each step was analyzed using a Non-parametric repeated ANOVA, Friedman's X2 r-test (Wilcoxon t-test with Bonferroni correction).

CHAPTER IV
RESULTS

A total of 5 individuals with a transtibial amputation participated in the study. All participants completed the outcome measures using AERO liner and PE-lite at least 30-days each and those liners satisfaction evaluated using OPUS and SCS. For pressure distribution tests, provided TSB socket for each participant, and evaluated in three different conditions such as PTB socket with PE-lite, PTB socket with AERO liner, and TSB socket with AERO liner.

4.1 Liner cost

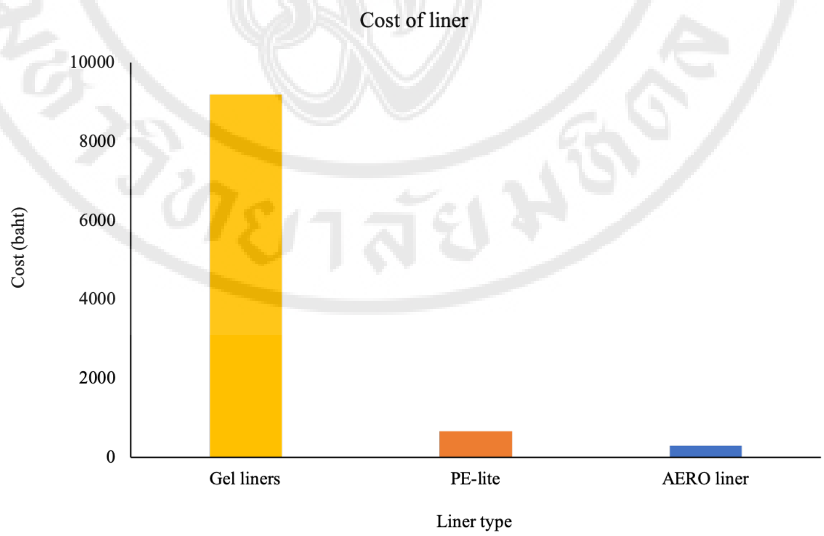


Figure 4.1 Each liners cost

Each interface material cost indicated figure 4.1. The gel liner is the cheapest liner that we could purchase in Thailand. It is almost 14 times expensive than PE-lite and the cost is around 9,200 baht ($295). On the other hand, AERO liner is slightly cheaper than PE-lite, it is 330 baht ($10).

4.2 30-day activity monitor

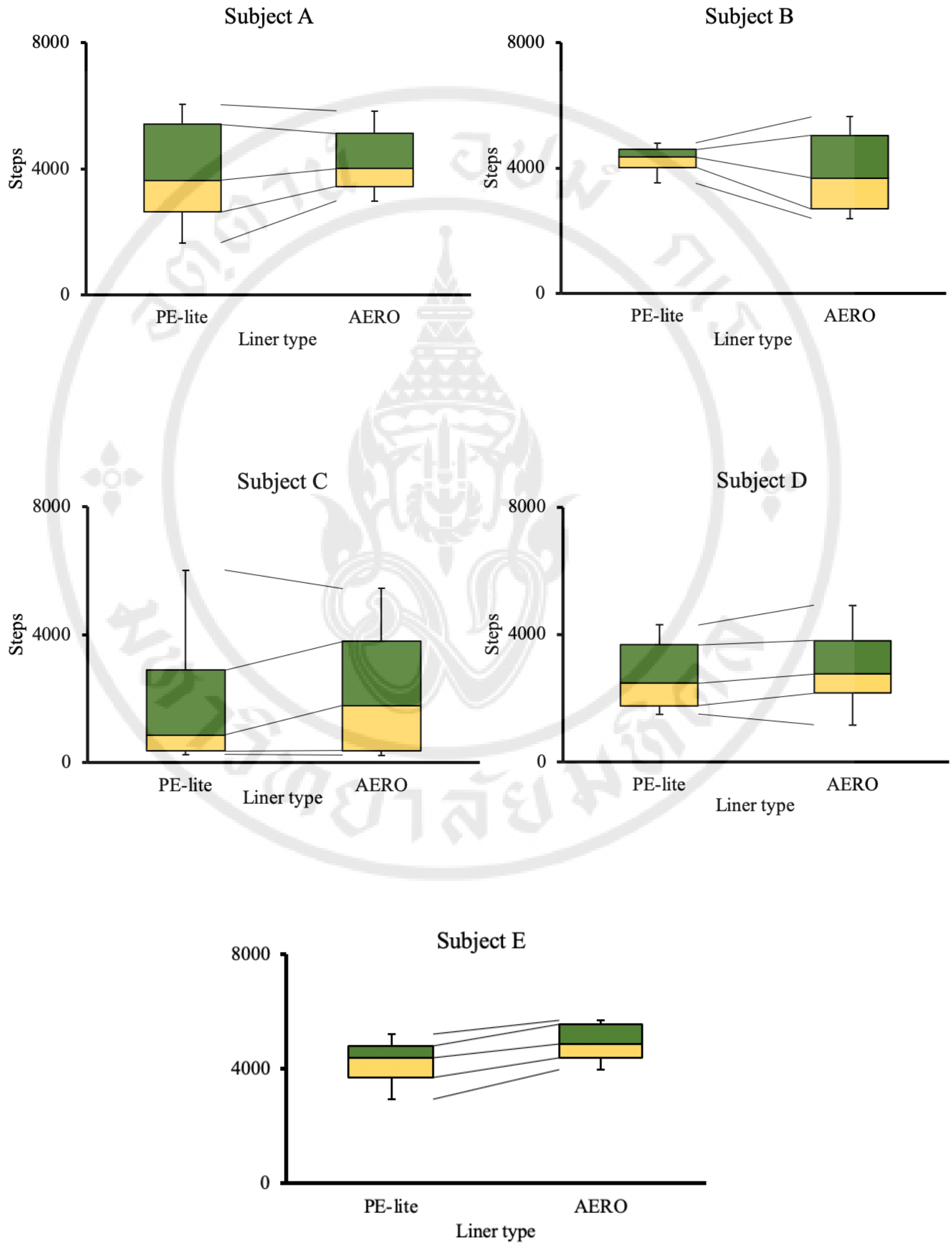


Figure 4.2 All patients step count for 30-days

All participant step count data for 30-days, using PE-lite and AERO liner, collected by a pedometer, shows Figure 4.2. The daily step counts were slightly increased using AERO liner except for participant B. However, there was no significant difference among all participants.

4.3 Orthotics and Prosthetics User's Survey

All participants answered questions, after using 30-days PE-lite and AERO liner, and the raw score was converted 100 scales using Rasch measure (0-100 scale). In Table 4.1 shows lower extremity functional status, Table 4.2 for health quality of life index, and in Tables 4.3 and 4.4 satisfaction with service and device.

Table 4.1 All participants score of Lower Extremity Functional Status (n=20)

Subject	PE-lite	AERO
A	42.9	45.8
B	65.4	57.6
C	54.3	58.3
D	59.7	59.7
E	58.3	59.0
Mean	56.1	56.1
SD	8.3	5.7

Table 4.2 All participants score of Health Quality of Life Index (n=23)

Subject	PE-lite	AERO
A	48.8	45.2

B	62.8	65.1
C	57.6	56.1
D	58.1	56.1
E	67.9	60.9
Mean	59.0	56.7
SD	7.0	7.4

Table 4.3 Total score of Satisfaction with Device for each participant (n=11)

Subject	PE-lite (SD)	AERO (SD)
A	39.9	43.9
B	43.9	54.9
C	58.5	50.7
D	47.5	52.0
E	52.0	45.6
Mean	48.3	49.4
SD	7.2	4.5

Table 4.4 Total score of Satisfaction with Service for each participant (n=10)

Subject	PE-lite	AERO
A	45.6	50.2
B	65.6	69.1

C	52.6	50.2
D	50.2	55.4
E	55.4	49.5
Mean	53.9	54.9
SD	7.4	8.2

From each participant, there were slight differences between PE-lite and AERO liner result, however, there were no significant different, when comparing all score.

4.4 Socket comfort score

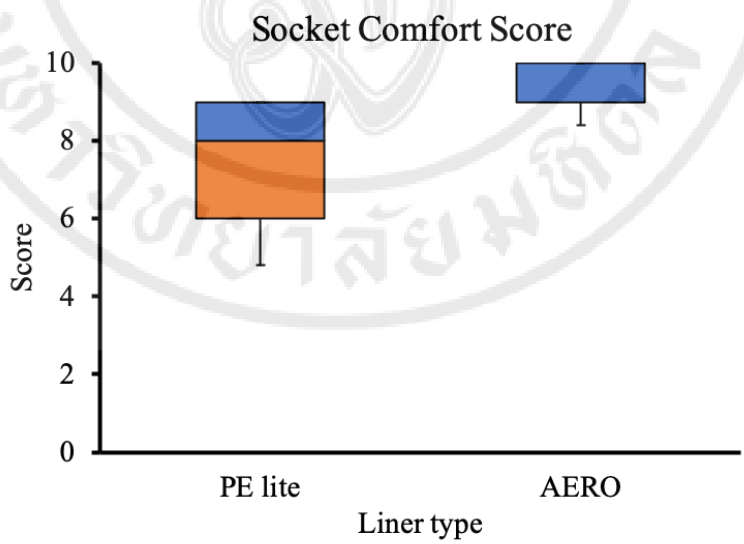
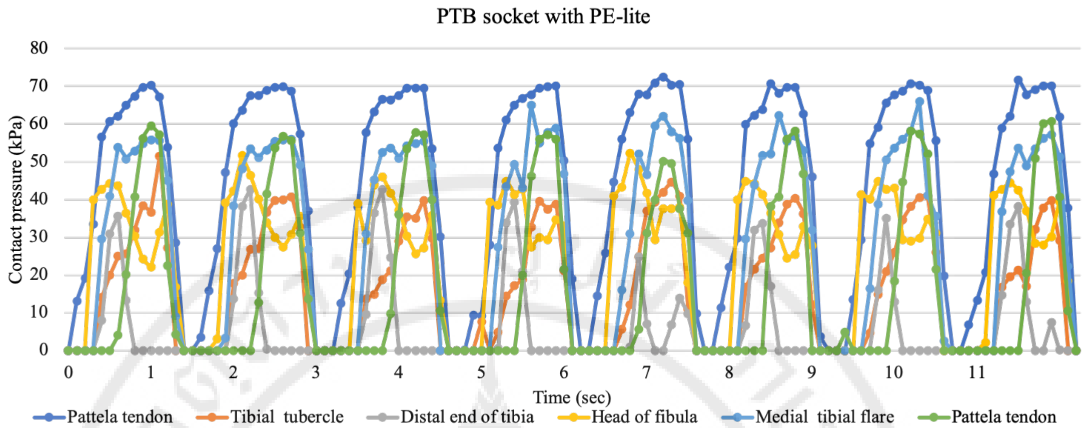


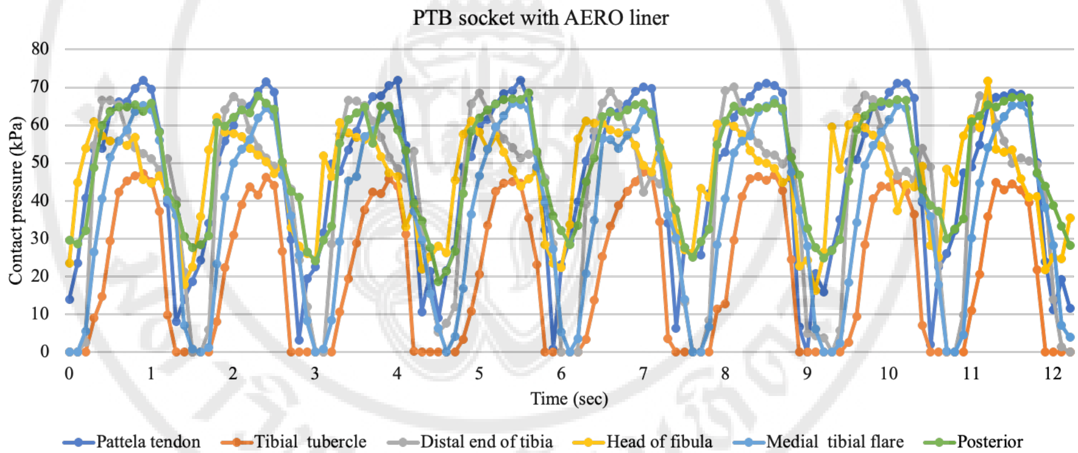
Figure 4.3 Socket comfort score of each liner

The graph shows a socket comfort score that asked each participant after use PE-lite and AERO liner for 30 days. The result of PE -lite was 7.2±2.1, and AERO liner was 9.2±0.8.

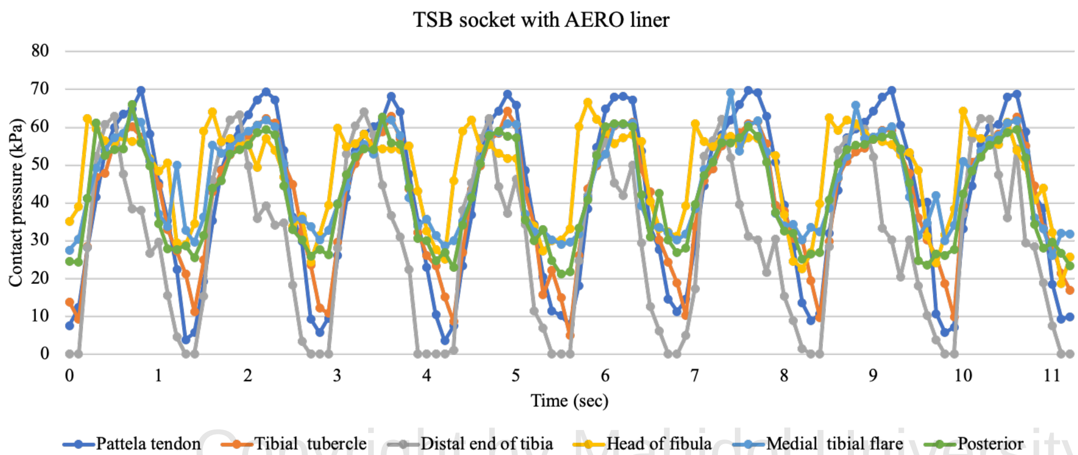
4.5 Pressure distribute evaluation



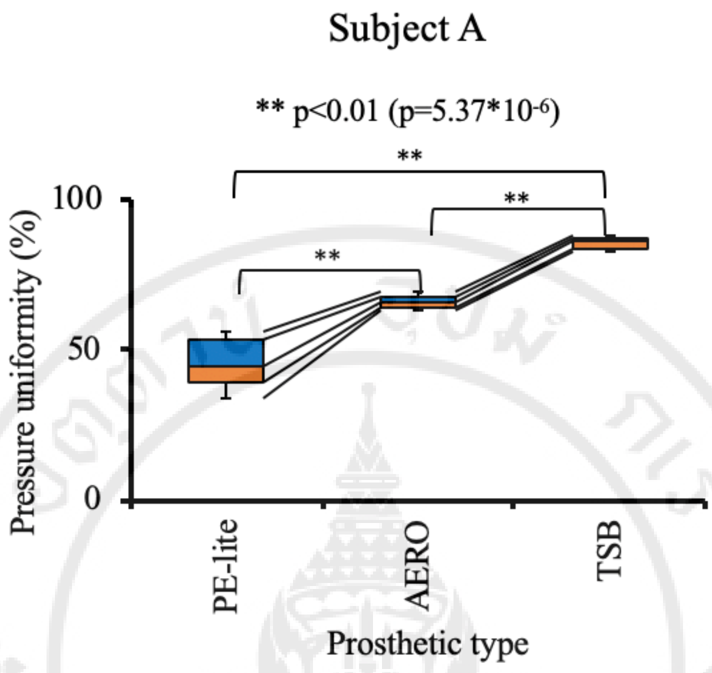
(a)



(b)



(c)

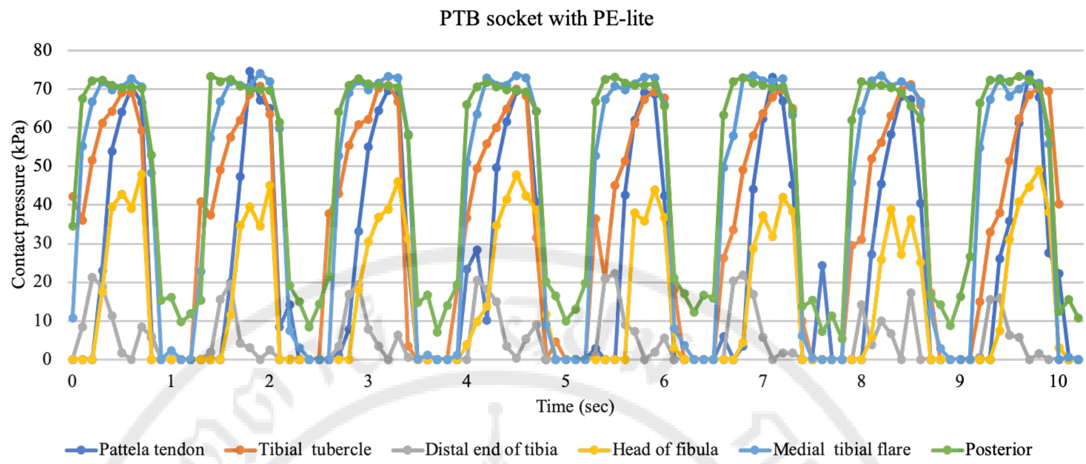


(d)

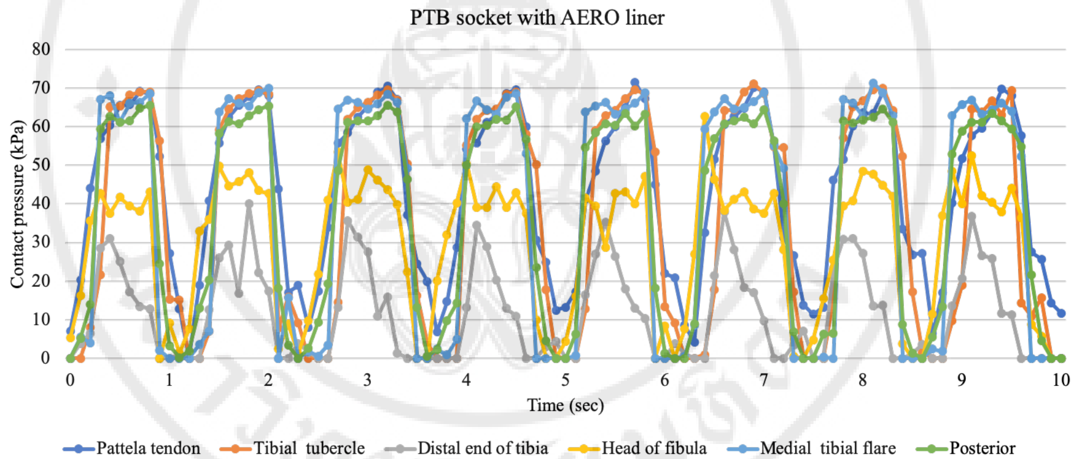
Figure 4.4 Participant A pressure uniformity of 30 steps from 2-minute walk test.

Illustration of the pressure distribution of 2-minute walk test (a) PTB socket with PE-lite. (b) PTB socket with AERO liner. (c) TSB socket with AERO liner. (d) Pressure uniformity of 3 different type device.

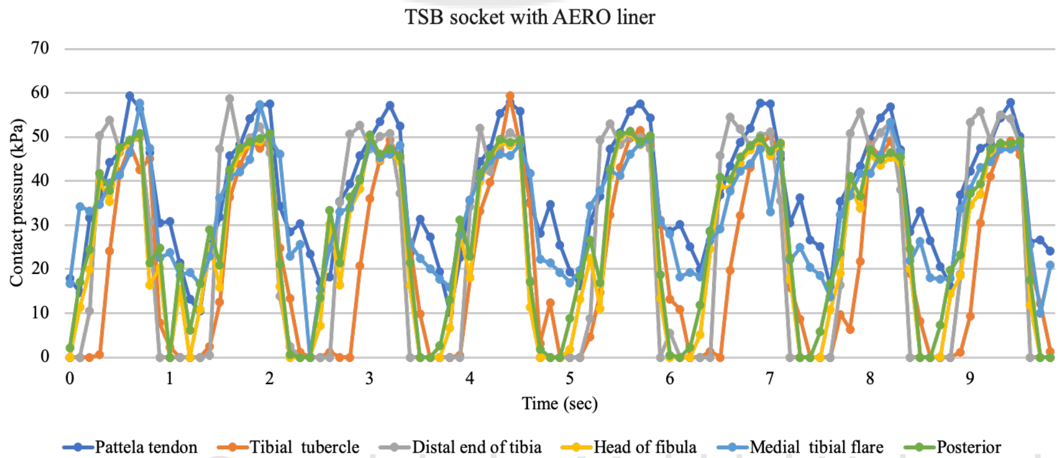
The pressure data for three different conditions of the participant A is shown in Figure 4.4. The largest difference pressure peak between maximum and minimum was 39.01 kPa in the PTB socket with PE-lite. On the other hand, when using AERO liner, the pressure at the distal end was increased and obtained more uniformity pressure, and the difference between maximum and minimum peak pressure was 23.7 kPa. In addition, the TSB socket with AERO liner applied the smallest difference of peak pressure was 9.84 kPa. Figure (d) shows the ratio of each difference ratio of pressure uniformity. Comparing each pressure uniformity, PE-lite with PTB socket was 45.37% ($p=5.37*10^{-6}$), AERO with PTB socket was 66.68% ($p=5.37*10^{-6}$), and the TSB socket with AERO liner was the most ideal, and it was acquired 85.6% ($p=5.37*10^{-6}$) of the pressure uniformity.


PTB socket with PE-lite
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

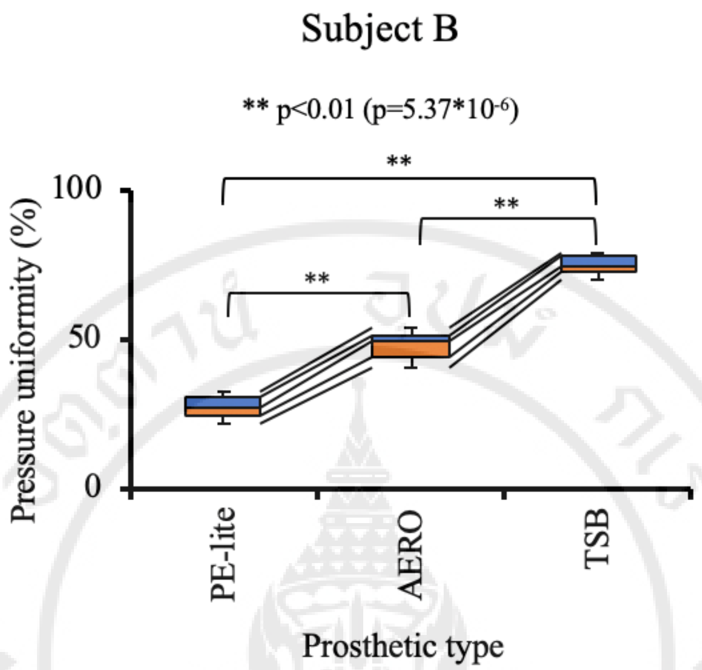
(a)


PTB socket with AERO liner
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(b)


TSB socket with AERO liner
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(c)

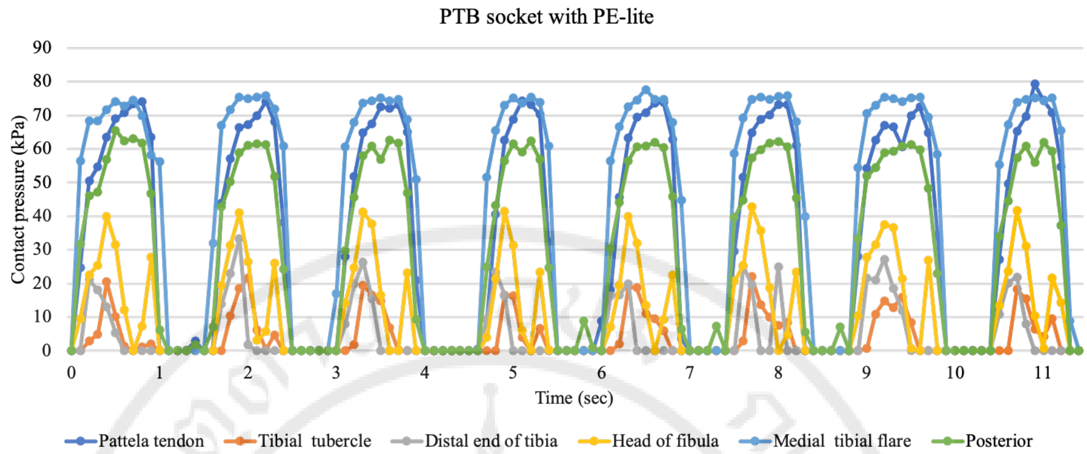


(d)

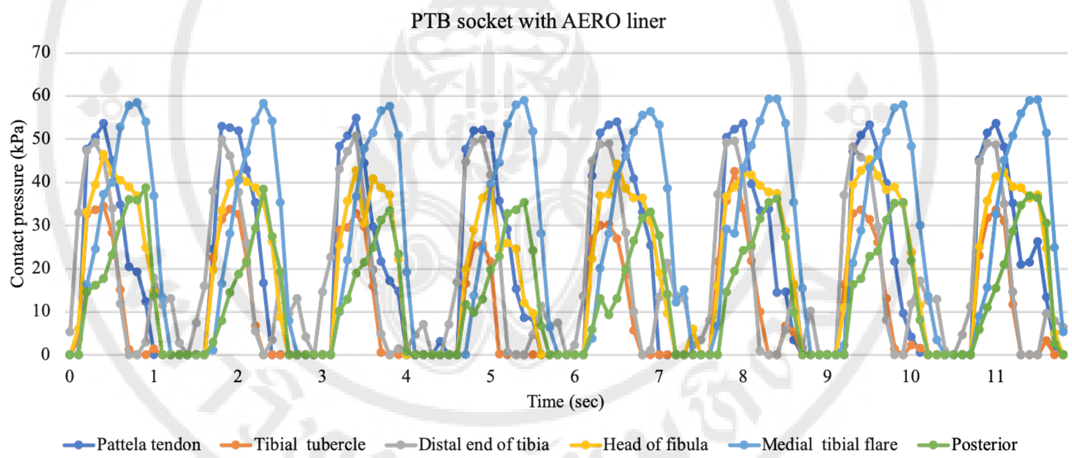
Figure 4.5 Participant B pressure uniformity of 30 steps from 2-minute walk test.

Illustration of the pressure distribution of 2-minute walk test (a) PTB socket with PE-lite. (b) PTB socket with AERO liner. (c) TSB socket with AERO liner. (d) Pressure uniformity of 3 different type device.

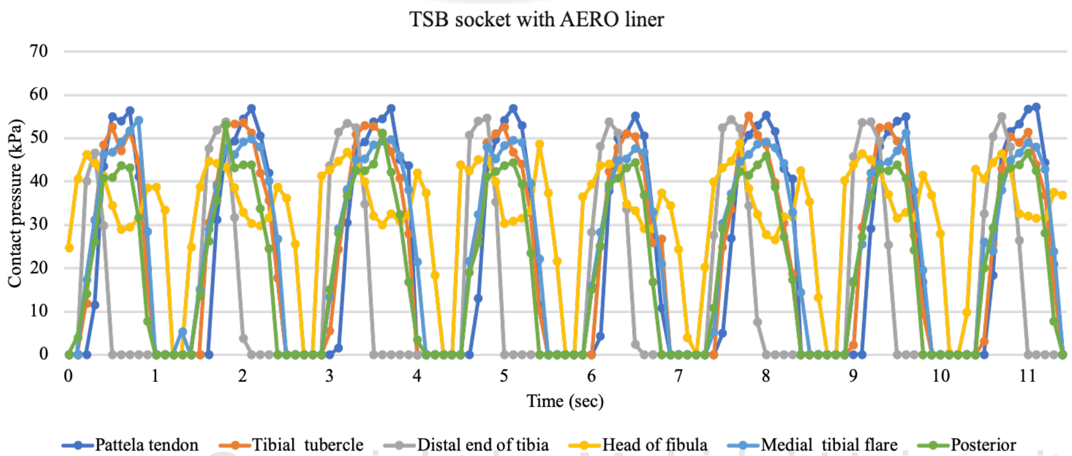
The graph of pressure distribution of participant B is shown in Figure 4.5. The PTB socket with PE-lite was the largest gap between maximum and minimum peak of pressure, and it was 53.97 kPa difference. The gap was decreased to 36.91 kPa when used AERO liner for PTB socket. Furthermore, the TSB socket with AERO liner was only 15.69 kPa gap of maximum and minimum peak pressure. For pressure uniformity ration, the PTB socket with PE-lite was 27.17% ($p=5.37*10^{-6}$), AERO with PTB socket was 48.0% ($p=5.37*10^{-6}$), and the TSB socket with AERO liner was provided more ideal pressure 74.55% ($p=5.37*10^{-6}$).


PTB socket with PE-lite
Contact pressure (kPa)
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tuberclе
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

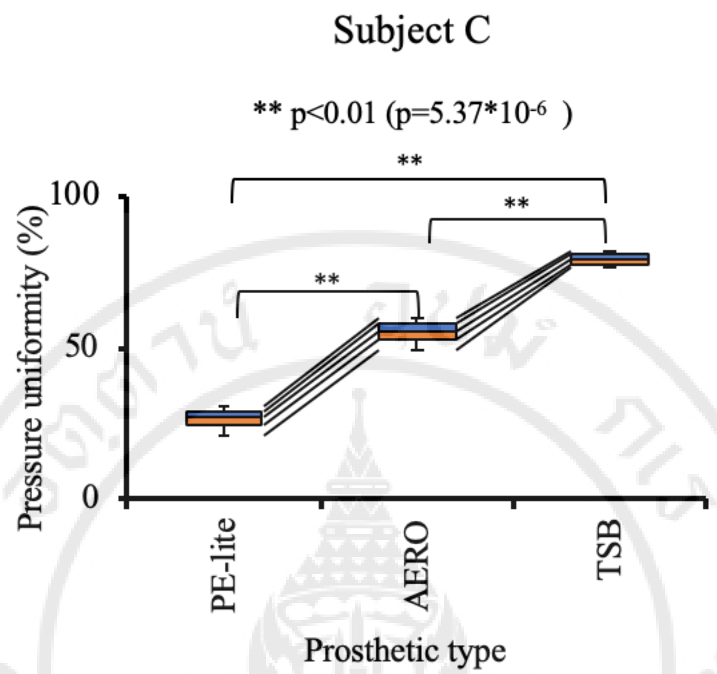
(a)


PTB socket with AERO liner
Contact pressure (kPa)
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(b)


TSB socket with AERO liner
Contact pressure (kPa)
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(c)

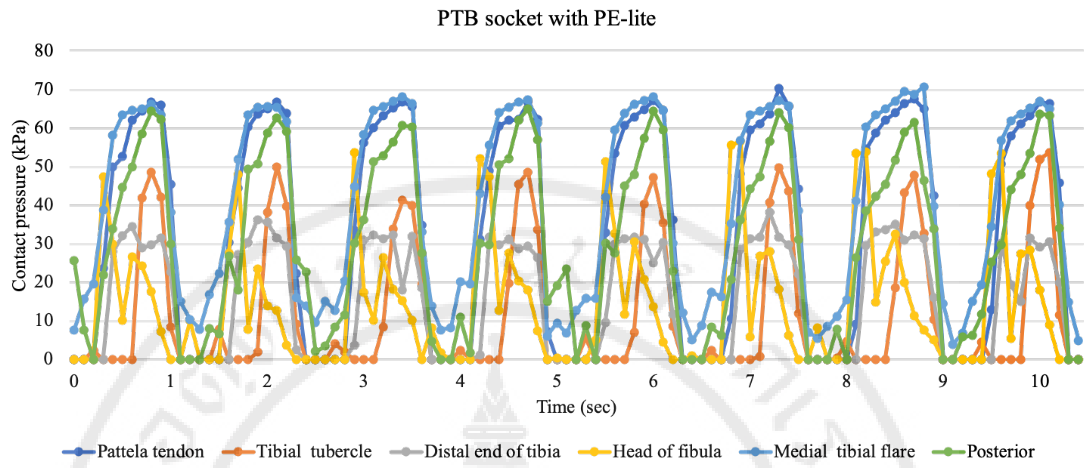


(d)

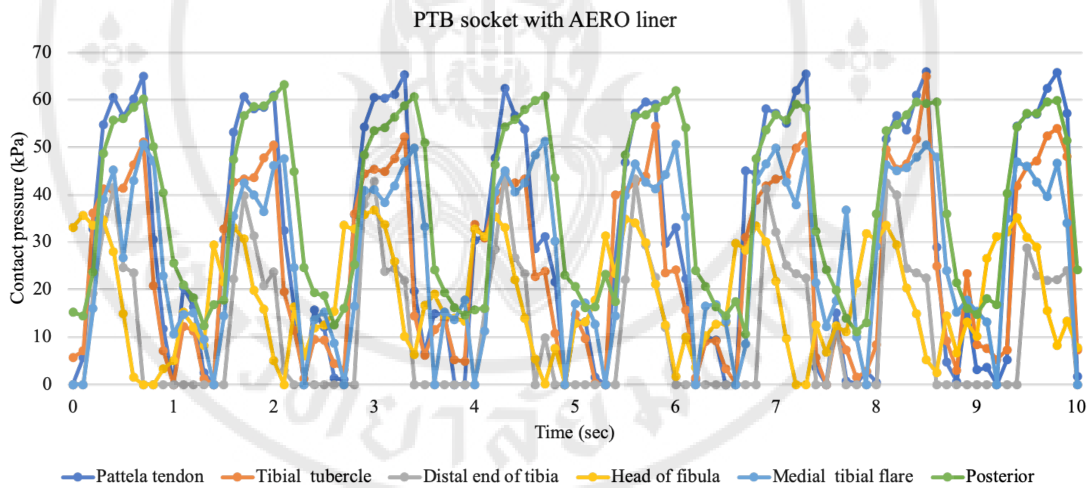
Figure 4.6 Participant C pressure uniformity of 30 steps from 2-minute walk test.

Illustration of the pressure distribution of 2-minute walk test (a) PTB socket with PE-lite. (b) PTB socket with AERO liner. (c) TSB socket with AERO liner. (d) Pressure uniformity of 3 different type device.

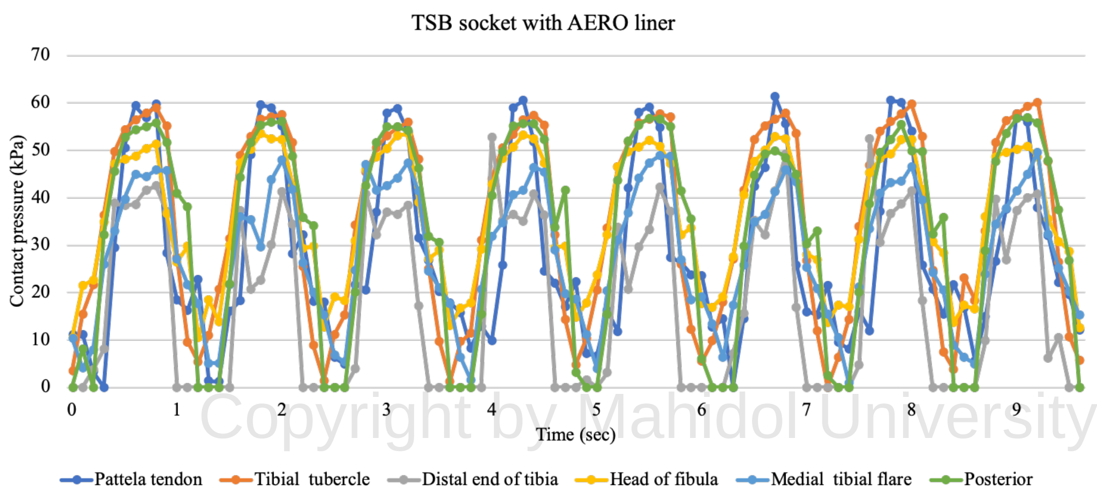
The pressure data for three different conditions of participant C is shown in Figure 4.6. The difference between maximum and minimum peak pressure of PTB socket with PE-lite was the largest inequality of 55.61 kPa. When intervening AERO liner for PTB socket, difference peak pressure decreased to 26.15 kPa. Then, TSB socket with AERO liner provided 11.59 kPa. Regards the ratio of pressure uniformity. The PTB socket with PE-lite was 26.71% ($p=5.37*10^{-6}$), and intervene AERO liner for PTB socket was 55.4% ($p=5.37*10^{-6}$), the TSB socket with AERO liner was indicated more ideal of the pressure uniformity, and it was 79.62% ($p=5.37*10^{-6}$).


PTB socket with PE-lite
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

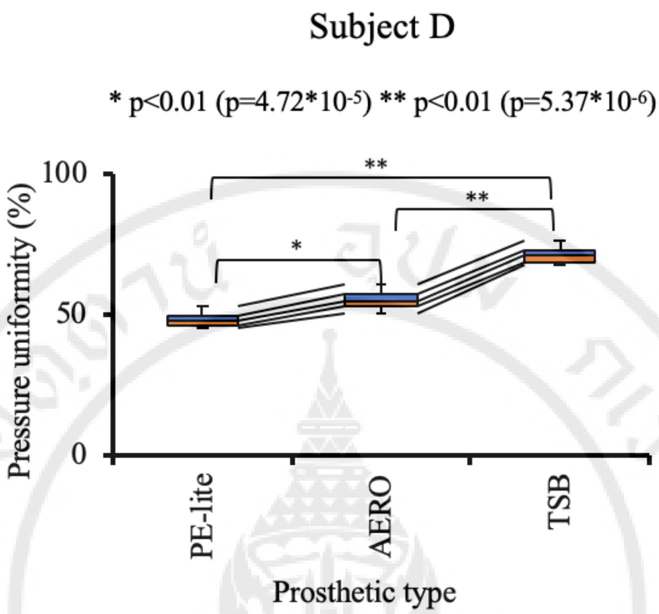
(a)


PTB socket with AERO liner
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(b)


TSB socket with AERO liner
Contact pressure (kPa)
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(c)

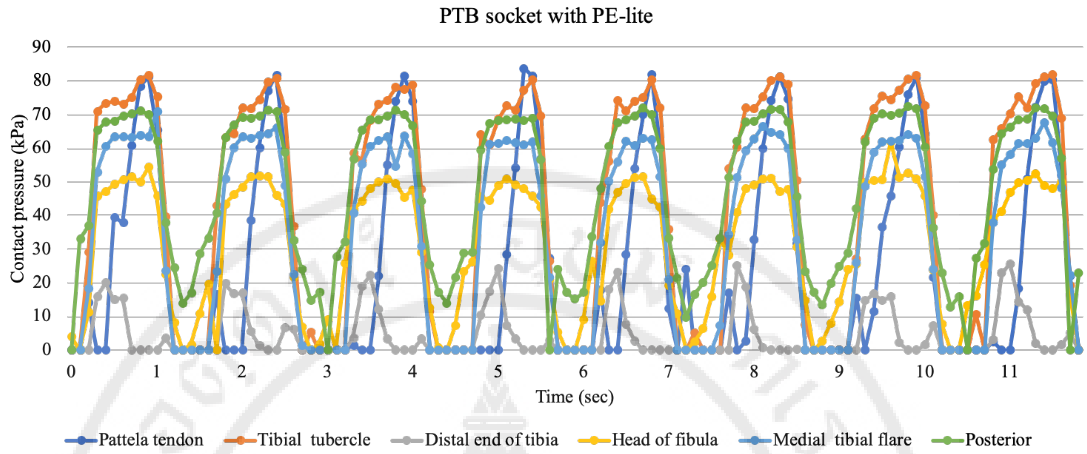


(d)

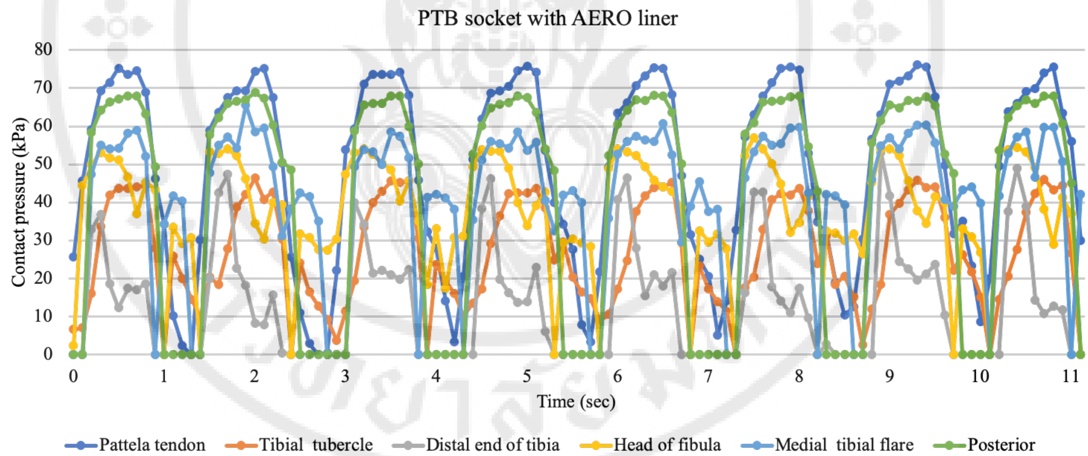
Figure 4.7 Participant D pressure uniformity of 30 steps from 2-minute walk test.

Illustration of the pressure distribution of 2-minute walk test (a) PTB socket with PE-lite. (b) PTB socket with AERO liner. (c) TSB socket with AERO liner. (d) Pressure uniformity of 3 different type device.

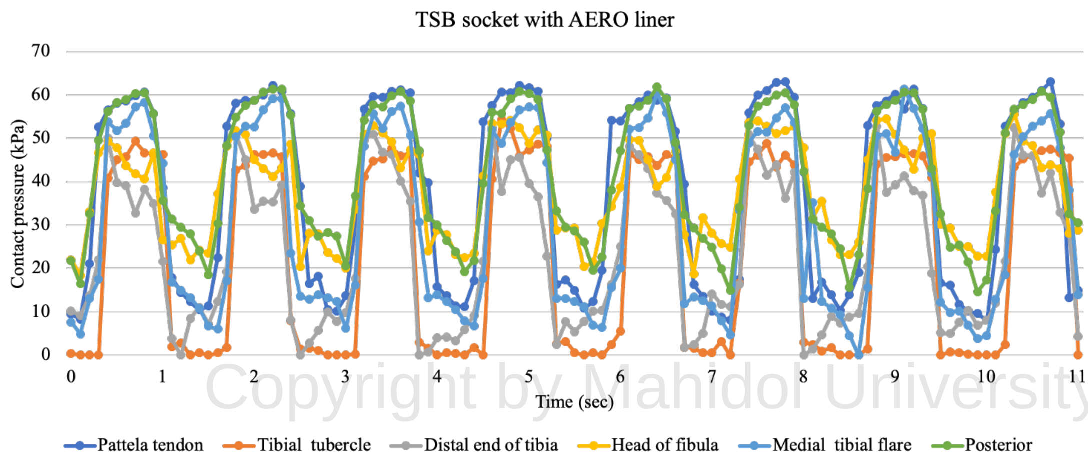
The graph of pressure distribution of participant D is shown in Figure 4.7. This participant's PTB socket with PE-lite was more uniform than other participants, and the difference peak pressure of maximum and minimum was 35.89 kPa. Then, this gap was decreased to 28.58 kPa when using AERO liner for PTB socket. Moreover, the TSB socket with AERO liner was only 17.23 kPa gap of maximum and minimum peak pressure. For pressure uniformity ration, the PTB socket with PE-lite was 48.84% ($p=4.72*10^{-5}$), AERO liner with PTB socket was 55.46% ($p=5.37*10^{-6}$), and TSB socket with AERO liner was provided ideal uniformity, and it was 71.42% ($p=5.37*10^{-6}$).


PTB socket with PE-lite
Contact pressure (kPa)
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

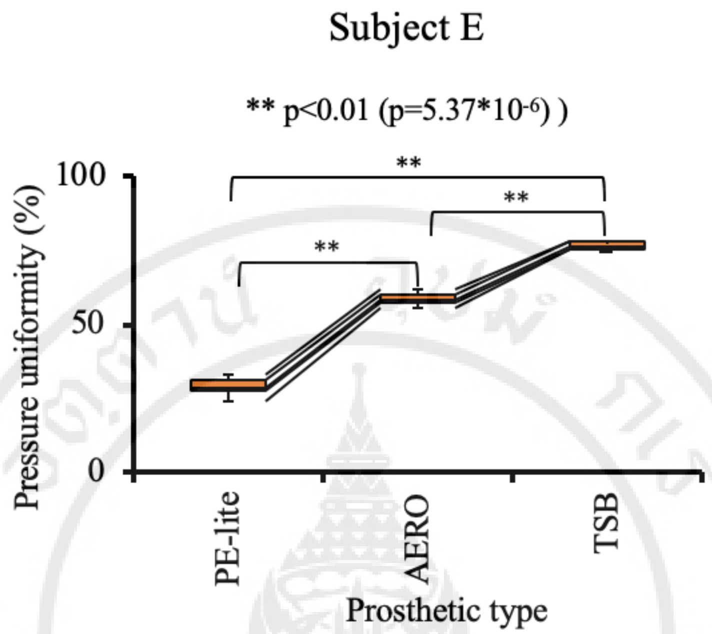
(a)


PTB socket with AERO liner
Contact pressure (kPa)
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(b)


TSB socket with AERO liner
Contact pressure (kPa)
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
11
Time (sec)
Pattela tendon
Tibial tubercle
Distal end of tibia
Head of fibula
Medial tibial flare
Posterior

(c)



(d)

Figure 4.8 Participant E pressure uniformity of 30 steps from 2-minute walk test.

Illustration of the pressure distribution of 2-minute walk test (a) PTB socket with PE-lite. (b) PTB socket with AERO liner. (c) TSB socket with AERO liner. (d) Pressure uniformity of 3 different type device.

The pressure data for three different conditions of participant E is shown in Figure 4.8. The difference between maximum and minimum peak pressure of PTB socket with PE-lite was the huge inequality of 58.29 kPa. When intervening AERO liner for PTB socket, difference peak pressure decreased to 31.71 kPa. In addition, TSB socket with AERO liner provided 14.69 kPa. Regards the ratio of pressure uniformity. The PTB socket with PE-lite was 28.81% ($p=5.37*10^{-6}$), and intervene AERO liner for PTB socket was 58.31% ($p=5.37*10^{-6}$), the TSB socket with AERO liner was indicated the most ideal of the pressure uniformity, and it was 76.38% ($p=5.37*10^{-6}$).

4.6 Material testing

FTIR tests revealed the composition of PE and EVA materials. As a result, only 2 chemical compositions different between PE-lite and EVA material such as carboxylic acid compound and calcium stearate. Each material chemical composition described Table 4.5.

Table 4.5 Two different materials chemical compositions list.

	PE-lite	EVA
Possible main chemical compositions	-Ethylene vinyl acetate copolymer (EVA) -Polyethylene (PE) -Small amount of eater compound -Small amount of calcium carbonate ($CaCO_3$) -Small amount of magnesium silicate -Very small amount of primary amide compound -Very small amount of silicon dioxide (SiO_2) -Very small amount of carboxylic acid compound -Trace amount of aromatic compound -Trace amount of calcium stearate	-Ethylene vinyl acetate copolymer (EVA) -Polyethylene (PE) -Eater compound -Calcium carbonate ($CaCO_3$) -Small amount of magnesium silicate -Very small amount of primary amide compound -Very small amount of silicon dioxide (SiO_2) -Trace amount of aromatic compound

CHAPTER V
DISCUSSION

The purpose of this study was to evaluate the feasibility of using a roll-on liner made from locally made and affordable materials. The previous study evidenced that about 0.5% of the general population are in need of prosthetics or orthotics devices, however, only about 90% of these patients have access to these necessary services. [3,11] Prosthesis which are provided in low-income settings have a unique set of issues related to material availability, patient residuum condition, prosthetist level of training, and material costs. [33] As a result, the PTB socket with PE-lite interface is widely used in developing settings because of a reduced overall prosthesis cost.[6] Dissatisfaction with prostheses is mainly caused by strains and injuries associated with the socket fit due to limb volume changes. Although this type of prosthesis has a long storied history, recent scholarship evidences negative residuum effects of partial weight-bearing, and increased pistoning between residuum and prosthetic interfaces.[25] A loose-fitting socket, enhances pistoning which has been suggested to be unfit for the patient's residuum health. Normally, the patient adjusts socket tightness by using residual limb socks and a stockinette.[32] In the current study, participants tended to add 2 to 3 stockinette, in addition, they applied 1 to 2 more stockinette if they felt looseness or volume changes. These user performed methods work to solve looseness of the residuum, however, it does not solve pistoning and socket compression demands.

On the other hand, roll-on liners are widely used by more than 85% of amputees in developed countries, [29] this liner provides benefits such as reduced pistoning and improved blood flow through total surface bearing prosthetic sockets. [25] The critical feature of the liners used in developed settings is the material, which uses a more stretchable and softer materials than PE-lite. Materials, such as silicone, thermoplastic elastomer, and polyurethane are common in developed settings. Roll-on liners have changed not only the number of interface materials available, but also the method of casting, model rectification and ultimately the weight bearing method of the transtibial prosthesis. Consequently, the prosthetist can provide a more comfortable and useful prosthesis for patients.

5.1 EVA material costs and compositions

The EVA material used in this study allows roll-on because of the material can stretch. The cost of EVA material is only 200 to 250 baht depending on the thickness. Considering the EVA sheet size and transtibial amputee residuum, 1000mm × 2000mm, at least 10 liners can be made from one EVA sheet. Furthermore, the prefabrication technique leads to a reduction of fabrication time when compared to a custom-made technique. For AERO liner prefabrication, it takes about 30-45 minutes to make one liner. Time could further be reduced by designating this task to be performed by technicians. The commercial product roll-on liners in Thailand are expensive for 9,200 baht and are only available to a few people. The commonly used PE-lite is 660 Thai baht, however, as described above, it is not preferable for patient residuum health when compared to roll-on liners.

Regarding the composition of the material, it was found that EVA contained the same components as PE-lite. However, there was a slight difference in the composition ratio. The EVA material contains more calcium carbonate (CaCO3) than PE-lite. The main use of calcium carbonate is in the construction industry, chalk in blackboard, agricultural chemicals, rubber, plastic, and adhesive. Calcium carbonate is widely used in daily life and is also a part of PE-lite. However, use in people who have allergies, might cause allergic reactions. It is important to determine patient allergies during assessment, similar to what is done with other types of liners.

5.2 Daily step count and patient satisfaction

The pedometer was provided to all participants in order to determine daily step count in PTB socket with PE-lite and AERO liner. All participants had at least one year of experience with their prostheses without any problems. Moderate intensity habitual physical activity improves health such as musculature, cardiorespiratory and bone health. In contrast, inactivity contributes to early mortality.[43] Thus, frequency of step counts is an important factor for maintaining health. Currently, a daily step count of about 4,400 is indicated to maintain overall health.[44] The participant who was not working had fewer daily activities than participants whom worked, thus, their number of steps showed an increasing trend when attending the temple. However, the result of average number of steps for all participants did not reach 4,400 steps, suggesting that participants mortality rate might increase in the future. There was a slight difference between PE-lite and AERO liner. AERO liner had the same effect on participant daily activity as PE-lite, this result suggests that AERO liner can be used clinically. Considering gait symmetry, it is not only weight bearing but also prosthetic suspension that are important factors. A good suspending prosthesis can increase the symmetry of gait and affects patient activity. [25] However, the current study did not evaluate this aspect.

Donning a roll-on liner is different from donning of a PE-lite pull through type liner. However, there was no discomfort from participants due to this different donning method, this result was similar to the functional comfort results of roll-on liner and PE-lite comfortability. [8] In addition, some participants stated that using the AERO liner increased the comfort of socket fitting of the prosthesis. However, four participants reported sweating more than PE-lite after long-term use. High perspiration was noted as one disadvantage of the TSB socket with gel liner when compared with the PTB socket with PE-lite.[31] Although the Roll-on liner adheres more closely to the skin and reduces the pistoning between the residuum and liner due to the high frictional force, there is no air ventilation, thus, the skin can tend to perspire. Sweat is a common problem for the prosthesis wearer, and is an important factor in comfort of a prostheses, especially in countries with high temperature and humidity. Therefore, it is necessary to maintain cleanliness by removing the prosthesis on occasion to wipe away sweat on the residuum.

Although there are some parts of the prosthesis that participant uses every day that cause sweating, this study showed that participants with higher activity showed sweating problems due to heat on the residuum. This is because it is predicted that the patient usually wears residual limb socks as a cushioning material for PE-lite, and the socks also have a sweat absorbing function, which permitted participants to wear a long time without discomfort even in the presence of sweat. However, the AERO liner increased sticking more closely to the residuum, which tended to improve operation of the prosthesis, and since there is no way for sweat to escape in a sealed state, sweat directly It is causing discomfort. By taking off the prosthesis occasionally to wipe the sweat off, it might possible to decrease the discomfort of sweating.

5.3 The pressure distribution of different type of liner

Pressure distribution affects user satisfaction, issues relevant to residuum interaction, and mechanical and biomechanical variables of the socket.[42] This study evaluated three device pressure uniformity on the residuum using a pressure sensor. The traditional style PTB socket with PE-lite reduced socket comfort due to point pressure around the proximal area. In this study, the patient's own device, PTB socket with PE-lite, evidenced about 26.71% to 48.84% pressure uniformity, which was the lowest uniformity when comparing to PTB socket with AERO liner and TSB socket with AERO liner. The average maximum peak pressure among the three devices was seen in the PE-lite device, as a result of impact, material hardness and pistoning between residuum and PE-lite. This result suggests insufficient shock absorption capabilities of PE-lite. In contrast, a TSB socket with liner has previously been shown to reduce pressure problems over PTB sockets with PE-lite.[9] When provided AERO liner with PTB socket, proximal pressure was slightly decreased, and the distal end had heightened pressure. The EVA material compressive property is similar to gel liners. [54] These results suggest that the compressive properties of the EVA material resulted in a softer liner than PE-lite, and the roll-on function enhanced an evenly distributed total contact to the residuum. Pressure during stance phase is also affected by alignment. Thus, participants who tend to have a prosthesis with a slightly abducted socket tended to have high pressure on the medial aspect of the socket, this phenomenon was observed both of PE-lite and AERO liner.

A thicker liner might provide a more comfortable walk and evenly distributed limb pressure, however, at a cost of increased instability during walking. [38] The study AERO liner thickness was 5mm which was the same as the participants PE-lite thickness. Due to the different material properties, it was found that pressure could be distributed without changing the thickness. Additionally, the AERO liner can have different thicknesses depending on the patient's residuum condition. PTB type prostheses tend to promote limb edema due to decreasing blood flow by pressure at the proximal part. [17] From our participant feedback, residuum volume tended to change every morning and afternoon. Residuum socks were used to quickly help increase whole limb volume. [32] The participants normally used residuum socks and stockinette of 2 to 3 ply to adjust their own residuum volume. Considering the pressure data obtained from these conditions of participant prosthesis, it can be inferred that the volume of the residuum had ultimately reduced after the prosthesis was delivered.

5.4 Shape of interface material

The form of the prefabricated AERO liner is a cylindrical shape, it is a direct reflection of the patient's residuum due to the EVA material properties which are stretchable, tensile, and compressive. This is totally different from the traditional PE-Lite interface, this prefabrication technique that makes use of the above-mentioned material properties have advantages of reducing the manufacture time of prosthesis and costs. Also, the AERO liner can be adjusted to fit the patients' residuum in a custom-made technique. Therefore, this technique is suitable for specific residuum patients, however, it is necessary to acquire a patient plaster model, which takes time for fabrication. The prefabrication AERO liner can have enough resemblance of the cylindrical and conical residuum. For patients with a cylindrical and conical shape who participated in this study, the pressure distribution with prefabrication AERO liner is actually similar to the custom made AERO liner. Manufacturing times do differ between the two methods, however, a cylindrical shape is the still the same result between the two final liners.

Considering the manufacturing time and cost, a prefabricated AERO liner is considered to be more suitable for RLE. In addition, the custom-made AERO liner is suitable for patients with a complicated residuum. PE-lite has always been one of the useful materials in developing situations due to low cost. When the density of liner is high, it is not capable of permitting roll-on donning, this inhibits the liner to accommodate the residuum during weight bearing. From the viewpoint of the manufacturing process, PE-lite requires molding from a plaster model made from the patient residuum. Thus, it adds additional fabrication time. Typically, during daily prosthesis use, the patient uses a stockinette to adjust socket tightness, however, this 'quick fix' does not truly solve prosthesis fit issues, even if the sock contours around the residuum shape. We need to not only study differences in material properties and geometries, but also the anatomical relationship these materials have between the limb and the material.

5.5 Appropriate prosthetic socket shape and suspension system

The prosthetic liner can be donned using different donning methods. Since 1950's, the pull-through donning of the PTB socket with PE-lite has been the most popular around the world, and it is still popular in RLE. [6] The PTB prosthesis decompresses the head of bone and tubercle area, and receives more load bearing on the posterior soft tissue and the patella tendon where anterior and posterior at the proximal area. In other words, the pressurized and the depressurized areas are clearly separated, and it is effective for amputees who have a bony shape at the distal end of tibia.

However, the patient satisfaction of prosthesis and function shoed less optimality when comparing TSB socket with gel liners mainly used in developed countries. The TSB socket can reduce socket volumes and equalize weight bearing pressures throughout the entirety of the socket, decrease fitting time, and enable higher activity levels when comparing PTB socket.[25] This allows increased surface area for weight bearing through reduced partial socket pressures. Thus, when using TSB socket, it is important to use an interface material that can aide in distributing pressure across the entire residuum, as the PE-lite liner with PTB style does not make provisions for load bearing over bony prominences. In the intact limb, the pumping action of the muscles is an important factor in moving venous blood back toward the heart. However, in the residuum, this important pumping action is reduced. There is a tendency for edema to develop in the dependent stump unless pressure is applied to the entire stump. Thus, TSB socket can help to prevent edema by whole contact pressure in the residuum. Moreover, TSB prosthesis provides structural integrity between residuum and prosthesis. Operability of the prosthesis is improved, and dependence on assistive walking devices can be reduced. [24]

From the result of pressure uniformity in this study, TSB socket is most appropriate for AERO liner, as indicated by the optimum uniformity. However, the casting method for TSB socket remains challenging. In recent years, various methods have been developed to make various types of prosthetic sockets. In this study, the TSB socket was made using a vacuum casting method, however, the socket tended to be slightly loose in three participants, and one stockinette was used. For the modification process, a 3% to 5% reduced circumference is recommended. We used a thin liner for casting to automatically apply 3-5% reduction, which made it easier to capture the boney anatomy and contours of the limb. Still, the socket tended to be slightly loose in all three participants, and one stockinette was eventually used. The prosthetist should consider whether to use a thinner liner for casting or increase the degree of plaster model modification when using the AERO liner.

Regarding prosthetic comfortable gait, weight bearing during the stance phase as well as prosthetic suspension during the swing phase is paramount. In general, in a PTB socket, the proximal socket contours are shaped to secure acquisition over the shape of the femoral condyles or to make use of a suspension strap below the supracondylar area for prosthetic suspension. These forms of suspension are common to developing settings but recent studies evidence improved suspension when using a silicone liner socket compared with the PTB supracondylar suspension. [2] The roll-on-liner reduces the piston between the stump and the liner, and the TSB method can create a more airtight socket. Moreover, a liner with a distal locking pin or a one-way valve attached to the socket with a knee sleeve is also a modern and quality suspension method. Those components provide the airtight socket environment, and increases negative pressure in the socket, which ultimately enhances prosthesis control.

The TSB socket made in this study used a cuff strap suspension which was the| same as the patient’s own prosthesis suspension system. However, it is necessary to consider an appropriate suspension system with AERO liner which will increase whole comfort of the transtibial amputee patient in developing countries in the future.

5.6 Limitation of the study

Developing countries still use many conventional style prostheses and, patients still encounter residuum problems. This study showed that the roll-on function of the AERO liner improves the pressure uniformity of the residuum during walking. However, the overall comfort was not increased due to sweating problems by hot weather and the suspension problems of the PTB prosthesis when using the AERO liner for one month. Therefore, considering a suitable suspension mechanism for AERO liner and sweating problems be needed for future studies. Perhaps a suction suspension which combines a knee sleeve will assist in this regard. In addition, by initially fitting patients with a TSB roll-on suction suspension AERO liner prothesis, one might be able to train these users to periodically swipe away sweat.

In this study, AERO liner was provided for the PTB prosthesis for daily use by the participants, therefore, no plaster model was made of the patient's prosthesis. Hence, fabrication of the AERO liner used the prefabricated technique, however, future research should study how the custom-made AERO liner shape compares to a similarly shaped PE-lite liner. Exploring this relationship might garner insight into the liner’s effect on pressure distribution.

CHAPTER VI
CONCLUSION

This study once again highlights the importance of different types of interface materials for the transtibial prosthesis. There are many advantages of roll-on liners, however, commercial roll-on liners are still expensive. The aim of this study was to identify the clinical utility and comfort of affordable EVA roll-on liners for transtibial amputees.

The interface material of choice is an important factor for comfortability of when using the transtibial prosthesis. PE-lite, which is widely utilized in RLE is affordable, however, there is a high possibility of edema and wound of the residuum because of pistoning and a loose fit. Roll-on liners made from affordable EVA materials were designed for five participants and evaluated to compare against participants own PE-lite during functional outcome measures of pressure distribution, daily activity, and questionnaire.

The EVA roll-on liner has better pressure distribution than a conventional PE-lite interface. In addition, by advancing sockets from a partial weight bearing type to a total surface weight bearing with EVA roll-on liner, a better fitting socket resulted and overall residuum health can be achieved.

This pilot study does not address nor does it evaluate the complete set of outcome measurements necessary for evaluating comfort during prosthetic gait. Not only weight bearing during stance phase but also suspension during the swing phase is must be considered. Moreover, patient perspiration while wearing the liner for daily use, and durability must be explored in future research.

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APPENDICES

APPENDIX A
ARDUINO SERIAL CODE

```
int fsrPin = 0; int fsrPin1 = 1;int fsrPin2 = 2;int fsrPin3 = 3;int fsrPin4 = 4;int fsrPin5
= 5;  int fsrReading;int fsrReading1;int fsrReading2;int fsrReading3;int
fsrReading4;int fsrReading5; int fsrVoltage;int fsrVoltage1;int fsrVoltage2;int
fsrVoltage3;int fsrVoltage4;int fsrVoltage5;

void setup() {
  Serial.begin(9600);
   Serial.println("Sensor1,Sensor2,Sensor3,Sensor4,Sensor5,Sensor6");
}


void loop() {
  fsrVoltage = map(fsrReading,0,1023,0,5000);
  fsrVoltage1 = map(fsrReading1,0,1023,0,5000);
  fsrVoltage2 = map(fsrReading2,0,1023,0,5000);
  fsrVoltage3 = map(fsrReading3,0,1023,0,5000);
  fsrVoltage4 = map(fsrReading4,0,1023,0,5000);
  fsrVoltage5 = map(fsrReading5,0,1023,0,5000);


  fsrReading = analogRead(fsrPin);
  fsrReading1 = analogRead(fsrPin1);
  fsrReading2 = analogRead(fsrPin2);
  fsrReading3 = analogRead(fsrPin3);
  fsrReading4 = analogRead(fsrPin4);
  fsrReading5 = analogRead(fsrPin5);
```



```
  Serial.print(fsrVoltage);
  Serial.print(" ");
```

```
  Serial.print(fsrVoltage1);
  Serial.print(" ");
  Serial.print(fsrVoltage2);
  Serial.print(" ");
  Serial.print(fsrVoltage3);
  Serial.print(" ");
  Serial.print(fsrVoltage4);
  Serial.print(" ");
  Serial.println(fsrVoltage5);

  delay (100);

}
```

APPENDIX B
List of OPUS questionnaire

OPUS Satisfaction with Device and Services

แบบสำรวจข้อมูลผู้ใช้กายอุปกรณ์เพื่อประเมินความพึงพอใจต่อกายอุปกรณ์และการให้บริการของนักกายอุปกรณ์และเจ้าหน้าที่คลินิกกายอุปกรณ์ ฉบับภาษาไทย

กรุณาระบุ วัน/เดือน/ปี ที่กรอกแบบสอบถาม

ID:

	กรุณาทำเครื่องหมาย Pในช่องคำตอบที่ตรงกับความคิดเห็นของท่านมากที่สุด	**เห็นด้วยอย่างยิ่ง**	**เห็นด้วย**	**ไม่แน่ใจ**	**ไม่เห็นด้วย**	**ไม่เห็นด้วยอย่างยิ่ง**
1	กายอุปกรณ์ของฉันสวมใส่ได้พอดี					
2	น้ำหนักของกายอุปกรณ์มีความเหมาะสม/ควบคุมง่าย					
3	กายอุปกรณ์ของฉันสวมใส่ได้สบายตลอดวัน					
4	กายอุปกรณ์ของฉันสวมใส่ได้ง่าย					
5	กายอุปกรณ์ของฉันดูดี สวยงาม					
6	กายอุปกรณ์ของฉันมีความคงทน					
7	การสวมใส่กายอุปกรณ์ของฉันไม่ทำให้เสื้อผ้าของฉันเกิดความเสียหาย					
8	ผิวหนังของฉันไม่มีรอยถลอกหรือการระคายเคือง					
9	กายอุปกรณ์ของฉันไม่ทำให้ฉันรู้สึกเจ็บปวดในขณะที่สวมใส่					
10	ฉันสามารถจ่ายค่ากายอุปกรณ์หรือค่าดูแลรักษากายอุปกรณ์ของฉัน ตามค่าใช้จ่ายจริงที่ต้องจ่ายเอง					
11	ฉันสามารถจ่ายค่าซ่อมแซมหรือค่าเปลี่ยนกายอุปกรณ์อันใหม่ได้ทันทีตามความจำเป็น					
12	ระยะเวลาที่ฉันได้รับการนัดหมายจากนักกายอุปกรณ์เป็นระยะเวลาที่เหมาะสม					
13	เจ้าหน้าที่ปฏิบัติต่อฉันด้วยความเอื้อเฟื้อและความเคารพต่อกัน					
14	ระยะเวลาที่ฉันรอเพื่อให้ได้รับบริการจากนักกายอุปกรณ์มีความเหมาะสม					
15	เจ้าหน้าที่คลินิกกายอุปกรณ์ให้ข้อมูลเกี่ยวกับตัวเลือกของกายอุปกรณ์ให้แก่ฉันอย่างเพียงพอครบถ้วน					
16	นักกายอุปกรณ์เปิดโอกาสให้ฉันบอกเล่าความกังวลใจเกี่ยวกับกายอุปกรณ์ของฉัน					
17	นักกายอุปกรณ์ยินดีรับฟังความกังวลใจของฉันและตอบคำถามของฉัน					
18	ฉันพึงพอใจต่อการฝึกที่ฉันได้รับเกี่ยวกับวิธีการใช้และการดูแลรักษากายอุปกรณ์ของฉัน					
19	นักกายอุปกรณ์ได้พูดคุยกับฉันถึงปัญหาที่ฉันอาจประสบเมื่อใช้กายอุปกรณ์					
20	เจ้าหน้าประสานการให้บริการในด้านต่างๆ กับนักกายภาพบำบัดหรือกิจกรรมบำบัดและแพทย์ของฉัน					
21	ฉันมีส่วนร่วมในการตัดสินใจกับทีมผู้ให้การรักษาในเรื่องการรักษาฉันและกายอุปกรณ์ของฉัน					

OPUS functional status measure

ID:

แบบสำรวจข้อมูลผู้ใช้กายอุปกรณ์เพื่อประเมินความสามารถในการทำกิจกรรมของผู้ใช้กายอุปกรณ์เทียมรยางค์ล่าง ฉบับภาษาไทย

กรุณาระบุ วัน/เดือน/ปี ที่กรอกแบบสอบถาม

คำศัพท์เฉพาะ

กายอุปกรณ์เสริม : อุปกรณ์ที่ช่วยประคอง

กายอุปกรณ์เทียม : สิ่งเทียมที่ต่อจากร่างกายเพื่อทดแทนส่วนที่ขาดหายไป

	ท่านมีความยาก/ง่ายในขณะทำสิ่งดังต่อไปนี้มากน้อยเพียงใด **กรุณาทำเครื่องหมาย √ ในช่องคำตอบที่ตรงกับความคิดเห็นของท่านมากที่สุด**	**ง่ายมาก**	**ง่าย**	**ค่อนข้างยาก**	**ยากมาก**	**ไม่สามารถทำกิจกรรมนี้ได้**	
1	อาบน้ำโดยใช้ฝักบัวหรือใช้ขันตักอาบ						
2	แต่งตัวท่อนล่าง (เช่นนุ่งกางเกงหรือกระโปรง ใส่ถุงเท้าหรือรองเท้า ใส่เข็มขัด)						
3	การใช้ชักโครกหรือส้วมนั่งยอง (ส้วมซึม)						
4	การลุกจากพื้น						
5	การทรงตัวขณะยืน						
6	ยืนเป็นเวลาชั่วโมงครึ่ง						
7	หยิบจับวัตถุสิ่งของจากพื้นในขณะยืน						
8	ลุกจากเก้าอี้						
9	ขึ้นและลงจากรถยนต์						
10	เดินเล่นภายในอาคาร (เช่นบ้าน ห้างสรรพสินค้า พิพิธภัณฑ์)						
11	เดินออกนอกตัวบ้านหรืออาคารบนพื้นที่ไม่เรียบเช่น ขรุขระ ลาดชัน พื้นต่างระดับ						
12	เดินในสภาพอากาศไม่ดี (เช่น ฝนตก ลมแรง มีผงฝุ่นในอากาศ)						
13	เดินเป็นเวลา 2 ชั่วโมง						
14	เดินขึ้นทางลาดชัน						
15	ขึ้นลงโดยใช้บันไดเลื่อน						
16	เดินขึ้นบันไดหนึ่งชั้นโดยใช้ราวจับ						
17	เดินขึ้นบันไดหนึ่งชั้นโดยไม่ใช้ราวจับ						
18	วิ่งประมาณ 100 เมตร						
19	ถือจานอาหารขณะกำลังเดิน						
20	การสวมใส่และการถอดกายอุปกรณ์						
21	ท่านสวมใส่กายอุปกรณ์กี่วันต่อสัปดาห์ (7วัน = 1 สัปดาห์) กรุณาระบุจำนวนวัน (0-7)						
22	ท่านสวมใส่กายอุปกรณ์กี่ชั่วโมงต่อวัน (24 ชั่วโมง = 1 วัน) กรุณาระบุจำนวนชั่วโมง (0-24)						
23	ผู้ป่วยคนอื่นๆได้กล่าวไว้ว่า "ฉันไม่ควรทำกิจกรรมทางกายที่ (อาจจะ) ทำให้เกิดความเจ็บปวดมากขึ้น" คุณรู้สึกอย่างไร	ไม่เห็นด้วยอย่างยิ่ง	ไม่เห็นด้วย	ไม่ค่อยเห็นด้วย	ไม่แน่ใจ	ค่อนข้างเห็นด้วย	เห็นด้วย

OPUS Health quality of life index

แบบสำรวจข้อมูลผู้ใช้กายอุปกรณ์เพื่อประเมินดัชนีคุณภาพชีวิตด้านสุขภาพ ฉบับภาษาไทย

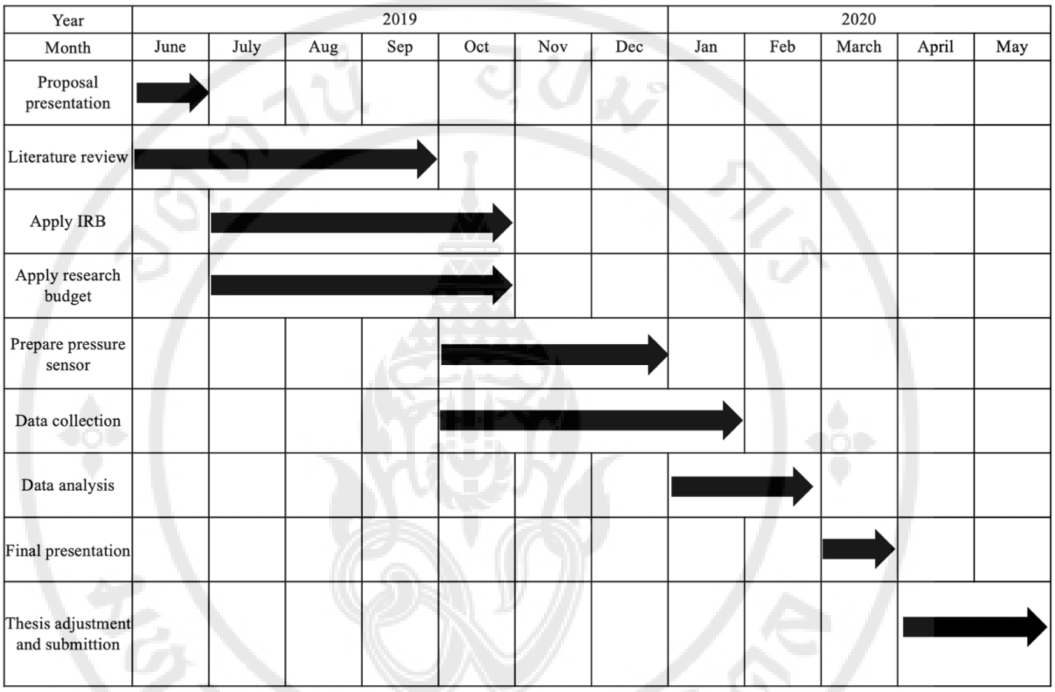
กรุณาระบุ วัน/เดือน/ปี ที่กรอกแบบสอบถาม

ID:

หมายเหตุ: สำหรับคำถามด้านล่าง คำว่า "สภาพร่างกาย" หมายถึงสภาพร่างกายที่ทำให้ท่านต้องใช้กายอุปกรณ์

		ไม่มีเลย	เล็กน้อย	พอสมควร	มาก	มากเกินไป
1	ท่านเก็บตัวเพื่อหลีกเลี่ยงปฏิกิริยาของผู้คนที่มีต่อร่างกายที่พิการหรือความจำเป็นที่ต้องใช้กายอุปกรณ์ของท่านมากน้อยแค่ไหน					
2	ท่านพบว่ากริยาท่าทางของผู้อื่นที่มีต่อสภาพร่างกายของท่านเป็นการดูหมิ่นมากน้อยเพียงใด					
3	เจตคติต่อเพื่อนมนุษย์ กฎหมาย หรือสิ่งแวดล้อมที่เป็นอุปสรรค ทำให้ท่านไม่สามารถทำในสิ่งที่ต้องการมากน้อยเพียงใด					
4	อาการปวดตามร่างกายของท่านรบกวนการทำกิจกรรมต่างๆ ของท่าน (ทั้งงานที่ทำงานและงานบ้าน) แค่ไหน					
5	สภาพร่างกายของท่านทำให้ท่านทำงานเสร็จน้อยกว่าที่ต้องการหรือไม่					
6	ปัญหาทางอารมณ์ของท่านทำให้ท่านทำงานเสร็จน้อยกว่าที่ต้องการหรือไม่					
7	สภาพร่างกายของท่านทำให้ความสามารถในการออกไปทำธุระเล็กๆน้อยๆของท่านมีข้อจำกัดมากน้อยแค่ไหน					
8	สภาพร่างกายของท่านทำให้ความสามารถในการทำงานอดิเรกของท่านมีข้อจำกัดมากน้อยแค่ไหน					
9	สภาพร่างกายของท่านทำให้ความสามารถในการทำงานบ้านของท่านมีข้อจำกัดมากน้อยแค่ไหน					
10	สภาพร่างกายของท่านทำให้ความสามารถในการทำงานที่ได้รับค่าตอบแทนของท่านมีข้อจำกัดมากน้อยแค่ไหน					
11	สภาพร่างกายของท่านทำให้ท่านทำงานหรือทำกิจกรรมต่างๆ ได้ไม่เท่าเดิมมากน้อยแค่ไหน					
12	ปัญหาทางอารมณ์ของท่านทำให้ท่านทำงานหรือทำกิจกรรมต่างๆ ได้ไม่เท่าเดิมมากน้อยแค่ไหน					
ในช่วงหนึ่งสัปดาห์ที่ผ่านมาท่านมีความรู้สึกต่อไปนี้บ่อยแค่ไหน?		ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	มี เล็กน้อย	ไม่เคย
13	รู้สึกมีชีวิตชีวา กระปรี้กระเปร่า					
14	รู้สึกว่าอารมณ์เย็นและสงบ					
15	มีพละกำลังมาก					
16	มีความสุข					
17	วิตกกังวล					
18	รู้สึกหดหู่เศร้าซึมมากจนไม่มีอะไรมาทำให้ท่านรู้สึกดีขึ้นได้					
19	รู้สึกท้อแท้ และเศร้าหมอง					
20	รู้สึกหมดเรี่ยวแรง					
21	รู้สึกเหนื่อยล้า					
22	หงุดหงิดอารมณ์เสียง่าย					
23	ไม่มีสมาธิหรือไม่สามารถจดจ่อกับสิ่งที่ทำได้					

APPENDIX C
Research schedule



APPENDIX D
HUMAN SUBJECT APPROVAL DOCUMENT

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Siriraj Institutional Review Board

Certificate of Approval

COA no. Si 652/2019

Protocol Title(English) : Development of an interface for the transtibial prosthesis user in resource Limited environments

Protocol Title(Thai) : การพัฒนาเบ้าอ่อนขาเทียมระดับใต้เข่าโดยใช้วัสดุภายในประเทศเพื่อลดต้นทุนการผลิต

SIRB Protocol No. : 260/2562(EC2)

Principal Investigator/Affiliation : Ms.Jutima Rattanakoch / Sirindhorn School of Prosthetics and Orthotics Faculty of Medicine Siriraj Hospital, Mahidol University

Research site : Faculty of Medicine Siriraj Hospital

Duration of research : 2 years

Approval date : September 20, 2019
Expired date : September 19, 2020

This is to certify that Siriraj Institutional Review Board is in full compliance with international guidelines for human research protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

(Prof. Chairat Shayakul, M.D.)
Chairperson

- 3 OCT 2019
date

(Prof.Dr. Prasit Watanapa, M.D., Ph.D.)
Dean of Faculty of Medicine Siriraj Hospital

- 4 OCT 2019
date

Approval includes :

1. SIRB submission form, date September 17, 2019
2. Proposal
3. Participant information sheet, date September 17, 2019
4. Informed consent form, date September 17, 2019
5. Case record form
6. Advertisement for recruitment
7. Curriculum vitae

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หน่วยพิมพ์โรงพยาบาลศิริราช 2341/3,000 แผ่น/ต.ค.57/M/2667/Mat.10023252/3060

BIOGRAPHY

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INSTITUTIONS ATTENDED	Bachelor of Prosthetics & Orthotics and Assistive Technology, Niigata University of Health and Welfare, 2009 – 2013.
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