INTERFACE PRESSURE BETWEEN SOCKET AND RESIDUAL LIMB IN PROSTHESIS WITH SEAL-IN X5 AND DERMO LINER DURING LEVEL GROUND, STAIRS, AND RAMP WALKING

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PREFACE

Five chapters of this thesis (Chapter 3-7) are written in the format of peer-reviewed journal articles, and therefore may contain some redundancies, especially in the introduction and methodology sections.

Chapter 3 contains selected text reprinted from Clinical Biomechanics, Vol.27 (9), Ali, S., Abu Osman, N. A., Mortaza, N., Eshraghi, A.,& Gholizadeh, H.,"Clinical investigation of the interface pressure in the transtibial socket with Dermo and Seal-In X5 liner during walking and their effect on patient satisfaction", pg. 943–948, Copyright 2013, with permission from Elsevier.

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Suspension Systems on Transtibial Amputees' Satisfaction and Perceived Problems With Their Prosthetic Devices", pg.1919–1923, Copyright 2013, with permission from Elsevier.

ABSTRACT

Transtibial amputation patients need prosthetic devices in order to regain their functional mobility and appearance. The socket and its design play a significant role in determining the wearer's quality of the fit..Prosthetic users experience pressure between the socket and residual limb during daily activities. The underlying soft tissues and skin of the residual limb are not accustomed to weight bearing; thus, there is the risk of degenerative tissue ulcer in the residual limb because of constant or repetitive peak pressure applied by the socket. The prosthetic users experience different pathways such as level ground, ramps, stairs and other uneven surfaces during their daily activities. An amputee is greatly affected when dealing with the environmental barriers such as slopes and stairs because of the reported high interface pressure between socket and residual limb. The interface pressure between the residual limb and prosthetic socket has a significant effect on an amputee's satisfaction and comfort. Suspension system and socket fitting in prosthetic devices significantly affect the amputee's comfort, mobility, and satisfaction. Prosthetic users required a comfortable liner, good suspension, and quality socket to avoid skin problems and to prevent discomfort while using the prosthesis for daily activities. Liners provide a comfortable interface by adding a soft cushion between the residual limb and the socket. Dermo and Seal-In X5 liners are two new interface systems and, due to their relative infancy, no literature were found about their interface pressure during level walking as well as stairs and ramp negotiations and their effect on patient's satisfaction. Therefore, the objectives of this study was to compare the interface pressure for these two liners during level walking as well as stairs and ramp negotiations and their effect on patients satisfaction and to compare it with the most common liner in today use (Pelite liner) and its effect on patient's satisfaction and perceived problems. In addition, investigation were carried out on the effect of suspension system on patient satisfaction and perceived problems associated with the

three liners.The selection of good prosthetic liner presents a challenging task in amputee rehabilitation. Two prostheses were fabricated for each of the10 amputees, one with the Seal-In X5 liner and one with the Dermo liner for comparison between Dermo, Pelite, and Seal-In X5 liners, 60 prostheses were fabricated. Interface pressure was measured during level walking, stairs and ramp negotiations. Each subject filled in a Prosthetic Evaluation Questionnaire (PEQ) questionnaire regarding his satisfaction with the three liners. Mean Peak Pressure (MPP) was significantly (P<0.05) low with Dermo liner during level walking as well as stairs and ramp negotiations compared with Seal-In X5 Liner. Participants were significantly (P<0.05) satisfied and fewer problems were recorded with Dermo liner compared with Seal-In X5 and Pelite liners. Hence, it can be concluded that the Dermo liner provides more comfortable socket-residual limb interface than the Seal-In X5 liner and showed that the Dermo liner is the best choice for transtibial users. However, despite these results, the Seal-In X5 liner offers better suspension.These results will help the clinicians and prosthetic practitioners in selecting of prosthetic liners and will also help the clinician in the fabricating of a good comfortable socket for transtibial users.

ABSTRAK

Pesakit amputasi bawah lutut memerlukan kaki palsu selepas pembedahan untuk memulihkan kembali mobiliti kerja mereka serta tujuan kosmetik. Reka bentuk soket memainkan peranan penting dalam menentukan kualiti prostesis dan menyediakan tekanan antara muka diantara prostesis dan anggota yang telah diamputasi.Semasa melakukan aktiviti harian, pengguna kaki palsu mengalami tekanan diantara soket dan anggota badan yang telah diamputasi.Tisu lembut dalaman dan kulit pada anggota badan yang telah diamputasi tidak mampu untuk menampungberat; justeru itu, terdapat risikoulser tisu degeneratif anggota badan disebabkan oleh tekanan secara berterusan atau berulang yang dikenakan oleh soket.Pengguna kaki palsu perlu berjalan diatas pelbagai permukaan seperti tanah rata, cerun, tangga, dan permukaan yang tidak rata semasa aktiviti harian mereka.Pesakit yang menjalani amputasi mengalami kesukaran untuk menangani halangan alam sekitar seperti cerun dan tangga kerana dilaporkan mengalami tekanan antara muka yang tinggi antarasoket dengananggota badan yang telah diamputasi.Tekanan antara muka diantara anggota badan yang telah diamputasi dengansoket kaki palsu memberi kesan yang besar ke atas kepuasan dan keselesaan pesakit.Sistem suspensi dan kepadanan soket dalam alatan prostesis memberi kesan signifikan terhadap keselesaan, mobiliti, dan kepuasan pesakit. Pengguna kaki palsu memerlukan pelapik yang selesa, suspensi yang bagus, dan soket yang berkualiti untuk mengelakkan masalah kulit dan rasa tidak selesa semasa menggunakan prostesis sewaktu aktiviti harian. Pelapik menyediakan permukaan yang selesa melalui perambahenstruktur kusyen lembut diantara anggota badan dengansoket. ‘DermoPelapik’ dan ‘Seal-In X5’ adalah dua pelapik yang menggunakan sistem antara-muka terbaru dan masih diperingkat awal.Oleh sebab itu tiada kajian ditemui mengenai tekanan antara muka untukkedua jenis pelapik ini semasa berjalan, menaiki tangga dan melaluicerun serta kesannya terhadap kepuasan pesakit. Justeru,, objektif kajian ini

adalah untuk membandingkan tekanan antara muka bagikedua-dua pelapik semasa berjalan.Mendatar sertmenggunakan tangga dan cerun, serta kesannya terhadap kepuasan pesakit dan membandingkan dengan “Pelite liner” yang biasa digunakan dewasa ini.Kesan terhadap kepuasan pesakit dan masalah yang timbul juga dikaji.Tambahan pula, kajian teleh dibuat terhadep kesan sistem suspensi terhadap kepuasan pesakit dan masalah yang dihadapi oleh pesakit berkaitan ketiga-tiga pelapik.Pemilihan pelapik prostetik yang terbaik adalah tugas yang mencabar dalam pemulihan dan rehabilitasi pesakit. Dua prostesis setiap seorang telah difabrikasi untuk setap seorang daripeda 10 orang pesakit, dengan satu pelapik yang digunakan untuk prostesis ini ialeh “Seal-In X5” dan satu lagi ialeh “Dermoliner”. Untuk perbandingan antara pelapik “Dermo”,“pelite”, dan “Seal-In X5”, 60 prostesis telah dihasilkan. Tekanan antara muka telah dikaji semasa berjalan latar sertu, mengunakan tangga dan cerun.Setiap subjek dikehendaki menjawab Soal Selidik Penilaian Prostetik (PEQ) mengenai kepuasan tentang ketiga-tiga pelapik. Purata Tekanan Puncak (PTP) menunjukkan nilai yang signiftan (P<0.05) rendah apabila menggunakan pelapik “Dermo Liner” semasa aktiviti berjalan datar serta, menggunakan tangga dan cerun berbanding pengunaan “Seal- In X5”. Peserta lebih berpuas hati (P <0.05) dan kurang masalah dilaporkan dengan menggunakan pelapik “Dermo” berbanding pelapik “Seal-In X5” dan “Pelite”. Kesimpulannya, pelapik “Dermo” menyediakan permukaan yang lebih selesa di antara soket dengan anggota badan yang telah diamputasi berbanding “Seal-In X5”.Ini menunjukkan bahawa pelapik “Dermo” adalah pilihan terbaik untuk pengguna prostesis amputasi bawah lutut.Walau bagaimanapun, di dapati pelapik Seal-In mempunyai suspensi yang lebih baik. Hasil kajian ini dapat membantu doktor dan pengamal prostetikdalam memilih pelapik prosthesis dan juga akan membantu pakar perubatan memfabrikasi soket yang lebih selesa dan baik untuk pengguna prostesis amputasi bawah lutut.

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Table of Contents

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

AALQ	Attitude to Artificial Limb Questionnaire
ARBIS	Amputation Related Body Image Scale
BIQ	Body Image Questionnaire
CAD-CAM	Computer Aided Design andCompute Aided Manufacturing
CIR	Centre for International Rehabilitation
FE	Finite Element
IPOP	Immediate Post Operative Prosthesis
MANOVA	Multivariate Analysis of Variance
MPP	Mean Peak Pressures
MFCL	Medicare Functional Classification Level
NHMS	National Health and Morbidity Survey
OPOT	Orthotics and Prosthetics National Outcomes Tool
PEQ	Prosthesis Evaluation Questionnaire PEQ
POP	Post Operative Prosthesis
POP	Plaster Of Paris
PSSS	Perceived Social Stigma Scale
PTB	Patellar Tendon Bearing
PTAs	Persons with Transtibial Amputation
PTB/SC	Patella Tendon Bearing Supracondylar
PTB/SC/SP	Patella Tendon Bearing Supracondylar Suprapatelar
PVD	Peripheral Vascular Diseases

RMM	Rapid Manufacturing Machine
SACH	Solid Ankle Cushioned Heel
SPSS	Statistical Package for the Social Sciences
TAPES	Trinity Amputation and Prosthesis Experience Scales
TF	Transfemoral
TSB	Total Surface Bearing
UMMC	University of Malaya Medical Centre
VA's	Veterans Affairs
WHO	World Health Organization

CHAPTER 1

1. INTRODUCTION

Transtibial amputation is the most common amputation in all major lower limb amputations. To achieve a successful amputation and achieve a good residual limb, surgeons try to balance the three criteria; accurate nerve ending placement, proper length of the bone and adequate soft tissue padding at the residual limb end. Adequate bone length provides a long lever arm which allows the amputee to retain more residual limb stability and function. A standard amputation occurs when 20 to 50% of the tibia length remains and at least 8 cm of tibia length below the knee joint is preserved to allow for a good prosthetic fit. In order to minimize friction between the bones, surgeons are using Achilles tendon as padding. One surgical technique extends the posterior flap and brings the superficial posterior leg muscles, the gastrocnemius and soleus muscles forward over the end of the residual limb to provide padding to the protruding distal end of the tibia and fibula (Loon, 1962). Figure 1.1 shows the resultant residual limb from this procedure. Soft tissue padding also functions as nerve endings receiving sites. These sites are needed as once the limb has been amputated; the nerves are severed as well. Nerve endings like bone length; need to be maximized in order to obtain maximum proprioception at the leg. However, caution must be taken by the surgeon to, elongated and serveved so that they retract upwards within the soft tissues to minimize pain. Nerve endings that are left at the periphery, scar tissue or throbbing vessels areas will be prone to irritation due to contact pressure from the prosthesis or other sources of contact. Depending on the surgical technique used, the shape of the residual limb will either be cylindrical or conical in post operation. Shape of the residual limb can influenced socket fit and suspension.

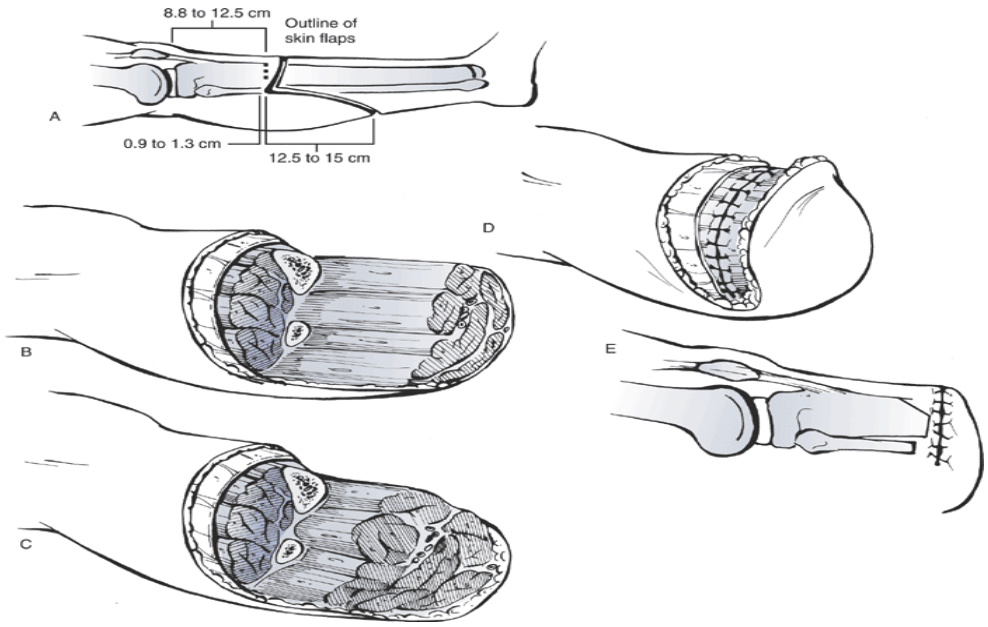

Figure 1.1: The extended posterior flap method brings the posterior muscles forward to create padding at the distal end of the residual limb for weight bearing and vascularisation (reproduced from Rockwood & Green's Fractures in Adults, 6th edition, 2006)

People with lower limb loss need prosthetic devices after amputation surgery in order to regain their functional mobility and appearance (Wolf et al., 2009). The socket design plays a significant role in determining the quality of the fit and provides an interface between the prosthesis and the residual limb (Jia et al., 2004a). Lower limb prosthesis should enable ambulation and improve the performance of daily routine activities. However, poor-fitted socket can lead to complications that have adverse effects on the activity level and gait of people with lower limb amputation (Gailey et al., 2008).

The distribution of interface pressure between the socket and residual limb is an important factor in socket design and fit. Lower limb prosthetic users experience pressure between the socket and residual limb during daily activities. The underlying soft tissues and skin of the residual limb are not accustomed to weight bearing; thus, there is the risk of soft tissue ulcer in the residual limb because of constant or repetitive peak pressure applied by the socket (Jia et al., 2004b). The pressure also can lead to various skin problems such as follicular hyperkeratosis, allergic contact dermatitis,

infection, and veracious hyperplasia (Dudek et al., 2008; Dudek et al., 2005; Lyon et al., 2000). Despite significant advances during the field of prosthetics in the previous decades, still many amputees' experience pressure ulcers associated with the use of prostheses. Sometimes, skin problems lead to chronic infection, which may necessitate re-amputation. This will prevent the long-term use of prosthesis, which significantly reduces the daily activities of prosthesis users and the quality of life (Ali et al., 2012b).

Many factors influence the use of prosthesis and the interface between prosthetic socket and skin, including shear force, moisture, distribution of weight, and temperature (Åström & Stenström, 2004; Bui et al., 2009). The main concern for the rehabilitation of individuals with prosthesis is the failure to use and accept prosthesis, because of discomfort within the prosthetic socket (Chadderton, 1978; Neumann et al., 2013; Nielsen et al., 1989).The mechanical interaction of residual limb and socket can affect the comfort and use of the prosthesis. Extra care should be taken into account during the designing and fitting of socket to avoid skin problems and discomfort while performing daily activities (Zhang & Roberts, 2000). Pressure should be distributed over the appropriate weight-bearing areas with reliefs over boney prominences, nerves and tendons to provide comfortable load transmission and good control for mobility, and to reduce skin damage by increasing the contact surface area. It is clear that socket design requires understanding of the of socket biomechanics with respect to residual limb, including interface pressure, during ambulation (Mak et al., 2001).

The transtibial prosthesis (TTP) users experience different pathways such as level ground, ramps, stairs and other uneven surfaces during their daily activities. The ability to negotiate environmental obstacles, such as ramps, uneven grounds, and stairs is a significant factor for the functional freedom (Gill et al., 1994). Studies showed that the lower limb amputee is greatly affected when dealing with the environmental barriers such as slopes and stairs because of the loss of foot and ankle mechanism and reported

high interface pressure (Dou et al., 2006; Jones et al., 2006). A number of skin issues might result from high interface pressure between the residual limb and socket wall during daily activities. These skin problems might disturb the everyday use of prosthesis and impede the independent life pattern (Koc et al., 2008; Meulenbelt et al., 2006).

Prosthetic users required a comfortable liner and appropriate socket to avoid skin problems and to prevent discomfort while using the prosthesis for daily activities (Dou et al., 2006; Lin et al., 2004). Cushioning effect of the liners lessens peak pressure and shear forces between the socket and residuum to prevent skin breakdown (Bertels & Kettwig, 2011). A numbers of liners are available for amputees. Clinicians have been using Pelite foam liner since 1950 (Ali et al., 2013; Coleman et al., 2004; Van de Weg & Van Der Windt, 2005). Pelite is a type of expanded cross-linked sponge foam which is shaped to fit to residuum to provide cushioning inside the socket.

Many types of strategies are used to achieved a variety of suspension with Pelite liner, including suprapatellar strap or cuff or supracondylar bulge or suspension sleeve worn over the socket and extending to mid-thigh (Coleman et al., 2004).Pelite liners are still used in practice, but modern liners are generally made from silicon and other elastomers that offer better suspension and cushion (Dietzen et al., 1991; Haberman et al., 1992; Madigan & Fillauer, 1991).Silicone and gel liners were introduced worldwide in the mid 1990s and were designed to lessen shear forces and produce better interface between residual limb and socket. Silicone liners are usually prescribed to prevent the formation of pressure sores (Wirta et al., 1990).One silicone liner is the Seal-In X5 liner (Fig. 1.2). Manufactuered by Ossur (Reykjavik, Iceland) and is composed of five seals that conform to the shape of the internal socket wall and the residual limb (Gholizadeh et al., 2011). Through this, the Seal-In X5 liner provides suspension without the need for an external sleeve or lock. Another common liner is known as Dermo liner, by Ossur

(Reykjavik, Iceland) and also made of silicone and provides suspension through a shuttle lock system.

Figure 1.2: Prosthetic liners. (Left) Seal-In X5 liner (Right) Dermo liner

Many studies have been carried out to investigate the interface pressure and stresses (Jia et al., 2005b; Sanders et al., 1998; Wolf et al., 2009). One of them compared the socket pressure of polyethylene foam liners with silicone liners (Dumbleton et al., 2009b). Some studies have investigated the effect of various casting techniques or socket design on the socket-residual limb interface pressure (Dumbleton et al., 2009b; Jia et al., 2005b; Lee & Zhang, 2007), while other studies have focused on the effect of alignment on interface pressure (Jia et al., 2008). But there was no study found to evaluate the interface pressure between socket and residual limb during level walking, stairs ascent, stairs descent, ramp ascent, and ramp descent with Dermo and Seal-In X5 liners as well as their effect on patient's satisfaction.

The need of evaluating and measuring prosthetic and orthotic practices has received growing recognition from the past several years (Fuhrer, 1995; Hoxie, 1995; Polliack & Moser, 1997). Reliable and valid self-report instruments that can help facilities evaluate patient outcomes are needed. Researchers had been developed many prosthetics/orthotics questionnaires to evaluate patient's satisfaction and problems with prostheses and orthoses. These include the Orthotics and Prosthetic Users Servey (OPUS) (Heinemann et al., 2003), Prosthesis Evaluation Questionnaire (PEQ) (Legro et al., 1998) (Legro et al., 1998) and Trinity Amputation and Prosthesis Experience Scales (TAPES) (Gallagher & MacLachlan, 2000). Prosthetics Evaluation Questionnaire (PEQ) is one of a common type of questionnaire and majority of the researchers mostly used PEQ to evaluate differences in performance, function, and satisfaction among different prosthetics techniques or components (Bill et al., 2010; Gauthier-Gagnon & Grise, 1994; Grise et al., 1993; Legro et al., 1998; Van der Linde et al., 2007). PEQ is used in the current study to investigate the effect of satisfaction and perceived problems during level walking and ramp and stairs negotiations between Dermo and Seal-In X5 liners. PEQ was also used to evaluate the satisfaction and perceived problems between the Dermo, Seal-In X5, and Pelite liners.

Currently, clinicians and prosthetic practitioners use different liners in Malaysia, but the commonly-used silicon liners are the new Dermo liner with pin and the Seal-In X5 liner system. Therefore, the objectives of this research are to compare the interface pressure that develops between the residual limb and socket with Dermo and Seal-In X5 liners during level walking, stairs ascent, stairs descent, ramp ascent, and ramp descent as well as their effect on patients satisfaction and finally, to compare these two liners with Pelite liner.

1.1. Objectives

This study on the transtibial prostheses has the following objectives:

I. To evaluate the interface pressure between the socket and the residual limb during level walking using the Dermo and Seal-In X5 liners and to assess its effect on patient's satisfaction.

II. To investigate the interface pressure during stairs ascent and descent between the socket and the residual limb during stair ascent and descent when using the Dermo and Seal-In X5 liners and its effect on patients satisfaction.

III. To evaluate the pressure between the socket and the residual limb during ramp ascent and descent when using the Dermo and Seal-In X5 liners and its effect on patient's satisfaction.

IV. To compare the effects of using the Dermo, Seal-In X5, liners and using the pelite liners on patient's satisfaction and perceived problems.

V. To investigate the effects of three dissimilar suspension systems (Dermo, Pelite, and Seal-In) on participant's satisfaction and perceived problems with their prostheses.

1.2. Thesis outline

This thesis consists of eight chapters, including the introduction. The content of each chapter is described as follows:

Chapter 2 contains a detailed literature review of topics related to the research, which includes lower-limb amputation, amputation causes, and rehabilitation after amputation, modular prosthesis, liners, fabrication of prosthesis, alignment, gait training and residual limb-socket interface pressure. The chapter also reviews the questionnaires used to evaluate the effects of the liners on patient's satisfaction and perceived problems.

Chapter 3 describes the interface pressure between the residual limb and socket when using the Seal-In X5 and Dermo liners and their effects on patient satisfaction during normal walking.

Chapter 4 describes the interface pressure between the residual limb and socket using the Seal-In X5 and Dermo liners and the effect on patient's satisfaction during stair ascent and descent.

Chapter 5 describes the interface pressure between the residual limb and socket when using the Seal-In X5 and Dermo liners and the effect on patient's satisfaction during ramp ascent and descent.

Chapter 6 includes a comparative study of the Dermo, Seal-In X5, and Pelite liners and their effects on patient's satisfaction and perceived problems.

Chapter 7 includes a retrospective qualitative study that investigates the effects of different suspension types on the satisfaction and perceived problems of patients with prostheses.

Chapter 8 contains the conclusions drawn from the thesis findings and explores possible future work for developing a new socket based on the current results.

CHAPTER 2

2. Background of the study

This chapter provides a comprehensive review of the literature on lower-limb amputation, rehabilitation after amputation, possible prosthetic treatment for amputees, different stages of prostheses, different methods of fabricating prosthesis, detailed overview of liners, measuring techniques of interface pressure between the socket and residual limb, and questionnaire evaluation.

2.1. Lower-limb amputation

The removal of body parts through surgery or trauma is called amputation. Amputation is used to control pain and disease progression in the affected extremities (e.g., gangrene and sarcoma). Amputation is performed at any level, but lower-limb amputations are the most common (Crenshaw & Wenger, 1987; Murdoch & Wilson, 1996). Amputation is categorized by amputation level and depends on the severity of the wound. Limb or part of limb abscentat by birth is the state called congenital limb amputation, and can affect any part of the limb (Woodman et al., 2004).

Archeological findings reveal that amputation procedures have been performed since ancient times. However, the earliest amputations were mainly performed to remove dead tissue because the early surgical techniques were unable to control blood loss (i.e., hemorrhaging), which results from cutting healthy arteries.

In ancient times, amputation procedures were extremely difficult to implement. A number of assistants had to restrain the patient, who was made to consume alcohol. The patient was awake and observed the entire amputation procedure (Fig. 2.1).

Figure 2.1: Ancient amputation procedure (reproduced from Amputation during the Golden Age of Piracy, 2003)

Ambroise Pare, a French surgeon, introduced an important technique called "vessel ligatures" in 1590, which decreased the risk of blood loss during amputation (Sachs et al., 1999). Jean-Loius Petit, also a French surgeon, introduced tourniquet technique in the 17th century to control blood loss during surgery, which was later called the Petit tourniquet (Sachs et al., 1999). Figure 2.2 shows the application of the tourniquet technique.

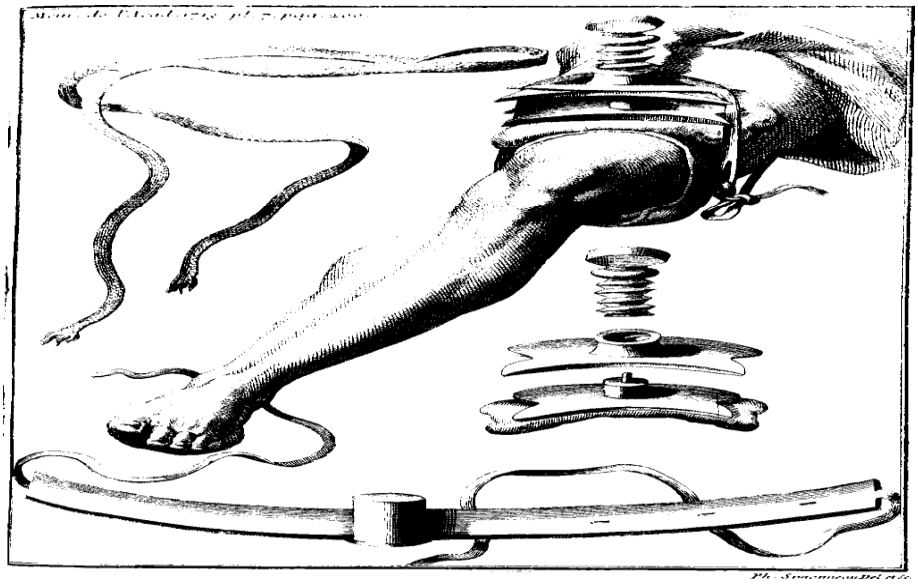

Figure 2.2: Application of the tourniquet and its components (reproduced from Sachs et al., 1999)

2.1.1. Lower limb amputation levels

a- Digit amputation: the removal of any digit.

b- Partial foot amputation (Chopart, Lisfranc, and ray): the foot is amputated at different levels.

c- Ankle disarticulation amputation: the ankle is amputated completely.

d- Transtibial amputation: the leg is amputated below the knee and above the ankle at any level.

e- Knee disarticulation: the leg is amputated through the knee joint.

f- Transfemoral amputation: the leg is amputated above the knee and below the hip at any level.

g- Hip disarticulation: the leg is amputated through the hip joint.

h- Hemipelvectomy: half of the hip bone is amputated.

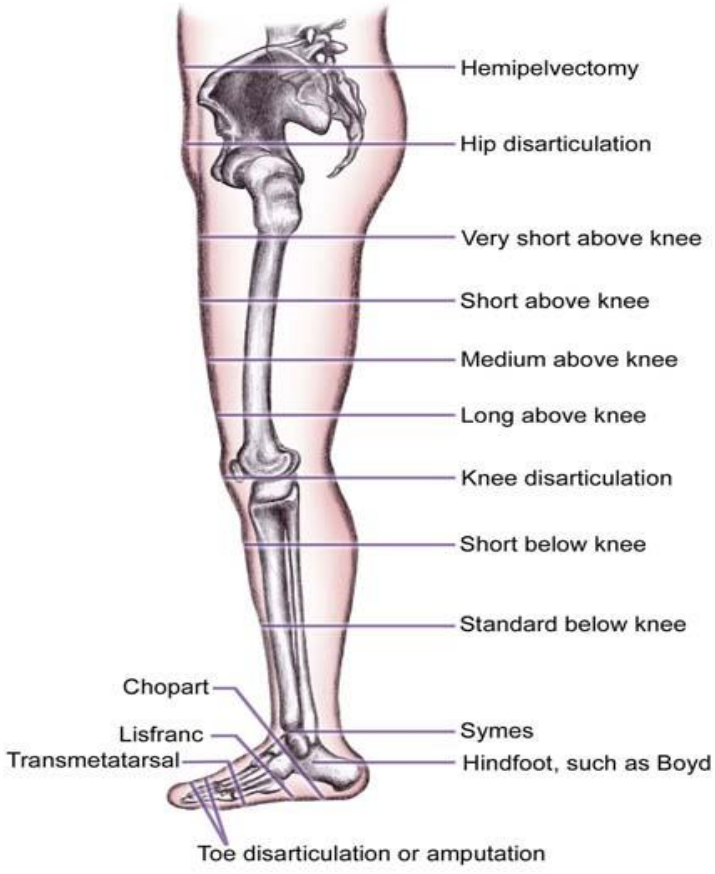

Figure 2.3: Various levels of lower-extremity amputations (reproduced from Amputations of the Lower Extremity, 2014)

2.1.2. Reason for amputation

Amputation has many reasons, but the most common are as follows:

a- Peripheral vascular diseases (PVD)

b- Trauma

c- Congenital disorders

d- Cancer

PVD with diabetes are the most common causes of amputation worldwide (Davis et al., 2004; Sachs et al., 1999). PVD with diabetes is the major cause of amputation in many developed and non-developed countries. The World Health Organization (WHO) declared in 2000 that at least 171 million people worldwide suffered from diabetes, which was 2.8% of the population (Yun et al., 2007). This number is increasing rapidly and is estimated to double by 2030. Diabetes mellitus occurs worldwide but is more common in developed countries, especially type 2 diabetes (Nathan et al., 2009). Statistics show that PVD and diabetes are the highest causes of amputation in the United States (70%), followed by trauma (22%), congenital diseases (4%), and tumors (4%) (Seymour, 2002).

In Malaysia, the major cause of amputation is diabetes, and more than 1.2 million of the Malaysian population is suffering from diabetes (Malaysian Diabetes Association, 2007). The International Diabetes Federation expects that diabetes will be highly prevalent in South East Asia by 2025. WHO estimates that a total of 2.48 million of the Malaysian population will be suffering from diabetes by 2030 (Shaw et al., 2010). The first National Health and Morbidity Survey (NHMS I) conducted in Malaysia in 1986 reported a 6.3% prevalence of diabetes, which had risen to 8.3% in the NHMS II conducted in 1996, and finly had risen to 20.8% in 2011. The risk of lower-limb amputation in Malaysia is 27.7 times more for diabetes than for other diseases according to the Malaysian Diabetes Association (NHMS I, 1985; NHMS II, 1996).

Blood vessel and nerve damages associated with diabetes cause severe infections that are difficult to treat. The feet are often the first to be affected. This condition worsens with poor blood circulation, which delays the healing process. When an individuals toes and feet lose the ability to feel, he/she is likely to injure them without knowing it. A slight injury, even a minor cut, can develop into an ulcer or a severe infection, which can result in amputation (Fig. 2.4).

Amputation due to trauma is mostly the result of vehicle and industrial accidents. Individuals born with congenital disorders or birth defects may have abnormally short limbs or no limbs at all (Fig. 2.5). Bone tumors called “osteosarcoma” can also be treated by amputation.

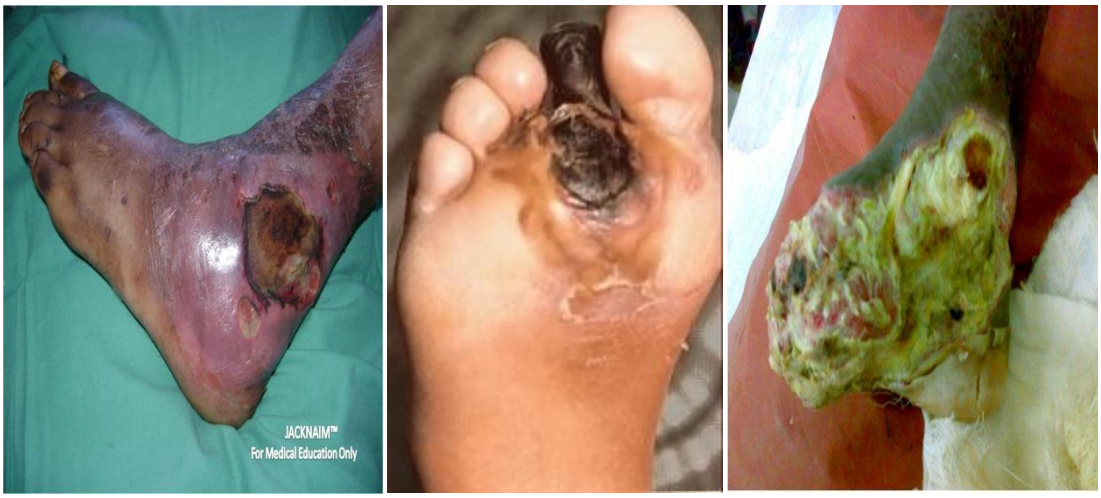

Figure 2.4: Diabetic foot ulcers on different levels of the lower limb, which result in amputation at different levels (reproduced from the medical notes of the author, 2010)

Transtibial amputation is the most common amputation level in all major lower limb amputations (Fig. 2.6). The joints play a major role in walking with prosthesis. Surgeons always protect the joints and fashion residual limbs at the distal practical level whenever possible. Short transtibial residual limbs make fitting extremely difficult whereas long transtibial residual limbs are prone to blood circulation problems.

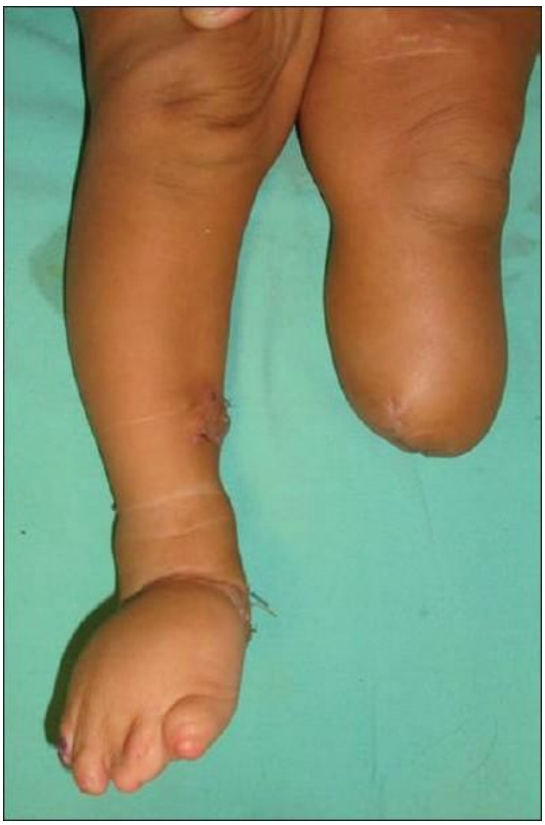

Figure 2.5: Congenital amputation (Agashe et al., 2011)

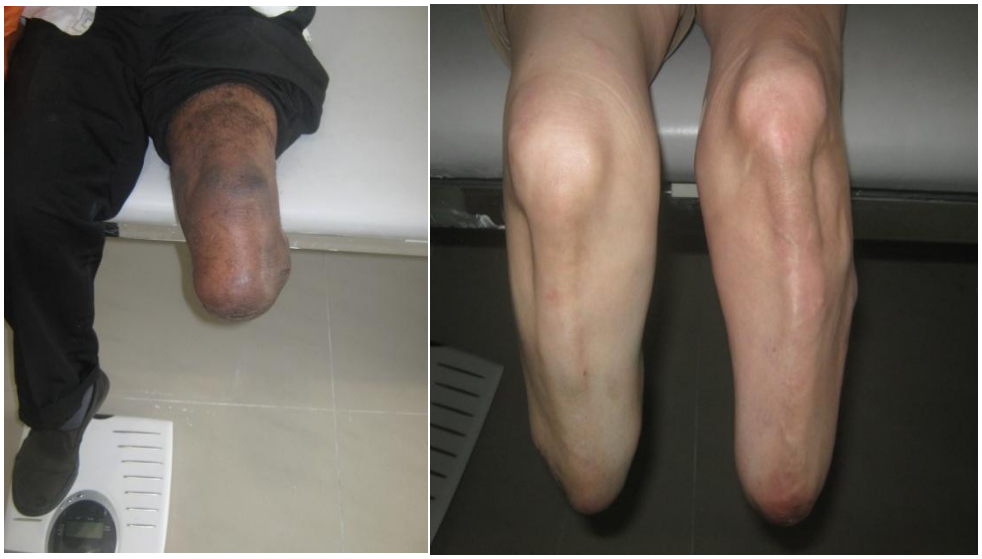

Figure 2.6: Residual limbunilateral residual limbs (left) and bilateral residual limbs (right)

2.2. Rehabilitation after amputation

Mobility is a fundamental physical requirement, and its restoration is the ultimate objective of rehabilitation programs following lower-limb amputations (Geertzen et al., 2001; Rommers et al., 2001). Rehabilitation must be initiated before and after amputation as soon as possible. The process is divided into nine phases: (2.2.1) preoperative treatment, (2.2.2) acute postsurgical wound healing, (2.2.3) pre-prosthetic residual limb, (2.2.4) stages of prosthesis, (2.2.5) prosthetic training, (2.2.6) community integration, (2.2.8) vocational rehabilitation, and (2.2.9) follow-up.

2.2.1. Preoperative treatment

Rehabilitation for amputees ideally commences before amputation. The rehabilitation team members communicate with the amputee and family members to discuss future plans. The team members develop a treatment plan then examine the mental and physical health conditions of the patient. Preoperative treatments develop amputation protocols and initiate future planning to help the amputee in long-term prosthetic treatment. The rehabilitation team provides information on phantom sensations and amputation implications (Ehde et al., 2000).

2.2.2. Acute postsurgical wound healing

This phase focuses on healing the wound, controlling the pain, rang of motion (ROM), mobility, and transfer training and dressing the residual limb for an enhanced residual limb.

2.2.3. Pre-prosthetic residual limb

The goal at this stage is to obtain a healthy residual limb. Different types of dressing are used to control the pain and to develop the residual limb of the amputee.

Some researchers propose a rigid dressing, whereas others propose a removable dressing. Some centers use elastic bandages and soft tissue mobilization (Mueller, 1982; Wu & Krick, 1979). Strengthening and cardio exercises strengthen the sound and amputated sides of lower-limb amputees. Trunk strength and balance must be observed because they facilitate sitting balance, bed transfer, and mobility. Contracture of the knee joint is a common complication. Knees must be constantly stretched to avoid developing contracture. Contracture significantly affects mobility and negatively affects the non-amputated leg.

2.2.4. Stages of prosthesis

Prosthetic treatment involves four stages of prosthetic device according to (Smith et al., 2004): post-operative, initial, preparatory, and definitive. Progressive treatment is desirable. However, most amputees are not in favor of all four prostheses, especially the post-operative and initial prostheses, which are directly molded on the residual limb. Special prostheses for cycling, swimming, and running can also be provided for some amputees.

2.2.4.1. Post-operative prosthesis

Post-operative prosthesis (POP) is fitted immediately or within seven days after amputation (Fig. 2.7). This method is feasible for any amputee but mostly prescribed for young and active individuals. POP is also known as immediate post-operative prosthesis (IPOP). IPOP provides exceptional results after regular check-ups and close supervision (Smith et al., 2003).

Firstly, IPOP controls post-operative bleeding and swelling after amputation, which generally minimizes pain. Secondly, IPOP remodels and shapes the residual limb to prepare for definitive prosthesis. Thirdly, IPOP provides psychological relief for

amputees. When a patient wakes up after surgery and observes a limb in place, this motivates him to walk again.

Figure 2.7: Post-operative prosthesis (reproduced from improving outcomes with immediate ostoperative prostheses, 2010)

2.2.4.2. Initial prosthesis

Initial fitting of the prosthesis is essential to rehabilitation success. Prompt and correct application of compression to the residual limb, together with the appropriate therapy, positively affects the rehabilitation process. This prosthesis is used after removing sutures from the residual limb, which is generally one week to four weeks after amputation. The plaster of Paris or fiberglass is directly molded on the residual limb because of atrophy. Changing the socket each week is necessary to accommodate the atrophy. A temporary prosthesis frame and air bladder are often used as an alternative socket. Initial prosthesis is often prescribed by hospitals and rehabilitation clinics for active amputees (Fig. 2.8).

Figure 2.8: Initial prosthesis (reproduced from the De la torre prosthetic and orthotic, Inc.)

2.2.4.3. Preparatory prosthesis

The amputee is provided with a preparatory prosthesis (Fig. 2.9), which is frequently used for several weeks or months until the residual limb stabilizes, before the definitive or permanent prosthesis is provided. The preparatory prosthesis accelerates the rehabilitation process and allows the amputee to be mobilized before the permanent prosthesis is given. Preparatory prosthesis helps control edema and properly shapes the residual limb. The socket for this prosthesis is usually made of plaster of Paris, fiberglass, or polypropylene thermoplastic. The socket is attached to the prosthetic foot through a pylon tube and suspended through a belt and suprapatellar cuff. Prosthetists and therapists closely work together to monitor the amputee during the rehabilitation process and regularly observe the residual limb to avoid complications. The amputee uses socks with the preparatory prosthesis to accommodate the shrinking of the residual limb. The preparatory prosthesis is generally used for three to six months, depending on the maturation speed of the residual limb.

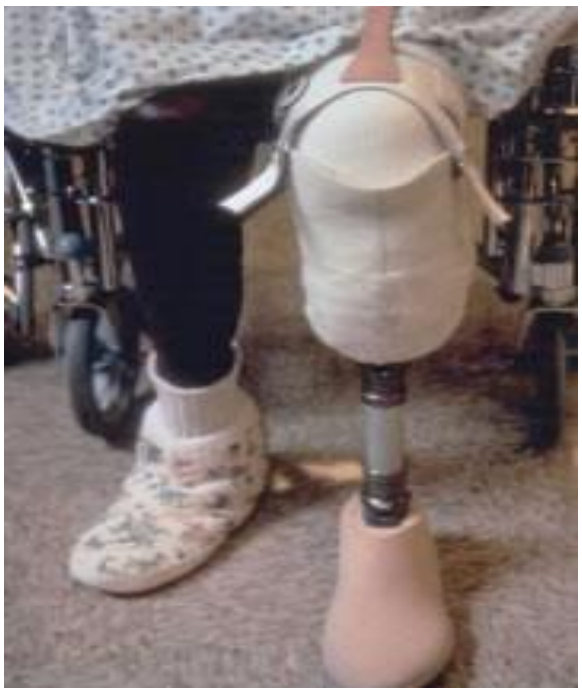

Figure 2.9: Preparative prosthesis (reproduced from transtibial suspension alternatives, 2008)

2.2.4.4. Definitive or permanent prosthesis

The definitive prosthesis is prescribed only when the residual limb of the amputee has stabilized to ensure that the new prosthesis can endure and only when the residual limb has matured. The average life span of the definitive prosthesis is three to five years, depending on the types of component used. The definitive prosthesis is often changed because of edema in the residual limb, weight loss or gain, and problems in the components (especially in the liner).The definitive prosthesis has two types: exoskeletal and endoskeletal.

2.2.4.4.1. Exoskeletal prosthesis

The exoskeletal prosthesis (2.10) also known as conventional or crustacean-type prosthesis is commonly made of wood or plastic. The prosthesis walls provide shape and have a weight-bearing function. This type of prosthesis has been effectively used for years and is the preferred prosthesis for patients, especially when geographical conditions do not allow the use of modular parts. This prosthesis type is durable and

heavy, and can hardly be modified once finished. Adjusting the alignment is difficult once the prosthesis is ready.

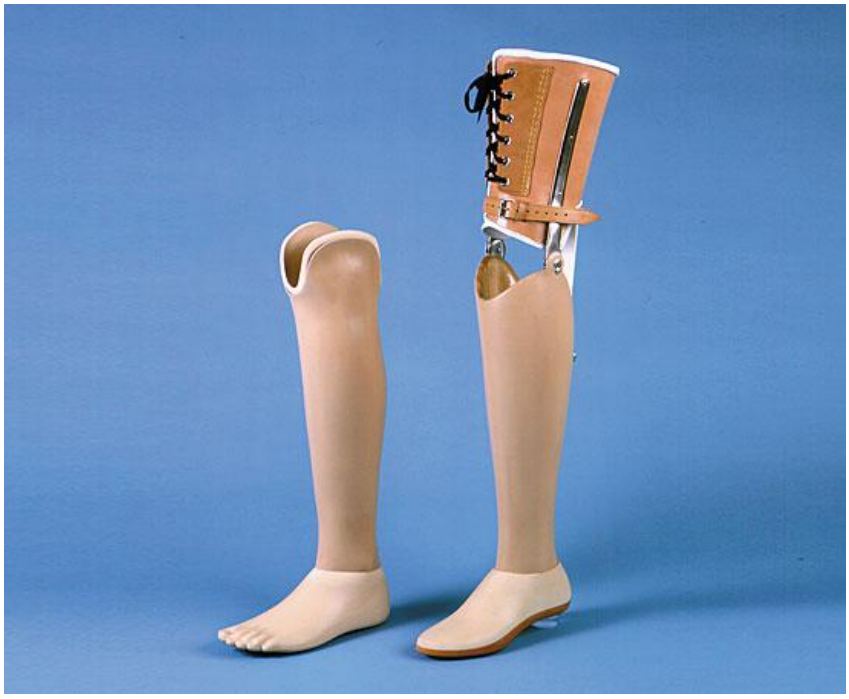

Figure 2.10: Exoskeletal prosthesis (reproduced from Otto Bock Health Care, 2014)

2.2.4.4.2. Endoskeletal prosthesis

The endoskeletal prosthesis is also known as the modular prosthesis (Fig. 1.11). This prosthesis is a lower-limb support that consists of an internal pylon, which is usually covered with a lightweight material (e.g., plastic or foam) to resemble the skin. The soft foam covers the internal structure of the prosthesis; it is removable and allows the prosthetist to modify the prosthesis when necessary. The endoskeletal prosthesis is lightweight and adjustable.

Figure 2.11: Endoskeletal prostheses (reproduced from LIMB orthotic and prosthetic services, 2014)

2.3. Details of endoskeletal prosthesis

The study focuses on transtibial prosthesis, which is for amputees with amputations above the ankle and has a fully functioning as a knee. The knee joint benefits amputees because it provides the power to lift or lower the body and helps maintain balance. The knee joint automatically bends the knee, shortening the overall leg length, from stance to swing phase; this act avoids the occurrence of toe-stubbing, which can lead to falls. If a transfemoral (TF) amputee wears prosthesis without a knee joint, then he/she will limp while walking to create foot clearance and to avoid stubbing his toes Transtibial amputation causes the loss of the ankle and foot functions. The ankle and foot play important roles in shock absorption, proprioception, and motion. The foot is the first part of the lower limb that comes into contact with the ground. The foot adjusts to different types of ground surfaces and conditions by deforming or stiffening to maintain balance. Foot nerve endings provide proprioception, which is the ability to feel its position and the surface type. The foot coupled with the ankle are the first shock absorbers of the body, which absorb the impact during heel strike and the remaining stance phase (Smith et al., 2003). Therefore, the artificial limb that replaces the amputated lower limb must recapture the functions of the knee joint, ankle, and foot to work well.

The modular prosthesis is an assembly of the socket, pylon tube, foot, suspension system, and liner. An adaptor connects these components together.

2.3.1. Socket

The socket is the most important part of the prosthesis because it is the interface with the residual limb. Sockets must be designed properly to achieve satisfactory load transmission, motion stability, and efficient mobility control. The essential ideology for socket design differs from either distributing most of the load over precise load-bearing

regions or consistently distributing the load over the entire limb. Prosthetists are interested in understanding the load-transfer pattern, regardless of design, because it can help them assess the quality of the fitting and develop their perspective on the underlying biomechanical basis (Mak et al., 2001). If the socket does not fit, then the leg will not be functional because of the poorly fitted socket; unfit sockets cause pistoning motions of the residual limb inside the socket, which result in skin abrasions, skin ulcers, and blisters (Dudek et al., 2005).

A few prosthetic socket designs are used for transtibial prostheses, such as the patellar-tendon-bearing (PTB) socket, total surface bearing (TSB) socket, patella-tendon-bearing-supracondylar (PTB/SC) socket, and patella-tendon-bearing supracondylar-suprapatelar (PTB/SC/SP) socket (Fig. 2.12). The PTB and TSB socket designs are commonly used in transtibial prosthesis.

2.3.1.1. PTB socket

The US Department of Veterans' Affairs (VA) Prosthetic and Sensory Aids Research Program developed the PTB transtibial prosthesis in 1957. The Prosthetics Research Group Biomechanics Laboratory at the University of California Berkeley set the first fitting and alignment of the PTB socket in 1957 (Fig. 2.14).

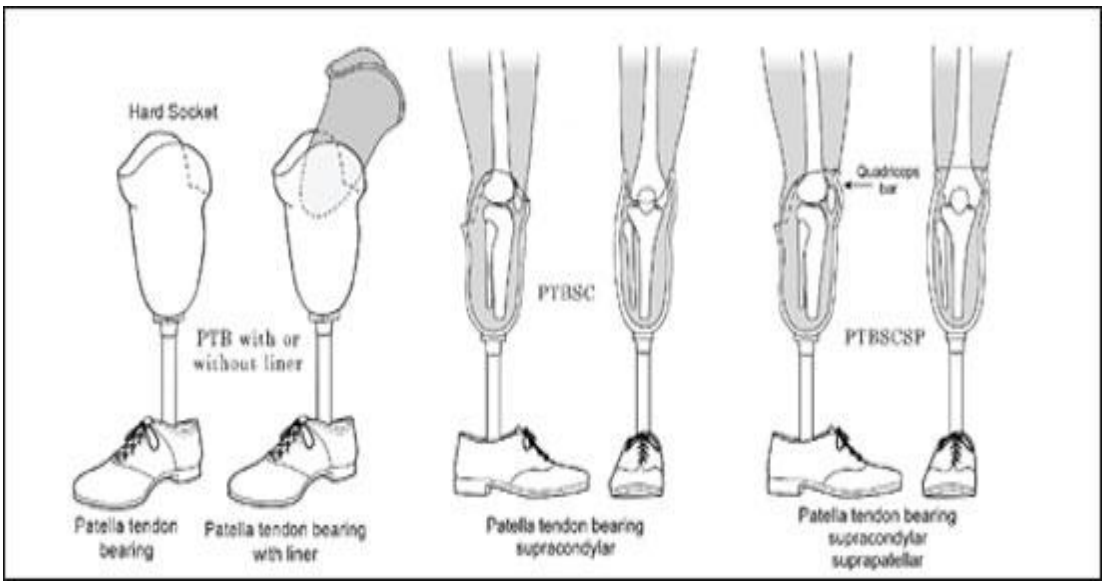

Figure 2.12: Different types of transtibial sockets (reproduced from lower-limb prosthetics, 2013)

Understanding the load shifting mechanics between the residual limb and prosthetic socket is the first step to obtaining a successful prosthesis fit (Lee et al., 2005). Certain areas of the residual limb, such as the fibular head, tibial crest, distal end of the tibia, distal end of the residual limb (in some cases), tibial tuberosity, and distal end of the fibula, cannot tolerate pressure. These areas are pressure-sensitive areas and must be relieved properly when modifying the positive model. Pressure over these areas cause discomfort and ulcers on the residual limb, which delays the prosthetic treatment. Meanwhile, certain areas, such as the popliteal fossa area, patella tendon, medial flare of the tibia, and proximal medial flare of the fibula, are pressure tolerant and can tolerate weight (Faustini et al., 2006). Pressure is exerted on these areas during modification to bear the body weight of the patient. Figure 2.13 presents the pressure-tolerant and pressure-sensitive areas.

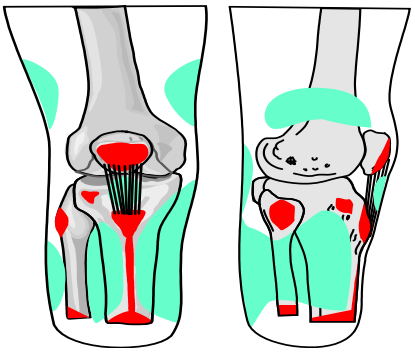

Figure 2.13: Pressure sensitive areas (red) and pressure tolerant areas (blue)

2.3.1.2. TSB socket

The TSB socket was introduced to address the issues faced with the PTB sockets (e.g., skin abrasions, limitation of knee flexion, excessive pressure on the patellar-tendon area, adventitious bursae, perspiration, anddermatitis) (Ahmed et al., 1994; Hirai et al., 1993; Takano et al., 1994). “Total contact” is a casting and fabrication technique that ensures the absence of space between the residual limb and prosthetic socket. All areas of the residual limb must be in enough contact with the prosthetic socket to attain TSB. Weight is born on the entire surface of the residual limb in the TSB socket, which results in a good fit, good pressure distribution on the residual limb, good blood circulation, and reduced pistoning motion (Fillauer et al., 1989a; Staats & Lundt, 1987). Weight is equally distributed on the entire residual limb. No extra pressure is exerted on the patella tendon or any other part of the residual limb. The socket takes the exact shape of the residual limb.

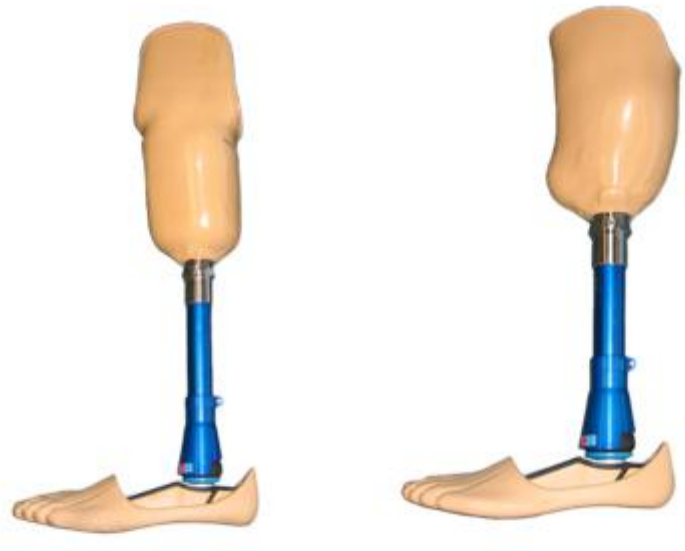

Figure 2.14: Transtibial sockets: prosthesis with PTB socket (left) and prosthesis with TSB socket (right) (reproduced from transtibial socket, 20110)

2.3.2. Pylon tube

The pylon tube connects the socket to the prosthetic foot and to other components and fills the space intended for the lower leg bones, tibia, and fibula (Fig. 2.15). The pylon transfers the body weight from the socket to the foot. The pylon is also called the shank of the prosthesis. Adaptors connect all these parts together, which allows and customization of the alignment for each prosthetic user. The ankle and foot of the transtibial prosthesis are also important. Most feet are attached directly to the pylon through adaptors. However, a dynamic ankle unit can be introduced to help the prosthetic user on slope, inclined stairs, and rough terrains.

Figure 2.15: Different sizes of pylon tubes (reproduced from ebay.com, 2010)

2.3.3. Suspension system

Suspension methods are used to hold the prosthesis onto the residual limb and allow comfortable sitting. Several suspention methods are available (Pritham, 1979): (1) the belt and suprapatellar cuff suspension method (Radcliffe et al., 1961); (2) the figure-of-eight shape beltis a variation of the suprapattelar cuff suspension (Girling & Cummings, 1972); (3) the sleeve suspension attaches the prosthesis to the residual limb, and the rubber sleeve causes negative pressure between the socket and residual limb (Chino et al., 1975; Ross, 1990); (4) the supracondylar-suprapatellar suspension, first introduced in the United States, stabilizes and suspends the prosthesis (Breakey, 1973); (5) the supracondylar suspension is a variation of the supracondylar-suprapattelar suspension and is usually used for long residual limbs (Wirta et al., 1990); (6) the thigh corset provides medio-lateral stability for users (Cummings et al., 1979); and (7) the silicone liner suspension employs various methods such as the distal locking pin, lanyard, and suction suspension (Ali et al., 2012a). Figure 2.16 shows the suction and pin and lock suspension systems.

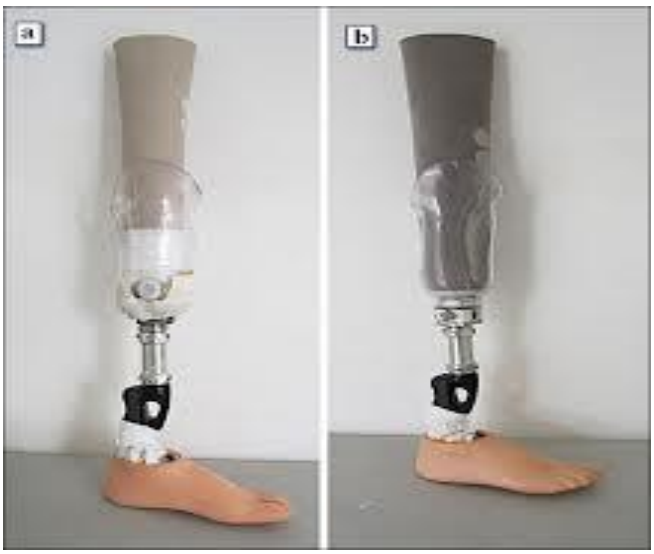

Figure 2.16: (a) Suction suspension system and (b) pin and lock suspension system

2.3.4. Liners

Liners are the interface between the prosthetic socket and residual limb and provide cushioning. Several liners are currently in use.

2.3.4.1. Pelite or polyethylene foam liner

Pelite has been used in transtibial prosthesis since 1950. Pelite is the most commonly used material in liners or soft sockets in developing countries. The polyethylene foam (closed-cell) is manufactured in various thicknesses and durometers (hardness). Pelite is thermo-formable and can be formed over the positive cast after heating (Fig. 1.17). The advantage of pelite and other similar materials is easy adjustment. Whenever the residual limb volume changes, additional pelite can be glued to the liner. Another advantage of pelite is that it can potentially be used for the supracondylar wedge of the prosthesis.

Figure 2.17: Polyethylene foam liner

2.3.4.2. Silicone liners

Kristinsson from Ossur introduced silicone liners in 1986, and researchers have been using it in transtibial prostheses since then (Kristinsson, 1993). The producers of silicone liners claim that these liners have several advantages over the standard prosthesis (i.e., PTB and Kondylen Bettung Munster with a supracondyler fitting, with or without suspension sleeve in the conventional prosthesis) (Fillauer et al., 1989b; Fitzlaff & Heim, 2002; Kristinsson, 1993). Silicone liners closely bond the residual limb and socket, which provides better interface and suspension than the other socket types. Silicone liners are also claimed to offer excellent skin protection and reduce friction between the residual limb and socket. Research evidance claim that wearing prosthesis with silicon liners result in improved comfort and enhanced cosmesis. Therefore, delicate skin can best benefit from using silicon liners (Lake & Supan, 1997). These improvements are due to the material properties of the silicon liner (i.e., adherence to the skin) and the way the residual limb is fitted in the socket (Fillauer et al., 1989b; Kristinsson, 1993). The silicon material is pliable, sticky, and closely follows the entire contour of the residual limb surface. An air tight seal is created between the liner and the skin. These properties also influence the soft tissue, which is compacted, formed, and controlled by the liner socket. The liner socket allows the use of the TSB principle

of the residual limb surface during prosthesis loading (Kristinsson, 1993). Enhanced comfort, improved suspension, and improved cosmesis have increased the prescription of silicon liners (Baars & Geertzen, 2005). Diffrent types of silicone liners are shown in Fig. 2.18. Manufacturers are developing new liners that claim to have superior qualities such as better suspension, less interface pressure etc; the effects of the new liners on patient satisfaction are unclear.

Figure 2.18: Different types of silicone liners (reproduced from Ossur, 2008)

2.4. Fabrication of prosthesis

A number of casting methods have been developed over the ages. In this section different methods are described and discussed.

2.4.1. PTB sockets

James Foort, who worked alongside C. W. Radcliff of the University of Berkely, developed the PTB socket in the 1950s. during a meeting of the Workshop Panel of Lower-Extremity Fitting in 1965, they listed down eight factors as guidelines to the proper fabrication of PTB sockets (Foort, 1965). These guidelines were in response to the substantial number of prosthetists who claimed that the maintenance and replacement costs of PTB prostheses outweighed the fabrication and functional advantages. The guidelines provided a detailed framework concerning PTB socket fabrication and potential problems, including PTB fitting techniques, plaster impression methods, model modification, residual limb shrinkage, perspiration and maceration of the residual limb, and joint-corset prostheses use. These factors clarify that socket casting does not have a definite, clear-cut technique and is as much an art form then as it is today. Socket casting requires knowledge, experience, and skill to modify and prescribe optimal socket shapes for unique residual limb conditions.

For PTB socket casting in particular, one would need to know the amount of pressure to apply and the area for this pressure application to create the pressure tolerant and sensitive areas that are characteristics of a PTB. Figure 2.19 shows the front, side, and back profile of a typical PTB socket. The contours at the patella tendon area and popliteal fossa area for example, can be distinguished from the rest of the socket area. The challenge in PTB socket casting is repeatability in producing these contours each time casting needs to be done. Studies have been conducted to show the difficulty in producing the exact socket shape each time casting is performed. Precision in

conventional socket casting technique is difficult to achieve as it is dependent on human skill and knowledge, both of which are highly subjective and prone to error.

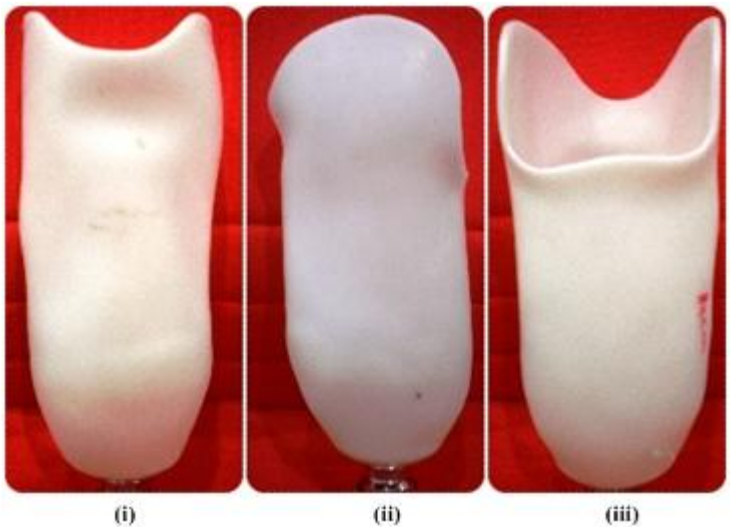

Figure 2.19: Front (i), side (ii), and back (iii) profiles of a PTB socket; the contours of the socket are clearly defined

2.4.2. CADVIEW

Lemaire and Johnson (1996) addressed the problem to produce consistent socket shapes in manual casting methods. They developed and integrated a quantitative method for defining and comparing manual socket modifications into the CADVIEW software package (Lemaire & Johnson, 1996). Their study aimed to provide quantitative information specific to the personal modification style of a prosthetist, which can be stored as a template for future modifications. The study found that variation between prosthetists was inevitable and significantly affected the resultant socket shape (Fig. 2.20). This variability is echoed by Buis et al. (2003) in their study, which compared consistency in socket shape for hands-on PTB and hands-off ICECAST compact concepts; precision and repeatability favored the hands-off technique (Buis et al., 2003). The study measured consistency using the standard deviations of radial measurements for 10 models of two casting methods. These measurements were taken at 72 circumferential locations and 13 predefined axial radiuses. The study results showed

that the average standard deviation of the hands-on concept was approximately double that of the hands-off concept. They concluded that the human factor significantly affects the consistency in socket shape, consequently affecting the prosthesis alignment.

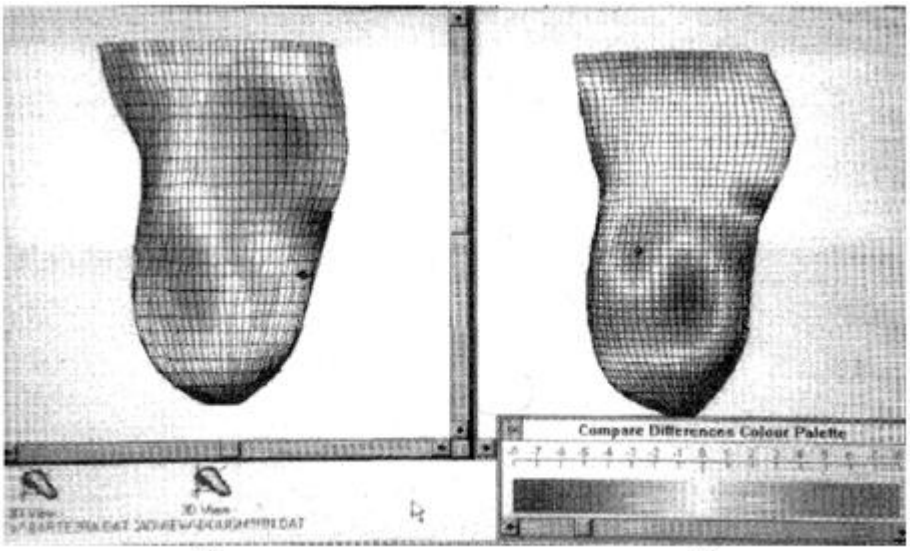

Figure 2.20:, The variation between prosthetists during casting; (i) and (ii) are the resultant socket shapes of the same residual limb casted by two different prosthetists. Reproduced from the paper published by Lemaire and Johnson (1996)

2.4.3. CAD CAM

Given that variability between prosthetists affects the socket shape and, in turn, socket fit and patient comfort, researchers have developed alternatives to the traditional socket casting method to eliminate the human factor. Shifting from the traditional casting method can improve the function of prosthetic sockets, make prosthetic services accessible, and reduce socket fabrication cost. This shift resulted in the use of computer-aided designs and computer-aided manufacturing (CAD-CAM) technologies in prosthetics and orthotics fabrication. The basis of CAD-CAM technology in prosthetic socket fabrication involves initially creating a digital representation of the residual limb topography. The digital images are then stored in a computer, and the desired modifications to the resultant socket shapes are done through a software interface. Once completed, the computer-generated images are fed into an automated carving machine

(e.g., computer numerically controlled machine) to generate the positive mold (Childress, 2002). Figure 2.21 shows the rapid manufacturing machine (RMM) at work. RMM is an example of a CAD-CAM driven technology developed by researchers at the National University of Singapore (Ng et al., 2002). James Foort developed the field of CAD-CAM in the 1960s. The field has been refined over the years and has the ability to recall shapes and consistently repeat exact modifications to allow additional accurate fittings. Steele (1994) surveyed facilities in prosthetics and orthotics fabrication using CAD-CAM and observed inconclusive statistics on the relationship between CAD-CAM and time and money savings. The study showed that 17% of those surveyed believed that CAD-CAM saved fabrication time, 39% believed it saved both time and money, and 43% believed it saved neither time nor money. This dissonance in the benefit of the CAD-CAM socket fabrication was due to the different systems utilized by different facilities at the time. However, a general consensus was reached by these different facilities, stating that the CAD-CAM technology provides long-term savings.

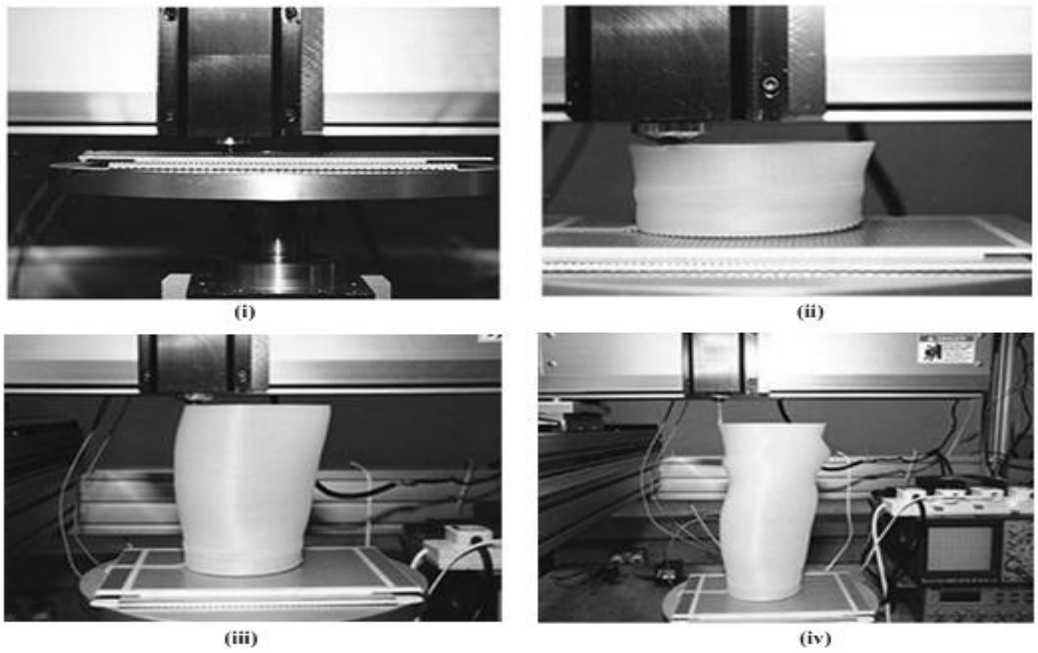

Figure 2.21: RMM shows the work of Ng et al. (2002), which fabricates a prosthetic socket in approximately 4 h; (i), (ii), (iii), and (iv) present the different stages of prosthetic sockets, manufactured from start to finish

Clinical evaluations of prosthetic sockets manufactured using CAD-CAM methods had been conducted in terms of comfort and function. Oberg et al. (1993) indicated that no significant differences can be observed between the two socket types in terms of gait and technical parameters, activity of daily living, and social functions. However, the technique has its fair share of setbacks. Cost and operating skills are the two main concerns. The high cost required to operate a CAD-CAM facility is due to the need for high-processing computers and automated carving machines. Staff must also be trained to transition smoothly from using conventional casting methods to using computer-interface commands for castings. Moreover, the maintenance cost adds to the total cost of CAD-CAM manufacturing facilities operations.

2.4.4. ICECAST Anatomy

The ICECAST Anatomy by Ossur provides an alternative to CAD-CAM assisted fabrication techniques. The system fabricates transtibial sockets consists of a casting bladder, pin-lock components, and ICEROSS silicone sleeve. The system uses air pressure as a casting medium. Basically, it pressurizes air to reposition the soft tissues of the residual limb, which creates additional anatomicallycorrect socket shapes based on the judgment of the prosthetist. Soft tissue displacement is achieved through the innovative design of individual pressure pockets inside the casting bladder (Fig. 2.22).

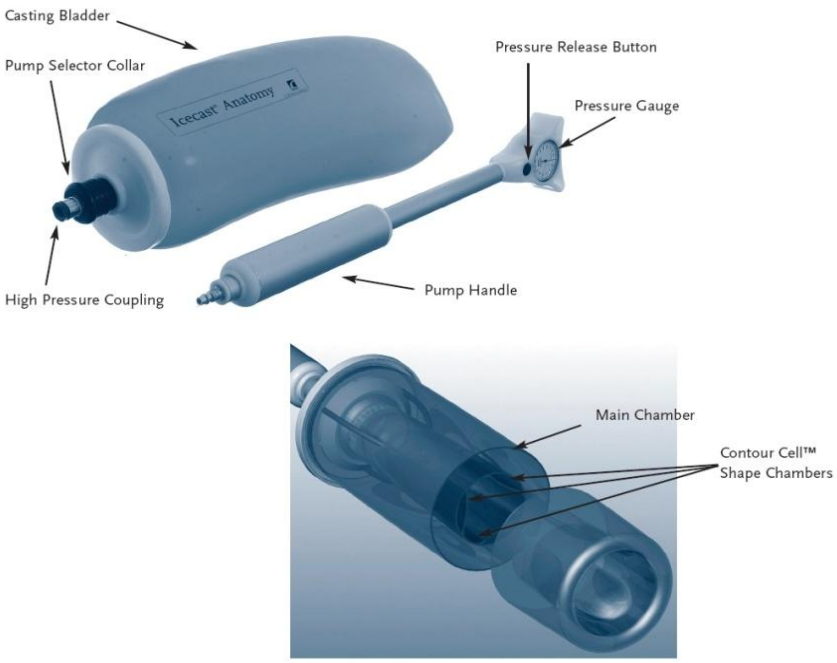

Figure 2.22: ICECAST anatomy casting system uses air pressure to perform prosthetic socket casting; Contour Cell ™ Shape Chambers are responsible for soft tissue displacement and are located inside the casting bladder (reproduced from Ossur, 2003)

The inflation of these pockets or Contour Cell ™ Shape Chambers can be adjusted according to the residual limb conditions. Ossur provides a pressure values chart as a guideline for ICECAST users, for casting sockets by taking into account the varying residual limb conditions (i.e., fleshy, muscular, or bony residual limbs) and the activity levels of the amputee (Fothergill, 2007). The chart attempts to objectify the amount of pressure employed during casting to produce consistent socket shapes regardless of who the prosthetist. These well-defined pressure ranges ensure sufficient pressure application that will create sockets of the same volume and with a close fit. These sockets eliminate the possibility of piston motion during walking. Figure 2.23 shows the casting method using the ICECAST system. The drawbacks of this system are the limb positioning and costs. Casting completed while the amputee is standing provides a better socket fit because the limb is under load, which is closer to the limb shape while walking, and thus guarantees a comfortable fit. However, similar with the

traditional method, ICECAST performs casting while the amputee is seated. ICECAST sockets are more expensive than the conventional sockets due to the higher cost of the ICECAST anatomy system and personnel.

Figure 2.23: Casting using the ICECAST Anatomy. Casting is performed while the amputee is seated, a non-weight-bearing state (reproduced from athlete brace, 2014)

2.4.5. Sand Cast

The high cost of socket manufacturing led to a new approach in prosthetic research that focused on low-tech fabrication methods. This branch of research looked into reducing fabrication cost and increasing the availability of prosthetic services to remote areas. Cost-cutting measures include casting using readily available resources and eliminating the need for multiple molds before final socket lamination. One such research was conducted by Wu et al. (2003), in which the authors developed a lower-limb prosthetic socket casting technique that uses sand as the main material. The system utilized the dilatancy principle, in which sand is compressed to obtain the negative and positive molds of the residual limb. Besides the simple and minimalistic techniques, the benefits of the system include casting while the limb is under load, accurate shape

representation, and short fabrication time. Fabrication time with this technique is significantly reduced because Plaster of Paris (POP) impressions are not required. Both negative and positive molds can instead be rapidly obtained in a two-step process. Figure 2.24 illustrates the casting process using the Centre for International Rehabilitation (CIR) sand-casting system.

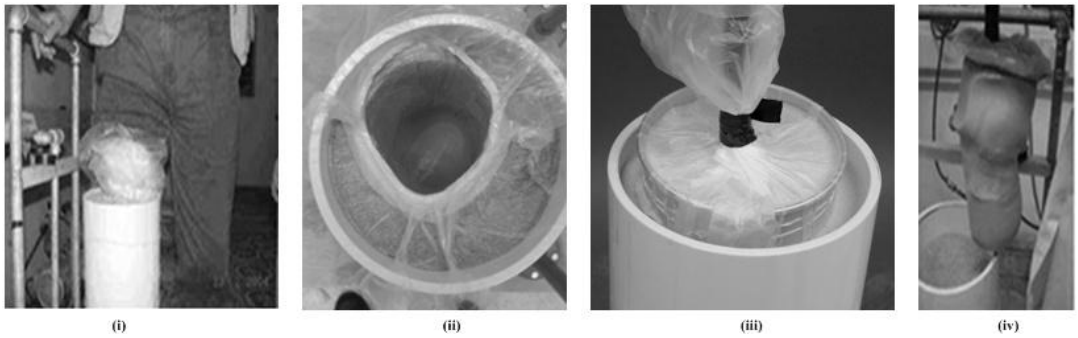

Figure 2.24: Casting process using the CIR sand-casting system (i) With sand-casting system, casting is conducted underneath while the subject stands; (ii) vacuum suction compresses the sand to create a negative mold of the residual limb; (iii) the negative mold is then filled with sand to create a positive mold; and (iv) the positive mold matches the contours of the residual limb (reproduced from Wu et al., 2004)

The system fabricates PTB sockets in which modifications are done to the positive mold to create load-bearing areas. At the time of publishing, preliminary studies conducted by the authors found the sand cast sockets to display high level of comfort. The efficiency of the CIR sand-casting technique was also studied by Jensen et al. (2005). The authors casted 35 amputees using the sand-casting system (Jensen et al., 2005). The accuracy of the casting process as explained by Wu et al. (2003) was confirmed in the present study, in which only 7% of all fabricated sockets were considered a total failure (Wu et al., 2003). In these cases, the casted sockets were wider than that of the residual limb, requiring four socks for a good fit.

2.4.6. Hydrostatic Casting

Another low-tech socket fabrication method that can be considered the no-frill counterpart to the ICECAST Anatomy system is hydrostatic casting. As the name indicates, hydrostatic casting performs socket casting through the use of water pressure. This technique can produce a low-cost socket with minimal dependence on expertise. Hydrostatic casting adopts methods from both ICECAST and sand casting. Similar to ICECAST, hydrostatic casting method uses POP for the negative and positive mold impressions. The use of POP is maintained because of its features of producing an accurate representation of the residual limb, availability, and inexpensive cost. Similar to sand casting, the hydrostatic casting system performs casting while the amputee is standing to obtain the limb shape under load. Given that hydrostatic casting relies on water pressure contained in the system to perform casting, the need for a constant supply of power is eliminated. The simplicity of the technique also presents a “plug and play” like feature, enabling the system to be brought to any area with water supply to perform casting (Convery & Buis, 1999).

2.4.7. Hand Casting

Despite numerous techniques that have been developed to fabricate sockets, manual socket fabrication is still the most commonly used technique worldwide. To produce well-fitting prosthesis, the prosthetist needs sufficient knowledge and years of experience. Socket design and shapes vary according to the different shapes of the residual limbs as well as the residual limb properties for each patient. However, socket fabrication methods are fully dependent on the skill of the prosthetist. Successful fitting of the prosthesis is dependent on the fit of the hard socket. Appropriate socket design is fundamental to achieve comfort, control, and suspension.

The following hand-casting instructions are intended as a recommendation to help create a well-fitting socket that accommodates the silicone liner with shuttle lock.

2.4.7.1. Marking

Liner is rolled on the residual limb, and the residual limb is covered with cellophane plastic. All sensitive areas (patella, tibial crest, tibial tuberosity, fibular head, fibular end, and other bony prominent and sensitive areas) and marking points (circumferences, medial–lateral, anterior–posterior, residual limb length, and any other important areas) are marked with white board marker (Fig. 2.25).

Figure 2.25.Residual limb marking

2.4.7.2. Measurements

Circumferences, medial–lateral, anterior–posterior, residual limb length, sound side measurements, and all other required measurements were obtained from the subjects by a certified prosthetist/orthotist (Fig. 2.26).

Figure 2.26: Taking measurements from residual limb

2.4.7.3. Casting

Two to three (depending on residual limb volume) POP bandages are wrapped around the residual limb to obtain a cast for modification (Fig. 2.27). This cast is called a negative cast.

Figure 2.27: POP wrapping on residual limb

2.4.7.4. Filling of negative cast

After obtaining the negative cast from the subject's residual limb, the cast is filled with POP powder paste to obtain a positive mold of the residual limb (Fig. 2.28). Negative cast is aligned in the wall frame, and then the cast wrap holder and POP powder paste is poured into the negative cast.

Figure 2.28: Filling of negative cast

2.4.7.5. Modification

The process involves a prosthetist modifying the positive model based on biomechanical principles to relieve pressure in the sensitive areas in the socket. Most of the positive models are modified on total contact design, in which the weight is distributed throughout the sub-tissues of the residual limb (Fig. 2.29).

Figure 2.29: Modification of negative cast

2.4.7.6. Making of test socket

The shuttle lock is aligned on the positive model (socket with Dermo liner only). A transparent plastic sheet is heated in the oven and molded on the positive model to fabricate a check socket (Fig. 2.30). After molding, the socket is finished using the router machine and cleaned with water.

Figure 2.30: Making the test socket

2.4.7.7. Socket assembly

After finishing the socket, the prosthetist assembles the socket with other components (Fig. 2.31). Once the prosthesis is assembled, the patient is asked to don the prosthesis. A team that includes a physiotherapist and the prosthetist observes the gait of the amputees and train them how to walk wearing the prostheses. Amputees are asked to walk wearing the test socket and to inform the team regarding any pain or discomfort in the socket. The prosthetist carefully observes the socket to confirm that the sockets are in total contact. Once the amputees and the observing team members are satisfied with the check socket, the prosthetist fabricates the definitive prostheses for each subject.

Figure 2.31: Check socket prosthesis assembly

2.4.7.8. Making of definitive prosthesis

The check socket is filled with POP paste. Once the POP hardens, the check socket is removed and the plaster mold is finished for lamination.

2.4.7.8.1. Making PVA bags and lamination

Prior to lamination, two PVA bags are constructed. In the lamination process, the first PVA bag is molded on the plaster model for isolation. Then, cotton stockinet and glass stockinet are rolled over on the positive model. Carbon fibers are placed for several amputees to provide more strength to the socket. A total of seven to eight layers of stockinet (four layers cotton and four layers of fiberglass stockinet) are rolled over on the positive model, and the second PVA bag is molded over the stockinet. Epoxy resin is poured into the second PVA bag and distributed equally on all surfaces of the positive model.

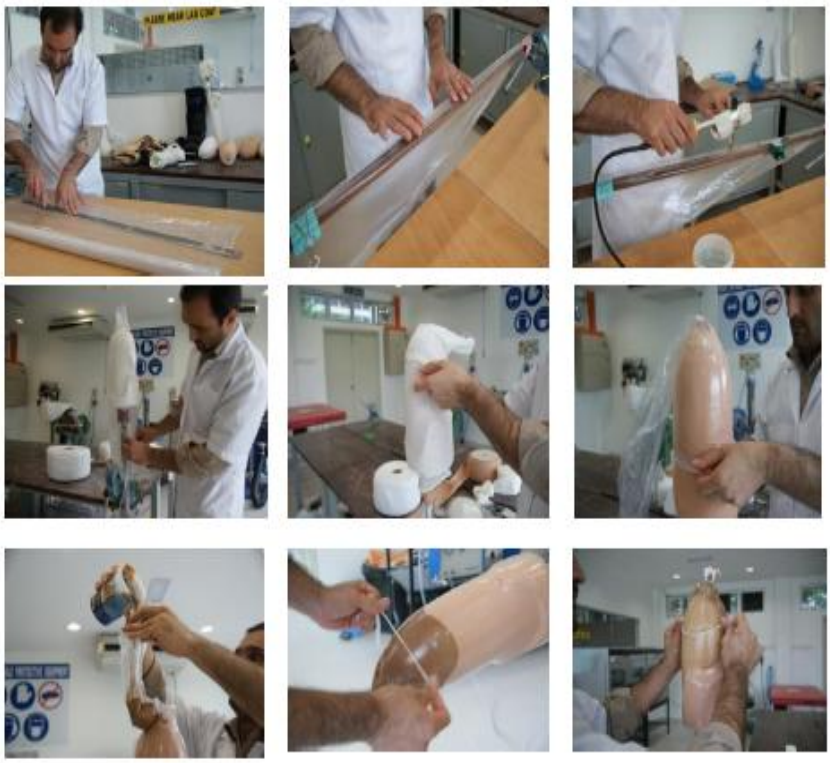

Figure 2.32: Procedures for making a definitive prosthesis

2.4.7.8.2. Finishing and assembly

Once the laminated socket hardens, the socket is cut and finished. After finishing, the socket is assembled with the other components (foot, pylon tub, and adaptors) and aligned.

2.5. Alignment

Alignment is the spatial relation between the socket and the other components of the prosthesis (Fig. 2.33). The purpose of alignment is to position the socket with respect to the other components so as to prevent undesirable movement patterns and create a desirable walking pattern (Chow et al., 2006). If successful alignment is not achieved, the amputee may experience discomfort with, and may stop wearing, the prosthesis. Bad alignment of the socket affects the gait pattern and results in discomfort, residual limb pain, and tissue breakdown (Hannah et al., 1984; Pinzur et al., 1995; Rossi

et al., 1995; Sanders et al., 1993). Therefore, aligning the prosthesis before delivering it to the amputee is important to avoid issues.

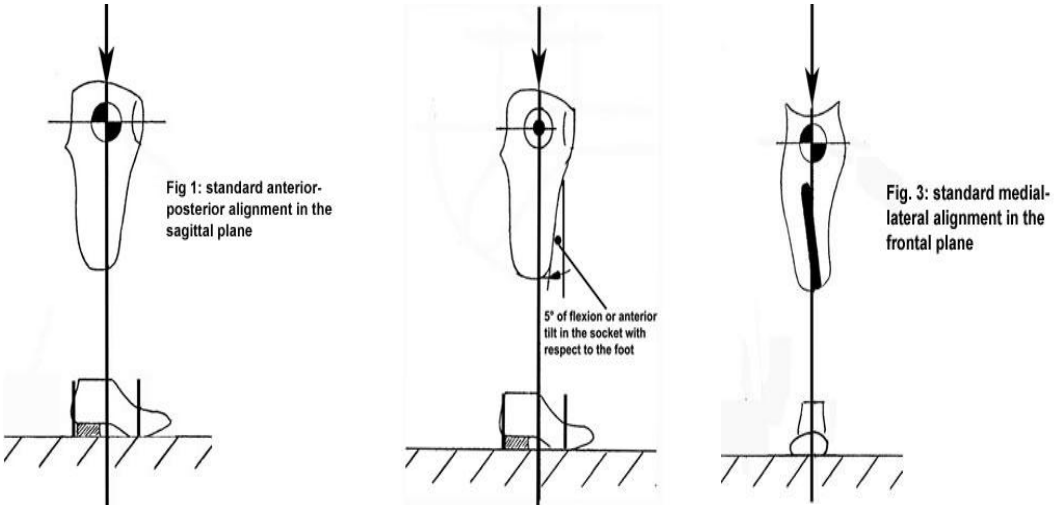

Figure 2.33: Socket alignment (Fig. 1) anterior–posterior alignment; (Fig. 2) anterior–posterior alignment with 5° flexion; (Fig. 3) medial–lateral alignment (picture taken from transtibial alignment (Noelle annon, 2002)

At present, prosthetists follow three types of alignment procedures, namely, bench, static, and dynamic alignment.

2.5.1. Bench alignment

In bench alignment, prosthetists align the socket with the other components on the table or bench to achieve an energy-sufficient, smooth gait pattern (Fig. 2.34). In a sagittal plane for prosthesis, the plumb line or laser liner should fall through the center of the socket, slightly anterior to the ankle joint axis, and through the middle of the weight-bearing surface of the heel and metatarsal heads. However, certain prosthetists prefer to provide 5° flexion to the socket in the initial bench alignment. In a frontal plan, the plumb line or laser liner should fall through the center of the socket and bisect the heel into two parts, looking from the back.

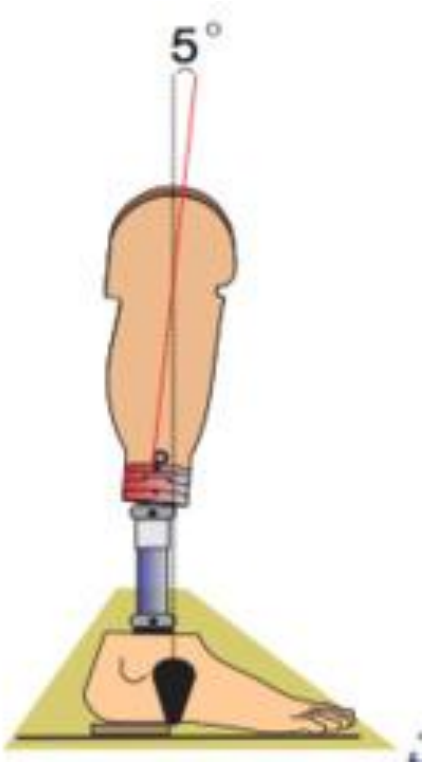

Figure 2.34: Bench alignment of prosthesis, sagittal view (i.e produced from Quizlet, 2014).

2.5.2. Static alignment

Static alignment is the procedure used to check and adjust the alignment while the patient is standing wearing the prosthesis after bench alignment (Fig. 2.35a). The objective of this alignment is to align the prosthesis components with the amputee's body position and weight line before walking.

2.5.3. Dynamic alignment

Once static alignment is finished, amputees are asked to walk, and then the prosthetist makes further adjustments to meet the amputee's needs. The prosthetist observes the gait of the amputee during the dynamic phase and listens to his/her feedback. The alignment is further adjusted until both prosthetist and amputee are satisfied (Fig. 2.35b). Dynamic alignment of the prosthesis relies on the analytical and observational skills of the prosthetist (Chow et al., 2006).

Figure 2.35: (a) static alignment and (b) dynamic alignment

2.6. Gait training

To determine the quality of transtibial prosthesis, prosthetic training is given to the patient by a therapist (Fig. 2.36).The significance of good gait training cannot be overstated. Several new amputees think that learning to walk with their prosthesis will be simple, and that seeing a physical therapist for strengthening and gait training is not necessary. These new amputees should understand that walking with prosthesis may not be as simple as they believe. In reality, most new amputees require months of practice with their prostheses. Most of the time, repetitive gait training and specific alterations are necessary before a person's gait becomes even, steady, and, most importantly, secure. In addition, a patient normally takes three months to nine months to regain the power and flexibility in their leg. Amputees, therapists, and prosthetists will work as a team to ensure that the rehabilitation is as quick and successful as possible. Gait analysis, a helpful analytical tool, is the systematic study of amputee locomotion, more specifically as a study of human motion, which uses the eye and the brain of observers, augmented by instrumentation for measuring body movements, body mechanics, and muscular activity. Gait analysis is used to assess, plan, and treat individuals with conditions affecting their ability to walk (Whittle, 2003).

Figure 2.36: Gait training of the amputee

Gait study divided the human walk into two phases: 1) stance phase: the period of time when the foot is in contact with the ground; and 2) swing phase: the period of time when the foot is not in contact with the ground or when foot is in the air. During stance phase, the leg undergoes sub-phases, which include heel strike, foot flat, mid-stance, heel off, and toe off. During swing phase, the leg goes into a series of events, which includes acceleration, mid-swing, and deceleration (Fig. 2.37). During gait training, transtibial amputees perform all these activities to approximate normal life. Transtibial amputees lose both the function of foot movements and ankle movements. The therapist tries to compensate for these movements, which occurs with relatively low magnitude and much later than the normal in prosthesis, in gait training (Whittle, 2003).

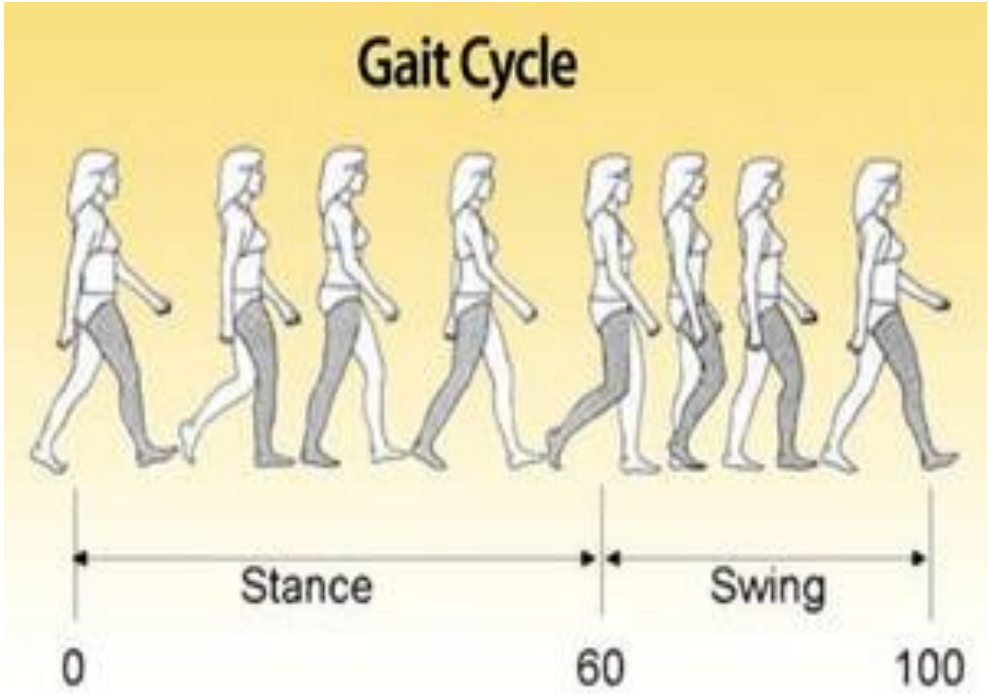

Figure 2.37: One gait cycle is defined as the time interval between two successive occurrences of one of the repetitive events in walking, namely, heel strike to heel strike, as shown here (reproduced from in motion, 2008)

2.7. Residual limb and socket interface pressure

Comfort is the main determinant to the efficiency and use of lower-limb prosthesis, and the prosthetic socket is the key to achieving comfort. Recognizing these considerations, various studies have been conducted to identify forces acting at the residual limb and socket interface, as well as the resulting pressure distribution during various points of the gait cycle (Wolf et al., 2009). Residual limb and socket interface studies provide insight on the actual forces and pressure experienced during gait and can be used to confirm the pressure perceived by socket users. Information on residual limb and socket interface pressure can also be used to evaluate socket fit. Users of lower-limb prostheses subject their residual limb tissue to mechanical loading when using their prostheses. Tissue responses to external forces are still being characterized, but the common adverse effects of loading include tissue breakdown, pain, and increase in skin temperature, skin abrasion, and pressure sores (Fig. 2.38).

Two types of forces are exerted onto the residual limb during walking, namely, vertical and shear forces. The vertical force is the ground's response to the amputee's body weight, and loading is usually represented in terms of the double hump force progression (Fig. 2.39). The vertical component of pressure resulting from this load supports only a portion of the body weight. The remaining load is transmitted by shear action (Zhang & Mak, 1996). Shear forces also occur because of friction between the residual limb and the socket. A loosely fitted socket encourages occurrences of piston motion, in which the residual limb rubs against the socket in a repetitive manner, resulting in an up and down motion of the residual limb inside the socket, often accompanied by a "whooshing" sound of air being pushed out. This repetitive rubbing eventually leads to skin abrasion, pressure sores, ulcers, and generation of excessive heat. However, functional forces are necessary to avoid slippage of the socket during swing phase. Ensuring a good socket fit helps prevent slippage. However, caution

should be taken to prevent an excessively tight fit. A socket that is too tight creates high pressure at the residual limb, thus preventing blood flow to the limb. This condition may aggravate the situation, especially for amputees who had had amputations due to PVD.

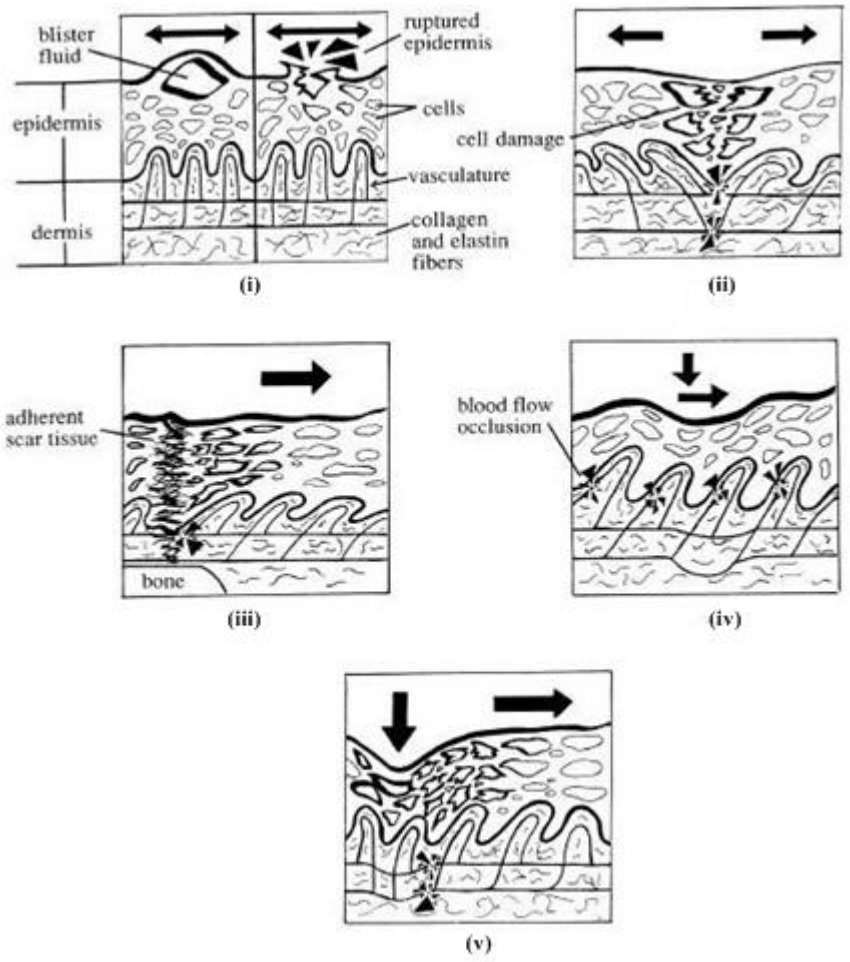

Figure 2.38: This figure shows the effect of external forces on the skin. (i) Cyclic shear force can cause cell separation within the epidermis, causing blisters and abrasions. (ii) Shear forces acting in opposite directions create tension on the skin, causing blanching and cell failure. (iii) Shear stress adjacent to scar tissue adherent to bone places tension on the intermediate skin. (iv) High static shear stress reduces the magnitude of normal stress necessary for blood flow occlusion. (v) Concentrated normal stress adjacent to shear stress will create tension at the intermediate skin areas (Sanders et al., 1992).

High-pressure applications at the residual limb have been found to cause ischemia and impairment of the lymphatic system, both of which lead to formation or pressure sores. Excessive pressure application can also be detrimental to amputees with

neuropathy or loss of normal sensory function. Amputees with neuropathy do not experience sensory feedback that informs them of pain and thus would continue using prosthesis although it exerts too much pressure onto the residual limb. This condition results in a higher rate of tissue breakdown than in others. Finding the balance between the right amounts of pressure application is the goal of residual limb and socket interface measurement. An ideal setup should be able to record real-time interface stress, both vertical load, shear, and its resultant pressure, without significant interference to the residual limb and socket interface (Zhang & Mak, 1996).

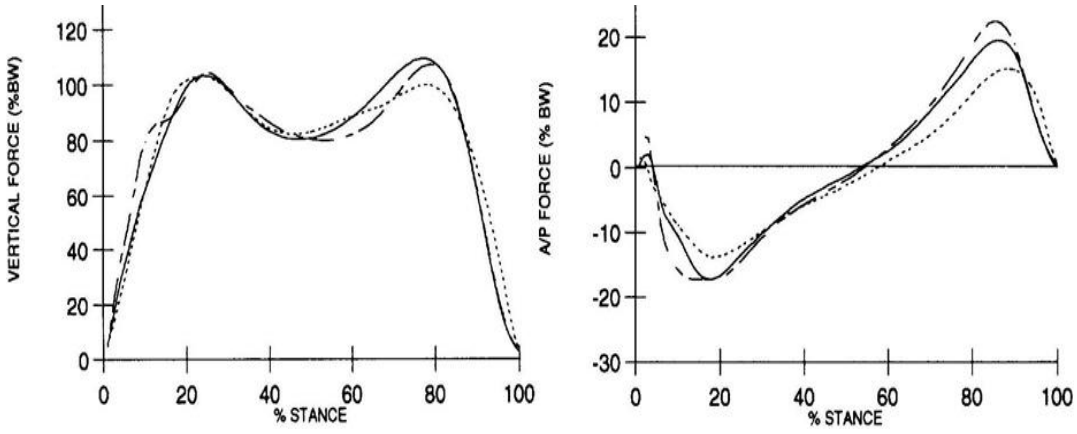

Figure 2.39: Vertical and anterior–posterior components of the ground reaction forces (non-amputee, amputee sound limb, amputated limb) (reproduced from Sanderson and Martin, 1997).

Various pressure measurement methods that indirectly and directly measure residual limb and socket interface pressure have been proposed and are described below.

2.7.1. Indirect residual limb and socket pressure measurement

This method involves the use of finite element (FE) techniques. Steege and Childress introduced the first FE models for the residual limb and prosthetic socket (Steege & Childress, 1988; Steege et al., 1987). Several other researchers have developed numerous other models to improve prosthetic design (Beil et al., 2002; Lin et

al., 2004; Quesada & Skinner, 1991; Reynolds & Lord, 1992; Silver-Thorn & Childress, 1997; Zhang et al., 1995). Development started from simple linear elastic models with simplified two-dimensional or symmetric geometry to the nonlinear models with more accurate geometry. Socket modification, varied external loads to simulate walking, nonlinear mechanical properties, and slip/friction boundary conditions have been addressed in different models (Jia et al., 2005a). These FE techniques first involve modeling the shape of the residual limb and/or socket, then inserting the soft tissue, bone and socket properties, defining boundary conditions, loading magnitudes and directions, and, finally, computing the resultant stress and pressure (Fig. 2.40).

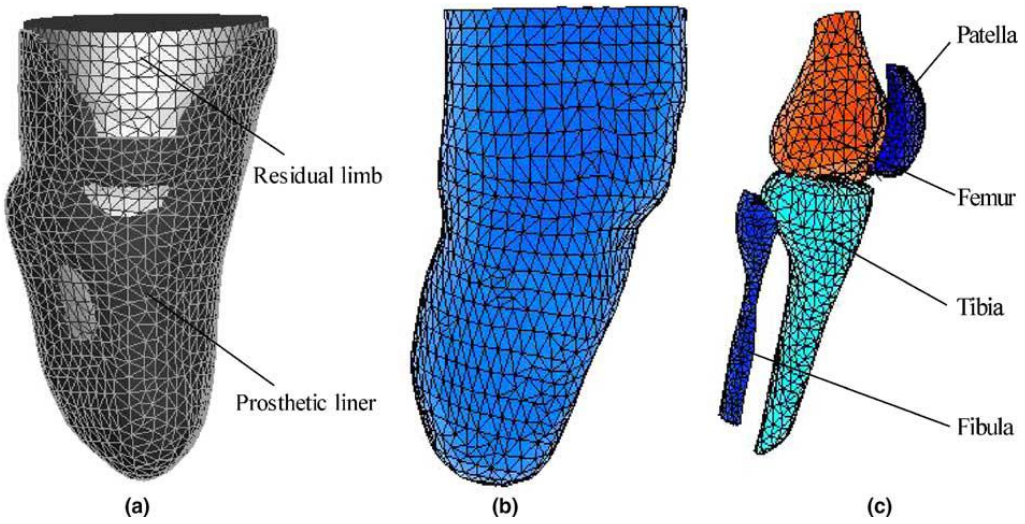

Figure 2.40: Finite element (FE) model for residual limb and prosthetic socket: (a) anterior view of FE model; (b) lateral view of soft tissue; and (c) moshed bones (Jia et al., 2005a)

FE software packages conventionally provide the resulting pressure and deformation, if any, in terms of two- or three-dimensional images. Modifications to the model can easily be made by changing the parameters and allowing the software to run the new calculation. FE methods allow for a predictive analysis of the residual limb and socket interface pressure, do not physically interfere with the mechanical condition of the interface, and reduce the need for amputee subjects. The geometries of the residual limb and socket have been modeled as one body in the previous literature but were

assigned with different mechanical properties, assumed to be of the same properties, treated as separate bodies with interface elements, or scanned to obtain an accurate representation. Mechanical properties for both soft tissue and bone have generally been assumed to be linearly elastic, isotropic, and homogenous. Loading placement and magnitude were dependent on the condition of interest. Lee et al. (2004), for instance, modeled the contact interface in their study to simulate donning of the limb into the socket and loading conditions at foot flat, mid-stance, and heel off during walking (Lee et al., 2004). For the pre-stress condition studied from donning of the socket, a load of 50 N was applied at the center of the knee joint with zero shear stress application. Shear was maintained at zero, given that no slippage was assumed to occur during donning of the socket. The subsequent loading conditions were modeled with magnitude obtained from kinematic data of a previous gait study. Forces were once again directed at the knee joint considering the assumption that knee joint angles did not change with different loading cases. Zhang et al. (1998), who in their study were interested in the roles of interface friction and distal end boundary conditions, applied distal end loading to three different models of residual limb and socket distal ends: model A, with a gap between the residual limb and the socket; model B, with residual limb and socket total contact; and model C, with sealed air cavity over the distal end (Zhang et al., 1998).

Figure 2.41 shows the different results obtained from these different studies, illustrating different data that can be obtained through FE studies. Although computational modeling provides an advantage to the measurement of prosthesis comfort, this method requires a large number of variables that must be accurately provided to obtain an exact simulation. In addition, modeling becomes more difficult as the situation studied progresses from static loading condition to a dynamic one that involves nonlinear approaches. These approaches require iterative procedures and long computation time. FE studies so far have proven to be beneficial in understanding

residual limb and socket interfaces but are a complex branch of research that requires reliable data inputs and computations for the technology to better approximate real-life situations.

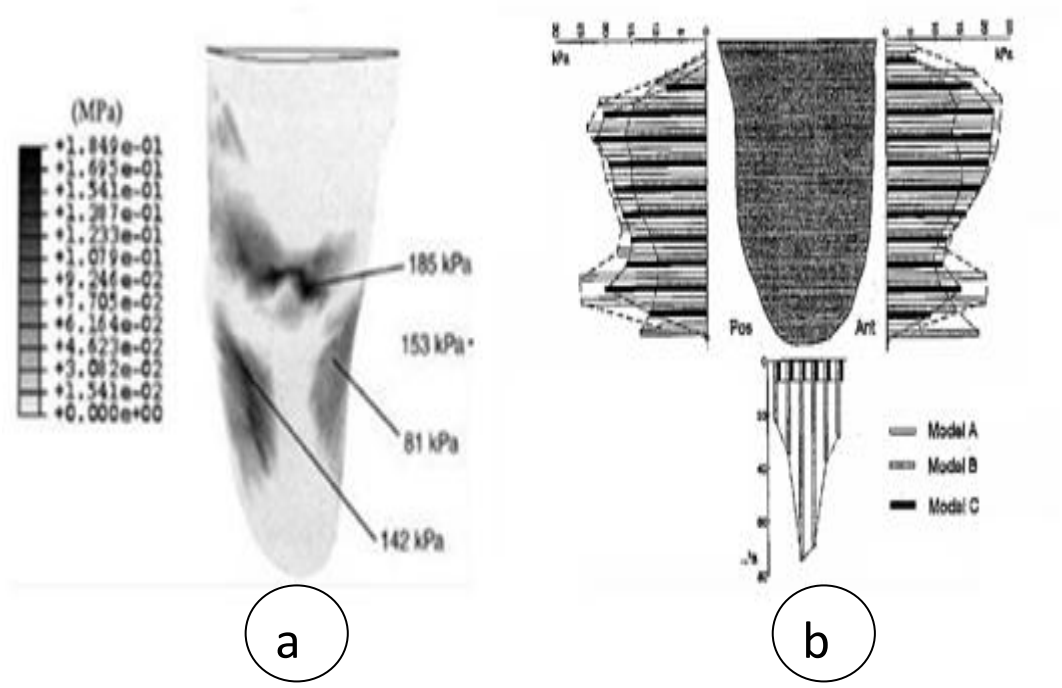

Figure 2.41: Samples of different outputs that can be produced with the use of different finite element software packages (a) Anterior–posterior contact normal stress distribution (Lee et al., 2004) and (b) pressure distribution over the entire residual limb for three different models (Zhang et al., 1996)

2.7.2. Direct residual limb and socket pressure measurement

This method involves recording of pressure through the use of transducers. These pressure transducers are either mounted inside the socket or placed at the interface between the residual limb and the liner or socket. The transducers used in previous studies range from simple strain gauges to pneumatic sensors, all with the goal of recording real-time residual limb and socket pressure distribution continuously over the period of a gait cycle. One such transducer was developed by Abu Osman et al., (2010) to measure the interface pressure at the anterior, posterior, medial, and lateral between the residual limb and socket (Abu Osman et al., 2010) (Fig. 2.42).

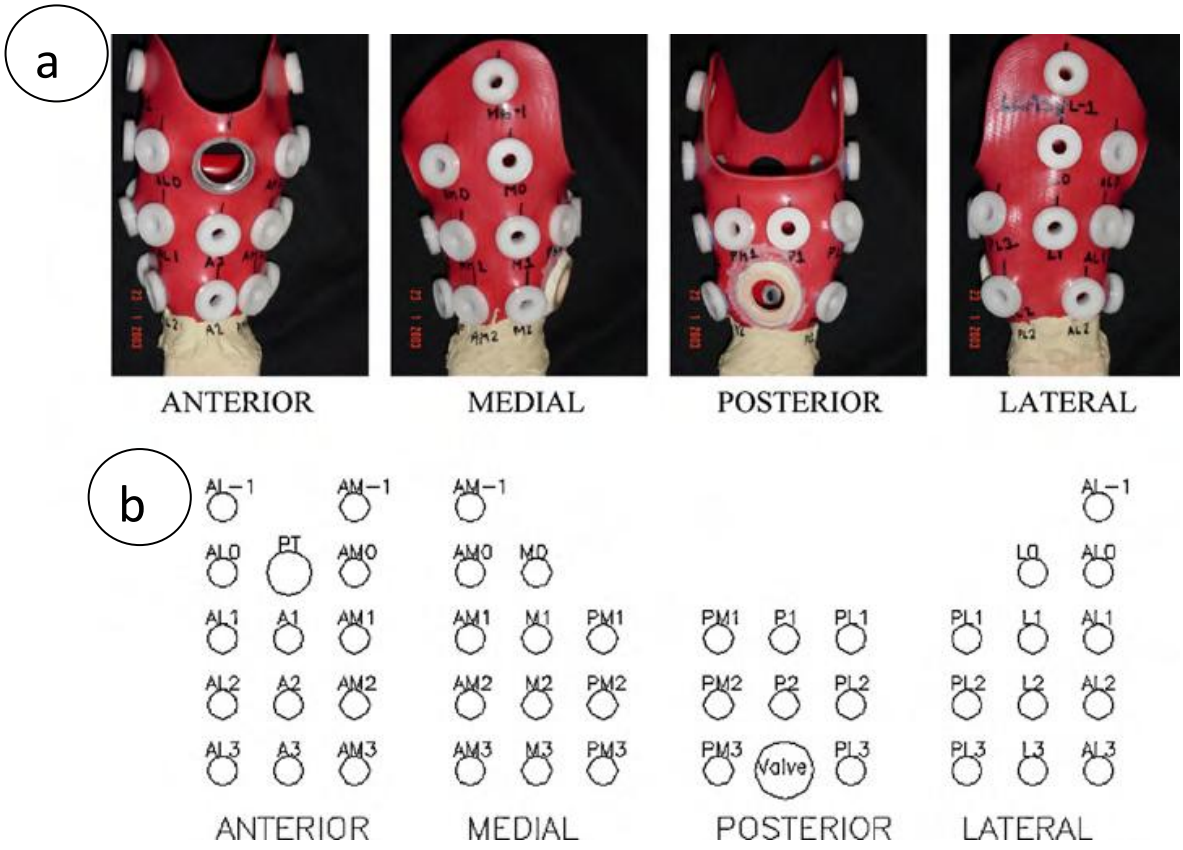

Figure 2.42: Transducer locations. (a) Sample of transducers on anterior, posterior, lateral, and medial surfaces on a socket. (b) Locations used throughout the study for the socket transducer locations. (Abu Osman et al., 2010)

Another type of custom-made electrohydraulic transducer was used in the same study by Abu Osman et al., (2010) to measure the pressure at the distal end of the residual limb. The electrohydraulic transducer consisted of a 28 mm diameter, 2 mm thick oil-filled polyvinyl chloride (PVC) bag connected via a PVC tube to a strain-gauged diaphragm transducer (Fig. 2.43).

Figure 2.43: Electrohydraulic pressure transducers (Abu Osman et al., 2010).

A type of transducer developed by Zhang et al. (1998) was able to measure shear forces locally experienced by the residual limb. Nine of these triaxial force transducers were mounted inside the socket walls at the lateral and medial supracondyle, patellar tendon, lateral and medial tibia, anterodistal area, popliteal depression, and lateral and medial gastrocnemius, so that localized pressures at these areas could be easily identified, recorded, and compared (Fig. 2.44).

The transducers were able to record normal and shear stresses during static (no weight, half-, and full-body weight on prosthetic limb) and dynamic (walking at self-selected speed) loading conditions (Zhang et al., 1998). The study, which recorded stresses on four PTB and one TSB socket users, found that peak stresses during walking doubled that of standing, that maximum pressure was often recorded at the popliteal areas, and that the largest shear stresses did not necessarily occur at points of high pressure. A similar transducer design was used by Goh et al. (2003) in their study investigating the pressure profiles of pressure cast prosthetic sockets (Goh et al., 2003). The transducers measuring normal pressure were placed flush in the socket walls to enable residual limb and socket interface pressure measurement without providing significant interference (Fig. 2.44). The study found no definite hydrostatic pressure

profile for the pressure cast socket, a result that is attributed to the complex nature of the residual limbs, different force interactions at the residual limb during gait, and small sample size. Individual test sockets that were drilled with holes to enable transducer placement were fabricated for each subject. Drilling holes into the socket not only interferes with the original socket shape and material consistency but also adds to the weight of the socket. Multiple transducers also create the need for multiple cables to be directed from the socket to the workstation for data transmission. In addition, placing the transducers at predefined points on the socket gives local pressure readings instead of the more descriptive overall map of residual limb and socket pressure distribution. This manner of interface pressure measurement is neither cost- nor time-efficient, because individual test sockets need to be fabricated to accommodate the transducers, enabling pressure measurement.

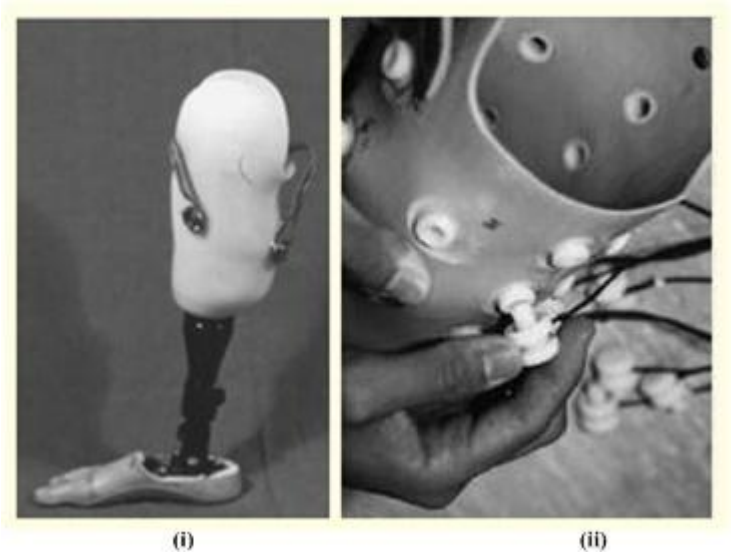

Figure 2.44: Different configurations of pressure transducers mounted on the socket are used to record residual limb–socket interface pressure. (i) Zhang et al. (1998) and (ii) Goh et al. (2003)

Alternatives to transducers mounted onto the socket walls as described above and shown in Fig. 2.44 are also widely utilized in residual limb and socket pressure measurements. Among the most widely used are paper-thin sensors that can be inserted in between the socket and residual limb without being hindrances to the user. These

sensors are not bulky, have a wider sensing area, are more pliable, and do not alter the physical properties of the socket, as no mounting is required. The two most common types of such sensors include the Rincoe Socket Fitting System and Tekscan Inc. F-socket Pressure Measurement System. Both sensors, which physically seem like strips of paper, are force-sensing resistors embedded in flat plastic enclosures (Fig. 2.45). The F-socket sensor uses force-sensing resistors based on piezoelectric ink sandwiched between two Mylar layers. The contact area between the ink particles will increase as pressure increases, changing resistance to current flows through the ink. Tekscan Inc. reports a nonlinearity of 5% and sensitivity of ±4 kPa. In a study conducted to validate these two systems for use in determining socket fit, results in favor of the F-socket system in terms of accuracy error were found. Another study by Buis and Convery (1997) showed Tekscan Inc.'s force-sensing resistors to present consistent output. Table 2.1, which was adapted from the results of the study, shows the input strain gauge pressure and the resultant output pressure from Tekscan's sensor (Buis & Convery, 1997).

Figure 2.45: (left) Rincoe and (right) F-socket force-sensing resistors are made to be paper-thin and pliable to allow easy inertion between the socket and residual limb (reproduced from (Polliack et al., 1998) and Tekscan(2007)

The F-socket was also found to conform better to irregular surfaces, considering that its Mylar substrate is more pliable and less brittle than the polyvinilidyne fluoride substrate used in the Rincoe system. The ability to conform to irregular surfaces would be an advantage in residual limb and socket pressure measurements because the residual limb is contoured differently for different individuals. Although the F-socket sensor recorded a higher drift and hysteresis error than the Rincoe system, the values for the F-socket were still within acceptable ranges. In addition, testing for sensor drift was conducted over a period of 20 min, a period that well exceed that which is needed for gait trials. Another advantage that the F-socket has over the Rincoe is in its column arrangements of individual sensels that make each column a separate unit, thus allowing the remaining columns to continue measurement although a column has been damaged. F-socket sensors present the resultant pressure distribution in a map-like image, allowing for an entire map of the residual limb to be constructed for an entire gait cycle (Neumann et al., 2005).

Table 2.1: Average Tekscan Inc. output pressure for known applied pressure

Strain gauge pressure (kPa)	Tekscan average pressure (kPa)
50	50.1
75	76.3
100	98.7
125	123
150	145
100	102

The F-Socket sensor (9811E) is basically a flexible, rectangular printed circuit with paper-like thickness (0.18 mm), thus making the sensor fit easily in the gap between the socket and the residual limb. Schematics for the F-socket sensor and its respective dimensions are shown in Figure 2.46 and Table 2.2.

Table 2.2: F-socket sensor (9811 E) general and sensing region dimensions

General dimensions (mm)	Overall length (L)	Overall width (W)	Tab length (A)	Matrix width (MW)	Matrix height (MH)	
	367.8	76.2	142.5	76.2	203.2	
Sensing region dimensions (mm)	Column width (CW)	Colum spacing (CS)	No. of column	Row width (RW)	Row spacing (RS)	No. of row
	6.4	12.7	6	7.9	12.7	16

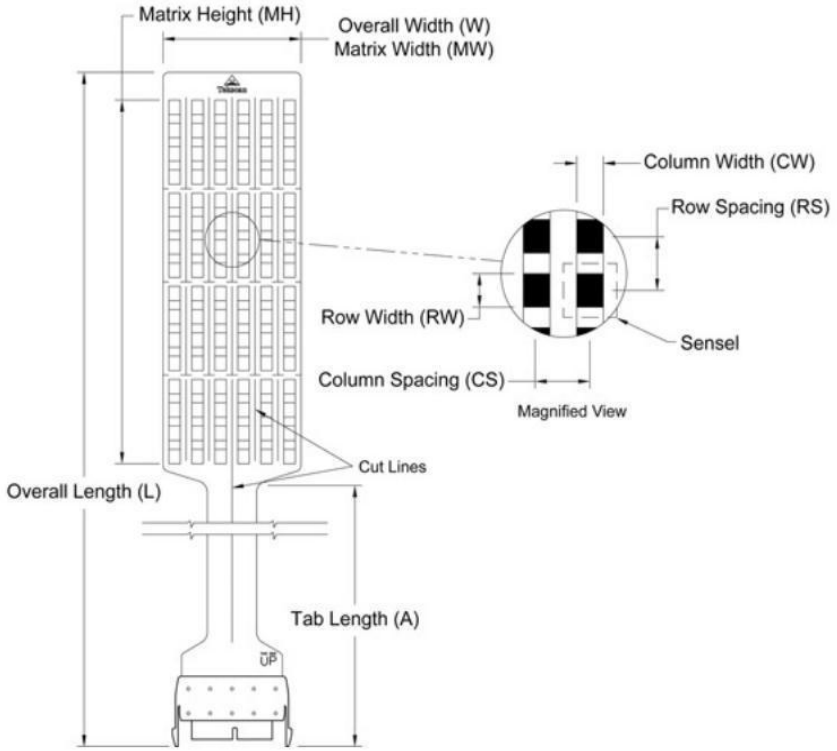

Figure 2.46: Tekscan Inc. F-socket sensor (9811 E) schematics

Basing on the resources available, as well as findings from the vast literature pool, the author of the present study has decided to study the residual limb and socket interface pressure between different liners (Dermo, Seal-In X5 liner, and pelite) by using F-socket sensors. This system allows for evaluating accurate interface pressure between the socket and residual limb.

2.8. Questionnaire

From the past several years, the need for evaluating and measuring prosthetics and orthotics practice has received growing recognition (Fuhrer, 1995; Hoxie, 1995). Reliable and valid self-report instruments that can help facilities to evaluate patient outcomes are necessary. The rehabilitation goals in providing orthotic and prosthetic devices include improving physical functioning and quality of life, and these goals require instruments that are specifically designed to quantify them. Much of the orthotic and prosthetic research over the past 40 years has focused on biomechanics and engineering. Examples of pioneering innovations include myoelectric prosthetic hands and the use of stronger yet lighter materials in the fabrication of prostheses and orthoses. Such innovations have considerably improved the function and appearance of these devices (Bowker, 1981), although user satisfaction and functional benefits have not been assessed in a comprehensive manner.

Questionnaires are the most reliable tools to measure the level of satisfaction, as well as problems encountered with orthoses and prostheses. Researchers have used numerous questionnaires to evaluate satisfaction and perceived problems with prostheses and orthoses. The developed Trinity Amputation and Prosthesis Experience Scales (TAPES) present one such questionnaire. Gallagher et al. (2000) introduced TAPES to evaluate the experience of lower-limb amputees with their prostheses. TAPES consists of three sections: activity restriction, psychosocial issues, and satisfaction with prosthesis (Gallagher & MacLachlan, 2000). Another questionnaire, "Development and measurement properties of the Orthotics and Prosthetics Users' Survey (OPUS): a comprehensive set of clinical outcome instruments," was developed by Heinemann et al. (2003) to evaluate prosthetic and orthotic functional status, quality of life, and satisfaction with devices and services that can be used in an orthotics and prosthetics clinic (Heinemann et al., 2003). The authors developed and revised four

instruments that differentiate patients with varying levels of lower-limb function, quality of life, and satisfaction with devices and services. Evidence of construct validity is provided by hierarchies of item difficulty that are consistent with clinical experience. Numerous other researchers develop prosthetics and orthotics questionnaires that aid amputees and prosthetic/orthotic practitioners in knowing about their prostheses and orthoses (Gauthier-Gagnon & Grise, 1994).

Prosthetic Evaluation Questionnaire (PEQ) is another type of questionnaire, which is grouped into 9 validated scales consisting of 82 items, with 111 additional individual questions pertaining to pain, satisfaction, transfer, self-efficacy, and prosthetic care. All PEQ scales have been validated for test–retest and internal consistency (Legro et al., 1998). The PEQ scales are independent of each other. Thus, using only the scales that are pertinent to your research question is reasonable. Visual analog scale format is used for PEQ questions, and each line is 100 mm long and is always measured from the left (0 to 100) (Legro et al., 1998).

CHAPTER 3

CLINICAL INVESTIGATION OF THE INTERFACE PRESSURE IN TRANSTIBIAL SOCKET WITH DERMO AND SEAL-IN X5 LINERS DURING WALKING AND THEIR EFFECT ON PATIENT SATISFACTION

Background: The interface pressure between the residual limb and prosthetic socket has a significant effect on an amputee's satisfaction and comfort. Liners provide a comfortable interface by adding a soft cushion betweenthe residual limb and the socket. The Dermo and the Seal-In X5 liner are two new interface systems and, due to their relative infancy, very little are known about their effect on patient satisfaction. The aim of this study was to compare the interface pressure with these two liners and their effect on patient satisfaction.

Methods: Nine unilateral transtibial amputees participated in the study. Two prostheses were fabricated for each amputee, one with the Seal-In X5 liner and one with the Dermo liner. Interface pressure was measured at the anterior, posterior, medial and lateral regions during walking on the level ground. Each subject filled in a Prosthetic Evaluation Questionnaire (PEQ) regarding the satisfaction with the two liners.

Findings: The mean peak pressures with the Seal-In X5 liner was 34.0% higher at the anterior, 24.0% higher at the posterior and 7.0% higher at the medial regions of the socket ($P=0.008$, $P=0.046$, $P=0.025$) than it was with the Dermo Liner. There were no significant differences in the mean peak pressures between the two liners at the lateral regions. In addition, significant difference was found between the two liners both for satisfaction and problems ($P<.05$).

Interpretation: There was less interface pressure between the socket and the residual limb with the Dermo liner. The results indicated that the Dermo liner provides more comfort in the socket than the Seal-In X5 liner.

3. Introduction

Transtibial amputation patients need prosthetic devices after amputation surgery in order to regain their functional mobility and appearance (Wolf et al., 2009). The socket design plays a significant role in determining the quality of the fit and provides an interface between the prosthesis and the residual limb (Jia et al., 2004). Appropriate socket fitting in prosthetic devices can have a significant effect on the patient's comfort, mobility and level of satisfaction with their prosthesis (Kristinsson, 1993; McCurdie et al., 1997).

Skin problems are common in prosthetic users and these can appear in the formof rashes, ulcers, irritation and allergies. Their presence is commonly attributed to one of several reasons: the inadaptability of the skin,due to the intolerance of pressure by the prosthetic socket on the residuallimb; bacterial proliferation as a result of a snugly-fitted socket that causes entrapment of perspiration in a closed environment; skin irritation or allergic reaction due to the materials used in the prosthetic socket and liners (Dudek et al., 2006; Dudek et al., 2005). Lower limb amputees commonly experienced residual limb skin problems with the use of the prostheses (Laing et al., 2011). Amputees often need to stop using the prosthesis entirely for a period of time as a result of the pain and discomfort caused by such skin problems. This condition can badly affect the mental wellbeing of a patient and will ultimately impact their satisfaction with a device (Meulenbelt et al., 2006).

It is crucial that the risk of these skin complications is taken into consideration during the design of the prosthetic socket and that the designof the device is based on a good understanding of the pressure that can occur between the amputee's residual limb and the prosthetic socket (Jia et al., 2008). In order to reduce the possibility of these skin issues occurring, liners are fit inside the socket to provide the residual limb with a soft cushion. Liners have a direct contact with the residual limb inside the socket and

play a significant role in transferring the load and distributing the interface pressure over the residual limb (Coleman et al., 2004; Lin et al., 2004).

Polyethylene foam liners with patellar tendon bearing (PTB) prosthetic socket have been in use since 1950; however, modern liners, which aregenerally made from silicone and other elastomers, offer better suspension and cushion (Dietzen et al., 1991; Haberman et al., 1992; Madiganand Fillauer, 1991). Silicon and gel liners were introduced worldwide in the mid 1990s and were designed to reduce shear forces and produce better interface bonds between the residual limb and the socket (Van deWeg and Van Der Windt, 2005). One of these silicone liners is known as the Seal-In X5 liner (Fig. 3.1). It was introduced by Ossur (Reykjavik, Iceland) and is composed of five seals that conform to the shape of the internal socket wall and the residual limb (Gholizadeh et al., 2011). Through this, the Seal-In X5 liner provides suspension without the need for an external sleeve or lock and claim to be a good choice for high impact activities. The Dermo liner (Reykjavik, Iceland) is also made of silicone; however, unlike the Seal-In X5 liner, it cushions the limb and provides suspension through a shuttle lock system (Fig. 3.1).

Many studies have been published out to investigate the interface pressure and stresses (Jia et al., 2005; Sanders et al., 1998; Wolf et al., 2009).One of them compared the socket pressure of polyethylene foam liners with silicone liners (Dumbleton et al., 2009). Some studies have investigated the effect of various casting techniques or socket design on thesocket-residual limb interface pressure (Dumbleton et al., 2009; Jiaet al., 2005; Lee and Zhang, 2007),while other studies have focused on the effect of alignment on interface pressure (Jia et al., 2008). However, none of these studies compared the effect of a Dermo liner that used a shuttle lock with a sealing system such as the Seal-In X5 liner. In the Seal-In X5 liner, the seals have the potential to impose extra pressure over the residual limb. This can cause excessive pressure, that in it can be a source of

problems for diabetic patients or amputees with sensitive residual limbs. The aim of this clinical study was to measure and evaluate the interface pressure in the Dermo liner during normal walking and compare it with the Seal-In X5 liner. The study also aimed to assess the effect that the two liners had on patients' satisfaction.

3.1. Methodology

3.1.1. Subjects

A total of nine unilateral transtibial amputees (7 males, 2 females) participated in this study. All the subjects were selected from the Departmentof Rehabilitation of the University Malaya Medical Centre (UMMC), Kuala Lumpur, Malaysia. The ethics committee of UMMC approved this study, and informed written approval was attained from all the subjects. The inclusion criteria consisted of a minimum 15 cm residual limb length (from the mid patella to the distal end of residual limb), no wound and ulcers in the residual limb, no volume changes, and the ability to walk without the use of assistive devices. It was a requirement that the participants are experienced prosthetic users (more than 6 months). A sample of convenience is used for this study.

3.1.2. Prosthetic interventions

Two prostheses were made for each subject, one with the Dermo liner with shuttle lock (Icelock-200 series) and another with the Seal-In X5 liner with valve (Icelock Expulsion, Valve 551). All the prostheses were fabricated with Flex-Foot Talux (Ossur, Reykjavik, Iceland). One registered prosthetist fabricated all the prostheses to avoid alterations due to manufacturing, alignment and fitting. A total surface bearing (TSB) socket was fabricated for all the subjects (Staats and Lundt, 1987). In order to become familiar with their new prosthetic devices, the subjects practiced walking in the motion analysis laboratory (Biomedical Engineering

Department, University of Malaya, Malaysia) and the prosthetist adjusted the fitting of the socket and alignment according to their needs. Subjects were required to use their prostheses for a minimum of four weeks. The subjects were asked to visit the brace and limb laboratory for follow up on a weekly basis to ensure that the fit of the prosthesis remained suitable.

3.1.3. Experimental setting and procedures

After four weeks of acclimation, the subjects attended the motion laboratory for pressure measurements. Four F-Socket sensors arrays 9811 (Tekscan Inc., South Boston, USA) were attached to the residual limb.The sensor arrays were positioned on the anterior, posterior, medial and lateral aspects of the residual limb (Fig. 3.1). The mid patella was taken as the reference line for the placement of medial, lateral and anterior sensors. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. Each sensor was trimmed to fit to the residual limb contours. To prevent sensor arrays displacement, the residual limb was covered with a cellophane cover. Following this, each sensor was attached to the cellophane covers by an adhesive spray (3M SprayMount Adhesive, 3 M corporate, St. Paul, USA). This sensor arrangement provided a pressure map that covered 90% of the residual limb during the gait. Tekscan software version 6.51 was used to record the interface pressure.

A Tekscan pressure bladder (PB100T, South Boston, USA) was used to equilibrate and calibrate the sensor arrays. Sensor arrays were placed inside the bladder and, according to the manufacturer's instructions, were subjected to a pressure of 100 kPa. Calibration was carried out based on each subject's body weight. That is, the applied pressure for calibration was the ratio of the subject's body weight to the respective sensor area (Buis, 1997).

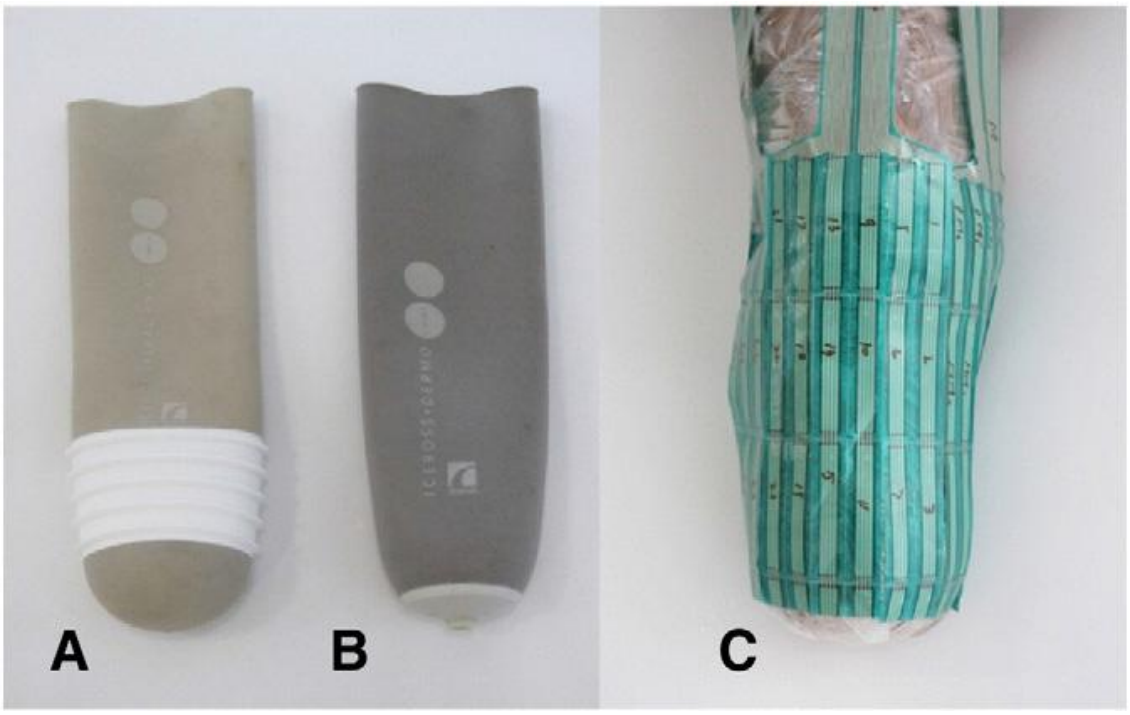

Figure 3.1: (A) Seal-In X5 Liner, (B) Dermo Liner, (C) Sensors attachments on residual limb.

3.1.4. Walkway and collection of the data

Subjects were asked to walk at a self-selected speed on a walk way that was 9-meter long and 5-meter wide. Prior to the data collection activity, the subjects were requested to walk on the walkway to familiarize with the procedure. Data acquisition was performed for 12 seconds with a sample rate of 50 Hz. The subjects completed four consecutive trials on the walkway and in each trial approximately eight to nine steps were taken. The middle step of each trial was chosen. The meanpeak pressures (MPP) of four trials were employed for the purposes of statistical analyses.

3.1.5. Questionnaire

After the experiments were completed, each subject completed a questionnaire that asked for further information about their satisfaction with the two liners. Various parts of the Prosthetics Evaluation Questionnaire (PEQ) were adopted for this questionnaire. The questionnaire was composed of the following three sections:

1- Demographic variables (sex, age, weight, height, amputation side, cause of amputation, activity level and time since first prosthesis).

2- Satisfaction (fitting, donning and doffing, suspension, sitting, walking on level surfaces, ascending and descending stairs, walking on uneven ground, cosmesis and overall satisfaction).

3- Problems (Wound, skin irritation, sweating, pistoning, rotation, residual limb swelling, smell, sounds and residual limb pain).

A scale of 0–100 was used to score all the questions, where 100 indicated"complete satisfaction or no problems" and 0 indicated "unsatisfied or extremely bothered."

3.1.6. Analysis of data

Since the sample size of this study was small (N=9), non-parametric test were used to analyze the data. Therefore we used Wilcoxon signed ranks test to compare with in-subject pressure measurements with the Dermo liner and Seal-In X5 liner for different regions in the socket. We also used Wilcoxon signed rank test to compare the satisfaction with the two liners. For the overall scores, which were distributed normally, paired-samples t-test was applied. Statistical analyses were carried out using Version 20 of SPSS, statistical software (SPSS, Chicago, IL).

3.2. Results

3.2.1. Subject's profile

The mean age of the subject's was (mean=49.3, SD=15.0) and their activity level, based on the Medicare Functional Classification Level (MFCL) (Dudek et al., 2008), was K2–K3 and K3–K4. All the subjects had undergone amputation surgery at least three and half years' prior to the study. The participants' demographic information is shown in Table 3.1.

Table 3.1: Demographic variables of the subjects

Weight (SD)		72.44 (16.30) Kg
Height (SD)		169.11(7.78) Cm
	Female	3 (33.30 %)
Gender (%)		
	Male	6 (66.70 %)
Body Mass Index (SD)		25.22 (4.83)
Age of the Patient (SD)		49.33 (15.05)
	K2-K3	8(88.90 %)
Activity Level (%)		
	K3-K4	1(11.10 %)
	Right	4(44.44 %)
Amputation Side (%)		
	Left	5(55.55 %)
	Trauma	3 (33.30 %)
Cause of Amputation (%)	Peripheral Vascular Disease (PVD)	2 (22.20 %)
	Diabetic	4 (44.50 %)

3.2.2. Interface pressure

Pressure measurements were extracted in twelve regions of the residual limb. The mean of peak pressures are presented separately in Table 3.2. The pressures of the four major regions of the residual limb are presented in Fig. 3.2. In both the anterior and posterior regions, the mean pressures for the proximal, middle sub-region areas were significantly higher ($P<0.05$) with the Seal-In X5 liner than they were with the Dermo liner. In both the lateral and medial regions, the pressure in the middle and distal sub-region area was significantly higher ($P<0.05$).

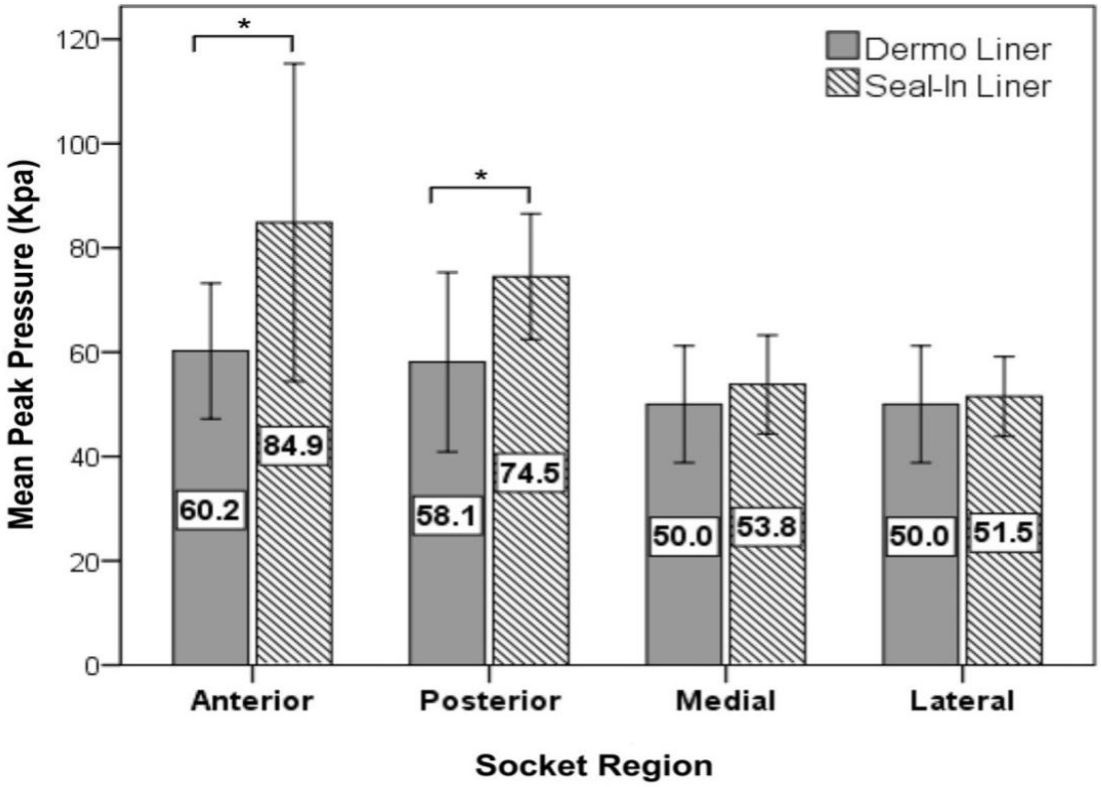

Figure 3.2: Mean peak pressure for the four major regions of the residual limb. The asterisks (*) indicate significant differences between the Dermo and Seal-In X5 liners

The MPP for the four major regions of the residual limb was also obtained. The MPP values for the whole anterior region of the residual limb was significantly higher for the Seal-In X5 liner compared to the Dermo liner ($P=0.008$, $Z=-2.66$; mean=84.90 kPa, SD=30.46; mean=60.2 kPa, SD=13.00, respectively). Moreover, at the posterior

region, MPP was significantly higher with the Seal-In X5 liner compared to the Dermo liner (P=0.046, Z=−1.99; mean=74.51 kPa, SD=12.04; mean=54.10 kPa, SD=11.21, respectively). There was astatistically significant difference between the pressure values for the two liners in the medial region of the residual limb, (P=0.025, Z=−2.24; Dermo: mean=50.00 kPa, SD=12.34; Seal-In X5: mean=53.80 kPa, SD=9.45). There was no statistically significant difference between the pressure values for the two liners in the lateral regions of the residual limb (P=0.601, Z=−0.42; Dermo: mean=50.00 kPa, SD=11.21; Seal-In X5: mean=51.50 kPa, SD=7.70) (Fig. 3.3).

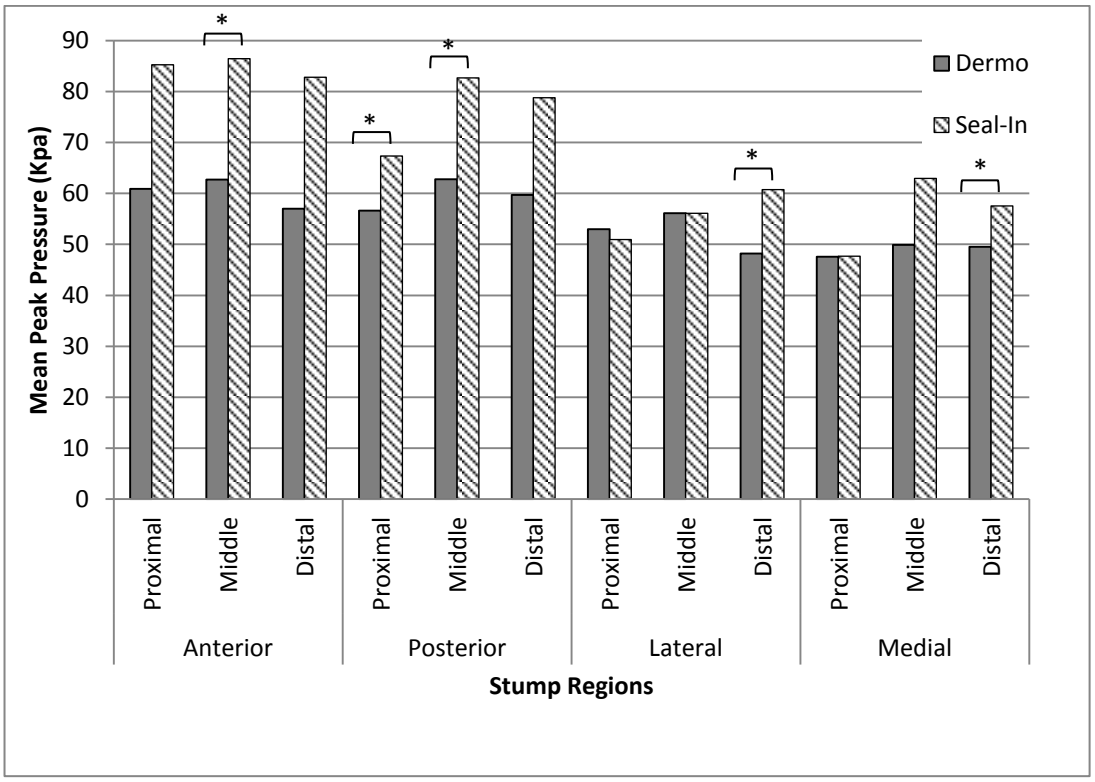

Figure 3.3: Mean peak pressure in all subsections of the residual limb. The asterisks (*) indicate significant differences between the Dermo and Seal-In X5 liner

3.2.3. Questionnaire

In five out of the nine questions on the satisfaction scale of the questionnaire, the Wilcoxon Signed Rank Test revealed statistically significant higher scores for the Dermo liner than those for the Seal-In X5 liner. However, the Seal-In X5 liner scored better on the question about the suspension of the prosthesis (Table 3.3).

In the element of the questionnaire that was aimed at assessing problems with a device, the Wilcoxon Signed Rank test showed significantly higher scores across five items for the Dermo liner and two items (including pistoning within the socket and unwanted sounds) for the Seal-In X5 liner (Table 3.3).

The overall scores (average) of the two scales of the questionnaire were also calculated and compared for the two liners. A paired-samplest-test was performed to compare the scores of satisfaction and problems scales for the Dermo and Seal-In X5 liners. In both scales, the subjects assigned significantly higher scores to the Dermo liner ($P<.05$) than they did to the Seal-In X5 liner.

Table 3.2: Mean peak pressure (kPa) at the anterior, posterior, medial and lateral sub-regions

Liner Type	**Anterior**			**Posterior**		
	Proximal	**Middle**	**Distal**	**Proximal**	**Middle**	**Distal**
Dermo Liner	60.9(19.1)	62.7(11.5)	57.0(14.4)	56.6(12.7)	62.8(23.2)	59.7(25.6)
Seal-InX5 Liner	85.3(31.3)	86.5(29.6)	82.8(35.4)	67.4(11.9)	82.7(22.7)	78.8(26.2)
P-value	0.038*	0.021*	0.011*	0.046*	0.028*	0.260
Z	-2.07	-2.31	-2.54	-1.99	-2.19	-1.125
Liner Type	**Medial**			**Lateral**		
	Proximal	**Middle**	**Distal**	**Proximal**	**Middle**	**Distal**
DermoLiner	47.6(13.9)	49.9(12.8)	49.5(19.0)	53.0(26.3)	56.1(14.5)	48.2(9.4)
Seal-In X5 Liner	47.7(10.2)	63.0(17.3)	57.6(17.5)	51.0(28.7)	56.1(5.8)	60.8(17.2)
P-value	0.674	0.008*	0.028*	0.767	0.889	0.093
Z	-0.42	-2.66	-2.19	-0.29	-0.14	-1.68

* Significant differences between the Dermo and Seal-InX5 liner

3.3. Discussion

Biomechanical understanding of the interface pressure between the socket and residual limb is one of the primary objectives in prosthetic rehabilitation (Mak et al., 2001). The level of patient satisfaction with prosthesis is said to be greatly dependent on the proper allocation of interface pressures at pressure-relief and pressure-tolerant areas of the residual limb (Haberman et al., 1992). Residual limb and socket interface pressure is considered to be of high significance when assessing the biomechanics of the dissimilar socket designs. Measuring the degree of these pressures is a direct technique that can be used to evaluate the comfort and fit of the socket (Laing et al., 2011). Two different interface liners for prosthesis were examined in this study: the Seal-In X5 liner and the Dermo liner with shuttle lock system.

The results of the study revealed that the MPP value in the Seal-In X5 liner was significantly higher for the whole anterior and posterior region of the residual limb than it was with the Dermo liner with shuttle lock. The average MPP difference was 34.04% at the anterior and 24.04% at the posterior region. In the study, the anterior proximal sub-region pressure was lower than the anterior middle sub-region for both liners. This finding is similar to the results of a study conducted by Dumbleton et al., which found that the interface pressure was the lowest at the proximal region of the residual limb (Dumbleton et al., 2009). This present study showed that the interface pressure in the Seal-In X5 was higher at the middle sub-region of the residual limb than it was with the distal and proximal sub-regions, both in the anterior/posterior and the medial/lateral aspects. This higher pressure might be associated with the five seals around the liner, which provide an airtight fit inside the socket. In the current study, the MPP at posterior-proximal region were recorded as 56.6 kPa, and 67.4 kPa for the Dermo liner and Seal-InX5 liner respectively. Beil and Street compared the interface pressure between the urethane liners using suction socket and pin and lock socket. Their study

revealed average pressures of 68.6 kPa and 66.4 kPa at the posterior proximal region for the suction and TSB socket respectively (Beil & Street, 2004). This is consistent with the current study's findings with regard to the Dermo liner. Overall, in the current study, the pressure was higher at all the sub-regions of anterior and posterior regions with the Seal-In X5 liner.

In the present study, there was a statistically significant difference between the two liners on the whole medial region and no statistically significant differences between the two liners on the whole lateral region of the residual limb were recorded. MPP values were significantly higher ($P<.05$) for the Seal-In X5 liner at the middle and distal sub-regions. This is also consistent with a study by Dumbleton et al., which identified higher pressure at the lateral distal end (Dumbleton et al., 2009). Three of the subjects in the current study refused to continue using the prosthesis with the Seal-In X5 liner on a long-term basis as they felt tightness and excessive pressure on the residual limb, particularly in the areas where the seals were located.

Significant differences were found between the two liners with respect to the levels of patient satisfaction and the problems they experienced. Subjects were more satisfied with the Dermo liner ($P<.05$) than they were with the Seal-In X5 liner. The overall score was (mean=80.59, SD=5.14) for the Dermo liner with shuttle lock compared to (mean=73.95, SD=4.03) for the Seal-In X5 liner. The average difference across the 9 questions on the satisfaction scale of the questionnaire was 8.67% higher for the Dermo liner and the mean difference for the problem and complaints scale of the questionnaire was 4.69% higher for the Dermo liner than the Seal-In X5 liner. These differences were both statistically significant.

Table 3.3: Satisfaction and problems with Dermo and the Seal-In X5 liner

	Dermo Liner Mean(SD)	Seal-In Liner Mean(SD)	P -value	Z	Effect Size
Satisfaction					
Fit of prosthesis	78.1(5.6) ↑	73.3(5.6)	0.011*	-2.46	0.58
Ability to don and doff the prosthesis	86.7(7.9) ↑	50.0(7.1)	0.011*	-2.68	0.63
Ability to sit with the prosthesis	77.2(7.1)	75.6(5.3)	0.47	NS†	-
Ability to walk with the prosthesis	84.2(5.3) ↑	76.1(5.5)	0.013*	-2.72	0.64
Ability to walk on uneven terrain	75.8(6.4) ↑	72.8(5.7)	0.034*	-2.12	0.50
Ability to walk up and down on stairs	75.0(9.4)	77.8(6.2)	0.251	NS	-
Suspension	82.2(3.6)	85.6(5.8) ↑	0.032*	-2.12	0.50
Appearance of the prosthesis	81.4(5.1)	83.9(4.2)	0.133	NS	-
Overall satisfaction with the prosthesis	84.7(5.7) ↑	70.6(4.6)	0.015*	-2.09	0.49
Overall Score	80.6(5.1)↑	73.9(4.0)	0.004*	t=9.02	0.91
Problems/Complaints					
Sweating	76.7(6.6)	73.9(9.6)	0.494	NS	-
Wounds/ingrown hairs/blisters	87.8(7.9) ↑	82.2(7.9)	0.041*	-2.06	0.49
Skin Irritations	84.4(8.8) ↑	77.2(9.7)	0.041*	-2.03	0.48
Pistoning within the socket	78.9(6.0)	86.7(5.6) ↑	0.013*	-2.14	0.50
Rotation within the socket	84.6(8.1)	82.8(9.1)	0.464	NS	-
Swelling of the residual limb	87.8(6.2) ↑	78.6(8.4)	0.013*	-2.54	0.60
Unpleasant smell of prosthesis or residual limb	82.8(7.5) ↑	74.4(4.6)	0.024*	-2.39	0.56
Unwanted sounds	77.8(3.6)	83.9(4.9) ↑	0.015*	-2.42	0.57
Pain in residual limb	86.7(4.3) ↑	73.0(8.0)	0.013*	-2.71	0.64
Overall Score	83.0(4.6)↑	79.2 (5.9)	0.012*	t=3.20	0.57

* Significant differences between the Dermo and Seal-In liner.

† Non significant

The results of this study revealed that the subjects preferred the Dermo liner with shuttle lock and, as such, it supports the findings of McCurdie et al., which clearly reported the preference to locking liners. Moreover, it is consistent with a recent study by Gholizadeh et al., which revealed higher patient satisfaction with the Dermo liner and shuttle lock when compared with the Seal-In X5 liner. However, Linde et al. stated that experts in the field of rehabilitation were more satisfied with the locking liners

(Linde et al., 2004).A study by Astrom and Stenstrom revealed that locking liners provided more comfort and a better fit within the socket (Åström andStenström, 2004) and their findings are consistent with those of the current study, where the subjects were more satisfied with the fit of the Dermo liner with shuttle lock. Another study by Klute et al.established that the participants were more satisfied with the (Klute et al., 2011). The results of the present study revealed that a subject's ability to walk with the prosthesis was higher and they walked more comfortably with the Dermo liner than they did with the Seal-In X5 liner. Similar findings were established in a study by Hatfield and Morrison (Hatfield and Morrison, 2001).

The socket fit and suspension in prostheses have significant impact on the user's mobility, comfort and satisfaction (Baars and Geertzen,2005). Within the questionnaire, the subjects rated the Seal-In X5 liner higher than the Dermo liner. Gholizadeh et al. also mentioned improved suspension with the Seal-In X5 liner (Gholizadeh et al., 2011). However, the findings of the current study contradict the study of Cluitmanset al., where enhanced suspension was measured with the locking liners (Cluitmans et al., 1994).

The ease with which a subject can don and doff a prosthetic device plays a significant role in prosthetic use and their satisfaction with that device (Baars et al., 2008; Gauthier-Gagnon et al., 1999). This study revealed that the subjects found doffing and donning the Seal-In X5 liner much more difficult than they did with Dermo liner. Similar findings were revealed by Gholizadeh et al. The subjects involved in this study, all of whom were over 50 years old, were not ready to accept the Seal-In X5 liner because of difficulties in donning and doffing the device and the excessive tightness of the socket. Furthermore, the satisfaction score was higher for the Dermo liner with shuttle lock than it was for the Seal-In X5 liner, with the exception of suspension. Moreover, statistical analysis showed significantly fewer problems with the Dermo liner

with the shuttle lock. It is acknowledged that the findings of the current study are limited to only nine subjects and to normal walking on level ground. Further clinical studies are required to evaluate the interface between the liner and socket and satisfaction during walking on uneven ground, stairs and slopes.

3.4. Conclusion

The selection of good prosthetic components is considered to present a challenging task in amputee rehabilitation. The result of the interface pressure analyses showed less pressure within the socket wearing the Dermo liner. Moreover, the subjects had less problems and complaints with the Dermo liner. Hence, it can be concluded that the Dermo liner provides more comfortable socket-residual limb interface than the Seal-In X5 liner. However, the Seal-In X5 liner offers better suspension. All these issues should be taken into account when choosing prosthetic components for amputees.

CHAPTER 4

INTERFACE PRESSURE IN SOCKET DURING ASCENT AND DESCENT ON STAIRS AND ITS EFFECT ON PATIENT'S SATISFACTION

Background: Amputees encounter stairs and steps during their daily activities. The excessive pressure between residual limb/socket may reduce the walking capability of prosthetic users during ascent and descent on stairs. The purposes of the research were to evaluate the interface pressure between Dermo (shuttlelock) and Seal-In X5 (prosthetic valve) interface systems during stairs ascent and descent, and to determine their satisfaction effects on users.

Methods: Ten amputees with unilateral amputation participated in the study. Interface pressure was recorded with F-socket transducer (9811E) during stair ascent and descent at self-selected speed. Each participant filled in a questionnaire about satisfaction and problems encountered with the use of the two interface systems.

Findings: The resultant mean peak pressure (kPa) was significantly lower for the Dermo interface system compared to that of the Seal-In X5 interface system at the anterior, posterior and medial regions during stair ascent (63.14 vs. 80.14, 63.14 vs. 90.44, 49.21 vs. 66.04, respectively) and descent (67.11 vs. 80.41, 64.12 vs. 88.24, 47.33vs. 65.11, respectively). Significant statistical difference existed between the two interface systems in terms of satisfaction and problems encountered ($P<0.05$).

Interpretation: The Dermo interface system caused less pressure within the prosthetic socket compared to the Seal-In X5 interface system during stair negotiation. The qualitative survey also showed that the prosthesis users experienced fewer problems and increased satisfaction with the Dermo interface system.

4. Introduction

Studies have revealed that lower limb prosthetic users consider discomfort as one of the most significant problems they face when using prosthesis. It is common for prosthetic users to experience pain and discomfort in the residual limb while wearing their prostheses (Lee et al., 2005). Lower limb prosthesis should enable ambulation and improve the performance of daily routine activities. However, poor-fitted socket can lead to complications that have adverse effects on the activity level and gait of people with lower limb amputation (Gailey et al., 2008).

The distribution of interface pressure between the socket and residual limb is an important factor in socket design and fit. Lower limb prosthetic users experience pressure between the socket and residual limb during daily activities. The underlying soft tissues and skin of the residual limb are not accustomed to weight bearing; thus, there is the risk of degenerative tissue ulcer in the residual limb because of constant or repetitive peak pressure applied by the socket (Jia et al., 2004). The pressure also can lead to various skin problems such as follicular hyperkeratosis, allergic contact dermatitis, infection and veracious hyperplasia (Dudek et al., 2005, 2008; Lyon et al., 2000).

Despite significant advances in the field of prosthetics in the previous decades, still many amputees experience pressure ulcers with the use of prostheses. Some times, skin problems lead to chronic infection, which may necessitate re-amputation. This will prevent thelong-term use of prosthesis, which significantly reduces the daily activities of prosthesis users and the quality of life (Ali et al., 2012).

Many studies have focused on interface pressure magnitude between the socket and residual limb during level walking (Convery & Buis, 1999; Goh et al., 2004; Silver-Thorn & Childress, 1996). However, a prosthesis user encounters stairs in his/her daily activities. The ability of a person to negotiate stairs and steps is a significant factor for

functional freedom. This ability allows a person to become more active in the society, and to perform different daily activities (Gill et al., 1994; Jones et al., 2006). The ability of amputees to negotiate steps and stairs is severely affected by the loss of ankle joint and foot as well as reduced muscles power, balance, mobility and stability, especially for young and strong amputees who perform manual labor and rigorous activities (Jones et al., 2006). It is important for prostheticusers to minimize the chances of pressure ulcers with underlying associated syndromes through information regarding the interface pressure between the socket and residual limb in dealing with stairs (Dou et al., 2006).

A high-quality interface systemis required to prevent skin complications that will produce excellent interface union between the residual limb and socket (Sewell et al., 2000; Van de Weg & Van Der Windt, 2005). Silicone interface systems are believed to reduce the friction between the skin and improve comfort both in rest and during walking (Cluitmans et al., 1994). Manufacturers of prosthetic products seek to develop new interface systems. Dermo and Seal-In X5 interface systems are two new systems that increase the contact areas and distribute the pressure at the socket walls. These are commonly prescribed for amputees. There is minimal knowledge on their effect on patient's satisfaction. The manufacturer claims an easy donning and doffing with the Seal-In X5 liner but during the clinical practice, patients complained of discomfort with the Seal-In X5 liner, particularly during walking and donning/doffing. The Dermo silicon interface system provides suspension through pin/lock, while the Seal-In X5 silicon liner incorporates a series of five integrated seals that conform to the shape ofthe residual limb and the internal socket wall, providing an airtight seal. The Seal-In X5 interface system is claimed to provide a good response in high impact activities due to improved coupling between the socket and seals. Users reported discomfort with the Seal-In X5 liner due to localized pressure at the seals and high activity level compared

to the Dermo interface system. This claim motivated us to determine the interface pressure generated by the two interface systems during stair ascent and descent. Only two studies have compared the interface pressure during stair negotiation with prosthesis (Dou et al., 2006; Wolf et al., 2009); however, no study has examined the effect of interface pressure on patient satisfaction and perceived problem during stair ascent and descent. Two studies have evaluated the interface pressure during level walking with these two systems (Ali et al., 2012; Eshraghi et al., 2013). Therefore, this study aimed to evaluate the interface pressure generated by these two interface systems, and to study the effect of interface pressure on patient satisfaction. It was our hypothesis that the subjects will experience less interface pressure and will be more satisfied with the Dermo interface system during stair negotiation compared to the Seal-In X5 interface system.

4.1. Methods

Ten amputees (seven males and three females) with amputation were recruited for this study. All the participants had undergone unilateral transtibial amputation at least four years prior to the study. The inclusion criteria were: ability to negotiate stairs without any assistive devices, absence of residual limb problems and absence of pathological problems,which affected the mobility of the participants. The detailed particularsof the participants are shown in Table 4.1. The Ethics committee of the University Malaya Medical Centre (UMMC) approved this study. Written consent was obtained from all the participants.

Twenty Total Surface Bearing (TSB) prostheses were fabricated using the Dermo with shuttle lock (Össur, Reyjavik, Iceland) and the Seal-In X5 with prosthetic valve (Össur, Reyjavik, Iceland). Double adapters of different sizes (7 cm and 10 cm) were used to adjust the length according to the patient's height. Flex-Foot Talux was utilized for all the prostheses based on the foot size of the participants. The following procedures were applied for casting and modification.

The interface system (3mm) was rolled on the subject's residual limb. Single layer of plastic was applied and it was insured that all the areas were covered. Pressure-sensitive areas were marked and all the required measurements (residual limb and sound side) were recorded on the measurement chart. The entire residual limb was wrapped with two rolls of 15 cm Plaster of Paris bandages and massaged properly until the cast dried. Trim lines were marked on the negative cast and they were filled with Plaster of Paris powder for modification. Negative cast was removed and it was ensured that all the marks were transferred to the positive model. All the unnecessary material was removed and the measurements were compared with the subject's measurements. Recommended reduction was done over the soft tissue areas and posterior of the residual limb. Minimal relief was applied to the bony areas and posterior trim lines were

marked for hamstring relief. Model was smoothened after finalizing all the measurements.

To assure the accuracy during casting, modification, fabrication and alignment, all the prostheses were fabricated by a single certified prosthetist,and the laser liner was used for the alignment (Mathur & Gupta, 2005). Initial fitting was performed at the Department of Biomedical Engineering, University of Malaya (Brace and Limb laboratory). Prostheses were adjusted according to the participant's requirements. After achieving fitting and alignment satisfaction with each prosthesis, the participants were asked to use each prosthesis for at least one month. The participants were also requested to visit the Motion Analysis Lab after one month of trial period for interface pressure measurements.

Four F-socket transducers 9811E (Tekscan, Inc., South Boston, USA) were attached to the posterior, anterior, lateral and medial compartments of the residual limb to obtain better insights on the pressure between the residual limb and socket. Medial, lateral and anterior sensors were attached at the mid patella level. The posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket. The residual limbs were covered with cellophane plastic wrap, and each transducer was attached to the cellophane plastic wrap with spray adhesive (Scotch Super Adhesive, 3M Corporate, St. Paul, USA) to ensure that the transducer was appropriately positioned on the residual limb. Each transducer was trimmed according to the contour of the residual limb. 90% of the residual limb was enclosed with these arrangements. Interface measurements were recorded using Tekscan software (version 6.51).

Transducers were positioned for equilibration and calibration inside a bladder and pressure of 100 kPa was applied according to the instructions of the manufacturer. We were aware of the limitations of the pressure measurement system employed, including hysteresis and drift. Inaccuracies between individual cells have also been

highlighted. However, by adopting a strict protocol to precondition, equilibrate, and calibratethe sensor array, we minimized the variation and inaccuracy of data recordings. We did the pre and post test to minimize the inaccuracies in the sensors (Fig. 4.1).

Figure 4.1: Placement of sensors on a residual limb

The participants were asked to ascend and descend a custom-made 82 cm wide staircase; consisting of 4 steps with step distance of 32 cm and step height of 14 cm. Data were recorded for two consecutive trials at the sample rate of 50 Hz for at least 6 cycles of ascent and descent. All the participants followed the same procedures to minimize variation in data collection and testing order of the interface systems was randomized. Each participant completed an orientation session of stair ascent and descent (Fig. 4.2) before the experiment.

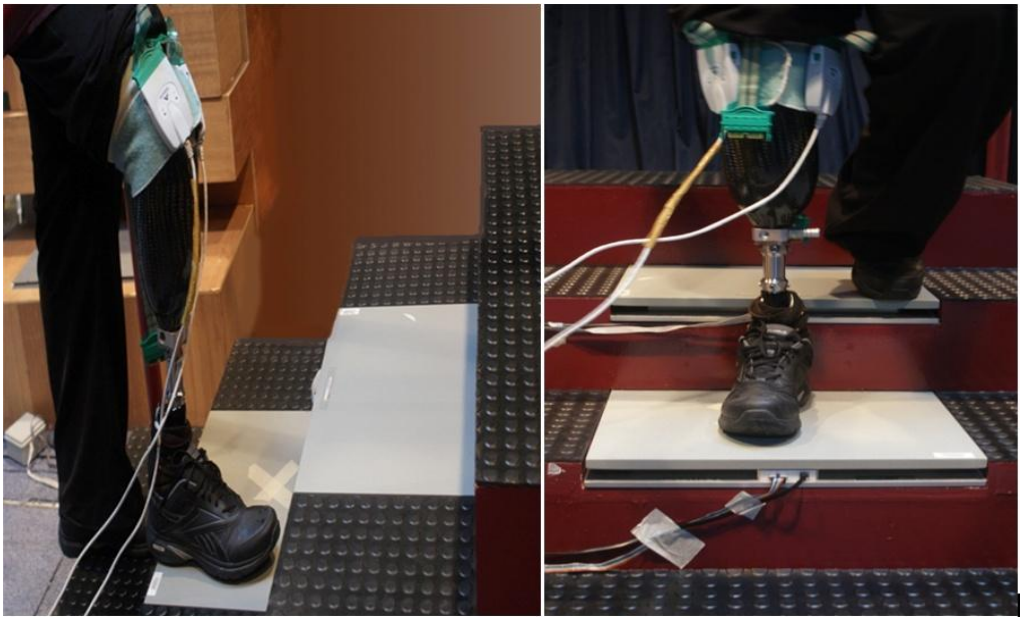

Figure 4.2: (Left) Stair ascent; (right) stair descent

The participants completed a questionnaire after the experiments to describe their one month experience with prostheses. We used a non validated survey to determine the level of problems encountered and satisfaction with the prosthesis during ascent and descent on stairs.

The following were asked from each participant regarding their satisfaction and problems with each prosthesis.

1. Satisfaction during stair ascent: Walking satisfaction during stair ascent; suspension satisfaction during stair ascent; balance satisfaction during stair ascent and overall satisfaction during stair ascent.

2. Satisfaction during stair descent: Walking satisfaction during stair descent; suspension satisfaction during stair descent; balance satisfaction during stair descent and overall satisfaction during stair descent.

3. Problem during stair ascent: Pain during stair ascent; pistoning during stair ascent and rotation of the socket during stair ascent.

4. Problem during stair descent: Pain during stair descent; pistoning during stair descent and rotation of the socket during stair descent.

Numerical scores of 0–100 were utilized for the entire questions to indicate the level of satisfaction and problems encountered. Zero (0) indicated “extremely bothered or unsatisfied” and 100 indicated“no problem or complete satisfaction”.

For each trial, the middle step was selected. The mean peak pressure (MPP) was calculated for all the trials. Non-parametric Wilcoxon signed-rank test was utilized to compare the pressure difference between the Seal-In X5 and Dermo interface systems at all the major regions (anterior, posterior, medial and lateral) and sub-regions (proximaland distal) of each major region of the residual limb. Paired samples t-test was applied to obtain the overall score, and compared the satisfaction and problems between the two interface systems.Valve $P < 0.05$ was set for the level of statistical significance. Statistical analysis was performed by using SPSS version 20 (SPSS, Chicago, USA).

4.2. Results

4.2.1. Participant's

Ten participants took part in this research, and their particulars are shown in Table 4.1.

4.2.2. Interface pressure during ascent

The MPP values of the 10 participants revealed a significant difference between three major regions ($P < 0.05$) and three sub-regions ($P < 0.05$) during ascent on stairs by performing Wilcoxon signed rank test (Fig. 4.3).

The magnitude of the MPP at the whole posterior region was significantly higher ($P = 0.031$, $Z = -2.09$) with the Seal-In X5 interface system (mean = 90.44 kPa, SD = 46.34) compared to the Dermo interface system (mean = 63.13, SD = 9.21). Furthermore, the MPP at the anterior region was significantly higher ($P = 0.002$, $Z = -2.80$) with the Seal-In X5 interface system (mean = 80.14 kPa, SD = 18.01) compared to the Dermo interface system (mean = 63.14 kPa, SD =13.40). Significant difference ($P = 0.031$, $Z = -2.09$) was also observed with the Seal-In X5 interface system (mean = 66.04 kPa, SD = 30.22) compared to the Dermo interface system (mean = 49.21 kPa, SD =8.03) at the medial region. A significant difference was recorded at the anterior and posterior proximal sub-regions of the Seal-In X5 and Dermo interface system. No statistical difference was recorded at the lateral regions of the two interface system. However, a significant differencewas observed at the medial distal sub-region of the residual limb (Table 4.2).

Table 4.1: Particulars of the participants

Subjects	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Age (year)	37	50	24	41	71	63	62	51	49	32
Height (cm)	175	171	170	180	180	173	160	163	165	171
Sex	Male	Male	Male	Male	Male	Male	Female	Female	Female	Male
Body mass (kg)	90	65	60	101	80	76		49	50	62
Cause of amputation	Trauma	Trauma	Trauma	Diabetes	Diabetes	PVD	Diabetes	PVD	Diabetes	Trauma
Amputation side	Left	Right	Left	Right	Left	Right	Left	Left	Rt	Rt
Activity level	3-4	3-4	3-4	3-4	2-3	2-3	2-3	3-4	3-4	3-4
Years since amputation	4	4	4	4	9	6	3	8	8	5
Residual limb length (from mid patella to residual limb end)	16	15.5	15.5	17	16.5	15.5	15	16.5	16.5	15.8

4.2.3. Interface pressure during descent

MPP was significantly higher ($P < 0.05$) with the Seal-In X5 interface system than with the Dermo interface system in the entire anterior (P = 0.031, Z = −2.09; mean = 80.41 kPa, SD = 22.11; mean = 67.11 kPa, SD = 17.40, respectively), posterior (*P*=0.012,Z = −2.39; mean = 88.24 kPa, SD = 39.21; mean = 64.12 kPa,SD = 12.35, respectively), and medial (P = 0.034, Z = −2.09; mean =65.11 kPa, SD = 30.04; mean = 47.33 kPa, SD = 16.31, respectively) regions. No significant difference was recorded at the lateral region between the Seal-In X5 and Dermo interface systems (*P*=0.64, Z= −2.09; mean = 65.23 kPa, SD = 21.01; mean = 64.23 kPa, SD = 15.01, respectively) (see Fig. 4.4). A significant increase in MPP was observed at the anterior distal, posterior proximal and medial distal region of the Seal-In X5 interface system unlike the Dermo interface system (Table 4.3).

With regard to satisfaction, participants gave significantly (*P*<0.05) higher scores to the Dermo interface system compared to the Seal-In X5 interface system for three out of the four questions. However, the Seal-In X5 interface system obtained higher score for the suspension of the prosthesis with the residual limb during stair negotiation. Overall satisfaction was significantly higher (*P*<0.05) for the Dermo interface system compared to the Seal-In X5 interface system (Table 4.3).

Concerning the problems encountered, significant differences (*P*<0.05) were recorded in terms of pain among others. The participants reported less pain with the Dermo interface system unlike the Seal-In X5 interface system (see Table 4.4).

Table 4.2: Mean peak pressure (kPa) at the anterior, posterior, medial and lateral sub-regions

Major regions	Sub-regions	Stairs ascent			Stairs descent		
		Dermo	Seal-In X5	P-value	Dermo	Seal-In X5	*P*-value
Anterior	Proximal	56.10(10.54)	69.02(18.43)	0.034*	59.11(18.10)	65.61(23.14)	0.286
	Distal	58.03(11.10)	64.04(22.40)	0.372	54.11(17.25)	67.05(24.16)	0.025*
Posterior	Proximal	57.10(10.26)	80.40(48.20)	0.055*	52.10(15.52)	82.14(38.31)	0.002*
	Distal	54.01(12.60)	59.10(17.51)	0.573	58.16(14.45)	68.56(23.83)	0.285
Lateral	Proximal	58.31(20)	61.13(19.44)	0.446	60.42(22.10)	55.45(19.03)	0.381
	Distal	63.13(16.36)	60.01 (11.21)	0.201	55.15(29.17)	57.30(12.20)	0.643
Medial	Proximal	45.56(10.54)	52.25(35.04)	0.953	45.05(13.31)	54.20(41.54)	0.954
	Distal	43.03(15.04)	52.20(12.24)	.004*	43.35(17.33)	50.24(13.03)	0.047*

*Significant differences in the interface pressure between the Dermo and Seal-In X5 interface system

Table 4.3: Satisfaction with Dermo and Seal-In X5 interface system during stairs ascent and descent

Stairs ascent

Satisfaction type/interface type	**Mean**	***P*-value**	**Z**
Walking satisfaction during stairs ascent		0.002*	-0.86
Dermo	84.50		
Seal-In X5	72.90		
Suspension satisfaction during stairs ascent		0.014*	-2.37
Dermo	72.50		
Seal-In X5	82.13		
Balance satisfaction during stairs ascent		1.006	0.00
Dermo	78.00		
Seal-In X5	78.00		
Overall satisfaction during stairs ascent		0.024*	-2.32
Dermo	78.30		
Seal-In X5	72.50		

Stairs descent

Satisfaction/interface type	**Mean**	***P*-value**	**Z**
Walking satisfaction during stairs descent		0.005*	-1.03
Dermo	85.00		
Seal-In X5	70.50		
Suspension satisfaction during stairs descent		0.002*	-2.69
Dermo	75.20		
Seal-In X5	85.21		
Balance satisfaction during stairs descent		0.313	-1.00
Dermo	75.20		
Seal-In X5	76.33		
Overall satisfaction during stairs descent		0.014*	-2.53
Dermo	84.20		
Seal-In X5	76.20		

*Significant differences between the Dermo and Seal-In X5 interface system.

Table 4.4: Comparison between Dermo and Seal-In X5 interface systems during stairs ascent and descent with regards to problem

Stairs ascent

Problem type/interface type	**Mean**	***P*-value**	**Z**
Pain during stairs ascent		0.005*	-2.67
Dermo	87.00		
Seal-In X5	64.10		
Pistoning during stairs ascent		0.142	-1.47
Dermo	72.00		
Seal-In X5	76.50		
Rotation of the socket during stairs ascent		0.484	-0.70
Dermo	85.50		
Seal-In X5	86.50		

Stairs descent

Problem type/interface type	**Mean**	***P*-value**	**Z**
Pain during stairs descent		0.011*	-2.55
Dermo	78.00		
Seal-In X5	70.00		
Pistoning during stairs descent		0.171	-1.36
Dermo	74.50		
Seal-In X5	79.00		
Rotation of the socket during stairs descent		0.482	-0.70
Dermo	85.50		
Seal-In X5	86.50		

*Significant differences between the Dermo and Seal-In X5 interface system.

4.3. Discussion

Selection of suitable interface system for lower limb amputee' plays a major role in the process of prosthetic rehabilitation. Fitting between the socket and residual limb is a key determinant for successful ambulation. A high-quality fit prosthesis offers a functional and comfortable limb, allowing pursuit of more vocational and recreational activities. Determination of the quality of fit remains a subjective process in the clinical setting and no compromise on appropriate fitting and assessment procedure (Dumbleton et al., 2009; Mak et al., 2001). Pressure measurements have the potential to provide information for the improvement of the prosthesis design.

Only two studies have compared the interface pressure during stair negotiation with prosthesis (Dou et al., 2006; Wolf et al., 2009); however, no study has examined the effect of interface pressure on patient satisfaction and perceived problem during stair ascent and descent.

The findings of this present study revealed that the MPP was significantly higher at posterior, anterior and medial regions with the Seal-In X5 interface system compared to the Dermo interface system both during stair ascent and descent (24.72%, 35.56% and 29.20%, respectively). MPP was lower both at the proximal and distal sub-regions with the Dermo interface system compared to the Seal-In X5 interface system.

This study showed that pressure was significantly higher at the proximal socket area, including patellar tendon, during ascent on stairs.These particular results are parallel to the findings of a research carriedout by Dou et al. (2006), which showed highest pressures at the patellar tendon area during stair ascent. However, Wolf et al. (2009) observed high pressure at the anterior distal area during ascent, which is contrary to our findings (Wolf et al., 2009). In our study, pressure magnitude was higher at the posterior proximal area. This finding contradicts the findingsof Dou et al. (2006).

The neutral position of the ankle limits knee movements and keeps knee flexion small; thus, pressure increases in the proximal anterior region.However, with the dorsi-flexed ankle, the knee flexion increases,and the ground reaction moves far behind; thus, the pressure load increases distally (McIntosh et al., 2006). In the present study, the participants experienced higher pressure at the anterior distal area with the Seal-In X5 interface system compared to the Dermo interface system during stair descent. This particular result is consistent with the findings of Wolf et al. (2009).

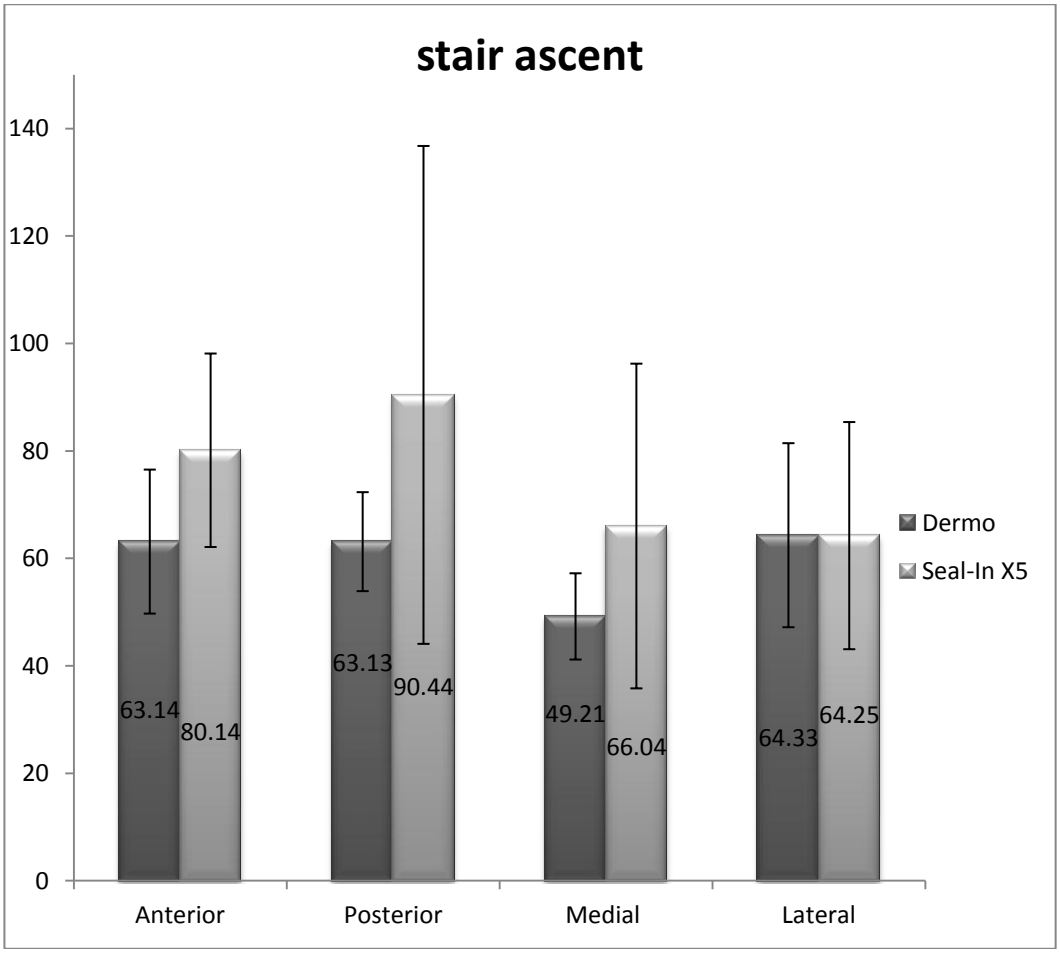

Figure 4.3: MPP for the four major regions of the residual limb during stair ascent.

Previous studies indicated that less pistoning occurs with the Seal-InX5 interface system compared to the Dermo interface system (Gholizadeh et al., 2011). In the present study, significant difference was observed in the amount of pressure generated by the two interface systems. A relation possibly exists between low pistoning and higher MPP

with the Seal-In X5 interface system. As the socket fit improves, the amount of pistoning will decrease. Thus, tight fit of Seal-In X5 socket might be associated with lower pistoning. On the other hand, this tight fit has caused higher pressure at the interface that might be harmful for residual limb. Although low pistoning and enhanced socket fit aregood qualities, increased interface pressure might disturb the blood flow and cause skin problems (Beil & Street, 2004; Bennett et al., 1979; Board et al., 2001).

Many researchers have utilized single-spot transducers to monitor the interface pressure among the socket and residual limb (Beil and Street, 2004; Beil et al., 2002; Wolf et al., 2009). The transducers employed in the current research were very thin that facilitated the placement between the residual limb and interface system, and covered more than 90% of the residual limb for a full pressure map. This particular quality of the transducer provides better sketch of the residual limb pressure compared to the single-spot transducers, and can offer additional important information for the clinical evaluation of pressure-related problems. We were aware of the limitations of the pressure measurement system employed, including hysteresis and drift. Inaccuracies between individual cells have also been highlighted. However, by adopting a strict protocol to precondition, equilibrate, and calibrate the sensor array, we minimize the variation and inaccuracy of data recordings.We did the pre and post test to minimize the inaccuracies in the sensors.

Previous studies indicate that the Dermo interface system with the pin/lock suspension provides a secure close contact. However, the pressure during swing phase can cause distal end residual limb problems (Klute et al., 2011). Such occurrences were not observed in the current study after the acclimation period.

As predicted, the results of this research revealed a significant difference with respect to the level of satisfaction and problems identified by participants who utilized the two different prosthetic interface systems. The participants experienced fewer

problems with the Dermo interface system compared to the Seal-In X5 interface system. Overall satisfaction was significantly higher for the Dermo interface system (8.01%) and participants had fewer problems with the Dermo interface system (9.97%).

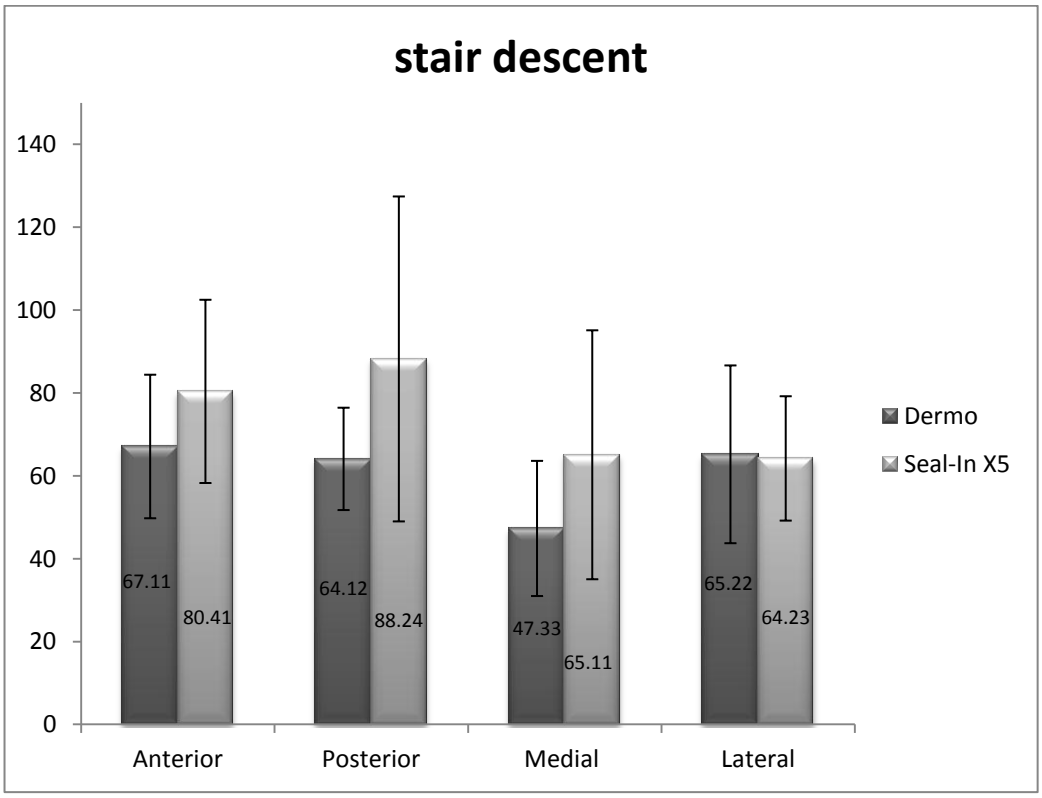

Figure 4.4: MPP for the four major regions of the residual limb during stair descent

4.3.1. Anecdotal evidence

The participants reported that they could walk for longer time while using prosthesis with the Dermo interface system compared to the Seal-In X5 interface system during stair negotiation. This finding is consistent with the results of Dou et al. (2006), which indicated a high activity level when walking with pin/lock system on all types of surfaces (Kluteet al., 2011). Pressure among the socket and residual limb is supposed to be a strong factor of the amputee's comfort (Dou et al., 2006; Sanders et al., 2006; Sewell et al., 2000). All the participants in the current study criticized the “comfort” with the Seal-In X5 interface system, which could have been the result of firm socket fit. Easy donning and doffing have positive effect on a user's experience with a

prosthetic device (Gholizadeh et al., 2013). In the present study, the participant's stated that they were less frustrated with the Dermo interface system than with the Seal-In X5 interface system. The results also support this statement.

Appropriate socket suspension increases prosthetic user's confidence and have important outcomes on user's comfort and satisfaction (Ali et al., 2012). Fifty percent of the participants stated that they felt more secure during stair ascent and descent with the Seal-InX5 interface system than with the Dermo interface system. Two of the participants perceived that the prosthesis with the Seal-In X5 interface system was more like a natural part of their body. However, Cluitmanset al. (1994) reported improved suspension with the pin/lock interface system, which contradicts to our results (Cluitmans et al., 1994).

Findings of the current study offer clinician's further insight into the mechanics of residual limb and socket pressure in amputees, and may provide helpful information for the socket design. However, larger sample size is required to evaluate the effect of interface pressure on patient satisfaction. A four-week acclimation period was provided to the subjects for the study prostheses, but some subjects might require a longer time. Subject's selection and retaining was also challenging.

4.4. Conclusion

The current study revealed that a high interface pressure exists between the residual limb and socket with the Seal-In X5 interface system.The Dermo interface system caused minimal pressure, and the participants were more comfortable while using it during stair negotiation compared to using the Seal-In X5.

CHAPTER 5

THE EFFECT OF DERMO AND SEAL-IN X5 PROSTHETIC LINERS ON PRESSURE DISTRIBUTIONS AND REPORTED SATISFACTION DURING RAMP AMBULATIONS IN PERSONS WITH LIMB LOSS

Background: Lower limb amputees are greatly affected in dealing with the environmental barriers such as ramps and stairs and reported high interface pressure between the residual limb and socket/liner. Interface pressure between the residual limb and socket/liner can affect the satisfaction and use of the prosthesis. Until now, little attention has been paid to interface pressure between socket and residual limb during ramp negotiation and its effect on amputee's satisfaction.

Aim and Design: The aim of this study was to evaluate the interface pressure produced by two different liners (Seal-In X5 and Dermo) between the residual limb and socket, and their effects on amputee's satisfaction during ramp negotiation.

Setting: The study was performed in rehabilitation and biomedical departments of University Malaya Medical Centre.

Population: Total ten (7 male, 3 female) amputees with unilateral amputation were included.

Methods: Two prostheses were fabricated for each amputee. After four weeks of acclimation period, interface pressure between socket and residual limb was measured during walking on ramp and Prosthetic Evaluation Questionnaire (PEQ) was filled for each liner.

Results: Mean peak pressure was significantly (P<0.05) lower with the Dermo liner compared with the Seal-In X5 liner in ramp walking. In addition, the participants were more satisfied with the Dermo liner (83.50 vs. 71.50) and mentioned fewer problems (87.00 vs. 69.00) compared with the Seal-In X5 liner during ramp negotiation.

Conclusion: It might be concluded that Dermo liner could be a good choice for the transtibial level of amputation due to relative decrease in interface pressure, satisfaction and fewer problems.

Clinical rehabilitation impact: The advantages of the Dermo liner may improve clinical rehabilitation of amputees, as it provides more satisfaction and experienced fewer problems during ramp negotiation. This provides an improved walking and better quality of life in long term.

5. Introduction

Many factors can influence the use of prosthesis and the interface between prosthetic socket and skin, including shear force, moisture, distribution of weight, and temperature (Åström & Stenström, 2004; Bui et al., 2009).The main concern for the rehabilitation of individuals with prosthesis is the failure to use and accept prosthesis, mainly because of discomfort within the prosthetic socket (Chadderton, 1978; Neumann et al., 2013; Nielsen et al., 1989).

The mechanical interaction of residual limb and socket can affect the comfort and use of the prosthesis. Extra care should be taken into account during the design and fitting of socket to avoid skin problems and discomfort while performing daily activities (Zhang & Roberts, 2000). Pressure should be distributed evenly over the residual limb to provide comfortable load transmission and good control for mobility, and to reduce skin damage by increasing the contact surface. It is clear that good socket design requires understanding of the bio-mechanics of socket and residual limb, including interface pressure, during ambulation (Mak et al., 2001).

Transtibial prostheses users experience different pathways such as level ground, ramps, stairs and other uneven surfaces during their daily activities. The ability to negotiate environmental obstacles, such as ramps and stairs is a significant factor for the functional freedom (Gill et al., 1994). Studies showed that lower limb amputee is greatly affected in dealing with the environmental barriers such as slopes and stairs because of the loss of foot and ankle mechanism and reported high interface pressure (Dou et al., 2006; Jones et al., 2006). A number of skin issues might result from high interface pressure between the residual limb and inner socket wall during daily activities. These skin problems might disturb the everyday use of prosthesis and impede the independent life pattern (Koc et al., 2008; Meulenbelt et al., 2006). Silicon liners are usually prescribed to prevent the formation of pressure sores (Baars & Geertzen,

2005).These liners are claimed to distribute the interface pressure between the residual limb and socket, and to provide a comfortable interface.

Currently, clinicians and prosthetic practitioners use different liners in Malaysia, but commonly-used silicon liners are new Dermo liner with pin, and the Seal-In X5 suspension system. The Dermo liner provides suspension through pin and lock mechanism, while the Seal-In X5 liner provides suspension through suction mechanism. Few studies have evaluated the interface pressure with these systems during level walking (Ali et al., 2012b; Eshraghi et al., 2013); however, the interface pressure between socket and residual limb during ramp negotiation is not clear. Researchers have investigated interface pressure between socket and residual limb in the past 46 years; however, most of the studies focused on the interface pressure during level walking (Ali et al., 2012b; Convery & Buis, 1998; Dou et al., 2006; Eshraghi et al., 2013; Seelen et al., 2003; Zhang & Roberts, 1993; Zhang et al., 1994). It is, therefore, important to collect the interface pressure data during ramp negotiation between the socket/residual limb, especially in young and active prosthetic users (K3 and K4) who take part in social activities and labor work. The purpose of this research was to compare the interface pressure between socket and residual limb with the Dermo and Seal-In X5 liners during ramp negotiation, and to survey their effects on users' satisfaction.

5.1. Materials and methods

5.1.1. Study population

All the subjects had a unilateral TT amputation since at least four years prior to the study. Only those individuals were selected who had not less than 12cm residual limb length, no significant problem in the residual limb, no orthopedic or rheumatic, neurologic or cognitive impairment additional to the amputation. Also, they were required not to take any medication that could influence balance, have severe heart problem, and could negotiate ramp without assistive devices. Only K2, K3 and K4 activity levels subjects were selected and theses levels of activities were defined based on Medicare Functional Classification Level (MFCL) (Dudek et al., 2008). These activity levels are defines as: K2 means "limited community ambulator", K3 means "community ambulator" and K4 were "high level user". Exclusion criteria were residual limb problems within the last 3 months prior to the study and abnormalities of the sound limb. The ethics committee of University of Malaya Medical Centre approved this research, and informed written consent was attained from all the subjects.

5.1.2. Prosthesis intervention

A certified prosthetist fabricated and aligned two prostheses for each subject. Prosthesis with the Dermo liner included total surface bearing (TSB) socket, shuttle lock system, double adapter and carbon Talux foot. The prosthesis with the Seal-In X5 liner included TSB socket, prosthetic valve, socket adapter, aluminum pylon tube, male and female pyramid adapters and carbon Talux foot. Before the fabrication of final sockets, each subject was fitted with transparent check socket to ensure that the socket was total surface bearing. All the subjects participated in dynamic gait alignment sessions. They were also requested to use each prosthesis for at least four weeks, and to

visit the Brace and Limb Laboratory once a week to monitor the residual limb health and fitting.

5.1.3. Sensors placement

In order to get better insight into the socket and residual limb interface, we used four F-socket sensors arrays (sensor type 9811E) with 8 inch length and 3 inch matrix width. Each sensor array is composed of 96 sensels. Each sensor array was affixed to the anterior, posterior, medial and lateral compartments of the residual limb and was trimmed according to the contours of the residual limb to allow 90 percent coverage (Fig.5.1). To ensure correct position of the sensor arrays, residual limb was covered with wrapping plastic and the trimmed sensor arrays were attached to the plastic using adhesive spray. To ensure that placement of the sensors was the same between sessions, the mid patella was taken as the reference line for the placement of medial, lateral and anterior sensors, while the posterior sensor was positioned approximately 1 cm above the posterior trim line of the socket.

5.1.4. Data collection

Prior to the experiment, sensor arrays were equilibrated and calibrated using Tekscan pressure bladder to eliminate the variation among load cells. According to the manufacturer's instruction, each sensor array was individually placed inside the pressure bladder coupled with an air compressor applying 100 kPa steady pressures for equilibration. After equilibration, the calibration was accomplished according to body mass of amputees.

The participants were requested to walk on a 7.5 degree incline and 4-meter long custom-made ramp with a comfortable cadence. Before the experiments, all the participants walked up/down the ramp with the experimental prostheses several times to

become accustomed to the protocol, and to condition the sensors. The same procedure was followed for all the participants.

The data was recorded for 10 seconds at sample frequency rate of 50 Hz. The subjects completed five consecutive trials; in each trial the data was recorded for at least six to eight steps during ascent and descent the ramp. F-scan provides the essential data from separate transducers attached to residual limb and displays the Mean Peak Pressure (MPP) value obtained from every sensor for each time frame. The area within each array is further divided into two: a proximal region and a distal region. The middle step was chosen from each trial and MPP of two trials were employed for the purpose of statistical analyses. Pressure data was collected using the Teksacn software (version 6.51).

5.1.5. Questionnaires

We used few elements of Prosthetic Evaluation Questionnaire (PEQ). PEQ measure the quality of life of amputees with prosthetic-related issues.After the experiments, all the subjects were questioned to evaluate the effect of satisfaction as well as perceived problems with each liner during ramp negotiation. We asked the following questions regarding satisfaction and perceived problems with each liner.

Satisfaction: Fitting, donning/doffing, ramp ascent, ramp descent and overall satisfaction.

Problems: Pain, Sounds, Sweating, Pistoning, Rotation, Smell and overall problems.

5.1.6. Statistical analysis

Paired sample *t*-test was employed to compare the MPP at the major and sub-regions at different areas of the residual limb for the two liners. We also used paired sample *t*-test to compare the satisfaction and problems with the two liners. Value

P<0.05 was set for the level of statistical significance. SPSS version 20.0 (SPSS, Chicago, IL) was used for statistical analysis.

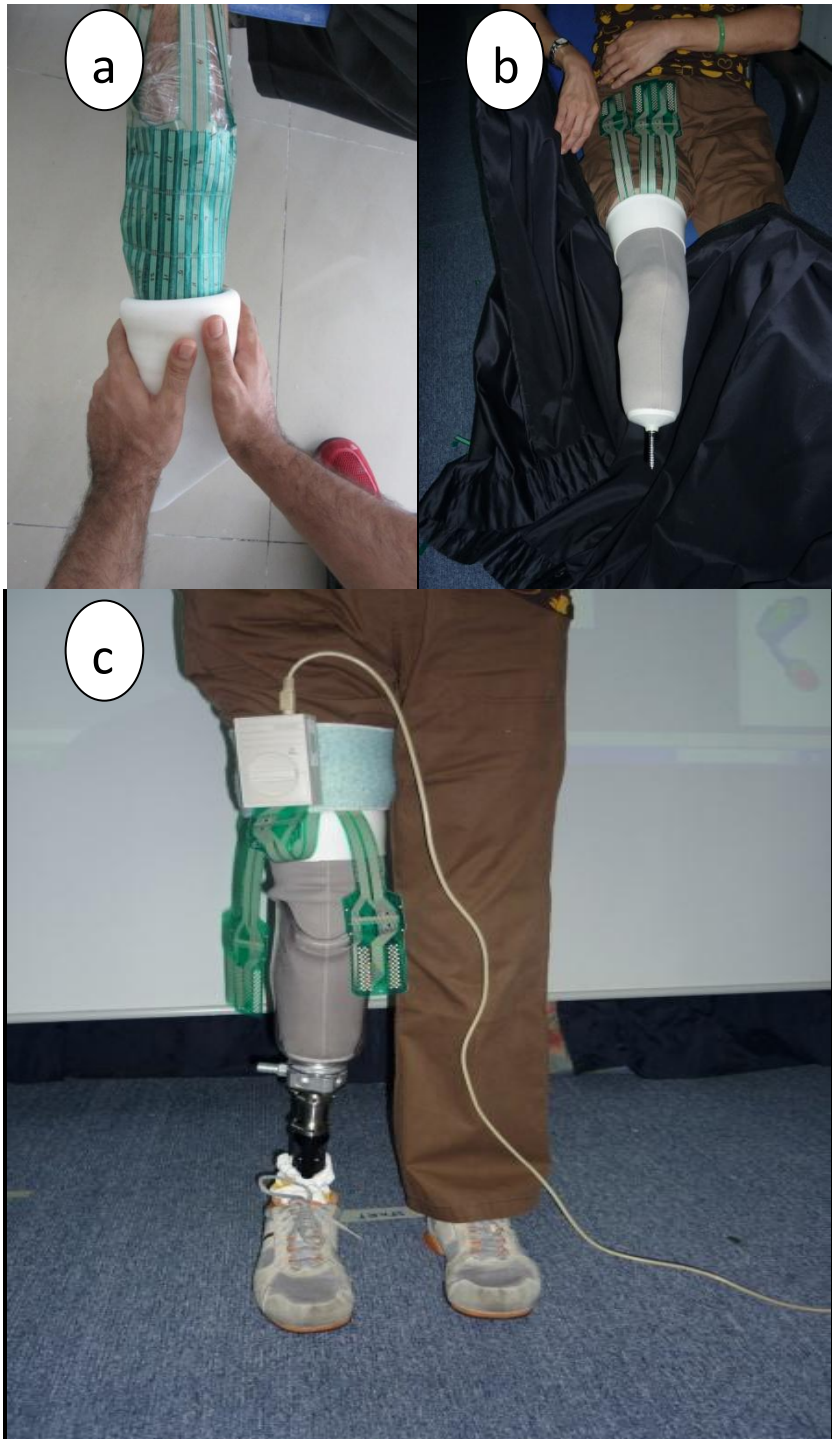

Figure 5.1: (a) Sensor attachments on stump, (b) Dermo interface system on attached sensors, (c) subject with study prosthesis

5.2. Results

5.2.1. Subjects' demographics

Total ten (30% female and 70% male) unilateral transtibial subjects participated in the study. Their mean age, height and body mass were 45.70 (16.48) years, 170.20 (6.89) cm and 75.90% (14.30) kg, respectively. The main causes of amputation were trauma (40%), diabetic (40%) and peripheral vascular disease (PVD) (20%), respectively. The numbers of right side amputees (60%) exceeded the numbers of left side (40%) amputees. Most of the participants (70%) reported activity level of K3-K4, while 30% reported activity level of K2-K3. Time since amputation was 4.40 (1.71) years. Demographics of ten subjects are shown in Table 5.1.

5.2.2. Residual limb and socket interface pressure

Using the MPP of the selected step for all the subjects, significant differences ($P<0.05$) were found between the two liners among the three major regions (anterior, posterior and lateral). During ramp ascent, the MPP (kPa) was significantly lower with the Dermo liner (60.57, 64.50 and 60.54, respectively) compared with the Seal-In X5 liner (83.48, 83.08 and 71.35, respectively). No significant difference was found between the medial regions with the two liners (Table 5.2).

During ramp descent significant differences were observed at the anterior, posterior and medial regions with the two liners. The participants experienced significantly lower MPP (kPa) with the Dermo liner at the anterior (66.43 vs. 85.21), posterior (61.64 vs. 90.03) and medial (48.16 vs. 64.36) major regions compared with the Seal-In X5 liner. No significant statistical differences were revealed during ramp ascent at the lateral region between the two liners (Table 5.2).

Table 5.1: Demographic characteristics of subject

Variable	**Results**
Sex	Male (70%)
	Female (30%)
Age (year)	45.70 (16.48)
Body Mass (kg)	75.90 (14.31)
Height(cm)	170.20 (6.89)
Activity level (%)	K2-K3 (30%)
	K3-K4 (70%)
Cause of amputation (%)	Trauma (40%)
	PVD (20%)
	Diabetic (40%)
Side of amputation	Right (60%)
	Left (40%)
Time since amputation (year)	4.40 (1.71)

There were also significant differences (P<0.05) between the two liners at the sub-regions during ramp ascent. The interface pressure was significantly lower with the Dermo liner compared with the Seal-In X5 liner at proximal anterior (57.42 vs. 71.14), posterior proximal (59.64 vs. 81.66), and posterior distal (51.73 vs. 65.28) sub-regions. The same was true with the lateral proximal, medial proximal and medial distal regions (Table 5.3).

During ramp descent, the MPP was lower at the anterior proximal (52.22 vs. 67.22), anterior distal (60.81 vs. 74.20), posterior proximal (57.34 vs. 72.07) and posterior distal (53.80 vs. 83.00) sub-regions, respectively with the Dermo liner. No

significant difference was seen at the lateral and medial proximal sub-regions between the two systems (Table 5.3).

5.2.3. Satisfaction and problems

Significant differences were found in satisfaction. In four questions out of five i.e. fitting, donning, doffing, ramp descent, and overall satisfaction, the participants were significantly satisfied with the Dermo liner compared with the Seal-In X5 liner (Table IV). Regarding the perceived problems, only two out of six questions showed significant differences (Table 5.4).

Table 5.2: MPP at the anterior, posterior, medial and lateral region during ramp ascent /descent

	Ramp ascent			Ramp descent		
	Seal-In X	**Dermo**	**P-Value**	**Seal-In X**	**Dermo**	**P-Value**
Anterior Mean (SD)	83.48(24.02)	60.57(05.37)	0.003	85.21(22.78)	66.43(16.37)	0.005
Posterior Mean (SD)	83.08(14.54)	64.50(11.62)	0.002	90.03(18.46)	61.64(15.62)	0.003
Lateral Mean (SD)	71.35(16.06)	60.54(10.08)	0.001	70.18(20.11)	67.07(18.66)	0.254
Medial Mean (SD)	53.58(7.77)	53.47(9.84)	0.942	64.36(14.86)	48.16(17.16)	0.011

SD = Standard deviation

5.3. Discussion

Distribution of Interface pressure between the socket and residual limb is an important indication of the success of socket design and fit. Amputees can feel pressure between the residual limb and socket during daily activities (Jia et al., 2004a; Portnoy et al., 2008). Although significant technical advances have been made in prosthetics technologies in fabrication of prostheses in the last few years, still some amputees experience high interface pressure between the socket/residual limb during walking, especially on stairs, ramp and uneven ground. This study compared the interface pressure between socket/residual limb with the Seal-In X5 and Dermo liners during ramp negotiation and their effects on users' satisfaction.

All the participants showed higher pressure with the Seal-In X5 liner and significant differences ($P<0.05$) were shown for the anterior, posterior and lateral regions ($P=0.003$, $P= 0.002$ and $P=0.001$, respectively) during the ramp ascent. During ramp descent, the statistics showed significant differences at the anterior, posterior and medial regions ($P=0.005$, $P=0.003$ and $P=0.011$, respectively). In addition, the participants were more satisfied and experienced fewer problems with the Dermo liner.

High MPP has been reported at the proximal anterior (PT bar) and posterior proximal (PP) regions during the stance phase of the gait with the patellar tendon bearing (PTB) socket. This is consistent with the study of Dou et al. which demonstrated higher pressure at the PT bar and popliteal depression (PD) while ascending ramp (Dou et al., 2006).Our study also revealed higher pressure at these areas (Table 5.3). On the other hand, lower pressure was recorded at the distal sub-region (kick point), which is compatible with the findings of Dou et al.(Dou et al., 2006) but contradicts the study of Wolf et al.(Wolf et al., 2009).

During ramp descent, the knee flexion moment is larger in contrast to the level walking (Riener et al., 2002). However, to guarantee stability with transtibial prosthesis,

the amputees position their prosthesis onto the lower step with extra extended knee, which decreases the magnitude of pressure at the anterior proximal and increases at the anterior distal area (Jones et al., 2006). This study obtained similar results with the above biomechanical changes of the knee during ramp ascent; the mean peak pressure was higher at the anterior distal sub-region compared with the anterior proximal sub-region. This is also consistent with the study of Dou et al.(Dou et al., 2006).

Different studies showed less pistoning with the suction sockets such as the Seal-In X5 liner (Board et al., 2001; Gholizadeh et al., 2012; Klute et al., 2011). In this study, pressure magnitude was significantly higher with the Seal-In X5 liner in all the regions of the residual limb that may result in less pistoning. These findings clarify the above- mentioned study results. Board et al.stated that suction mechanism leads to elevated magnitude of pressure and socket fit (Board et al., 2001). However, in return, the increase in net pressure causes blood flow disturbance and residual limb muscle loss (Board et al., 2001). The Seal-In X5 liner in our study also showed higher pressure magnitude, and the participants reported that tight fit during walking created discomfort and/or pain. Apparent significant differences were measured between the two interfaces systems during the stance phase of the gait, while identical body mass was applied over the same surface in the two sockets. This is in contrast with the study of Beil et al., where the research team reported more pressure in stance phase (Beil & Street, 2004).

The results of the questionnaire revealed a preference for the Dermo over the Seal-In X5 liner. The participants rated that their residual limb was healthier when wearing the Dermo liner and they were more satisfied compared with the Seal-In X5 suspension system. The participants stated that their abilities to ambulate were significantly higher while wearing the Dermo liner. These results are consistent with the findings of Klute et al., where the participants reported high performance with locking liners (Klute et al., 2011). Comfort of the socket is disturbed by the increased pressure

between the socket/residual limb (Dou et al., 2006; Sanders et al., 2006); this might be the reason that the participants were less satisfied with the Seal-In X5 liner.

Silicon liners are rolled on over the residual limb to achieve prosthesis fit. Easy doning and doffing play significant role in the satifaction of users. Doning and doffing was significantly easier with the Dermo liner (P=0.00). Ninty percent (90%) of the subjects reported difficult doning and doffing with the Seal-In X5 liner and revealed that the doning and doffing was very irritating. These difficulties in doning and doffing might be due to the five seals located arround the liner, which produce friction and do not slide easily, unless using lubricating spray. Despite all others problems, few participants reported more stable ramp negotiation with the Seal-In X5 liner because of the firm contact with the residual limb. This is consistent with the results of Gholizadeh et al. where participants were more stable during walking with the suction liner (Gholizadeh et al., 2012).

Table5.3: MPP (kPa) at the anterior, posterior, lateral and medial sub-regions

Walking	Liner	Anterior Mean (SD)		Posterio Mean (SD)		Lateral Mean (SD)		Medial Mean (SD)	
		Proximal	Distal	Proximal	Distal	Proximal	Distal	Proximal	Distal
Ramp ascent	Seal-In X5	71.14(9.35)	63.67(32.12)	81.66(18.92)	65.28(12.88)	66.89(17.27)	69.56(10.74)	63.95(13.79)	60.83(17.36)
	Dermo	57.42(7.12)	50.15(15.31)	59.64(18.29)	51.73(20.01)	56.86(20.29)	62.99(19.34)	44.16(11.12)	39.14(18.32)
	P-Value	0.001	0.133	0.003	0.024	0.003	0.214	0.001	0.006
Ramp descent	Seal-In X5	67.22(25.38)	74.20(28.30)	72.07(13.24)	83.00(20.23)	55.67(20.75)	61.19(19.62)	49.63(14.19)	54.11(18.18)
	Dermo	52.22(10.99)	60.81(20.02)	57.34(13.56)	53.80(18.55)	49.32(11.09)	56.34(12.74)	44.26(18.11)	39.82(19.02)
	P-Value	0.034	0.021	0.003	0.001	0.152	0.291	0.433	0.011

SD = Standard deviation

In summary, the MPP was significantly lower with the Dermo liner during ramp ascent and descent. All the participants reported that they were more active and mobile with the Dermo liner as compared with the Seal-In X5 liner; they could walk for longer time with the Dermo liner. The results clarify that the participants were more satisfied and experienced less problems with the Dermo liner. The results of this study may provide useful and valuable information to the clinicians and prosthetic practitioners. It may also help in producing an interface liner that can provide a comfortable interface pressure between the socket/residual limb. However, the sample size in this study was smaller and it was a challenge to compare the results with other studies due to the use of different sensors and activity level. Participant's selection and retaining was also challenging. Further study is needed with larger simple size and longer acclimation period to measure the effect of different liners on participants' satisfaction.

Table 5.4: Satisfaction and problems with Dermo and Seal-In X5 liners

Description	Dermo (SD)	Seal-In X5 (SD)	P-Value
Fitting satisfaction	83.10 (8.130)	76.20 (7.81)	0.005
Donning/Doffing satisfaction	86.00 (8.75)	65.50 (7.61)	0.003
Ramp-down satisfaction	83.50 (5.79)	77.00 (5.37)	0.001
Ramp-up satisfaction	79.00 (9.36)	77.50 (10.60)	0.391
Overall satisfaction	83.50 (8.54)	71.50 (7.47)	0.002
Sounds problem	72.50 (10.06)	74.00 (8.43)	0.341
Pain problem	84.00 (5.16)	72.00 (6.32)	0.004
Sweating problem	78.00 (7.52)	68.80 (10.85)	0.003
Pistoning problem	75.00 (5.50)	75.00 (7.81)	0.842
Rotation problem	80.00 (8.16)	82.00 (6.32)	0.261
Smell problem	77.50 (7.16)	78.00 (7.52)	0.591
Overall problems	87.00 (6.32)	69.00 (5.67)	0.003

Satisfaction: 100 indicated “completely satisfied” and 0 represented “unsatisfied”
Problem: 100 represented “not bothered at all” and 0 indicated “extremely bothered”

5.4. Conclusion

The study findings revealed that high magnitudes of pressure were recorded with the Seal-In X5 liner during ramp negotiation. Amputees feel more satisfied and encountered minimum prosthetic issues using the Dermo liner. The Dermo liner might be the better choice for prosthetic users.

CHAPTER 6

COMPARATIVE STUDY BETWEEN DERMO, PELITE, AND SEAL-IN X5 LINERS: EFFECT ON PATIENT'S SATISFACTION AND PERCEIVED PROBLEMS

Purpose: This study aimed to compare the effect of satisfaction and perceived problems of the amputees when using Pelite, Dermo with shuttle lock, and Seal-In X5 liners.

Material and Methods: A total of thirty amputees (17 male, 13 female) volunteered to take part in this research. Two prostheses were fabricated for each participant. Prosthetic Evaluation Questionnaire (PEQ) was filled-in by the participants with the three liners.

Results:The statistics highlights that Dermo liner showed significantly higher score (P=0.05) in walking, walking on uneven surfaces, stairs walking, fitting, donning/doffing, sitting, suspension and overall satisfaction with Dermo liner compared with Seal-In X5 and Pelite liners. Overall satisfaction was 34 % higher with Dermo liner than Seal-In X5 liner and 28 % higher than Pelite liner. Participants reported less problems with Dermo liner and significant differences (P<0.05) were recorded between the three liners in sweating, skin irritation, frustration and pain compared with Seal-In X5 and Pelite liners.

Conclusion: Participants experienced high level of satisfaction and faced fewer problems with Dermo liner.These results showed that there is a strong indication that the Dermo liner is a good choice for users and might help the clinicians and prosthetic practitioners in selection criteria of prosthetic liners.

6. Introduction

Manufacturing of devices suited to individuals is a key element to recover physical capabilities. One such device is prosthesis which is aimed to substitute the loss of a limb which has lost its cosmetic and desirability for the amputee. Lower limb prosthesis can be composed of several components such as the socket, liner, shank, ankle and foot. Among these components socket and liner are the important parts of the prosthesis due to its interface among the residuum and socket (Ali et al., 2012b; Goh et al., 2004; Jia et al., 2004b). Poor socket fitting due to enhanced pressure between socket and residuum greatly reduces the activity level of prosthetic users (Sanders et al., 2000a; Zhang & Roberts, 2000). Amputees hold high ambulatory loading during using the prostheses in their daily activities, which is usually transferred to skeletal structure from the prosthesis via interface among residuum and prosthetic socket (Åström & Stenström, 2004; Mak et al., 2010; Sanders et al., 2000b). Residuum tissues are not accustomed to shear loading and skin pressure during activities. Amputee's skin is vulnerable to develop cyst, edema, dermatitis and blisters, it is not uncommon to experienced residuum skin problems in lower limb amputee's (Hall et al., 2008; Lee et al., 2002), which effect the performance and comfort of the amputee (Zhang et al., 1998).

Prosthetic users required a comfortable liner and good socket to avoid skin problems and to prevent discomfort while using the prosthesis for daily activities (Dou et al., 2006; Lin et al., 2004). Cushioning effect of the liners lessens peak pressure and shear forces between the socket and residuum to prevent skin breakdown (Bertels & Kettwig, 2011). To make the prosthetic socket more comfortable prosthetic liners are frequently prescribed for lower limb amputees (Boutwell et al., 2012). A numbers of liners are available in the market for amputees. Clinicians have been using Pelite foam liner since 1950 (Ali et al., 2013; Coleman et al., 2004; Van de Weg & Van Der Windt,

2005). Pelite is a type of expanded cross-linked sponge foam which is shaped to fit to residuum to provide cushioning inside the socket. Many types of strategies are used to achieved a variety of suspension with Pelite liner, including suprapatellar strap or cuff or supracondylar bulge or suspension sleeve worn over the socket and extending to mid-thigh (Coleman et al., 2004).

Lately, liners with superior quality have been introduced in the market. Manufacturers claim that the new liners are more comfortable with better suspension and provide relief of dermatological problems compared with previous prosthetic designs (Baars & Geertzen, 2005; Hall et al., 2008). A wide range of liners with various properties are offered today, including the recent offering of Iceross Dermo and Seal-In X5 liners (Figure 6.1). Both the liners composed of silicon material but the suspension mechanism is different. Dermo liner suspension is based on shuttle lock system, while Seal-In X5 liner has five seals around the liner for suspension conforming to the residuum shape and socket inner wall, establishing an air tight seal. Silicon liners are rolled on the patient's residuum, which enhance the contact surface with socket and provides a comfortable cushion between the prosthetic socket and residuum.

Researchers have been developed many prosthetics/orthotics questionnaires to evaluate patients' satisfaction with prostheses and orthoses (Bill et al., 2010; Gallagher & MacLachlan, 2000; Gauthier-Gagnon & Grise, 1994; Grise et al., 1993; Heinemann et al., 2003; Legro et al., 1998; Van der Linde et al., 2007). Prosthetics Evaluation Questionnaire (PEQ) is one of the common type of questionnaire and majority of the researchers have mostly used PEQ to evaluate differences in performance, function and satisfaction among different prosthetics technique or components (Bill et al., 2010; Gauthier-Gagnon & Grise, 1994; Legro et al., 1998; Van der Linde et al., 2007). The PEQ is grouped into nine validated scales which consist of eighty two items, and there are a number of one hundred and eleven additional individual questions pertaining to

pain, satisfaction, transfer, self efficacy and prosthetic care. All the scales of PEQ have been validated for test-retest and internal consistency (Legro et al., 1998). The PEQ scales are not dependent on each other, so it is reasonable to use only the scales that are pertinent to your research question. Visual analog scale format is used for PEQ questions and each line is 100 mm long and is always measured from the left (0-100) (Legro et al., 1998).

Many studies have been carried out to check the level of satisfaction and problems with liners but most of the studies are just a questionnaires survey or interview based study without fabricating prostheses for participants (Datta et al., 1996; Hatfield & Morrison, 2001; McCurdie et al., 1997). However, there's no comparative study in the literature regarding the satisfaction and perceived problems among the Pelite, Seal-In X5 and Dermo liners. Therefore this study aimed to compare the effect of satisfaction and perceived problems among Pelite, Dermo liner with pin/lock and Seal-In X5 liner on the amputees.

6.1. Materials and methods

6.1.1. Participants

Thirty amputees (17 male, 13female) volunteered to take part in this research. All the participants had a unilateral transtibial amputation minimum 3 years prior to this study, which were using PTB and KBM sockets prosthesis with Pelite liner, single axis foot and solid ankle cushioned heel (SACH) foot. The detailed particulars are shown in the Table 6.1. University Malaya Medical Centre ethics committee approved this study, and the participants gave his/her written consent.

6.1.2. Prosthetic intervention

A total of sixty prostheses were made-up with Seal-In X5 liner with Icelock Expulsion Valve 551, Dermo liner with Icelock-200 series, socket adaptor, pylon tube, male pyramid adapter, female pyramid adapter, double adapter and SACH foot. We fabricated two prostheses for each participant, one TSB with Dermo liner and other TSB socket with Seal-In X5 liner. First we fabricated the prostheses with Dermo liner. Dermo liner was applied to the participant residuum properly and cellophane was applied on the liner to protect it. All the measurements and boney prominent regions were marked with transparent marker and the residuum measurements were documented. POP bandages were applied to residuum and massaged properly. Once the cast dried, it was removed from the participant residuum. All the marks were refreshed and negative cast was filled with POP powder. Recommended reduction was done from the positive model after removing the negative cast. Positive model was properly clean and lock was attached to the distal part of the model. Transparent plastic molding was done to get a clear socket. Clear socket was smoothed and attached with the other components. Same procedure was repeated for Seal-In X5 liner socket except expulsion Valve was used instead of lock.

Table 6.1: Characteristics of the participants

Age: years, mean (SD)		46.02±15.10
Sex: *n* (%)	male	17 (56.6 %)
	female	13 (43.33 %)
Weight: kg, mean (SD)		75.73±14.03
Height: cm, mean (SD)		170.14±6.70
Education; *n* (%)	High School	6 (20 %)
	Diploma	8 (26.66 %)
	Degree	9 (30 %)
	P.Graduate	7 (23.33 %)
Years since Amputaion: mean (SD)		7.57±3.56
Reason for amputation: *n* (%)	Diabetic	12 (40 %)
	Trauma	9 (30 %)
	PVD	5 (16.66 %)
	Other	4 (13.33 %)
Amputation side	Right	12 (40 %)
	Left	18 (60 %)
Activity level: *n* (%)	K2	7 (23.33 %)
	K3	6 (20%)
	K4	7 (23.33 %)
Prosthetics use every day: hours (SD)		9.23±2.90

PVD: Peripheral Vascular Disease

In PTB socket participants were using supracondyler suspension system and suprapatellar strap, while in TSB socket the suspension was provided through Pin/lock with Dermo liner and vacuum suspension with Seal-In X5 liner. Participant walked with the two new prostheses under the supervision of the certified prosthetist to become

familiar with them. Once the participants were satisfied with the fitting, his/her next step was to use each prosthesis for at least 60 days. Participants were requested to come to the brace and limb laboratory once a week for prostheses reviews and if required adjustment.

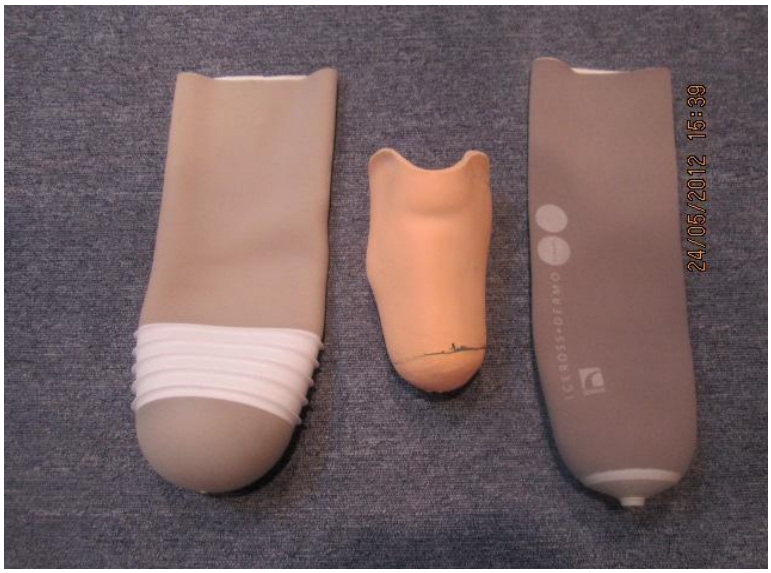

Figure 6.1: Types of liner, from left to right, Seal-In X5 liner, Pelite Liner, and Dermo liner

6.1.3. Questionnaire

In order to study the effect of the three different prosthetic liners on participant's satisfaction and to identify their problems with the use of the prosthesis, we used some elements of the PEQ. The questionnaire consists of demographic variables (sex, age, education level, marital status, height and weight), amputation side, cause of amputation, and years since amputation. In addition, we asked some question related to the activity levels of the participants. Four activity levels were as follows: house hold ambulator (K1), limited community ambulator (K2), community ambulator (K3) and high level user (K4). Medicare Functional Classification Level (MFCL) defined these level of activities (Hafner & Smith, 2009). The questionnaire also included questions about participant's satisfaction and asked for details of any prosthetic-related problems

that the participant experienced with each liner. In the satisfaction section of the questionnaire, participants were asked about the walking ability of the prosthesis, prosthetic fit, ability to walk up and down stairs, donning and doffing ability with their prostheses, uneven surfaces walking ability, prosthesis appearance, sitting ability with prosthesis, feeling with prosthesis, weight of the prosthesis and overall satisfaction. Problems with the prosthesis consisted of sweating, skin irritation, wounds, pain, swelling; bad smell of residuum or prosthesis, sounds and frustration with the prosthesis. A scale 0 – 100 was used to score overall satisfaction with the prosthesis, with 0 indicating that a participant was "unsatisfied" with his/her liner and 100 being indicative of "completely satisfied". We used the same 0 – 100 scale of measurement for problems related variables, where 0 indicated "extremely bothered" and 100 indicated "not at all bothered".

6.1.4. Data collection

To avoid any mistake, researcher explained all the questions of the questionnaire one by one to all the participants and teach them, how to record your satisfaction or problems score with each prosthesis. Three separate PEQ were completed from each participant with the three different prostheses. As all the participants were using Pelite liner before the study prostheses, therefore questionnaire with Pelite liner were completed on first visit of each prosthesis before the casting for TSB sockets. After the 60 days trial period with each study prosthesis, the participants came to laboratory to complete the questionnaires for Dermo and Seal-In X5 liners prostheses to score and share his/her experience about the liners.

6.1.5. Statistical Analysis

We used non-parametric statistical analysis for data to evaluate the differences between the three liners on four main regions (Anterior, posterior, medial, and lateral) and sub-regions (proximal and distal) of each main region. Therefore we used Kruskal-wallis test to compare the satisfaction and perceived problems between the three liners. Analysis was performed by using version 21 of SPSS (SPSS Inc., Chicago, IL, USA) and level of significance was set at $P< 0.05$ for all analyses.

6.2. Results

The finding highlights that participant were more satisfied with Dermo liner and showed significantly higher score (P<0.05) compared with Pelite and Seal-In X5 liners (Table 6.2). No differences were recorded with the three liners in sitting with prosthesis, appearance of prosthesis and weight of the prosthesis (Table 6.2). Donning and doffing was significantly challenging with Seal-In X5 liner compare with Pelite and Dermo liners (59.00 vs. 87.00 and 92.00, respectively). Overall satisfaction score was (mean=85.00, SD=2.5) with Dermo and (means=63.00, SD=7.91) with Seal-In X5 liner and (mean=66.00, SD=11.25) with Pelite liner (Table 6.2).

Participants experienced less sweating with Pelite liner compared with Dermo and Seal-In X5 liners (mean=92, SD=5.37 vs. mean=76, SD=5.1 vs. mean=67, SD=2.58, P<0.013, respectively). More frustration, pain and skin irritation was recorded with the Seal-In X5 and Pelite liners (Table 6.2). No significant differences were observed in swelling, wound, smell and sound with the three liners (Table 6.2).

6.2.1. Comparison between Dermo and Seal-In X5 liners

Participants showed significant (P<0.05) differences between Dermo and Seal-In X5 liners in seven questions out of ten. Participant's experienced 43.71% higher satisfaction during donning and doffing, 43.82% during level walking with Dermo liner compared with Seal-In X5 liners. Satisfaction was 50.34% more during feeling with the prosthesis and 29.45% higher during walking on uneven surfaces with the Dermo liner compared with Seal-In X5 liners. Overall, participants were 29.72% more satisfied with Dermo liner compared with Seal-In X5 liner. Participants noticed significantly less problems with regard to sweating (76.00 vs. 67.00, P=0.006), skin irritation (90 vs. 83, P=0.003*),* pain (99.00 vs. 80.00, P=0.023*)* and frustration (90.00 vs. 71.00, P=0.012) with Dermo liner compared with Seal-In X5 liner, respectively (Table 6.3).

Table: 6.2 Comparison between the three liners

Satisfaction				
Variable	**Dermo**	**Seal-In X5**	**Pelite**	***P*-value**
Fit of prosthesis	87.00 (2.53)	78.00 (2.73)	74.00 (4.10)	0.013
Donning/doffing	92.00 (2.63)	59.00 (12.41)	87.00 (8.12)	0.003
Sitting with prosthesis	90.00 (6.70)	87.00 (4.27)	83.00 (6.32)	0.061
Walking with prosthesis	89.00 (5.17)	57.00 (12.70)	78.00 (5.37)	0.003
Walking on Uneven surface	74.00 (5.70)	55.00 (8.35)	66.50 (4.74)	0.025
Walking on stairs	67.00 (5.35)	62.00 (7.17)	62.50 (5.40)	0.014
Appearance of prosthesis	87.00 (2.73)	87.00 (2.73)	85.00 (4.71)	0.510
Feel with prosthesis	92.00 (2.73)	55.00 (11.24)	69.00 (7.10)	0.002
Weight of prosthesis	86.00 (5.47)	86.00 (5.47)	86.00 (5.16)	1.001
Suspension	88.50 (7.07)	91.00 (7.37)	74.50 (11.41)	0.003
Overall Satisfaction	85.00 (2.5)	63.00 (7.91)	66.00 (11.25)	0.004
Problems				
Variables	**Dermo**	**Seal-In X5**	**Pelite**	***P*-value**
Sweating	76.00 (5.1)	67.00 (2.58)	92.00 (5.37)	0.006
Sound	80.00 (6.66)	82.00 (8.10)	80.00 (6.66)	0.742
Skin irritation	90.00 (0.00)	83.00 (5.41)	75.00 (7.45)	0.023
Smell	78.00 (8.11)	78.00 (7.91)	75.00 (8.81)	0.692
Wound	92.00 (8.10)	90.00 (9.42)	85.00 (9.42)	0.192
Pain	99.00 (2.10)	80.00 (3.33)	70.00 (5.77)	0.012
Frustration	90.00 (3.33)	71.00 (7.10)	71.00 (6.14)	0.001
swelling	88.00 (2.60)	88.00 (4.21)	85.00 (4.71)	0.181

Satisfaction: 100 represented “completely satisfied” and 0 indicated “not satisfied at all”
Problem: 100 represented “not bothered at all” and 0 indicated “extremely bothered”

6.2.2. Comparison between Dermo and Pelite liner

Participant were more satisfied with Dermo liner compared with Pelite liner and demonstrated significant (P<0.05) differences during fit of the prosthesis (87.00 vs. 74.00; P= 0.002, respectively), donning/doffing (92.00 vs. 87.00; P=0.051, respectively), sitting with the prosthesis (90.00 vs. 83.00; P=0.033, respectively), walking with prosthesis (89.00 vs. 78.00; P=0.004, respectively), walking on uneven surfaces (74.00 vs.66.50; P= 0.007, respectively), feel with the prosthesis (92.00 vs. 669.00; P= 0.004, respectively) and suspension with the prosthesis (88.50 vs.74.50; P=0.011, respectively). Appearance and weight of the prosthesis doesn't show any differences (Table 6.4). Overall satisfaction was 25.16% higher with Dermo liner compared with Pelite liner. Higher score was obtained with Dermo liner compared with Pelite liner during residuum skin irritation (90.00 vs. 75.00; P=0.001, respectively), pain (90.00 vs. 70.00; P=0.005, respectively) and frustration with the prosthesis (90.00 vs. 71.00; P=0.003, respectively). Sweating was significantly less with pelite liner compared with Dermo liner (92.00 vs. 76.00; P=0.001, respectively). Sound, smell and wound between the two liners were not statistically significant (Table 6.4).

6.2.3. Comparison between Seal-In X5 and Pelite liner

Participants were significantly satisfied with Pelite liner compared with Seal-In X5 liner during donning/doffing (59.00 vs.87.00; P=0.002, respectively), walking (57.00 vs. 78.00; P=0.004, respectively), walking on uneven surfaces (55.00 vs. 66.50; P= 0.003, respectively) and feel with the prosthesis (55.00 vs. 69.00; P=0.002, respectively).

Table 6.3: Comparison between Dermo and Seal-In X5 liners

Satisfaction			
Variable	**Dermo**	**Seal-In X5**	***P*-value**
Fit of prosthesis	87.00 (2.53)	78.00 (2.73)	0.013
Donning/doffing	92.00 (2.63)	59.00 (12.41)	0.023
Sitting with prosthesis	90.00 (6.70)	87.00 (4.27)	0.234
Walking with prosthesis	89.00 (5.17)	57.00 (12.70)	0.032
Walking on Uneven surface	74.00 (5.70)	55.00 (8.35)	0.004
Walking on stairs	67.00 (5.35)	62.00 (7.17)	0.036
Appearance of prosthesis	87.00 (2.73)	87.00 (2.73)	1.023
Feel with prosthesis	92.00 (2.73)	55.00 (11.24)	0.004
Weight of prosthesis	86.00 (5.47)	86.00 (5.47)	1.003
Suspension	88.50 (7.07)	91.00 (7.37)	0.461
Overall Satisfaction	85.00 (2.5)	63.00 (7.91)	0.231
Problems			
Variables	**Dermo**	**Seal-In X5**	***P*-value**
Sweating	76.00 (5.1)	67.00 (2.58)	0.006
Sound	80.00 (6.66)	82.00 (8.10)	0.510
Skin irritation	90.00 (0.00)	83.00 (5.41)	0.003
Smell	78.00 (8.11)	78.00 (7.91)	0.876
Wound	92.00 (8.10)	90.00 (9.42)	0.634
Pain	99.00 (2.10)	80.00 (3.33)	0.023
Frustration	90.00 (3.33)	71.00 (7.10)	0.012
swelling	88.00 (2.60)	88.00 (4.21)	0.574

Satisfaction: 100 represented “completely satisfied” and 0 indicated “not satisfied at all”
Problem: 100 represented “not bothered at all” and 0 indicated “extremely bothered”.

Suspension was significantly better with Seal-In X5 liner (see Table 6.5). As for the problems faced with the two liners, significantly less sweating (92.00 vs.67.00; *P*=0.023, respectively) was recorded with Pelite liner and less pain (80.00 vs. 70.00; *P*=0.032, respectively) was observed with Seal-In X5 liner. No difference was observed in smell, wound, and swelling with the two liners (Table 6.5).

6.3. Discussion

Proper fitting of socket have significant effect on patient's satisfaction, comfort and mobility (Ali et al., 2012a). We found significant differences between the three liners both in satisfaction and perceived problems. Participant demonstrated more satisfaction and fewer problems with Dermo liner compared with Pelite and Seal-In X5 liner.

In this study, the participants favored the Dermo liner with shuttle lock over the Pelite liner and Seal-In X5 liner. These findings reflect to the previous study results (McCurdie et al., 1997), where clear preference was given for locking liners, while in other studies Boonstra et al. and Coleman et al.showed Pelite liner to be more favorable (Boonstra et al., 1996; Coleman et al., 2004). These studies oppose the findings of our research and were considerably less positive towards locking liners. The current study also mirror to the study of S.Ali et al. with regard Dermo and Seal-In X5 liner (Ali et al., 2012b).

Lower limb prosthesis should be functional and comfortable for the user, to give the best prospect of continued use (Dumbleton et al., 2009a). In the study of Hatfield and Morrison (Hatfield & Morrison, 2001) the participants felt more comfortable with the locking liners.Another study revealed that locking liners improved socket comfort when compared with Pelite liner (Åström & Stenström, 2004). In previous study the researchers also revealed that participants were more comfortable during walking and stairs negotiations with locking liners (Datta et al., 1996; Yigiter et al., 2002). The same was true with our study as the participants showed more satisfaction during walking, walking on stairs and walking on uneven ground with the locking liner.

Skin problems are often experienced with the prostheses use and appears an amputee in the form of skin irritation, ulcers and abrasion (Dudek et al., 2005; Laing et al., 2011).

Table 6.4: Comparison between Dermo and Pelite liner

Satisfaction			
Variable	**Dermo**	**Pelite**	***P*-value**
Fit of prosthesis	87.00 (2.53)	74.00 (4.10)	0.002
Donning/doffing	92.00 (2.63)	87.00 (8.12)	0.051
Sitting with prosthesis	90.00 (6.70)	83.00 (6.32)	0.033
Walking with prosthesis	89.00 (5.17)	78.00 (5.37)	0.004
Walking on Uneven surface	74.00 (5.70)	66.50 (4.74)	0.007
Walking on stairs	67.00 (5.35)	62.50 (5.40)	0.003
Appearance of prosthesis	87.00 (2.73)	85.00 (4.71)	0.336
Feel with prosthesis	92.00 (2.73)	69.00 (7.10)	0.004
Weight of prosthesis	86.00 (5.47)	86.00 (5.16)	1.002
Suspension	88.50 (7.07)	74.50 (11.41)	0.011
Overall satisfaction	85.00 (2.5)	66.00 (11.25)	0.007
Problems			
Variables	**Dermo**	**Pelite**	***P*-value**
Sweating	76.00 (5.1)	92.00 (5.37)	0.001
Sound	80.00 (6.66)	80.00 (6.66)	1.002
Skin irritation	90.00 (0.00)	75.00 (7.45)	0.001
Smell	78.00 (8.11)	75.00 (8.81)	0.642
Wound	92.00 (8.10)	85.00 (9.42)	0.082
Pain	90.00 (2.10)	70.00 (5.77)	0.005
Frustration	90.00 (3.33)	71.00 (6.14)	0.003
swelling	88.00 (2.60)	85.00 (4.71)	0.130

Satisfaction: 100 represented “completely satisfied” and 0 indicated “not satisfied at all”
Problem: 100 represented “not bothered at all” and 0 indicated “extremely bothered”

These skin problems lead to discomfort and pain and in some cases amputees stop using the prosthesis for a period of time completely. This situation can impact on satisfaction level of the amputees with prosthesis and badly consequence his/her mental eudemonia (Meulenbelt et al., 2006). In the current research, less irritation and pain was experienced with the Dermo linerwith shuttle lock compared to other liners, which mirror to the studies of previous researchers (Ali et al., 2012b; Datta et al., 1996). However, more sweating was experienced with the Dermo and Seal-In X5 liner compared with Pelite liner in our study which reflect the study of Hachisuka et al., where less sweating was reported with Pelite liner (Hachisuka et al., 1998)**.**Participants feel more satisfied and experienced less pain with the Dermo liner, which lead them to walk more without any difficulties.

Fitting of socket and suspension system of prosthesis have great impacts on the participant's comfort, satisfaction and mobility. Silicon liners are rolled over the residuum and closely attached to the skin of the residuum which creates a bond between the residuum and the liner. These qualities of the silicon liners have a positive outcome on suspension of the prosthesis (Baars & Geertzen, 2005). Two research team revealed improved suspension with the silicon liners in their research (Cluitmans et al., 1994; Yigiter et al., 2002). In another study researchers observed improvement in silicon liner suspension in 63% of participants compared to Pelite liner (Hachisuka et al., 1998). These studies mirror with our results, where participants were more satisfied with Seal-In X5 and Dermo liner suspension. Many researchers recorded increase in the appearance of the prosthesis with the silicon liners which contradict the results of current study (Datta et al., 1996; Hachisuka et al., 1998). In the present research participant showed the same interest in the appearance of all the three types of prostheses.

Easy donning and doffing of the prosthesis has important effect on the prosthetic users. Significant easy donning and doffing (P<0.00) has revealed with the Dermo liner in the current study compared with other liners. This is same with the previous study, where the research team revealed favor donning and doffing with the locking liners (Yigiter et al., 2002), while in another study the researchers found both decrease and improvement (Datta et al., 1996). The entire participants reported significant difficulties in donning and doffing with Seal-In X5 liner in this research, which might be concluded that it is due to the five seals around the liner. These results reflect the study of S.Ali et al., where Dermo liner showed high score for donning and doffing compared with Seal-In X5 liner(Ali et al., 2013).

To compare the present study results with the existing literaturewas a challenge. There is no report available to compare the satisfaction and perceived problems between these three liners, especially between the Seal-In X5 and Pelite liner. In summary, all the participants felt satisfied with the Dermo liner and revealed high performance during walking on level walking, stairs, and uneven surfaces. The results also clarify that the participants experienced less problems and frustration with the Dermo liner.

Table 6.5: Comparison between Seal-In X5 and Pelite liner

Satisfaction			
Variable	**Seal-In X5**	**Pelite**	***P*-value**
Fit of prosthesis	78.00 (2.73)	74.00 (4.10)	0.021
Donning/doffing	59.00 (12.41)	87.00 (8.12)	0.002
Sitting with prosthesis	87.00 (4.27)	83.00 (6.32)	0.141
Walking with prosthesis	57.00 (12.70)	78.00 (5.37)	0.004
Walking on Uneven surface	55.00 (8.35)	66.50 (4.74)	0.003
Walking on stairs	62.00 (7.17)	62.50 (5.40)	0.933
Appearance of prosthesis	87.00 (2.73)	85.00 (4.71)	0.334
Feel with prosthesis	55.00 (11.24)	69.00 (7.10)	0.002
Weight of prosthesis	86.00 (5.47)	86.00 (5.16)	1.000
Suspension	91.00 (7.37)	74.50 (11.41)	0.004
Overall satisfaction	63.00 (7.91)	66.00 (11.25)	0.531
Problem			
Variables	**Seal-In X5**	**Pelite**	***P*-value**
Sweating	67.00 (2.58)	92.00 (5.37)	0.023
Sound	82.00 (8.10)	80.00 (6.66)	0.515
Skin irritation	83.00 (5.41)	75.00 (7.45)	0.022
Smell	78.00 (7.91)	75.00 (8.81)	0.341
Wound	90.00 (9.42)	85.00 (9.42)	0.202
Pain	80.00 (3.33)	70.00 (5.77)	0.032
Frustration	71.00 (7.10)	71.00 (6.14)	0.872
swelling	88.00 (4.21)	85.00 (4.71)	0.113

Satisfaction: 100 represented “completely satisfied” and 0 indicated “not satisfied at all”
Problem: 100 represented “not bothered at all” and 0 indicated “extremely bothered”

6.4. Conclusion

The present study demonstrated that the prosthetic liners influence the level of satisfaction of users. It also showed that Dermo liner is the most favored and these results might help the clinicians and prosthetic practitioners in selection criteria of prosthetic liners. However, further study (with larger sample size and more detail questionnaire) is needed to comprehensively compare the effect of these three liners on amputee's satisfaction and perceived problems.

CHAPTER 7

QUALITATIVE STUDY OF PROSTHETIC SUSPENSION SYSTEMS ON SATISFACTION OF INDIVIDUAL'S WITH AMPUTATION'S AND PERCEIVED PROBLEMS WITH THEIR PROSTHETIC DEVICES

Objective: The aim of this study was to investigate the effects of three dissimilar suspension systems, namely the polyethylene foam liner, the silicon liner with shuttle lock and the seal-In liner, on participant's satisfaction and perceived problems with their prostheses.

Design: Questionnaire survey.

Setting: Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran and Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Malaysia.

Participants: A total of 243 persons with unilateral amputation, using prostheses with polyethylene foam liner, silicon liner with shuttle lock and Seal-In liner.

Intervention: Not applicable.

Main Outcome Measure: Descriptive analyses were performed on the demographic information, satisfaction and prosthesis-related problems of the study participants.

Results**:** The results showed significant differences between the three groups regarding the degree of satisfaction and perceived problems with the prosthetic device. Analyses of the individual items revealed that the study participants were more satisfied with the Seal-In liner and experienced fewer problems with this liner. The silicon liner with shuttle lock and Seal-In liner users reported significant differences in maintenance time compared with the polyethylene foam liner. Users of the silicon liner with shuttle lock experienced more sweating, while those who used the Seal-In liner had greater problems with donning and doffing the device.

Conclusion: The results of the survey provide a good indication that prosthetic suspension is improved with the Seal-In liner as compared with the polyethylene foam liner and silicon liner with shuttle lock. However, further prospective studies are needed to investigate which system provides the most comfort and the least problems for participants.

7. Introduction

The suspension system and socket fitting in prosthetic devices have significant impacts on the participant's comfort, mobility and satisfaction (Kristinsson, 1993; McCurdie et al., 1997). Secure suspension decreases residual limb movement within the prosthetic socket by firm attachment of the prosthesis to the residual limb (Van de Weg & Van Der Windt, 2005). Conversely, inappropriate suspension can deteriorate the prosthetic socket fitting, and a poorly fit socket can cause the pain and skin ulcers. These problems may result in unwillingness or inability to use the prosthesis until the pain is relieved and the ulcers healed by the person using the prosthesis (Hoaglund et al., 1983; Levy et al., 1962; Lyon et al., 2000).

There are several methods of suspending prosthesis to the residual limb (Pritham C, 1979). These include:

1) Belt and suprapatellar cuff, which is the most common suspension method and usually the most effective for the majority of wearers (Radcliffe et al., 1961);

2) Figure-of-eight belt, which is a variation of the suprapatelar cuff suspension (Girling & Cummings, 1972);

3) Sleeve suspension, which can develop negative pressure between the socket and residual limb (Chino et al., 1975; Ross, 1990);

4) Supracondylar-suprapatellar (Breakey, 1973);

5) Supracondylar, which is a variation of supracondylar-suprapatelar suspension and is usually used for long residual limbs (Wirta et al., 1990);

6) Thigh corset, which provides more medio-lateral (ML) stability for the users (Cummings et al., 1979);

7) Silicon liner suspension, such as distal locking pin, lanyard and suction suspension (Kapp, 1999).

Patellar tendon bearing (PTB) prosthesis with polyethylene foam liners have been in use since 1950. They are fitted within the socket to provide the residual limb with a soft cushion (Coleman et al., 2004). Polyurethane foam liners are still used in practice, but modern liners are generally made from silicon and other elastomers that offer better suspension and cushioning (Dietzen et al., 1991; Haberman et al., 1992; Madigan & Fillauer, 1991). Silicon and gel liners were introduced worldwide in the mid 1990s and were designed to lessen shear forces and produce better interface bond (Van de Weg & Van Der Windt, 2005). A new type of silicon liner, called the Seal-In liner, utilizes a membrane lip, which is placed circumferentially around the distal end of the liner (Sensinger et al., 2009).

The efficiency of the suspension systems can be evaluated both objectively and subjectively with the use of questionnaires. Researchers have developed numerous questionnaires as a means of assessing consumers' satisfaction with prosthetics and orthotics (Boone & Coleman, 2006; Ferriero et al., 2005; Grise et al., 1993; Legro et al., 1998).The Prosthetic Evaluation Questionnaire (PEQ) has been used to investigate satisfaction and perceived problems among prosthetic users. Dillingham et al., (2001) carried out a survey regarding the use and satisfaction of prosthetic devices with 146 participants, the majority of whom were not satisfied with their prostheses due to pain and skin problems(Dillingham et al., 2001). A study by Kark and Simmons also demonstrated that their study participants were unsatisfied with their prostheses (Kark & Simmons, 2011). A research study showed that 77% of their participant's were more satisfied with their pin and lock system compared with the polyethylene foam liner(Coleman et al., 2004).On the contrary, in a prospective study almost all of the participants (75%) preferred the polyethylene foam liner (Boonstra et al., 1996). Van de Weg et al., (2005) conducted a study on effect of three interfaces on satisfaction and

perceived problems. No significant differences were reported (Van de Weg & Van Der Windt, 2005).

After review of number of studies, only one study has been conducted on the satisfaction with seal-In suspension concept (Gholizadeh et al., 2012). However, the study sample was small. Moreover, some of the existing findings on the satisfaction with different suspension systems had contradictory results. Therefore, the study was aimed to investigate the effects of three different suspension systems on participant's satisfaction and perceived problems with their prostheses. The three systems are the polyethylene foam liner, the silicon liner with shuttle lock, and the Seal-In liner. It is hypothesized that participants would be more satisfied with the Seal-In liner compared with the other two systems.

7.1. Methods

7.1.1. Study Participants

The research team carried out a questionnaire survey among persons with amputations (PTAs) in Janbazan Medicaland Engineering Research Centre (JMERC), Tehran, Iran. We selected 303 men with unilateral (traumatic) amputation from the JMERC database and distributed the questionnaire among them. Participants were required to have used their prostheses for a minimum of 1 year. The satisfaction and perceived problems with the following suspension systems were compared: the polyethylene foam liner, the silicone liner with shuttle lock, and the seal-in liner (Fig. 7.1).

The study was approved by the JMERC and the University Malaya Medical Centre ethics committees.

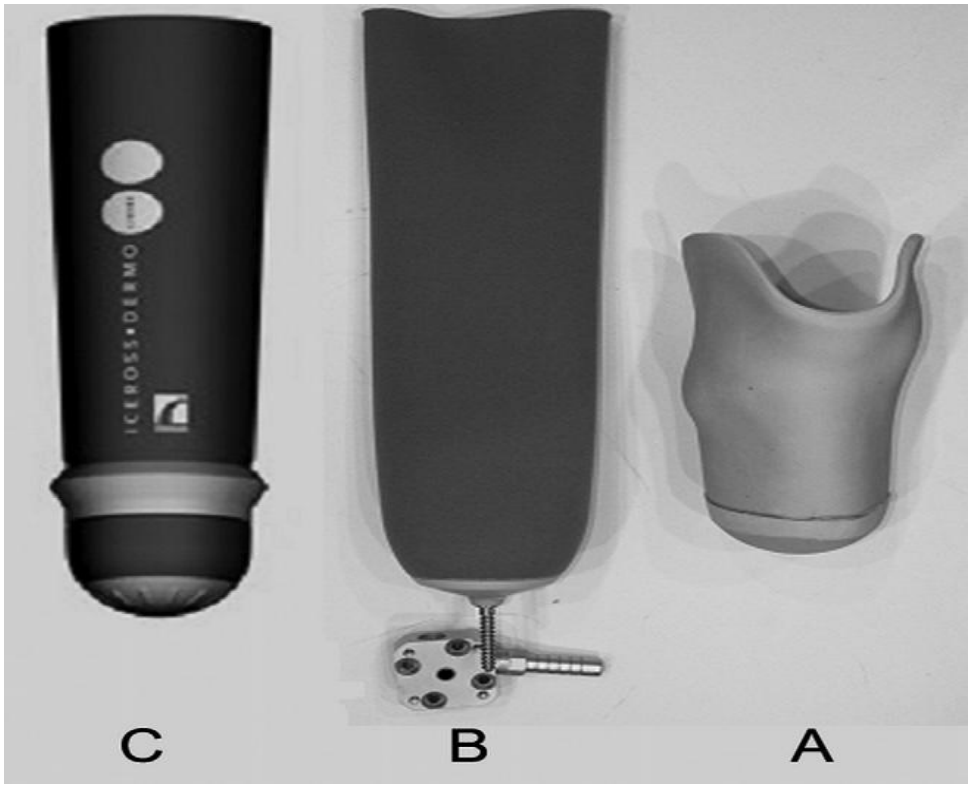

Figure 7.1: Three different suspension systems: polyethylene foam liner (A), silicone liner with shuttle lock (B), and seal-in liner (C)

7.1.2. Questionnaire

To study the effect of the 3 different suspension systems on participant's satisfaction and to identify the perceived problems with the use of the prosthesis, we adopted some elements of the Prosthetic Evaluation Questionnaire. A Persian version of the questionnaire was produced to be used for the participant's at JMERC. The survey was composed of demographic variables (age, sex, education level, marital status, weight, height), cause of amputation, amputation side, and time since last prosthesis. In addition, we asked some questions related to the use and maintenance of the prosthesis, and activity levels of the participants.The activity level was defined based on the Medicare Functional Classification Level (Hafner & Smith, 2009). Four activity levels were as follows: household ambulator (K1), limited community ambulator (K2), community ambulator (K3), and high level user (K4). The questionnaire also included questions about the participant's satisfaction and asked for details of any prosthetic-related problems that the participant experienced with each liner. In the satisfaction section of the questionnaire, participants were asked about the prosthetic fit, their ability to walk with the prosthesis, their ability to walk up and down stairs, their ability to don and doff the prosthesis, their ability to walk on diverse surfaces, the appearance of the prosthesis, the appearance of the suspension, their ability to sit with the prosthesis, and their overall satisfaction. Problems with the prosthesis consisted of sweating, skin irritation, wounds, ulcers, blisters, pistoning within the socket, rotation within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sounds, and pain in the residual limb. A scale from 0 to 100 was used to score overall satisfaction with the prosthesis, with 0 indicating that a participant was "unsatisfied" with the linera nd 100 indicating that a participant was "completely satisfied". For the variables related to

problems/complaints, each item was also measured on a scale from 0 to 100, where 0meant “extremely bothered” and 100 meant “not at all bothered”(Legro et al., 1998).

7.1.3. Analysis procedures

Descriptive analyses were used to analyze the demographic information of the participants. To analyze the participant satisfaction and examine problems related to the liners, we used Multivariate Analysis of Variance (MANOVA) to compute the means of the items related to each type of liner and determine the significance. All data analyses were done using SPSS 16.0.

7.2. Results

7.2.1. Participant's Profile

A total of 243 questionnaires (80.19%) were returned. Themean age, weight, and height of the participant's were44.02±6.26 years, 85.09±15.54kg, and 176.14±6.69cm, respectively.Forty-nine percent of the participants were universitygraduates, 34.6% had a diploma, 12.8% had attended high school, and 3.7% had an elementary school education. Theaverage number of years PTAs had been using prosthesis was22.01±5.95. The number of left-sided PTAs (60.9%) exceededthe number of right-sided PTAs (39.1%). Most of the participant's (63.4%) reported an activity level of K3, followed by18.9% reporting a level of K4 and 17.7% a level of K2. Onaverage, PTAs had used their prosthesis for 11.67±3.25h/d.The average age of the liner was 21.02±14.48 months. There was a significant difference (P<0.05) between the maintenancetime among the 3 suspension systems. The silicone liner withshuttle lock had the longest maintenance time of 2.98±2.63hours per year, followed by the seal-In liner with 2.53±1.52hours per year and the polyethylene liner with 0.54±0.45 hoursper year. Most of the PTAs used the polyethylene foam liner (41.2%). Table 7.1 describes the characteristics of the participants.

Table7. 1: Characteristics of the Survey Respondents (n=243)

Age: years, mean (SD)		44.02±6.26
Gender: male, *n* (%)		243 (100)
Weight: kg, mean (SD)		85.09±15.54
Height: cm, mean (SD)		176.14±6.69
Education: *n* (%)	Elementary	9 (3.7)
	High School	31 (12.8)
	Diploma	84 (34.6)
	Graduate	119 (49.0)
Years since first prosthesis: mean (SD)		22.01±5.95
Cause of amputation: *n* (%)	Trauma	243 (100)
Amputation side:	Right	95 (39.1)
	Left	148 (60.9)
Activity level: *n* (%)	K2	43 (17.7)
	K3	154 (63.4)
	K4	46 (18.9)
Prosthetics use every day: hours (SD)		11.67±3.25
Maintenance per year: hours (SD)		1.88±2.07
Age of Liner: months (SD)		21.02±14.48
Type of liner: *n (%)*		
Silicon liner with shuttle lock		85 (35)
Silicon Seal-In liner		58 (23.9)
Polyethylene foam liner		100 (41.2)

Note: value are mean ± SD or n (%)

7.2.2. Satisfaction and Use

Most of the PTA used the prosthesis for more than 11.67 hours per day and it was not found to be significantly different between the three suspension systems. The mean overall satisfaction on a 0-100 point numerical rating scale was 63.10 for the polyethylene foam liner, 75.94 for the silicon liner with shuttle lock and 83.10 for the

Seal-In liner. As shown in Table 7.2, PTA was more satisfied with the Seal-In liner suspension. The *p*-values in the test of between participants effect, which in fact are the results of three separate univariate MANOVA as a step down analysis, showed that the suspension type had a significant correlation with all satisfaction items ($P<.05$) for all items). This can be further understood by looking at Table 7.2 which shows the ranking by the satisfaction ratings.

7.2.3. Problems/Complaints

The multivariate tests in Table 7.3 show that there was a significant difference between the nine complaint/problem items ($P<.05$) among the three suspension systems. The *p*-values in the test of between-participants effect showed that the suspension type has a significant correlation with all complaint/problem items ($P<.05$). The only exception was the "sweat complaint", which had a*P*-value of .074. Participants found donning and doffing to be more difficult with the Seal-In liner, while pistoning was recorded the highest for the polyethylene foam liner (Table 7.3).

Table 7.2: Satisfaction and use with three studied suspension systems

Satisfaction Type/Liner Type	Mean	*P- value	Ranking†
Fitting satisfaction		.002	
Silicone liner with shuttle lock	79.59		2
Polyethylene foam liner	64.82		3
Seal-In liner	87.09		1
Donning and doffing satisfaction		.001	
Silicone liner with shuttle lock	71.44		2
Polyethylene foam liner	79.68		1
Seal-In liner	57.24		3
Sitting satisfaction		.004	
Silicone liner with shuttle lock	68.80		3
Polyethylene foam liner	76.44		2
Seal-In liner	79.41		1
Walking satisfaction		.003	
Silicone liner with shuttle lock	72.80		2
Polyethylene foam	65.21		3
Seal-in liner	84.66		1
Uneven walking satisfaction		.001	
Silicone liner with shuttle lock	63.91		2
Polyethylene foam liner	54.10		3
Seal-In liner	77.93		1
Stair satisfaction		.002	
Silicone liner with shuttle lock	68.75		2
Polyethylene foam liner	60.83		3
Seal-In liner	80.60		1
Suspension satisfaction		.005	
Silicone liner with shuttle lock	81.72		2
Polyethylene foam liner	55.20		3
Seal-In liner	93.71		1
Cosmetic satisfaction		.004	
Silicone liner with shuttle lock	69.05		3
Polyethylene foam liner	73.27		2
Seal-In liner	83.10		1
Overall satisfaction with prosthesis		.003	
Silicone liner with shuttle lock	75.94		2
Polyethylene foam liner	63.14		3
Seal-In liner	83.10		1

*Greater mean indicates more satisfaction and use

†Satisfaction increases from the ranking 3 to 1

7.3. Discussion

Prosthetic satisfaction is a multifactorial issue. These aspects mainly include prosthetic alignment, prosthetic components, prosthetists skill, residual limb condition, level of activity, and socket fit (Legro et al., 1998).We investigated different suspension systems as an influencing factor on PTAs use and satisfaction with the prostheses.

The findings supported our hypothesis that participants would be more satisfied with the seal-In liner compared with other 2 systems.With the exception of the "sweat complaint," significant differences were found between different suspension systems with respect to perceived problems. Sweating was reported more often by PTAs with the locking liner (55 score) than by those with the polyethylene foam and seal-In liners. In addition, we registered significant differences between different suspension liners with respect to participant use and satisfaction. However, the overall satisfaction rating was higher with the seal-In liner (83.10 score) when compared with the locking liner (75.94%) and the polyethylene foam liner (63.14 score).

In this study, the participants preferred the silicone liner with shuttle lock and seal-In liner over the polyethylene liner. These results contradict the findings of Coleman et al.,(2004) and Boonstraet al.,(1996) which studies showed the polyethylene foam liner to be more favourable (Boonstra et al., 1996; Coleman et al., 2004). The findings of both crossover studies were considerably less positive towards locking liners; however, the study by McCurdie et al (McCurdie et al., 1997) clearly demonstrated the preference for locking liners. Van der Linde et al (Linde et al., 2004) indicated that professionals in the field of rehabilitation preferred a locking liner in their research study. Vacuum suspension is said to improve proprioception in prosthetic users, (Street, 2006) and this may be one possible explanation of preference for the seal-in liner.

Table 7.3: Comparison between 3 different suspension systems with regard to complaints/problems

Problem/ Liner Type	Mean*	*P*-value	Ranking†
Sweat complaint		**.**074	
Silicone liner with shuttle lock	55.00		3
Polyethylene foam liner	60.16		2
Seal-In liner	64.78		1
Wound complaint		.002	
Silicone liner with shuttle lock	81.85		2
Polyethylene foam liner	75.04		3
Seal-In liner	95.17		1
Irritation complaint		.005	
Silicone liner with shuttle lock	81.28		2
Polyethylene foam liner	75.10		3
Seal-In liner	94.66		1
Pistoning within the socket		.006	
Silicone liner with shuttle lock	84.18		2
Polyethylene foam	63.95		3
Seal-in liner	96.47		1
Rotation within the socket		.002	
Silicone liner with shuttle lock	80.18		3
Polyethylene foam liner	81.65		2
Seal-In liner	99.57		1
Inflation complaint		.021	
Silicone liner with shuttle lock	86.75		2
Polyethylene foam liner	89.64		3
Seal-In liner	94.91		1
Smell complaint		.004	
Silicone liner with shuttle lock	72.49		2
Polyethylene foam liner	63.94		3
Seal-In liner	94.91		1
Sound complaint		.003	
Silicone liner with shuttle lock	70.21		3
Polyethylene foam liner	80.28		2
Seal-In liner	96.81		1
Pain complaint		.004	
Silicone liner with shuttle lock	80.62		3
Polyethylene foam liner	81.18		2
Seal-In liner	92.67		1

*Greater mean indicates more satisfaction and use
†Satisfaction increases from the ranking 3 to 1

Hatfield and Morrison (Hatfield & Morrison, 2001) revealed that their participants who used locking liners felt more comfortable. Astrom and Stenstrom (Åström & Stenström, 2004) stated that locking liners delivered improved socket comfort when compared with

polyethylene liners. The same was true with our study, as the participants were more satisfied with the locking liner and seal-In liner during activities that involved walking, walking on uneven ground, and walking onstairs.

Enhanced suspension and cosmesis of the prostheses had a positive effect on prosthetic function and the participant's satisfaction (Wirta et al., 1990). The current study showed improved suspension with the silicone liner with shuttle lock and seal-In liners when compared with the polyethylene foam liner. Cluitmans et al (Cluitmans et al., 1994) and Baars and Greetzen (Baars & Geertzen, 2005) found improved suspension with the locking liners. The ease of donning and doffing has an important effect on prosthetic use (Baars et al., 2008, Gauthier-Gagnon et al., 1999). Our results showed that participant's who used the polyethylene and locking liners found donning and doffing easier than those who used the seal-In liner. The data revealed that the polyethylene liner was the most durable of the 3 suspension systems. This is compatible with the findings of Van de Weg and Van der Windt (Van de Weg & Van Der Windt, 2005) and Coleman et al (Coleman et al., 2004).

The only study on the effect of seal-In liners on participant's satisfaction revealed that the participants were more satisfied with the seal-In liner than the locking liner (Gholizadeh et al., 2012). However, this study did not purely examine satisfaction and perceived problems. Similarly, we found that all the satisfaction parameters were higher for the seal-In liners than they were for the locking system and the polyethylene foam liner. Furthermore, statistical analyses revealed that the participants had fewer problems with the seal-In liner than they did with the 2 other liners. Nevertheless, donning and doffing the seal-In liner was difficult, which is also consistent with the findings of Gholizadehet al.(Gholizadeh et al., 2012).

7.4. Study Limitations

One limitation of this study was that it was difficult to fabricate 3 individual prostheses with 3 different suspension systems for each of the participants to give equal chance for the comparison. Furthermore, the trajectory of prosthetic suspension systems, including the timing and extent of prostheses used undereach was not determined. Future research should determine the factors affecting the prescription or selection of the suspension type by the prosthetist and PTA.

7.5. Conclusions

In this study, the participants reported significant differences in their experiences with different suspension systems. There is clear evidence from this study that supports the view that the seal-In liner has higher user's satisfaction. There is also good reason to believe that the prosthetic suspension may be improved with the seal-In liner. A further study with a larger number of participants is needed to compare the seal-In liner with other suspension systems.

CHAPTER 8

CONCLUSION AND FUTURE DIRECTIONS

Suspension system and socket fitting in prosthetic devices significantly affect the amputee's comfort, mobility, and satisfaction. Lower-limb prosthetic users experience pressure between the socket and residual limb during daily activities. The underlying soft tissues and skin of the residual limb are not accustomed to weight-bearing; thus, the risk of degenerative tissue ulcer in the residual limb exists because of constant or repetitive peak pressure applied by the socket. Liners are one of the most important parts of amputees' prostheses. Silicon liners are considered to be the best liners for residual limb and claim numerous advantages. As mentioned in Chapter 1, no detailed study has been conducted to check the interface pressure between socket and residual limb with common silicon liners (Dermo and Seal-In X5 liner) during level walking, stair, and ramp negotiations, as well as to evaluate their effect on patient satisfaction. Therefore, to fill this gap, this study aimed to evaluate the interface pressure between socket and residual limb during level walking and stair and ramp negotiations.

8. Conclusions

As highlighted in Chapter 1.1, this thesis contains five objectives. This study aims to investigate the effect of different suspension system and evaluate the interface pressure between socket and residual limb during level walking and during stair and ramp negotiations, as well as their effect on patient's satisfaction. The study also aims to compare the effect of Dermo, Seal-In X5, and pelite liners on amputees' satisfaction and perceived problems.

The qualitative study revealed that the Seal-In suspension system provides more favorable suspension compared to locking and Pelite liners. Participants were very satisfied with Seal-In suspension system.

The result of interface pressure analyses showed that less pressure is experienced within the socket when wearing the Dermo liner during level walking. Moreover, the subjects had fewer problems and complaints with the Dermo liner. Hence, we can conclude that the Dermo liner provides more comfortable socket–residual limb interface than the Seal-In X5 liner during level walking. However, despite this result, the Seal-In X5 liner offers better suspension during level walking.

Prosthesis users experience different pathways, such as level ground, ramps, stairs, and other uneven surfaces, during their daily activities. Studies showed that lower-limb amputees are greatly affected in dealing with the environmental barriers, such as slopes and stairs, because of the loss of foot and ankle mechanism, and reported high interface pressure (Dou et al., 2006; Jones et al., 2006).

This study revealed that high interface pressure exists between the residual limb and socket with the Seal-In X5 interface systems. The Dermo interface system caused minimal pressure, and the participants were more comfortable while using this system during stair negotiation. The participants were more confident and comfortable with the use of the Dermo interface system during stair negotiation. The findings of this study revealed that high magnitude of pressure during ramp ascent and descent was recorded with Seal-In X5 liner. Amputees feel more satisfied and experienced minimum prosthetic issues using Dermo liner during ramp negotiation.

During comparison between Dermo, pelite, and Seal-In X5 liners, participants were more satisfied, experienced fewer problems, and preferred Dermo liner over other liners. Dermo liner may be the best choice for transtibial prosthetic users.

In summary, less interface pressure was recorded in all types of walking with Dermo liner. This study also demonstrated that interface pressure between socket and residual limb, and prosthetic liners influence user satisfaction levels. The study results showed that Dermo liner is the best choice for transtibial users for all types of walking.

These results will also help clinicians and prosthetic practitioners in their selection criteria for prosthetic liners.

8.1. Future direction

The distribution of interface pressure between the socket and residual limb is an important factor in socket design and fit. This study shows that more pressure is borne on the residual limb than the socket Decreasing interface pressure between socket and residual limb is important for better walking and healthy residual limb. The researcher is aiming to develop a socket that creates less interface pressure between the socket and residual limb.

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APPENDIX

LIST OF PUBLICATIONS AND PAPERS PRESENTED

A.1 Peer-reviewed publication

1. Ali, S., Abu Osman, N. A., Naqshbandi, M. M., Eshraghi, A., Kamyab, M., & Gholizadeh, H., (2012). Qualitative Study of Prosthetic Suspension Systems on Transtibial Amputees' Satisfaction and Perceived Problems With Their Prosthetic Devices. *Archives of physical medicine and rehabilitation*, 93(11), 1919-1923.

2. Ali, S., Osman, N. A. A., Mortaza, N., Eshraghi, A., &Gholizadeh, H., (2012). Clinical investigation of the interface pressure in the trans-tibial socket with Dermo and Seal-In X5 liner during walking and their effect on patient satisfaction. *Clinical Biomechanics*, 27(9), 943-048.

3. Ali, S., Osman, N. A., Eshraghi, A., Gholizadeh, H., &Abd Razak, N.A., (2013). Interface Pressure in Transtibail Socket during Ascent and Descent Stairs and its Effect on Patient Satisfaction. *Clinical Biomechanics*, 28(9-10), 994-999.

4. Ali, S., Osman, N. A., Hussain S., Abd Razak, N.A., (2014). The effect of Dermo and Seal-In X5 prosthetic liners on pressure distributions and reported satisfaction during ramp ambulation in persons with transtibial limb loss. *European Journal of Rehabilitation Research*. (In press)

5. Ali, S., Osman, N. A., Arifin, A., Gholizadeh, H., &Abd Razak, N.A., (2014). Comparative study between Dermo, Pelite and Seal-In X5 liners: Effect on patient's satisfaction and perceived problems. *Scientific World Journal*, 2014 (2014).

A. 2 Abstract in conferences

1. Ali, S.,Abu Osman, N. A., Eshraghi, A., Gholizadeh, H., Abdul Latif, L., Varadan, P., N.Abd Razak 2013. The effect of Dermo and Seal-In X5 liner on Transtibial Amputees Satisfaction. *ISPO* world congress India 2013. *Prosthetics and Orthotics International, 2013.*

2. Ali, S., Osman, N. A., Varadan, P., GholizadehH., EshraghiA., Hussain, S.(2013). Interface Pressure Distribution in Two Transtibial Prosthetic Liner Systems During Walking on Ramp Up and Down and Effect on Patient Satisfaction. O&P World Congress (2013), Orlando, Florida, USA.

A.3 Study Questionnaire

University Malaya Medical Centre (UMMC)
University Malaya

Study questionnaire

A: Patient information

Sex: ☐ Male ☐ Female Marital status ☐

Age: …… Weight (Kg): ……

Height (cm): ……...

Education: ☐ Primary ☐ Secondary School ☐ Diploma ☐ Graduate

☐ Post Graduate

Years since first prosthesis: …….

Cause of Amputation: ☐ Trauma ☐ Vascular disease ☐ Tumor ☐ Diabetics

☐ Other_____

Amputation side: ☐ Right ☐ Left ☐ Bilateral

Liner: Sports liner with lock ☐ Polyethylene foam ☐ Other_____

Level of Activity (Prosthetic K Level): ☐ K1-K2 ☐ K2-K3 ☐ K3-K4

Which liner did you have before? ☐ Sports liner with lock ☐ Polyethylene foam

☐ Other_____

How satisfied are you with your current interface and prosthesis compared with the previous one? ☐ More Satisfied ☐ Less satisfied ☐ No difference ☐ No opinion

How many hours you use prosthesis every day? _____

How many times (per year) you go to the clinic for prosthetics maintenance? _____

How do you rate the durability of the liner? ☐

☐ Very durable ☐ Durable ☐ Poorly durable ☐ Not durable

B. Use and satisfaction.

How satisfied are you with the following?

1: Fit of prosthesis (comfort to wear):

Unsatisfied Completely satisfied

2: Ability to don and doff prosthesis:

Unsatisfied Completely satisfied

3: Ability to sit with prosthesis:

Unsatisfied Completely satisfied

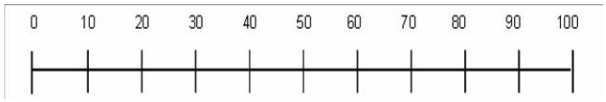
4: Ability to walk with prosthesis:

Unsatisfied Completely satisfied

5: Ability to walk on uneven terrain:

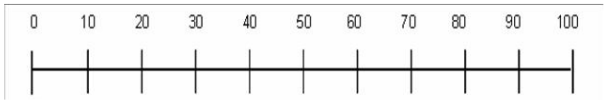
Unsatisfied Completely satisfied

6: Ability to walk up and down stairs:



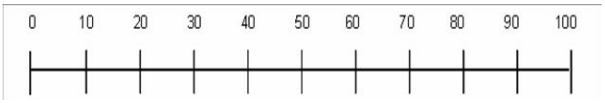
Unsatisfied Completely satisfied

7: suspension:



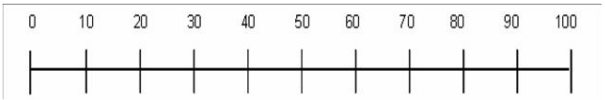
Unsatisfied Completely satisfied

8: Appearance of prosthesis:



Unsatisfied Completely satisfied

9: Overall satisfaction with the prosthesis:



Unsatisfied Completely satisfied

C. Prosthesis related problems/complaints.

Please answer, based on your experiences of the past 4 weeks:

How bothered were you with any of the following problems during the last 4 weeks?

1: Sweating:

Extremely bothered Not at all

2: Wounds/ingrown hairs/blisters:

Extremely bothered Not at all

3: Skin irritations:

Extremely bothered Not at all

4: Pistoning within the socket:

Extremely bothered Not at all

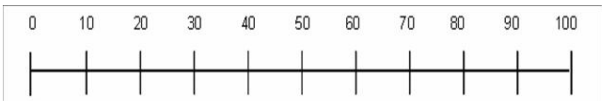
5: Rotation within the socket:

Extremely bothered Not at all

6: Swelling stump:

Extremely bothered Not at all

7: Unpleasant smells of prosthesis or stump:

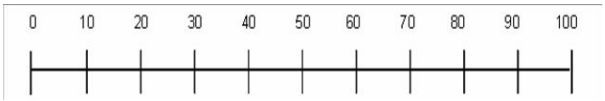


Extremely bothered Not at all

8: Unwanted sounds:

Extremely bothered Not at all

9: pain in stump:



Extremely bothered Not at all

Date _____ Patient Signature_____