

STUDY OF STUMP-LINER/SOCKET INTERFACE MOVEMENT FOR
ICEROSS SEAL-IN[®] X5 AND DERMO[®] LINERS IN TRANSTIBIAL
AMPUTEES

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ABSTRACT

The method of attachment of prosthesis to the residual limb (suspension) and socket fitting is a critical issue in the process of providing an amputee with prosthesis. Different suspension methods try to minimize the pistoning movement inside the socket to enhance the amputee's gait and satisfaction. The ICEROSS Seal-In[®] X5 and Dermo[®] Liner by Ossur are new suspension liners that intend to reduce pistoning between the socket and liner. Since the effects of these new liners on suspension during ambulation are unclear, this study aimed to evaluate the pistoning effect of these liners on ten transtibial amputees. To achieve the aim of the study, two prostheses with ICEROSS Seal-In[®] X5 and the ICEROSS Dermo[®] Liner were fabricated for each subject by the researcher himself. The vertical displacement within the socket in static positions and during the gait (dynamic) was measured using two novel methods (Vicon motion system and a photographic method) for the first time in this study. The reproducibility of measurements in different trials of one session and between two sessions by two observers was shown to be high. These new methods enabled the researcher to measure the pistoning between the liner and prosthetic socket. The results demonstrated that the pistoning within the socket when ICEROSS Seal-In[®] X5 was used decreased (71%) in comparison to the ICEROSS Dermo[®] Liner. Furthermore, a significant difference between the two liners under different static and dynamic conditions was found ($p < 0.05$). Participants needed to put in extra effort for donning and doffing the prosthesis with ICEROSS Seal-In[®] X5 liner; however, this type of liner provided less pistoning during the ambulation. These new approaches that use the motion analysis system or photographic method in this study can be an alternative for measuring the pistoning effect in the prosthetic socket.

ABSTRAK

Kaedah penyambungan prostesis kepada anggota kaki (penggantungan) dan pemasangan soket merupakan isu kritikal dalam proses menyediakan orang yang kehilangan anggota dengan prostesis. Kaedah penggantungan yang berbeza cuba diterapkan untuk meminimumkan pergerakan pempistonan di dalam soket untuk meningkatkan gaya berjalan dan kepuasan kepada orang yang kehilangan anggota. ICEROSS Seal-In[®] X5 dan Dermo[®] Liner oleh Ossur adalah pelapik penggantungan baru yang dicadangkan untuk mengurangkan pempistonan antara soket dan liner. Sejak kesan liner baru ini mengenai penggantungan semasa ambulasi tidak jelas, kajian ini bertujuan untuk menilai kesan pempistonan pelapik baru ini kepada sepuluh orang yang kehilangan anggota pada paras transtibial. Untuk mencapai matlamat kajian, dua prostesis dengan ICEROSS Seal-In[®] X5 dan ICEROSS Dermo[®] Liner telah direka untuk setiap subjek oleh penyelidik sendiri. Anjakan tegak dalam soket dalam kedudukan statik dan pada gaya berjalan (dinamik) adalah diukur dengan menggunakan dua kaedah baru (gerakan sistem VICON dan kaedah fotografi) buat kali pertama dalam kajian ini. Penghasilan semula pengukuran dalam ujian yang berlainan dalam satu sesi dan antara dua sesi oleh dua pemerhati telah menunjukkan ukuran yang tinggi. Kaedah baru ini membolehkan penyelidik mengukur pempistonan antara pelapik dan soket prostetik. Keputusan menunjukkan bahawa pempistonan pada soket ICEROSS Seal-In[®] X5 menunjukkan penurunan (71%) berbanding dengan Liner ICEROSS Dermo[®]. Tambahan pula, perbezaan yang ketara antara kedua-dua liner di bawah keadaan statik dan dinamik yang berlainan diperolehi ($p < 0.05$). Peserta memerlukan usaha tambahan untuk memakai dan menanggalkan prostesis dengan ICEROSS Seal-In[®] X5; walau bagaimanapun, jenis pelapik yang disediakan kurang pempistonan semasa ambulasi. Pendekatan-pendekatan baru yang menggunakan sistem

gerakan analisis atau kaedah fotografi dalam kajian ini boleh menjadi satu alternatif untuk mengukur kesan pempistonan dalam soket prostetik.

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DEDICATION PAGE:

To the memory of my eternal love, my mother

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LIST OF ISI PUBLICATIONS

The research described in this thesis has led to the presentations and publications of the following:

Journals

1. **Gholizadeh, H.**, Abu Osman, N.A., Kamyab, M., Eshraghi, A., Wan Abas, W.A.B., Azam, M.N. Transtibial prosthetic socket pistoning: Static evaluation of Seal-In[®] X5 and Dermo[®] Liner using motion analysis system. **Clinical Biomechanics**. 2012; 27:34-39.
2. **Gholizadeh, H.**, Abu Osman, N.A., Kamyab, M., Eshraghi, A. Lúðvíksdóttir, Á.G., Wan Abas, W.A.B. Clinical evaluation of two prosthetic suspension systems in a bilateral transtibial amputee. **American Journal of Physical Medicine & Rehabilitation**. 2011, DOI: 10.1097/PHM.0B013e31823c74d7
3. **Gholizadeh, H.**, Abu Osman, N.A., Lúðvíksdóttir, Á.G., Eshraghi, A., Kamyab, M., Wan Abas, W.A.B. A new approach for the pistoning measurement in transtibial prosthesis. **Prosthetics and Orthotics International**. 2011; 35 (4): 360-364
4. **Gholizadeh, H.**, Abu Osman, N.A., Eshraghi, A. Effect of Vacuum-assisted Socket and Pin Suspensions on Socket Fit. **Archive of Physical Medicine and Rehabilitation**. 2012 (Accepted)
5. **Gholizadeh, H.**, Abu Osman, N.A., Eshraghi, A., Ali, S., Sævarsson, S.K., Wan Abas, W.A.B. Transtibial prosthetic suspension: less pistoning versus easy donning and doffing, **Journal of Rehabilitation Research & Development**. 2012, (Accepted)
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7. Eshraghi, A., **Gholizadeh, H.**, Abu Osman, N.A., Comments on "Assessment of amputee socket-stump-residual bone kinematics during strenuous activities using Dynamic Roentgen Stereogrammetric Analysis" (Volume 43, Issue 5, 2010), **Journal of Biomechanics**. 2011; 44(16):2851-2.

Proceedings

1. **Gholizadeh H.**, Abu Osman N.A., Lúðvíksdóttir Á.G., Kamyab M., Eshraghi A., Wan Abas W.A.B., (2011). A New Method for Measuring Pistoning in Lower Limb Prosthetic. In NA. Abu Osman, W.A.B. Wan Abas, A. K. Abdul Wahab and Hua-Nong Ting (Eds.) *5th Kuala Lumpur International Conference on Biomedical Engineering 2011IFMBE* Volume 35, Part 16, (pp.728-731), Berlin Heidelberg: Springer. DOI: 10.1007/978-3-642-21729-6_177
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TABLE OF CONTENTS

ABSTRACT	iii
ABSTRAK	iv
ACKNOWLEDGEMENTS	vi
DEDICATION PAGE:	vii
LIST OF ISI PUBLICATIONS	viii
LIST OF FIGURES	xiii
LIST OF TABLES	xv
LIST OF ABBREVIATIONS/NOTATIONS	xvi
CHAPTER ONE: INTRODUCTION	1
1.1 Limb loss	1
1.2 Causes of Amputations	2
1.3 History of prosthetics	3
1.4 Prosthesis	4
1.5 Processes of making a trans-tibial prosthesis (Iceross system)	5
1.5.1 Patient evaluation	5
1.5.2 Measurements	5
1.5.3 Casting	6
1.5.4 Pouring	6
1.5.5 Modification	7
1.5.6 Making the test socket and checking on the patient	7
1.5.7 Socket Fabrication and Assembly and Alignment	8
1.5.8 Gait Training	8
1.5.9 Advance Gait Training	8
1.6 Suspensions (Traditional and contemporary suspension)	8
1.7 Liners	10
1.7.1 Pelite	11
1.7.2 Silicon liners	11
1.8 Objectives of the Study	13
1.9 Hypothesis	13
CHAPTER TWO: LITERATURE REVIEW	14
2.1 Evaluating of prosthetics suspension systems	14
2.1.1 Study population	17
2.1.2 Prosthesis specifications	18
2.1.3 Data presentation	19

2.1.4	Pistoning measurement methods	20
2.1.5	Static pistoning	23
2.1.6	Dynamic pistoning.....	25
2.1.7	Amount of pistoning.....	28
CHAPTER THREE: METHODOLOGY		34
3.1	Variables.....	34
3.2	Subjects.....	35
3.3	Flowchart of the study	37
3.4	Socket casting.....	38
3.5	Standard Operating Procedure.....	39
3.5.1	Patient's evaluation and socket casting.....	39
3.5.2	Making checking socket and prosthetic alignment.....	40
3.5.3	Making definitive socket.....	42
3.6	Data acquisition (Vicon system).....	43
3.6.1	Measuring the pistoning in static position	44
3.6.2	Measuring the pistoning in dynamic position.....	50
3.7	Data acquisition (photographic method).....	52
3.7.1	Equipments and Measurements	52
3.7.2	Position for measuring pistoning.....	53
3.7.3	Measuring pistoning	54
3.8	Questionnaire.....	55
CHAPTER FOUR: RESULTS		56
4.1	Pistoning measurements (static Position).....	56
4.1.1	Adding loads	56
4.1.2	Removing loads	57
4.2	Pistoning measurements (Dynamic Evaluation).....	61
4.3	Satisfaction	61
CHAPTER FIVE: DISCUSSION		67
5.1	Evaluation of current methods.....	68
5.2	Adding loads	69
5.3	Removing loads.....	70
5.4	Pistoning during gait cycle.....	71
5.5	Satisfaction	72
5.6	Photographic method	73
5.7	Limitations of the Study.....	75
CHAPTER SIX: CONCLUSIONS		76

REFERENCES..... 78

Appendix A- Medical Ethics committee approval

Appendix B- publications

Appendix C- Prosthetics components

Appendix D- List of prosthetics components donated by Össur

(Reykjavik, Iceland)

Appendix E- Questionnaire

Appendix F- Definition and Abbreviation

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LIST OF FIGURES

Figures	Titles of Figures	Page
Figure 1.1	: Typical 18th century transtibial amputation (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith 2004)	1
Figure 1.2	: Various levels of lower-extremity amputations (Reproduced from Wound healing complications associated with lower limb amputation – Harker et al., 2006)	3
Figure 1.3	: Cosmetic wooden hallux prosthesis found on female mummy circa 1000 BCE. Note laced leather band around forefoot (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith, 2004)	4
Figure 1.4	: Patient evaluation	5
Figure 1.5	: Stump measurement	6
Figure 1.6	: Casting procedures	6
Figure 1.7	: Modification of positive cast	7
Figure 1.8	: Making the test socket and checking on the patient	7
Figure 1.9	: Static alignment and dynamic alignment	8
Figure 1.10	: skin problems in transtibial amputees	9
Figure 1.11	: Suprapatellar strap (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith 2004).	10
Figure 1.12	: Pin and lock system	10
Figure 1.13	: Polyethylene foam material	11
Figure 1.14	: Seal-In X5 liner	12
Figure 1.15	: Dermo liner	12
Figure 1.16	: Donning and Doffing with Seal-In X5 transtibial liner (Reproduced from Össur, 2008).	12
Figure 2.1	: Different suspension systems in transtibial amputees (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith 2004).	15
Figure 2.2	: Axial movement detector (Reproduced from Witra et al., 1990)	20
Figure 2.3	: Measuring the tibia vertical movement by radiographic method (Reproduced from Grevsten and Erikson, 1975)	21
Figure 2.4	: Radiographic method for measuring pistoning (Reproduced from Soderberg et al., 2003)	23
Figure 2.5	: Spiral CT examination (Reproduced from Madsen et al., 2000)	25

Figure 2.6	: Non contact sensor for measuring pistoning inside the socket (Reproduced from Sanders et al., 2006)	26
Figure 2.7	: Measuring pistoning using Roentgen Stereogrammetric Analysis (Reproduced from Papaioannou et al., 2010).	27
Figure 2.8	: Vertical displacement of socket & skin markers (Reproduced from Papaioannou et al., 2010)	30
Figure 3.1	: Patients' evaluation and measurements	37
Figure 3.2	: Process flow of the project	37
Figure 3.3	: Prosthetic liner used in this project	38
Figure 3.4	: Prosthetic foot (Talux-Ossur)	39
Figure 3.5	: The casting and modification process	40
Figure 3.6	: Procedures of making checking socket	41
Figure 3.7	: Adjusting the prostheses alignment	41
Figure 3.8	: Process of making the socket with epoxy resin	42
Figure 3.9	: Position of markers in measuring the pistoning in full weight bearing position (A) and semi weight bearing position (B), the left side shows the position of markers on the socket and the liner.	45
Figure 3.10	: Process of adding and removing loads	46
Figure 3.11	: A bird-eye's view of the cameras and force plates setup. The seven cameras were placed at the four corners of the room and two in line with the force plates. The two force plates were embedded in the middle of the capture volume.	48
Figure 3.12	: (up) Full body marker placements, (down) only sixteen markers of the lower body are used for this study	49
Figure 3.13	: A) full weight bearing; B) non weight bearing; C) adding load	54
Figure 4.1	: The pistoning (static) between socket and Dermo [®] liners in subjects 2 and 5	59
Figure 4.2	: The pistoning (static) between socket and Seal-In [®] X5 liners in subjects 2 and 5	60
Figure 4.3.	: The average of pistoning between the liners and socket in different gait cycle (n=10)	62
Figure 4.4	: Sample pistoning patterns with Seal-In [®] X5 and Dermo [®] liner during one gait cycle for subjects 2 (top) and 5(bottom)	63
Figure 4.5	: The comparison of mean displacement in different phases of the gait cycle (n=10)	64

LIST OF TABLES

Table	Title of Table	Page
Table 2.1	: Characteristics of the subjects	18
Table 2.2	: Study population	19
Table 2.3	: Distribution of studies based on the methodology and prosthetic components	22
Table 3.1	: Variables (Independent and dependent) from the primary and secondary	35
Table 3.2	: Subjects' characteristics	36
Table 3.3	: Lower limb marker labels, definitions and positions	50
Table 4.1	: Average of displacement (SD) between two markers after adding and removing load in six subjects	58
Table 4.2	: The average of pistoning between the liners and socket in different gait	65
Table 4.3	: Comparison of satisfaction and perceived problem with Dermo [®] and Seal-In [®] X5	66

LIST OF ABBREVIATIONS/NOTATIONS

%	Percentage
mm	Millimeter
g	Gram
3D	Three dimensional
AP	Antro posterior
ROM	Range of motion
ICEROSS	Icelandic Roll on Silicone Socket.
PVD	Peripheral vascular disease
N	Newton
HZ	Hertz
SD	Standard deviation
BK	Below knee
TSB	Total surface bearing

CHAPTER ONE: INTRODUCTION

1.1 Limb loss

Limb loss in its acquired form is called amputation which usually is the result of disease, injury or surgery. On the other hand, congenital limb loss or limb deficiency (all or part of the limb) is present at the birth (Douglas, 2004).

In fact, amputation of the limb is generally the final option taken in order to save the remaining limbs from any further damage.



Figure 1.1: Typical 18th century transtibial amputation (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith 2004).

Figure 1.1 shows a typical 18th century transtibial amputation performed swiftly without anesthesia. The assistant on the right compressed the thigh to control hemorrhage. All tissues were divided at the same level, commonly resulting in a residual limb of poor quality.

1.2 Causes of Amputations

According to Douglas G. Smith (2004), causes of amputation can be classified under any of the followings:

1. Trauma
2. Tumors
3. Peripheral vascular disease (PVD)
4. Congenital limb deficiencies

Today peripheral vascular disease (PVD) is considered as the most common cause of amputation among adults. Any damage to the arteries and veins are referred to as PVD. PVD is uncommon in the pediatric age group (Seymour, 2002). Recent statistics show that vascular disease is the highest cause of amputation by 82%, followed by 22% of trauma, 4% of congenital and 4% of tumors in the US (Seymour, 2002).

Diabetic individuals are 15 times more likely to develop lower limb amputation compared with the healthy people. In Malaysia, the prevalence of Diabetes mellitus was reported to be 6.3% in 1986 (first national health and morbidity survey; NHMS 1) and 8.2% in 1996 (NHMS 2). Furthermore, world health organization (WHO) has estimated that by 2030, 2.48 million diabetic cases will be found in Malaysia (prevalence of 10.8%), which would be 164% increase compared with the year 2000. Unfortunately, foot or above the ankle amputation would be necessary for most of them due to peripheral ischemia or severe infection (National Orthopaedic Registry of Malaysia, 2009). According to the Malaysian Diabetes Association (2007), the risk of a lower limb amputation is 27.7 times greater for a diabetic case.

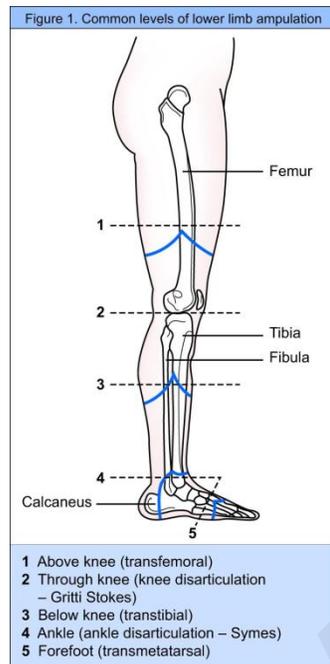


Figure 1.2: Various levels of lower-extremity amputations (Reproduced from Wound healing complications associated with lower limb amputation – Harker et al., 2006)

The most prevalent amputation level is transtibial which is also called “below-knee” (BK). It is not surprising, then, that it has attracted so much attention in rehabilitation, surgical literature and prosthetics (Figure 1.2) (Douglas, 2004).

1.3 History of prosthetics

The distinct but interdependent fields of amputation surgery and prosthetics have historical roots extending back to about 1800 BCE when, according to the Rig-Veda, the Indian warrior-Queen Vishpla had her leg amputated, was fitted with a metal prosthesis (iron), and subsequently returned to lead her troops. The oldest archeological evidence of amputation dates back to 45,000 years ago. Study of a male Neanderthal skeleton, found in

present day Iraq, indicated that he had survived to age 40 years with an atrophic right upper limb that had been amputated just above the elbow. The oldest surviving prosthesis (roughly 1000 BCE) is an artistically carved wooden hallux (Figure 1.3) found on a female mummy in the west Theban Necropolis. It is held in place by a laced leather band around the forefoot and shows signs of wear from use (Douglas, 2004).



Figure 1.3: Cosmetic wooden hallux prosthesis found on female mummy circa 1000 BCE. Note laced leather band around forefoot (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas, 2004)

1.4 Prosthesis

Prosthesis is an artificial limb which is meant to mimic the form and/or function of a body part or a missing limb. Comfort, easy donning and doffing, durability, light weight and pleasing cosmesis are ideal prosthetic specifications. Appropriate mechanical function and low maintenance needs should be added to the aforementioned list. As a final point, the

amputee's motivation largely influences the prosthetic use since whole rehabilitation efforts will fail if the patient is reluctant to wear the prosthesis (Douglas, 2004)..

1.5 Processes of making a trans-tibial prosthesis (Icercross system)

1.5.1 Patient evaluation

The clinic team should thoroughly analyze available patient information before considering specific socket designs, suspension systems, components, and the indications and contraindications for each. Several factors influence the prosthetics prescription. These factors include activity level, geographic location, time since amputation, medical condition, soft tissue, skin problems, shape of the residual limb, condition of knee joint, condition of the thigh, musculature, range of motion, patient goal, employment and sport (Figure 1.4).



Figure 1.4: Patient evaluation

1.5.2 Measurements

Circumference around stump, medial-lateral, anterior-posterior and height measurements are taken by a qualified prosthetist (Figure1.5).



Figure 1.5: Stump measurement

1.5.3 Casting

Prosthetist casts the residual stump with Plaster of Paris bandages for making the socket of the prosthesis. This cast is called a negative cast (Figure 1.6).



Figure 1.6: Casting procedures

1.5.4 Pouring

This is a process where the negative cast is filled with Plaster of Paris paste to make a positive mould of the stump.

1.5.5 Modification

This is a process where a prosthetist modifies the positive mould based on the biomechanical principles to relieve pressure in sensitive areas in the socket (Figure 1.7). Most of the positive moulds are modified on total contact design where weight is distributed throughout the sub tissues of the stump.



Figure1.7: Modification of positive cast

1.5.6 Making the test socket and checking on the patient

Testing or checking the socket is made by forming a heated sheet of clear plastic over the positive cast (Figure 1.8).



Figure 1.8: Making the test socket and checking on the patient

1.5.7 Socket Fabrication and Assembly and Alignment

Socket is made out of polypropylene sheet or Resin Epoxy. Prosthetist assembles and aligns the components (Bench alignment, Static alignment and dynamic alignment) (Figure 1.9)



Figure 1.9: Static alignment and dynamic alignment

1.5.8 Gait Training

A team of physiotherapists trains the patient to walk near to normal walking patterns inside and outside parallel bars (Figure 1.9).

1.5.9 Advance Gait Training

Advance gait training is given to the patient for walking in different uneven terrain and crossing the ground related obstacles found in day-to-day life.

1.6 Suspensions (Traditional and contemporary suspension)

The main role of suspension systems in lower limb prostheses is to secure the socket to the amputee's stump and to decrease the motion that takes place between residual limb

and prosthetic socket during ambulation. In fact, fitting and suspension play significant roles in prosthetic function and comfort (Kristinsson, 1993; Tanner and Berke, 2001; Baars and Geertzen, 2005; Isozaki et al., 2006). Appropriate suspension system and prosthetic components can improve the amputee's gait and decrease their energy expenditure (Schmalz et al., 2002).

In addition, amputees consider fitting and suspension of prosthesis as important factors affecting their satisfaction (Datta et al., 1996; Fillauer et al., 1989; Legro et al., 1999). In some studies regarding lower limb prosthesis, suspension with an Icelandic Roll-On Silicone Socket (ICEROSS) system was preferred by the amputees because of better suspension, fit, stump protection and comfort when compared with the other suspension methods (Heim et al., 1997). Silicone liners also improved the prosthetic function compared to other suspension systems (Legro et al., 1999; Baars and Geertzen, 2005; Trieb et al., 1999).

Poor suspension can cause: pistoning (vertical movement) within the socket; gait deviation; skin breakdown; discomfort; and finally patient's dissatisfaction (Figure 1.10).



Figure 1.10: skin problems in transtibial amputees

Several suspension devices are available for the transtibial prosthesis, from a simple suprapatellar strap (Figure 1.11) to Supracondylar System (PTS) or (PTB/ SC), Supracondylar/ supra -patellar system (PTB /SC/SP), Thigh Corset, Waist Belt, Sleeve, Pin/Shuttle (Figure 1.12), Suction or vacuum, and osseointegration.

The prescription of an appropriate suspension system for patients who have undergone transtibial amputation can play a significant role in the rehabilitation process (Baars et al., 2008; Gholizadeh et al., 2011a).



Figure 1.11: Suprapatellar strap (Reproduced from Atlas of amputation and Limb Deficiencies- Douglas G. Smith 2004).



Figure 1.12: Pin and lock system

1.7 Liners

Liners act as an interface between the residual limb and socket to provide added comfort and protection. Some individuals with transtibial amputations may prefer not to wear a liner and instead have the residual limb and sock against the hard socket. This socket without liner is primarily indicated for a residual limb with intact sensation, good

soft tissue coverage, and no sharp bony prominences. Soft liners are recommended to individuals with PVD; those with thin, sensitive, or scarred skin; and patients with sharp bony prominences. The added protection of a soft liner may also benefit the highly active individual.

1.7.1 Pelite

The most common material used as liner or soft socket is Pelite. This polyethylene foam (closed-cell) is manufactured in various thickness and durometers (hardness). The Pelite (Figure 1.13) is thermo-formable so that it can be formed over the positive cast after heating. One advantage of Pelite and other similar materials is easy adjustment. In fact, whenever the stump volume changes, additional Pelite can be glued to the liner. Another advantage is the potential to be used for supracondylar wedge of transtibial prosthesis.



Figure 1.13: Polyethylene foam material

1.7.2 Silicon liners

The silicon liner socket has been used in the trans-tibial prosthesis since 1980s. Silicon liner sockets are sleeves of silicon material that are rolled onto the stump and fix the prosthesis to it (Baars and Geertzen, 2005). Enhanced comfort, improved suspension and cosmesis have led to increased prescription of the silicon liners (Baars et al., 2008). The recent development of the prosthetic liner Seal-In[®] X5 by Össur (Reykjavik, Iceland) is a

new suction suspension liner with hypobaric sealing membrane around the silicon liner without an external sleeve or shuttle lock which increases surface contact with the socket wall (Figure 1.14-16).



Figure 1.14: Seal-In X5 liner



Figure 1.15: Dermo liner

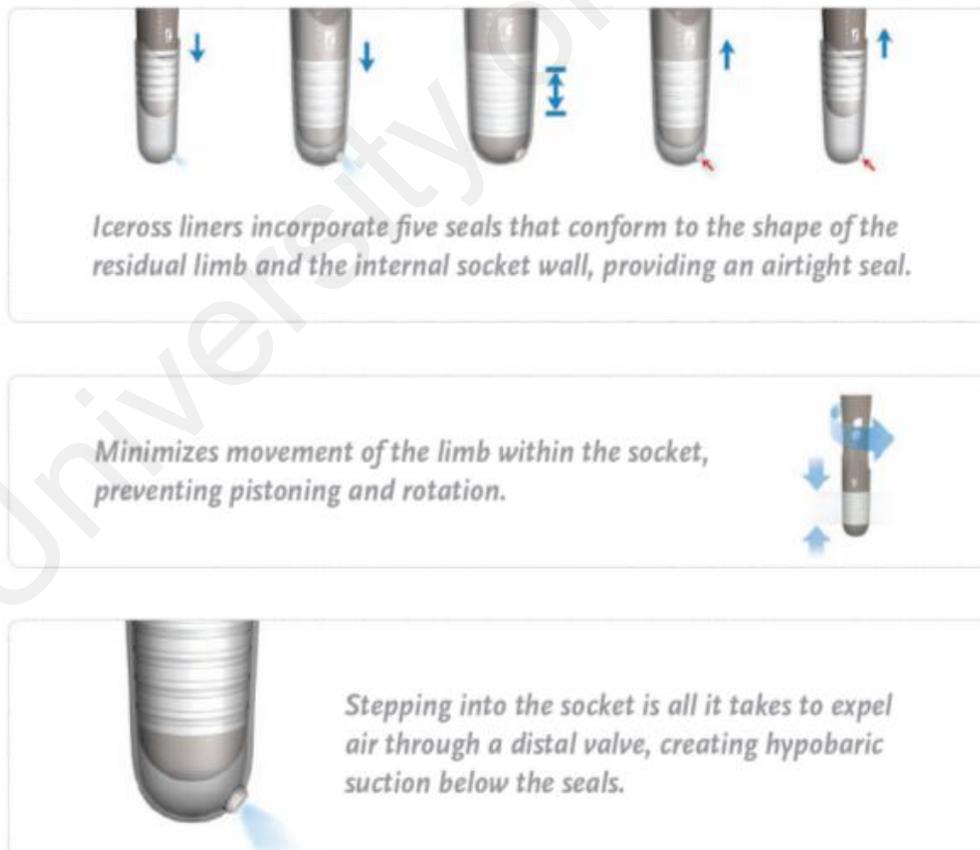


Figure 1.16: Donning and Doffing with Seal-In X5 transtibial liner (Reproduced from Össur, 2008).

1.8 Objectives of the Study

This study aimed to compare the effects of the new Seal-In[®] X5 Liner and Dermo[®] Liner (Figure 1.14,15) on transtibial prosthetic pistoning and satisfaction using Vicon motion system and some part of PEQ questionnaire. In the literature review, to the best of the researcher's knowledge, no study regarding the effects of these two Liners on transtibial prosthetic suspension and patient's satisfaction was found. Furthermore, two new methods for measuring the pistoning within the transtibial socket were introduced and assessed.

1.9 Hypothesis

H0 1 = Piston motion between socket and silicon liner (shuttle lock) is similar to that of between socket and Seal-in liner in different static positions.

H1 1 = Piston motion between socket and silicon liner (shuttle lock) is significantly different from the piston motion between socket and Seal-in liner in different static positions.

H0 2 = Piston motion between socket and silicon liner (shuttle lock) is similar to pistoning between socket and Seal-In X5 liner during gait.

H1 2 = Piston motion between socket and silicon liner (shuttle lock) is significantly different from pistoning between socket and Seal-In X5 liner during gait.

H0 3 =, Patient's satisfaction and comfort with silicon liner (shuttle lock) are identical to patient's satisfaction and comfort with Seal-In X5 use.

H1 3 = Comfort and patient's satisfaction with silicon liner (shuttle lock) are significantly different from comfort and patient's satisfaction with Seal-In X5 use.

CHAPTER TWO: LITERATURE REVIEW

This chapter provides relevant supporting information to support the methodology and protocols employed in this study. The method of attachment of prosthesis to the residual limb (suspension) and socket fitting is a critical issue in the process of providing an amputee with prosthesis. Different suspension methods try to minimize the pistoning movement inside the socket. The Seal-In[®] X5 and Dermo[®] Liner by Ossur are new suspension liners that intend to reduce pistoning between the socket and liner (Ossur, 2011). In this literature review, previous methods used by other researchers for measuring the pistoning in transtibial or transfemoral amputees are discussed and reviewed.

2.1 Evaluating of prosthetics suspension systems

The way a prosthesis is attached to the stump or residual limb is called suspension (Douglas, 2004). Common suspensions (traditional suspensions and modern suspensions) are Supracondylar Cuff, Supracondylar System (PTS) or (PTB/ SC), Supra-condylar/ supra-patellar system (PTB /SC/SP), Thigh Corset, Waist Belt, Sleeve, Pin/Shuttle, Lanyard and suction or vacuum system (Figure 2.1).

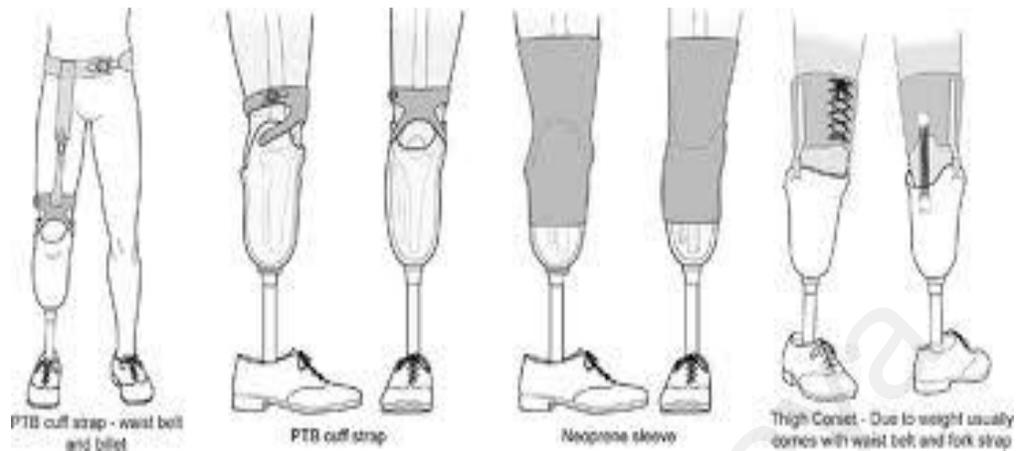


Figure 2.1: Different suspension systems in transtibial amputees (Reproduced from Atlas of Amputation and Limb Deficiencies- Douglas G. Smith 2004).

Suspension systems are meant to ensure firm attachment of upper and lower prosthetic limbs to the body (Klute et al., 2010; Beattie, 2001). There are different suspension systems available for lower limb prostheses such as cuff, supracondylar-suprapatellar socket (SC/SP), rubber sleeve, Icelandic Roll-On Silicone Socket (ICEROSS), suction socket and vacuum assisted socket system (VASS). Recently prosthetic components are also directly attached to the stump's bone called Osseointegration (Wirta et al., 1990; Baars and Geertzen, 2005; Street, 2006; Ferraro, 2011). Prosthetist should determine the suspension system based on the level of amputation, the residual limb condition and amputee's activity level.

Suspension system and fitting of the socket in prosthetic devices have significant roles in the prosthetic function, patient mobility and satisfaction (Kristinsson, 1993; Isozaki et al., 2006). According to the research findings and amputees' statements, prosthetic fitting and suspension closely depend on each other and both are correlated to the comfort and

functional efficiency of the prosthesis (Fillauer et al., 1989; Datta et al., 1996; Legro et al., 1999). For instance, several studies indicated that ICEROSS system was preferred by the lower limb amputees because of good suspension and fitting within the socket and improved function. Patient's comfort and satisfaction were also higher with this system compared to other suspension systems such as the belt used with patellar tendon bearing (PTB) socket (Baars and Geertzen, 2005; Legro et al., 1999; Heim et al., 1997; Bruno and Kirby, 2009).

The forces (e.g. ground reaction force and torque) exerted on the lower limb during quiet standing and walking can displace the prosthetic limb on the stump. The displacement is developed during the swing phase of gait and it is reversed when the limb is bearing weight during the stance (Douglas, 2004). Pistoning or vertical movement inside the socket is said to be one of the major indications of successful or unsuccessful suspension in lower limb prosthesis (Newton et al., 1988). Poor suspension has negative effects on the residual limb skin, amputee's gait and comfort (Narita et al., 1997; Dillingham et al., 2001; Schmalz et al., 2002; Geertzen, 2006; Meulenbelt et al., 2006).

Different researchers are working on suspension systems to increase the options available to the clinicians (Trieb et al., 1999). The ability to measure pistoning helps evaluating the quality of suspension in lower limb prosthesis (Commean et al., 1997; Madsen et al., 2000; Sanders et al., 2006). Pistoning movement of the stump or the position of the bone has been assessed. Some of the methods include radiography and cineradiography (Narita et al., 1997), ultrasound (Convery and Murray, 2000), roentgenology (Söderberg et al., 2003) and spiral computerized tomography (CT) (Madsen et al., 2000). Photoelectric sensor and custom-made transducers have been also utilized (Sanders et al., 2006; Abu Osman et al., 2010a,b). Despite its importance, pistoning in lower limb prosthesis has been studied narrowly. The available literature on the socket

fitting and suspension is mainly focused on pressure distribution, shear force and friction (Zhang et al., 1998; Abu Osman et al., 2010b).

2.1.1 Study population

The number of subjects participated in the studies, except from case studies ranged from 7 (Lilja et al., 1993) to 22 (Grevsten and Erikson, 1975). The age of participants varied widely from 15 (Yigiter et al., 2002) to 81 (Bocobo et al., 1998). Some papers were case studies (e.g., Commean et al., 1997; Sanders et al., 2006; Söderberg et al., 2003; Convery and Murray, 2000; Tanner and Berke, 2001). Time since amputation was from one month (Grevsten and Erikson, 1975) to 46 years (Söderberg et al., 2003); however, it has not been mentioned in some studies. Both unilateral and bilateral amputees have been included but the subjects were mostly unilateral transtibial amputees. The cause of amputation was mostly trauma, but also included diabetes, infection, arteriosclerosis, tumor, burn, Berger's disease and congenital limb defects (Table 2.1).

Some articles only included subjects that had used the prosthesis long time before attending the study, but one study's inclusion criteria was first time prosthetic fit (Yigiter et al., 2002). Male and female subjects were both included but male amputees were dominant (Table 2.1).

Table 2.1: Characteristics of the subjects

Study (n=15)	Age (year)	Cause of amputation (%)	Stump length (cm)
Grevsten & Erikson (1975)	28-66	Unknown	5 - 22.5
Newton et.al. (1988)	Unknown	Unknown	Unknown
Wirta et al. (1990)	23-76	Trauma, Infection, diabetes, Disease, Congenital	8 -19
Lilja et al. (1993)	61-79	Diabetes mellitus (5), arteriosclerosis (2)	10 - 20
Commean et al. (1997)	56	Unknown	Unknown
Narita et al. (1997)	19-74	Traumatic injuries (6), tumors (2), burns (1)	13 - 29
Bocobo et al. (1998)	39-81	Vascular disease, trauma	Unknown
Convery & Murray (2000)	39	Industrial accident	18
Madsen et al. (2000)	Unknown	Unknown	Unknown
Board et al. (2001)	32-64	Trauma	Unknown
Tanner & Berke (2001)	37	Trauma	Short stump
Yigiter et al. (2002)	15-37	Traumatic injuries	12.5 - 17.5
Soderberg et al.(2003)	69	Trauma	10
Sanders et al. (2006)	60	Traumatic injury	Unknown
Papaioannou et al. (2010)	Unknown	Unknown	14.8

2.1.2 Prosthesis specifications

Transtibial prostheses were mainly Total Surface Bearing (TSB) and Patellar Tendon Bearing (PTB). The only transfemoral prosthetic socket was quadrilateral suction socket with single axis foot and mechanical knee joint. Suspension systems included supracondylar/suprapatellar (SC/SP), supracondylar (SP), cuff, waistband with cuff, elastic sleeve and supracondylar wedge. In most of the aforementioned studies the type of the

liners was unclear but those who mentioned the liner type had employed Pelite, silicone liner and urethane liner.

2.1.3 Data presentation

Except from case studies, in four studies data for each patient was given individually (Table 2.2).

Table 2.2: Study population

Study (n=15)	Sample size	Study design	Data presentation per patient
Grevsten & Erikson (1975)	22	CSS	Yes
Newton et al. (1988)	8	CSS	No
Wirta et al. (1990)	20	CSS	No
Lilja et al.(1993)	7	CSS	Yes
Commean et al (1997)	1	CS	Yes
Narita et al (1997)	9	CSS	No
Bocobo et al. (1998)	12	CSS	No
Convery & Murray (2000)	1	CS	Yes
Madsen et al. (2000)	19	CSS	Yes
Board et al. (2001)	11	CSS	Yes
Tanner & Berke (2001)	1	CS	Yes
Yigiter et al. (2002)	20	CSS	No
Soderberg et al.(2003)	1	CS	Yes
Sanders et al.(2006)	1	CS	Yes
Papaioannou et al.(2010)	10	CSS	No

CS= Case Study, CSS= Case Series

2.1.4 Pistoning measurement methods

Imaging methods have been used to evaluate the position of bones inside the prosthetic socket. They consisted of roentgenology, cineradiography (Figure 2.3), fluoroscopy and roentgen stereophotogrammetric analysis. Ultrasonic methods used transducers which were fixed over the socket. Some studies showed roentgenological examinations to be valuable for studying the position of stump relative to the prosthetic socket (Grevsten and Erikson, 1975). Spiral or helical computerized tomography (CT) also provides a high resolution, 3-D image of the stump and prosthesis (Madsen et al., 2000).

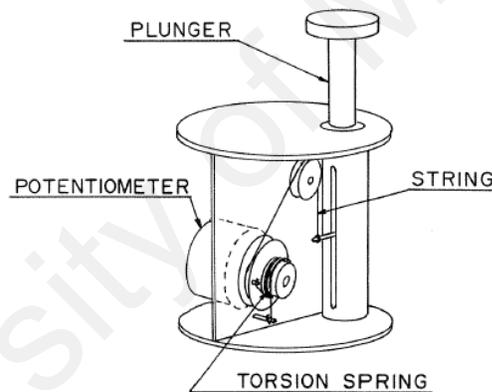


Figure 2.2: Axial movement detector (Reproduced from Witra et al., 1990)

Based on the literature review, in order to check pistoning inside the socket, most of the researchers measured the displacement between the bone and the socket, the liner and socket or the soft tissue by using different techniques in static position (Newton et al., 1988; Madsen et al., 2000; Söderberg et al., 2003; Yigiter et al., 2002; Tanner and Berke, 2001) or during dynamic tasks (Sanders et al., 2006; Lilja et al., 1993; Papaioannou et al. 2010; Murray and Convery, 2000; Bocobo et al., 1998). Therefore, the methods were classified according to static or dynamic pistoning which is presented below (Table 2.3).

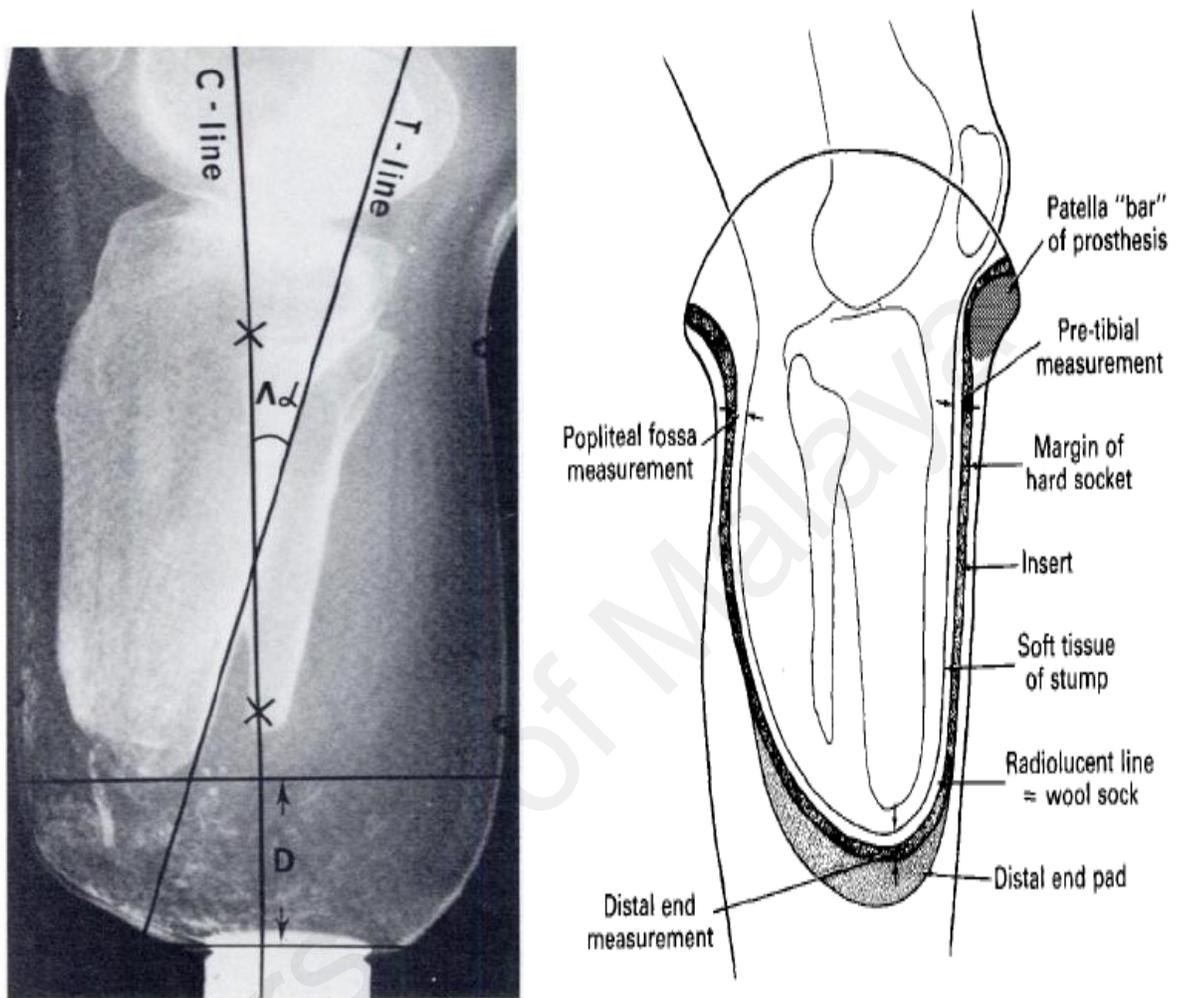


Figure 2.3: Measuring the tibia vertical movement by radiographic method

(Reproduced from Grevsten and Erikson, 1975)

Table2.3: Distribution of studies based on the methodology and prosthetic components

Study	Year of publication	Method		Instrument	Level of amputation	Socket type	Soft liner type	Measurement Interface		
		Static	Dynamic					Skin/soft tissue-liner/socket	Bone-soft tissue/socket	Liner-socket
Grevsten & Erikson	1975	#	-	Roentgenology	TT*	SS	-	yes	Yes	No
Newton et.al.	1988	#	-	X-ray	TT	PTB	Soft liner	Yes	No	No
Wirta et al.	1990	-	#	Axial movement detector	TT	PTB	Polyethylene foam liner	Yes	No	No
Lilja et al.	1993	#	-	X-ray	TT	PTB	-	No	Yes	No
Commean et al.	1997	#	-	Spiral x-ray CT (SXCT)	TT	PTB	Sponge insert	Yes	Yes	No
Narita et al.	1997	#	#	X-ray Cineradiography	TT	PTB TSB	Silicone liner (ISROSS)	No	Yes	No
Bocobo et al.	1998	-	#	Videofluoroscopic	TT	PTB	Polyethylene foam liner Kemblo insert	Yes	Yes	Yes
Convery & Murray	2000	#	#	Ultrasound transducers	TF [†]	Quadrilateral SS	-	No	Yes	No
Madsen et al.	2000	#	-	CT Scanner	TT	Unknown	Unknown	Yes	No	No
Board et al.	2001	#	-	X-ray radiography (plain)	TT	SS VS	Urethane liner Sleeve	Yes	Yes	Yes
Tanner & Berke	2001	#	-	X-ray radiography (plain)	TT	TSB	Neoprene	Yes	Yes	No
Yigiter et al.	2002	#	-	-	TT	PTB TSB	Soft liner	No	No	Yes
Soderberg et al.	2003	#	-	Roentgen stereophotogrammetry	TT	TSB	Silicone liner (TEC)	No	Yes	No
Sanders et al.	2006	-	#	Photoelectric sensor LVDT	TT	PTB	-	Yes	No	No
Papaioannou et al.	2010	-	#	Dynamic roentgen stereophotogrammetry	TT	PTB VS	Silicone liner	Yes	Yes	No

2.1.5 Static pistoning

Back in 1975, Grevsten and Erikson (Grevsten and Erikson, 1975), and later in 1980s, Newton et al. (Newton et al., 1988) were among the first to study PTB prosthesis by roentgenology. The pistoning motion was studied in 4 and 2 weight bearing positions, respectively.

Some researchers tried to mimic the gait by adding loads to the prosthesis in static position (Narita et al., 1997; Commean et al., 1997). In a study, pistoning of the tibial end was assessed in four simulated phases of the gait cycle. They used a board tilted 15 degrees to locate the limb in same positions of heel strike and toe-off. To imitate the swing phase, they positioned the prosthetic limb at 45 degrees relative to the floor (Lilja et al., 1993). The same positions were used in a study with roentgen stereophotogrammetry for 4 types of suspension (supracondylar, patellar tendon bearing strap, distal pin suspension and vacuum suspension with expulsion valve). One kilogram load was applied to the prosthetic foot to replicate the centrifugal force (Söderberg et al., 2003).

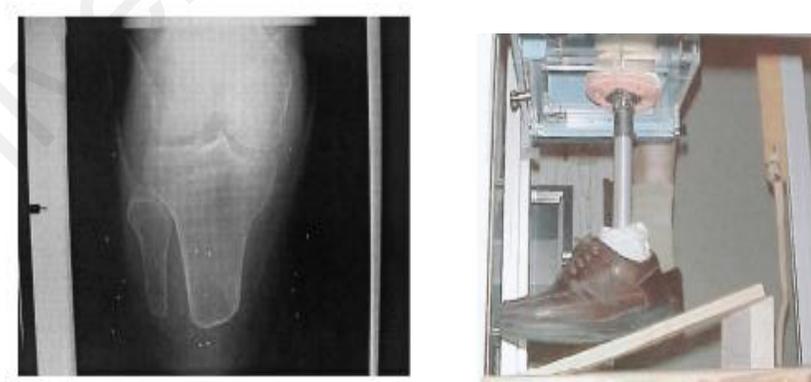


Figure 2.4: Radiographic method for measuring pistoning (Reproduced from Soderberg et al., 2003)

In another study, to simulate the swing phase of gait, a 5-kilogram load was applied to the foot of the prosthesis, and an x-ray was taken with the prosthesis suspended at a knee flexion angle of 30°. On the radiograph, the tibial bone displacement relative to the socket bottom was measured by calculating the value difference between the weight-bearing and non weight bearing positions (Narita et al., 1997).

An x-ray study determined the femur position while bearing the weight over the transfemoral prosthetic limb and also in non weight bearing condition. Two 5MHz linear transducers were used for quality imaging of the femur. A separate ultrasonic scanner was used for each transducer (Convery and Murray, 2000). The amputee was asked to have a normal stride. While weight bearing, he pulled the prosthetic heel backwards as stance, or pulled the toe of the prosthetic foot forwards similar to the swing stance. Abduction and adduction were replicated by pushing the prosthetic foot laterally or medially, respectively.

The effect of neoprene sleeve on the vertical tibia and stump displacement was compared with shuttle lock suspension system (Tanner and Berke, 2001). The pistoning motion was derived from total six radiographs for two suspension systems in three weight bearing positions (full, partial and non). The distance between each of a) end of tibia and, b) distal residual limb soft tissue to proximal lock was measured on the x-ray films (Tanner and Berke, 2001). One prosthesis with shuttle lock was fabricated but the pin was removed in order to evaluate the neoprene sleeve.

Yigiter et al. (2002) assessed the suspension in PTB and TSB sockets by marking the anterosuperior edge of the socket while standing and during the swing phase. However, no data has been represented on how the exact measurement was done.

Loads of 44.5 and 88.9 N were used to simulate swing phase during walking and running, respectively in a study of pistoning with X-ray. The X-rays were taken while the

subject was lying supine and the data of loaded and unloaded positions were compared (Board et al., 2001).

Some researchers tried to find solutions to apply weight to the prosthetic limb. Commean et al. (1997) used a harness in order to apply the force to the prosthesis by the shoulders. In another study, Madsen et al. (2000) designed a loading device for the Spiral CT method that allowed applying large loads. The applied load was determined by the subject's weight (full and half body mass).

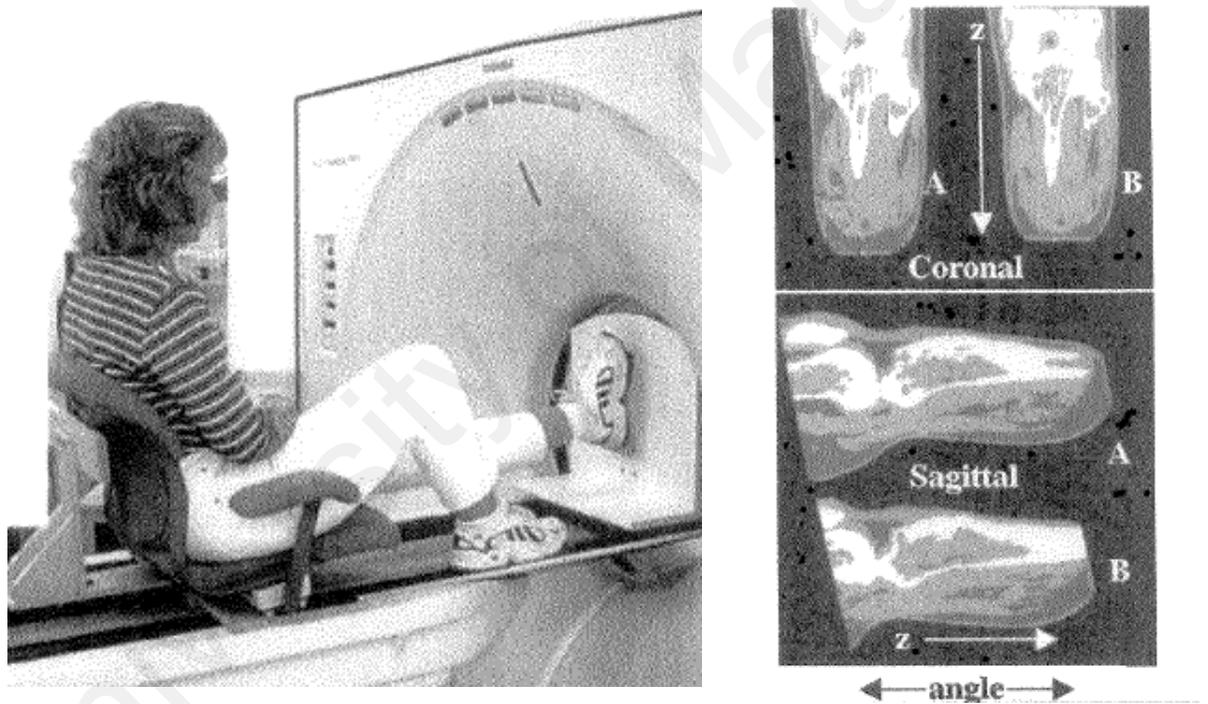


Figure 2.5: Spiral CT examination (Reproduced from Madsen et al., 2000)

2.1.6 Dynamic pistoning

A few studies have been focused on the pistoning during gait (Table 3). Sanders et al. (2006) used a non-radiological tool to measure the position of the distal end of the

residual limb surface in relation to the socket when walking on a 18.5 meter walkway. A holder containing the photoelectric sensor was mounted on the inside distal socket wall.

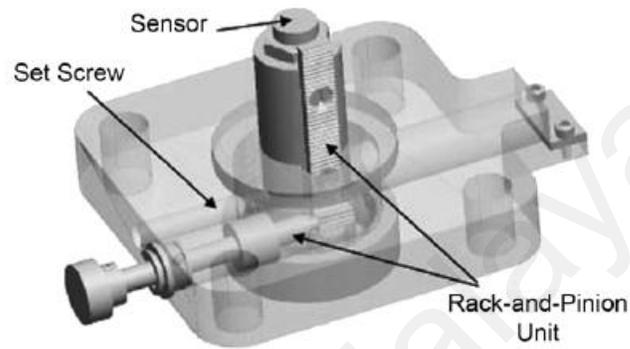


Figure 2.6: Non contact sensor for measuring pistoning inside the socket
(Reproduced from Sanders et al., 2006)

In another study, a walking machine was used for walking with prosthesis and the measurements subsequently made by cineradiography during one gait cycle. The distance between the socket and distal tibia was measured and the movement of the stump was calculated by subtracting the value in the weight-bearing position from the value in the suspension position (Narita et al., 1997).

In a study of the effect of below-knee suspension systems, Wirta et al. (1990) placed a potentiometer as an axial movement detector at the distal end of the socket. The subjects were asked to walk a 7.5 meter distance at usual, fast and slow speeds. The following seven suspension systems were compared: cuff (PTB/C), supracondylar, supracondylar (SC), figure-of-eight supracondylar strap, waistband and cuff, suprapatellar (SCSP), rubber sleeve and supracondylar wedge.

In a videofluoroscopic research study, the participants were asked to walk at a comfortable speed on a treadmill. They raised the treadmill so that the knee and stump were fully visible. Leaded elastic markers were attached to some prosthetic components outside and inside the socket. Three exposure rates of 50, 80 and 110 were selected and the results were compared. Anteroposterior and mediolateral views were taken. A video camera was used to record the treadmill gait during the mean trial time of 40 S (Bocobo et al., 1998). Two researchers evaluated the recorded videos and their agreement over detecting a particular component (stump or prosthesis) was taken as the reference.

Papaioannou et al. (2010) presented a new method of three-dimensional (3D) socket–stump telescopic movement evaluation while performing tasks on the force plate. They measured the piston motion between the skin and socket by roentgen stereogrammetric system through attachment of tantalum pigments on the bone, skin and socket. The authors claimed their method to be a very accurate technique for the assessment of pistoning between the stump, socket and bone (Figure 2.7).

In an ultrasound study on trans-femoral prosthesis, two video recorders were utilized to capture the femur motion at 25 HZ during gait (Convery and Murray, 2000).

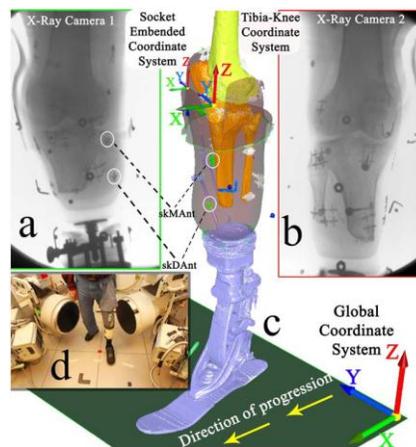


Figure 2.7: Measuring pistoning using Roentgen Stereogrammetric Analysis

(Reproduced from Papaioannou et al., 2010).

2.1.7 Amount of pistoning

Grevesten and Erikson (1975) found 11.3mm bone displacement in relation to the socket with suction-based PTB prosthesis. In another study with a PTB prosthesis, the average distal tibia vertical movement during a gait cycle was 57mm (Lilja et al., 1993).

Wirta et.al (1990) compared the vertical movement of conical and cylindrical residual limb shapes and reported a mean pistoning movement of 19.1mm at the end of the residual limb. In both conical and cylindrical stumps, rubber sleeve had the least pistoning among the seven evaluated systems (Wirta et al., 1990).

In 1997, the slippage between the skin and socket and also tibia movement was monitored to evaluate the prosthetic fit in a transtibial subject. For simulating the gait, they used two axial loadings of 44.5 and 178 N. They mentioned 10mm tibial slippage and about 7mm for the distal end of skin relative to the socket (Commean et al., 1997). However, it is not clear what suspension system was used.

In an x-ray study, the tibial displacement between the stance and swing phase was 25.3 ± 9 mm for the TSB prosthesis and 36 ± 5.6 mm for the PTB prosthesis (Narita et al., 1997). The translation for the TSB prosthesis was significantly lower ($p < 0.05$) and the suspension effect of the TSB prosthesis consequently superior to that of the PTB prosthesis (Narita et al., 1997). Similarly, another study on the pistoning effects of PTB and TSB sockets revealed less displacement with TSB (40mm). The marker was placed on the sock over the stump (Yigiter et al., 2002).

Bocobo et al. (1998) described two case reports out of 12 subjects. Only one case was reported to have PTB socket, and they did not provide the value of pistoning. It was stated that in one subject significant piston action was observed possibly by comparison between two phases of gait; however, they did not mention in which phase it was the most.

The pistoning movement was measured by subtracting the position of patellar tendon bar marker from the knee joint during two gait phases.

A spiral CT study did not represent any specific value for the pistoning; only a figure legend showed a difference ranging from 0 to 32mm of displacement between full body weight and non loading conditions (Madsen et al., 2000).

In the comparison of normal valve transtibial socket to an electric vacuum prosthesis, the amounts of liner displacement and tibia bone relative to the end of socket marker were 40mm and 70mm less, respectively. The amount of pistoning with normal suction reported to be 50mm. Although the pistoning was measured statistically under loads, the majority of subjects also stated they felt less pistoning with vacuum compared to normal suction during the walking (Board et al., 2001).

When the shuttle lock system was evaluated versus the no-lock condition, the value of tibial end displacement from the proximal edge of the lock was almost equal in both suspension conditions in three different loading positions. However, there was less soft tissue displacement noted with shuttle lock. The patient also preferred the shuttle lock due to less pistoning feeling. They concluded that the amputee's opinion about the pistoning was more related to the soft tissue movement than the tibia (Tanner and Berke, 2001).

The pistoning of the tibia within the KBM socket with supracondylar strap was showed to be about 35mm, while the pin and sleeve resulted in approximately 17mm (Söderberg et al., 2003).

Sanders et al. (2006) pointed out that after toe off the residual limb came out of the socket about 30mm. Overall, 40mm stump displacement in proximal direction at the end of the swing phase was found. Additionally they stated that pistoning in PTB without strap was more compared with when strap was used (0.8mm more). After 5-min rest, 3.7mm

more pistoning was found (before rest: 39.8mm, after rest 43.5mm for PTB with supracondylar strap).

The latest roentgen stereogrammetric study surprisingly showed 151mm pistoning movement in the fast stop task and 19mm for the step down between the markers on the skin and socket (Figure 2.8). Except from one case that used a customized vacuum socket with silicone liner, the type of suspension systems has not been indicated (Papaioannou et al., 2010a).

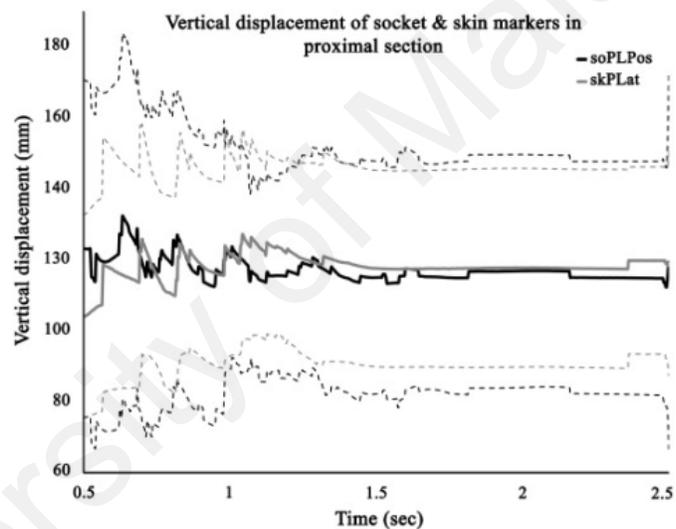


Figure 2.8: Vertical displacement of socket & skin markers

(Reproduced from Papaioannou et al., 2010)

In the only study on transfemoral prosthesis, Convery and Murray in (2000) measured the amount of vertical movement of femur during the gait by using two ultrasonic transducers. However, they stated that the displacement was monitored by X-ray images and the pistoning was determined by the distance between the end of femur and the distal transducer. After the subject changed his position from full weight to non weight bearing the femur displacement was found to be 1mm.

Suspension systems should help firm prosthetic attachment to the limb. With suspension systems based on the suction concept, the displacement of the stump's bones is said to reduce to half which will in turn result in increased stability between stump and socket. Skin sores are also prevented (Grevsten and Erikson, 1975). Above all, less pistoning means more normal gait and the amputee will feel like the prosthesis is a part of his/her body (Newton et al., 1988; Goswami et al., 2003).

Different methods have been used to evaluate pistoning in lower limb prosthesis in static and less in dynamic positions. Radiological methods have been more popular to measure the pistoning; however, some of them are rarely available to the prosthetists due to the costly equipments and complex time consuming data collection. Besides that, there is the concern of exposing the patient to the X-ray (Kendall et al., 1992). In addition, although some of these studies tried to be precise in the X-ray examinations, there is still some inaccuracy in these measurements (Grevsten and Erikson, 1975). The measurements may vary a little owing to minor changes in distances between the extremity and the film. In order to get higher resolution images, some studies tried different exposures rates.

Using CT scanners has some advantages like having high spatial resolution, showing 3-D information of the prosthesis and the internal tissues of the stump, but the challenge is that they require the subjects to be positioned supine. Madsen et al. (2000) stated that with evolution in CT imaging systems, their device could be easily adapted to perform more sophisticated loading protocols. The harness that Commean et al. (1997) used to apply load had several limitations because it took a long time to set up and the subject needed to be cooperative.

The use of photoelectric sensor reported to have some limitations because it was not wireless and a cable connected the sensor to data acquisition system. But it was said to be overcome by radio-frequency telemetry systems. Another problem was that a liner with

shuttle lock and pin could not be used because it was impossible to make a hole at the end of the liner (Sanders et al., 2006).

Diagnostic ultrasound was said to have no known side effects. However, there are concerns about the accuracy and frequency of data acquisition. Also, utilizing the ultrasound during gait can be very labor intensive and not clinically feasible (Convery and Murray, 2000).

Only two studies indicated that the trials were repeated 3 to 5 times (Narita et al., 1997; Sanders et al., 2006) and this can raise concerns about the reliability of the data presentations. However, to some extent, it can be interpreted as the ethical issue of x-ray exposure. Finally, to our knowledge no one has set a limit for the acceptable amount of pistoning. Only Newton et al. (1988) stated that vertical displacement of 10 mm or less is considered ideal and comfortable; however, they did not provide any evidence to support that statement.

Most of the studies measured the pistoning by simulating the gait through applying static loads. The logic behind the load appliance said to be simulation of centrifugal or inertial force that acts on the limb during walking (mostly swing). Some say that the pendulum dynamic applies to the swinging lower limb (Doke et al., 2005); therefore, this inertial force is influenced by the segment weight (here the prosthesis mass). Nevertheless, similar loads were used for different subjects that are controversial. Many researchers employed radiological methods but they also reported that the radiographic apparatus and the calibration cage restricted the system.

Overall, some important points can be inferred from the evaluation of the available literature. With regard to the complicated equipments and techniques, existing methods seem to be far from being practical in a clinical setting, and they might only be suitable for manufacturers to evaluate their suspension system products, including liners. Since

reducing the pistoning significantly contributes to optimal prosthetic fit, further research with larger sample size seems necessary to invent and evaluate accurate, safe and simple methods of pistoning measurement which are widely available to every prosthetist. Moreover, there are many different liners that have not yet been studied from the pistoning point of view. Since prostheses are the core element of these study practices, the researchers should ensure that the fabrication and fitting process will be committed by one single prosthetist to avoid bias.

However, these methods require complicated devices and settings, and it is not possible for every rehabilitation clinic to provide such costly imaging systems. Even if the amputee is referred to an imaging center, still there might be the risk of repeated exposure to the X-ray. Therefore, these studies have been mostly limited to the laboratory and could not be used clinically.

CHAPTER THREE: METHODOLOGY

Chapter 3 describes two different methodologies for measuring pistoning between the liner and socket during static and dynamic position carried out on 10 transtibial amputees using two different sockets (Dermo liner and Seal-In[®] X5 liner).

3.1 Variables

Vicon motion system was used to collect the data from the experiments. The requirements of this system are named as the independent variables and the data obtained from the experiments by Vicon system were considered as the dependent variables. This group of variables (Table 3.1) can then be classified into primary data (measuring pistoning between both liners and socket in static positions) and secondary data (measuring pistoning between both liners and socket during gait).

Table 3.1: Variables (Independent and dependent) from the primary and secondary data

Primary Data (measuring pistoning between both liners and socket in static positions)	Independent variables	MX-F20 Camera maximum frame rate at full resolution (500 fps) MX-F20 Camera maximum pixels per second (1,024,000,000) MX-F20 Camera strobe type (Infrared, 850 nm) Static position (Full, semi, and non weight bearing) Adding and removing Load 30 N Adding and removing Load 60 N Adding and removing Load 90N Liner type (Seal-In X5 liner and Dermo liner)
	Dependent variables	Pistoning (vertical movement) within the socket in different static position and after adding loads
Secondary Data (Pistoning measurement during gait)	Independent variables	MX-F20 Camera maximum frame rate at full resolution (500 fps) MX-F20 Camera maximum pixels per second (1,024,000,000) MX-F20 Camera strobe type (Infrared, 850 nm) Gait protocol (Plug in gait) Liner type (Seal-In X5 liner and Dermo liner)
	Dependent variables	Pistoning (vertical movement) within the socket during the gait (self selected speed)

3.2 Subjects

Ten male unilateral transtibial amputees with a mean age of 43 (SD 16.5) and mobility grade K2–K3 (the ability to ambulate and cross environmental obstacles such as stairs, curbs, or uneven surfaces), based on the American Academy of Orthotists and Prosthetists, participated in this study on a voluntary basis. The mean time since amputation was 5 years. All subjects had undergone amputation at least 3 years before participating in the study. Ethical approval was granted from the University of Malaya Medical Centre

(UMMC) Ethics Committee (see Appendix A). All subjects were asked to provide a written informed consent. Characteristics per subject are listed in Table 3.2.

The inclusion criteria were transtibial amputees with at least 13 cm stump length (inferior edge of patella to distal end of the stump), stable limb volume, intact upper limbs (hand strength), no pain or wound in their stumps, and mobility without assistive devices, such as cane (Figure 3.1).

Table 3.2: Subjects' characteristics

Subject no.	Age	Height(cm)	Mass(Kg)	Cause of amputation	Amputated side	Stump length(cm) ¹	Mobility grade ²
1	45	168	75	Diabetic	left	14	K2
2	35	173	90	Trauma	left	15	K3
3	22	168	60	Trauma	left	14	K3
4	71	181	75	Diabetic	left	13.5	K2
5	49	167	64	Trauma	Right	13	K3
6	37	177	99	Diabetic	Right	17	K2
7	51	160	57	Diabetic	Right	14	K3
8	52	165	60	Diabetic	left	15	K3
9	62	169	72	Trauma	Right	13	K2
10	34	172	86	Trauma	left	16	K3

¹ Stump Length: Inferior edge of patella to distal end of the stump

² Based on American Academy of Orthotists and Prosthetists



Figure 3.1: Patients' evaluation and measurements

3.3 Flowchart of the study

A flowchart of methodology of the study is shown in Figure 3.2. Details on the methodology are given in Chapter three.

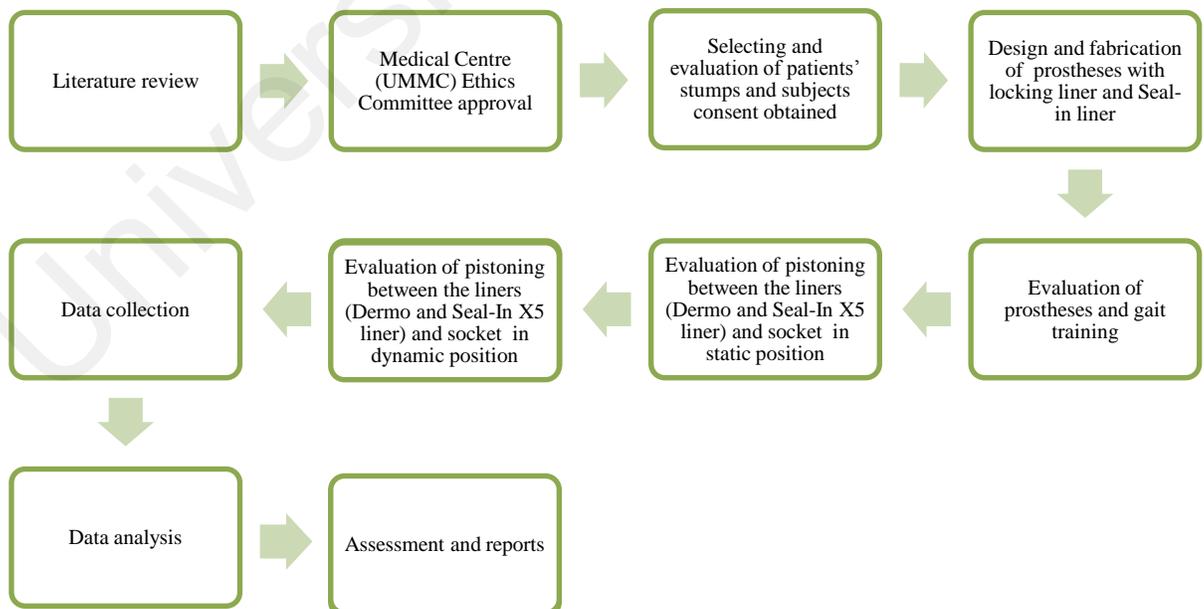


Figure 3.2: Process flow of the project

3.4 Socket casting

In this study, two transtibial prostheses with similar feet (Flex-Foot Talux[®]) and two different liners, Iceross Dermo[®] Liner with shuttle lock (Icelock-clutch 4 H214 L 214000) and Iceross Seal-In[®] X5 transtibial liner with valve (Icelock Expulsion Valve 551), were made for each subject by a Registered Prosthetist and Orthotist (Figure 3.2, 3.3, 3.4). All the prostheses were made by a single prosthetist (researcher) to avoid variability due to manufacture, fit, and alignment. The method for casting the amputees stump is described in the following paragraph.

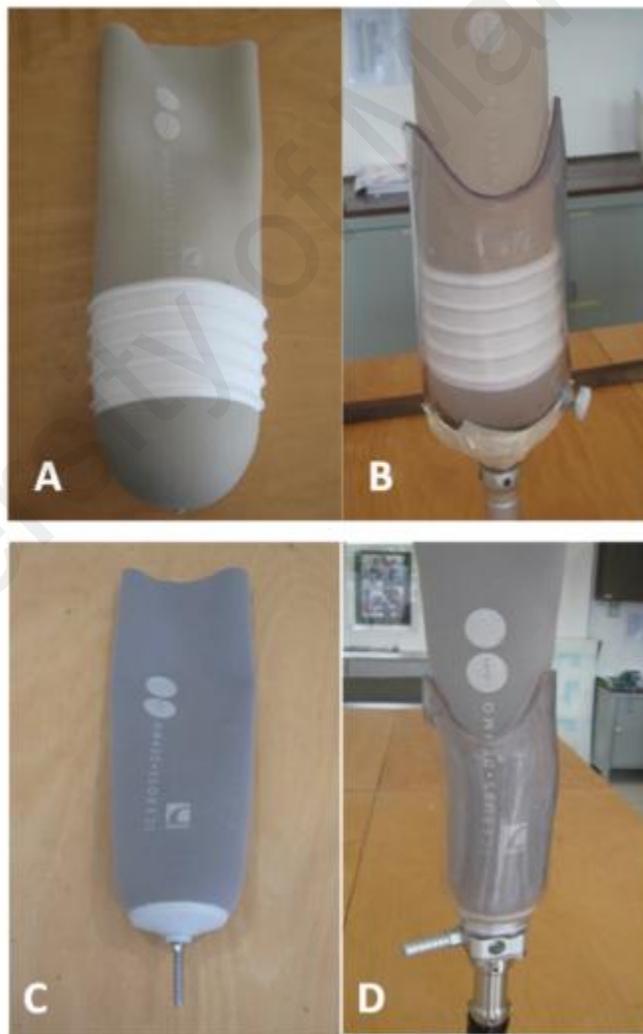


Figure 3.3: Prosthetic liner used in this project; Seal-In X5 (A,B), Dermo (C,D)



Figure 3.4: Prosthetic foot (Talux-Ossur)

3.5 Standard Operating Procedure

3.5.1 Patient's evaluation and socket casting

After evaluation of the stump, the subjects were asked to wear the liner for at least 10 minutes and flex and extend the knee to see whether the liner size is suitable. Then, the stump was measured for the modification process.

Figure 3.5 shows the casting and modification process. When each subject stated that he is comfortable with the liner, a plastic (cellophane) was wrapped around the liner to protect the liner from the Plaster of Paris. The researcher wrapped the Plaster of Paris (POP) bandage around the stump and liner and the POP massaged until it was hard. In this research, all the sockets were Total Surface Weight Bearing (TSB). The POP was left for 3 to 5 minutes to be hard enough. Then, the negative cast was removed and the negative edges were trimmed. The negative cast was filled with POP powder to make positive cast.

The POP was left to be hard enough. Then the bandage was removed from the positive cast (Figure 3.5). In this step, based on the measurements, the positive cast was modified again.



Figure 3.5: The casting and modification process

3.5.2 Making checking socket and prosthetic alignment

After the positive cast was ready, a checking socket with transparent plastic (Northplex[®], North Sea Plastic LTD 12mm) was made to check the fitness of the socket. The fitness of the socket was checked before assembling of the components. Figure 3.6 shows the procedures of making checking socket. When checking socket was ready, the components were assembled and prosthetic alignment was adjusted. To adjust the alignment (Figure 3.7), first, Bench alignment was conducted (the components were aligned in the workshop). Then, the prosthesis was checked on the subjects and they were asked to wear the prostheses and stand on the prostheses in order to check the static alignment and prosthetic height. After adjusting static alignment, the subjects were

requested to walk inside the Brace and Limb Laboratory to see and adjust their alignments.

Figure 3.7 shows the process of adjusting the prostheses alignment.

Two prostheses were made for each subject and this process we repeated for each of the prosthesis (with Dermo[®] liner and Seal-In[®] X5 liner).



Figure 3.6: Procedures of making checking socket

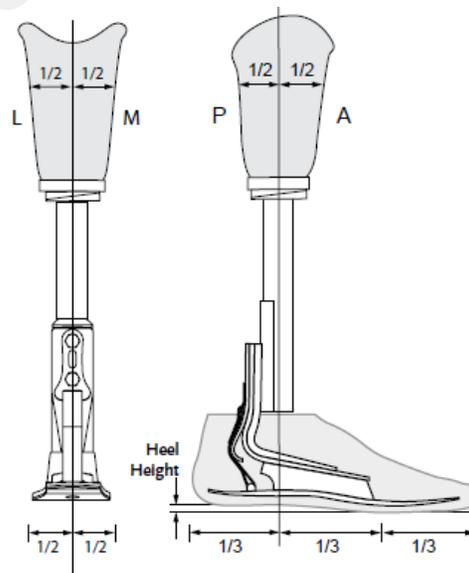


Figure 3.7: Adjusting the prostheses alignment

3.5.3 Making definitive socket

After checking the fitness of the socket and conducting the first experiment (the primary data was obtained by measuring pistoning between both liners and socket) the transparent socket was changed to definitive socket by using resin epoxy and stockinet.

For measuring pistoning between the liners and socket, it was needed to see within the socket and that is why transparent socket was used in the primary experiments. However, for measuring the differences between seal-In[®] X5 and Dermo[®] liner, the normal socket with resin or polypropylene can be used. Figure 3.8 shows the process of making the socket with epoxy resin.



Figure 3.8: Process of making the socket with epoxy resin

3.6 Data acquisition (Vicon system)

The main objectives of this study were to measure pistoning inside the prosthetic socket during gait, standing with two liners (Dermo[®] and Seal-In[®] X5).

Certain loads were added to the prosthetic leg in standing to simulate the centrifugal forces that tend to displace prosthetic leg during normal and fast walking.

In order to calculate centripetal force the following original formula was used (Winter, 2005):

$$F_c = ma_c \quad a_c = \frac{v^2}{r} \quad \longrightarrow \quad F_c = \frac{mv^2}{r}$$

Where F_c is centripetal force, m is the mass of prosthetic leg, a_c = centripetal acceleration (m/s^2), v is the peak linear velocity of the center of mass of the lower leg during swing phase, and r is the distance from knee to center of mass of lower leg.

Adding the formula to determine peak linear velocity resulted in a new equation for centripetal force as follows:

$$F_c = \frac{mv^2}{r} \quad v = \frac{2\pi r}{T} \quad \longrightarrow \quad F_c = \frac{m\left(\frac{2\pi r}{T}\right)^2}{r} \quad F_c = \frac{4\pi^2 mr}{T^2}$$

Where, T is time to swing the prosthetic leg in a curved path.

As it can be inferred from the formula, the loads can vary greatly depending on the size of the person, prosthesis mass and locomotion speeds. Therefore, the loads applied in this study should be considered as average approximations.

3.6.1 Measuring the pistoning in static position

The prosthetist checked the alignment and fit of the prosthetic socket; then, all the subjects were given a trial period of at least 4 weeks to become accustomed to the new prostheses. Following this trial period, subjects attended the motion analysis laboratory for monitoring the pistoning within the socket by collecting data via a 7-camera Vicon 612 system (Oxford Metrics; Oxford, UK). Sixteen reflective markers according to the Helen Hayes marker set were attached to the subjects' prosthesis and sound lower limbs. On the prosthetic side, the knee and tibia markers were located on lateral proximal socket wall (LPS) and lateral distal of the socket (LDS), respectively (Figure 3.9). In order to measure the liner vertical movement, two extra markers were attached to a) lateral liner below the knee joint (LLin1) and b) 5 cm below the LLin1 (LLin2).

Pilot study showed that the knee flexion and extension can bias the real amount of pistoning and should be eliminated. Therefore, in order to ensure the measurement accuracy, two extra markers (LLin1, 2) were attached over the liner below the knee level to avoid the knee motion. Static trials were carried out using dead weights. The trials were developed to ensure accurate application of loads in the vertical direction, held rigidly in a vertical attitude, and then loaded using weights hung from the prosthetic foot via wire. To simulate the centrifugal force during gait (Board et al., 2001; Commean et al., 1997; Narita et al., 1997), known loads (30, 60, and 90 N) were then applied to the prosthetic foot (Flex-Foot Talux[®]) and then unloaded (Figure 3.10) while the signal outputs were recorded using the motion analysis system. The trials were repeated five times. Each subject was required to complete different static conditions such as single limb support on prosthetic limb (full-weight bearing), double limb support (semi-weight bearing), non-weight bearing (subjects suspended the prosthetic limb from the edge of a table), and adding and removing the loads

on the prosthetic limb. Each subject went through three different vertical loading conditions.

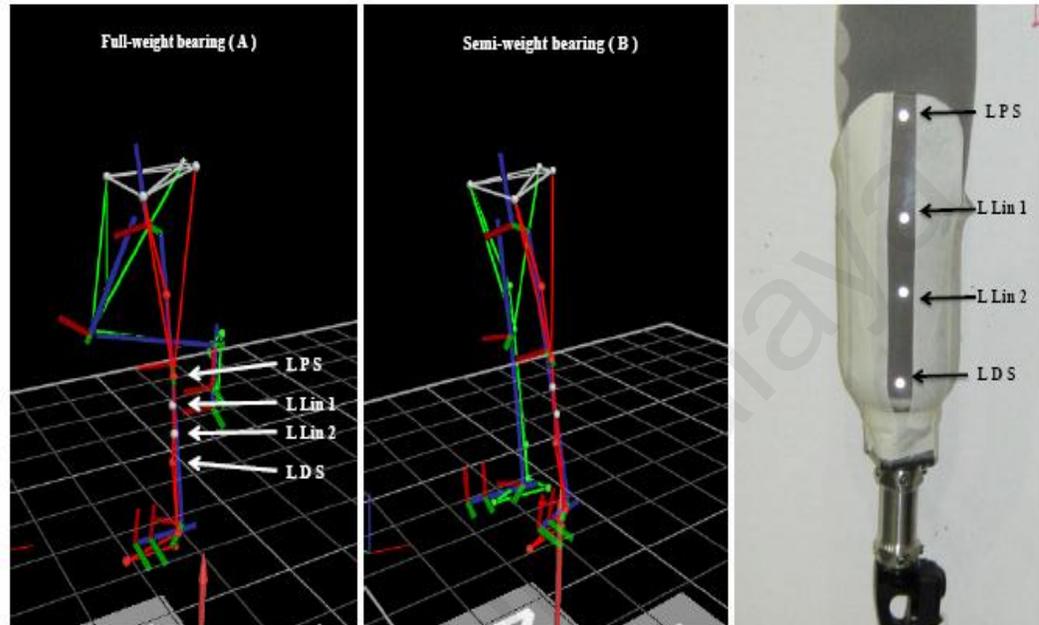


Figure 3.9: Position of markers in measuring the pistoning in full weight bearing position (A) and semi weight bearing position (B), the left side shows the position of markers on the socket and the liner.

Using a transparent socket enabled the researcher to locate markers on the liner inside the hard socket (two fine, paper-thin 2D markers were attached on the liner inside the hard socket) so that the cameras could detect the marker and the researcher would be able to see the pistoning movement inside the socket. Moreover, by locating the markers all on one segment, that is the tibia, knee flexion and thereby any fake displacement could be avoided. During the pilot trials, it was noticed that a transparent socket resulted in

reflections that were detected as markers by the cameras; hence, the transparent socket wall was covered with paper tape excluding the areas to which two new markers were added.

For calculating pistoning within the socket, the distance between two markers was used (one marker on the liner (LLin1) and another one on the socket (LPS) during full-weight bearing on the prosthesis as a baseline. Then, the other conditions were compared with the baseline to identify any pistoning movement.

LLin1, (x_1, y_1, z_1)

LPS, (x_2, y_2, z_2)

Distance between LLin1 and LPS =

$$\sqrt{(x_2 - x_1)^2 + (y_2 - y_1)^2 + (z_2 - z_1)^2}$$

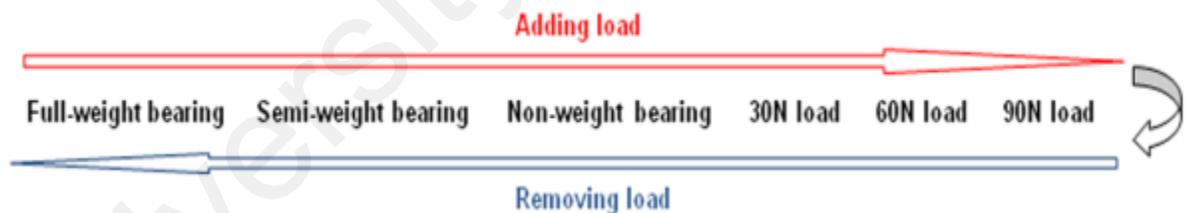


Figure 3.10: Process of adding and removing loads

Statistical data was analyzed with SPSS 17.0, and P -values of 0.05 or less were chosen to reflect statistical significance. Wilcoxon test was employed to compare the effect of two liners on the pistoning.

The four MX-F20 cameras were positioned at the four corners of the room (Figure 3.11) and the remaining three at the midpoint of the room's width. With such an

arrangement and taking into account the dimensions of the room, the maximum capture volume of the cameras combined is 37.5 m³. A capture volume enclosed an area where any point within it could be detected by at least 2 cameras. In principle, a point in the capture volume has to be visible to at least 3 cameras in order for the system to reconstruct a 3D image of the point. This configuration gave the optimal amount of overlapping images at any point within the capture volume and was sufficient for capturing 3 complete gait cycles. These cameras operated at the frame rate of 500 fps at full resolution and each has a resolution of 1600 x 1280 pixels, allowing them to track changes (pistoning) in the gait in real time. System calibration for the MX-F20 cameras was carried out to allow Vicon Nexus to calculate the relative location and orientation of all cameras. This step when done accurately, allows the software to reconstruct a 3D image of the subject's movement in space based on the calibration done.

Two types of calibrations were incorporated onto the system prior to the gait trials of each subject. In theory, recalibration is only conducted each time a camera is physically moved. The MX-F20 cameras at the Motion Analysis Laboratory were mounted onto the walls and thus disturbance to the cameras' positions were rare. Therefore, calibration is not a stringent procedure. However, to employ a good practice, the system was calibrated before a gait trial begins for each subject. Static and dynamic calibrations were carried out for a complete calibration of the system. Static calibration calculates the origin and determines the orientation of the capture volume while the dynamic calibration calculates the relative positions and orientations of the cameras.

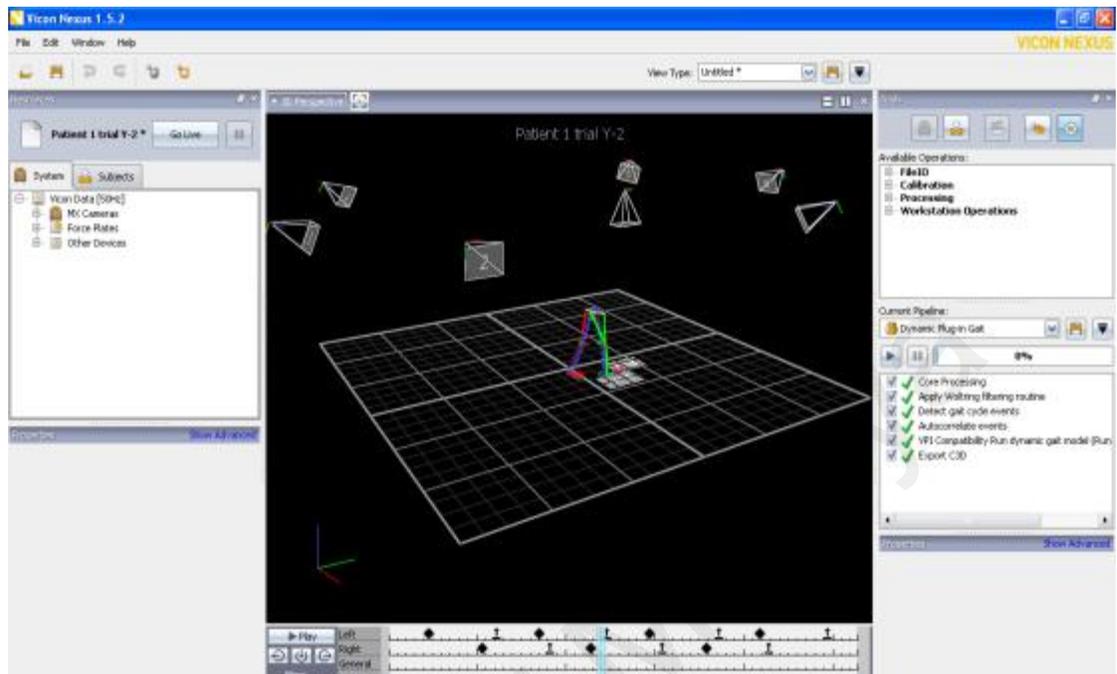


Figure 3.11: A bird-eye's view of the cameras and force plates setup. The seven cameras were placed at the four corners of the room and two in line with the force plates. The two force plates were embedded in the middle of the capture volume.

Once the system is ready, the subjects need to be prepared to facilitate data capture. This particular clinical trial is interested in investigating the effect of different prosthetic suspension system on the amount of pistoning during gait of TTB amputees. Therefore, data capture focuses on the lower limb part of the body. In order for the MX-F20 infrared cameras to recognize the subject walking within the capture volume, markers need to first be placed on the subject. Markers are spheres that reflect light from the strobe back to the camera. Sixteen 14 mm diameter markers were placed onto the bony prominences of the lower limb in order to create a lower limb skeletal of the subject. Markers on the prosthetic side were placed on the prosthetic leg where their positions were estimated from that of the

sound limb. Figure 3.12 shows the marker placements and the resultant skeletal image. Subjects were advised to wear tight fitting pants to prevent artefact from the movements of loose clothing as the cameras pick up any movement at the markers' surrounding areas as that of the marker itself. Table 3.3 gives the definition of the marker labels shown in Figure 3.12.

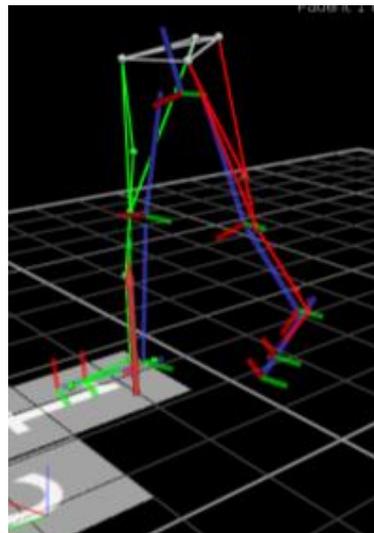
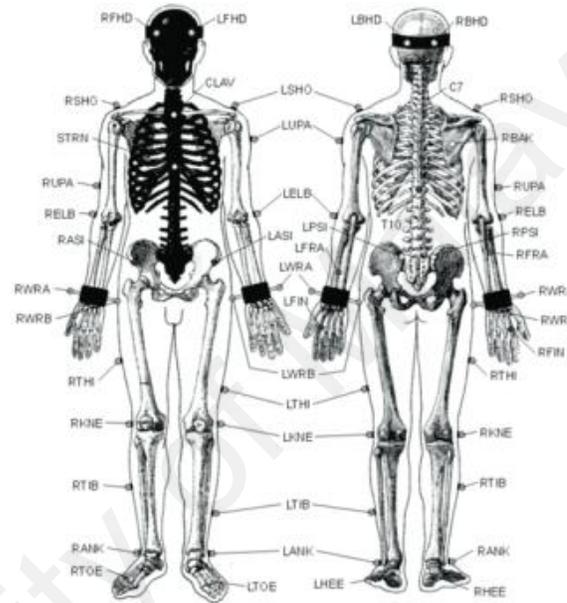


Figure 3.12: (up) Full body marker placements, (down) only sixteen markers of the lower body are used for this study

Table 3.3: Lower limb marker labels, definitions and positions

Marker label	Definition	Position
LASIS	Left anterior waist	Left front waist
RASIS	Right anterior waist	Right front waist
LBWT	Left posterior waist	Left back waist
RBWT	Right posterior waist	Right back waist
LTHI	Left thigh	On the outside of the left thigh below hand swing
LKNE	Left knee	On the outside of the left knee joint
LTIB	Left tibia/shin	On the outside of the left lower leg
LANK	Left ankle	On the bony prominence on the outside of the left ankle
LHEE	Left heel	On the back of the left foot
LMET	Left metatarsal	On the second metatarsal
RTHI	Right thigh	On the outside of the right thigh below hand swing
RKNE	Right knee	On the outside of the right knee joint
RTIB	Right tibia/shin	On the outside of the right lower leg
RANK	Right ankle	On the bony prominence on the outside of the right ankle
RHEE	Right heel	On the back of the right foot
LMET	Left metatarsal	On the second metatarsal

Note: The right thigh and tibia markers are placed lower than the left marker to make it easier to distinguish the left from the right part of the body when viewed through the Vicon software.

3.6.2 Measuring the pistoning in dynamic position

Our aim in this part was to measure the pistoning movement between Seal-In[®] X5 and Dermo[®] liner within the socket and patient's satisfaction during the normal walking. Therefore, to avoid any errors in the study due to different alignments and manufacturing of the prostheses, all 20 prostheses were made by one prosthetist (the researcher). All subjects were requested to wear the same shoes during adjusting the alignments and experiments.

Following this trial period, subjects attended the motion analysis laboratory for pistoning evaluation by collecting data via a 7- infrared camera (Vicon 612 system) (Oxford Metrics; Oxford, UK). The accurate Vicon motion system with accuracy level of less than ± 0.1 mm and sampling rate of 200 Hz were used for Vicon motion system.

The reproducibility of measurements was evaluated by intraobserver intrasession, intraobserver intersession and interobserver intersession variability. Two observers performed the experiments in two sessions with one week interval. Sixteen reflective markers according to the Helen Hayes marker set were attached to the subjects' prostheses and sound lower limbs. On the prosthetic side, the knee and tibia markers were located on lateral proximal socket wall (LPS) and lateral distal end of the socket (LDS), respectively (Fig. 3.9). In order to measure the liner vertical movement, two extra markers were attached to a) lateral liner below the knee joint (LLin1) and b) 5 cm below the LLin1 (LLin2).

The pilot study showed that the knee flexion and extension can bias the real amount of pistoning and should be eliminated. Therefore, in order to ensure the measurement accuracy, the two extra markers (LLin1, 2) were attached over the liner below the knee level to avoid the knee motion. Using a transparent socket enabled us to locate markers on the liner inside the hard socket (two fine, paper-thin 2D markers were attached on the liner inside the hard socket) so that the cameras could detect the marker and the researcher would be able to see the pistoning movement inside the socket. Moreover, by locating the markers all on one segment, that is the tibia, knee flexion and thereby any fake displacement could be avoided.

During the pilot trials, it was noticed that a transparent socket resulted in reflections that were detected as markers by the cameras; hence, the transparent socket wall was covered with paper tape excluding the areas to which two new markers were added. Transparent plastic (Northplex[®], North Sea Plastic LTD 12mm) was used in the experiment

to see the movement of the liner inside the socket. Before the test, subjects were requested to walk in the motion analysis to be familiar with the environment. Each subject was recommended to walk with self selected speed in motion analysis laboratory. The trials were recorded five times for each subject. Five appropriate trials for each subject were selected. One trial was considered as an appropriate trial that all the markers captured by the cameras. Moreover, one gait cycle was chosen to check the liner movement (pistoning) within the socket.

All the subjects were requested to walk in the most comfortable speed and normally in the motion laboratory from the starting point to the end line (8 meter walkway) to avoid any changes in gait patterns by the subjects. Sometimes the patients had to repeat the trials and to be sure that the subjects were not fatigue, they were asked to rest when they felt tired. For calculating pistoning within the socket, the distance between markers on the liner and on the socket during the gait was used to identify any pistoning movement.

Statistical data was analyzed using SPSS 17.0, and P-values of 0.05 or less were chosen to reflect statistical significance. In order to analyze, the gait was divided into eight phases namely initial contact, loading response, midstance, terminal stance, preswing, initial swing, midswing and terminal swing.

3.7 Data acquisition (photographic method)

3.7.1 Equipments and Measurements

In order to identify the pistoning movement inside the prosthetic socket, the same setting of the previous proposed method was used. The equipments consisted of:

- i. 30, 60 and 90N load;
- ii. A camera (Canon PowerShot A470);

- iii. Two reference rulers attached to the lateral side of the limb and the socket (Figure 3.13A) to measure the real displacement on the photographs;
- iv. Five markers.

Four of the markers were located as follows: greater trochanter (A), proximal edge of the liner (B), proximal edge of the socket (C), and distal end of the socket (D). To optimize the previous method, one extra marker (E) was attached to the liner at the level of the posterior-proximal prosthetic wall (Figure 3.13A). It was meant to eliminate knee flexion or extension effect.

3.7.2 Position for measuring pistoning

For each of the following positions (compressive and tensile loading to replicate the gait), a photograph was taken from a certain distance in such a way that the markers and the reference rulers could be clearly observed:

- i. Subjects standing full weight bearing on prosthetic limb. This was considered the baseline position, with which all other positions were compared (Figure 3.13A);
- ii. Subjects standing without bearing weight on prosthesis, with the knee extended (Figure 3.13B);
- iii. Applying the 30, 60 and 90N loads consecutively, along the longitudinal axis of the prosthesis (Figure 3.13C).

It was also assured that they were not at an angle from the camera stand. We attached one ruler on the thigh as a measuring reference for the markers on the femur. And, the ruler on the socket was used as a measurement reference for the markers on the socket.

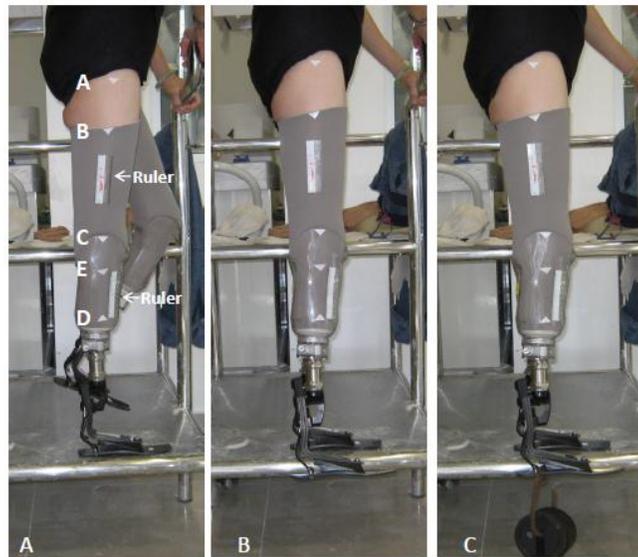


Figure 3.13: A) full weight bearing; B) non weight bearing; C) adding load

3.7.3 Measuring pistoning

To calculate the distances between the markers, all the photos were taken from a fixed distance using a tripod. This distance was one meter for all the subjects and the camera was at the level of the anatomical knee center. Each subject performed the test 3 times and the average value was used for analysis. The distances between the markers (AB, AC, AD and ED) in full weight bearing were used as the base values. For instance, the pistoning (displacement) between the markers E and D in non weight bearing condition was calculated as follows: ΔED (non weight bearing) = ED_2 (the distance in non weight bearing) – ED_1 (the distance in full weight bearing).

$$\Delta ED \text{ (no weight)} = ED \text{ no weight} - ED \text{ standing}$$

$$\Delta ED \text{ (30N)} = ED \text{ 30 Newton} - ED \text{ standing}$$

$$\Delta ED \text{ (60N)} = ED \text{ 60 Newton} - ED \text{ standing}$$

$$\Delta ED \text{ (90N)} = ED \text{ 90 Newton} - ED \text{ standing}$$

3.8 Questionnaire

After the experiments the subjects were asked to complete one questionnaire for each liner. Parts of the PEQ questionnaire were applied for the qualitative analysis (Legro et al., 1998; Van de Weg et al., 2005). The questionnaire was composed of the following three sections (Appendix E):

- Demographic data (sex, age, cause of amputation, weight, height and time since amputation);
- Satisfaction (fitting, donning and doffing, sitting, walking on level surface, walking on unlevel ground, walking up and down the stairs; cosmesis; overall satisfaction);
- Problems (sweating, wound, skin irritation, pistoning, pain, inflation (swelling), smell, unwanted sounds).

Each area was rated on a scale from 0 to 100, where 0 indicated “dissatisfaction or extreme problems” with the system and 100 indicated “complete satisfaction or no problems”.

Statistical data was analyzed with SPSS 18.0, and P-values of 0.05 or less were chosen to reflect statistical significance. The gait cycle (stance and swing) was divided into eight phases. The stance phase consisted of: initial contact, loading response, midstance, terminal stance and preswing; and the swing phase consisted of: initial swing, midswing and terminal swing.

CHAPTER FOUR: RESULTS

Chapter 4 details the outcome of the pistoning movement between the soft liners (Seal-In[®] X5 transtibial and Dermo[®] liner) and socket during static and dynamic position.

4.1 Pistoning measurements (static Position)

The results obtained from the static evaluation of Seal-In[®] X5 and Dermo[®] Liner showed that there was a significant difference between the two liners ($P < 0.05$). Pistoning between Seal-In[®] X5 and the socket was not the same as that with Iceross Dermo[®] Liner and socket (71% less). The average displacement in the six subjects between the two liners and the socket under different static conditions (after adding loads and after removing loads) is listed in Table 4.1.

The subjective feedback of the participants indicated less skin stretch, and more feeling of security (two amputees) with Seal-In[®] X5 Liner. However, diabetic subjects' main complaint was about donning and doffing the Seal-In[®] X5; and when they were asked to choose one liner, they preferred Dermo[®] Liner. When the loads were added to the prosthesis, the subjects felt more comfortable at the end of residual limb with the Seal-In[®] X5.

4.1.1 Adding loads

The results showed that there was no pistoning movement between the socket and both liners while changing the position from full-weight bearing to semi-weight bearing. The mean of pistoning in the six subjects was 2 mm (SD, 0.5) between the Dermo[®] Liner and socket while changing from semi-weight bearing to non-weight bearing position, but

the average of pistoning in the six subjects was zero with Seal-In[®] X5 transtibial liner (100% less than Dermo[®] Liner). There was a significant difference ($P<0.02$) between the two liners after the subjects changed their positions to non-weight bearing. After adding 30 N to the prosthetic limb, there was 1 mm (SD, 0.8) displacement between Seal-In[®] X5 and socket (50% less), but the average displacement was 2 mm (SD, 0.5) between Dermo[®] Liner and the socket, and the difference between the two liners was significant ($P<0.04$).

After adding 60 N to the prosthesis, the average displacement was 1 mm (SD, 0.5) between Seal-In[®] X5 liner and the socket (75% less), and about 4 mm (SD, 1.6) pistoning was seen between Icross Dermo[®] Liner and the socket ($P<0.04$). The analysis of the data showed the maximum amount of pistoning within the socket after adding 90N to the prosthetic limb. On average, 2 mm (SD, 1) pistoning occurred with Seal-In[®] X5 (60% less) and 5 mm (SD, 1.5) with Dermo[®] Liner ($P<0.02$), after adding 90 N load.

4.1.2 Removing loads

During the process of removing the loads, 30 N was removed first. The average displacement did not change with Seal-In[®] X5 (2 mm) when compared to that when 90 N load was added to the prosthesis, but it remained at 4 mm (SD, 1.4) with Dermo[®] Liner ($P<0.03$) after removing 30N load. After removing another 30 N, the amount of vertical movement was 2 mm (SD, 1) and 4 mm (SD, 1.5) with Seal-In[®]X5 and Dermo[®] Liner, respectively ($P<0.04$) (The average displacement did not change). However, there was no significant difference ($P<0.06$) between the two liners after removing the entire load. When the subject again changed to semi-weight bearing position, 1 mm (SD, 0.5) pistoning was remained when Seal-In[®] X5 Liner was used, while Dermo[®] Liner returned to the base

position (full-weight bearing) ($P<0.04$). The pistoning between socket and two different liners in subjects 2 and 5 are illustrated in Figure 4.1. and 4.2.

Table 4.1: Average of displacement (SD) between two markers after adding and removing load

	Adding Load (mm)						Removing Load (mm)					
	Full weight bearing (SD)	Semi weight bearing (SD)	Non weight bearing (SD)	30N (SD)	60N (SD)	90N (SD)	90N (SD)	60N (SD)	30N (SD)	Non weight bearing (SD)	Semi weight bearing (SD)	Full weight bearing (SD)
Seal-In® X5	0	0	0	1(0.8)	1(0.5)	2(1)	2(1)	2(1)	2(1)	2(1)	1(0.5)	0
Iceross Dermo®	0	0	2(0.5)	2(0.5)	4(1.6)	5(1.5)	5(1.5)	4(1.4)	4(1.5)	3(0.9)	0	0

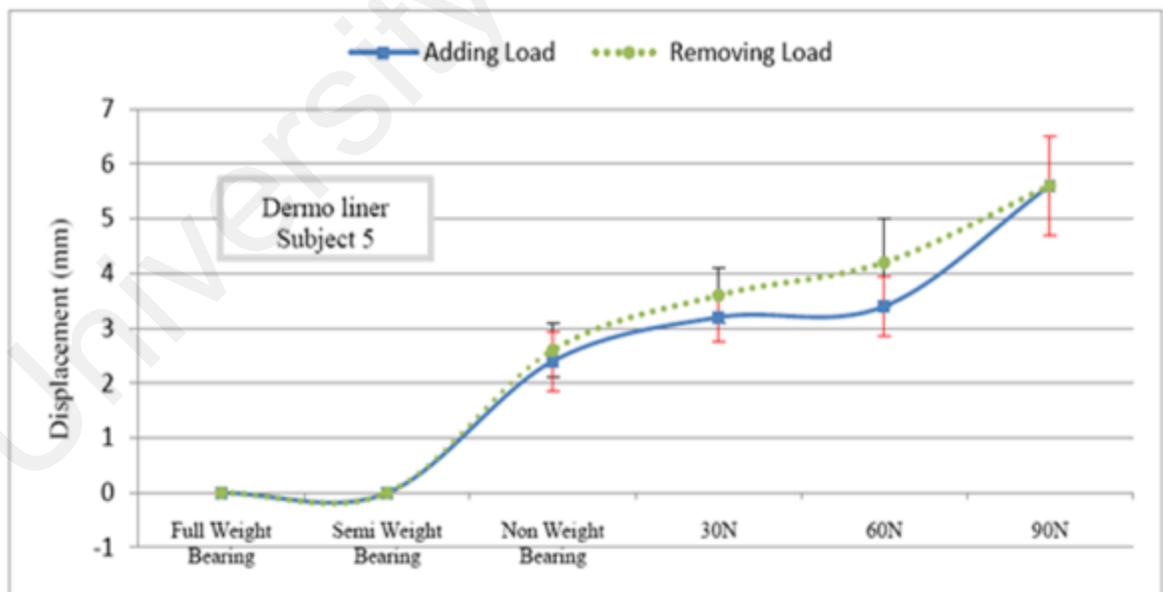
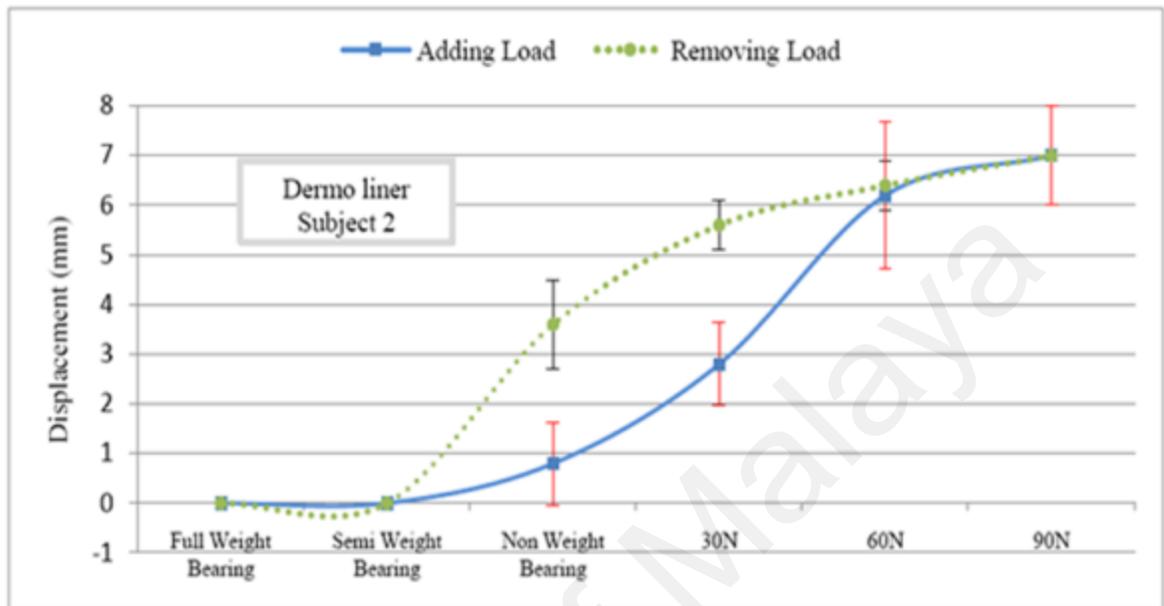


Figure 4.1: The pistoning (Static) between socket and Dermo[®] liners in subjects 2 and 5

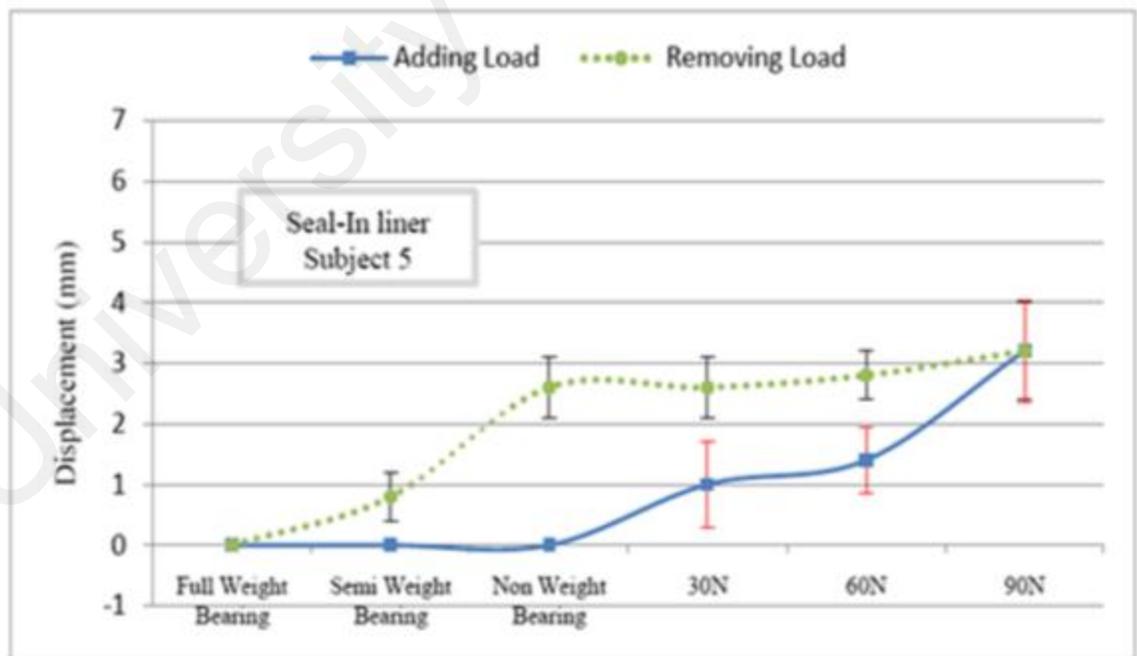
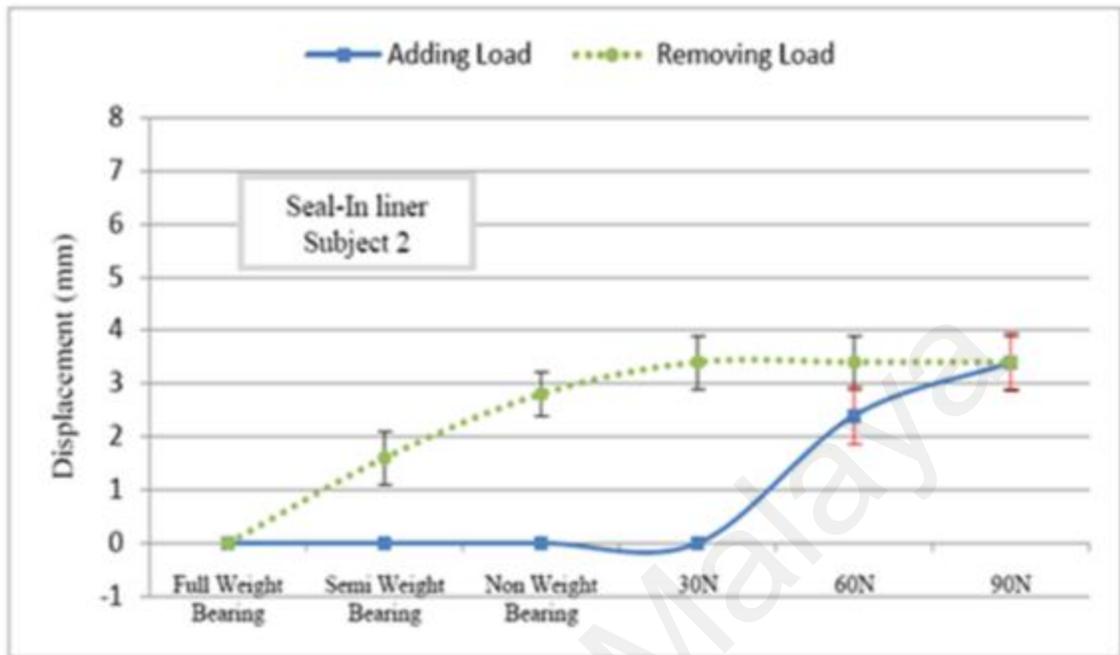


Figure 4.2: The pistoning (Static) between socket and Seal-In[®] X5 liners in subjects 2 and 5

4.2 Pistoning measurements (Dynamic Evaluation)

The intraclass correlation coefficient (ICC) of intraobserver intrasession, intraobserver intersession and interobserver intersession was 0.92, 0.87 and 0.79, respectively.

The results of Vicon motion analysis showed that the overall amount of pistoning in Seal-In[®] X5 was less than Dermo liner and there is a significant difference between two liners ($P < 0.05$). Most differences were seen during initial contact, and swing phase (initial swing, midswing, and terminal swing). There were no pistoning movement between Dermo[®] liner and socket during midstance, terminal stance and preswing. However, still a little pistoning between Seal-In[®] X5 and socket in midstance and terminal swing were seen (see Table 4.2 and Figure 4.3, Figure 4.4 and 5).

4.3 Satisfaction

The questionnaire survey revealed that the subjects were overall more satisfied ($P < 0.05$) with the Dermo[®] liner than they were with the Seal-In[®] X5 liner. Nevertheless, many of them mentioned increased levels of pain and pistoning within the socket with the Dermo[®] liner. Donning and doffing was more difficult with the Seal-In[®] X5 liner, but the subjects were more satisfied with the socket fit. The participants also stated that, when the Seal-In[®] X5 liner was used, the prosthesis acted like a natural part of their body and that they did not experience any traction at the end of the liner (Table 4.3).

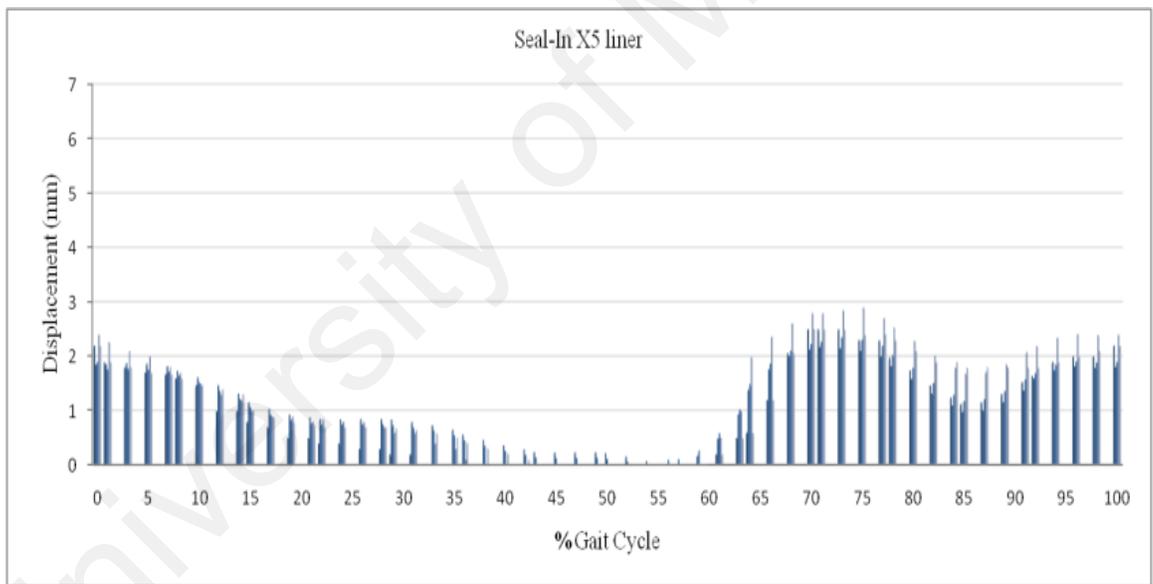
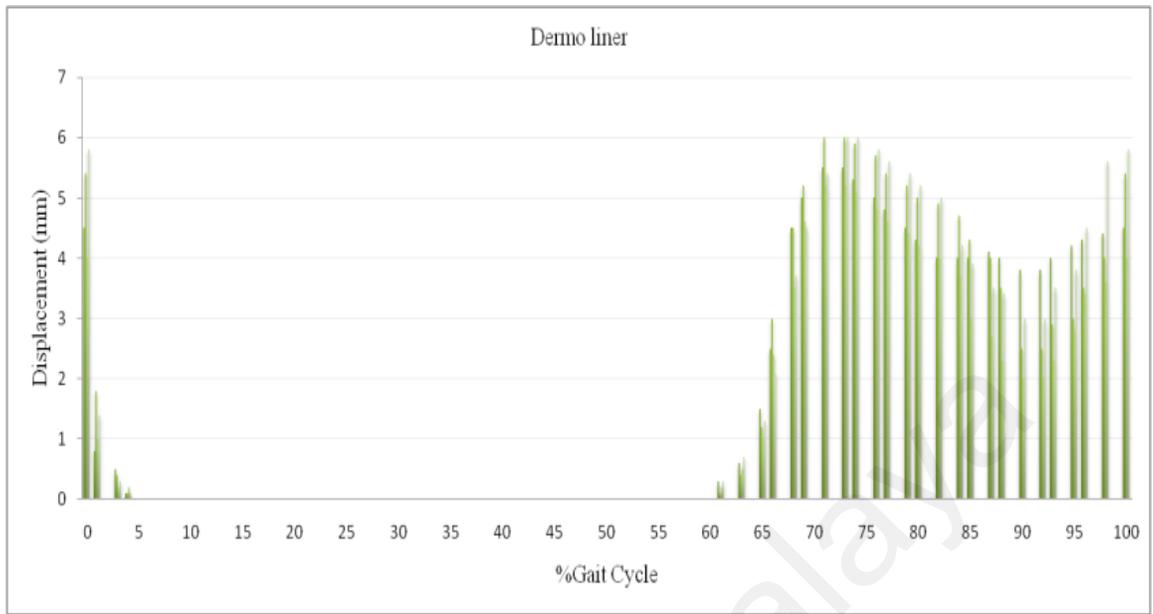


Figure 4.3: The average of pistoning between the liners and socket in different gait cycle (n=10)

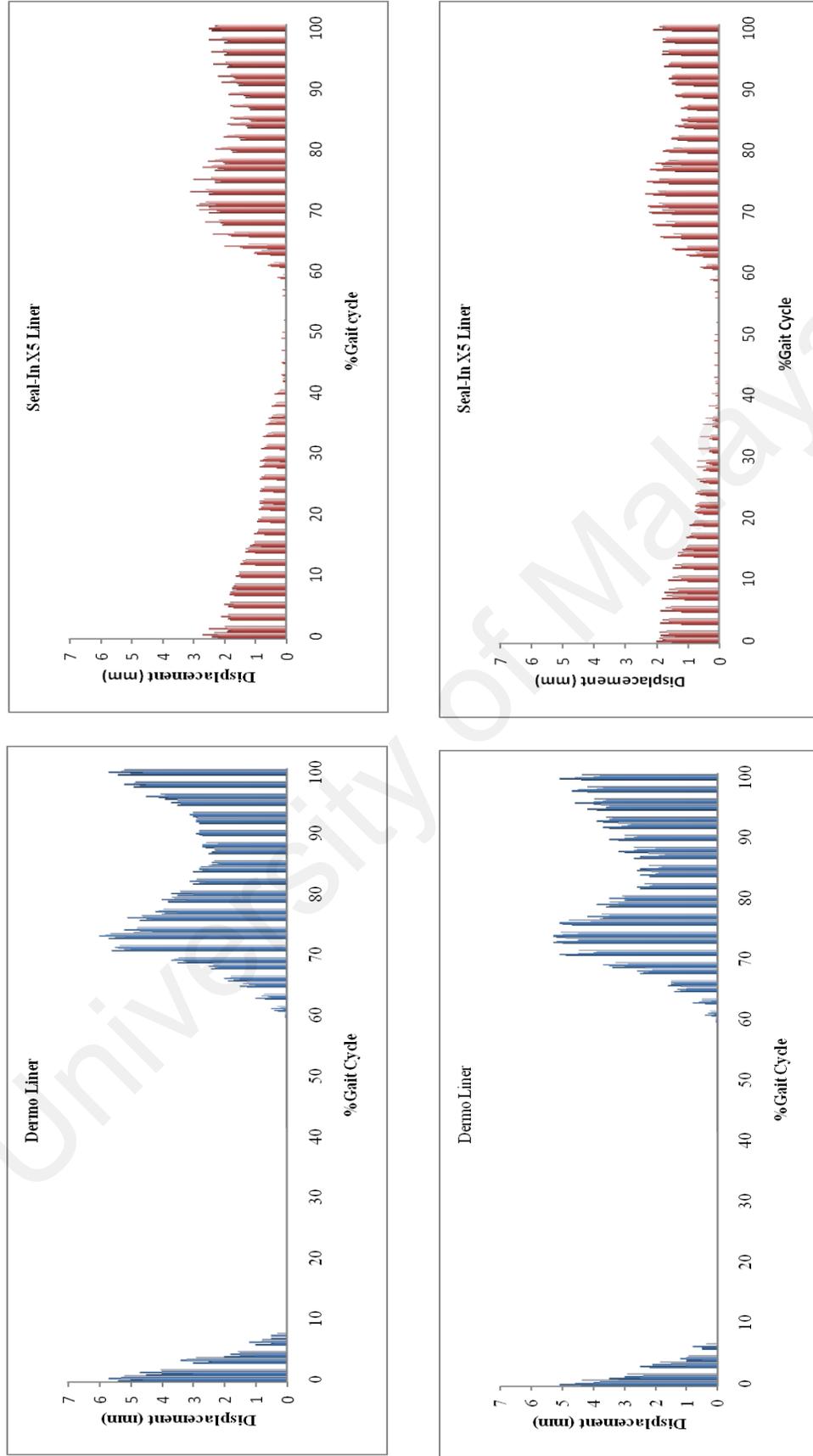


Figure 4.4: Sample pistoning patterns with Seal-In[®] X5 and Dermo[®] liner during one gait cycle for subjects 2 (top) and 5(bottom)

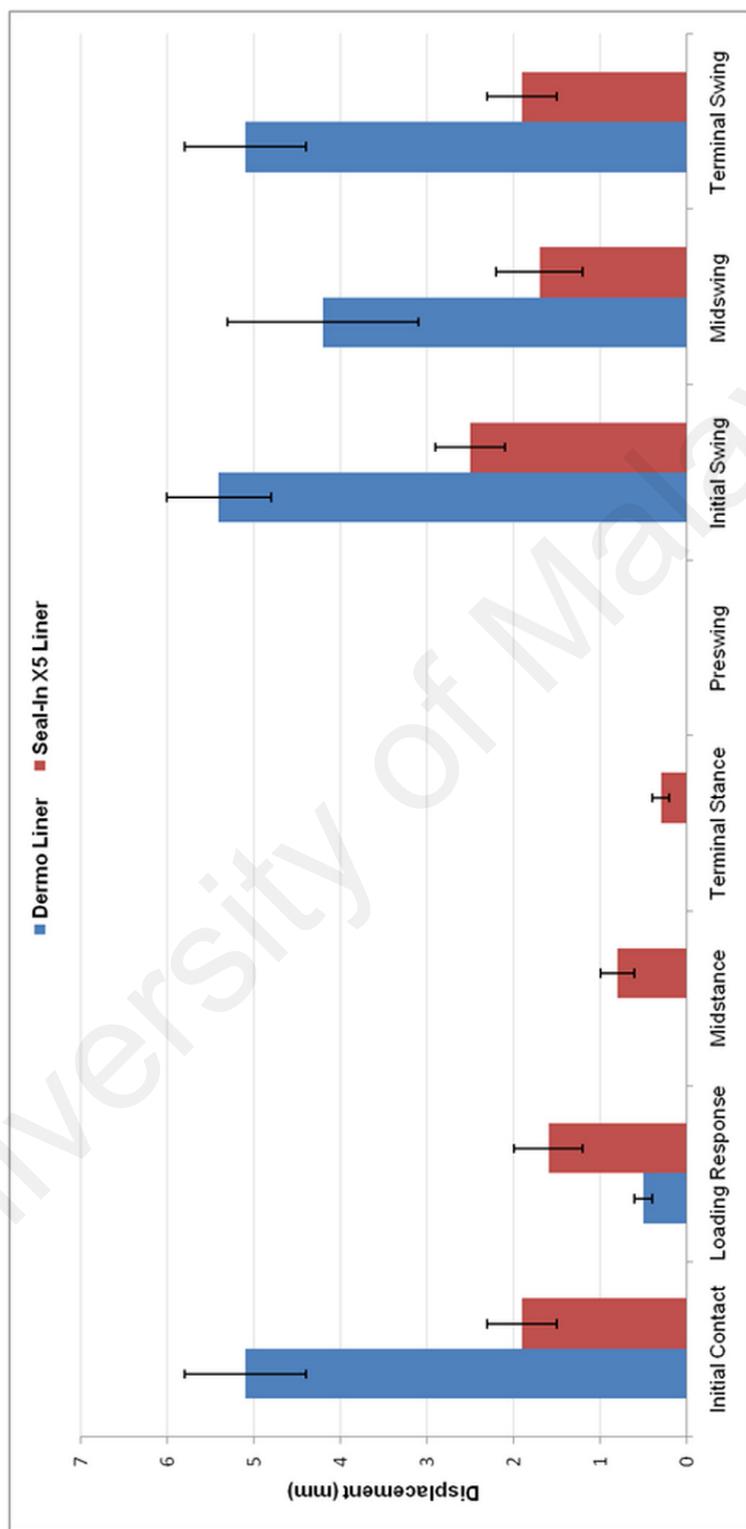


Figure 4.5: The comparison of mean displacement in different phases of the gait cycle

Table 4.2: The average of pistoning between the liners and socket in different gait cycle

Gait cycle	Liners	Mean (mm)	Std. Deviation	P value
Initial contact	Dermo [®]	5.1	0.7	.000*
	Seal-In [®] X5	1.9	0.4	
Loading response	Dermo [®]	0.5	0.1	.000*
	Seal-In [®] X5	1.6	0.4	
Mid stance	Dermo [®]	0	0	.000*
	Seal-In [®] X5	0.8	0.2	
Terminal stance	Dermo [®]	0	0	.019*
	Seal-In [®] X5	0.3	0.1	
Pre swing	Dermo [®]	0	0	-
	Seal-In [®] X5	0	0	
Initial swing	Dermo [®]	5.4	0.6	.000*
	Seal-In [®] X5	2.5	0.4	
Mid swing	Dermo [®]	4.2	1.1	.000*
	Seal-In [®] X5	1.7	0.5	
Terminal swing	Dermo [®]	5.1	0.7	.000*
	Seal-In [®] X5	1.9	0.4	

* Indicates statistically significant values.

Table 4.3: Comparison of satisfaction and perceived problem with Dermo[®] and Seal-In[®]

Satisfaction	Liner Type	Mean ¹	P value	Problem	Liner Type	Mean ²	P value
Fitting satisfaction	Dermo [®]	75.59	.003*	Sweat complaint	Dermo [®]	70.53	.082
	Seal-In [®] X5	87.09			Seal-In [®] X5	72.50	
Donning and doffing satisfaction	Dermo [®]	87.50	.000*	Wound complaint	Dermo [®]	100	-
	Seal-In [®] X5	35.44			Seal-In [®] X5	100	
Sitting satisfaction	Dermo [®]	76.30	-	Irritation complaint	Dermo [®]	100	-
	Seal-In [®] X5	77.80			Seal-In [®] X5	100	
Walking satisfaction	Dermo [®]	78.25	.001*	Pistoning within the socket	Dermo [®]	72.50	.000*
	Seal-In [®] X5	85.80			Seal-In [®] X5	95.75	
Uneven walking satisfaction	Dermo [®]	75.20	.040*	Pain complaint	Dermo [®]	70.83	.000*
	Seal-In [®] X5	80.30			Seal-In [®] X5	83.52	
Stair satisfaction	Dermo [®]	76.50	.087	Swelling (edema) complaint	Dermo [®]	100	-
	Seal-In [®] X5	78.75			Seal-In [®] X5	100	
Overall satisfaction with prosthesis	Dermo [®]	85.77	.004*	Smell complaint	Dermo [®]	95.8	.153
	Seal-In [®] X5	75.20			Seal-In [®] X5	94	
Cosmetic satisfaction	Dermo [®]	82.50	.460	Sound complaint	Dermo [®]	74.85	.000*
	Seal-In [®] X5	80.75			Seal-In [®] X5	95.5	

¹ Greater mean means higher satisfaction

² Greater mean means less complaints/problems

*Indicates statistically significant values

CHAPTER FIVE: DISCUSSION

This chapter discusses the results in great details and gives proof-based reasoning that relates the results to the questions posed in the thesis.

In this study, two different suspension systems, Iceross Dermo[®] Liner (Össur) with shuttle lock and Iceross Seal-In[®] X5 Transtibial Liner with valve, were compared. The simple and accurate Vicon motion system with accuracy level of less than ± 0.1 mm (Jenkins S., 2005) under different static positions was used to find the effects of these liners on prosthetic suspension, especially to check the pistoning occurring between the liner and socket in six transtibial amputees.

Pistoning is the most important indicator that shows the successful function of the prosthetic suspension system. Pistoning of less than 10 mm gives a feeling of added fit and security to the amputees (Newton et al., 1988). However, there is not enough evidence to support this pistoning threshold. In addition, in 2002, a research study was conducted on 20 transtibial amputees to compare Total Surface Bearing (TSB) and Patellar Tendon Bearing (PTB) sockets (Yigiter et al., 2002). Their study showed that there is a significant difference between the two types of sockets ($P < 0.05$), and pistoning in TSB is less than that in the PTB prosthesis

5.1 Evaluation of current methods

Based on the literature review, in order to check the pistoning inside the socket, most of the researchers measured the displacement between the bone and the socket or the soft tissue by different techniques in static position (Madsen et al., 2000; Yigiter et al., 2002; Söderberg et al., 2003) or during the gait (Lilja et al., 1993; Sanders et al., 2006). Some researchers tried to mimic the gait by adding loads to the prosthesis in static positions; however, no sound reasoning was provided for the load selection (Board et al., 2001; Commean et al., 1997; Narita et al., 1997).

In 2006, a noncontact sensor was used to monitor the pistoning between the stump and socket during the gait in supracondylar socket with Pelite liner; however, the authors could not measure the pistoning between the silicon liner and socket by this sensor (Sanders et al., 2006). In a recent study, a new method of three-dimensional (3D) socket–stump telescopic movement evaluation while performing tasks on the force plate was presented (Papaioannou et al., 2010). They measured the piston motion between the skin and socket by roentgen stereogrammetric system through attachment of tantalum pigments on the bone, skin and socket.

Evaluation of piston motion has been performed with various prosthetic sockets and soft interfaces. The researchers have either used PTB socket with Pelite liner (Newton et al., 1988; Wirta et al., 1990; Commean et al., 1997; Narita et al., 1997; Yigiter et al., 2002; Sanders et al., 2006) and/or TSB socket with silicone liner (Narita et al., 1997; Board et al., 2001; Tanner and Berke, 2001; Yigiter et al., 2002). The reported ranges of pistoning between the liner and socket with these two prosthetic designs show that less pistoning occurs with TSB socket and silicone liner (2-5 mm) compared with PTB socket and Pelite liner (6-41.7 mm).

The aforementioned methods are complicated for measuring the pistoning between the liner and the socket but Vicon motion system brings the possibility of easy and fast determination of pistoning between the liner and the socket. It can also be a safe method if exposing to X-ray is a concern (Sanders et al., 2006). Nevertheless, the current method using the Vicon system cannot be employed to monitor the tibial movement within the soft tissue.

5.2 Adding loads

The results of this study on the six subjects showed a significant difference between the two liners under different static conditions ($P < 0.05$). Iceross Seal-In[®] X5 Transtibial Liner helped in decreasing the pistoning through vacuum inside the socket and ensured firm attachment to the socket wall. Therefore, in the non-weight bearing condition, the average of pistoning was zero and even after adding 30 N and 60 N loads to the prosthesis, there was only 1 mm pistoning between Seal-In[®] X5 Liner and the socket. However, the mean displacement in the six subjects with Dermo[®] Liner was about 2 mm during non-weight bearing which is similar to the work of Tanner and Berke (2001) with silicon liner and shuttle lock. After adding 30 N load to the prosthesis, 2 mm of pistoning was still found (Table 4.1); however, there was about 4 mm displacement after adding 60 N load. The Seal-In[®] X5 Liner's attachment to the socket wall possibly resulted in significant reduction in pistoning and rotation inside the socket.

After adding different loads, the Dermo[®] Liner's contact with the socket decreased possibly due to the liner stretch and the rotation would have also increased, whereas in Seal-In[®] X5 Liner, the attachment was not lost even after adding 90 N load and rotation was not allowed. The mean pistoning for six subjects after adding 90 N was only 2 mm

with Seal-In[®] X5 Liner, while mean pistoning with Dermo[®] Liner was about 5 mm which resembles the results of Board et al.'s (2001) study. Furthermore, amputees stated improved security with Seal-In[®] X5 Liner during the addition of different loads.

Moreover, during the training sessions in the clinic to adapt to the new liner and prosthetic foot, two subjects reported that they felt more secure with the Seal-In[®] X5 Liner compared to the Dermo[®] Liner system and conceived the prosthesis as a part of their body. Also, after adding loads with Seal-In[®] X5 Liner, the subjects felt more comfortable at the end of the stump, possibly due to the elimination of the skin stretch at the end of the stump.

5.3 Removing loads

After removing the loads, it was observed that the liners, especially Seal-In[®]X5 Liner, did not return to the first position (Table 4.1, Figure 4.1, Figure 4.2) until the subject put all the weight on the prosthetic limb (full-weight bearing). As shown in Table 4.1, after removing 30 N from 90 N load, no displacement was found in Seal-In[®] X5 Liner, that is, the displacement remained at 2 mm for Seal-In[®] X5 liner, which is equal to that observed after adding 90 N, while the pistoning decreased 1 mm in the case of Dermo[®] Liner (mean, 4 mm). But when the load decreased to 30 N, the two liners showed the same behavior so that the displacement with Dermo[®] Liner and Seal-In[®] X5 remained the same as in the previous step. Even after removing all the loads, no displacement was seen in Seal-In[®] X5 liner and it did not show the same displacement when compared with the first non-weight bearing condition. While in Dermo[®] Liner, there was a decrease in displacement by 1 mm, 1 mm more displacement was found compared with the first non-weight bearing condition.

In the case of Dermo[®] Liner, during the second semi-weight bearing position, all pistoning due to the addition of load disappeared (zero) but in Seal-In[®] X5 liner, possibly

due to the high friction between the liner and socket, 1 mm pistoning was observed, and then became zero under full-weight bearing condition on the prosthetic limb.

5.4 Pistoning during gait cycle

The results revealed significant differences between the two liners during different gait cycles ($P<0.05$) and it was only during the pre swing phase that both liners demonstrated similar behaviors (Figure 4.3, Figure 4.4 and 5, Table 4.2). During initial contact, 5.1mm (SD, 0.7) pistoning was observed between the Dermo[®] liner and the socket. But it rapidly decreased to 0 at the end of loading response until initial swing possibly due to the presence of less friction between the liner and socket (Gholizadeh et al., 2011 a, c). There was only 1.9 mm (SD, 0.4) of pistoning during initial contact with Seal-In[®] X5 liner. This amount of pistoning did not reach 0, even in terminal stance. That was attributed to the firm attachment of the liner to the socket wall. There was therefore significant differences between the Dermo[®] and the Seal-In[®] X5 liners ($P<0.05$).

Maximum displacement in ten subjects with the Dermo[®] and the Seal-In[®] liners during the initial swing phases was approximately 5.4mm (SD, 0.6) and 2.5mm (0.4), respectively. Pistoning might have been high in this phase of gait due to maximum flexion in the knee joint. This amount of pistoning was lower than that observed in a previous study by Sanders et al., which examined PTB socket and Pelite liners (Sanders et al., 2006). After the initial swing phase, the amount of pistoning in the Dermo[®] liner decreased more than that in the Seal-In[®] X5 liner. It could be to the result of lower friction between the liner and socket (Gholizadeh et al., 2011 a, c).

Finally, pistoning motion between the liners and socket increased during the terminal swing phases due to centrifugal forces. There was a significant difference between

the two liners in this phase of the gait ($P<0.05$). The Seal-In[®] X5 liner's attachment to the socket wall possibly resulted in a significant reduction in pistoning inside the socket.

5.5 Satisfaction

Prosthetic satisfaction is a multi-factorial issue that is influenced by several aspects (Berke et al., 2010; Legro et al., 1999). The subjects require more time and effort when donning and doffing the Seal-In[®] X5 liner (Gholizadeh et al., 2011 a, c). They also need to have lubricant sprays with them to facilitate donning. Moreover, hand dexterity is more critical for donning and doffing a Seal-In[®] X5 liner than it is for donning and doffing the Dermo[®] liner. All locking liners usually have an umbrella-shaped feature at the distal part. Weight bearing during ambulation over this rigid and small-sized pin may result in pain at the distal end of the residual limb (Street, 2006). The total contact fit also deteriorates, especially if the residual limb is pointed and bony.

The Seal-In[®] X5 liner seems to resolve the so-called problem of “milking” or distal tissue stretching caused by the pin and lock (Beil and Street, 2004). This milking phenomenon can also result in pain, particularly at the end of the tibia and along the tibial crest. The subjects in the current study had significantly less pain with the Seal-In[®] X5 liner than they did with the pin and lock suspension (Dermo[®] liner).

Several factors influence satisfaction with prosthetic devices. Little is known about the effects of different prosthetic components and systems on amputee satisfaction. Whilst almost half of the lower limb amputees (57%) in one study were not satisfied with their prostheses (Dillingham et al., 2001), effortless donning and doffing does appear to have a positive effect on patient's experiences of prosthetic use (Baars et al., 2008). The subjects of this study were mainly dissatisfied with donning and doffing the Seal-In[®] X5 system and

many of them specified that donning and doffing was significantly easier with the Dermo[®] liner system. Subjects stated a preference for this suspension system over the Seal-In[®] X5 for long-term use.

5.6 Photographic method

Lack of pistoning is considered as the most important indicator of the successful function of the prosthetic suspension system (Newton et al., 1988). In this study, an attempt was made to improve a new technique for measuring the pistoning between the prosthetic liner and socket. The same setting of the previous proposed method (Gholizadeh et al., 2011b, c, d) was used as well. In order to eliminate the effect of knee angle during different static positions, one extra marker was attached (E) to the liner inside the socket. Furthermore, the transparent socket enabled the researcher to detect the liner movement inside the socket.

As it was expected, there was no displacement between the markers C and D after the subjects changed their positions from full weight bearing to non weight bearing, or even after load increase. The reason was that the markers C and D were located on a solid object and the distance was constant.

The displacement between the markers A and C or D was not similar to the markers E and D. The standard deviation for these markers also showed a wide range of pistoning between the subjects in different static positions. These wide ranges of pistoning might be the result of the knee angle effect. These data were not supported by the previous findings in the literature (Eshraghi et al., 2011).

After adding one marker (E) inside the socket, it was noticed that the displacement between markers E and D support the previous findings by the other researchers. For instance, 13 (9.1mm) displacements were found (average in eight subjects) between the markers A and C, while 2 mm (SD, 0.7) displacements were found between the markers E and D after changing the position from full weight bearing to non weight bearing. The amounts of vertical movements (pistoning) between the markers E and D for the subjects of this study resemble the findings of previous studies (Newton et al., 1998; Sanders et al., 2006).

The angles of knee and hip joints were different in full weight bearing position, non weight bearing and after adding the loads. Furthermore, the vertical movement between the markers E and D increased smoothly from full weight bearing through adding 90N load (no significant difference was found). This finding was attributed to the facts that these two markers were located on one single segment and also knee and hip angle alteration did not affect them. During full weight bearing position on prosthetic leg, the knee was fully extended, while in non weight bearing position or after adding the loads was flexed slightly and this change resulted in the displacement of marker C. Therefore, the markers should be preferably positioned on one segment like E and D on the tibial segment. It was also noticed that the soft tissue around the knee caused rolling of the liner. The wrinkles disappeared in non weight bearing and resulted in unreal displacement. Since the pistoning (vertical movement inside the socket) is usually only few millimeters, the evaluation should be as accurate as possible.

In summary, by using only two markers, one marker on the socket (D) and one marker inside the socket (on the liner; E), it will be possible to measure the pistoning between the liner and socket.

5.7 Limitations of the Study

There were some limitations during the study. There was no standard criterion regarding the exact load application in prosthetic users possibly due to the variations in prosthetic components, mass, walking speed, etc. Only two liners were evaluated in this experiment, which can be regarded as a limitation considering the varieties of available liner types. Also, no direct comparison between the results and the methodology used in this study can be made with other studies that employed different methodologies.

Further research should be conducted to compare more suspension alternatives in the market. That may provide a guideline to suspension system selection. Future research should also investigate and compare the proprioception effects of these suspension systems.

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CHAPTER SIX: CONCLUSIONS

In conclusion, amputee's rehabilitation is a challenging procedure which requires expertise especially in the selection of prosthetic components based on amputee's need. This study showed that Seal-In[®] X5 liner decreases the pistoning significantly, which can be attributed to high friction between each liner and socket. In addition, a significant difference was found between Seal-In[®] X5 and Dermo[®] Liner ($P < 0.05$) under different static conditions. The values of pistoning with both liners support the amounts of displacement found for silicon liners and TSB sockets by other researchers.

The ease of donning and doffing has a significant effect on prosthetic use (Baars et al., 2008). Although the Seal-In[®] X5 users found it hard to don or doff the liner, the pistoning showed to be statistically less than Dermo Liner. Nevertheless, two active subjects in this study (K3) preferred to use Seal-In[®] X5 Liner despite the difficulty in donning and doffing. It might be concluded that the difference in pistoning may not be clinically significant and that other factors may play a greater role in the subject comfort and confidence once a reasonable level of pistoning is reached. Since vacuum suspension is said to enhance proprioception in prosthetic users (Street, 2006), it might be the reason why these two subjects favored Seal-In[®] X5 Liner. However, it was not the purpose of this study to evaluate the proprioception effect of liners. In fact, in this study the patients were asked to express their subjective feelings so that a further study to objectively investigate the proprioception is recommended.

All the subjects claimed that skin stretch was less with Seal-In[®] X5 Liner. However, donning and doffing was the main complaints with the Seal-In[®] X5 and subjects preferred Dermo[®] Liner. Furthermore, the use of the Vicon system brings with it the possibility of easy and quick determination of static pistoning between the liner and the socket; at the

same time, it is not harmful for the subject's body when compared with X-ray. However, future studies comparing these different methodologies are also needed to assist with interpretations across studies or to identify a "gold standard" to which other methodologies can be compared.

In this study a new method was introduced to evaluate the pistoning between the prosthetic liner and the socket in transtibial amputees. The vertical movement can be measured by this simple technique by every prosthetist in any clinical setting. It is hoped that the proposed method can enhance the quality of gait and patient's satisfaction in lower limb amputees. Future research is also recommended for different liners and with a larger sample size to verify this preliminary result.

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