

CLINICAL EVALUATION AND IMPROVEMENT OF PROSTHETIC  
SUSPENSION SYSTEMS FOR LOWER LIMB AMPUTEES

HOSSEIN GHOLIZADEH VAZVANI

THESIS SUBMITTED IN FULFILLMENT OF  
THE REQUIREMENTS FOR  
THE DEGREE OF DOCTOR OF PHILOSOPHY

FACULTY OF ENGINEERING  
UNIVERSITY OF MALAYA  
KUALA LUMPUR

2015

# UNIVERSITY MALAYA

## ORIGINAL LITERARY WORK DECLARATION

Name of Candidate: **Hossein Gholizadeh Vazvani** (I.C/Passport No:)

Registration/Matric No: **KHA110119**

Name of Degree: **PhD of Engineering**

Title of Project Paper/Research Report/Dissertation/Thesis ("this Work"):

### **CLINICAL EVALUATION AND IMPROVEMENT OF PROSTHETIC SUSPENSION SYSTEMS FOR LOWER LIMB AMPUTEES**

Field of Study: **Biomedical Engineering (Biomechanics of Prosthetics)**

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## ABSTRACT

The method of attachment of a prosthesis to the residual limb (suspension system) is a critical issue in the process of providing prosthesis to an amputee. Proper fit of the stump inside the socket and appropriate selection of prosthetic suspension positively affect the amputees' gait, distribution of pressure within the socket, and amputees' satisfaction. This research aimed to: (1) conduct a survey to compare the effects of seal-in liner and common suction socket (CSS) on transfemoral amputees' satisfaction; (2) compare the effects of the Seal-In liner (suction) and Dermo liner (Pin/lock) on transtibial amputees' gait performance; and (3) design and evaluate (mechanical testing, pressure mapping, gait evaluation, and satisfaction survey) a new prosthetic suspension system. The survey study showed that the overall satisfaction increased with the use of the Seal-In liner compared with the CSS ( $P < 0.05$ ). The transfemoral amputees also suffered fewer problems with the use of the Seal-In liner. Comparison of the effects of the Seal-In liner (suction) and Dermo liner (pin/lock) on transtibial amputees' gait revealed much symmetry in temporal-spatial parameters between the prosthetic and sound limbs using the suction system. However, the two systems exhibited insignificant difference ( $P > 0.05$ ). Evaluation of kinetic data and subjects' feedback showed that the participants were more confident to use the suction socket, and the sockets were more suitable for walking. However, the participants expressed more complaints with this system because of difficulty in donning and doffing. Factors influenced by the prosthetic suspension system were derived through an extensive systematic literature review, and a new suspension system (Holo) using Velcro or Hook and Loop concept was designed and fabricated. The universal testing machine was used to evaluate the mechanical properties of the designed suspension system. For validation, the Holo was compared with three other common suspension systems, namely, the pin/lock, seal-in, and magnetic suspension system. The maximum tensile load that the new system could

bear (before failure) was 490 N (SD, 5.5). However, the pin/lock system could tolerate loading of 580 N (SD, 8.5). The magnetic (MPSS) and seal-in (suction) could tolerate loads of 350.9 N (SD, 7.0) and 310 N (SD, 8.4), respectively. Comparison (interface pressure) between the pin/lock and the Holo system showed that high pressure was applied to the residual limb at the distal region of the stump by the pin/lock system during ambulation. The new coupling system could distribute the pressure more uniformly over the residual limb. PEQ results indicated that the participants were generally pleased with the new system, particularly with easy donning and doffing procedures. Gait evaluation (case study) demonstrated a slightly higher walking speed and stride length with the new socket with Velcro suspension system than with the pin/lock system. Kinetic results also revealed that the patient were more confident to walk with the Holo system. The Holo suspension system may be used as an alternative suspension system for lower-limb amputees because the biomechanical findings were consistent with the ranges in the literature.



## ABSTRAK

Kaedah suspensi protesis untuk anggota residual badan (sistem suspensi) adalah isu yang kritikal dalam proses menyediakan protesis untuk amputi. Kesesuaian anggota residual di dalam soket dan pilihan sistem suspensi yang sesuai mempunyai kesan positif ke atas amputi dari segi gaya berjalan, pengagilan tekanan dalam soket, dan kepuasan. Kajian ini bertujuan untuk: (1) menjalankan bancian demi membandingkan kesan Seal-In dengan soket sedutan biasa (CSS) terhadap kepuasan amputi atas-lutut, (2) membandingkan kesan pelapik Seal-In dengan pelapik Dermo (Pin/kunci) terhadap prestasi gaya berjalan amputi bawah-lutut, dan (3) merekabentuk dan menilai (ujian mekanikal, pemetaan tekanan, penilaian gaya berjalan) sistem suspensi yang baru. Kajian telah menunjukkan kepuasan keseluruhan meningkat dengan penggunaan pelapik Seal-In berbanding CSS ( $P < 0.05$ ). Tambahan pula, masalah yang dihadapi oleh amputi atas-lutut berkurangan dengan penggunaan pelapik Seal-In. Perbandingan kesan pelapik Seal-In (sedutan) dengan pelapik Dermo (pin / kunci) pada gaya berjalan amputi bawah-lutut menunjukkan bahawa terdapat peningkatan simetri dalam parameter temporal-spatial antara anggota protesis dengan anggota asal apabila menggunakan sistem sedutan. Walau bagaimanapun, perbezaan antara dua sistem tersebut tidak ketara ( $p > 0.05$ ). Penilaian data kinetik dan maklum balas subjek menunjukkan bahawa para peserta lebih yakin menggunakan soket sedutan dan soket jenis ini lebih sesuai untuk aktiviti berjalan. Namun begitu, para peserta memberikan lebih rungutan terhadap sistem ini disebabkan kesukaran ketika proses memakai dan menanggalkan sistem tersebut. Melalui kajian literatur yang sistematik dan mendalam, faktor yang dipengaruhi oleh sistem suspensi telah dikenalpasti, dan sistem suspensi baru (Holo) yang menggunakan konsep Velcro atau cangkuk dan gelung telah direka bentuk. Mesin ujian universal telah digunakan untuk menilai sifat-sifat mekanik sistem suspensi yang direka. Untuk pengesahan, sistem Holo telah dibandingkan dengan tiga sistem suspensi

yang biasa, iaitu pin / kunci, Seal-In dan sistem suspensi magnet (MPSS). Beban tegangan maksimum yang boleh di tanggung oleh sistem baru (sebelum kegagalan) ialah 490 N (SD, 5.5). Walau bagaimanapun, sistem pin / kunci boleh menampung bebanan sehingga 580 N (SD, 8.5) . Sistem magnet (MPSS) dan Seal-In (sedutan) masing-masing mampu menampung bebanan sehingga 350.9 N (SD, 7) dan 310 N (SD, 8.4). Berdasarkan keputusan PEQ, para peserta secara amnya berpuas hati dengan sistem yang baru, disebabkan oleh proses memakai dan menanggal yang mudah. Perbandingan (tekanan antara-muka) antara pin / kunci dan sistem Holo menunjukkan tekanan yang lebih tinggi telah dikenakan pada anggota residual di kawasan hujung anggota residual ketika menggunakan sistem pin / kunci semasa berjalan. Sistem gandingan baru boleh mengagihkan tekanan yang lebih seragam di seluruh anggota residual. Penilaian gaya berjalan (kajian kes) menunjukkan kelajuan berjalan dan panjang langkah yang lebih tinggi apabila menggunakan soket baru dengan sistem suspensi Velcro berbanding dengan sistem pin / kunci. Selain itu, keputusan kinetik mendedahkan bahawa peserta lebih yakin untuk berjalan dengan sistem Holo. Sistem suspensi Holo boleh digunakan sebagai sistem alternatif bagi sistem suspensi anggota residual untuk amputi anggota-bawah kerana penemuan biomekanik adalah skonsisten dengan julat yang terdapat di dalam literatur.

## PUBLICATIONS

### ISI Journal:

1. **Gholizadeh H**, Abu Osman NA, Eshraghi A, Ali, S , N. AbdRazak, Transtibial prosthesis suspension systems: systematic review of literature, **Clinical Biomechanics**, 2014; 29.1: 87-97. (ISI-Cited Publication)
2. **Gholizadeh H**, Abu Osman NA, Eshraghi A, Ali S. Transfemoral prosthesis suspension systems: systematic review of literature, **American journal of Physical Medicine and Rehabilitation** (2014 Sep;93(9):809-23. (ISI-Cited Publication)
3. **Gholizadeh H**, Abu Osman NA, Eshraghi A, Ali S, Yahyavi ES. Satisfaction and problems experienced with transfemoral suspension systems: a comparison between common suction socket and Seal-In liner. **Archives of Physical Medicine and Rehabilitation**, 2013;94(8), 1584-1589. (ISI-Cited Publication)
4. **Gholizadeh H**, Abu Osman NA, Eshraghi A, Ali S. The Effects of Suction and Pin/Lock Suspension Systems on Transtibial Amputees' Gait Performance , **PLOS ONE** 2014: e94520. (ISI-Cited Publication)
5. **Gholizadeh H**, Abu Osman NA, Eshraghi A, Afirin NA. Evaluation of a New Suspension System For Limb Prosthetics. (**Biomedical Engineering Online**, 2014, 13:1 doi:10.1186/1475-925X-13-1 (ISI-Cited Publication)
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7. **Gholizadeh, H.**, Abu Osman NA, Eshraghi, A., & Razak, N.A. Clinical implication of interface pressure for a new prosthetic suspension system. **Biomedical engineering online**, 2014, 13:89 doi:10.1186/1475-925X-13-89) (ISI-Cited Publication)

## ACKNOWLEDGMENT

In the name of Allah, the most compassionate, the most merciful

My journey to completion of this project has been, among other things, exciting, challenging, enlivening, arduous, and greatly satisfying. It would not have come to fruition in such a complete and purposeful way without the support of several individuals.

First and foremost, I would like to express profound gratitude to my supervisor, Professor Noor Azuan Abu Osman, for his valuable support, encouragement, supervision and useful suggestions throughout this research work. His moral support and continuous guidance enabled me to complete my thesis successfully.

I am deeply indebted to Dr. Hadi Salehi, from Islamic Azad University, Najafabad Branch, Iran, who helped me to determine my future educational path. I would also like to acknowledge the help of my friends Dr. Arezoo Eshraghi, Dr. Nader Ale Ebrahim, Mr. Mohd Firdaus Mohd Jamil, Ms. Ása Guðlaug Lúðvíksdóttir, Mr. Knut Lechler , and Mr. Scott Elliott for their technical supports. Furthermore, I am grateful to the journals' editors and anonymous reviewers for their helpful comments and suggestions on my research during the consideration to publish our articles.

Most of all, my love, sincere admiration, concern, and apologies go to my best friend, my wife. This thesis would not have been written without her active support and enduring tolerance. I am also thankful to my daughters, Kiana and Kimiya, for their emotional supports. I am as ever, especially indebted to my parents for their love and support throughout my life. They gave birth to me, raised me, supported me, taught me and loved me.

This study was supported by the Malaysia UM/MOHE/HIR Project No. D000014-16001.

Hossein Gholizadeh Vazvani

## **DEDICATION PAGE**

To the memory of my eternal love, my mother.

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## **LIST OF ABBREVIATION**

|         |   |
|---------|---|
| AALQ    | : Attitude to Artificial Limb Questionnaire                       |
| ANOVA   | : Analysis of variance  |
| AP      | : Antro posterior   |
| ARBIS   | : Amputation Related Body Image Scale                             |
| BIQ     | : Body Image Questionnaire  |
| BK      | : Below knee  |
| CSS     | : Common Suction Socket   |
| GRF     | : Ground reaction force   |
| Holo    | : Hook and Loop   |
| HSM     | : Hypobaric Sealing Membrane                                      |
| IC      | : Ischial containment   |
| ICEROSS | : Icelandic Roll on Silicone Socket                               |
| JMERC   | : Janbazan Medical and Engineering Research Center                |
| KBM     | : Kondylen bettung munster  |
| MAS     | Marlo Anatomical Socket   |
| MPSS    | : Magnetic prosthetic suspension system                           |
| OI      | : Osseointegration  |
| OPOT    | : Orthotics and Prosthetics National Outcomes Tool                |
| OPUS    | : Orthotics and Prosthetics Users' Survey                         |
| PEQ     | : Prosthesis evaluation questionnaire                             |
| POP     | : Plaster of Paris  |
| PSSS    | : Perceived Social Stigma Scale                                   |
| PTB     | : Patellar Tendon Bearing   |
| PTS     | Patellar Tendon supracondylar                                     |
| PVD     | : Peripheral vascular disease                                     |
| QL      | : Quadrilateral   |
| ROM     | : Range of motion   |
| SACH    | : Solid ankle cushion heel  |
| SCS     | : Socket Comfort Score  |
| SCSP    | : Supra condylar supra patellar                                   |
| SD      | : Standard deviation  |
| SI      | Symmetry Index  |
| SPSS    | Statistical Package for the Social Sciences                       |
| TAPES   | : Trinity Amputation and Prosthesis Experience Scales             |
| TF      | : Transfemoral  |
| TSB     | : Total surface bearing   |
| TT      | : Transtibial   |
| TTP     | Transtibial prosthesis  |
| UMCIC   | : University of Malaya Center of Innovation and Commercialization |
| WHO     | : World health organization                                       |
| 3S      | : Silicone Suction Suspension                                     |



# CHAPTER 1

## INTRODUCTION

### 1.1. Background

Amputation is a surgical technique that has long been used as the final option for saving the remaining limbs from any further damage (Smith et al., 2004). The oldest archeologic evidence of amputation dates to 45,000 years ago, founded in present day Iraq. During the 18th century, limb amputation was performed quickly without anesthesia. Figure 1.1 shows an assistant compressing the thigh or arm to control bleeding during amputation. Surgeons divided tissues at the same level, commonly resulting in a residual limb of poor quality.



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

Based on the literature, the main reasons for amputation can be classified under any of the following conditions: peripheral vascular disease (PVD), trauma, tumors, and congenital limb deficiencies. These reasons may also vary in different countries. The main reason for amputation in developed countries is disease. Currently, PVD is the

most common reason for amputation among adults in developed countries (Branemark, 1977); such condition is often related to diabetes mellitus. Recent statistics show that vascular disease is the leading cause for amputation in the US by 82%, followed by trauma with 22%, congenital disease with 4%, and tumors with 4% (Seymour, 2002). In developing or undeveloped countries, trauma and injuries from war are the main reasons for amputation.

In Malaysia, the First National Health and Morbidity Survey (NHMS 1) reported that the prevalence of diabetes mellitus was 6.3% in 1986 and would reach 8.2% after 10 years or by 1996 (NHMS 2009a,b). Furthermore, the prevalence of diabetes would reach 10.8% by 2030 in Malaysia (2.48 million diabetes cases will occur); such increase would reflect 164% of the World Health Organization (WHO) estimation in 2000. Unfortunately, lower-limb amputation (mostly foot) would be necessary for most diabetic patients because of peripheral ischemia or severe infection (National Orthopedic Registry of Malaysia, 2009). The need for lower-limb amputation is 27.7 times greater in diabetic cases than in other conditions (Malaysian Diabetes Association, 2007).

The literature shows different levels of lower-extremity amputation (Figure 1.2). The incidence of transtibial (also called “below-knee”) amputations is very high. This level of amputation has received considerable attention in training and education for surgery, rehabilitation, and prosthetics in the past decades. However, some individuals who underwent transtibial amputation never recover completely (Smith et al., 2004). Surgical techniques for limb amputation generally focus on tissue design or muscle padding to cover the distal flap. The outcome is expected to be a residual limb with cylindrical shape, good padding of distal tibia, and stable muscles. Prosthetic fit for areas with poor soft-tissue padding is very challenging (Smith et al., 2004).

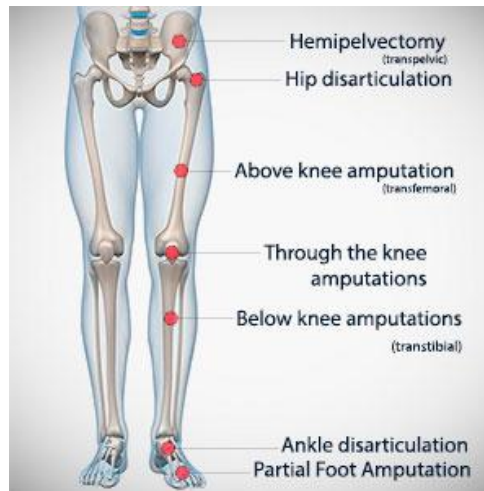


Figure 1.2: Various levels of lower-extremity amputations (Reproduced from <http://www.cpousa.com/prosthetics/lower-extremity/2013>)

## 1.2. History of prosthesis

Artificial limb or prosthesis is one of the main elements in the rehabilitation process after limb amputation. According to the Rig-Veda, the Indian warrior, Queen Vishpla, had her leg amputated, was fitted with a metal (iron) prosthesis, and subsequently returned to lead her troops. Study of a male Neanderthal skeleton, found in present day Iraq, indicated that the person had survived to age of 40 years with an atrophic right upper limb that had been amputated just above the elbow.

Based on the Atlas of Amputation and Limb Deficiencies (Smith 2004), 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 (Smith et al., 2004). In 2006, archaeologists found an artificial eyeball in the Burnt City (located in southeastern Iran) dated back to between 2800 and 2900 BCE (Figure 1.4).



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- Smith et al., 2004)



Figure 1.4: The World's Oldest known prosthesis (Prosthetic eye) (Reproduced from [http://www.iranreview.org/content/Documents/Iran\\_s\\_Burnt\\_City.htm](http://www.iranreview.org/content/Documents/Iran_s_Burnt_City.htm))

A prosthesis is an artificial device that mimics the form and/or function of a body part. Non-use or limited use of prosthetic devices is a concern for any rehabilitation team. Ideal prosthetic specifications are comfort, durability, light weight, easy donning and doffing, and pleasing cosmesis. Proper mechanical function and low-maintenance needs should also be added to these specifications. Whole rehabilitation efforts will fail if the patient is reluctant to wear the prosthesis (Smith et al., 2004). Therefore, the amputee's motivation could mainly influence prosthetic use.

In recent decades, prosthetic components and systems have been developed enormously to the level at which amputees can even participate in the Paralympic Games. However, many amputees remain reluctant to use prostheses because of various physiological and psychological problems, despite key advances in prosthetic device

research and development. Therefore, evaluation and improvement of current prosthetic systems would help overcome prosthetic drawbacks, thereby resulting in higher satisfaction with prostheses.

The present study focused on lower-limb prostheses. The main components for a lower-limb prosthesis usually consist of a soft liner (as cushion for the residual limb's skin), socket, suspension system (to securely maintain the prosthetic limb over the residual limb), joint (knee (in transfemoral prosthesis); tube adapter or pylon (corresponds to the amputated thigh or shank), and prosthetic foot. These components are connected through adapters with possibility of alignment adjustments (by alignment screws) between each pair of components (Figure 1.5).

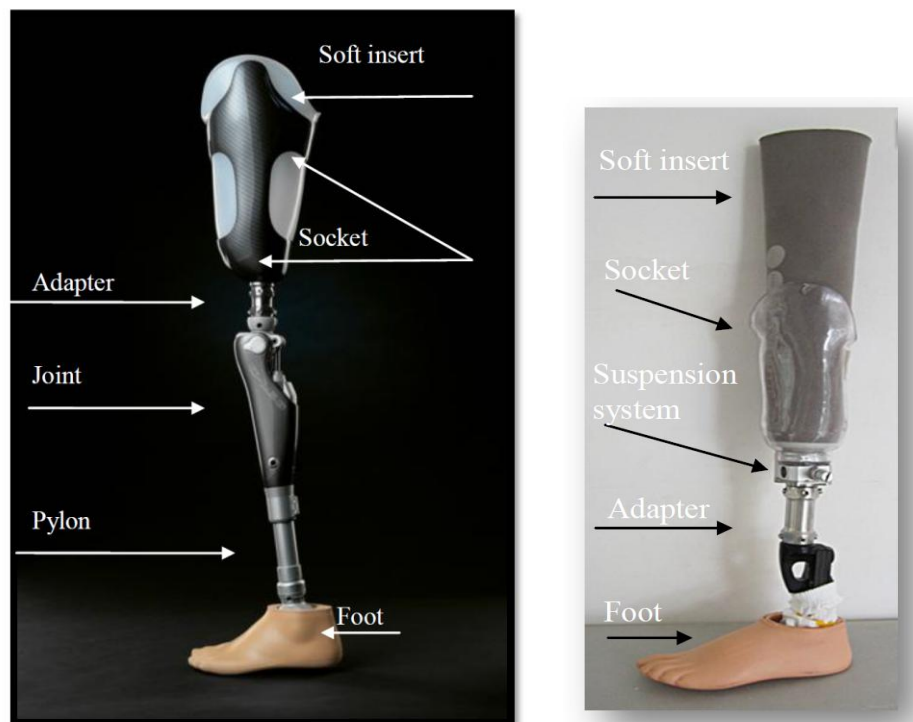


Figure 1.5: (left);Transfemoral prosthesis (modular), (right); transtibial prostheses (modular)

### **1.3. Prosthetic components (socket, soft liner, and suspension system)**

#### **1.3.1. Socket design**

Successful rehabilitation of an amputee is pertinent to the design and fit of the socket as the weight-bearing capabilities of the residual limb and the foot are dissimilar (Goh et al., 2004). The use of a lower-limb prosthetic socket mainly aims to stabilize the residual limb in the sagittal and coronal planes, attain body-weight support, voluntarily control the prosthetic knee, ensure proper function of muscles, and achieve harmony of appearance, function, and comfort, both dynamically and statically. The distribution of interface pressure between the socket and the tissues of the residual limb regulates the user's comfort; thus, such consideration is important in the socket design (Goh et al., 2004). The residual limb is exposed to shear stresses and pressures at the interface of prosthetic socket and residual limb during ambulation (Sanders et al., 2000). The pressures at the socket/skin interfaces vary considerably among individuals, sites, and clinical conditions.

The introduction of new designs and materials has revolutionized the design of transtibial prostheses after World War II (Sewell et al., 2000). Patellar tendon-bearing (PTB) cast is the conventional socket design for transtibial amputees; such cast is usually made of lamination materials (such as epoxy resin) or thermoplastics (such as polypropylene). Variations of the PTB socket shapes for transtibial prostheses have been developed since 1957 (Radcliffe c 1961). The weight-bearing areas are limited in such socket shape and could produce piston motion within the socket. The patellar tendon is the main structure of weight-bearing in the PTB prosthesis (Yigiter et al., 2002) (Figure 1.6). Different trim lines exist for PTB sockets, such as supracondylar (SC) or supracondylar suprapatellar (SCSP).

The total surface-bearing (TSB) socket or design is accompanied by a gel or silicone liner. The TSB socket was developed (Figure 1.7) to distribute the loads more evenly over the residual limb (Kristinsson Ö, 1993; Staats and Lundt, 1987). Yigiter et al. (2002) stated that gait symmetry, balance, and weight acceptance could improve with TSB socket compared with PTB. Narita et al. (1997) also found superiority of TSB over PTB socket regarding amputees' satisfaction and improved stability. However, Selles et al. (2005) have found no significant differences between these two systems regarding changes in socket function (gait characteristics, PEQ scores, and mobility-related activities).

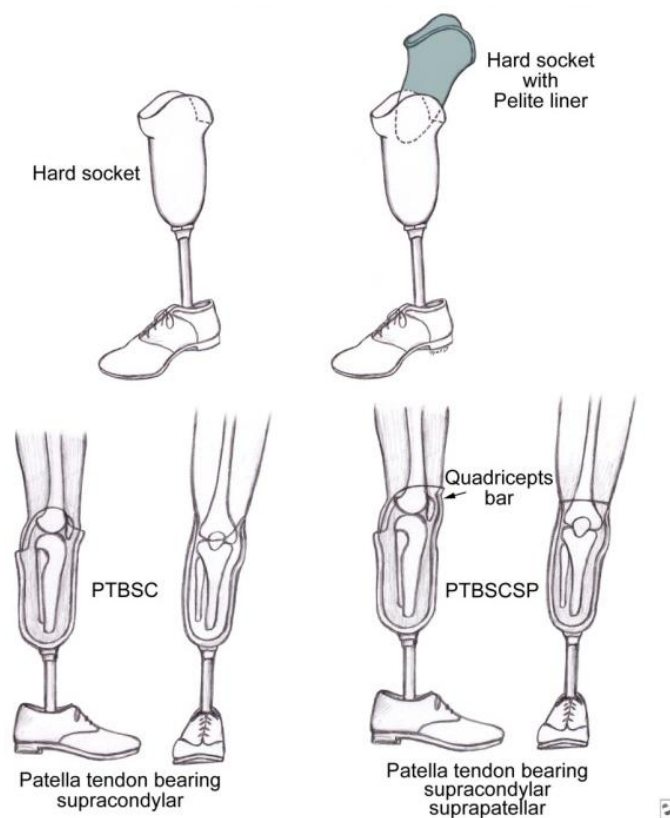


Figure 1.6: Common PTB prosthesis (Top); PTBSC (patella tendon bearing supracondylar) (Down-left); PTBSCSP (patella tendon bearing supracondylar-suprapatellar) (Reproduced from <http://thehealthscience.com/showthread.php?842905-Lower-Limb-Prosthetics>)



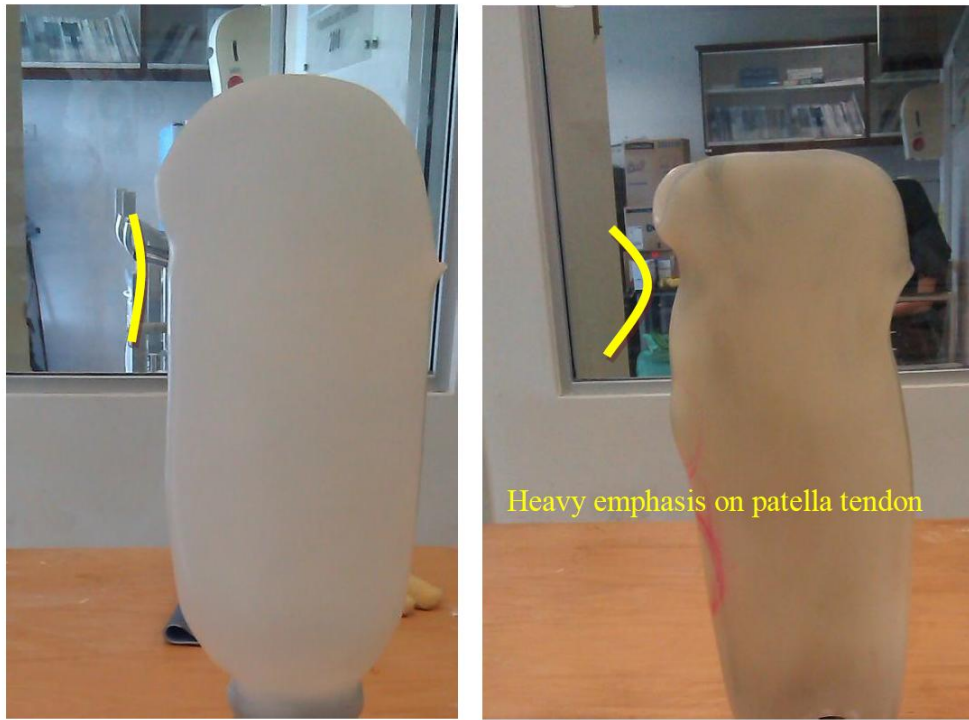


Figure 1.7: TSB socket (left); PTB socket (right)

In PTB prosthesis, the focus was more on the patellar tendon bar, which increases weight bearing in the area, than on the TSB socket. However, the TSB socket shape is more anatomical, and loads (body weight) are distributed more evenly between the residual limb and the socket.

Two recent socket designs for transfemoral prostheses (TFPs) are ischial containment (IC) socket and quadrilateral (QL) socket (Kapp S, 1999; Schuch, 1992). The proximal brim contours differentiate these two designs; the ischium is contained inside the IC socket but not in the QL socket (Figure 1.8). An evolution in the development of the IC socket is the M.A.S. socket developed by Marlo in 1999 (Fairley, 2004).



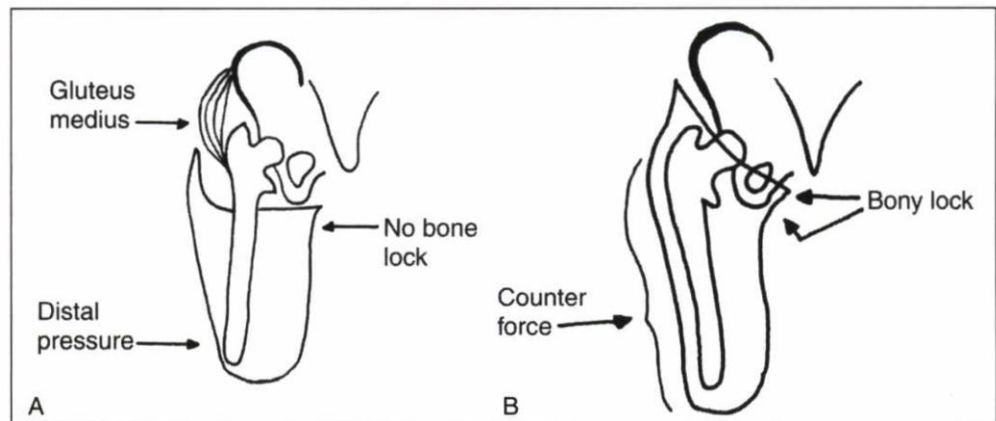


Figure 1.8: AP view of quadrilateral socket (A); ischial containment socket (B)  
 Reproduced from Michael JW: Current concepts in above-knee socket design. Instr  
 Course Lect 1990;39:373-378.)

The QL socket allows lateral socket displacement during stance phase. Pelvic stability is compromised because of the absence of a proximal bone lock, such as the IC socket. However, ischial tuberosity is locked in the IC socket, and stability is increased.

### 1.3.2. Soft liner and suspension system

Liners are soft inserts between the socket and the residual limb, which provide comfort and skin protection. Various soft liners are available in the market. Two of the most common soft liners in the market are Pelite and silicone liners. Pelite liners are conventional liners made of polyethylene foam sheet, which are used with PTB sockets (Figure 1.9). Vertical movement or pistoning between the residual limb and the socket is the main problem in Pelite liners (Eshraghi et al., 2011; Ali et al., 2012a). Silicon liners were introduced in 1986, and their main advantage was enhanced bond with the stump, which improved suspension compared with other soft sockets (Baars et al., 2008). Silicon liners (Figure 1.10) can reduce pistoning of the stump and the bone compared with polyethylene foam (Pelite) liners (Narita et al., 1997; Söderberg et al., 2003; Yigiter et al., 2002). Such reduction has been shown either clinically or by questionnaire. Tanner and Berke (2001) found only 2 mm of pistoning of the residual

limb with silicone liner and shuttle lock inside the TSB socket, whereas Sanders et al. (2006) indicated 41.7 mm of pistoning of 41.7 mm with the PTB socket.

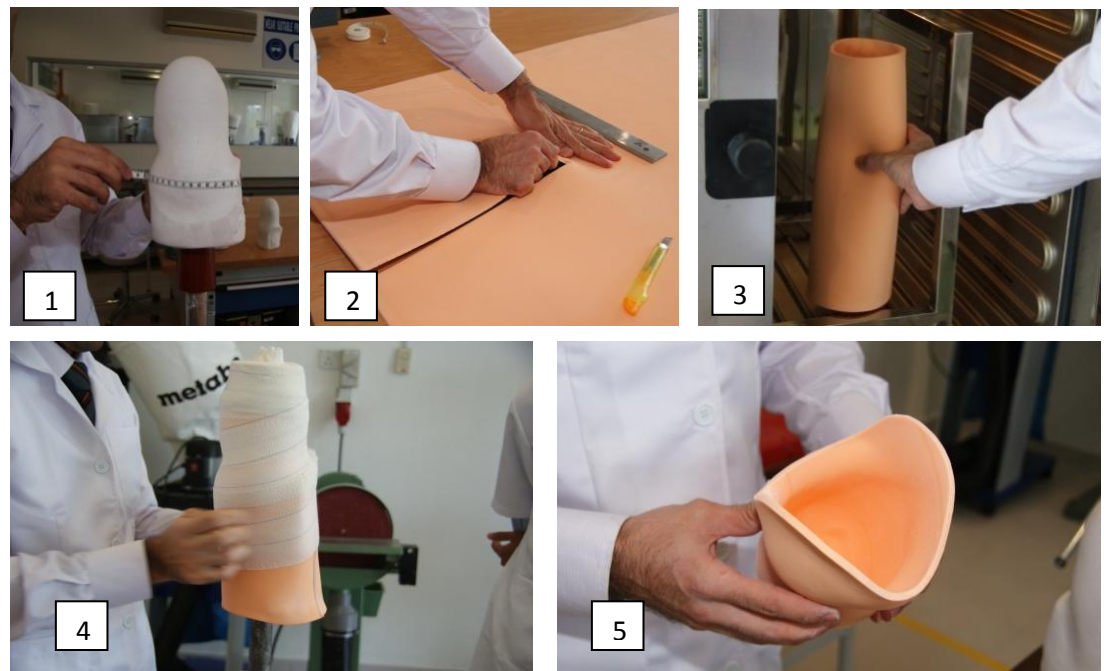


Figure 1.9: Procedure of making transtibial soft socket ( made of the polyethylene foam sheet).



Figure 1.10: Silicone liner (left) with pin/lock system (suspension system) (right)

Suspension systems play a significant role in lower-limb prosthetic function. A proper suspension system can eliminate piston movement (vertical movement) and unwarranted translation between the socket and residual limb (Gholizadeh et al., 2012b,c; Eshraghi et al., 2011). Momentum, gravity, and other ambulation forces, predominantly during the swing phase of gait, displace the prosthesis on the residual limb (Smith et al., 2004). Suspension is attained either anatomically or externally through various components. Several suspension devices are available for transtibial prostheses, from a simple SP strap to SC system (PTS) or (PTB/SC), SCSP system (PTB/SC/SP), thigh corset, waist belt, sleeve, pin/shuttle, suction or vacuum, and osseointegration.

Prescription of an appropriate suspension system for patients who have undergone lower-limb amputation can play a significant role in the rehabilitation process (Baars et al., 2008; Gholizadeh et al., 2011). Generally, current suspension systems attempt to fix the residual limb inside the socket through a single distal pin/lock, suction, lanyard, or magnetic coupling (Eshraghi et al., 2013a,b; Beil and Street, 2004; Street, 2006). Pin/lock systems apply tension distally to the residual limb and compression proximally during the swing phase of gait. Amputees with contracture may also experience difficulty in using the pin/lock systems. Compared with other systems, suction systems (Figure 1.11) result in improved fit and reduce pistoning within the socket (Gholizadeh et al., 2012a,b,c). However, donning or doffing of the prosthesis is a concern. A lanyard suspension system (Figure 1.12) consists of a lanyard cord attached to the distal part of the silicone liner, similar to that of the pin/lock system. Dietzen et al. (1991) used Velcro (instead of the rope in the lanyard system) as suspension for transfemoral amputees.

Magnetic prosthetic suspension system (MPSS) (Figure 1.13) is used with silicone liners as one of the most common soft interfaces (Eshraghi et al., 2013a,b). MPSS incorporates a cap that is matched to both the liner's distal end and the main body of the coupling device. The dimensions of the cap is comparable to the liner proportions. Magnetic power is developed through the body of the coupling that also intensifies the magnetic field by flanges. A mechanical switch is used to control the magnetic power.



Figure 1.11: suction system using Seal-In X5 liner



Figure 1.12: Lanyard system (reproduced from [www.o-pspecialists.com](http://www.o-pspecialists.com))



Figure 1.13: Magnetic transtibial suspension system (Eshraghi et al.2013)

Many prosthetic suspension systems are currently applied with TFPs; among these systems are the Silesian belt, hip joint with pelvic band, suction socket, and silicone liners with or without a shuttle lock (Dietzen et al., 1991; Carroll et al., 2006a,b; Klute et al., 2010). The Silesian belt and hip joint with pelvic band provide easy donning for geriatric users and good suspension for users with short residual limb (Dietzen et al., 1991; Schuch, 1992). Conventional suction suspension consists of a hard socket with a one-way valve at the distal end of the socket. A suction suspension system allows greater freedom of mobility, maximizes use of the residual limb's remaining muscles, and provides more comfort and better cosmetic appearance than the Silesian belt (Figure 1.14) or hip joint with pelvic band (Dietzen et al., 1991). However, suction sockets are unsuitable for prosthesis users with volume fluctuation of their residual limbs as socket fit and suspension will diminish. In geriatric users or those with vascular disease, suction sockets may cause edema at the end of the residual limb (Dietzen et al., 1991).

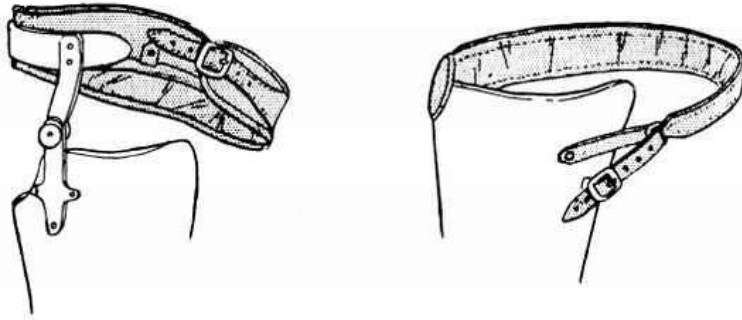


Figure 1.14: Two methods (old) of the transfemoral suspension system. Right: Silesian belt; Left: Hip joint, pelvic band, and waist belt. (Reproduced from Wilson AB Jr: Limb Prosthetics, ed 6. New York, Demos Publications, 1989, p 58. Used by permission.)

#### 1.4. Processes of making a lower limb prosthesis (trans-tibial-Iceross system)

##### 1.4.1. Amputee evaluation

The clinic team should thoroughly analyze available patient information before considering specific socket designs, suspension systems, components, and indications and contraindications for each. Several factors influence the prescription for prosthetics. These factors include activity level, geographic location, time since amputation, medical condition, soft tissue, skin problems, shape of residual limb, condition of knee joint, condition of thigh, musculature, range of motion, patient goal, employment, and sports (Smith et al., 2004) (Figure 1.15).



Figure 1.15: Physical examination (left) and measurement of the residual limb (right)

### 1.4.2. Measurement

Circumference around the stump, medial-lateral, anterior-posterior, and height measurements are obtained by a qualified prosthetist (Figure 1.15, right). The circumference of the stump at 4 cm from the distal end should be considered for selecting the correct liner size.

### 1.4.3. Taking impression (casting)

Different methods are used by clinicians to imitate the shape of residual limb. The most common technique to create a negative cast from residual limb is the use of Plaster of Paris (POP) (manual technique). POP bandages are used for casting to obtain an accurate impression of the stump (Figure 1.17). Scanning the residual limb instead of using plaster is another technique used by clinicians.



Figure 1.17: Casting procedures (transtibial casting).

### 1.4.4. Making positive cast and modification

Modification is a process in which the negative cast is filled with POP paste to form a positive cast of the residual limb (Figure 1.18). After the positive cast is dried, the prosthetist modifies the positive mold based on biomechanical principles to relieve pressure on sensitive areas in the socket. In this study, the positive molds are modified



on total contact design (TSB), in which weight is distributed throughout the sub-tissues of the stump.



Figure 1.18: Procedure of making positive cast and modification.

#### **1.4.5. Making the test socket and testing on amputee**

After the positive cast is modified, a test socket is fabricated using transparent thermoplastic sheets, thereby enabling visualization through its walls. The NorthPlex 12 mm (North Sea Plastics Ltd.) was used in this study. In the thermoforming procedure, the plastic is draped over the modified positive cast (Figure 1.19). To check the fitting of the test socket on the residual limb, a special jig (Figure 1.20) is first used while standing. The transparent socket allows inspection of the areas under high or low pressure. Afterward, the prosthetist assembles and aligns the prosthetic components then checks the prosthesis while the amputee is walking along parallel bars.

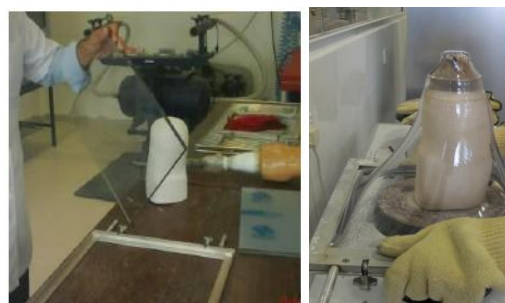


Figure 1.19: Procedure of TT check socket fabrication from transparent sheet (left).





Figure 1.20: Procedure of check socket assembling and fitting.

#### 1.4.6. Definitive socket, prosthesis assembly/aligning, and gait training

The socket is made of polypropylene sheet (10 mm to 12 mm) or epoxy resin and stockinet (Figure 1.21). The prosthetist assembles and aligns the components through three steps, namely, bench alignment (aligning the prosthetic components in the workshop based on the manufacturer's guidelines), static alignment (aligning the prosthesis when the subject is standing), and dynamic alignment (during ambulation). To learn walking with the new prosthesis (on even/uneven terrain, stair and ramp negotiation, and across the curbs as part of activities of daily living), the amputee needs to undergo functional training (Figure 1.22).

To verify the quality of the prosthesis and suspension systems, subjective feedback, gait analysis, and pressure mapping could be applied as useful investigative tools. Given the prosthetic socket and soft liners are always in close contact with the residual limb during use and act as the weight-bearing components, the socket has to be designed not to cause any discomfort, such as pain, difficulty during donning and doffing, piston movements, skin irritation, and perspiration.



Figure 1.21: Lamination of definitive socket using epoxy resin.

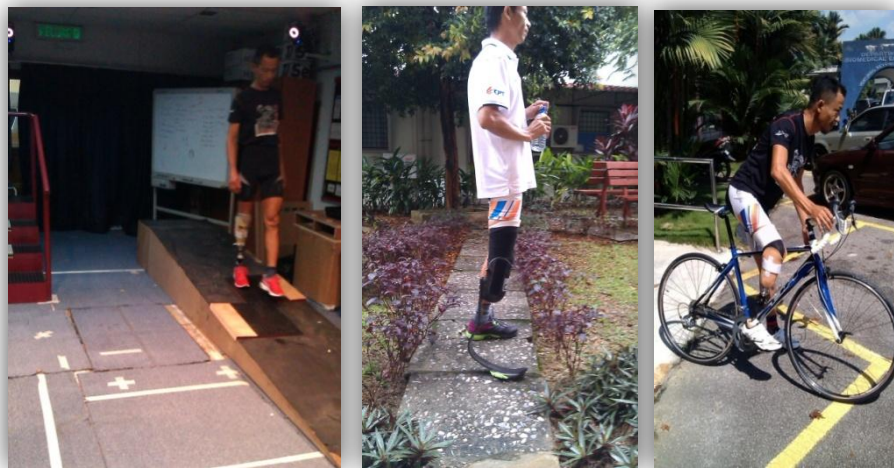


Figure 1.22: Some activities of daily living with the final prosthesis.

## 1.5. Problem statement

Non-use or limited use of prosthetic devices is a concern for rehabilitation of amputees. Provision of good prosthesis is the key element in an amputee's rehabilitation. Each amputee's functional needs and his/her satisfaction with the prosthesis should be considered when selecting a suspension system. A better understanding of suspension systems may facilitate the selection of appropriate

suspension system based on the amputee's needs. Thus, knowledge on prosthetic suspension for facilitating amputees' rehabilitation should be expanded.

The prosthetic suspension system can fix the residual limb within the socket and avoid rotation and vertical movement (pistoning). Easy donning and doffing of the prosthesis also totally depend on the soft liner and suspension system. Poor suspension could negatively affect the amputees' comfort, satisfaction, activity level, and rehabilitation process ( Van de Weg & Van der Windt, 2005).

Liner technology has evolved significantly, and many liners with different properties are currently available (Sanders et al., 2004). Clinicians often attempt to select appropriate liners (soft socket) for each subject based on their personal experience and manufacturers' technical information (Klute et al., 2010; McCurdie et al., 1997). Silicon liners were introduced in 1986, and their main advantage was enhanced bond with the stump, thereby improving suspension compared with other soft inserts (Baars et al., 2008). Coleman et al. (2004) reported that amputees are more satisfied with silicone liner (using pin/lock systems) than with polyethylene foam liner. Yigiter et al. (2002) stated that gait symmetry, balance, and weight acceptance could improve with TSB socket (using silicone liner as soft liner) compared with PTB (using Pelite as soft liner). Narita et al. (1997) also found superiority of TSB over PTB socket regarding amputees' satisfaction and improved stability. Van der Linde et al. (2004) also suggested that professionals in the field of prosthetics preferred the pin/lock system (van der Linde et al., 2004). However, Selles et al. (2005) found no significant differences between these two systems regarding changes in socket function (gait characteristics, PEQ scores, and mobility-related activities).

A questionnaire survey was also conducted by the research team, which includes the author of this thesis, on 243 unilateral transtibial amputees to clarify the former

findings. Three different suspension systems were evaluated in this retrospective study as follows: polyethylene foam liner (Pelite), pin/lock system, and Seal-In suspension. The findings indicated that the suspension was improved, and the participants were more satisfied with the TSB socket using silicone liner than with the PTB using polyethylene foam liner (Ali et al., 2012a). However, the subjects were more satisfied with the Pelite soft liner regarding easy donning and doffing of the prosthesis than with the Seal-In liner and pin/lock system. Previous prospective studies also showed some disadvantages, such as increased sweating and difficulty in donning and doffing, which are also attributed to the silicone liners (Gholizadeh et al., 2012a,b,c). Based on the literature, the ease of donning and doffing is significantly important for prosthesis users (Gholizadeh et al., 2011, Gholizadeh et al., 2012a,b,c; Baars, Dijkstra, & Geertzen, 2008; Baars & Geertzen, 2005).

Previous research by the author of this thesis on pin/lock and seal-in systems on transtibial amputees have shown more vertical movement (pistoning) in pin/lock suspension system during ambulation (Gholizadeh et al., 2011, 2012b,c). This system also applies compression on the residual limb proximally and tension distally during the swing phase of the gait. This skin stretch at the pin site is called milking. The milking phenomenon may cause the short-term (edema and redness) and long-term (discoloration and thickening) transformations, particularly at the distal end of the residuum (Beil & Street, 2004). This compression can result in pain (Beil & Street, 2004; Gholizadeh et al., 2012), discomfort, and residual limb atrophy or volume loss. Although the Seal-In liner could improve the suspension and decrease the pistoning within the socket, donning and doffing are the main issues in transtibial amputees (Gholizadeh et al., 2012b,c).

No study has compared the effects of these two common suspension systems on amputees' gait performance. As transtibial and transfemoral amputation levels differ regarding residual limb size and shape, gait pattern, pistoning, appearance, and function, the effects of suspension systems on satisfaction would also vary. Therefore, a survey study on transfemoral amputees should be conducted to enhance our understanding about the effects of this new suspension system (Seal-In) on transfemoral amputees' satisfaction. Designing a new suspension system to overcome some disadvantages of the current systems would also be necessary.

## **1.6. Objective of the Study**

This study aimed to:

- i. conduct a survey study on transfemoral amputees regarding the effects of Seal-In on transfemoral amputees' satisfaction
- ii. compare the effects of the new Seal-In Liner (suction) and Dermo Liner (Pin/Lock) on amputees' gait and satisfaction using motion analysis system and some parts of the PEQ questionnaire
- iii. design and develop a new suspension system for lower-limb prosthetics
- iv. find out and compare liner-residual limb pressure profiles and satisfaction between a newly designed prosthetic suspension system and the most common suspension system in the market (pin/lock system).

## **1.7. Hypothesis**

H01= Satisfaction rates (in transfemoral amputees) with the seal-in suspension system will be similar (no significant difference) to the common suction socket systems.

H11= Satisfaction rates with the seal-in suspension system will be significantly different from the common suction socket systems.

H02= Kinetic and kinematic gait parameters with the seal-in liner will be similar (no significant difference) to the pin/lock system.

H12= Kinetic and kinematic gait parameters with the seal-in liner will be significantly different from the pin/lock system.

H03 = Mean peak pressure with the new prosthetic suspension system will be similar (no significant difference) to the pin/lock system.

H13 = Mean peak pressure with the new prosthetic suspension system will be significantly different from the pin/lock system.

H04= Satisfaction rates with the new prosthetic suspension system will be similar (no significant difference) to the pin/lock, seal-in, and magnetic suspension systems.

H14= Satisfaction rates with the new prosthetic suspension system will be significantly different from the pin/lock, seal-in, and magnetic suspension systems.

## **CHAPTER 2**

### **LITERATURE REVIEW**

#### **2.1. Overview**

This chapter provides an outline of the body of knowledge regarding the lower-limb prosthesis to support the methodology and protocols applied in this study. In this chapter, prosthetic socket, soft insert, and suspension systems used for transtibial and transfemoral amputees will be examined. This chapter also elaborates the methods of assessing the suspension systems' efficiency, such as questionnaire survey, gait evaluation, and interface pressure. This chapter is divided to two main parts, namely, transtibial and transfemoral prostheses.

In recent years (1990 to 2013), lower-limb amputation and prosthesis have become interesting topics in publications (Figure 2.1, 2.2). The distribution of published articles per year (Web of Science<sup>®</sup>) shows a positive trend in research on amputation and prosthetic limbs. The number of papers published during this period regarding amputation and prosthetic limbs increased by almost 10% and 50%, respectively.

Recent publication by the author of this thesis (Gholizadeh et al., 2014d) showed that the publication count is an indicator of research productivity and used to rank authors, universities, and countries (Liu & Cheng, 2005; Narin & Hamilton, 1996). The number of citations of previously published works is an indicator of its subsequent recognition and influence on a field of study. Reviewing articles that are frequently cited can provide information about the dominant areas of a discipline and also highlight the growth of particular fields (Joynt & Leonard, 1980; Kelly et al., 2010).



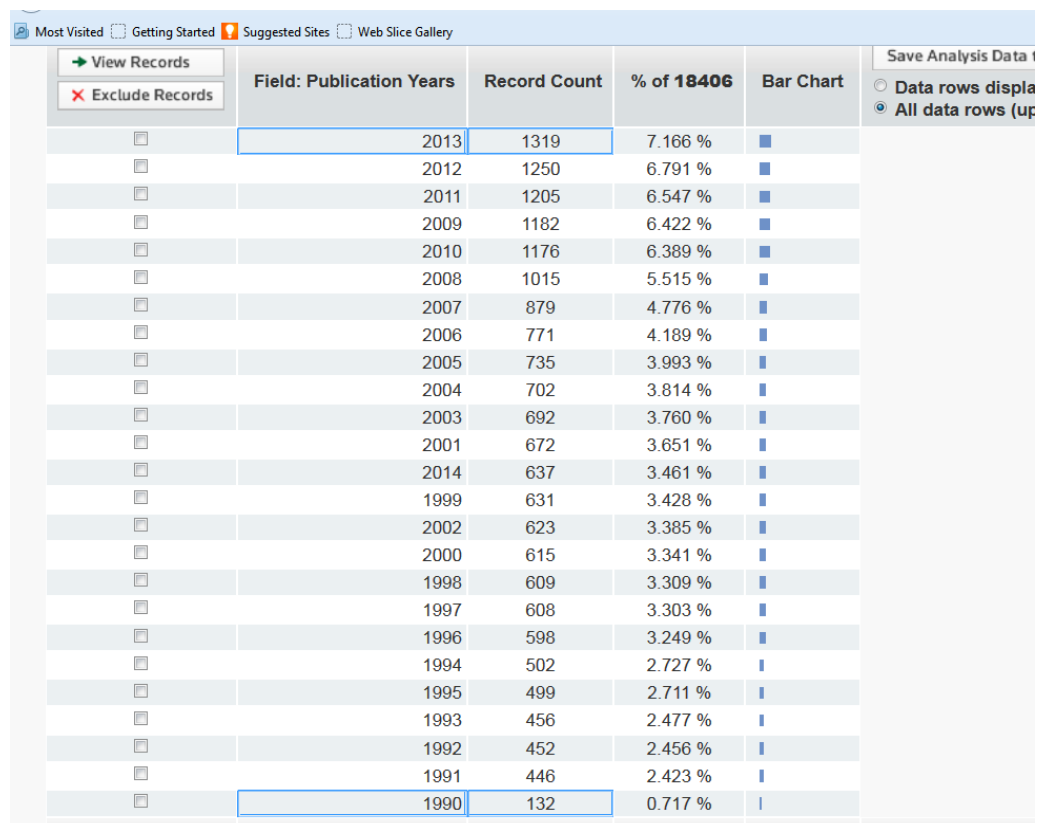


Figure 2.1: Publication trend related to "amputation". (source Web of Science®)

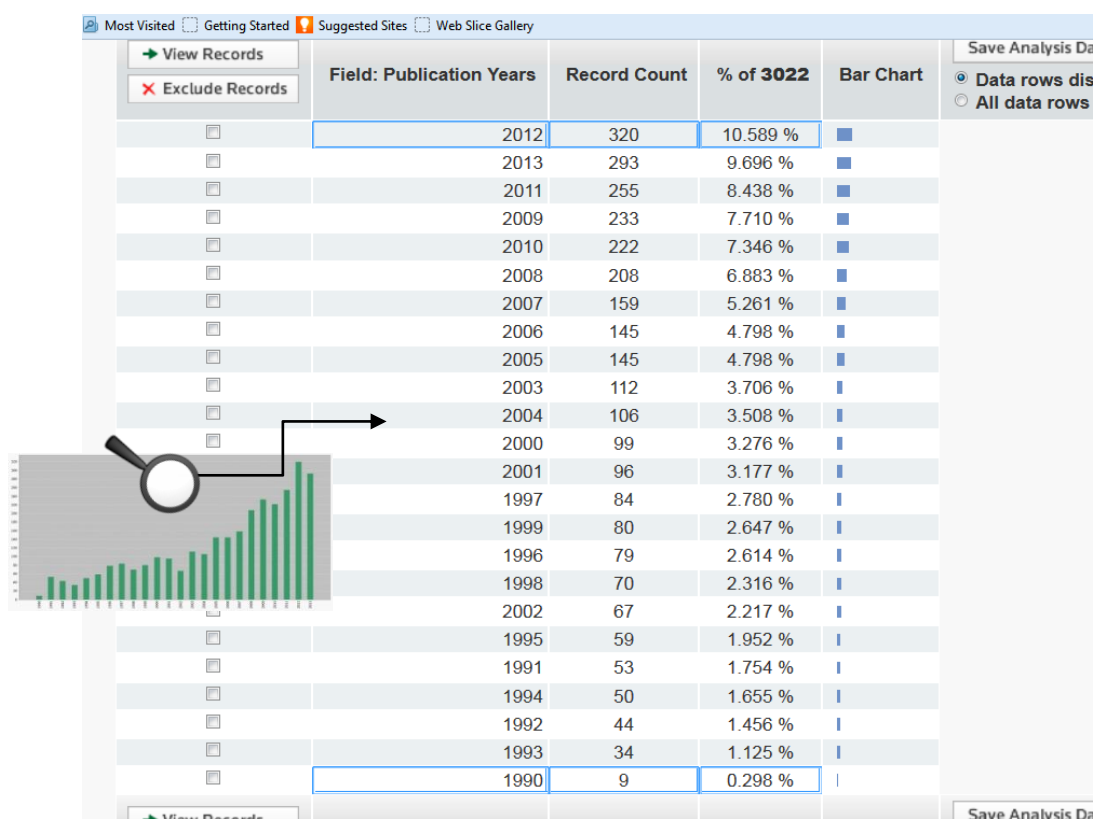


Figure 2.2: Publication trend in the field of "limb prosthesis". (Source Web of Science®)

## 2.2. Transtibial prosthesis

The incidence of transtibial amputations is very high. This level of amputation has received considerable attention in training and education for surgery, rehabilitation, and prosthetics in the past decades. However, some transtibial amputees never recover completely (Smith et al., 2004). To perform a successful transtibial (below-knee) amputation, three criteria are considered by surgeons, namely, maximum bone length, sufficient soft-tissue padding, and accurate placement of nerve endings. Surgical techniques for limb amputation generally focus on the tissue design or muscle padding to cover the distal flap. The outcome should result in a residual limb with cylindrical shape (Figure 2.3), good padding of distal tibia, and stable muscles. Prosthetic fit for areas with poor soft-tissue padding is very challenging (Smith et al., 2004).

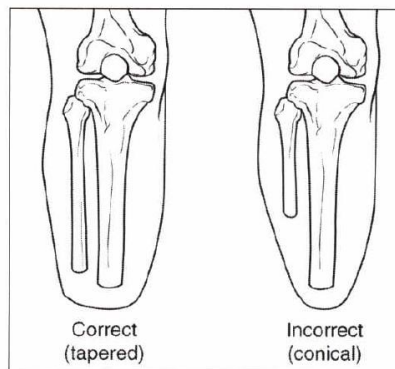


Figure 2.3: Residual limb with cylindrical (tapered) and conical shape.  
(Reproduced from Atlas of Amputation and Limb Deficiencies- Smith et al., 2004).

Maximizing the bone length will allow the amputee to remain more active and stable. However, long transtibial amputation is not preferred because of poor blood supply at the distal end of the leg (Figure 2.4).

Energy expenditure in transtibial amputees is higher than in normal people and lower than in transfemoral amputees. Transtibial amputees could also exhibit more symmetric gait than transfemoral amputees. Based on the literature, transtibial

amputation is the most common among the major lower-limb amputation. The ratio of two transtibial amputations to every transfemoral amputation was reported (Smith et al., 2004; Seymour, 2002).

Tibia and fibula bones are attached at the knee and ankle joints. The distal part of this connection will be removed during surgery. To minimize friction between the bones, surgeons should manipulate the leg muscles that will be used as padding. One surgical technique extends the posterior flap and brings the superficial posterior leg muscles, namely, gastrocnemius and soleus, forward over the end of the residual limb to provide padding to the protruding distal end of the tibia and fibula (Smith et al., 2004) (Figure 2.3). The shape of the residual limb is critical in ensuring proper socket fit. Nerve endings should be maximized according to bone length to achieve the highest proprioception in the leg. However, to minimize pain at the end of the residual limb, the severed nerve endings must be positioned in soft tissues.

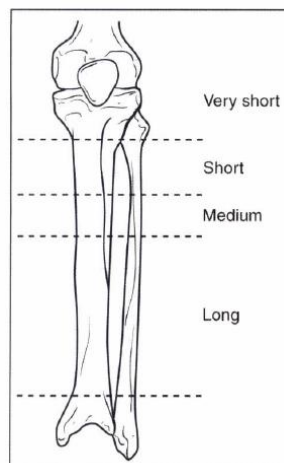


Figure 2.4: Levels of transtibial amputation

Amputees' statements and research findings suggest that suspension and prosthetic fit are strongly related to functional efficiency and comfort levels (Beil, Street, & Covey, 2002; Eshraghi et al., 2012a). Walking pattern, residual limb soft tissue and skin, and comfort can be jeopardized by poor suspension (Eshraghi et al.,

2012a; Gholizadeh et al., 2012a,b; Papaioannou, Mitrogiannis, Nianios, & Fiedler, 2010; Peery, Ledoux, & Klute, 2005; Smith, 2004).

The distribution of interface pressure between the socket and the tissues of the residual limb regulates the amputee's comfort; thus, such distribution is important in the socket design (Goh et al., 2004; Abu Osman et al., 2010). The residual limb is exposed to shear stresses and pressures at the interface of the prosthetic socket and the residual limb during ambulation (Sanders et al., 1997). Various suspension systems and socket designs also exhibit different effects on the interface pressure during ambulation (Mak et al., 2001; Beil and Street, 2004). The positive pressure applied to the soft tissue results in fluid loss and volume change (Ferne & Holliday, 1982; Goswami, Lynn, Street, & Harlander, 2003).

### **2.2.1. Prosthetic socket and suspension systems (transtibial prosthesis)**

The literature shows several transtibial socket and suspension systems available for lower-limb amputees. Not only the amputees' functional needs, but also their satisfaction with the prosthesis should be considered when selecting an appropriate suspension system. Clear insights into suspension systems will facilitate selection for prosthetics (Eshraghi, Abu Osman, Gholizadeh, et al., 2012a,b; Garrison, 2003; Susan Kapp, 1999; Nelson et al., 2006; Schaffalitzky et al., 2012; Zhang et al., 1998).

A transtibial prosthesis generally consists of the following parts: socket, soft insert, suspension system, adapter (to attach the socket to the pylon or shank), pylon, and prosthetic foot. The literature indicates that the two primary designs for transtibial prostheses are: (1) the historic prosthesis (back to 1696), which consists of an open-

ended socket (from wood), thigh corset, and side joints; and 2) the PTB prosthetic design.

In the first design, the thigh corset is used to take the load off the stump. To provide knee stability (control knee hyperextension and medial-lateral stability), the side joints are used in this design. An open-ended socket is used to provide cool surrounding for the residual limb. However, this design demonstrates some disadvantages, such as heavy and bulky prosthesis, lack of total surface contact between the stump and the socket (creates distal edema and high pistoning), and thigh atrophy (caused by thigh corset).

The PTB socket was developed in the late 1950s at the University of California in Berkeley. Basically, this prosthesis applies load to each part of the residual limb based on the ability of the limb to tolerate load. The main area for load bearing is the patellar tendon in this design (Smith et al., 2004). Lateral and medial tibial flares are also appropriate for load bearing (Figures 2.5 and 2.6). Contact between the socket and the residual limb is more common with the PTB design and may decrease edema but increase proprioception.

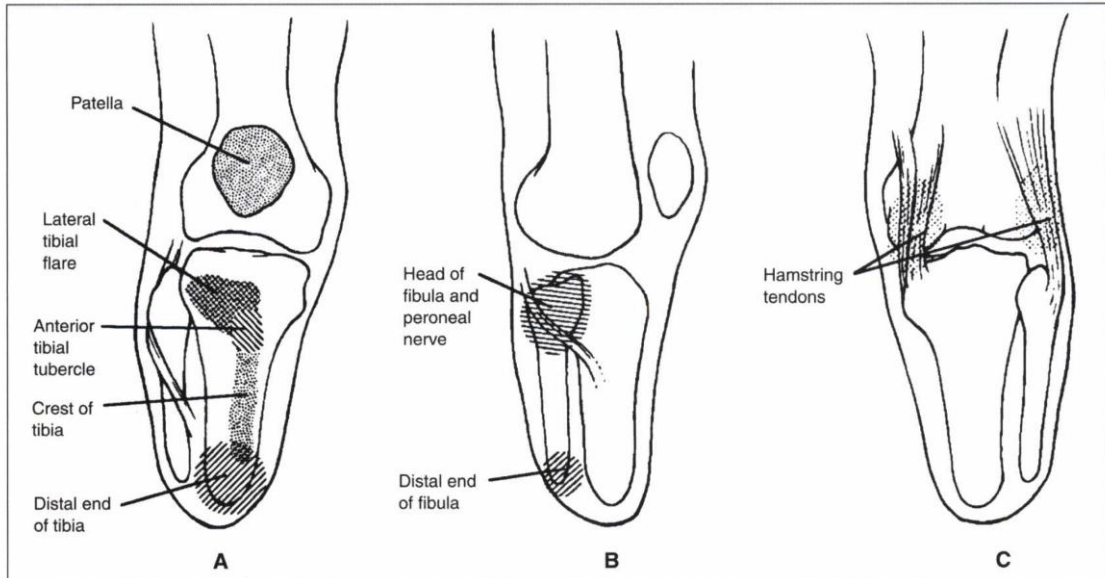


Figure 2.5 Areas requiring pressure relief in a PTB socket. A:anterior; B: lateral view; C: posterior view (Reproduced from Atlas of Amputation and Limb Deficiencies- Smith et al., 2004).

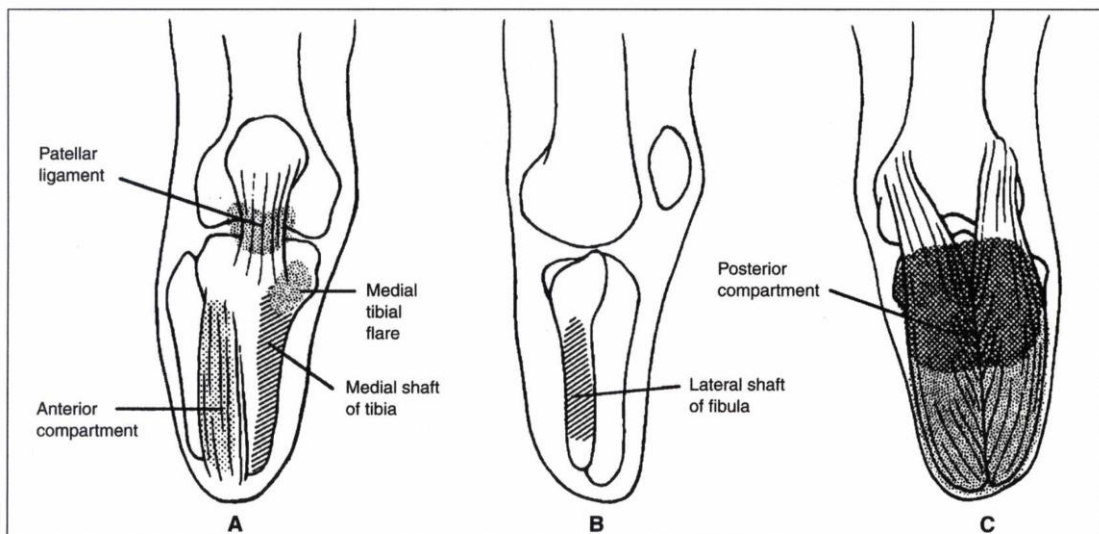


Figure 2.6 Pressure tolerant areas in a PTB socket. A:anterior; B: lateral view; C: posterior view (Reproduced from Atlas of Amputation and Limb Deficiencies- Smith et al., 2004)

The PTB prosthesis is a good alternative for amputees with stable knee and good patellar ligament. Several variations (socket designs) for PTB prostheses are developed after the 1950s to enhance socket suspension and medial-lateral stability by changing the socket trim lines. Some of these designs are: 1) PTB-SC (PTB socket with SC socket), 2) PTB/SP (PTB socket with SP socket), and 3) PTB-SC/SP (PTB socket with SCSP socket) (Figure 2.7).

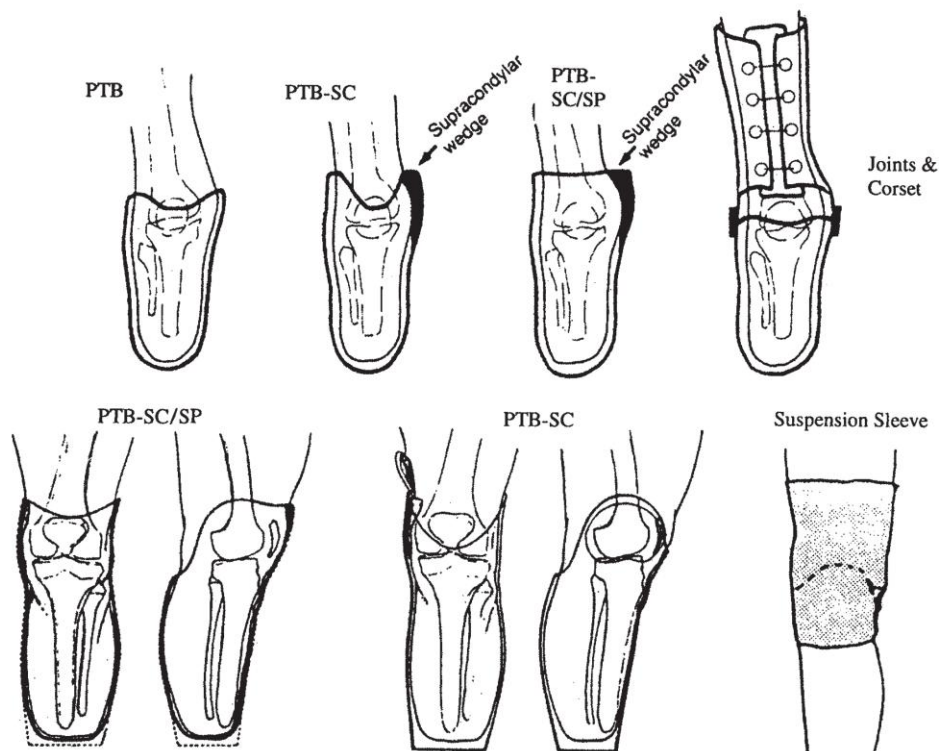


Figure 2.7 : Different PTB prosthesis (different suspension systems). (Reproduce from Design of artificial limbs for lower extremity amputees, Silver-Thorn, 2003).

The SC cuff and sleeves are suspension systems for PTB prostheses. Suction or vacuum concept is also an alternative suspension system for transtibial amputees. This system is commonly used for transfemoral amputees.

The introduction of new designs and materials has revolutionized the design of transtibial prostheses after World War II (Sewell et al., 2000). Subsequently, the silicone suction suspension (3S) (Fillauer et al., 1989) and Iceross (Kristinsson, 1993;

Baars and Geertzen, 2005) sockets were introduced to the market. These systems were characterized by improved techniques of suspension, TSB, and hydrostatic loading (Staats and Lundt, 1987; Sewell et al., 2000).

Although many prosthetic suspension systems are available, physicians and prosthetists set selection criteria mainly based on subjective experiences (van der Linde et al., 2004). Clinical prescription guidelines should be provided for prosthetic suspension systems to ensure efficient and consistent health care. A systematic literature review may contribute significantly to the development of such guidelines for better understanding of this concept (Woolf et al., 1999; van der Linde et al., 2004).

The advantages and disadvantages of various transtibial suspension systems have been examined subjectively and objectively in the literature. Upon a systematic review of the literature, the author of this thesis aimed to contribute to the development of guidelines for the current transtibial prosthetic suspension. Given that the number of citations of previously published works is an indicator of subsequent recognition and influence on an area of study, the number of citations that each paper has received and the journals with more publications in this field will be determined.

#### **2.2.2. Method for systematic review (Transtibial)**

A systematic search was performed to find related research articles from the Web of Science, ScienceDirect, and PubMed databases. The cut-off date was April 2013. The following keywords, as well as their combinations and synonyms, were used: transtibial prosthesis, prosthetic suspension, lower-limb prosthesis, below-knee prosthesis, prosthetic liner, transtibial, and prosthetic socket. Related papers cited in the references were also checked.



The systematic criteria were set to facilitate the selection of articles. The studies were included if they evaluated the transtibial prosthetic suspension system, were written in the English language, and aimed to provide insights into various suspension systems for transtibial prosthesis. Study design (case series of five or more subjects, retrospective or prospective), research instrument, sampling method, and outcome measures and protocols were reviewed (van der Linde et al., 2004). Prospective studies were preferred, but well-documented case series were also accepted.

Subsequent to primary selection based on abstracts, the quality of each study was assessed using a 12-element checklist (Appendix D). The checklist was based on two available tools for quality assessment, which were primarily used to assess randomized controlled trials (van der Linde et al., 2004). Van der Linde et al. (2004) adapted the original checklist in their study for possible use in non-randomized controlled trials. In the current study, the same checklist was used with minor modifications. As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, blinding in studies is impractical on suspension systems. Therefore, the item B7 regarding blinding in our study (Appendix D) was excluded (van Tulder et al., 1997; Verhagen et al., 1998).

Based on the score levels, a criterion was scored “0” if it is not applicable and “1” if applicable. Two reviewers separately examined the papers. In cases of discrepancy, a second review would be initiated to arrive at a consensus (van der Linde et al., 2004).

The studies were categorized as follows:

- A-level: Those articles that gained at least 10 or more points; 6 points from the A and B criteria; and a positive score timing of the measurement (criterion B8).

- B-level: Those articles with a total score between 6 and 9, including a positive score for timing of the measurement (criterion B8).

- C-level: Those articles with a total score of at least 6 out of the A- and B-criteria with an invalid score on B8. Studies that achieved at least 6 out of 9 points for the A- and B-criteria were included in the review.

Finally, to determine the number of citations that each paper had received from other researchers, the Google Scholar database was used.

### **2.2.3. Results**

A total of 516 research papers were identified, among which 250 were similar in terms of keywords and databases (Figure 2.8). The title and abstract of every study was assessed. Some of the 266 papers were related to upper-limb or above-knee prosthetics, applied computational models, or case studies and were thus excluded. At this stage, 22 related studies were kept. An additional 45 articles were found from the references, and following the abstract check, only nine studies were found suitable. Finally, 31 articles were selected for this systematic review. Seven out of 31 papers were survey studies (Cluitmans et al., 1994; Datta et al., 1996; Hachisuka et al., 2001; Van de Weg and Van der Windt, 2005; Webster et al., 2009; Ferraro, 2011; Ali et al., 2012a), and the rest of the articles were selected as basis for evaluation of the methodological quality (Table 2.1, Figure 2.8).

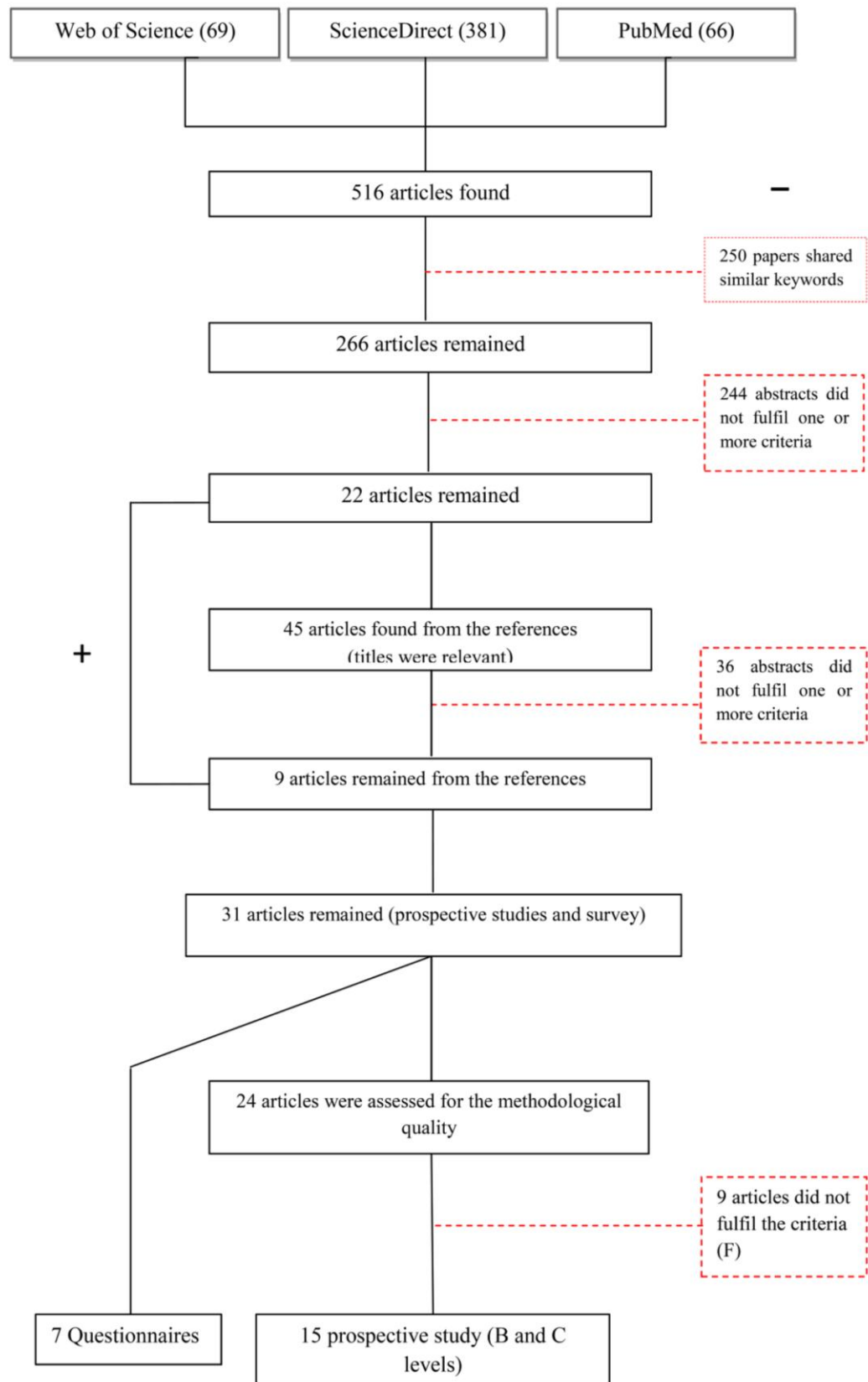


Figure 2.8: Selection algorithm for this literature review (Transtibial).

Table 2.1: Number of papers based on the journal

| Journal name   | Number of papers | Failed | Remained papers   |        |
|--|------------------|--------|-------------------|--------|
|  |                  |        | Prospective study | Survey |
| Journal of Prosthetics and Orthotics                   | 2                | –      | 0                 | 2      |
| Occupational Medicine                                  | 1                | 1      | 0                 | 0      |
| American Journal of Physical Medicine & Rehabilitation | 1                | –      | 1                 | 0      |
| Medical Engineering & Physics                          | 1                | 1      | 0                 | 0      |
| Clinical Biomechanics                                  | 3                | –      | 3                 | 0      |
| Archive of Physical Medicine and Rehabilitation        | 5                | –      | 3                 | 2      |
| Journal of Rehabilitation Research and development     | 9                | 5      | 4                 | 0      |
| Prosthetics and Orthotics International                | 9                | 2      | 4                 | 3      |
| Total  | 31               | 9      | 15                | 7      |

Five articles were classified as A-level (Yigiter et al., 2002; Coleman et al., 2004; Selles et al., 2005; Boutwell et al., 2012; Eshraghi et al., 2013a), nine articles were classified as B-level (Wirta et al., 1990; Hachisuka et al., 1998; Åström and Stenström, 2004; Klute et al., 2011; Gholizadeh et al., 2012b; Gholizadeh et al., 2012c; Eshraghi et al., 2012b; Ali et al., 2012b; Brunelli et al., 2013), one paper was classified as a C-level (Board et al., 2001), and nine papers failed (F). The major distinction between the studies of B- and C-levels was the negative score for time to adapt with prosthesis (criterion B8) (van der Linde et al., 2004). The majority of the papers in this literature review were from the United States and Malaysia (Figure 2.9).

The most number of citations (48) was for the study of Board et al.(2001) published in the *Prosthetics and Orthotics International* journal. Six out of 22 papers were published in 2012. The highest number of participants in the prospective studies was 32 (Hachisuka et al., 1998), and the lowest was five (Klute et al., 2011).

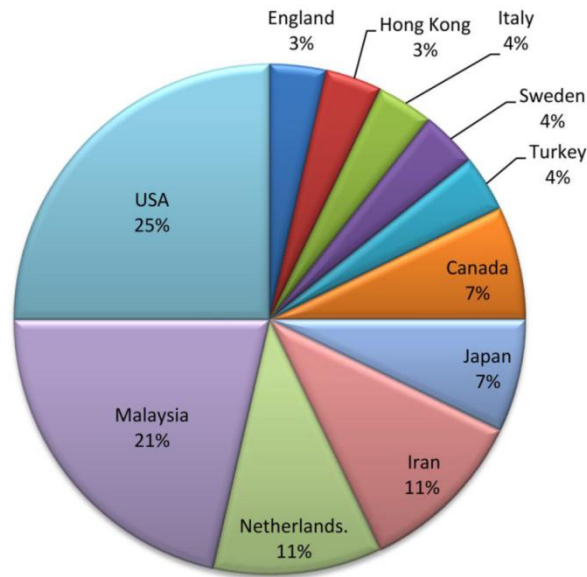


Figure 2.9: The percentage of published articles in the field of prosthetic limb suspension.

The number of subjects used in the survey studies ranged from 13 (Ferraro, 2011) to 243 (Ali et al., 2012a). Although individuals with unilateral and bilateral amputation were included, the participants were mostly unilateral amputees. Trauma was the main cause of amputation; however, tumor, diabetes, disease, infection, and congenital limb deficiencies were also listed (Tables 2.2, 2.3, and 2.4).

Eight out of the 15 prospective studies evaluated the suspension system in terms of vertical movement or pistoning inside the socket, between the soft liner and socket, or between the skin/bone and socket (Gholizadeh et al., 2012b,c; Eshraghi et al., 2012b; Wirta et al., 1990; Brunelli et al., 2013; Board et al., 2001; Yigiter et al., 2002; Klute et al., 2011). A range of imaging methods, including motion analysis system and radiography, was applied to assess the bone/skin/liner position within the prosthetic socket. In some studies, gait was simulated to measure pistoning (Yigiter et al., 2002; Gholizadeh et al., 2012c; Eshraghi et al., 2012b; Brunelli et al., 2013; Board et al., 2001), whereas suspension was investigated through real gait experiments in other studies. The transtibial prostheses used were mainly TSB.

The suspension systems used in the prospective studies are as follows (Table 2.3):

- TSB socket with pin/lock system that uses Dermo liner, TEC liner, Alpha liner (3,6, and 9 mm, elastomeric gel liner, and ICEX system) (Manucharian, 2011)
- TSB socket with suction or vacuum system that uses Seal-In X5 liner, polyurethane liner, and neoprene sleeve
- TSB socket with magnetic lock system

PTB and KBM (Selles, 2005) sockets, such as SCSP, SC, PTB socket with cuff (PTB/C), PTB socket with waistband and cuff (PTB/WB), PTB socket with figure-of-eight SP strap (PTB/F8), rubber sleeve(RS), articulated supracondylar wedge (ASCW). The Prosthesis Evaluation Questionnaire was the main tool used in the prospective studies. The suspension systems used in the survey studies are as follows (Table 2.4):

- TSB socket with pin/lock system (Iceross liner, Faillauer liner, and polyurethane liner)
- TSB socket with suction or vacuum system
- Osseointegration

Table 2.2: Methodological assessment of reviewed studies sorted in ascending order according to the year of publication

| Author/s                  | Journal  | Year, pages   | Times cited** | Outcome measures  | Subjects (Reason, Level of Amputation, Sex, Age, activity level)  | Selection of patients |    |    |    |           | Intervention and Assessment |    |     |    |    | Statistical validity |     |     |     |     | Total score | Level of evidence |          |
|---------------------------|--|---------------|---------------|---|---|-----------------------|----|----|----|-----------|-----------------------------|----|-----|----|----|----------------------|-----|-----|-----|-----|-------------|-------------------|----------|
|                           |  |               |               |   |   | A1                    | A2 | A3 | A4 | A - score | B5                          | B6 | B7# | B8 | B9 | B- Score             | C10 | C11 | C12 | C13 |             |                   | C- Score |
| Wirta et al., 1990        | Journal of Rehabilitation Research and development | 1990, 385-396 | 17            | Pistoning of stump in socket, knee flexion-extension, harmonic ratios (gait symmetry), subjective responses, suspension discrimination  | Cause of amputation?* TT, 15 males, 5 females, 49 (23_76), K2-3   | 1                     | 1  | 1  | 0  | 3         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 9                 | B        |
| Hachisuka et al. 1998     | Archive of Physical Medicine and Rehabilitation    | 1998, 783-789 | 29            | Donning and doffing, ease of swing, pain during walking, knee flexion and extension, pistoning during walking, skin irritation, perspiration, odour, staining of the socket, appearance and durability of the socket                                  | Trauma 21, diabetic gangrene 4, vascular disease 3, Other 4, TT, 27 males, 5females, 44.5(16), K?*        | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 8                 | B        |
| Board et al.,2001         | Prosthetics and Orthotics International            | 2001, 202-209 | 48            | Volume changes, pistoning between the bone and socket, gait symmetry, step length, stance duration  | Trauma, TT, 11, 45 (32-64), K?  | 1                     | 1  | 1  | 1  | 4         | 1                           | 1  | _   | 0  | 1  | 3                    | 0   | 1   | 0   | 1   | 2           | 9                 | C        |
| YİĞİTER et al., 2002      | Prosthetics and Orthotics International            | 2002, 206_212 | 18            | Balance, socket volume, pistoning, temporal-distance characteristic (step length (cm), stride length (cm), step width (cm), free cadence (step/min), fast cadence (step/min), walking velocity (cm/s), stride length/lower limb length                | Trauma, TT, 13 males, 7 females , 27.8 (7), K2-3  | 1                     | 1  | 1  | 1  | 4         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 10                | A        |
| Coleman et al., 2004      | Journal of Rehabilitation Research and development | 2004, 591-602 | 16            | PEQ, residual limb volume, step activity, pain, socket comfort, daily ambulatory function, physical changes, subject preference and feedback  | Trauma, TT, 10 males, 3 females, 49.4 (9.6), K2-3   | 1                     | 1  | 0  | 1  | 3         | 1                           | 1  | _   | 1  | 1  | 4                    | 1   | 1   | 1   | 1   | 4           | 11                | A        |
| Astrom I & Stenstrom 2004 | Prosthetics and Orthotics International            | 2004, 28-36   | 10            | Self-administrated questionnaire, gait symmetry index, temporal and stride variables (speed, step time, single support, step length), kinematics variables (knee extension-flexion - knee load response, knee varus-valgus, knee rotation), interview | Trauma (15), tumour (1), infection (2), diabetes (3), Other (8), TT, 24 males, 5 females, 39 (7_78), K2-3 | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 8                 | B        |

Table 2.2(Continued): Methodological assessment of reviewed studies sorted in ascending order to the year of publication

| Author/s                | Journal  | Year, page      | Times cited | parameters  | Subjects (Reason, Level of Amputation, Sex, Age, activity level)                 | Selection of patients |    |    |    |           | Intervention and Assessment |    |     |    |    | Statistical validity |     |     |     |     | Total score | Level of evidence |          |
|-------------------------|--|-----------------|-------------|---|--|-----------------------|----|----|----|-----------|-----------------------------|----|-----|----|----|----------------------|-----|-----|-----|-----|-------------|-------------------|----------|
|                         |  |                 |             |   |  | A1                    | A2 | A3 | A4 | A - score | B5                          | B6 | B7# | B8 | B9 | B- Score             | C10 | C11 | C12 | C13 |             |                   | C- Score |
| Selles, et al., 2005    | Archive of Physical Medicine and Rehabilitation        | 2005, 154-161   | 19          | Gait evaluation (walking speed, stride frequency, stride length (m), swing asymmetry, stride length asymmetry), economic variable [cost, cpo time for delivery (h) ,CPO time after delivery, delivery time, visits for delivery , visits after delivery, total visits], prosthesis function, activity monitoring, PEQ | Trauma, disease, PVD, TT, 26 (12TSB, 14PTB), TSB 67.6(13.5), PTB 57.9(15.6), K?* | 1                     | 1  | 0  | 1  | 3         | 1                           | 1  | _   | 1  | 1  | 4                    | 1   | 1   | 1   | 1   | 4           | 11                | A        |
| Klute et al.2011        | Archive of Physical Medicine and Rehabilitation        | 2011, 1570_1574 | 5           | Activity level, residual limb volume before and after a 30-minute treadmill walk, pistonning, and PEQ   | Trauma 4, vascular 1, TT, 5, 56(9), K?*  | 1                     | 1  | 0  | 1  | 3         | 0                           | 1  | _   | 1  | 1  | 3                    | 1   | 0   | 0   | 0   | 1           | 7                 | B        |
| Gholizadeh et.al. 2012c | Clinical Biomechanics                                  | 2012, 34-39     | 6           | Pistonning between the liner and socket (static positions)  | Trauma and diabetes, TT, 6 males, 43 (16.5), K2-3                                | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 0   | 0   | 1   | 1           | 7                 | B        |
| Boutwell et al., 2012   | Journal of Rehabilitation Research and development     | 2012, 227-240   | 2           | Skin-liner interface , walking speed (m/s), vertical GRF loading peak (%BW), timing of vertical GRF loading peak (%GC), fore-aft GRF braking peak (% BW), timing of fore-aft GRF braking peak (% GC), stance-phase knee flexion (°), pelvic obliquity ROM (°), questionnaire  | Trauma, disease, PVD, TT, 4 males, 7 females, 55.9 (8.9), K?*                    | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 1   | 1   | 1   | 1   | 4           | 10                | A        |
| Gholizadeh et.al, 2012b | Journal of Rehabilitation Research and development     | 2012, 1321-1330 | 2           | Pistonning between the liner and socket, PEQ  | Trauma, diabetes, TT, 10 males, 45.8 (14.4), K2-3                                | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 8                 | B        |
| Eshraghi et.al, 2012b   | American Journal of Physical Medicine & Rehabilitation | 2012, 1028-1038 | 1           | Pistonning between the liner and socket (static positions), PEQ   | Trauma, diabetes, TT, 10 males, 42(12.8), K2-3                                   | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | _   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 8                 | B        |



Table 2.2(Continued): Methodological assessment of reviewed studies sorted in ascending order to the year of publication

| Author/s         | Journal                                      | Year, page    | Times cited | parameters   | Subjects (Reason, Level of Amputation, Sex, Age, activity level) | Selection of patients |    |    |    |           | Intervention and Assessment |    |     |    |    | Statistical validity |     |     |     |     | Total score | Level of evidence |          |
|------------------|--|---------------|-------------|--|--|-----------------------|----|----|----|-----------|-----------------------------|----|-----|----|----|----------------------|-----|-----|-----|-----|-------------|-------------------|----------|
|                  |  |               |             |  |  | A1                    | A2 | A3 | A4 | A - score | B5                          | B6 | B7# | B8 | B9 | B- Score             | C10 | C11 | C12 | C13 |             |                   | C- Score |
| Ali et al, 2012b | Clinical Biomechanics                        | 2012, 943–948 | 0           | Skin-liner interface pressure, PEQ   | Trauma, diabetes, TT,7 males, 2 females, 49.3 (15), K2-3-4       | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | –   | 1  | 1  | 4                    | 0   | 0   | 0   | 1   | 1           | 7                 | B        |
| Brunelliet 2013  | al., Prosthetics and Orthotics International | 2013, 1_9     | 0           | Pistoning (static positions), (level walking and treadmill (metabolic data), PEQ, , Timed Up & Go Test; HSQ;; LCI: | Trauma, vascular, infection, TT, 10 males, 44.9 (9.5), K3-4      | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | –   | 1  | 1  | 4                    | 0   | 1   | 0   | 1   | 2           | 8                 | B        |
| Eshraghi 2013    | et.al, Clinical Biomechanics                 | 2013, 55–60   | 0           | Skin-liner interface pressure  | Trauma, diabetes, TT, 9 males , 3 females , 46.8 (12.3), K2-3    | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | –   | 1  | 1  | 4                    | 1   | 1   | 1   | 1   | 4           | 10                | A        |

TT= transtibial; PEQ= Prosthesis Evaluation Questionnaire; HSQ= Houghton Scale Questionnaire; LCI= Locomotors Capability Index; PVD= Peripheral Vascular Disease; CPO= Certified Prosthetist and Orthotist; TSB= Total Surface Bearing; PTB= Patellar tendon Bearing; K-level = (K1, 2, 3, 4); BW= Body Weight; GC= Gait Cycle; GRF= Ground Reaction Force

\* It is not clear (the authors did not mention in the article)

\*\* Based on Google scholar

# As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, it is not feasible to do blinding in studies on suspension systems. Therefore, we excluded the item B7 regarding the blinding in our study.

Table2.3: Main findings from the reviewed studies (prospective) on the prosthetic suspension system

| Author/s                  | Prosthetic suspension system   | Other prosthetic components           | Findings  | Level of evidence |
|---------------------------|--|---------------------------------------|---|-------------------|
| Wirta et al., 1990.       | SCSP, SC, (PTB/C, PTB/WB, PTB/F8,RS, Articulated supracondylar wedge *   | polyethylene foam liner and SACH foot | Pistoning was correlated poorly with the shape and length of the residual limb. There was no relation between pistoning and walking velocity. Conical residual limbs exhibited less pistoning than cylindrical ones. There was no correlation between the knee flexion-extension deviations with harmonic ratios or pistoning. The longer and the cylindrical-shaped residual limb associated with the higher harmonic ratios.                                      | B                 |
| Hachisuka et al. 1998     | PTB, KBM, TSB  | Seattle foot or Flex Walker II        | Perspiration was not a concern with the Fillauer liner. ICEROSS increased perspiration in eleven subjects, but it decreased after some weeks or months or usage. The TSB and PTB sockets did not demonstrate difference in vapor penetrability. The majority of below-knee amputees preferred the TSB prosthesis due to higher comfort.   | B                 |
| Board et al.,2001         | TEC interface systems (urethane liners and suspension sleeves) with one-way valve, TEC interface systems with electric vacuum pump   | SACH foot, Flex foot                  | Approximately 6.5% of the limb volume was lost during walking. However, vacuum resulted in average of 3.7% of volume gain. A higher negative pressure was resulted from the vacuum during the swing phase. Also, the limb and tibia moved axially 4 and 7mm less, respectively.   | C                 |
| YİĞİTER et al., 2002      | PTB and TSB sockets  | Dynamic foot                          | The step length at amputated side showed a decrease in the TSB socket compared to the PTB socket. The amputated side tolerated more weight. The TSB socket also resulted in improved balance was found to be better in than the PTB in both eyes-opened and closed conditions. Performance time was less during walking with TSB socket   | A                 |
| Coleman et al., 2004      | Alpha® elastomeric gel liner with locking pin suspension versus Pe-Lite liner with neoprene sleeve   | –                                     | Pe-Lite™ system was favored over the Alpha® in ambulation. Pain, satisfaction, and comfort showed no differences. Ambulatory intensity profiles showed no significant change.   | A                 |
| Astrom I & Stenstrom 2004 | polyurethane concept (TEC" Interface), Previous suspension used by the subjects (ICEROSS, vaccum, and EVA)   | -                                     | Twenty out of 29 amputees still used the polyurethane liner after five years. Nineteen participants indicated it to be the best system they had used. The polyurethane liner increased comfort and the physical activity and it remained unchanged for five years..   | B                 |
| Selles, et al., 2005      | ICEX (TSB) Versus PTB Socket   | -                                     | Both ICEX TSB and the PTB socket resulted in similar functional outcomes (ADL, patient satisfaction, and gait characteristics) and equal prosthetic mass. The economic variables were significantly different. The initial fitting process and fabrication of the TSB socket was significantly shorter, but more expensive. Patients' perceptions regarding the sockets did not differ. The PTB group demonstrated a higher activity level of activity at baseline. | A                 |
| Klute et al.2011          | The VASS (custom urethane TEC liner or polyurethane Liner, Harmony sleeve, Harmony vacuum pump, The pin suspension system ( Alpha Spirit, uniform, 6-mm-thick liner with integrated locking pin) | Seattle Light foot                    | Limb pistoning reduced with the VASS. The participants preferred the pin/lock system and they could take almost half as many steps as pin/lock with the VASS. The pin/lock suspension required fewer check sockets and a shorter time to acquire an adequate fit.   | B                 |

Table 2.3 (continued). Main findings from the reviewed studies (prospective) on the prosthetic suspension system

| Author/s                | Prosthetic suspension system  | Other prosthetic components                     | Findings  | Level of evidence |
|-------------------------|---|---|---|-------------------|
| Gholizadeh et.al. 2012c | Seal-In X5 liner with valve , Dermo liner with shuttle lock (Icelock).  | Talux foot                                      | Significant difference was seen between the two liners. Pistoning with the Seal-In X5 was 71% less than the Dermo liner. Significant difference was also found under different static conditions. The Seal-In liner was more difficult for donning and doffing but the pistoning was less. Two out of 6 subjects preferred the Seal-In liner.   | B                 |
| Boutwell et al., 2012   | Alpha® gel liners—3 and 9 mm thickness  | Otto Bock 1D35 foot                             | The socket pressure was more uniformly distributed with the thicker gel liner. However, the thicker gel liner did not increase the walking speed. The subjects experienced higher instability while walking with the thicker liner. The loading peak value of the vertical GRF significantly increased with the 9 mm liner. The perceived comfort was increased with the thicker liner and most of the participants preferred that over the thinner liner .                             | A                 |
| Gholizadeh et.al. 2012b | Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur)                           | Talux foot                                      | The Dermo liner showed higher pistoning values than the Seal-In X5 liner throughout the gait cycle ( $P < 0.05$ ). Based on the PEQ, overall patient satisfaction was higher with the Dermo liner. Nevertheless, the Dermo liner caused higher pain and pistoning. The subjects were more satisfied with the socket fit of the Seal-In X5 but it was more difficult to don & doff the liner. No traction was experienced at the end of the liner.                                       | B                 |
| Eshraghi et.al, 2012b   | Seal-In X5 liner with valve , Dermo liner with shuttle lock (Icelock), Magnetic lock system   | Talux foot                                      | The suction system exhibited the lowest pistoning. Similar peak pistoning values were observed for the new magnetic lock and the pin/lock system ( $P = 0.086$ ). Significantly higher satisfaction rates were revealed with the new system in walking, stair negotiation, donning and doffing, uneven walking, and overall satisfaction ( $P < 0.05$ ). Prosthetic suspension was found compatible between all three systems. Fewer problems were reported with the new magnetic lock. | B                 |
| Ali et al, 2012b        | Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214,                                  | Talux Foot                                      | The Dermo liner caused less interface pressure within the socket and less problems were perceived by the subjects. Better suspension was resulted with the Seal-In X5 liner .   | B                 |
| Brunelliet al., 2013    | Seal-In X5 liner, suction suspension system with sleeve   | Sprilgite foot, Styrene gel liner, Polyurethane | Pistoning was significantly reduced by the hypobaric Iceross Seal-In® X5. The energy cost of walking and functional mobility showed no statistical changes.   |                   |
| Eshraghi et.al, 2013    | Seal-In X5 liner with valve (Icelock Expulsion Valve 551, Össur) and Dermo liner with shuttle lock (Icelock Clutch 4H 214, Össur), New magnetic lock system | Talux Foot                                      | The new magnetic suspension system resulted in reduced pressure within the socket, especially during swing. During stance, all the three systems demonstrated higher peak pressure magnitudes at the anterior socket than the posterior. However, during one gait cycle, even pressure distribution was seen at the medial, lateral and posterior surfaces.   | A                 |

\* (SCSP): Supracondylar, suprapatellar; (SC): Supracondylar; (PTB/C): PTB socket with Cuff; (PTB/WB): PTB socket with waistband and cuff; (PTB/F8): PTB socket with figure-of-eight suprapatellar strap; (RS): Rubber sleeve; (ASCW): Articulated supracondylar wedge; (PTB): Patellar tendon bearing; (TSB): total surface bearing; (KBM): (Kondylen-Bettung Münster)

Table 2.4: Main clinical findings of the reviewed studies (survey) on the prosthetic suspension system

| Author/s   | Journal   | Year , page        | Times cited | Outcome measures  | Subjects (Reason & Level of Amputation, gender, Age , activity level)  | Prosthetic suspension  | Result (Outcome)   |
|--|---|--------------------|-------------|---|--|--|--|
| Ali et al, 2012a                                   | Archive of Physical Medicine and Rehabilitation | 2012 , 1919 – 1923 | 0           | PEQ (satisfaction (fitting ,donning and doffing, sitting, walking, uneven walking, stair satisfaction, suspension satisfaction, cosmetic ,overall satisfaction with prosthesis), problems (sweat, wound, irritation, pistoning, rotation, inflation, smell, sound, pain )   | Trauma, TT, 243 males, 44 (6.2), K2-3-4  | Seal-In liner, silicone liner with shuttle lock, and Pe-Lite liner | Donning and doffing was easier for those amputees that used the polyethylene and pin/lock liners in comparison to the Seal-In liner. The most durable system was the polyethylene liner. The Seal-In liner demonstrated higher satisfaction parameters than the pin/lock and the polyethylene foam liner. In addition, fewer problems were experienced with the Seal-In liner..  |
| Hachisuka et al. 2001                              | Archive of Physical Medicine and Rehabilitation | 2001 , 1286 - 1290 | 16          | Hygiene problems (perspiration, eruptions, itching, odour) and explanatory values include TSB use, daily life activity, and washing of limb and prosthetic  | Trauma 49 , tumour 10<br>PVD 11,<br>diabetic 12 ,<br>congenital 1<br>TT, 65 males, 18 females, 53.4 (14.4), K2-3-4                       | ICEROSS (44)<br>3S (31)<br>Fillauer Silicone Suspension Liner (8)  | Males had more problems with perspiration than females. There was direct correlation between the perspiration and hours of use. Skin problems had direct association with age. However, itching and odor became less with age. Active subjects had higher itching problem. Perspiration, itching, odor, and skin break down were associated with residual limb hygiene and silicone liner in over 40% of participants with the TSB socket and silicone liner |
| F. B. VAN DE WEG & D. A. W. M. VAN DER WINDT, 2005 | Prosthetics and Orthotics International         | 2005 , 231-239     | 9           | PEQ, fit of prosthesis (comfort to wear), ability to don and doff prosthesis, ability to sit with prosthesis, ability to walk with prosthesis, ability to walk on uneven terrain, ability to walk up and down stairs, appearance of prosthesis sweating, wounds/ingrown hairs/blisters, skin irritations, painful stump, swelling stump, unpleasant smells, unwanted sounds | Vascular 83, trauma 93,<br>other (congenital deformities, infection, etc.), 33 unclear 11,<br>TT, 132 males, 88 females, 62.1(17.5), K?* | Pelite, silicone, and polyurethane liners                          | Some inherent weaknesses of liners first remain to be solved. In developing countries in particular, with high durability and low cost, a prerequisite, PTB or PTB-related prostheses might continue to be the first choice. Most of the literature originates from industrialized nations, which may explain any bias towards technological advances  |

Table 2.4 (continued): Main clinical findings of the reviewed studies (survey) on the prosthetic suspension system

| Author/s               | Journal                                 | Year, page    | Times cited | Outcome measures   | Subjects (Reason & Level of Amputation, gender, Age [yr], activity level) | Intervention (Prosthetic suspension)   | Result (Outcome)  |
|------------------------|---|---------------|-------------|--|---|--|---|
| Christie Ferraro, 2011 | Journal of Prosthetics and Orthotics    | 2011, 78-81   | 3           | ABC scale ( stability during activities and the probability of future falls, overall comfort, skin issues, volume fluctuations, ease of knee flexion, perceived pistoning, and activity level)   | reason for amputation?, TT,TF, 13 subjects, age?*, K2-3-4                 | Pin/lock suspension, vacuum suspension | Patients stated decreased pistoning with vacuum systems in comparison to pin/lock suspension. Pin/lock liners caused higher skin problems including blister compared with the vacuum. Blisters may be experienced with vacuum suspension in the case of an air gap or improper fit. The lack of blisters may be taken as evidence that the newer vacuum suspension sockets fit the patients properly. Increased activity levels in some patients wearing vacuum systems.  |
| DATTA et al.,1996      | Prosthetics and Orthotics International | 1996, 111-115 | 27          | Use of waking aids (indoor-Outdoors- rough ground-Bad weather), pain, skin breakdown, sweating, comfort (wearing, walking, donning and doffing, maintenance, stair)  | Trauma, diabetes, other, TT, 54 subjects, 48.3, K?*                       | Pelite (PTB) and Iceross               | Use of the ICEROSS resulted in significant increase in sweating after the three weeks. But afterwards there was no significant difference between the ICEROSS and PTB. Participants were more satisfied with the ICEROSS in terms of comfort in stairs negotiation. But they stated increased sweating, skin rash and itching with the ICEROSS. However, some reported easier wash of the ICEROSS.  |
| Cluitmans et al.,1994  | Prosthetics and Orthotics International | 1994, 78-83   | 34          | Duration of old prosthesis use, problems with old prosthesis, donning and doffing, ease of maintenance, hygiene, suspension, standing, getting up, walking, necessity of walking aid, walking speed and distances, walking on uneven surfaces, climbing, cycling, getting in and out of the car, and final verdict of patient. Perspiration, Itching, Soreness, Local pressure, Creasing at the back of knee during knee flexion | Trauma, vascular, other, TT, Male, Female, 35-70, K?*                     | Iceross with KBM and PTB sockets       | When the suspension system was changed to silicone roll-on socket, the subjects initially complained of itching, more perspiration, and soreness. The participants stated discomfort at the popliteal area when using ICEROSS. Blisters were also a concern, especially at the proximal edge of the liner. The majority of participants did not indicate any complication for donning & doffing. However, a few found it difficult, particularly for quick wear in the middle of night to reach the toilet. Vision-impaired subjects preferred the shuttle lock over the conventional Pelite. The ICEROSS improved suspension and function significantly. |

Table 2.4 (continued): Main clinical findings of the reviewed studies (survey) on the prosthetic suspension system

| Author/s             | Journal                              | Year, page    | Times cited | Outcome measures  | Subjects (Reason & Level of Amputation, gender, Age [yr], activity level)   | Intervention (Prosthetic suspension) | Result (Outcome)  |
|----------------------|--------------------------------------|---------------|-------------|---|---|--------------------------------------|---|
| Webster et al., 2009 | Journal of Prosthetics and Orthotics | 2009. 215-222 | 8           | Ambulation distance, use of assistive devices, ability to use prosthesis, employment status, prosthesis for work activities, prosthesis interfering with work,  | Trauma, diabetes, other, TT, TF, 56 transtibial (39 males, 17 females), transfemoral (14 males, 1 female), age (18-65), K?* | Osseointegration                     | The study found addressing some problems with this new method such as infection problem, failure of implant and extended rehabilitation procedure with the osseointegration will be essential to improve prescription and acceptance of this system by amputees.  |
|                      |                                      |               |             | (ADVANTAGES) prosthetic function, walking ability, easy and quick attachment, activity level and lifestyle, attachment and suspension, comfort, skin breakdown, risk of infection, potential for limited activity due to failure, |   |                                      | (ADVANTAGES) The subjects who were more satisfied with this new system stated 92% prosthetic function was improved, 88% walking ability, 83% Easy and quick attachment, 79% activity level, 75% decrease pain, 50% less skin problems, 79% better suspension, and 67% improved feeling of the prosthesis.   |
|                      |                                      |               |             | (DISADVANTAGES) risk of bone fracture, potential to lose more residual limb, multiple surgeries, presence of percutaneous rod, bent or broken implant, long-term antibiotic use, need to avoid running                            |   |                                      | (DISADVANTAGES) The subjects who were not satisfied with osseointegration mentioned: 75% Risk of infection increased, 65% Potential for limited activity, 35% difficult for running, 50% more antibiotic use, 56% need more operation (surgery), 65% need longer rehabilitation period, 63% increased risk of fractures, 52% Implant problem (broken or bent) |

# TT= transtibial; PEQ= prosthesis Evaluation Questionnaire; PVD= Peripheral vascular disease, TSB= Total Surface Bearing; PTB= Patellar tendon Bearing; K-level = (K1, 2, 3, 4); ABC= Activity Balance Confidence;

\* It is not clear (the authors did not mention in the article)

#### **2.2.4. Discussion**

Web of Science, PubMed, and ScienceDirect databases were searched for relevant studies on transtibial prosthetic suspension systems. The search mainly aimed to determine the advantages and disadvantages of suspension systems in the literature. Several systems are commonly used for transtibial prostheses, such as TSB socket (i.e., pin/lock, magnetic lock, suction, or vacuum system), and PTB and KBM (Kondylen-Bettung Münster) sockets (i.e., SCSP, SC, cuff, waistband, figure-of-e SP strap, RS, and ASCW) with or without polyethylene soft insert (i.e., Pelite). The studies also revealed the latest developments in osseointegration, which enables the direct connection of the residual limb to prosthetic components.

Google Scholar database was used to determine the number of citations for each paper as this database covers most peer-reviewed and non-peer-reviewed journals among other citation indexes (Scopus and Web of Science) (Farhadi et al., 2013). This number shows how many times these papers (results) were considered by other researchers and is dependent on the year of publication. Ten out of 22 papers were published between 2011 and 2013 (until April). This finding may show that research on the transtibial suspension systems has grown recently and could be a reason for receiving fewer citations. The majority of the papers in this literature review were from the United States and Malaysia.

Prosthetists should decide whether a suspension system is suitable or not for various residual limb conditions, such as residual limb length, shape (i.e., cylindrical or conical), muscle strength, soft tissue, bony prominence, pain, aspiration of amputee, level of activity, upper-limb strength, and amputees' budget. However, no conclusive evidence has been offered that can clearly define the most feasible suspension system for transtibial amputees.

The criterion B7 (blinded outcome assessor-Appendix) was not applied for evaluating the studies on suspension systems. This criterion can be attributed to the research design, which cannot be facilitated in a blind study. When the amputees want to wear the prosthesis, they can easily identify the difference between the suspension systems. This situation could have created respondent bias. However, in other studies on knee joint or foot, performing a blind test was easy (Boonstra et al., 1996; Postema et al., 1997; Boonstra et al., 1995), and the researcher easily covered the components.

Measurement of pistoning or vertical movement inside the socket was used by researchers to check the quality of a suspension system in transtibial prosthesis (Lilja et al., 1993; Newton et al., 1988; Sanders et al., 2006; Madsen et al., 2000; Bocobo et al., 1998; Stiefel et al., 2009; Gholizadeh et al., 2012a,b,c; Eshraghi et al., 2012b; Klute et al., 2011; Board et al., 2001; Street, 2006). Suction or vacuum suspension systems can diminish the displacement of the stump inside the socket, unlike the pin/lock or the use of sleeve (Arndt et al., 2011; Brunelli et al., 2013). Consequently, solidity between the residual limb and the socket is increased, and gait asymmetry and skin sores are reduced (Sanderson and Martin, 1997; Rusaw and Ramstrand, 2011; Grevsten and Erikson, 1975). Suction or vacuum systems, which use a seal-in liner or cushion liner and sleeve can decrease pain at the distal end of the residual limb, specifically for bony residual limbs (Gholizadeh et al., 2012a). Studies show that amputees suffer less pain during the stance phase as these liners have a softer distal end than the pin/lock system.

The milking problem (distal tissue stretching) of the pin/lock system is also decreased during the swing phase (Beil and Street, 2004; Eshraghi et al., 2013a; Eshraghi et al., 2012b). Distal tissue stretching can lead to pain, particularly at the cut end of the tibia and along the tibial crest (Krosin, 2004). Vacuum suspension increases the stump volume by 3.7% (Board et al., 2001). However, donning and doffing are more



difficult to perform when suction or vacuum systems are used instead of the pin/lock systems or PTB prosthesis, particularly for older amputees or for those with upper-limb problems, such as stroke patients (Ali et al., 2012a; Gholizadeh et al., 2012b,c; Eshraghi et al., 2012b). Easy donning and doffing is very important in relation to the night-time toilet habits of amputees. Fabricating proper suction and vacuum systems also requires more time than for PTB and TSB with the pin/lock system (Klute et al., 2011). Fewer check sockets and/or less time is required to achieve sufficient fit. Furthermore, proper suction and vacuum systems are not good choices for amputees who have fluctuation in their stumps.

Compared with the pin/lock system, the new magnetic lock can partly resolve the milking phenomenon (Eshraghi et al., 2012b). The pistoning measurements reveal values comparable with those of the pin/lock system. However, a suction system with a Seal-In liner causes less pistoning. Prosthetic users preferred the magnetic lock over the pin/lock and Seal-In liner for donning and doffing (Eshraghi et al., 2013).

This literature review reveals that thicker liners are more comfortable and can distribute the pressure more evenly over residual limbs. However, amputees' instability is increased during walking (Boutwell et al., 2012). The TSB socket allows for higher weight bearing through the use of the amputated leg compared with the PTB socket. Both open- and close-eyed conditions also show good balance (Yigiter et al., 2002). Better balance can be associated with overall contact of the TSB socket to the skin, which provides improved proprioception and pressure distribution.

High perspiration is one of the disadvantages of the TSB socket with silicone liner, polyurethane, or TEC liner compared with the PTB socket with Pelite insert because of less ventilation between the skin and the soft liner. Amputees with excessive soft tissues at the popliteal fossa also experience difficulty in using a sleeve or silicone

liner because of the creasing during knee flexion (Hachisuka et al., 1998; Hachisuka et al., 2001).

Based on the literature, the TSB socket with pin/lock system is preferred by the majority of amputees. Online worldwide survey by the author of this thesis also showed that the silicone liner with the pin/lock system was the first choice of prosthetists among three different suspension systems, namely, PTB with Pelite soft liner, Iceross with Pin/Lock, and suction system. To date, no clinical evidence can prove that the Iceross is the standard system for all transtibial amputees (Datta et al., 1996). Coleman et al. (2004) and Selles et al. (2005) stated that no significant difference could be found regarding satisfaction, pain, comfort, and functional outcome with the TSB and PTB sockets.

Ali et al. (2012a) found that donning and doffing are more difficult with the suction system (Seal-In liner) than with the PTB (with polyethylene soft insert) and Iceross with pin/lock. This finding is similar to that of the prospective studies (Gholizadeh et al., 2012b,c; Eshraghi et al., 2012b; Cluitmans et al., 1994; Brunelli et al., 2013). The polyethylene foam insert was also more durable than the silicone liners, which is in accordance with the findings of Van de Weg and Van der Windt (2005) in the Netherlands. In developing countries, a suspension system with high durability and low cost should be the first choice of amputees.

Hachisuka et al. (1998) reported that perspiration in prosthesis was less in female amputees than in males. Datta et al. (1996) observed that perspiration increased upon using the Iceross but decreased after three weeks. Daily wash of the stump and silicone liner is important to control odor, perspiration, itching, and eruption (Baars and Geertzen, 2005; Hachisuka et al., 2001). Ferraro (2011) found greater vertical

movement inside the socket with the pin/lock systems than with the vacuum suspension. This observation is consistent with that of other studies (Gholizadeh et al., 2012a,b).

#### **2.2.5. Conclusion**

Methodical assessment, along with knowledge and expertise, can contribute to the selection of a suitable type of prosthesis for an amputee. Suction systems can diminish the displacement of the stump inside the socket and decrease the gait asymmetry and pain at the distal end of the residual limb compared with other systems. However, donning and doffing are more difficult with this system. Moreover, such system is not a good choice for amputees who have fluctuation in their stumps.

This literature review reveals that thicker liners are more comfortable and can distribute the pressure more evenly over the residual limb. However, amputees' instability is increased during walking. High perspiration is one of the disadvantages of the TSB socket with silicone liner, polyurethane, or TEC liner compared with the PTB socket with Pelite insert.

In developing countries, a suspension system with high durability and low cost (such as Pelite) should be the first choice of amputees. In summary, no clinical support is available to suggest the kind of suspension system that could influence as a “standard” system for all transtibial amputees. However, the TSB socket with pin/lock system (Iceross) was preferred by the majority of users. Researchers and manufacturers should focus more on socket fit, durability, donning and doffing procedure, cost, and sweating problem for the design of new prosthetic suspension systems.

### 2.3. Transfemoral suspension system

Incidence of transfemoral amputation is less compared with transtibial amputation. Based on the literature, energy expenditure is almost 65% higher in transfemoral amputees than in normal people. Surgeons attempt to save the length of a residual limb as much as possible (Smith et al., 2004). Maximizing the bone length (could create longer lever arm) will allow the amputee to remain more active and stable (Figure 2.9).

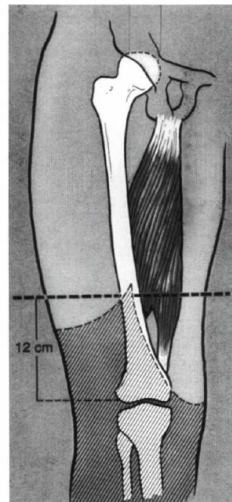


Figure 2.9: Proposed skin flaps and level of bone section (Reproduced from Atlas of Amputation and Limb Deficiencies- Smith et al., 2004).

Prosthetists seek to restore an amputee's ability in activities of daily living by ensuring proper prosthetic fit (Radcliffe, 1955). Thus, the user's mobility, comfort, and satisfaction are associated with socket fit and proper choice of suspension system (Kristinsson, 1993; Baars and Geertzen, 2005; Ali et al., 2012 a; Highsmith et al., 2010; Neumann et al., 2005).

Transfemoral prosthesis mostly includes a socket, suspension system, adapter, knee joint, shank or pylon, and prosthetic foot. The main concepts for transfemoral prosthesis are as follows: (1) to facilitate muscle function by appropriate contouring of

the residual limb, (2) to apply load to the skeletal structures, (3) to improve functionality by stretching the hip muscles, and (4) to minimize pressure on the stump skin by maximizing contact (Michael, 1990; Radcliffe, 1955).

Leather was the most common material for transfemoral socket until the World War I. Leather was eventually replaced by wood (plug fit socket), and the final socket was covered with a cotton sock. Considering wooden sockets did not provide any suction, bulky suspension accessories such as a harness should be used (Smith et al., 2004). Although the suction socket was introduced in the 1930s, it was not commonly used until veterans of World War II were fitted with this type of socket. The socket consisted of an empty distal stump about 5 cm below the distal end, which was sealed by a valve. The valve ensured air isolation, and the resultant vacuum maintained close contact between the stump and the socket. However, the suction socket usually results in edema, particularly in long-term use (Hagberg et al., 2008; Smith et al., 2004).

The two main socket designs for transfemoral prosthesis are QL socket and IC socket, introduced in the 1950s and 1980s, respectively (Kapp, 1999; Schuch and Pritham, 1999; Klotz et al., 2011). The QL socket at the University of California in Berkeley was designed by Radcliffe and Foort. Their design (Figure 2.10) provides a total contact between the socket and the residual limb without weight bearing at the end of the socket. The proximal brim contours differentiate these two designs; the ischium is contained inside the IC socket but not in the QL socket. In the IC socket, the posterior wall could support ischial tuberosity from rotation or sliding within the socket better than with the QL socket (Sabolich, 1985).

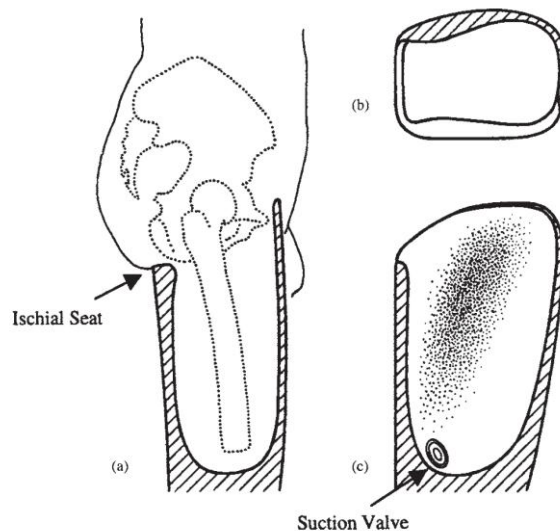


Figure 2.10: Quadrilateral suction socket; (a) lateral view, (b)cross section view, (c)suction valve.

The IC socket could also improve the amputee's gait by placing the femur into adduction position (Sabolich, 1985; Hachisuka et al., 1999). Compared with the QL socket, the IC design is wider in the anterior-posterior dimension and narrower in the medial-lateral dimension. The ischium is also contained inside the socket. An evolution in the development of the IC socket is the ischial-ramal containment socket or the Marlo Anatomical Socket (MAS) developed by Marlo in 1999. In this design, the ischial ramus angle plays an important role. The medial aspects of the ramus and ischial tuberosity are encapsulated within the medial aspect of the socket brim; to avoid pressure on the ramus (ascending part), the medial wall is lowered anteriorly (Fairley, 2004).

Clinicians should attain comprehensive knowledge of socket design and proper suspension systems based on the amputees' needs (Schuch and Pritham, 1999). Several suspension systems are currently used with transfemoral prostheses, including hip joint with pelvic band, the Silesian belt, silicone liners with or without a shuttle lock, and suction socket (Dietzen et al., 1991; Carroll and Edelstein, 2006; Klute et al., 2010; Kapp, 2000). A hip joint with pelvic band and the Silesian belt are preferred by geriatric

amputees for ease of use, as well as by amputees with short residual limbs because of good suspension (Dietzen et al., 1991; Smith et al., 2004). Some advantages of suction suspension system are greater use of stump's residual muscles, higher mobility, and better cosmetic appearance and comfort than the hip joint with pelvic band and the Silesian belt (Dietzen et al., 1991). However, suction sockets do not accommodate residual limb fluctuation, which diminishes socket fit and suspension. In geriatric users or those with vascular disease, suction sockets may cause edema at the end of the residual limb (Dietzen et al., 1991; Gholizadeh et al., 2012a; Fillauer et al., 1989). In the 1980s, silicone and polyurethane liners were introduced in lower-limb prosthetics. These liners can decrease shear forces between the socket and the residual limb, thereby improving suspension and controlling the volume fluctuation of the residual limb (Fillauer et al., 1989; Baars and Geertzen, 2005). The roll-on silicone liner provides enhanced suspension, comfort, stability, and cushioning compared with suction sockets and polyethylene foam liners (Sanders et al., 2004; Beil et al., 2002; Coleman et al., 2004). Various techniques are used to couple the liner and the residual limb in the lower-limb sockets, including lanyard, distal pin and shuttle lock, vacuum/suction seals, and magnetic lock (Wirta et al., 1990; Trieb et al., 1999). The Seal-In liner system (a new vacuum suspension liner with hypobaric sealing membrane around the silicon liner without pin and lock system or an external sleeve) (Gholizadeh et al., 2011) can increase the surface contact with the socket wall. The resultant vacuum reduces the rotation, translation, and pistoning movements inside the lower-limb socket (Gholizadeh et al., 2012a; Ali et al., 2012a).

Bone anchorage is another alternative to the conventional suspension techniques. Osseointegration (OI) was introduced in Sweden (Branemark et al., 2001) in 1990 and is recently used in other countries, such the United Kingdom (Sullivan et al., 2003; Smith et al., 2004). A titanium implant provides the anchorage “by the formation of

bony tissue around it without growth of fibrous tissue at the bone-implant interface”(Branemark et al., 2001). Dentists have used the concept of osseointegration for dental implants since 1965 (Branemark, 1977).

Selection criteria for prosthetic suspension systems and socket forms mainly follow the clinician’s subjective experiences, amputation etiology, amputee’s functional capacity, and even patient choice and opinion (van der Linde et al., 2004; Schaffalitzky, 2010). Prosthetic prescription should ideally match biomechanical characteristics. Therefore, clinical prescription guidelines can ensure consistent and efficient health care. The development of such guidelines is facilitated through systematic review of the literature by highlighting the gaps (van der Linde et al., 2004; Woolf et al., 1999). To date, no sound technical guideline or consensus over selection criteria is available (van der Linde et al., 2004).

Subjective and objective evaluation of various transfemoral suspension systems have been conducted. This study aims to systematically review the literature to develop guidelines for the available transfemoral suspension systems. The number of citations that each paper has received and the journal with more publications in this field were checked.

### **2.3.1. Methodology for systematic review (Transfemoral)**

Related research articles were searched from the PubMed, ScienceDirect, and Web of Science databases. The end search date was May 2013. The related keywords and their synonym combinations were: transfemoral prosthesis, above-knee prosthesis, transfemoral, prosthetic liner, prosthetic suspension, lower-limb prosthesis, and prosthetic socket. The references of the obtained papers were also added to the search.



The systematic criteria were set to facilitate the selection of articles. The criteria for selecting articles are as follows: The studies were included if they evaluated the transfemoral prosthesis suspension system, were written in the English language, and aimed to provide insights into various suspension systems for transfemoral prosthesis.

Each paper's abstract was reviewed to determine the sampling method, design (prospective, retrospective, and case series), outcome measures, research instrument, and protocols (van der Linde et al., 2004). Subsequently, two reviewers separately assessed the quality of each study using a checklist consisting of 12 items (Appendix D). The checklist was based on two available lists for quality assessment primarily used to assess randomized controlled trials (van Tulder et al., 1997; Verhagen et al., 1998; English et al., 1995). As such, another checklist was necessary to tailor for non-randomized controlled trials. Every criterion was scored "1" if it was applicable or "0" if not applicable. Those papers that successfully controlled the measurement and selection bias were preferred (van der Linde et al., 2004). Finally, categorization was performed as follows:

- A-level: Those articles that gained at least 11 or more points; 6 points from the A and B criteria; a positive score for blinded outcome assessment (criterion B7); and timing of the measurement (criterion B8).

- B-level: Those articles with a total score between 6 and 10, including a positive score for timing of the measurement (criterion B8).

- C-level: Those articles with a total score of at least 6 out of the A- and B-criteria with an invalid score on criteria B7 and B8.

As such, studies that achieved at least 6 out of 9 points for the A- and B-criteria were included in the review (van der Linde et al., 2004).

### 2.3.2. RESULTS

From 420 articles, 155 papers were identical in databases and keywords (Figure 2.11). From the remaining 265 papers, some were excluded as were case studies, computational models or focused on below-knee or upper-limb prosthetics. Another 10 papers were included from the references. A total of 26 papers were systematically reviewed, including 9 survey and 17 prospective studies. Table 2.5 and Figure 2.11 present the methodological quality evaluation. Ten papers could not achieve A, B, or C levels; 15 articles were classified under B level (Erikson and James, 1973; Fishman et al., 1987; Gottschalk et al., 1989; Flandry et al., 1989; Gailey et al., 1993; Dillingham et al., 2001; Macchi et al., 2004; Hagberg and Brånemark, 2009a; Hagberg et al., 2008; Dudek et al., 2005; Hagberg et al., 2005; Tillander, 2010; Klotz et al., 2011; Tranberg et al., 2011; Gholizadeh et al., 2012a); and one paper obtained A level (Macchi et al., 2004). The majority of the papers had been published in the *Prosthetics and Orthotics International* journal. The most number of citations in Google Scholar was 87 (Table 2.6) for an article by Dillingham et al. (2001). The sample size in the prospective studies ranged from 4 (Klotz et al., 2011) to 100 subjects (Hagberg and Brånemark, 2009) (Table 2.7) and 16 (Dillingham et al., 2001) to 159 subjects (Dudek et al., 2005) in the survey studies. The majority of participants were unilateral amputees. The main reason for amputation was trauma followed by tumor, diabetes, disease, infection, and congenital limb deficiencies (Tables 2.7 and 2.8). Sweden and United States had more publications regarding transfemoral prosthesis (6 and 5 out of 16 articles, respectively). Lower-limb amputees stop using prosthesis not only because of high energy expenditure, but also as a result of skin problems, discomfort, and perspiration (Tables 2.9 and 2.10).

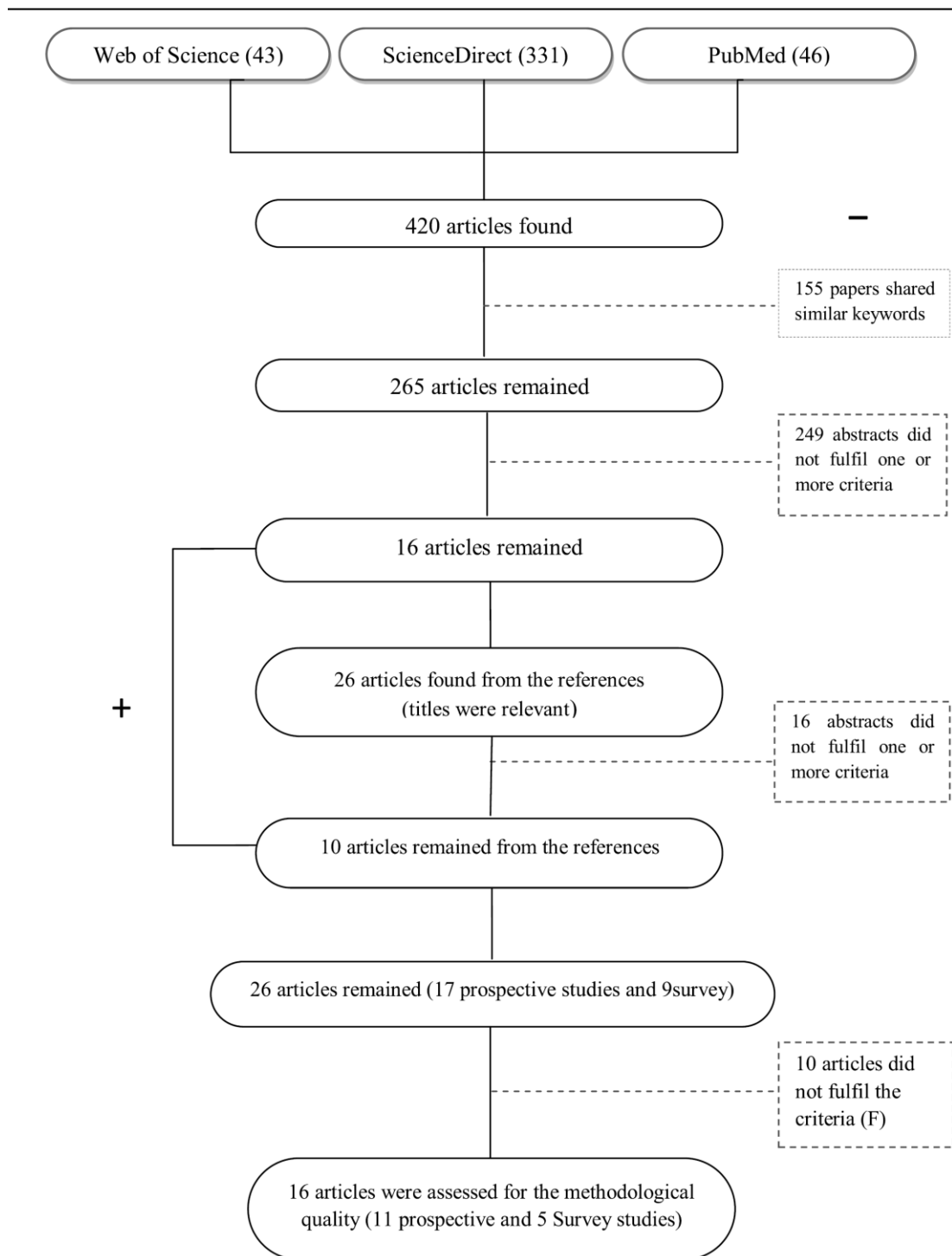


Figure 2.11: Selection algorithm for this literature (transfemoral)

Most studies on transfemoral prosthetic suspension focused on osseointegration method, IC socket, and common suction socket (CSS) or QL. The prosthetic suspension

used in prospective studies are as follows (Table 2.7): CSS with or without Silesian bandage, pelvic band, or flexible socket; Icelandic–Swedish–New York (ISNY) socket with Silesian bandage or suction as a suspension system; IC socket consists of contoured adducted trochanter (CAT)/controlled alignment method (CAM), normal shape-normal alignment (NSNA), narrow medial-lateral (M-L), and osseointegrated bone-anchored prosthesis.

The suspension systems in retrospective studies are as follows: IC socket consisting of CAT/CAM socket with or without silicone suspension, CSS with or without strap or silicone suspension (Seal-In liner), and osseointegration.

Table 2.5: Number of articles based on the journal

| Journal Name  | No.<br>Articles | Failed | Remained Articles |        |
|---|-----------------|--------|-------------------|--------|
|   |                 |        | Prospective Study | Survey |
| <i>Journal of Prosthetics and Orthotics</i>                       | 1               | —      | 1                 | —      |
| <i>Gait &amp; Posture</i>   | 1               | —      | 1                 | —      |
| <i>Annals of Physical and Rehabilitation Medicine</i>             | 1               | —      | 1                 | —      |
| <i>Clinical Orthopaedics and Related Research</i>                 | 2               | —      | 2                 | —      |
| <i>Journal of Pediatric Orthopaedics</i>                          | 1               | —      | 1                 | —      |
| <i>Upsala Journal of Medical Sciences</i>                         | 1               | —      | 1                 | —      |
| <i>Journal of Bone &amp; Joint Surgery, British Volume</i>        | 1               | 1      | —                 | —      |
| <i>Journal of UOEH</i>  | 1               | 1      | —                 | —      |
| <i>American Journal of Physical Medicine &amp; Rehabilitation</i> | 2               | —      | 1                 | 1      |
| <i>Clinical Biomechanics</i>                                      | 1               | 1      | —                 | —      |
| <i>Archive of Physical Medicine and Rehabilitation</i>            | 4               | 1      | —                 | 3      |
| <i>Journal of Rehabilitation Research and development</i>         | 2               | 1      | 1                 | —      |
| <i>Prosthetics and Orthotics International</i>                    | 8               | 5      | 2                 | 1      |
| Total   | 26              | 10     | 11                | 5      |

Table 2.6: (Prospective and survey studies) \* Survey studies

| Author/s                         | affiliation   | Title  | citation (Google Scholar) | Citation (Scopus) | H-index |
|----------------------------------|---|--|---------------------------|-------------------|---------|
| Erikson James, 1973              | and Uppsala University Hospital, Department of Diagnostic Radiology, Uppsala, Sweden                        | Roentgenological Study of Certain Stump-Socket Relationships in Above-knee Amputees with Special Regard to Tissue Proportions, Socket Fit and Attachment Stability | 4                         | 1                 | 14      |
| Fishman, et al.,1987             | Weill Cornell Medical College, Department of Obstetrics and Gynecology, New York, United States             | Icelandic-Swedish-New York above-knee prosthetic sockets: Pediatric experience   | 4                         | 1                 | 4       |
| Gottschalk et al., 1989          | University of Texas South western Medical Center, United States   | Does Socket Configuration Influence the Position of the Femur in Above-Knee Amputation?  | 27                        | –                 | 8       |
| Flandry et al., 1989             | Hughston Clinic, P.C., Columbus, United States  | The Effect of the CAT-CAM Above-Knee Prosthesis on Functional Rehabilitation   | 19                        | 14                | 12      |
| Gailey et al., 1993              | US Department of Veteran Affairs, Functional Outcomes Research and Evaluation Center,Miami, United States   | The CAT-CAM socket and quadrilateral socket: a comparison of energy cost during ambulation   | 26                        | 21                | 6       |
| Trieb et al., 1999*              | Klinikum Wels, Department of Orthopaedics, Wels, Austria  | Silicone soft socket system: Its effect on the rehabilitation of geriatric patients with transfemoral amputations  | 8                         | 6                 | 23      |
| Dillingham et al., 2001*         | University of Pennsylvania, Department of Physical Medicine and Rehabilitation, Philadelphia, United States | Use and Satisfaction with Prosthetic Devices Among Persons with Trauma-Related Amputations A Long-Term Outcome Study   | 87                        | 66                | 18      |
| Macchi, et al., 2004             | University of Florence, Faculty of Medicine, Florence, Italy  | Prosthesis intolerance in patients with transfemoral amputation: a videocapillaroscopic study  | 3                         | 2                 | 14      |
| Hagberg et al., 2005             | Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden,  | Socket versus bone-anchored trans-femoral prostheses: hip range of motion and sitting comfort  | 47                        | 30                | 10      |
| Dudek et al., 2005*              | University of Ottawa, Department of Medicine, Ottawa, Canada  | Dermatologic Conditions Associated With Use of a Lower-Extremity Prosthesis  | 28                        | 19                | 5       |
| Hagberg et al., 2008*            | Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden,  | Osseointegrated trans-femoral amputation prostheses: prospective results of general and condition-specific quality of life in 18 patients at 2-year follow-up      | 48                        | 29                | 10      |
| Hagberg, Bränemark, Rickard,2009 | Kerstin Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden,                                | One hundred patients treated with osseointegrated transfemoral amputation prostheses–rehabilitation perspective  | 55                        | 35                | 10      |
| Tillander et al., 2010           | Göteborg University, Department of Infectious Diseases, Goteborg, Sweden,                                   | Osseointegrated titanium implants for limb prostheses attachments: infectious complications  | 21                        | 13                | 1       |
| Klotz et al., 2011               | Centre de médecine physique et de réadaptation de la Tour-de-Gassies, Bruges, France,                       | Influence of different types of sockets on the range of motion of the hip joint by the transfemoral amputee  | 2                         | 1                 | 1       |
| Tranberg et al., 2011            | Sahlgrenska Academy, Department of Orthopaedics, Gothenburg, Sweden,  | Improvements in hip-and pelvic motion for patients with osseointegrated trans-femoral prostheses   | 7                         | 3                 | 8       |
| Gholizadeh et al.,2013*          | Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Malaysia.               | Satisfaction and problems experienced with transfemoral suspension systems: a comparison between common suction socket and Seal-In liner                           | 0                         | 0                 | 2       |

Table 2.7 (Prospective studies): Methodological assessment of reviewed studies (sorted in ascending order according to the year of publication)

| Author(s)                                | Subject  |                           |                              |   |                     | Intervention (Prosthetic suspension)   | Selection of patients |    |    |    |           | Intervention and assessment |    |     |    |    |           | Statistical validity |     |     |     |           | Total score | Level of evidence |
|--|--|---------------------------|------------------------------|---|---------------------|--|-----------------------|----|----|----|-----------|-----------------------------|----|-----|----|----|-----------|----------------------|-----|-----|-----|-----------|-------------|-------------------|
|  | Cause of amputation                                      | Level of amputation       | Sex                          | Age (SD)  | K level             |  | A1                    | A2 | A3 | A4 | A - score | B5                          | B6 | B7* | B8 | B9 | B - Score | C10                  | C11 | C12 | C13 | C - Score |             |                   |
| Erikson and James, 1973                  | Unknown  | TF                        | 25 M                         | 42 (12)   | K2-K3               | Total-contact suction socket of laminated plastic (quadrilateral)  | 1                     | 1  | 1  | 0  | 3         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 1   | 1   | 4         | 11          | A                 |
| Fishman, et al., 1987                    | Infection, congenital, truma, sarcoma, arterial puncture | TF                        | 10 (7M, 3F)                  | 10.4 (3.9)  | Juvenile (5.2-15.6) | ISNY socket (with Silesian bandage or suction) and quadrilateral socket with Silesian bandage or pelvic band.***   | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 0                    | 1   | 0   | 1   | 2         | 8           | B                 |
| Gottschalk et al.,1980                   | Truma, PVD (pripheral vascular disease)                  | TF                        | 50 (44M, 6F)                 | 17-70 (QL group), 25-60 (IC group)                                  |                     | Ischial containment (CAT/CAM - contoured adducted trochanter / controlled alignment method) NSNA (normal shape normal alignment), Narrow medial-lateral ischial containment socket) and quadrilateral socket (include hard socket or flexible socket). | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 0                    | 1   | 0   | 1   | 2         | 8           | B                 |
| Flandry et al.,1989                      | Unknown  | TF                        | 5 M                          | 34.4  | K2-K3               | CAT-CAM and common suction socket (Quadrilateral)  | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 0                    | 0   | 0   | 1   | 1         | 7           | B                 |
| Gailey et al., 1993                      | Non-vascular pathology                                   | TF                        | 20 M <sup>#</sup>            | CAT-CAM 37.2 (11.3)<br>Quadrilateral 34.6 (9.8), Normal (33.2 (9.5) | K2-K3?              | Ischial containment socket (CAT-CAM), common suction socket (quadrilateral), control group. ***  | 1                     | 0  | 0  | 1  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 0                    | 1   | 0   | 1   | 2         | 8           | B                 |
| Macchi, et al., 2004                     | Diabetic-non diabetic                                    | TF                        | 70 (59M, 11F)                | 69 (5.4)  | K2-K3               | Icelandic–Swedish–New York socket.   | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 5         | 1                    | 1   | 1   | 1   | 4         | 10          | A                 |
| Hagberg et al.,2005                      | Truma, Tumor, Other                                      | TF                        | 63 (43 vacuum socket, 20 OI) | 51(11.7), 46 (11.3)   | K3                  | Trans-femoral socket prosthesis(common suction socket (quadrilateral), ischial containment socket) and osseointegrated bone-anchored prosthesis.   | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 1   | 1   | 4         | 10          | A                 |
| Hagberg, Kerstin Bränemark, Rickard,2009 | Trauma 67, Tumor 21, Vascular 3, Diabetes 2, Infection 7 | TF                        | 100 (61 M, 39 F)             | 43 (12.9)   | K2-K3               | Osseointegrated trans-femoral prosthesis   | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 0   | 1   | 3         | 9           | B                 |
| Tillander et al., 2010                   | Trauma or Neoplasia                                      | 32 TF, 1 TB, 6 upper limb | 39 (21M, 18F)                | 49.3  | Unknown             | Osseointegration (TF,TT, upper limb)   | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 1   | 1   | 4         | 10          | A                 |
| Klotz et al., 2011                       | 3 trumatic, 1 vascular                                   | TF                        | 4 M                          | 51  | K3                  | common suction socket (quadrilateral, ischial containment socket, ischial-ramal containment socket (also called the Marlo Anatomical Socket (MAS)  | 1                     | 1  | 1  | 0  | 3         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 1   | 1   | 4         | 11          | A                 |
| Tranberg et al.,2011                     | 13 trumatic, 4 tumor, 1 infection, 1 arterial embolism   | TF                        | 19 (10 F, 9 M)               | 44.2 (13.7)   | K3                  | OI and TF socket   | 1                     | 1  | 1  | 0  | 3         | 1                           | 1  | -   | 1  | 1  | 4         | 1                    | 1   | 1   | 0   | 3         | 10          | A                 |

Table 2.8 (survey studies): Methodological assessment of reviewed studies sorted in ascending order according to the year of publication

| Author(s)               | Subject                                     |  |                           |   |          | Intervention (Prosthetic suspension)   | Selection of patients |    |    |    |           | Intervention and assessment |    |     |    |    |          | Statistical validity |     |     |     |          | Total score | Level of evidence |
|-------------------------|---|--|---------------------------|---|----------|--|-----------------------|----|----|----|-----------|-----------------------------|----|-----|----|----|----------|----------------------|-----|-----|-----|----------|-------------|-------------------|
|                         | Cause of amputation                         | Level of amputation                                  | Sex                       | Age (mean or range ± SD)  | K- level |  | A1                    | A2 | A3 | A4 | A - score | B5                          | B6 | B7* | B8 | B9 | B- Score | C10                  | C11 | C12 | C13 | C- Score |             |                   |
| Trieb et al.,1999       | Unknown                                     | TF   | 76 (49 Males, 27 Females) | 49-83   | K2-K3    | CAT-CAM) socket with a silicone suspension and without silicone suspension). | 1                     | 1  | 1  | 0  | 3         | 1                           | 0  | -   | 1  | 1  | 3        | 1                    | 1   | 1   | 1   | 4        | 10          | A                 |
| Dillingham et al., 2001 | Truma (78)                                  | Foot, ankle, transtibial, through knee, transfemoral | 16 TF                     | Age at time of injury(32.9 (10.6)), Time since injury (7.5 (2.8)) | K2-K3    | Above-knee prosthesis suspended by: Strap/other mechanism Suction suspension | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4        | 1                    | 1   | 0   | 1   | 3        | 9           | B                 |
| Dudek et al.,2005       | Truma, PVD                                  | TF,TT,other  | 159 (TF)                  | 745 (159TF)   | Unknown  | Common suction socket, silicone liner, silesian belt, others                 | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4        | 1                    | 1   | 0   | 1   | 3        | 9           | B                 |
| Hagberg et al., 2008    | Truma (12), tumor (5), arterial embolus (1) | TF   | 18 (10F, 8M)              | 45  | K1-3     | Osseointegration   | 1                     | 0  | 1  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4        | 0                    | 1   | 0   | 1   | 2        | 8           | B                 |
| Gholizadeh et al.,2013  | Truma                                       | TF   | 90 M                      | 47.7(7)   | K2-K3    | Seal-In Liner and Common Suction Socket                                      | 1                     | 1  | 0  | 0  | 2         | 1                           | 1  | -   | 1  | 1  | 4        | 1                    | 1   | 0   | 1   | 3        | 9           | B                 |

\* As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, it is not feasible to do blinding in studies on suspension systems. Therefore, we excluded the item B7 regarding the blinding in our study.

**(Table 2.7-note)**

\*\*\* Only in two studies the authors mentioned other prosthetics components; Fishman, et al., (different knee joint (Hydraulic, polycentric, manual lock, non articulated, constant (sliding - friction) FOOT: SACH) and Gailey et al. (Prosthetic knee (SA/Hyd, 4 Bar, SA/Pneu, SA/Fric), prosthetic foot (Seattle , Multiflex, SACH, Greissinger)

# 10 subjects wearing Ischial containment socket (CAT-CAM), 10 subjects using quadrilateral socket. Also they use 10 non amputated subjects as a control group.

\* As the amputees can easily identify the difference between the suspension systems when they want to wear the prosthesis, it is not feasible to do blinding in studies on suspension systems. Therefore, we excluded the item B7 regarding the blinding in our study.

Table 2.9 (Prospective studies): Main findings from the reviewed studies on the prosthetic suspension system

| Author/s                 | Objective and parameters  | Result (Outcome)  | Level of evidence |
|--------------------------|---|---|-------------------|
| Erikson, and James, 1973 | To studies concerning the socket fit and the relative movement between the stump bone and socket. The examinations concerning soft tissue evaluation in the intact thigh and the stump (without prosthesis), Socket fit and relative movement between the femoral stump and the socket (quadrilateral) were also performed with the patient standing, wearing the prosthesis.   | <p>The cross-section of residual femoral bone increased somewhat after the amputation as a result of the total reduction in volume of the stump, but decreased in relation to the cross section of the intact femur by an average of about 27 %.</p> <p>Considerable bone atrophy in the femoral stump. There was total contact between the stump and the socket (suction socket- quadrilateral) in about two-fifths of the patients. Of the remaining, different space was noted without bearing weight at the distal end between the stump and socket.</p>  | A                 |
| Fishman, et al.,1987     | To compare ISNY and common suction socket (quadrilateral with Silesian bandage or pelvic band): <b>POSITIVE</b> reaction regarding ISNY: <b>Comfort</b> (lighter. Less sweating, softer, prefer Silesian bandage to pelvic band, no groin irritation, prefer total suction to Silesian, non specific positive comments) , <b>Function</b> ( easier to walk, better gait, easier to run, easier to dance , easier to hop and skip, easier to jump, easier to rise from the floor, easier to doff) , <b>Cosmetics</b> ( less bulky, does not show under the trousers, like to see amputation limb, less noisy, no positive comments) <b>Overall</b> (non specific comment regarding preferring for ISNY socket) Negative reaction: <b>Comfort</b> ( Hotter, Preferred to wear stockinet) <b>Cosmetic</b> ( Poor frame appearance, poor drape of trousers over socket, unsatisfactory frame colour) , <b>Function</b> ( hard socket is safer, more difficult to don) | ISNY socket improved appearance, function, comfort and growth adjustability features compared with common suction socket ( quadrilateral with Silesian bandage or pelvic band ) in Juvenile. Using ISNY socket could help the younger children to use suction as their suspension system instead of pelvic band or Silesian band. Nevertheless, femur angle in these two systems are similar Seventy percent of children and their parents indicated better function with ISNY. Sixty percent appearance of new design. the costs associated with materials and initial fabrication time are not significantly higher than for common suction sockets. The ease of socket replacement and adjustments may well significantly reduce the long-term costs of prosthetics care, especially for children.   | B                 |
| Gottschalk et al.,1989   | To determine the Position of the residual femur in the above-knee prosthetics socket of various type, to highlight the reasons for malalignment of the residual femur, to recommend methods that can restore the anatomical position of the stump (statically and dynamically)  | The anatomical axis of the normal femur was the same in both groups of patients (Ischial containment and Quadrilateral socket). The position of the residual femur in the quadrilateral sockets varied from 8° to 12°abduction, while in the ischial containment sockets the femur position varied from 8 to 14° abduction. The configuration of the socket did not affect the position of the femur in the socket. Although the narrow mediolateral socket concept has some merits, the anatomical alignment of the femoral bone should be achieved by proper myodesis of the adductor muscles at the time of surgery. No statistically significant difference in the abduction angles of the amputated femurs between quadrilateral socket and ischial containment socket. The success of the prosthetic fitting, i.e., the optimal restoration of function and comfortable ambulation, depends on the anatomical alignment and dynamic functioning of the transfemoral amputation stump. | B                 |
| Flandry et al.,1989      | Five, rehabilitated, unilateral above-knee amputees using common suction socket (quadrilateral) were converted to ischial containment socket (Contoured Adducted Trochanteric-Controlled Alignment Method), to determine the effect on ambulatory function. (1) assessment of Functional level of ambulation, (2) amputee's subjective assessment by questionnaire, (3) observed gait, (4) femoral shaft adduction angle, (5) observed and instrumented gait analysis, (6) dynamic body torques, and (7) energy cost of walking.  | <p>The CAT-CAM socket was stated superior by 4 patients.Stability and comfort increased by using CAT-CAM</p> <p>prosthesis. Most gait deviations improved or disappeared Level of ambulatory independence increased with CAD-CAM compared to quadrilateral socket. Femoral shaft inclination angles improved an average of 6.5° toward adduction in 4 patients. The compensatory lateral trunk lean in patients with quadrilateral sockets, disappeared after conversion. Customary gait velocities were increased, while the quantity of oxygen consumed per meter was decreased between 9 up to 50%.</p>  | B                 |
| Gailey et al.,1993       | To compare oxygen uptake and heart rate in three different groups ( ischial containment socket (CAT CAM), common suction socket (quadrilateral) and control group ). Means and standard deviations of non-exercise and exercise oxygen uptake and heart rate (during slow speed and fast speed) in three groups (CAT CAM, quadrilateral and control group) and Means and standard deviations of oxygen uptake and heart rate  | VO2 and heart rate showed significant differences between the control group and CATCAM subjects at the slower speed. The control group and subjects using the common suction socket (quadrilateral) socket also showed significantly different differed VO2 and HR at the slower pace. More energy expenditure and higher HR was required for faster pace than slower speed. At faster pace, significantly higher energy expenditure was observed in the quadrilateral than the CAT-CAM group. Thus, ambulation at normal pace using the CAT-CAM socket design requires less energy than QUAD socket design. Users of CAT-CAM socket design consumed less energy than those who used a quadrilateral socket. None of the socket designs showed energy advantage at slower pace.   | B                 |



Table 2.9 (continued): Main findings from the reviewed studies (prospective) on the prosthetic suspension system

| Author/s                     | Parameter   | Result (Outcome)   | Level of evidence |
|------------------------------|---|--|-------------------|
| Macchi, et al.,2004          | The aim of this article was to investigate, by videocapillaroscopy, the microcirculation of the skin of the stump in 70 consecutive patients with unilateral transfemoral amputation (prosthesis with an Icelandic–Swedish–New York socket).  | The diabetic microangiopathy might be associated with neuropathy, and makes the stump skin more susceptible to the prosthesis impact. Prosthesis intolerance is highly associated with the diabetes-like microvascular changes both in non-diabetic and diabetic patients.   | A                 |
| Hagberg et al.,2005          | To report on Hip range of motion (ROM) among active prosthesis users, when wearing and not wearing trans-femoral socket prosthesis (common suction socket (quadrilateral), and ischial containment socket) and to compare with individuals rehabilitated with an osseointegrated bone-anchored prosthesis. In addition, discomfort when sitting with the prosthesis, is reported in both groups. Active hip range of motion on the affected hip without wearing the prosthesis and on the contralateral hip for the S group (n=43) and the OI group (n=20). | Transfemoral socket (common suction socket (quadrilateral), and ischial containment socket) significantly reduced the active hip ROM. Discomfort when sitting was common among prosthetic user. The discomfort during sitting increases when hip flexion motion is less than 90°. Users of bone-anchored prosthesis (osseointegration) had a normal hip ROM and reported minor discomfort when sitting.  | A                 |
| Hagberg, and Brånemark, 2009 | To describe the current rehabilitation protocol, OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) and illustrates the overall results. Radiography, registration of Complications, hip ROM, walking energy cost, computerized gait analyses, and self-reported health related quality of life (HRQOL), the condition-specific assessment by the Q-TFA,  | Sixty eight patients continued using their prostheses (follow-up: 3 months– 17.5 years) and 32 discontinued (4 were deceased, 7 before second surgery, 6 were in initial training, 4 were not using prosthesis, and 11 had the implant removed). The majority of failures occurred before we established the OPRA protocol. Quality of life was improved and success rate of 94 percent was achieved at the 2-year follow-up. OPRA method can make activities of daily life easier for more patients at younger ages. Their patients expressed severe socket-related problems when wearing the prosthesis with suction socket (such as pain, sweating, sitting discomfort, sores and skin irritation, difficulty donning). | B                 |
| Tillander et al.2010         | To determine the frequency and describe the presentation of infectious complications with osseointegration, also evaluated the bacterial flora at the skin-penetration area and its relation to the development of local and implant-related infection. Bacterial colonization and infection at the beginning of the study and at follow-up (Possible/probable/definite implant infection, Local soft tissue infection in the skin penetration area, Superficial colonization without signs of infection,)  | The incidence of implant infection was five percent at the beginning and 18% at follow-up. Antibiotic treatment recovered infection in one patient and the implant of another patient was removed. However, infectious complications occur in approximately two-fifths of the amputees during a 3-year period, mostly as local infections in the skin penetration area and more rarely as low-activity implant-associated infections.. In superficial and deep cultures, the most common bacteria were Staphylococcus aureus and coagulase-negative staphylococci. The titanium implant system caused few infections leading to implant removal or disability.   | A                 |
| Klotz et al.2011             | To compare the individual influence of different types of socket designs (without a socket, with a common suction socket (quadrilateral),ischial containment socket, ischial-ramal containment socket (also called the Marlo Anatomical Socket (M.A.S)) on The hip's range of motion in transfemoral amputees. Hip's range of motion (Flexion ,Extension, Sagittal joint amplitude, Abduction, Adduction, Frontal joint amplitude, Global amplitude)  | The global amplitude of the hip joint was reduced, regardless of the socket type, compared to physiological conditions without a socket. The ischial-ramal containment socket (M.A.S) restricted global amplitude of the hip joint less than the other two sockets. The three studied socket types had a negative impact on the physiological functioning of the hip joint; however, the ischial-ramal containment socket resulted in the least movement restriction.  | A                 |
| Tranberg et al.2011          | To compare Changes in Hip and pelvic kinematics in 19 trans-femoral amputees, who were treated with an osseointegrated trans-femoral prosthesis (comparison between using socket and OI). Hip extension angle during stance phase, hip extension angle of the non-amputee side during stance phase of sound leg, anterior pelvic tilt angle during stance phase of prosthetic leg   | Hip extension in patients with osseointegrated prosthesis increased significantly by 7.38. But the pre-operative anterior pelvic tilt decreased by 4.08. Values for pelvic tilt and hip extension became close to controls. Hip extension and anterior pelvic tilt significantly changed in patients treated with osseointegration. The changes were moderate but in the long-term may have a positive effect on low back biomechanics reduce the risk of low back pain.   | A                 |

Table 2.10 (survey studies): Main findings from the reviewed studies on the prosthetic suspension system

| Author/s               | Objective and parameters  | Result (Outcome)  | Level of evidence |
|------------------------|---|---|-------------------|
| Trieb et al.,1999      | To compare a contoured adducted trochanteric controlled alignment method (CAT-CAM) socket with a silicone suspension system ( silicone-suction sockets ) and without silicone suspension.   | Patients with the CAT-CAM socket with silicone liner had a significantly greater improvement in traversed distance and inpatient stay in the rehabilitation center was 5 days less. Furthermore, they had to receive less adjustment (only 21% of them needed adjustment) compare to the amputees that using the socket without silicone liner (67 % needed adjustment). No significant difference was seen in satisfaction, average duration of daily use, and the use of assistive devices for gait. Therefore, it is preferable to provide these sockets to geriatric amputee patients rather than CAT-CAM sockets without silicone suspension sleeves. silicone-suction sockets have economic advantages and lead to more gains in ambulation and, therefore, better quality of life.   | A                 |
| Dillingham et al.,2001 | To document and examine the use, satisfaction, and problems with prosthesis among traumatic lower limb amputees. Demographic characteristics (sex, education, Age at time of injury, Time since injury, Married at time of injury). Clinical characteristics (Injury characteristics, Mechanism of injury, Level of amputation) Use and satisfaction with prosthesis (Prosthesis use, Satisfaction with prosthesis, Problems with prosthesis) Health services use, insurance coverage, and knowledge about prosthesis (Service utilization, Knowledge about prosthesis, Specific components of prosthesis), Problems with residual limb, Problems with contralateral limb   | The vast majority of persons with trauma-related lower limb amputations used a prosthetic device quite intensively; but many were not satisfied with the prosthesis level of comfort. Only 43% of amputees were completely or very well satisfied with the comfort of their devices. These findings highlight the need for further improvements in prosthetic socket fabrication and in the development of interfacing materials that minimize discomfort among amputees.   | B                 |
| Dudek et al.,2005      | To document the incidence of skin problems among lower-limb amputees and factors associated with skin problems (with different socket and suspension system). Age, Sex, Age at amputation , Amputation level, Reason for amputation, Comorbidities, Smoking history, Occupation, None or single cane, Two canes, crutches, walker, Walking distance, Time with current prosthesis, Transfemoral socket type, Transfemoral suspension, Ulcer , Irritation, Inclusion cyst, Callus, Verrucous hyperplasia, Blister, Fungal infection, Cellulites.   | At least 1 skin problem was evident in 337 residual limbs (40.7%). Amputation level, type of walking aid, being employed and absence of peripheral vascular disease were independently linked with at least 1 skin problem. Risk of developing skin problems in more active amputees is higher.   | B                 |
| Hagberg et al.,2008    | To analyse general and condition-specific health related quality of life (HRQL) parameters. SF-36 (Physical Functioning (PF), Role functioning from a Physical Perspective (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role functioning from an Emotional perspective (RE) and Mental Health (MH). Q-TFA (Prosthetic Use score, Prosthetic Mobility score, Problem score and Global score  | At follow-up, all the patients except one used the OI-prosthesis (osseointegration). Four of the SF-36 scales (Physical Functioning, Role Functioning Physical, Body Pain and Physical Component Score) and all four Q-TFA scores (Prosthetic Use, Prosthetic Mobility, Problems and Global Health) significantly improved at follow-up indicating better general physical HRQL, better prosthetic mobility, better global amputation situation, increased prosthetic use, and fewer problems .   | B                 |
| Gholizadeh et al.,2013 | To compare a seal-in liner with the common suction socket with regards to patient satisfaction and problems experienced with the prosthesis. Demographic questions: such as age, height, weight, amputation side, time since amputation, hours of daily prosthetic use, and activity level. Satisfaction questions: ability to don and doff the prosthesis, perception of prosthetic fit, ability to sit with the prosthesis, ability to walk with the prosthesis, ability to walk on different surfaces, and perception of prosthetic appearance. problems questions: sweating, skin irritation, wounds, swelling (edema) of the residual limb, pistoning within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sound, pain in the residual limb, and durability of the suspension systems. | Overall, the majority of transfemoral amputees were more satisfied with the Seal-In liner than the common suction socket. If the Seal-In liner durability is increased, could be a good alternative for transfemoral suspension. Satisfaction showed significant difference in terms of fitting, sitting, and donning and doffing between the Seal-In Liner and the common suction socket suspension system. However, walking (even and uneven surfaces), cosmetic appearance of the prosthetic devices, and stair negotiation showed no significant differences. The mean overall satisfaction score for the Seal-In liner was higher than the common suction socket suspension. The respondents had significantly more problems with the common suction socket system compared with the Seal-In liner. The common suction socket caused more difficulties in terms of sweating, wounds, pain, irritation, pistoning, swelling, smell, and sound. Suspension durability of the common suction socket was significantly higher. | B                 |

### 2.3.3. DISCUSSION

This study mainly aimed to review articles and search for the advantages and disadvantages of different transfemoral suspension systems in three main databases, namely, PubMed, Web of Science, and ScienceDirect. The literature indicated that the suspension system and socket design significantly affect the amputee's satisfaction, mobility, and comfort (Kristinsson, 1993; Baars and Geertzen, 2005; Dietzen et al., 1991; Klute et al., 2010; Trieb et al., 1999).

In this study, the number of citations that each paper has received during the past years was checked. This number may indicate how many times these papers (their results) were used by other researchers. This number also depends on the year of publication. However, some of the papers could not receive good citation even after 20 years of publication. Compared with transtibial prosthetic suspension (Baars and Geertzen, 2005), few studies have explored the transfemoral prosthetic suspension systems, which could be attributed to the small number of citations. Furthermore, 69% of all publications regarding transfemoral suspension systems evaluated in this study were conducted in the United States and Sweden. Thus, the type of health care system experienced by the study participants in these two countries was explored.

Dillingham et al. (2001) inspected satisfaction of lower-limb prosthetic users, including transfemoral amputees, based on a retrospective design. Most of the transfemoral participants had either used strap or suction suspension (CSS). However, they did not investigate the correlation between the suspension system and patients' satisfaction, and more than 57% of the participants were unsatisfied with the prostheses (Dillingham et al., 2001). Gholizadeh et al. (2013) reported higher satisfaction and fewer problems with the silicone liner (Seal-In) on 90 traumatic transfemoral amputees than with CSS. Only durability was higher with the CSS system. Besides, appearance,

walking on level and unlevel grounds, and stair negotiation did not demonstrate significant difference between the two systems. However, transtibial prosthesis users did not prefer the Seal-In liner because of difficulty in donning and doffing (Gholizadeh et al., 2012b; Gholizadeh et al., 2012c), whereas transfemoral amputees preferred this liner. This preference can be attributed to the degree of soft-tissue firmness in transfemoral and transtibial residual limbs.

The findings of Gholizadeh et al. were similar to those of Haberman et al. (1992) and Heim et al. (1997) on transfemoral socket with silicone liner as a suspension system. They also stated that the silicone liner could increase function of the prosthesis, comfort, skin protection, cushioning, and quality of the suspension compared with the CSS system. The IC socket (CAT/CAM) was also compared with and without silicone liner by Trieb et al. (1999). The findings revealed that the participants could use silicone liner for longer period and together with decreased skin trauma, resulted in improved quality of life (Trieb et al., 1999). Silicone liners can also cause considerable improvement in the prosthesis function as suspension, cushioning, and skin protection are enhanced (Heim et al., 1997). This finding is similar to those of other researchers on silicone liner as a suspension (Heim et al., 1997; Haberman et al., 1992; Gholizadeh et al., 2012a, Koike et al., 1981). Based on another study, discomfort and edema are usually caused by CSS (Levy, 1980). Dudek et al. (2005) mentioned that the type of socket and suspension mechanism and socket shape did not influence the possibility of developing skin problems (such as skin ulcer, irritations, inclusion cysts, or calluses).

Koike et al. (1981) introduced a transfemoral double socket (the TC double socket) for transfemoral amputees (Koike et al., 1981). Using this system resulted in satisfactory results, particularly in donning and doffing compared with the CSS. This system was mainly attributed to the inner socket flexibility that sustained close contact

constantly and decreased the edema (Koike et al., 1981). Positive effect of easy donning and doffing on user's satisfaction with prosthesis has been previously reported (Gholizadeh et al., 2012a; Haberman et al., 1992; Baars et al., 2008; Gholizadeh et al., 2012b,c) Transfemoral amputees who are using elastic bandages to reduce the friction while donning the CSS (suction socket without soft insert) find it more difficult compared with using silicone liner (Gholizadeh et al., 2013). By contrast, less effort is needed to don the silicone liner in sitting position, which does not entail balance skills needed for donning the CSS. A study on 440 transfemoral amputees also confirmed easier donning of a flexible internal socket than the suction socket (Koike et al., 1981). Compared with the CSS, in which the suction is created between the skin and socket walls, the silicone liner (using seal-in liner or sleeve) suction is generated between the soft liner and socket wall; the soft tissue is saved from the negative pressures caused by the socket. Residual limb pain is decreased by the silicone liner in residual limb during walking compared with the CSS (Gholizadeh et al., 2013). This effect is partly attributed to enhanced volume control and skin protection, as a result of coupling between the skin and liner compared with the suction socket (Gholizadeh et al., 2013; Erikson and James, 1973). Nevertheless, durability remains a concern in silicone liners because these materials are frequently under tensile and compressive loading (Cochrane et al., 2001; Hatfield and Morrison, 2001; Coleman et al., 2004; Van de Weg and Van der Windt, 2005).

The ISNY socket also exhibited similar results to the CSS (Fishman et al., 1987) in adult (Kawamura and Kawamura, 1986) and juvenile (aged between 5.2 to 15.6 years) amputees. The ISNY socket system also consists of two parts (a rigid part for transferring the weight and a flexible part to support the residual limb tissue) (Kawamura and Kawamura, 1986). This system could enhance comfort as the socket

shape changes based on muscle contraction and improve the gait compared with the CSS (with hard socket wall) (Kawamura and Kawamura, 1986).

The CSS could not be a good choice for young amputees because of difficulty in donning the prosthesis (Tooms, 1990). Some clinicians prescribe the CSS for amputees >6 years of age, and others prescribe this system for those >14 years old (Smith et al., 2004; Fishman et al., 1987).

Using ISNY socket could help the younger children to use suction as their suspension system instead of pelvic band or Silesian band. Nevertheless, femur angles in these two systems are similar. Likewise, when quadrilateral socket (with Silesian bandage or pelvic band) and ischial containment sockets (with suction as suspension) were compared, the socket configuration did not appear to have any effect on the femur position in the socket (Levy, 1980; Dudek et al., 2005; Gottschalk et al., 1989). This finding is similar with Gottschalk et al. (1989) that stated that the appropriate surgical procedure for transfemoral amputation has a main role in the proper prosthetic comfort and functional restoration (Gottschalk et al., 1989). On the contrary, Flandry et al. (1989) and Hachisuka et al. (1999) tested on adult amputees using these two kinds of socket with suction as a suspension system. Hachisuka et al. (1999) mentioned that ischial containment socket could improve amputee's gait by putting the femur into the adduction position. Moreover, similar to the findings of Gaily et al. (1993), Flandry et al. (1989) noticed that oxygen consumption is higher with common suction socket (quadrilateral) shape. (Flandry et al., 1989; Gailey et al., 1993).

In another study by Klotz et al., they compared the hip range of motion in three different systems (common suction socket (quadrilateral), ischial containment socket (CAT/CAM), and ischial-ramal containment socket (MAS)). The three studied socket

types had a negative impact on the physiological functioning of the hip joint; however, the MAS resulted in the least movement restriction (Haberman et al., 1992).

Lower-limb amputees stop using prosthesis not only because of high energy expenditure, but also as a result of skin problems, discomfort and perspiration (Baars and Geertzen, 2005; Brånemark et al., 2001; Carroll and Edelstein, 2006; Dillingham et al., 2001; Koike et al., 1981; Cumming et al., 2006; Gauthier-Gagnon et al., 1999; Pohjolainen et al., 1989; Fairley, 2004; Hagberg et al., 2005). Therefore, osseointegration was assumed to solve this problem by eliminating the socket. Currently, this technique is mainly performed on transfemoral amputees having problems of short stump, soft tissue scarring, skin infections, and volume fluctuation with conventional sockets (Klotz et al., 2011; Hagberg and Brånemark, 2001; Hagberg and Brånemark, 2009; Hagberg et al., 2005). According to Hagberg et al. (2005), the hip joint range of motion is significantly decreased, whereas the discomfort in sitting is increased with common suction socket (quadrilateral) and ischial containment socket in comparison to osseointegration. Osseointegrated prosthesis is believed to help in the rehabilitation of transfemoral amputees by increasing the quality of life (Hagberg et al., 2005; Hagberg and Brånemark, 2009). However, there are some unresolved problems in the technique, such as the risk of infection and fracture and the long process of rehabilitation; the technique is not a good option for higher levels of activity. Tillander et al. (2010) also stated that the prevalence of infectious complications is about two-fifths of the amputees during a 3-year period.

#### **2.3.4. CONCLUSIONS**

Transfemoral prosthetic suspension has received less attention in comparison to transtibial prosthesis. The rehabilitation of amputees is challenging as it necessitates team work and amputee's enthusiasm to complete a long and costly procedure. In summary, no clinical support is available to suggest which kind of transfemoral suspension system could have an influential effect as a "standard" system for all the transfemoral amputees. However, among different prosthetic suspension systems, the use of silicone liner or double socket could increase the function of prosthesis, comfort, skin protection, cushioning, and the quality of the suspension system.



## **2.4. Suspension systems studied in this thesis**

To choose the appropriate prosthetic components (based on patient's need) between a number of varieties of the components available in the market is a difficult task for clinicians. Many factors should be critically considered during the selection of components, such as the patient's weight, level of amputation, activity level, length, shape, and condition of his/her residual limb, as well as the budget of the patient. The clinician should introduce few suitable components (advantages and disadvantages) to their amputees, and finally let them choose in accordance to their situations.

Based on the systematic review and the previous research by the author of this thesis, the TSB socket with pin/lock system is a more common prosthetic suspension system in the market. However, there are some disadvantages for this kind of suspension system. The recent development of the prosthetic liner Seal-in 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 the surface contact with the socket wall. Previous number of research by the author of this thesis showed that Seal-in liner could control the pistoning within the socket during ambulation. The MPSS is also developed by the research team, including the author of this thesis, using the silicone liners.

### **2.4.1. Pin/lock suspension systems**

It is difficult for prosthetists to choose from pin locks (Figure 2.12) among several pin lock designs available in the market. Every pin lock has particular features that may be favorable or unfavorable for a certain amputee.

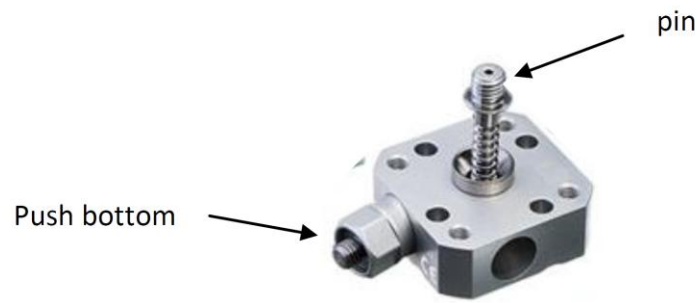


Figure 2.12. Shuttle lock system.

Pin/lock suspension systems secure the soft liner (Figure 2.13) to socket via a stainless steel pin attached to the end of the soft liner. The amputees could release the pin from the socket by pressing a button on the exterior wall of the socket.



Figure 2.13. The pin/lock liner.

Shuttle lock, clutch lock, and smooth lock are the more common pin/lock systems in the market. Among them, the shuttle locks are the most common and are used in this thesis for the subjects. These locks have a one-way gear mechanism that assists in engaging and locking the pin. With the push button, the gear mechanism is moved away from the pin, and it is possible for the pin to be released from the lock, as the rotation of the gear is only possible in one direction (Figure 2.14).

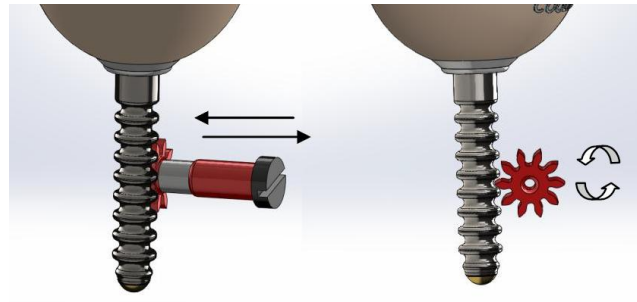


Figure 2.14. Gear mechanism could rotate only in one direction. Pin could be released when the gear mechanism was slid away by the push button.

To don the prosthesis, the pin should be in same direction with the residual limb and the lock mechanism. Hence, it would be difficult to use the pin/lock system if the amputee has contractures in his/her stump.

To determine the correct liner size, prosthetist should measure the circumference of the stump at 4 cm from the distal end with the tissue hanging down (Ossur catalogue). The prosthetist can choose the liner size based on this measurement, or choose the closest size below the measurement if the acquired measurement is between the sizes.

#### **2.4.2. Seal-In suspension**

A recent development is the prosthetic liner Seal-In by Össur (Reykjavik, Iceland) that is a new suction suspension liner with hypobaric sealing membrane around the silicon liner, without an external sleeve or shuttle lock that increases surface contact with the socket wall (Figure 2.15, 2.16 ). Therefore, no additional lock system or external sleeve is needed to fix the stump inside the socket.

The Seal-In liner is recommended for use with a TSB socket. Furthermore, using Icelock Expulsion Valve is necessary to create a suction or vacuum inside the socket.



Figure 2.15. Seal-In X5 liner.

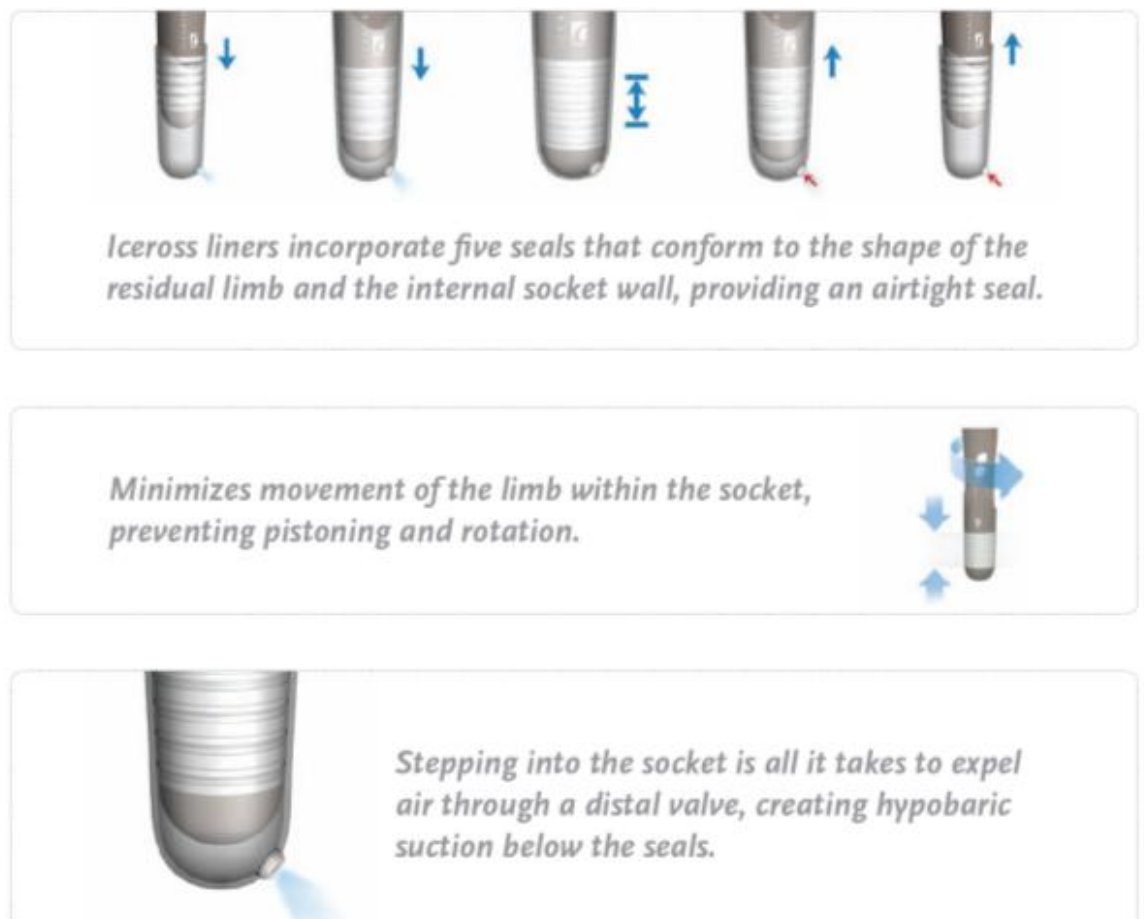


Figure 2.16. Seal-In could decrease the pistoning (reproduced from Ossur web site).

Hand dexterity and strength should be sufficient to roll the liner onto the residual limb. The residual limb length should be at least 11–13 cm (at least three seals should be housed fully inside the prosthetic socket) and the circumference of the stump at 4 cm from the distal end should be considered in choosing the correct liner size same with other Iceross liner. The clinicians can choose the liner size based on this measurement or the closest size below the measurement.

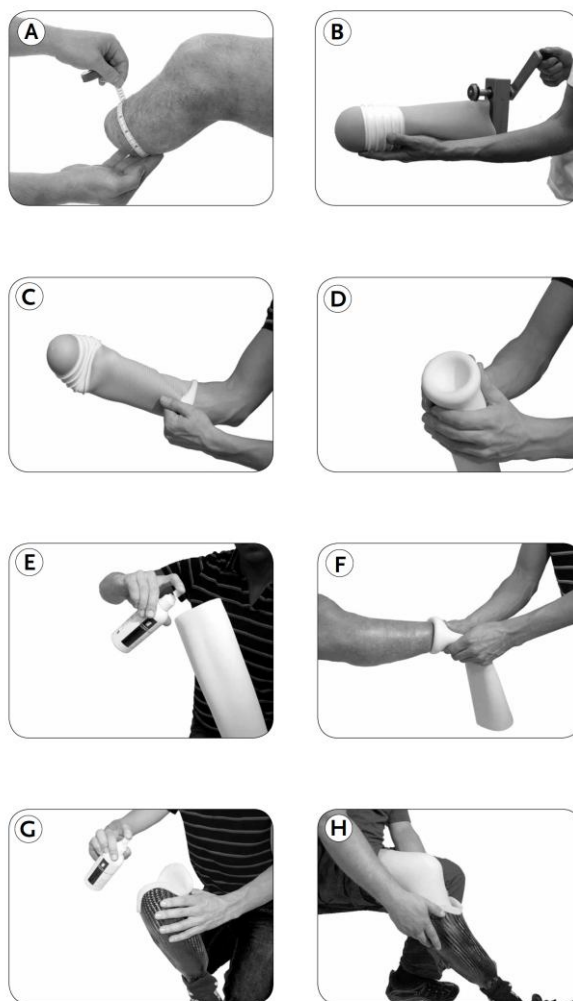


Figure 2.17. The procedures of donning the Seal-In liner in transtibial amputees (reproduced from Ossur web site).

### 2.4.3. Magnetic suspension system

The mechanical magnetic suspension system is a new system which holds the residual limb (stump) inside the prosthesis by fixing the distal part of the soft liner inside the socket (similar to pin/lock system) (Figure 2.18). In Seal-In liner, the attachment is between the liner and the socket walls. This system consists of three parts as follows: the source of magnetic power, switch to connects or disconnects the coupling device, and a metal plate that is attached to the silicone liner. The silicone liner holds the stump and provides comfort.

Like the other systems, the amputee has to wear the soft liner, puts the stump inside the socket, and stand to wear the prosthesis. The switch must be in On position mode. The residual limb will be fixed inside the socket by the magnetic field. When the amputee wants to remove the stump from the socket, he/she needs to position the switch to the “Off” mode.



Figure 2.18. Magnetic suspension system (reproduced from Eshraghi et al., 2013).

## **2.5. Measures of suspension efficiency**

### **2.5.1. Satisfaction survey**

The rehabilitation of people with amputation is a challenge as it requires teamwork and necessitates the person's willingness to accomplish a time-consuming and costly prosthetic training. Satisfaction with prosthesis is a multi-factorial issue. Some of these factors are dependent on the level of amputation, prosthetic components and alignment, prosthetist's skills, level of activity, and socket fit (Legro et al., 1998; Raichle et al., 2008; Subbarao & Bajoria, 1995; Ruth & Neil, 1999). The level of amputation is one of the significant factors that can notably affect prosthetic use and user satisfaction (Raichle et al., 2008). Subjective perceptions of amputees concerning the prosthesis can possibly be well defined through the related studies. Hence, it is possible to achieve consensus regarding the importance of the proper selection of prosthetic components for them.

Several questionnaires have been developed to evaluate the patients' satisfaction with prostheses and orthoses. These include the Attitude to Artificial Limb Questionnaire, Amputation Related Body Image Scale, Body Image Questionnaire, Orthotics and Prosthetics National Outcomes Tool, Orthotics and Prosthetics Users' Survey, PEQ, Perceived Social Stigma Scale, Socket Comfort Score, and the Trinity Amputation and Prosthesis Experience Scales (Gallagher & MacLachlan, 2000; Heinemann et al., 2003; Legro et al., 1998; Grise' et al., 1993; Gauthier-Gagnon & Grise', 1994; Berke et al., 2010; Van der Linde et al., 2007). To date, a majority of the researchers have evaluated the differences in function, performance, and satisfaction between the different prosthetic components or techniques using the PEQ (Van der Linde et al., 2007; Legro et al., 1998; Ali et al., 2012).

The PEQ, consists of 82 items grouped into nine subscales, measures the prosthetic-related quality of life. Moreover, there are a number of individual questions pertaining to satisfaction, pain, ambulation, prosthetic care, and self-efficacy, which are not contained in the subscales. The PEQ scales are not dependent on each other; therefore, it is reasonable to use only those scales that are of interest to a given study. The questions are scored using a visual analogue scale (100 mm line). The PEQ has been reported to have a good reliability (internal consistency and test-retest) and good-to-excellent construct validity in people with lower-limb amputation (Legro et al., 1998).

Based on the literature, the majority of studies on satisfaction with prostheses has focused on patients with transtibial amputation (Ali et al., 2012; Wirta et al., 1990). In a retrospective study, Dillingham et al. (2001) examined the satisfaction of lower limb traumatic amputees, including both transtibial and transfemoral amputees. More than half of the participants (57%) were not satisfied with their prostheses, however, the correlation between the suspension system and patients' satisfaction was not investigated (Dillingham et al., 2001). Coleman et al. (2004) and Selles et al. (2005) stated that no significant differences could be found in terms of satisfaction, pain, comfort, and functional outcome between TSB and PTB sockets. In a prospective study, Trieb et al. (1999) compared the satisfaction of transfemoral amputees with a contour adducted trochanteric controlled-alignment socket, with and without a silicone liner. They reported that the socket with the silicone liner could be used for longer hours and reduced skin trauma.

There is a minimal study on the relation between the transfemoral suspension system and satisfaction (Trieb et al., 1999; Koike et al., 1981; Haberman et al., 1995; Levy, 1980). The common suction socket system is said to cause discomfort and edema.



Koike et al. (1981) introduced a new transfemoral double socket, reporting that the participants were satisfied with the new system, particularly for donning and doffing, as compared with the common suction socket. The flexibility of the inner socket, which they believed to maintain a close contact with the residual limb at all times and reduced edema associated with the common suction socket, was reported to be the main reason for such finding.

The ease of donning and doffing has a positive effect on an amputee's experience with prosthesis (Haberman et al., 1995; Baars et al., 2008; Gholizadeh et al., 2012b,c) and is very important in relation to the night time toilet habits of the amputees. Donning and doffing are more difficult to perform when suction or vacuum systems are used rather than the pin/lock systems or PTB prosthesis, particularly for older amputees or for those with upper limb problem such as stroke patients (Gholizadeh et al., 2012a,b, c; Eshraghi et al., 2012 b; Ali et al., 2012a).

### **2.5.2. Prosthesis pressure profile**

The pressure distribution at the socket-stump interface can be influenced by the suspension system and the socket shape. Prosthetic interface pressure can determine the amputees' comfort (Sanders et al., 1998; Mak et al., 2001; Beil and Street, 2004; Jia et al., 2004; Dumbleton et al., 2009; Wolf et al., 2009; Laing et al., 2011). The load exerted on the residual limb have been evaluated either by simulation techniques (Silver-Thorn and Childress, 1996; Commean et al., 1997; Lin et al., 2004) or using various transducers (Zhang et al., 1998; Convery and Buis, 1999; Laing et al., 2011). Lower limb amputees feel pressure at the socket-stump interface during daily activities. The soft tissue and the skin of the residual limb are not adapted to load bearing; therefore, degenerative tissue ulcer might develop as a consequence of the repetitive or constant pressure exerted by the socket (Jia et al., 2004). Other skin problems may also

appear such as infection, follicular hyperkeratosis, verrucous hyperplasia, and allergic contact dermatitis (Dudek et al., 2005; Baars et al., 2008).

Pressure measurements was facilitated by the commercially-designed systems, such as the Tekscan (Figure 2.19, Figure 2.20) F-Socket pressure measurement system, Rincoe socket fitting system, and Novel Pliance System. The F-socket transducer (types 9810 and 9811) is a force-sensing resistor (Polliack et al., 2000). Every sensor array comprised of printed circuits divided into load sensing regions. The smallest sensing element of the sensor consists of two thin, flexible mats holding the pressure-sensitive ink applied in columns, and the rows between them. The juncture of the column and row forms the smallest element of area sensing known as the sensel. Each 9811E sensor has 96 sensels exhibited in an array of six columns and 16 rows. The advantages of F-Socket sensors include the satisfactory sensitivity, flexible and thin sheet, frequency response, and good resolution (Buis & Covery, 1997). The system has some disadvantages including signal drift, hysteresis, unidentified shear coupling effects, and sensitivity to temperature (Buis & Covery, 1997; Polliack et al., 2000).



Figure 2.19. Transducers for in-socket pressure mapping; Tekscan F-Socket system.

### **2.5.3. Gait Analysis**

The proper fit of the stump inside the prosthetic socket and the appropriate selection of prosthetic suspension have positive effects on the amputees' gait and can decrease the energy consumption during ambulation (Baars and Geertzen 2005; Ku et al., 2012; Czerniecki and Gitter, 1996; Bateni and Olney 2002). Symmetry between the limbs represents a healthy gait and is one of the primary objectives of rehabilitation for the lower limb amputees (Isakov et al., 2000). The gait pattern of a person with lower limb amputation is not as symmetrical as that of healthy individuals in terms of ground reaction force (GRF), time, distance of walking, and joint angles (Bateni and Olney 2002; Robinson et al., 1987). The GRF is defined as the percentage of body weight applied to the limb during the stance phase of gait, and the force that is generated for forward propulsion (Kishner, 2010). Bateni and Olney (2002) reported that there was a higher range of motion in the hip and knee on the prosthetic side than the sound limb in transtibial amputees during walking. Moreover, the step length was longer than the sound limb due to the shorter stance time on the prosthetic side (Bateni and Olney, 2002). One of the main goals in the rehabilitation of lower limb amputees is to improve the amputees' gait pattern to let it appear as similar to the gait of healthy individuals as possible. As such, many researchers have used three-dimensional motion analysis to investigate the gait parameters of transtibial amputees during the different activities using various prosthetics components (Bateni and Olney, 2002; Sanderson and Martin, 1997). Therefore, gait analysis system might be used to make decisions for the rehabilitation protocols.

In this present study, a combination of 7 MX-F20 infrared cameras and two Kistler force plates integrated into the Vicon Nexus make up the motion capture system. These cameras operated at the frame rate of 500 fps at full resolution, and each have a resolution of  $1600 \times 1280$  pixels, allowing them to track changes in the gait in real time. Basically, the Kistler force plate is a two metal plates sandwiching four strain gages that are positioned at the four corners of the plates. The two force plates used were embedded into the floor, at about midpoint of the capture volume, allowing them to capture one complete gait cycle.

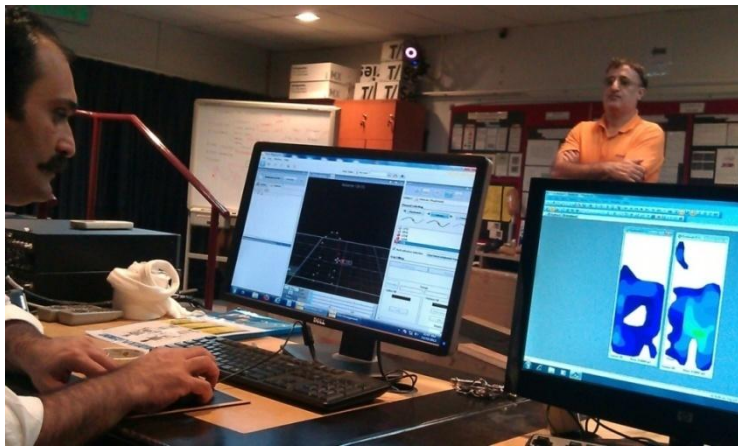


Figure 2.20. Subject calibration.

Before the subject calibration, a system calibration for the MX-F20 cameras was conducted to allow the Vicon Nexus to calculate the relative location and orientation of all cameras. This step allows the software to reconstruct a 3D image of the subject's movement in space based on the calibration done, when done accurately. The system is calibrated before a gait trial begins for each subject to employ a good practice. Static and dynamic calibrations were performed for a complete calibration of the system. Static calibration calculates the origin and determines the orientation of the capture volume, whereas the dynamic calibration calculates the relative positions and orientations of the cameras.

## CHAPTER 3

### METHODOLOGY

#### 3.1. Flowchart of the study

Figure 3.1 shows the flowchart of the methodology in the study. Details on the methodology are given in Chapter Three.

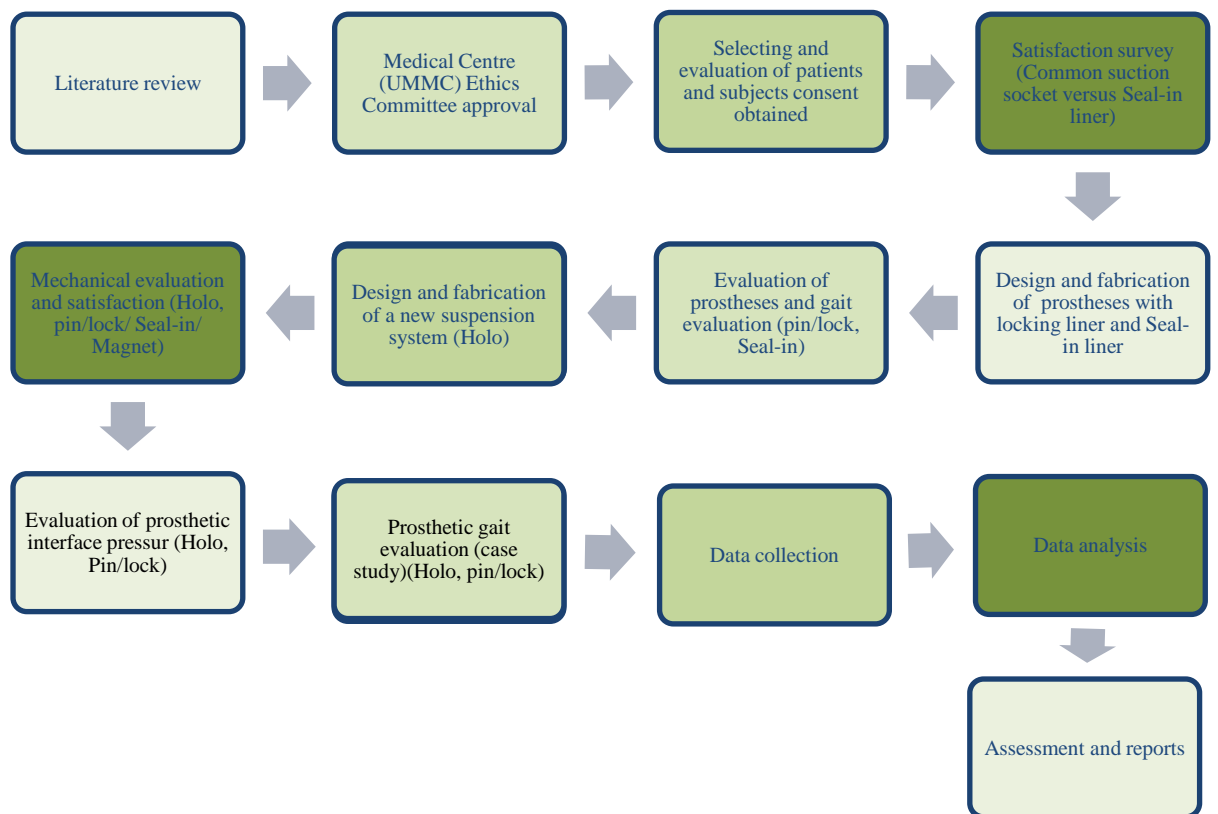


Figure 3.1.Flowchart of the methodology of the study.

### **3.2. Satisfaction survey (Common suction socket versus Seal-In liner)**

#### **3.2.1. Participants**

A total of 112 persons with transfemoral amputation from Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran, and the Prosthetic Laboratory, Department of Biomedical Engineering, University of Malaya, Malaysia, who met the inclusion criteria, were invited to participate in this present study. The inclusion criteria required that individuals with transfemoral amputation had used both suspension systems for at least a period of two years prior to the commencement of this project. They were also required to be using the Seal-In Liner (Iceross Dermo Seal-In Liner) (Figure 3.2) at the time of entry to the study. The prostheses had already been fabricated, and subjects were asked to recall their experiences; hence, the study was a retrospective one. All participants first experienced the use of the common suction socket; the Seal-In liner system was introduced years after the common suction socket, hence, the participants were elected to transition to use the said liner system.



Figure 3.2. The transfemoral Seal-In liner (with a hypobaric sealing membrane around the liner) used in this present study.

JMERC and the University of Malaya ethics committees granted ethical approval for the study. Following the acquisition of a written consent, the subjects were asked to complete a questionnaire based on the PEQ, which measured their level of satisfaction with both suspension systems (Van de Weg and Van Der Windt, 2005). All of the participants filled in one questionnaire for each suspension system. The questionnaires were either mailed to the participants or were distributed to them by visiting them at the center.

### **3.2.2. Questionnaire**

To study the effect of the different suspension systems on the satisfaction of prosthesis users, a questionnaire was prepared based on the PEQ and a study by Van deWeg and Van Der Windt (Van de Weg and Van Der Windt, 2005).

The first section incorporated demographic questions, such as age, height, weight, amputation side, time since amputation, hours of daily prosthetic use, and activity level, which was completed by a registered prosthetist. Activity levels (K level) were based on the Medicare Functional Classification Level (American Academy of Orthotists and Prosthetists (2010). This classification system determines the following activity levels: no ability or potential to ambulate (K0), limited and unlimited household ambulator (K1), limited community ambulator (K2), community ambulator (K3), and high-level user (K4). This first section was also sent to the participants to update the data at the time of entry to the study.

The second section of the questionnaire consisted of questions (Table 3.1) related to satisfaction, including the ability to don and doff the prosthesis, perception on the prosthetic fit, ability to sit with the prosthesis, ability to walk with the prosthesis, ability to walk on different surfaces, and the perception on the prosthetic's appearance. In the

third section, to examine the possible problems with the prosthetic suspension mechanism, participants were asked whether they suffered from any of the following problems while using each suspension system: sweating, skin irritation, wounds, swelling (edema) of the residual limb, pistoning within the socket, unpleasant smell of the prosthesis or residual limb, unwanted sound, pain in the residual limb, and durability of the suspension systems.

Table 3.1. The questionnaire items related to the satisfaction and problems with the suspension systems.

| Questions regarding Satisfaction | Questions regarding Problem |
|----------------------------------|-----------------------------|
| Fitting                          | Sweat                       |
| Donning and Doffing              | Wound                       |
| Sitting                          | Pain                        |
| Walking                          | Irritation                  |
| Walking (Uneven surface)         | Pistoning                   |
| Stair Negotiation                | Swelling (edema)            |
| Cosmetic appearance              | Smell                       |
| Overall satisfaction             | Sound                       |
|                                  | Durability                  |
|                                  | Overall Problems            |

The PEQ items were scored on a range between 0 and 100, where 0 indicated dissatisfaction or being extremely bothered, whereas 100 indicated complete satisfaction



or being not bothered at all (Legro et al.,1998). Moreover, average scores for the questions were calculated to determine the overall satisfaction and problems (Legro et al., 1998).

### **3.2.3. Analysis procedures**

Statistical analyses were performed with SPSS 17.0, and p-value of 0.05 was chosen to reflect the statistical significance. Eighteen two-tailed paired samples t-tests (equal to the number of questions) with Bonferroni adjustment were employed to compare the effects of each suspension system on the satisfaction with the prosthesis.

## **3.3. Gait analysis (Pin/lock and Seal-In liner)**

### **3.3.1. Subjects**

Ten unilateral transtibial amputees were found eligible to participate in this study as samples of convenience. Ethical approval was obtained from the University of Malaya Medical Centre (UMMC) Ethics Committee. All the subjects were required to sign a written consent form.

The inclusion criteria for the study consisted of unilateral transtibial amputation, walking without the walking aids, steady limb volume during the previous year, pain- and ulcer-free stump, and stump length of more than 11 cm. The latter was considered optimal for the use of the Seal-In transtibial liner, as stated by the manufacturer (Össur, 2008).

### 3.3.2. Procedures

The participants were using different suspension systems (such as PTB or TSB) prior to the study, hence, a single-registered prosthetist designed and aligned two transtibial prostheses for each subject to prevent any bias in the results (Figure 3.3, 3.4). Only the suspension systems were different, whereas all other components including the feet were similar for both prostheses. One prosthesis used the Iceross Dermo Liner with shuttle lock (pin/lock system) and the other used the Iceross Seal-in liner with valve (suction system) (Gholizadeh et al., 2012b,c). The subjects used Flex-Foot and the two suspension systems (Seal-In and Dermo liner) for the first time in this study. The present study was not blinded as our subjects easily could distinguish between the suspension systems.



Figure 3.3. Transtibial amputees' evaluation, casting, and modification process.



Figure 3.4. The process of making the transtibial socket with transparent plastic (check socket) and epoxy resin (final socket).

Prior to the experiment, the subjects participated in a gait training for the new prostheses, which took place in the Brace and Limb laboratory (Department of Biomedical Engineering, University of Malaya, Malaysia).

The prosthetist ensured similar lower limb height and toe-out angle and that there was no gait deviation. Bench alignment (Figure 3.5) and dynamic alignment during standing and walking were performed. A four-week acclimation period was allocated for each prosthetic leg and the subjects used identical shoes during training and experiments.

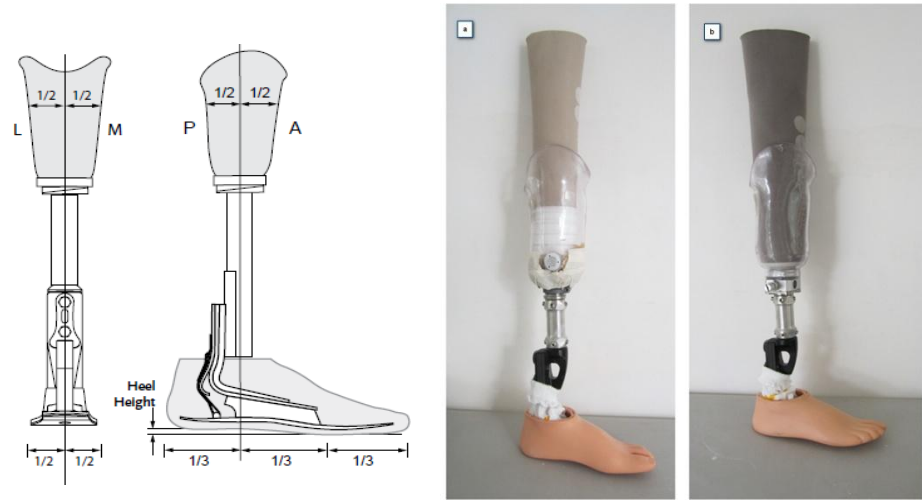


Figure 3.5. Adjusting the prostheses alignment.

Kinematic and kinetic gait evaluations were completed using the Vicon 612 system (7 MXF20 motion capture cameras; Plug-in-Gait, Oxford Metrics; Oxford, UK) (Figure 3.6). The data collection frequency was set at 50 Hz for the synchronized cameras and the two force plates (Kistler). Sixteen reflective markers were attached to the subjects' prosthetic and sound lower limbs (according to the Helen Hayes marker set), whereas the knee and tibia markers for the prosthetic limb were affixed to the lateral proximal and lateral distal socket walls, respectively. To recognize the subject walking within the capture volume using the MX-F20 infrared cameras, markers need to be placed first on the subject. These 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 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 3.7 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 3.2 gives the definition of the marker labels shown in Figure 3.7.

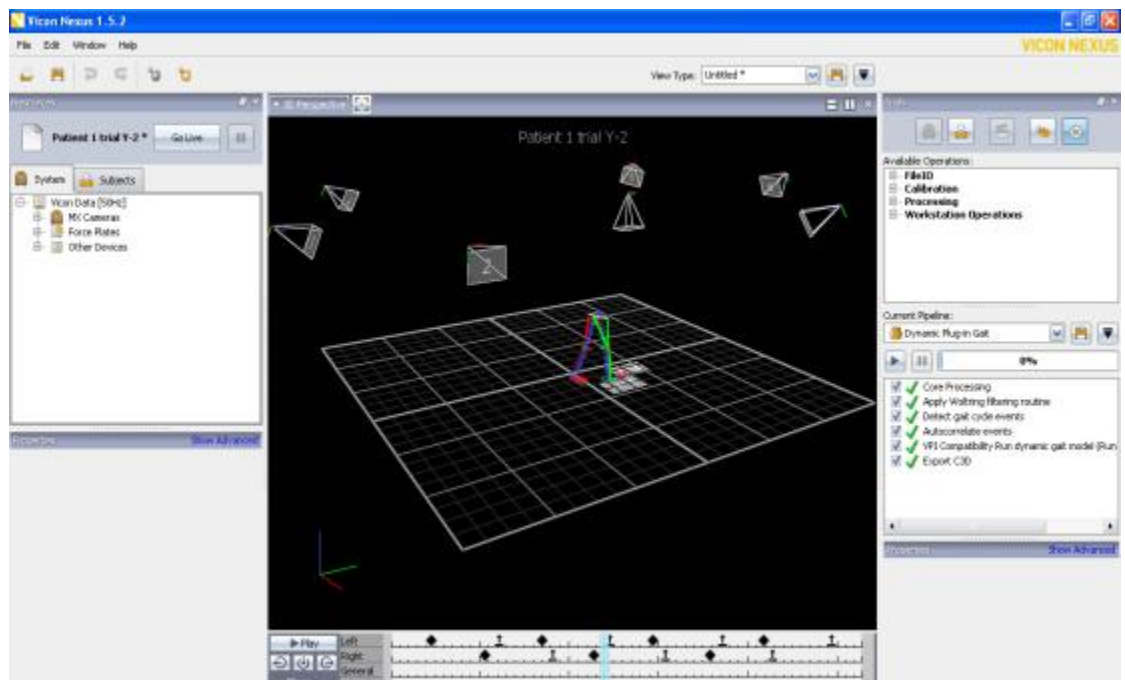


Figure 3.6. A bird-eye's view of the cameras and the force plates setup. The seven cameras were placed at the four corners of the room and two in line with the force plates. The two force plates were embedded in the middle of the capture volume.

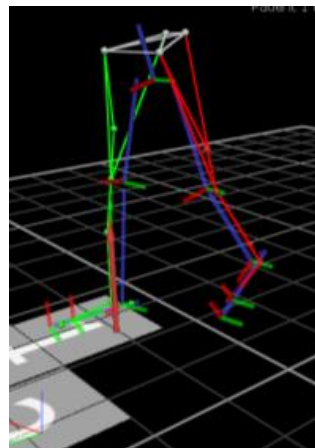
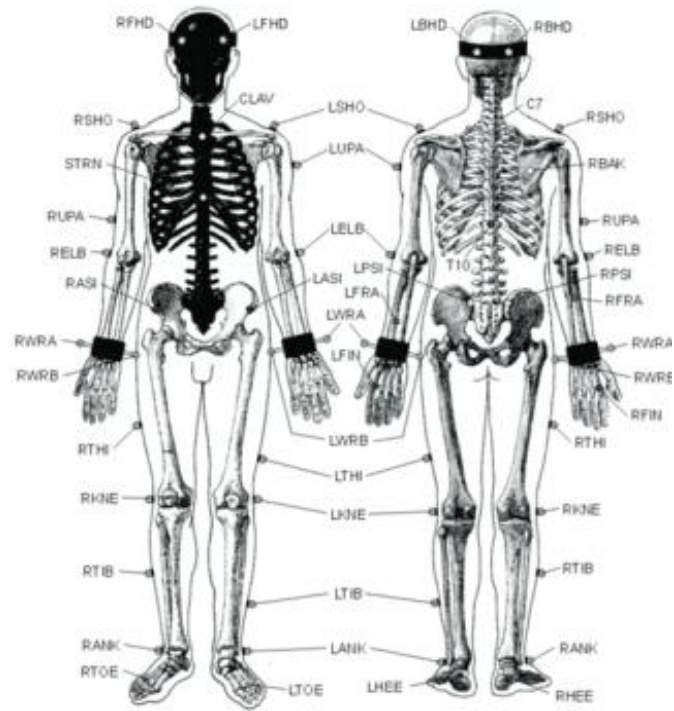


Figure 3.7. Full body marker placements (top) and sixteen markers of the lower body (bottom) are used for this study ( Helen Hayes marker set).

Following this, each subject completed five gait trials at a self-selected pace for each suspension system. A trial was considered to be appropriate, provided that both feet landed properly on the force plates (whole foot was on the force plate). To determine proper landing on the force plate, a video recorder was used, and an assistant

stood one meter away from the force plate to check the foot position. All the subjects were asked to walk at their most comfortable speed in the motion laboratory on 10-meter walkway (Astrom and Stenstrom, 2004).

Table 3.2. 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                                 |

The right thigh and tibia markers were placed lower than the left marker to make an easy distinction of the left from the right part of the body when viewed through the Vicon software.

The 10-meter walkway is a common practice in research studies (Astrom and Stenstrom, 2004). Prior to the test, the participants were asked to practice walking in the experiment setting to make them accustomed to the environment. The proper landing of the foot on the force plate proved to be challenging (due to the masking of the force plates' location); therefore, the participants were required to repeat the trials at times.

Nevertheless, the participants were not informed of which trial is proper or why they were asked to repeat a trial. To minimize the effect of fatigue, the participants were allowed to take rest whenever necessary. During the pilot study, when the patients became tired, the speed of gait was not consistent between the trials. The pin/lock system was tested first for all the amputees, followed by the suction socket, to ensure consistency.

### 3.3.3. Data analysis

The walking speed was inconsistent, hence, the data for each time frame were normalized for the whole stride time (Farahmand et al., 2006). The vertical and fore-Aft GRF were also normalized to the body mass.

As symmetry is indicative of a normal gait, the symmetry index (SI) was used to compare the non-amputated and amputated limbs (Herzog et al., 1989; Robinson et al., 1987) with the pin/lock and the suction socket (Baker and Hewison 1990; Chow et al., 2006). To calculate SI, a modified equation from the work of Herzog et al. (1989) was used:

$$SI = \frac{V_{\text{non-amputated leg}} - V_{\text{amputated leg}}}{\frac{1}{2}(V_{\text{non-amputated leg}} + V_{\text{amputated leg}})} * 100\%$$

In this formula,  $V_{\text{amputated leg}}$  represents the data for the amputated leg during gait (for different gait parameters, such as step length and swing time), and  $V_{\text{non-amputated leg}}$  is the data for the sound limb. The value of SI indicates how similar the variables (amputated leg and non-amputated leg) are. A value of 0 shows that the two variables are completely similar, or the symmetry is perfect. Based on the works of Astrom and Stenstrom (2004), a value of until 10% can be considered as a good symmetry. The following variables were calculated (Table 2): step length, walking



speed, stance and swing time (percentage), ground reaction force (GRF), fore-aft GRF, hip, knee and ankle range of motion during stance, and swing (Winter, 1988).

Statistical data were analyzed using SPSS 17.0, and p-values of 0.05 or less reflected the statistical significance. Paired-samples t-test was employed to compare the effect of two systems on gait variables. The statistical tests were applied to all gait variables independently for both suspension systems, as well as the amputees' sound limb. Moreover, the average of the obtained data for each gait parameter through five successful trials was calculated for both suspension systems. Lastly, the overall average of gait parameters was calculated for all the participants to compare the suspension systems.

#### **3.4. Designing a new suspension system (Holo)**

The main factors to consider when designing a prosthetic suspension (soft liner and lock system) are safety, comfort, function, easy donning/doffing, durability, cosmetic appearance, and cost (Figure 3.8). With these factors in mind, the new system was designed using silicone liners that are widely available and commonly used.



Figure 3.8. The ideal suspension system.

Hook and loop (Velcro) was used as the main part of this suspension system (as a lock system). Two small openings were created on the socket wall (medial and lateral), which are in the proximal and distal parts of the socket (Figure 3.9). The proximal opening was created below the knee center in the transtibial socket to avoid any limitation in knee flexion. These two openings must be parallel and in the socket direction. The hook fastener (Polyester Hook & Loop Velcro V-STRONG, 100%) was used on the socket wall (rolling belt), whereas the loop fastener was attached to the soft liner (silicone liner) (Figure 3.9). Furthermore, a small piece of hook (3 cm<sup>2</sup>) was attached at the distal end of the socket.

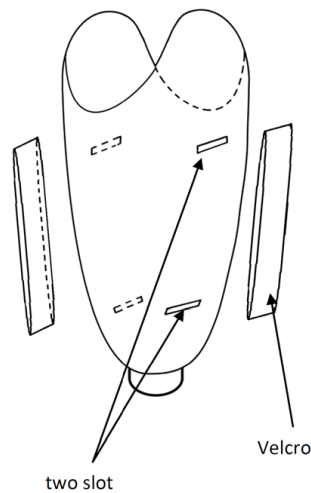


Figure 3.9. The position of the Velcro on the socket walls.

The new suspension system was tested mechanically (Figure 3.10) before it was tested on the subjects. Mechanical testing under tensile loading was performed using the universal testing machine INSTRON 4466 to determine how much tensile force each suspension system (lock mechanism) could tolerate before it fails (Figure 3.10). Furthermore, the other suspension systems used were tested for comparison with the new design.

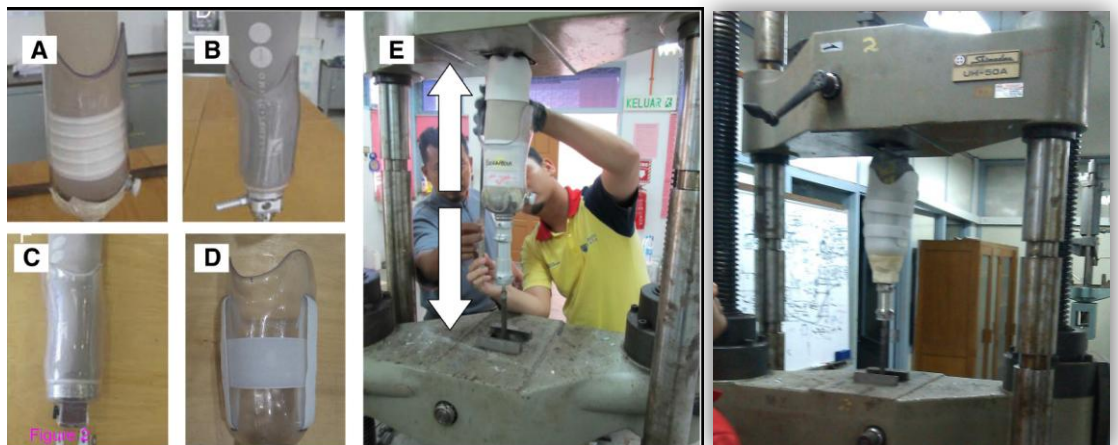


Figure 3.10. Mechanical testing; the Seal-In (A); Dermo liner (B); magnet (C); new system (D); and the tensile testing machine (E).

### **3.4.1. Participants and experiment**

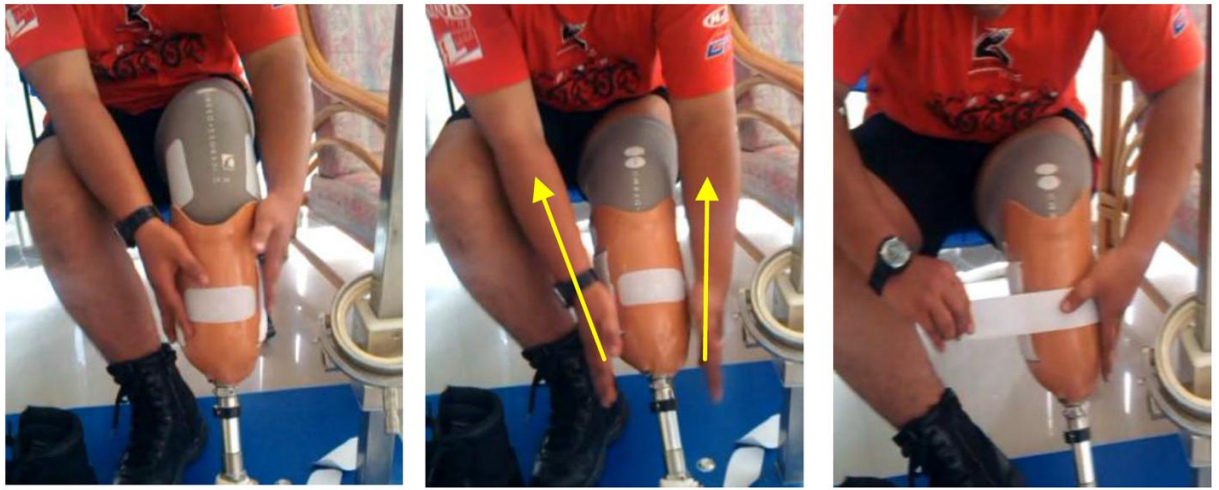
The study was approved by the Medical Ethics Committee, University of Malaya Medical Centre. Nine transtibial amputees participated in the study. Following the acquisition of written informed consent, each participant was provided with four transtibial prostheses (pin/lock, Seal-In, magnetic (MPSS), and the Holo suspension system) (Figure 3.11). To ensure a consistent prosthetic quality, fabrication and aligning were done by a single prosthetist. All the subjects were fitted with a transparent check socket to ensure that the TSB of the socket. They were asked to walk with their new prostheses in the prosthetic laboratory (Department of Biomedical Engineering, University of Malaya, Malaysia) to become familiar with and adapt to the new sockets (Figure 3.12). All the subjects were given a trial period of at least four weeks (for each suspension systems) to become accustomed to the new prostheses.



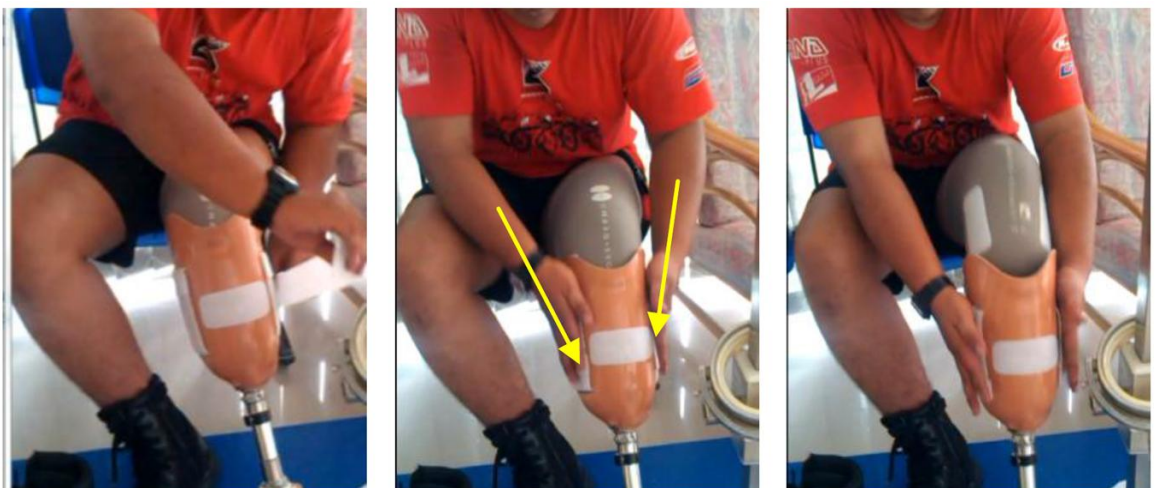
Figure 3.11. The process of making the new suspension system and donning.

### 3.4.2. Data Analysis

Qualitative analyses were performed on the respondents' demographic data. SPSS 18.0 (IBM Corporation; Armonk, New York) for the data analyses, and a p-value set at 0.05 was used. Furthermore, the cost of the new system was compared with the common suspension system (pin/lock systems).



Donning



Doffing

Figure 3.12. The donning and doffing process of the new system.

### **3.5. Pressure mapping**

#### **3.5.1. Subjects**

As a sample of convenience, a total of 10 subjects were selected to participate in the study upon signing a written consent. The University of Malaya Ethics Committee issued the ethical approval. The inclusion criteria were as follows: the ability to ambulate without assistance, no ulcer on the residual limb, no volume fluctuation at the stump, and the use of prosthesis within the last six months.

#### **3.5.2. Prosthesis**

A new prosthesis with pin lock suspension system was fabricated for each participant. One of the researchers (a registered prosthetist) performed all the processes from the casting to aligning. Flex-Foot (Talux), pylon, clamp adaptor, silicone liner, and shuttle lock were used to fabricate the prostheses. A transparent check socket was manufactured to ensure the TSB concept (Staats and Lundt, 1987). Afterwards, the subjects were ambulated with the new prostheses in the laboratory (Department of Biomedical Engineering, University of Malaya, Malaysia) to become accustomed to the new foot (Flex-Foot Talux<sup>®</sup> (Össur)) and socket. A four-week trial period was given to all the participants to become fully accustomed to the new prosthesis. The Velcro was used as a new suspension system, instead of the pin/lock mechanism (Figure 3.11). The pin was removed from the soft liner, and the loop fastener was affixed to the silicone liner (Figure 3.11). The Velcro strap (hook) was attached to the socket wall (rolling part).

The hook is often referred to as the male portion, whereas the loop is referred to as the female portion. Two small openings were created on the socket wall (medial and lateral) in the proximal and distal regions of the socket. The hook fastener (Polyester

Hook & Loop Velcro V-STRONG, 100%) was used on the socket wall and the loop fastener on the soft liner (silicone liner) (Figure 3.11). This type of Velcro was chosen because it is easily accessible.

The same socket and alignment of the pin/lock system was used for the prosthesis with the new suspension. The participants were asked to use this prosthesis for four weeks, similar to the pin/lock system, to familiarize them with the new suspension system. Following this trial period, the participants were required to walk on level ground with self-selected speed for the interface pressure evaluation.

### **3.5.3. Experimental process**

F-Socket transducers 9811E (Tekscan Inc., South Boston, USA) were used to measure the interface pressure. Generally, the pressure measurement sensors for prosthesis interface should be thin. The F-socket sensors have a thickness of 0.18 mm, with high resolution, and good flexibility (Figure 3.13). Before the experiments, the sensors were calibrated to reduce the possible differences between each cell load. Equilibration and calibration were performed according to the manufacturer's instructions (Figure 3.14). For the equilibration, the transducers were inserted separately into a bladder coupled with an air compressor, and a persistent pressure was applied (100 kPa). The calibration was done according to the body mass. Pre and post trials were logged, while each sensor was inside the bladder, to ensure accurate test results. The sampling rate of pressure sensors was 50 Hz.

The sensor mats were cut to match the contour of the residual limb and were situated on the medial (Med), lateral (Lat), anterior (Ant), and posterior (Pos) surfaces of the stump. Bonding agent (3M Spray Mount Adhesive) was used to fix the sensors to the residuum prior to donning the silicone liners to prevent displacement (Figure 3.15).



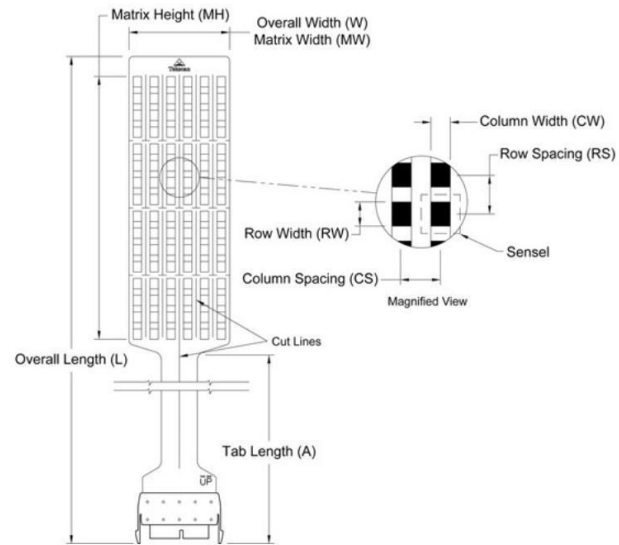


Figure 3.13. The sensor used in the study (F-Socket transducers 9811E).

Force plate data were concurrently recorded to identify the gait cycle by two Kistler force plates (sampling rate of 50 Hz). The participants walked on a 10-meter walk way at a self-selected speed. Prior data collection, they practiced the experiment protocol. The participants accomplished five trials, and the mean value of the middle steps was used for the analysis. The differences in the peak pressure were defined within the sensor areas. Each transducer was additionally divided into proximal, middle, and distal sub regions.

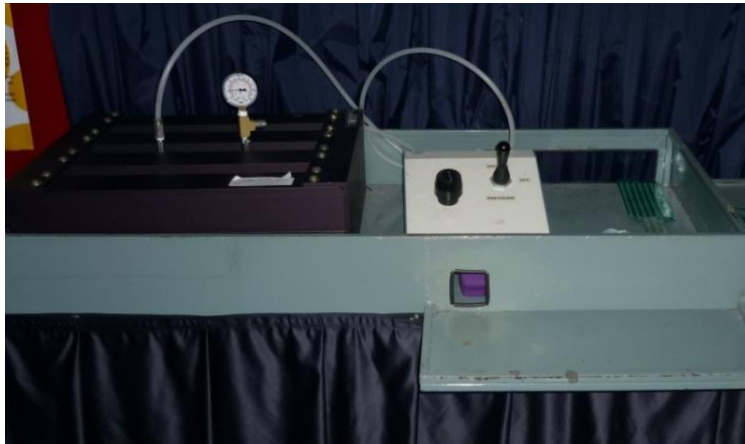


Figure 3.14. The pressure bladder used for the F-Socket sensor equilibration and calibration.

#### **3.5.4. Subjective feedback**

Satisfaction with each suspension system was evaluated using a questionnaire and subjective feedback was also collected for each system (After 4 weeks of acclimation). Some parts of the prosthesis evaluation questionnaire (PEQ) to distinguish the perceptions of subjects towards the two suspension systems were used (Legro et al., 1998). The questionnaire inquired about the ability to put on or take off the prosthesis, fit of prosthesis, ambulatory ability with the prosthesis on even and uneven grounds, ability to negotiate the stairs, satisfaction while sitting with prosthesis, complaints of the respondents about rotation and pistoning inside the socket, sweating, swelling, bad smell, irritating sound, pain and one question regarding the overall satisfaction with the systems. The rate of satisfaction was from 0 to 100 (“100” equal to “highly satisfactory”). Complaint scores of 0 indicated “highly bothering” and 100 meant “not bothering whatsoever”.

### 3.5.5. Analysis of data

For the variables that were normally distributed, the paired sample t-test was used to compare the pressure values. The confidence interval of 95% was set for this experiment

( $P < 0.05$ ), and SPSS software (SPSS, Chicago, IL) version 17.0 was used for the statistical analyses.



Figure 3.15. The F-Socket transducers 9811E (Tekscan Inc., South Boston, USA) were used to measure the interface pressure.

### **3.6. Case study (pressure mapping/gait evaluation)**

The subject was a young transtibial amputee (25-yr-old female) whose lower limb was amputated two years ago. She consented to participate in the study.

The subject had excessive, unstable soft tissue at the end of the bulbous residual limb (Figure 3.16). She was referred to the Brace and Limb Laboratory, University of Malaya because of the pain at the end of the tibia and patellofemoral arthritis. She had used the transtibial prosthesis (PTB socket) with silicone liner (6 mm thickness), pin/lock, and energy storing foot for two years (Figure 3.16) and experienced a severe crackling sensation when moving the knee, which was loud enough to be heard by others. Furthermore, it was difficult for her to align the distal pin due to the residual limb shape.

#### **3.6.1. Socket fabrication and pressure mapping**

The interface pressure between the old socket and the stump during walking (level ground, stair and ramp ascent and descent) was evaluated. A new prosthesis was designed to distribute the load evenly on the stump and facilitate prosthetic donning. Velcro was used to suspend the prosthesis. Two small openings were created on the medial and lateral socket walls (Figure 3.17).



Figure 3.16. Stump in different views (knee is in full extension).

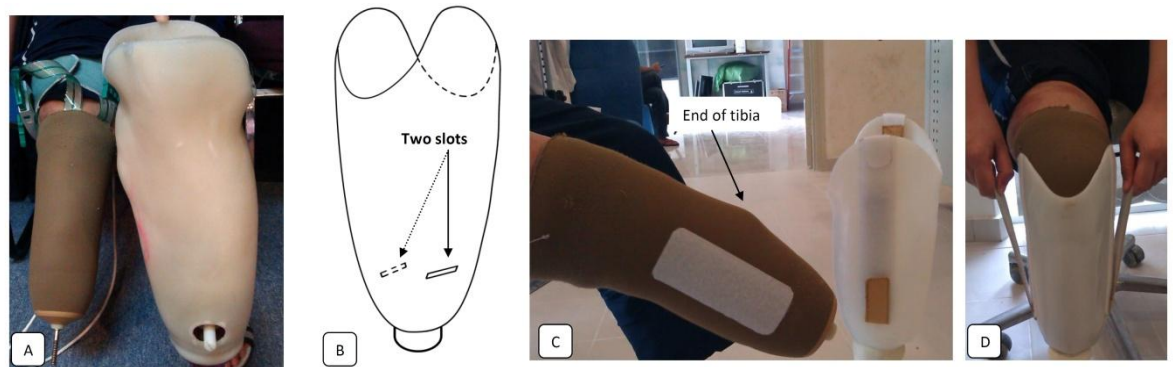


Figure 3.17. Prosthetic used in the present study: old PTB prosthesis with pin/lock system (A); new TSB prosthesis with pin/lock system (B); opening clutch mechanism and push button (C); attaching Velcro (loop) to the soft liner (D); Velcro (hook) on the socket wall (E); and new TSB prosthesis with Velcro suspension system (F).

The subject was fitted in a transparent check sockets (12 mm, Northplex®, North Sea Plastics Ltd) to ensure TSB. Following the evaluation of fit and gait, she was asked to use the new prostheses for one month to adapt to the new system. She had adapted to the large differences in the pressure magnitudes in the former prosthesis; hence, it was difficult for her to use the new socket with the even distribution of the load on the residual limb at first. She was asked to gradually increase the time of prosthesis wearing and weight-bearing on the prosthetic socket. The subject achieved a total of 12 hours of prosthetic use after about three weeks when she became comfortable with the socket during walking.

The interface pressure between the stump and the socket was mapped and compared during walking on the level ground and on ascending and descending the stair and ramp. The subject was asked to walk in the motion analysis laboratory at a self-selected speed on the level ground, stairs, and slop prior to the experiment to accustom her to the environment. Four F-Socket sensors (9811, Tekscan Inc., USA) were placed



on the residual limb over the medial, lateral, anterior, and posterior surfaces to measure the pressure. The pressure profile was mapped using the Tekscan software version 6.51.

Prior to the experiment, the sensor arrays were equilibrated and calibrated using the Tekscan pressure bladder to eliminate the variation among the load cells. The calibration was performed according to the subject's body mass. Three separate experiments were conducted for the level walking and stair and ramp negotiations (Figure 3.18). The subject was required to ascend and descend a four-meter custom-made ramp. She was also asked to ascend and descend a custom-made staircase of 82 cm width, with four steps of 14 cm height. The steps were 32 cm apart. She completed five trials for each condition.

The participant's feedback on each system was also determined. The questions (some parts of the PEQ questionnaire) were related to the ability of walking with prosthesis, prosthetic fit, ability to don and doff the prosthesis, distal skin traction, residual limb pain, and overall satisfaction.



Figure 3.18. The subject descending a custom-made staircase.

### **3.6.2. Gait evaluation**

Gait evaluation was accomplished using the Vicon 612 (6 MXF20 cameras; Plug-in-Gait, Oxford Metrics; Oxford, UK). The frequency of data collection was 200 Hz for the synchronized force plates (Kistler) and cameras. According to the Helen Hayes marker set, sixteen reflective markers were fixed to the sound and prosthetic lower limbs. The tibia and knee markers for the prosthetic limb were attached to the lateral distal and lateral proximal socket walls, respectively.

Five gait trials were recorded at self-selected speed for each prosthesis on a 10-meter walkway. In an appropriate trial, the whole foot was required to land inside the borders of force plates. A video recorder determined the proper foot position on the force plate (Sanders et al., 2000). Furthermore, the subject practiced walking in the laboratory before the experiment to accustom her to the environment. The average values of gait parameters were calculated through the five trials. The amputee's subjective feedback was obtained to evaluate the level of satisfaction with each prosthesis type.



## CHAPTER 4

### RESULT

#### 4.1. Satisfaction survey (Common suction socket versus Seal-In liner)

##### 4.1.1. Respondents' Profile

Ninety subjects out of the 112 who were invited returned the completed questionnaires (80.35% response rate). The mean age of the respondents was 47.7 years (SD 7.0), and all of them were males. All of the selected participants had lost their limbs because of trauma. The average weight and height of the respondents were 80.6 kg (SD 12.2) and 173.6 cm (SD 7.5), respectively. Fifty four (60%) of the 90 subjects with unilateral transfemoral amputation had their left legs amputated. The majority of the respondents (63.3%) had an activity level of K3. Table 4.1 provides the detailed data about the study sample.

Table 4.1: The mean characteristics of the respondents as obtained from the returned questionnaires.

| Mean (SD)                    |       |            |
|------------------------------|-------|------------|
| Age (years)                  |       |            |
| 47.77 (7.0)                  |       |            |
| Height (cm)                  |       |            |
| 173.67 ( 7.5)                |       |            |
| Years since amputation       |       |            |
| 23.80 (4.2)                  |       |            |
| Weight (kg)                  |       |            |
| 80.63 (12.2)                 |       |            |
| Activity level               | K2    | 33 (36.7%) |
|                              | K3    | 57 (63.3%) |
| Amputation side              | Right | 36 (40%)   |
|                              | Left  | 54 (60%)   |
| Daily prosthetic use (hours) |       |            |
| 11.80 (3.34)                 |       |            |

#### **4.1.2. Use and Satisfaction**

The level of subjects' satisfaction between the Seal-In liner and the CSS suspension system differed significantly in terms of fitting, sitting, donning, and doffing ( $P<0.05$ ). However, satisfaction with the prosthesis showed no significant differences in terms of walking (even and uneven surfaces), cosmetic appearance of the prosthetic devices, and stair negotiation (Table 4.2). The overall mean satisfaction score for the Seal-In liner was 76.12 (SD 8.9), whereas 69.04 (SD 8.3) for the CSS suspension. Table 4.2 presents the mean scores related to the satisfaction and problems with the Seal-In liner and CSS system.

#### **4.1.3. Problems and Complaints**

The respondents indicated more problems with the CSS system compared to the Seal-In liner, and there were significant differences between the two systems ( $P<0.05$ ). The subjects experienced more difficulties with the CSS in terms of sweating, wounds, pain, irritation, pistoning, swelling, smell, and sound. Nevertheless, the durability of the suspension system was significantly higher with the CSS ( $P=0.000$ ) (Table 4.2). The overall mean scores for the problems experienced with the Seal-In and CSS were 89.68 (SD 3.2) and 78.37 (SD 7.5), respectively.

Table 4. 2. Satisfaction and problems identified by the respondents in Seal-In and common suction socket (CSS).

|                           | Mean (SD)     |              | Sig. (two-tailed) |
|---------------------------|---------------|--------------|-------------------|
|                           | Seal-In liner | CSS          |                   |
| Fitting*                  | 92.33 (9.1)   | 85.89 (7.7)  | 0.000             |
| Donning & Doffing*        | 83.33 (9.4)   | 54.83 (17.5) | 0.000             |
| Sitting*                  | 81.67 (12.0)  | 75.28 (11.1) | 0.000             |
| Walking*                  | 74.11 (14.1)  | 72.08 (12.7) | <b>0.068</b>      |
| Walking (Uneven surface)* | 69.11 (14.2)  | 67.04 (12.5) | <b>0.064</b>      |
| Stair negotiation*        | 61.17 (11.2)  | 59.17(10.8)  | <b>0.070</b>      |
| Cosmetic appearance*      | 71.11(12.7)   | 68.92(10.2)  | <b>0.053</b>      |
| Overall Satisfaction*     | 76.12 (8.9)   | 69.04 (8.3)  | 0.000             |
| Sweat†                    | 78.40 (14.6)  | 66.60 (17.7) | 0.000             |
| Wounds†                   | 100 (0)       | 81.50(13.5)  | 0.000             |
| Pain†                     | 93.67 (7.6)   | 81.83 (12)   | 0.000             |
| Irritation†               | 100 (0)       | 96.50 (5.1)  | 0.000             |
| Pistoning†                | 97.67 (3.1)   | 88.50 (7.7)  | 0.000             |
| Swelling (edema)†         | 98.89 (3.4)   | 86 (12.9)    | 0.000             |
| Smell†                    | 88.17 (12.6)  | 54.40 (21.3) | 0.000             |
| Sound†                    | 97.67 (4.2)   | 59.33 (20.2) | 0.000             |
| Durability†               | 52.67 (13.2)  | 90.67 (8.8)  | 0.000             |
| Overall Problems†         | 89.68 (3.2)   | 78.38 (7.5)  | 0.000             |

Note: Non-significant differences are in bold.

\* 0 indicates dissatisfaction; 100 represents complete satisfaction

† 0 indicates extremely bothered; 100 represents not being bothered at all

## 4.2. Gait analysis (Pin/lock and Seal-In liner)

### 4.2.1. Gait Results

The mean age, height, and weight of the participants were 45.8 years (SD, 14.4), 170 cm (SD, 6), and 73.8 kg (SD, 14.2), respectively. The mean stump length was 14.5 cm (SD, 1.3), and the causes for amputation were trauma and diabetes (Table 4.3).

The study results showed that the step length and swing time on the prosthetic side were longer than that of the sound limb with both suspension systems, and that the prosthetic and sound limbs behaved significantly different ( $p < 0.03$ ) (Table 4.4). Moreover, stance time was shorter for the prosthetic limb than the sound limb.

Table 4.3. The characteristics of each of the individual participants.

| Subject no. | Age | Height (cm) | Mass (Kg) | Cause of amputation | Amputated side | Stump length (cm) <sup>1</sup> | Mobility grade <sup>2</sup> |
|-------------|-----|-------------|-----------|---------------------|----------------|--------------------------------|-----------------------------|
| 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                          |

<sup>1</sup>Stump length: inferior edge of patella to distal end of the stump

<sup>2</sup>Based on the American Academy of Orthotists & Prosthetists

Table 4.4. The average and standard deviation (in bracket) of gait parameters in ten transtibial amputees during their level walking at a self-selected speed.

| Parameters                                  | Suction<br>(Seal-In) |                | Symmetry<br>(%) | Pin/Lock<br>(Dermo) |             | Symmetry<br>(%) |
|---|----------------------|----------------|-----------------|---------------------|-------------|-----------------|
|   | Prosthetic           | Sound          |                 | Prosthetic          | Sound       |                 |
|   | Limb                 | Limb           |                 | Limb                | Limb        |                 |
| Step length (m)                             | 0.61 (0.06)          | 0.57<br>(0.05) | -6.8            | 0.62 (0.05)         | 0.54 (0.04) | -13.8           |
| Stride length (m)                           | 1.20 (0.09)          |                | 0               | 1.10 (0.08)         |             | 0               |
| Walking speed (m/s)                         | 0.94 (0.05)          |                | 0               | 0.93 (0.06)         |             | 0               |
| Stance time (% of gait cycle)               | 62.3 (2.4)           | 65.6 (2.5)     | 5.2             | 61.7 (1.6)          | 66.7 (1.6)  | 7.8             |
| Swing time (% of gait cycle)                | 37.7 (2.3)           | 34.4 (2.5)     | -9.2            | 38.3 (1.7)          | 33.3 (1.5)  | -14.0           |
| Hip position at initial foot contact (°)    | 32.8 (2.1)           | 35.9 (3.6)     | 9.0             | 33.2 (3.4)          | 32.6 (1.9)  | -1.8            |
| Maximum hip extension (°)                   | 3.0 (1.8)            | -2.1 (1.0)     | -200            | 2.6 (1.5)           | -2.4 (2.1)  | -200.0          |
| Hip range (°)                               | 37.3 (2.8)           | 38.4 (3.4)     | 2.9             | 36.1 (2.8)          | 37.2 (3.0)  | 3.0             |
| Knee position at initial foot contact (°)   | 5.4 (4.6)            | 1.4 (1.0)      | -117.6          | 5.7 (3.6)           | 4.1 (2.5)   | -32.7           |
| Maximum knee flexion at stance (°)          | 13.7 (2.9)           | 15.1 (1.7)     | 9.7             | 12.5 (3.4)          | 13.4 (4.1)  | 6.9             |
| Maximum knee flexion during swing (°)       | 75.4 (2.4)           | 55.1 (3.1)     | -31.1           | 66.9 (3.9)          | 52.5 (3.7)  | -24.1           |
| Knee range of motion (°)                    | 70.7 (3.5)           | 56.1 (2.2)     | -23.0           | 61.5 (3.2)          | 52.6 (3.1)  | -15.7           |
| Ankle position at initial foot contact (°)  | -0.8 (1.5)           | 2.1 (1.0)      | 200.0           | 0.2 (1.1)           | -4.2 (1.3)  | -200.0          |
| Maximum ankle plantar flexion at stance (°) | -7.2 (2.4)           | -6.6 (3.1)     | -8.7            | -5.9 (3.4)          | -5.9 (2.7)  | 0.0             |
| Maximum ankle dorsiflexion at stance (°)    | 14.5 (2.3)           | 7.3 (1.9)      | -66.1           | 15.1 (1.3)          | 8.1 (2.4)   | -60.3           |
| Maximum ankle plantar flexion at swing (°)  | 0.3 (0.6)            | -13.2 (2.9)    | 200.0           | 1.4 (1.8)           | -12.1 (0.9) | 200.0           |
| Ankle range of motion (°)                   | 21.7 (2.2)           | 20.7 (3.6)     | -4.7            | 20.9 (3.2)          | 20.1 (1.9)  | -3.9            |
| Vertical GRF, 1 <sup>st</sup> peak (N)      | 99.7 (3.8)           | 121.1(2.4)     | 19.4            | 104.2 (4.2)         | 121.7 (2.7) | 15.5            |
| Vertical GRF, 2 <sup>nd</sup> peak (N)      | 102.6 (4.9)          | 101.9 (3.1)    | -0.7            | 101.1 (3.9)         | 99.0 (2.4)  | -2.0            |
| Fore-aft GRF, 1 <sup>st</sup> peak (N)      | 5.4 (1.0)            | 7.8 (1.8)      | 36.4            | 4.6 (2.8)           | 9.3 (2.1)   | 67.6            |
| Fore-aft GRF, 2 <sup>nd</sup> peak (N)      | -8.0 (1.7)           | -7.5 (1.5)     | -6.5            | -8.1 (1.1)          | -7.1 (1.4)  | -13.2           |

The maximum knee flexion during the swing phase was 75.4° and 66.9° for the suction and pin/lock systems, respectively. There was a significant difference between the two systems ( $p<0.04$ ). Asymmetry existed in the ankle dorsiflexion and plantar flexion at stance and the swing phase between the sound and prosthetic limbs (Figure 4.1,4.2).

Significant differences ( $p<0.03$ ) were identified in the vertical ground reaction force between the two systems only at the first peak (loading response). Asymmetry in timings of the first peak was observed with the pin/lock system. Weight transfer during the transition from double to single limb support occurred in a shorter period for the sound limb as compared to that of the prosthetic limb. Furthermore, data analysis showed a significantly higher magnitude of the first peak vertical GRF between the sound limb and prosthetic side in both suspension systems ( $p<0.000$ ).

Table 4.4, Figures 4.1, and 4.2 show the average values of gait parameters and symmetry for both the suction (Seal-In) and pin/lock (Dermo) suspension systems of the ten participants.

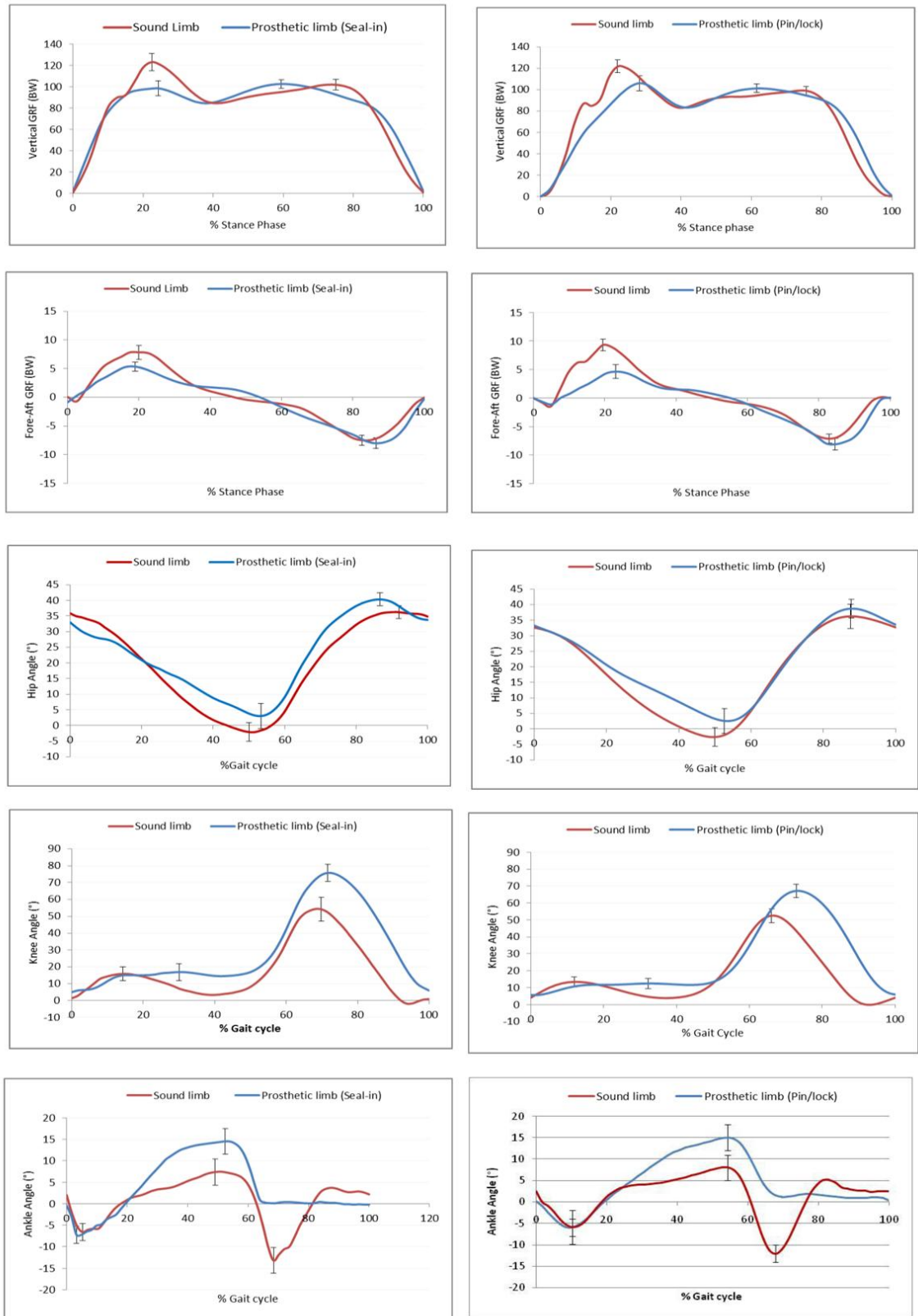


Figure 4.1. Kinematic patterns for the prosthetic and intact legs with the suction (Seal-In) and pin/Lock (Dermo) suspension systems of the ten participants (mean values).

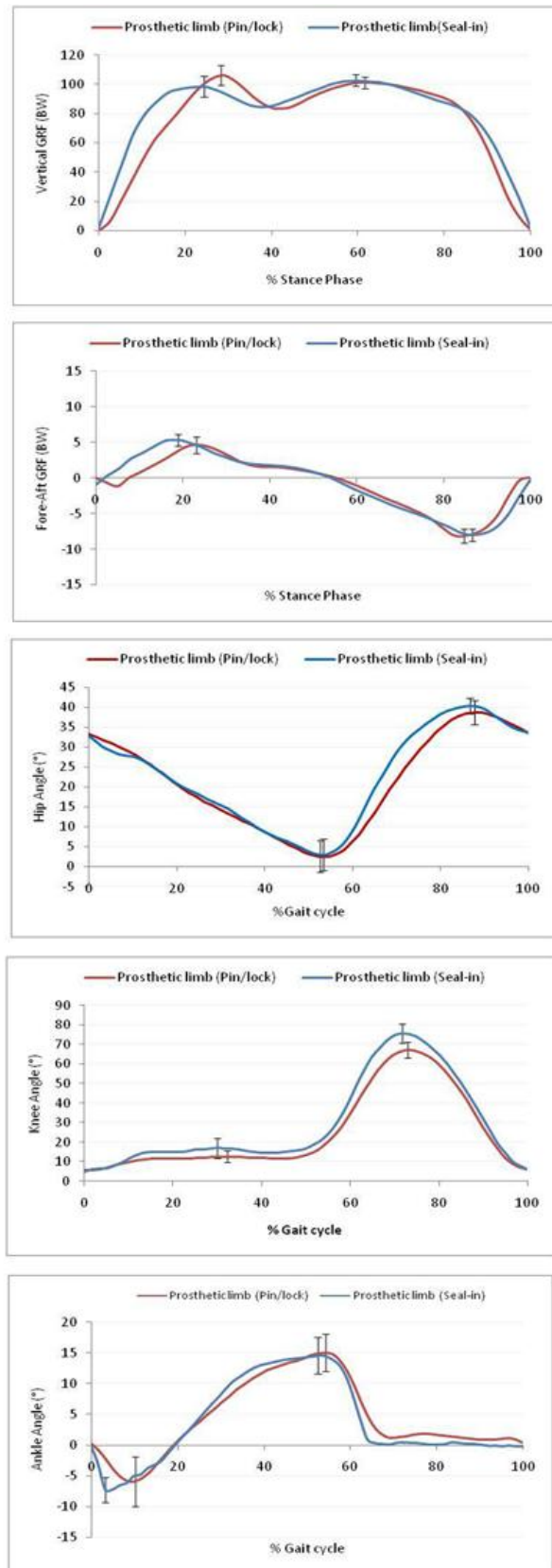


Figure 4.2. Comparison between the suction and pin/lock systems (prosthetic limb).



### **4.3. Mechanical evaluation result (Holo)**

#### **4.3.1. Mechanical test**

The new system could bear a maximum tensile load of 490 N (SD, 5.5). Movement within the socket was only 4 mm (between the liner and the socket) during the 30 seconds of tensile loading. The pin/lock system could tolerate loading of 580 N (SD, 8.5); however, the lock system lost its function after three trials. The MPSS and Seal-In (suction) could tolerate loads of 350.9 (SD, 7) and 310 N (SD, 8.4), respectively. With the pin/lock and magnetic system, there was no movement between the end of the liner and socket, and there were 18 and 12 mm of traction in the silicone liner, respectively. Furthermore, a 7 mm of movement between the liner and socket with the seal-in liner was observed before the system failed.

#### **4.3.2. Subject characteristic**

The subjects in this study were all males. Diabetes and trauma were the common causes of amputation, and the mean age (year) and height (cm) of the participants were 42.2 (SD, 14.7) and 174.1 (SD, 7.2), respectively (Table 4.5, Table 4.6). On average, the participants went through amputation 9.7 (SD, 7.5) years prior to the study. The average mass of prostheses (transtibial) for the magnetic (MPSS) suspension, pin/lock (Icelock 200 Series Clutch 4H 214), suction (seal-in x5), and the new Holo system among the nine transtibial subjects were 1.89, 1.80, 1.65, and 1.60 kg, respectively.

Table 4.5. Characteristics of the participants.

| Subject no. | Age | Height (cm) | Mass (kg) | Level of amputation | Cause of amputation | Time since amputation | Stump length(cm) | Mobility grade | Stump appearance and problem with own prosthesis   |
|-------------|-----|-------------|-----------|---------------------|---------------------|-----------------------|------------------|----------------|--|
| 1           | 39  | 170         | 65        | TT                  | Trauma              | 5                     | 14               | K4             | Bony and conical in shape. The bony end of the residual limb was painful during the swing phase of gait. He was using pin/lock system prior to the study.  |
| 2           | 23  | 167         | 82        | TT                  | Trauma              | 3                     | 15               | K3             | Cylindrical in shape. He was using PTB socket with Pelite (soft liner). He encountered numerous problems with prosthesis, such as pain, wound at the end of his stump, and too much movement (pistoning) within the socket. Most of the weight was centralized at the end of the socket. |
| 3           | 51  | 172         | 67        | TT                  | Trauma              | 5                     | 14               | K3             | Bony and conical in shape. The bony end of the residual limb and fibular head were painful during the swing phase of gait and while wearing the prosthesis. He was using pin/lock system prior to the study.   |
| 4           | 40  | 180         | 95        | TT                  | Diabetes            | 7                     | 16               | K2             | Cylindrical in shape. He was using pin/lock system prior to the study. He encountered difficulties in aligning the pin while wearing the prosthesis. He experienced a disorder in his left hand.   |
| 5           | 75  | 182         | 75        | TT                  | Diabetes            | 8                     | 13               | K2             | Bony and conical in shape. The bony end of the residual limb was painful during the swing phase of gait. He was using pin/lock system prior to the study.  |
| 6           | 45  | 185         | 84        | TT                  | Trauma              | 26                    | 12               | K3             | Short stump. He was using PTB socket with Pelite (soft liner). He had pain at the end of stump and too much movement (pistoning) within the socket. Most of his weight was centralized at the end of the socket.   |
| 7           | 41  | 173         | 95        | TT                  | Trauma              | 5                     | 14               | K3             | Cylindrical in shape. He was using pin/lock system prior to the study. He did not have any problem with his prosthesis.  |
| 8           | 34  | 175         | 78        | TT                  | Trauma              | 10                    | 28               | K3             | Cylindrical in shape. He did not feel any pain at the stump. He was using pin/lock system prior to the study.  |
| 9           | 32  | 163         | 72        | TT                  | Trauma              | 18                    | 25               | K2             | Conical in shape. Bony prominence was evident at the end of his stump. He did not feel any pain at the stump. He was using pin/lock system prior to the study.   |

Table 4.6. A compilation of the subjective feedbacks of the participants.

| Subject no. | Subject's preference | Mobility grade | Subjective feedback |  |
|-------------|----------------------|----------------|---------------------|--|
| 1           | Seal-In              | 1              | K4                  | He did not feel any pain at the distal of his residual limb with the Seal-In and the new suspension system during walking. He gained more confidence and also stated that the Seal-In was more suitable than the other suspension systems. Despite that it is more challenging to remove the prosthesis, he still preferred to use the seal-in system.   |
|             | Pin/Lock             | 4              |                     |  |
|             | Magnetic             | 2              |                     |  |
|             | Hook/Loop            | 3              |                     |  |
| 2           | Seal-In              | 4              | K3                  | He was more satisfied with the silicone liners compared to the PTB with Pelite liner. After changing to silicone liner (TSB socket), he did not have any pain at the distal end of the residual limb, and the wound was healed after two weeks. He felt more confident with the silicone liner and different lock systems (pin/lock, magnet or Holo). Among the four systems in this study, he preferred the Holo, the magnetic system, and the pin/lock system. |
|             | Pin/Lock             | 3              |                     |  |
|             | Magnetic             | 2              |                     |  |
|             | Hook/Loop            | 1              |                     |  |
| 3           | Seal-In              | 4              | K3                  | He did not feel any pain at the distal of residual limb with the seal-in and the new suspension system. However, he had pain during donning and doffing with the seal-In liner. He stated that the Seal-In was more suitable during walking, but wearing and removing the prosthesis was extremely more difficult compared to the other suspension systems.  |
|             | Pin/Lock             | 3              |                     |  |
|             | Magnetic             | 1              |                     |  |
|             | Hook/Loop            | 2              |                     |  |
| 4           | Seal-In              | 4              | K2                  | It was very difficult to use the seal-In due to upper limb weakness. He preferred the hook and loop, pin/lock, and magnetic systems mostly because of their easy donning and doffing.  |
|             | Pin/Lock             | 2              |                     |  |
|             | Magnetic             | 3              |                     |  |
|             | Hook/Loop            | 1              |                     |  |
| 5           | Seal-In              | 4              | K2                  | He did not feel pain with the Seal-In and the new suspension system. Nevertheless, he preferred the new suspension system because of its advantages of easy donning and doffing. He was not happy with the tearing noise during doffing of the prosthesis.   |
|             | Pin/Lock             | 3              |                     |  |
|             | Magnetic             | 2              |                     |  |
|             | Hook/Loop            | 1              |                     |  |
| 6           | Seal-In              | 4              | K3                  | Pain at the end of the socket was less with the TSB socket compared to the PTB socket. He was satisfied with the pin/lock, hook/loop, and magnetic systems, whereas he felt more socket fit and less rotation inside the socket with the seal-in. He mentioned that he is not going to use the Seal-In because of the difficulty in donning and doffing.   |
|             | Pin/Lock             | 1              |                     |  |
|             | Magnetic             | 3              |                     |  |
|             | Hook/Loop            | 2              |                     |  |
| 7           | Seal-In              | 3              | K3                  | He felt more socket fit and higher confidence with the Seal-In during walking, however, he was not satisfied with the donning and doffing procedures. He preferred to use the pin/lock and magnetic systems. He was not happy with the hook/lop system because of the sound developing during doffing of the prosthesis.   |
|             | Pin/Lock             | 1              |                     |  |
|             | Magnetic             | 2              |                     |  |
|             | Hook/Loop            | 4              |                     |  |
| 8           | Seal-In              | 4              | K3                  | He was happier with the pin/lock and Holo systems because of the easy donning and doffing procedures. He also felt less traction at the end of the socket with Holo and seal-in system.  |
|             | Pin/Lock             | 1              |                     |  |
|             | Magnetic             | 3              |                     |  |
|             | Hook/Loop            | 2              |                     |  |
| 9           | Seal-In              | 4              | K2                  | He felt more comfortable at the distal end with the Seal-In and the new suspension system, and he was more confident during walking. Regarding the donning and doffing, he preferred the pin/lock and Holo system. He chose the pin/lock as his first choice because of its easy donning and doffing.  |
|             | Pin/Lock             | 1              |                     |  |
|             | Magnetic             | 3              |                     |  |
|             | Hook/Loop            | 2              |                     |  |



Figure 4.3. Subject 1 while using the new system for walking (A), cycling (B), and running (C).

#### 4.4. Pressure Mapping (Holo)

##### 4.4.1. Participants' profile

The mean weight and age of the subjects were 76.4kg (SD, 13.6) and 40.5 years (SD, 14.8); respectively (Table 4.7). The participants' activity level was K2-K3 as measured based on the American Academy of Orthotists & Prosthetists grading system. The amputation surgery for all the participants was done at least 3 years prior to the study. Table 4.7 presents the demographic information of participants.

Table 4.7. The demographic information of the participants.

| Subject no. | Age (Year) | Height (cm) | Mass (Kg) | Level of amputation | Cause of amputation | Time since amputation (year) | Stump length (cm) | Mobility grade | PSS <sup>#</sup> |
|-------------|------------|-------------|-----------|---------------------|---------------------|------------------------------|-------------------|----------------|------------------|
| 1           | 39         | 170         | 65        | TT*                 | Traumatic           | 5                            | 14                | K4             | Pin/Lock         |
| 2           | 23         | 167         | 82        | TT                  | Traumatic           | 3                            | 15                | K3             | Pelite           |
| 3           | 51         | 172         | 67        | TT                  | Traumatic           | 5                            | 14                | K3             | Pin/Lock         |
| 4           | 40         | 180         | 95        | TT                  | Diabetic            | 7                            | 16                | K2             | Pin/Lock         |
| 5           | 75         | 182         | 75        | TT                  | Diabetic            | 8                            | 13                | K2             | Pin/Lock         |
| 6           | 45         | 185         | 84        | TT                  | Traumatic           | 26                           | 12                | K3             | Pelite           |
| 7           | 41         | 173         | 95        | TT                  | Traumatic           | 5                            | 14                | K3             | Pin/Lock         |
| 8           | 34         | 175         | 78        | TT                  | Traumatic           | 10                           | 28                | K3             | Pin/Lock         |
| 9           | 32         | 163         | 72        | TT                  | Traumatic           | 18                           | 25                | K2             | Pin/Lock         |
| 10          | 25         | 162         | 51        | TT                  | Tumour              | 3                            | 16                | K3             | Pin/Lock         |

\* TT= Trans-tibial

# Prosthetic suspension systems used by the subjects before entering this present study

#### **4.4.2. Interface pressure**

Pressure data were extracted for 12 regions of the residual limb. Table 4.9 presents the pressure values for the socket regions. With the pin/lock system, the proximal residuum showed slightly higher pressure (not significantly) in anterior ( $P<0.251$ ), posterior ( $P<0.956$ ), and medial ( $P<0.062$ ) regions (Table 4.9) during the stance phase of gait. There were no significant differences in the pressure applied to the middle of the stump for both suspension systems, except for the lateral and medial sides that exhibited significantly higher pressure with the new suspension system ( $P<0.006$  and  $P<0.005$ , respectively).

Furthermore, significantly higher pressure was applied to the residual limb at the distal region of the stump by the pin/lock system in anterior, posterior, and medial areas during the stance phase of gait. The pressure applied to the lateral distal stump was also higher with the pin/lock, but was not significantly different ( $P<0.092$ ).

The results showed a significantly higher pressure values at the proximal and distal residual limb using the pin/lock suspension system during the swing phase of gait. Moreover, the pressure applied to the middle stump was higher at the anterior (0.072), posterior (0.099), lateral (0.001), and medial (0.001) areas during the swing phase.

Table 4.9. Mean peak pressures (stance and swing) for the four major regions of the residual limb.

|                    | Descriptive Statistics |    |  |                |        |                                       |                |        |
|--------------------|------------------------|----|--|----------------|--------|---------------------------------------|----------------|--------|
|                    | Suspension type        | N  | Mean peak pressure Stance <sup>#</sup> | Std. Deviation | Sig    | Mean peak pressure Swing <sup>#</sup> | Std. Deviation | Sig    |
| Anterior Proximal  | Pin/lock               | 10 | 53.3                                   | 14.5           | 0.251  | 15.2                                  | 2.1            | 0.001* |
|                    | Holo                   |    | 48.5                                   | 11.8           |        | 4.8                                   | 2.7            |        |
| Anterior Middle    | Pin/lock               | 10 | 46.6                                   | 10.7           | 0.220  | 14.5                                  | 3.2            | .072   |
|                    | Holo                   |    | 48.1                                   | 12.3           |        | 11.4                                  | 1.9            |        |
| Anterior Distal    | Pin/lock               | 10 | 50.4                                   | 12.1           | 0.001* | 24.3                                  | 2.4            | 0.001* |
|                    | Holo                   |    | 44.5                                   | 14.2           |        | 3.1                                   | 1.1            |        |
|                    |                        |    |  |                |        |                                       |                |        |
| Posterior Proximal | Pin/lock               | 10 | 46.5                                   | 11.2           | 0.956  | 18.9                                  | 3.5            | 0.001* |
|                    | Holo                   |    | 46.3                                   | 14.7           |        | 5.4                                   | 1.7            |        |
| Posterior Middle   | Pin/lock               | 10 | 46.4                                   | 14.5           | 0.577  | 13.4                                  | 2.1            | 0.099  |
|                    | Holo                   |    | 45.8                                   | 14.1           |        | 11.2                                  | 1.8            |        |
| Posterior Distal   | Pin/lock               | 10 | 62.2                                   | 19.9           | 0.003* | 31.8                                  | 4.3            | 0.001* |
|                    | Holo                   |    | 57.8                                   | 20.2           |        | 6.1                                   | 2.8            |        |
|                    |                        |    |  |                |        |                                       |                |        |
| Lateral Proximal   | Pin/lock               | 10 | 50.1                                   | 18.9           | 0.434  | 17.3                                  | 3.1            | 0.001* |
|                    | Holo                   |    | 51.5                                   | 19.8           |        | 7.9                                   | 2.7            |        |
| Lateral Middle     | Pin/lock               | 10 | 53.9                                   | 13.5           | 0.006* | 24.3                                  | 4.2            | 0.001* |
|                    | Holo                   |    | 57.3                                   | 12.7           |        | 8.7                                   | 1.2            |        |
| Lateral Distal     | Pin/lock               | 10 | 60.7                                   | 19.5           | 0.092  | 19.4                                  | 2.6            | 0.001* |
|                    | Holo                   |    | 58.6                                   | 21.2           |        | 8.6                                   | 2.3            |        |
|                    |                        |    |  |                |        |                                       |                |        |
| Medial Proximal    | Pin/lock               | 10 | 43.3                                   | 14.4           | 0.062  | 17.3                                  | 3.6            | 0.009* |
|                    | Holo                   |    | 42.3                                   | 13.2           |        | 8.6                                   | 1.4            |        |
| Medial Middle      | Pin/lock               | 10 | 49.3                                   | 11.9           | 0.005* | 26.5                                  | 4.1            | 0.001* |
|                    | Holo                   |    | 53.3                                   | 11.2           |        | 6.9                                   | 2.2            |        |
| Medial Distal      | Pin/lock               | 10 | 47.8                                   | 9.6            | 0.003* | 17.6                                  | 2.3            | 0.001* |
|                    | Holo                   |    | 44.1                                   | 10.8           |        | 9.4                                   | 2.1            |        |

#### **4.4.3. Subjective feedback**

The participants were generally satisfied with the new system (Table 4.10). There was no significant difference between the new system and the pin/lock system during sitting ( $P<0.656$ ), walking ( $P<0.223$ ), climbing the stairs ( $P<0.086$ ), and sweating ( $P<0.586$ ). However, the participants were content with the new system (HOLo) due to easy donning and doffing, although it was not significantly different ( $P<0.077$ ). Also, less movement was seen between the liner and socket. There was no traction or pain at the distal liner with new system. The HOLo created more noise compared to the pin/lock system, but not significantly higher ( $P<0.343$ ). The irritating noise (tearing noise from the Hook and Loop) was only heard during the doffing (Table 4.10).



Table 4.10: Subjective feedback with two suspension systems

| Paired Samples Statistics |                     |                    |      |                |                 |
|---------------------------|---------------------|--------------------|------|----------------|-----------------|
|                           |                     | Suspension systems | Mean | Std. Deviation | Sig. (2-tailed) |
| Satisfaction              | Fit                 | Pin/lock           | 77.5 | 3.0            | .012*           |
|                           |                     | Holo               | 81.9 | 3.2            |                 |
|                           | Donning/<br>Doffing | Pin/lock           | 75.3 | 4.6            | .077            |
|                           |                     | Holo               | 76.7 | 4.9            |                 |
|                           | Sitting             | Pin/lock           | 79.1 | 5.1            | .656            |
|                           |                     | Holo               | 79.8 | 3.1            |                 |
|                           | Walking             | Pin/lock           | 76.0 | 2.9            | .223            |
|                           |                     | Holo               | 76.8 | 2.7            |                 |
|                           | Stair               | Pin/lock           | 75.8 | 3.0            | .086            |
|                           |                     | Holo               | 77.7 | 1.9            |                 |
| Problem                   | Sweating            | Pin/lock           | 73.3 | 3.5            | .586            |
|                           |                     | Holo               | 72.7 | 4.2            |                 |
|                           | Pistoning           | Pin/lock           | 79.3 | 3.8            | .020*           |
|                           |                     | Holo               | 84.1 | 4.6            |                 |
|                           | Rotation            | Pin/lock           | 80.1 | 2.5            | .002*           |
|                           |                     | Holo               | 83.5 | 3.2            |                 |
|                           | Sound               | Pin/lock           | 72.7 | 3.1            | .343            |
|                           |                     | Holo               | 70.3 | 2.7            |                 |
|                           | Pain                | Pin/lock           | 77.0 | 2.7            | .062            |
|                           |                     | Holo               | 79.4 | 3.9            |                 |
| Overall satisfaction      |                     | Pin/lock           | 76.3 | 1.1            | .015*           |
|                           |                     | Holo               | 78.7 | 3.4            |                 |

Note: The satisfaction rate ranged from 0 to 100 (from 0 to 100, the satisfaction increased). Complaint scores of 100 indicated “not bothering” and 0 meant “extremely bothering”.

## **4.5. Case Report (Pressure/Gait)**

### **4.5.1. Pressure mapping**

Pressure measurements were logged over the 12 sites of the residual limb. Figures 4.4 and 4.5 depict the mean peak pressures during walking on the level ground and on the incline and stairs (up and down), respectively. With the old prosthesis, the proximal residual limb, particularly the patellar ligament (anterior proximal), tolerated most of the load during level walking (115 (5.2) kPa), which was almost 10 times higher than the mean peak pressure applied to the anterior distal residual limb (12 (3.4) kPa). Furthermore, the pressure applied to the posterior distal (110 (4.5) kPa) was higher than the posterior proximal (57 (2.7)) with the old prosthesis (Figure 4.4). Our subject experienced a higher pressure at the lateral side compared to the medial side with both systems (old prosthesis with the pin/lock and new prosthesis with the Velcro) and more pressure over the proximal and distal residual limb during swing phase of gait with the old prosthesis.

The pressure in the new socket was distributed more evenly (Figure 4.4) over the residual limb (anterior, posterior, medial, and lateral) during walking, and extra load was successfully relieved from the anterior proximal (patellar bar). During walking, the mean peak pressure did not exceed 60 kPa over the anterior, posterior, and medial surfaces of the socket. However, the mean peak pressure over the lateral aspect reached 84 kPa.

The subject also experienced higher pressure over the anterior proximal aspect of the stump (patellar ligament) during the ramp and stairs negotiation with the old prosthesis (Figure 4.5). The slope and stairs were 132 (6.1) and 117 (4.1) kPa high when the subject walked down, respectively. Similar to the level walking, the lateral aspect of

the socket also applied a higher pressure to the stump during the ramp and stairs negotiation (Figure 4.5)

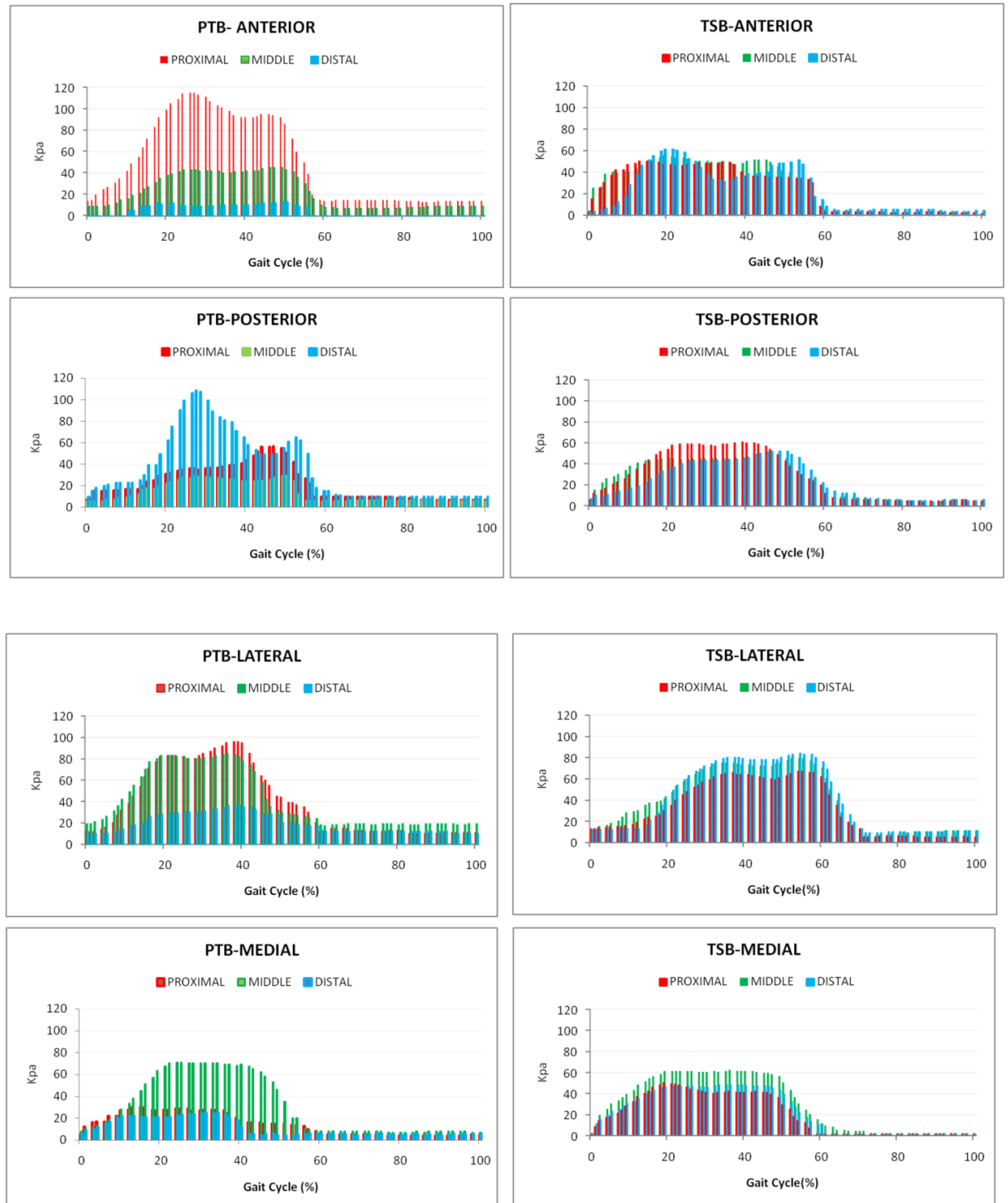


Figure 4.4. Interface pressure during normal walking (self-selected speed).

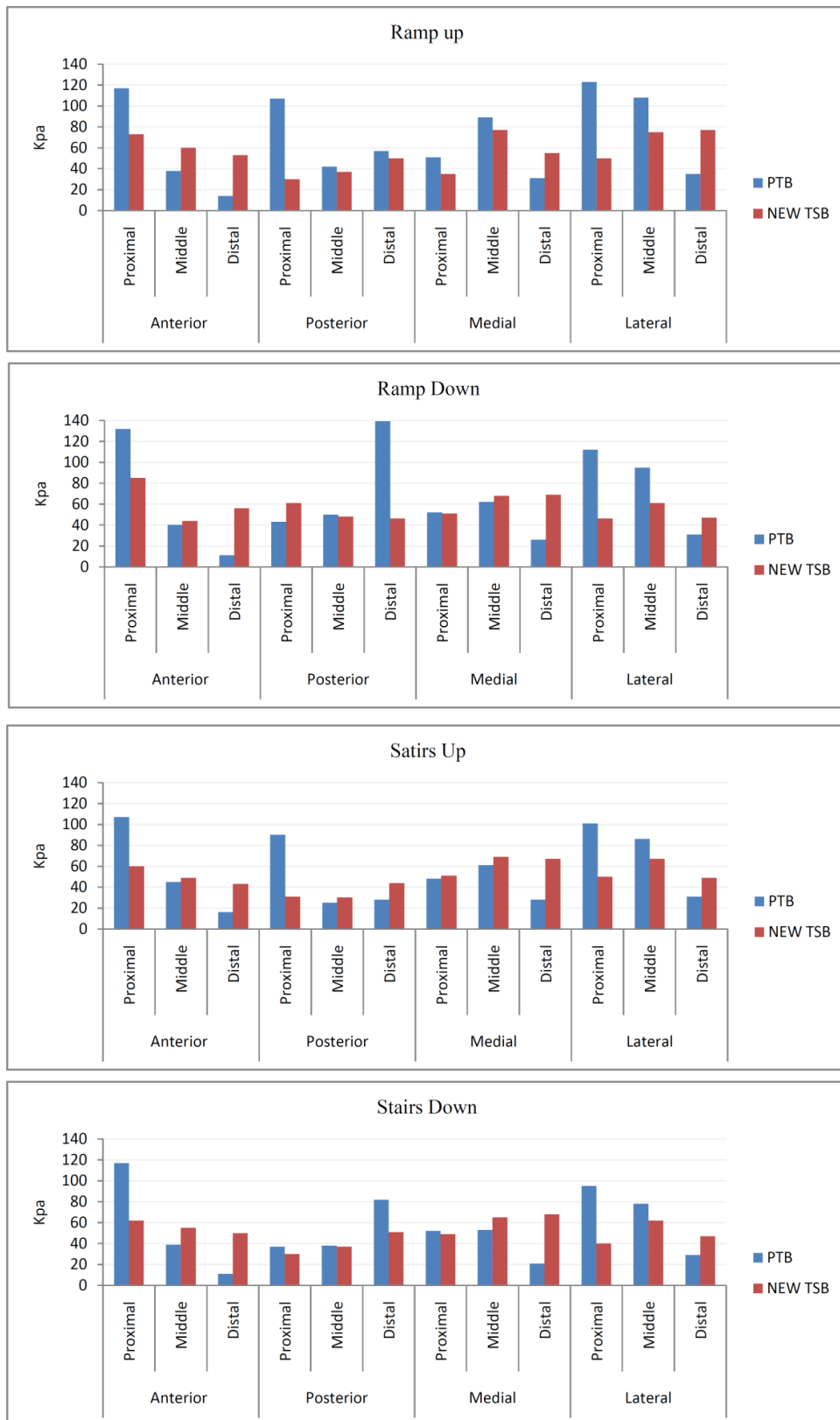


Figure 4.5. The average peak pressure, based on the liner type and sensor site on the ramp (up and down) and stairs (up and down).

#### **4.5.2. Gait evaluation**

The swing time and step length of the prosthetic side were higher than the sound limb. Accordingly, the stance time of the sound limb was longer than the prosthetic (Table 4.10), and the walking speed and stride length of the new prosthesis with Velcro were higher to some extent (0.92 (0.02) m/s and 1.23 (0.04) m, respectively).

The hip range of motion of the prosthetic side was 46.4 (2.7), 44.4 (0.8), and 42.6 (2.7) degrees in the old prosthesis, new prosthesis with pin/lock, and new prosthesis with Velcro, respectively (Table 4.11, Figure 4.6). However, the knee range of motion was higher in both of the new systems compared to the old prosthesis. Higher ankle plantar flexion and range of motion were also observed in the new systems during the gait.

The vertical GRF (first and second peaks) was high in the new Velcro system as 107.5 (2.4) N, whereas 112.4 (0.8) N on the prosthetic side. The vertical GRF with the Velcro was also higher for the sound limb when compared to the other systems (Table 4.11), whereas the first peak of fore-aft GRF or deceleration force was higher with the old prosthesis (Figure 4.7). However, the acceleration force or second peak of the new systems was higher.

#### **4.5.3. Subjective feedback**

The subject stated that she was satisfied with the new socket. She could not feel any difference between the systems during sitting, but she could walk faster with the new prosthesis and experienced less traction and pain at the end of the stump. She was also more satisfied with the donning and doffing procedures for the new system as there

was no pin to align. Furthermore, she was more confident during walking with the new prosthesis without any rotation inside the socket as compared to the old prosthesis. Interestingly, she could not walk with her old prosthesis after two months as it caused excessive pressure over the anterior proximal aspect of the socket (patellar ligament).

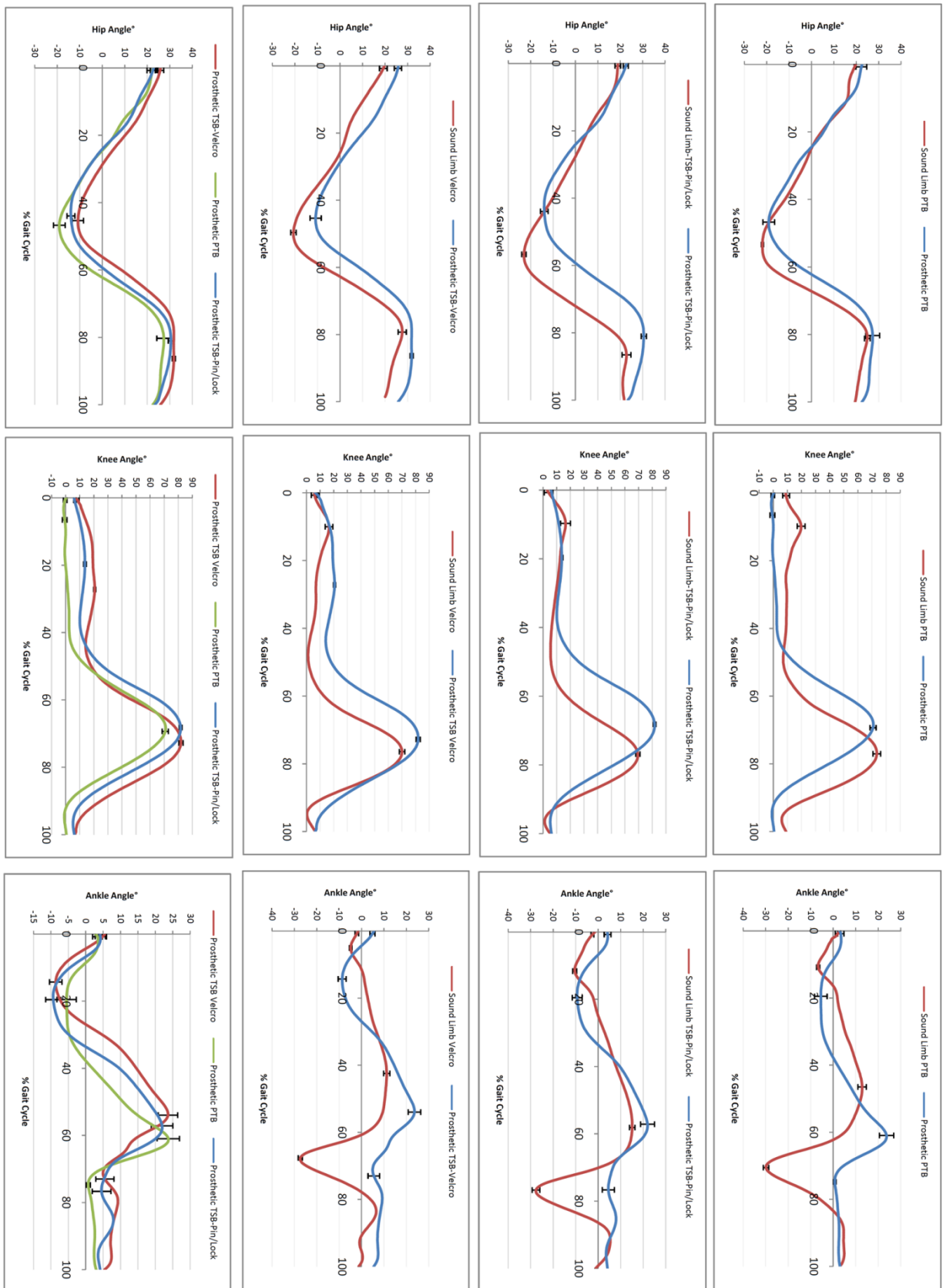


Figure 4.6. Kinematic patterns for the prosthetic and intact leg in three different systems.

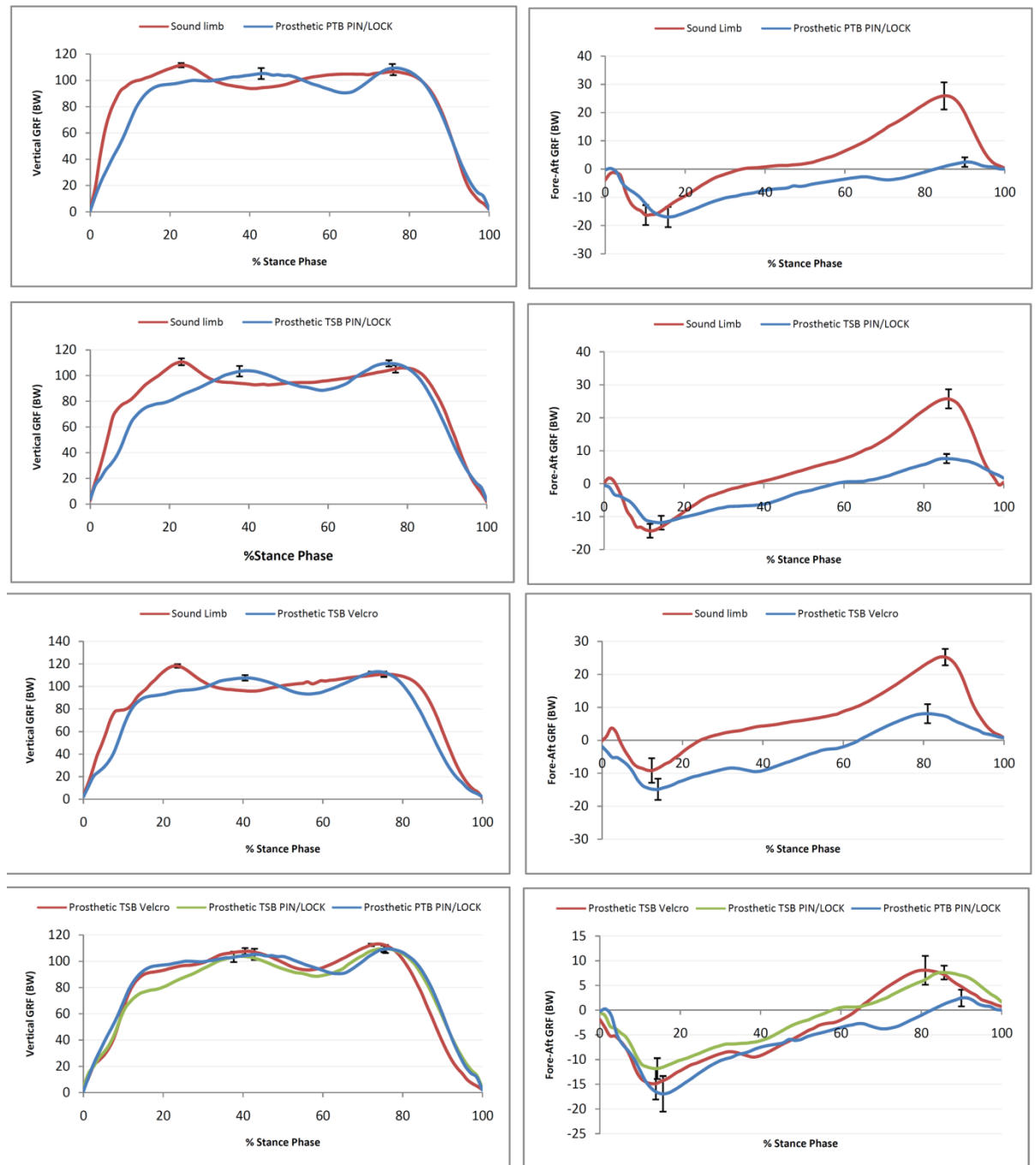


Figure 4.7. Kinetic patterns for the prosthetic and intact leg in three different systems



Table 4.11. Average values of gait parameters during the level walking of the subjects.

| Parameters  | Old Prosthesis <sup>1</sup> |            | New Prosthesis (pin/lock) <sup>2</sup> |            | New prosthesis (Velcro) <sup>3</sup> |            |
|---|-----------------------------|------------|--|------------|--------------------------------------|------------|
|   | Prosthetic                  | Sound      | Prosthetic                             | Sound      | Prosthetic                           | Sound      |
| Step length (m)   | 0.61                        | 0.57       | 0.62                                   | 0.59       | 0.64                                 | 0.59       |
| Stride length (m)   | 1.18(0.04)                  |            | 1.21(0.03)                             |            | 1.23 (0.04)                          |            |
| Walking speed (m/s)   | 0.90(0.02)                  |            | 0.91(0.01)                             |            | 0.92 (0.02)                          |            |
| Stance time (% of gait cycle)   | 59.3(1.4)                   | 65.1(2)    | 59.4(2.3)                              | 67.1(1.5)  | 58.6(2)                              | 64.3(1.9)  |
| Swing time (% of gait cycle)  | 40.7(1.4)                   | 34.9(2)    | 40.9(2.3)                              | 32.9(1.5)  | 41.4(2)                              | 35.7(1.9)  |
| Hip position at initial foot contact (°)                              | 22.6(2.4)                   | 19.8(0.2)  | 22.8(1.1)                              | 18.9(1.3)  | 26.5(1.6)                            | 19.2(1.7)  |
| Maximum hip extension (°)   | -19.1(2.6)                  | -21.5(0.6) | -13.9(1.7)                             | -23.5(1)   | -10.8(2.3)                           | -20.7(1.2) |
| Maximum hip flexion (°)   | 27.3(3.1)                   | 25(1.3)    | 30.4(1.2)                              | 22.7(2)    | 31.8(0.7)                            | 27.6(1.8)  |
| Hip ROM(°)  | 46.4(2.7)                   | 46.9(0.2)  | 44.4(0.8)                              | 45.8(1.6)  | 42.6(2.7)                            | 48.3(1.5)  |
| Knee position at initial foot contact (°)                             | 0.4(0.9)                    | 8.9(2.4)   | 6(0.7)                                 | 3.2(3.1)   | 6.5(1)                               | 5.8(2.5)   |
| Maximum knee flexion at stance (°)(Midstance)                         | -0.6(1.7)                   | 19.8(1.8)  | 13.7(0.9)                              | 16.5(3.6)  | 20.6(0.8)                            | 16.6(2.8)  |
| Maximum knee flexion during swing (°)                                 | 70.8(2.2)                   | 73.5(2.7)  | 81.7(1.1)                              | 69.5(1.5)  | 81.9(1.5)                            | 70.3(2)    |
| Knee ROM (°)  | 72.5(1.8)                   | 67.5(2.5)  | 76.4(1.6)                              | 68.2(2.1)  | 75.5(1.3)                            | 69.6(3.2)  |
| Ankle position at initial foot contact (°)                            | 2.8(1.4)                    | 3(1.2)     | 4.1(1.5)                               | -1.4(6)    | 5.4(1.1)                             | -1.6(8)    |
| Maximum ankle plantar flexion at stance (°)(heel strike to foot flat) | -5.5(2.8)                   | -6.7(0.7)  | -9.3(2.2)                              | -10.3(9)   | -8.6(1.8)                            | -4.8(6)    |
| Maximum ankle dorsiflexion at stance (°)                              | 23.7(3.2)                   | 12.8(1.9)  | 21.9(3.1)                              | 15.1(1.2)  | 23.6(2.9)                            | 11.3(1.4)  |
| Maximum ankle plantar flexion at toe off (°)                          | 0.7(0.6)                    | -29.8(1.2) | 4.5(2.8)                               | -27.5(1.7) | 5.5(2.6)                             | -27.4(9)   |
| Ankle ROM (°)   | 29.2(2.7)                   | 42.6(1.6)  | 31.3(3.8)                              | 42.7(1.4)  | 32.1(2.2)                            | 38.7(1.2)  |
| Vertical GRF, 1 <sup>st</sup> peak (N)                                | 105.2(4.2)                  | 111.5(1.6) | 103.3(4)                               | 110.5(2.6) | 107.5(2.4)                           | 118.2(1.6) |
| Vertical GRF, 2 <sup>nd</sup> peak (N)                                | 109.3(1.2)                  | 106.4(2.4) | 109.4(2.3)                             | 105.8(4.2) | 112.4(0.8)                           | 110.8(2.3) |
| Fore-aft GRF, 1 <sup>st</sup> peak (N)                                | -16.9(3.6)                  | -16.2(3.5) | -11.8(2.7)                             | -14.3(2.1) | -14.9(3.2)                           | -9.1(3.7)  |
| Fore-aft GRF, 2 <sup>nd</sup> peak (N)                                | 2.4(1.7)                    | 25.8(4.8)  | 7.5(1.4)                               | 25.7(2.9)  | 8.1(2.9)                             | 25.3(2.5)  |

<sup>1</sup> silicone liner and pin/lock with PTB socket

<sup>2</sup> silicone liner and pin/lock with TSB socket

<sup>3</sup> silicone liner and Velcro with TSB socket

## CHAPTER 5

### DISCUSSION

#### 5.1. Satisfaction survey (Common suction socket versus Seal-In liner)

The rehabilitation of a person with amputation is a challenge as it requires team work and necessitates a person's willingness to accomplish the time-consuming and costly prosthetic training. Prosthetic satisfaction is a multi-factorial issue. Some of these factors are dependent on the level of amputation, prosthetic components and alignment, prosthetist's skills, level of activity, and socket fit (Legro et al., 1998; Raichle et al., 2008; Subbarao and Bajoria, 1995; Ruth and Neil, 1999). The level of amputation is one of the significant factors that can notably affect prosthetic use and the user's satisfaction (Raichle et al., 2008). Based on the literature, the majority of studies about satisfaction with prostheses has focused on patients with transtibial amputation (Ali et al., 2012a; Schuch, 1992; Wirta, 1990). In a retrospective study, Dillingham et al. (2001) examined the satisfaction of persons with lower limb traumatic amputation, which included persons with amputation at the transfemoral level. The transfemoral subjects had used either a strap or suction suspension. About 57% of the participants were not satisfied with their prostheses, however, the correlation between the suspension system and patients' satisfaction was not investigated (Dillingham et al. 2001).

The results of the current study revealed that the participants were more satisfied, and fewer problems were experienced with the Seal-In liner. The only exception was durability, which was found to be higher with the suction system. Furthermore, there was no significant difference in walking on even and uneven surfaces, stair negotiation, and appearance between the two systems.

There is a minimal study on the relationship between the suspension system and satisfaction (Trieb et al., 1999; Koike et al., 1981; Haberman et al., 1999). CSS are said to cause discomfort and edema (Levy, 1980). Koike et al. (1981) introduced a new transfemoral double socket and reported that the participants were satisfied with the new system in comparison to the CSS, particularly for donning and doffing. The flexibility of the inner socket, which they believed maintained close contact with the residual limb at all times and reduced the edema associated with the CSS, is believed to be the underlying reason of such finding (Koike et al. 1981). The present study concurs with these findings as the participants were more satisfied with the Seal-In system, which also has a soft inner socket. The subjects also experienced less swelling using the Seal-In liner compared to the CSS system ( $P < 0.000$ ).

In a prospective study, Trieb et al. (1999) compared the satisfaction with transfemoral prostheses when wearing a contour adducted trochanteric controlled-alignment socket (CAT/CAM) with and without a silicone liner. They reported that the socket could be used for longer hours and could reduce skin trauma with the silicone liner, resulting in enhanced quality of life. Similarly, participants in the current study were more satisfied with the Seal-In silicone liner and experienced less problems.

The silicone liner creates a negative pressure on people with transfemoral amputation, resulting in concurrent movement of the liner and skin (Haberman et al., 1992). Seal-In liners also generate suction at the inner socket wall through vacuum between the seals and socket. Therefore, the soft tissue is protected from the stresses associated with the CSS. Haberman et al. (1992) concluded that silicone liners resulted in a level of suspension and comfort that is not possible with the CSS system. The use of silicone liners greatly improved the function of the prosthesis, as well, because of the

enhanced suspension, skin protection, and cushioning (Heim et al., 1997). Similarly, the respondents in the current study were more satisfied with the Seal-In liner ( $P<0.000$ ).

Ease of donning and doffing has been reported to have a positive effect on a patient's experience with a prosthetic device (Haberman et al., 1992; Baars et al., 2008; Gholizadeh et al., 2012b,c), which is supported by the present study. The participants involved in the current study were more satisfied with the process of donning and doffing of the Seal-In liner than that of the CSS. Elastic bandage was used to lessen the friction when the patient dons the residual limb into the hard socket in the CSS; however, the present study suggests that donning a suction socket using an elastic bandage is a challenge. The silicone liner can be donned in a sitting position with less effort, and it does not require balance skills normally associated with donning the CSS while standing (Haberman et al., 1992). These findings are consistent with the study by Koike et al. (1981) on 440 transfemoral subjects. They observed easier donning while sitting with a flexible internal socket in comparison to the suction socket (Koike et al. 1981). The present study has a completely different obtained results from the previous work on the transtibial Seal-In liner with regard to the donning and doffing process (Gholizadeh et al., 2012b,c; Ali et al., 2012a). Individuals with transtibial amputations were not happy with the Seal-In liner because of the difficulty of donning and doffing, whereas those with transfemoral amputation stated fewer problems with this type of liner. Transfemoral prostheses are heavier than transtibial; therefore, enhanced fit by the Seal-In liner possibly resulted in higher satisfaction in the transfemoral subjects. Furthermore, soft tissue of the residual limb is less firm in persons with transfemoral amputation than transtibial.

No significant difference was observed in the satisfaction during ambulation (walking on level ground, walking on uneven surface, and stair negotiation), hence, the

participants were more satisfied with the static items of satisfaction. However, it does not undermine the improved results with the Seal-In liner in comparison to the CSS as static scenarios are critical in daily activities.

The durability of silicone liners has long been debated. As the liner is constantly under compressive and tensile loading, its longevity is a concern (Cochrane et al., 2001). Research showed that alpha cushion and locking liners have a durability of 6.6 and 6.7 months, respectively (Hatfield et al., 2001). Similarly, Össur provides a warranty of six months for its Seal-In liners. Low durability necessitates the frequent replacements of the liners, which will be costly for the users. Thus, the question of how durability might be enhanced is raised. Some authors addressed this issue by the addition of cloth and matrix material to the surface of the liners (Cochrane et al., 2001; Coleman et al., 2004). In the current study, participants reported a significantly less durable Seal-In liner than the CSS ( $P<0.000$ ). Despite the low durability, participants were more satisfied with the Seal-In liner than the CSS. Further research and development is needed to enhance the liner's longevity. Another idea is that if the liners must be replaced frequently, they must be made of cheaper material such as plant-based substances; two liners can also be provided to each prosthetic user to increase the liner's life by the alternate use.

Seal-In liner was reported to decrease the pistoning inside the socket and increase the patient's confidence during walking (Gholizadeh et al., 2012b,c, 2013). Our participants reported less problems with pistoning in the Seal-In liner compared to the CSS, which can be attributed to the total contact between the seals and the socket wall. They also experienced less pain in their residual limb, possibly as a result of better skin protection, volume control, less friction, suction, and edema at the end of the residual

limb because of the full contact between the liner and skin when wearing the Seal-In liner (Gholizadeh et al., 2012b,c). Both suspension systems in this study are considered suction suspension, however, one applies suction to the skin (CSS), whereas the other creates suction mostly between the liner and socket wall. Silicone liners are used to reduce skin irritation or breakdown that is a common problem with prostheses (Levy, 1980). Participants in this study also stated less irritation, pain, and wounds using the Seal-In liner, which can be another possible reason why they preferred the Seal-In liner.

The subjects reported less problems with sound in the CSS socket during walking. This finding is consistent with our previous study on subjects with transtibial amputation (Gholizadeh et al., 2012b,c). Moreover, sweating and smell decreased with the use of the Seal-In liner compared to the CSS, possibly because of the enhanced fitting between the skin and the liner in this system.

#### **5.1.1. Study Strengths**

The Seal-In liner has been introduced just recently, however, this study provides a qualitative data on a large number of transfemoral prosthetic users who experienced the use of Seal-In. Furthermore, all participants had used both systems, hence, they were able to compare between the CSS and the Seal-In liner. As the mean time since amputation was 23.80 years in the study sample, they could provide a better subjective feedback than the new prosthesis users.

#### **5.1.2. Study Limitations**

We acknowledge that all the participants were male individuals with traumatic amputation; therefore the findings cannot be generalized to females with transfemoral amputation or those with peripheralvascular disease. Another drawback of this

retrospective survey might be the fact that the participants had to recall their experience with the CSS system as they were all using Seal-in liners at the time that the study was conducted. Furthermore, the study approach was not mechanistic as it only relied on the participants' subjective statements regarding the suspension system. Hence, objective exploration is needed.

## **5.2. Gait evaluation (Pin/lock, Sealin)**

In this study, two different suspension systems, the pin/lock and suction, were compared in terms of their effect on kinetic and kinematic gait parameters. The systems had been previously studied both statically and dynamically to investigate the socket fit and the level of pistoning within the socket (Gholizadeh et al., 2012 a,b,c). The previous findings revealed that the suction suspension created a better socket fit.

Pitkin (1997) and Astrom and Stenstrom (2004) stated that the better the socket fit is, the lower would be the asymmetry between the sound and prosthetic legs, which will result in close to normal gait in amputees. This present study hypothesized that suction suspension can improve the amputee's gait and conjectured that gait symmetry would increase with the use of suction suspension system.

### **5.2.1. Ground reaction forces**

Ground reaction force mirrors the external forces applied to the legs (Engsberg et al., 1993; Stergiou et al., 2002). Two peaks can be detected in GRF; the first peak reflects the quality of shock absorption by the locomotor system during gait. Significant differences ( $p < 0.00$ ) were found in the vertical GRF (first peak) with both suspension systems. Research findings have shown significantly higher magnitude of the first peak vertical GRF for the sound limb. Therefore, the sound limb can bear more load than the

prosthetic limb during loading response (Vanicek et al., 2009; Bateni and Olney 2002). The magnitude of the first peak for sound limb in both systems was similar to the average magnitude in normal people (Winter, 1991; Perry, 1992).

Figure 4.1 shows an asymmetry in the timings of the first peak with the pin/lock system for the sound limb, as compared with the amputated leg when using suction or the Seal-In suspension system. The weight shift might then happened over a shorter period for the contralateral limb from double to single limb support. Hence, the participants had less confidence to bear weight (from heel strike to loading response) on the prosthetic side when using the pin/lock system. This finding also provides good evidence to support the previous questionnaire surveys (Ali et al., 2012a; Brunelli et al., 2013) that revealed more confidence when using the prosthetic device with the suction socket.

Moreover, vertical GRF graphs revealed that the midstance time on the prosthetic side (using suction or pin/lock system) was shorter than the sound side. There was no significant difference in the magnitude of the second GRF between the sound and prosthetic legs for none of the suspension systems, which can be interpreted that the subjects could bear similar loads on both the sound and prosthetic legs (with both systems) from midstance to toe off.

By looking at the pattern of resultant fore-aft GRF, similar acceleration forces (horizontal propulsive force) are evident for both legs; nevertheless, deceleration force (braking force toward posterior) is larger at the sound limb. Previous findings confirmed this observation with some slight differences in the magnitudes that can be attributed to the variations in the walking speed, prosthetic components, and prosthetic foot. Both the magnitude of deceleration force and the duration was dissimilar between the legs, with the sound limb having a shorter duration than the prosthetic side, which is similar with



the finding of Zmitrewicz et al. (2006). The deceleration force appeared later in the gait cycle for the prosthetic limb, specifically with the pin/lock system. As it was hypothesized, this may suggest that the participants were more confident to bear weight on the sound limb.

The propulsion forces with both the suction and pin/lock systems were of similar magnitudes for both the sound and prosthetic limbs. Propulsive forces contribute to steady speed of walking, balanced loading, and symmetrical gait pattern. The observed constant magnitudes of propulsion forces for the sound and prosthetic limbs signified a good balance (symmetry) between the legs, particularly with the suction suspension system.

### **5.2.2. Temporal-spatial parameters**

Time-distance parameters provide information about the position and timing of gait. The temporal-spatial results with the two suspension systems supported the findings of previous research (Winter, 1991; Perry, 1992; Isakov et al., 2000). Prosthetic gait is distinguished by a longer step length, lower walking speed, higher cadence, and higher swing time when compared with both normal individuals and the amputee's sound leg (Winter, 1991; Perry, 1992; Nolan et al, 2003).

In the current study, both suspension systems caused longer step length on the prosthetic side. Therefore, it can be interpreted as longer period of swing phase, which would be accompanied by a longer time of load bearing on the contralateral limb. Amputees adopt longer step lengths on prosthetic limbs to off-load the amputated side. There was also significant differences between the prosthetic and sound limbs with the suction ( $p<0.05$ ) and pin/lock systems ( $p<0.02$ ).

Walking speed indicates the ability to transfer load from one leg to another and to preserve forward momentum of body mass. The subjects that walked at a speed of 0.94 and 0.93 m/s when using the suction and pin/lock systems, respectively. TTB amputees walked at a lower speed compared with the able-bodied individuals (1.2–1.5 m/s) (Winter, 1991; Perry, 1992; Moosabhoy and Gard, 2006; Isakov et al., 2000). The tendency to walk at a slightly higher speed when using the suction system is possibly because of greater confidence that the subjects had with the prosthesis.

### **5.2.3. Joint angle**

The kinetic data provided the information on the angular and linear motions of the body segments. Both prosthetic (pin/lock and suction) and sound limbs were found to have similar angular motion at the hip and knee. The most remarkable difference was observed at the ankle joint, which is in line with previous studies on the different prosthetic ankle types that also determined that the ankle affected the degree of control over the prosthesis (Marinakis, 2004; Vanicek et al., 2009; Collins and Kuo 2010). Gait progression is altered when the anatomical ankle joint is missing, as the ankle plantar flexion generates over 80% of the mechanical power during normal walking. Not all prosthetic foot designs can compensate this action; therefore, various prosthetic feet result in different ankle joint angles.

The knee range of motion with the pin/lock system was more consistent between the prosthetic and sound limbs than with the suction socket (61.5, 52.5 vs. 70.7, and 56.1, respectively), and there was significant difference between the two systems.

There was asymmetry between ankle angles for right and left legs using both systems, specifically at the end of the stance and preswing phases. Maximum

dosiflexion at the stance phase reached 14.5 and 15.1 degrees in the suction and pin/lock systems, respectively, which was possibly due to more flexibility in the prosthetic foot.

During training in the prosthetic laboratory, all the subjects stated that the Talux foot was more comfortable than the foot they usually used, specifically during heel strike and push off. They claimed that the foot acted like a spring, and that it helped them to walk faster (Gholizadeh et al., 2012).

### **5.3. Mechanical evaluation (Holo)**

Prosthetists need to decide whether a suspension system is suitable or not for residual limb length, shape (i.e., cylindrical or conical), muscle strength, soft tissue, bony prominence, pain, aspiration of amputee, level of activity, upper limb strength, and amputee's financial situation. In this study, a new simple method for suspending the residual limb within the prosthetic socket was introduced and tested. Furthermore, the new system was compared with three different prosthetic suspension systems to examine the maximum tensile load that each system could bear and their effects on the patient's satisfaction.

#### **5.3.1. Mechanical test**

Based on the literature, load of 30 N to 50 N was applied on the prosthetic leg (suspension system) in the swing phase of gait. In each gait cycle, this amount of load was applied to the suspension system in less than one second during the swing phase (Perry, 1992). Weight of prosthesis is one factor that can influence the amputee's satisfaction with the device (Pezzin et al., 2004), specifically in children and elderly amputees. The results show that the prosthesis could be made lighter by using the Holo

system. The MPSS, pin/lock, and seal-in suspension systems were heavier than our new system by 15.3%, 11.1%, and 3%, respectively.

Among the four systems tested in this study, the pin/lock system could tolerate the highest loading (580 N). Our new suspension system could bear 490 N of tensile loading before it failed, which is almost 10 times more than the applied load in normal walking. This test proved that the safety of our system is similar to that of other suspension systems. Even after applying large amount of load, only 4 mm of vertical movement occurred within the socket in the new system (between the liner and socket walls) during the 30 seconds of tensile loading. The lesser movement in this new system is comparable to the MPSS (Eshraghi et al., 2013b) and the pin/lock systems and can be attributed to the full attachment between the liner (loop) and socket walls (hook). Low movement inside the prosthetic socket has significant effect on the function of the prosthesis and the amputee's satisfaction (Gholizadeh et al., 2012b,c; Eshraghi et al., 2012a, b).

#### **5.4. Pressure Mapping (Holo)**

Proper prosthetic rehabilitation relies on understanding the biomechanics of pressure between the socket and residual limb among other factors. Appropriate fit and suspension of the socket for individuals with lower limb amputation have substantial roles in the rehabilitation. The clinicians need to be conscious about the effects of various suspension methods and prosthetic socket designs on residual limb and user satisfaction. The interface pressure of various prosthetic sockets has been evaluated (Convery and Buis, 1999; Mak et al., 2001; Abu Osman et al., 2010; Özçakar et al., 2009; Sanders et al., 1997). The level of user satisfaction with a prosthesis is very much reliant on the appropriate pressure at the pressure-tolerant and pressure-relief areas of the residuum. This research evaluated the effect of a new suspension system (Holo) on

the pressure distribution inside the socket, as compared with the pin/lock suspension system.

The pressure distribution was almost even at the anterior, posterior, medial, and lateral surfaces during the stance in both systems. Less than 100 kPa average peak pressure was observed during the gait cycle, reflecting the outcomes of preceding studies on the TSB systems (Sanders et al., 2000; Dumbleton et al., 2009; Beil and Street, 2004). Pressure at the distal area of residual limb was higher than the proximal area (not the anterior side) throughout the stance with both systems, which is consistent with the findings of Dumbleton et al. (2009).

Prosthesis is suspended through the application of pressure at various sites of the stump that can considerably affect the comfort during ambulation. The pin/lock users experience traction at the distal stump during the swing phase (Beil and Street, 2004). Simultaneously, proximal tissues bear high compression that may interrupt the fluid stream. This phenomenon may cause vein problems and edema and can also result in the color change and skin thickening, specifically at the distal area of the residual limb (Beil and Street, 2004). This study conjectured that increased contact area with the Holo system may decrease the stretch. Significant differences were observed at different stump surfaces (Table 4.10). Less peak pressures were observed at the proximal and distal residual limb on all surfaces with the Holo system during the swing phase of gait, which agrees with the results of Beil and Street (2004) who reported a more uniform interface pressure with a suction system. The current research is in line with their findings as the distribution of pressure with the pin/lock was less uniform in comparison to the Holo system; however, Holo is not a suction system. Similar to the suction system, the residual limb had higher contact with the socket in the new system compared with the pin/lock suspension. High contact between the socket and stump

could produce a more uniform pressure. In Holo, the pressure was mostly concentrated at the middle of the residual limb, similar to the Seal-In liner (Ali et al., 2012b) and which might be due to the location of the Velcro in the new system, as compared with the seal area in the Seal-In system. This result also agrees with the findings of Ali et al. (2012b).

According to the literature, the Seal-In suspension system causes minimum pistoning inside the socket in comparison to the pin/lock suspension (Gholizadeh et al., 2012 b,c). Subjective feedback showed that less piston movement was created by the new suspension system within the socket.

Lanyard suspension system (US 20050256589 A1) comprises a lanyard cord that is attached to the distal part of the silicone liner, similar to the pin/lock system, and a lanyard lock mechanism is also attached to the end of the prosthetic socket. In this system, the silicone liner is fixed inside the socket by only a distal cord, and the liner can easily rotate inside the socket or create milking that is similar to the pin/lock system. However, in the Holo system, two Velcros (medial and lateral sides of the liner) fixed the liner inside the socket, and the liner is in contact with the socket on most of its surface, which could eliminate the rotation and milking problems.

#### **5.4.1. Questionnaire**

The PEQ is widely used to assess satisfaction with prosthesis and it has good reported validity and reliability. We used only some items of this questionnaire in this study. The soft silicone liner is attached to the socket only by a distal pin in the pin/lock systems; therefore, the users feel pain and distal end traction, primarily during the swing phase of gait (Street, 2006). Socket fit was stated to be lower compared to the new system. Yet, the users were generally satisfied with the new system owing to the easy procedure of

donning and doffing. The prosthesis use can change tremendously depending on the ease of donning and doffing, particularly in relation to the night-time toilet habits (Gholizadeh et al, 2014 a,b,c). Firm bound between the socket walls and soft liner in the Seal-In liners may produce a sense of confidence for the users during walking. However, donning and doffing is a demanding task, mainly for the elderly or amputees with upper limb disorders, such as stroke. In the new system, the liner is fixed firmly to the socket walls like the Seal-In liners; yet, the donning and doffing is as easy as with the pin/lock system (Gholizadeh et al., 2014c). Based on the literature, it can be difficult for amputees with long residuum to use the pin/lock system (transfemoral, transtibial and knee disarticulation). Similarly, if the user has stump contracture, it can be challenging to align the pin. With the HOLO (Gholizadeh et al., 2014c), extra space is not needed at the end of socket and it is a good option for residual limbs with long length and contracture.

#### **5.4.2. Limitation and strength**

Variation in the residual limb dimensions may affect the pressure distribution;. Thus, a larger sample size is needed to find possible relationships between the dimension of residual limb and pressure distribution. The pressure profile can be also compared for various activities and walking surfaces.

In this study, a registered prosthetist performed all the processes from the casting to aligning the new prostheses. Same socket, prosthetic components (foot, pylon, and silicone liner), and alignment were used for both suspension systems to decrease the bias in the results.

## **5.5. Case Report (Pressure/Gait)**

### **5.5.1. Pressure mapping**

High values of interface pressure have been reported at the anterior proximal socket (PTB bar) with the PTB design. In this case study, the magnitude of pressure applied to the anterior proximal region of the PTB prosthesis with 6 mm silicone liner was 10, 8, and 12 times higher than the distal region during level walking, slop up and down, respectively. Additionally, the pressure was 7 and 11 times higher than the distal region during stairs ascent and descent.

Able-bodied individuals can easily negotiate ramps and stairs. However, these tasks can become challenging when the motor functions are altered because of the limb loss. The anterior proximal socket area exhibited higher mean peak pressure during the stair and ramp ascent and descent, which is consistent with the findings of Dou et al. (2006). However, Wolf et al. (2009) reported high pressure at the anterior distal region during the stair ascent, which is contrary to our findings. Dou et al. (2006) also observed an increased pressure at the anterior proximal and posterior proximal (popliteal area) regions during the ramp ascent, which is consistent with our observations.

The pin/lock liners exert compression on the residual limb proximally and tension distally during the swing phase of gait (milking) (Beil and Street, 2004). This milking phenomenon is probably the cause of short (edema and redness) and long-term (discoloration and thickening) transformations, particularly at the distal end of the residuum (Beil and Street, 2004, Street, 2006). Similarly, we found that the pressure was higher with the amputee's former prosthesis (the pin/lock system) during the swing phase of gait (Figure 4.4). Subjective feedback showed improved contact between the liner and socket and decreased traction and rotation inside the socket with the new



system. The subject also reported a stretch at the distal tissue of the residual limb during the swing phase using the pin/lock system.

The average magnitudes of pressure within the new socket was less than 80 kPa that mirrored the findings of previous studies on the TSB systems (Dumbleton et al., 2009; Ali et al., 2012b). Moreover, pressure was distributed quite evenly in the new TSB socket without the pin/lock suspension during ambulation (Figure 4.4 and 4.5).

The subject stated that she was satisfied with the new socket. She could not feel any difference between the systems during sitting. The walking velocity was not measured, but subjective feedback revealed faster walking with the new prosthesis and less traction and pain at the end of the stump. The subject was also more satisfied with the donning and doffing procedures of the new system because there was no pin to align. Furthermore, she was more confident during walking with the new prosthesis without any rotation inside the socket compared to the old prosthesis. Interestingly, she could not walk with her old prosthesis after two months because it caused her excessive pressure over the anterior proximal aspect of the socket (patellar ligament).

Different suspension systems distribute the pressure differently over the residual limb (Eshraghi et al., 2013a). Based on our findings, the patellar tendon was the main site of weight bearing within the PTB socket with the silicone liner during ambulation. Dietzen et al.(1991) mentioned the use of Velcro as suspension system for transfemoral amputees, however, that system is a kind of lanyard system. The use of Velcro instead of the rope is the only difference with the new system (Dietzen et al.,1991). Two pieces of Velcro (medial and lateral sides of the liner) fixed the liner inside the socket (not the distal part) in the new system, which could decrease the rotation and milking problems. Furthermore, using the Velcro can be a good alternative for lower limb amputees with

unusual stump shape. The new suspension method might reduce the traction at the end of the residual limb during the swing phase of gait and facilitate prosthesis donning.

### **5.5.2. Gait evaluation**

Proper fitting of the prosthetic socket and surgery for lower limb amputees have substantial roles in the rehabilitation. Prosthesis design and function are contingent on the length of the residual bone among other factors (Smith, 2004). Furthermore, the prosthetic function is influenced by the coverage of soft-tissue (end of the stump) as the sore residual limb will limit the force that the amputee can comfortably generate to control the prosthesis (Smith, 2004). Good socket fit is said to result in less asymmetry between the prosthetic and sound legs, leading to close-to-normal gait (Åström and Stenström, 2004). Clinicians should pay attention to the effects of the different suspension methods and prosthetic sockets on the residual limb and satisfaction. In this case study, two different suspension (Velcro and pin/lock) and socket designs (TSB, PTB) were compared for an unusual case of transtibial amputation.

The articular cartilage along the trochlear groove and below the patella wears away and gets swollen when the patellofemoral joint is affected, which can be caused by the mismatch patella and femur trochlear groove during the knee motion and that there is an excessive stress on the cartilage (Saleh, Arendt et al. 2005). Consequently, the cartilage erodes and the affected person feels crackling sensation (crepitus) when moving the knee, which can be so loud at times that others can hear it. As the damage increases, the kneecap is stuck when the knee is extended. With the old prosthesis, the pressure magnitude applied to the anterior proximal was extremely high during ambulation. The increased stresses on the cartilage and the change in the position of patella on the trochlear groove probably wears down the cartilage in short term.

GRF is a representative of the external forces exerted on the lower limbs (Engsberg et al. 1993). GRF has two main peaks; the first one mirrors the degree of shock absorption during gait. In prosthetic research, higher first peak vertical GRF of the sound limb has been reported. During loading response, more load might be tolerated by the sound leg compared to the prosthetic limb (Vanicek et al. 2009). The value of the first peak of the sound limb was comparable to the mean value of normal individuals with all the systems (Eng and Winter 1995). On the contrary, the prosthetic limb exhibited a higher magnitude of the second peak GRF with all prostheses (Figure 4.7). With the Velcro system, the first and second peaks were higher on the prosthetic side as compared to the old prosthesis and new prosthesis with the pin/lock system. Therefore, the user was more confident to walk using the new socket with Velcro suspension system, supporting the subject's feedback on having more confidence with the Velcro mechanism.

There was asymmetry in the timings of the first peak of the prosthetic leg compared to the sound limb (Figure 4.7), which can be attributed to the shorter time of the weight shift for the sound limb from the double to single limb support. Thus, the subject was less confident to put weight on the prosthesis from heel strike to loading response. Furthermore, the graphs of vertical GRF demonstrate that the time of midstance was shorter for the prosthetic limb than the sound side. Likewise, the sound and prosthetic legs showed similar magnitudes of 2nd GRF (Figure 4.7), implying that the patient applied comparable loads to both legs from the midstance to toe off.

The pattern of fore-aft GRF reveals similar acceleration forces for the new socket with pin/lock and Velcro (7.5 (1.4) and 8.1 (2.9) N, respectively). The new systems showed acceleration forces nearly three times the old prosthesis (2.4 (1.7) N). Propulsive (acceleration) forces control the walking speed and balance the loading for a

symmetrical gait pattern. The prosthetic limbs showed lower magnitudes of propulsion forces than the sound limb, particularly with the old prosthesis (10.8 times lower), indicating less symmetry. The extent of propulsion forces for the prosthetic legs was 3.1 and 3.4 times lower in the new socket with Velcro and pin/lock, respectively. The duration of deceleration force was also dissimilar between the legs, as the duration was shorter for the sound leg than the prosthetic side, which agrees with the findings of Zmitrewicz et al. (2006). The deceleration force was also observed later in the gait of the prosthetic leg, particularly with the old prosthesis.

Position and timing of gait are extracted from the time-distance parameters. The prosthetic gait is differentiated by higher cadence, longer step length, and longer swing time (Winter, et al. 1990, Perry and Davids 1992). In this study, longer step length was observed on the prosthetic side in all the systems, which can be inferred as a longer swing phase, together with a longer load bearing on the sound limb. Speed of walking denotes the ability to shift load from one leg to another and to maintain an advancing momentum of the body weight. Lower limb amputees walk slower than the healthy individuals (1.2–1.5 m/s) (Winter et al. 1990, Perry and Davids 1992, Vanicek et al. 2009). Our subject's walking speed was 0.92 m/s with the new Velcro system that was slightly higher than the old prosthesis (0.90 m/s).

Nearly similar range of motion at the ankle, knee, and hip joints were observed with all the prostheses. The greatest difference between the prosthesis and sound limb was observed at the ankle joint, which conforms to the previous findings (Marinakis 2004, Collins and Kuo 2010). At the absence of the anatomical ankle joint, gait progression is altered as the ankle plantar flexion produces more than 80% of the power during walking in healthy individuals. Our results (maximum ankle plantar flexion at toe off) also showed a significant difference between the sound limb and prosthetic side

in all the systems with identical prosthetic foot. Furthermore, at the stance phase, the peak dorsiflexion of the prosthetic side was higher for all the systems compared to the sound limb, which can be attributed to the elasticity of the prosthetic foot.

## CHAPTER 6

### CONCLUSION AND FUTURE DIRECTIONS

In this chapter, the findings of the publications are summarized. Directions for forthcoming research are suggested to expand the research outcomes.

#### 6.1. Summary and conclusions

Amputee's rehabilitation is a challenging procedure which requires expertise, specifically in the selection of prosthetic components based on amputee's need. All our hypothesis in this research were accepted (null hypothesis is rejected). The following conclusions are drawn for each specific objective.

- I. Prosthetic satisfaction is a multi-factorial issue. The majority of participants with transfemoral amputation were more satisfied with the Seal-In liner than the common suction socket. If the durability of the Seal-In liner were increased in some way, it would address the main issue with Seal-in liners.
- II. The amputee's gait performance was positively influenced by the Seal-in liner because of the better suspension and fit within the socket compared to pin/lock system. Nevertheless, the overall satisfaction with prosthesis was higher with the pin/lock system because of the easy donning and doffing. Good prosthetic suspension system must secure the residual limb inside the prosthetic socket and make donning and doffing procedures easier.
- III. The new suspension system is a good alternative for individuals with transtibial amputation as it could solve some problems with the current systems. This system may

have some advantages for amputees, including the ease of donning/doffing, firm attachment to the socket, low weight, and low cost.

IV. Pressure distribution within the socket could be affected by the socket design and the suspension system. The use of Velcro as suspension system might facilitate the donning of prosthesis and reduce traction at the end of the residual limb during the swing phase of gait. The new coupling system was proved compatible with the pin/lock system in terms of suspending the leg and amputee's satisfaction.

V. Holo suspension system had positive effect on the amputee's gait performance because of the better socket fit and suspension. Moreover, less time and effort were needed to wear the prosthesis; less pain and traction were also created at the distal residual limb.

## **6.2. Direction for future research**

This present study proposed a promising suspension system for lower limb amputees with improved interface pressure distribution, gait biomechanics during walking, and finally enhanced the amputees satisfaction rates. Further research is needed to evaluate more amputees (upper and lower limbs) and to prepare a guideline for the selection of the suspension system. Moreover, sweat control was found to be a major concern with the available prosthetic soft liners. The donning and doffing procedure for soft liners is also problematic for some users, particularly those with upper limb weakness.

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## **APPENDIXES**

**APPENDIX A1, A2** (Medical Ethics committee approvals)

**APPENDIX B**(General contribution of the research and Awards)

**APPENDIX C** (Publications)

**APPENDIX D** (Check list for the systematic literature review)

**APPENDIX E1, E2** (Prosthetic components donated by Ossur company)

**APPENDIX F** (Abbreviation)

**APPENDIX G** (Visualization of the research)

## Appendix A1 (Seal-in liner and Dermo liner)

15 Sya'aban 1431H  
27 Julai 2010

**Mr. Hossein Gholizadeh Vazvani**  
Jabatan Kejuruteraan Bioperubatan  
Fakulti Kejuruteraan  
Universiti Malaya



Tuan,

**SURAT PEMAKLUMAN KEPUTUSAN PERMOHONAN MENJALANKAN PROJEK PENYELIDIKAN**

Fundamental study of differences between seal-in and locking liners on gait and comfort in trans-tibial amputees

Protocol No. :

**MEC Ref. No : 799.7**

Dengan hormatnya saya merujuk kepada perkara di atas.

Bersama-sama ini dilampirkan surat pemakluman keputusan Jawatankuasa Etika Perubatan yang bermesyuarat pada 21 Julai 2010 untuk makluman dan tindakan tuan selanjutnya.

2. Sila maklumkan kepada Jawatankuasa Etika Perubatan mengenai butiran kajian samada telah tamat atau diteruskan mengikut jangka masa kajian tersebut.

Sekian, terima kasih.

Yang benar,

Norashikin Mahmood  
Seliasaha  
Jawatankuasa Etika Perubatan  
Pusat Perubatan Universiti Malaya

s.k Ketua  
Jabatan Kejuruteraan Bioperubatan  
Fakulti Kejuruteraan  
Universiti Malaya

## Appendix A2 ( Design and evaluation of a new suspension system)



**UNIVERSITI  
MALAYA**

**PUSAT PERUBATAN UM**

**MEDICAL ETHICS COMMITTEE  
UNIVERSITY MALAYA MEDICAL CENTRE**

ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA  
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

|  |                |   |
|--|----------------|---|
| <b>NAME OF ETHICS COMMITTEE/IRB:</b><br>Medical Ethics Committee, University Malaya Medical Centre   |                | <b>ETHICS COMMITTEE/IRB REFERENCE NUMBER:</b><br><br>907.26 |
| <b>ADDRESS:</b> LEMBAH PANTAI<br>59100 KUALA LUMPUR  |                |   |
| <b>PROTOCOL NO:</b><br><br><b>TITLE:</b> Design, development and clinical evaluation of a new prosthetic suspension system for lower limb amputees |                |   |
| <b>PRINCIPAL INVESTIGATOR:</b> Mr. Arezoo Eshraghi   |                | <b>SPONSOR:</b><br>FRGS                                     |
| <b>TELEPHONE:</b>  | <b>KOMTEL:</b> |   |

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

- [✓] Application Form
- [✓] Study Protocol
- [ ] Investigator's Brochure
- [✓] Patient Information Sheet
- [✓] Consent Form
- [ ] Questionnaire
- [✓] Investigator(s) CV's (Mr. Arezoo Eshraghi)

Ver date: 06 Mar 12

Ver date:

Ver date:

and have been [✓]

- [✓] Approved
- [ ] Conditionally approved (identify item and specify modification below or in accompanying letter)
- [ ] Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

*Investigator are required to:*

- 1) follow instructions, guidelines and requirements of the Medical Ethics Committee.
- 2) report any protocol deviations/violations to Medical Ethics Committee.
- 3) provide annual and closure report to the Medical Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.
- 5) note that Medical Ethics Committee may audit the approved study.

Date of approval: 21<sup>st</sup> MARCH 2012

c.c Head  
Department of Biomedical Engineering  
Faculty of Engineering, UM

Deputy Dean (Research)  
Faculty of Medicine

Secretary  
Medical Ethics Committee  
University Malaya Medical Centre

**PROF. DATUK LOOI LAI MENG**  
Chairman  
Medical Ethics Committee

## Appendix B1 (Patent 1)



Our Ref : 2014/PT/TMI/PTA6.49/APP/0176/LLK  
Your ref: UM.TNC2/UMCIC/603/508  
Date : 21 FEBRUARY 2014

By email, fax: 03-79676291  
(without enclosure) & post

**UNIVERSITY OF MALAYA**  
Pusat Inovasi Dan Pengkomersilan (UMCIC),  
Aras 5, Kompleks Ippp Dan Makmal Kemudahan Berpusat,  
Universiti Malaya,  
50603 Kuala Lumpur, Malaysia.  
[Attn: Prof Loo Chu Kiong/Prof. Dr. Rofina Yasmin Othman /Mr Ashraf/ Mdm Mawar/  
Cik Ainol]

Dear Sir/Madam,

|                           |  |
|---------------------------|--|
| <b>Title</b>              | <b>: A LIMB PROSTHESIS SUSPENSION SYSTEM</b>                                   |
| <b>Application Number</b> | <b>: PI2014700107</b>  |
| <b>Filing Date</b>        | <b>: 15 JANUARY 2014</b>   |
| <b>Country</b>            | <b>: MALAYSIA</b>  |
| <b>Applicant</b>          | <b>: UNIVERSITI MALAYA</b>   |
| <b>Inventor</b>           | <b>: 1. ASSOC PROF DR NOOR AZUAN ABU OSMAN</b><br><b>2. HOSSEIN GHOLIZADEH</b> |

We refer to the above matter.

Kindly find enclosed herewith copies of:

1. Certificate of Filing
2. Preliminary Examination – Clear Formalities report
3. Patent Form 5 – Request for Substantive Examination

We shall attend to the necessary and keep you duly informed. Should you require further information, please do not hesitate to contact us.

Thank You.

Yours sincerely,

**TRADEMARK2U SDN BHD**

  
**LAU LI KIAW**  
[PATENT DEPARTMENT]

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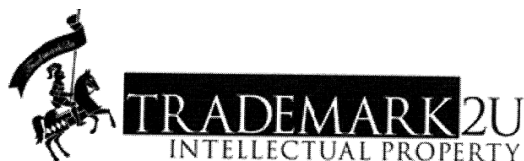
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NRIC No :  
Date :

**TRADEMARK2U SDN BHD** (670910-M)  
Registered Trademark, Industrial Design, Patent Agent/Consultant  
No. 1, Block C, Jalan Dataran SD 1, Dataran SD PJU 9,  
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Tel: (603) 6274 5352 Fax: (603) 6274 4795, 6273 6388  
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## Appendix B2 (Patent2)



Our Ref : 2013/PT/TMI/PTA5.68/APP/0209/CJW  
Your ref: UM.TNC2/UMCIC/603/517  
Date : 3<sup>rd</sup> April 2013

By email, fax: 03-79676291  
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**UNIVERSITY OF MALAYA**  
PUSAT INOVASI DAN PENGKOMERSILAN (UMCIC),  
ARAS 5 KOMPLEKS IPPP DAN MAKMAL KEMUDAHAN  
BERPUSAT, UNIVERSITI MALAYA,  
50603, KUALA LUMPUR, MALAYSIA.  
[Attn: Dr Yusniza Kamarulzaman/Mr Ashraf/Mdm Mawar/Cik Ainol]

Dear Madam,

**Title : LINER FOR PROSTHETIC LIMB**  
**Application Number : PI 2013700414**  
**Filing Date : 13<sup>th</sup> MARCH 2013**  
**Country : MALAYSIA**  
**Applicant : UNIVERSITI MALAYA**  
**Inventor : PROF MADYA DR NOOR AZUAN ABU OSMAN; HOSSEIN GHOLIZADEH**

We refer to the above matter.

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1. Certificate of Filing
2. Preliminary Examination – Clear Formalities report
3. Patent Form 5 – Request for Substantive Examination

We shall attend to the necessary and keep you duly informed. Should you require further information, please do not hesitate to contact us.

Thank You.

Yours sincerely,

**TRADEMARK2U SDN BHD**

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**[PATENT DEPARTMENT]**

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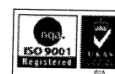
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(Signature & Company stamp)

Name :  
NRIC No :  
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**TRADEMARK2U SDN BHD** (670910-M)  
**Registered Trademark, Industrial Design, Patent Agent/Consultant**  
No. 1, Block C, Jalan Dataran SD 1, Dataran SD PJU 9,  
Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia.  
Tel: (603) 6274 5352 Fax: (603) 6274 4795, 6273 6388

Email: [sales@trademark2u.com](mailto:sales@trademark2u.com)

Website: [www.trademark2u.com](http://www.trademark2u.com)



Certificate No. : 19668



## Appendix B3 (Awards)

- **Ministry of Higher Education Bright Sparks Fellowship**, 2012
- Awarded with **Forchheimer** prize, ISPO 2013
- Awarded with **Gold medal** in the *ITEX 2013* for the “*A Novel Eco-Friendly Prosthetic Suspension System*” in the 24<sup>th</sup> International Invention, Innovation & Technology Exhibition, Kuala Lumpur, Malaysia
- Awarded with **Gold medal** in the *ITEX 2012* for the “*New Suspension Device For Lower Limb Prostheses*” in the 23<sup>rd</sup> International Invention, Innovation & Technology Exhibition, Kuala Lumpur, Malaysia
- Awarded with **Silver medal** in the *Malaysia Technology Expo 2012* for the “*Novel prosthetic suspension system*”, Kuala Lumpur, Malaysia

**Appendix B4 (Accepted for commercialization by Ossur (Iceland))**

**First prototype (silicone liner with loop fabric)**



# Appendix C1 (The research described in this thesis led to the following ISI publication)

**1.Gholizadeh, H.,** Abu Osman, N. A., Eshraghi, A., Ali, S., & Razak, N. A. Transtibial prosthesis suspension systems: Systematic review of literature. **Clinical Biomechanics**, Q2

Clinical Biomechanics 29 (2014) 87–97



Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: [www.elsevier.com/locate/clinbiomech](http://www.elsevier.com/locate/clinbiomech)



Review

## Transtibial prosthesis suspension systems: Systematic review of literature

H. Gholizadeh\*, N.A. Abu Osman, A. Eshraghi, S. Ali, N.A. Razak

Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Malaysia

### ARTICLE INFO

Article history:  
Received 22 June 2013  
Accepted 21 October 2013

Keywords:  
Transtibial prostheses  
Prosthetic liner  
Prosthetic suspension  
Lower limb prosthesis  
Below-knee prosthesis  
Prosthetic socket  
Amputees

### ABSTRACT

**Background:** Today a number of prosthetic suspension systems are available for transtibial amputees. Consideration of an appropriate suspension system can ensure that amputee's functional needs are satisfied. The higher the insight to suspension systems, the easier would be the selection for prosthetists. This review attempted to find scientific evidence pertaining to various transtibial suspension systems to provide selection criteria for clinicians.

**Methods:** Databases of PubMed, Web of Science, and ScienceDirect were explored to find related articles. Search terms were as follows: "Transtibial prosthesis (32), prosthetic suspension (48), lower limb prosthesis (54), below-knee prosthesis (58), prosthetic liner (20), transtibial (193), and prosthetic socket (111)". Two reviewers separately examined the papers. Study design (case series of five or more subjects, retrospective or prospective), research instrument, sampling method, outcome measures and protocols were reviewed.

**Findings:** Based on the selection criteria, 22 articles (15 prospective studies, and 7 surveys) remained. Sweat control was found to be a major concern with the available suspension liners. Donning and doffing procedures for soft liners are also problematic for some users, particularly those with upper limb weakness. Moreover, the total surface bearing (TSB) socket with pin/lock system is favored by the majority of amputees.

**Interpretation:** In summary, no clinical evidence is available to suggest what kind of suspension system could have an influential effect as a "standard" system for all transtibial amputees. However, among various suspension systems for transtibial amputees, the Iceross system was favored by the majority of users in terms of function and comfort.

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### 1. Introduction

A number of prosthetic suspension systems are available for transtibial amputees. Not only the amputee's functional needs, but also satisfaction with prosthesis should be taken into account when selecting an appropriate suspension system. The clearer the insight into suspension systems, the easier will be the selection for prosthetist (Eshraghi et al., 2012a; Gholizadeh et al., 2012a,b; Schaffalitzky et al., 2012; Zhang et al., 1998).

Non-use or limited use of prosthetic devices is a concern for any rehabilitation team. The provision of a good prosthetic suspension system is the key element in the rehabilitation process of persons with lower limb amputation (Garrison, 2003; Gholizadeh et al., 2012a,b; Kapp, 1999; Nelson et al., 2006; Schaffalitzky et al., 2012; Zhang et al., 1998). Excessive translation, rotation, and vertical movements between residual limb and socket should be prevented through the suspension system (Eshraghi et al., 2012b; Gholizadeh et al., 2011, 2012a,b,d; Klute et al., 2011; Smith et al., 2004). As amputees' statements and research findings suggest, suspension and prosthetic fit are strongly related to functional efficiency and comfort levels (Beil et al., 2002; Gholizadeh et al., 2012a). Walking pattern, residual limb soft tissue and skin, and comfort can be jeopardized by poor suspension (Gholizadeh et al., 2012a,b,d; Papaioannou et al., 2010; Peery et al., 2005; Smith et al., 2004).

\* Corresponding author.  
E-mail addresses: [hgholizadeh@um.edu.my](mailto:hgholizadeh@um.edu.my), [hgholizadeh87@yahoo.com](mailto:hgholizadeh87@yahoo.com) (H. Gholizadeh).

The introduction of new designs and materials revolutionized the design of transtibial prostheses after World War II (Sewell et al., 2000). A thigh corset was used as suspension years prior to the introduction of the patellar-tendon bearing (PTB) prosthesis (Radcliffe et al., 1961). The PTB socket quickly became popular, and subsequently, various materials and suspension methods were applied (Sewell et al., 2000). Afterwards, the silicone suction suspension (3S) (Fillauer et al., 1989) and Iceross (Baars and Geertzen, 2005; Kristinsson, 1993) sockets were introduced to the market. These systems were characterized by improved techniques of suspension, total surface bearing (TSB), and hydrostatic loading (Sewell et al., 2000; Staats and Lundt, 1987).

Another popular suspension system in lower limb prostheses is the soft socket or liner that comes with accessories, such as a lock system that bonds to other prosthetic components (Gholizadeh et al., 2012a; Kristinsson, 1993). Although a number of prosthetic suspension systems are available, physicians and prosthetists set selection criteria mainly based on subjective experiences (van der Linde et al., 2004). Ideally, prosthetic prescription should follow the biomechanical characteristics to fulfill the amputees' needs. Clinical prescription guidelines should be provided for prosthetic suspension systems to ensure efficient and consistent health care. A systematic literature review may contribute significantly to the development of such guideline as it can bring knowledge gaps to light (van der Linde et al., 2004; Woolf et al., 1999). To the best of the authors' knowledge, there is no consensus over selection criteria and no sound technical guideline is available (Dasgupta et al., 1997; van der Linde et al., 2004).

# Appendix C2

## 2. Gholizadeh H, Abu Osman NA, Eshraghi A, Transfemoral prosthesis suspension systems: systematic review of literature, *American journal of Physical Medicine and Rehabilitation* Q1

### Authors:

Hossein Gholizadeh, MEngSc  
Noor Azuan Abu Osman, PhD  
Arezo Eshraghi, MSc  
Sadeeq Ali, BSc

### Affiliations:

From the Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Kuala Lumpur, Malaysia.

### Correspondence:

All correspondence and requests for reprints should be addressed to: Hossein Gholizadeh, MEngSc, Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, 50603 Kuala Lumpur, Malaysia.

### Disclosures:

Hossein Gholizadeh, Arezo Eshraghi, and Sadeeq Ali are PhD students. Supported by Malaysia UM/MOHE/HIR (project no. D000014-16001). Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.

### Editor's Note:

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site ([www.ajpmr.com](http://www.ajpmr.com)).

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*American Journal of Physical Medicine & Rehabilitation*  
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DOI: 10.1097/PHM.0000000000000094

[www.ajpmr.com](http://www.ajpmr.com)

Limb Prosthesis

## LITERATURE REVIEW

### Transfemoral Prosthesis Suspension Systems

#### A Systematic Review of the Literature

#### ABSTRACT

Gholizadeh H, Abu Osman NA, Eshraghi A, Ali S: Transfemoral prosthesis suspension systems: a systematic review of the literature. *Am J Phys Med Rehabil* 2014;00:00-00.

The purpose of this study was to find the scientific evidence pertaining to various transfemoral suspension systems to provide selection criteria for clinicians. To this end, databases of PubMed, Web of Science, and ScienceDirect were explored. The following key words, as well as their combinations and synonyms, were used for the search: *transfemoral prosthesis, prosthetic suspension, lower limb prosthesis, above-knee prosthesis, prosthetic liner, transfemoral, and prosthetic socket*. The study design, research instrument, sampling method, outcome measures, and protocols of articles were reviewed. On the basis of the selection criteria, 16 articles (11 prospective studies and 5 surveys) were reviewed. The main causes of reluctance to prosthesis, aside from energy expenditure, were socket-related problems such as discomfort, perspiration, and skin problems. Osseointegration was a suspension option, yet it is rarely applied because of several drawbacks, such as extended rehabilitation process, risk for fracture, and infection along with excessive cost. In conclusion, no clinical evidence was found as a "standard" system of suspension and socket design for all transfemoral amputees. However, among various suspension systems for transfemoral amputees, the soft insert or double socket was favored by most users in terms of function and comfort.

**Key Words:** Rehabilitation, Limb Prosthesis, Amputation Stumps, Walking, Review

Transfemoral Prosthesis Suspension Systems

1



## Appendix C3

3. Gholizadeh, H., Abu Osman, N. A., Eshraghi, A., Ali, S., & Yahyavi, E. S. (2013). Satisfaction and problems experienced with transfemoral suspension systems: a comparison between common suction socket and Seal-In liner. **Q1**



Archives of Physical Medicine and Rehabilitation

journal homepage: [www.archives-pmr.org](http://www.archives-pmr.org)

Archives of Physical Medicine and Rehabilitation 2013;94:1584-9



### ORIGINAL ARTICLE

## Satisfaction and Problems Experienced With Transfemoral Suspension Systems: A Comparison Between Common Suction Socket and Seal-In Liner



Hossein Gholizadeh, MEngSc,<sup>a,b</sup> Noor Azuan Abu Osman, PhD,<sup>a</sup> Arezoo Eshraghi, PhD,<sup>a,b</sup> Sadeeq Ali, MEngSc,<sup>a</sup> Elham Sadat Yahyavi, MEngSc<sup>b,c</sup>

From the <sup>a</sup>Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Kuala Lumpur, Malaysia; <sup>b</sup>Orthotics and Prosthetics Department, Faculty of Rehabilitation Sciences, Tehran University of Medical Sciences, Tehran, Iran; and <sup>c</sup>Department of Electrical and Electronic Engineering, Faculty of Engineering and Built Environment, University Kebangsaan Malaysia, Bangi, Malaysia.

### Abstract

**Objective:** To compare a seal-in liner with the common suction socket with regards to patient satisfaction and problems experienced with the prosthesis.

**Design:** Retrospective survey.

**Setting:** A medical and engineering research center and a department of biomechanical engineering.

**Participants:** Men (N=90) with traumatic transfemoral amputation who used both suspension systems participated in the study.

**Intervention:** Two prosthetic suspension systems: a seal-in liner and common suction socket.

**Main Outcome Measures:** Two questionnaires were completed by each subject to evaluate their satisfaction and problems experienced with the 2 suspension systems. Satisfaction and problems with the prosthetic suspension systems were analyzed in terms of fitting, donning and doffing, sitting, walking, stair negotiation, appearance, sweating, wounds, pain, irritation, pistoning, edema, smell, sound, and durability.

**Results:** The study revealed that the respondents were more satisfied with a seal-in liner with regards to fitting, sitting, and donning and doffing. Overall satisfaction increased with the use of a seal-in liner compared with the suction socket ( $P<.05$ ). However, satisfaction with the prosthesis showed no significant differences in terms of walking (flat and uneven surfaces), appearance, and stair negotiation. Furthermore, problems experienced differed significantly between the 2 suspension systems ( $P<.05$ ). Sweating, wounds, pain, irritation, pistoning, edema, smell, and sound were less problematic with the use of a seal-in liner, whereas durability was significantly better with the suction socket.

**Conclusions:** The results of the survey suggest that satisfaction and problems with prosthetic suspension in persons with transfemoral amputation can be improved with a seal-in liner compared with the suction socket, provided that the durability of the liner is enhanced.

Archives of Physical Medicine and Rehabilitation 2013;94:1584-9

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Choice of suspension system and socket fit have significant influence on a patient's comfort, mobility, and satisfaction with prosthetic devices.<sup>1-3</sup> The suspension system prevents rotation, translation, and vertical movement of the prosthesis in relation to the residual limb. Poor suspension can have negative effects on rehabilitation and can affect the mobility level and comfort of persons with transtibial amputation.<sup>1,4</sup> While this may also apply to

individuals with transfemoral amputation, it has not yet been investigated.

Presently, a number of prosthetic suspension systems are used with transfemoral prostheses; among them are the Silesian belt, hip joint with pelvic band, suction socket, and silicone liners with or without a shuttle lock.<sup>5-7</sup> A Silesian belt and hip joint with pelvic band provide easier donning for geriatric users and good suspension for users with a short residual limb.<sup>5,8,9</sup> Conventional suction suspension consists of a hard socket with a 1-way valve at the distal end of the socket. A suction suspension system allows greater freedom of mobility, maximizes the use of the residual limb's remaining muscles, and provides more comfort and good

Supported by Malaysia (grant no. UM/HR/MOHE D000014-16001).  
No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

0003-9993/13/\$36 - see front matter © 2013 by the American Congress of Rehabilitation Medicine  
<http://dx.doi.org/10.1016/j.apmr.2012.12.007>

# Appendix C4

## 4.Gholizadeh H, Abu Osman NA, Eshraghi A, Ali S. The Effects of Suction and Pin/Lock Suspension Systems on Transtibial Amputees' Gait Performance , PLOS ONE,Q1

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PLOS ONE

### The Effects of Suction and Pin/Lock Suspension Systems on Transtibial Amputees' Gait Performance



Hossein Gholizadeh\*, Noor Azuan Abu Osman, Arezoo Eshraghi, Sadeeq Ali

Department of Biomedical Engineering, Faculty of Engineering, University of Malaya, Kuala Lumpur, Malaysia

#### Abstract

**Background:** The suction sockets that are commonly prescribed for transtibial amputees are believed to provide a better suspension than the pin/lock systems. Nevertheless, their effect on amputees' gait performance has not yet been fully investigated. The main intention of this study was to understand the potential effects of the Seal-in (suction) and the Dermo (pin/lock) suspension systems on amputees' gait performance.

**Methodology/Principal Findings:** Ten unilateral transtibial amputees participated in this prospective study, and two prostheses were fabricated for each of them. A three-dimensional motion analysis system was used to evaluate the temporal-spatial, kinematics and kinetics variables during normal walking. We also asked the participants to complete some part of Prosthesis Evaluation Questionnaire (PEQ) regarding their satisfaction and problems with both systems. The results revealed that there was more symmetry in temporal-spatial parameters between the prosthetic and sound limbs using the suction system. However, the difference between two systems was not significant ( $p < 0.05$ ). Evaluation of kinetic data and the subjects' feedback showed that the participants had more confidence using the suction socket and the sockets were more fit for walking. Nevertheless, the participants had more complaints with this system due to the difficulty in donning and doffing.

**Conclusion:** It can be concluded that even though the suction socket could create better suspension, fit, and gait performance, overall satisfaction was higher with the pin/lock system due to easy donning and doffing of the prosthesis.

**Trial Registration:** irct.ir IRCT2014012816395N1

**Citation:** Gholizadeh H, Abu Osman NA, Eshraghi A, Ali S (2014) The Effects of Suction and Pin/Lock Suspension Systems on Transtibial Amputees' Gait Performance. PLoS ONE 9(5): e94520. doi:10.1371/journal.pone.0094520

**Editor:** Amir A. Zadpoor, Delft University of Technology (TUDelft), Netherlands

**Received:** April 24, 2013; **Accepted:** March 14, 2014; **Published:** May 14, 2014

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**Funding:** This study was supported by Malaysia UM/MOHE/HIR (Project Number: D000014-16001). The prosthetic components were donated by Össur (Reykjavik, Iceland). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing Interests:** The authors declare that this study was supported by Malaysia UM/MOHE/HIR Project No. D000014-16001 and all prosthetic components were donated by the Össur (Reykjavik, Iceland). We contacted (Jun 2010) Össur regarding the possibility of donation of prosthetic components and providing some technical information. We did not receive any financial support through this company and they only donated the components. All the authors declare that no benefits in any form have been received or will be received from Össur. Furthermore, this does not alter our adherence to all the PLOS ONE policies on sharing data and materials.

\* E-mail: gholizadeh@um.edu.my

#### Introduction

Suspension systems are necessary components of lower limb prostheses as they help to ensure secure coupling between the residual and prosthetic limbs [1]. Proper fit of the stump inside the prosthetic socket and appropriate selection of prosthetic suspension have positive effects on amputees' gait, and can decrease energy consumption during ambulation [1–4]. Symmetry between the limbs represents a healthy gait and is one of the primary objectives of rehabilitation for lower limb amputees [5]. The gait pattern of a person with lower limb amputation is not as symmetrical as that of healthy individuals in terms of ground reaction force (GRF), time, distance of walking and joint angles [4,6]. Among these parameters, the GRF is defined as the percentage of body weight applied to the limb during the stance phase of gait and the force that is generated for forward propulsion [7]. Bateni et al. (2002) reported that there was a higher range of motion in the hip and knee on the prosthetic side than the sound limb in transtibial amputees during walking. Moreover, the step

length was longer than the sound limb due to the shorter stance time on the prosthetic side [4]. In the rehabilitation of lower limb amputees, one of the main goals is to improve the amputees' gait pattern so that it appears as similar to gait of healthy individuals as possible. As such, many researchers have used three-dimensional motion analysis to investigate the gait parameters of transtibial amputees during different activities using various prosthetics components [4,8,9]. Therefore, gait analysis system might be used as a diagnostic tool to make decisions for the rehabilitation protocols.

Suspension systems play fundamental roles in prosthetic function and patient's satisfaction [10]. Silicone liners (with total surface bearing socket (TSB)) are the most favorable form of suspension system as they provide better suspension, fit, and function during ambulation when compared with the more traditional systems, such as patellar tendon bearing (PTB) socket with Pelite liners [10–14].

Prosthetic suspension using the Seal-in liner and valve can improve socket fit and decrease pistoning movement (vertical



## Appendix C5

5. Gholizadeh, H., Abu Osman NA, Eshraghi, A., Ali, S., Arifin, N., Evaluation of new suspension system for limb prosthetics. **Biomedical engineering online**, Q2

Gholizadeh et al. *BioMedical Engineering OnLine* 2014, **13**:1  
<http://www.biomedical-engineering-online.com/content/13/1/1>



### RESEARCH

### Open Access

## Evaluation of new suspension system for limb prosthetics

Hossein Gholizadeh\*, Noor Azuan Abu Osman, Arezoo Eshraghi, Sadeeq Ali, Nooranida Arifin

\* Correspondence:  
gholizadeh@um.edu.my  
Department of Biomedical  
Engineering, Faculty of Engineering,  
University of Malaya, Kuala Lumpur,  
Malaysia

### Abstract

**Background:** Good prosthetic suspension system secures the residual limb inside the prosthetic socket and enables easy donning and doffing. This study aimed to introduce, evaluate and compare a newly designed prosthetic suspension system (HOL) with the current suspension systems (suction, pin/lock and magnetic systems).

**Methods:** All the suspension systems were tested (tensile testing machine) in terms of the degree of the shear strength and the patient's comfort. Nine transtibial amputees participated in this study. The patients were asked to use four different suspension systems. Afterwards, each participant completed a questionnaire for each system to evaluate their comfort. Furthermore, the systems were compared in terms of the cost.

**Results:** The maximum tensile load that the new system could bear was 490 N (SD, 5.5) before the system failed. Pin/lock, magnetic and suction suspension systems could tolerate loads of 580 N (SD, 8.5), 350.9 N (SD, 7) and 310 N (SD, 8.4), respectively. Our subjects were satisfied with the new hook and loop system, particularly in terms of easy donning and doffing. Furthermore, the new system is considerably cheaper (35 times) than the current locking systems in the market.

**Conclusions:** The new suspension system could successfully retain the prosthesis on the residual limb as a good alternative for lower limb amputees. In addition, the new system addresses some problems of the existing systems and is more cost effective than its counterparts.

**Keywords:** Transtibial prostheses, Prosthetic liner, Prosthetic suspension, Lower limb prosthesis, Below-knee prosthesis, Prosthetic socket, Amputees

### Background

About 1.6 million individuals with limb loss lived in the United States according to 2005 statistics (about 0.05% of the community). This number is predicted to be doubled to 3.6 million by the year 2050 [1].

Non-use or limited use of prosthetic devices is concern for rehabilitation of amputees. Provision of good prosthesis is also the key element in the rehabilitation of persons with amputation. The amputee's functional needs and his/her satisfaction with the prosthesis should be taken into account when selecting a suspension system [1-7].



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## Appendix C6

6.Gholizadeh, H., Abu Osman NA, Eshraghi, A., & Razak, N. A. A. Clinical implication of interface pressure for a new prosthetic suspension system. **Biomedical engineering online**, Q2

Gholizadeh et al. *BioMedical Engineering OnLine* 2014, **13**:89  
<http://www.biomedical-engineering-online.com/content/13/1/89>



### RESEARCH

### Open Access

## Clinical implication of interface pressure for a new prosthetic suspension system

Hossein Gholizadeh\*, Noor Azuan Abu Osman, Arezoo Eshraghi and Nasrul Anuar Abd Razak

\* Correspondence:  
gholizadeh@um.edu.my  
Department of Biomedical  
Engineering, Faculty of Engineering,  
University of Malaya, 50603 Kuala  
Lumpur, Malaysia

### Abstract

**Background:** Prosthesis suspension systems can alter the distribution of pressure within the prosthetic socket. This study evaluates a new suspension system for lower limb prostheses, and aims to compare the interface pressure and amputees' satisfaction with the new system compared with a common prosthetic suspension system (pin/lock).

**Methods:** Ten transtibial amputees walked at a self-selected speed on a level ground with two different suspension systems, namely the pin/lock and HOLO system. The interface pressure was measured using the F-socket transducers at the proximal, middle and distal sites of residual limb. Furthermore, subjective feedback was logged to compare two systems.

**Results:** The pressure was significantly higher at the proximal and distal areas with the pin/lock suspension system during the swing phase of gait ( $P < 0.05$ ). Subjective feedback also showed traction at the stump with the pin/lock system. There were no significant differences in the pressure applied to the mid-anterior and mid posterior stump for both suspension systems. However, the lateral and medial sides exhibited higher pressure with the new system during stance phase.

**Conclusions:** The intention of this study was to deepen understanding on the effect of suspension system on the load distribution over the residual limb. The new coupling system was proved compatible with the pin/lock system in terms of suspending the leg and amputee's satisfaction. On the other hand, the HOLO system could distribute the pressure more uniformly over the residual limb.

**Keywords:** Lower limb, Pressure, Prostheses, Transtibial, Amputation, Prosthetic liner, Prosthetic suspension, Below-knee prosthesis, Prosthetic socket, Amputees

### Background

One of the main concerns of prosthetic rehabilitation team is non-use or limited use of prosthesis. Provision of good prosthesis based on the amputee's functional needs and satisfaction with the device is also important [1-4].

Suspension system, including the socket, is the most important component of prosthesis, which is directly in contact with the residual limb. Unwarranted translation, rotation and piston movement between the socket and residual limb should be avoided via proper suspension [1,5-7]. Several suspension systems are available for upper and lower limb amputees. The main parts of every suspension system are 1) a soft liner and 2) a lock (coupling) system [6,8]. Most of the current suspension systems use



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## Appendix C7:

7. **Gholizadeh H**, Abu Osman NA, Eshraghi A,Afirin NA, Yang CT. A comparison of pressure distributions between two types of sockets in a bulbous stump. **Prosthetics and Orthotics international**. (Accepted-2014)

## **Appendix C8** (The research described in this thesis led to the following presentation)

### **Proceedings**

- 1. Gholizadeh H, Abu Osman N.A, Eshraghi A, Kamyab M, Saeedi H, Ali S, Mohammadi M, (2012). Amputee's Satisfaction with Two Different Transfemoral Suspension Systems and the Experienced Problems. *10 th Iranian Orthotics and Prosthetics Congress.***
- 2. Gholizadeh H, Abu Osman N.A, Eshraghi A, S. Ali, E. S. Yahyavi, Clinical assessment of two common suspension systems for transtibial amputees. *ISPO 2013 World Congress.***
- 3. Gholizadeh H, Abu Osman N.A, Eshraghi A, S. Ali. Transfemoral Suspension Systems: A Comparison Between Common Suction Socket and Seal-In liner. *O&P World Congress (2013), American Orthotic and Prosthetic Association (AOPA)***
- 4. Gholizadeh H, Abu Osman N.A, Eshraghi A, S. Ali. A Clinical Comparison Between Two Common Transtibial Prosthetic Suspension Systems, *O&P World Congress (2013), American Orthotic and Prosthetic Association (AOPA)***
- 5. Gholizadeh H, Abu Osman N.A, Eshraghi A, Saeedi H, Anoushe SZ, Abd Razak NA, Clinical assessment of a new prosthetic suspension system, *11th Iranian Orthotics and Prosthetics Congress.***
- 6. Gholizadeh H, Abu Osman N.A, Eshraghi A, Saeedi H, Anoushe SZ, Abdollah V, Safaeepor Z. Systematic review of literature: Transtibial prosthesis suspension systems. *11th Iranian Orthotics and Prosthetics Congress.***

## Appendix D

### Methodological Criteria (Van Der Linde, et al, 2004)

Score\*\*

|                             |     |  |  |
|-----------------------------|-----|--|--|
| Selection of Patients       | A1  | Adequacy of the Description of Inclusion and Exclusion Criteria: This criterion tested whether the patient's sample was sufficiently defined with the used selection criteria, such as age, gender, level of amputation, reason for amputation, activity level of the amputee, time since onset, stump condition, and comorbidity.   |  |
|                             | A2  | Functional Homogeneity: The homogeneity of the study sample was assessed for all the study designs. In view of the clinical guideline development, at least the activity level of the included subjects should be reasonably equal. When the activity level of the patients was not described, sufficient indication of the level of amputation, the reason for amputation, and the age of the subjects were required to estimate the activity level of the patients globally. When the study sample was heterogeneous, a stratified analysis of the outcome was required to obtain a "1" score. |  |
|                             | A3  | Prognostic Comparability: As for group designs, the study groups should be comparable for possible confounding factors, such as time since onset and time since first walking with the prosthesis. In the case of a within-subjects design, this criterion was scored "1."   |  |
|                             | A4  | Randomization: In group designs, an adequate randomization procedure should have been applied. If the randomization procedure was described and the procedure reasonably excluded bias, this criterion was scored as "1." In within-subjects designs, this criterion was applied to the sequence of interventions [2].   |  |
| Intervention and Assessment | B5  | Experimental Intervention: The experimental intervention had to be given explicitly in such detail as to duplicate the study as possibly described.  |  |
|                             | B6  | Co-interventions: This criterion tested whether co-interventions were avoided or were comparable between the study groups.   |  |
|                             | B7* | Blinding: In any case, the outcome assessor had to be blinded to the intervention. In many studies investigating prosthetic components, blinding of the patients is always difficult to assure. Therefore, this type of blinding was required only for studies using subjective outcome measures.  |  |
|                             | B8  | Timing of the Measurement: This criterion pertained to the moment that the outcome was assessed in relation to the time period subjects given to adapt to the prosthetic change. An adequate adaptation period was required.   |  |
|                             | B9  | Outcome Measures: The outcome parameters should be adequate in relation to the purpose of the study, and they should have been collected with the use of a standardized protocol.  |  |
| Statistical validity        | C10 | Dropouts: The number of dropouts and the reason for dropping out had to be sufficiently reported. A dropout rate of more than 20% was considered as insufficient.  |  |
|                             | C11 | Sample Size: The sample size ( $n$ ) in relation to the number of independent variables ( $K$ ) was adequate if the ratio $n:K$ exceeded 10:1.   |  |
|                             | C12 | Intention to Treat: Intention to treat analysis should be assessed in the case of dropouts.  |  |
|                             | C13 | Data Presentation: This criterion required that the adequate point estimates and measures of variability were presented for the primary outcome measures.  |  |

1. Van Der Linde, et al, 2004. A systematic literature review of the effect of different prosthetic components on human functioning with a lower-limb prosthesis. Journal of rehabilitation research and development, 41, 555-570.)

2. Piantadosi S. Clinical trials as experimental designs. In: Barnett V, Bardley RA, Fisher NI, Hunter S, Kadane JB, Kendall DG, et al., editors. Clinical trial: a methodological perspective. New York, Chichester, Weinheim, Brisbane, Singapore, Toronto: John Wiley & Sons, Inc; 1997. p. 61–105.

\*As the suspension system is in close contact with the residual limb and when the amputees want to wear the prosthesis, they can easily identify the difference between the suspension systems. This situation could have created respondent bias. We did not use this item in our review. \*\* Based on score levels, a criterion was scored "0" if it is not applicable and "1" if applicable

## Appendix E1 (Prosthetics components used in this study)

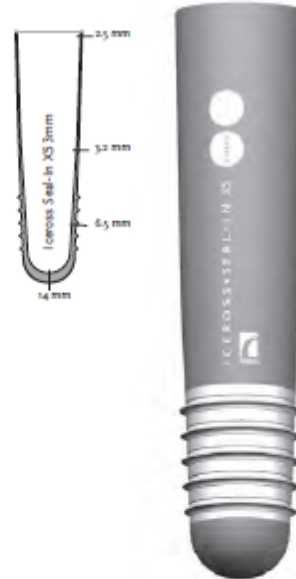
### ICEROSS SEAL-IN® X5 TRANSTIBIAL LINER



The Iceross Seal-In X5 incorporates a series of five integrated seals that conform to the shape of the residual limb and the internal socket wall, providing an airtight seal.

Ossur recommends that Iceross Seal-In X5 Transtibial Liner is used in conjunction with the Icelock® 500 Series Expulsion Valve.

| USER INFORMATION  |   |
|-------------------|---|
| Amputation Level: | Transtibial                                       |
| Impact Level:     | All   |
| LINER INFORMATION |   |
| Size Standard:    | 18, 20, 22, 23, 5, 25, 26, 5, 28, 30, 32, 34, 36. |
| Profile:          | 3mm   |
| Matrix:           | 10-13cm   |



#### SUSPENSION METHOD



SEAL-IN X5

#### FEATURES



CUSHION



MATRIX



FABRIC COVER



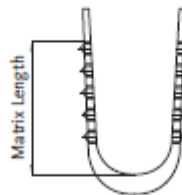
ACTIVE SKIN CARE



MENTHOL CARE

#### MINIMUM RECOMMENDED LENGTH OF RESIDUAL LIMB

| LINER SIZE | MATRIX LENGTH |
|------------|---------------|
| 18         | 10cm          |
| 20-25      | 11cm          |
| 28-30      | 12cm          |
| 32-36      | 13cm          |



Matrix size varies depending on the liner size, the smaller the liner the shorter the matrix.

#### PART NUMBER INFORMATION - ICEROSS SEAL-IN X5 TRANSTIBIAL LINER

| PART#    | PROFILE | SUSPENSION METHOD | MATRIX  |
|----------|---------|-------------------|---------|
| I-36630X | 3mm     | Seal-In X5        | 10-13cm |

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## ICERROSS DERMO® LOCKING LINER WITH WAVE



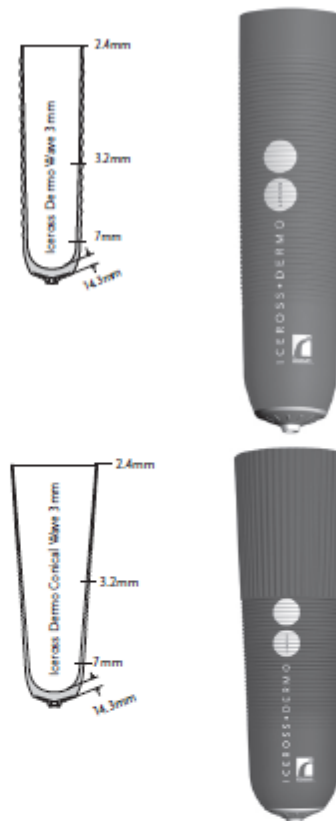
Made with the softest silicone, Iceross Dermo cushions the limb while actively caring for the skin. Ideal solution for people with vascular problems or sensitive skin.

Iceross Dermo features horizontal waves designed for easier flexion at the knee. Iceross Dermo Conical also features vertical waves intended to reduce pressure at the wider, proximal end and help prevent the edges from rolling down.

A premium suspension liner that provides superb softness, gentle skin contact and unique Active Skin Care ingredients. The combination of DermoGel® silicone with an ultra-strong and elastic Supplex® fabric cover offers excellent durability and an intimate fit.

Ossur recommends that Iceross Dermo Liner with Wave is used in conjunction with the Icelock® 600 series.

| USER INFORMATION  |   |
|-------------------|---|
| Amputation Level: | Transfemoral  |
| Impact Level:     | Low to Moderate   |
| LINER INFORMATION |   |
| Size Standard:    | 16, 18, 20, 22, 23.5, 25, 26.5, 28, 30, 32, 34, 36, 40, 45. |
| Size Conical:     | 18, 20, 22, 23.5, 25, 26.5, 28, 30, 32, 34, 36.             |
| Profile:          | 3mm   |
| Matrix:           | 10cm or Custom 2-14cm*                                      |



### SUSPENSION METHOD



LOCKING

### FEATURES



MATRIX



FABRIC COVER



ACTIVE SKIN CARE



WAVE



SILKEN INNER SURFACE

### PART NUMBER INFORMATION - ICERROSS DERMO LINER WITH WAVE

| PART#    | PROFILE          | SUSPENSION METHOD | MATRIX           |
|----------|------------------|-------------------|------------------|
| I-4313XX | 3mm Wave         | Locking           | 10cm             |
| I-4223XX | 3mm Wave         | Locking           | Custom (2-14cm)* |
| I-4913XX | Conical 3mm Wave | Locking           | 10cm             |

\*For a custom matrix, please specify the required matrix length on your order. Please note that deviation in the stabilizing matrix length can be +/- 1.5cm.

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The tarsal core and Achilles strap provide multi-axial function, while the Achilles strap enhances forward motion, giving users ideal proportions of balance and agility.

Emulating many of the anatomical features of the human foot, the Talux has been specially designed to provide fluid, natural walking motion in a variety of terrains, for users of low to moderate activity. Talux now comes with a sandal toe for ease of footwear selection.



| USER INFORMATION        |                              | FOOT INFORMATION          |   |
|-------------------------|------------------------------|---------------------------|---|
| Amputation Level:       | Transfemoral and Transtibial | Categories:               | 1-8                                     |
| Impact Level:           | Low to Moderate              | Sizes:                    | 23-30                                   |
| Maximum Patient Weight: | 147kg (325lbs)               | Weight of Foot: (Size 27) | 740g (26.1oz) w/ Pyramid and Foot Cover |
|                         |                              | Build Height: (Size 27)   | 172mm (7") w/ Pyramid and Foot Cover    |
|                         |                              | Heel Height:              | 10mm (3/8")                             |
|                         |                              | Adapter Options:          | Tube kit or male pyramid                |

|                       |                       |                           |                       |
|-----------------------|-----------------------|---------------------------|-----------------------|
|                       |                       |                           |                       |
| FULL LENGTH TOE LEVER | PROPORTIONAL RESPONSE | ACTIVE TIBIAL PROGRESSION | CARBON-X® ACTIVE HEEL |

|                               |            |
|-------------------------------|------------|
|                               |            |
| MULTI-AXIAL GROUND COMPLIANCE | SANDAL TOE |

## CATEGORY SELECTION CHART

### LOW IMPACT

| WEIGHT KG  | 45-52      | 53-59   | 60-68   | 69-77   | 78-88   | 89-100  | 101-116 | 117-130 | 131-147 |
|------------|------------|---------|---------|---------|---------|---------|---------|---------|---------|
| WEIGHT LBS | 97-115     | 116-130 | 131-150 | 151-170 | 171-194 | 195-220 | 221-256 | 257-287 | 288-324 |
| FOOT SIZE  | CATEGORIES |         |         |         |         |         |         |         |         |
| 23-24      | 1          | 1       | 2       | 3       | 4       | 5       | N/A     | N/A     | N/A     |
| 25-26      | N/A        | N/A     | 2       | 3       | 4       | 5       | 6       | 7       | N/A     |
| 27-28      | N/A        | N/A     | N/A     | 3       | 4       | 5       | 6       | 7       | 8       |
| 29-30      | N/A        | N/A     | N/A     | N/A     | 4       | 5       | 6       | 7       | 8       |

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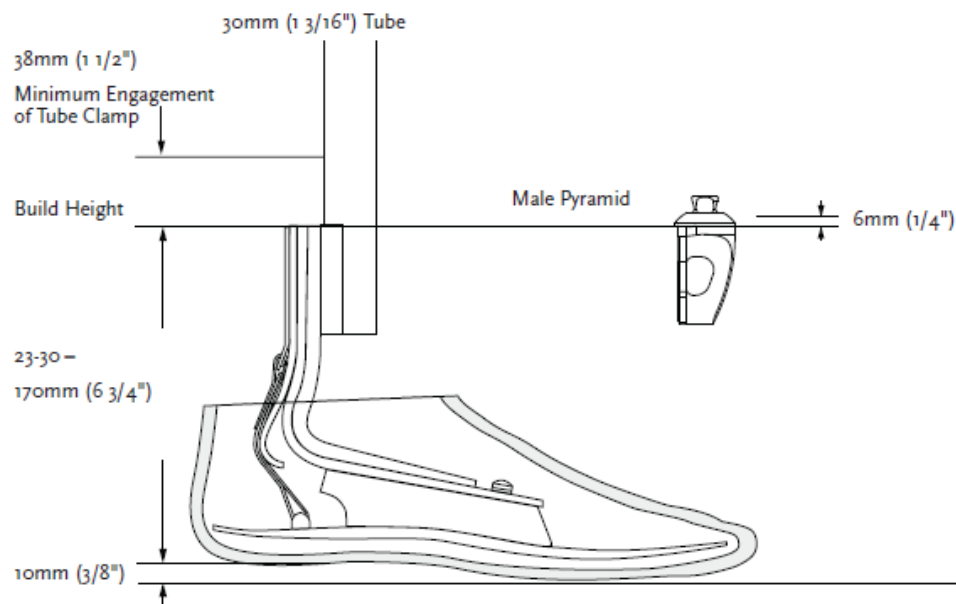
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## CATEGORY SELECTION CHART

### MODERATE IMPACT

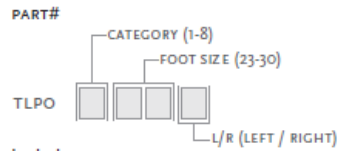
| WEIGHT KG  | 45-52      | 53-59   | 60-68   | 69-77   | 78-88   | 89-100  | 101-116 | 117-130 | 131-147 |
|------------|------------|---------|---------|---------|---------|---------|---------|---------|---------|
| WEIGHT LBS | 97-115     | 116-130 | 131-150 | 151-170 | 171-194 | 195-220 | 221-256 | 257-287 | 288-324 |
| FOOT SIZE  | CATEGORIES |         |         |         |         |         |         |         |         |
| 23-24      | 1          | 2       | 3       | 4       | 5       | N/A     | N/A     | N/A     | N/A     |
| 25-26      | N/A        | 2       | 3       | 4       | 5       | 6       | 7       | 8       | N/A     |
| 27-28      | N/A        | N/A     | 3       | 4       | 5       | 6       | 7       | 8       | N/A     |
| 29-30      | N/A        | N/A     | N/A     | 4       | 5       | 6       | 7       | 8       | N/A     |

## CLEARANCE



## KITS

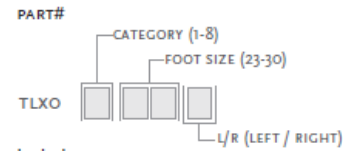
### TALUX MALE PYRAMID OPTION



Includes:

- Foot Module
- Achilles Strap
- Tarsal Core
- Attachment Hardware
- Male Pyramid

### TALUX WITHOUT ADAPTER



Includes:

- Foot Module
- Achilles Strap
- Tarsal Core
- Attachment Hardware

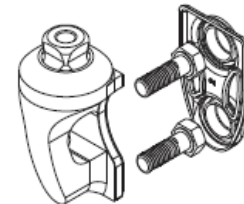
## KITS

### MALE PYRAMID ADAPTER KITS

| PART#      | WEIGHT | CAT.      |
|------------|--------|-----------|
| FFC2210003 | 180g   | 6.3oz 1-6 |
| FFC2210004 | 220g   | 7.8oz 7-8 |

Includes:

- Pyramid
- Bolt Caps
- Hardware (M8 or M10 bolts)
- Loctite 410

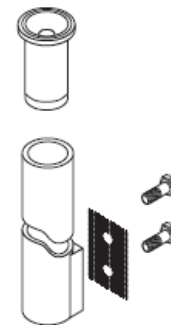


### 30MM (1 3/16") CARBON FIBER TUBE KIT

| PART#    | WEIGHT | LENGTH           | CAT. |
|----------|--------|------------------|------|
| TLX01011 | 216g   | 7.6oz 229mm 9"   | 1-6  |
| TLX01012 | 275g   | 9.7oz 229mm 9"   | 7-8  |
| TLX01013 | 293g   | 10.3oz 381mm 15" | 1-6  |
| TLX01014 | 369g   | 13oz 381mm 15"   | 7-8  |

Includes:

- Carbon Fiber Tube
- Attachment Hardware ( 5/16" UNF bolts)
- Friction Pads
- Loctite
- Tube Insert (cat. 7-8)



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## KITS

### ACHILLES STRAP KITS

| PART#    | CAT. | FOOT SIZE |
|----------|------|-----------|
| TLX01002 | 1-6  | 23-26     |
| TLX01003 | 7-8  | 23-26     |
| TLX01004 | 1-6  | 27-30     |
| TLX01005 | 7-8  | 27-30     |

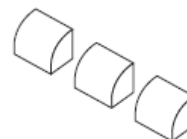
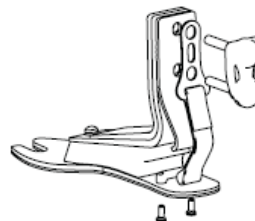
Includes:

- Strap
- Hanger
- Pin
- Bolts

| PART#    | DESCRIPTION    |
|----------|----------------|
| TLX01001 | Heel Wedge Kit |

Includes:

- 3 Wedges
- Adhesive



## COMPONENTS

### TUBE INSERT

| PART#    | WEIGHT    | DIAMETER     | CAT. |
|----------|-----------|--------------|------|
| A-718009 | 18g 0.60z | 30mm 1 3/16" | 7-8  |

| PART#    | DESCRIPTION       |
|----------|-------------------|
| CM160016 | Loctite 410 black |



### ATTACHMENT BOLTS FOR 30MM (1 3/16") TUBE

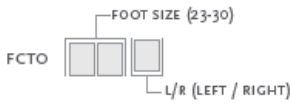
| PART#    | CAT. | SIZE       | LENGTH |
|----------|------|------------|--------|
| CM130219 | 1-6  | 24 x 5/16" | 1 3/4" |
| CM130213 | 7-9  | 24 x 3/8"  | 1 3/4" |

### ATTACHMENT BOLTS FOR PYRAMID

| PART#    | CAT. | SIZE | LENGTH      |
|----------|------|------|-------------|
| CM130234 | 1-6  | M8   | 35mm 1 3/8" |
| CM130223 | 7-8  | M10  | 35mm 1 3/8" |

COSMETIC FINISHING

PART#



Includes:

- Foot Cover\*
- Attachment Plate
- Flex Foot Sock

\*Please specify when ordering brown covers add "BR" to the part#.

| PART#    | DESCRIPTION    | SIZE  |
|----------|----------------|-------|
| FCX63006 | Flex-Foot Sock | 22-25 |
| FCX63007 | Flex-Foot Sock | 26-30 |



## ICELOCK® 200 SERIES



The Icelock 200 series offers strong and durable locks with removable clutch mechanisms. The locks provide easy and secure wind-down donning as well as an easy release unlocking mechanism.

Icelock 200 series is a great product for transfemoral amputees and is therefore ideal to use in conjunction with the Iceross® Transfemoral liner.



### CLUTCH LOCKS

- Easy release unlocking mechanism
- Low build height and light-weight
- Wear-resistant stainless steel pin guide
- Secure clutch mechanism tested to tolerate at least 300kg (660lbs) pull
- Ability to change from Lanyard to Clutch
- All impact levels

### DIAGRAM

ICELOCK CLUTCH 211



With Pyramid\* Adapter

ICELOCK CLUTCH 211



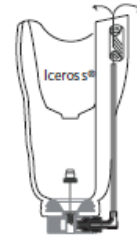
Without Pyramid\* Adapter

ICELOCK CLUTCH 214



With 4-Hole Adapter

ICELOCK LANYARD 234



With 4-Hole Adapter

\* Note: pyramid must be purchased separately

### ICELOCK 211 OVERVIEW



Attachment Pin, Clutch



Icelock Clutch 211



Icelock Stainless Steel Pyramid 273  
Icelock Titanium Pyramid 272

# ICELOCK® 200 SERIES

## DIAGRAM

### ICELOCK 214 OVERVIEW



Attachment Pin, Clutch



Fabrication Ring



Clutch Mechanism and Lock Body, 4-Hole

## PART NUMBER INFORMATION - LOCKS

| PART#    | DESCRIPTION                     | RATINGS |  | BUILD HEIGHT |        | WEIGHT |       |
|----------|---------------------------------|---------|--|--------------|--------|--------|-------|
| L-211000 | Icelock Clutch 211 (No Adapter) | N/A     |  | 21mm         | 13/16" | 78g    | 2.8oz |



| PART#    | DESCRIPTION                                  | RATINGS |        | BUILD HEIGHT |    | WEIGHT |       |
|----------|--|---------|--------|--------------|----|--------|-------|
| L-214000 | Icelock Clutch 214 (Aluminum 4-Hole Adapter) | 120kg   | 265lbs | 25mm         | 1" | 186g   | 6.6oz |



To change from clutch to lanyard, order L-292050 Lanyard Adaptation Kit.

| PART#    | DESCRIPTION         | RATINGS |        | BUILD HEIGHT |       | WEIGHT |       |
|----------|---------------------|---------|--------|--------------|-------|--------|-------|
| L-234000 | Icelock Lanyard 234 | 120kg   | 265lbs | 9mm          | 6/16" | 76g    | 2.7oz |



To change from lanyard to clutch, order L-292020 Clutch Mechanism and T-wrench.

## PYRAMIDS FOR ICELOCK CLUTCH 211

| PART#    | DESCRIPTION                  | RATINGS |        | BUILD HEIGHT |       | WEIGHT |       |
|----------|------------------------------|---------|--------|--------------|-------|--------|-------|
| L-272000 | Icelock Titanium Pyramid 272 | 166kg   | 365lbs | 9mm          | 6/16" | 76g    | 2.7oz |



| PART#    | DESCRIPTION                         | RATINGS |        | BUILD HEIGHT |       | WEIGHT |       |
|----------|-------------------------------------|---------|--------|--------------|-------|--------|-------|
| L-273000 | Icelock Stainless Steel Pyramid 273 | 100kg   | 220lbs | 8mm          | 5/16" | 64g    | 2.3oz |



## ADAPTERS

| PART#    | DESCRIPTION                     | WEIGHT LIMIT |        |
|----------|---------------------------------|--------------|--------|
| A-233100 | 4-Hole Male Pyramid, Aluminum   | 100kg        | 220lbs |
| A-242100 | 4-Hole Female Pyramid, Aluminum | 100kg        | 220lbs |
| A-235100 | 4-Hole Male Pyramid, Titanium   | 166kg        | 365lbs |
| A-245100 | 4-Hole Female Pyramid, Titanium | 166kg        | 365lbs |

Socket adapters see table of contents for page.

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Life Without Limitations®

## ICELOCK® 500 SERIES



Both Icelock Expulsion Valve 551 and 552, are designed to be used with all suction suspension systems. The valves are positioned in a housing that seals securely against the inner surface of the hard socket near the distal end. The valves expell air under positive pressure when entering a socket. During removal of the prosthesis the push button needs to be compressed to allow air back into the hard socket. The Icelock 500 Series can be used for all impact levels.

| PART#    | DESCRIPTION                 |
|----------|-----------------------------|
| L-551000 | Icelock Expulsion Valve 551 |

The Icelock 551 Valve is an auto-expulsion and push button suction release in the same compact, easy to install package. (M 10). The valve is recommended for both Transtibial and Transfemoral users. The kit includes a flexible socket housing.

| PART#    | DESCRIPTION                 |
|----------|-----------------------------|
| L-552000 | Icelock Expulsion Valve 552 |

The Icelock 552 Valve is an auto-expulsion and push button suction release in the same compact. The valve is recommended for Transfemoral users. The core of the valve can be unscrewed when removing a sock through the valve. The valve can be used with a flexible interface.



## **Appendix E2** (List of prosthetics components donated by Ossur (Iceland) Company)

Iceross Seal-In® X5 Transtibial Liner (n=10)

Iceross® clean & simple lubricant spray (n=10)

Iceross Dermo Locking liners (n=10)

shuttle lock (Icelock-clutch 4 H214 L 214000) (n=10)

4 Hole Male pyramid (n=10)

Icelock Expulsion Valve 551(n=10)

4-Prong Socket Adapter (n=10)

Male Pyramid Insert For Prong (n=10)

Female Pyramid Tube Clamp (n=10)

Female Pylon - Short (n=10)

Flex-Foot Talux® (n=10)

Cosmetic finishing (n=10)



## Appendix F

### Definition and Abbreviation

**Abduction:** Motion of a body part away from the mid-line of the body. Abduction and adduction are the clockwise and counterclockwise rotations of the leg, respectively, while the foot is in contact with the ground.

**Abrasion:** Wearing away of the skin by rubbing or friction.

**Adherent Scar Tissue:** Scar tissue formed in the healing process which sticks to underlying tissue such as muscle or fascia or bone.

**AK:** Above knee also referred to as "transfemoral."

**Alignment:** Position of the prosthetic socket in relation to the foot and knee.

**Amputation:** Loss or absence of all or part of a limb.

**Anterior:** Front, as front portion of a shoe or foot.

**Atrophy:** Condition where muscle loss occurs due to lack of use.

**Bilateral amputee:** A person missing either both arms or both legs, a double amputee.

**Bilateral transfemoral amputee:** Both legs are amputated above the knee.

**Bilateral transtibial amputee:** Both legs are amputated below the knee.

**Biomechanics:** Applying the mechanical principles to the study of how the human body moves.

**BK:** Below knee also referred to as "transtibial".

**Check or Test Socket:** A temporary socket that is often transparent and made over the plaster model to aid in obtaining the proper fit and function of the prosthesis.

**Congenital Amputee:** Individual born missing a limb(s). Technically, these individuals are not amputees, but are "limb deficient."

**Cosmesis:** Used to describe the outer, aesthetic covering of a prosthesis. Refers to the realistic appearance of the prosthesis when a "naturalistic" treatment is attempted.

**CP (Certified Prosthetist):** A person who has passed the certification standards set by the American Board of Certification in Prosthetics.

**CPO (Certified Prosthetist-Orthotist):** A person who has passed the certification standards set by the American Board of Certification in Prosthetics and Orthotics.

**Custom Fit:** Fitting an individual with an item/device made from an image of the individual's anatomy, fabricated according to the needs of that individual.

**Definitive or "Permanent" Prosthesis:** A replacement for a missing limb or part of a limb, which meets the accepted check-out standards for comfort, fit, alignment, function, appearance, and durability.

**Distal:** (1) The end of the residual limb. (2) Farther from the central portion of the body. Opposite of proximal.

**Disarticulation:** An amputation through a joint, commonly the hip, shoulder, knee, ankle, elbow, or wrist.

**Donning and Doffing:** Putting on and taking off a prosthesis, respectively.

**Dorsiflexion:** Related to the ankle joint, pointing the toe/foot upward toward the body. Dorsiflexion and plantarflexion describe the up and down movements at the ankle that enable the leg to move forward over the foot, pushing the forefoot to the ground.

**Edema:** A local or generalized condition in which the body tissues contain an excess of fluid.

**Elastic Wrap:** Elasticized bandage used to prevent swelling and encourage shrinkage and maturation of the residual limb.

**Endoskeletal Prosthesis:** Prosthesis built more like a human skeleton with support and components on the inside. This design may have a soft cosmetic cover on the outside.

**Energy storing foot:** A prosthetic foot designed with a flexible heel. It is designed with a spring that stores energy when weight is applied to it and releases energy when the amputee transfers weight to the other foot.

**Exoskeletal Prosthesis:** A prosthesis that is hollow on the inside and with a hard outer surface to bear weight.

**Extension:** Extending out the leg; straightening the joint resulting in an increase of angle;

moving the lower leg away from the back of the thigh (compare to Flexion).



**Extremity or limb:** Relating to the arm or leg.

**Flexion:** Moving in the lower leg towards the body; moving the lower leg toward the back of the thigh.

**Gait:** The range of motions involving how an amputee walks.

**Heel Strike:** The degree of force with which the heel makes contact with the ground during the walking or running gait.

**Holo:** Hook and Loop suspension system.

**Kinematics:** Observation of the recorded amputee motion to determine the proper alignment and load-line.

**Knee Disarticulation (KD) or through the knee (TDK):** Amputation of the leg through the knee.

**Knee-flexion angle:** Measured in degrees, the range of motion that an artificial knee can bend.

**Lateral:** To the side, away from the mid-line of the body.

**Liner:** Suspension systems that are used to attach prosthesis to the residual limb and/or provide additional, comfort, and protection of the residual limb. These liners may be made of silicon, pelite, or gel substances.

**Medial:** Toward the mid-line of the body.

**Orthotics:** The profession of providing devices to support and straighten the body.

**Orthotist:** A skilled professional who fabricates orthotic devices that are prescribed by a physician.

**Orthosis:** A device that is used to protect, support, or improve the function of the moving parts of the body. Singular for a supportive device (plural is orthoses).

**Partial Foot Amputation:** An amputation on the front part of the foot.

**Phantom sensation:** The normal ghost image of the absent limb may feel normal at times, but can be uncomfortable or painful at other times.

**Pin:** A locking pin is attached to the end of a silicone liner as part of the suspension system. Pins are either smooth or serrated and slide into a clutch-like locking mechanism. To remove the leg, a small button is pressed, which releases then pin.

**Pin-lock:** Also called a “shuttle-lock” suspension system; used to hold the prosthetic limb to the residual limb.

**Pistoning:** Refers to the residual limb slipping up and down inside the prosthetic silicone liner or socket while walking. Sweating exacerbates this situation.

**Plantar:** Bottom of the foot.

**Plantarflexed/Plantarflexion:** Means that the toe is pointing down toward the sole, almost like pushing the gas pedal down and simulating that position or alignment.

**Ply:** Thickness of the stump sock material, such as 1-ply, 2-ply, 3-ply, and 4-ply. The higher the ply number is, the thicker the sock will be. The addition or the removal of sock plies is often required as a result of swelling of the residual limb or as an amputee gains or loses weight.

**Popliteal area:** Refers to the anatomical structures located in the back of the knee.

**Posterior:** The back side of the body or part in question, i.e., posterior knee or patellar region.

**Prostheses:** More than one prosthesis.

**Prosthesis:** An artificial part of the body.

**Prosthetics:** The profession of providing cosmetic and/or functional restoration of missing human parts.

**Prosthetist:** A person involved in the science and art of prosthetics; one who designs and fits artificial limbs.

**Proximal:** Nearer to the central portion of the body; opposite of distal.

**PTB:** Patellar Tendon Bearing, below the knee (BK) Prosthesis, where weight is on the tendon below the kneecap.

**Pylon:** A rigid member, usually tubular, between the socket or knee unit and the foot that provides the weight bearing support shaft for an endoskeletal prosthesis.

**Range of motion:** The amount of movement that a limb has in a specific direction at a specific joint, such as your hip or knee.

**Residual limb:** The portion of the arm or leg remaining after the amputation. Some people refer to it as a "stump".

**SACH Foot (Solid-Ankle Cushion Heel):** Foot that is used since the Civil War.

**Silicone Liner:** Used with pin-lock suspension systems.

**Skin Shearing:** A line of itchy blisters that can be caused by abnormal pressure, friction, or by shearing of the skin against “tacky” silicone or plastic. Clinically, the two most common areas where shearing is noticed when using silicone suspension sleeves are at the proximal liner trimline (top edge of the liner) and the posterior distal aspect (behind the knee area) of the residual limb.

**Socks:** Prosthetic socks have provided cushioning and are means to adjust the volume of the socket. They are available in several materials including wool, cotton, and synthetics. Sock thickness is measured by the "ply" rating, most commonly from 1-ply to 6-ply. By varying the ply number and/or the number of socks worn, amputees can adjust for changes in the size of their residual limb. Prosthetic socks should protect the skin against the destructive forces of pressure and friction in the skin-socket interface, meanwhile absorbing perspiration with a wick-like action and allowing ventilation.

**Socket:** The major component of a prosthetic device that the arm can rest in.

**Stance phase:** When the amputee is standing with the foot on the ground and with the knee slightly locked (hyperextended). The weight distribution is slightly behind the load line, hence, the knee is slightly hyper-extended to prevent it from buckling.

**Stump:** A word commonly used to refer to the residual limb.

**Supercondular Suspension:** A method of holding on prosthesis by clamping on the bony prominence above a joint, called "condyles."

**Suspension system(s):** The method used to hold the prosthesis on the body. The three primary methods are (1) suction sockets, (2) roll-on silicone rubber liners with locking pins on the end, and (3) belts.

**Swing phase:** Prosthesis moving from full flexion to full extension that is usually used in reference to prosthetic knee units; when the amputee swings the leg forward from being bent at the knee to being locked straight vertical. Range of the gait when the foot is off the ground.

**Symes amputation:** An amputation through the ankle joint that retains the fatty heel pad portion and is intended to provide end weight bearing.

**Toe-off:** Transferring of the weight from the toe to begin the swing phase; refers to the instant of final contact between the shoe and the floor. The point of final contact between shoe and floor is generally the very front, bottom edge of the foot.

**Transtibial amputation:** BK amputee, part of the tibia remains intact as part of the residual limb.

**Transfemoral amputation:** above the knee amputee, part of the femur remains intact as part of the residual limb.

## **APPENDIX G** (Visualization of the research)

### **ResearchGate:**

[http://www.researchgate.net/profile/Hossein\\_Gholizadeh2](http://www.researchgate.net/profile/Hossein_Gholizadeh2)

### **Forchheimer Prize**

<http://www.ispoint.org/news/forchheimer-prize-awarded-hossein-gholizadeh-and-co-authors>



### **ResearcherID:**

<http://www.researcherid.com/rid/G-4838-2010>

### **ORCID:**

<http://orcid.org/0000-0001-5847-7985>

### **Google Scholar:**

<http://scholar.google.com.my/citations?user=qc86XtwAAAAJ&hl=en>